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XXIV SCIENTIFIC CONGRESS OF DIABETES POLAND 18–20 MAY 2023 | KATOWICE – ABSTRACTS

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ORAL SESSIONS OF ORIGINAL PAPERS
SESSION OF ORIGINAL PAPERS 1
Chairs: Marta Wróbel, Elektra Szymańska-Garbacz

U1
DOES BETTER CARDIORESPIRATORY FITNESS INCREAS THE CHANCE OF A PARTIAL CLINICAL REMISSION AMONG ADULTS WITH TYPE 1 DIABETES? THE EVIDENCE FROM THE DIAB1FIT STUDY (NCT04968171)

Justyna Flotyńska[1], Dariusz Naskręt[2], Paweł Niedźwiecki[2], Agata Grzelka-Woźniak[2], Anita Kaczmarek[2], Aleksandra Pypeć[2], Aleksandra Cieluch[2], Dorota Zozulińska-Ziółkiewicz[2], Aleksandra Uruska[2]

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Introduction: An essential process affecting the course of type 1 diabetes (DM1) is the appearance and duration of clinical remission. There are many factors that promote remission and influence positively the course of the disease. One of the most important is physical activity. Maximal oxygen capacity (VO_2max) is an objective measure of the body's aerobic capacity. To assess VO_2max, oxygen uptake should be measured directly during the exercise test. Evaluation of physical capacity in adults with DM1 and its relationship with the occurrence of partial clinical remission (pCR) during two years follow-up (DIAB1FIT STUDY NCT04968171).

H1: The greater the physical capacity at the beginning of DM1, the greater the chance of remission.

Material and methods: Participants were recruited during 2 years (2019–2021) and observed from diagnosis. The inclusion criteria were: age above 18 years old, newly diagnosed DM1 confirmed with antibodies, whereas the exclusion criteria were: CRP > 5 mg/l, unstable hypo/hyperthyroidism (TSH beyond normal range), other endocrinological disorders, contagious diseases, renal or liver diseases, pregnancy, antineoplastic therapy in less than 2 years and any psychological or psychiatric disorder. Everyone was treated with functional intensive insulin therapy from the onset of diabetes. The pCR was assessed by the following mathematical formula: HbA_{1c} (%) + [4 x insulin dose (U/kg/d)]. The result ≤ 9 indicates pCR. VO_2max was assessed between 6th and 24th month of diabetes duration using an ergospirometer (COSMED K5 System), during an exercise test carried out on a cycloergometer (RAMP incremental exercise test).

Results: The study group consisted of 32 adults (4 women and 28 men) with DM1, aged 27 (22.0–30.5) years and with A1c 6.9 (6.1–7.5) % – at the time of the exercise test. People with pCR were proved to have higher VO_2max level (36.0 [33.0–41.5] vs. 30.9 [26.5–34.4] ml/min/kg, p = 0.009), lower glucose level before exercise (134 [101–183] vs. 210 [149–227] mg/dl, p = 0.020) and at the top of exercise (140 [113–160] vs. 183 [145–227] mg/dl, p = 0.044). Univariate and multivariate regression confirmed a significant association between VO_2max and presence of pCR, independent of age, sex, BMI and smoking (AOR 1.26 [1.05–1.52], 0.015).

Conclusions: The higher VO_2max, the bigger chance of partial clinical remission at two years of type 1 diabetes. Therefore, the results presented in this study confirmed the importance of physical activity in promoting partial clinical remission.

Source of funding: Diabetes Poland Grant

U2
METABOLIC PARAMETERS IN PATIENTS WITH SUSPECTED REACTIVE HYPOGLYCEMIA

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Introduction: It remains unclear whether reactive hypoglycemia is a disorder caused by metabolic disturbance or the result of inappropriate eating habits. The diagnostic scheme for this disorder has also not been established. Evaluation of metabolic parameters in patients admitted to the hospital with suspected reactive hypoglycemia.

Material and methods: the study group (SG) included non-diabetic individuals with symptoms consistent with reactive hypoglycemia (n = 40). The control group (CG) included individuals without hypoglycemic symptoms and any medical history of metabolic disorders (n = 35). In both groups, fasting glucose, fasting insulin, and lipid profile were evaluated. A 75 g five-hour Oral Glucose Tolerance Test (OGTT) with an assessment of glucose and insulin was performed, and insulin resistance was estimated using the Homeostatic Model Assessment for Insulin Resistance (HOMA-IR). In the SG, Mixed Meal Tolerance Test (MMTT) was conducted.

Results: in OGTT in the SG 30% of patients (n = 12) had hypoglycemic symptoms (HS) and glucose level < 55 mg/dl, 25% of patients (n = 10) manifested hypoglycemic symptoms without significant glucose decline, and in the CG 23% (n = 8) had biochemical hypoglycemia without accompanying clinical symptoms. In the SG, 43% (n = 17) of patients reported HS during MMTT but none had a glucose concentration < 55 mg/dl. Patients from the SG with hypoglycemic symptoms and biochemical hypoglycemia had lower HOMA-IR (1.2 ±0.5 vs. 1.8 ±0.8, p = 0.029), and lower insulin value (22.7 ±10.9 lU/ml vs. 43.4 ±35.0 lU/ml, p < 0.001) at the second hour of OGTT compared to the patients without HS or biochemical hypoglycemia. From the entire lipid profile, only the mean total cholesterol value was significantly higher (p = 0.024) in the SG in comparison with the CG but did not exceed the standard reference range.

Conclusions: No metabolic disturbances have been observed in patients with hypoglycemic symptoms and biochemical hypoglycemia in OGTT. The glycemic decline in OGTT has not been associated with hyperinsulinemia. Hypoglycemia in the OGTT is an unreliable criterion in the diagnosis of patients with symptoms of postprandial hypoglycemia.

U3
CHARACTERISTICS, MORTALITY AND CLINICAL OUTCOMES OF HOSPITALIZED PATIENTS WITH COVID-19 AND DIABETES – A REFERENCE SINGLE-CENTER COHORT STUDY FROM POLAND

Michał Kania[1], Konrad Mazur[1], Michał Terlecki[2], Bartłomiej Matejko[1], Jerzy Hohendorff[1], Zlata Chaykivska[3], Mateusz Fiema[3], Marianna Kopka[3], Małgorzata Kostrzycka[3], Magdalena Wilk[1], Tomasz Klupa[1], Przemysław Witek[1], Barbara Katra[1], Marek Klocek[2], Marek Rajzer[2], Maciej T. Małecki[1]

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Introduction: By the end of January 2023, COVID-19 was diagnosed in more than 6.4 million people in Poland. Based on the previous studies, it is estimated that 10–20% of these COVID-19 patients also suffer from diabetes. In the course of COVID-19, diabetes has been recognized as a major risk factor for its severity, an admission to the intensive care unit and mortality. We evaluated the characteristics and risk factors associated with undesirable outcomes in diabetic patients (DPs) hospitalized due to COVID-19.

Material and methods: The data analysis of patients admitted between March 6' 2020 – May 31' 2021 to the University Hospital in Krakow (Poland), a reference center for COVID-19, was performed. The data was gathered from medical records.

Results: A total number of 5191 patients was included, of which 2348 (45.2%) were women. Patients were at median age 64 (IQR 51–74) years, 1364 (26.3%) were DPs. DPs, compared to non-diabetics, were older (median age 70 years, IQR 62v77 vs. 62, IQR 47–72, $p < 0.001$) and had a similar gender distribution. DPs were admitted to the ICU more frequently (15.7% vs. 11.0%, $p < 0.001$) and required mechanical ventilation more often (15.5% vs. 11.3%, $p < 0.001$). DP group had a higher mortality (26.2% vs. 15.7%, $p < 0.001$). In a multivariate logistic regression, factors associated with a higher risk of death were: age > 65 years, glycemia > 10 mmol/l, higher CRP and D-dimer level, pre-hospital insulin and loop diuretic use, presence of heart failure, and chronic kidney disease. Factors contributing to lower mortality were in-hospital use of statin, thiazide diuretic and calcium channel blocker.

Conclusions: In this large COVID-19 cohort, DPs constituted more than a quarter of hospitalized patients. Risk of death and other outcomes compared to non-diabetics was higher in this group. We identified a number of clinical, laboratory, and therapeutic variables associated with the risk of hospital death in DPs.

U4
DIABETES AS A RISK FACTOR OF DEATH IN HOSPITALIZED COVID-19 PATIENTS – AN ANALYSIS OF A NATIONAL HOSPITALIZATION DATABASE FROM POLAND, 2020

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Introduction: Diabetes has been associated with a higher risk of unfavourable outcomes and poor prognosis in the course of COVID-19. There are few analyses of datasets from the nationwide level of COVID-19 patients. In this nationwide retrospective study, we evaluated the risk of in-hospital death attributed to diabetes in COVID-19 patients.

Material and methods: We analysed data from discharge reports sent to the Polish National Health Fund (Narodowy Fundusz Zdrowia, NFZ) from 2020 of hospitalized COVID-19 patients. Several multivariate logistic regression models were used. In each model, in-hospital death was estimated with explanatory variables. Models were built either on the whole cohorts or cohorts matched with propensity score matching (PSM). They examined either main effects or included interaction of diabetes with other variables.

Results: We included 174,621 patients with COVID-19 hospitalized in the year 2020. Among them, there were 40,168 diabetic patients (DPs), and the proportion of DPs in this group was higher than in the general population (23.0% vs. 9.5%, $p < 0.001$). Overall, 17,438 in-hospital deaths were recorded, and the mortality was higher among DPs than non-diabetics (16.3% vs. 8.1%, $p < 0.001$). Multivariate logistic regressions showed that diabetes was a risk factor of death, regardless of sex and age. In the main effect analysis, odds of in-hospital death were higher by 28.3% for DPs than for non-diabetic patients. Similarly, PSM analysis including 101,578 patients, of whom 19,050 had diabetes, showed that the risk of death was higher in DPs regardless of sex with odds higher by 34.9%. The impact of diabetes differed among age groups and was the highest for patients aged 60–69.

Conclusions: This nationwide study confirmed that diabetes was an independent risk of in-hospital death in the course of COVID-19. However, the relative risk differed across the age groups.

U5
GLUCOSE MONITORING INTENSITY, GLYCEMIC CONTROL AND CLINICAL OUTCOMES OF HOSPITALIZED COVID-19 PATIENTS – A REFERENCE SINGLE-CENTER COHORT STUDY FROM POLAND

Michał Kania[1], Konrad Mazur[2], Zlata Chaykivska[2], Mateusz Fiema[2], Marianna Kopka[2], Małgorzata Kostrzycka[2], Magdalena Wilk[1], Jerzy Hohendorff[1], Tomasz Klupa[1], Przemysław Witek[1], Barbara Katra[1], Maciej T Małecki[1]

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Introduction: Hyperglycemia at admission was earlier reported as a risk factor for in-hospital severe course and death from COVID-19. We aimed to describe the glucose monitoring intensity as well as the association between glycemic control and clinical outcomes in the hospitalized patients with COVID-19.

Material and methods: We performed a retrospective analysis based on the medical record of COVID-19 adult patients with diabetes hospitalized between March 6 – October 30' 2020 in the University Hospital in Krakow, a tertiary reference center.

Results: We analyzed data of 157 diabetic patients for whom blood glucose measurement (BGM) data was available. Patients were on average 68.2 ±11.8 years old. Women constituted 42.2% (n = 68) of the group. There were 27 (17.2%) patients admitted to the ICU, 22 (14.0%) requiring mechanical ventilation, and 26 (16.6%) who died.

The mean total number of BGMs for one patient during the hospitalization was 57.7 ±47.1 and mean number of BGMs per day was 1.9 ±1.7. Patients treated with insulin in the period preceding the hospitalization, as compared to those with no history of pre-hospital insulin use, had higher the in-hospital mean number of BGMs (3.6 ±2.7 vs. 2.3 ±2.6; $p < 0.001$). In-hospital treatment with insulin, mostly intensive insulin therapy, was associated with higher mean number of in-hospital BGMs as compared to the rest of the group (3.5 ±2.5 vs. 2.0 ±2.39; $p < 0.001$). There were 9056 BGMs recorded over the period of 3494 patient-days (pds). The number of BGMs > 250 mg/dl was 1001 (11.1%), > 180 mg/dl – 2875 (31.7%) and 70–180 mg/dl – 5950 (65.7%). There were 534 pds (15.3%) with at least 1 BGM > 250 mg/dl and 1194 pds (34.2%) with at least 1 BGM > 180 mg/dl.

The mean in-hospital blood glucose (BG) was 159.1 ±44.1 mg/dl. 23.5% of patients had mean in-hospital BG > 180 mg/dl. Non-survivors had higher in-hospital mean BG (196.7 ±81.5 vs. 153.6 ±50.0 mg/dl; $p < 0.001$), more recorded hyperglycemic BGMs > 250 mg/dl (5.0 ±19.0 vs. 1 ±8.0; $p = 0.009$), and less recorded normoglycemic BGMs (13.0 ±35.0 vs. 32.0 ±27.0, $p < 0.001$) as compared to survivors.

Conclusions: Among hospitalized diabetic patients with COVID-19, approximately two third of BGMs were within the therapeutic targets 70–180 mg/dl. The frequency of BGMs in patients not receiving insulin seems to have been adequate, while in patients treated with insulin was lower than recommended by the guidelines, what can be probably explained by the medical staff effort to reduce physical contact with infected patients. In-hospital hyperglycemia was associated with higher mortality.

SESSION OF ORIGINAL PAPERS 2

Chairs: Aleksandra Uruska, Katarzyna Cyganek

U6

METABOLIC CONTROL AND PRESENCE OF CHRONIC COMPLICATIONS OF TYPE 1 DIABETES – 25 YEARS OF POZNAN PROSPECTIVE STUDY

Aleksandra Cieluch[1], Aleksandra Araszkiewicz[1], Dariusz Naskręt[1], Agata Grzelka-Woźniak[1], Aleksandra Uruska[1], Dorota Zozulińska-Ziółkiewicz[1]

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Introduction: 100 consecutive adults with newly diagnosed type 1 diabetes (T1D) treated from the moment of diagnosis with intensive insulin therapy were included in the PoProStu study in the years 1994–1998. At diagnosis they were educated on proper insulin doses' adjustment.

The aim of study was assessment of metabolic control and the presence of chronic diabetes complications in patients with T1D, participants of the PoProStu study, after 25 years of disease duration.

Material and methods: 71 people (27 women) aged 47 (43–51), diabetes duration 25 (24–26) years were included in the analysis. During the observation, 5 people died, 9 people resigned from participation in the study, 15 people were lost to follow-up. Anthropometric data, metabolic control (A1c, lipid profile, blood pressure values), and the presence and severity of chronic complications of diabetes (retinopathy, diabetic kidney disease, peripheral and autonomic neuropathy, macroangiopathic complications with the assessment of the thickness of the intima-media complex) were evaluated.

Results: After 25 years of follow-up, the median body weight was 82 (70.3–94.6)kg, BMI 26.4 (23.0–30.0) kg/m^2, insulin requirement 0.61 (0.5v0.72)U/kg/day, A1c values 7.9 (7.3–8.6)%. The percentage of patients with A1c ≤ 6.5% was 10% and ≤ 7% was 18%. Median serum cholesterol LDL was 104 (82.6–125.3) mg/dl, non-HDL 121 (98–150.8) mg/l, HDL 67 (55–75) mg/dl, total cholesterol 192 (167–207.8) mg/dl, triglycerides 90.5 (68.9–119.5) mg/dl. None of the patients reached their LDL cholesterol target. Due to previously diagnosed dyslipidemia, 21% of patients were treated with a statin. The median systolic blood pressure was 135.0 (123.3–147.0) mm Hg and the diastolic blood pressure was 82 (77.3–90) mm Hg. 48% of patients had previously been diagnosed with hypertension. 25% of the study group were smokers. Diabetic retinopathy was diagnosed in 23 people (33%) (including 6 cases of proliferative retinopathy), diabetic kidney disease in 25 people (35%), peripheral neuropathy in 25 people (35%), cardiac autonomic neuropathy in 16 people (24%), diabetic foot syndrome in 3 people (4%), macroangiopathy in 17 people (24%) (including 4 patients after myocardial infarction and 2 patients with a history of ischemic stroke). The presence of atherosclerotic plaque in the carotid arteries was found in 13 patients (18%), while the median intima-media thickness was 0.74 (0.64–0.85) mm. 37% of people did not develop any complications of the disease.

