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**Poster Board No. 1**

**Effects of Metformin and Alogliptin On Body Composition in People with Type 2 Diabetes**

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**Aims/Introduction**

The present study was to investigate effects of metformin and a DPP-IV inhibitor alogliptin on body composition in a 12-week randomized add-on trial in Japanese participants with type 2 diabetes.

**Materials and Methods**

84 participants with poorly controlled type 2 diabetes undergoing antidiabetic therapy were randomly assigned to receive alogliptin (25 mg, once daily) or metformin (1000 mg, twice daily) for 12 weeks. The primary efficacy endpoint was body composition. The secondary endpoints included factors associated with decreased body weight.

**Results**

Compared with the baseline values, alogliptin significantly increased body weight ( $66.5 \pm 19.2$  to  $67.6 \pm 19.3$  kg), BMI ( $25.4 \pm 6.1$  to  $25.8 \pm 6.3$  kg/m<sup>2</sup>), and fat mass ( $20.3 \pm 12.8$  to  $21.8 \pm 14.5$  kg), whereas metformin had no significant effect on body composition. Alogliptin was inferior to metformin in reducing body weight ( $0.84 \pm 1.57$  vs.  $-0.35 \pm 1.53$  kg,  $P = 0.002$ ), BMI ( $0.34 \pm 0.69$  to  $-0.15 \pm 0.56$  kg/m<sup>2</sup>,  $P = 0.002$ ), and fat mass ( $1.49 \pm 5.06$  vs.  $-0.04 \pm 1.81$  kg,  $P = 0.042$ ). BMI at baseline was associated with changes in body weight negatively in the metformin group and positively in the alogliptin group.

**Conclusions:** Metformin and alogliptin exert opposite effects on body weight in type 2 diabetic patients with overweight. The higher the BMI, the more metformin reduces body weight and alogliptin increases weight.

**Poster Board No. 2**

**Diabetes Mellitus Increase Mortality Risk in Coronary Artery Disease Patients Undergoing Coronary Artery Bypass Grafting Surgery**

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**Background**

Multiple studies had shown that coronary artery disease has been the principal cause of mortality in patients with diabetes mellitus (DM). Furthermore, DM is a major risk predictor for unfavorable outcomes in patients undergoing cardiac revascularization either percutaneous coronary intervention or coronary artery bypass grafting surgery.

**Objective**

To investigate whether the presence of DM increase mortality risk in patients undergoing CABG.

Methods: A retrospective single-center study was performed. A special database was created to include all EuroSCORE II variables, EUROScore II predicted mortality and actual mortality of 1718 patients undergoing Coronary Artery Bypass (CABG) surgery in Malaysia from 1st January 2016 till 31st December 2016.

Univariate and multivariate logistic regressions were done to identify significant predictors of in-hospital mortality among this group of patients.

**Results**

More than 50% of patients undergoing CABG surgery are diabetic (56.3%) while 20.3% are on long-term insulin. In terms of mortality, a significantly higher proportion of in-hospital mortality was observed among patients with DM (5.7%) compared to those without DM (3.4%). On univariate logistic regression analysis, both non-insulin dependent DM (OR: 1.737, 95% CI 1.072 - 2.815,  $p = 0.025$ ) and insulin-dependent DM (OR: 1.960, 95% CI: 1.209 – 3.179,  $p = 0.006$ ) are significant predictors of in-hospital mortality in this group of patients undergoing CABG surgery. However, in multivariate logistic regression, which took into consideration of other related variables in the EUROScore II, only female gender, age more than or equal to 65 years old, serum creatinine more than 120  $\mu\text{mol/litre}$  and longer ICU stays are significant predictors of in-hospital post-CABG mortality.

**Conclusion**

A higher in-hospital mortality risk post-CABG was observed in patients with DM. However, insulin-dependent diabetes mellitus was not a significant risk factor for in-hospital mortality in this group of patients.

Keywords: Coronary artery disease (CAD), Diabetes Mellitus (DM), EUROScore II, mortality.



**Poster Board No. 3**

**Enhanced Accumulation of Advanced Glycation End Products (AGEs) is Associated with The Severity of Aortic Stenosis in Patients with Type 2 Diabetes**

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**Background**

Increased oxidative stress together with formation of advanced glycation end products (AGEs) and chronic inflammation are involved in atherosclerosis development/progression, particularly in diabetic patients. The role of AGEs in the progression of aortic stenosis (AS) is unknown.

**Objectives**

To evaluate whether patients with AS and concomitant type 2 diabetes mellitus (AS-DM) have increased accumulation of AGEs within aortic valves compared with isolated AS and to determine the association between *in loco* AGEs accumulation and inflammation within aortic valves.

**Methods**

We enrolled 30 patients (16 women), aged 64.2±8.6 years with severe AS (mean transvalvular gradient=52.1±13.4 mmHg), including 15 subjects with type 2 DM (glycaemia, 5.7±1.7mM, glycated haemoglobin, HbA1c, 6.3±1.2%), who underwent aortic valve replacement. Immunofluorescence analyses were performed using primary monoclonal antibodies (all from Abcam) against AGEs (1:500), AGE receptors RAGE (1:100), interleukin-6 (IL-6, 1:800) and reactive oxygen species (ROS1) (1:100). Per each valve 30 images were taken and the percentage of positively-stained areas or the fluorescence intensity (FI) were analyzed using Olympus BX43 microscope equipped with software CellSenseStandard.

**Results**

AGE-positive (37.4±16.6%, FI=3318±1394 units), and RAGE-positive (15.6±8.1%, FI=2603±521 units) areas were increased in AS-DM valves compared with AS valves (10.9±4.2%, FI=1910±486 units and 3.7±2.3%, FI=1514±353 units, respectively, all p0.001). Patients with AS-DM had elevated valvular expression of ROS (9.6%±2.9, IF=1846±298 units) and IL-6 (4.7±1.7%, IF=2256±434 units) as compared to AS subjects (5.2±2.1%, IF=1528±262 units and 1.9±1.3%, IF=1776±293 units, respectively, all p0.05). In AS-DM patients AGE-positive areas correlated with HbA1c (r=0.4, p0.05), and tended to be associated with serum glucose levels (r=0.45, p=0.056). Of note, the magnitude of AGE-positive area was associated with maximal gradient (r=0.53, p0.05).

**Conclusions**

Enhanced accumulation of AGEs due to hyperglycaemia and increased expression of RAGE receptor along with increased oxidative stress might contribute to AS progression in diabetic patients (financial support: Polish National Science Centre, UMO-2015/19/B/NZ5/00647).

**Poster Board No. 4**

**Mauritius, The New Kid on The Block for Clinical Research in Type 2 Diabetes in Children**

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**Background/Objective**

The declaration of type 2 diabetes (T2D) as an international public health issue has, for the first time, deemed a non-infectious disease as a serious global health threat at par with infectious diseases. The island of Mauritius is historically known as a famous tourist destination. However, it has not been spared from the grip of diabetes and for decades, it has figured among the top 10 countries with the highest incidence of the disease. Importantly, T2D is no longer limited to adults as the epidemic is also emerging in children and adolescents. Due to its unique multi-ethnic population (Indians, Africans, Chinese and Caucasians) and compelling disease profile, Mauritius represents a useful model for clinical research in T2D and related co-morbidities.

**Methods**

Data from published literature and archives from the Ministry of Health and local diabetes charities were researched.

**Results/Findings**

29% of all deaths in Mauritius is directly linked to T2D, ranking the island as number two worldwide for diabetes-associated deaths. With ~40% of Mauritians being overweight, obesity is a major risk factor for diabetes, along with possible impact from the maternal environment *in-utero* during gestational diabetes. Among children aged 5-18 years, 22% are overweight and have elevated blood glucose levels. This is closely associated with increasing numbers of children being diagnosed with T2D. Evidence suggests that T2D phenotype in the youth differs from that of adults and may involve a unique pathophysiology. Thus, findings from studies done in adults cannot be simply extrapolated to children and separate studies are warranted.

