LATE BREAKING ABSTRACTS

Abstract #1300

ACHIEVING A COMPOSITE ENDPOINT OF A1C, BODY WEIGHT, AND SYSTOLIC BLOOD PRESSURE REDUCTION WITH CANAGLIFLOZIN IN PATIENTS WITH TYPE 2 DIABETES

Katherine Merton, PhD, MBA1, Michael Davies, PhD2, Ujjwala Vijapurkar, PhD2, Doreen Inman, PharmD, MBA, BCPS, CDE1, Gary Meininger, MD2


Objective: Achieving glycemic control, weight loss, and blood pressure (BP) reduction are important components of type 2 diabetes mellitus (T2DM) management as many patients with T2DM are overweight/obese and/or have hypertension. Canagliflozin (CANA), an SGLT2 inhibitor, has demonstrated improvements in glycemic control along with reductions in body weight and BP in patients with T2DM. This post hoc analysis evaluated achievement of a composite endpoint of A1C, body weight, and systolic BP (SBP) reduction with CANA versus placebo (PBO).

Methods: This analysis was based on pooled data from four 26-week, randomized, double-blind, PBO-controlled, Phase 3 studies in patients with T2DM (N = 2,313; mean age, 56 y; A1C, 8.0%; body weight, 89 kg; SBP, 128 mmHg). The proportion of patients with T2DM achieving the composite endpoint of A1C reduction ≥0.5%, body weight reduction ≥3%, and SBP reduction ≥4 mmHg at Week 26 (21.1%, 25.3%, and 5.7%, respectively; differences vs PBO [95% CI] of 15.4% [12.0, 18.9] and 19.6% [16.0, 23.2]) was generally well tolerated, with a safety profile similar to that seen in across Phase 3 CANA studies.

Conclusion: Patients with T2DM were more likely to achieve clinically important reductions in A1C, body weight, and SBP with CANA versus PBO.

Abstract #1301

LIRAGLUTIDE ACUTELY INHIBITS GLUCAGON, LIPOLYSIS AND KETOGENESIS IN TYPE 1 DIABETES

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Objective: In view of the occurrence of diabetic ketoacidosis associated with the use of SGLT2 inhibitors in patients with type 1 diabetes and absence of this complication in patients treated with liraglutide in spite of reductions in insulin doses, we investigated the effect of liraglutide on ketogenesis.

Methods: Sixteen patients with inadequately controlled type 1 diabetes on CSII (mean age: 40 years; mean HbA1c: 7.7%) were divided into two groups of 8 patients each. They were maintained on their basal insulin infusion and were followed up in our clinical research unit for 5 hours after an overnight fast. Eight patients were injected with liraglutide 1.8 mg and the other 8 were injected with placebo.

Results: The patients injected with placebo maintained their glucose and glucagon concentrations without an increase but there was a significant increase in FFA (from 0.3 to 0.5 mM), acetoacetate (from 0.4 to 0.75 mM and β-hydroxybutyrate (from 0.22 to 0.5 mM) concentrations. In contrast, liraglutide significantly reduced the increase in FFA, and totally prevented the increase in acetoacetate and β-hydroxybutyrate concentrations while suppressing glucagon concentrations (from 82 to 65 ng/L) as well.

Discussion: Our data show clearly that inadequately controlled patients with type 1 diabetes on basal insulin who maintain fasting blood glucose concentrations without further increase, experience an increase in FFA concentrations. In contrast, liraglutide significantly reduced the increase in FFA, and totally prevented the increase in acetoacetate and β-hydroxybutyrate concentrations while suppressing glucagon concentrations (from 82 to 65 ng/L) as well.

Conclusion: We conclude that acute treatment with liraglutide...
Abstract #1302

COMPARISON OF COMPUTER-GUIDED VERSUS STANDARD INSULIN INFUSION REGIMENS IN PATIENTS WITH DIABETIC KETOACIDOSIS

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Objective: Continuous insulin infusion (CII) is widely accepted as the standard of care for the treatment of patients with diabetic ketoacidosis (DKA). A variety of standard (paper form-based) and computer-based algorithms have been shown to be effective in the management of hyperglycemia in critically ill patients. It is not known, however, if computer-based algorithms are superior to standard protocols in the management of patients with DKA.

Methods: Accordingly, this retrospective multicenter study was conducted, comprised of 2,665 patients with DKA treated with either a computer-guided program (Glucommander [GM], n= 1750) or standard protocols [SP] (n=915) in 34 medical institutions in the US. Assessments were made for differences in time to resolve hyperglycemia (<200 mg/dL), acidosis (HCO3 < 18 mmol/L), and the number of hypoglycemic events (BG <70 mg/dL and <40 mg/dL). Average blood glucose (BG) was higher on presentation 598 mg/dL GM v. 425 mg/dL SP; p<0.001 and serum Bicarbonate lower 13.6 mmol/L GM v. 17.3 mmol/L; p<0.001.

Results: Use of GM resulted in shorter time to BG < 200 mg/dL ( 9.1 v. 11.0 hour; p<0.001) with fewer hypoglycemic events: BG<70 mg/dL (13% GM v. 35% SP; p<0.001), BG<40 (0.5% GM V. 6.6% SP; p<0.001) and shorter median hospital length of stay: 3.2 days GM v. 4.5 SP; p<0.001.

Discussion: In conclusion, use of a computer-based insulin dosing algorithm was safe and provided more rapid achievement of BG <200 mg/dL and resolution of acidosis (bicarbonate >18 mmol/L) than use of standard (paper) based orders. Despite patients on GM having higher overall initial BG and lower bicarbonate time to resolution of acidosis and attaining BG < 200 mg/dL was quicker with use of GM than SP.

Conclusion: In conclusion, the use of Glucommander is safe and is associated with significantly less hypoglycemia and shorter median length of hospital stay than standard orders for treatment of DKA. Prospective randomized clinical trials comparing the safety, efficacy and costs of computer-based algorithms versus standard CII regimens are warranted.

Abstract #1303

TYPE 1 DIABETES MELLITUS, DIABULIMIA, AND AN SGLT2 INHIBITOR RESULTING IN SEVERE EUGLYCEMIC DIABETIC KETOACIDOSIS

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Objective: Eating disorders (ED) are common in women with type 1 diabetes mellitus (T1DM). A specific form of ED is diabulimia, the withholding of insulin treatment for weight loss through hyperglycemia. The aim of this report is to present a case of euglycemic ketoacidosis in a patient with T1DM and diabulimia who repeatedly used canagliflozin (SGLT2I) for suspected weight control.