Conclusions: Despite the progress in treatment, 25 years after the diagnosis of T1D, every fifth patient achieves the general goal of glycemic control, none of the patients meets all the criteria of metabolic control, and every third patient has chronic complications of the disease.

U7
RHINENCEPHALON NEURODEGENERATION UPON MAGNETIC RESONANCE IMAGING IN ADULTS WITH TYPE 1 DIABETES MELLITUS

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Introduction: Rhinencephalon imaging in patients with diabetes and dysosmia may bring important insights into advancement of chronic complications of diabetes. The goal of the study was to assess neurodegenerative changes of rhinencephalon in patients with Type 1 Diabetes Mellitus (T1DM) upon magnetic resonance imaging (MRI) with additional focus on the relation between those changes and dysosmia in patients with T1DM and diabetic peripheral neuropathy.

Material and methods: The study group consisted of type 1 diabetic patients 18–65 years of age and disease duration > 10 years. Control group included diabetes-free subjects. The control group was divided according to the presence of diabetic peripheral neuropathy. Complete otorhinolaryngological examination and olfactory assessment with Sniffin'Sticks was performed. To evaluate the morphology of the rhinencephalon, magnetic resonance imaging of the head was performed. T1 and T2, 3D MPRANGE sequences were used to perform volumetric measurements of the olfactory bulbs and pyriform cortices thickness.

Results: We examined 32 subjects, 24 male median age 43.5 years (IQR: 37.0–48.5)], with disease duration of 24.5 years (IQR: 20.5–27.0), HbA_{1c} 7.9% (IQR: 7.4–8.4). Control group consisted of 6 subjects, 4 male [median age of 41,0 years (IQR: 36.0–48.0)]. Significantly lower olfactory test results in TDI (Threshold-Differentiation-Identification) [31.5 (IQR: 28.7–33.6) vs. 34.1 (IQR: 33.2–37.2), $p = 0.02$] and olfactory threshold [7.0 (IQR: 6.5–8.0) vs. 8.5 (IQR: 8.0–9.0); $p = 0.049$] were obtained in the study group as compared to the controls. Summarized olfactory bulbs volumes [65.8 mm^3 (IQR: 57.9–71.7) vs. 75.8 mm^3 (IQR: 74.8v76.7); $p = 0.0005$], as well as separately right [33.4 mm^3 (IQR: 28.6–36.2) vs. 37.5 mm^3 IQR (36.9–38.8); $p = 0.001$] and left [32.6 mm^3 (IQR: 29.1–35.4) vs. 37.9 mm^3 (IQR: 37.2–38.8); $p = 0.0006$] olfactory bulb volumes were significantly smaller in patients with T1DM than in the controls. Smaller thickness of the left pyriform cortex was found in the study group as compared to the controls [3.1 mm (IQR: 2.7–3.4) vs. 3.6 mm (IQR: 3.5–4.1); $p = 0.02$]. In patients with diabetes and neuropathy significantly smaller olfactory bulb volumes were found as compared to patients without this complication [58.1 mm^3 (IQR: 54.0–70.9) vs. 69.8 mm^3 (IQR: 65.0–72.2); $p = 0.02$]. In the group of all subjects submitted to the MRI, statistically significant correlations between olfactory test results and summarized olfactory bulb volumes (RS = 0.32; $p = 0.048$) as well as pyriform cortices thicknesses on both sides were found (for the right: RS = 0.36; $p = 0.028$ and left: RS = 0.43; $p = 0.006$).

Conclusions: In adults with T1DM olfactory function is worse than in the healthy controls, and measurements of rhinencephalon structures are smaller. The smaller the size of rhinencephalon structures the worse the olfactory function.

Source of funding: Diabetes Poland Grant (2019)

U8
EVALUATION OF SELECTED METABOLITES OF KYNURENINE PATHWAY IN TYPE 1 DIABETES

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Introduction: The kynurenine pathway (KP) is the main route of tryptophan (TRP) – an exogenous amino acid-metabolism. It leads to the production of many bioactive compounds, such as kynurenine (KYN), kynurenic acid (KYNA), 3-hydroxykynurenine (3-HKYN), anthranilic acid (AA), 3-hydroxyanthranilic acid (3-HAA) and nicotinamide adenine dinucleotide (NAD+). Literature data indicate that alterations in TRP metabolism *via* KP are observed in obesity, type 2 diabetes, atherosclerosis, and heart failure. Higher concentrations of 3-HKYN were reported in patients with diabetic retinopathy, and it was shown to be associated with an increased risk of acute coronary incidents. In contrast, AA is a metabolite with antihyperglycemic properties. However, studies considering changes in TRP metabolism in type 1 diabetes (T1D) are scarce. The purpose of the study was to evaluate alterations in TRP metabolism *via* KP in patients with T1D in comparison to healthy subjects and to assess their association with diabetes incidence and metabolic control parameters.

Material and methods: The study included 50 subjects with T1D (24 women/26 men) aged 20–60 years with a median diabetes duration of 9 years (IQR: 2–18) and 43 healthy controls (22 women/21 men) matched for age, gender, and BMI.

Methods: In all participants, anthropometric parameters, HbA_{1c} (in the T1D group), serum levels of CRP, glucose, creatinine, and lipids were assessed. Serum concentrations of TRP, KYN, 3-HKYN, 3-HAA were estimated by high-performance liquid chromatography (HPLC).

Results: T1D group had higher TRP, KYN, 3-HKYN concentrations ($p < 0.0001$; $p = 0.003$; $p < 0.0002$), lower AA concentrations ($p = 0.003$), and KYN/TRP, AA/KYN, 3-HAA/AA, 3-HKYN/3-HAA ratio values ($p = 0.005$; $p = 0.041$; $p = 0.001$; $p = 0.001$) than controls. Positive correlations were found between HbA_{1c}, diabetes duration and KYN concentrations ($r = 0.422$, $p = 0.002$; $r = 0.343$, $p = 0.015$), as well as between diabetes duration and 3-HAA concentrations ($r = 0.283$, $p = 0.046$). In the T1D group, subjects with $HbA_{1c} > 7\%$ ($n = 33$) had higher KYN concentrations (Me = 2.614 μM; IQR: 2.037–3.00; $p = 0.011$) compared to those with $HbA_{1c} \leq 7\%$ (Me = 1.998 μM; IQR: 1.807–2.306). Univariable logistic regression analysis revealed the association between TRP, AA, and 3-HKYN concentrations and the presence of T1D (OR = 1.143; OR = 0.963; OR = 1.092, respectively).

Conclusions: Poor metabolic control of diabetes is associated with impaired TRP metabolism in T1D patients. A shift in TRP metabolism toward the increased formation of 3-HKYN, a precursor of neurotoxic KP metabolites (quinolinic acid and xanthurenic acid), with a concomitant reduction in AA concentrations, may be associated with a greater risk of developing chronic diabetic complications in individuals with T1D.

U9
VASCULAR AGE AND ARTERIAL STIFFNESS IN THE ASSESSMENT OF CARDIOVASCULAR RISK AMONG YOUNG ADULTS WITH TYPE 1 DIABETES

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Introduction: Type 1 diabetes mellitus (T1DM) leads to macrovascular complications and cardiovascular disease (CVD). Cardiovascular risk (CVR) in people with T1DM is assessed using ESC criteria from 2019. However, recent studies suggest alternative methods more accurate for T1DM like Steno Type 1 Risk Engine (ST1RE), vascular age (VA) based on common carotid intima-media thickness (cIMT), and arterial stiffness (AS). We aimed to investigate the association between VA, AS, ST1RE, and ESC CVR categories in people with T1DM.

Material and methods: The study group comprised 61 T1DM adults aged 18–45 with diabetes duration of at least 5 years without CVD and hypertension. Medical history, anthropometrical features, and laboratory results were collected and used to calculate 10-year CVR using ST1RE. The cIMT automatic measurement was performed using a GE Vivid S6 device and Carotid Analyzer for Research software. Based on cIMT we calculated VA and used vascular instead of chronological age to estimate the modified ST1RE score. We assessed AS by measuring 24-hour aortic pulse wave velocity (aPWV) with a brachial oscillometric device (Arteriograph 24). The participants were divided into 3 CVR categories using ESC criteria and ST1RE scores based on VA. We performed descriptive statistics, Cohen's kappa coefficient, Spearman rank correlation, ANOVA Kruskal-Wallis, χ^2 tests, and multiple logistic and linear regression analyses.

Results: We investigated $n = 61$ individuals with a median age of 30.0 (25.0–36.0) years and a diabetes duration of 15.0 (9.0–20.0) years. 33 (54.1%) of them were males. The aPWV was positively related to VA (Rs = 0.31; $p = 0.01$) and ST1RE score based on VA (Rs = 0.36; $p < 0.01$). ST1RE categories based on VA showed significantly higher agreement ($\kappa = 0.14$; $p = 0.02$) with the ESC 2019 criteria than the standard ST1RE ($\kappa = 0.00$; $p = 0.92$). The aPWV was getting higher with each next ESC 2019 category – 6.62 (6.51–7.32) m/s at moderate risk, 7.50 (7.00–8.05) m/s at high risk, and 8.33 (7.52–9.21) m/s at very high risk ($p = 0.02$). The multiple logistic regression model revealed that aPWV was positively associated with high versus low and moderate CVR based on ST1RE score with VA (OR = 2.58; 95% CI: 1.04–6.42; $p = 0.04$). The association was independent of sex, glycated hemoglobin, diabetes duration, the presence of diabetic complications, and BMI.

Conclusions: Among individuals with T1DM, AS and, VA are positively associated with ESC criteria and ST1RE scores. Cardiovascular risk categories based on ST1RE with vascular instead chronological age have better agreement with the ESC criteria.

U10
CamAPS FX IN CHILDREN WITH TYPE 1 DIABETES IN POLAND – THE FIRST ENCOURAGING EXPERIENCE FROM TWO DIABETES PEDIATRIC CENTERS

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Introduction: The hybrid closed-loop system (HCL) is designed to maintain glucose concentrations at a set target by combining information from continuous glycaemic monitoring (CGM) with an algorithm that allows automatic insulin delivery (AID). The CamAPS FX system is the second officially available AID in Poland. The aim of the study was to compare the metabolic control of children with type 1 diabetes treated with the CamAPS FX to previous therapy.

Material and methods: Eleven children (8 boys) participated in the study. The mean age of the children was 11.72 ±3.28 years and the duration of disease was 3.44 ± 2.93 years . Before connection to AID, 2 patients were treated with multiple injections, the others were treated with a personal insulin pump. The CGM reports were analyzed from two weeks prior to AID connection and two weeks on CamAPS FX.

Results: The time spent in the glycemia range of 70–180 mg/dl (TIR) before AID was 69.00 ±25.47% and increased to 77.45% ±16.96 $p < 0.05$ after starting the AID. Other results are shown in the table.

Conclusions: The use of the CamAPS FX in children with type 1 diabetes significantly increases the time spent in target glycaemia compared to the prior treatment mode.

Parameters	CGM metrics from initial treatment mode (pen/pump)	AID using CamAPS FX
Average sensor glucose [mg/dl]	153.82 ±51.74	141.24 ±29.77
Coefficient of variation (%)	34.97 ±7.10	34.31 ±7.74
Glucose management indicator (%)	6.99 ±1.24	6.69 ±0.71
Total daily insulin [j.]	36.05 ±17.11	38.08 ±22.09
Time spent > 180 mg/dl (%)	27.63 ±36.74	19.45 ±17.45, $p < 0.05$
Time spent 70–180 mg/dl (%)	69.00 ±25.47	77.45 ±16.96, $p < 0.05$
Time spent < 70 mg/dl (%)	3.36 ±2.84	3.00 ±1.73

AID – automatic insulin delivery, CGM – continuous glycaemic monitoring

U11
HOW DOES PHYSICAL ACTIVITY CHANGE AFTER THE DIAGNOSIS OF TYPE 1 DIABETES IN ADULTS – INLIPODIAB1 STUDY

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Introduction: The course of type 1 diabetes (DM1) is closely related to lifestyle, including physical activity (PA). Studies indicate that PA may have a beneficial effect on β-cell function, glycemic control and the complications occurrence. Data on PA a year after diagnosis of DM1 is limited. We investigated whether the first year of DM1 affects the adoption of PA in adults with DM1.

Material and methods: 139 adults with DM1 (97 (69.8%) males, aged 26.3 ±5.9 years, were enrolled in the prospective study – InLipoDiab1 study (NCT02306005). Data on PA, anthropometric and laboratory parameters were collected at onset of DM1 and at follow-up visit after 12 months. PA assessments were based on self-reported PA; PA was considered as activity taken at least 2–3 times/week (minimum 150 minutes/week). Participants were divided into 4 subgroups based on changes in self-reported PA. The endpoint was the evaluation of the subgroup after 12 months of observation.

Results: After a year, a statistically significant greater number of participants did not engage in PA (69.2% vs. 30.8% $p < 0.001$). It was shown that the largest number of individuals abandoned PA after the diagnosis ($n = 50$, 35.97%) or still didn't engage in PA ($n = 33$, 23.74%). The fewest number of people maintained their previous PA ($n = 19$, 13.66%) or initiated PA ($n = 18$, 12.95%). Participants were also divided into 3 groups based on the percentage change in body weight during the 1 year of DM1: < 0% ($n = 41$, 29.5%), from 0 to ≤ 5% ($n = 43$, 30.9%), > 5% ($n = 55$, 39.6%). A larger portion of the group that increased body weight (> 5%) did not engage in PA after a year (73.9% vs. 26.1%, $p = 0.002$).

Conclusions: A disturbing phenomenon has been observed, indicating that after a year, most people did not engage in PA, which may be accompanied by a considerable increase in body weight.

U12
PREGNANCY PLANNING AND INSULIN DOSE ARE CRUCIAL FOR PREGNANCY OUTCOMES IN TYPE 1 DIABETES

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Introduction: Despite continuous progress in care of pregnant women with type 1 diabetes (T1DM), pregnancy in such patients is still associated with an increased number of perinatal complications affecting both fetus and mother, compared to general pregnant population. The Great Orchestra of Christmas Charity (WOŚP) program enables use of insulin pumps (CSII) with continuous glucose monitoring (CGM) at the stage of procreation and pregnancy in T1DM patients, which improves quality of treatment and pregnancy outcomes. Analysis of factors related to pregnancy outcomes in patients qualified for the WOŚP program.

Material and methods: T1DM patients (n = 50), aged 23–45, initiating CSII + rtCGM system at the stage of planning/early pregnancy or later in case of unplanned pregnancy were qualified for the study. We analyzed occurrence of preterm birth, neonatal growth related to gestational age, glycemic control, insulin requirements and maternal weight gain.

Results: Mean age of pregnant women was 29.8 ±3.9 years, duration of T1DM 14.23 ±6.75 years. Only 20 women (40%) planned pregnancy and used CSII + rtCGM before pregnancy or in its first weeks. 45 pregnancies (90%) were delivered by cesarean section. Patients with planned and unplanned pregnancy achieved significant improvement in metabolic control, however, women who planned pregnancy delivered their babies later, had a lower number of preterm births, achieved better glycemic control measured by HbA_{1C} and by TIR and TAR values before and throughout entire pregnancy. There were no differences in TBR. Also weight and daily insulin dose were not significantly different between these two groups. Women in whom daily insulin dose increased > 30 IU (or 0.294 IU/kg) during pregnancy had a greater weight gain (15.3 ±3.4 vs. 10.7 ±5.1 kg, p < 0.001), which correlated with a higher birthweight of the newborn 3604 ±555 vs. 3145 ±776 g, p = 0.040) and all 7 cases of birthweight > 4000 g occurred in this group (p = 0.010).

Conclusions: Women with T1DM planning pregnancy achieved better glycemic control before conception and throughout pregnancy, which translated into better obstetric outcomes. Since TIR in m mothers was below target values (and was frequent even in planned pregnancies), modification of the current glycemic targets should be considered from the planning stage, to enable achievement of glycemic goals and reduce the risk of complications. Increase in the daily dose of insulin was closely correlated with mothers' weight gain and newborns' birth weight. Therefore, diet should be closely monitored to avoid excessive escalation of insulin dose and excessive weight gain during pregnancy.

