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ORAL PRESENTATIONS

O01

User Experience and Glycemic Outcomes with a Patch Insulin Pump for Type 1 Diabetes in India

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Keywords
• Devices

Background and Aims

The Omnipod 5, a patch insulin pump, utilizes automated insulin delivery (AID) with real-time glucose monitoring and a mobile app. This study explores user perception and outcomes of the Omnipod 5 among individuals with type 1 diabetes (T1D) in India, where the device is unavailable commercially. All the users procured the AID from abroad and were on multiple daily injections (MDI) previously.

Materials and methods

Data from the Omnipod 5 App and Dexcom Clarity were analyzed for glycemic outcomes, time in range (TIR), time below range (TBR), and time above range (TAR) during AID. User experience was assessed through the INSPIRE Questionnaire for Parents of Youth with Type 1 diabetes, administered postintervention.

Results

Three female T1D users participated (age: 7±3.60 years; diabetes duration: 4.6±3.21 years). Clinical parameters improved (Table 1). The INSPIRE questionnaire showed high scores, with users strongly agreeing with statements. Users praised the Dexcom G6 calibration-free feature, tubing-free design, and easy infusion set change. Manual interventions and hypoglycemic episodes reduced. Parents reported improved diabetes management and reduced stress. Convenience and reduced manual interventions were highlighted.

Questionnaire responses aligned with user experiences, supporting the Omnipod 5's positive impact.

Graph/Table :

Glycemic Outcomes	Omnipod 5 AID	MDI	P-value
Time in Range (TIR)	88.0±6.08%	52.6±5.6%	<0.001
Time Below Range (TBR)	4.3%	18.6%	<0.001
Time Above Range (TAR)	6.3%	27.6%	<0.001
HbA1c	6.43±0.32%	8.2±0.26%	<0.001
Total Daily Insulin Dose	14±5 units/day	22±5 units/day	-

Conclusion

The Omnipod 5-patch insulin pump improved glycemic outcomes and reduced insulin needs for T1D individuals. Positive user experiences emphasize convenience and flexibility. This study underscores patch pump benefits, urging increased availability in India.

O02

Early Screening for foot problems in people with diabetes is the need of the hour – "Save the Feet and Keep Walking Campaign" in India

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Keywords
• Diabetic foot and skin disorders

Background and Aims

The prevalence of foot problems among people with diabetes in India at a national level is lacking. Hence this study was aimed to assess the burden of high-risk feet in people with diabetes across India. This

analysis included assessment of loss of protective sensation (LOPS), other foot problems and peripheral arterial disease among people with diabetes.

Materials and methods

A national level project "Save the Feet and Keep Walking" campaign was conducted by the Research Society for the Study of Diabetes in India (RSSDI). A cross-sectional survey and diabetic foot screening was conducted across various diabetes clinics in India from 10th July 2022 to 10th August 2022. A modified tool based on 3-minute foot examination was used to assess the foot problems [Miller JD et al., 2014]. Around 10000 doctors with RSSDI membership were involved to conduct this foot screening at their respective clinics.

Several online training programs were conducted for the doctors and they were also given a standardised monofilament for detection of LOPS prior to the start of the foot screening programme. A video demonstration of foot examination was uploaded online along with the instructions and a web link was provided for online data collection using the semi-structured questionnaire. People with diabetes aged above 18years who visited the clinics during the study period were examined for foot problems. A total of 54000 people with diabetes participated in these screening camps. Around 33259 participants with complete information were included for the final analysis. The foot at risk was categorised into very low or no risk, low risk, moderate and high risk based on International Working Group on the Diabetic Foot 2019 [Schaper NC et al.,2019].

Results

Nearly 75% of the participants were aged above 45 years. Around 49% had duration of diabetes for more than 5 years and uncontrolled diabetes (HbA1C>8%). Previous history of foot ulcer was noted in 20% and around 15.3% had lower limb amputation. Nearly 45% of them had burning or tingling sensation in the feet. One-fourth of the participants had deformities and did not have palpable dorsal pedis and posterior tibial pulses. LOPS was observed in 24%. Assessment of level of foot risk showed that one-fourth (25.2%) of them had high risk feet whereas 5% were at low and 2.5% were at moderate risk respectively. An increasing trend prevalence of moderate and high risk feet. Diabetic kidney and retinal complications were present in 70% and 75.5% of people with high risk feet.

Conclusion

One-fourth of people with diabetes were found to have high risk feet in India. Majority of the people who had high risk feet also had diabetic kidney and retinal complications. It is important to examine all the people with diabetes for foot problems to reduce the burden of treatment cost and improve the quality of life.

O03

Survival of people with type 2 diabetes who underwent major diabetic foot amputation from 2010 to 2019: A study from South India

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Keywords
• Diabetic foot and skin disorders

Background and Aims

Diabetic foot complication is common and if untreated or late presentation of the same may lead to foot amputation. The reports on survival rate of people who underwent major diabetic amputation in Indian context is less. Hence, this study aimed to assess the survival rate of people who underwent diabetic amputation from 2010 to 2019.

Materials and methods

A retrospective analysis was done in November 2022 and collected data on survival status of the people with type 2 diabetes(T2DM) who had undergone foot amputation from 2010 to 2019 using the medical records. Details such as age, duration of diabetes, presence of co-morbid and diabetic complications were collected. Information of death and its' reason was obtained from medical records of patients or through telephonic follow up of patients or family members. A total of 346 individuals had undergone amputation during 2010 to 2019. Out of 346, data was collected for a total of 211 individuals. Among them 89 were survived and 122 died post amputation during the data collection. The individuals were grouped into group1(survived) and group2(died). The survival time was calculated in months and Kaplan-Meier survival analysis was performed to estimate the cumulative median survival time.

Results

The mean age of the individuals was 62.4±9.2 years. The previous history of foot ulcer and amputation, presence of nephropathy, retinopathy and Peripheral Arterial disease(PAD) were similar between the groups. Presence of hypertension (57.8 vs. 78.5%; p=0.012) and cardio-vascular disease(CVD) (40.6 vs. 70.3%; p<0.001) were significantly higher in group2. Median cumulative survival time of the participants was 67 months (95% CI 52.2-81.8). 9% died within 30 days of post-amputation. Survival time did not differ between individuals who had undergone below or above knee amputation. But, survival time differed significantly among those with and without co-existence of PAD and CVD[44 months(95% CI 27.6-60.4)vs. 76 months (95%CI 46.1-106); p=0.02]. The reasons for death were as follows: 30.3% had myocardial infraction, age related or chronic illness (25.4%) and uncontrolled diabetes (20.5%).

Conclusion

The median survival of the people with type 2 diabetes who underwent major foot amputation was 5.6 years.

Co-existence of PAD and CVD had a significant impact on the survival period.

O04

Glucometer Usage and Type 2 Diabetes Mellitus Management: A Study in Uttar Pradesh, India

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Keywords
• Devices

Background and Aims
India, especially Uttar Pradesh (UP), plays a pivotal role in the global diabetes pandemic due to its massive population of 240 million as of 2019. However, comprehensive data on diabetes in UP is lacking. To address this gap, the RSSDI UP chapter is conducting extensive research to provide valuable insights and highquality data on diabetes. This initiative can offer essential guidance for individuals, healthcare providers, and policymakers.
In parallel, glucometers are gaining popularity in India for diabetes management. These portable devices enable proactive blood glucose monitoring. As part of the RSSDI UP chapter's broader study, the analysis aims to compare regular glucometer users with those who do not use this device.
Materials and methods
The study seeks to represent the entire population of people with diabetes receiving treatment across various healthcare settings in the state of UP. It included people seeking treatment for Type 2 Diabetes Mellitus (T2DM) at 22 selected sites (18 zones & 75 districts of UP) through an electronic health record (MEDEVA).
Results
Data from 4037 patients with T2DM was included in the analysis. The patients had an average age of 52.4 years, with gender distribution of 54.4% male and 45.6% female. The mean HbA1c of these patients was 8.1%, with an average duration of T2DM for 10.6 years.
Out of the 4037 patients with T2DM, responses regarding glucometer usage were available for 2997. Among these, 2261 patients (75%) utilized glucometers to monitor their blood sugar levels. Patients using glucometers tended to be slightly older (average age of 53.5 years) compared to those who did not (average age of 47.9 years). No significant gender differences were observed.
On average, patients who used a glucometer checked their blood glucose levels 5.8 times in the last 1 month (n=1853).
The mean HbA1c of patients using a glucometer (7.8%) was significantly lower than that of those not using it (9.0%). Furthermore, fasting blood glucose levels as well as postprandial glucose levels among glucometer users were significantly lower compared to non-users.
Conclusion
This study offers valuable insights into the significance of glucometer usage within the UP population.

O05

EFFECT OF VITAMIN D DEFICIENCY AND BMI ON TB TREATMENT OUTCOMES AMONG PEOPLE WITH TYPE 2 DIABETES: A STUDY FROM SOUTH INDIA

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Keywords
• Other complications

Background and Aims
Low VitaminD(VitD) 25(OH)D may influence adverse TB treatment outcomes in diabetes(DM). Studies on effect of baseline VitD deficiency on treatment outcomes are limited from India. We aimed to assess and compare prevalence of VitD deficiency and treatment outcomes among people with TBDM and TB nonDM.
Materials and methods
Baseline data of 483 newly diagnosed PTB patients screened by OGTT from an observational study(EDOTS) conducted from 2014 to 2018 in TB clinics, Chennai was used(culture negative, preDM excluded) and divided into TBnonDM(n=139), TB newDM(NDM)(n=97) and TB knownDM(KDM)(n=166) groups.
Demographic, anthropometric(BMI;low(L)-<18.5,high(H)≥18.5kg/m2), TB treatment outcomes were recorded.VitD (ng/ml)was measured by electrochemiluminescence and were categorised into < 20 as deficient, 21–29 insufficient and ≥ 30ng/ml optimal.
Results
TBDM group were older(47.6±9.7vs39.3±10.6;p<0.001) and had higher BMI (20.2±3.9vs17.3±2.9;p<0.001) thanTBnonDM. VitD levels were significantly lower in TBDM than TBnonDM (16±8.5vs21.7±11.5; p<0.001). VitD deficiency was significantly higher in TBDM (72.9%) and TBNDM (66%) compared to TBnonDM (50%;p<0.001). VitD insufficiency was similar in groups. Among those with VitD deficiency, cure rate was higher in TBKDM (88.6%) and among them 73.1vs.26.9% had HvsLBMI, in NDM (83%;61.4vs.38.6%) whereas nonDM (80.9%) cure rate was lower in HBMI(27.5%). Treatment failures were higher in NDM (9.4%) than nonDM (7.9%) but ≥80% had LBMI in both groups. KDM had 5.7% failures (50% each in LvsHBMI). Relapse was higher in nonDM (6.3%) and nearly 75% had LBMI. In NDM and KDM relapse was 3.8% and 50% each in LvsHBMI. Death rate was higher in nonDM(4.8%) and 100% had LBMI. Death rate was 3.8 and 1.9% in NDM and KDM and 50% each in LvsHBMI.
Conclusion
Vitamin D deficiency was highly prevalent among TBDM than TB nonDM. Among those who had had higher treatment failures and three-fourth of them had low BMI. Relapse and death rates were higher in nonDM and >75% of them had low BMI.

O06

Understanding Dyslipidemia Prevalence and Patient Profile in Type 2 Diabetes Mellitus: A Study in Uttar Pradesh, India

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Keywords
• Dyslipidaemia, lipoproteins

Background and Aims
India significantly contributes to the global diabetes epidemic. Uttar Pradesh (UP), with a population of 240 million (as of 2019), comprising 17.5% of India's population, is of critical importance. The population of UP is equivalent to Germany, UK, & France combined, & its area is comparable to the UK. Nevertheless, comprehensive

data on diabetes in UP is lacking compared to other Indian regions. To fill this gap, Research Society for the Study of Diabetes in India (UP chapter) is conducting a large-scale study to provide highquality data & insights on diabetes, supporting individuals with diabetes, physicians, & policymakers in effective diabetes management.
The study aims to create a profile of the diabetic population, emphasizing demographics, comorbidities, & duration of Type 2 Diabetes Mellitus (T2DM), while also estimating the prevalence of associated complications.

Materials and methods

The study seeks to represent the entire population of people with diabetes receiving treatment across various healthcare settings in the state of UP. It included people seeking treatment for T2DM at 22 selected sites (18 zones & 75 districts of UP) through an electronic health record (MEDEVA).

Results

Out of the 3,412 patients with T2DM in the study, 4.7% (n=160) had Dyslipidemia (DL). The average age of patients with DL was 53.9 years, with 62.5% being male. Their average BMI was 29.4 kg/m² (n=115). The average duration of T2DM was 11 years (n=144), & for DL, it was 4.8 years (n=60).
Among the patients with DL & available medication data (n=114), around 67% were on statins.
Table 1 shows average HbA1c, associated complications, & lipid profiles.
Graph/Table :

Table 1: Profile of Users and Non-users of Glucometer	
Mean HbA1c	8.2%
Diabetic Complications	
None	66.9%
Neuropathy	22.5%
Nephropathy	6.9%
CVD / CHD	5.0%
Retinopathy	3.8%
Diabetic Foot	1.9%
Vasculopathy	1.3%
Lipid Profile	*Mean (mg/dL)*
Cholesterol Total	191.9 (n=112)
LDL cholesterol	98.7 (n=110)
HDL cholesterol	44.7 (n=108)
Triglyceride	259.3 (n=109)

Conclusion

This study provides valuable insights into the relationship between T2DM, DL, & associated complications in the studied population of UP.

O07

The Effect Of Progressive Muscle Relaxation Therapy On Diabetes Distress And Anxiety Among People With Type 2 Diabetes

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Keywords
• Exercise physiology • Psychological aspects

Background and Aims

Diabetes Distress and Anxiety Disorders are the most common infirmity in people with diabetes.Jacobson's Progressive Muscle Relaxation therapy is an effective technique that helps to restore the health of sick people by giving contentment,both physically and mentally and achieve healing.There are limited studies avilable in this context.Hence the aim of this research was to see the effect of Progressive Muscle Relaxation (PMR) therapy on diabetes dstress and anxiety in people with Type 2 Diabetes Mellitus(T2DM).The secondary aim was to see the impact of PMR therapy on Glycemic control in people with T2DM.

Materials and methods

In this randomized intervention study 80 participants were selected according to the inclusion and exclusion criteria from a tertiary care center for diabetes in chennai from March 2023 to May 2023 and randomized into Group1 intervention(N=40) and control (N=40).Pre test was done with Diabetes Distress Scale (DDS) and Generalized Anxiety Disorder Scale(GAD).A score of >=3 in DDS scale was considered as diabetes distress and a score between 18 to 21 in GAD scale was considered as severe anxiety.HbA1c,Fasting Blood Sugar(FBS) & Post Prandial Blood Sugar (PPBS),Creatinine,eGFR and lipid levels were recorded at baseline and follow up for both the groups.The intervention group participants received the PMR therapy for 12 weeks along with their regular oral hypoglycemic drugs and they were monitored through weekly follow up sessions.The control group participants received breathing exercises once and advised to continue their regular oral hypoglycemic drugs.A post test was conducted for both the group participants after three months.

Results

The mean age was 51 in the control group and 49 in the intervention group. There was a significant decrease in the Pre test versus post test scores of DDS (3.5 vs 1.5, P<0.001) and GAD (18 vs 5.3, P<0.001) and a significant reduction was noted in the mean HbA1c (9.9 vs 7.4, P<0.001), FBS (199 vs 129, P<0.001), PPBS (319 vs 193, P<0.001) in the intervention group.In the control group significant increase was noted in the DDS score(3.7 vs 4.1, P=0.001), GAD score (17.5 vs 18.1, P=0.81), HbA1c (8.5 vs 9.5, P<0.001), FBS (157 vs 173, P=0.07) and PPBS (319 vs 193, P=0.04). There was a significant difference between the intervention and control group in the base line versus follow up (mean difference) in DDS (2.0 vs 0.2, P<0.001), GAD (12.6 vs 0.4, P <0.001). HbA1c (2.4 vs 0.9, P<0.001), FBS (69.9 vs 15.9, P<0.001), PPBS (125.8 vs 28.3, P<0.001). There was an improvement seen in the Cholesterol, eGFR, Creatinine levels in the intervention group.

Conclusion

The study findings suggested that Progressive Muscle Relaxation therapy had a postive effect on the diabetes distress and anxiety among the people with type2 diabetes.It is evident from the results that PMR helps to improve glycemic control among people with T2DM.

O08

PREVALENCE OF XEROSIS AMONG TYPE 2 DIABETIC PATIENTS: A MULTICENTRIC STUDY IN INDIA

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Keywords
• Diabetic foot and skin disorders

Background and Aims
Background: Diabetes can lead to changes in skin physiology and reduce the skin's ability to retain moisture, resulting in dryness and roughness. Studies have reported prevalence of xerosis in diabetics ranging from 25% to 82%.
Aim: This study aims to describe the prevalence of xerosis among type-2 diabetes mellitus (T2DM) patients in India and explore its associated factors.
Materials and methods
A cross-sectional multicentric study was conducted in India during the month of May, 2023. The data were collected from the health facilities identified in each zone. From each site, 100 Diabetic patients attending a physician's OPD were selected and findings documented. The data was analysed using appropriate statistical methods.
Inclusion Criteria
T2DM
Age > 18 years
Patient consenting to participate.
Results
A total 631 patients were included. The prevalence of xerosis in diabetics was 30.3%. Prevalence of xerosis was less in poorly controlled diabetics (RBS >200 mg/dl) compared to T2DM with good glycemic control (RBS <200 mg/dl) (35.9% vs 64.1%) and more in females compared to males (53.7% vs. 44.6%). The prevalence of xerosis was 26.7% in obese individuals, 56.3 % in T2DM with hypertension, 91.6 % in T2DM aged >40 years.
Conclusion
Prevalence of Xerosis in T2DM is quiet high in India, particularly in diabetic patients aged >40 years, females, hypertensive and obese diabetics. Skin care should be an integral part of management of diabetes and physicians should make it an essential part of documentation during examination of diabetic patients.

O09

Stress hyperglycemia as a predictor of mortality in near-hanging patients: A Fiveyear retrospective study from a tertiary care centre

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Keywords

Background and Aims
Stress hyperglycemia is defined as admission blood glucose (ABG) levels of 140 mg/dL or more in nondiabetic patients. Hanging is the most common method of suicide in India. When hanging patients reach the hospital for treatment, their neurological outcome ranges from full recovery to severe neurological impairment or death. This study looked at the clinical profile, stress hyperglycemia and predictors of mortality in near-hanging patients.
Materials and methods
This retrospective study was conducted from May 2017 to April 2022. Patients aged ≥18 years with "nearhanging" diagnosis were included, while those who adopted alternate suicide methods, brought dead, or discharged against medical advice were excluded. Demographic, clinical and treatment details were collected from case records. Neurological outcome at discharge was assessed using the Glasgow Outcome Scale (GOS). Admission blood glucose (ABG) levels were noted, and stress hyperglycemia was diagnosed if the ABG level was ≥140mg/dL.
Results
The study involved 323 patients, 60% men and a median (IQR) age of 30 (20-39). At the time of admission, Glasgow coma score (GCS) ≤8 in 110 (34%) patients and 21 (6.5%) had hanging-induced cardiac arrest. About 101 patients required ICU care. Ten patients (3%) were known diabetics. Admission blood glucose levels were available for 276 patients. Among ABG available patients, eight (2.8%) were diabetics and 268 patients (97.2%) were non-diabetics. The mean (SD) ABG level of all patients was 135.7 (58.6) mg/dL. The mean (SD) ABG levels of diabetics and non-diabetics were 205(75) and 133.7 (56.9) mg/dL, respectively.
Among the non-diabetics, stress hyperglycemia was present in 32% of patients (86/268). Good neurological recovery was found (GOS-5) in 82.8% (222/268) of patients, and the death rate (GOS-1) was 9.3% (26/268).
Univariate logistic regression showed that stress hyperglyemia was significantly associated with mortality (p=0.015) with an odds ratio of 2.75 (95% CI: 1.2- 6.2). In the multivariable logistic regression analysis, stress hyperglycemia, hypotension, hanging-induced cardiac arrest and cerebral edema were found to be significantly associated with mortality.
Conclusion
The majority of near-hanging patients had a good neurological recovery. Stress hyperglycemia was present in one-third of hanging victims, and was one of the significant predictors of mortality. Aggressive management should be considered for near-hanging patients having stress hyperglycemia to improve their outcomes.

O10

A study of tuberculosis in diabetic patients

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Keywords
• Nutrition and diet • Other complications

Background and Aims
• People with diabetes are immune deficient so there is increased risk of progressing from latent to active TB
• Diabetics have a 2-3 times increased risk of TB
• Around 10% of TB cases globally are associated with diabetes
• Early diagnosis will helps in improve care and control of both TB and Diabetes
• Each TB patients should be screened for diabetes (WHO Recommendation)
• In high prevalent areas screening for TB in diabetic patients should be considered as a priority (WHO Recommendation)
• Diabetics diagnosed with TB have a greater risk of death at the time of TB treatment or due to TB relapse after completion of treatment
AIM: To study the clinical profile of Tuberculosis among Diabetic patients
Materials and methods
This is a cross sectional study which includes 100 diabetic patients with Tuberculosis who presented to department of General medicine in St. Johns's Medical College and Hospital.
They were subjected to detailed clinical examination and relevant investigation.
Results
• In our study, 9% of the cases showed an ESR value of >100 mm/hr; 48% of cases showed ESR between 50-99 mm/hr; 29% of cases were with ESR 21-49 mm/hr; remaining 14% had an ESR of <20 mm/hr

• The mean total leukocyte count in our study is 10760. Cases with extensive TB had normal leukocyte count and vice versa
• Inspite of increased bacterial count in cavitary lesions rate of smear positivity seems to be less in these cases due to fatiguability of muscles as a result of poor glycaemic control and weak expectoration
• In 39% of patients right side involvement was seen. In 30% of patients left side involvement was predominant which combinedly accounts to 69% . 31% of cases had lesions bilaterally 34% of patients showed lower zone changes out of which 4 patients were below 40 years and 30 patients were above 40 years. This accounts to a P value less than 0.05
• The radiographic features in DM-TB showed that 55% of cases showed cavity; 36% of the cases showed fibrotic lesions; 36% of cases had infiltration; pleural effusion was seen in 23%; 6% showed consolidatory changes; 5% had hydropneumothorax; aspergilloma was associated in 3% of cases; 2% showed bronchiectasis

Conclusion

• Male population accounted to 70% and females to 30% with M:F ratio of 2.3:1 of which 78% of the individuals are in the age group of more than 40 years.
• The major clinical presentation is anorexia (82%), cough (77%) and loss of weight(44%)
• Past H/O TB is seen in 20% of cases and family H/O TB in 15%
• Out of the total male patients, 68.5% are smokers. 12% of total cases had clubbing of which 85% was associated with advanced stage of TB
• 55% of cases have anaemia out of which 7% are severely anaemic
• ESR >50 mm/hr is noted in 57% of cases
• The mean FBS value is 236.4 mg/dl and the mean PPBS value is 351.5 mg/dl
• Sputum positivity in age less than 40 years is 86% and 54% in age more than 40 years
• Bilateral involvement is seen in 31% of cases
• The most common lung change noted in both less than and more 40 years age group is cavitation (55%)

O11

Unveiling the Impact of Early Gestational Diabetes Mellitus: Prevalence, Risks, and Strategies for Optimizing Pregnancy Outcomes

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Keywords
• Pregnancy

Background and Aims

Gestational Diabetes Mellitus (GDM) is a prevalent complication of pregnancy, characterized by elevated blood sugar levels that develop during pregnancy in women who previously exhibited normal glucose levels.

This condition poses significant health risks for both the mother and the baby, and its global prevalence is increasing. Despite the implementation of various treatment strategies, such as dietary modifications, lifestyle changes, and insulin therapy, concerns persist regarding the potential for adverse pregnancy outcomes in women diagnosed with GDM, particularly during the early stages of pregnancy. This study aimed to evaluate the prevalence, clinical characteristics, and pregnancy outcomes of high-risk women with GDM diagnosed before 24 weeks of gestation (referred to as early GDM) and those with pre-existing diabetes.

Materials and methods

The study conducted an analysis of the outcomes of 4,873 women who received care at an antenatal diabetes clinic between 2012 and 2022. These women received treatment according to consistent glycemic targets.

The participants were categorized into four groups: those with pre-existing diabetes (65 women), those diagnosed with gestational diabetes mellitus (GDM) before 12 weeks of pregnancy (68 women), those diagnosed between 12 and 23 weeks of pregnancy (1,247 women), and those diagnosed at or after 24 weeks of pregnancy (3,493 women).

Results

The study found that hypertensive complications during pregnancy, including conditions such as preeclampsia, preterm delivery, cesarean section, and neonatal jaundice, were more prevalent among women with pre-existing diabetes and those with early gestational diabetes mellitus (GDM) (all with a p-value of less than 0.001). In women diagnosed with GDM before 12 weeks of gestation, the rates of macrosomia (largerthan-average babies) were comparable to those in women with pre-existing diabetes (21.8% vs. 20.3%, with a p-value of 0.8). Similarly, the rates of babies classified as "large for gestational age" were also similar (39.6% vs. 32.8%, with a p-value of 0.4). Additionally, there was no significant difference in the rate of neonatal intensive care admissions between these two groups (38.5% vs. 39.7%, with a p-value of 0.9).

Conclusion

The study findings suggest that GDM diagnosed in early pregnancy is associated with an increased risk of adverse pregnancy outcomes, including fetal macrosomia, cesarean deliveries, gestational hypertension, preeclampsia, and neonatal hypoglycemia. Despite the implementation of various treatment strategies, GDM. Healthcare providers should closely monitor and provide comprehensive care for women with GDM, particularly when it is diagnosed in the first trimester, to optimize pregnancy outcomes and ensure the health of both the mother and the baby.

O12

Foot complications in type 2 diabetic nephropathy-results from a tertiary hospital in South India

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Keywords
Prevention of type 2 diabetes • Nephropathy

Background and Aims

Background: Foot problems are a common concern for individuals with diabetes mellitus whose untimely management increases risk for amputation & disability. Uraemic waste accumulation caused by renal function decline may aggravate neuropathic symptoms, thereby leading to foot complications among another group of individuals diagnosed with type 2 diabetic nephropathy.

Aim: To report the common foot complications experienced by individuals with type 2 diabetic nephropathy.

Materials and methods

Materials & Methods: Out of 283 screened, the study included 206 participants with type 2 diabetic nephropathy, aged 45 to 70 years, with an estimated glomerular filtration rate (eGFR) above 15mL/min/1.73m2 who visited the study centre at a tertiary hospital in South India. A qualified physiotherapist trained in podiatry observed the feet of individuals for foot complications like dry skin, altered skin colour, toe deformities, ingrown toenails, bunions, callus, infection, fissures, prominent metatarsal heads & ulcers.

Results

Results: The demographic characteristics of participants were mean age (years) 58.3±7.44, body mass index (kg/m2) 26±4.22, glycated

haemoglobin (%) 8.28±1.80, median duration (years) of type 2 diabetes & nephropathy as 10 & 2 years respectively. The common foot complications among participants were as follows: dry skin (85.9%), fissures (21.8%), ingrown toenails (19.4%), prominent metatarsal head (18%), toe deformities (13.1%), altered skin colour (10.2%), diabetic foot ulcer (9.2%), callus (4.4%), foot infection (2.9%) & bunions (1.5%).

Conclusion

Conclusion: The present study observed that foot complications are present among individuals with type 2 diabetic nephropathy. Thus, diabetic foot care & footwear education, are equally important for prevention of foot complications among them.

O13

Etiology of Pleural effusion in chronic kidney disease patients with and without diabetes: A comparative analysis

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Keywords
• Nephropathy • Other complications

Background and Aims

Pleural effusion is a common complication in chronic kidney disease (CKD) patients, and its etiology may vary depending on the presence of comorbidities such as diabetes. This study investigated the underlying causes of pleural effusion in CKD patients, comparing those with and without diabetes.

Materials and methods

A prospective analysis was conducted on a cohort of 176 CKD patients with pleural effusion, who were categorized into two groups: CKD patients with diabetes and CKD patients without diabetes. Clinical and demographical data, laboratory results, and radiological findings were collected to identify the etiological factors contributing to pleural effusion.

Results

In our study of 176 chronic kidney disease (CKD) patients with pleural effusion, we found distinct patterns between those with and without diabetes. Among diabetic patients, 56% had transudative pleural effusion, primarily due to cardiac failure (63%). In contrast, only 36% of non-diabetic CKD patients had transudative effusion, with 48% attributed to cardiac failure.

Among diabetic patients with exudative effusion (39 out of 88), 18 had parapneumonic effusion, while 56 out of 88 non-diabetic patients exhibited the same. Both groups had three patients with positive GeneXpert results in pleural fluid, with a slightly higher rate in the diabetic group (3 out of 39 vs. 3 out of 56). Empirical anti-tuberculosis therapy was given to 15 non-diabetic patients and 9 diabetic CKD patients.

Hypoalbuminemia, the second most common cause of pleural effusion, was seen in 45% of diabetic CKD patients and 50% of non-diabetic CKD patients.

In our study, there were 20 in-hospital deaths, with the majority (15%) occurring in the diabetes with CKD group, compared to 7% in the non-diabetic CKD group.

Conclusion

Diabetic CKD patients predominantly exhibit transudative pleural effusion linked to cardiac failure, while parapneumonic effusion. Tuberculosis etiology varies between the two groups, with GeneXpert results suggesting diabetes doesn't significantly impact tuberculosis-related pleural effusion diagnosis. Non-diabetic CKD patients more frequently receive empirical anti-tuberculosis therapy. Hypoalbuminemia contributes to pleural effusion in both groups, emphasizing its importance in clinical management. Moreover, in-hospital mortality is notably higher among diabetic CKD patients (15%) compared to non-diabetic CKD patients (7%), indicating a higher risk associated with diabetes in this context.

O14

Subclinical cardiovascular autonomic dysfunction in prediabetics

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Keywords
• Neuropathy: autonomic, incl. erectile dysfunction

Background and Aims

Cardiovascular autonomic dysfunction (CAD) is characterized by abnormalities in heart rate control, as well as defects in central and peripheral vascular dynamics. CAD is associated with higher cardiovascular morbidity and mortality rates and poor quality of life in diabetic individuals. In initial stages, CAD may be diagnosed and reversed. In advanced stages, only symptomatic treatment can be done. Hence early diagnosis of autonomic neuropathy in prediabetics is needed. The study aims to assess baseline sympathetic and parasympathetic parameters of autonomic functions in prediabetic subjects using heart rate variability and to assess sympathetic and parasympathetic parameters after reactivity tests namely Lying to standing test, Deep breathing test, Valsalva maneuver and Cold pressor test.

Materials and methods

Cross sectional study 45 patients of pre diabetes between 18 to 45 years age were assessed for Heart rate variability and other reactivity tests as mentioned above. Instrument used was 8 channel Digital physiograph Lab Chart AD instrument Australia. Autonomic scores were calculated and categorized as per Bellavere's criteria and Indian Autonomic scoring system .

Results

Parasympathetic domain of Heart rate variability shows loss in 64 percent prediabetics and sympathetic domain shows loss in 80 percent prediabetics. Reactivity tests also depicts borderline loss of autonomic responses. 24 percent prediabetics have early CAD as per Bellavere criteria.

Conclusion

Thorough detection of subclinical autonomic dysfunction in pre-diabetic patients is of vital importance for risk stratification and subsequent management. CAD which is reversible in early stages, is of great significance in reducing cardiovascular morbidity and mortality. Early screening for CAD, even in prediabetics, may help in early diagnosis and adequate steps being taken in mitigating its outcomes.

O15

Association of diabetes duration and common barriers in achieving good glycemic control in people with Type 2 Diabetes Mellitus in Mumbai

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Keywords
• Nutrition and diet • Hypoglycaemia • Pathogenic mechanisms / complications

Background and Aims
Type 2 diabetes is a prevalent chronic condition worldwide. Approximately 537 million adults (20-79 years) are living with diabetes. Achieving glycemic control is crucial in managing diabetes to prevent long-term complications. The study aims to identify the association of diabetes duration and common barriers in achieving glycemic control and provides analysis of the glycemic control in people with type 2 diabetes in Mumbai. The limited studies available on diabetes care in India indicate that 50 to 60% of diabetic patients do not achieve the glycemic target of HbA1c below 7% leading to delayed recognition of complications.
Materials and methods
An observational study conducted amongst 135 individuals with type 2 diabetes in Mumbai. Inclusion criteria was people with type 2 diabetes mellitus with more than one year and in the age group of 18 years to 65 years. The subjects were divided equally into two groups, Group A (known case of T2DM for 1- 4 years) and Group B (known case of T2DM for >5 years). The study had 53% males and 47% females.
Results
The mean HbA1c levels among Group A was found to be 7.8%, and Group B was 8.6%, indicating suboptimal glycemic control in Group B in comparison with Group A. The data shows that 1-4 years after diagnosis of diabetes, the percentage of people with diabetes (PWD) experiencing hypoglycemic episodes, (<70mg/dl) as measured by self-monitoring of blood glucose (SMBG), is 1% while for those having T2DM for 5+ years, the percentage increases to 2%. Hyperglycemia episodes (>200mg/dl) on SMBG is seen in 33% of PWD with T2DM for 1-4 years, while 32% of PWD with T2DM for 5+ years have hyperglycemia episodes. It was seen that 2% of PWD having T2DM for 1-4 years experienced both hypoglycemia and hyperglycemia (glycemic variability) whereas, for those with T2DM for 5+ years, the percentage significantly increased to 10%. Lastly, 20% of PWD had no acute complications (hypoglycemia or hyperglycemia or glycemic variability) regardless of the duration of T2DM. 64% of the total subjects had hyperglycemia episodes once in 7-15days, 4% had hypoglycemic episodes once in 1-2 months, and 12% had glycemic variability. The study also reveals four major causes associated with poor glycemic control namely; a) Lack of regular physical activity: Group A reported inadequate physical activity (66%) as compared to Group B (49%) that contributed significantly for poor glycemic control. b) Unhealthy lifestyle: Only 24% of Group A followed healthy lifestyle in comparison to Group B (37%). c) Self- monitoring of blood glucose levels: Monitoring of blood glucose levels (average: twice a day for three times/week) was more in Group B (37%) as compared to Group A (25%); however the percentage of acute complications (hypoglycemia, hyperglycemia and glycemic variability) was higher in Group B as compared to Group A. d) Follow-up with Diabetes Care Team: 63% of the total subjects followed up regularly with the doctor, and 23% followed up regularly with the dietitian.
Conclusion
The findings highlight need for addressing the gaps through targeted interventions and educational programs thereby reducing the risk of developing chronic complications of diabetes among individuals with type 2 diabetes.

O16

Newer versus Existing Molecules in Diabetes: A Report on comparative clinical outcomes in out-patient department patients

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Keywords
• Incretin based therapies 43 Novel agents

Background and Aims
Background
India has an overwhelming burden of diabetes globally, ranking second in terms of the number of people living with diabetes, which has been predicted to sustain till 2045. We also rank third in the number of annual deaths due to diabetes. Besides diabetes, what is emerging is the overlooked co-existence of abdominal obesity, typical dyslipidaemia and hypertension that raise the incidence of morbidity and mortality. However, there is huge scope of improvement if we adapt the newer advances in diabetes management that range from diagnostics like CGMS to therapeutics like the incretin therapies or SGLT2 inhibitors. These newer agents target pathophysiological defects that were earlier unaddressed.
Aims
At our out-patient department, we tested adding SGLT2-inhibitors (SGLT2-i), DPP4-inhibitors (DPP4-i) and Imeglimin and compared it with using pre-popular molecules such as Sulphonylureas (SU) and metformin in varied presentations of type 2 diabetes (T2D).
Materials and methods
Patients above 18 years of age with uncontrolled T2D not on Insulin started on combinations of SUs, SGLT2-i, DPP4-i, Imeglimin and Metformin were picked up retrospectively for our study. Their journey from presentation to 3 months down the line was assessed and analysed. Major focus was on change in HbA1c, change in FBS/PPBS, change in weight in the patients started on newer drug options versus the popular SUs and metformin.
Results
Patients started on combinations of metformin with newer drugs such as the SGLT2-i and DPP4-i showed sooner glycaemic reductions as early as 15 days from initiation with effective weight reductions as well at the first follow up. Maximum glycaemic reductions were seen with triple combinations of SGLT2i, DPP4i and metformin. Glycaemic changes were more marked in postprandial glucose as compared to fasting levels. Also, the two classes given together showed better tolerance to side effects due to their complementary action. Only 1% of patients had to discontinue therapy due to side effects. Besides, suspected hypoglycaemia was seen only in the SU using patients. Using Imeglimin alongside DPP4i and SGLT2i helped in patients with higher HbA1cs. Patients on therapy with both DPP4i and SGLT2i scored better in efficacy than those on either of the two classes grouped with metformin. Additional extra-glycaemic benefits such as weight reduction, blood pressure reduction helped the metabolic corrections in these patients.
Conclusion
It is time that we approach T2DM as a part of metabolic dysfunction instead of just targeting glucose reductions. We must choose new therapy options that provide multiple benefits including organ protection. SGLT2-Inhibitors, DPP4-Inhibitors address pathophysiological defects that are otherwise not worked upon by SUs or Metformin. This strategy in T2D management provides holistic metabolic health corrections.

O17

Microvascular and macrovascular complication in patients with young and late onset type 2 diabetes mellitus

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Keywords
Epidemiology • Neuropathy: somatic • Macrovascular disease

Background and Aims
Prevalence of young onset type 2 DM, was dramatically increasing. Earlier age at onset of T2DM is of great concern since it translates to a greater duration of exposure to hyperglycaemia and/or represent an inherently more aggressive metabolic phenotype with rapid onset of beta cell failure and insulin resistance and associated with consequent development of chronic vascular complications of diabetes during the most productive years of an individual's life. Aim of study to see difference between micro and macrovascular complication of young and late onset type 2 diabetes mellitus.
Materials and methods
A cross sectional study was conducted at our tertiary care centre for assessing the prevalence of both microvascular and macrovascular complications in young and late onset type 2 diabetes in patients with age of onset less than 40 and more than 40 years respectively.
Results
A total of 246 patients are recruited, 123 in each group. Mean age of young onset diabetes and late onset diabetes patients were 46.2 and 57.6 years respectively. BMI, waist circumference and presence of dyslipidaemia was comparable in both the groups. Family history of diabetes was present in 81.3 % of young onset and 55.3 % of late onset diabetes (p value<0.01). Young onset diabetes patients have higher HbA1c at presentation than late onset ones (p<0.01). Among microvascular complications, neuropathy was more in late onset diabetes (p<0.05) and retinopathy and nephropathy prevalence was almost similar (p value 0.3 and 0.7 respectively) in both the groups. Among macrovascular complications cardiovascular disease were more in late onset diabetes (p value=0.05), however prevalence for cerebrovascular disease and peripheral vascular disease (p value 0.52 and 0.3 respectively) was similar in both the groups
Conclusion
In our study except for neuropathy and CAD which was more prevalent in late onset group, all other complications were similar in both the groups.