Case Presentation: A 27 year-old female with a history of T1DM (age of 3) and an ED that developed in adolescence presented with weakness. The patient reported that at home, she took Glargine 15 units at bedtime and canagliflozin. She did not use pre-meal insulin. Laboratory results revealed a blood glucose level of 134 mg/dL, an anion gap of 25, elevated serum ketones, serum bicarbonate of 6 mg/dL, pH of 7.08, all consistent with euglycemic DKA. The patient was started on intravenous hydration, sodium bicarbonate, and an insulin drip. The metabolic acidosis was refractory to treatment and continuous veno-venous hemodialysis was employed. After recovery, she admitted to omitting her pre-meal insulin for the purpose of purging. She had been admitted in 2014 with hyperglycemic DKA and was taking canagliflozin at that time. At discharge she was instructed not to use canagliflozin. Another treating endocrinologist had asked her to stop taking canagliflozin in 2015 after the FDA alert of the risk for euglycemic DKA. Despite these warnings, she willingly accepted treatment with canagliflozin by her primary care physician prior to this admission. Upon discharge, she was instructed not to use any type of SGLT2I and was referred for inpatient management of her eating disorder.

Discussion: This is a unique case of a patient with T1DM and an ED who knowingly used canagliflozin for glycemic control and weight management. A literature search was unable to find a similar report. Studies of therapeutic effects of SGLT2I in individuals with T1DM have shown favorable effects on reducing HbA1c, body weight, and total daily insulin dose have been reported. The 2015
FDA warning of SGLT2I therapy and concomitant DKA did acknowledge that cases occurred in T1DM, in which increasing off-label use of SGLT2I was observed, due to the favorable insulin-independent glucose-lowering, and weight-loss effects. The etiology of DKA with SGLT2I is multi-factorial and includes raised glucagon levels in an under insulinized state, placing a patient such as ours who was practicing insulin purging at high risk.

**Conclusion:** Clinicians must pay special attention to patients with T1DM with eating disorders not only for insulin purging behavior but also for the risk of SGLT2I use as a potential means of weight control both of which can result in life threatening DKA.

Abstract #1304

**A STUDY TO DEVELOP A NOVEL PATIENT-REPORTED (PRO) INSTRUMENT TO ASSESS SATISFACTION WITH ACROMEGALY TREATMENT: THE ACRO-TSQ**

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**Objective:** Somatostatin analogs (SSAs) are primary medical treatment for acromegaly, but have been limited to intramuscular or subcutaneous injections. While an oral SSA formulation is in development, there are currently no patient-reported outcome (PRO) instruments available to assess treatment satisfaction/burden related to route of administration (including the potential use of an oral SSA). The goal of this study was to develop a new acromegaly-specific treatment satisfaction questionnaire, herein referred to as Acro-TSQ. The new 29-item Acro-TSQ covers symptoms/symptom control, gastrointestinal SE and ISR and their impact on daily activities, emotional impact of treatment, convenience/ease of use, and overall satisfaction.

**Conclusion:** Patients with acromegaly experience symptoms and SE from their condition and treatment, which may impact daily life. Acro-TSQ, a novel PRO instrument designed to measure treatment satisfaction/burden related to route of administration, was found to be comprehensive, clear and relevant and is currently being validated in an ongoing study (N=79).

Abstract #1305

**INCIDENCE OF NEW DIABETES FOLLOWING CABG SURGERY: ANALYSIS OF A SINGLE CENTRE REGISTRY DATA.**

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**Objective:** In non-diabetics undergoing coronary bypass surgery, the risk of subsequently developing Type 2 diabetes is not known. To determine the incidence of new diabetes and the impact of diabetes on ICU and hospital stay in patients undergoing CABG surgery (normothermic) we performed this study. Our primary objective was to analyze the hypothesis - CABG surgery per se poses a risk factor for development of diabetes amongst euglycemic and prediabetics.

**Methods:** Prospectively collected data among consecutive adult cardiac surgical patients who underwent CABG surgery was analyzed. The institutional ethics committee clearance was obtained to analyze the data and hospital authorities permitted the use of anonymized data of individual patients.
**Abstracts – Late Breaking**

**Results:** 1559 subjects, males-1355, females - 254 were analyzed, 933 were non-diabetics and 626 diabetics. Among the 933 non-diabetics patients, 57 patients (6.1%) continued to have persistently high glucose levels at discharge from the hospital at a mean 11.7 ± 5.7 days after CABG surgery. These cases were diagnosed as diabetes de novo or New Onset Diabetes After CABG, at discharge from the hospital. The incidence rate was 61/1000. There was a strong correlation between the duration of ICU stay and development of diabetes (r=0.138, P<0.001) and overall hospital stay and development of diabetes (r=0.163, P<0.001). 44.6 % of the patients who developed diabetes after CABG surgery had IGT (random glucose >140 mg/dl) preoperatively as compared to only 13.7 % of subjects in the non diabetic group.

**Discussion:** Our study shows that although CABG surgery restores vascularization, it introduces a new cardiovascular risk- diabetes mellitus. In non-diabetics undergoing CABG surgery, the risk of subsequently developing diabetes is not known. Prediabetes and stress of CABG surgery itself can lead to new onset diabetes soon after surgery. Postoperatively, higher blood glucose is observed in the hypothermic CABG surgery, our all patients underwent normothermic surgery. Considering the rate of conversion of IGT to overt diabetes as about 5-6% per year a figure of 61/1000 is quite surprisingly huge. In these patients the stress of surgery, inotrope usage and prolonged duration of ICU stay could be the responsible factors. Development of diabetes in non-diabetic patients soon after CABG carries important economic implications.

**Conclusion:** This study shows that CABG surgery per se can produce new diabetes. This is more likely in susceptible individuals who have prediabetes or carry other risk factors for diabetes. In these patients the stress of surgery, inotrope usage and prolonged duration of ICU stay could be the contributory factors.

**Abstract #1306**

**IMPROVED INPATIENT HYPOGLYCEMIA RATES WITH ELECTRONIC GLYCEMIC MANAGEMENT SYSTEM**

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**Objective:** Hypoglycemia is a common adverse event for patients treated with insulin in the hospital. Fear of hypoglycemia commonly leads clinicians to deviate from best practice recommendations for inpatient insulin management (e.g. basal bolus). The aim of this study is to compare hypoglycemia rates for inpatients treated with insulin managed on an electronic Glycemic Management System (eGMS) vs. patients managed by Usual Care (UC).

**Methods:** 13,351 patients treated with eGMS and 45335 patients treated with UC were studied. The target blood glucose (BG) was set at 100-180 mg/dL. We evaluated the percent of patients experiencing mild to moderate hypoglycemia (BG: <70, <60, <50 mg/dL) and severe hypoglycemia (BG <40 mg/dL) on eGMS vs. UC. Admission blood glucose and mean blood glucose were also measured for both groups. Known risk factors for hypoglycemia, such as renal insufficiency, poor nutritional intake, or prior hypoglycemia are incorporated into the eGMS insulin dosing algorithm.