**Conclusion**

Here, we describe the local diabetes profile, the legal framework for clinical research and regulatory process for conducting clinical studies in Mauritius, and the competency/infrastructure of the island for participating in multi-centric studies.

**Poster Board No. 5**

**Association of Polymorphism of Adiponectin with Blood Adiponectin Concentrations and Insulinresistance  
In Patients with DM T2 of the Azerbaijani Population**

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**The Purpose of The Study**

Adiponectin gene polymorphism ADIPQQ-g93054571A G and its association with adiponectin concentration and insulin resistance (IR) in patients DMT2

**Materials and Methods**

Surveyed serum concentration of adiponectin, glycosylated hemoglobin (HbA1) and insulin in Azerbaijanis 86 patients with DMT2: 55 men, 31 women. The average age  $51.79 \pm 7.94$ . Average disease duration  $8.58 \pm 2.53$ . The definition of polymorphism of adiponectin (ADIPQQ-g93054571 A G) conducted by the method of using MALDI-TOF mass spectrometer

**The Results**

Hb1 amounted to  $8.72 \pm 2.0\%$  adiponectin median for men was  $4.39 \pm 3.59 \mu\text{g/ml}$  ( $n 6.9 \pm 1.82 \mu\text{g/ml}$ ), for women  $6.73 \pm 6.02 \mu\text{g/ml}$  ( $n 10, 01 \pm 2.24 \mu\text{g/ml}$ ) mutant homozygous form of AA from 80 patients (93,02%) and mutant heterozygous form AG at 6 patients (6,97%). Mutant homozygous form AA associated with low levels of adiponectin in patients with mutant version of the gene was determined by adiponectin, average Hb1  $8.26 \pm 2.3\%$ . Determined: adiponectin for men  $6,13 \pm 4,33 \mu\text{g/ml}$ , for women -  $7,45 \pm 5,14 \mu\text{g/ml}$  and association of homozygous form AA polymorphism adiponectin gene. Patients with mutant genotype in homozygous form (AA) adiponectin polymorphism of adiponectin level in the blood was 7 (3.22%) and 5 (0.3%) with a mutant version of polymorphism in the heterozygous form (GG) was within the N range, 34 patients' blood adiponectin proved to be reduced averaged  $4.6 \pm 2.14 \mu\text{g/ml}$ . Association of high frequency (93,02%) mutant variant (AA) gene polymorphism adiponectin (ADIPQQ-g93054571A G) in homozygous form, with low adiponectin amid glucose toxicity (HbA1-8,  $26 \pm 2.3\%$ ) and high IR.

**Poster Board No. 6**

**Multidimensional Risk Factors Identification, Association and Intelligent Intervention for Type 2 Diabetes Mellitus**

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**Background**

The prevalence of type 2 diabetes mellitus (T2DM) is increasing. Systematic risk surveillance and interventions for T2DM have expanded globally over the past decade. However, the magnitude of risk factors and the effect of interventions remain uncertain.

**Objective**

We aimed to identify risk factors for T2DM from different dimensions, assess their relative risks, and reveal the importance of intelligent intervention for T2DM.

**Methods**

We systematically searched PubMed, Web of Science, Embase and Cochrane Library database and performed an umbrella review of published meta-analyses to summarise the risk factors associated with T2DM. Knowledge mapping was used to visualise these multidimensional risk factors. We then compared intelligent interventions with traditional diabetes management models. The effectiveness evaluation on HbA1c reductions from baseline was ranked by the cumulative ranking probabilities.

**Results**

Data from 2588 individual studies, representing 111.38 million participants, were included in the analysis. A total of 260 risk factors with risk estimates were extracted from 150 meta-analyses. These factors were classified into seven groups: environmental/occupational risks, behavioural risks, metabolic risks, health intervention, social/psychological/cultural/economic risks, disease, and treatment. For their relative risks (RRs), the most powerful factor associated with increased risk for T2DM was hepatitis C cirrhosis (RR: 8.71, 95% CI: 1.28-59.50), while the most powerful factor associated with decreased risk was serum total osteocalcin (RR: 0.23, 95% CI: 0.12-0.46). When comparing different management models, an integration model of education, nursing, and wireless technology showed superior reductions in HbA1c from baseline compared to usual care.

**Conclusion**

A total of 260 risk factors associated with T2DM have been identified in this study. The intelligent intervention is superior to the traditional model in reducing blood glucose levels. These findings will provide a new perspective for comprehensive prevention and control strategy of T2DM worldwide.

**Funding**

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**Poster Board No. 7**

**A Novel Insulin Depletion Protocol Combined with Stable Tracer Approach Assessing Intermediate Metabolism Can Be Efficiently Used for Investigation of the Development of Diabetic Ketoacidosis**

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**Background**

Sodium/glucose co-transporter 2 (SGLT2) inhibitors have been approved for the treatment of type 2 diabetes mellitus and are being considered as an add on therapy option for type 1 diabetes (T1DM). General safety concerns rose when the FDA issued a warning stating that SGLT2 inhibitors may increase the risk of euglycaemic diabetic ketoacidosis (euDKA). In this context, it is critical to understand whether and how SGLT2 inhibitors mechanistically contribute to DKA development.

**Objective**

This study aims to safely and accurately analyse the development of DKA during insulin depletion experiment and to investigate the impact of SGLT2 inhibitor treatment on the DKA development.

**Methods**

The study is designed as an open, randomized, two-arm, crossover, bi-centric trial. In total, 16 male, C-peptide negative T1DM subjects will undergo two insulin depletion experiments of which one will be preceded by a 7-day treatment period with dapagliflozin while the other one will be performed without any prior SGLT2i treatment. During run-in phase of the insulin depletion experiment, blood glucose will be kept stable at 100 mg/dL by variable insulin infusion. After baseline steady-state has been achieved, insulin administration will be completely withdrawn for a maximum of 14 hours or until any of the escape conditions will be met. Subsequently, during a 12-hour recovery phase DKA treatment will be assured. During the whole experiment blood samples for relevant metabolic parameters will be drawn. Additionally, stable isotope tracers will be used to estimate endogenous glucose production, peripheral glucose uptake and lipolysis.

**Conclusion**

Taking the results of the preceding feasibility study into account, this study design can be used to safely and accurately analyse the DKA development and evaluate the effects of SGLT2 inhibition on this process. The study is designed to bring further insights into the physiologic impact exhibited by SGLT2 inhibitors in T1DM.



**Poster Board No. 8**

**Predictive Characteristics of Metabolic Syndrome for Type 2 Diabetes in Primary Care: 10-year Prospective Study**

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**Background and aims**

Mildly elevated fasting plasma glucose (FPG) and triglyceride (TG) levels could indicate an increased risk for type 2 diabetes (T2D), in particular for people who are overweight some time before diagnosis. The aim of the study was to discover which parameters of metabolic syndrome (MS) are most important in predicting development of T2D in 10 years in primary care (PC).

**Materials and methods**

The standard FPG test was conducted for 1105 PC patients. 844 (424 males and 420 females) with normal glucose values (nGLU) and age  $\geq 45$  were enrolled into 10-year prospective study. MS parameters - glucose, cholesterol, waist circumference (WC) and blood pressure (BP) were evaluated by standard measurements. Patients were divided into two groups: those who have been diagnosed with T2D in ten years and those with nGLU.