O18

Clinical utility of Triglyceride Glucose Index in predicting Non Alcoholic Fatty Liver Disease in Polycystic Ovarian Syndrome

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Keywords
• Insulin sensitivity and resistance • Non-alcoholic fatty liver disease (NAFLD)

Background and Aims
The prevalence of NAFLD in PCOS women in India has been reported as 83%. NAFLD is related to prediabetes, type 2 DM, dyslipidaemia, hypertension, cardiovascular disorder. Insulin resistance (IR) is one of major causes of NAFLD. The hyperinsulinemic euglycemic clamp is the gold standard for diagnosis of IR but it is time consuming, costly and technically challenging so surrogate markers like Homeostasis model assessment for insulin resistance (HOMA-IR) emerged to estimate IR. But there are few limitations like absence of standardization, high cost and the lack of availability of the insulin assay technique. Recently, the triglyceride glucose (TyG) index, has emerged as a reliable surrogate marker of IR. In this study we aim to elucidate the relationship between NAFLD and TyG index and compare effectiveness of TyG index and HOMA-IR in identifying NAFLD in PCOS women and to calculate the prevalence of NAFLD and prediabetes in PCOS women
Materials and methods
It is a single centered, hospital based, cross-sectional study at out patient department of Osmania general hospital . After ethical committee approval people satisfying Rotterdam criteria of PCOS are being recruited with written and informed consent. These patients are evaluated for fasting insulin, lipid profile, glycaemic status, USG abdomen or fibro scan for fatty liver. TyG index calculated as ln [fasting TG (mg/dl)x fasting blood glucose(mg/dl)/2] and HOMA IR was calculated in these patients
Results
This study is still ongoing . This is an interim analysis. The prevalence of NAFLD in PCOS patients is 55.13% (n=111). The prevalence of prediabetes in PCOS was found to be 15% (n=105). The prevalence of NAFLD (n= 79) increased with increase in TyG index and HOMA IR. An unadjusted regression analysis was performed. When highest quartile was taken as reference category (odds ratio = 1) lowest quartile of HOMA IR and TyG index had Odds ratio of prevalence of NAFLD of 0.137 (p=0.007) and 0.153 (p=0.009) respectively. According to receiver operating characteristic analysis , HOMA IR is superior to TyG index in predicting NAFLD [0.74 (p=0.00) vs 0.68 (p=0.004)]
Conclusion
Both HOMA IR and TyG index can be used for predicting the prevalence of NAFLD but HOMA IR was found to be a better predictor in interim analysis.

O19

Studying glycaemic journey of 33 patients with Type 1 Diabetes Mellitus using AGP reports

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Keywords
• Insulin therapy

Background and Aims
Background
Type 1 Diabetes (T1D) is usually overlooked due to its affection in 5% of population as compared to the 95% of patients type 2 diabetes. T1D is also mostly assumed to be associated with poorer outcomes with lesser scope for improvement due to the highly dynamic glucose levels in lieu of its pathophysiology – lack of physiological insulin and thereby dependence on external insulin. But with advances in technology like the continuous glucose monitoring (CGM), we can now decode the actual glycaemic journey of these patients with T1D to help them better understand the impact of various factors on their

glucose levels and thus make necessary interventions to target better clinical outcomes.

Aim: To study the glycaemic journey of patients with T1D using AGP reports and comparing it with Hba1c.

Materials and methods

Methodology: AGP reports using freestyle libre pro were collected for 33 patients with T1D from a multidisciplinary clinic in Mumbai. Demographic data like gender, height, weight, duration of diabetes, most recent HbA1c (within last 3 months), insulin dosage, type of insulin and insulin regimen were collected from the medical records available at the clinic. A detailed analysis was done studying the data obtained for the 33 patients.

Results

Off the 33 patients, 20 were male, 13 were female, with a mean BMI of 22. Around 5 patients were on the insulin pump while remaining 28 were on MDI therapy. The commonest insulin regimen used was basal bolus therapy - regular insulin and glargine. The mean total daily dosage (TDD) of Insulin was 47.42. The average HbA1c was 7.76. Off all, 9 patients had either one or more comorbidity or complication whereas, 24 had no complications or comorbidities. In terms of glycaemic control, 12 patients had HbA1c between the range of 7-8%, with around 9 patients with HbA1c below 7% and 4 patients had A1c >9%. Within CGM metrics, the time in range (TIR) showed a wide distribution from 21% to 77%. Similarly, the time above range (TAR) and time below range (TBR) also showed wide variations from as little as 6% to as high as 73% and from 1% to 42% respectively. Only 1 patient achieved target TIR of >70%, 3 achieved target TBR of <4% and 7 achieved target TAR of <25%. Almost 51% of patients had a TBR between 10 to 20%. It was interesting to note that among the 9 patients who had an A1c of <7%, their TBR ranged from 6% to 42% with none <4%. Lowest HbA1c level was seen with the highest time spent below range and similarly lower HbA1cs were associated with higher time spent below range. However, the average glucose as seen even with the CGMs did not predict this possibility. Thus, the significance of being able to visualise the glycaemic profile uncovering the missed highs and lows 24x7 for up to 14 days.

Conclusion

We can clearly conclude from the above study that HbA1c is very poor predictor of hypoglycaemia for patients with T1D with no consideration of glycaemic variability. Patients with similar HbA1c can have very different glycaemic profiles. Hence, HbA1c has low reliability as a guide for taking clinical decisions in T1D as to whether focus should be on reducing hyper or hypoglycaemia. AGP is a very important clinical tool especially for management of T1D and is a necessity to understand the glycaemic profile of these patients to ensure apt decisions be it food choices, carbohydrate counting, insulin dosing or even exercise or other activities.

O20

Association of hand grip strength with diabetic neuropathy among people with type 2 diabetes:A preliminary report from South India

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Keywords
• Neuropathy: somatic

Background and Aims

Diabetic Peripheral Neuropathy (DPN) may contribute to the decrease of muscle quality in people with diabetes. The loss of skeletal muscle mass and function is a major component of frailty, and it is highly prevalent in people with type 2diabetes (T2DM). Hand grip strength (HGS), is a simple anthropometric measurement and it is an indicator of upper body muscle strength. There is limited evidence available on the association of HGS and DPN in the Indian context. Hence, we aimed to investigate the association between HGS and DPN among people with T2DM.

Materials and methods

A cross sectional study was conducted among 148 (M: F 79:69) participants from June to August 2023 in a tertiary care center for diabetes in South India. The Michigan Neuropathy Screening Instrument (MNSI) was used to assess DPN. It includes 2 assessments: 1)15-item self-administered questionnaire (MNSI-Q). A score of ≥4 was considered abnormal. 2) A physical examination of the lower extremity (MNSI-PE). A score ≥2 was considered abnormal. Grip strength was measured using JAMAR's Hydraulic Hand Dynamometer. The cut off point for low grip strength is <26 kg in men and <18 kg in women (AWGS Guidelines). Body composition such as protein, minerals, skeletal muscle mass (SMM), skeletal muscle index (SMI), body fat mass (BFM), percentage of body fat (PBF), Body mass index (BMI) were measured using Bioelectrical Impedance Analysis (BIA).

Results

Median age of the study participants was 52 years and median duration of diabetes was 5.5 years. The presence of DPN was confirmed in 53.5% of men and 46.5% of women on assessment. Median HGS in the dominanat hand was significantly lower in people with DPN than in people without DPN in both male and female (22vs33,p<0.001) and (16vs20,p=0.003). Median age was significantly higher in people with low HGS and neuropathy as compared to people without neuropahy(57vs48,p=0.001). PBF was higher in people with low HGS and with neuropathy than people without neuropathy (43 vs 33%,p=0.691). Multivariate logistic regression analysis showed that neuropathy was independently associated with age, duration of diabetes and HGS (p<0.001 for all).

Conclusion

This preliminary analysis revealed that low hand grip strength was found to be associated with Diabetic Peripheral Neuropathy among people with type 2 diabetes.

O21

Evaluation of the Stigma and Discrimination faced by the people with diabetes post amputation - A cross sectional study

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Keywords
Epidemiology

Background and Aims

During post amputation period, perceived social support, adaptation to the prosthesis, amputation type, presence of pain, self-esteem and body image issues are among the factors reported to affect daily living and psychosocial functionality. Discrimination and stigma occurs when people are treated unfairly because they are seen being different from others. Stigmatization and discrimination is noticed among people who had undergone major amputation due to diabetes.

However, most measures of experienced stigma have not been psychometrically evaluated in the Indian context. Hence, we aimed to investigate whether people with type 2 diabetes with post major amputation experienced stigma and discrimination (DISC-12) and assessed the reliability of the DISC-12. We also measured the functional independence in basic activities of daily living (ADL).

Materials and methods

This cross - sectional study was conducted among 90 (M: F= 71:19) participants aged above 30 who underwent a major amputation in a tertiary care centre for diabetes, South India. Demographics and clinical details were recorded. Discrimination and Stigma scale [DISC-12] and ADL questionnaire was administered for all the participants. The four parts in the Scale: Part I contains 22 questions about times when you have been treated unfairly. Part II contains 4 questions about times when you have stopped yourself from doing things because of how others might respond. Part III contains 2 questions about how you may have overcome stigma and discrimination. Part IV contains 6 questions asked about any times when you have been treated more positively because of a major amputation. Responses were rated on a four Likert scale (0=not at all, 1=a little, 2=moderately, and 3=a lot) with a "not applicable" response option for items that the patients judged as not relevant to their situation. Scores on the Positive Treatment subscale were reverse coded so that a high score indicated a lack of positive treatment. The total score for each subscale was generated by counting the number of items on which the score was 1, 2, or 3 (negative scores), with higher scores indicating greater stigma. ADL scale quantifies functional independence in the activities of daily living by analyzing six basic items: hygiene, dressing, toileting, locomotion, continence and meals. Reliability was assessed as internal consistency of DISC-12 using Cronbach's alpha coefficient. Data were analyzed by using descriptive statistics.

Results

The mean age of the participants was 63.4 ±8.4 years. Cronbach's alpha coefficients were high for the entire DISC - 12 (0.875). Mean score on the DISC-12 were mean SD, 13.8(8.7) for experienced discrimination, 1.27 (1) of anticipated discrimination, 2.87 (1.5) for overcoming stigma and 7.60 (1.4) for positive treatment. The frequency of those who reported positively in each subscale was high (34.84, 13.88, 71.65, and 57.03%). Among the participants, 82 (91%) were partially autonomous, 6 (7%) were completely dependent and 2 (2%) were completely autonomous for activities of daily living (ADL=0).

Conclusion

The reliability of the DISC-12 was better. People with type 2 diabetes who were partially autonomous perceived a positive attitude towards stigma. The instrument has to be validated in the population.

O22

Correlation of TIR and Weight loss in prediabetes and moderately controlled Type 2 Diabetes – A Multicentre Study

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Keywords
Prevention of type 2 diabetes • Weight regulation and obesity • Nutrition and diet • Devices

Background and Aims

The metric of time-in-range has been recognized as a significant indicator of blood glucose levels, providing a more comprehensive understanding of glycaemic management in individuals with diabetes and obesity, beyond the limitations of relying just on HbA1c measurements. This study examines the efficacy of time-inrange, a novel metric derived from continuous glucose monitoring, as an outcome measure for assessing the correlation between weight changes and overall and daytime time in range (TIR, 70-140 mg/dL) in a behavioural weight loss program.

Materials and methods

The data utilized in this investigation were obtained from the Personal Diet investigation, a six-month weight reduction trial conducted among persons who had prediabetes or moderately managed type 2 diabetes (HbA1c levels below 8%) from Sevana Hospital, Pattambi, Kerala and Kaveri Healthcare, Bangalore, Karnataka. The intervention involved the implementation of remote behavioural counselling and dietary selfmonitoring through the use of a smartphone application. The individuals in the study utilized Abbott Freestyle Libre Pro continuous glucose monitoring (CGM) devices, which were blinded, for a maximum duration of two weeks during the first assessment and for a period of six months. Participants were classified into three categories, namely "Improved," "No Change," or "Declined," based on clinically significant changes in two time in range (TIR) metrics: "All-TIR," which includes all continuous glucose monitoring (CGM) readings, and "Day-TIR," which includes CGM measurements from 6am to midnight. The statistical analysis employed one-way ANOVAs to establish the relationships between categories of TIR change and the percentage of weight change.

Results

We analysed baseline and 6-month CGM data from 75 participants (age 60±10 years, 55% male, BMI 30.5±5.0 kg/m2, HbA1c 5.7±0.5%). When stratified by Day-TIR change, improved lost more weight than No Change and Declined (p=0.005) (Figure 1). When using All-TIR to stratify, there were no significant weight change differences across groups (p=0.15).

Conclusion

The results of this study showed that participants who had an improved day time TIR as opposed to their overall TIR lost more weight over the course of the study.

O23

Impact of a self efficacy theory based foot self care education intervention among people with type 2 diabetes mellitus: A quasi-experimental study

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Keywords
Epidemiology • Education • Diabetic foot and skin disorders • Pathogenic mechanisms / complications

Background and Aims

Suboptimal foot self-care practices can compromise physical function and quality of life. This study aimed to evaluate the effectiveness of DM self-care intervention based on the behaviour change theory on foot selfcare behaviour among people with type 2 diabetes mellitus (T2DM) living in rural areas.

Materials and methods
A quasi-experimental study was conducted among patients with T2DM living in rural areas of Punjab, North India. Based on Bandura's theory of self-efficacy (SE), eight diabetes self-care education interventions were designed, implemented over six weeks, and followed up on for six months. Primary healthcare personnel interacted face-to-face with T2DM patients throughout the intervention. At baseline, there were 283 participants with T2DM in the intervention arm and 291 in the control arm. Of these, 86% in the intervention arm and 81% in the control arm completed the endline assessment. A baseline and an endline survey were conducted using the Nottingham Assessment of Functional Foot (NAFF) and Diabetes Management Self-Efficacy (DMSE) questionnaires. Outcomes were net proportion changes of people with T2DM having optimal diabetes self-care self-efficacy and foot self-care behaviour. Data were analysed using per-protocol analysis. Confounder adjustment was done using Difference in Difference (DiD) analysis with a Generalised Estimating Equation model (GEE).p<0.05 was considered as significant.
Results
Participants' median (IQR) age was 58 years (50-65 years). The median (IQR) duration of T2DM was five years (4-7 years). In the post-intervention phase, there was a significant net increase in the proportion of participants having optimal DMSE (39%; 95% CI: 25% -52%, p<0.001). In the post-intervention phase, there was a significant difference between the proportion of the population practising optimal foot self-care in the intervention arm (32%; 95% CI: 23-40, p<0.001) and the control arm (-18%; 95% CI: -25. -10, p<0.001). After controlling for confounders at the post-intervention phase, the results of the Logistic GEE model further demonstrate that the odds of engaging in optimal foot care activities in the intervention arm were aOR 7.82 times (95% CI: 5.29-10.94, p<0.001) than those in the control arm.
Conclusion
A diabetes self-care education intervention based on behaviour change theory aids in promoting optimal DMSE and foot care practices among T2DM patients in rural areas.

O24

A study on the effect of left ventricular mass index adjustment of ejection fraction on the assessment of left ventricular function and cardiovascular risk in diabetes

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Keywords

Background and Aims
Cardiovascular disease (CVD) is the leading cause of death in people with diabetes. LVEF and LV mass were found to be major independent predictors of future CVD. T2DM was associated with a 1.5-fold increase in the risk of having LV mass above the 75th percentile of the general population. But so far no attempts were made to look at the association between LVMI-adjusted EF and MACE in diabetes patients. Our study tried to assess this association and the predictive potential of high LVMI on the composite of 5-point MACE.
Aim: To compare measured and LVMI-adjusted EF in T2DM patients, to assess the impact of LVMI adjustment on various categories of LV systolic dysfunction, and to assess the association between LVMI and LVMI-adjusted EF and CV events.
Materials and methods
We analyzed the echocardiographic data of 426 patients and their LVMI-adjusted EF was calculated and compared with measured EF, and they were followed over a mean of 2 (±1) years.
Results
On LVMI adjustment, EF significantly reduced from 48.92% to 45.92% (P=0.0341), 36.52% to 32.67% (P=0.0033) and 30% to 24.36% (P=0.0476) and the prevalence of LV systolic dysfunction increased from 1.17% to 9.86%, 0.7% to 3.29% and 0.7% to 2.3% in the mild, moderate and severe categories respectively. Total MACE was significantly higher in the high LVMI group compared to the normal LVMI group [Odds ratio-47.5; 95% CI: 6.5-346.7; P=0.001]. The sensitivity and specificity of high LVMI in predicting MACE were 25% and 99% with positive and negative predictive values (%) of 95 and 72 respectively.
Conclusion
This study found that LVMI adjustment of EF significantly altered EF measurements in the LV systolic dysfunction categories, and low LVMI-adjusted EF and high LVMI were significantly associated with MACE.

O25

Superior Glycemic Control with Once-Weekly Insulin Icodec with a Dosing Guide App vs. Once-Daily (OD) Basal Insulin Analogs in Insulin-Naïve T2D—ONWARDS 5

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Keywords
• Insulin therapy

Background and Aims
ONWARDS 5 (NCT04760626), a 52-week, open-label, randomized, phase 3a trial with real-world elements, assessed effectiveness and safety of once-weekly insulin icodec with a dosing guide app (icodec) vs OD basal insulin analogs (degludec, glargine U100 or glargine U300) in insulin-naïve adults with T2D.
Materials and methods
Participants (mean: 59.3 yrs; 32.8 kg/m2) were randomized 1:1 to icodec or OD analogs. The dose guidance app aided icodec titration; OD analogs were titrated as per standard of care.
Results
Estimated mean A1C change from baseline (BL) to week 52 was greater with icodec (-1.68%-points, BL 9.0%) vs OD analogs (-1.31%-points, BL 8.9%) confirming non-inferiority (p<0.0001) and superiority (p=0.009) of icodec vs OD analogs. Patient-reported outcomes (DTSQ and TRIM-D) were statistically significant in favor of icodec vs OD analogs at week 52. Rates of level 2 (<54 mg/dL) or level 3 (severe) hypoglycemia were low for both

treatments (0.19 [icodec] vs 0.14 [OD analogs] events per person-year of exposure). There were no significant differences between treatments in time to treatment discontinuation/intensification.

Conclusion

Overall, icodec with a dosing guide app showed superiority in A1C reduction, and significant improvement in treatment satisfaction and compliance scores vs OD analogs, with low hypoglycemia rates, in insulin-naïve adults with T2D in a real-world setting

O26

Systemic Immune Inflammatory Index Emerging as a Novel Parameter in Treatment of Diabetic Depression

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Keywords
• Inflammation in type 2 diabetes • Psychological aspects • Other complications

Background and Aims

In our daily practice 20 to 30 percent cases of diabetic depression get unnoticed. Early intervention with antidepressants to these patients helps to decrease diabetes risk and its complications. Therefore, it is both urgent and necessary to identify depression in patients with Diabetes. Preclinical and clinical studies have shown a causal link between sterile low-grade inflammation and depression in patients with Diabetes. "SYSTEMIC IMMUNE INFLAMMATORY INDEX " emerged as a novel marker for many diseases like diabetes, cancer, covid 19 Aim:: To investigate relationship between SII and diabetic depression and show SII superiority over other inflammatory markers like NLR, PLR, MLR.

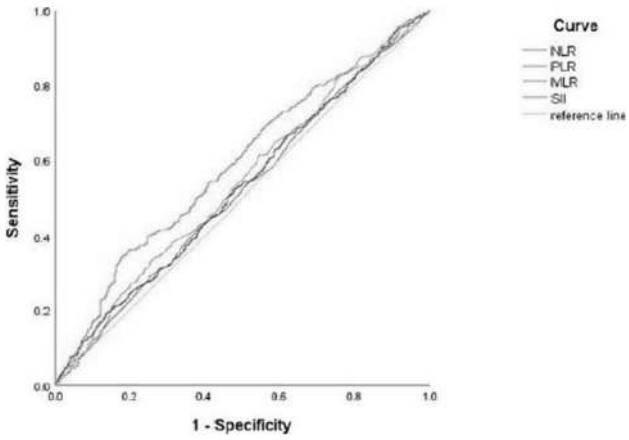
Materials and methods

PHQ-9 (Patient Heatlh Questionnaire -9)was used to evaluate and confirm depression in the subjects. Medical auditing patient data of diabetic patients along with their CBP and SII was calculated from the equation, SII = P x N/L, where P, N and L are the peripheral blood platelet, neutrophil and lymphocyte counts per liter respectively. The optimum cutoff point for SII for a favorable prognosis was determined to be (390×109 cells/L). Patients taken for the study were of elderly age group with more than 45 years with diabetes mellitus and had been under our treatment since last 5 years. (patients who had other severe inflammatory pathologies like (appendicitis,pancreatitis,cancer) were excluded from the study. SPECIFICTY AND SENSITIVITY OF SII was also compared with other inflammatory markers like NLR, PLR AND MLR to show the superiority of SII over other parameters.

Results

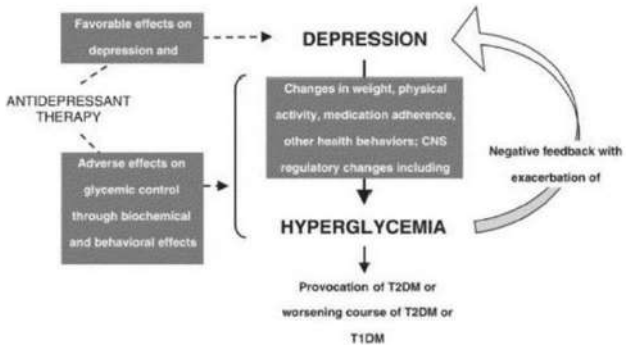
A total of 1000 patients elderly diabetic(age more than 45 years) were evaluated using PHQ-9 in which 30 percent(300) of the patients were found to have depression. SII for all the 1000 patients were taken and compared in which diabetic patients who were found to have depression had high SII levels (>390×109 cells/L.)compared to patients without depression indicating that SII was a independent risk factor for diagnosing ,evaluating diabetic depression. Another important thing noticed is that SII compared with other parameters like NLR,PLR,MLR showed high sensitivity (as shown in the graphical representation of the abstract)

Graph/Table:



Variables	Area under the curve	Standard error	p	95% CI
NLR	0.540	0.016	0.012	0.509–0.572
PLR	0.527	0.016	0.095	0.495–0.558
MLR	0.517	0.016	0.286	0.486–0.548
SII	0.585	0.016	<0.001	0.554–0.616

NLR, neutrophil-to-lymphocyte ratio; PLR, platelet-to-lymphocyte ratio; MLR, monocyte-to-lymphocyte ratio; SII, systemic immune-inflammation index.



Conclusion

Our data gathered from the study showed SII as a single independent highly sensitive marker for diabetic depression. And SII coupled with PHQ-9 Questionnaire are easily accessible and cost effective solutions for identifying and treating patients with diabetic depression which saves lot of money and time for the patients and treating doctors.

O27

Trabecular bone bone score, bone mineral density, and fractures in patients of chronic kidney disease with and without type 2 diabetes mellitus

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Keywords
• Other complications

Background and Aims
Chronic kidney disease-mineral bone disease (CKD-MBD) is a common yet neglected long-term complication of CKD. The primary objective of this study was to compare the proportion of patients with low trabecular bone score (TBS) in the CKD patients with diabetes mellitus (CKD-DM) and the CKD patients without DM (CKD-NDM). The secondary objectives were to compare bone mineral density (BMD) and morphometric vertebral fractures (VF) between the two groups.
Materials and methods
Patients of CKD with an estimated glomerular filtration rate (eGFR) < 60 mL/min/1.73m2, and not initiated on maintenance hemodialysis were recruited in the study. They were classified into the CKD-DM or the CKD-NDM group based on the presence of DM. Both groups were matched for age and gender. A detailed history was taken, and a physical examination was done to rule out secondary causes of osteoporosis. Serum creatinine, electrolytes, 25 hydroxy vitamin [25 (OH)D], and intact parathyroid hormone (iPTH) were analysed. Areal BMD was assessed using Hologic Discovery Wi dual-energy X-ray absorptiometer. TBS was estimated from spine BMD images using TBS iNsight software v 3.1.1 (Medimaps, Geneva). A dorsolumbar spine radiograph was performed to look for morphometric VFs.
Results
306 participants with CKD (153- diabetic and 153 non-diabetic) were included. The baseline characteristics were comparable between the two groups except for a higher BMI [24.13 (21.9-27.5) vs 21.86 (19.7-24.4) kg/m2], higher waist circumference [92.5 (85-99) vs 85 (80-93) cm], higher eGFR [31 (15.5-42.5) vs 25 (13-34) ml/min/1.73m2], lower magnesium [2 (1.8-2.2) vs 2.1 (1.8-2.4) mg/dl], and lower 25(OH)D [28.82 (21.3-38.6) vs 36.11 (28.4-47.3) ng/ml] in the CKD-DM group. The proportion of patients with low bone turnover (iPTH levels < 80 pg/ml) was higher in the CKD-DM group (34.2% vs 27.1%). The proportion of patients with low TBS was similar between the two groups (39.86% vs 41.83%; p=0.727). The BMD at lumbar spine (LS) [0.977 (0.877-1.128) vs 0.945 (0.814-1.148) g/cm2; p=0.219] and distal forearm (FA) [0.689 (0.618-0.736) vs 0.661 (0.576-0.731) g/cm2; p = 0.053] were also comparable between the two groups. However, BMD at femur neck (FN) [0.707 (0.624-0.798) vs 0.665 (0.586-0.768) g/cm2; p=0.012] and total hip (TH) [0.862 (0.760-0.951) vs 0.811 (0.713-0.916) g/cm2; p=0.006] were higher in the CKD-DM group. The prevalence of morphometric VF was similar between the two groups (8.5% vs 5.2%; p=0.258).
Conclusion
In this cohort of pre-dialysis stage 3-5 CKD patients, the prevalence of low TBS, BMD at LS and distal FA were similar between the CKD-DM and the CKD-NDM groups. The BMD at FN and TH was higher in CKDwith DM compared to CKD without DM.

O28

Clinical Profile of Peripheral Neuropathy in Diabetes Mellitus patients: Realworld Multicenter, Cross-Sectional, Observational Study (CPR Study)

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Keywords
• Neuropathy: autonomic, incl. erectile dysfunction

Background and Aims
The present cross-sectional retrospective observational study was designed with the objective to assess the signs and symptoms of peripheral neuropathy pertaining to identification of "at risk foot" in diabetes mellitus patients.
Materials and methods
A total of 17377 consecutive patients with diabetes mellitus from 1228 centres across India were analysed for foot complications. A pre-designed questionnaire for symptoms of neuropathy was administered to consecutive patients of diabetes visiting the out-patient department. In addition foot inspection was performed by the trained person at each center to identify corn, calluses, deformity, hallux valgus.
Results
In total there were 17377 diabetes mellitus patients analysed with an average age of 51.7±9.6 years. Among them there were 1173 (6.8%) type 1 diabetes mellitus (T1DM) patients and 16204 (93.2%) type 2 diabetes mellitus (T2DM) patients. Dry skin of the foot was the most frequent complaint (n=7658, 44.1%) followed by burning (n=5350, 30.8%), muscle cramps (n=4343, 25%), loss of sensation (n=3999, 23%) tingling (n=3891, 22.4%), and infection (n=3712, 21.4%). Type 1 diabetes mellitus patients had higher HbA1c (8.1 ± 2.2 % vs.7.7 ± 2.2 %, p<0.001), higher frequency of hammer toe (14% vs 10.2%), corn (19.9% vs 11.2%), than type 2 diabetes mellitus (T2DM) patients. However, type 2 diabetes mellitus (T2DM) patients have higher random blood glucose (191.3 ±46.6 mg/dL vs.174.7 ± 42.2 mg/dL, p<0.001), a higher frequency of dry skin feet (45.1% vs 69.6%), tingling (22.6% vs 77.4%), burning (31% vs 27.3%) and loss of sensation (23.7% vs 13.5%) than T1DM patients. On average patients had 2.1 ± 1.7 symptoms. Both HbA1c and age significantly correlated with the number of symptoms (R=0.2 for both).
Conclusion
People with diabetes have high prevalence of symptoms pertaining to lower limb. Type 2 diabetes mellitus (T2DM) patients are particularly vulnerable to have "at risk foot".

O29

Unraveling the Impact of DNA Methylation on Nrf2 in the progression of Diabetic Foot Ulcers

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Keywords
Diabetes epigenetics • Hypoglycaemia • Diabetic foot and skin disorders • Pathogenic mechanisms / complications

Background and Aims
Epigenetic modifications within the promoter region of Nrf2 have emerged as significant contributors to the pathogenesis of diabetic foot ulcers (DFUs). Altered methylation patterns in CpG islands within this region have been implicated in the progression of DFUs. This study aims to investigate methylation patterns within the NRF2 promoter in DFU tissue biopsies and elucidate the relationship between promoter methylation and Nrf2 gene expression
Materials and methods
A comprehensive cohort of 60 DFU patients (32 males, 28 females), 20 healthy individuals with normal glucose tolerance (Normal skin), and 40 DFU patients (20 with acute, uninfected DFUs and 20 with chronic, infected DFUs) were included. Expression levels of Nrf2 and its downstream targets, as well as DNMT genes (DNMT1, 3A, 3B), were analyzed using qPCR. Methylation levels in the Nrf2 promoter were assessed using Methylation-Sensitive Restriction Enzyme (MSRE) qPCR, and comprehensive methylation patterns explored via Bisulphite Genome Sequencing (BGS).
Results
A significant reduction in the expression of the pivotal transcription factor NRF2 and its downstream targets, including catalase, heme oxygenase-1, glutathione peroxidase-1, and NAD(P)H quinone dehydrogenase 1, was observed in DFU subjects. Elevated expression of DNMTs (1, 3A, and 3B) was identified in DFU patients, contributing to diminished Nrf2 expression. The methylation percentage increased with disease progression, escalating from 11% in early-stage DFUs (G0) to 26% in advanced DFUs (G3). A meticulous analysis of two CpG islands within the Nrf2 promoter revealed escalating methylation patterns accompanying disease progression.
Conclusion
This study highlights the prevalence of increased DNA methylation within the Nrf2 promoter, serving as a hallmark of DFU progression. The augmented expression of DNMTs and reduced Nrf2 expression were intricately linked to this distinctive methylation pattern. A comprehensive examination of CpG islands within findings underscore the potential of targeted epigenetic interventions as a promising approach to manage and treat DFUs.

O30

Diabetes in resource constrained settings

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Keywords
• Nutrition and diet • Education • Diabetes in childhood

Background and Aims
This study was conducted to assess the effectiveness of a culturally-tailored, education module suited to the resource-constraints of children with Type 1 Diabetes (T1D) on their glycemic control (HbA1C), health related quality of life (HRQOL), adherence, total daily insulin dose (TDD) and clinically important events like hypo/hyperglycemia and Diabetic Ketoacidosis (DKA).
Materials and methods
Using a quasi-experimental design, 94 children (47 in each group) and their caregivers attended either the existing enhanced education program, or the structured, culturally-tailored education program with low reading level in Hindi and Punjabi language. Outcomes were assessed at baseline, 3 months and 6 months. Adherence and HRQOL was assessed using the standardised Hindi versions of 'DSMP-SR' and 'PedsQL 3.2 Diabetes Module' respectively.
Results
86 children completed follow-ups. The mean age of children was 8.2±4 years, 55% were females; mean duration of diagnosis was 1.9±3 years. All children were on multiple daily injections, basal-bolus regimen. Educational level of mothers was below high school level in 58%, 66% belonged to rural habitat, and 53.4% fathers were daily wagers. Few children (15%) had a caregiver other than parent. HbA1C results significantly reduced at 6 months in both the intervention (IG) (12.2±2.6 to 8.2±1.8, p-0.00) and control group (CG) (12.0±3 to 8.2±1.6, p-0.00) but between-group difference was not significant at 3 (p-0.92) or 6 months (p-0.73). The adherence and HRQOL had a significant improvement in the IG than CG at both follow-ups (p-0.00). The TDD and frequency of hypo/hyperglycemia and DKA was lower in the IG than CG at both follow-ups, but not statistically significant.
Conclusion
A culturally-tailored education module is effective in improving the HRQOL and adherence among children with T1D living in resource-constrained settings without deteriorating their glycemic control.

O31

Comparison of intermittent fasting and continuous energy restriction on body composition and multiple metabolic factors in adults with obesity

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Keywords
• Nutrition and diet • Socio-economic aspects

Background and Aims
Intermittent fasting (IF) as a weight loss strategy may have more beneficial effects on body composition and metabolic parameters as compared to continuous energy restriction (CER). We compared the effect of 5:2 IF, alternate day fasting (ADIF) and CER on weight loss, body composition and metabolic parameters.
Materials and methods
A total of 90 subjects with obesity were recruited (18-60 years). They were randomly assigned to three groups - Group 1, 5:2 IF (n=34); Group 2, ADIF (n=32); and Group 3, CER (n= 24) for three months. All subjects were given standard exercise advice. Anthropometric, biochemical, body composition, physical activity assessment using GPAQ were done at baseline and after 3 months.
Results
Mean baseline BMI was comparable in all the three groups (34.6, 32.4, 32.5 kg/m2). Weight loss observed in the three groups was 7.2% ($p<0.05$), 2.5% and 1.5% in groups 1, 2 and 3, respectively. Similarly, reduction in waist circumference was 4.7 ($p<0.05$), 1 and 2.74 cm in groups 1, 2 and 3, respectively. Significant changes in post prandial blood glucose were observed in ADIF group and cholesterol was significantly reduced in both ADF and CER group. Fasting insulin (20.7%,

11.7% and 14%, p<0.001 for all) and leptin levels (19.2%, 8.6% 6.5%) decreased significantly and adiponectin levels increased significantly (51.1%, 34% and 44.2%) in groups 1, 2 and 3, respectively.

Conclusion

5:2 IF was associated with greater beneficial effects on weight, body composition, insulin resistance and adipokines as compared to CER over a short duration of three months in adults with obesity.

O32

Out-of-pocket expenditure among patients with diabetes mellitus attending a tertiary care hospital in North India: A facility based cross-sectional study

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Keywords
• Socio-economic aspects

Background and Aims

Diabetes is one of the leading causes of morbidity and mortality worldwide and a major problem in India. Financing health care through out-of-pocket payments results in catastrophic health expenditure and impoverishment. The aim of the present study is to estimate the out-of-pocket expenditure on diabetes care of patients attending a public tertiary care hospital in India.

Materials and methods

In this hospital based cross-sectional survey study, patients attending OPD of a tertiary care hospital in New Delhi were included. A detailed form containing questions regarding sociodemographic information, and expenditures on various heads of diabetes care like, investigations, medications, transportation etc. was used to conduct the survey and information about out-of-pocket expenditure was obtained.

Results

In this survey 281 subjects with type 2 diabetes participated, with mean age of 47±8.6 y, with almost equal number of males and females. More than 60% of the participants were from the middle- or lower-income group and the majority of the participants (54%) hailed from urban setting and remaining 46% from rural or urban slum setting. Mean duration of diabetes was 5.8±5 y. The mean expenditure reported on diabetes care was about 10±11% [5% (0.2-50%)] of their monthly family income. Direct cost of diabetes care like drugs, investigations, consultation etc. was about ₹2744±3449 [1700 (100-16000)]. Indirect cost of diabetes care like transportation, days of work and wages loss was ₹828±1113[Rs 500(100-5000). The cost of drugs and investigations is the highest burden, with mean expenditure of ₹1334±1356 [800 (60-5000)] on drugs and ₹864±1340 [Rs 425(0-6000) on investigations.

Conclusion

In the context of a developing nation like India, this study on individuals with type 2 diabetes sheds light on the significant financial strain imposed by the condition. With a substantial portion of participants from lower-income backgrounds, the research highlights the formidable direct and indirect costs of diabetes care, particularly on medication and investigations. Addressing these economic challenges is imperative for equitable healthcare access.

O33

Profiling of Epigenetic Markers and its correlation with Nrf2 in the progression of Diabetic Nephropathy

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Keywords
Diabetes epigenetics • Socio-economic aspects • Nephropathy • Pathogenic mechanisms / complications

Background and Aims

Nuclear factor erythroid-2-related factor 2 (Nrf2) is pivotal in maintaining cellular balance. Regulating Nrf2 expression is a key target in managing Diabetic Nephropathy (DN), where epigenetic factors are believed to exert influence. Epigenetic modulation of Nrf2 involves histone deacetylases (HDACs) and DNA methyltransferases (DNMTs). This study aims to profile all classes of HDAC expression and correlate it with Nrf2 in the context of DN progression.

Materials and methods

A total of 108 participants were categorized into three groups: group 1 (Normal glucose tolerance, n=25), group 2 (type 2 diabetes mellitus, T2DM; n=23), and group 3 (DN). Group 3 was subdivided into microalbuminuria (n=30) and macroalbuminuria (n=30) subgroups based on estimated glomerular filtration rate (eGFR). Gene expression of NRF2, HDACs, and DNMTs targets were assessed using qPCR. Statistical analysis included Mann–Whitney U test for significance and Spearman's correlation for assessing HDACs and DNMTs correlation with NRF2

Results

In DN subjects, Nrf2 gene expression was significantly reduced compared to healthy controls. Concomitantly, HDAC3/7/8/9/10/11 and SIRT1/2/3/4/7 showed significant downregulation in DN subjects compared to T2DM. Conversely, HDAC1/2/4/5/6 exhibited significant upregulation in DN subjects versus T2DM. Notably, a negative correlation between Nrf2 and HDAC1/2/4/5/6 underscores Nrf2-HDAC axis imbalance

Conclusion

This investigation underscores the distinct effect of HDAC4 on the disruption of Nrf2 expression and the progression of disease among the 18 tested HDAC isoforms. These findings emphasize the imperative of deciphering the intricate role of HDACs in diabetic kidneys. Such insights hold promise for the emergence of innovative therapeutic strategies involving HDAC inhibitors to effectively mitigate the advancement of the disease.

O34

MicroRNA-125b-5p Modulates Vitamin D Resistance by Targeting CYP24A1 in the Progression of Gestational Diabetes Mellitus

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Keywords
• Insulin sensitivity and resistance • Socio-economic aspects • Pregnancy • Pathogenic mechanisms / complications

Background and Aims
Vitamin D deficiency during pregnancy is associated with increased risks of preeclampsia, cesarean delivery, neonatal bacterial vaginosis, and gestational diabetes. The enzyme CYP24A1 plays a crucial role in vitamin D metabolism, affecting its homeostasis. This study focuses on investigating the regulatory role of miRNA in CYP24A1 during the progression of gestational diabetes mellitus (GDM) and validating this relationship through silencing experiments in trophoblast cells.
Materials and methods
An observational study included 150 pregnant women categorized as healthy (NGDM), early-onset GDM (eGDM), and GDM patients. Blood samples were collected around 12 weeks of gestation for gene expression analysis of miR-125b-5p and CYP24A1 using qRT-PCR. Human trophoblastic cells (BeWo) were exposed to hyperglycemic conditions to mimic GDM. The impact of miR-125b-5p on CYP24A1 regulation was assessed through antimiR-125b and miR-125b mimic transfections
Results
MiR-125b-5p, a potential regulator of CYP24A1, exhibited decreased expression in GDM and eGDM patients compared to healthy pregnancies, with a positive correlation to vitamin D levels. Hyperglycemic conditions suppressed miR-125b-5p and elevated CYP24A1 expression in BeWo cells. Transfection with antimiR-125b increased CYP24A1 levels, while miR-125b mimic reduced CYP24A1 expression. Treating trophoblast cells overexpressing miR-125b with calcitriol revealed reduced CYP24A1 levels under hyperglycemia.
Conclusion
This study highlights the potential role of miR-125b in regulating vitamin D metabolism via CYP24A1, influencing the progression of GDM. These findings offer insights into vitamin D resistance in GDM and identify a novel miRNA-CYP24A1 interaction. This research contributes to understanding GDM development and suggests avenues for further exploration.