**Results:** The incidence of patients experiencing any hypoglycemia (BG <70 mg/dL) was 13.8% for eGMS vs. UC at 21.7%. Rates with eGMS were uniformly lower than with UC: BG < 60 mg/dL 6% v. 13.7%, BG < 50 2.5% v. 7.7%. Severe hypoglycemia experienced with UC was 4-fold higher than eGMS (3.6% v. 0.9%). Overall BG seen with eGMS were lower 178 mg/dL compared to UC 188 mg/dL.

**Discussion:** A lower rate of hypoglycemia at all levels was seen with eGMS compared to UC. This suggests that the ability to achieve glycemic control with less hypoglycemia is enhanced by using best practice methodologies coupled with algorithms that recognize known patient risk factors for hypoglycemia.

**Conclusion:** The eGMS had lower rates of hypoglycemia and lower average BG compared to UC. Achievement of glycemic targets with minimal hypoglycemia may be accomplished by utilization of features that target known risk factors for hypoglycemia and titrate insulin to goal using a prescribed BG target range.

**Abstract #1307**

**GLP-1RECEPTOR AGONISTS REVERSE ALBUMINURIA**

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**Objective:** Exenatide exerts an ROS suppressive and anti-inflammatory effects and promotes the Nrf-2 dependent anti-oxidant genes (NQO-1, GST-1P and HO-1). This led us to hypothesize that exenatide and possibly other GLP-1 receptor agonists may be nephroprotective.

**Methods:** A series of 466 patients were studied sequentially
over a period of 3 years for the evolution of albuminuria. 

**Results:** Of the patients who were on GLP-1 receptor agonists (on exenatide and liraglutide, group A) and had macroalbuminuria, 23% became microalbuminuric and 2.8% became normoalbuminuric at one year while in those on other anti-diabetic drugs (group B), only 12.3% became microalbuminuric and none became normoalbuminuric (p=0.0005). In those with microalbuminuria in group A, 25.1% became normoalbuminuric while none developed macroalbuminuria. In those microalbuminuric patients in group B, 4.6% developed macroalbuminuria per annum and only 6.9% became normoalbuminuric (p<0.0001). In patients who were normoalbuminuric and in group B, 2.3% became microalbuminuric and 0.4% developed macroalbuminuria. In comparison, those normoalbuminuric patients in group B, 4.4% developed microalbuminuria and 0.36% developed macroalbuminuria. There was no significant difference in HbA1c between those on GLP-1RA and other drugs. The systolic blood pressure at the end of follow up was lower by 3mm in the group on GLP-1RA. The unexpected deterioration of albuminuria in those on GLP-1RA was associated with inadequate glycemic control. Over a 3 year follow up, those on GLP-1RA had a mean decrease of albuminuria by 39.6 mg/g (from 88.8 to 50.0; p<0.0001) against a mean increase of 5.6 mg/g (from 81.1 to 87.2) in those on other drugs.

**Discussion:** GLP-1RA treatment was associated with a significant reversal of albuminuria in patients with macroalbuminuria and microalbuminuria and a significant reduction in progression to albuminuria in those with normoalbuminuria when compared with patients treated with other drugs. The differences in albuminuria between the two groups are independent of glycemic control.

**Conclusion:** On the basis of the above data, it is clear that treatment GLP-1RA not only helps to reverse established albuminuria, but also prevents development of albuminuria when compared to other anti-diabetic drugs.

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**Abstract #1308**

**U200 LISPRO IMPROVES GLUCOSE CONTROL COMPARED TO U500 REGULAR INSULIN IN CONTINUOUS SUBCUTANEOUS INSULIN INFUSION (CSI) IN PATIENTS WITH DIABETES WITH HIGH INSULIN REQUIREMENTS**

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**Objective:** Patients with high (>200 units/d) insulin requirements may benefit from use of U500 insulin in CSI to improve glycemic control over U100 insulin regimens. However, U500 insulin in CSI has a delayed time-action profile and long duration of action which may worsen postprandial hyperglycemia and lead to delayed hypoglycemia from “stacked” insulin doses. U500R insulin also must be dosed 30 to 60 minutes prior to meals. U200 lispro is a novel twice concentrated formulation of the rapid-acting insulin analogue lispro with a more rapid pharmacodynamic profile and less propensity for stacking which can meet the dose requirements of these patients. This pilot study of 10 patients using U500 insulin via CSI was undertaken to assess the feasibility of U200 lispro in CSI to improve overall and postprandial glucose control and improve the timing of meal boluses.

**Methods:** 10 patients with T2DM and 1 with T1DM using U500R insulin in CSI with stable pump settings were recruited at office visits in November of 2015 to participate in a pilot study of U200 lispro in CSI for a 4 week trial. Patients underwent baseline HbA1c and 7 day continuous glucose monitor (CGM) study (Dexcom) on U500R insulin, then were switched to U200 lispro at equivalent pump settings for basal infusion rates, bolus ratio and correction doses. Insulin-on-board time was changed from 6 hours for U500 insulin to 3 hours for U200 lispro. Patients were instructed to bolus at the beginning of each meal. Patients used U200 lispro via CSI for 2 weeks, had pump settings adjusted if necessary, and continued U200 lispro for an additional 4 weeks followed by a second CGM study and HbA1c.

**Results:** Conversion of U500R insulin to U200 lispro in CSI for 4 weeks resulted in similar glycemic control (HbA1c) with a 9% decrease in total daily insulin dose (p = 0.15) and a mean aggregate post-prandial glucose reduction of 20.5 mg/dl (p = NS). Post-meal glucose reductions were 20 mg/dl after breakfast, 27 mg/dl after lunch, and 15 mg/dl after supper after switching from U500R insulin to U200 lispro by CSI for 4 weeks. Time spent in the target BG range (80 – 180 mg/dl) by CGM increased from 43% to 59% (p = .046). Patients expressed
higher satisfaction with U200 lispro by CSII owing to the ability to bolus immediately before eating with 9 out of 10 patients preferring to remain on U200 lispro.

**Conclusion:** U200 lispro via CSII improves time spent in euglycemia by CGM with a trend towards improved post-prandial glucose control. Patient satisfaction improved using U200 lispro compared to U500R insulin in CSII. Further studies of U200 lispro in CSII in high dose insulin patients are indicated.

**Abstract #1309**

**A PROSPECTIVE, OPEN LABEL, PARALLEL GROUP, RANDOMIZED CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFECT OF FLAVOURED OATS IN PRE-DIABETES SUBJECTS**

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**Objective:** The primary objective of the study was to evaluate the effect of flavoured oats as a part of breakfast in pre-diabetes using Ambulatory glucose profile (AGP) and Satiety.