SESSION OF ORIGINAL PAPERS 3

Chairs: Edward Franek, Katarzyna Nabrdalik

U13

IS INEFFICIENT ANTIOXIDANT DEFENSE IN CARBOHYDRATE METABOLIC DISORDERS RESULT FROM ALTERED EXPRESSION OF MIRNA TARGETING mRNA CATALASE, SUPEROXIDE DYSMUTASE 3 AND GLUTATHIONE PEROXIDASE 3 IN PEOPLE OVER 65 YEARS OF AGE

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Introduction: Hyperglycaemia, a basic symptom of carbohydrate metabolism disorders (CMD, including prediabetes and type 2 diabetes), contributes to oxidative stress (OxS). OxS is a direct cause of the development of diabetic complications. One of the mechanisms regulating the level of antioxidant enzymes is the expression microRNA which target mRNA. To check whether the expression of miR-30b, miR-21 and miR-196a targeting respectively mRNAs CAT, SOD3 and GPx3, in plasma in people over 65 years of age with prediabetes and type 2 diabetes (and total CMD) compared to subjects with normal carbohydrate metabolism is associated with antioxidant proteins' level.

Material and methods: The study was conducted on 126 Caucasian patients, allocated to CMD group (n = 88) and control group (n = 38). Additionally, in the group with CMD, the subgroup with prediabetes (n = 37) and T2DM (n = 51) were distinguished. The level of antioxidant enzymes (CAT, SOD3, GPx3) was measured by ELISA tests. The expression level of miR-30b, miR-21, miR-196a was determined by Real Time PCR, miR-16-5p and miR-103a-3p were used as reference genes. Expression results were analysed using the method $2^{-\Delta}$Ct. Dunn's multiple comparison test was employed to check the differences between the groups. Spearmen's correlations were made between the level of antioxidant enzymes and the expression of the studied miRNAs.

Results: The level of SOD3 and GPx3 was markedly reduced in CMD group, the analysis in subgroups showed a significantly reduced level of these enzymes in T2DM group, and a trend toward decrease in group with prediabetes. No changes in the CAT level were observed in the studied groups. The analysis of microRNAs expression showed that only miR-196a was elevated in CMD group and T2DM group, although it did not reach statistical significance. The expression of miR-30b did not differ significantly between the study groups. However, miR-21 expression was significantly reduced in CMD group. In addition, a negative weak correlation was found between SOD3 level and miR-21 expression in CMD group (Rho –0.280, p = 0.008) and in T2DM group (Rho –0.400, p = 0.004).

Conclusions: The decreased plasma level of GPx3 in CMD patients may be a result of up-regulation of miR-196a, although the correlation between GPx3 and miR-196a was not detected. Spearman correlations showed that miR-21may regulate SOD3 mRNA. The obtained results show that CAT level does not depend on the expression of miR-30b. It seems that other factors regulating the expression of SOD3 mRNA, apart from miR-21, may be responsible for its reduced level.

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U14
EFFICACY OF FREMS (FREQUENCY RHYTHMIC ELECTRICAL MODULATED SYSTEM) WITH ALPHA-LIPOIC ACID IN THE TREATMENT OF SYMPTOMATIC DIABETIC PERIPHERAL POLYNEUROPATHY

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Introduction: Frequency Rhythmic Electrical Modulated System (FREMS) is a method of transcutaneous treatment based on frequency-modulated electromagnetic neural stimulation. It is helpful in chronic pain conditions. Its efficacy in symptomatic diabetic peripheral neuropathy (SDPN) still lacks enough research.

Material and methods: A randomized, single-blind, sham-controlled trial in individuals with SDPN as an add-on therapy compared to standard therapy with α-lipoic acid. Participants were randomized to FREMS and standard of care (n = 24) versus standard of care (n = 20). The primary endpoints were between-group differences in pain intensity, quality of life and treatment response compared to baseline after 5 days of treatment and 8 weeks of follow-up.

Results: In the first phase of study, there were 24 individuals in the FREMS group and 20 in the sham-FREMS group who filled out their VAS scale and CGI-I scale after 5 days completely. In the second phase, follow-up pain diaries (after 8 weeks) were filled out by 23 patients in the FREMS group and 16 in the sham-FREMS group. The superiority of FREMS therapy versus placebo in pain alleviation was observed on the last day of follow-up based on VAS scores on the last day of treatment and after 5 days of therapy. The symptoms' improvement assessed by CGI-I rating scale was noticeable after 8 weeks following the treatment period. The general health improvement was measured by a vertical visual analogue scale used as a quantitative measure of health outcome reflecting the patient's own judgment (EQ-5D-5L questionnaire). After 5 days of neural stimulation there was a statistically significant increase in the health outcome in the FREMS group compared to the time before the treatments. Still, significant results persisted after 8 weeks of self-observation compared to the time before the procedures and compared to the time after 5 weeks of treatments. There were non-significant differences observed in the instrument pain assessment. No relevant side effects were recorded during the study.

Conclusions: FREMS as an addition to α-lipoic acid therapy occurred to be a beneficial method of treatment in individuals with SDPN. The effectiveness of the add-on FREMS therapy lasted longer than α-lipoic acid only. The general health improvement after FREMS was observed after 5 days of treatment and persisted after 8 weeks of observation. Larger trials with longer phage of follow-up are needed to confirm the preliminary results and to assess the duration of treatment effects.

U15
THE POLISH VALIDATED MNSI SCALE – RULES OF USE

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Introduction: Professionals are obligated to monitor signs and symptoms of peripheral, sensorimotor diabetic neuropathy at least annually according to the Polish Diabetes Association guidelines. The use of validated scales facilitates this task, however, the most frequently used one-MNSI (Michigan Neuropathy Screening Instrument) has not been available in POLAND so far. The aim of the study was to validate MNSI in Polish (PL) and point out the most important, potential problems regarding its use in everyday practice.

Material and methods: Using a test (A1, B1) and re-test (A2, B2) with a 7–14 days break formula 80 patients with diabetes were surveyed (part A) and examined (part B). Then, based on a gold standard-nerve conduction study (NCS) neuropathy was confirmed or ruled out. Reliability of the MNSI-PL was assessed using the Cronbach's α, Kuder-Richardson formula 20 (KR-20), split-half reliability, the Gottman split-half tests and correlation between first and second half was accessed. Stability was assessed using an intraclass correlation coefficient (ICC). For external validation, we used simple linear correlation, binomial regression, and agreement between two different tools using a Bland-Altman plot analysis.

Results: The Cronbach's α was: 0.81 for A and 0.87 for B and confirm internal consistency; ICC was: 0.73 for A and 0.97 for B showing high stability for test-retest. The correlation between MNSI-PL and NCS was $p < 0.005$. We found the cut-off points of ≥ 3 for section A (sensitivity of 90–100%; specificity of 33v40%, parts A1 and A2, respectively) and ≥ 2 for section B (sensitivity of 81–84%; specificity of 60–70%, parts B1 and B2, respectively) were obtained for neuropathy confirmation when based on NCS.

Conclusions: The MNSI-PL is a reliable and valid instrument in screening for diabetic neuropathy. During the cultural adaptation, some changes were proposed to improve clarity for professionals and patients. The test should be performed with medical staff help for part A in some cases (elderly). We obtained similar results as the other authors in their local work.

The study results have been accepted for publication in the World Journal of Diabetes.

U16
METFORMIN INDUCES APOPTOSIS OF PANCREATIC CANCER CELLS BY ALTERING LEVELS OF HISTONE ACETYLTRANSFERASES

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Introduction: Literature data indicate that metformin induces apoptosis, inhibits the growth and proliferation of cancer cells. One of the proposed mechanisms responsible for its anticancer properties is the effect on enzymes regulating the histone acetylation status. The aim of the study was to check whether histone deacetylase: SIRT-1 and histone acetyltransferases: PCAF, CBP, p300 are involved in metformin-induced apoptosis of pancreatic cancer cells.

Material and methods: The study was performed on the pancreatic cancer cell lines 1.2B4 and PANC-1. 1.2B.4 and PANC-1 cells were treated with metformin, an inhibitor of histone acetyltransferases; CTK7A (HATi) and the combination of HATi with metformin for 24, 48 and 72h. Cell viability was determined by the MTT assay and the percentage of cells in early apoptosis was estimated by flow cytometry. mRNA and protein expression of SIRT-1, PCAF, CBP, p300 were analyzed by RT-PCR and Western blot. Caspase-9 (apoptosis marker) activity was also assessed.

Results: Metformin induced a dose-dependent decrease in the viability of 1.2B4 and PANC-1. Cytometric analysis and assessment of caspase 9 levels showed that metformin-induced death was mainly by apoptosis. Evaluation of mRNA expression levels showed that metformin significantly increased SIRT-1 and PCAF mRNA in PANC-1 and SIRT-1 in 1.2B4 cells. In turn, at the protein level, metfomin-induced decrease in PCAF levels was observed in both cell lines. Combined incubation of cells with metformin and an inhibitor of histone acetyltransferases; CTK7A (HATi) protected against metformin-induced apoptosis. This was related to a decrease in the mRNA expression of the studied genes and an increase in the SIRT-1 protein level and a decrease in PCAF in PANC-1 cells. For 1.2B4 cells, it was observed that the combined incubation with metformin and HATi resulted in a decrease in the mRNA level of all studied genes after 48 h and an increase in histone acetylotransferases after 24 h. The protein level in these cells increased for SIRT-1, CBP and p300 after 24 h and CBP and p300 at 72 h after combined metformin and HATi incubation.

Conclusions: The obtained results indicate that the pro-apoptotic effect of metformin on human pancreatic cancer cells is related to its effect on histone acetylotransferases` levels. However, we observed some differences between PANC-1 and 1.2B4 cells. PCAF plays a major role in PANC-1 cells whereas PCAF, CBP and p300 play a major role in 1.2B4 cells.

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U17
THE RELATIONSHIP BETWEEN BRAIN STRUCTURES' VOLUME, BODY MASS INDEX AND METABOLIC PARAMETERS IN WOMEN WITH DEPRESSIVE SYMPTOMS

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Introduction: Depression is a heterogeneous disease, which might have different clinical presentations. The prevalence of depression is approximately 5%, while subclinical depressive symptoms are more frequent. Depressive disorders are more frequent in women compared to men. According to the literature, obesity but also underweight increased the risk of depression. The study aimed to examine the association of the volume of brain structures with body mass index (BMI) and metabolic parameters in women with depressive symptoms.

Material and methods: The analysis included 265 women aged 20–70 years: 131 with BMI ≥ 25 kg/m^2 (37 women with score in the Beck Depression Inventory – BDI – 10 or above and 94 women in the control group), and 134 women with BMI < 25 kg/m^2 (37 women with score in the BDI 10 or above and 97 women in control group). Current use of antidepressive or antipsychotic medications was the main exclusion criterion. Clinical examination and biochemical measurements were performed. Body composition was estimated by dual-energy X-ray absorptiometry and android, visceral and gynoid fat percentage were calculated. Women underwent 3T brain magnetic resonance imaging scanning, and morphometric analysis of brain structure was conducted with Freesurfer program 7.2.0.

Results: The study and control groups with BMI ≥ 25 kg/m^2, as well as the study and control groups with BMI < 25 kg/m^2, did not differ in age (56 vs. 52 years, p = 0.120 and 42 vs. 40 years, p = 0.201). Women with BMI ≥ 25 kg/m^2 and depressive symptoms had lower volume of right nucleus accumbens compared to the control group (0.51 vs. 0.55 cm^3, p = 0.007). Women with BMI ≥ 25 kg/m^2 and depressive symptoms had more frequent metabolic syndrome and higher visceral fat percentage compared to the control group (56.76 vs. 29.79%, p = 0.004 and 3.95 vs. 3.29%, p = 0.039). In women with BMI ≥ 25 kg/m^2 and depressive symptoms, we observed correlations between right nucleus accumbens volume and somatic-vegetative depressive symptoms in BDI (R = –0.37, p = 0.024), visceral fat percentage (R = –0.48, p = 0.003), and metabolic syndrome parameters: fasting glucose level in the blood (R = –0.42, p = 0.011) and value of diastolic blood pressure (R = –0.33, p = 0.049). Women with BMI < 25 kg/m^2 and depressive symptoms had lower left superior frontal gyrus, left middle frontal gyrus and left insula volume compared to the control group (18.14 vs. 18.93 cm^3, p = 0.030; 17.94 vs. 18.96 cm^3, p = 0.044; 6.13 vs. 6.47 cm^3, p = 0.021).

Conclusions: The presence of depressive symptoms in overweight or obese women might be associated with alterations in mesolimbic dopamine system, while in underweight or normal weight women with brain structures connected with cognitive control.

POSTER SESSIONS OF ORIGINAL PAPERS
POSTER SESSION OF ORIGINAL PAPERS 1.1
Chair: Grzegorz Dzida

P1
HEALTHCARE PROFESSIONAL PERCEPTION OF GLUCOSE MONITORING IN PATIENTS WITH DIABETES HOSPITALIZED DUE TO COVID-19

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Introduction: Glucose monitoring (GM) in diabetic patients (DPs) hospitalized due to COVID-19 aims to achieve glycemic control while minimizing the exposure of medical staff and use of protective materials. We examined its perception by healthcare professionals.

Material and methods: A questionnaire consisted of 20 questions addressing medical staff experience and perception concerning GM in DPs hospitalized due to COVID-19 was designed. This questionnaire was distributed among employees of a hospital that served as the reference COVID-19 hospital during the pandemic. We received 132 replies, 87 from physicians and 45 from nurses, respectively. Large proportion of respondents perceived GM in hospitalized DPs with COVID-19 as a significant problem (43.19%). The most frequently pointed GM related problem was shortage of time of the medical staff (57.58%).

Results: However, only 28.03% of employees reported that the modification of hypoglycemic therapy based on GM occurred more rarely than before pandemic. Most responders reported no CGMS use (12.88%). There were differences in responses between physicians and nurses. The nurses had longer professional experience, less frequently reported GM as a significant problem and the modification of hypoglycemic therapy occurring more rarely than before pandemic. At the same time, they more frequently reported a fear of infection as factor influencing monitoring decisions and patient complains concerning inadequate GM frequency. Additionally, physicians differently from nurses reported tools for transferring GM results from "clean" to "dirty" ward with e-mails and CGMS applications being used more frequently and telephones less frequently.

Conclusions: Glucose monitoring in hospitalized COVID-19 patients with diabetes constitutes an unsolved problem, although its perception may vary between different professions. There is a need to work out universal standards for GM in hospitalized DPs with infectious viral diseases, such as COVID-19.

P2
PHARMACEUTICAL AVAILABILITY OF INSULIN FROM DEVELOPED HYDROGEL PREPARATIONS FOR SKIN APPLICATION

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Introduction: Hydrogels represent a modern, intensively developing drug form. They have three-dimensional (3D) network structures and show compatibility with body tissues. The topical application of hydrogel has been found to promote regeneration and wound healing processes. The skin application of insulin, on the other hand, can have a beneficial effect on the treatment of ulcers arising as a complication of diabetes without affecting blood glucose levels. The development of a hydrogel with insulin may aid wound healing therapy in patients with diabetic foot syndrome. The aim of this study was to develop a formulation and technology for the preparation of a hydrogel carrier for the topical application of insulin.

Material and methods: Hydrogels were prepared according to the recommendations of Polish Pharmacopoeia XII. Substrates based on sodium alginate, chitosan with methylcellulose, carboxymethylcellulose, and methylcellulose, which contained insulin (Insulatard® Penfill®) at a dose of 1 mg/g, were tested. An in vitro insulin release study was performed in USP apparatus 2 (vessel volumes 200 ml) at 100 rpm (Erweka DT600, Husenstamm, Germany) using the Enhancer Cell™ with a surface area of 3.80 cm^2 (Erweka, Husenstamm, Germany). A Spectra/Por 2 semipermeable dialysis membrane with a pore size of 12–14 kD was used for the analyses. The release profiles of hydrogels with insulin were compared using the DDSolver1 software [1].

Results: Hydrogels with insulin showed skin-compatible pH. The formulations developed were characterised by a prolonged insulin release profile. Methylcellulose-based hydrogels respectively released 73% of the API at 330 minutes, carboxymethylcellulose-based hydrogels released 84% at 390 minutes, sodium alginate hydrogels released 60% of the API at 240 minutes, and chitosan-based hydrogels with methylcellulose released 65% of the insulin dose at 390 minutes.

Conclusions: Preformulation studies indicate that formulaic hydrogels may be potential insulin carriers in therapy supporting the treatment of the diabetic foot. A carboxymethylcellulose-based carrier was optimal in terms of hormone release. The insulin release profile from this carrier is similar to the methylcellulose-based carrier (f1 = 10.19, f2 = 58.53).