035

A pilot study on the pathological relevance of Phthalates in South Indian T2DM patients

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Keywords
Environmental factors (viruses, nutrients, toxins)

Background and Aims
Phthalates, the low volatile, stable environmental pollutants have recently been associated with endocrine, respiratory and reproductive disorders. While several countries have examined in detail their association in human pathologies, studies regarding phthalate exposure in the T2DM population is obscure in India. Therefore, the present study aimed to determine the concentration of phthalate esters (DMP, DBP and DEHP) in a pilot population of healthy volunteers, T2DM patients of south India.
Materials and methods
The Phthalate concentration in the peripheral blood samples of consenting, randomly recruited 15 healthy volunteers, and 15 T2DM patients was carried out using standardized GC-MS protocols. In brief, the study samples were extracted using Strata SPE cartridges (30mg, 1 ml), preprocessed, eluted in 100% acetonitrile, dried at 45°C under rotavapor, reconstituted with acetonitrile, and then analyzed using GC-MS.
Results
The study results indicated that the mean±SE values of the BMI of the T2DM patients was significantly higher [27.52±1.17, ($p<0.05$)] than the healthy volunteers (23.46± 1.04). The mean concentrations of the phthalate esters DMP, DBP and DEHP in the healthy volunteers was 1.29±0.44, 187.16±97.52 and 33.73±5.97 respectively, and 2.06±0.99, 177.28±70.99,3055.39 ±602.5 in T2DM patients, respectively. The T2DM patient population exhibited significantly high levels of DEHP ($p<0.05$)
Graph/Table :

S.No	Parameters	Healthy Volunteers (mean ± SE)	T2DM Patients (mean ± SE)
1	BMI	23.46± 1.04	27.52±1.17 *
2	DMP	1.29±0.44	2.06±0.99
3	DBP	187.16±97.52	177.28±70.99
4	DEHP	33.73±5.97	3055.39±602.5*

Levels of Phthalates in Healthy volunteers, T2DM patients: DEHP levels were significantly higher ($p<0.05$) in T2DM patients of the study population.

Conclusion
Taken together, it can be deduced that the phthalate exposure in the regional T2DM population could be significantly high. The association of phthalates with the incidence, pathogenesis of T2DM in the regional population is currently being evaluated.

O36

Severity of diabetic retinopathy in stages of diabetic nephropathy based on KDIGO among people with type 2 diabetes in South India

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Keywords
• Nephropathy

Background and Aims
The rate of Diabetic retinopathy (DR) in type 2 diabetes (DM) using new classification of CKD by KDIGO is unknown in Indian context. The aim of this study was to see the rate and severity of DR in diabetic nephropathy (DN) based on KDIGO.
Materials and methods
In this cross sectional study, 534 participants with DM were screened for both DN (GFR and ACR) and DR from Mar - Dec 2022 in a tertiary care center for Diabetes, Chennai and grouped into CKD stages by using KDIGO - 1(G1A1, G2A1), 2 (G1A2, G2A2, G3aA1), 3 (G3bA1, G3aA2) and 4 (G3bA2, G4A1, G4A2, G5A1, G5A2). DR examination was done by retina specialists using Fundus Photography and slit lamp and graded as NPDR (mild, moderate, severe) and PDR (early, high risk) based on ETDRS (Early Treatment Diabetic Retinopathy Study) scale.
Results
Median age and duration of DM was 58 and 13years. Proportions in CKD stages were: 1 (28.7), 2(29.6), 3 (22.3) and 4 (19.5) %. DR in CKD stages: 1(16.4), 2 (36.7), 3(54.7) and 4 (73.1) %. The rate of DR increased with advanced stages of CKD. Rate of NPDR and PDR in stage 2 was higher than stage 1(33.5 vs 15.7%; p=0.06 and 3.2 vs 0.7%; p=0.005). Rate of NPDR in stage 3 and 4 were similar (42.9 vs 42.3%) whereas rate of PDR in stage 4 was significantly higher than stage 3 (30.8 vs 11.8; p<0.001). Odds ratios of DR increased from stage 2 to 4 [OR 2.96 (95% CI 1.73 - 5.1; p < 0.001)], [6.16 (3.5-10.8); p<0.001] and [13(7.6 - 25.6); p < 0.001].
Conclusion
A strong association of DR was noted with the late stages of CKD according to KDIGO in people with type 2 DM. Early evaluation of renal/ retinal status is recommended to prevent blindness and end stage renal disease.

O37

Proportion of people living with type 2 diabetes achieving ≥ 20% reduction in insulin use with oral semaglutide compared with placebo

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Keywords
• Incretin based therapies 43 Novel agents

Background and Aims
The Phase 3a programme for oral semaglutide (PIONEER 8 trial) demonstrated significant glucose-lowering efficacy of oral semaglutide vs placebo (pbo) in patients (pts) with T2D inadequately controlled with insulin. Additionally, those assigned to oral semaglutide (7 or 14 mg daily) had a lower total daily insulin dose at end of treatment (week 52) relative to baseline, vs those treated with pbo, suggesting an insulin-sparing effect.
Materials and methods
This post-hoc analysis of PIONEER 8 aimed to characterize the transition of adding a GLP-1RA to insulin therapy and to quantify reductions in total insulin dose seen with the addition of oral semaglutide. A 20% reduction in total daily insulin dose was recommended at randomization up to week 8. Total daily insulin was not to exceed pre-randomization dose between weeks 8 and 26 but as freely adjustable at the investigator's discretion from week 26 to 52.
Results
For all doses of oral semaglutide, a greater proportion of pts were able to maintain a greater level of insulin dose reduction vs pbo at week 26. Greater proportions of pts on oral semaglutide 3, 7, and 14 mg achieved ≥20% reductions in insulin vs those in the pbo group at both weeks 26 and 52 (27.5%, 28.9%, 31.2% vs 12.4% and 19.5%, 25.0%, 32.0% vs 5.7%, respectively; P<0.001 for all).
Conclusion
Addition of oral semaglutide in patients with T2D permits a significant reduction in insulin dose, which may provide benefits(e.g. lower risk of hypoglycemia and weight gain) long-term.

O38

CGM Outcomes and Hypoglycemia Duration with Once-Weekly Insulin Icodec vs. Once-Daily Insulin Glargine U100 in Insulin-Naïve T2D - ONWARDS 1 Exploratory Analysis

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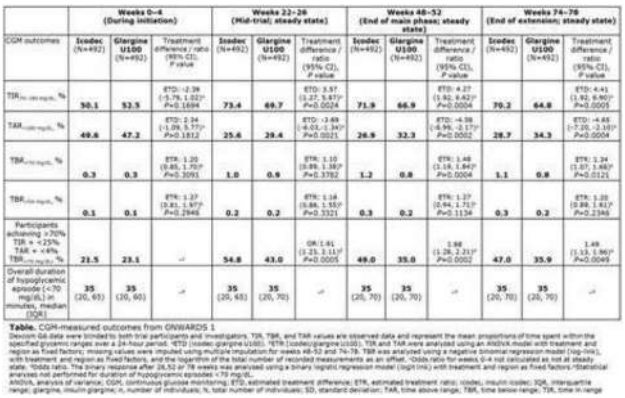
Keywords
• Insulin therapy

Background and Aims
In ONWARDS 1, a phase 3a, treat-to-target trial (NCT04460885) in insulin-naïve T2D randomized 1:1 to once-weekly icodec or once-daily glargine U100, time in, above and below range (TIR, TAR, TBR) and hypoglycemia duration were assessed with double-blinded CGM at pre-specified periods throughout the trial.
Materials and methods
TIR (70-180 mg/dL), TAR (>180 mg/dL), TBR (<70 and <54 mg/dL), median duration of hypoglycemia <70 mg/dL and the proportion of an episode spent <54 mg/dL were assessed at weeks (wks) 0-4, 22-26, 48-52, and 74-78.
Results
At wks 22-26, 48-52, and 74-78, mean TIR with icodec met the recommended target of >70%, and TIR and TAR were significantly improved with icodec vs glargine, with no significant difference between arms in TBR <54 mg/dL (table). There was a difference in favor of glargine in TBR <70 mg/dL at wks 48-52 and 74-78, but mean TBR <70 mg/dL and TBR <54 mg/dL were below recommended targets (4% and 1%, respectively) at all time periods for both arms. TIR, TBR and TAR did not differ significantly between arms at wks 0-4. Median duration of hypoglycemia <70 mg/dL and proportion of time <54 mg/dL were similar between arms at all time periods.

Graph/Table:



CGM outcomes	Weeks 0–4 (During initiation)			Weeks 22–26 (Mid-trial; steady state)			Weeks 48–52 (End of main phase; steady state)			Weeks 74–78 (End of extension; steady state)		
	Icodec (N=492)	Glargine U100 (N=492)	Treatment difference / ratio (95% CI); P value	Icodec (N=492)	Glargine U100 (N=492)	Treatment difference / ratio (95% CI), P value	Icodec (N=492)	Glargine U100 (N=492)	Treatment difference / ratio (95% CI), P value	Icodec (N=492)	Glargine U100 (N=492)	Treatment difference / ratio (95% CI), P value
TIR, [low–high mg/dL], %	30.1	32.5	ETD: -2.39 (-5.79, 1.02)[a]; P=0.1694	73.4	69.7	ETD: 3.57 (1.27, 5.87)[a]; P=0.0024	71.9	66.9	ETD: 4.27 (1.92, 6.62)[a]; P=0.0004	70.2	64.8	ETD: 4.41 (1.92, 6.90)[a]; P=0.0005
TAR, [>high mg/dL], %	49.6	47.2	ETD: 2.34 (-1.09, 5.77)[a]; P=0.1812	25.6	29.4	ETD: -3.69 (-6.03, -1.34)[a]; P=0.0021	26.9	32.3	ETD: -4.38 (-6.94, -1.17)[a]; P=0.0082	28.7	34.3	ETD: -4.45 (-7.20, -1.10)[a]; P=0.0094
TBR, [<low mg/dL], %	0.3	0.3	ETR: 1.20 (0.85, 1.70)[b]; P=0.3091	1.0	0.9	ETR: 1.10 (0.99, 1.38)[b]; P=0.3782	1.2	0.8	ETR: 1.48 (1.18, 1.84)[b]; P=0.0004	1.1	0.8	ETR: 1.34 (1.07, 1.68)[b]; P=0.0121
TBR, [<low mg/dL], %	0.1	0.1	ETR: 1.27 (0.81, 1.97)[b]; P=0.2946	0.2	0.2	ETR: 1.16 (0.86, 1.55)[b]; P=0.3321	0.3	0.2	ETR: 1.27 (0.94, 1.71)[b]; P=0.1134	0.3	0.2	ETR: 1.20 (0.89, 1.61)[b]; P=0.2346
Participants achieving >70% TIR + <25% TAR + <4% TBR, [<70 mg/dL], %	21.5	23.1	-[c]	54.8	43.0	OR: 1.61 (1.23, 2.11)[b]; P=0.0005	49.0	35.0	1.68 (1.28, 2.21)[b]; P=0.0002	47.0	35.9	1.49 (1.13, 1.96)[b]; P=0.0049
Overall duration of hypoglycemic episode (<70 mg/dL) in minutes, median (IQR)	35 (20, 65)	35 (20, 60)	-[c]	35 (20, 65)	35 (20, 70)	-[c]	35 (20, 70)	35 (20, 70)	-[c]	35 (20, 70)	35 (20, 70)	-[c]

Table. CGM-measured outcomes from GRWARDIS 1

Devoid GA data were blinded to both trial participants and investigators. TIR, TBR, and TAR values are observed data and represent the mean proportions of time spent within the specified glycaemic ranges over a 24-hour period. [a]ETD (icodec glargine U100). [b]ETR (icodec/glargine U100). TIR and TAR were analysed using an ANCHA model with treatment and region as fixed factors; missing values were imputed using multiple imputation for weeks 48–52 and 74–78. TBR was analysed using a negative binomial regression model (log-link), with treatment and region as fixed factors, and the logarithm of the total number of recorded measurements as an offset. [c]Odds ratio for weeks 0–4 not calculated as not at steady state. [d]Odds ratio. The primary response after 26,52 or 78 weeks was analysed using a binary logistic regression model (logit link) with treatment and region as fixed factors. [e]Statistical analyses not performed for duration of hypoglycaemic episodes <70 mg/dL.

ANCHA, analysis of variance; CGM, continuous glucose monitoring; ETD, estimated treatment difference; ETR, estimated treatment ratio; icodec, insulin icodec; IQR, interquartile range; glargine, insulin glargine; n, number of individuals; %, total number of individuals; SD, standard deviation; TAR, time above range; TBR, time below range; TIR, time in range

Conclusion

In summary, TIR and TAR at wks 22-26, 48-52, and 74-78 were significantly improved with icodec vs glargine U100, with no significant difference in TBR <54 mg/dL and a similar duration of hypoglycemia <70 mg/dL between arms.

O39

Verifying the use of FIB4 and BARD scores to negate advanced fibrosis in people with type 2 diabetes using transient elastography in a tertiary care centre in India

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Keywords
• Non-alcoholic fatty liver disease (NAFLD)

Background and Aims

As per the recent ICMR study,11.4% of India's population is diabetic, 15.3% have prediabetes 28.6% of Indians have generalized obesity, and 39.5% have abdominal obesity. Non-alcoholic fatty liver disease (NAFLD) and Type 2 diabetes (T2DM) are common conditions that co-exist often and can act synergistically to cause adverse effects. Its association with central obesity and insulin resistance is well established. The presence of NAFLD precludes complications in people with Diabetes, both cardiovascular and liver-related like cirrhosis and hepatocellular carcinoma. Liver biopsy is the gold standard for diagnosing advanced fibrosis but is usually not feasible in routine clinical practice, Transient elastography is accepted as a viable non-invasive alternative but is not universally available due to high cost. FIB4 and BARD scores are easy to perform in routine clinical practice and can guide for referral for transient elastography or liver biopsy. The aim of this study was to assess the utility of these simple scores (FIB4 and BARD) to exclude advanced fibrosis in people with type 2 diabetes.

Materials and methods

A total of 133 consenting people were subjected to fibro scan (Echosens,Paris, France).It was done empty stomach,10 valid LSM(Liver stiffness measurement)values with an IQR/median <30% were obtained. Serum markers (AST, ALT, Platelet count) were measured, and FIB 4 and BARD scores were calculated using standard equations. LSM (liver stiffness measurement) cut-off value of 11.4 was used to exclude advanced fibrosis.

Results

Out of 133 people with diabetes in the study ,51.1% males and 48.9% were females, with a mean age of 50years, BMI 26.6, hba1c 8.7%, duration of diabetes 7.6yrs. The average Liver stiffness measurement (LSM) was 9.1, mean AST was 36 U/Ml and ALT 38.5U/Ml, platelet count 208cubic mm. Mean FIB4 score was 1.7 and BARD score was 3. 82.7% had a LSM value of <11.5 and 17.3% had a LSM value of>11.5%, neither BARD score nor FIB4 had significant correlation with liver stiffness measurement. Fib4 had a (Negative predictive value) NPV of 83.6% and BARD score had a NPV of 85.7% to exclude advanced fibrosis (>11.4)

Conclusion

A FIB 4 score of less than 2.6 and BARD score of less than 2 have a high negative predictive value to exclude advanced fibrosis. Because of the high incidence of NAFLD in people with diabetes, these should be routinely used to exclude advanced fibrosis and decision for referral for fibro scan and liver biopsy.

O40

Short-term efficacy and safety of basal-bolus insulin regimes in diabetic renal transplant recipients in early post-transplant outpatient settings

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Keywords
• Insulin therapy • Nephropathy

Background and Aims

Glycemic control impacts allograft and patient survival in patients undergoing renal transplant. We evaluated short term treatment outcomes of basal-bolus regimes in outpatient diabetes management in renal transplant recipients with pre-existing diabetes.

Materials and methods

A prospective observational study over 24 weeks on 112 subjects who underwent renal transplantation were evaluated for HbA1c, FBS, PPBS, creatinine, eGFR, weight and hypoglycemic episodes on basal-bolus regimes over 24 weeks.

Results

There were significant reductions in mean HbA1c (8.9% to 7.2%) (p<0.001), FBS (237.9 mg/dL to 122.277 mg/dL)(p<0.001) and PPBS (342.223 mg/dL to 172.973 mg /dL)(p<0.001) with basal-bolus insulin regime. Fifty-one (45.54%) patients achieved HbA1c <7% while 52 (46.43%) had HbA1c between 7-8%. There was significant but minimal 1.243 kg weight gain associated with basal bolus therapy. Weight gain was higher in the glargine group (p=0.044). There was no difference in either baseline or end-of-study HbA1c, FPG, PPG, creatinine and eGFR between basal insulin groups (degludec vs. glargine) prandial insulin groups (regular vs. analogue). Incidence of nocturnal hypoglycemia was significantly higher in glargine compared to degludec group, though there was no difference in overall or daytime confirmed symptomatic hypoglycemia.

Conclusion

In diabetes patients undergoing renal transplant, basal-bolus regimes was effective and safe in outpatient diabetes management in early post-renal transplant period. There was almost no difference in treatment related outcomes (safety and efficacy parameters) between basal insulin groups (degludec vs. glargine) and prandial insulin groups (regular vs.

analogue), apart from higher nocturnal hypoglycemia in glargine group compared to degludec group.

O41

A study of Association between Serum Uric Acid levels and Diabetic Peripheral Neuropathy

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Keywords
• Inflammation in type 2 diabetes • Neuropathy: somatic • Pathogenic mechanisms / complications

Background and Aims
Diabetic neuropathy is one of the most prevalent and dreadful complications of diabetes mellitus, with high rates of morbidity and mortality and causing a significant financial drain on the community. One of the most important elements in the development of diabetic peripheral neuropathy is oxidative stress. It is postulated that uric acid can act either as a pro-oxidant or as an anti-oxidant, either aiding or hindering the process of microvascular injury. Hence, the study aimed to investigate the association between Serum Uric Acid levels and diabetic peripheral neuropathy in patients with type 2 diabetes.
Materials and methods
In this case-control study, a total of 120 subjects from a tertiary hospital in Karnataka were included. Among the 120 subjects, cases were 60 diabetic neuropathy patients and control included 60 diabetics without neuropathy. Diabetic Neuropathy was assessed utilizing Diabetic neuropathy symptom score and diagnosed by Vibration perception threshold - VPT or nerve conduction study in certain cases. Further serum uric acid levels were measured. Data were described in terms of range; mean ± standard deviation (± SD), median, frequencies, and relative frequencies (percentages) as appropriate. Comparison of quantitative variables between the study groups was done using Student t-test and Mann Whitney U test for independent samples for parametric and non-parametric data respectively.
Results
The average age of subjects among those with neuropathy was 57.6 ± 9.98 years, whereas the average of subjects in those without neuropathy was 50.7± 12.85 years. The average HbA1C was 9.57 ± 2.36 in those with diabetic neuropathy and 8.94 ± 2.06 in those without diabetic neuropathy. The mean serum uric acid level was higher in those with neuropathy (5.25 ±1.33 mg/dL) compared to those without neuropathy (4.45 ±1.05 mg/dL).
Graph/Table :

	Our study		J. Kiani et al		Jiang TN et al		N Papanas et al		Santi Manickam et al		Dessy Putri Sukarno et al		Umar Farooq Dar et al	
	Cases	Control	Cases	Control	Cases	Control	Cases	Control	Cases	Control	Cases	Control	Cases	Control
Subjects	60	60	42	42	503	321	64	66	50	50	15	15	88	112
Age	57.63 ± 9.98	50.75 ± 12.85	54.6 ± 6.9	55.8± 5.8	59.8 ± 9.5	46.1 ± 11.8	63.0 ±2.8	62.4 ± 3.1	56.4 ± 9.3	59.9 ± 10.3	51.60 ±6.52	53.53± 4.72	-	-
BMI (kg/m2)	26.04 ± 4.57	25.56 ± 4.16	29.3 ± 4.1	27.6 ± 3.9	25.8 ± 3.9	26.6 ± 4.2	31.5 ±1.8	32.0 ± 1.8	-	-	-	-	-	-
Males (%)	71.7	53.3	38.1	38.1	49.7	65.7	48.8	48.5	-	-	33.3	33.3	-	-
Duration of diabetes (years)	9.7±3.5	8.1±3.8	9.7 ± 4.2	9.1 ± 5.2	9.0	3.0	9.5± 2.1	9.1 ± 2.1	-	-	-	-	>10 years in 72.7%	>10 years in 45.5 %
HbA1C	9.57 ± 2.36	8.94 ± 2.06	8.1 ± 1.3	7.9 ± 1.5	9.9 ± 2.3	10.1 ± 7.1	7.7 ± 0.4	7.8 ± 0.7					> 7 in 85.2 %	>7 in 64.2 %
Uric acid (mg/dL)	5.25 ± 1.33	4.45 ± 1.05	4.70 ± 0.96	4.36 ± 0.89	4.95 ± 1.41	5.29 ± 1.56	8.1 ± 1.4	5.7 ± 1.3	6.56 ± 2.30	4.73 ± 1.10			5.25 ± 1.06	5.28 ± 1.1

Conclusion
The study showed higher uric acid levels in patients with diabetic peripheral neuropathy. Elevated serum uric acid levels may be considered as a risk factor for diabetic peripheral neuropathy in clinical practice. Future studies are warranted to study this relationship.

O42

Impact of Insulin Injection Techniques on Uncontrolled Diabetes

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Keywords
• Insulin therapy

Background and Aims
Inadequate insulin administration due to incorrect techniques can severely hinder diabetes management. This study aimed to assess insulin injection practices among individuals with uncontrolled diabetes.
Materials and methods
A cross-sectional survey was conducted on consecutive insulin-using individuals with diabetes who visited our center for the first time. The survey covered injection methods, pen device usage, insulin storage, and hypoglycemic episodes. Descriptive statistics summarized the data.
Results
All participants (n=168, Age: 48±20.72 years, Female: 33%, Duration of diabetes: 10.5±8.29 years, Duration of insulin usage: 6.66±7.23 years, Mean HbA1c: 10.25±5.61%) were using insulin pens for administration. The distribution of insulin regimens was as follows: 12% were on basal bolus, 68% on premix insulin, and 20% were on basal insulin. No significant differences in insulin injection errors were observed based on gender, age, duration of diabetes, or duration of insulin usage. Injection parameters and percentages as indicated in table 1. LH associated with 3.5 times higher severe hypoglycemia risk. After education and support: A1C reduced to 8.3 ± 3.5%, low glucose episodes decreased to 7%, hyperglycemia to 20%, and lipohypertrophy reduced to 0%.
Graph/Table :

Table 1: Impact of insulin injection techniques

Parameters	Percentage	
	Baseline	6 months of education
Preferred Injection Site		
Abdomen	86%	95%
Thighs	11%	5%
Arms	3%	**0%**
Reported Site Rotation	60%	100%
Hypo Episodes	36%	7%
Hyperglycemia	45%	20%
Lipohypertrophy	13%	**0%**
Reused Needles	99%	35%
Incorrect Insulin Storage	1%	**0%**
A1C	**10.25±5.61%**	**8.3 ± 3.5%**

Conclusion
Effective insulin injection education and continuous support are pivotal for proper technique and enhanced diabetes management. Addressing injection errors can lead to better outcomes in diabetes care.

043

Diabetes Management Score

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Abstract
Introduction: Adherence to Diet, Exercise, and medications play an important role in patient outcomes of diabetes like HbAlC, blood glucose fasting and post prandial. Adherence to pharmaco therapy,diet and exercise is usually not systematically evaluated and recorded in day-to-day practice. A need was felt to include these in diabetes management protocol. A scoring system was designed to assess and record the adherence to medication,diet,and exercise- denoted by M,D & E respectively and composite score was defined as the sum of all the scores.Maximum score for each domain was 5 and for composite score 15,scores for each domain were assigned by the doctor based on short interviews using predefined criteria during the consultation.
Method: Data was extracted from the EMR of 3338 persons with diabetes (pwd) 11502 composite scores, total of 5451- HbAlC, blood sugar fasting- 8225 and blood sugar post prandial-4486 corresponding values. Pearsons Coefficient of variation r was used to assess the correlation between the composite score and diabetes outcomes like HbAlc, blood sugar fasting and post prandial,data was also analyzed to assess the glycemic outcomes related to individual scores (M,D &E).
Result: The analysis of data demonstrated a strong negative correlation between composite scores and average of HbAlC's, blood sugar fasting and post prandial, with pearsons coefficient of correlation r- -0.99, -0.97 and -0.98 respectively, moderate correlation between all the composite scores and respective individual HbAlC's , blood sugar fasting and post prandial coefficient of correlation r- -0.36, -0.38, -0.45 respectively, implying that a decrease in average of glycemic parameters- HbAlC, blood glucose fasting and post prandial was observed with an increase in the composite score i.e-better adherence to pharmacotherapy,diet and exercise.
We also assessed the correlation between the change () of composite score and the resultant change() in HbAlc,blood sugar fasting & pp;which exhibited an L shaped relationship- majority of the patients demonstrated a strong negative correlation in all the parameters,few demonstrated a positive correlation- which indicates the need for radical change in therapy.
Amongst patients with similar composite scores- those with lower D (diet) scores had poorer glycemic outcomes. Patients with M scores of 4 or less had higher average glycemic parameters. Patients with decreasing diet(D) or exercise (E) scores while other scores being equal -had poorer average glycemic outcomes, an increase in average HbAlC of 0.97% was noted in patients with similar M & E scores but decreasing diet control, patients with lower exercise score (E) but similar M & D scores,had an increase in average HbAlC of 0.56%.
Condusion: Diabetes management score is a simple yet important tool which can be used to assess the treatment of diabetes patients. It correlates well with the measurable outcomes in persons with diabetes like HbAlc, blood sugar fasting & post prandial, It can be used to motivate patients to achieve better control and help convince them in improving adherence to medication, diet and exercise while also making radical changes to therapy like including insulin if required. The score may also be used as a predictive tool to make a prognosis of outcomes and guide the current therapy.

Paper Presentation

P01

Efficacy and safety of two doses of FDC of Dapagliflozin, Sitagliptin and Metformin Immediate Release tablets in Type 2 Diabetes: A Phase 3 study

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Keywords
• Oral therapies: metformin, sensitizers and other non- secretagogues

Background and Aims
Type 2 diabetes mellitus (T2DM), a multifactorial progressive disease, requires multiple agents to achieve optimum glycemic control. Fixed-dose combination (FDC) regimen improves treatment adherence, can provide tight glycemic control, and may delay need of insulin therapy.
Materials and methods
This is a post hoc analysis of a Phase 3, randomized, open-label, active-controlled study (CTRI/2022 /04/041817), which included T2DM Indian patients (HbA1c 7.5%-11%) who were on FDC of sitagliptin + metformin (50+500 mg or 50+1000 mg) twice daily (BID) for ≥8 weeks at screening. Eligible patients were randomized to receive FDC of dapagliflozin + sitagliptin + metformin immediate release (IR) (5mg+50mg+500mg BID [low dose, test 1] OR 5mg+50mg+1000mg BID [high dose, test 2]) or FDC of sitagliptin + metformin IR (50mg+500mg BID [low dose, Comparator 1] OR 50mg+1000mg BID [high dose, comparator 2]) respectively for 16 weeks, based on metformin dose at screening. This post hoc analysis aimed to assess glycemic outcomes and safety profile of low dose group (test 1 vs comparator 1) and high dose group (test 2 vs comparator 2).
Results
Subgroup analysis included total 272 patients (test 1 [n=75], comparator 1 [n=75], test 2 [n=61] and comparator 2 [n=61]. Mean ± SD reduction in HbA1c was statistically significant from baseline to week 16 in both low dose group (test 1 vs comparator 1: -2.04% ± 1.15% vs -1.32% ± 1.06%; p<0.0001) and high dose group (test 2 vs comparator 2: -2.11% ± 1.26% vs -1.45% ± 1.23%; p<0.0001). Statistically significant reduction in HbA1c from baseline to week 12 was observed in low dose group (test 1 vs comparator 1 [-1.34% ± 0.98% vs -0.74% ± 0.93%, p<0.0001) and high dose group (test 1 vs comparator 1 [-1.40% ± 1.06% vs -0.80% ± 1.12%, p<0.0001). Proportion of patients achieving HbA1c <7% was significantly higher in test arm 2 vs comparator arm 2 (31.1% vs 11.5%, p=0.0080 at week 12 and 54.1% vs 31.1%, p=0.0104 at week 16). Reduction in fasting and post-prandial blood glucose levels from baseline to week 16 was significant in test arms and comparator arms for both low dose and high dose groups. No severe/serious adverse events or hypoglycemia events were reported.
Conclusion
FDC of dapagliflozin + sitagliptin + metformin IR BID (5mg+50mg+500mg [low dose] and 5mg+50mg+1000mg [high dose]) demonstrated superior efficacy compared to FDC of sitagliptin +metformin IR BID (50mg+500mg [low dose] OR 50mg+1000mg [high dose]), respectively. Study medications were safe and well-tolerated.

P02

Efficacy and Safety of Sitagliptin, Metformin and Glimepiride in Type 2 Diabetes: A Phase 3, Double-Blind, Active-Controlled Study

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Keywords
• Oral therapies: metformin, sensitizers and other non- secretagogues
• Hypoglycaemia

Background and Aims
Sitagliptin addition to lower dose glimepiride & metformin is likely to improve glucose induced insulin secretion & decrease glucagon levels leading to improved glycemic control & reduced hypoglycemia events. Thus, we evaluated the efficacy & safety of FDC Sitagliptin+Glimepiride+Metformin (50/1/1000 mg) BID (comprising of lower dose of glimepiride) in comparison to coadministration of metformin 1000 mg BID & glimepiride 2 mg BID in T2DM.
Materials and methods
This is a phase 3, randomized, double-blind, double-dummy, active-controlled study (16 weeks) followed by an open-label, single-arm study (12 weeks). We included adult patients with HbA1c ≥8% & ≤11% taking glimepiride 4 mg & metformin ≥1500 mg per day. Patients were randomized to either FDC of Sitagliptin+Glimepiride+Metformin (50/1/1000 mg) BID (test) OR co-administration of metformin 1000 mg BID & glimepiride 2 mg BID (comparator). At Week 16, patients in test group with HbA1c ≥8% were up titrated to Sitagliptin+Glimepiride+Metformin FDC (50/2/1000 mg) BID (test) till Week 28. For comparator group, Week 16 was end of study. Primary endpoint was change in HbA1c from baseline to Week 16. [CTRI/2021/11/038169]
Results
A total of 392 patients were randomized (test [n=190]; comparator [n=202]). Both treatments demonstrated significant reduction in HbA1c at Week 12 & 16 ($p<0.0001$ each). Adjusted mean change (SE) in %HbA1c was statistically significant in the test group at Week 16 [test vs comparator: -1.79 (0.07) vs -1.27 (0.06), $p<0.0001$]. Statistically significant reduction in FBG & PPBG from baseline to Week 12 & 16 was observed ($p<0.0001$ each) & reduction was comparable between the groups. Proportion of patients achieving HbA1c <7.0% was statistically significant in test versus comparator (32.1% vs 12.6%, $p<0.0001$) at Week 16. Test group demonstrated statistically significant reduction in HbA1c, FBG & PPBG from baseline to Weeks 24 & 28 ($p<0.0001$ each). Overall 75 adverse events were reported (test vs comparator: 39 vs 36). No patient required hypoglycaemia management & safety profile was similar in test & comparator groups.
Conclusion
Sitagliptin+Glimepiride+Metformin FDC demonstrated superior efficacy to comparator. Study medications were safe & well tolerated.

P03

Efficacy and safety of Sitagliptin, Metformin and Glimepiride FDC tablets in Indian Type 2 Diabetes: A subgroup analysis of patients aged <50 years

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Keywords
• Oral therapies: metformin, sensitizers and other non- secretagogues
• Hypoglycaemia

Background and Aims
Findings from the National Family Health Survey estimates prevalence of T2DM in the age group of 35-49 years as 9.19%. This follows the trends observed in Asians and Indians that T2DM occurs at a younger age and at a lower BMI. Use of FDC of DPP4 inhibitors, sulfonylurea, and metformin may improve treatment compliance and provide superior glycemic control, leading to better patient outcomes. We present here subgroup analysis(n=230) of patients with age <50 years at 16 weeks from a phase III randomized, doubleblind study(N=392).
Materials and methods
This is a subgroup analysis of Phase 3 study (CTRI/2021/11/038169) Sitagliptin+Glimepiride+Metformin FDC (50/1/1000 mg) in patients with T2DM. This study included patients with HbA1c ≥8% to ≤11% and received either FDC of Sitagliptin+Glimepiride+Metformin tablet (50/1/1000 mg) BID (Test) or coadministration of metformin 1000 mg BID and glimepiride 2 mg BID (Comparator) for 16 weeks. For this analysis, individuals were categorized into subgroups (S1, S2) based on baseline age (S1: age ≥40 to < 50 years; S2: age <40 years).
Results
At baseline 230 patients were <50 years of age. HbA1c at baseline in both arms was comparable [Test, S1: 9.27± 0.76, S2: 9.16± 0.73, vs Comparator, S1: 9.10± 0.74, S2: 9.10± 0.72]. Significant reduction from baseline HbA1c was observed in all groups at Week 16. In all subgroups of Age <50 years adjusted mean change (SE) in %HbA1c was statistically significant in the test group at Week 16 [test vs comparator: S1: - 1.66(0.09) vs -1.2(0.09), $p=0.0004$; S2: -2.43(0.13) vs -1.42(0.12), $p<0.0001$]. In Test arm, significantly more patients achieved HbA1c <7.0% compared to Comparator at Week 16 [test vs comparator: S1: 29.40% vs 6.40%, $p=0.0002$; S2: 59.50% vs 16.30%, $p=0.0001$]. All treatments were well tolerated across all subgroups.
Conclusion
FDC of Sitagliptin+Glimepiride+Metformin demonstrated superior efficacy to Comparator in all subgroups of age <50 years and all treatments were well tolerated.

P04

A New Paradigm of Diabetes Treatment: Triple-drug Fixed-dose Combination of Dapagliflozin + Glimepiride + Metformin Extended Release

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Keywords
• Oral therapies: metformin, sensitizers and other non- secretagogues

Background and Aims
Type 2 Diabetes Mellitus (T2DM), one of the most common metabolic disorders, is caused by a combination of defective insulin secretion and insulin sensitivity. The progressive ß-cell loss and dysfunction leads to worsening of metabolic control over time. The anti-diabetic treatment should focus on the goal of achieving glycaemic control, reducing risk of complications, and minimizing treatment burden without compromising tolerability.
The American Diabetes Association and Research Society for the Study of Diabetes in India guidelines recommend dual or triple combination therapy with metformin. Fixed-dose combination (FDC) therapies have advantages such as complementary mechanism of action, synergistic effects, better tolerability, reduced pill burden and cost savings. Thus, FDC could be specifically useful in T2DM where polypharmacy is a frequent problem. Moreover, FDCs targeting multiple pathways improve glycaemic control and may reduce risk of associated complications. Each 10% rise in adherence leads to 0.1% decrease in HbA1c.
Materials and methods
Dapagliflozin, an SGLT-2 inhibitor, blocks reabsorption of filtered glucose in the kidney, increases urinary glucose excretion and thus, reduces blood sugar levels. Its action is independent of pancreatic β-cell function and modulation of insulin sensitivity. It also reduces cardiovascular and kidney outcomes in T2DM patients. Glimepiride acts by stimulating insulin release from pancreatic β cells. Its use is associated with comparatively lesser hypoglycaemic events and has established CV safety profile. Metformin has clear benefits in relation to glucose metabolism and diabetes-related complications.
Results
Dapagliflozin, glimepiride and metformin individually have well-established efficacy and tolerability profile. Previously published studies have shown benefits of combination of dapagliflozin with metformin and glimepiride. The combination resulted in increased insulin sensitivity, reduced insulin resistance along with decreased body weight and a greater number of patients achieved target HbA1c.
Conclusion
Thus, use of FDC of dapagliflozin, glimepiride and metformin will provide fast and profound glycaemic control due to their complimentary mechanisms of actions. This FDC will improve compliance and reduce potential complications with less risk of hypoglycaemia.

P05

Efficacy and Safety of Dapagliflozin, Sitagliptin, and Metformin IR FDC in Indian T2DM: A subgroup analysis of mild renal impairment (eGFR 60 to <90)

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Keywords
• Oral therapies: metformin, sensitizers and other non- secretagogues

Background and Aims
Chronic kidney disease (CKD) affects nearly 2 of every 5 T2DM patients. A cross-sectional study in India showed a positive correlation between duration of diabetes and stage of CKD, as 44.29% of population had 1-5 years as duration of diabetes and majority had Stage 1 and Stage 2 CKD. Use of fixed-dose combination (FDC) regimen may provide superior glycaemic control, leading to better patient outcomes in T2DM patients with mild renal impairment.
Materials and methods
This is a subgroup analysis of Phase 3, randomized, open-label study (CTRI/2022/04/041817) which included T2DM Indian patients (HbA1c 7.5%-11%) who were on FDC of sitagliptin + metformin (50+500 mg or 50+1000 mg) twice daily (BID) for ≥8 weeks at screening. Eligible patients were randomized to receive FDC of Dapagliflozin+Sitagliptin+Metformin immediate release (IR) (5+50+500/1000mg) BID [Test] OR Sitagliptin+Metformin IR (50+500/1000mg) BID [Comparator] respectively for 16 weeks, based on metformin dose at screening. This subgroup analysis aimed to assess glycaemic outcomes in patients with baseline eGFR 60 to <90 mL/min/1.73m2.
Results
This analysis included 55 patients [Test: 27; Comparator: 28]. Statistically significant reduction ($p < 0.0001$) in HbA1c from baseline to weeks 6, 12 and 16 were observed in both Test and Comparator. Reduction in HbA1c was significantly superior in the Test against Comparator at weeks 12 and 16 [$p=0.0189$; $p=0.0020$; respectively]. Proportion of patients achieving HbA1c <7% at Week 16 in Test vs Comparator: 53.8% vs 32.1%, respectively. All treatments were well tolerated.
Conclusion
FDC of Dapagliflozin+Sitagliptin+Metformin IR demonstrated significantly superior efficacy over Comparator in the subgroup of eGFR 60 to <90 mL/min/1.73m2 in terms of reduction of HbA1c at weeks 12 and 16. All treatments were well tolerated.