**Methods:** A prospective open parallel group study in India was planned. A total of 60 subjects with age between 30 – 45 years of either sex were included in the study, who were Pre-diabetics and had willingness to maintain current activity levels as well as to follow the prescribed diet were included in the study. The study consisted of two groups: viz., Test group and Control group. Test Group (Group I) consumed flavoured oats for breakfast. Control Groups (i.e., Group II) consumed traditional breakfast.

The primary outcome measures consisted of ambulatory blood glucose for 14 days compared to baseline as well as satiety and fullness. The secondary outcome measure included improvements in Fasting blood glucose, Post Prandial blood glucose for 14 days compared to baseline as well as in weight management.

**Results:** The mean FBG and PPBG glucose between test and control were not significant (FBG p<0.052, PPBG: p<0.001) but a trend for lower glycemic variability at the end of 14 days. The Mean VAS score of food satisfy the appetite [1.62 ± 2.14 (p value <0.05)], feeling energetic [1.70 ± 1.98 (P value 0.001)], feeling hungry between meals [-1.81 ± 2.08 (P value 0.001)], food craving [*-1.28 ± 1.26(P value 0.001)], strong food craving [*-3.47 ± 3.23 (p value 0.001)], resist food craving [*-1.07 ± 1.20 (p value 0.001)], response to food craving [*-1.16 ± 1.20 (p value 0.001)] and control on eating [*-2.83 ± 2.95 (p value 0.001)] when compared; the change was significantly more in Test than Control.

**Conclusion:** We conclude that flavoured oats in breakfast in pre-diabetics contributes to lower glucose variability and statistically significant impact on satiety and fullness. Therefore functional foods like flavoured oats may have a role in lowering glycemic variability in pre-diabetics as well as in weight management.

**Abstract #1310**

**EVALUATING THE EFFICACY OF BLENDED OIL IN COMPARISON WITH ANTI-OXIDANTS IN OLIVE OIL**

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**Objective:** The primary objective of the study was to evaluate the effect blended edible oil on Low density lipoproteins (LDL) level in comparison with the control groups contains three variants of olive oil.

**Methods:** The study consisted of four groups; viz., Test group and three Control groups. Test Group (Group I) consumed food prepared in a blend of Rice Bran Oil and Safflower Oil (70:30) with antioxidants. Control Groups (i.e., Group II, III and IV) consumed food prepared in commercially available edible Olive Oil (Olive Oil 1, 2, 3). The primary outcome measures consisted of LDL values on Day 90 of study compared to baseline. The secondary outcome measures included improvements in Total cholesterol (TC), high density lipoprotein (HDLC), very low density lipoprotein (VLDL) and triglyceride (TG) values, Apo-lipoproteins A1 & B values, Oxidized low-density lipoprotein (Ox LDL), Superoxide Dismutase (SOD) on Day 90 compared to baseline.

**Results:** Low density lipoprotein cholesterol (LDL-C) showed a decrease of -44.27 ± 18.68 mg/dl, -19.04 ± 14.87, -18.61 ± 10.75 and -25.61 ± 14.23 mg/dl (p < 0.001 by ANOVA) from baseline in test and control groups respectively during 3 months. Similarly for total cholesterol (TC) there was a reduction of -48.30 ± 18.96, -21.96 ± 17.78, -21.94 ± 15.09 and -29.07 ± 16.30 mg/dl (p < 0.001 by ANOVA) from baseline in test and control groups respectively during 3 months. Therefore functional foods like flavoured oats may have a role in lowering glycemic variability in pre-diabetics as well as in weight management.
03.75) (p < 0.001 by ANOVA, between the groups). Apo B, OxLDL and SOD showed improvement of -06.17 ± 20.99 units/dL, -06.73 ± 03.23 and 00.010 ± 00.015 mg/L in test group. An increase of ApoB: 02.11 ± 18.17, 02.89 ± 21.92, -1.94 ± 15.45; OxLDL: 000.02 ± 04.33, -00.67 ± 03.85, 00.41 ± 4.91; SOD: -00.004 ± 00.016, -00.003 ± 0.014 and -00.001± 0.016 was seen in the control group respectively (p < 0.001 by ANOVA, between the groups for SOD and OxLDL); (p < 0.029 by ANOVA for Apo B). The Test Group product showed statistically significant reduction in TC, TG, VLDL & rise in HDL-C compared to the control groups. Ox-LDL, Apo-B and SOD showed statistically significant improvement in the Test group as compared to the controls, but not so in Apo-A1.

**Conclusion:** Results support the test hypothesis that consumption of RBO & Safflower Oil as a blend with antioxidants in 70:30 proportion reduces selected risk factors implicated in causation & progression of Atherosclerotic Heart Disease.

**Abstract #1311**

**SAROGLITAZAR IN NON-ALCOHOLIC FATTY LIVER DISEASE**

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**Objective:** To evaluate the safety and efficacy of saroglitazar in patients with non-alcoholic fatty liver disease (NAFLD) associated dyslipidemia.

**Methods:** This is a single centre, single arm, prospective, open label study of saroglitazar. Patients with type 2 diabetes and associated dyslipidemia were screened for the presence of NAFLD through ultrasound elastography (fibroscan). Only patients who had sonographic evidence of NAFLD were included in this study. Total 221 patients with type 2 diabetes, dyslipidemia and NAFLD were identified and included in this study. The baseline demographics of the patients were; mean age 58 years, 58.37 % male participants, mean BMI 28.9 kg/m2. The average duration of diabetes was 6.5 years. All patients were on on-going antidiabetic medications. At baseline, 47.96 % of patients were on statin therapy. The baseline HbA1c and TG levels were 8.9 % and 321 mg/dL respectively. Saroglitazar 4mg once daily was initiated in all patients and follow-up was done at 12 week and 24 week period. Standard lipid lowering and anti-diabetic as per usual care were continued.

**Results:** At 24 weeks follow-up, the triglycerides level was reduced to 129 mg/dL (p<0.001). Glycosylated hemoglobin (HbA1c) was reduced from 8.9 % to 8.1% at 24 week treatment of saroglitazar. At 24 weeks follow-up, 86 patients out of 221 showed sonographic improvement in fatty liver and 68 cases showed normalization of liver enzymes. The serum alanine aminotransferase (ALT) value was reduced form 89 U/L at baseline to 21 U/L at 24 weeks treatment of saroglitazar. No any adverse event reported.