**Results**

During 10 years 168 patients died, 76 had major cardiovascular events thus excluded from analysis, 23 had developed T2D and 577 had normal FPG results at the follow-up. Patients with developed T2D in 10 years had higher FPG levels of 5.47 vs 5.27 mmol/l ( $p=.042$ ), higher TG levels of 1.47 vs. 1.18 mmol/l ( $p=.035$ ), lower high-density lipoprotein cholesterol (HDL-C) levels of 1.24 vs 1.48 mmol/l ( $p=.022$ ) and larger WC 106 vs. 92 cm ( $p.001$ ) at the beginning of the study. Logistic regression analysis revealed that the only predictor of T2D was WC ( $p.001$ ). ROC curve analysis ( $AUC=.736$ ,  $p.001$ ) revealed that WC's critical value in predicting development of T2D was 99.5 cm (with sensitivity .682 and specificity.698).

**Conclusion**

WC is the predictor of T2D in PC. It is important to follow up patients with small elevations of FPG and TG, also HDL-C decrease for incident T2D in PC.

**Poster Board No. 9**

**Effects of Korean Red Ginseng In Diabetic Nephropathy**

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Korean Red ginseng(KRG) has been used as a traditional medicine for centuries by the people of China, Korea and Japan. The purpose of this study was to evaluate the therapeutic effects of Korean red ginseng on streptozotocin(STZ)- induced diabetic rats.

The STZ induced diabetic rats revealed decline in bodyweight gain and showed improvement in the kidney weight gain, urination and water intake levels, however, these diabetic inducible abnormalities can be normalized by the oral administration of KRG with the dose rates of 250mg/kg and 500mg/kg daily till 8 weeks.

Amongst the renal functioning parameters, elevated blood urea nitrogen(BUN) reduced in the KRG treated rats, conversely no change has been detected in creatinine level of rats. Furthermore, KRG administration with dose rates of 250mg/kg and 500mg/kg body weight in the diabetic rats depicted decrease in blood glucose level and glycated hemoglobin(HbA1C), intimating that KRG can prevent the pathogenic complications of diabetes rendered by impaired glucose metabolism. KRG caused reduction of albumin in urine and advanced glycation end products(AGEs) from the kidney of diabetic induced rats. In vivo western blot results suggest that the expressions of  $\alpha$  SMA and TGF- $\beta$ 1 decreased with KRG treatment. In vitro results revealed that the overexpression of the light chain3(LC3), ras homolog enriched in brain(RHEB), activated protein kinase(AMPK), mechanistic target of rapamycin(mTOR) and tuberous sclerosis complex(TSC) have been faded with KRG treatment in dose dependent manner.

Intriguingly, KRG ameliorated the pathologic conditions associated with diabetic nephropathy and indicated that it has therapeutic affects against diabetic nephropathy.

**Poster Board No. 10**

**Assessments of Abuse Drugs and Clinical Laboratory Tests Variations in Fresh Samples**

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**Background and Aim**

In this study N=480 fresh blood and urine samples of abusers were screened to diagnosis of abuse drugs and some under medication drugs. All of the study population had age range between (Mean  $\pm$ SD) = 45 $\pm$ 20. Then all of blood samples were examined through as a view point of clinical laboratory methods.

**Methods**

First all Fresh urine and blood samples were examined to confirm presence morphine drugs, Heroin, Morphine, BNZ, codeine, MethylenDioxy mphetamine, Tramadol, Buprexin, Cocaine, Phencyclidine, methadone, THC, Amphetamine, TCA, Phenobarbital, methamphetamine, ... dependency on their addiction, so all samples were confirmed by two tests. Then they were examined to other clinical laboratory tests. All data analyzed with one way and two way Anova Turkey and t-test. When comparing the test results p-value  $0 \geq 0.05$  were considered as significance level. The Pvalue of this study for some study groups were P = 0.001 too.

**Results**

The results of this study were showed that 3% of abusers had mild increase in hematocrite level and 2% of narcotic drugs abusers had mild lower level of blood sugars than normal range and 3% of participants had increase liver enzymes: ALT, AST, ALP or LFT and 0.5% of them had renal failure. Although blood level Urea and creatinin were examined to evaluation of their renal failure, Because some of abusers directly consumed full long time agonist or partial agonists drugs such as Buprexin for their maintance medication in clinics.

**Conclusion**

According to results of this study we conclude that between all drug analytical methods the cheapest and easiest tests of opioids and other drugs in urine and blood samples. Also doing test on blood samples have high importance in distinguishing and confirming of all drugs and other parameters in fresh samples and drug toxicity. We purpose that this methods will be suitable to distinguish of abuse drugs and detection of other important parameters of clinical laboratory tests such suger level, urea level, enzyme level.. in other fresh biological samples in future.

**Poster Board No. 11**

**Frequency of Hypoglycemic Events and Hypoglycemic Fear in Patients with Type 2 Diabetes Initiating a Second-Line Therapy in Gulf: The DISCOVER Study**

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**Background and Aims**

This data belongs to an interim analysis of DISCOVER a 3-year prospective, large multicenter cohort study with 15000 patients enrolled in 38 countries. The four Gulf countries (Bahrain, Kuwait, Oman and UAE (United Arab Emirates)) in this analysis represent 247 patients with type 2 diabetes.

Age adjusted comparative diabetes prevalence in Gulf countries is high, UAE (17.2%), Kuwait (17.9%), Bahrain (16.3%), Qatar (16.3%), Oman (12.0%).

Treatment aimed at decreasing blood glucose, improving quality of life and decreasing complications. Lack of efficacy mandates addition of a new agent. Changes in weight and hypoglycemic events led to modifications in therapy. We described clinical, laboratory characteristics and history of hypoglycaemia.

**Materials and Methods**

Descriptive analysis to report demographic, baseline characteristics, clinical and laboratory profiles, hypoglycemic attacks history and hypoglycemic fear survey (HFS-II).

HFS-II is a 33-item questionnaire with subscales measuring behaviors to avoid hypoglycemia and worries about hypoglycemia and negative consequences from both. Responses recorded on a 5-point Likert scale. Scores range 0-132, higher scores indicating increased fear of hypoglycemia.

**Results**

247 patients initiating a second-line treatment were recruited; 70% males, mean age 50.5 ( $\pm 11.5$ ) years, median disease duration 61.7 months (IQR: 34.6 to 119.2 months).

The mean clinical characteristics of study population: weight:  $88 \pm 19.9$  kg, BMI:  $31.5 \pm 6.5$  Kg/m<sup>2</sup>, waist circumference:  $94.6 \pm 14.9$  cm, systolic blood pressure:  $138.4 \pm 16.3$  mmHg, diastolic blood pressure:  $79.2 \pm 11$  mmHg. Baseline laboratory profile summarized in table 1.

At recruitment 2 patients reported major & 25 patients reported minor hypoglycaemic events. The median (IQR) of hypoglycemic fear scores were: 8 (2-15) behaviors, 11 (2-22) worries, and 23 (6.5-37) composite.

**Conclusion**

Patients initiating second-line treatment had poor glycemic control and uncontrolled lipid profile reflecting low efficacy of first-line treatment. 11% patients reported hypoglycemic events (0.8% major and 10.2% minor), hypoglycemia fear scores were at the lower end of the range.

| Variable                            | Mean $\pm$ SD    |
|-------------------------------------|------------------|
| HbA1C (%)                           | 8.7 $\pm$ 1.8    |
| Fasting blood glucose (mg/dl)       | 174.4 $\pm$ 57   |
| Random blood glucose (mg/dl)        | 223.6 $\pm$ 81.2 |
| Post-prandial blood glucose (mg/dl) | 220.2 $\pm$ 52.6 |
| HDL cholesterol (mg/dl)             | 42.9 $\pm$ 12.1  |
| LDL cholesterol (mg/dl)             | 108.8 $\pm$ 37.4 |
| Total cholesterol (mg/dl)           | 176 $\pm$ 42.2   |

**Poster Board No. 12**

**Treatment Patterns and Associated Factors in 247 Patients with Type 2 Diabetes Initiating a Second-Line Therapy In GULF: The DISCOVER Study**

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**Background and aims**

Aim was to investigate T2DM management patterns in patients initiating a second line anti-diabetic treatment (add-on or switch), after first line oral treatment with mono/dual or triple therapy.