P06

Effect of Dapagliflozin, Sitagliptin, and Immediate Release Metformin on Fasting Blood Glucose in Indian Patients with T2DM: Post-hoc Analysis of Phase 3 Study

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Keywords
• Oral therapies: metformin, sensitizers and other non- secretagogues

Background and Aims
Dapagliflozin, sitagliptin, metformin together can lead to increased glucose excretion, slow inactivation of incretin hormones, and can lower both, fasting and postprandial glucose. We conducted a post-hoc analysis of the phase 3 clinical study to evaluate the efficacy of fixed dose combination (FDC) of Dapagliflozin, Sitagliptin, and Metformin IR (5+50+500/1000mg) in T2DM.
Materials and methods
This is a post-hoc analysis of a phase 3, randomized, open label, active-controlled study (16 weeks treatment). Study included adult T2DM patients with HbA1c ≥7.5% and ≤11% taking FDC of Sitagliptin and Metformin (50 mg+500/1000 mg) twice daily (BID). Patients were randomized to BID dose of FDC of Dapagliflozin+Sitagliptin+Metformin IR tablet (5+50+500/1000mg) (Test) OR FDC of Sitagliptin and Metformin IR (50+500/1000 mg) (Comparator). In this analysis, we evaluated the change in fasting blood glucose (FBG) and proportion of patients achieving FBG <115 mg/dL at Week 16. [CTRI/2022/04/041817]
Results
A total of 272 (136 in each arm) patients were included in this analysis. Patients in both the treatment arms demonstrated significant reduction in FBG from baseline at Week 6, 12 and 16 (p<0.0001). Test arm demonstrated statistically significant improvement from baseline FBG as compared to comparator at Week 6 (-29.0±35.08 vs -17.1±43.07; p<0.0001), Week 12 (-39.1±39.14 vs -27.6±46.14; p<0.0001) and Week 16 (-36.9±44.87 vs -30.6±47.82; p= 0.0065). In Test arm, significantly more patients achieved target FBG <115 mg/dL compared to comparator at Weeks 12 (25.2% vs 9.6%; p=0.0012) and 16 (29.6% vs 17%; p=0.0209). Total 13 treatment emergent AEs (6 in test, 7 in comparator) were reported; most were mild and unlikely related to study drugs. None of the patients reported hypoglycaemia or any other serious or severe adverse events during the study. Study treatments were well tolerated.
Conclusion
FDC of Dapagliflozin+Sitagliptin+Metformin IR tablet demonstrated statistically significant reduction in FBG at Weeks 12 and 16 compared to comparator. Study medications were well tolerated.

P07

Fixed Dose Combination of Dapagliflozin, Glimepiride and Metformin ER tablets in Indian patients with Type 2 Diabetes: Phase 3 study results

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Keywords
• SGLT inhibitors • Hypoglycaemia

Background and Aims
Considering progressive nature of type 2 diabetes mellitus (T2DM), use of fixed-dose combination (FDC) of sodium-glucose-cotransporter-2 inhibitors, sulfonyl urea, and metformin can provide better glycemic control, improve therapy compliance with less risk of weight gain and may have cardio- and reno-protective function. Study objective was to evaluate efficacy and safety of triple-drug FDC vs two-drug FDC combination in Indian patients with T2DM.
Materials and methods
This phase 3, two-arm, open-label, and active-controlled study (CTRI/2022/03/041424) included patients aged 18-65 years with HbA1c 8-11% and were on glimepiride+metformin extended-release [ER]/prolongedrelease [PR]/sustained-release (1+1000mg/day) therapy at screening. Total 395 eligible patients were randomized in 1:1 ratio to either receive triple-drug FDC of dapagliflozin+glimepiride+metformin ER tablets (10mg+1mg+1000mg) once daily (OD), test arm or dual-drug FDC of glimepiride+metformin PR (1mg+1000mg) OD, comparator arm for 16 weeks. Post Week 16, up-titrated dose of study medications (triple-drug FDC [10mg+2mg+1000mg] and dual-drug FDC [2mg+1000mg]) were provided to patients with HbA1c >7% till Week 28. Primary endpoint was mean change in HbA1c from baseline to Week 16.
Results
Mean±SD change in HbA1c from baseline to Week 16 was significantly greater in test arm (-1.98%±1.01%) vs comparator arm (-1.64%±0.86%) (p=0.0047). Mean change in HbA1c from baseline to Week 12 was significantly greater in test arm (-1.37%±0.93%) vs comparator arm (-1.01%±0.79%) (p<0.0001). Proportion of patients achieving HbA1c <7% in test arm was significantly higher compared to comparator arm at Week 12 (19.1% vs 6.5% [p=0.0002] and at Week 16 (52.6% vs 36.7% [p=0.0015]), respectively. Significant reductions in HbA1c, fasting and post-prandial blood glucose levels were observed in each arm from baseline to Weeks 8, 12, 16, and 28. Total 6 patients required rescue medication. One hypoglycaemia (grade 1) event was reported. No serious adverse events were reported.
Conclusion
FDC of glimepiride+metformin PR in reducing HbA1c from baseline to Week 16. Study medications were well-tolerated.

P08

Efficacy and safety of FDC of Dapagliflozin, Glimepiride and Metformin ER tablets in Indian Type 2 Diabetes: A subgroup analysis of patients aged <50 years

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Keywords
• SGLT inhibitors • Hypoglycaemia

Background and Aims
Indian patients develop T2DM at younger age compared to Caucasians. In like manner, coronary artery disease occurs at a younger age in Indians with over 50% of CVD mortality occurring in individuals aged <50 years. Chronic kidney disease affects nearly 2 of every 5 T2DM patients and further increases risk of vascular complications. Triple FDCs of sulfonylurea and metformin with SGLT2 inhibitors may provide better glycaemic control, improve therapy compliance

and may have cardio- and reno-protective function. We present here subgroup analysis(n=213), at 16 weeks, of patients <50 years of age from a phase III open-label study(N=392) conducted to evaluate efficacy and safety of triple-drug FDC vs two-drug FDC combination in Indian patients with T2DM.

Materials and methods

T2DM patients with stable total daily dose of Glimepiride 1 mg and Metformin SR/PR/ER 1000 mg and HbA1c ≥8% and ≤11% at screening were randomized to FDC of dapagliflozin+glimepiride+metformin ER tablets (10mg+1mg+1000mg) once-daily (OD) [test, N=101(n=56; Age≥40 to <50 years and n=45; Age<40 years)] or FDC of glimepiride+metformin PR (1mg+1000mg) OD [comparator, N=112 (n=62; Age≥40 to <50 years and n=50; Age<40 years] for 16 weeks. Primary endpoint was mean change in HbA1c from baseline to Week 16. (CTRI/2022/03/041424)

Results

At baseline 213 patients were <50 years of age. HbA1c at baseline in both arms was comparable (test, 9.10±0.89 [≥40 to<50 years], 8.95± 0.77[<40 years], vs comparator, 8.98±0.68[≥40 to<50 years], 9.02±0.71[<40 years]). Significant reduction from baseline HbA1c was observed in all groups at Week 16. At Week 16, proportion of patients achieving HbA1c<7% was significantly more in test arm. Adjusted mean change (SE) in %HbA1c of patients in the age group ≥40 to <50 years was significantly better in the test group at Week 16 [-1.87(0.11)] vs comparator arm (-1.52(0.1)) (p=0.0198). Adjusted mean change (SE) in HbA1c of patients in the age group <40 years was significantly more in the test group at Week 16 (-2.45(0.1)) vs comparator arm (-1.93(0.1)) (p=0.0005). Proportion of patients in the age group ≥40 to <50 years achieving HbA1c <7% in test arm was significantly higher compared to comparator arm at Week 16 (54.50% vs 27.90% [p= 0.0035]. Proportion of patients in the age group <40 years achieving HbA1c <7% in test arm was significantly higher compared to comparator arm at Week 16 (72.70% vs 52% [p= 0.0391]. Study medications were well tolerated without incidence of any serious adverse event.

Conclusion

FDC of dapagliflozin+glimepiride+metformin ER demonstrated significantly superior efficacy over FDC of glimepiride+metformin PR in reducing HbA1c from baseline to Week 16 in T2DM patients aged <50 years. Study medications were well tolerated.

P09

Efficacy and safety of Dapagliflozin, Sitagliptin and Metformin IR in Indian patients with T2DM: A subgroup analysis of Phase 3 study based on HbA1c

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Keywords
• Oral therapies: metformin, sensitizers and other non- secretagogues

Background and Aims

Dapagliflozin reduces reabsorption of filtered glucose and lowers renal threshold for glucose, sitagliptin slows inactivation of incretin hormones, and metformin decreases hepatic glucose production and intestinal glucose absorption and improves insulin sensitivity by increasing peripheral glucose uptake and utilization. Fixed-dose combination (FDC) regimen may provide superior glycemic control, leading to better patient outcomes in T2DM patients.

Materials and methods

This is a subgroup analysis of Phase 3, randomized, open-label study (CTRI/2022/04/041817) which included T2DM Indian patients (HbA1c 7.5%-11%) who were on FDC of sitagliptin + metformin (50+500 mg or 50+1000 mg) twice daily (BID) for ≥8 weeks at screening. Eligible patients were randomized to receive either FDC of Dapagliflozin+Sitagliptin+Metformin Immediate Release (IR) (5+50+500/1000mg) BID [Test] OR Sitagliptin+Metformin IR (50+500/1000mg) BID [Comparator] respectively for 16 weeks, based on metformin dose at screening. This subgroup analysis aimed to assess glycemic outcomes and safety profile in patients with baseline HbA1c 7.5 to <9% [Subgroup 1 (S1)] and 9-11% [Subgroup 2 (S2)].

Results

This analysis included 270 patients [S1: Test=77 and Comparator=79; S2: Test=57 and Comparator=57]. Both subgroups demonstrated statistically significant reduction in HbA1c from baseline to weeks 12 and 16 in both Test and Comparator arms. Reduction in HbA1c was significantly superior in the Test against Comparator at weeks 12 and 16 in both subgroups [S1: p=0.0002 (at weeks 12 and 16); S2: p<0.0001(at weeks 12 and 16)] (Table 1). Statistically significant reductions in PPBG and FBG from baseline to Weeks 6, 12 and 16 were observed in both Test and Comparator arms across subgroups. Reduction in FBG was significantly superior in the Test against Comparator at weeks 6, 12 and 16 in S1 [p=0.0015; p=0.0003; and p=0.0079; respectively] and at weeks 6 and 12 in S2 [p=0.0033; and p=0.0371; respectively]. In S1, significantly more patients in Test arm achieved HbA1c<7% at Week 12 (p= 0.0462) while in S2, significantly more patients in Test arm achieved HbA1c<7% at Weeks 12 and 16 (p= 0.0318 and p= 0.0001; respectively). All treatments were well tolerated and no patients reported clinically significant hypoglycemia requiring management.

Conclusion

FDC of Dapagliflozin+Sitagliptin+Metformin IR demonstrated significantly superior efficacy over Comparator in both HbA1c subgroups in terms of reduction of HbA1c. All treatments were well tolerated.

P10

Efficacy and Safety of Two Strengths of Sitagliptin, Metformin and Glimepiride in Type 2 Diabetes Mellitus: A Subgroup Analysis of Phase 3 Study in India

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Keywords
• Oral therapies: metformin, sensitizers and other non- secretagogues

Background and Aims

Addition of sitagliptin to a lower dose glimepiride and metformin is likely to decrease glucagon levels and improve glucose-induced insulin

secretion, improving glycemic control and reducing hypoglycemia events. This is a subgroup analysis of the phase 3 clinical study conducted to evaluate the efficacy and safety of two fixed-dose combinations (FDCs) of Sitagliptin+Glimepiride+Metformin (50+1+1000 mg, 50+2+1000 mg) twice daily (BID) in type 2 diabetes mellitus (T2DM).

Materials and methods

This is a subgroup analysis of a phase 3, randomized, double-blind, double-dummy, active-controlled study (16 weeks) followed by an open-label, single-arm study (12 weeks). Study included adult Indian patients with HbA1c ≥8% and ≤11% taking glimepiride 4 mg and metformin ≥1500 mg per day. Patients were randomized to FDC of sit agliptin+glimepiride+metformin tablet (50+1+1000 mg) BID (Test 1 arm) OR co-administration of metformin 1000 mg BID and glimepiride 2 mg BID. At Week 16, test arm patients with HbA1c ≥8% were uptitrated to FDC with glimepiride 2 mg BID (Test 2 arm) and those with HbA1c <8% continued with FDC containing 1mg glimepiride given BID (Test 1). This analysis includes test arm patients who entered the open-label phase. The glycemic parameters and safety profile of all patients were evaluated from baseline to Weeks 24 and 28 and from Week 16 to Weeks 24 and 28. [CTRI/2021/11/038169]

Results

A total of 182 patients included in this subgroup analysis received Test 1 from baseline to Week 16. At Week 16, 52 patients with HbA1c ≥8% were uptitrated to Test 2. Remaining 130 patients continued to receive Test 1 till Week 28. Both Test 1 and Test 2 arms demonstrated significant reduction in mean HbA1c from baseline to Week 24 and 28 as well as from Week 16 to Week 28 ($p<0.0001$ each) (Table 1). Statistically significant reduction in FBG and PPBG from baseline to Week 24 and 28 were observed in both the Test arms ($p<0.0001$ each). Overall 8 adverse events (unlikely related) were reported during Weeks 16 to 28, including one hypoglycaemia event (level 1) requiring no intervention.

Conclusion

Patients who responded to low dose FDC (with glimepiride 1 mg) at Week 16 continued to demonstrate further significant improvement in glycemic parameters. Patients who required uptitration (FDC with glimepiride 2 mg) demonstrated significant improvement in glycemic parameters at Week 28 compared to Week 16. Both the FDCs were safe and well tolerated.

P11

Efficacy and safety of Sitagliptin, Metformin and Glimepiride FDC in Indian Type 2 Diabetes: A subgroup analysis of patients with mild renal impairment (eGFR 60to <90)

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Keywords
• Oral therapies: metformin, sensitizers and other non- secretagogues

Background and Aims

Chronic kidney disease (CKD) affects nearly 2 of every 5 type 2 diabetes (T2D) patients. A cross-sectional study in India showed a positive correlation between duration of diabetes and stage of CKD, as 44.29% of population had 1-5 years as duration of diabetes and majority had Stage 1 and Stage 2 CKD. In the UKPDS, evolution from microalbuminuria to macroalbuminuria occurred at a rate of 2.8%/year, and change over from macroalbuminuria to renal dysfunction or end-stage kidney disease occurred at a rate of 2.3%/year. Also, UKPDS data demonstrated that intensive approach to glycemic control in newly diagnosed T2D patients was associated with a reduced risk of clinically evident complications. Use of fixed-dose combination (FDC) of DPP4 inhibitors, sulfonylurea, and metformin may improve treatment compliance and provide superior glycemic control, leading to better patient outcomes. We present here subgroup analysis(n=114) of patients with eGFR 60 to <90 at 16 weeks from a phase III randomized, double-blind study(N=392).

Materials and methods

This is a subgroup analysis of Phase 3 study (CTRI/2021/11/038169) Sitagliptin+Glimepiride+Metformin FDC (50/1/1000 mg) in patients with T2D. This randomized double-blind, double-dummy, active controlled study included patients with HbA1c ≥8% to ≤11%. patients received either FDC of Sitagliptin+Glimepiride+Metfor min tablet (50/1/1000 mg) BID (Test) or co-administration of metformin 1000 mg BID and glimepiride 2 mg BID (Comparator) for 16 weeks. This is a subgroup analysis of patients with eGFR 60 to <90 mL/min/1.73m2.

Results

At baseline 114 patients had eGFR between 60 to <90mL/min/1.73m2. HbA1c at baseline in both arms were comparable [Test, 9.07± 0.62 vs Comparator, 9.18± 0.63]. Significant reduction from baseline HbA1c was observed in all groups at Week 16. Adjusted mean change (SE) in %HbA1c was significantly superior in the test group at Week 16 [test vs comparator: -1.86(0.11) % vs -1.46(0.12) %, p=0.0161], Figure 1. In Test arm, significantly more patients achieved HbA1c <7.0% compared to Comparator at Week 16 [test vs comparator: 39.7% vs 16.7%, p=0.0071], Figure 2. All treatments were well tolerated.

Conclusion

FDC of Sitagliptin+Glimepiride+Metformin demonstrated significantly superior efficacy over Comparator arm in the subgroup of eGFR 60 to <90 mL/min/1.73m2. Both treatments were well tolerated.

P12

Efficacy and Safety of Sitagliptin, Metformin and Glimepiride FDC in Indian patients with T2DM: A subgroup analysis of Phase 3 study based on BMI

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Keywords
• Oral therapies: metformin, sensitizers and other non- secretagogues

Background and Aims

Type 2 diabetes mellitus (T2DM) occurs at younger age and at lower levels of BMI in Indians compared with Caucasians. However, Generalised obesity defined as a BMI of 25 kg/m2 was observed in 28.6% of patients in ICMR-INDIAB-17 study, depicting a varied presentation

of T2DM in India. Use of fixed-dose combination (FDC) of DPP4 inhibitors, sulfonylurea, and metformin may improve treatment compliance and provide superior glycemic control, leading to better patient outcomes. We present here subgroup analysis of patients categorized by baseline BMI at 16 weeks from a phase III randomized, double-blind study(N=392).

Materials and methods

This is a subgroup analysis of Phase 3 study (CTRI/2021/11/038169) of Sitagliptin+Glimepiride+Metformin FDC (50/1/1000 mg) in patients with T2DM (n=392). This study included patients with HbA1c ≥8% and ≤11% and BMI ≤45kg/m2 and patients received either FDC Sit agliptin+Glimepiride+Metformin (50/1/1000 mg) BID (Test) or co-administration of metformin 1000 mg BID and glimepiride 2 mg BID (Comparator) for 16 weeks. For this analysis, individuals were categorized into subgroups (S1, S2, S3) based on baseline BMI (S1: BMI <23 kg/m2; S2: BMI ≥23 - <25 kg/m2; S3: BMI ≥25 kg/m2).

Results

A total of 392 patients were randomized (test [n=190]; comparator [n=202]). Both treatments demonstrated significant reduction in HbA1c at Weeks 12 and 16 (p<0.0001 each) from baseline. In all subgroups of BMI adjusted mean change (SE) in %HbA1c was statistically significant in the test group at Week 16 [test vs comparator: S1: -1.95(0.15) vs -1(0.14), p<0.0001; S2: -1.82(0.11) vs -1.12(0.12), p<0.0001; S3: -1.71(0.09) vs -1.44(0.08), p=0.0254], Figure 1. In Test arm, significantly more patients aceived HbA1c <7.0% compared to Comparator at Week 16 [test vs comparator: S1: 32.3% vs 2.80%, p=0.0012; S2: 34.40% vs 7.70%, p=0.0006; S3: 30.50% vs 18.20%, p=0.0388], Figure 2. All treatments were well tolerated across all subgroups.

Conclusion

FDC of Sitagliptin+Glimepiride+Metformin demonstrated superior efficacy to Comparator in all subgroups of BMI and all treatments were well tolerated.

P13

Efficacy and safety of FDC of Dapagliflozin, Glimepiride and Metformin ER tablets in Indian T2D Patients: a subgroup analysis of patients with generalised obesity (BMI≥25)

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Keywords
• SGLT inhibitors • Hypoglycaemia

Background and Aims

Type 2 diabetes mellitus (T2DM) is a progressive disease frequently leading to cardio-renal complications. Also, generalised obesity (BMI ≥25) is observed in 28.6% of Indian diabetic population. Use of fixed-dose combination (FDC) of SGLT2 inhibitors, sulfonylurea, and metformin can provide better glycemic control, improve therapy compliance with less risk of weight gain and may have cardio- and reno-protective function. We present here subgroup analysis(n=216) of patients with BMI ≥25 at 16 weeks from a Phase 3 open label study(N=392) conducted to evaluate efficacy and safety of triple-drug FDC versus two-drug FDC combination in Indian patients with T2DM.

Materials and methods

T2DM patients receiving stable total daily dose of Glimepiride 1 mg and Metformin SR/PR/ER 1000 mg and HbA1c ≥ 8% and ≤ 11% at screening were randomized to daily dose of triple-drug FDC of dapa gliflozin+glimepiride+metformin ER tablets (10mg+1mg+1000mg) once-daily (test, n=104) or dualdrug FDC of glimepiride+metformin PR (1mg+1000mg) once-daily (comparator, n=113) for 16 weeks. Primary endpoint was mean change in HbA1c from baseline to Week 16.

Results

At baseline, generalised obesity was observed in 217 patients. HbA1c at baseline in both arms was comparable (test, 8.99±0.83 vs comparator, 8.95±0.72). Significant reduction from baseline HbA1c was observed in all groups at Week 16. At Week 16, proportion of patients achieving HbA1c<7% was significantly more in test arm. Adjusted mean change (SE) in HbA1c was statistically significant in the test group at Week 16 [test; -1.9% (0.09) vs comparator; -1.57% (0.08); p=0.0063], Figure 1. Proportion of patients achieving HbA1c <7% in test arm was significantly more compared to that in comparator arm at Week 16 (47.10% vs 31.90%; p=0.0225), Figure 2. In overall study the number of adverse events in the test and comparator arm were similar. Study medications were well tolerated without incidence of any serious adverse event.

Conclusion

Triple-drug FDC of dapagliflozin, glimepiride and metformin ER demonstrated superior efficacy over dualdrug FDC of glimepiride+metformin PR in reducing HbA1c from baseline to Week 16 in subgroup of patients with BMI ≥ 25. Proportion of patients achieving HbA1c<7% was significantly more in test arm at 16 weeks. Study medications were well-tolerated.

P14

Efficacy and Safety of Dapagliflozin, Sitagliptin, and Extended Release Metformin in Type 2 Diabetes Mellitus in India: A Phase 3 Study Subgroup Analysis Based on HbA1c

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Keywords
• Oral therapies: metformin, sensitizers and other non- secretagogues
• Hypoglycaemia

Background and Aims

Dapagliflozin increases urinary glucose excretion, sitagliptin slows the inactivation of incretin hormones, and metformin lowers basal and postprandial glucose. We conducted a subgroup analysis to evaluate the efficacy and safety of triple-drug fixed-dose combination (FDC) of Dapagliflozin+Sitagliptin+ Metformin extendedrelease (ER) in T2DM.

Materials and methods

This is a subgroup analysis of a phase 3, randomized, open label, active-controlled study (16 weeks treatment) which randomized

Indian T2DM patients with HbA1c (≥8% to≤11%) taking metformin immediate-release/ER 1500-2000 mg/day. Patients received once daily dose of FDC of Dapagliflozin+Sitagliptin+ER-Metformin tablet (10+100+1000 mg) (Test) OR co-administration of Sitagliptin and SR-Metformin (100+1000 mg) (Comparator 1) OR FDC of Dapagliflozin+ER-Metformin (10+1000 mg) (Comparator 2). This subgroup analysis aimed to evaluate glycemic and safety parameters from baseline to Week 16 in two subgroups based on baseline HbA1c, i.e, subgroup 1 (S1: 8%-9.5%) and subgroup 2 (S2: >9.5%-11%). [CTRI/2021/11/038176]

Results

A total of 295 (96 in test, 101 in comparator 1, and 98 in comparator 2) and 101 (36 in test, 34 in comparator 1, and 31 in comparator 2) patients were included in S1 and S2, respectively. At Week 16, patients in all three treatment arms, in both subgroups, demonstrated significant improvement in HbA1c from baseline (p<0.0001 each). In both subgroups, test arm demonstrated statistically significant improvement as compared to comparator arms at Week 16 (Table 1). Statistically significant reduction in FBG and PPBG from baseline to Week 16 were observed in all three treatment arms (p<0.0001 each). In S1, proportion of patients achieving HbA1c <7.0% was statistically significant in test versus comparator 1 (43.8% vs 15.5%, p<0.0001) and comparator 2 (43.8% vs 25.3%, p=0.0095) at Week 16. Study medications were well tolerated.

Graph/Table :

Table 1. Reduction in Mean HbA1c from Baseline to Week 16

Test product	Test	Comparator 1	Comparator 2	Test Vs Comparator 1	Test Vs Comparator 2
Subgroup 1 (HbA1c 8% to 9.5% at Baseline) (Mean±Standard Deviation)					
HbA1c at Baseline	8.64±0.44	8.64±0.44	8.64±0.43	0.9348	0.9328
HbA1c at Week 16	7.09±0.72	7.40±0.66	7.34±0.72		
Change from Baseline	-1.55±0.77	-1.23±0.59	-1.31±0.66		
P value	<0.0001	<0.0001	<0.0001	0.0007	0.0110
Subgroup 2 (HbA1c >9.5% to 11% at Baseline) (Mean±Standard Deviation)					
HbA1c at Baseline	10.21±0.37	10.19±0.40	10.25±0.42	0.8792	0.6822
HbA1c at Week 16	7.91±1.07	8.62±1.00	8.64±0.82		
Change from Baseline	-2.29±1.07	-1.57±0.84	-1.61±0.84		
P value	<0.0001	<0.0001	<0.0001	0.0018	0.0025

Conclusion

In both subgroups, test arm demonstrated statistically significant reduction in glycemic parameters at Week 16. FDC of Dapagliflozin+Sitagliptin+ER-Metformin tablet demonstrated superior efficacy regardless of the baseline HbA1c value. All three treatments were well tolerated.

P15

Effect of Dapagliflozin, Sitagliptin, and Extended Release Metformin on Fasting Blood Glucose in Indian Patients with T2DM: A Post-hoc Analysis of Phase 3 Study

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Keywords
• Oral therapies: metformin, sensitizers and other non- secretagogues
• Hypoglycaemia

Background and Aims

Dapagliflozin, sitagliptin, metformin together can lead to increased glucose excretion, slowed inactivation of incretin hormones, and lowered basal and postprandial glucose. We conducted a post-hoc analysis of the phase 3 clinical study to evaluate the efficacy of fixed dose combination (FDC) Dapagliflozin, Sitagliptin, and Extended Release (ER) Metformin (10+100+1000 mg) in T2DM.

Materials and methods

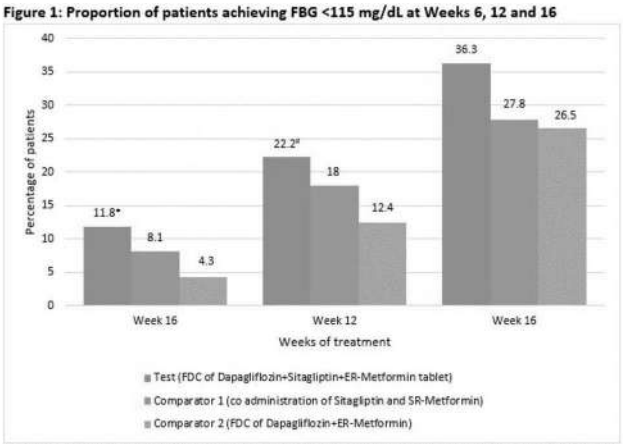
This is a post-hoc analysis of a phase 3, randomized, open label, active-controlled study (16 weeks treatment). Study included adult patients with HbA1c ≥8% and ≤11% taking metformin IR/ER 1500-2000 mg/day. Patients were randomized to once daily dose of FDC of Dapagliflozin+Sitagliptin+ER-Metformin tablet (10+100+1000 mg) (Test) OR co-administration of Sitagliptin and SR-Metformin (100+1000 mg) (Comparator 1) OR FDC of Dapagliflozin+ER-Metformin (10+1000 mg) (Comparator 2). In this analysis, we evaluated the improvement in fasting blood glucose (FBG) at Week 16. [CTRI/2021/11/038176]

Results

A total of 415 (137 in Test, 139 in Comparator 1, and 139 in Comparator 2) patients were included in this analysis. At Week 16, patients in all three treatment arms demonstrated significant improvement in FBG from baseline (p<0.0001 each). At Week 16, test arm demonstrated statistically significant improvement in FBG as compared to comparator 1 (p=0.0226), and the results were comparable with comparator 2 (p=0.0542). In Test arm, significantly higher proportion of patients achieved target FBG <115 mg/dL at weeks 6 and 12 compared to Comparator 2 (p=0.0228 and p=0.0373, respectively) (Figure 1).

Graph/Table :

Figure 1: Proportion of patients achieving FBG <115 mg/dL at Weeks 6, 12 and 16



*: In Test arm, significantly higher proportion of patients achieved target FBG <115 mg/dL at Week 6 compared to Comparator 2 (p=0.0228).
#: In Test arm, significantly higher proportion of patients achieved target FBG <115 mg/dL at Weeks 12 compared to Comparator 2 (p=0.0373).

Conclusion

FDC of Dapagliflozin+Sitagliptin+ER-Metformin tablet demonstrated statistically significant reduction in FBG at Week 16 compared to Comparator 1 and significantly more patients achieved target FBG compared to Comparator 2 at weeks 6 and 12.All treatments were well tolerated.

P16

Subgroup Analysis of Phase 3 study of FDC of Dapagliflozin, Glimepiride, and Metformin Extended Release in Type 2 Diabetes Mellitus Patients with Mild Renal Impairment

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Keywords
• SGLT inhibitors • Hypoglycaemia

Background and Aims
As type 2 Diabetes Mellitus (T2DM) has a progressive nature, addition of SGLT2 inhibitors to metformin and sulfonylurea can provide better glycemic control, improve therapy compliance and may have additional cardio-and reno-protective function. Subgroup analysis aimed to assess efficacy and safety of triple-drug fixed-dose combination (FDC) vs dual-drug FDC in T2DM patients with mild renal impairment (baseline eGFR [60 to < 90 mL/min/1.73 m2]).

Materials and methods
This is a subgroup analysis of a Phase 3, randomized, open-label, active-controlled study (CTRI/2022 /03/041424), which included T2DM Indian patients (HbA1c 8%-11%) who were on Glimepiride + Metformin sustained release/prolonged release (PR)/extended release (ER) (1mg+1000mg/day) at screening. Eligible patients were randomized to receive FDC of dapagliflozin + glimepiride + metformin ER tablets (10mg+1mg+1000mg once daily [OD, test arm]) OR FDC of metformin PR + glimepiride tablets (1000mg+1mg OD [comparator arm]) for 16 weeks. This subgroup analysis evaluated glycemic and safety parameters in test arm vs comparator arm in patients with mild renal impairment (baseline eGFR [60 to < 90 mL/min/1.73 m2]).

Results
This Subgroup analysis included total 86 patients (test arm [n=41] and comparator arm [n=45]. Mean ± SD reduction in HbA1c was statistically significant from baseline to week 16 in test arm vs comparator arm: -1.71% ± 0.85% ± vs -1.31% ± 0.82%; p=0.0264). Statistically significant reduction in HbA1c from baseline to week 12 was observed in test arm vs comparator arm [-1.12% ± 0.66% vs -0.81% ± 0.58%, p= 0.0182). Proportion of patients who achieved HbA1c <7% was significantly higher in test arm vs comparator arm (14.6% vs 0%, p= 0.0096) at week 12. Reduction in HbA1c, post-prandial and fasting blood glucose levels was statistically significant within test arm and comparator arm at weeks 8, 12, and 16. No severe/serious adverse events were reported, one mild asymptomatic hypoglycemia event was reported which required no active intervention.

Conclusion
T2DM patients with mild renal impairment showed significant reduction in HbA1c with triple FDC of dapagliflozin + glimepiride + metformin Hydrochloride ER demonstrating superiority compared to dual FDC of metformin PR + glimepiride (1000mg+1mg OD [comparator arm]) at weeks 12 and 16. Study medications were well tolerated.

P17

Efficacy and Safety of Sitagliptin, Glimepiride, and Metformin IR in Indian patients with T2DM: A Phase 3 Study Subgroup Analysis Based on HbA1c

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Keywords
• Oral therapies: metformin, sensitizers and other non- secretagogues
• Hypoglycaemia

Background and Aims
Sitagliptin addition to metformin and a lower dose of glimepiride can decrease glucagon levels and improve glucose-induced insulin secretion, providing improvement in glycemic control and reduction in hypoglycemia events. We conducted a subgroup analysis to assess the efficacy and safety of fixed dose combination (FDC) of Sitagliptin+Glimepiride+Metformin in patients with T2DM.

Materials and methods
This is a subgroup analysis of a phase 3, randomized, double-blind, double-dummy, active-controlled study (16 weeks) followed by an open-label, single-arm study (12 weeks). Study included adult Indian patients with HbA1c ≥8% and ≤11% taking glimepiride 4 mg and metformin ≥1500 mg/day. Patients were randomized to receive FDC of Sitagliptin+Glimepiride+Metformin tablet (50+1+1000 mg) BID (Test) OR co-administration of metformin 1000 mg BID and glimepiride 2 mg BID (Comparator) for 16 weeks. This subgroup analysis aimed to evaluate glycemic and safety parameters in two subgroups based on baseline HbA1c, i.e, subgroup 1 (S1: 8%-9.5%) and subgroup 2 (S2: >9.5%-11%) during double-blind period. [CTRI/2021/11/038169]

Results
A total of 286 (137 in test and 149 in comparator) and 106 (53 in test and 53 in comparator) patients were included in S1 and S2, respectively. At Week 12 and 16, patients in both arms in both subgroups demonstrated significant improvement in HbA1c from baseline (p<0.0001 each). In both subgroups, test arm demonstrated statistically significant improvement in HbA1c as compared to comparator arm at Week 16 (S1: p<0.0001; S2: p= 0.0013) (Table 1). Statistically significant reduction in FBG and PPBG from baseline to Weeks 6, 12 and 16 were observed in both arms in both subgroups (p<0.0001 each). In S1, proportion of patients achieving HbA1c <7.0% was statistically significant in test versus comparator (S1:38.1% vs 15.1%, p<0.0001) at Week 16. Study medications were safe and well tolerated.

Graph/Table :

Table 1. Reduction in Mean HbA1c from Baseline to Week 16

Test product	Test	Comparator	Test Vs Comparator
Subgroup 1 (HbA1c 8% to 9.5% at Baseline) (Mean±Standard Deviation)			
HbA1c at Baseline	8.77±0.33	8.76±0.35	0.7031
HbA1c at Week 16	7.18±0.89	7.61±0.74	
Change from Baseline	-1.60±0.89	-1.15±0.75	
P value	<0.0001	<0.0001	<0.0001
Subgroup 2 (HbA1c >9.5% to 11% at Baseline) (Mean±Standard Deviation)			
HbA1c at Baseline	10.23±0.45	10.20±0.45	0.7568
HbA1c at Week 16	7.93±1.08	8.57±1.17	
Change from Baseline	-2.30±1.02	-1.62±1.12	
P value	<0.0001	<0.0001	0.0013

Conclusion
Test arm demonstrated statistically significant reduction in HbA1c at Week 16 in both subgroups. Sitagliptin+Glimepiride+Metformin tablet demonstrated superior efficacy in both HbA1c subgroups. All treatments were well tolerated.

P18

Effect of Sitagliptin, Metformin, and Glimepiride on Fasting Blood Glucose in Indian Patients with T2DM: A Post-hoc Analysis of Phase 3 Study

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Keywords
• Oral therapies: metformin, sensitizers and other non- secretagogues
• Hypoglycaemia

Background and Aims
Adding sitagliptin to metformin and a lower dose of glimepiride can provide benefits including decreased glucagon levels and improved glucose-induced insulin secretion, thereby glycemic improvements and reduced hypoglycemia events. We conducted a post-hoc analysis of the phase 3 clinical study to evaluate the efficacy and safety of fixed dose combination (FDC) of Sitagliptin+Glimepiride+Metformin (50+1+1000 mg) BID in T2DM.
Materials and methods
This is a post-hoc analysis of a phase 3, randomized, active-controlled, double-blind, double-dummy study (16 weeks) followed by an open-label, single-arm study (12 weeks). Study included adult Indian patients with HbA1c ≥8% and ≤11% taking glimepiride 4 mg and metformin ≥1500 mg/day. Patients received FDC of Sitagliptin+Glimepiride+Metformin tablet (50+1+1000 mg) BID (Test arm) OR co-administration of metformin 1000 mg BID and glimepiride 2 mg BID (Comparator arm) for 16 weeks. In this analysis, we evaluated the improvement in fasting blood glucose (FBG) at Week 16. [CTRI/2021/11/038169]
Results
A total of 392 (190 in Test arm and 202 in Comparator arm) patients were included in this analysis. At Weeks 6, 12 and 16, patients in both treatment arms demonstrated significant improvement in FBG from baseline ($p<0.0001$ each). At Week 16, Test arm had higher proportion of patients achieving FBG <115 mg/dL (Test vs Comparator: 27.8% vs 21.2%). In Test arm, the proportion of patients achieving both, target HbA1c <7% and target FBG <115 mg/dL at Week 16 was statistically significant as compared to Comparator (Test vs Comparator: 14.2% vs 6.4%, $p=0.0123$) (Table 1).

Graph/Table :

Table 1. Proportion of Patients Achieving Both HbA1c <7% and FBG <115 mg/dL at Weeks 6, 12 and 16

Weeks	Test (N=190)	Comparator (N=202)	Test Vs Comparator
Week 6	33 (17.4%)	33 (16.3%)	0.7850
Week 12	16 (8.4%)	9 (4.5%)	0.1469
Week 16	27 (14.2%)	13 (6.4%)	0.0123

Test: Sitagliptin+Glimepiride+Metformin tablet (50+1+1000 mg)
Comparator: Co-administration of metformin 1000 mg and glimepiride 2 mg

Conclusion
Significantly more proportion of patients achieved target HbA1c and target FBG with FDC of Sitagliptin+Glimepiride+Metformin at Week16 compared to co-administration of metformin and high dose glimepiride. Both treatments were well tolerated.

P19

Effect of FDC of Sitagliptin, Glimepiride and Metformin IR on post-prandial blood glucose in patients with T2DM: A post-hoc analysis of phase 3 study

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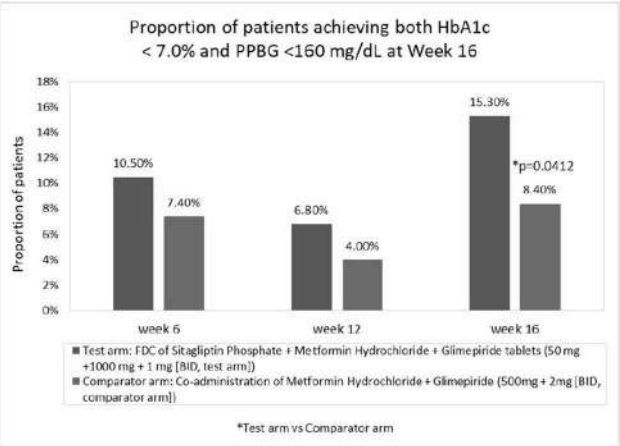
Keywords
• Oral therapies: metformin, sensitizers and other non- secretagogues
• Hypoglycaemia

Background and Aims
Addition of sitagliptin to a lower dose glimepiride and metformin is likely to decrease glucagon levels and improve glucose-induced insulin secretion, improving glycemic control and reducing hypoglycemia events. We conducted a post-hoc analysis of the phase 3 clinical study to evaluate the efficacy and safety of fixeddose combinations (FDCs) of Sitagliptin+Glimepiride+Metformin [50 mg + 1 mg + 1000 mg] in patients with type 2 diabetes mellitus (T2DM).
Materials and methods
This is a post-hoc analysis of a phase 3, randomized, double blind, active-controlled study (CTRI/2021/11/038169) which included T2DM Indian patients (HbA1c 8%-11%) who were on Glimepiride (4mg/day) and Metformin (≥1500mg/day) therapy at screening. Eligible patients were randomized to receive either FDC of Sitagliptin + Glimepiride + Metformin IR tablets (50 mg + 1 mg + 1000 mg BID [Test]) OR co-administration of Metformin + Glimepiride (500mg + 2mg BID [Comparator]) for 16 weeks. This posthoc analysis evaluated control of postprandial blood glucose (PPBG) at week 16.
Results
This post-hoc analysis included total 392 patients [Test: 190 and Comparator: 202]. Statistically significant reduction in PPBG from baseline was observed in both Test and Comparator arms at weeks

6, 12 and 16 (p<0.0001 each). At week 16, numerically higher proportion of patients achieved PPBG <160 mg/dL in Test arm [Test vs Comparator: 26.7% vs 24.7%]. Proportion of patients who achieved both HbA1c <7% and PPBG <160mg/dL was significantly higher in test arm vs comparator arm (15.3% vs 8.4%, p= 0.0412) at week 16. Safety profile was comparable in both treatment arms and no serious adverse events were reported.