**Discussion:** NAFLD and non-alcoholic steatohepatitis (NASH) are hepatic manifestation of metabolic syndrome. Currently all therapies of NAFLD and NASH are experimental. Saroglitazar is a novel dual PPAR α and γ agonist available for the last 2 years in India for the treatment of diabetic dyslipidemia. Saroglitazar has been found to be safe and effective in pivotal phase 3 randomized, controlled clinical trials conducted in patients with hypertriglyceridemia in type 2 diabetes. In current study, 39% patients of diabetic dyslipidemia showed improvement in fatty liver on fibroscan evaluation. A biopsy driven randomized, controlled clinical trial is required to establish the efficacy of saroglitazar in patients with NAFLD and NASH.

**Conclusion:** Saroglitazar can be a potential therapeutic option for the treatment of NAFLD and NASH associated with metabolic syndrome.

**Abstract #1312**

**PRIMARY ALDOSTERONISM: UTILITY OF LEFT ADRENAL VEIN ALDOSTERONE RATIO TO PREDICT UNILATERAL DISEASE**

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**Objective:** It has been suggested that the aldosterone:cortisol ratio of the left adrenal vein when compared to the ratio in the inferior vena cava (LAV/IVC) can accurately discriminate between unilateral and bilateral disease in the setting of failed cannulation of the right adrenal vein (RAV) in patients with primary aldosteronism (PA) undergoing adrenal venous sampling (AVS). We aimed to evaluate this against a large cohort of patients with PA.

**Methods:** Retrospective analysis of prospectively collected data was performed for patients with PA who underwent AVS between 2010-2016 at a single institution. Inclusion criteria were a conclusive diagnosis of PA and successful bilateral AVS as confirmed by LAV/IVC and RAV/
IVC cortisol ratio >5:1 during continuous cosyntrpin infusion. Unilateral disease was defined by an aldosterone lateralization ratio (ALR) \( \geq 4 \) on AVS and an undetectable plasma aldosterone concentration following unilateral adrenalectomy off spironolactone/eplerenone. Bilateral adrenal aldosterone hypersecretion was defined as an ALR<3. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of previously published LAV/IVC aldosterone ratio thresholds of \( \geq 5.5 \) for left and \( \leq 0.5 \) for right-sided disease were then determined by utilizing our patient cohort for the purposes of validation. We evaluated the ability of the test to discriminate unilateral from bilateral disease, and the ability to predict the presence of right or left unilateral disease.

**Results:** Inclusion criteria were met in 120 patients: 57 with bilateral and 63 with unilateral disease (33 left, 30 right). All AVS procedures were performed by a single experienced interventional radiologist with a 95% success rate. LAV/IVC aldosterone values were different between unilateral and bilateral disease (\( P<0.0001 \)) with the following ranges: right 0.03-1.3, left 0.7-13.6, and bilateral 0.54-11.8. Cortisol-corrected LAV/IVC aldosterone ratio utilizing cutoff values of >5.5 and <0.5 yielded sensitivity of 55%, specificity of 91%, PPV of 88% and NPV of 65% overall. For right unilateral disease, the cutoff values gave sensitivity of 77%, specificity of 100%, PPV of 100% and NPV of 93%. For left unilateral disease, cutoff values gave sensitivity of 36%, specificity of 94%, PPV of 71% and NPV of 80%.

**Conclusion:** Cortisol-corrected LAV/IVC aldosterone ratio with a cutoff value of <0.5 performed well in identifying patients with right-sided unilateral disease. However, utilization of LAC/IVC aldosterone ratio of >5.5 would have resulted in unilateral adrenalectomy in 29% of patients with bilateral disease. Therefore, a cutoff of 5.5 cannot be reliably used to identify left-sided unilateral disease.

**Abstract #1313**

**IDENTIFYING BARRIERS AND USING NOVEL TECHNIQUES TO IMPROVE MANAGEMENT OF UNCONTROLLED DIABETES: TEAM DM STUDY**

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**Objective:** Diabetes mellitus (DM) is a major cause of morbidity and mortality which requires vigilant patient self-management to minimize the risk of developing long-term complications associated with significant increases in patient morbidity, mortality, and healthcare costs. The goal of the Telephonic Engagement for Advanced Management of Diabetes Mellitus (TEAM-DM) study was to demonstrate an improvement in the hemoglobin A1c, identify of barriers to care and assess self-rated confidence in achieving disease management goals.

**Methods:** This was a mixed-methods interventional prospective cohort study conducted between June 2015 and January 2016. Adult patients (n=46, age 55 ± 8 years) with an HbA1c >9% were called and enrolled in a Diabetes Care Plan (DCP). Practitioners reviewed with patients their HbA1c, medications and diabetes management. Motivational interviewing was used to identify and encourage lifestyle changes and assess self-rated confidence in disease management. Repeat A1c along with BMP were obtained at 24 week follow up. The primary endpoint was a reduction in HbA1c. Secondary objectives included identifying barriers to care and effective lifestyle modifications.

**Results:** Completion of a DCP had a positive effect with a significant reduction in HbA1C, average 14.9% (CI 97% P≤0.05), on 24 week follow up. The most common pharmacotherapies used were insulin (58.14%) and metformin (55.81%). Patients with private insurance demonstrated greater improvement compared to Medicare (A1c 14.9% vs 8%). Medical comorbidities (26%) and financial hardship (21%) were the most frequently identified barriers to optimal disease control. The most common self-reported lifestyle change was improved diet. Further regression analysis demonstrated a strong correlation between A1C improvement and patient confidence and other patient behavior predictors (patient goals and importance of making a change). We developed a general linear model for predicting patient progress using multivariate criteria.

**Discussion:** There exists a need to improve patient compliance especially of patients with uncontrolled disease. Enrolled patient demonstrated a significant improvement in A1c and we were able to demonstrate a positive correlation between patient confidence and A1c improvement. Additionally, our study is the first is able to identify and overcome barriers of care to these difficult to manage patients.

**Conclusion:** Completion of the DCP via telephone interviews is a simple, cost-effective complement to traditional clinic visits in improving HbA1C and increasing patient engagement. It is especially significant in medicine today where patient compliance and disease control are used to measure physician success and reimbursement.
Abstract #1314

EVALUATION OF TENELIGLIPTIN ACROSS THE INDIAN URBAN SETTING- INITIAL REAL WORLD EXPERIENCE

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Objective: Teneligliptin is the recent DPP IV inhibitor introduced for the Indian patients, which has a unique structure characterized by five consecutive rings and documented to produce a potent effect. Early Initiation of gliptin as a pharmacological approach to address the pathophysiological defect in the Indian diabetics need to be understood from the varied geographic, multi-ethnic patient perspective. We report the interim results from an outcome based retrospective analysis of the study for the effectiveness of teneligliptin for the glycemic control across varied demographic profiles as part of the ongoing multi centric, collaborative approach in the Indian urban setting amongst 174 continuous users, in the real world clinical practice setting

Methods: The baseline glycemic parameters, demographics, ongoing therapy and impact on the glycemic control were analysed through the records of patients (101 males, 73 females), who filled at least one teneligliptin prescription between July 2015- February 2016 during the first 8 months of the availability of teneligliptin in India. Mann Whitney test was used for statistical analysis.