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P3
CLINICAL EVALUATION OF TYPE 1 DIABETIC PATIENTS EDUCATED WITH STRUCTURED DIABETES EDUCATION PROGRAM GOPUMP DURING "INSULIN PUMP WEEK" – PRELIMINARY DATA

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Introduction: Therapeutic education is the foundation of care for individuals with type 1 diabetes (T1D) and is particularly important in treatment with continuous subcutaneous insulin infusion (CSII). It should be carried out using a structured program for diabetes education (SPED). This study aims to clinically assess patients educated through "Insulin Pump Week" using the SPED GoPump.

Material and methods: The study included 50 patients (32 women) aged 28 (21–33) years with a duration of T1D 15 (10–22) years who participated in the "Insulin Pump Week." Anthropometric data, metabolic control of diabetes (A1c, lipid profile), data from the standardized DTSQ questionnaire, ambulatory glucose profiles from personal pumps and glucose-meter/CGM/FGM were evaluated. The project involves re-evaluation after 6 and 12 months of participating in the SPED GoPump. It will allow the assessment of the influence of SPED GoPump on metabolic control outcomes and treatment effects.

Results: Nine individuals (18%) reported smoking. Diabetic retinopathy was found in 14% of the participants and neuropathy in 4%. The score in the DTSQ was 33.5 (30.3–36.8). The BMI was 23.2 (20.5–24.6) kg/m^2, A1c 7.6 (6.9–8.2)%, total serum cholesterol – Ch-C 166.0 (142.5–183.0) mg/dl, HDL-cholesterol 63.0 (55.3–70.0) mg/dl, LDL-cholesterol 80.0 (67.5–112.3) mg/dl, and triglycerides 75.5 (61.3–98.0). Twenty-two individuals (44%) used CGM/FGM. TIR (time in range: 70–180 mg/dl) was 53.0 (40.0–63.0)%. The duration of CSII treatment was 8.0 (5.0–11.8) years. The pumps used by participants were: Medtronic (72%), AccuChek Spirit Combo (24%), and Ypsomed (4%). The daily insulin dose per kilogram of body weight (DDI/kg/b.w.) was 0.69 (0.56–0.76)U, and the percentage of basal rate in the proportion of basal/bolus was 40.0 (34.3–44.8)%. CSII treatment duration positively correlated with age (rs = 0.60, $p < 0.05$) and Ch-C (rs = 0.31, $p < 0.05$) and negatively with A1c (rs = –0.36, $p < 0.05$) and DDI/kg/b.w. (rs = –0.50, $p < 0.05$). A positive correlation was found between TIR and CSII treatment duration (rs = 0.31, $p < 0.05$), Ch-C (rs = 0.38, $p < 0.05$), LDL-C (rs = 0.38, $p < 0.05$), and non-HDL-C (rs = 0.35, $p < 0.05$). DDI/kg/b.w. negatively correlated with age (rs = –0.55, $p < 0.05$), duration of CSII treatment (rs = –0.50, $p < 0.05$), and the basal/bolus ratio (rs = –0.33, $p < 0.05$). A positive correlation was found between BMI and the duration of CSII treatment (rs = 0.35, $p < 0.05$) and negative between DTSQ score and HDL-C (rs = –0.42, $p < 0.05$).

Conclusions: The glycemic control in young adults with a long history of T1D treated with CSII indicates the need for SPED interventions to improve treatment outcomes. The baseline data of the prospective study show that the longer the duration of CSII treatment, the better the glycemic control and the lower the daily insulin requirements, but the higher BMI.

**These authors contributed equally to this work.*

P4
ASSESSMENT OF RELATIONSHIP BETWEEN INTERMEDIATE INSULIN RESISTANCE COEFFICIENTS AND PERCENTAGE OF FAT BODY AND VISCERAL FAT INDEX

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Introduction: Insulin resistance is a disorder of glucose homeostasis in which tissues become less sensitive to insulin, despite normal or increased insulin blood levels. The golden diagnostic standard is the glucose clamp, consisting in calculating tissue glucose consumption, which is, however, a time-consuming and complicated method. In epidemiological studies, severity of insulin resistance is estimated by using common indicators that are HOMA-IR and QUICKI. In addition, it was found that the ratio of TG to HDL-C shows a strong prediction for insulin resistance. For one of the main reasons insulin resistance is considered an obesity disease, which is a significant problem of modern medicine. It can be recognized with easy-to-measure parameters, including body mass index (BMI), waist circumference (WC) or waist hip ratio (WHR). Unfortunately, these parameters are characterized by a large percentage of false results, so it is advisable to search for more precise, but also easy to obtain diagnostic indicators. Promising seems to be the use of coefficients obtained during bioimpedance analysis of body composition, i. e. visceral fat rating (VFR) and body fat percentage (BF%) determining the percentage of this tissue in the whole body. To analyze the relationship and usefulness of the standard obesity indices compared to the parameters obtained from the bioimpedance analysis in the assessment of the severity of insulin resistance in obese patients.

Material and methods: The study included 702 obese patients aged 44. 1 ±13. 8 years, including 557 women (79%) and 145 men (21%).

Results: A retrospective analysis of data from medical records was performed, with particular attention to anthropometric data (age, gender, BMI, WC), bioimpedance analysis (BF%, VFR) and indirect insulin resistance indices (HOMA-IR, QUICKI index, TG/HDL ratio). Sensitivity and specificity of bioimpedance indices were compared with classical anthropometric data. Statistical analysis was performed in Statistica using the analysis of ROC curves using the Youden index and tangential method, comparing AUC for individual indicators.

Conclusions: Visceral fat rati may be a useful additional biomarker in the assessment of insulin resistance in patients with obesity disease.

P5
PREDIABETES AND METABOLIC SYNDROME IN PATIENTS WITH POLYCYSTIC OVARY SYNDROME IN ASSOCIATION WITH BODY WEIGHT

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Introduction: Polycystic ovary syndrome (PCOS) is associated with high incidence of overweight and obesity, although it might also affect normal-weight women. Patients with PCOS are characterised by an increased prevalence of metabolic disturbances. Data from literature indicate that the risk of metabolic disturbances is varied in this group of patients and might also be increased in lean PCOS patients, although the results of previous studies are equivocal. The assessment of metabolic disturbances' prevalence in women with PCOS, taking into account the influence of body weight.

Material and methods: The study population comprised 677 young women (aged 17–35 years), divided into 4 groups: normal-weight PCOS (n = 212), overweight/obese PCOS (n = 216), normal-weight controls (n = 173), and overweight/obese controls (n = 76). Anthropometric measurements and oral glucose tolerance test (OGTT) were performed in the study participants. The concentrations of lipids and sex hormones were measured, and transvaginal ultrasound was performed. The prevalence of metabolic syndrome (MetS), central obesity, prediabetes, and dyslipidaemia was assessed.

Results: Normal-weight PCOS patients were younger in comparison to both groups of overweight/obese women (23 vs. 25 years and 23 vs. 25.5 years; $p < 0.001$). Fasting glucose concentrations in overweight/obese PCOS patients were significantly higher than in normal-weight PCOS patients (89 vs. 87 mg/dl; $p = 0.013$), while mean glucose concentrations during OGTT were significantly higher comparing to the other three groups (114.6 vs. 100.0; 99.5; 102.6; $p < 0.001$). Additionally, higher values of HOMA-IR (3.24 vs. 1.83; 2.24; 1.80; $p < 0.001$) and lower values of Matsuda index (3.08 vs. 5.80; 4.91; 5.44; $p < 0.001$) were observed in overweight/obese PCOS patients in comparison to the other groups.

The prevalence of MetS, central obesity, prediabetes, hypertriglyceridaemia and decreased HDL-cholesterol concentrations was higher in both groups of women with overweight/obesity comparing to the groups of normal-weight women ($p < 0.05$). Prediabetes, hypertriglyceridaemia, and MetS were approximately twice as common in PCOS women with overweight/obesity in comparison to control women with overweight/obesity (22.2% vs. 11.8%; 20.8% vs. 8.2%; 32.2% vs. 17.8%, respectively). No differences in the concentrations of glucose and lipids or values of insulin sensitivity indices were observed between the groups of normal-weight women. The prevalence of metabolic disturbances was also comparable between these two groups.

Conclusions: The obtained results suggest that the risk of metabolic disturbances in normal-weight PCOS patients seems to be comparable to healthy women. PCOS patients with overweight/obesity are characterised by lower insulin sensitivity and higher prevalence of metabolic disturbances than women with comparable BMI without PCOS.

P6
THE USE OF TROPOCOLLAGEN IN THE TREATMENT OF DIABETIC FOOT ULCER – CASE REPORT

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Introduction: Tropocollagen is a complex biopolymer secreted by fibroblasts, a precursor of mature collagen. It is a structural basis for collagen fibers polymerized in the intercellular space. The wound healing process in diabetes is disturbed, and the pace of their healing is often phased, slow, requiring the use of a variety of approaches. Tropocollagen is currently rarely used in the treatment of diabetic foot ulcers and its effectiveness in healing such wounds is unproven. Examples of patients in whom local injections of collagen accelerated wound healing suggest its potential value for diabetic ulcers' treatment. A case report of the patient with an extensive neuropathic diabetic ulcer, in whom the use of tropocollagen I injections significantly accelerated the progress of treatment.

Material and methods: Using photo documentation with a description of the healing process, we aimed to show how the use of collagen turned out to be one of the key elements of healing. Collagen preparations with a constant, standardized composition were used, containing auxiliary substances, stored in sterile vials, from which they are ready for injection.

Results: We present a case of extensive neuropathic ulceration in diabetic foot syndrome, which is an example of the effective use of local subcutaneous/intradermal injections of tropocollagen.

Conclusions: The use of these preparations seems to be a noteworthy element of wound healing support.

POSTER SESSION OF ORIGINAL PAPERS 1.2

Chair: Michał Holecki

P7

EVALUATION OF THE EFFECT OF SGLT-2 INHIBITOR OR GLP-1 RECEPTOR AGONISTS USE ON BIOCHEMICAL METABOLIC PARAMETERS, BODY MASS COMPOSITION MODIFICATION, BLOOD PRESSURE REGULATION AND SELECTED VASCULAR PARAMETERS IN OBESE PATIENTS WITH TYPE 2 DIABETES.

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Introduction: Diabetes mellitus is a group of metabolic diseases characterised by abnormally high blood glucose levels arising from a deficiency of properly functioning insulin.

A patient with diabetes who develops complications should be treated with SGLT2 inhibitors, GLP-1 inhibitors or a combination of these medicaments. The new drugs are antidiabetic, but in a series of studies a significant reduction in cardiovascular risk is observed, regardless of the mechanism of glycaemic regulation. The aim of this study is to evaluate the effect of an SGLT-2 inhibitor or GLP-1 receptor agonists on blood pressure regulation and selected vascular parameters in obese patients with type 2 diabetes.

Material and methods: The study will be an observational, prospective study. No randomisation will be used, as the drugs will be used according to medical indications. The patient's profile and the benefits of the appropriate drug group will be the deciding factor. Patients with type 2 diabetes mellitus in association with obesity BMI > 30, requiring immediate hospitalisation, with glycated haemoglobin (HbA_{1c}): ≥ 7%, and BMI: ≥ 30 kg/m^2. After qualifying for the study, all patients underwent a medical examination during which RR, HR, weight, height, waist circumference and hip circumference were measured.

A body composition analysis was carried out using a bioimpedance body composition analyser.

A basic laboratory profile was performed (peripheral blood count, HbA_{1c}, creatinine, urea, uric acid, electrolytes, lipidogram, NTproBNP, CRP, TSH, ALT, general urine examination). The assumed duration of the study is 36 months. The first examination will take place during hospitalisation, followed by follow-up visits at 3, 6, 9, 12, 24 and 36 months of the study. The specified time intervals will allow differences in the measured parameters to be observed.

Results: An observation period of 9 months has been carried out.In the first study group of patients using I-SGLT-2, the following were observed: a reduction in HbA_{1c} of approximately 5%,slight changes in cholesterol levels, a 20% reduction in NTproBNP, 1.5% increase in BMI. The mean age was 55 years.In the second study group of patients using a GLP-1 receptor agonists, a 21% reduction in HbA_{1c}, an 8% reduction in BMI, a 13% reduction in total cholesterol and a 31% reduction in tri glycerides were observed. The mean age was 50 years.In the third study group of patients using GLP-1 receptor agonists and SGLT2 inhibitor together, the greatest reduction in HbA_{1c} of approximately 42% was observed. Total cholesterol was reduced by about 41%, LDL by about 60%, TG by 53%, BMI was reduced by 7%.The mean age was 47 years.

Conclusions: The results obtained so far suggest that combined effect of SGLT2 inhibitor and GLP-1 receptor agonists therapy should be widely recommended, however it is significantly more effective in improving blood glucose control rather than in reducing body weight.

P8
ALPACA WOOL TOE CAPS AS A METHOD OF CARE FOR HAMMERTOES IN PATIENTS WITH DIABETES

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Introduction: A hammertoe is a deformity most often affectingthe proximal interphalangeal joint of the second toe, causing it to be bent, and posing a risk ofcorns. Hammertoes are often associated with diabetes, leading to the diabetic foot. To show the role of a nurse in the process of nursing hammertoes in people with type 2 diabetes by crocheting alpaca wool toe caps.

Material and methods: The study used a proprietary questionnaire of 10 questions and a physical examination of the toes. The study included 80 patients with type 2 diabetes, aged 50–80 years (45 women, 35 men). The study was held at the Diabetes Outpatient Clinic from January to May 2022.

Results: All the examined patients suffered from hammertoe deformities, mainly of the second toe, with calluses on the dorsal surface exposed to pressure. Only 10% of the respondents had a normal BMI, while 30% were overweight and 60% were obese. More than half of the respondents (57%) admitted wearing too tight shoes. Men (20%) wore tight socks and women (40%) wore high heels. The vast majority of patients (80%) worked in a standing position for several hours. After having conducted the physical examination of the toes and having diagnosed hammertoes in all respondents (100%), I crocheted alpaca wool caps for the deformed second toes so as to prevent the development of corns or calluses that may become inflamed, leading to the diabetic foot syndrome. All patients (100%) described alpaca wool caps as soft, warm, comfortable to wear and easy to put on.

Conclusions: Hand crocheted toe caps made of alpaca wool protect and separate the affected toes. They prevent toes from rubbing against each other, thus reducing pain and increasing walking comfort.People wearing alpaca caps on hammer toes have not been observed to develop a diabetic foot syndrome.

P9
POST-TRANSPLANT HYPOGLYCEMIA – A CASE STUDY

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[2]Section at the Student Scientific Group at the Chair and Department of Endocrinology, Diabetology and Metabolic Diseases, Medical University of Lublin, Lublin, Poland
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Introduction: The most common cause of G5 stage chronic renal disease eligible for transplantation treatment is type 2 diabetes mellitus. The same disorders of carbohydrate metabolism leading to the development of end-stage renal disease can cause impaired graft function. Post-transplant hyperglycemia is a well-known complication and results from complications following immunosuppressive treatment and glucocorticosteroid therapy. Post-transplant hypoglycemia is a completely different phenomenon, so far practically not described in the available literature. The aim of this paper was to present the case of a patient with symptomatic hypoglycemia observed immediately after renal transplant.

Material and methods: Analysis of available medical records and statistical parameters from the LibreView glycemic monitoring system reports.

Results: The procedure of allogeneic left renal transplantation, collected from a cadaver, was performed in 2021, in a 24-year-old patient with end-stage renal disease in the course of hypertensive disease. The surgery was performed without complications, and the kidney resumed normal function immediately after transplantation. Immediately after the procedure, the patient was connected to LibreView system. The reference range of blood glucose was set at 70–180 mg/dl. From the eleventh postoperative day, the patient was observed to have typical symptoms of hypoglycemia. The symptoms correlated with the reduced glycemic levels found in LibreView and from venous blood. After analyzing the available data, it was found that for a period of 14 days after transplantation, the patient's average blood glucose level was 105 mg/dl, with a range of 99–167 mg/dl in the first week after surgery and 62–87 mg/dl in the second week. For 33% of the monitored time, a glycemia < 70 mg/dl was documented, of which 6% was < 54 mg/dl. Hypoglycemic episodes were documented 22 times during the study period, the lowest measurement of which was 40 mg/dl. The patient's lowered glycemia occurred most often during the night and morning hours (2am–10am). The diagnosis of hypoglycemia was deepened with the determination of inflammatory parameters, insulin, C-peptide, HbA_{1c}. The function of adrenocorticotropic axis, calcium and phosphate metabolism were also evaluated, and a full metabolic evaluation was performed. The results of the above tests remained within the ranges of reference norms.