Graph/Table :



Conclusion

Significantly more proportion of patients achieved target HbA1c and target PPBG with FDC of Sitagliptin+Glimepiride+Metformin at Week16 compared to co-administration of metformin and high dose glimepiride. Both treatments were well tolerated.

P20

LV MASS REDUCTION WITH DAPAGLIFLOZIN AND EMPAGLIFLOZIN IN T2DM – A COMPARITIVE STUDY

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Keywords
• SGLT inhibitors • Cardiac complications

Background and Aims

An observational study was done in people with diabetes who were prescribed SGLT2 inhibitors (Dapagliflozin and Empagliflozin) to compare the quantum of LV mass reduction in them with each molecule from the baseline, over a period of one year, along with the comparision in weight, blood pressure and HbA1c reduction with their use.

Materials and methods

Adults with T2DM detected for ≥ 2 years with hypertension, having eGFR ≥ 60 ml/min/1.73m2, and HbA1c ≥7% but ≤ 10% were included for this observational study. They were divided in two groups - A and B. Those in group A were given Empagliflozin 10mg OD and those in group B were given Dapagliflozin 10 mg OD. Both the groups were on Metformin 1000 mg or more per day along with other oral antihperglycemic agents or Insulin to target HbA1c ≤ 7% (monitered once every 3 months). All of them were also on ARB with/without other antihypertensives, to target blood pressure < 130/80 mm of Hg, as well as statins (Atorvastatin or Rosuvastatin). All of them underwent 2D Echocardiography at the first visit to assess LV mass. 50 people were included in each group. HbA1c, blood pressure, creatinine, FBS, PPBS. and body weight were recorded on every scheduled followup visit at 3 months interval. A repeat Echocardiography to assess the LV mass was done at the end of one year. Those with HbA1c ≥ 7.5%, eGFR < 45, and blood pressure > 130/80 mm of Hg were excluded. Finally the data of 20 PWD in Group A and 18 in Group B were compared.

Results

LV mass reduction was significantly greater in Group B (mean reduction of 3.6 gm/m2) in comparision to Group A (mean reduction of 2.1 gm/m2).

Conclusion

This observational study showed that Dapagliflozin is a more effective SGLT2 inhibitor in comparision to Empagliflozin as far as LV mass reduction is considered in people with T2DM. Larger studies on similar head to head comparisions should be done for reaching a final conclusion.

P21

Enhancing type 2 diabetes classification strategies: data- driven comparative insights from cluster analysis and sub-phenotyping

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Keywords
• Insulin sensitivity and resistance

Background and Aims

Most existing sub-classification efforts have predominantly focused on either clustering or pathophysiological phenotyping, but rarely both. To address this gap, our study aimed to compare these two classification techniques using homeostatic model assessment (HOMA) estimates and then assess their accuracy in sub-classifying type 2 diabetes.

Materials and methods

We analyzed baseline data from patients (n=281) with diagnosed Type 2 Diabetes (T2D) (<2-year duration) enrolled in a one-year online diabetes management program at Freedom from Diabetes Clinic, India. Using k-means clustering, we grouped patients based on age, BMI, HbA1C, insulin resistance (HOMA2-IR), and beta-cell function (HOMA2-B). Additionally, the same patients were also categorized into 3 sub-phenotypes: insulinopenic, classical, and hyperinsulinemic T2D, using version 2 of the revised homeostatic assessment model (HOMA2 calculator) to estimate IS (HOMA2%IS) and beta cell function (HOMA2%B). Sankey diagrams were also plotted to compare patient flow across sub-phenotypes.

Results

Cluster analysis yielded 4 distinct clusters: SIDD (Severe insulin-deficient diabetes), SIRD (Severe insulinresistant diabetes), MOD (Mild obesity-related diabetes), and CIRDD (Combined insulin-resistant and deficient diabetes). Through sub-phenotyping we classified patients into

hyperinsulinemic, insulinopenic, and classical T2D. Additionally, another category 'Nascent' {high Insulin Sensitivity (IS) and high beta cell function)} was observed. We observed that all 89.3%, 30.9%, and 69.7% of patients classified in SIRD, MOD, and CIRDD clusters exhibited hyperinsulinemic phenotype. While 55.2% and 34.3% of SIDD cluster patients exhibited classical and insulinopenic phenotypes, respectively, MOD (42.7%) and CIRDD (30.3%) clusters exhibited Nascent phenotype.

Conclusion

Sub-phenotyping misdiagnosed the Nascent group as non-diabetic based on high insulin sensitivity and high beta cell function whereas clustering correctly identified these patients as having MOD or CIRDD diabetes. This suggests that clustering may be superior in classifying type 2 diabetes rather than pathophysiological sub-phenotyping which relies only on HOMA estimates. Further large-scale studies may help corroborate our findings.

P22

Prevalence and predictors of anxiety and depression among individuals with type 2 diabetes in India

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Keywords
• Psychological aspects • Other complications

Background and Aims

The available literature suggests the adverse effects of depression and anxiety in the management of type 2 diabetes (T2D). Nevertheless, there is a scarcity of comparable data available from India. The aim of this study was to identify the prevalence and predictors of depression and anxiety in T2D patients in the Indian population.

Materials and methods

A cross-sectional study that included 6424 patients with T2D was conducted from July 2021 to July 2023 at Freedom from Diabetes Clinic in Pune, India. Data on medical history, anthropometry, and biochemical parameters were collected. Anxiety and depression were measured using the validated tools: Generalized Anxiety Disorders (GAD-7) and Patient Health Questionnaire (PHQ-9).

Results

The prevalence of anxiety and depression based on the community cut-off (score ≥5, including mild anxiety/depression) was 45.1% and 48.4%. With the clinical cut-off (score ≥10, moderate to severe anxiety/depression), the prevalence of anxiety and depression was 16.3% and 17.8%, respectively. The median age, duration of diabetes, and HbA1c were 50 years, 7.5 years and 7.5% respectively. Gender, age, self-reported stress before diabetes, duration of diabetes, family history, marital status (unmarried), habit of smoking, higher BMI, poor glycemic control, usage of insulin, and presence of comorbidities like hypertension and cholesterol were significantly associated with increased prevalence of anxiety and depression ($p<0.05$).

Conclusion

Younger age, gender (female), stress prior to diabetes, poor diabetes control, use of insulin, comorbid anxiety and depression, higher BMI, and unmarried individuals were significant factors associated with anxiety and depression. Considering the substantial prevalence of anxiety and depression, integrating psychological intervention into T2D management is advisable for its effective management.

P23

Expert opinion on the current role of Sitagliptin & its fixed-dose combination in the management of T2DM in clinical practice

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Keywords
• Oral therapies: metformin, sensitizers and other non- secretagogues

Background and Aims

DM is associated with an elevated risk of cardiovascular-renal disease. This expert opinion guides a better understanding of the role of Sitagliptin in current Indian clinical practice

Materials and methods

The expert opinion was developed based on focused group discussions among 41 Indian Endocrinology and Diabetology experts' opinions and clinical recommendations meeting the needs of patients with diabetes in Indian clinical practice.

The experts discussed and summarized, the role of Sitagliptin and its fixed-dose combination (FDC) in newly diagnosed T2DM patients based on clinical insights and review of available clinical evidence.

Results

The opinions of the experts are summarized under the following headings

1: Expert Opinion on Choice of Therapy in newly diagnosed T2DM

• Annual screening & early intensive treatment should be considered in all patients.

• The choice of therapy is based on the patient's age, HbA1c levels, co-morbidities, economic status, and compliance with the therapy

• When A1C is ≥1.5% (12.5 mmol/mol) above the desired glycemic target, many individuals will require dual combination therapy to achieve and maintain their target A1C level

• The preferred choice of therapy in newly diagnosed patients will be a combination of DPP-4i with metformin with HbA1c >8.5% as it provides reasonable glycaemic control without the risk of hypoglycaemia.

• DPP4i and SGLT2i on average cause a reduction of 0.5-0.8 in HbA1C, if the target levels to be reduced are higher than desired then the addition of a sulfonylurea is required.

• Triple therapy with Metformin, DPP4i & SGLT2i is beneficial in optimal glycemic control

• Metformin + Sulfonylurea + DPP4i combination is preferred as initial therapy in patients who have higher HbA1c (average~9.5%) and are not suitable for injectable insulin therapy.

• For patients with a risk of Atherosclerotic Cardiovascular Disease (ASCVD), Sodium-glucose Cotransporter-2 Inhibitors (SGLT2i) + Metformin can be preferred as initial therapy.

2: Expert Opinion on Role of Sitagliptin in T2DM Therapy

• Experts considered Sitagliptin can be used in T2DM therapy across age groups and has robust clinical evidence with proven cardiac neutrality in Cardiovascular Outcome Trial (CVOT) Study

• In T2DM patients with CKD, Sitagliptin dosage adjustment based on eGFR levels is to be followed.

Experts preferred Sitagliptin 50mg in T2DM with CKD patients.

• Sitagliptin is considered beneficial for elderly T2DM patients owing to the robust availability of safety data in the elderly patients.

3: Expert Opinion on placement of FDC of Sitagliptin in T2DM Therapy

• Sitagliptin Metformin Sustained Release (SR) 50mg/500mg; Sitagliptin Metformin SR 100/500mg & 100mg/1000mg are prescribed based on therapeutic need of the patient for glycemic control.
• GI side effects are less with extended-release formulations compared with immediate-release formulations of metformin
• Sitagliptin & Dapagliflozin dual drug therapy and Sitagliptin, Metformin & Dapagliflozin triple drug therapy can benefit in T2DM Management as it efficacious, well tolerated & targets different pathways of hyperglycemia.

Conclusion

With a convenient once-daily oral regimen, low potential for pharmacokinetic interactions, and good efficacy and safety profiles, Sitagliptin & its FDC remain an essential option in the management of patients with T2DM.

P24

An Association Between Sleep Quality And Glycaemic Control In Diabetic Patients At A Tertiary Care Center

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Keywords
• Psychological aspects • Other complications

Background and Aims

Diabetes mellitus (DM) is one of the main chronic medical conditions worldwide in all nationalities and social classes and its prevalence is on the rise.It causes several complications like sleep disorders which have been unnoticed and documented. During the previous decades, the prevalence of sleep disturbances and deprivation has increased dramatically.Sleep and wakefulness problems are common in T2DM due to physiological imbalances and co-morbid sleep disorders, which result in poor sleep Quality

Aim: To study the sleep quality and quality of life of patients with type 2 diabetes (T2D) and its impact on glycemic control

Materials and methods

The observational study, conducted in a tertiary care hospital. A total of 55 Patients of type 2 diabetes mellitus attending the medicine opd and ward were recruited into the study. Sleep pattern was assessed by Pittsburg Sleep Quality Index (PSQI), a person with PSQI global score of 5 and above was considered as "poor sleeper".

Results

The study found that there is a significance (p value of 0.046) with uncontrolled diabetes (HbA1C >6.5) and poor sleep quality (PSQI >5). Moreover females were the groups with poor sleep quality when compared to males (p value of 0.022) and the co morbidities (P=0.049) and duration of illness within 4-8years (p value =0.027) presents positive correlation with the PSQI values.

Conclusion

The prevalence of poor sleep quality is very high in diabetic patients and is strongly associated with diabetic. Poor sleep quality is associated with poor glycemic control.

P25

Assessment of Liver Function and Ultrasonographic Changes in Patients with Type 2 Diabetes Mellitus

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Keywords
• Other complications

Background and Aims

Unraveling T2DM's impact on LFT & USG for better care To analyze LFT and liver ultrasound changes in Type 2 Diabetes patients at Aditya Diagnostics and Hospitals, correlating findings with diverse presentations

Materials and methods

Study conducted at Aditya Diagnostics & Hospitals, Dibrugarh for 1 year (Jan 1, 2021, to Jan 1, 2022). Hospital-based observational analytic cross-sectional study with 130 cases from the medicine ward, chosen using inclusion/exclusion criteria.

Results

• Majority aged 50-59 (40.8%), male-to-female ratio 2.93:1.
• 66.15% normal BMI, 33.85% BMI > 25 kg/m².
• 60% abnormal waist-to-hip ratio (WHR).
• Most T2DM cases <5 years (37.7%).
• Significant abnormal liver function tests:
Total bilirubin, conjugated bilirubin, unconjugated bilirubin, total protein, S. albumin, S. Globulin, S. AST, S. ALT, S. ALP, S. GGT: 25.38%, 40.76%, 1.5%, 44.61%, 36.15%, 25.38%, 21.53%, 23.84%, 36.15%, 4.6%.
• Abnormal ALT and ALP linked to abnormal liver ultrasound; AST, albumin, total bilirubin not.
• Elevated FBS, PPBS, HbA1c in abnormal ultrasounds.
• Significant ALT-liver ultrasound association, none for AST.
• No treatment-liver ultrasound linkage.
• Liver ultrasound-BMI significant, more obese had issues.
• ALT, AST not significantly linked to BMI.
• ALT, AST, liver ultrasound, WHR showed significant associations; higher rates of abnormalities in obese patients.

Conclusion

• Majority aged 50-59 (40.8%), male-to-female ratio 2.93:1.
• No significant sex-related associations with abnormal ALT or USG.
• 60% had an abnormal waist-to-hip ratio (WHR), 66.15% normal BMI, 33.85% BMI > 25 kg/m².
• Diabetes duration positively correlated with ALT ($p>0.05$), not with AST, ALP, or TP.
• Abnormal ALT and ALP significantly associated with abnormal USG ($p<0.05$); AST, albumin, total bilirubin not ($p>0.05$).
• Abnormal USG linked to higher FBS, PPBS, HbA1c.
• No treatment-USG association observed.
• Significant USG-BMI association ($p<0.05$); no significant BMI-ALT or BMI-AST association ($p>0.05$).
• Significant ALT, AST, USG-WHR associations ($p<0.05$)

P26

Rationale and Study Design of Evaluation of Effectiveness and Safety of Telmisartan and Amlodipine Fixed Dose Combination in Indian Hypertensive Patients (TACT-India)

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Keywords
• Hypertension

Background and Aims
Hypertension is a prevalent health condition among the Indian population, leading to severe health complications if left untreated. Recent studies reported a hypertension prevalence of 35% among adult population in India and hypertension is attributable to 10.8% of all deaths in India. Recent hypertension management guidelines recommend the initiation of antihypertensive therapy with a two-drug combination and preferred combination comprise of a RAS blocker (either an ACE inhibitor or an ARB) with a CCB or Thiazide/Thiazide-like diuretic. However, there is lacunae of real-world large-scale longitudinal studies on the safety and effectiveness of Telmisartan and Amlodipine fixed-dose combination (FDC) in Indian patients.
Materials and methods
The evaluation of the effectiveness and safety of Telmisartan and Amlodipine FDC in Indian hypertensive patients (TACT-India) is a prospective, longitudinal, multicentre, observational study. The primary objective of the study is to evaluate the effectiveness of Telmisartan and Amlodipine FDC and the secondary objective is to evaluate the safety of the combination. Overall, 10,000 HF patients will be included from 1000 study sites across India. The primary endpoint of this study is to assess the change in the systolic blood pressure (SBP) from baseline to 8 weeks. The secondary endpoint is to evaluate the percentage of patients achieving Blood Pressure goal (SBP <140 mm Hg & diastolic blood pressure [DBP] < 90 mm Hg) at 8 weeks, to evaluate the safety of Telmisartan plus Amlodipine FDC, and to analyze the demographic characteristics, comorbidities, concomitant medications in hypertensive patients. Data will be recorded from the time point when the patient was initiated on Telmisartan plus Amlodipine FDC as part of routine clinical practice.
Conclusion
The TACT-India study expected to reveal the real-world effectiveness of the FDC of Telmisartan and Amlodipine in the management of Hypertension. To our knowledge, this is a first-of-its-kind study with a large sample size of India Hypertensive patients. The findings of this study will help to understand the effectiveness of the FDC in reducing SBP, the patients achieving their target BP goal, and the safety profile of the combination. Moreover, the study will identify the demographics, comorbidities, concomitant medication, and clinical and laboratory parameters of hypertensive patients in India.

P27

Long term effect of personalised multi interventional habit based program on HbA1c, FBS, weight and medications assessed every three months for a duration of 9 months

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Keywords
• Insulin sensitivity and resistance • Nutrition and diet • Health care delivery

Background and Aims
Type 2 Diabetes Mellitus (T2DM) is not only one of the leading causes of mortality but also a burden which increases healthcare costs, increase in medication use and possible threat to vital organs. Digital healthcare: telemedicine along with virtual frequent personal coaching have helped management of diabetes at a large scale with an enormous impact on the greater population. This retrospective study looks at sustained improvement in HbA1c , FBS, weight and medications in 136 participants of the Sugarfit's Diabetes Reversal Program (SDRP) over 9 months.
Materials and methods
SDRP is a personalised intervention program that uses technology-enabled medical management, dedicated diabetes experts to provide customised nutrition, progressive fitness, and behavioural modification which were intensified over 9 months. Participants who enrolled in SDRP and completed their 9 month long journey were recruited in this study. Analysis was made every quarter. At the end of 3 months(Q1), 6 months(Q2) and 9 months(Q3). The primary outcome was reduction in Hba1c. Secondary outcomes were reduction in FBS, weight and glucose lowering medications.
Results
Average Hba1c of the participants in the baseline was 7.6±1.6% and was seen dropping to 6.5±0.6% in Q1, 6.2±0.5% in Q2 and 6.1±0.3 in Q3. FBS dropped from 145±46mg/dl to 117±23 in Q1, 104±20 in Q2 and 102±16 in Q3. Weight was reduced from 82.4±17.8kgs to 74.2±15.5kgs in Q1, 73.1±12.8kgs in Q2 and 72.2±12.6 in Q3. Patients on oral hypoglycemic medications showed a significant decrease in dose and a large number were able to completely stop. Metformin showed a decrease in dosage but was mostly continued except for a few clients. Only 2 clients were on Insulin, one of them stopped Insulin and one decreased their dose by 22%.
Conclusion
The findings indicate that a comprehensive multi-interventional diabetes reversal program such as SDRP, can help in significant and sustained improvement in HbA1c level, glycemic control, weight loss and reduction in glycemic medications in adults with T2DM.

P28

To study rifampicin resistance by cartridge based nucleic acid amplification test amongst patients of sputum smear positive pulmonary tuberculosis with diabetes mellitus

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Keywords
• Other complications

Background and Aims
India has the largest number of tuberculosis (TB) cases in the world (estimated at 2.8 million incident cases per annum). India has the second largest number of diabetic people in the world.So we had examined whether diabetes(DM) being an immune suppressive condition is also responsible for development of drug resistance TB (DR-TB).
Materials and methods
It was a cross-sectional study.Conducted at Kingsway Chest Centre (O.P.D), Department of Respiratory Diseases & Tuberculosis, Rajan

Babu Institute for Pulmonary Medicine and Tuberculosis (RBIPMT), North Delhi Municipal Corporation, GTB Nagar, Kingsway Camp, Delhi All sputum smear positive pulmonary TB(PTB) patients with history of DM or patients who were diagnosed DM by fasting plasma glucose > 126mg/dl were included in the study. For control of diabetes, HbA1c was tested; for susceptibility of Rifampicin, CBNAAT was done in enrolled patients.

Results

Total number of patients enrolled in the study were 129. All the patients were sputum smear positive pulmonary tuberculosis with diabetes mellitus. Out of 129 , 41 were Rifampicin resistant and 88 were Rifampicin sensitive. Rifampicin resistant in new cases was found in 14 out of 56 patients (25%) and in retreated cases it was found in 27 out of 73 patients (37%). Based on national DR surveys carried out in India, 2.84% among new TB cases and11.62 % among previously treated TB cases have MDR-TB but in this study the percentage was much higher among patients of TB with co-existing Diabetes as stated above. There was paradoxical significance (p value=0.04) found in between education and Rifampicin resistance in this study. Patients with HbA1c <9 were 79 out of which 19 were rifampicin resistant , 60 were rifampicin sensitive PTB and 50 patients with HbA1c >9 ; 22 were resistant and 28 were rifampicin sensitive PTB. There was statistical significance (p value = 0.01) present between HbA1c >9 and rifampicin resistance. Among males, HbA1c >9 was found to be significantly (p value 0.01) associated with Rifampicin resistance.It was observed that in BMI group 18.5 – 22.9 (normal for Asians) , HbA1c > 9 was significantly(p value 0.01) associated with Rifampicin resistance. It was also observed in the same BMI group that patients who were retreated for PTB their HbA1c >9 was significantly (p value0.03) associated with Rifampicin resistance.

Conclusion

In this study sputum smear positive PTB patients also suffering from DM having Poor glycemic control (HbA1C>9) was significantly associated with Rifampicin resistance. Poor glycemic control was found to be an independent risk factor for Rifampicin resistance when compared with age, socioeconomic factors , h/o ATT, h/o diabetes mellitus , BMI ,sputum AFB grades , smoking and alcohol consumption. In patients with cavity or extensive lesion on CXR, good glycemic control (HbA1c <9) was significantly associated with a better prognosis i.e., Rifampicin sensitivity.

P29

A cross-sectional survey of clinicians to understand the practice-pattern and utility of Dapagliflozin in Indian patients

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Keywords
Epidemiology • SGLT inhibitors • Health care delivery • Cardiac complications

Background and Aims

Introduction / Background: Dapagliflozin is approved in India based on controlled clinical studies. Despite the robust evidence from randomized controlled trials and strong recommendations by international organizations, less than 10% of patients with an indication for SGLT2i are prescribed this class of medication, and real-world Indian data on clinical utility is scarce.

Aim: This survey was conducted with an objective to understand the perspectives of Indian physicians on the effects of Dapagliflozin in diabetes and heart failure patients.

Materials and methods

Methods: This cross-sectional, questionnaire-based survey was conducted among 285 practicing physicians across the country, through an online survey platform. We developed a 10-item online questionnaire which included area and duration of practice, details about prescribing patterns of SGLT2i and clinical outcomes after 3 months of usage. All the parameters were summarized using descriptive statistics. IBM SPSS Statistics was used for biostatistical analysis.

Results

Results: Responses from all 285 doctors were captured and analysed. About 66% of the physicians replied that T2DM followed by T2DM plus CVD, HF and CKD, as their most commonly prescribed indication of dapagliflozin. 52% opined HF as the second-most commonly prescribed indication. While majority of the doctors preferred dapagliflozin monotherapy, 32% preferred to prescribe it as an add-on to metformin and most of them [85%] preferred the 10mg strength. Sitagliptin was the most preferred DPP4i along with dapagliflozin [56%]. Majority [62%] of the physicians mentioned that they see a modest 0.5 – 1% reduction in HbA1c after 3 months with dapagliflozin. While 81% of the physicians mentioned that they have observed some BP reduction with dapagliflozin, about 20% of them mentioned that a 2-5 mmHg reduction in BP is observed. About 11% of the doctors mentioned that dapagliflozin results in 2-3Kg weight reduction as well in diabetic patients. Majority [79%] of the physicians preferred dapagliflozin to be prescribed in HF patients with diabetes. The safety and tolerability of dapagliflozin was rated as good-to-excellent by 88% of the physicians.

Conclusion

Conclusions: The findings from the survey highlight the prescribing patterns and clinical benefits of dapagliflozin in T2DM and HF patients. The molecule is gaining more share into HF management amongst the physicians, with its recent approval that places it beneficial across the spectrum of HF management.

P30

Triple-drug fixed-dose combination of Sitagliptin + Glimepiride + Metformin Extended Release: New addition in the Anti-diabetic armamentarium

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Keywords
• Oral therapies: metformin, sensitizers and other non- secretagogues

Background and Aims

Type 2 diabetes (T2DM) is a chronic disease that involves multiple pathophysiological defects, including impaired islet function and insulin resistance, resulting in impaired glucose tolerance and inappropriately high fasting hepatic glucose production. Metformin is a first-line treatment that may not remain effective long-term. Considering progressive nature of the disease and its associated complications,

combination therapy with other oral or injectable anti-diabetics having complimentary mechanisms of action, aiming to improve efficacy, adherence, tolerability and reduced risk of complications should be preferred.

Materials and methods

The American Diabetes Association and Research Society for the Study of Diabetes in India guidelines recommend initiating combination therapy, for patients with HbA1c >1.5% above target, whereas American Association of Clinical Endocrinologists guidelines recommend dual or possibly triple-combination therapy, usually including metformin for newly diagnosed type 2 diabetes patients and an entry HbA1c >9.0% and/or >1.5% above target.

Conclusion

Metformin reduces hepatic glucose production and intestinal absorption of glucose, and improves insulin sensitivity by increasing peripheral glucose uptake and utilization. Sitagliptin inhibits DPP-4 enzyme that degrades and inactivates GLP-1. The elevated GLP-1 level results in increased insulin release after meals, improved glucose tolerance, and decrease glucagon secretion. It is reported that adding DPP-4 inhibitor and reducing dose of sulfonylurea provides better glycemic control without increasing risk of hypoglycemia. Metformin, glimepiride and sitagliptin have well-established efficacy and tolerability profile individually and are commonly co-administered in clinical practice. In past, published studies on co-administration of these drugs showed additional reduction of 0.6%-0.9% in HbA1c. It is reported that each 10% increase in compliance was associated with a 0.1% HbA1c reduction. Considering polypharmacy is a frequent problem in T2DM, having a fixed-dose combination of sitagliptin, glimepiride, and metformin would provide faster, stronger and durable glycaemic control without compromising tolerability. The FDC will also improve treatment compliance and may help patients to achieve their glycaemic targets and reduce potential risk of complications.

P31

Evidence based clinical case presentation of Diabetis induced asymptomatic leukocytosis

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Keywords
• Other complications

Background and Aims

1>In several studies WBC as a marker of subclinical inflammation with insulin resistance and Type 2 Diabetes has been reported . 2> Elevated WBC even within normal rage is associated with chronic complications in Type 2 DM.

Materials and methods

49y/f came in opd for consultation
k/c/o DM since 5 yrs
no h/o any major illness in past
currently complaint of weakness.
No fever/cough/burning micturition/joint pain in last 3 months
1st visit –T – 95.8F, Pulse -82/min, spo2 – 97%. BP -142/86mmof Hg. BS- F-148mg/dl, PP – 216mg/dl, Sr. creat -0.49, CBC – Hb-11 , TLC 13500, N68L21M5E6B0 PLT COUNT – 3Lakhs, RA TEST – NORMAL, Urine R N M- Sugar 2+, rest n
OHA CHANGED, AS TLC counts are high broad spectrum Antibiotic started for 5 days. Asked for fu
After 10FU – No complaint. BS F- 126 mg/dl, PP- 189 mg/dl, TLC -14000
Continue same oha , no antibiotic given. Advise follow up after 1 month
After 1 month - No complaint. BS F – 108mg/dl, PP – 156mg/dl. TLC -14900 Peripheral smear – normal.
Done Blood culture , Chest x ray both are normal
Referred to Haematologist i/v/o INCRASED TLC
Haematologist asked for 1. FISH for BCR, ABL. 2. CBC.3. Peripheral Smear 4.CRP Quantitative And started with Tab. Amoxycillin + clavulinic acid (625) twice a day for 5 days.
After 5 days 1. CBC – Hb-12.2, TLC 14.17, N63.7, L24.6,E4.9, M6,B0.8, PLT COUNT-2.10. CRP- 2.76, FISH TEST – Normal.
USG abdomen and pelvis - Mild hepatomegaly with Grade 1 fatty liver, CA 125 – Normal Sr. Procalcitonin - Normal
Decided Bone Marrow Aspiration and Biopsy
Bone Marrow Aspiration and Biopsy – Normal

Results

As all possible causes for raised TLC worked out but everything is normal. The possible diagnosis of this case 1) Diabetic Leuctocytosis 2) Idiopathic Leucocytosis.

Conclusion

Leucocytes can be activated by glycation end products, oxidative stress, angiotensin II resulting from hyperglycemia and can produce factors like tumour necrosis factor – alpha and interleukin beta 1 that involve chronic diabetes complication.

P32

ILLNESS PERCEPTIONS AND BARRIERS TO DIABETES SELF MANAGEMENT- A STUDY FROM HYDERABAD, INDIA

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Keywords
Prediction of type 2 diabetes • Nutrition and diet • Psychological aspects • Pathogenic mechanisms / complications

Background and Aims

The clinical management of diabetes requires diligent self-management. The study explores illness perceptions, perceived barriers and glycemic control amongst Indian diabetic patients.

Materials and methods

Two hundred and sixty (n=260) consenting subjects from an Outpatient diabetic clinic were administered scales to assess illness perceptions and perceived environmental barriers to adherence to diabetes treatment advice.

Results

Subjects did not perceive their Illness to be excessively threatening, but higher scores were associated with poorer glycemic control. Although environmental barriers were only ‘rarely’ or ‘sometimes’ perceived, higher scores were associated with poorer glycemic control. Finally, personal control over the illness (amongst illness perceptions), and forgetfulness and finding time at work (amongst perceived barriers) together accounted for nearly 24% of the HbA1C variance.

Conclusion

This study found that diabetic patients’ illness perceptions are strongly associated with how environmental barriers are perceived, and they

together, contribute to nearly 24% of HbA1C variance. An important clinical implication is that an education program encourages patients to take control over their illness by following an activity schedule that includes all elements of diabetes care could have a significant effect upon glycemic control.
In practice, this effect could be similar to that of one additional anti-diabetic drug at a community level.

P33

Evaluation of Medication Adherence in Geriatric Patients with Type 2 Diabetes through Real Time Medication Monitoring and Clinical Pharmacological Reconciliation

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Keywords
• Health care delivery

Background and Aims
To evaluate the effect of medication adherence tool and clinical pharmacological reconciliation in improving medication adherence among geriatric patients with type 2 diabetes mellitus (T2DM) attending the OPD.
Materials and methods
In this factorial randomized controlled trial, elderly (>60 years) patients with T2DM on oral antidiabetic agents having a having a medication adherence rate of <80% in the last 12 months were randomly assigned to one of the four groups: medication adherence device plus standard of care (SOC), clinical pharmacological intervention plus SOC, medication adherence device plus Clinical pharmacological intervention plus SOC, and SOC for 12 months. The medication adherence was a device with an integrated alarm system to remind the patients to take their medications. Clinical Pharmacological Intervention was provided by a Clinical Pharmacologist applying the following principles: evaluating if the duly prescribed medicine is unnecessary or redundant, or no or a wrong medicine is prescribed for a given indication, de-prescribing of medicines that are unnecessary or redundant or contraindicated or not well tolerated, identifying omissions and commissions during transition of care, tailoring the dose adjusting to the individual need and perspectives. Pill counting method was used to detect medication adherence. Naranjo ADR causality assessment scale was used to assess ADRs.
Results
The medication adherence device plus SOC group demonstrated an adherence rate of 73.1% with an ADR rate of 12.1%, while the clinical pharmacological intervention plus SOC group showed an adherence rate of 75.3% with an ADR rate of 6.1%. The combined intervention of Medication adherence device plus Clinical pharmacological intervention plus SOC exhibited the highest adherence rate at 82.1% with an ADR rate of 17.6%. In comparison, the SOC group had an adherence rate of 70.0% with an ADR rate of 16.3%.
Conclusion
The preliminary findings suggest that incorporating medication adherence devices and/or clinical pharmacological interventions in addition to the SOC may lead to improved medication adherence, lower ADRs, and better glycemic control in elderly patients with T2DM on oral anti-diabetic medications.

P34

Comparative Study of Glycemic Control in Low Dose or Non-Sulphonylurea based Therapy vs. Optimal to Full Dose Sulphonylurea based Therapy for Type 2 Diabetes Management

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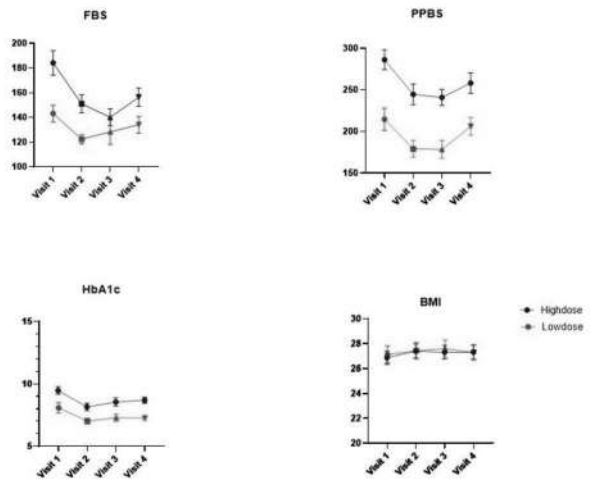
Keywords
• Oral therapies: secretagogues • Hypoglycaemia

Background and Aims
Background:
Type 2 Diabetes Mellitus management comprises diverse pharmacological intervention strategies, each targeting one or more pathophysiological pathways. Achieving the target glycemic control often necessitates the use of multiple drugs. Notably, insulin and Sulphonylureas pose the highest risk of hypoglycemia events, which potentially affects treatment adherence and consequently long-term glycemic stability. Conversely, Non-Sulphonylurea options demonstrate a lower propensity for hypoglycemia. Despite the clinical favorability of low-dose, patients with diabetes are initiated on optimal doses of Sulphonylurea.
Aim: This study aims to elucidate the comparative response to antidiabetic therapy between the two groups.
Materials and methods
Methods: The study participants (N = 121) were grouped based on their medication status into Non-Sulphonylurea/ low dose Sulphonylurea (N = 45) and optimal dose Sulphonyluea group (N = 76). The demographic and glycemic parameters were evaluated over a period of 1 to 3 years. GraphPad PRISM was used to conduct the data analysis. A p-value of <0.05 was considered to be statistically significant.
Results
Results:
The patients in both groups had a similar demographic profile. The patients on optimal dose group had significantly higher HbA1c levels as compared to those on low dose (p=0.0017). Among those taking optimal dose, insulin therapy was prescribed to around one-third of patients. The study findings observed a significant decrease in FBS with both Non-Sulphonylurea /low dose Sulphonylurea (p=0.0474) and Sulphonylurea with optimal dose (p= 0.0399) treatments during visit 2. The significant decrease in Fasting Blood Glucose levels among patients on optimal dose existed until visit 3 as compared to their initial values (p=0.0024). A comparison of Post Prandial Blood Glucose levels between the groups observed a similar trend of notable decrease until visit 3. Among those on the optimal Sulphonylurea dose, glucose estimation during visit 3 observed a significant difference when compared to visit 1 (p= 0.0307). Despite treatment with optimal Sulphonylurea doses in combination with other medications, these patients failed to achieve effective glycemic control. Both HbA1c and Body Mass Index had a similar trend over the visits.

Graph/Table :

Figure 1: Visit-wise trend analysis of glycemic parameters and BMI between the study groups.



Conclusion

Conclusion:

The results of this study advocate for considering alternative drug combinations over Sulphonylurea in the pursuit of sustained glycemic control and reducing the risk of important adverse effects such as hypoglycemia events affecting treatment adherence. Further research is warranted to validate the efficacy of these alternative approaches over extended periods.

P35

Markers for Remission in Type 2 Diabetes - A Study on Diabetes Remission Predictive Algorithm

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Keywords

Diabetes epigenetics • Carbohydrate metabolism • Weight regulation and obesity • Nutrition and diet

Background and Aims

Type 2 diabetes (T2D) has long been believed to be a progressive chronic disease needing lifetime medications as per guidelines proposed by various agencies. However, research is now emerging that suggests remission is a possibility. However data is lacking as to who is suitable and what factors may influence this approach. Our study is to understand various factors that can predict reversibility.

Materials and methods

The team of endocrinologists and nutritionists at our centres developed a tool which may predict the potential for patients with type 2 diabetes who can attempt such a reversal program. (picture 1) A total of 30 patients who visited our centres are screened for this and are registered into the study. The Health data is captured in our electronic databases and multiple factors including their attitude towards diabetes, lifestyle, emotional and physical health parameters are assessed alongside their biochemical and demographic details.

We conducted a study at IDEA clinics by providing a healthy, balanced diet with carbohydrate and calorie restriction, individualized as per various algorithmic protocols with close contact with endocrinologists who periodically reviewed medications.

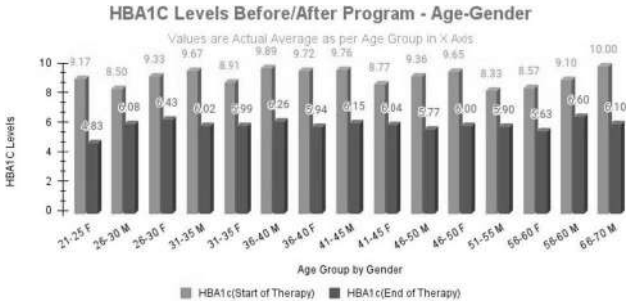
The duration for this intensive therapy was between 100 and 120 days. We recorded and analyzed all the data that we collected from the patients. At 3 months, 6 months and 1 year we reviewed the patients parameters and assessed how many continued to remain in remission. Through this study we found that Diabetes Remission is beneficial and all suitable patients should be offered such therapy.

Results

Our study demonstrated the following.

1. Weight loss percentage obtained during the program. We observed every patient for 100 - 120 days. We categorize them according to their age group. Every age group got an average of above 7% of weight loss through the program. AGE did not influence in determining weight loss achieved.
2. Reduction in HbA1c levels during the program. Persons within all age groups got a reduction in their HbA1C levels. *AGE was not a barrier in achieving target HbA1C levels.*

Graph/Table :



Conclusion

Our study demonstrated that chances of reversal were overall greater for patients who scored high on our algorithmic tool. Further the value of individual parameters that influenced the score was analyzed and it appears that BMI appears to be the critical component in reversal. Other factors like Age of patient, duration of diabetes, HbA1c at onset of diabetes along with physical and mental health of patients demonstrated significant impact on overall outcomes of remission possibility in study group. According to our study,Diabetes remission is a possible alternative to traditional diabetes management. Further studies over this model can help healthcare providers to predict remission possibility in Type 2 Diabetes diagnosed patients.

P36

To audit the 5S behaviours of Physical Activity among the sub urban population of Mumbai with Type 2 Diabetes Mellitus (T2DM)

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Keywords

Background and Aims

BACKGROUND:- T2DM is a chronic metabolic disorder, in management of which lifestyle modification(LSM) is cornerstone. LSM is a fundamental aspect of T2DM care and it includes diabetes self – management and education support (DSMES), medical nutrition therapy (MNT), physical activity, smoking cessation counselling and psychosocial care. In 2022, the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) published a consensus report targeting the management of T2DM which emphasised the importance of regular aerobic exercise and resistance exercise. Both forms of physical activity can improve blood sugars, HbA1C levels, flexibility, and balance.The ADA and EASD has categorised physical activity behaviours into 5 S. The 5 S stands for:- Sitting, Stepping, Sweating, Strengthening, Sleep. The current study aims at auditing these 5S behaviours in suburban Mumbai population.

OBJECTIVES :-

The study aims to audit these 5S behaviours in Mumbai suburban population. To determine the factors affecting the 5S behaviours and the impact of these behaviour patterns on HbA1C and body mass index(BMI).

Materials and methods

METHODOLOGY:- A Retrospective, questionnaire based study was conducted in the Endocrinology out patient department at tertiary care institute in Mumbai suburban district. The demographic background, anthropometric measurements, HbA1C levels, sleep cycle and daily physical activity schedule including the 5S behaviours were recorded. The data generated was then statistically analysed using the JASP version 0.17 (JASP Team [2023]) for MS Windows.