Results: At teneligliptin initiation, 34.3% used teneligliptin concomitantly with three or more other antihyperglycemic agents. Metformin, sulphonylurea, pioglitazone, basal insulin, insulin, SGLT 2 inhibitors continued in 91%, 84%, 31%, 14%, 6%, 6% patients, respectively. 3 patients from the ongoing gliptins were shifted to the teneligliptin due to the inadequate glycemic control. 7.4 % (n=13) patients were drug naïve. At the follow up point of atleast 3 months, the HbA1c reductions were (mean 1.28 ± SD 0.54) were statistically significant (baseline 10.2 ± 0.5 Vs at 3 months 8.1 ± 0.2; 95% CI -3.47 to -0.12; p=0.02).

Discussion: INITIATE program is the largest and the earliest collaborative real time experience ever done in India for any of the gliptins conducted immediately after the launch. Teneligliptin in our real world setting achieved greater absolute glycemic response as compared to the controlled clinical trials, possibly as the higher baseline HbA1c level at initiation; which is a strong predictor of HbA1c reduction.

Conclusion: The learning from this retrospective evaluation could be the future basis to prospectively explore the benefits of teneligliptin beyond the glycemic control. Larger long term continuous future research would further document the effectiveness of teneligliptin in India. It would be important to relate these results with the longer follow up data which is expected to emerge in due period of time.

Abstract #1315

REDUCED HYPOGLYCEMIA AND COMPARABLE EFFICACY WITH INSULIN GLARGINE 300 U/ML VS INSULIN GLARGINE 100 U/ML IN INSULIN-NAIVE TYPE 2 DIABETES SUBJECTS IN RELATION TO PRE-BREAKFAST SELF-MONITORED PLASMA GLUCOSE LEVELS

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Objective: This post-hoc analysis of an insulin-naïve type 2 diabetes (T2D) population initiating basal insulin (EDITION 3; NCT01676220) investigated clinical outcomes in relation to the American Diabetes Association (ADA) recommended pre-breakfast self-monitored plasma glucose (SMPG) level of <130 mg/dL after 6 months of treatment.

Methods: Overall, 432 subjects treated with insulin glargine 300 U/mL (Gla-300) and 430 treated with insulin glargine 100 U/mL (Gla-100) were analyzed; mean age 58 and 57 years, 58% male, baseline A1C 8.5 and 8.6%, fasting plasma glucose 180 and 185 mg/dL, respectively. A1C change, proportion of subjects reaching A1C <7.0%, and hypoglycemia rates were assessed at 6 months in subjects who achieved and did not achieve pre-breakfast SMPG <130 mg/dL.

Results: SMPG <130 mg/dL was achieved by 74% and 74% of Gla-300- and Gla-100-treated subjects, respectively. A1C reductions were comparable in Gla-300- and Gla-100-treated subjects achieving SMPG <130 mg/dL (-1.4% vs -1.4%, respectively; P=NS). A1C reductions in those not achieving SMPG <130 mg/dL were -1.1% vs -1.3% (P=NS). Similarly, comparable proportions of Gla-300- and Gla-100-treated subjects who achieved SMPG <130 mg/dL reached A1C <7.0% (55% vs 52%, respectively;
In those not achieving SMPG <130 mg/dL, a lower proportion of subjects reached A1C <7.0% (22% vs 23%; P=NS). Event rates for any time of day hypoglycemia (24 hours) with plasma glucose ≤70 mg/dL were lower in Gla-300-treated subjects regardless of achievement of SMPG <130 mg/dL (<130 mg/dL: 2.73 vs 4.35 events/patient-year for Gla-300 vs Gla-100; ≥130 mg/dL: 1.04 vs 1.72 events/patient-year for Gla-300 vs Gla-100; all P<0.05). Event rates for any nocturnal hypoglycemia (with plasma glucose ≤70 mg/dL, occurring between 00:00 and 05:59) were comparable in both treatment groups (<130 mg/dL: 0.93 vs 0.95 events/patient-year for Gla-300 vs Gla-100; ≥130 mg/dL: 0.21 vs 0.47 events/patient-year for Gla-300 vs Gla-100; all P=NS). There were no differences in severe hypoglycemia rates.

Discussion: The majority of Gla-300- and Gla-100-treated insulin-naive T2D subjects achieved the ADA recommended pre-breakfast SMPG target of <130 mg/dL. In those achieving and not achieving SMPG <130 mg/dL, A1C reductions and proportions of subjects achieving A1C <7.0% were comparable for Gla-300- and Gla-100-treated subjects, but hypoglycemia at any time of day was significantly lower in Gla-300-treated subjects.

Conclusion: In previously insulin-naive subjects with T2D, Gla-300 confers comparable efficacy and reduced hypoglycemia at any time of day vs Gla-100, irrespective of achievement of ADA recommended pre-breakfast SMPG levels.

Abstract #1316

IMPACT OF UPPER RESPIRATORY TRACT INFECTION ON THE SAFETY OF TECHNOSPHERE® INHALED INSULIN IN PATIENTS WITH TYPE 1 OR TYPE 2 DIABETES

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Objective: Technosphere® Inhaled Insulin (TI) is a dry powder formulation of recombinant human insulin for inhalation developed for treating patients (pts) with type 1 diabetes (T1D) or type 2 diabetes (T2D). Upper respiratory tract infections (URTIs) might cause concern in pts with diabetes, including risk of hyperglycemia. This post-hoc analysis of 9 studies with TI (one Phase 2b, eight Phase 3 randomized clinical trials) assessed the safety of TI during URTIs in pts with T1D or T2D.

Methods: Pt-level data from the safety population in the TI arm were grouped based on URTIs, which were documented by each trial investigator. The URTI group included data for pts with ≥ 1 URTI episode, during URTI periods; the No-URTI group included data for pts during non-URTI periods, and those without any URTI over the trial. Hyperglycemia and ketoacidosis were defined by each trial investigator. Hypoglycemia was defined as symptomatic hypoglycemia and/or a blood glucose level < 70 mg/dL. Overall adverse events (AEs) excluded hyperglycemia, hypoglycemia and URTIs. Event rates were compared using a non-linear regression model with a negative binomial distribution.