Conclusions: Dyglycemic disorders are common after renal transplantation, but hypoglycemia among such patients is rare and has no clear explanation in the scientific literature. It's important to remember that any abnormality of carbohydrate metabolism affects the general condition of patients and the function of transplanted organs. Therefore, every renal transplant patient should remain under coordinated nephrology-diabetes-transplant care.

P10
THE RELEVANCE OF BODY FAT PERCENTAGE AND VISCERAL FAT RATING OBTAINED BY BIOIMPEDANCE IN ASSESSING THE RISK OF CARBOHYDRATE METABOLISM DISORDERS

Dominik Porada[1], Jakub Gołacki[1], Jakub Wronecki[1], Ewelina Niedzielska[1], Aneta Szafraniec-Porada[1], Monika Lenart-Lipińska[1], Beata Matyjaszek-Matuszek[1]

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Introduction: Two parameters, body mass index (BMI) and waist circumference (WC), whose elevated values are risk factors for carbohydrate metabolism disorders, are commonly used in the diagnosis of obesity. Obesity is one of the main risk factors for the development of type 2 diabetes (T2D), however, sometimes these parameters are not sufficient for a full clinical evaluation, as they do not reflect the severity of the main pathomechanism for the development of T2D – the adiposopathy – a condition resulting from the secretion of pro-inflammatory and hormonally active substances by visceral fat tissue. Therefore, there is a need to incorporate new parameters into clinical practice to determine total body fat (BF%, body fat percentage) and to determine the amount of intra-abdominal fat (VFR, visceral fat rating). Both parameters are obtained by bioimpedance body composition analysis and correlate with dual-energy X-ray absorptiometry (DXA), which has risks due to exposure to ionizing radiation. To evaluate the importance of BF% and VFR in the analysis of the risk of developing carbohydrate metabolism disorders in patients with obesity.

Material and methods: We analyzed data of 702 patients with obesity, including 557 women and 145 men, with an age of 44.09 ±13.78 years, a BMI of 36.89 ±6.11 kg/m^2 and a mean WC for women of 109.51 ±12.85 cm and men of 124.25 ±15.22 cm. Analysis of the medical records of the patients of the obesity treatment program, with particular emphasis on anthropometric data, body composition analysis by bioimpedance and laboratory assessment of carbohydrate metabolism. Statistical analysis of the collected study material was developed using analysis of variance by ANOVA with subsequent post-hoc analysis.

Results: Carbohydrate metabolism disorders were observed in 355 patients (50.57% of the study population), including the presence of impaired fasting glucose in 93 patients, impaired glucose tolerance in 68 patients, "double pre-diabetes" in 53 patients and T2D in 137 patients (19.52%). There was a significantly lower VFR value in women compared to men, and a lower BF% value in men compared to women. A particularly significant difference in VFR values was observed between patients with T2D and patients without any carbohydrate metabolism disorders. There was no statistically significant difference in BF% between the metabolic disorder groups analyzed.

Conclusions: The statistical analysis performed indicates the usefulness of VFR analysis as a screening parameter for stratifying the risk of developing carbohydrate metabolism disorders in obese patients, especially with regard to the risk of T2D.

P11
STEATOHEPATITIS AND DIABETES MANAGEMENT A CASE REPORT

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Introduction: Obesity and diabetes mellitus are associated with non-alcoholic fatty liver disease (NAFLD) and progressive liver damage. Hipertransaminasemia is a main symptoms of liver injury or non-alcoholic steatohepatitis (NASH) onset. There are literature data of beneficial effects of GLP-1 receptor agonists on both diabetes and NASH treatment.

Case report: A 52-years-old obese women with 3-year history poor metabolic control type 2 diabetes and with hipertransaminasemia treated Heparegen without success. She was admitted to hospital with polydipsia, polyuria, dehydration, without acidosis. Her medical history was PCO syndrome.

In physical examination: obesity – BMI = 35 kg/m^2. The laboratory testing on hospital admission were: glucose = 383 mg/dl; HbA_{1c} = 14.7%, C-peptide = 3.19 ng/ml. Blood pH in normal range.

Since the diagnosis of diabetes, elevated ALT concentrations – subsequent measurements were: 210, 190, 203 IU/l. In tests: HbsAg, HCV *p*-bodies, ANA2, ASMA – negative. Elevated cholesterol values: total was 201, LDL = 126 and triglycerides = 330 mg/dl. Abdominal ultrasonography and CT showed hepatic steatosis. Calculated degree of fibrosis according to NAFLD Fibrosis Score Calculator = 2.0 (a value greater than 0.675 means severe fibrosis – grade F3–F4).

Parameters	At the beginning of hospitalisation	After dulaglutide tratment
Cholesterol [mg/dl]	201	172
TG [mg/dl]	330	130
LDL [mg/dl]	126	100
Non-HDL [mg/dl]	145	115
Fasting glucose [mg/dl]	385	127
HbA_{1c} (%)	14.7	6.3
AspAT [U/l]	150	29
AIATt [U/l]	206	49

AspAT – aspartate aminotransferase, HDL – high-density lipoprotein cholesterol, LDL – low-density lipoprotein cholesterol, TG – triglycerides

During hospitalization she was treat intensive insulin therapy and after glucose normalization, GLP-1 receptor agonist (dulaglutide) was recommend. Metformin treatment was maintained. Post-hospital treatment was metformin XR 2000 mg/day, dulaglutide 1.5 mg. Control examinations after 4 months showed a glucose and lipids controls significant improvement and transaminase normalization. The GLP-1 receptor agonists and metformin treatment was continued and, because of better liver function, atorvastatin was added to treatment.

Conclusions: This case report showed beneficial effects GLP-1 receptor agonists on both diabetes and NAFLD treatment.

P12
TIRZEPATIDE-INDUCED WEIGHT LOSS IN TYPE 2 DIABETES IS INDEPENDENT OF NAUSEA, VOMITING, OR DIARRHOEA

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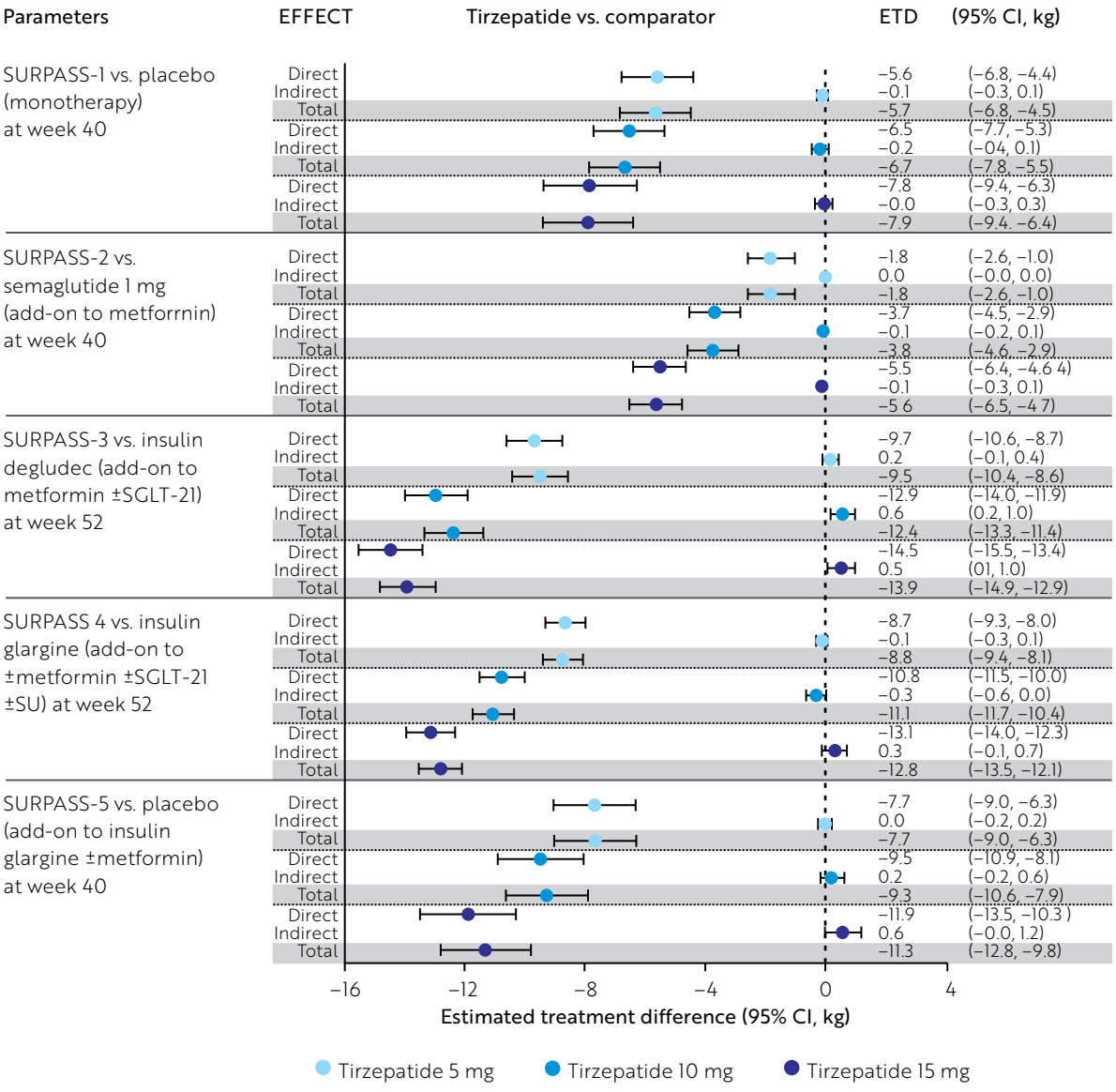
Introduction: Tirzepatide (TZP), a glucose-dependent insulinotropic polypeptide (GIP)/glucagon-like peptide-1 (GLP-1) receptor agonist, demonstrated superior reduction in HbA_{1c} and body weight vs. comparators in participants with type 2 diabetes (T2D) across the SURPASS 1–5 randomised clinical trials. The most common adverse events (AEs) in TZP-treated participants were gastrointestinal (GI) in nature. This post hoc analysis evaluated the impact of nausea, vomiting, or diarrhoea AEs on weight loss with TZP across the SURPASS 1–5 trials.

Material and methods: The phase 3 SURPASS 1–5 trials included participants with T2D (drug-naïve or on background glucose-lowering medications). Trial participants were randomised (1 : 1 : 1 : 1, except in SURPASS-4 with 1 : 1 : 1 : 3 randomisation) to once-weekly TZP (5, 10, 15 mg) or comparator (placebo, semaglutide 1 mg once weekly, or titrated



daily basal insulins). Participants within trials were subdivided by self-reporting (yes/no) of any nausea, vomiting, or diarrhoea. Change from baseline in body weight at the primary endpoint was assessed within each trial and subgroup. Mediation analyses were conducted to evaluate the contribution of direct and indirect (mediated by nausea, vomiting, or diarrhoea) effects of TZP on weight change vs. comparators.

Results: Across the SURPASS 1–5 trials (SURPASS 1, N = 475; SURPASS 2, N = 1876; SURPASS 3, N = 1435; SURPASS 4, N = 1989; SURPASS 5, N = 471), 19–36% of TZP-treated participants reported nausea, vomiting, or diarrhoea vs. 5–26% of those in the comparator arms. Mean weight loss at the primary endpoint with TZP was similar in participants reporting nausea, vomiting, or diarrhoea (–6.16 to –14.86 kg) vs. those who did not report these GI AEs (–6.17 to –13.29 kg). Mediation analyses (Figure) suggest that the estimated treatment difference (ETD) of change from baseline in weight (95% confidence interval [CI]) favoured all doses of TZP (total and direct effects). The contribution of nausea, vomiting, or diarrhoea (indirect effects) to TZP-induced weight loss was minimal (Figure), if any, representing ≤ 5% of the total effect across all trials. In some instances, TZP vs. comparators led to slightly greater weight loss in participants without GI AEs compared with those reporting GI AEs, leading to positive ETD values for indirect effects (Figure).

Conclusions: Superior weight loss with TZP appears to be independent of reported nausea, vomiting, or diarrhoea AEs across the SURPASS 1–5 clinical trials.

Source of funding: Eli Lilly and Company

POSTER SESSION OF ORIGINAL PAPERS 1.3
Chair: Aleksandra Uruska

P13
EXPRESSION OF SELECTED microRNAS IN ADIPOSE TISSUE-DERIVED MESENCHYMAL STEM CELLS AND METABOLIC SYNDROME – PRELIMINARY RESULTS

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Introduction: Adipose tissue is rich in multipotent mesenchymal stem cells (AdMSC), which secrete microRNAs (miR). Although miR are involved in pathogenesis of metabolic syndrome, the role of those secreted by AdMSC remains elusive.

We aimed to assess expression of selected miR by AdMSC in relation to basic metabolism parameters in non-diabetic adults.

Material and methods: For this preliminary study 10 obese, 8 overweight and 5 normal weight subjects with no inflammatory or cancerous disease were enrolled, including 19 female and 4 male, 6 prediabetic and 17 euglycemic ones.

Results: AdMSC were harvested from abdominal subcutaneous fat collected with liposuction and cultured in standard conditions. Expressions of four miR reported in metabolic disturbances: miR-21, miR-122, miR-155 and miR-192 were estimated with RT-PCR. Total and visceral fat were assessed with bioimpedance.

Expression of miR-21, miR-122, or miR-192 did not correlate with any clinical parameter. On the other hand, expression of miR-155 [$2^{-\Delta Ct} \times 10^{-3}$] was lowest in obese subjects (3.69 ±2.67 vs. 7.07 ±4.42 in overweight and 10.25 ±7.05 in normal weight ones, $p = 0.04$, K-W ANOVA). It correlated inversely with BMI, total fat mass, visceral adiposity, and serum CRP, whereas positively (marginally statistically significantly) with serum HDL-cholesterol (Table).

Conclusions: Expression of miR-155 in AdMSC appears blunted in visceral obesity, which correlates with HDL-dyslipidemia and microinflammation. This calls for further study of AdMSC miR secretome in the pathogenesis of metabolic syndrome with focus on miR-155.

Parameters	Mean ± SD (min–max)	Spearman rank correlation with			
		miR-21	miR-122	miR-155	miR-192
		2.13 ±1.85 (0.29–7.59)	0.18 ±0.13 (0.01–0.42) × 10^{-3}	6.29 ±5.0 (1.11–20.12) × 10^{-3}	0.63 ±0.24 (0.27–1.18) × 10^{-3}
Age (years)	43.0 ±8.9 (28–63)	–0.8	–0.16	–0.28	–0.14
BMI (kg/m^2)	30.3 ±7.5 (21.4–47.6)	–0.21	0.08	**–0.65** ***p*** **< 0.01**	–0.19
Total fat tissue [kg]	31.9. ±14.0 (14.0–60.5)	–0.11	–0.10	**–0.49** ***p*** **= 0.02**	–0.28
Viscera fat indicator	8.7 ±4.1 (3–17)	–0.09	–0.04	**–0.55** ***p*** **= 0.01**	–0.36
HOMA-IR	2.6 ±2.5 (0.6–11.5)	–0.18	0.19	–0.32	–0.20
Fasting serum glucose [mg/dl]	85.0 ±10.7 (65.0–108.1)	–0.08	0.16	–0.21	0.12
HbA_{1c} (%)	5.4 ±0.4 (4.8–6.1)	–0.03	0.18	–0.12	0.05
Serum HDL-cholesterol [mg/d]	63.2 ±11.9 (43.6–87.0)	–0.11	–0.21	**0.39** ***p*** **= 0.06**	–0.11
Serum LDL-cholesterol [mg/dl]	113.5 ±31.3 (42.2–176.0)	0.16	0.02	0.08	–0.01
Serum triglycerides [mg/dl]	111.2 ±60.0 (38.0–252.5)	0.24	0.34	–0.06	0.15
eGFR [ml/min/1.73 m^2]	82.6 ±12.1 (65.2–115.1)	–0.31	–0.11	–0.22	–0.06
Serum CRP [mg/l]	3.0 ±4.2 (0.1–13 .4)	–0.23	–0.02	**–0.61** ***p*** **< 0.01**	–0.11

microRNA expression calculated as $2^{-\Delta Ct}$ values, expression related to SNORD6 control

CRP – C-reactive protein, eGFR – estimated glomerular filtration rate

P14
A DIFFERENTIAL DIAGNOSIS OF TYPE OF DIABETES IN A LEAN PERSON WITH A LESION IN THE PANCREAS A – CASE REPORT

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Introduction: The identification of type of diabetes mellitus in lean adult could be a problem. The type 1, type 2 and pancreatic cancer- associated diabetes would be included in differential diagnosis.