Results

RESULT:- The study included a total of 356 participants(188 females and 168 males) .Prolong sitting (>4 hours) was seen in 212 (59%) participants , usually seen in subjects who were employed or had work from home routine, about 113 (31%) participants recorded the step count of >6000 out of which only 18 (5%) participants had step count above 10000 steps while 199 (55%) participants did not record their steps. 149 (41 %) of individuals in the study recorded were sleeping for less than 7 hours and snoring was seen in 210 (58%) individuals. Absence of strength training and lack of sweating was observed in 218 participants (61%) ;and only 117(32%) participants were regularly doing moderate intensity workouts. Prolonged sitting was associated with an increase in HbA1c by 0.5 points. Age had a decreasing effect on HbA1c, with an average decrease of 0.024 per year increase in age. Age, strength training, male gender, 6-8 hours of sleep, and routine had a decreasing effect on BMI, while snoring correlated with an increase in BMI by 3.480 points. The incidence of drowsiness and shifts based job (Rotational and night) had an increased incidence with an odds ratio of 4.930 while Commuting with one's own vehicle decreased the incidence of drowsiness by 57.8% (odds ratio = 0.422).

Conclusion

CONCLUSION:- Parameters indicates that reduced physical activity behaviours as audited by 5S approach are widely prevalent in Mumbai suburban population and it has an adverse impact on HbA1C& BMI.

P37

Sleep duration and its effect on glycemic variability(GV) next day in type 2 diabetics (T2D)

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Keywords

Diabetes epigenetics • Other hormones • Nutrition and diet • Education

Background and Aims

Glycemic variability (GV) is the fluctuations in blood sugar levels over a period of time. High GV leads to increased cellular oxidative stress which is now being understood as a precursor for endothelial damage and vascular complications. Hence, low GV should be an important goal in diabetes management. Poor sleep contributes to fluctuations in blood sugar levels. Here, we have studied the influence of sleep on GV the next day. This is a retrospective study of 144 T2D patients to investigate an association between sleep time and length to GV the next day.

Materials and methods

Sugar levels were monitored through a continuous glucose monitor (CGM) device worn for a period of 14 days by participants enrolled in Sugarfit's Diabetes Reversal program (SDRP). Participants were expected to log their sleep, food, physical activity and medication data during the 14 days of CGM on the sugarfit app. 144 participants with sleep logs of time and duration on the app were selected for the study. They were then segregated into 2 groups. Group 1 slept for 6 hrs or more and those in Group 2 slept less than 6 hours.

Results

Group 1- with an average of 7.8±0.76 hours of sleep duration and average start time of sleep 22.42pm showed a GV of 18.2±4.4% the following day. Group 2- with an average of 5.7±0.4 hours of sleep duration and an average start time of sleep 23.21pm showed a GV of 23.5±8.9%. Group 2 in comparison to group 1 who had longer sleep hours showed a higher GV by 22.5%

Conclusion

It is a well known fact that shorter sleep hours and late hours is a risk factor to insulin resistance and increased blood sugar levels. On analysis of the data in our cohort of T2D patients, longer duration of sleep was associated with a better GV the next day. The limitations of this study were assessment of uninterrupted vs interrupted sleep which we intend to also analyse in the near future by deep technology driven data collection.

P38

Personalized Nutrition and Lifestyle Interventions for Enhanced Glycemic Control and Weight Reduction in Individuals with Diabetes Weighing Over 100 Kilograms

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Keywords
• Weight regulation and obesity • Nutrition and diet • Education

Background and Aims
The increasing global prevalence of both obesity and diabetes poses significant challenges to public health. Research underscores the critical role of weight reduction in achieving improved glycemic control. This study focuses on individuals weighing over 100 kilograms, aiming to advance diabetes management within this specific population.
Materials and methods
The Sugarfit Diabetes Reversal and Management Program (SDRMP) is an innovative personalized intervention that integrates technology-enabled medical guidance with a dedicated team of diabetes experts overseen by physicians. It tailors nutrition plans, gradually enhances physical fitness, and supports behavior modification. This retrospective study evaluates participants enrolled in the SDRMP over the previous year, all of whom weigh over 100 kilograms. Their progress is tracked over six months, with assessments including HbA1c, Fasting Blood Sugar (FBS), and weight loss.
Results
Among the 246 study participants, 213 were male, and 13 were female, with an average age of 43.57 (±9.75). Baseline measurements revealed an average HbA1c level of 8.67 (±1.82), an FBS of 168.46 (±60.85), and an average weight of 112.52 kilograms (±16.14). Remarkably, significant reductions in all three parameters were observed within three months, with values decreasing to 7.44±1.45, 136.62±46.56, and 105.29±11.85 kilograms, respectively. These improvements continued over six months, further lowering measurements to 7.31±1.44, 132.37±45.60, and 104.33±12.36 kilograms.
Conclusion
Acknowledging the multifaceted nature of diabetes management, this study underscores the importance of personalized nutrition and lifestyle interventions tailored to the specific needs of individuals weighing over 100 kilograms. These initial findings highlight the potential for substantial advancements in diabetes care within this distinctive demographic.

P39

Experience with New Age Medicines in Diabetes: SGLT2-Inhibitors and DPP4-Inhibitors in Indian Patients

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Keywords
• SGLT inhibitors

Background and Aims
Background
Amongst lifestyle diseases, Diabetes is one gaining maximum attention globally and in India due to its rising numbers of affection. Over the years, in lieu of the changing environment and lifestyle habits of our current generations, there has been a shift within the age at diagnosis of diabetes – from late 40's to the early 20's. Various newer advances have been flooding the space of diabetes ranging from drugs to diagnostics to digital health solutions backed up with ample research. However, diabetes control remains at a meagre 15.7% as per the recent NCD survey 2022.
Current issue points out lack of usage of such advancements in diabetes to obtain better control due to various reasons. Situation demands widening our practice and experiencing these newer therapies, diagnostics and digital solutions in our daily life towards managing diabetes.
Aim
At our out-patient department, we tested the newer drug classes SGLT2-inhibitors (SGLT2-i) and DPP4-inhibitors (DPP4-i) in varied presentations of type 2 diabetes.
Materials and methods
Patients above 18 years of age with uncontrolled type 2 diabetes either on Insulin or never on Insulin but started on the combination of SGLT2-i and DPP4-i were picked up retrospectively for our study. Their demographics and clinical parameters were ensured for comparisons. Their journey from presentation to 6 months down the line was assessed and analysed. Major observations were change in HbA1c, change in FBS/PPBS, change in weight and BMI. Lipid profiles and creatinine values were observed too for any drastic changes.
Results
Patients started on both SGLT2-i and DPP4-i showed better tolerance to side effects due to the complementary action of the two classes. Efficacy too showed tremendous improvement in patients who had erstwhile never seen their glucose results so much better. Overall, feeling of well-being of patients amplified multi-fold by adopting these newer drugs for diabetes management.
Conclusion
Interestingly, the SGLT2-i and DPP4-i drug classes together, did not just fare as safer options than few existing molecules but also showed remarkable extra-glycaemic benefits beyond glucose control.

P40

Beyond BMI: Unveiling Hidden Risks of Insulin Resistance and Cardiovascular Disease in Non-Obese Adolescents

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Keywords
Prediction of type 2 diabetes • Insulin sensitivity and resistance • Health care delivery • Diabetes in childhood

Background and Aims
Insulin resistance (IR) is becoming increasingly prevalent among adolescents, with limited studies focusing on those with normal weight. There is a pressing need to explore risk predictors of IR in this demographic to facilitate early intervention and management. This study aims to determine the prevalence of IR and to identify associated cardiometabolic risks in normal-weight adolescents, emphasizing the limitations of relying solely on BMI for assessing health risks.
Materials and methods
Eighty-two normal-weight adolescents aged 10-19 years participated in this cross-sectional observational study. A thorough collection of data included demographic information, medical histories, lifestyle habits, and detailed physical examinations focusing on specific manifestations such as acanthosis nigricans and gynecomastia. Biochemical evaluations of plasma glucose, insulin, HOMA-IR, lipid profiles, and hs-CRP were conducted. Statistical analysis was performed using student's t-test, odds ratio, chi-square test, and correlation coefficients.
Results
The findings revealed a significant prevalence of insulin resistance and metabolic syndrome in normal-weight adolescents. Several markers of

IR were identified, including cutaneous markers, waist circumference, waistto-hip ratio, plasma insulin, serum triglycerides, HDLc, and ALT levels.

Conclusion

A normal BMI and euglycemia are not definitive indicators of the absence of insulin resistance. Comprehensive screening for markers of IR is essential for all adolescents, irrespective of their BMI. The markers identified in this study can also serve as predictive tools for cardiovascular risks in adolescents, necessitating further screenings for those identified as insulin-resistant or at risk to detect components of metabolic syndrome.

P41

Prevalence of Clinically Significant Liver Fibrosis as measured by Transient Elastography in Indian individuals with Type 2 Diabetes Mellitus

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Keywords
• Non-alcoholic fatty liver disease (NAFLD)

Background and Aims

There is high prevalence of Nonalcoholic Fatty Liver Disease (NAFLD) in individuals with Type 2 Diabetes mellitus (T2D) and available evidence suggests higher prevalence of NASH and advanced stages of fibrosis among T2DM. Data regarding prevalence of Clinically Significant Liver Fibrosis (CSLF) in individuals with T2D is scare. We investigated the prevalence of Transient Elastography (TE) proven CSLF among patients of T2D attending Diabetes Clinic in a tertiary care center.

Materials and methods

A cross-sectional descriptive evaluation Study of 603 consecutive adults with T2D was conducted to detect CSLF using TE. Steatosis was diagnosed using Controlled Attenuation Parameter (CAP) >237dB/m.

Results

The prevalence of CSLF was 22.7% and the prevalence of steatosis 58.9% in our study. Higher BMI (P = 0.001), aspartate aminotransferase (AST; P=0.0001), alanine aminotransferase (ALT; P=0.0001) and low platelets (P=0.0001) were independent factors associated with CSLF. Elevated ALT and AST (≥40 units/L) levels were present in only 27.7% and 37.2% of individuals with CSLF, respectively. Twenty-six (4.31%) individuals had LSM > 13.0 kPa.

Conclusion

CSLF is highly prevalent in T2D patients attending a tertiary diabetes care centre with majority of such individuals having normal transaminase levels. Higher BMI, AST, ALT values and lower platelet counts are associated with liver fibrosis.

P42

Women with Type 1 Diabetes: Navigating Glycemic Control Challenges During Menstruation

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Keywords
• Other hormones

Background and Aims

Women with Type 1 Diabetes face unique challenges in managing their blood glucose levels due to the dynamic hormonal fluctuations associated with the menstrual cycle. This research study investigates the impact of menstrual cycle-related hormonal changes on glycemic control in women with Type 1 Diabetes, focusing on identifying key challenges and strategies for effective management.

Materials and methods

The primary methodology employed in this scientific paper is an extensive literature review. Peer-reviewed articles, medical journals, and relevant research publications were systematically analyzed. The literature review focused on three main areas:

1. Physiological Impact: Examining the physiological mechanisms underpinning the influence of hormonal changes during the menstrual cycle on insulin sensitivity and resistance, as well as their implications for glycemic control in women with Type 1 Diabetes.
2. Challenges and Risk Factors: Identifying and summarizing the documented challenges, risk factors, and complications associated with managing blood glucose levels during menstruation, drawing from empirical studies and clinical reports.
3. Management Strategies: Exploring the various strategies and interventions proposed in the literature to mitigate the glycemic control challenges specific to women with Type 1 Diabetes during menstruation, including adjustments in insulin therapy, dietary modifications, and lifestyle recommendations.

Results

The findings from the literature review provide valuable insights into the physiological mechanisms at play, the challenges faced by women with Type 1 Diabetes during menstruation, and the strategies that have been proposed in existing research to address these challenges.

Conclusion

Women with Type 1 Diabetes encounter distinct glycemic control challenges during menstruation, driven by hormonal fluctuations. The literature review underscores the importance of personalized approaches to diabetes management that consider individual hormonal profiles and cycle-specific insulin requirements. Raising awareness about these challenges and integrating education into diabetes care can empower women with Type 1 Diabetes to navigate their menstrual cycle while maintaining stable blood glucose levels. This research contributes to a deeper understanding of the complexities involved in managing Type 1 Diabetes in women and highlights the need for tailored strategies to address menstrual cycle-related fluctuations in glycemic control.

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Gender differences in screening, management and control of type 2 diabetes mellitus in western India - A multicentre prospective study

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Keywords
Epidemiology • Oral therapies: metformin, sensitizers and other non-secretagogues • Education

Background and Aims

Background and aims - Gender-based discrepancies can impact multiple facets of screening, management, & regulation of Type 2 Diabetes

Mellitus (T2DM). These variations can affect the availability of healthcare, strategies for treatment & eventual health results. Tailoring interventions to address specific challenges faced by both men & women can lead to better outcomes & improved overall health. The aim of the present study was to understand the gender differences, if any, in the screening, management & control of T2DM.

Materials and methods

Materials and methods - The real-world study encompassed patients with T2DM receiving consistent medical attention at 12 healthcare facilities in Western India. Leveraging MEDEVA (EMR), an integrated research platform, the study meticulously documented medical histories, laboratory results, & prescribed medications. The data extracted for analysis spanned from December 1, 2022, to August 15, 2023.

Results

Results - The study included 1495 patients with T2DM, comprising 46% females and 54% males. Their average ages were 53.1 years (males) and 52.4 years (females), showing no significant gender-related age difference. The average diabetes duration was 7.2 years (males) and 7.0 years (females). Regarding oral antidiabetic drugs (OADs), Biguanides were most common (87%), followed by Sulfonylureas (63%), DPP4 inhibitors (49%), Thiazolidinediones (34%), SGLT2 inhibitors (26%), and Alpha-glucosidase inhibitors (22%). Gender differences were notable in Thiazolidinediones (30% females, 38% males). Males exhibited a higher prevalence of being on over three drug classes (38% males vs. 30% females). Nevertheless, there were no significant gender-based discrepancies in glycemic control. HbA1c levels were 8.32% (males) and 8.24% (females). Fasting blood sugar (FBS) was 146 mg/dL (males) and 141 mg/dL (females), while postprandial blood sugar (PPBS) was 202 mg/dL (males) and 211 mg/dL (females).

Conclusion

Conclusion - This real-world study offers valuable information on gender differences in T2DM management.

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Prevalence of PreDiabetes among Bengaluru Urban Population: A pilot study

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Keywords

Background and Aims

In recent decades there has been a huge transition in the incidence of prediabetes which is higher than the incidence of diabetes in India. This pilot study addresses the lack of data on the prevalence of prediabetes among the Bengaluru population in the year 2023.

Materials and methods

The screening was conducted free of cost in 4 different sites throughout Bengaluru. The study population comprised 130 subjects screened over a month time. Prediabetes was defined based on Random blood sugar levels > 150 mg/dl and biomarkers like Glycated hemoglobin levels> 5.7% and < 6.4%. Co-morbid conditions and anthropometric measurements like height, weight, waist circumference, and hip circumferences were also compared. The data obtained was statistically analyzed and interpreted.

Results

The prevalence of prediabetes was 16.15% with a mean value of Random blood sugar 135 mg/dl ± 63.8, HbA1c 6.36% ± 2.29, BMI 26.19 mg/dl ±4.28, and Waist-to-hip ratio 0.94 ± 0.10. Subjects with High BMI, High waist-to-hip ratio, and preexisting co-morbid conditions were more prone to prediabetes. The results exhibitedthat the prevalence of prediabetesamong the Bengaluru population was higher than the average prediabetes status of the Indian urban population.

Conclusion

Observations of the study revealed that there is a high and increased rate of prediabetes in the Bengaluru population which requires immediate public health initiatives and lifestyle modification with Diet and Exercise interventions to control and prevent prediabetes and its future complications.

P45

Assessment of Th9 and Treg Cell Frequencies and Th9/Treg Ratio in Anti-diabetic drug Treatment Groups: Impact of Vildagliptin

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Keywords
• Inflammation in type 2 diabetes • Nephropathy

Background and Aims

Th9 and Treg cells are vital for immune balance. We investigate their status in various drugtreated diabetic groups, with a focus on Vildagliptin, a Dipeptidyl peptidase-4 inhibitor. This study assesses Th9 and Treg cell frequencies and Th9/Treg ratios in anti-diabetic drug treatment groups, emphasizing Vildagliptin.

Materials and methods

This study analyzed Th9, Treg, and Th9/Treg ratio in various patient populations. The diabetic patient's groups examined were a combination group receiving Metformin (M), Glimepiride (G), Dapagliflozin (D), and Vildagliptin (V) (n=8), a combination group with MGD (n=6), a non-antidiabetic treatment group (n=28), and untreated healthy controls (n=36). Blood samples (2 ml) were collected from all the participants. After the staining of samples, the Th9 and Treg cell percentages were assessed by flow cytometry (BD FACSCanto II). We performed data analysis via FlowJo v8.0 software.

Results

Th9, Treg, and Th9/Treg ratios were compared. Vildagliptin in MGDV showed a lower Th9 frequency (Median 15.1, IQR 6.55) than non-diabetic (Median 18.2, IQR 6.90), while MGD without Vildagliptin had a higher frequency (Median 20.55, IQR 5.73). MGDV had higher Treg levels (Median 2.74, IQR 0.38) than non-diabetic (Median 2.36, IQR 1.01). Th9/Treg ratio was lower in MGDV (Median 6.21, IQR 3.17) than non-diabetic (Median 8.23, IQR 3.55), suggesting immune balance by Vildagliptin.

Conclusion

Vildagliptin impacts Th9, Treg frequencies, and Th9/Treg ratios. Lower Th9 in MGDV and higher Treg suggest immune modulation. This highlights Vildagliptin's potential for regulating Th9 and Treg cells and immune balance in diabetes treatment.

P46

PTEN-Mediated Regulation of IL-9 by miR-181b-5p in Diabetic Nephropathy

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Keywords
• Clinical immunology • Inflammation in type 2 diabetes • Psychological aspects • Nephropathy

Background and Aims
This study investigates the interplay between PTEN expression, cytokines like IL-9, and regulatory miRNAs in Diabetic Nephropathy (DN).
Materials and methods
Peripheral blood samples from DN patients and healthy controls were collected. IL-9 serum levels were quantified using an ELISA kit. RNA from PBMC was extracted, reverse transcribed, and quantified via real-time PCR. Mann-Whitney U tests determined statistical significance ($p < 0.05$).
Results
Comparison of Healthy Controls (HC, n=36) and Diabetic Nephropathy (DN, n=38) revealed significant differences in HbA1c, FBS, Urea, Creatinine, and eGFR values ($p < 0.001$), with DN exhibiting higher values. Further analysis categorized data into PTEN down-regulated (PTEN FCE: <1) and upregulated groups (PTEN FCE: >1). IL-9 levels in the down-regulated group had a median of 4.92 pg/mL (IQR 0.777 pg/mL), while the upregulated group had a median of 4.50 pg/mL (IQR 0.322 pg/mL). For miR-181b-5p, the down-regulated group showed a median FCE of 2.86 (IQR 1.23), while the upregulated group had a median FCE of 1.00 (IQR 1.22). Mann-Whitney U tests indicated significant differences in IL-9 ($p = 0.011$), miR-181b-5p ($p < .001$), and PTEN ($p < .001$).
Conclusion
These findings underscore the intricate relationship between PTEN expression, immune cell cytokines, and regulatory miRNAs, shedding light on potential pathways relevant to immune regulation. Understanding these connections is crucial for insights into immune-related diseases and the development of targeted therapies. The associations between PTEN, IL-9, and miR-181b-5p provide valuable insights into the complex regulation of immune responses in DN.

P47

Study of Correlation of Osteoarthritis with Metabolic Syndrome. Does Turneric Have a Beneficial Effect in Osteoarthritis?

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Keywords
Environmental factors (viruses, nutrients, toxins) • Inflammation in type 2 diabetes • Nutrition and diet •
Other complications

Background and Aims
Osteoarthritis (OA) is a type of joint disease linked to mechanical loading. Metabolic Syndrome is more prevalent among osteparthritis patients.
➢ Turmeric (Curcuma longa) has anti-inflammatory properties.
➢ The Research Question of the Study were:
1) Is there a correlation between Osteoarthritis and Metabolic Syndrome?
2) Does Turmeric have a beneficial effect in Osteoarthritis?
➢ The AIM of the study was, "To study the Correlation of Osteoarthritis with Metabolic Syndrome and to see the effect of turmeric in Osteoarthritis patients.
Materials and methods
SAMPLE SIZE
Primary study
Sample size is calculated by using the formula:
-p1 =OR1/OR1+ OR2 = 0.55
-p2= OR2/OR1 + OR2= 0.53
Error ratio e = 0.25
Type 1 error α=5%
Type II error b = 10% for detecting results with 90%power of study
Data lost 10%
Then the sample size comes out to be n=150 in each group = Total 300.
Secondary study
Sample size is calculated by using the formula:
n= (Z×a + Z b)2 [1 - p1 + 1 - p2]
[ln(1 - e)]2 [p1 p2]
where
p1 = 0.333 , p2 = 0.442
Error ratio e = 0.4
Type 1 error α=5%
Type II error b = 10% for detecting results with 90%power of study
Data lost 10%
Then the sample size comes out to be n=75 in each group = Total 150.
METHODOLOGY
Primary Study -
Patients of Osteoarthritis (study subjects according to ARA Criteria) were evaluated for presence of metabolic syndrome according to IDF criteria in comparison to subjects without Osteoarthritis .150patients who consented to take part in the study were taken in each group.
Secondary Study -
Study subjects were randomised in two groups using the single blinding method. Each group comprised of 75 patients each, who gave consent for the study.
Group I- received turmeric filled capsules - 1 gm tds(total 3 gm /day}
Group 2- placebo (protien powder 500mg x tds) for 4 months.
Results
Metabolic SyndromeAmong was found in 17.3% case subjects while among the control group it was found only in 7.3% subjects. Therefore highly significant association was seen between metabolic syndrome and osteoarthritis (p=0.008).
On comparing the WOMAC scores change from 1st visit to last visit between Group-I and Group-II, it was found that the mean WOMAC score change of Group-I was 20.44±14.11 while the mean WOMAC score change of Group II was 5.04±8.26. The mean WOMAC score change in Group I was found to be significantly more than the change in Group II (p<0.001).
On comparing the hsCRP level change from 1st visit to last visit between Group-I and Group-II, it was found that the mean hsCRP level change of Group-I was 4.42±3.94 while the mean hsCRP level change of Group II was 0.43±1.29. The mean hsCRP level change in Group I was found to be significantly more than the Group II (p<0.001)
On comparing the IL-6 level change from 1st visit to last visit between Group-I and Group-II, it was found that the mean IL-6 level change of Group-I was 6.10±8.84 while the mean IL-6 level change of Group II was 0.35±2.54. The mean IL-6 level change in Group I was found to be significantly more than the Group II (p<0.001)
Conclusion
I have concluded that ostwoaethritis is an inflammatory disease. Turmeric has beneficial effects in osteoarthritis not only on inflammation, but also on pain score like WOMAC

P48

Therapeutic role and potential benefits of GLP-1 RAs (+/- SGLT2i) in the treatment of type 2 diabetes - A preliminary report from South India

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Keywords
• Weight regulation and obesity • Incretin based therapies 43 Novel agents

Background and Aims
Glucagon - Like Peptide, receptor agonists (GLP-1 RAs) and SGLT2 inhibitors have been considered as an important treatment option for type2 diabetes (T2DM). Evidence suggests that GLP-1 RAs and SGLT2i are effective in achieving glycemic control and weight loss. There is limited data available on the beneficial effects of GLP-1 RAs and SGLT2i from the Indian context. Hence, we aimed to demonstrate the potential benefits of GLP-1 RAs and SGLT2i in the treatment of T2DM.
Materials and methods
In this retrospective observational study a total of 61 participants were enrolled and followed up from August 2022 to August 2023 in a tertiary care center for diabetes, Chennai, South India. Out of 61, seven participants discontinued GLP-1 RAs due to side effects and affordability. The remaining 54 (M: F 26: 28) participants were included in the final analysis. The participants were divided into two groups based on their treatment. Group1 (n= 25) without GLP-1 RAs and SGLT2i with SU and/or Biguanides and/or DPP4i and Group2 (n=29) with GLP-1 RAs (+/- SGLT2i) + SU and/or Biguanides and/or DPP4i. Clinical, Anthropometric, Biochemical, medication details were recorded at baseline and follow up after 6 months. Descriptive statistics done and paired and students't' test was used to test the significance.
Results
At baseline, the two study groups were matched for age (P= 0.729), BMI (P= 0.09) and duration of diabetes (P=0.105). At baseline and follow up, there was no significant difference noted between the groups in fasting glucose (P=0.09), (P=0.92), postprandial glucose levels (P=0.79), (P=0.43) and HbA1c (P=0.184), (P=0.21). In group1, there was a significant increase in weight at follow-up (79 vs 80.4) (P=0.023), a slight decrease in BMI (32.3 vs 33.1) (P=0.01), significant decrease in HbA1c (8.6 vs 7.6) (P=0.007). There is no significant difference noted in glucose levels.
In group 2, there was a significant reduction in weight (89.8 vs 88) (P=0.001), BMI (34 vs 33.3) (P=0.006), fasting glucose (189 vs 140) (P=0.002), Post prandial glucose (253 vs 210) (P=0.04). HbA1c also showed significant reduction (9.3 vs 8.1) (P<0.001). A greater reduction was noted in mean difference of weight (Group 2 vs Group 1; 1.8 vs -1.3) (P<0.001), BMI (0.63 vs 0.03) (P=0.01). HbA1c also showed higher reduction in group 2 as compared to group 1(1.1 vs 0.9) (NS).
Conclusion
Significant weight reduction and achievement of good glycaemic control was observed among those who were on GLP-1 RAs (+/- SGLT2i). The findings need to be confirmed in a large sample.

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Effect of diabetes education on glycemic control among newly registered people with type 2 diabetes in a tertiary care centre for diabetes

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Keywords
• Education

Background and Aims
Diabetes is a serious and life-threatening disease. However, it can be managed well through regular treatment and monitoring. Diabetes education and self-care behaviour plays a vital role in diabetes management. Literature stated that there is a direct link between diabetes education and metabolic control. Therefore, this study was aimed to evaluate the effect of diabetes education on glycemic control among people with type 2 diabetes.
Materials and methods
A retrospective study was conducted among 326 (M:F; 189:137) people who visited a specialty centre for diabetes first time for diabetes treatment and came for the follow-up after 3months from Jan to Dec 2022. These individuals attended diabetes education session for the first time and they were categorized into four groups Group1(GP1) (n=53): people with no changes in drugs, Group2(GP2)(n=58): people with changes in drugs, Group3(GP3)(n=129): people with newly added drugs, Group4(GP4)(n=86): people with newly started drugs. Education was given on medications, diet, physical activity, SMBG, behavioral habits and related life style modifications. Socio demographic details and clinical profile, anthropometric measurements, behavioral habits, were collected at baseline(BL). Biochemical parameters such ad fasting blood glucose(FBS), post prandial blood glucose(PBS), glycosylated haemoglobin(HbA1c%), lipid profile were recorded at BL and also in follow-up(FU) visit.
Results
The median age and duration of diabetes of the study participants was 52 and 4 years. Around 76.5% of them were obese. Majority were treated with two or more drugs and the major drug class changed in GP1 at baseline were ∞-glucosidase inhibitors (50.9% to 22.6%) and SGLT2i (5.7% to 43.4%). In GP3, DPP4-inhibitors added to 59% more from 14% and SGLTi added to 26% more from 1.6%. Good glycaemic control was observed in all the four study groups at FU compared to BL. GP1(BL vs FU 8.3vs7.2, p<0.001) and GP2(7.1vs6.6, p=0.001) showed significant reduction in HbA1c% only. GP3 (FBS 152vs117; PBS260vs195; HbA1c8.4vs.6.9, p<0.001) and GP4 (FBS 168vs115, PBS275vs180, HbA1c8.6vs6.8, p<0.001) showed significant reduction in glucose and in HbA1c% levels. Total cholesterol (GP1: 173vs154, GP2 171vs157, GP3 183vs155 and GP4 190vs158, p<0.01) and LDL cholesterol (GP1 91vs80, GP2 98vs 81, GP3 100vs81, GP4 116vs83, p<0.01) were significantly reduced in all the groups from BL to FU. Triglycerides (GP3(140vs107, p=0.033); GP4(127vs109, p<0.001) and HDL (GP3 40vs45, p=0.021); GP4 42vs44, p=0.045) were also significantly reduced at FU only in GP3 and GP4.

Conclusion
People for those the drugs were not changed also showed good impact on glycemic control may be due to diabetes education. A similar prospective study including information on treatment adherence may help us to confirm this finding.

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Phase IV, Prospective, Randomized, Multi-centric Confidence Trial: Subgroup analysis

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Keywords
• Oral therapies: metformin, sensitizers and other non- secretagogues

Background and Aims
Primary Objective
To evaluate safety & tolerability of the FDC of Alogliptin plus Metformin & Alogliptin in treatment of T2DM.
Secondary Objective
To evaluate efficacy of FDC of Alogliptin plus Metformin & Alogliptin in treatment of T2DM.
Materials and methods
Multi-centre, Prospective, Randomized, open-label, randomized, comparative, parallel-group, phase IV clinical study. Out of 344 patients completed the study, 166 patients were received FDC of Alogliptin + Metformin and 178 were received Alogliptin. Duration of study was 180 days & follow up on 30, 60, 90 & 180 days. HbA1c, FPG & PPG analysed at the end of 180 days. Safety evaluations were performed by assessing AE, SAE, Safety Lab tests, vitals.
Results
Out of 344 patients, 59.30 % patients were male, 63.37 % patients having duration of diabetes between 13-24 months. 43% patients suffering from hypertension. After 6 months mean reduction of HbA1c from baseline of 8.17±0.57 was -2.07 ($p<0.001$) in Alogliptin plus Metformin group. In Alogliptin group there was mean reduction of HbA1c -1.29 from baseline of 8.16±0.51 ($p<0.001$).
At 6 months FPG reduced from 196.59±34.48 to 92.94±8.50 in Alogliptin plus Metformin group with mean reduction of -103.65 ($p<0.001$). Whereas in Alogliptin group FPG reduced from 210.64±20.00 to 150.32±22.06 with mean reduction of -60.32 ($p<0.001$).
There was a mean reduction of PPG by -143.11($p<0.001$) from baseline of 286.38±19.75 to 143.27±8.76 after 6 months in Alogliptin plus Metformin group while mean reduction of PPG by -89.36 ($p<0.001$) from baseline value of 283.88±20.84 to 194.52±24.58 after 6 months in Alogliptin group. 25/166 (15.10%) of patients experienced 10 adverse events in FDC of Alogliptin plus Metformin and 23/178 (12.90%) of patients experienced 10 adverse events in Alogliptin group.
No SAE was reported in either treatment groups. All the reported adverse events were mild in severity. FDC of Alogliptin and Metformin & Alogliptin Tablets was not associated with any additional safety risks to patients.
Conclusion
Alogliptin and FDC of Alogliptin + Metformin found to be well tolerated without any serious adverse event. Alogliptin and FDC of Alogliptin + Metformin is found to be promising option in management of T2DM in relation to safety and efficacy.

P51

Survey on Understanding Choice of DPP4i/SGLT2i as Combination Therapy in T2DM

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Keywords
• Incretin based therapies 43 Novel agents • Health care delivery • Cardiac complications

Background and Aims
Background: Dipeptidyl peptidase 4 inhibitors (DPP4i) and sodium glucose co-transporter 2 inhibitors (SGLT2i) represent drug classes that have independently demonstrated glucose lowering efficacy. Various DPP4i and SGLT2i combinations are available for use in India. There is a need to evaluate the choice of preferred DPP4i/ SGLT2i combination among Indian healthcare practitioners (HCPs) for managing type 2 diabetes mellitus (T2DM).
Aim: To evaluate the choice of DPP4i/SGLT2i based combinations used in T2DM management among Indian HCPs.
Materials and methods
Methodology: A cross-sectional questionnaire-based survey of HCPs was conducted across India from December 2022 to March 2023. Data was analyzed and expressed as descriptive statistics.
Results
Results: A total of 1033 HCPs participated in the survey with the majority of them being in the 31-50 age range (71.73%), having a postgraduate degree in medicine (MD; 66.6%) and having a private consulting practice (74.93%). In clinical practice, when DPP4i/SGLT2i combination is added to patients uncontrolled on metformin monotherapy, 44.82% HCPs mentioned that they would expect an HbA1c reduction of 1-1.5% while 34.66% HCPs mentioned to expect a reduction of 1.5%-2%. When asked to opine on the preferred DPP4i/SGLT2i combination in various T2DM patient groups, most HCPs chose sitagliptin/dapagliflozin combination as the preferred option: T2DM with atherosclerotic cardiovascular disease (81.51%), T2DM with heart failure (79.28%), T2DM with chronic kidney disease (53.63%). Among the various DPP4i/SGLT2i combinations, most HCPs (67.67%) opined sitagliptin/dapagliflozin as the combination associated with fewer adverse events in T2DM patients. When asked about average duration for which patients continue on DPP4i/SGLT2i combination in routine practice, almost half of the HCPs (48.4%) mentioned ≤6 months, 22.07% HCPs mentioned >6-12 months and 29.53% HCPs mentioned more than 12 months. On enquiring about triple combination of metformin/DPP4i/SGLT2i, ~60% of HCPs anticipated an HbA1c reduction of >1.5% with the triple combination, in T2DM patients uncontrolled on dual therapy. On enquiring about advantages of metformin/sitagliptin/dapagliflozin over other triple combinations, the top 3 advantages were 'providing strong and durable glycaemic reduction' (51.69%), 'providing efficacy while being safe on cardiovascular/ renal outcomes' (46.37%) and being 'truly once-daily formulation' (41.05%).
Conclusion
Conclusion: The survey results indicate that sitagliptin/dapagliflozin is the most preferred SGLT2i/DPP4i combination among Indian HCPs in a wide range of T2DM patients.

P52

Effect of using the mySugr app on Glycemic Control in T1D patients - A real-world analysis from India

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Keywords
Prediction and prevention of type 1 diabetes • Devices

Background and Aims
To describe the use of the mySugr patient mobile application by patients with Type 1 Diabetes and the impact on glycemic control based on estimated HbA1c (eHbA1c).
Materials and methods
Retrospective analysis of mySugr users with a self-reported diagnosis of T1DM who had at least two blood glucose logs a day on 14 days (Class G2D14) of each month. Class G2D14 is the lowest testing adherence needed to calculate eHbA1c. Users were selected based on consistent testing over three months with a logging class of G2D14 or more.
Results
In 2022, India had a total of 61,368 active users of the mySugr application. 14.1% of those had type 1 diabetes, with a monthly average user base of 2,952 people. The average change in glycemia was associated with self-monitoring of blood glucose (SMBG), which was documented in the mySugr application. People with type 1 diabetes testing class G2D14 or higher were included in the analysis (n=666). The average estimated HbA1c at baseline was 8.0% and after three months had decreased to 7.6%, representing a decrease of 0.41% ($p < 0.05$).
Conclusion
In a real-world setting, the use of mySugr was associated with a clinically relevant and statistically significant reduction in eHbA1c. Given the correlation between glycemic control and the development of complications, the use of the mySugr app and regular blood glucose testing can help patients to achieve better glycemic control, reduce the incidence of complications and improve their quality of life.

P53

Effect of using a Blood Glucose Meter connected with the mySugr app on engagement and glycemic control of people with Type 2 diabetes - A Real-World Data Analysis from India

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Keywords
• Devices

Background and Aims
To describe the engagements of people with Type 2 Diabetes Mellitus (T2DM) with the mySugr® mobile application and the impact on glycemic control based on estimated HbA1c (eHbA1c) and Points In Range (PIR).
Materials and methods
A retrospective analysis of T2DM mySugr users who had actively synchronized Blood Glucose (BG) data in the mySugr application was performed. BG data were logged either through Blueetooth® synchronization (connected users) or manually (non-connected users). Subgroup analysis of T2DM connected mySugr users, who had at least 2 BG logs per day for 14 days of each month for six months, was performed.
Results
From January 2022 to July 2023, India had a total of 39,019 active T2DM users of the mySugr app; 76% were connected users. Connected users had a higher number of BG logs compared to non-connected users (90.8 logs vs 48.75 logs). The average duration users remained active was 6.7 months in connected users and 3.11 months in non-connected users. In a subgroup of 226 T2DM connected users, eHbA1c decreased from 7.24% at baseline (t0) to 6.94% after six months of use (t1) of the mySugr app; the number of PIR increased from 69.8% at t0 to 75.3% at t1 and the number of Points Above Range (PAR) decreased from 28.65 at t0 to 23.2% at t1.
Conclusion
Engaging people with diabetes in their diabetes management journey and retaining that engagement is a challenge for healthcare professionals. mHealth platforms can trigger an effective engagement of people with diabetes. In a real-world setting, T2DM connected users of the mySugr app showed higher engagement and retention compared to T2DM non-connected users. Connecting a BG device to a mHealth platform was associated with a clinically significant reduction of 0.3% eHbA1c, an increase of 5.5% of PIR and a decrease of 5.3% of PAR in the mySugr user data evaluation.

P54

Once- Weekly Subcutaneous Semaglutide 2.4 mg in Adolescents With Overweight or Obesity

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Keywords
• Weight regulation and obesity

Background and Aims
STEP TEENS was the first phase 3a trial to examine the efficacy and safety of once-weekly subcutaneous semaglutide 2.4 mg (sema) + lifestyle intervention in adolescents (12 to <18 yrs) with obesity (BMI ≥95th percentile), or overweight (BMI ≥85th percentile) with ≥1 weight-related comorbidity.
Materials and methods
Participants were randomized 2:1 to sema (n=134) or matching placebo (PBO; n=67).Endpoints (baseline [BL]–wk. 68) were %-change in BMI (primary); ≥5% weight loss (WL; confirmatory secondary); and ≥10, ≥15, and ≥20% WL, change in cardiometabolic risk factors and quality of life (QoL; secondary), assessed by the treatment policy estimand. Primary and confirmatory secondary endpoints were controlled for multiplicity.
Results
Of 201 adolescents (62.2% female; mean age 15.4 yrs, body weight 107.5 kg, BMI 37.0kg/m2) randomized, 89.6% completed treatment. Mean change in BMI (BL–wk 68) was –16.1%(sema) vs 0.6% (PBO; estimated treatment difference [ETD]: –16.7%-points; 95% CI: −20.3, −13.2;$p<0.0001$). ETD in body weight %-change

(BL–wk 68) for sema vs PBO was –17.4%-points (95% CI:–21.1, –13.7; p<0.0001). More participants achieved ≥5, ≥10, ≥15, and ≥20% WL with sema vs PBO (72.5 vs 17.7%, 61.8 vs 8.1%, 53.4 vs 4.8%, 37.4 vs 3.2%; p<0.0001). Waist circumference,HbA1c, and lipids (except HDL) were reduced with sema (p<0.05). Sema improved overall weight-related QoL (p=0.038) and physical comfort (p=0.005). Adverse events (AEs) were reported by78.9% (sema) and 82.1% (PBO) of participants. Serious AEs were reported by 11.3% (sema) and 9.0% (PBO) of participants. More participants reported gastrointestinal AEs with sema (61.7%) vs PBO (41.8%). In each group, 4.5% of participants stopped treatment due to AEs.