Results: All pts in the URTI group (n=245) and No-URTI group (n=2,591) experienced at least one episode of hyperglycemia. The annualized rate of hyperglycemia/ketoacidosis was greater in pts with URTIs vs those without (12.19 vs 2.66 events/year, corresponding to an estimated ratio of 4.58 events/year [CI: 3.71, 5.64]; P=0.01). Pts with URTIs had a lower incidence of hypoglycemia, compared with those without (29.8 vs 48.9%; n=258 and n=2,501, respectively), corresponding to a difference of -19.1% (CI: 13.1, 25.0; P=0.0001) between groups. The annualized rate of hypoglycemia was comparable in the two groups (7.29 vs 8.14 events/year, URTI vs No-URTI; P=0.51). Regardless of URTI, all pts experienced at least one AE, and the annualized rate of overall AEs was greater in pts with URTIs vs those without (13.76 vs 3.39 events/year; n=246 and n=2,595, respectively), corresponding to an estimated ratio of 4.06 events/year (CI: 3.27, 5.03; P=0.01) between groups.

Discussion: Pts with diabetes on TI had a lower incidence of hypoglycemia and a comparable annualized rate of hypoglycemia during URTI vs non-URTI periods. The incidences of hyperglycemia/ketoacidosis and overall AEs were comparable between the two groups, while their annualized rates were moderately increased in pts with URTI.

Conclusion: Therapy with TI for the management of diabetes was associated with lower incidence of hyperglycemia in pts with an URTI, compared with those without, while incidence of hyperglycemia was similar.

Abstract #1317

COST AND CHARACTERISTICS OF DIABETIC KETOACIDOSIS IN EASTERN VIRGINIA

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Objective: Diabetic ketoacidosis (DKA) is a serious acute complication of diabetes which poses a significant financial burden on the U.S. healthcare system, costing $2.4 billion USD in 2009 (CDC 2014). In this study we
describe characteristics, cost of stay (COS) and length of stay (LOS) for DKA hospitalizations in our region to better understand the cost burden in our area.

Methods: De-identified hospital discharge records from 2008-2014 were obtained from the Virginia Health Information (VHI) database. Main inclusion criteria were diagnostic code for DKA and zip code. LOS and COS were analyzed by demographics, admit source, comorbid diagnoses, insurance payer, and discharge status using Wilcoxon each pair tests, p<0.05, using JMP 12.0 software.

Results: 7,288 records were obtained. Values presented as median (IQR).

Demographics include median age was 34 yrs (26 yrs) and a slight female majority (52.1%). T1DM patients (65.5%) predominated over patients with T2DM (34.6%). 95.8% of admissions were via an emergency department. At discharge, a majority of patients (83.7%) were discharged to home self-care; 15.9% were discharged/transfered under medical supervision; 0.4% expired. 31.5% of patients had a comorbid diagnosis of history of noncompliance with medical treatment. The most common payer was private insurance 34.3%, followed by uninsured 27.3%, Medicaid 19.7%, and Medicare 16.5%.

The median COS was $12507 USD ($10656). The median LOS was 3 d (2 d).

Between all insured (72.4%) vs. uninsured (27.3%), uninsured patients ranged 8-75 yrs, median 35 (25); insured patients ranged 0-94 yrs, median 31.5 (21). LOS and COS were both higher for insured, $13401 ($11744), 3 d (2 d), than uninsured, $10714 ($7656), 2 d (1 d). 90.4% of insured had charges associated with radiology vs. 29.8% uninsured.

Discussion: From 2008-2014, the cumulative cost of DKA hospitalizations in the region was $122.8 million. Of that cost, $27.7 million was attributable to the care of uninsured patients. The cost of uninsured patient care remained immense in spite of the fact that median LOS and COS were significantly lower for uninsured patients insured patients. In order to reduce this cost further without compromising care quality, we need to focus on preventing admissions and readmissions for DKA. While our dataset did not contain readmission data, the frequent comorbid diagnosis of “history of noncompliance” suggests readmission as a contributory factor.

Conclusion: DKA continues to present a financial burden to healthcare systems. In spite of receiving financially efficient care, uninsured patients in our system still contributed a large portion of the cost of care.

Abstract #1318

ADOPTION OF A STANDARDIZED INSULIN DOSING REGIMEN IN HOSPITALIZED PATIENTS WITH HYPERGLYCEMIA

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Objective: Current guidelines recommend against oral hypoglycemic agents and sliding scale correctional insulin for the treatment of hyperglycemia in hospitalized patients. Our objective was to describe the adoption and effectiveness of a simple, scheduled basal-bolus insulin regimen for these patients.

Methods: We studied a non-randomized quality improvement initiative focused on optimizing the treatment regimen for non-critically ill patients admitted to an acute care hospital with a diagnosis of diabetes and blood glucose levels greater than 180 mg/dL. Four contracted hospitalist groups participated in the initiative and changed their practice to start patients on 0.4 units/kg Total Daily Dose (TDD) of basal and prandial subcutaneous insulin with a low correctional scale. Glargine was given once daily, and lispro was administered before meals for those patients who were on solid, carbohydrate-controlled diets. Daily adjustments were made to the insulin regimen based on the fasting and pre-meal blood glucose levels. Changes to the scheduled insulin regimen were based on the amount of correctional insulin received in the previous 24 hours. Point of care capillary blood glucose results from May to August of 2014 (the 4 months preceding implementation of the recommended dosing) were compared to those from January to April of 2015 (4 months after the intervention).

Results: Patient volumes and patient-days were similar in the two periods (Pre: 2357 patients, 9910 patient-days and Post: 2519 patients, 10898 patient-days). After implementation, the overall use of oral hypoglycemic agents decreased by 70%. The percent of patient-days with an average glucose between 70-180 mg/dL increased by 7.5%, and patient-days with a blood glucose greater than 300 mg/dL decreased by 25.8% (X2=62.6 p<0.001 and 58.8 p<0.001, respectively). There was no significant change in the percent of patient-days with a blood glucose <70 mg/dL. The Quality Hyperglycemic Score, a composite score of days with any blood glucose <40 mg/dL, <70 mg/dL, average blood glucose 70-180 mg/dL, and BG >300 mg/dL, improved by 14.2%, from 76.1 to 86.9.

Conclusion: A standardized basal-bolus insulin regimen with a starting dose of 0.4 units/kg was readily adopted by hospitalist physicians and resulted in improved glucose
control without increasing hypoglycemia in non-acute hospitalized patients with hyperglycemia.

Abstract #1319

THYROID AND DIABETES: THE CO-EXISTING TWINS: APOLLO SUGAR ELECTRONIC MEDICAL RECORDS ANALYSIS

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Objective: Our study aimed to assess the prevalence and predictors of thyroid dysfunction in patients with Type 2 Diabetes Mellitus.

Methods: Present study is a cross-sectional study where patients with confirmed diagnosis of Type 2 Diabetes Mellitus(T2DM) were included in the study. Data was taken from Apollo’s electronic medical records (EMR) and patient’s health records (PHR). Required data including socio-demographic information, smoking status, alcohol status and biochemical parameters including blood glucose, thyroid panel, cholesterol levels and serum creatinine were collected from the patient database.