**Materials and methods**

This data belongs to interim analysis of DISCOVER a 3-year prospective, large multicenter cohort study with 15000 patients enrolled in 38 countries. The Gulf countries (Bahrain, Kuwait, Oman and UAE (United Arab Emirates)) in this analysis represent 247 patients from 12 centers with T2DM.

Parameters assessed were patterns of antidiabetic treatment, reasons for initiating second line treatment and adherence to standard guidelines of diabetes care (ADA/AACE).

**Results**

247 patients initiating second line treatment ;70% male, mean age 50.5 ( $\pm$ 11.5) years. Most common first line treatment-Metformin monotherapy (n=90, 36.44%) followed by Metformin+Sulfonylurea (n=67, 27.13%) and Metformin+DPP4i (dipeptidyl peptidase-4 inhibitor) (n= 34,13.8%). For second line, Metformin+DPP4i dual therapy was most common (n=64, 25.91%) followed by Metformin/DPP4i/Sulfonylurea triple therapy (n = 49,19.84%). Reasons for addition to first line therapy was: lack of efficacy of first line (90.3%), weight gain (17.8%), patient request (4.9%), physician's preference (4.9%). Considerations for selecting second line treatment: efficacy (65.2%), effect on weight (44.1%), low risk of hypoglycaemia (27.9%), tolerability (25.5%). Target goal set by 87% patients initiating second-line treatment.

Median treatment targets: HbA1C: 7%, fasting plasma glucose: 126 mg/dl, random plasma glucose: 144.1 mg/dl, and postprandial plasma glucose: 180 mg/dl.

**Conclusion**

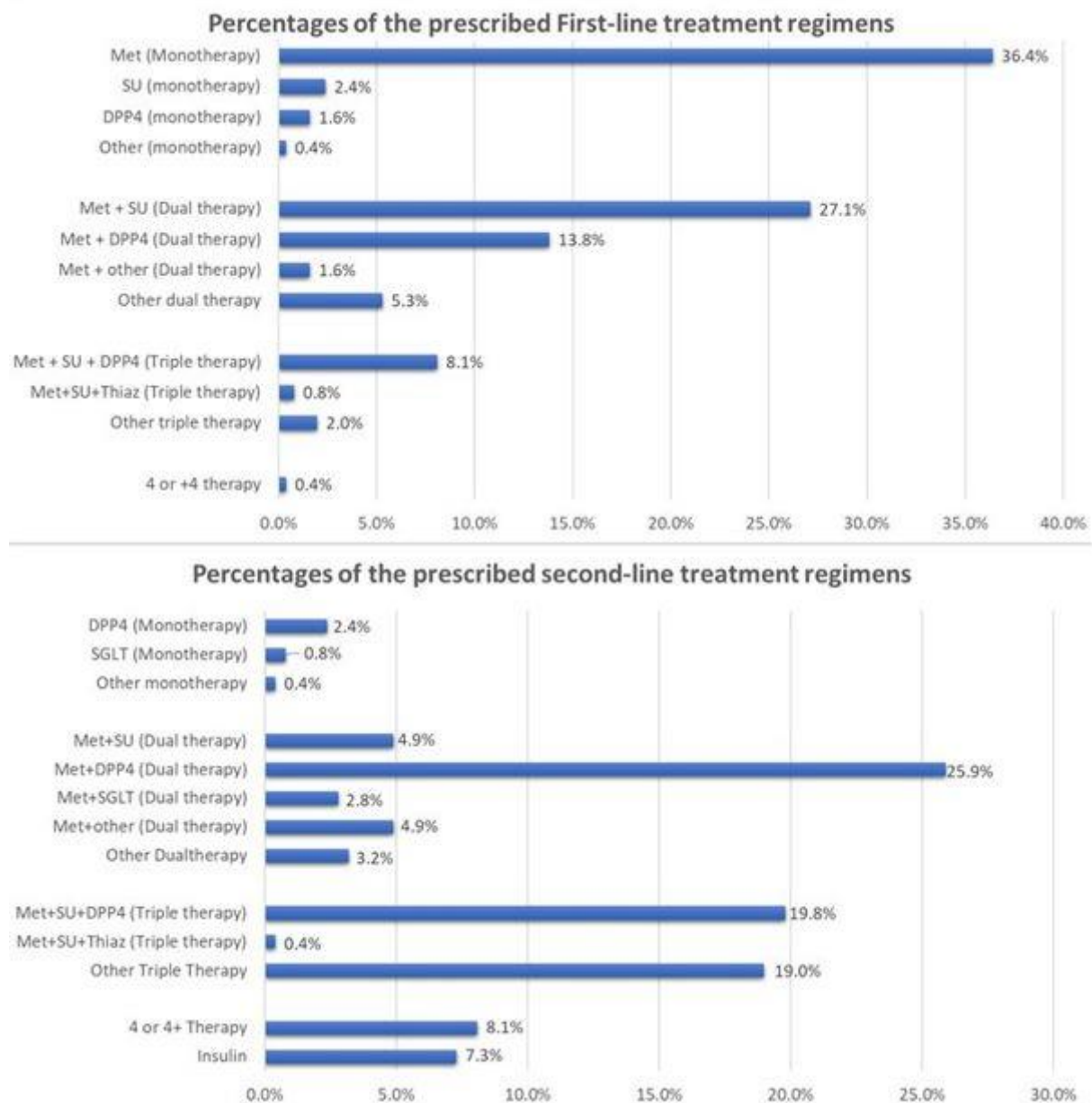
Treatment modifications are a result of lack of efficacy of first-line treatment.

Additional second-line treatment initiation based on efficacy, effect on body weight, risk of hypoglycaemic events, and tolerability.

First-line initiated in accordance with standard guidelines(AACE/ADA) in 87.8% patients with metformin being prescribed as monotherapy or combinations. For second-line metformin was prescribed for 58.7% patients.

Variations in second-line therapy options in Gulf are aligned with recommendations of the standard guidelines of Diabetes<sup>1,2</sup>.





#### References

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**Poster Board No. 13**

**C-Peptide Microcirculation Effects Dependence on Different HbA1C Levels**

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**Background**

In studies published earlier, treatment with C-peptide of T2DM patients didnt give a positive result. It was decided to evaluate C-peptide effect on microcirculation in T2DM dependence on HbA1C levels.

**Objective**

Microcirculation features between C-peptide serum level subgroups with low ( $\leq 400$  pmol/l), normal ( $400 < 1000$  pmol/l) and highly normal secretion ( $\geq 1000$  pmol/l) in groups with HbA1C 7% (46 patients, men 54%, aged  $53.2 \pm 1.28$ ),  $7\% \leq \text{HbA1C} < 9\%$  (64 patients, men 55%, aged  $53.6 \pm 1.16$ ) and HbA1C  $\geq 9\%$  (51 patients, men 51%, aged  $53.5 \pm 1.2$ ) of T2DM patients were compared.

**Methods**

To evaluate capillary density, coiling, segments diameters, perivascular zone size and blood velocity digital nailfold capillaroscopy was performed. Statistical analysis was conducted using software package SAS 8.1.

**Results**

In HbA1C 7% low C-peptide serum level adversely affects capillary arterial segment narrowing, polymorphism and coiling tendency ( $p < 0.05$ ). C-peptide highly normal level revealed capillaroprotective effect in capillary coiling decrease ( $p = 0.02$ ), arterial ( $9.41 \pm 0.41$   $\mu\text{m}$ ) and venous ( $13.67 \pm 0.66$   $\mu\text{m}$ ) segments expansion ( $p < 0.005$ ).