Conclusion

In adolescents with overweight/obesity, sema resulted in significant reductions in BMI, body weight and waist circumference, and improvements in cardiometabolic risk factors and QoL. Sema was generally well tolerated with a safety profile consistent with the GLP-1RAclass

P55

Profiling of autonomic neuropathy by assessing the short-term heart rate variability in peripheral neuropathy of type 2 diabetes.

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Keywords
• Health care delivery • Neuropathy: autonomic, incl. erectile dysfunction • Macrovascular disease

Background and Aims

Neuropathy is a common complication of type 2 diabetes (T2DM). Neuropathy includes peripheral small fibre sensorimotor and autonomic neuropathy. As both the neuropathy affect neurons in a length-dependent manner, often autonomic neuropathy coexists with sensorimotor neuropathy in T2DM.

Aim: To assess the short-term HRV profile among T2DM patients with symptoms of peripheral sensorimotor neuropathy

Materials and methods

A cross-sectional study was conducted in the Department of Physiology in collaboration with the Medicine Department AIIMS Kalyani. Eighty patients with T2DM who attended a diabetic clinic of 43 males and 37 females aged 45 to 65 years were studied. The duration of their illness ranges from 1 to 16 years. Diagnosed cases of T2DM included in the study were with symptoms of diabetes plus random blood glucose concentration ≥ 200 mg/dL, fasting plasma glucose ≥ 126 mg/dL, and 2-h plasma glucose ≥ 200 mg/dL during the oral glucose tolerance test. People with T2DM with comorbid conditions affecting the autonomic nervous system were excluded.

Diabetic peripheral neuropathy was assessed clinically (dry foot, shiny skin etc.), Michigan neuropathy screening Instrument questionnaire scoring (MNSI), 10g monofilament test, and Vibration perception test (VPT) by bioasthesiometer. Autonomic function testing was done with Physiograph Polyrite-D instrument-bio-amplifiers, 4 channels and accessories following standard guidelines. The study was done after the consent of the patients and upon ethical clearance from the Institutional Research Cell. Peripheral neuropathy was defined by a Michigan score ≥7.

Results

Data was analysed between two groups; Group A with MNSI score of <7 and Group B with MNSI score of ≥7. The VPT was 18.38 ± 9.74 in Group A and 22.05 ± 9.79 in Group B for the right foot. The VPT was 18.16 ± 9.99 in Group A and 21.83 ± 9.81 in Group B for the left foot. The SDNN, RMSSD and Total Power were 29.43±23.63, 21.55±15.15 and 224.73±199.68 respectively in Group A. While in Group B SDNN, RMSSD and Total Power were 23.35±15.36, 17.03±9.35 and 261.28±566.51 respectively. The mean LF power (ms2), HF power (ms2) and LF/HF ratios were 53.29, 45.17, and 1.58 compared to Group A is suggestive of diminished total autonomic modulation. The RMSSD and HF band is decreased in Group B as compared to Group A which is indicative of an imbalance of parasympathetic activity in peripheral neuropathy.

Conclusion

The diabetics with a Michigan score of 7 or greater show more sympathovagal imbalance. Further study is needed to note the effect of increased sympathovagal imbalance in diabetic peripheral neuropathy so that effective preventive measures may be ensured.

P56

Meralgia paresthetica in diabetes- usg guided procedures - game changer in the recent trend

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Keywords
• Neuropathy: somatic • Other complications

Background and Aims

Background and Aims:Meralgia paraesthetica is a mononeuropathy where a patient presents with tingling and burning pain in the thigh lateral aspect which is due to the compression of the lateral femoral cutaneous nerve of thigh. This condition being more prevalent in diabetic patients is due to the predisposition of it's anatomy, nerve damage due to diabetes and obesity which is also concomitantly seen in most of the diabetic patients that makes it more prone for entrapment. Although the diagnosis is clinching, many patients are highly bothered due to restriction of day to day activities and the poor outcomes with routine medications used for neuropathic pain. However in the recent times, USG guided procedures like hydrodissection and Pulse Radiofrequency and surgical procedures like neurectomy and neurolysis have drastically improved patient's outcome.

Materials and methods

Materials and Methods:My presentation is based on an observational study of 6 diabetic patients who had Meralgia paraesthetica and already had received treatment with drugs like GABA analogues, Amitryptyline etc, but showed poor treatment response. Hence, USG guided procedures like hydrodissection with local anaesthetic ropivacine or lignocaine plus dexamethasone was started initially and patients were followed periodically. Maximum of 3 cycles of hydrodissection was done followed by Pulse Radiofrequency procedure in patients who showed persistent symptoms in spite of 3 cycles. Patients were observed for nearly 2 months and their pain scale was assessed after each procedure and at the end of 2 months. The diabetic status of the patients were also observed and treated simultaneously to achieve strict glycemic control.

Results
Results:It was observed that out of 6 patients, one was a newly diagnosed diabetic. Rest 5 were known diabetics for more than 5 years , out of which 4 had a HbA1C of more than 8%. Based on the observation for 2 months, 2 patients needed 2 cycles of hydrodissection, 2 patients needed 3 cycles of hydrodissection and 2 patients required 3 cycles of hydrodissection and a single session of USG guided Pulse Radiofrequency procedure. The pain scale at the end of each procedure was 1/10 and 2/10 to 3/10 at the end of 2 months follow up for all 6 patients. It was also observed that strict glycemic control also added on to the better outcome of patients.
Conclusion
Conclusion:It was observed that patients with long-standing and poor glycemic control required treatment for a longer time in comparison to those who were newly detected and had a good glycemic control. Also patients who needed USG guided Pulse Radiofrequency therapy in spite of 3 cycles of hydrodissection had very poor glycemic control with the HbA1c of more than 10%. All patients showed an excellent response at the end of treatment process and experienced a better lifestyle than before. Hence newer modalities of treatment for Meralgia paraesthetica has shown to improve the patients outcome to a great extent in comparison to the oral drugs used for treating neuropathic pain usually and has now become a game changer in the treatment of Meralgia araesthetica.

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Warning Signals of Diabetes in Indian Women

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Keywords
Prediction of type 2 diabetes

Background and Aims
Diabetes affects Indian women very early in life, and if undetected causes hyperglycaemia during pregnancy. Undetected, diabetes in women without sufficient follow-up results in heart and renal disease with poor outcomes. A low-cost screening method to find non-communicable diseases in Indian women is the Mini female health program (MFHP). We analysed the association of diabetes and various non-communicable diseases in women enrolled in the Mini Female Health Program.
Materials and methods
An urban teaching hospital in India was the site of this cross-sectional observational study. Consent, a medical history review, a physical examination, and investigations were all part of the MFHP. The non-communicable diseases (NCDs) we investigated were anemia, thyroid problems, hypertension, diabetes, and obesity. The following age categories (18-30, 31-40, and > 41 years) were used to stratify the analysis. Diabetes and other characteristics were evaluated between groups, and connections between the two were observed.
Results
A total of 600 individuals were recruited, 468 with blood test results were included and relation between diabetes and other parameters was studied. 79.7% of women were below 40yrs of age, data reflects mostly of young women population of reproductive age group. Diabetes was more common in women with BMI > 25(7.3%), women above 31 years were more prone to diabetes (7.9 below 40years and 8.4% in those above 41 years), women with high waist circumference were associated with high sugars(7.8%), similarly those with high waist to height ratio (7%). Women who had been found to have hypertension also had diabetes (12.1%), and their likelihood of having diabetes was higher (6.6%) the more aberrant findings, such as more than two NCDs.
Graph/Table :

Variables	Categories	Numbers	Values		P
			Normal (%)	Diabetes (%)	
BMI_(Asia-pacific)	<18.5	51	98.0	2.0	
	18.5-23.0	109	99.1	0.9	
	23.0-25.0	136	93.7	6.3	0.053
	=25.0	172	92.7	7.3	
Age in Years	18-30	233	97.9	2.1	**0.014**
	31-40	140	92.1	7.9	
	>=41	95	91.6	8.4	
Waist Circumference(cm)	Normal (<80)	173	99.4	0.6	**0.001**
	Central Obesity (=80)	295	92.2	7.8	
Waist Height Ratio	Normal(<0.5)	126	100.0	0.0	**0.001**
	Abnormal(=0.5)	342	93.0	7.0	
TSH-thyroid disorders	Normal(<0.27-4.0)	358	95.3	4.7	0.502
	Thyroid disorders (=4 &<0.27)	110	93.6	6.4	
Hypertension	Normal(<140 or <90)	402	96.0	4.0	**0.005**
	HTN (=140 & or <90)	66	87.9	12.1	
Haemoglobin(g/dl)	Normal (=12)	246	95.5	4.5	0.498
	Anaemic(<12)	222	94.1	5.9	
Number of NCDs per woman	Nil+1	106	100.0	0.0	**0.006**
	2 and above	362	93.4	6.6	

TABLE 1: Distribution of RBS and other variables (N=468)

Conclusion
Ageing, central obesity, hypertension, and having more than two NCDS in women are statistically linked to diabetes. Contrary to BMI, which was a poor predictor, central obesity in women was linked to diabetes in our study. We advise women to start participating in frequent health screening programs like the MFHP early in life so that simple lifestyle changes can be made to prevent central obesity, which can result in future diabetes and other NCDs.

P58

A cross-sectional study on the prevalence and predictors of undiagnosed type 2 diabetes mellitus among adult population in a tertiary care teaching hospital

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Keywords
Epidemiology • Education • Hypertension • Pathogenic mechanisms / complications

Background and Aims
Diabetes mellitus is a heterogeneous metabolic syndrome characterized by chronic hyperglycemia due to insulin resistance, insufficiency, or both. The prevalence of diabetes in India has increased significantly in recent decades, and many cases of diabetes are undiagnosed or unrecognized. It is therefore imperative to have robust and comprehensive estimates of the magnitude of diabetes and its risk factors to enable planning for targeted policy and interventions. We defined 'undiagnosed diabetes' as individuals who did not know about their diabetes status but had high random (≥200 mg/dL) or fasting (≥126 mg/dL) blood glucose levels. In this study, we aimed to estimate the prevalence of undiagnosed cases of type 2 diabetes mellitus and assess the high-risk predictors among adult individuals as per the ADA diabetes risk test attending the hospital's outpatient department.
Materials and methods
It was a cross-sectional study. Adult patients (above 18 years old, either sex) attending Medicine outpatient clinics for other complaints were approached for the study. The patients were recruited by consecutive random sampling. These patients were screened for American Diabetes Association (ADA) Risk Score after giving voluntary informed consent. The patient was considered to be in the high-risk group if the ADA Risk Score was more than 5. These patients in the high-risk group were then further assessed for anthropometric measurements and random blood sugar (RBS). The patients having random blood sugar more than equal to 200 mg/dl were further investigated for fasting blood sugar (FBS), postprandial blood sugar (PPBS), and glycosylated hemoglobin (HbA1c) for confirmation of undiagnosed diabetes mellitus.
Results
In the study, 503 patients were screened for undiagnosed diabetes mellitus. 109 (21.66%) patients were found to be in the high-risk group as per the ADA Risk Score. The prevalence of undiagnosed diabetes mellitus was 1.83% (2 patients out of 109 patients). The independent risk factors associated with the patients undergoing screening were age (odd ratio[OR], 1.31; 95% confidence interval [Cl], 1.23 to 1.40), female (odd ratio[OR], 6.45; 95% confidence interval [Cl], 2.45 to 16.95), family history of diabetes mellitus (odd ratio[OR], 6.01; 95% confidence interval [Cl], 2.20 to 16.42), smoking (odd ratio[OR], 2.30; 95% confidence interval [Cl], 0.58 to 9.08), weight (odd ratio[OR], 1.23; 95% confidence interval [Cl], 0.93 to 1.62) and systolic blood pressure (odd ratio[OR], 1.04; 95% confidence interval [Cl], 1.01 to 1.07). The patients having an ADA Risk Score of ≥5 were found to have a significant association with independent risk factors of age, sex, physical activity, family history of diabetes mellitus, weight, body mass index, hypertension, and random blood sugar.
Conclusion
A substantial portion of India's diabetic population is at risk of not being diagnosed with the disease because they are unaware of their condition. The identification of undiagnosed instances that may benefit from additional targeting of modifiable risk factors can be done with the use of routine screening for an aberrant glucometabolic status. This study demonstrates that raising diabetes awareness and focusing on risk factors may aid in the early detection of diabetes in adults.

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Decoding Optimal Metabolic Health Through Continuous Glucose Monitoring

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Keywords
Prevention of type 2 diabetes • Insulin sensitivity and resistance • Devices

Background and Aims
Metabolic health is a key determinant of overall health and well-being. Individuals with diabetes are at increased risk of developing chronic diseases, such as heart disease, stroke, and kidney disease. There is a need for accurate and reliable methods to assess metabolic health in individuals with diabetes. The aim of this study was to explore the correlation between Actofit's Metabolic Score and clinical biomarkers of metabolic health in individuals with diabetes.
Materials and methods
The study included 132 individuals with diabetes. The Metabolic Score was calculated based on glucose variability, average glucose, and time in target metrics. Clinical biomarkers of metabolic health included blood sugar, triglycerides, high-density lipoprotein (HDL) cholesterol, blood pressure, and waist circumference.
Results
A strong positive correlation was found between the Metabolic Score and the Quality of Life Instrument for Indian Diabetes Patients (QOLID) score, both pre- and post-treatment. The study suggests that higher Metabolic Scores are associated with improved quality of life.
Conclusion
The findings of this study suggest that Actofit's Metabolic Score has the potential to be a valuable tool for assessing metabolic health in individuals with diabetes. The score is correlated with clinical biomarkers of metabolic health and is associated with improved quality of life. These findings underscore Actofit's potential to predict metabolic health, influence behavior change, and inform personalized interventions.
The study also has some limitations. The sample size was relatively small, and the study was conducted in a single center. Further research is needed to confirm the findings of this study in a larger and more diverse population. Overall, the findings of this study suggest that Actofit's Metabolic Score is a promising tool for assessing metabolic health in individuals with diabetes. The score is correlated with clinical biomarkers of metabolic health and is associated with improved quality of life. These findings underscore Actofit's potential to predict metabolic health, influence behavior change, and inform personalized interventions.

P60

Place of imeglimin in the management of type 2 diabetes mellitus as per Indian clinicians: a cross-sectional survey

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Keywords
• Insulin sensitivity and resistance • Oral therapies: secretagogues

Background and Aims
Imeglimin is a first-in-class novel oral agent recently approved for the treatment of Type 2 diabetes mellitus (T2DM). However, there is limited data available regarding use of imeglimin in clinical practice. We aimed to determine place of imeglimin in the management of T2DM in India.
Materials and methods
A cross-sectional, observational, questionnaire-based survey was conducted among clinicians across India. The survey questions covered the reasons for prescribing imeglimin, its effect on glycemic control, safety profile, and use as an add-on therapy.
Results
The survey questionnaire was answered by 260 diabetologists and endocrinologists. Overall, 98% of the survey respondents agreed that there is a need for newer oral drugs in the management of T2DM with the majority (62%) stating that only <5-40% of their patients are at target HbA1c.
Imeglimin was considered as a promising drug by 64% of the survey respondents. Majority (87%) of the respondents prescribed imeglimin due to its unique action as both an insulin sensitizer and insulin secretagogue and its effect on mitochondrial dysfunction. Among the respondents, 72% preferred to use imeglimin as an add-on therapy to oral drugs, 8% preferred it as an add-on to insulin, 16% as monotherapy, while 4% would like more data before prescribing it. Majority (65%) of the clinicians started imeglimin with 500 mg twice daily dose while the rest started with 1000 mg twice daily.
A mean decrease in fasting blood glucose level of 5-10 mg/dl was reported by 38%, 11-15 mg/dl by 33%, and 16-20 mg/dl by 18% of the survey respondents. Similarly, a mean decrease in post prandial blood glucose level of 5-10 mg/dl was reported by 36%, 11-15 mg/dl by 31%, and 16-20 mg/dl by 24% of the survey respondents. An approximate HbA1c level decrease of 0.5-1% with imeglimin treatment was reported by 52% of the respondents.
Overall, 70% of the respondents have prescribed imeglimin in chronic kidney disease (CKD) patients and among them, 78% had found it to be effective and safe in mild to moderate CKD. Majority of the survey respondents reported that less than 10% of their patients experienced gastrointestinal (GI) side effects due to imeglimin.
Conclusion
Imeglimin is considered a promising molecule in the management of T2DM. It is preferred as an add-on therapy and provides effective glycemic control with less incidence of GI side effects.

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Effect of Matta Rice Vs Ponni Rice on Post Lunch Blood Glucose levels among People with Type 2 Diabetes:A Randomized crossover study from South India

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Keywords
• Nutrition and diet

Background and Aims
Matta rice has low glycemic index and high fiber content compared to Ponni rice. Limited evidence was available on the post lunch blood glucose (PLBG) levels of people with diabetes (DM) consuming Matta rice and Ponni rice. Our aim was to see the effect of Pre- lunch and post lunch blood glucose levels after the consumption of Matta rice and Ponni rice among people with T2DM.
Materials and methods
A total of 70 (M: F=44:26) participants were enrolled for this randomised crossover study conducted between March 2023 to May 2023 in a tertiary care centre for diabetes Chennai. Participants were randomized into two groups Group A (n=35) and Group B (n=35), Group A was given Matta rice and Group B was given Ponni rice for two weeks. After one week wash out period, 10 participants in Group A and 11 in Group B were dropped out from the study. Hence the remaining 23 in Group A and 24 in Group B were given Ponni rice and Matta rice for two weeks respectively. Individual diet plan was advised to all the participants and emphasized on the meal plate with a balanced distribution of cereals, pulses and vegetables. At baseline, anthropometric measurements, biochemical profile, blood pressure and 24 hr dietary recall were recorded. Pre and post lunch capillary blood glucose levels were collected at 7th and 14th day of follow up. The acceptability of Matta rice was evaluated using satiety visual analog scale. Statistical analysis was done using SPSS 29.
Results
The Participants median age was 52(28,60), median duration of diabetes was 7(2,10) years and median HbA1c was 6.7(6.6,7.5). There was a significant reduction in Pre-lunch blood glucose levels at 14th day from baseline (-4.5mg/dl vs.-1.4mg/dl, p=0.002) and also found significant reduction in Post lunch blood glucose levels at 14th day from baseline (-31.53mg/dl vs.-6.51mg/dl, p=0.007) in Matta rice group compared to Ponni rice group. There was a significant reduction in PLBG levels on 7th day 167.15±36.25 (P=0.01) and 14th day 164.45±30.86 (p=0.01) from baseline 195.98±43.64, among those who consumed Matta rice. But there was no significant reduction found in those consumed Ponni rice at follow up on 7th day 165.70±25.86 (P=0.18) and 14th day 165.65±33.87 (P=0.21) from baseline172.17±34.47.It was observed that there was a significant reduction in calorie intake among the participants when they consumed Matta rice (baseline Vs 14th day:1473 Vs1296 kcals; p<0.001).
Conclusion
Consumption of Matta rice showed restricted calorie intake which helped in the reduction of post lunch blood glucose levels as compared to Ponni rice in people with type2 diabetes. Matta rice provided good satiety and fullness which was beneficial for controlling hyperglycemia.

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Real-world Effectiveness Study of Vildagliptin Sustained Release Formulation in Southern Region of Indian T2DM Patients – Post Hoc Analysis of NOVELTY

Study.

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Keywords
• Oral therapies: metformin, sensitizers and other non- secretagogues

Background and Aims
The vildagliptin sustained-release formulation, delivering a daily dose of 100 mg, has not been subject to any real-world investigations into its effectiveness and tolerability among patients with type 2 diabetes mellitus (T2DM) in the Southern Region of India.
Aim of the study is to assess the effectiveness and tolerability of Vildagliptin XR amongst T2DM patients from the southern region of India as a sub-group analysis of NOVELTY India study
Materials and methods
The NOVELTY India study a single-arm, observational, prospective, open-label and multicenter study conducted with 1691 patients at 118 sites across India from January 2022 to March 2023. This is a post-hoc analysis of 618 patients at 43 sites from the southern region of India. Patients with T2DM who had not been adequately controlled with metformin XR (HbA1c >7.0%) and who were between the ages of 18 to 78 of either sex were included in the study. In addition to their current treatment plan, they received 100 mg of vildagliptin XR once a day. The primary endpoint was a change in HbA1c at 3 months. Other endpoints included change in fasting and postprandial plasma glucose (FPG and PPG), the proportion of patients reaching HbA1c <7%, and adverse events observed during study period. The mean glucose and HbA1c levels were compared between the start of the study and the end using a paired t-test. Ethics Committee approval for the study and Informed consent from the participants were taken.
Results
From the southern region of India, a total of 618 patients were enrolled. At baseline the mean age of all participants was 53.33 ± 11.04 years, 324 were male participants, duration of diabetes was 54.25 ± 57.90 months, weight 71.21± 13.93 kg and mean HbA1c was 8.53 ± 1.43 %. At the end of 3 months, vildagliptin XR resulted in a significant reduction (vs. baseline) in mean HbA1c by 0.95% (95%CI 0.87-1.04; p<0.001). Significant reduction of 21.95 mg/dL (95%CI 19.12-24.79; p<0.001) in FPG and 44.87 mg/dL (95%CI 40.65-49.08; p<0.001) of PPG were also observed during the study period. By the end of the study, 28.64% of patients achieved HbA1c <7.0% target. Only 1 adverse event was reported, which was considered to be of mild severity. Most investigators agreed that adding vildagliptin XR was effective (98.9%) and tolerable (98.9%) in their patients. Most patients (95.6%) reported that they were extremely satisfied/ satisfied with the treatment.
Conclusion
Vildagliptin XR notably improved glycemic parameters and was well tolerated in T2DM patients from the Southern region of India.

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Real-world Effectiveness Study of Vildagliptin Sustained Release Formulation in Eastern Region of Indian T2DM Patients – Post Hoc Analysis of NOVELTY

Study.
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Keywords
• Oral therapies: metformin, sensitizers and other non- secretagogues

Background and Aims
A sustained-release formulation of Vildagliptin allows once-daily administration of vildagliptin 100 mg. The effectiveness of Vildagliptin sustained release (XR) in the Eastern part of Indian type 2 diabetes mellitus (T2DM) patients, has not been examined in a real-world setting.
The aim of the study is to assess the effectiveness and tolerability of Vildagliptin XR amongst T2DM patients from the eastern region of India as a sub-group analysis of the NOVELTY India study.
Materials and methods
The NOVELTY India study is a single-arm, observational, prospective, open-label, and multicenter study conducted with 1691 T2DM patients at 118 sites across India from January 2022 to March 2023. This is a post-hoc analysis of 249 Patients at 18 sites from the eastern region of India. The study included people with T2DM with HbA1c >7.0% on metformin XR and were in the age range of 18 to 78 of either sex. Their current regimen was supplemented with 100 mg of vildagliptin XR once daily.
The primary endpoint was a change in HbA1c at 3 months. Other endpoints included changes in fasting and postprandial plasma glucose (FPG and PPG), the proportion of patients reaching HbA1c <7%, and adverse events observed during the study period. The ethics committee's approval and the patient's informed consent were obtained. A paired t-test was used to compare the mean HbA1c and glucose levels between the baseline and end of the study.
Results
From the eastern region of India, a total of 249 patients were enrolled. At baseline the mean age of all participants was 53.8 ± 11.11 years, 162 were male participants, duration of diabetes was 58.25 ± 48.24 months, mean weight was 67.38 ± 9.48 kg and mean HbA1c was 8.22% ± 1.62%. At the end of 3 months, vildagliptin XR resulted in a significant reduction (vs. baseline) in mean HbA1c by 1.06% (95% CI 0.92-1.2; p<0.001). Significant reduction of 29.78 mg/dL (95% CI 25.83-33.72; p<0.001) in FPG and 51.61 mg/dL (95% CI 45.18-58.04; p<0.001) in PPG were also observed during the study period. By the end of the study, 42.97% of patients achieved HbA1c<7.0% target. No adverse events were reported. Most investigators agreed that adding vildagliptin XR was effective (99.2%) and tolerable (99.2%) in their patients. All the patients reported that they were extremely satisfied/ satisfied with the treatment.
Conclusion
Vildagliptin XR was well tolerated and significantly improved glycemic indices in people with T2DM in the Eastern region of India.

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Real-world Effectiveness Study of Vildagliptin Sustained Release Formulation in Northern Region of Indian T2DM Patients – Post Hoc Analysis of NOVELTY Study

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Keywords
• Oral therapies: metformin, sensitizers and other non- secretagogues

Background and Aims
Vildagliptin sustained release is a formulation providing vildagliptin 100 mg with a once-daily dosing frequency. However, there is no real-world study that evaluates the effectiveness of vildagliptin sustained release (XR) in Indian type 2 diabetes mellitus (T2DM) patients.
The aim of the study is to assess the effectiveness and tolerability of Vildagliptin XR amongst T2DM patients from the northern region of India as a sub-group analysis of the NOVELTY India study
Materials and methods
The NOVELTY India study is a single-arm, observational, prospective, open-label and multicenter study conducted with 1691 T2DM patients at 118 sites across India from January 2022 to March 2023. This is a post-hoc analysis of 296 patients at 19 sites from the northern region of India Patients aged between 18 to 78 years of either sex with T2DM inadequately controlled with metformin XR (HbA1c >7.0%) were enrolled in the study. Vildagliptin XR of 100 mg once daily was added to their ongoing regimen. The primary endpoint was a change in HbA1c at 3 months. Other endpoints included change in fasting and postprandial plasma glucose (FPG and PPG), the proportion of patients reaching HbA1c <7%, and adverse events observed during the study period. The mean HbA1c and glucose levels were compared between baseline and at end of study by paired t-test. The ethics committee's approval and the patient's informed consent were obtained.
Results
From the northern region of India, a total of 296 patients were enrolled. At baseline the mean age of all participants was 52.5 ±10.98 years, 167 were male participants, duration of diabetes was 29.3 ± 36.37 months, mean weight was 74.4 ± 14.49 kg and mean HbA1c was 8.25 ± 1.01%. At the end of 3 months, vildagliptin XR resulted in a significant reduction (vs. baseline) in mean HbA1c by 1.08% (95% CI 0.97-1.19, p<0.0001). Significant reduction of 43.2 mg/dL (95% CI 37.87- 48.54; p<0.001) in FPG and 56.22 mg/dL (95% CI 49.98 - 62.45; p<0.001) in PPG were also observed during the study period. By the end of the study, 41.55% of patients achieved HbA1c<7.0% target. Very few adverse events (2) were reported, which were all considered to be of mild severity. Most investigators agreed that adding vildagliptin XR was effective (91.2%) and tolerable (91.6%) in their patients. Most patients (87.5%) reported that they were extremely satisfied/ satisfied with the treatment.
Conclusion
Under real-life settings, Vildagliptin XR remarkably improves glycemic parameters and was well tolerated in people with T2DM from the Northern region of India.

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Metformin Induced Vitamin B12 Deficiency

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Keywords
• Oral therapies: metformin, sensitizers and other non- secretagogues

Background and Aims
Metformin is by far the most prescribed antidiabetic medication as monotherapy or in combination with other drugs. It's favorable efficacy, cost and side effect profile has made it a popular drug among physicians.Gastrointestinal side-effects and lactic acidosis related to metformin are commonly recognised; however, the associated vitamin B12 deficiency is less well known.
AIM:To study the correlation between dose and duration of Metformin use and Vitamin B12 deficiency
Materials and methods
Prospective, observational, cross sectional, hospital-based study, Sample size of: 205 study period of 2 years (2020-22)
INCLUSION CRITERIA: • Type 2 Diabetics as per ADA guidelines • Age 30-80 years • On Metformin
EXCLUSION CRITERIA: • Patients with liver failure, chronic liver disease • Pregnancy • Hypothyroidism, autoimmune thyroid disease • Patients with Renal failure (Creatinine Clearance <30ml/min/stage 4 and above) • People suffering from bowel disorders such as – Atrophic gastritis, Pernicious anemia, IBD, Chronic Pancreatitis, Whipple's disease, Parasitic Infections, • Post bowel surgeries such as Gastrectomy, Terminal Ileal resection surgeries and Bariatric surgeries • Patients treated for Vitamin B12 deficiency with a course of Injection Vitamin B12
STATISTICAL Comparison of quantitative variables statistical analysis was done using ANOVA, Comparison of categorical data was done using Chi Square and A p value less than 0.05 was considered statistically significant
Results
The mean age of the study population in the present study was 59.51±10.98 years. Males constituted 58.5% and females 41.5% with a male to female ratio of 1.4: 1. Vitamin B12 deficiency was seen in a total of 35 subjects accounting to 17.1% of total deficiency. It was found that higher doses of metformin caused more significant interference with B12 absorption from the gut, leading to more likely occurrence of B12 deficiency. Additionally, longer the duration of metformin use higher is the risk of developing B12 deficiency. Metformin induced cobalamin deficiency can cause new onset peripheral neuropathy or worsen nerve damage in patients with pre-existing diabetic peripheral neuropathy
Conclusion
Patients on long term metformin therapy are at a high risk of developing B12 deficiency and peripheral neuropathy with vegetarians having an added risk of developing B12 deficiency. Thus, frequent screening for B12 deficiency in patients on long term metformin would be useful in preventing further complications from the same.

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Real-world Effectiveness Study of Vildagliptin Sustained Release Formulation in Western Region of Indian T2DM Patients – Post Hoc Analysis of NOVELTY Study

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Keywords
• Oral therapies: metformin, sensitizers and other non- secretagogues

Background and Aims
The vildagliptin sustained-release formulation offers a 100 mg dose meant to be taken once a day. Nevertheless, there exists a gap in real-world research assessing the effectiveness of this extended-release version of vildagliptin in individuals with type 2 diabetes mellitus from the western part of India. In this sub-group analysis

of NOVELTY India study, we aim to determine the effectiveness and tolerability of vildagliptin XR in T2DM patients from the western region of India.

Materials and methods

The NOVELTY India study is a single-arm, observational, prospective, open-label, and multicenter study conducted with 1691 T2DM patients at 118 sites across India from January 2022 to March 2023. This is a post-hoc analysis of 528 patients at 37 sites from the Western region of India. Patients with T2DM between the ages of 18 to 78 of either sex who had their blood sugar levels unsatisfactorily controlled with metformin XR (HbA1c >7.0%) were included in the study. Vildagliptin XR, 100 mg, was added to their existing regimen once a day. The primary endpoint was a change in HbA1c at 3 months. Other endpoints included changes in fasting and postprandial plasma glucose (FPG and PPG), the proportion of patients reaching HbA1c <7%, and adverse events observed during the study period. The mean HbA1c and glucose levels were compared between baseline and at end of study by paired t-test. The patient's informed consent was obtained, as well as the ethics committee's approval.

Results

From the western region of India, a total of 528 patients were enrolled. At baseline the mean age of all participants was 52.86 ± 10.91 years, 304 were male participants, duration of diabetes was 38.77 ± 49.41 months, mean weight was 73.42 ± 12.07 kg and mean HbA1c was 8.55 ± 1.25%. At the end of 3 months, vildagliptin XR resulted in a significant reduction (vs. baseline) in mean HbA1c by 1.06% (95% CI 0.79-1.32; p<0.001). Significant reductions of 27.14 mg/dL (95% CI 24.16-30.11; p<0.001) in FPG and 46.82 mg/dL (95% CI 42.28-51.37; p<0.001) in PPG were also observed during the study period. By the end of the study, 28.64% of patients achieved HbA1c<7.0% target. No adverse events were reported. Most investigators agreed that adding vildagliptin XR was effective (94.7%) and tolerable (94.5%) in their patients. Most patients (93.8%) reported that they were extremely satisfied/ satisfied with the treatment.

Conclusion

Vildagliptin XR significantly improves glycemic control and other glucose-related parameters in Indian patients with T2DM from Western regions who were inadequately controlled with metformin monotherapy.

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Diabetes treatment with dapagliflozin and its combinations: Insights from clinical practice

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Keywords
• SGLT inhibitors

Background and Aims

Despite global guidelines recommending the initiation of SGLT2i drugs like Dapagliflozin in type 2 diabetes (T2DM) patients with cardiovascular (CV) or renal risk, its clinical translation is still lacking in India. The aim of the study was to understand clinicians' perspectives regarding the association of CV risk and T2DM in Indian patients, and the need for the use of combination therapies with Dapagliflozin in T2DM patients, in Indian clinical practice.

Materials and methods

A cross-sectional, questionnaire-based survey involving 873 diabetologists and consulting clinicians was conducted. The survey questionnaire consisted of 30 questions that accessed T2DM patient profiles and clinicians' preference for treatment approach, dapagliflozin use for cardiorenal protection and its combination therapy.

Results

In routine clinical practice, 73% clinicians observed more than 20 T2DM patients in a week. Majority of these patients (91%) were aged between 40 – 60y. The clinicians observed that these patients presented with varying comorbid conditions like obesity (39%), coronary artery disease (38%) and chronic kidney disease (14%). 37% clinicians said CV risk was observed in 50 – 80% T2DM patients. In the treatment of T2DM patients 44% clinicians preferred SGLT2i followed by DPP4i (31%) and SU (28%) as the first choice of antidiabetic class of drug other than metformin. Among the SGLT2i class, Dapagliflozin (91%) was the most preferred choice. According to 55% clinicians the most prominent clinical benefit of Dapagliflozin was reduction in HF hospitalization and 69% suggested Dapagliflozin to be the most effective SGLT2i in patients with renal impairment. 94 % clinicians agreed that early initiation and aggressive intensification of combination therapy should be done and 58% preferring SGLT2i based combinations in this regards. In case of SGLT2i + DPP4i fixed dose combinations (FDC) for T2DM patients with CV or renal risk, 79% clinicians preferred Dapagliflozin based FDC (66 %: Dapagliflozin+ Sitagliptin & 13%: Dapagliflozin + Vildagliptin) while 76% strongly recommended the FDC for triple combination of Dapagliflozin + Sitagliptin + metformin. All the clinicians agreed that SGLT2i drugs like Dapagliflozin must be initiated in T2DM patients with comorbidities and 98% opined that SGLT2i like Dapagliflozin is one drug across HF spectrum among T2DM patients. However, 89% clinicians were concerned with Dapagliflozin underutilization in Indian patients.

Conclusion

The findings from the survey highlight the clinical benefits of Dapagliflozin and its FDCs in T2DM patients with CV/renal risk. Early initiation and aggressive intensification with Dapagliflozin FDCs in T2DM patients are highly recommended.

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Similar Hypoglycemia Duration with Once-Weekly Icodec vs. Degludec or Glargine U100 in Insulin-Treated T2D-A Post Hoc CGM Analysis from ONWARDS 2 and 4

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Keywords
• Hypoglycaemia

Background and Aims
Once weekly (OW) icodec is a basal insulin in development. Hypoglycemia duration during the switch (weeks 0-4) and steady state (weeks 22-26) periods from two phase 3, randomized, treat-to-target trials in T2D was investigated, using double-blinded Dexcom G6 CGM.
Materials and methods
Insulin-treated individuals were randomized to OW icodec or once-daily (OD) degludec (ONWARDS 2), or OW icodec or OD glargine U100 with mealtime insulin aspart (ONWARDS 4). When switching, a one-time only additional 50% icodec dose was administered. Basal insulins were titrated weekly.
Results
Median hypoglycemia <70 mg/dL duration for episodes lasting ≥ 15 minutes and the proportion of such episodes spent <54 mg/dL were assessed. Median duration of hypoglycemia <70 mg/dL was similar between icodec and comparators during switch and at steady state, with no apparent clustering in either time-period. At steady state (icodec/degludec and icodec/glargine U100), of the episodes <70 mg/dL, 66.6/63.9% and 60.4/60.0% spent no time <54 mg/dL; 23.2/26.6% and 29.2/28.8% included episodes <54 mg/dL for ≥15 minutes; and 10.2/9.5% and 10.4/11.2% included episodes <54 mg/dL for <15 minutes, respectively.
Conclusion
In insulin-treated T2D, the duration of hypoglycemic episodes <70 mg/dL was similar, with no apparent clustering, during switch and at steady state for OW icodec versus OD degludec or glargine U100

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Influences of Glycosylated Hemoglobin and Body Mass Index on Atherosclerosis by Means of Carotid Intima-Media Thickness

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Keywords
• Weight regulation and obesity • Cardiac complications

Background and Aims
Numerous studies have highlighted a strong correlation between carotid intima-media thickness (CIMT) and the degree of coronary stenosis in individuals with type 2 diabetes (T2D), even among those without prior coronary artery disease. These studies have also demonstrated that CIMT measurements possess the ability to predict future cardiovascular events independently. This underscores the dual role of CIMT measurements, not only as a tool to evaluate the advancement of the disease but also as a valuable noninvasive method for gauging prospective cardiovascular risk. The aim of this study is to examine CIMT in individuals with diabetes and to analyze how factors such as HbA1c and BMI impact the development of atherosclerosis, as assessed through CIMT measurements
Materials and methods
Between March 2022 and February 2023, a longitudinal study was carried out involving 35 participants in the age range of 40 to 50 years, with diabetes. The study was conducted in the central region of India. After obtaining the informed consent a comprehensive clinical examination and initial investigations were conducted for each participant. Carotid ultrasound using B-mode imaging was performed on all subjects to measure carotid intima-media thickness (CIMT). CIMT values falling within the range of 0.05 to 0.06 cms were classified as normal, while values exceeding this range were categorized as abnormal. All data analyses were executed using SPSS version 12.0 and Microsoft Excel. Quantitative data was presented as mean values with standard deviations, while qualitative data was expressed as percentages. To ascertain statistical significance, either the Chi-square test or Fisher's exact test was employed.
Results
The study involved 35 people with diabetes. Approximately 60% (n =21) of participants were males. Higher values of CIMT were associated with a longer duration of diabetes (82%,> 5-year duration), and higher HbA1c values. 74.2% of males (n=26) had higher CIMT as compared to 57% (n=8) females. Out of 27 subjects with BMI>25, twenty had higher CIMT.
Conclusion
Reduced glycemic control and extended disease duration exert distinct detrimental impacts on CIMT among T2DM patients. Additionally, an elevated body mass index (BMI) contributes to an increased predisposition for higher IMT values. Consequently, the early identification of the disease, effective management of glycemic levels, and vigilance regarding conventional cardiovascular risk factors all assume crucial roles in slowing down initial atherosclerotic changes. In the long run, these measures hold the potential to be instrumental in preventing chronic cardiovascular, cerebrovascular, and peripheral vascular complications and fatalities associated with diabetes mellitus.

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Ferroptosis: A Promising Therapeutic Target for Diabetes and its Complications

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Keywords
Prediction of type 2 diabetes • Beta cell damage, degeneration and apoptosis • Insulin sensitivity and resistance • Nutrition and diet

Background and Aims
Ferroptosis, an emerging form of regulated cell death, is characterized by iron-driven lipid peroxidation and the generation of reactive oxygen species. It has gathered attention for its involvement in diabetes pathogenesis. Accordingly, targeting ferroptosis presents a promising therapeutic approach for managing diabetes and its associated complications. This study aims to elucidate the mechanistic aspects of ferroptosis and assess its potential as a therapeutic target in diabetes and related complications.
Materials and methods
A comprehensive review of scientific literature databases, including PubMed, ScienceDirect, EMBASE, Google Scholar, and Web of Science, was conducted to analyze the role of ferroptosis in diabetes and its complications.
Results
Numerous preclinical investigations have highlighted the correlation between diabetes-related complications and the activation of ferroptosis pathways. These findings suggest that modulating key factors in ferroptosis could hold promise for diabetes management. Targeting dysregulated iron homeostasis has emerged as a potential avenue to restore cellular balance during diabetes onset. The identification of

novel ferroptosisrelated biomarkers provides insight into the intricate mechanisms underpinning ferroptosis in the context of diabetes.