Case report: A 69-year-old woman with 5-year history of diabetes was admitted to the hospital for weight loss diagnose and to determine the type of diabetes. First, she was treat metformin alone and later sulfonylurea (gliclazide) was added. From the beginning, the poor metabolic control was observed with HbA_{1c} constantly above 8%. 4 years ago a cystic changes in the pancreas and elevated TSH levels was found.

In physical examination: thin (BMI = 24,3 kg/m^2); RR 125/80; In laboratory tests: fasting glucose = 145 mg/dl; HbA_{1c} = 8.12%, C-peptide (ng/ml) fasting = 1.17, after meal = 4.41. Abnormal lipid profile: LDL cholesterol = 122 mg/dl; TSH = 2.35 µIU/ml; anti-TPO antibodies = 183.8 IU/ml; Ca19-9 = 10.8 (norm), abdominal CT: cystic lesion in the body of the pancreas 10x8 mm with probable association with Wirsung's duct – IPNM (intraductal papillary mucinous neoplasm)? Cholecystolithiasis. Transesophageal ultrasound of the pancreas (EUS) was performed – examination not confirming the connection with Wirsung's duct. The result of the anti-GAD test > 2000. Diagnosed: Slow-onset type 1 diabetes, autoimmune thyroid disease in euthyreosis, pancreatic cysts.

We started basal insulin treatment but was necessary addition of small doses of insulin mealtime. The total daily dose of insulin, for good glycemic control, was 15–18 U/day.

Due to the result of LDL-cholesterol, statin was added. After insulin treatment we observed a gradual increase in weight.

Conclusions: In lean adults, it is necessary to differentiate between the type 1, type 2 or secondary diabetes associated with pancreatic cancer. Anti-GAD antibodies and C-peptide is useful in differentiation. In many adult patients with type 1 diabetes, insulin secretion is maintained for a long time, therefore the C-peptide plasma concentration at the lower limit of normal cannot be used as a differentiating criterion. Diabetes may be the first symptom of pancreatic cancer and appears even 2 years before clinical diagnosis, therefore each change in the pancreas must be carefully diagnosed.

P15
ANALYSIS OF PREDICTIVE FACTORS OF METFORMIN MONOTHERAPY FAILURE IN PATIENTS WITH TYPE 2 DIABETES

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Introduction: For many years, metformin has been the first-line treatment for managing type 2 diabetes, however, in many patients, metformin monotherapy is not sufficient to maintain metabolic control of the disease, as expressed by failure to achieve therapeutic goals in terms of glycemia, body weight, blood pressure and lipid parameters. In the light of current research and ongoing discussions about the appropriate timing of treatment intensification, the search for clinical and biochemical predictors of metformin monotherapy failure could support clinical decisions when initiating diabetes treatment. To identify demographic and clinical factors in a group of patients with t. 2 diabetes to predict failure of metformin monotherapy.

Material and methods: We analyzed data of 1880 patients with t. 2 diabetes treated at the Diabetes Outpatient Clinic between years 2005 and 2022 who were initiated on metformin monotherapy, searching for factors that may correlate with metformin failure defined as: addition of another anti-diabetic drug or failure to achieve HbA_{1c} < 7% within 18 months of starting metformin treatment. The analysis included: blood glucose levels and HbA_{1c} at the time of diagnosis, coexisting components of the metabolic syndrome, and selected parameters of cardiometabolic and anthropometric assessment.

Results: In the analyzed population of patients with diabetes mellitus t. 2, a high rate of failure of metformin monotherapy was observed. Among the factors most strongly correlated with metformin treatment failure were baseline HbA_{1C}, age, male gender, and comorbid cardiovascular complications.

Conclusions: The results suggest that the most significant factor correlating with early metformin failure is the severity of the disease and the patient's metabolic status prior to the initiation of therapy, which supports the thesis that in selected groups of patients, intensive pharmacological treatment should be considered from the time of diagnosis of type 2 diabetes in order to attain better metabolic control of the disease.

P16
THE RELATIONSHIP BETWEEN SERUM VASPIN CONCENTRATION AND INSULIN RESISTANCE IN PATIENTS WITH OBESITY

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Introduction: Adipose tissue is a highly active endocrine organ that regulate an energy homeostasis through secreting numerous of bioactive molecules, as vaspin. Due to its insulin-sensitizing functions and protective role in vasculature and adipose states, vaspin has been speculated as a beneficial adipokine and a candidate biomarker in metabolic disorders. The study aimed to determine the association of vaspin concentration with insulin resistance (IR) in obese patients.

Material and methods: Out of the recruited 60 participants, 40 (aged 43.3 ±13.4 years) were assigned to the study (obese patients) and 20 (aged 38.9 ±14.7 years) to the control group (normal-weight subjects). Anthropometric parameters (body weight, height, waist and hip circumference) were measured, anthropometric indexes were calculated. Body composition (i.a. body adipose tissue, lean body mass) was assessed using the bioimpedance method with Bioscan 920-2 device. Blood pressure measurements were taken 3 times and an average value was taken. Serum vaspin concentration, interleukin 6 level (IL-6) as well as hs-CRP value were assessed using an appropriate ELISA Kits. Other biochemical analyses, performed with standard commercial tests, included: fasting glucose, insulin and lipid profile. HOMA-IR was calculated using the appropriate formula.

Results: Vaspin level was significantly higher in the obese patients in comparison to the controls (0.82 ±0.62 vs. 0.43 ±0.59; < 0.001). In the study group, a positive correlations between vaspin concentration and the percentage of adipose tissue (r = 0.382; p = 0.015) as well as hs-CRP concentration (r = 0.428; p = 0.006) has been evaluated. In the overall population, vaspin correlated positively with body weight (r = 0.452, p < 0.001), BMI (r = 0.558, p < 0.001), waist circumference (r = 0.490, p < 0.001), the percent and mass of body adipose tissue (r = 0.616 and r = 0.507, p < 0.001). Vaspin concentration correlated also positively with triglycerides (r = 0.337; p < 0.008), hs-CRP (r = 0.614; p < 0.001) and IL-6 (r = 0.457; p < 0.001) levels. Furthermore, a positive correlation between vaspin concentration and IR markers as insulin level (r = 0.341; p < 0.008) and HOMA-IR value (r = 0.382; p < 0.003) has been found. The analysis of logistic regression showed that BMI increased was the biggest factor stimulating vaspin concentrations (OR = 8.5; CI: 1.18–61.36; p = 0.0049).

Conclusions: Elevated vaspin level in obese patients may imply its compensatory role against obesity and insulin resistance. Moreover, vaspin concentration is associated with cardiometabolic risk-related factors in obesity, thus can be considered as a new therapeutic approaches in i.a. carbohydrate metabolism disorders. Nevertheless, further research is needed to support these conclusions.

P17
EVALUATION OF THE SONIC HEDGEHOG AND NOTCH PATHWAYS GENE EXPRESSION IN SUBCUTANEOUS AND VISCERAL ADIPOSE TISSUE DEPENDING ON THE PRESENCE OF METABOLIC SYNDROME

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Introduction: Obesity is associated with insulin resistance, which consequence is the metabolic syndrome (MS). Metabolic disturbances may result from impaired adipogenesis, i.e. the formation of adipocytes from mesenchymal stem cells located in stroma vascular fraction (SVF) of adipose tissue. Recent studies indicate the role of the Sonic Hedgehog (SHH) and NOTCH pathways in adipogenesis and metabolism of carbohydrates and lipids. However, the involvement of these pathways in the pathogenesis of obesity and its metabolic complications in humans is still unclear. The aim of study was to evaluate the SHH and NOTCH pathways genes expression in subcutaneous (SAT) and visceral (VAT) adipose tissue of obese people depending on the presence of MS, and their association with MS.

Material and methods: The study included 20 subjects with BMI 42 ±3.9 kg/m^2 who underwent the bariatric surgery. Patients were divided into subjects with MS (n = 10) and without MS (n = 10). The 2 g of SAT and VAT were collected from all subjects. The portion of fat was digested with collagenase to obtain the SVF. The expression of SHH (SMO, GLI1), NOTCH (NOTCH1, HES1) pathway genes and adipogenesis markers (CEBPA, CEBPB, PPARG) was measured in the obtained material (SVF, SAT, VAT).

Results: In subjects with MS the expression of SMO and HES1 in SVF SAT (all $p < 0.003$) and GLI1 in SVF VAT ($p = 0.03$) was lower. In the same group SVF SAT PPARG and SVF VAT CEBPA, PPARG (all $p < 0.02$) were lower. The expression of CEBPA and PPARG (all $p < 0.05$) was also lower in SAT of subjects with MS. In the entire group, expression of NOTCH1 in SVF SAT and GLI1 in SVF VAT was positively correlated with CEBPA and CEBPB in the respective SVF (all $p < 0.05$), and expression of SMO in SAT and NOTCH1 in VAT was positively correlated with CEBPA and CEBPB in the respective tissue (all $p < 0.004$). In all subjects SVF SAT SMO expression was negatively correlated with cholesterol, triglyceride and HbA_{1c} (all $p < 0.04$). In subjects with MS the expression of NOTCH1 in SAT and GLI1 in VAT was positively correlated with fasting glucose, and NOTCH1 in VAT was positively correlated with fasting insulin (all $p < 0.05$). In subjects without MS SAT GLI1 and HES1 were negatively correlated with HOMA-IR, and VAT SMO, NOTCH, HES1 were negatively correlated with fasting insulin and HOMA-IR (all $p < 0.03$).

Conclusions: Sonic Hedgehog and NOTCH pathways may be associated with impaired adipogenesis and the induction of metabolic disturbances in obese humans.

P18
DOES HYPERGLYCEMIA INCREASE THE RISK OF HYPOTHYROIDISM IN PATIENTS WITH OBESITY

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Introduction: The coexistence of carbohydrate metabolism disorders and thyroid diseases is of great interest of both diabetologists and endocrinologists. It is well known that hormones of thyroid gland are important regulators of glucose metabolism. Co-occurrence of diabetes type one with autoimmune thyroid disease in autoimmune polyglandular syndromes is not controversial. However, the data on the relationship between thyroid function and type 2 diabetes (T2D) are not so unequivocal and many studies indicate a higher incidence of thyroid diseases in patients with obesity disease. According to the recommendation of the Polish Diabetology Society, every patient with diabetes should have the diagnostic process extended with the assesment of TSH and, in selected cases, ATPO antibodies. In the presented work, authors, following the recommendations of PTD, tried to answer the question: is there a difference in the occurrence of hypothyroidism, including autoimmune, in obese patients with type 2 diabetes or prediabetes, compared to obese patients with normoglycemia.

Material and methods: The analysis included 702 patients (557 F and 145M) aged 16 to 76, with obesity, hospitalized for treatment of primary disease. Among them 351 people (50%) had diagnosed hyperglycaemia: 137 patients (19.52%) had T2D and 214 (30.48%) had prediabetes (impaired fasting glucose and/or impaired glucose tolerance). According to the recommendations of PTD, all patients were assessed for thyroid hormone function based on the measurement of TSH and, in 625 cases, also FT4. In 202 patients aTPO antibody concentration was measured. The obtained results were analysed using STATISTICA 13 and χ^2 tests were used where applicable.

Results: Elevated TSH concentration was found in 15 patients, including 3 with T2D, 7 with prediabetes and 5 with normoglycaemia. ATD was found in 153 patients, including 22 patients with T2D (16.07% of all diabetic patients), 47 patients with prediabetes (21.76% of all with prediabetes) and 82 patients (23.63%) without carbohydrate metabolism disorders. These differences were statistically significant (p = 0.015). Diabetic patients were also the least likely to take levothyroxine, regardless of diagnosis of ATD (24.82%).

Conclusions: A higher incidence of hypothyroidism and ATD in group of obese patients with T2D and prediabetes compared to patients with obesity without carbohydrate metabolism disorders was not observed, which suggests that hyperglycemia itself does not impact on thyroid function. To confirm this observation, it would be necessary to carry out the study in the control group of people with T2D with normal body weight.

POSTER SESSION OF ORIGINAL PAPERS 1.4

Chair: Przemysław Witek

P19

THE SILESIA DIABETES-HEART STUDY: MACHINE LEARNING FOR THE PREDICTION OF CARDIOVASCULAR EVENTS IN DIABETIC PATIENTS – PRELIMINARY RESULTS

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Introduction: It is estimated that the number of patients with diabetes worldwide will reach 783 million in 2045 and the leading cause of death remain cardiovascular events. The challenge for modern medicine is to find a method to identify high risk patients based on easy to obtain clinical data. In contrast to the methods of classical statistics, machine learning (ML) algorithms allow for the prediction of the occurrence of medical events and have already found to be useful in clinical practice. To use ML methods to predict the occurrence of new cardiovascular events in a group of 4 000 patients with diabetes over a minimum of 6-month follow-up period from hospital discharge.

Material and methods: Demographic and clinical data, including laboratory and imaging results of diabetic patients hospitalized in the Department of Internal Medicine and Diabetology in Zabrze, Poland. The study is single-center, prospective and observational (a minimum 10-year follow-up of patients is planned), part of The Silesia Diabetes-Heart Project (ClinicalTrials.gov NCT05626413). The analysis of the collected data is based on ML methods to identify patients with the highest risk of cardiovascular events based on medical data available in everyday practice. Prospective assessment of patients for the occurrence of new cardiovascular events after hospital discharge is conducted during a telephone interview at a minimum interval of 6 months after hospital discharge.

Results: To date, medical data have been collected and a prospective analysis of 1735 patients hospitalized between years 2016 and 2021 (mean age 59.07 years, SD 17.35; diabetes duration of 11.19 years, SD 9.11; HbA_{1c} 9.12%, SD 2.38; 52.97% women) has been performed. The majority of patients (78.67%) had type 2 diabetes. The created algorithm identified 12 easy-to-obtain clinical variables (coronary artery disease, heart failure, peripheral arteriosclerosis, stroke, presence of diabetic foot, chronic kidney disease, percentage of eosinophilia, potassium levels, and treatment with clopidogrel, heparin, proton pump inhibitor or loop diuretic), which identify those at highest risk of a cardiovascular event during the follow-up period after hospital discharge. The method used has correctly classified the occurrence of cardiovascular events in 63.33% of patients (AUC: 0.72, 95% CI: 0.66–0.77).

Conclusions: This preliminary analysis shows using ML methods allowed the identification of diabetic patients with a high risk of new cardiovascular events, who could be missed by standard clinical evaluation. This prediction is based on a small number of easily obtainable clinical parameters.

P20
THE USE OF GLP-1 RECEPTOR AGONISTS IN THE TREATMENT OF OBESITY COMPLICATED WITH TYPE 2 DIABETES HELPS ACHIEVE VARIOUS GOALS

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Introduction: Obesity is a complex, multifactorial disease that is the main risk factor in the development of many metabolic complications, such as type 2 diabetes. Evaluation of the importance of GLP-1 receptor agonists in the treatment of obesity and metabolic disorders resulting from it.

Material and methods: The medical record of 702 patients with obesity disease (557 females and 145 males), hospitalized in day hospital, was analyzed. Patients were between 16 and 76 years old (avg. 44.09 ±13.78), with body mass index (BMI) (between 23.2–76.58 kg/m^2 (avg. 36.89 ±6.11) and waist circumference (WC) in the range of 74–204 cm (avg for females 109.51 ±12.85 and males 124.25 ±15.22). Additionally patients have had their blood pressure, lipid profile and HbA_{1c} measured. All patients underwent cycle of dietary education. From the group of 137 patients with diagnosed type 2 diabetes (either newly or already under treatment) 20 patients aged 25–70 (avg 52.6 ±11.0. 7 male, 13 female), who consented to treatment with GLP-1 receptor agonists and were admitted for subsequent hospitalization 6–12 months after initialization of treatment. Gathered data was evaluated in STATISTICA 13, *t*-Student test for dependent variables was used where applicable.

Results: The mean HbA_{1c} concentration during the first hospitalization was 6.68% ±0.94 (min. 5.2, max. 9.4), after 6 months 5.7% ±0.45 (min. 5.0 max. 7.1), total reduction of 0.98% ±0.95. In addition, a reduction in BMI was observed from 41.51 ±6.59 kg/sqm (min. 27.8, max. 54.0) to 38.78 ±4.93 kg/sqm (min. 28.4, max. 49.83). There was also a reduction in the waist circumference of 126.47 ±14.71 cm (min. 95.0, max. 153.0) to 121.18 ±10.81 cm (min. 96.0, max. 140.0). All those differences were statistically significant. In the lipid profile, there was statistically significant reduction of triglyceride concentration (from 175.27 ±82.17mg/dl to 144.60 ±66.56 mg/dl), the difference between total cholesterol, HDL and LDL were slight and not statistically significant. Also reduction of average blood pressure was observed, however the difference was not statistically significant.