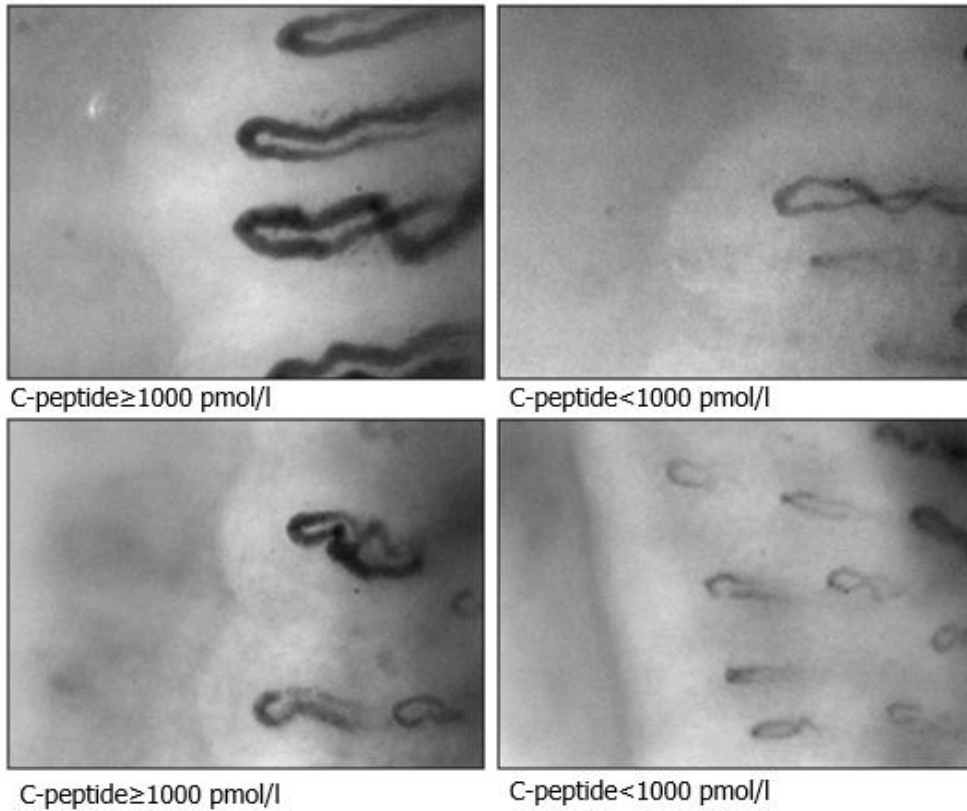
In  $7\% \leq \text{HbA1C} < 9\%$  C-peptide highly normal level reflected capillaroprotective effect, but with less extent then in HbA1C 7%. Capillary apex ( $p < 0.01$ ) and arterial segment expansion ( $8.29 \pm 0.27$   $\mu\text{m}$  versus  $7.03 \pm 0.49$ ,  $p < 0.05$ ) and polymorphism tendency were founded. Low C-peptide level adversely affects trend of capillary narrowing, polymorphism and coiling increase ( $p < 0.05$ ).

C-peptide highly normal level positive capillary effect wasn't found in HbA1C  $\geq 9\%$ , on the contrary it affects negatively capillaries with coiling increase ( $p = 0.04$ ) and density decrease tendency.

**Conclusion**

Highly normal C-peptide secretion has a positive effect on capillaries contributing to their expansion, reducing coiling ( $p < 0.05$ ). Reduced C-peptide secretion leads to capillary narrowing, coiling and polymorphism ( $p < 0.05$ ). High normal C-peptide secretion capillaroprotective effect was observed in HbA1C 7%, decreases in  $7\% \leq \text{HbA1C} < 9\%$  and then disappears in HbA1C  $\geq 9\%$  due to glucose toxicity and insulin resistance development.

Capillary network of patient in dynamic



**Poster Board No. 14**

**The Course of Gestational Diabetes with Regards to The Different Methods of Its Diagnosis**

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**Introduction**

Gestational diabetes mellitus (GDM) is defined as the type of glucose intolerance of variable severity first diagnosed in pregnancy. GDM is associated with severe pregnancy outcomes for both women and their children. Based on IADPSG guidelines, fasting plasma glucose testing in the early pregnancy and 75-g oGTT at 24–28 weeks of gestation is recommended for detection of GDM.

Aim: To compare the course of gestational diabetes in women diagnosed with GDM in different phases of pregnancy.

**Methods**

Pregnant women (n=418) were stratified into the three groups of women: with fasting plasma glucose (FPG)  $\geq 5.1$  mmol/l in the first trimester (n=109), FPG  $\geq 5.1$  mmol/l before oral glucose tolerance test (oGTT) in the second trimester (n=209) and impaired postprandial glucose tolerance during the oGTT (1h oGTT PPG  $\geq 10.0$  mmol/l and/or 2h oGTT PPG  $\geq 8.5$  mmol/l, n=100) in the second trimester.

**Results**

Impaired FPG in early pregnancy was associated with higher body weight ( $78.3 \pm 19.1$  and  $74.2 \pm 16.7$  vs.  $67.2 \pm 15.7$  kg; p0.001) and BMI ( $27.9 \pm 6.6$  and  $26.4 \pm 5.8$  vs.  $24.4 \pm 5.2$  kg/m<sup>2</sup>; p0.001) and more frequent insulin treatment (14.7% vs. 7.1% and 4.0%; p0.05). Women with impaired FPG more frequently underwent a caesarean section (39.7% vs. 25.1% and 31.0% p0.05). Their children had higher prevalence of neonatal hypoglycemia (14.1% vs. 10% vs. 7.0%) and higher birth weight ( $3415.6 \pm 529.0$  vs.  $3372.2 \pm 552.2$  and  $3199.0 \pm 560.5$  g; p0.05). Statistically significant differences in the incidence of maternal and neonatal complications were not observed.

**Conclusion**

Diagnosis of GDM according to impaired FPG predisposes to more intensive treatment and is associated with a higher birth weight of children and more frequent caesarean section.

Supported by AZV NV18-01-00139, IGA\_LF\_2018\_010 and MH CZ DRO (FNOI, 00098892)

**Poster Board No. 15**

**The First Clinical Trial Testing GNBAC1 an Anti-HERV-W-Env Monoclonal Antibody in Type 1 Diabetes Patients**

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<sup>2</sup>Endocrinology, Box Hill Hospital, Australia

**Background**

We describe a newly identified therapeutic target for type 1 diabetes: an envelope protein of endogenous retroviral origin called Human Endogenous Retrovirus W Envelope (HERV-W-Env). HERV-W-Env was found to be detected in the blood of around 60% of type 1 diabetes (T1D) patients and is expressed in acinar pancreatic cells of 75% of T1D patients at post-mortem examination. Preclinical experiments showed that this protein displays direct cytotoxicity on human  $\beta$ -islet cells. In vivo HERV-W-Env impairs the insulin and glucose metabolism in transgenic mice expressing HERV-W-Env. GNBAC1, an IgG4 monoclonal antibody, has been developed to specifically target HERV-W-Env and to neutralize the effect of HERV-W-Env *in vitro* and *in vivo*.

**Objective**

This is a Phase IIa clinical trial to assess GNBAC1 safety and efficacy for the first time in patients with T1D.

**Method**

This is a randomized placebo controlled 2-arm study with the objective of showing the safety and pharmacodynamics response of GNBAC1 (clinicaltrials.gov: NCT03179423). Sixty four patients with type 1 diabetes were included. GNBAC1 is tested versus placebo at the dose of 6 mg/kg administered intravenously; 6 drug administrations are performed at 4-week administration intervals. The primary endpoint records adverse events and serious adverse events and laboratory data. Secondary endpoints are: glycated haemoglobin levels; C-peptide levels 2 hours after maximum meal tolerance test; fasting and postprandial blood glucose; change from baseline in percentage of subjects not requiring insulin; daily use of insulin. Type 1 diabetes and other autoimmune related antibodies are also assessed.