Case Presentation: A total of 4547 patients with T2DM were included in the study. Thyroid dysfunction was found in 1207 subjects with prevalence rate of 26.5% (95% CI, 25.2% – 27.8%). Thyroid dysfunction was more common (P <0.01) in female (76.3%) patients compared to male (41.4%) patients. Among patients with T2DM, Hba1c, total cholesterol and blood pressure were found to be higher in patients with thyroid dysfunction compared to patients without thyroid dysfunction. Female gender (Odds Ratio, 4.5 (95%, 3.9 – 5.3), P <0.01), high Hba1c (OR, 1.24 (95%, 1.12 – 1.38), P <0.01) and total cholesterol (OR, 1.01 (95% CI, 1.00 – 1.02), P = 0.022) were found to be a significant risk factors of Thyroid Dysfunction.

Discussion: Type 2 diabetes mellitus (T2DM) is one of the global health problem due to its burden of vascular complications. Several studies have shown that patients with T2DM have higher risk of thyroid dysfunction. But these data are sparse in the Indian context. Moreover predictors that are associated with thyroid dysfunction and Diabetes were not well studied.

Conclusion: Present study found a high prevalence of hypothyroidism in patients with T2DM. Female gender, higher blood glucose and total cholesterol were found to be significantly associated with hypothyroidism and Diabetes. This study raises the possibility to screen every T2DM patient for hypothyroidism.

Abstract #1320

A FOLLOW-UP STUDY OF APPLICATION OF STEM CELLS IN THE DIABETIC PATIENTS WITH LIMB ISCHEMIA

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Objective: Earlier we have reported the three months follow- up of successful application of autologous peripheral blood mononuclear cells (PBMNC) in five patients with limb ischemia due to diabetes. As a continuation of the previous study, herein we report the long term results of the twenty-three patients treated by PBMNC after a follow-up for five years, and the short term results of the eight patients treated by human umbilical cord derived mesenchymal stem cells (UCMSC) after a follow-up for six months in the clinical trial (NCT02287831).

Methods: Twenty-three Diabetic patients with Fontaine Stage III (4 cases) or IV (9 cases) limb ischemia were given intramuscular injections of their autologous PBMNC in the PBMNC transplant group. Eight Diabetic patients with Fontaine Stage III (3 cases) or Fontaine Stage IV (5 cases) limb ischemia treated by UCMSC in the UCMSC transplant group. The patients have been followed up at regular intervals after the treatment with relevant clinical investigations.

Results: In the patients of the PBMNC transplant group, their main manifestations, including lower limb rest pain and ulcers, were significantly improved, but one of them received a lower limb amputation at the end of the 3-month follow-up. One patient died due to a complication of cerebral hemorrhage, which was unrelated to the PBMNC injection, in four years after the transplantation. Fifty year continuous follow-up revealed that the healed tissue of ulcers remained healthy in the fifteen patients, fourteen of the patients are able to walk without support with a pain free walking distance of greater than 100m, and total three of the patients received a lower limb amputation. In the UCMSC transplant group, intramuscular administration of UCMSC resulted in improved main manifestations, including lower limb rest pain and ulcers, and improved blood flow and vascular density, were observed. None of them received a lower limb amputation at the end of the 6-month follow-up. TNF-α and IL6 serum levels increased at 24h after treatment and then decreased at 1month compared with that before treatment. There were
no adverse effects specifically due to cell transplantation in any of the patients.  

**Discussion:** The therapeutic effect of UCMSC in diabetic patients with limb ischemia could be related with its anti-inflammatory and immunomodulation properties, which have been found in our studies.  

**Conclusion:** These results provide pilot evidence indicating that the autologous transplantation of PBMCN represents a safe and effective therapeutic approach for limb ischemia due to diabetes. The transplant therapy by UCMSC also could to be safe and effective in patients with critical limb ischemia patients due to diabetes.

**Abstract #1321**

**COMPARISON OF EFFECTIVENESS OF SGLT2 INHIBITORS IN THE INDIAN MULTI ETHNIC TYPE 2 DIABETES PATIENTS– REAL WORLD EXPERIENCE**

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**Objective:** India holds a unique distinction that all the three SGLT2 inhibitors available in advanced countries have been launched in shortest period of one year from March-Oct 2015. It is imperative to understand efficacy and safety of in real world setting with comparative parameters.  

**Methods:** We analysed interim results from an outcome based retrospective study (CADRE). Each patient amongst continuous users at 12 weeks on Canagliflozin, Dapagliflozin, Empagliflozin as add on drug to ongoing therapy was comprehensively evaluated clinically and investigations were conducted as per guidelines derived standardised protocol utilised in our tertiary care set up.  

**Results:** 130 patients were initiated with 1 each on dapagliflozin and empagliflozin withdrew due to genital infection and vertigo. 128 (canagliflozin n=62, dapagliflozin n= 56, empagliflozin n = 10) completed earliest defined follow up of 12 weeks, recent most follow up completed on March 19, 2016. Mean age 50.8±9.2 yrs, diabetes duration 7.7±6.2 yrs, weight 83.14±14.2 kg, BMI 31.2±5.9, HbA1c 9.36±1.8% (CI 9.0-9.6). HbA1c reduced significantly as compared to baseline (9 vs 7.9%, difference -1.1) (p<0.0001). 14.4 % (n=17) additional patients added to pool achieving the goal of HbA1c level < 7% after 12 wks. HbA1c reductions, FPG, PPG, body weight, sBP, dBP ± SD in were not statistically significant across groups, Canagliflozin, Dapagliflozin and Empagliflozin (-1.408± 1.53, -0.85 ±1.33, -0.75 ± 3.71), (-34.66 ± 65.42, -28.45 ± 54.97, -51.9 ± 59.22), (-63.65 ± 94.47, -48.43 ± 86.57, -82.4 ± 73.82), (-1.64 ± 2.483, -1.99 ± 2.729, -0.75 ± 3.71), (-5.097 ± 16.13, -6.25 ± 15.84, 2 ± 14.76), (-0.1613 ± 10.25, -2.42 ± 7.88, -9.16 ± 43.17).

**Conclusion:** This is the first ever, largest real world study, conducted immediately after the launch of SGLT2 inhibitors in the country. Patient population represents multi-ethnic diversity of country with distant referrals. Our unique patient education initiatives enabled close follow up and minimised patients lost to follow up.  

**Discussion:** Comprehensive patient record formats encompassed parameters to be assessed and explore the benefits of beyond glycemic effects and provided insights to pleiotropic effects. The SGLT2 inhibitors are a useful addition to enhance the standard of care in the Indian people with diabetes.