Conclusion

Developing precise strategies to manipulate ferroptosis could offer therapeutic targets to safeguard beta cell function and mitigate complications associated with diabetes. While these findings hold potential, further research is necessary to unravel the complexities of ferroptosis within the framework of diabetes and translate these insights into effective clinical interventions.

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Once-weekly subcutaneous semaglutide 2.4 mg on metabolic syndrome in the 2-year, randomised controlled STEP 5 trial

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Keywords
Prevention of type 2 diabetes • Weight regulation and obesity • Education • Other complications

Background and Aims

Metabolic syndrome (MetS) is associated with an increased risk of cardiovascular disease and type 2 diabetes. Obesity is a key driver of MetS. In the STEP 5 trial, treatment with once-weekly subcutaneous semaglutide 2.4 mg resulted in 15.2% weight loss after 104 weeks vs 2.6% with placebo. This post hoc analysis of STEP 5 investigated the effect of 2 years of treatment with semaglutide on MetS

Materials and methods

304 adults with overweight/obesity (BMI ≥30 kg/m2 , or ≥27 kg/m2 with ≥1 weight-related comorbidity), without diabetes, were randomised 1:1 to semaglutide 2.4 mg or placebo (both plus diet and physical activity) for 104 weeks. We assessed MetS prevalence at baseline and weeks 52 and 104, and weight loss from baseline to week 104 (<10%/≥10%). MetS was defined as the presence of ≥3 National Cholesterol Education Program Adult Treatment Panel III criteria. Results are based on observed data from the in-trial period. P values were from a chi-square test of proportions. Analyses were not adjusted for multiplicity.

Results

There were 89 participants with MetS at baseline in the semaglutide group and 79 in the placebo group. Significantly greater proportions of participants had remission of MetS at weeks 52 and 104 with semaglutide vs placebo (p<0.01; Figure), and significantly lower proportions developed MetS (1.7% vs 23.2%, week 52; 7.1% [2 of these 4 participants were off drug] vs 25.9%, week 104; both p<0.01). When considering the degree of weight loss (<10%/≥10%) in both the semaglutide and placebo groups, semaglutide led to a higher rate of MetS remission in participants with <10% weight loss than placebo at both 52 weeks (57.9% vs 25.0%) and 104 weeks (39.5% vs 15.3%), with fewer participants developing MetS (6.3% vs 23.9%, week 52; 23.5% vs 28.9%, week 104). Weight loss of ≥10% led to higher MetS remission rates, which were similar in semaglutide- and placebo-treated participants (63.0% vs 66.7%, week 52; 71.1% vs 83.3%, week 104); no semaglutidetreated participants developed MetS with ≥10% weight loss (0.0% vs 22.2%, week 52; 0.0% vs 11.1%, week 104).

Conclusion

A greater proportion of participants treated with once-weekly subcutaneous semaglutide 2.4 mg achieved remission of MetS, and fewer developed incident MetS, compared with placebo. These benefits were maintained over 2 years of semaglutide treatment. These results suggest that the positive effects of semaglutide on MetS could potentially impact the progression to type 2 diabetes and cardiovascular disease while patients are taking the drug. However, these data should be interpreted with caution due to the small participant numbers involved.

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Marathon Runners in India: Exploring Chronic Medical Conditions and the Health Care Utilization

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Keywords
• Exercise physiology • Health care delivery

Background and Aims

Marathons stand as one of the most rigorous and testing endurance events, drawing a varied spectrum of participants ranging from amateur enthusiasts to professional athletes of high caliber. Individuals engaged in marathon running often come with concurrent health conditions that exert an influence on their training regimen and their ability to take part in such events. Effectively managing these coexisting health issues holds utmost importance in the context of participating in marathons. We aimed to study the characteristics, comorbidities, and healthcare-seeking behavior of marathon runners in India.

Materials and methods

An observational cross-sectional study employing a digital questionnaire was executed among marathon runners spanning several cities in India from April 2023 to June 2023. A cohort of 224 adults within the age range of 18 to 60 years was included, with all participants providing informed consent prior to participation.

Results

This study garnered responses from 224 participants, with 82.3% of them identifying as male. Among the participants, 84.9% were married, and 77% were employed in the private sector. The largest segment of respondents (40.6%) fell within the age bracket of over 50 years. The majority (85%) of the participants were married, while 56.9% adhered to a vegetarian diet. Approximately 47.6% had been engaged in running for a duration of 4 to 9 years, and 44.9% indicated a preference for a marathon distance of 21 km. About 92.4% responded that the sole purpose of running in a marathon is to stay healthy and keep fit and 35% preferred the half marathon. About 56% were involved in some sports activity prior and 90% opined they follow a healthy lifestyle. On comorbidities, hypertension was most prevalent (23.2%) followed by diabetes (13%), hyperlipidemia (9.3%), and asthma (2.2%). Around 73.1% mentioned that they do not take regular medication for chronic medical conditions. Among people with diabetes, the majority were on OADs. About 95% do not take any pain medications during a marathon, and 65.5 % are aware of the risks and side effects of pain medications. A total of 29 % were not aware of the precautions to be taken for running a marathon with chronic medical conditions. On the periodicity of medical health checkups, 62.3% did it annually, and 17.5 % did not do it at all. Around 69.6% do not consult a physician to get advice before a marathon. Regarding the satisfaction level with running related medical services, 44 % were satisfied and 15.5% were very satisfied. On the level of satisfaction after running a marathon 71 % were very satisfied and 27 % were satisfied. About 95.5% believed they had a better quality of life by participating in marathons.

Conclusion

The findings of this study revealed a noticeable deficiency in understanding regarding chronic medical conditions like diabetes, and

hypertension and the essentiality of adopting a healthcare-seeking approach among marathon runners. It is imperative to deliver targeted medical awareness and education to marathon runners, especially those with concurrent health conditions, as well as to the entire running community. This proactive approach aims to mitigate the broader impact of such health issues.

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Efficacy and safety of FDC of Dapagliflozin, Glimepiride and Metformin IR tablets in Type 2 Diabetes: A Phase 3, Active-controlled study

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Keywords
• SGLT inhibitors • Hypoglycaemia

Background and Aims
Complementary mechanisms of dapagliflozin, glimepiride & metformin immediate release (IR) in FDC is suggested to offer better glycemic control, improved compliance without additional risk of weight gain & may have cardio & reno protective action. The current study evaluated efficacy & safety of triple drug FDC vs 2 drug combination in Indian T2DM patients.
Materials and methods
This phase 3, 4-arm, open-label, active-controlled study (CTRI/2022/06/043249) randomized 536 patients (HbA1c ≥8% & ≤11%) who were on metformin 1000-2000mg/day & glimepiride 2mg/day at screening) in 1:1:1:1 ratio (134 patients in each arm). Patients received FDC dapagliflozin+glimepiride+metformin IR tablets (5mg+1mg+500mg BID [test 1]/5mg+1mg+1000mg BID [test 2]) OR co-administration of glimepiride+metformin IR (1mg+1 tablet of 500mg BID [comparator 1]/1mg+2 tablets of 500mg BID [comparator 2]) for 16 weeks. Post Week 16, respective arms were up-titrated with dose of glimepiride (2mg) to patients with HbA1c ≥7%. Primary endpoint was mean change in HbA1c from baseline to Week 16.
Results
Adjusted mean (SE) change in HbA1c was statistically significant from baseline to Week 16 in test 1 [-2.17% (0.11)] vs comparator 1 [-1.64% (0.11), p=0.0005]. Similarly, statistically significant reduction from baseline to Week 16 was observed in test 2 [-2.25% (0.07)]) vs comparator 2 [-1.72% (0.07), p<0.0001]. Proportion of patients achieving HbA1c <7% was significantly higher in test 1 (70.68%) vs comparator 1 (46.62%, p=0.0002) & in test 2 (78.36%) vs comparator 2 (53.38%, p<0.0001), respectively at Week 16. Reduction in PPBG & FBG was statistically significant in test 2 vs comparator 2 at Week 16 from baseline in favour of triple FDC. Statistically significant reduction in HbA1c, FBG & PPBG was observed in each arm from baseline to Weeks 8, 12, 16 & 28. No patient required rescue medication. No hypoglycemia or SAE was reported.
Conclusion
FDCs of dapagliflozin+glimepiride+metformin IR tablets demonstrated superior efficacy to two drug combination in reducing HbA1c from baseline to Week 16. Study medications were safe & well tolerated.

P74

Personalized Glycemic Response Based Fitterfly Diabetes CGM Program Improved Dietary Practices, Glycemic Control, And Weight Among People with Poorly Controlled Diabetes

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Keywords
• Health care delivery

Background and Aims
This study evaluates the effectiveness of personalized glycemic response (PGR) based Fitterfly Diabetes CGM digital therapeutics program to improve dietary practices, glycemic control, and weight among people with poorly controlled type 2 diabetes mellitus (T2DM).
Materials and methods
De-identified data of 120 participants with T2DM (baseline HbA1c > 8.0%, mean age: 49.4 ± 12.1 years, female: 30.0% (36/120)) enrolled in the program were analyzed. In week 1, all participants adhered to their usual lifestyle, and blood glucose levels monitored using CGM were correlated with daily meals and lifestyle to understand PGR. In week 2, a modified lifestyle plan was introduced and followed till the end of the program. Participants completed 90 days on the program with access to Fitterfly mobile application which enabled digital logging of meals and physical activity along with remote expert coaching (psychologists, physiotherapists, and nutritionists). The data has been shown as median (IQR).
Results
After 7 days on the modified plan, a significant median increase in TIR by 10.1 (1.3, 24.3)% from a baseline of 56.2 (38.1, 74.3)% and a significant median decrease in TAR by 10.3 (-26.1, -1.4)% from a baseline of 42.4 (19.5, 60.9)% was observed (P<0.0001 for both). After completion of the program, a significant median reduction in intake of calories and fats by 302.5 (-501.4, -111.2) kcal and 12.1 (-24.1, -1.3) gm was observed from a baseline of 1572.0 (1322.0, 1807.0) kcal and 61.2 (49.1, 76.6) gm (P<0.0001 for both). A significant median reduction in weight by -2.0 (-4.0, -1.0) kg was observed (P<0.0001). Participants with baseline HbA1c of 8-10%, 10-12%, and ≥12% showed a reduction in HbA1c by 1.5%, 3.5%, and 5.0% respectively (P<0.001 for all).
Conclusion
Significant changes in the dietary pattern were observed after the completion of the Fitterfly Diabetes CGM program. The program can lead

to improved diabetes management among people with poorly controlled diabetes.

P75

To study and compare the level of various inflammatory markers in diabetic and non diabetic covid 19 patients

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Keywords
• Inflammation in type 2 diabetes

Background and Aims
Background:The host inflammatory response to SARS-CoV-2 infection contributes towards the lung injury seen in patients with COVID-19. However, the pathways involved, how they impact disease severity, remain poorly understood. Identifying mediators that reflect disease severity might allow for the definition of 'treatable traits', and the stratification of patients into the most appropriate clinical care pathways. Diabetes has been described as a chronic inflammatory state evident by raised inflammatory markers such as C-reactive protein (CRP). Hyperglycemia upregulates the expression of proinflammatory cytokines, setting up the stage for a hyper-inflammatory response in acute infection which has been proposed to result in multiorgan failure and death in COVID-19
AIM:To Study and compare various inflammatory markers in Diabetic and Non-Diabetic Covid19 Patients
Materials and methods
METHODS: The retrospective case control study was carried out in Department of Medicine, L.L.R.M. Medical College, Meerut during the first and second waves of Covid-19 pandemic after obtaining ethical clearance. A total of 162 hospital admitted Covid-19 patients were selected randomly. Out of these, 81 were Diabetic cases with 50 males and 31 females. The other, 81 were non-diabetic controls with 53 males and 28 females.
Results
RESULTS: In diabetic group the mean value of serum ferritin was 918.92 vs 822.91 in non-diabetic patients. The mean value of D dimer was 5.54 in diabetic patients vs 3.11 in non-diabetic patients. The mean value of CRP was 76.51 in diabetic patients vs 65.27 in non-diabetic patients. The mean value of ESR was 42.01 vs 22.81 in non-diabeticpatients.
Conclusion
CONCLUSION: The various Inflammatory mediators were found to be much higher in diabetic cases group vs nondiabetic control group. Thus, these mediators can help establish that covid 19 disease leads to a much severe inflammatory response in diabetics vs nondiabetics.

P76

Real-World Outcomes of Fitterfly Diabetes Program on Glycemic Control and Weight Management in people with newly Diagnosed Type 2 Diabetes

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Keywords
• Health care delivery

Background and Aims
Achieving optimal glycemic control and shedding excess weight during the early stages of diabetes can help safeguard β-cell function and minimize the risk of complications. Digital therapeutics (DTx) offer scientifically grounded strategies for fostering lasting changes in behavior that enhance glycemic control. The study assessed the real-world outcomes of lifestyle change with the Fitterfly program in improving glycemic control and managing weight in newly diagnosed Type 2 Diabetes.
Materials and methods
We analyzed deidentified data of 147 participants with T2DM [diabetes duration < 1-year, mean age: 43.74 ± 10.80 years,32.65% (48/147) female]. Participants completed a 90-day program and had access to the Fitterfly mobile application for digital meal and physical activity tracking. They received remote lifestyle coaching and video consultations with experts, including psychologists, physiotherapists, and nutritionists. Baseline BMI was used to categorize the members as normal (≤ 22.9 kg/m²), overweight (23.0-24.9 kg/m²), and obese (≥ 25.00 kg/m²). The outcomes were assessed at the start and end of the program. Data are presented as mean (lower & upper 95%CI).
Results
For all participants, baseline median values were: HbA1c 7.70 (7.40-8.00) %, weight 80 (77-82) kg, and BMI 29 (28-30) kg/m². HbA1c, weight, and BMI were reduced by 1.2 (0.89,1.50) %, 3 (2.50,3.60) kg, and 1.10(0.90,1.30) kg/m2 respectively ($p<0.0001$ for all). Among participants with baseline HbA1c of ≤ 6.4%, 6.5-8.0%, 8.0-10%, and ≥10% the HbA1c was reduced by 0.15 (0.05, 0.26) %, 1 (0.60, 1.50) %, 1.90 (1.40, 2.30) %, and 4.40 (3.40,5.40) % respectively ($p<0.001$ for all). Post-program, 79.59 % (117/147) participants achieved a recommended HbA1c value of ≤7%, and 66.67% (98/147) members exhibited HbA1c ≤6.5. BMI among participants in the normal, overweight, and obese categories was reduced by 0.56(0.29,0.83) kg/m2, 0.77(0.35,1.20) kg/m2, and 1.20(0.98,1.50) kg/m2 ($p<0.02$) respectively.
Conclusion
Lifestyle management with Fitterfly improved glycemic control and facilitated weight loss among individuals recently diagnosed with Type 2 Diabetes. By providing sustained support for the implementation of lifestyle modifications, this program plays a crucial role in the comprehensive management of diabetes.

P77

Effect of FDC of Dapagliflozin, Glimepiride and Metformin ER in Type 2 Diabetes: Subgroup Analysis of patients with baseline HbA1c (8% to 9.5% and >9.5% to 11%)

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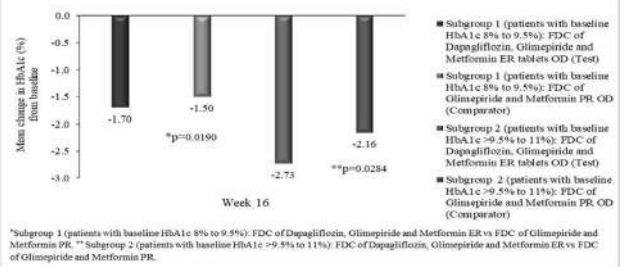
Keywords
• Insulin sensitivity and resistance • SGLT inhibitors • Hypoglycaemia

Background and Aims
Addition of sodium-glucose cotransporter inhibitors to metformin and sulfonyl urea is recommended by ADA and EASD, if glycemic goals are not met. Triple fixed-dose combination (FDC) of Dapagliflozin, Glimepiride, and Metformin can provide superior glycemic control, improve therapy compliance with less risk of weight gain and may have cardio- and reno-protective function. This subgroup analysis evaluated efficacy and safety of triple FDC vs dual FDC combination in patients with baseline HbA1c subgroups.
Materials and methods
This is a subgroup analysis of phase 3, two-arm, open-label, and active-controlled study (CTRI/2022/03/041424) which randomized Indian type 2 diabetes mellitus (T2DM) patients with HbA1c (8%-11%) at screening to receive triple FDC of Dapagliflozin+Glimepiride+Metformin ER tablets (10mg+1mg+1000mg) once daily [OD, Test arm] OR dual FDC of Glimepiride+Metformin PR (1mg+1000mg) OD, Comparator arm for 16 weeks. This subgroup analysis aimed to evaluate glycemic and safety parameters in the 2 subgroups: baseline HbA1c 8%-9.5% (Subgroup 1[S1]) and baseline HbA1c >9.5%-11% (Subgroup 2[S2]) at Week 16.
Results
This subgroup analysis included total 394 patients (S1: Test [n=141], Comparator [n=159]; S2: Test [n=53] and Comparator [n=41]. Reduction in HbA1c was statistically significant from baseline to Week 16 in S1 (Test: -1.70%±0.83% vs Comparator: -1.50%± 0.77%; p=0.0190) and in S2 (Test: -2.73%±1.09% vs Comparator: -2.16±0.99%; p=0.0284), Figure 1. Similar observation was noted from baseline to Week 12. Proportion of patients achieving HbA1c<7% was significantly higher in Test vs Comparator in S1 (59.0% vs 43.0%, p=0.0061) and S2 (34.6% vs 12.2%, p=0.0128), at Week 16. Statistically significant reduction in HbA1c, FBG and PPBG was observed in each group from baseline to Weeks 8, 12, and 16. Study medications were well tolerated.
Graph/Table :

Figure 1: Change in HbA1c at Week 16 in patients with baseline HbA1c subgroups



*Subgroup 1 (patients with baseline HbA1c 8% to 9.5%): FDC of Dapagliflozin, Glimepiride and Metformin ER vs FDC of Glimepiride and Metformin PR. ** Subgroup 2 (patients with baseline HbA1c >9.5% to 11%): FDC of Dapagliflozin, Glimepiride and Metformin ER vs FDC of Glimepiride and Metformin PR.

Conclusion
FDC of Dapagliflozin+Glimepiride+Metformin ER demonstrated superior glycemic control (reduction in HbA1c) compared to FDC of glimepiride+metformin PR at Week 16 irrespective of baseline HbA1c levels which may help to prevent micro and macrovascular complications and delay the need for insulin therapy. Study medications were well-tolerated.

P78

Prescription pattern and effectiveness of empagliflozin and linagliptin FDC in patients with T2DM having comorbidities

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Keywords
• SGLT inhibitors

Background and Aims
Considering the growing prevalence of type 2 diabetes mellitus (T2DM) and frequent comorbidities in affected individuals, investigating the prescription patterns of the empagliflozin (Empa) and linagliptin (Lina) fixed-dose combination (FDC) becomes pivotal. This study aims to shed light on how healthcare practitioners (HCPs) navigate the complexities of T2DM management in the presence of various comorbid conditions, contributing to a more comprehensive understanding of real-world treatment strategies.
Materials and methods
This cross-sectional survey was conducted among HCPs across India between May 2023 and July 2023. The questionnaire included 18 questions. The responses collected were analyzed and presented as descriptive statistics.
Results
A total of 57 HCPs (endocrinologists and diabetologists) participated in the survey. The dosage of Empa 10 mg + Lina 5 mg was the most preferred by 64.9% of HCPs. The majority of the participants preferred using this combination as the third add-on therapy in T2DM patients inadequately controlled on metformin plus other antihyperglycemic drugs (82.5%), followed by patients with T2DM with high risk of atherosclerotic cardiovascular disease (ASCVD) (80.7%). Empa-Lina FDC was preferred by 96.5% of participants in T2DM patients with heart failure (HF). The most compelling reasons to start combination therapy were reported as T2DM patients with HF (45.6%) and T2DM patients inadequately controlled on metformin plus other antihyperglycemic drugs (43.8%). The dose of Empa 25 mg + Lina 5 mg was preferred in T2DM patients with high risk for ASCVD and with HF by 82.5% and 61.4%, respectively, whereas dose of Empa 10 mg + Lina 5 mg was preferred in T2DM patients with ASCVD and with chronic kidney disease (CKD) by 63.2% and 94.7% of HCPs, respectively. Weight loss in obese T2DM patients was the most reported advantage apart from blood glucose reduction by 68.4% of participants. The mean reduction of FBG and PPBG after at least 12 weeks of treatment with Empa-Lina FDC observed was 41.5 (22.3) mg/dL and 72.6 (19.9) mg/dL, respectively. The mean reduction in HBA1c after at least 12 weeks of treatment was 1.6% (0.7). The majority of participants observed improvement in patients with CKD after initiation of Empa-Lina FDC. The commonly reported adverse events were urinary tract infections (10.5%) and gastrointestinal disturbances (5.3%).
Conclusion
Results demonstrate that Empa-Lina FDC is highly preferred not only because of its glycemic benefits but also because of its overall cardio-renal-metabolic effects.

P79

PRE MEAL ALMOND INTAKE AND GLYCEMIC CONTROL (PPBS)

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Keywords
• Nutrition and diet • Education

Background and Aims
TO STUDY THE EFFECT OF PRE MEAL INTAKE OF ALMOND ON PPBS LEVEL IN T2DM PATIENTS
Materials and methods
80 T2DM PATIENTS OF AGE GROUP 40-55 YEARS COMPRISING OF BOTH MALE AND FEMALE, WHO ARE UNCONTROLLED ON METFORMIN 1000 mg BD AND GLIMEPIRIDE 2 mg BD ARE DIVIDED INTO 2 GROUPS OF 40 , AND THE TWO GROUPS ARE NAMED INTERVENTION AND CONTROL GROUP.
INTERVENTION GROUP WERE ASKED TO TAKE 20 gm OF ALMOND 30 MINUTES BEFORE LUNCH AND DINNER AND COUNSELLED FOR STRICT MAINTAINANCE WHILE CONTROL GROUP WERE NOT ASKED TO TAKE ALMONDS.
NO ADDITIONAL EXERCISE REGIME FOR EITHER GROUP.
Results
BOTH THE GROUPS WERE FOLLOWED FOR 4 MONTHS AND THEIR PPBS WERE MEASURED EVERY WEEKLY AND IT WAS FOUND THAT INTERVENTION GROUP HAD AN AVERAGE PPBS FALL OF 46 mg/dl.
Conclusion
T2DM PATIENTS WHO CONSUME 20 gm OF ALMOND 30 MINUTES BEFORE LUNCH AND DINNER CAN HAVE A BETTER GLYCEMIC CONTROL (PPBS)

P80

GREATER TIME SPENT IN GLYCAEMIC CONTROL WITH ORAL SEMAGLUTIDE VS ORAL COMPARATORS

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Keywords
• Incretin based therapies 43 Novel agents

Background and Aims
This exploratory analysis aimed to determine time spent with HbA1c <7.0%, and the likelihood of maintaining this glycaemic target by patients with type 2 diabetes in PIONEER efficacy trials of ≥52 weeks' duration
Materials and methods
Patients in the PIONEER 2, 3, 4 and 7 trials were randomised to oral semaglutide vs active comparators (empagliflozin 25 mg, sitagliptin 100mg, liraglutide 1.8mg once daily). Outcomes were evaluated for oral semaglutide vs active comparators using on-treatment without rescue medication data for all randomised patients. A binary endpoint of achieving HbA1c <7.0% at both week 26 and 52 of each trial (week 78 for PIONEER 3) was analysed using a logistic regression model, with treatment, region and strata as categorical fixed effects and baseline value as a covariate
Results
Mean baseline HbA1c ranged from 8.0 to 8.3%. The median duration of time spent with HbA1c <7.0% was greater with oral semaglutide vs oral comparators. The mean and median duration of time spent in glycaemic control with oral semaglutide was like that seen with liraglutide. Greater proportions of patients had HbA1c <7.0% for ≥38 weeks with oral semaglutide than with empagliflozin (46% vs 28%, respectively) and sitagliptin (PIONEER 3: 45% vs 28%, respectively; PIONEER 7: 27% vs 14%, respectively) but not liraglutide (46% vs 48%, respectively). The odds of patients achieving HbA1c <7.0% at both week 26 and 52 were significantly greater with oral semaglutide vs comparators
Conclusion
In PIONEER trials of ≥52 weeks, oral semaglutide resulted in greater time spent at glycaemic target and a greater likelihood of maintaining glycaemic control vs oral comparators. Patients receiving oral semaglutide spent a similar time in glycaemic control vs liraglutide, despite a longer dose escalation with oral semaglutide

P81

Multifactorial risk reduction with oral semaglutide versus comparators in the treatment of type 2 diabetes

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Keywords
• Incretin based therapies 43 Novel agents

Background and Aims
Therapies that address multiple risk factors may help patients with type 2 diabetes (T2D) to improve their cardiometabolic risk profile. This exploratory analysis aimed to evaluate the efficacy of oral semaglutide in improving multiple cardiometabolic risk factors vs comparators.
Materials and methods
In the PIONEER phase 3a clinical trial programme, patients with T2D were randomised to oral semaglutide 14 mg vs comparators (empagliflozin 25 mg, sitagliptin 100 mg, liraglutide 1.8 mg or placebo [pbo]). This post hoc analysis evaluated the proportion of patients who achieved specific cardiometabolic endpoints (reductions in HbA1c ≥1%, body weight ≥5%, systolic BP ≥5 mmHg or LDL cholesterol ≥0.5 mmol/L or an increase in eGFR ≥0 mL/min/1.73 m2) by the end of the PIONEER 1-8 trials, and the proportion achieving 2,3 and 4 or more of these endpoints. Data were analysed using logistic regression model.
Results
Across trials, greater proportions of patients achieved each endpoint with oral semaglutide vs comparators. Reductions in HbA1c ≥1% occurred in 47.3-77.1% with oral semaglutide vs 32.8-51.4% with

active comparators or 8.5-23.7% with pbo. Reductions in body weight ≥5% occurred in 30.8-49.8% with oral semaglutide vs 12.7-41.0% with active comparators or 5.4-16.3% with pbo. Reductions in systolic BP ≥5 mmHg occurred in 47.9-62.5% with oral semaglutide vs 48.8-59.7% with active comparators or 40.1 – 57.9% with pbo. Reductions in LDL cholesterol ≥0.5 mmol/L occurred in 20.2-27.4% with oral semaglutide vs 13.7-21.1 with active comparators or 12.7-21.7% with pbo. Increases in eGFR ≥0 mL/min/1.73 m2 occurred in 45.1-54.6% with oral semaglutide vs 37.0-50.0% with active comparators or 32.4-44.5% with pbo. Significantly greater proportions of patients achieved improvements in 2,3 or 4 or more endpoints with oral semaglutide vs comparators across all trials.

Conclusion

Multifactorial risk factor management is fundamental to long-term risk reduction in patients with T2D. Oral semaglutide was more effective at improving multiple cardiometabolic risk factors vs comparators, indicating its potential to help address the full cardiometabolic profile for patients with T2D.

P82

Prevalence of chronic Kidney Disease in Type 2 Diabetes patients : A cross sectional study from Western India

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Keywords
Epidemiology • Nephropathy

Background and Aims

Main aim of this study is to estimate prevalence of chronic kidney disease (CKD) in Type 2 Diabetes patients from North Gujarat.

Materials and methods

This Cross-sectional, Observational, single centre study had enrolled five hundred eighty-four patients who visited the Ayush Diabetes Clinic. Enrolment were done after obtaining the written consent. Inclusion criteria involved patients with HbA1C level of more than 6.5% or currently undergoing treatment for diabetes and age more than 30 years and above. Details regarding patients' demographic profile, serum HbA1C, creatinine and spot Urine albumin creatinine ration (UACR)levels, duration of diabetes, anthropometric parameters and eGFR were recorded from each patient.

Results

Mean age of the study participants was 54.8 years with average weight of 69 kg[and was comparable between CKD vs non-CKD patients.. Prevalence of CKD was found to be 54.5% (urinary albumin creatinine ratio (UACR) ≥30 mg/g and/or eGFR <60 mL/min/1.73 m2) in Type 2 diabetes patients. These patients were more male (69%) with relatively older (23 of the patients were more than 65 years of age in contrast to 13% in non-CKD group). A significant difference in the diabetes duration (121 vs 80 months; $p<0.05$) and HbA1C (9.3% vs 8.3%; $p<0.05$) levels was observed between patients suffering from CKD and non-CKD patients. Out of 584, 7% and 32.5% of the patients were suffering from macroalbuminuria and microalbuminuria respectively. Statistically significant difference was observed in patients falling into various stages of CKD with respect to their diabetes duration (mean duration of diabetes in months: normoalbuminuric – 95.24, microalbuminuria – 102, macroalbuminuria – 174; $p<0.05$). Out of 584, 51% of the patients had mildly decreased eGFR whereas 17% had mild to moderate reduction in eGFR. Kidney failure was observed in 0.3% of the patients. Prevalence of hypertension was 5% in CKD patients as compared to non-CKD (3.7%) diabetic patients. Mean systolic and diastolic blood pressure of the study participants were 126- and 79-mm hg respectively.

Conclusion

As Chronic kidney disease is associated with cardiovascular morbidity and mortality, this study highlights the importance of screening Type 2 diabetes for chronic kidney disease. Advanced age, diabetes duration are important risk factors and need to be emphasised from preventive interventions. Identify CKD in early stages of Type 2 Diabetes helps to choose newer drugs which can retard progression of CKD.

P83

Impact of lifestyle intervention on glycemic control and remission in type 2 diabetes patients with normal BMI

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Keywords
• Weight regulation and obesity • Nutrition and diet

Background and Aims

Current evidence supports weight-loss-induced Type 2 Diabetes (T2D) remission in overweight and obese populations. However, T2D among individuals with a normal BMI can be a surprising and complex phenomenon and so could be remission. This study aimed to evaluate the impact of a one-year lifestyle intervention program on glycemic control and T2D remission and to identify factors associated with remission in normal BMI T2D patients.

Materials and methods

Retrospective data was collected from T2D patients with normal BMI (18.5 – 25 kg/m2) participating in a one-year lifestyle modification program (April-December 2021) at the Freedom from Diabetes Clinic, Pune. The intervention comprised of a plant-based diet, physical activity, psychological support, and medical management. Baseline and endline anthropometric and biochemical parameters were analysed. Homeostatic Model Assessment of insulin resistance (HOMA- IR) was calculated using the HOMA2 calculator. Remission was defined as maintaining HbA1c < 6.5% for a minimum of 3 months without the use of antidiabetic medication.

Results

The mean age of the study population (n = 1136, 72.3% males) was 52.3 ± 11 years. Post-intervention, remission was observed in one-fourth (25.2%) of the population. A significant improvement ($p<0.01$) in glycemic control (median HbA1c value decreased from 7.4% to 6.7%) and weight (mean weight reduced from 63.9 kg to 61.9 kg) was observed. A higher likelihood of remission was associated with weight loss > 5% following the intervention

($p < 0.05$). Furthermore, 35% of patients only on oral hypoglycemic agents (OHA) or both OHA and insulin at baseline achieved medication-free status post-intervention. Remission rates were significantly higher among individuals with later disease onset (> 40 years), shorter disease duration (≤ 6 years), lower baseline insulin resistance (HOMA-IR < 2.5), and those with no prior drug history ($p<0.01$).

Conclusion

Factors linked to higher remission rates were weight loss of more than 5%, later disease onset, shorter disease modification that goes beyond traditional obesity-centric strategies to achieve T2D remission among normal BMI individuals.

P84

Ischemia Modified Albumin may be a useful predictor for early detection of Diabetic foot ulcers- A Preliminary Report

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Keywords
• Diabetic foot and skin disorders

Background and Aims

Diabetic foot ulcer (DFU) is one of the major complications of diabetes; high risk of infection and ischemia are usually seen among people with DFU which leads to hospital admissions and amputation. Accurate diagnosis of DFU severity through biomarkers will assist in reducing impact on quality of life. The aim of this study was to investigate the serum Ischemia Modified Albumin (IMA) levels pre and post treatment among people with DFU

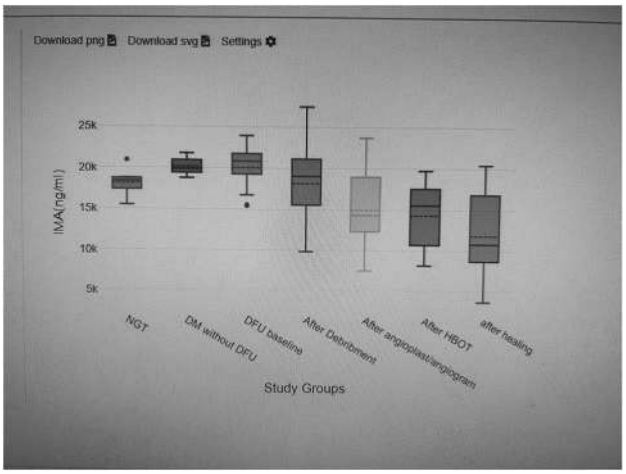
Materials and methods

A total of 37 (M: F19:18) individuals were selected and categorized into 3 groups; normal glucose tolerance (NGT) (N=10), Type2 diabetes without any complications (DM) (N=10), and DM with DFU (N=17). DFU group is further subdivided into 2 groups without peripheral artery disease (nonPAD) and with PAD. Anthropometric, clinical, demographic, biochemical data such as total albumin, ESR and WBC count were recorded. Serum IMA levels were measured using Human IMA ELISA kit (ELK biotechnology) at baseline for all the participants and for DFU cases IMA levels were estimated at 4 intervals i.e. Pre and Post debridement, after HBOT therapy and after healing (after 1 month) in nonPAD and Pre and Post angiogram/angioplasty after HBOT therapy and after healing (after 1 month) in PAD.

Results

Mean age was 51.6±12.8 years. There is no difference between age, lipid profile, urea, creatinine, e GFR. A significant difference was noted in glucose levels, ESR, total albumin, WBC count, and HbA1c in the study groups. Serum IMA levels at baseline in the DFU groups were significantly higher than in the DM and NGT groups ($P < 0.001$), whereas IMA levels when compared at 4 regular intervals showed drastic reduction in people with DFU after 30 days of treatment ($p=0.005$). IMA levels did not show any significant difference after HBOT therapy in people with DFU, might be due to the production of free oxygen radicals during HBOT therapy ($p=0.23$).

Graph/Table :



Conclusion

In this preliminary report IMA was found to be a highly sensitive marker and can be used as a predictor for early detection of DFU.

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Rationale and Study Design of Real-World Effectiveness and Safety of Torsemide and Spironolactone Fixed Dose Combination in Indian Heart Failure Patients (RESTORE-HF Study)

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Keywords
• Cardiac complications

Background and Aims

Heart Failure (HF) is responsible for 1.8 million hospitalizations annually in India. The in-hospital HF mortality rate in India is higher 10–30.8% compared with 4–7% in Western countries. Effective control of congestion or fluid accumulation is the mainstay of HF management. Recent HF guidelines recommend the use of loop diuretics (such as Torsemide) as the principal pharmacologic therapy for decongestion in HF management. Mineralocorticoid receptor antagonists (MRAs) such as Spironolactone blocks aldosterone to minimize fluid retention, relieve symptoms, and lower HF mortality and hospitalizations. The MRAs are recommended by European Society of Cardiology and American College of Cardiology guidelines (Class I -A) for the management of HF with reduced ejection fraction (HFrEF). When taken as a fixed dose combination (FDC), Torsemide and Spironolactone may synergistically manage fluid retention and improve heart failure outcomes. While torsemide and spironolactone are widely administered individually for HF, evidence on their usage as a FDC is limited.

Materials and methods
Real-world effectiveness and safety of Torsemide and Spironolactone FDC in Indian Heart Failure patients (RESTORE-HF Study) is a prospective, longitudinal, multicentre, observational study. The objective of the study is to evaluate the effectiveness and safety of Torsemide and Spironolactone FDC in HF. Overall, 3000 HF patients will be included from 150 study sites across India. The primary endpoint of this study is to evaluate the change in body weight from baseline to 3 weeks. The secondary endpoint is to evaluate the functional effectiveness through change in NYHA functional class from baseline to 3 weeks, and to evaluate safety of the FDC and to analyse the demographic characteristics, comorbidities, and concomitant medications in HF patients. Data will be recorded from the timepoint when the patient was initiated on Torsemide plus Spironolactone FDC as part of routine clinical practice.
Conclusion
The RESTORE-HF study is expected to reveal the real-world effectiveness and safety of the FDC of Torsemide and Spironolactone in HF patients. Moreover, the study will identify the demographics, comorbidities, and clinical and laboratory parameters of HF patients in India.

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A study of autoantibodies their associa,on with clinical characteris,cs in Type 1 DM subjects from South India

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Keywords
Type 1 Diabetes, AutoanLbody level, GAD65, IA2, IAA, C-pepLde

Backgrounds and Aims
Type 1 diabetes is a complex, chronic metabolic condiLon which causes hyperglycemia due to autoimmune or idiopathic destrucLon of the pancreaLc beta cells leading to absolute insulin deficiency. Here, we study the autoanLbody level distribuLon in Type 1 diabeLcs which can help in diagnosis, and correlate it with the paLents clinical characterisLcs.
Materials and methods
A cross secLonal study was conducted in a terLary care center in South India – clinically diagnosed type 1 diabeLcs were included in the study. 453 paLents were included consecuLvely and the following parameters were studied in them and correlated : Age, Sex, BMI, DuraLon of diabetes, GAD anLbody, IA2 anLbody, IAA anLbody, HbA1c, non fasLng C-pepLde levels.
Results
Of the 453 paLents, the age range was from 3-60 years, with an average age of 16.7 +/- 7.5 years. 252 (55.6 %) were male and 201 (44.4 %) were female. The mean BMI was 19.6 +/- 4.4 kg/m2, while most of the subjects 46.4 % were lean having a BMI < 18.5, a small percentage of 12.1 % were obese with a BMI > 25.
The mean HbA1c was 10.3 +/- 2.5 % and mean duraLon of diabetes was 8.4 +/- 6.5 years. 155 of the total paLents (34.2 %) were GAD posiLve, 145 (32 %) were IA2 posiLve, and 22 (4.9 %) were IAA posiLve. Only 13.2 % paLents had a posiLve non fasLng C-pepLde level. Of those with duraLon of diabetes less than 1 year, GAD posiLvity was seen in 48.1 % but decreased to 29.5 % in those with diabetes duraLon > 10 years. While IA2 posiLvity was only 18.5 % in diabetes < 1 year, but 32.7 % in diabetes duraLon > 10 years.
Conclusion
A significant number of type 1 DiabeLcs may be autoanLbody negaLve at presentaLon, in which case C-pepLde levels and clinical judgement would help in the diagnosis.
GAD anLbody would be a becer autoimmune marker in those with newly diagnosed diabetes in suspected type 1 diabeLcs, while IA2 and GAD anLbodies could both be used for diagnosis in those with long standing diabetes.