**Results**

The full safety and efficacy results at 6 months will be presented.

**Conclusions**

This first safety and efficacy study of the monoclonal antibody GNBAC1 in type 1 diabetes patients is the first clinical step in the development of an innovative non-immunomodulatory disease modifying treatment for type 1 diabetes.



**Poster Board No. 16**

**Safety and Efficacy of a New Biguanide Compared with Metformin Hydrochloride Over Metabolic Control in Diabetic Patients**

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<sup>4</sup>*Unidad de Investigación y Desarrollo, Laboratorios Silanes, S.A. de C.V., Mexico*

**Background**

Metformin Glycinate is a recently developed drug with a different pharmacokinetic profile than the one of Metformin Hydrochloride; it also has additional signaling pathways to control hyperglycemia, making it a proposal for glycaemia control treatment.

**Objective**

To compare safety and efficacy of 1,050 mg (twice daily) of Metformin Glycinate versus 850 mg (twice daily) of Metformin Hydrochloride treatment over 12 months in Type 2 Diabetes Mellitus (T2DM) patients (being 2,100 mg of Metformin Glycinate equivalent to 1,700 mg/day of Metformin Hydrochloride). Clinical Trials Identifier: NCT01386671.

**Methods**

Controlled, randomized, multicenter, 2 treatments, double blind, clinical trial with T2DM adult patients (over 18 years old; 10 years top of T2DM diagnosis) who received either: 850 mg (twice daily) of Metformin Hydrochloride (Group A) or 1,050 mg (twice daily) of Glycinate Metformin (Group B) for 12 months. 203 patients were randomized, 101 for Group A and 102 for Group B. Descriptive and inferential statistic was used with a confidence interval of 95%.

**Results**

Each group showed statistical differences (reduction) in HbA1c, fasting glucose, weight and BMI compared with baseline measurements. There were no differences in mean HbA1c and fasting glucose between groups. Efficacy of HbA1c for group A was 57.4% and group B 63.93% (efficacy set as HbA1c 7%); fasting glucose 89.2% of efficacy in group A and 83.1% in group B (efficacy set as  $\leq 160$  mg/dL). A total of 133 adverse events (AE) related to treatment were reported (41.4% for Group A and 26.6% for group B;  $p$  value of 0.03). Inferiority analysis was carried out with Farrington-Manning test resulting in 0.069 (CI90%; -0.079, 0.216) at twelve months of treatment.

**Conclusion**

During this study there were no differences in efficacy between groups, however Glycinate Metformin Group showed a better safety profile. It is concluded that Glycinate Metformin is not inferior to Metformin Hydrochloride.

**Poster Board No. 17**

**A Phase 3 Comparison of a Ready-To-Use Liquid Glucagon Rescue Pen to Glucagon Emergency Kit for the Symptomatic Relief of Severe Hypoglycemia**

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**Objective**

A novel ready-to-use stable liquid Glucagon Rescue Pen (GRP; Xeris Pharmaceuticals) auto-injector, was evaluated for relief of symptoms during rescue treatment of severe hypoglycemia.

**Method**

A Phase 3 randomized, controlled, single-blind, crossover clinical trial enrolled 81 adults with T1D to compare subcutaneous 1 mg doses of the GRP versus Glucagon Emergency Kit (GEK; Eli Lilly) for the treatment of insulin-induced severe hypoglycemia in adults. Serial assessments of 4 autonomic, 4 neuroglycopenic, average total symptoms, and sensation of hypoglycemia were performed at each treatment visit.

**Result**

The mean time to symptom relief from the time receiving glucagon treatment was comparable between the GRP and GEK for autonomic symptoms ( $9.9 \pm 6.45$  min and  $9.8 \pm 6.86$  min,  $p=NS$ ), neuroglycopenic symptoms ( $10.3 \pm 8.92$  min and  $9.9 \pm 7.22$  min,  $p=NS$ ), average total symptoms scores ( $13.0 \pm 9.23$  min and  $11.9 \pm 7.57$  min,  $p=NS$ ), and mean time to resolution of the global feeling of hypoglycemia ( $11.6 \pm 6.51$  min and  $13.1 \pm 7.93$  min,  $p=NS$ ). All subjects achieved successful plasma glucose recovery. The overall incidence of all adverse events (AEs) was comparable in both groups; the most commonly reported AE was mild to moderate nausea (GRP 36.8%, GEK 33.2%) and vomiting (GRP 26.3%, GEK 14.1%). No SAEs occurred related to GRP.

**Conclusion**

The prompt relief of neurologic symptoms is critical in the rescue of severe hypoglycemic emergencies. The GRP achieved both autonomic, neuroglycopenic, and average total symptom relief during induced severe hypoglycemia. GRP achieved successful plasma glucose recovery in a reliable manner, was safe and well tolerated, and had an incidence of nausea and vomiting comparable to GEK. These results demonstrate that ready-to-use GRP is a viable alternative to currently available GEK.

**Poster Board No. 18**

**Efficacy and Safety of MYL-1501D Versus Insulin Glargine in Patients with Type 1 Diabetes Mellitus:  
Results of the INSTRIDE 3 Phase 3 Study**

**Thomas Blevins<sup>1</sup>, Abhijit Barve<sup>2</sup>, Yaron Raiter<sup>3</sup>, Patrick Aubonnet<sup>4</sup>, Sandeep Athalye<sup>5</sup>, Bin Sun<sup>2</sup>, Rafael Muniz<sup>2</sup>,  
Michael Ankersen<sup>2</sup>**

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<sup>2</sup>*Diabetes, Mylan Inc., USA*

<sup>3</sup>*Diabetes, Mylan EPD, The Netherlands*

<sup>4</sup>*Diabetes, Mylan EPD, Switzerland*

<sup>5</sup>*Diabetes, Biocon Research Limited, India*

**Background**

MYL-1501D, recently approved by the European Medicines Agency, is being developed as a biosimilar to insulin glargine or a follow-on biologic in the United States.

**Objective**

The aim of the INSTRIDE 3 study was to assess whether patients with type 1 diabetes mellitus can switch between MYL-1501D and reference insulin glargine (Lantus®; Sanofi-Aventis US LLC, Bridgewater, NJ) through testing equivalence after 36 weeks between 2 treatment sequences.

**Methods**

Eligible patients from INSTRIDE 1 who completed 52 weeks of Lantus treatment were randomized 1:1 to the reference sequence (n=63) to receive Lantus for 36 weeks or to the treatment-switching sequence (n=64) to receive MYL-1501D (weeks 0-12), Lantus (weeks 12-24), and MYL-1501D (weeks 24-36). Change in glycated hemoglobin (HbA<sub>1c</sub>) from baseline to week 36 was the primary efficacy endpoint used to demonstrate equivalence between the 2 sequences. Secondary endpoints included metabolic measures (eg, change from baseline to week 36 in fasting plasma glucose and self-monitored blood glucose), insulin dose, immunogenicity, and adverse events, including hypoglycemia.

**Results**

Both sequences received comparable insulin doses over 36 weeks of treatment. Mean changes in HbA<sub>1c</sub> (least squares [LS] mean ± standard error) from baseline to week 36 were -0.05 ± 0.032 and -0.06 ± 0.034 for the treatment-switching and reference sequences, respectively (LS mean difference, 0.01; 95% CI, -0.085 to 0.101). Fasting plasma glucose remained stable, with no significant changes from baseline in either sequence and no significant differences between sequences at any time point (*P*0.05). Safety and immunogenicity profiles of the 2 sequences were comparable.