Conclusions: Addition of GLP-1 receptor agonists to the treatment of patients with T2D allowed for satisfactory effects of obesity treatment and improvement of carbohydrate balance, which may lead to remission of type 2 diabetes in the future.

P21
QUALITY OF LIFE AND PARAMETERS OF METABOLIC CONTROL IN PATIENTS WITH LONG-TERM TYPE 1 DIABETES TREATED WITH INTENSIVE INSULIN THERAPY SINCE 1994.

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Introduction: Clinical course of long term type 1 diabetes (T1D) and quality of patients life depends on metabolic control of the disease and the development of acute and chronic complications, as well as model of treatment and glucose monitoring devices used. To present cases of the patients, in which use of intensive model of insulin therapy and various glucose monitoring systems helped improve glucose control and quality of life.

Material and methods: Retrospective analysis of available medical records of two patients with T1D with long term, unstable course of the disease over 40 years of medical history.

Case reports: A 62-year-old man with a 43-year history of uncontrolled T1D, complicated by the development of micro- and macroangiopathy, treated with intensive insulinotherapy based on analog insulins (aspart + degludec). HbA_{1c} in 1994 was 8.7%. Before using FreeStyle Libre, in May and July 2016, only 34% of glycemic tests (out of 500) remained within the target values (70–140 mg/dl), 53% remained above and 13% below the recommended values. HbA_{1C}, due to a large variability of glycemic values, was at the level of 6.1–6.4%, this was a false result. The patient has been using the FreeStyle Libre system intermittently since September 2016. In October 2016, 52% of blood glucose measurements remained within the target values, 38% above, 10% below the recommended values. Currently, the TIR is 75%, HbA_{1c} in January 2023 was 6.1%, and the complete elimination of severe hypoglycaemia continues. The second patient is a 63-year-old man with T1D for 45 years, with chronic macro- and microangiopathic, treated with intensive insulinotherapy based on analog insulins (lispro + degludec). HbA_{1c} in 1994 7.0%, in 1998 8.2%. The use of insulinotherapy allowed for the improvement of the patient's glycemic control (HbA_{1c} XI-22 7.1%, VIII-22 7.8%, V-21 8.1%, X-20 HbA_{1c} 9.0%) and the absence of episodes of severe hyperglycemia from 2017.

Conclusions: In the first patient, the use of a flash glucose monitoring system (FreeStyle Libre) allowed for a significant improvement in the quality of life, better understanding of the mechanisms of action of one's body in diabetes and control of glycemic control of diabetes at a satisfactory level. In the second patient, the use of a model of intensive insulin therapy with the traditional method of glucose monitoring also allowed for better control of glycemic control of diabetes, but to a less satisfactory extent than in the first patient.

P22
THE SILESIA DIABETES-HEART STUDY – TOWARD APPLYING MACHINE LEARNING TO IDENTIFY DIABETIC NEUROPATHY – THE STUDY PROTOCOL

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Introduction: The presence of diabetic peripheral neuropathy (DPN) and cardiovascular autonomic neuropathy (CAN) are some of the most common complications of diabetes, but are also risk factors for cardiovascular disease (CVD). What is important is that CAN may be asymptomatic in this group of patients. Diagnosis of DPN and CAN are time-consuming and therefore often overlooked in everyday medical practice. DPN is present in 10–34% of patients with type 1 diabetes mellitus (T1DM) and in 8–25% with type 2 diabetes mellitus (T2DM), whereas CAN is present in approximately 10% of T1DM and 5% of T2DM patients. The use of machine learning (ML) to identify patients with these complications may contribute to discriminate people at risk of CVD. To develop new algorithms with the use of advanced data mining and ML techniques to diagnose patients with DPN and/or CAN based on routinely assessed biochemical parameters in blood and urine samples, fundus results and basic clinical data.

Material and methods: This observational, prospective (minimum 10 years of patients' follow-up) single-center study is a part of The Silesia Diabetes-Heart Project (ClinicalTrials.gov NCT05626413). We plan to examine minimum 1,000 diabetic patients hospitalized in the Department of Internal Medicine and Diabetology in Zabrze, Poland, as well as those responding to invitation placed on advertising posters. Demographic, laboratory (HbA_{1c}, albuminuria, eGFR and lipid profile) and patient's clinical data are collected. Physical examination (including feet examination for DPN) and the examination for CAN is performed (Ewing's battery with the DiCAN – Diabetic Cardiovascular Autonomic Neuropathy device). Eye examination for the presence of diabetic retinopathy using a Fundus Camera is performed. ML techniques will be used for data analysis.

Results: Thus far, 192 patients (53.13% women; mean age 51.90 years (SD 17.65)), with a diagnosis with diabetes for a mean period of 12.19 years (SD 9.26) have been examined. Most participants (66.67%) had T2DM. The mean HbA_{1c} value in the study group was 8.88% (SD 2.13). Based on the examination with the DiCAN, CAN was diagnosed in 23.43% of patients (out of them 15.56% had early and 28.89% severe CAN).

Conclusions: The basic analysis of the patients examined so far indicates a high incidence of CAN, therefore it is essential to search for the possibility of simple identification of patients with this complication and ML methods provide it.

P23
PULMONARY FUNCTION TEST AS A NON-INVASIVE METHOD FOR THE DIAGNOSIS OF DIABETIC PULMONOPATHY – PILOT STUDY

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Introduction: Chronic inflammation and hyperglycemia-induced oxidative stress play one of the major roles in the development of chronic complications in diabetes. In the vascular endothelium, due to non-enzymatic protein glycation and glucose autooxidation, the formation of toxic oxygen occurs, which stimulates the secretion of vascular endothelial growth factor and is responsible for the characteristic vascular tumorigenesis in diabetes. Increased endothelial prothrombotic activity and dysregulation of vascular wall tension result in impaired capillary blood flow. These mechanisms, inducing chronic inflammation, underlie the well-studied microvascular complications of diabetes. Although hyperglycemia has systemic effects, in the world of diabetes science, the lungs are one of the least cared for target organs. The relationship between diabetes and deterioration of lung function has been widely discussed for many years, and functional testing appears to be the best non-invasive evaluation of respiratory function. The aim of this study was to present the results of pulmonary function tests among patients with T2DM, without overt clinical angiopathic complications.

Material and methods: Analysis of the results obtained from 15 patients (8K,7M), with a mean age of 62 years (±12.29), diagnosed with T2DM, disease duration of 11.2 years (±7.71), HbA_{1c} in the range of 5.3–11% (7.31% ±1.93), fasting blood glucose in the range of 74–317 mg/dl (128 mg/dl ±56.8) undergoing spirometry, DL_{CO} and 6MWD. We applied analysis of medical records.

Results: Based on the available data, there was a statistically significant positive correlation between HbA_{1c} levels and FEV1 (p = 0.016), FVC (p = 0.031), MMEF (p = 0.017) and DL_{CO} (p = 0.017). In addition, a trend toward impaired alveolo-capillary barrier function with the duration of T2DM was highlighted, but this correlation was not statistically significant (p = 0.590). There was also significance between fasting blood glucose levels and the severity of fatigue on the Borg scale after 6MWD (p = 0.010) and patient age (p = 0.013), which had an inverse correlation with distance traveled (p = 0.066).

Conclusions: The data presented didn't allow a clear determination of the type of pulmonary dysfunction, with a trend toward impaired alveolar-capillary barrier function with the duration of T2DM, which is most likely due to the insufficient size of the study population. Whereas, it was concluded that the initiation of pulmonary function diagnosis among patients with T2DM, cannot be made dependent on a single HbA_{1c} determination. Evaluation of 3-month glycemic control, doesn't define the entire course of T2DM. Diabetic pulmonopathy seems to be a clinically relevant and insufficiently studied problem, and therefore further scientific studies in this direction are indicated.

P24
ASSESSMENT OF IMMUNE CELL SUBPOPULATIONS IN WHOLE BLOOD AND TYPE I AND II INTERFERONS RECEPTORS IN SUBJECTS WITH VARIOUS DEGREES OF GLUCOSE TOLERANCE

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Introduction: Insulin resistance is associated with the development of chronic low-grade inflammation. The COVID-19 pandemic indicates increased susceptibility to viral infection, a more severe course of infection, and higher mortality in people with obesity and/or type 2 diabetes (T2D). Monocytes and T lymphocytes have key functions in the body's defense against pathogens. A major role in the antiviral immune response is played by interferons (IFNs) α, β (type I), and γ (type II), which act on immune cells by interacting with specific receptors on their surface. Recent studies suggest the relationship between type I and II IFNs and insulin resistance. The mechanisms responsible for the impaired antiviral response in obesity and T2D are unclear, and their association with insulin resistance is unknown. Assessment of peripheral blood immune cell subpopulations and receptors for type I (IFN-α/βR1) and type II IFN (IFNGR1) on their surface in subjects with various degrees of impaired glucose metabolism.

Material and methods: 22 subjects (BMI 27.99 ±8.78 kg/m^2) without impaired glucose tolerance and 18 subjects (BMI 35.83 ±5.19 kg/m^2) with prediabetes (impaired fasting glucose or impaired glucose tolerance) or newly diagnosed T2D were included in the study. The blood samples were analyzed by flow cytometry using antibodies directed against surface markers enabling detection of populations and subpopulations of lymphocytes, monocytes, and IFN-α/βR1, IFNGR1. The absolute number of cells, with the expression of surface receptors for IFN, was assessed by analyzing their percentage in relation to the morphological examination.

Results: In obese subjects with prediabetes or T2D we indicated a higher percentage of helper (Th) lymphocytes (p = 0.032), cytotoxic (Tc) lymphocytes (p = 0.030), and non-classical monocytes (p = 0.002) compared to those without impaired glucose metabolism. There was higher expression of IFN-α/βR1 on Th lymphocytes (p = 0.009), Tc lymphocytes (p = 0.021), monocytes (p = 0.002), and in a subpopulation of classical monocytes (p = 0.002) in the prediabetic or T2D group. In this group of patients, we also found higher expression of IFNGR1 on non-classical monocytes (p = 0.002). In the whole study population, we found positive correlations between IFN-α/βR1 expression on Th lymphocytes and fasting glucose (p < 0.001) and HbA_{1c} (p < 0.001). IFNGR1 expression on non-classical monocytes was positively correlated with BMI (p = 0.013), waist circumference (p = 0.006), fasting glucose (p = 0.017), triglyceride (p = 0.014), HOMA-IR index (p = 0.02) and negatively with HDL-cholesterol (p = 0.002).

Conclusions: The altered profile of surface receptors for type I and type II IFNs on lymphocytes and monocytes may suggest an impaired antiviral response in the early stage of T2D development.

POSTER SESSION OF ORIGINAL PAPERS 2.1
Chair: Andrzej Gawrecki

P25
DEGREE OF DISEASE ACCEPTANCE AMONG YOUNG ADULTS WITH TYPE 1 DIABETES

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Introduction: Type 1 diabetes, due to its chronic nature, can significantly affect the acceptance of the disease and the quality of patients' life. The aim of the study was to determine the impact of various factors on the degree of acceptance of the disease among young adults with type 1 diabetes.

Material and methods: The study involved 121 people (85 women and 36 men aged 18–29), suffering from type 1 diabetes on average 10.6 ±7.4 years ($\bar{x}$ ±SD), treated with continuous subcutaneous insulin infusion (CSII) therapy using a personal insulin pump (54.5%) or multiple daily insulin injections (MDII) therapy (45%). The original questionnaire and the Acceptance of Illness Scale (AIS) were used. The scale contains eight statements describing the negative consequences of poor health; it ranges from 8 to 40 points. The higher the score on the scale, the greater the degree of acceptance of the disease. The questionnaire consists of 28 questions on socio-demographic factors, self-control, self-acceptance of the disease, and quality of life.

Results: The quality of life score on a scale from 0 to 100 was 72.13 ±17.85 points, and 47.1% of respondents rated their quality of life as good. The AIS scale score was 27.86 ±8.77 points. Factors significantly affecting self-assessment of quality of life and the level of acceptance for the disease were determined.

Women's self-assessment of quality of life (69.41 ±17.26) was worse than men's (78.56 ±17.79). The impact of professional and social activity was determined. Quality of life was worst among the unemployed (62.67 ±21.53) and those who declared the necessity to withdraw from social activity because of the disease ($p = 0.003$).

The level of acceptance of the disease was significantly lower ($p = 0.036$) among unemployed respondents (24.83 ±8.36) compared to those who worked physically (29.40 ±8.82) or mentally (29.00 ±8.67). There was also less acceptance of the disease among respondents who declared the necessity to withdraw from social activity ($p < 0.001$) compared to those who decided that the illness did not limit them (19.00 ±6.87 vs. 31.44 ±7.35), and in those who experienced ailments that required systematic assistance from a psychologist ($p = 0.001$). A positive correlation was observed between quality of life and acceptance of the disease ($r = 0.360$, $p < 0.001$).

Conclusions: Young adults with type 1 diabetes showed a moderate level of disease acceptance. Influential factors were professional work, an active lifestyle and the absence of diabetes-related problems requiring psychological care. Better quality of life was associated with greater acceptance of the disease.

P26
THE IMPACT OF BODY POSITION ON ORAL GLUCOSE TOLERANCE TEST RESULTS IN HEALTHY, YOUNG SUBJECTS

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Introduction: Oral glucose tolerance test (OGTT) is a common method of measuring insulin sensitivity and resistance. It is a basic tool to diagnose diabetes mellitus in ambulatory and hospital conditions in patients with risk factors. Official guidelines suggest that patient undergoing oral glucose tolerance test should be rested during exam. However, it is not specified whether it must be sitting or supine position. Blood glucose level and regulation of insulin secretion are under rigid control of sympathetic nervous system, which activity depends on body position. Supine position significantly outbalances sitting position during OGTT in hospitals and could have a great impact on test results and further misdiagnosis of diabetes mellitus. To investigate blood glucose levels response to the body position in young, healthy adults.

Material and methods: Study was conducted with an approval of appropriate Bioethical Commission. 12 volunteers (age 18–25, males: 7) with no diagnosed diseases were enrolled into the study. Each of them was examined in both supine and sited positions with 4 weeks interval between. First position was selected randomly. Tests were performed in the morning after fasting for at least 12 hours. After 5 minutes of rest in selected position first blood sample was drawn. Afterwards, the glucose solution (75 g in 300ml of water) was administrated and another blood samples were drawn in 30, 60 and 120 minutes after glucose administration. The blood samples were tested for an insulin and glucose concentration.

Results: There is a significant increase in glucose concentration in 30 minutes of the test in supine position in comparison to the sitting position are presented in the chart.

Conclusions: Body position has significant influence on blood glucose level, especially in hospital ward conditions

Source of funding: Medical University of Warsaw students mini-grant nr 31/M/MG/N/21

Parameters	0 min		30 min		60 min		120 min	
	S	L	S	L	S	L	S	L
Glucose [mg/dl]	91.3 ±5.52	90.8 ±5.56	123.7 ±28.20	135.4 ±15.93*	110.1 ±28.26	114.1 ±26.0	88.5 ±15.91	97.3 ±19.66
Insulin [mlU/l]	6.5 ±2.72	5.8 ±2.27	64.6 ±30.72	56.5 ±17.35	57.5 ±31.36	43.3 ±20.15	38.5 ±18.13	31.4 ±12.64

*S – sitting position, L – supine position, *p < 0.05 as compared to the sitting position*

Chart: arithmetic mean ±standard deviation

P27
EXOGENOUS INSULIN DOES NOT AFFECT THE THYROID VOLUME IN ADULTS WITH TYPE 1 DIABETES

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Introduction: Insulin is a hormone known for its anabolic activity. It has been widely reported in the literature that insulin stimulates the proliferation of a wide variety of cells, including thymocytes. Several studies have shown that thyroid volume is usually larger in type 1 diabetes compared with healthy controls. Insulin resistance was associated with thyroid volume in both type 1 and type 2 diabetes. Less is known about the possible cause of these changes. The aim of the study was to measure the relationship between the dose of exogenous insulin on thyroid volume.