**Conclusion**

Change from baseline to week 36 in HbA<sub>1c</sub> in patients switching between MYL-1501D and Lantus was equivalent to that observed in patients receiving Lantus for the entire study, and there were no new or different safety signals when switching between treatments.

**Poster Board No. 19**

**Zygosid-50 - the Novel Drug Candidate for Treating Type 2 Diabetes - Entering Phase I & IIa**

Dror Chevion<sup>1</sup>, **Mottie Chevion**<sup>1,2</sup>, Vladimir Vinokur<sup>2</sup>

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<sup>2</sup>*The Hebrew University-Hadassah Medical School, The Hebrew University of Jerusalem, Israel*

**Background**

Following the high efficacy of treating diabetic Sand Rats (presented at WCTD 2017 & CODHy 2018) we have obtained proof of concept for similar therapeutic activities in the db/db mouse model of type II human diabetes (T2D). In coordination with the FDA we are completing some TOX studies and preparing for Clinical Phases I & IIa Trials under IND.

**Objectives**

Examine the anti-T2D therapeutic efficacy of Zygosid-50 - our novel & safe drug, using the db/db mouse mode.

**Methods**

db/db (male) mice (10 week old, from Jackson Labs, USA) were treated (by i.p. injection) with Zygosid-50 (6 mg/kg, 3x/week) starting on Day 1 and continuing till Day 50.

**Results**

Diabetic db/db mice with initial BGL 500 mg/dl were treated, with minor changes in their BGL for ~17 days. Then, by Day 27, a downturn of BGL occurred to (average) value =253 mg/dl. By Day 49 the BGL=329 mg/dl, compared to 598 mg/dl for the Non-treated animals! Lowering body weight, by nearly 20%, was observed for the treated animals (from 47g to 38g on Day 45). The treatment also caused marked improvement of the GTT curves (conducted on Day 45), as compared to NON-treated mice. Parallel experiments using db/db mice of the same sub-type, supplied by Envigo, Israel, were conducted and showed analogous results.

**Conclusion**

Zygosid-50 demonstrated high therapeutic efficacy treating T2D, in the two animal models: the Sand Rat (previously shown) and the db/db mouse demonstrated here. Importantly, no adverse effects could be detected.

We are confident that Zygosid-50 will provide relief for millions of patients.

**Poster Board No. 20**

**A Novel Stepwise eu-, Hyper-, and Hypoglycaemic Clamp Using Stable Tracer Method for Comparison of Glucose Fluxes and Lipolysis in Type 1 and Type 2 Diabetes Mellitus**

Eva Svehlikova<sup>1</sup>, Stefanie Sach-Friedl<sup>1</sup>, Hans-Peter Schadler<sup>2</sup>, Thomas Augustin<sup>2</sup>, Christoph Magnes<sup>2</sup>, Anita Eberl<sup>2</sup>, Sophie Narath<sup>3</sup>, Martina Urschitz<sup>1</sup>, Michael Wolf<sup>1</sup>, Gerlies Treiber<sup>1</sup>, Thomas Pieber<sup>1,2,3</sup>

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<sup>2</sup>*HEALTH – Institute of Biomedicine and Health Sciences, Joanneum Research, Austria*

<sup>3</sup>*CBmed, Center for Biomarker Research in Medicine, Austria*

**Background**

Recently it was proposed that some diabetes medications shift the fuel balance towards lipolysis and ketogenesis.

**Objective**

The aim of this study was to establish a novel stable tracer method to assess endogenous glucose production (EGP) and lipolysis (rate of appearance [Ra] glycerol) during eu-, hyper-, and hypoglycaemia in patients with type 1 (T1DM) and type 2 diabetes mellitus (T2DM).

**Methods**

A stepwise eu- (5.5 mmol/L) and hyperglycaemic (11.1 mmol/L) clamp with ambient insulin levels was followed by an insulin induced (T1DM: 1.5mU/kg/min; T2DM: 2.5mU/kg/min) hypoglycaemic clamp (5.5, 3.5, 2.5 mmol/L). Primed tracer infusion of [6,6-<sup>2</sup>H<sub>2</sub>]glucose and [1,1,2,3,3-<sup>2</sup>H<sub>5</sub>]glycerol was used to assess EGP and Ra glycerol throughout all glycaemic levels. Ten C-peptide negative T1DM (age 42±14 yrs, diabetes duration 21±13 yrs, BMI 23.2±2.0 kg/m<sup>2</sup>) were compared to 17 metformin only treated T2DM patients (age 53±6 yrs, diabetes duration 6.6±5.1 yrs, BMI 28.9±3.3 kg/m<sup>2</sup>).

**Results**

Glucagon levels were significantly lower in T1DM compared to T2DM during euglycaemia (P0.001) and during hypoglycaemia (at 2.5 mmol/L: P0.001). At euglycaemia insulin, EGP, Ra glycerol and ketones were comparable in T1DM and T2DM (all ns). During hyperglycaemia EGP (P0.02), Ra glycerol (P0.02) and ketones (P0.001) were substantially higher in T1DM, but insulin was lower (P0.02). During induction of hypoglycaemia EGP and ketones were comparable, but T2DM had higher Ra glycerol (P0.01) despite higher insulin levels (P0.001). Free fatty acid (FFA) levels were not different throughout the clamp.

**Conclusion**

This novel stepwise clamp using a stable tracer method allows assessment of glucose fluxes (EGP and peripheral glucose uptake) and lipolysis (Ra glycerol) over a wide range of glycaemic levels in subjects with diabetes. Distinct differences in fuel shifts (e.g. in lipolysis) are not detected by FFA measurement, but by rate of appearance of glycerol using a stable tracer method.



**Poster Board No. 21**

**Effectiveness of An mHealth Intervention for Type 2 Diabetes: A Longitudinal Cohort Study**

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<sup>3</sup>*School of Nursing, Tianjin Medical University, China*

<sup>4</sup>*iHealth Labs Inc, iHealth Labs Inc, China*

**Background**

Mobile health (mHealth) intervention has been the focus of current researches on noncommunicable diseases control and management. The effectiveness evaluation based on real world data will provide a strong evidence for mHealth interventions spreading.

**Objective**

This study aimed to assess whether mHealth intervention with real time advice for diabetes whole course management conducted by the multidisciplinary team would improve the blood glucose control in patients with type 2 diabetes.

**Methods**

From February to August 2018, we recruited 209 participants (131 male and 78 female) with type 2 diabetes aged 23 to 64 from Metabolic Diseases Hospital of Tianjin Medical University. Participants received the real time health intervention based on mobile app and smart wearable medical devices. All of the participants completed two investigations at baseline and six months follow-up. Main outcomes included glycosylated hemoglobin (HbA1c), fasting plasma glucose (FPG), and 2-hour postprandial blood glucose (2hPG).

**Results**

Compared with the baseline, at six months follow-up, the percentage of HbA1c < 7% among all the participants had doubled (75.60% vs. 35.41%); the percentage of HbA1c > 9% substantially decreased (1.44% vs. 22.01%). The percentages of FPG 4.4-7.0 mmol/L at baseline and six months follow-up were 37.32% and 56.46%, respectively, whereas, the percentage of FPG > 9 mmol/L decreased from 26.79% (baseline) to 5.74% (six months follow-up). After six months follow-up, the percentage of 2hPG ≤ 10 mmol/L increased by 26.8, and the percentage of 2hPG > 10 mmol/L decreased to 11.00%.

**Funding**

The National Natural Science Foundation of China (91746205, 71673199, 7167031431), the Project Scientific of Tianjin Science and Technology Commission of China (15ZXHLSY00460).

**Poster Board No. 22**

**The Glucagon- To- Insulin Ratio Reflects the Metabolic Milieu in A Specific Manner Under the Sequential Combination Therapy with Canagliflozin Followed by Tenueligliptin**

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**Background and objective**

The detail mechanism of the improvement in blood glucose by SGLT2 inhibitors and DPP 4 inhibitors remains unclear.

**Methods**

26 poorly controlled (HbA1c 10.7%) T2DM patients (19 men and 51 years) were incorporated into a step regimen which started 100mg per day of canagliflozin (CANA) at day 0 and added 20mg per day of tenueligliptin (TENE) at day 3. Subjects underwent solid mixed meal tests three times, on days 0, 3 and 5. The glucose, insulin and glucagon were measured. We calculated glucagon insulin ratio ( $G/I = \text{glucagon} / \text{insulin}$ ).

**Result**

Administration of CANA for 4 days brought about 15% decrease FPG accompanied by about 10% decrement in fasting IRI. Meanwhile, fasting IRG was increased significantly by about 11%, thus fasting IRG to IRI ( $G/I$ ) ratio exhibited a significant increase by 43%. To elucidate the interaction of these parameters, correlation analysis was performed at fasting state. The magnitude of change in FPG correlated with change in fasting IRI positively and, stronger correlation was observed between the changes in FPG and those in  $G/I$  ratio. On the other hand, the changes in FPG negatively correlated to those in fasting IRG without significance. Addition of TENE on CANA for 3 days reduced FPG mildly by 6.2%. Contrary to the effect of CANA, fasting IRI showed a tendency to increase by 17% along with decrement in FPG. The level of fasting IRG also exhibited opposite trend to CANA showing a decrease by 3.6%. The magnitude of changes in FPG correlated with changes in fasting IRI positively and changes in IRG negatively and, stronger correlation was observed between the changes in FPG and those in  $G/I$  ratio.

**Conclusion**

The new finding of this study was the strong correlation between the magnitude of changes in FPG correlated with those in  $G/I$  ratio.

**Poster Board No. 23**

**Effect of Remote Glucose Monitoring Utilizing Computerized Insulin Dose Adjustment Algorithms on HbA1c Levels: A Pilot Project**

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**Background**

Adjusting insulin doses is very challenging for primary care physicians because of infrequent office visits and time constraints at the visit. For patients, frequent office visits are a barrier.

**Objective**

To use FDA-approved, computerized insulin dose adjustment algorithms and remote glucose monitoring to circumvent both of these issues.

**Methods**

Diabetic patients in a safety net clinic who took insulin for at least 6 months with HbA1c levels  $\geq 8.0\%$  were enrolled. An iHealth glucose meter was attached to a smartphone containing an app downloaded from the Web that automatically transmitted glucose values to a secure, HIPAA-approved server. There the values were analyzed by the algorithms and a report with recommendations for dose changes was generated and sent every 2-3 weeks to a clinic nurse practitioner who could accept, modify or reject the recommendations. A clinic staff person contacted the patient with the insulin dose changes. The new doses served as the basis for the next report.

**Results**

Twenty-eight diabetic patients (one type 1) reached three months and 17 completed 6 months. Their mean age ( $\pm$  SD) was  $55.9 \pm 8.6$  years, 15 were females and 13 were males. There were 20 Latinos, 4 African-Americans, 3 Caucasians, and 1 Asian. Their insulin regimens were: basal alone – 11, basal/bolus – 14 and self-mixed/split – 3. Non-insulin drugs were not changed. **Baseline A1C levels of 10.0% decreased to 8.1% after 3 months and to 7.6% after 6 months.** Their total insulin doses increased by 24%. There were no episodes of severe hypoglycemia (requiring 2<sup>nd</sup> party assistance) nor emergency room visits for hypoglycemia.

**Conclusion**

Remote glucose monitoring utilizing computerized insulin dose adjustment algorithms to analyze glucose values and generating recommendations for dose changes at more frequent intervals markedly improved HbA1c levels in poorly controlled diabetic patients without clinic visits.

**Poster Board No. 24**

**Association of Metabolic Surgery with All-cause Mortality among Individuals with Diabetes**

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**Background**

Metabolic surgery is an effective approach to management of obesity in persons with diabetes. Specifically, metabolic surgery is associated with significant weight loss, improved diabetes control, and higher remission rates of type-2 diabetes. Metabolic surgery is also associated with reduced all-cause mortality in the overall bariatric surgery population, but less is known about mortality experience in patients with diabetes.

**Objective**

To assess the association between metabolic surgery and all-cause mortality in a large matched cohort of obese individuals with diabetes.

**Methods**

A retrospective cohort study that included patients from a large Israeli HMO (Clalit) with diabetes who underwent metabolic surgery during the years 2005 and 2014. Using a sequential (time-dependent) stratification matching, three matched non-surgical patients were selected for each surgical patient, based on age, sex, and BMI. Follow up period was from index-date (date of surgery) until occurrence of event (all-cause mortality) or end of study period (December 31 2015). Unadjusted and adjusted Stratified Cox proportional hazards regression were used to assess the hazard ratio (HR) and 95% CI for the association between exposure to metabolic surgery and all-cause mortality.

**Results**

2,391 individuals with diabetes underwent metabolic surgery during the study period (Laparoscopic banding [n=764], gastric bypass [n=524], laparoscopic sleeve gastrectomy [n=1,100]). Of these, 51 (2.1%) died during follow-up (Median [IQR]: 46 months [30-67]). Adjusted hazard ratios (HRs) for mortality among non surgical vs. surgical patients with diabetes were as follows: HR<sub>total</sub>: 2.36 (1.72-3.22); HR<sub>band</sub>: 2.75 (1.68-4.51); HR<sub>sleeve</sub>: 1.90 (1.10-3.34) HR<sub>bypass</sub>: 2.78 (1.23-4.21).

**Conclusion**

Among obese patients with diabetes in the intermediate period, the 3 common types of metabolic surgery are associated with a lower risk for all-cause mortality.

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**Clinical Use of Glycated Albumin as a Non-Traditional Measure of Glycemic Status**

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**Background**

Glycated Albumin (GA) has been suggested as an additional or alternative biomarker to circumvent some of the limitation of HbA1c. The much shorter half-lives of albumin compared to haemoglobin makes it more responsive to changes in glycemic status. Moreover, GA shows a stronger correlation with continuous glucose measurement over 1 to 2 days than HbA1c, so it may reflect glycemic variability and glucose excursions more accurately. Although GA represents a promising biomarker for the evaluation of glycemic status in both experimental and clinical settings, its introduction in clinical practice requires further validation in relation to basic interpretative criteria and diagnostic accuracy.

**Objectives**

i) to define reference limit of GA with a direct approach; and ii) to evaluate diagnostic accuracy of GA in predicting diabetes in asymptomatic subjects at risk of suffering from diabetes.

**Methods**

One thousand thirty-four consecutive blood donors were recruited for reference range definition. Asymptomatic subjects at risk for diabetes were recruited for diagnostic accuracy study. GA was measured by an enzymatic-colorimetric method.

**Results**

The calculated GA URL in blood donors was 14.5% (95% CI: 14.3–14.7). Among subjects at risk of diabetes, GA median levels were 13.2% (IQR:12.2–14.4). Eighteen subjects (5.4%) were classified as diabetics based on their HbA1c. GA was significantly correlated with HbA1c ( $r=0.31$ ;  $P=0.0001$ ). According to ROC curve analysis, GA identified subjects with diabetes with a sensitivity of 72.2% (95% CI: 46.5–90.3) and a specificity of 71.8% (95% CI: 66.5–76.7) (AUC: 0.80; 95% CI:0.75–0.84;  $P=0.0001$ ) at the cut-off of 14%.

**Conclusion**

The knowledge of GA distribution in healthy subjects is essential to promote its introduction in both research and clinical practice. GA can also be considered a useful biomarker of glycemic status that can predict diabetes with high accuracy.