Material and methods: 83 adult participants (54% women and 46% men) aged 23 (IQR: 20–28) with type 1 diabetes courses longer than 1 year were enrolled in a prospective, cohort study. The control group consisted of 27 healthy adults (67% women and 33% men) aged 23 (IQR: 21–24). All participants with type 1 diabetes in a state of euthyroidism were treated with an intensive insulin therapy regimen and used a continuous subcutaneous infusion pump. During the 3-month observation period, every participant with type 1 diabetes achieved a mean daily dose of insulin (DDI). In addition, thyroid stimulating hormone (TSH), free triiodothyronine (fT3), free thyroxine (fT4), glycated hemoglobin (HbA_{1c}) and thyroid autoantibodies (anti-TPO, anti-Tg) levels were assessed in the study and control group. Ultrasound examination of the thyroid gland was performed with measurements of the thyroid volume based on three-dimensional measurements.

Results: There was no statistically significant difference in the thyroid volume in patients with type 1 diabetes compared to the control group (p = 0.71). The was no statistically significant correlation between the mean DDI and thyroid volume (r = 0.003, p = 0.98). The results indicated a weak positive correlation between DDI and TSH (rho = 0.23, p-value = 0.03). No correlations were found between DDI and fT3, fT4, HbA_{1c} levels. After excluding patients with positive anti-thyroid antibodies: anti-TPO or anti-TG, also no relationship was found between DDI and the volume of the thyroid gland (r = –0.02, p = 0.86). There was no statistically significant relationship between the daily dose of insulin per kilogram of body weight and the thyroid volume. There was no association between thyroid volume and duration of type 1 diabetes.

Conclusions: There was no difference in thyroid volume between participants with type 1 diabetes and healthy adults Daily dose of insulin is not associated with thyroid volume in adult participants with type 1 diabetes.

P28
ADAPTIVE OPTICS IMAGING OF CONES IN PATIENTS WITH TYPE 1 DIABETES MELLITUS

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Introduction: Diabetic eye disease remains one of the major causes of complete vision loss worldwide and it constitutes an independent risk factor for myocardial infarction or stroke. The pathophysiological mechanism leading to diabetic retinopathy (DR) involves neurovascular damage to the retina. The adaptive optics method makes it possible to perform non-invasive in vivo assessment of the retinal vasculature and photoreceptors. To assess retinal photoreceptors in patients with type 1 diabetes mellitus (DM1).

Material and methods: The study encompassed 27 DM1 patients (17 females) aged 42.11 ±9.69 years with a mean diabetes duration of 22.07 ±10.28 years, without diagnosed DR, and 41 healthy volunteers (20 females) aged 41.02 ±9.84 years. The measurements included: peripheral blood pressure, central blood pressure taken non-invasively in the aorta, pulse wave velocity and indices of metabolic control in diabetes. Parameters of retinal cones were assessed with an Imagine Eyes (rtx1) retinal camera using the method of adaptive optics. Statistical analysis was performed with the use of IMB SPSS version 23 software.

Results: The group of DM1 patients did not differ significantly in age, BMI, central and peripheral blood pressure or ocular length compared to the control group. Intraocular pressure (IOP) in both groups was normal, yet significantly higher in the DM1 group, at 16.9 ±3.2 vs. 14.0 ±1.8 mm Hg, (p = 0.004). There was a significantly (p = 0.01) lower number of regular cones in the DM1 group compared to the control group, respectively 93.1 ±4.0 vs. 95.5 ±2.4%, and a significantly (p = 0.016) lower number of cones in the hypertensive DM1 group compared to the normotensive DM1 group. Additionally, this parameter in all participants of the study correlated negatively with blood pressure values (peripheral systolic r = –0.034; p = 0.007; peripheral diastolic r = –0. 32, p = 0.010; central systolic r = –0.31, p = 0.013; central diastolic r = –0.30, p = 0.015).

Conclusions: The presented research demonstrates significant changes affecting photoreceptors in DM1 patients. Retinal assessment with a rtx1 camera offers a non-invasive insight into early lesions in retinal nerve cells in diabetic patients. Similar changes may occur in the brain and require further investigation.

POSTER SESSION OF ORIGINAL PAPERS 2.2
Chair: Magdalena Szopa

P29
IMPAIRED CHOLESTEROL EFFLUX CAPACITY IN PEOPLE WITH TYPE 1 DIABETES AND NON-ALCOHOLIC FATTY LIVER DISEASE (PROSPECTIVE InLipoDiab1 STUDY)

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Introduction: Non-alcoholic fatty liver disease (NAFLD) is associated with a higher risk of atherosclerotic cardiovascular disease, also among people with type 1 diabetes (DM 1). The protective antiatherosclerotic effect is to be drawn to, among others, HDL particles (HDL-P) *via* cholesterol reuptake mechanism (cholesterol efflux capacity, CEC). People with DM 1 are characterized by high levels of serum HDL-cholesterol (HDL-C), but it is also known that their function of HDL-P is impaired. To assess HDL-P CEC in DM 1 patients during the first year of follow-up, in relation to the NAFLD prevalence.

Material and methods: The analysis included 46 patients (34 men, 74%) with newly diagnosed DM 1, recruited for the Insulin Therapy and Lipoproteins' Profile in Type 1 Diabetes (InLipoDiab1) study. At onset, the mean age was 27 ±5 years. CEC was evaluated in collaboration with UT Southwestern Medical Center, Dallas, TX, USA by measuring the efflux of labeled cholesterol from J774 murine macrophages into the acceptor HDL-P in patients' serum. The study was performed at two points: before the first administration of exogenous insulin and after one year of insulin therapy. In addition, the prevalence of NAFLD was assessed during the follow-up of patients by liver elastography using the Fibroscan device. NAFLD was diagnosed based on the value of the controlled attenuation parameter (CAP) ≥ 238 dB/m.

Results: Significantly lower values of CEC measured at the DM 1 onset and CEC measured after 12-months were found in patients with NAFLD: 0.063 ±0.012 vs. 0.077 ±0.0018, $p = 0.02$ and 0.061 ±0.009 vs. 0.078 ±0.015, $p = 0.001$ respectively.

Moreover, a negative correlation between CEC assessed 12-month after DM 1 onset and the CAP value was found ($Rs = -0.59$, $p < 0.001$).

Conclusions: In people with DM 1 and prevalent NAFLD in the course of the disease, CEC function is impaired from the diabetes onset.

P30
LONGITUDINAL TRANSCRIPTOMIC CHANGES IN THE SELECTED INSULIN SIGNALING GENES IN WOMEN WITH GESTATIONAL DIABETES, FROM THE THIRD TRIMESTER OF PREGNANCY TO 1 YEAR POSTPARTUM

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Introduction: Previous studies have shown that impaired insulin signaling is linked to gestational diabetes mellitus (GDM); however, changes in the expression of insulin signaling components in leukocytes of GDM patients during and after pregnancy are still largely unknown. To determine transcriptomic changes in the genes engaged in the insulin signaling pathway in leukocytes of women with GDM from third trimester of pregnancy (Time point 1: TP1) to 1 year postpartum (Time point 2: TP2), and to correlate these changes with clinical phenotypes of the patients, and to identify potential predictors of abnormal glucose tolerance (AGT) development at 1 year after GDM.

Material and methods: 37 GDM patients (14 patients with AGT at TP2), and 30 healthy pregnant women (control group) were enrolled into the study. Gene expression profiles of insulin receptor (*INSR*), insulin receptor substrates-1 and -2 (IRS1 and 2), and phosphatidylinositol-3-kinase subunit p85α (*PIK3R1*) were determined by quantitative real time PCR. The logistic regression models with areas under the receiver operating characteristic (ROC) curves (AUCs) were used for prediction of postpartum AGT.

Results: From TP1 to TP2, there was a significant increase in *PIK3R1* expression, fasting plasma glucose (FPG), and HbA_{1c} and a significant decrease in 2 h post-load glucose, insulin, CRP, all maternal lipids (TC, LDLC, HDL-C, and TGs), HOMA-B and HOMA-IR. At TP2, insulin and HOMA-IR were higher and *IRS1* expression was lower than in the control group (all $p < 0.05$). Pregnancy *IRS1* expression negatively correlated with gestational weight gain and TGs, *IRS2* positively correlated with pre-pregnancy BMI and FPG, and *PIK3R1* positively correlated with all blood glucose measures at the OGTT. At TP2, only *INSR* positively associated with 2 h post-load glucose. The logistic regression model based on *INSR* expression at TP1 (OR = 6.83, $p = 0.041$) and pre-pregnancy BMI (OR = 1.32, $p = 0.034$) had a good accuracy for predicting the AGT at TP2 (AUC = 0.83 ±0.08).

Conclusions: Compared with healthy pregnancies, women with prior GDM displayed decreased insulin sensitivity that was accompanied by *IRS1* downregulation and *PIK3R1* upregulation in leukocytes. Postpartum *INSR* expression was associated with glucose metabolism, whereas *IRS1*, *IRS2*, and *PIK3R1* transcripts were related to glucose or lipid metabolism or parameters of maternal obesity. Leukocyte *INSR* expression, along with pre-pregnancy BMI could be of great value for the development of prediction strategy against AGT in GDM pregnant women.

P31
MATURITY ONSET DIABETES OF THE YOUNG TYPE 2 AS THE CAUSE OF IMPAIRED FASTING GLUCOSE

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Introduction: MODY (MODY – an acronym for Maturity Onset Diabetes of the Young) is a group of rare and genetically determined forms of diabetes whose symptoms appear in people aged 15–35 years and whose clinical course is similar to type 2 diabetes. The best-known form, caused by a mutation in the gene for glucokinase, is MODY 2. Clinical symptoms usually appear in childhood or early adolescence. The clinical course of MODY 2 is usually mild. It is predominantly treated with a low glycaemic index diet and physical activity. Insulin administration is only required during pregnancy. The purpose of a case report is to present a possibility of MODY type 2 in young non-obese patient with impaired fasting glucose, in whom diabetes mellitus type 1 was excluded.

Material and methods: The diagnosis of a 35-year-old female patient was initiated after an abnormal fasting blood glucose result. No osmotic symptoms were observed. No autoantibodies typical of type 1 diabetes were detected. Both of the patient's parents had diabetes. The patient's mother was two times pregnant, with gestational diabetes mellitus in only 1 of them. Genetic testing was performed on the patient and her parents. The tests were carried out using the NGS technique (next-generation sequencing), and the result was confirmed using the Sanger method.

Parameters	Planned pregnancy, *n* = 20	Unplanned pregnancy, *n* = 30	*p*-value
	Mean ±SD	Mean ±SD	
Age (years)	30.30 ±3.96	29.47 ±3.95	0.469
T1DM duration (years)	11.98 ±7.00	15.73 ±6.24	0.053
Pump + rtCGM initiation (week)	**5.30 ±6.11**	**12.18 ±4.72**	**< 0.001**
Week of delivery	**37.70 ±1.19**	**36.17 ±2.63**	**0.010**
Preterm birth, *n* (%)	**2 (10.0)**	**12 (40.0)**	**0.046**
Birth weight [g]	3570 ±525	3259 ±783	0.239
LGA, *n* (%)	6 (30.0)	8 (27.6)	0.890
Pregestational HbA_{1c} (%)	**6.88 ±0.60**	**7.70 ±1.35**	**0.023**
I trimester HbA_{1c} (%)	**6.10 ±0.51**	**7.34 ±1.66**	**< 0.001**
II trimester HbA_{1c} (%)	**5.62 ±0.40**	**6.43 ±1.08**	**< 0.001**
III trimester HbA_{1c} (%)	**5.69 ±0.63**	**6.28 ±0.73**	**0.005**
Weight I trimester [kg]	65.40 ±7.92	65.48 ±9.72	0.977
Weight end of pregnancy [kg]	79.02 ± 8.37	78.17 ±10.82	0.767
Weight gain [kg]	13.62 ±3.76	12.69 ±5.44	0.699
Daily insulin dose I visit [IU]	35.97 ±9.73	41.07 ±11.78	0.115
Daily insulin dose last visit [IU]	6.,98 ±20.52	74.93 ± 28.90	0.400
Daily insulin dose increment [IU]	32.01 ±17.85	33.87 ±25.84	0.898
TIR I (%)	**68.89 ±12.25**	**53.96 ±15.67**	**0.001**
TIR I ≥ 70%, *n* (%)	**10 (55.6)**	**4 (14.8)**	**0.010**
TIR II (%)	**75.67 ±10.18**	**61.80 ±14.11**	**< 0.001**
TIR II ≥ 70%, *n* (%)	**15 (83.3)**	**10 (40.0)**	**0.011**
TAR I (%)	**26.17 ±9.06**	**42.56 ±18,49**	**0.001**
TAR I < 25%, *n* (%)	**10 (55.6)**	**4 (14.8)**	**0.010**
TAR II (%)	**20.83 ±10.10**	**35.00 ±16.05**	**0.002**
TAR II < 25%, *n* (%)	**13 (72.2)**	**8 (32.0)**	**0.022**

T1DM – type 1 diabetes meirus, LGA – large for gestabono age, TOR – time in range (70–180 mg/dl, 3.9–10.0 mmol/l), TAR – TIME ABOVE RANge (> 180 mg/dl, > 10.0 mmol/l)
Pregnancy course and outcomes: planned vs. unplanned pregnancy. Significant difirences in bold

Results: The patient and her mother had the heterozygous c.1151C > T variant in the GCK gene responsible for developing MODY type 2. This mutation hadn't been detected in the test of patient's father. The patient became pregnant shortly after diagnosis. She was on insulin therapy during pregnancy. After the childbirth the treatment was discontinued.

Conclusions: Based on the presented case we prove that genetically determined forms of diabetes should be considered when making a diagnosis. This allows for the selection of the appropriate treatment and may affect the normal course of pregnancy.

P32
FIRST PRESENTATION OF TYPE 1 DIABETES COMPLICATED BY SEVERE KETOACIDOSIS AND HYPERGLYCAEMIC-HYPERMOLARS STATE IN A 14-YEAR-OLD PATIENT WITH HNF1B GENE MUTATION

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Introduction: HNF1B MODY diabetes associated with the HNF1B gene mutation is a rare form of diabetes (1–5% of monogenic diabetes). The protein coded by this gene plays a role in the tissue-specific regulation of gene expression in various organs (liver, kidneys, intestines, pancreas), affecting their development and function. Clinical symptoms of the mutation are predominantly renal hypoplasia and cysts (mainly in the cortical layer) and others, such as pancreatic atrophy, liver dysfunction, reproductive system anomalies. The hyperglycemic-hypermolar state is a severe, acute complication of diabetes, most often occurring in people with neurological disorders and carries significant risk of complications. Type 1 diabetes is the most common form of diabetes in children (~96%).

Case report: A 14-year-old patient, with a history of cystic and tubulointerstitial kidney disease associated with the HNF1B gene mutation (ADTKD-HNF1B) and prematurity (28Hbd) with its numerous complications, has been in care of nephrological team for many years. She also had been a patient of Diabetes Clinic. Prediabetes had been observed in 2021: in OGTT: impaired fasting glucose (102 mg/dl), dysglycemia at 60' (178 mg/dl), with HbA_{1c} of 5.1%. In March 2022, HbA_{1c} had been 5.2%, in November the patient had not been reporting diabetes symptoms, she had not been monitoring her glycaemia. In December there had been a severe deterioration of her health. The girl was admitted to the hospital in a serious condition, unconscious, in hypovolemic shock. Her tests results revealed hyperglycemia (> 1500 mg/dl), metabolic acidosis (pH = 6.9, BE = 4.3, HCO3 = –26.5), serum osmolality of 380 mOsm/kg H_2O. Hyperglycemic-hypermolar syndrome and diabetic ketoacidosis were diagnosed. After intensive hydration, stabilization of arterial pressure was obtained and the girl was transferred to the ICU and then to the Department of Pediatric Diabetology of the GCZD in Katowice. Severe electrolyte and acid-base disorders were observed (Na 169 mmol/l, plasma osmolality 37 0mOsm/kg H_2O, pH 7.25–7.53 BE – 11.7–15.5 HCO3 15.4–36.3), requiring long-term intensive metabolic surveillance with intravenous hydration, continuous adjustments of electrolyte, insulin therapy and DVT prophylaxis. Slowly, the improvement of homeostasis and clinical condition were observed.

Outstanding tests results: HbA_{1c} 17%, C-peptide 0.82 ng/ml, anti-GAD antibodies 4061 U/ml.

The whole picture corresponds with the diagnosis of type 1 diabetes in a girl with the HNF1B gene mutation. The possibility of concomitant development of HNF1B MODY (former MODY5) diabetes associated with the HNF1B gene mutation should be taken into account.

Conclusions: The concomitant presentation of separate health conditions can significantly modulate their clinical picture.

POSTER SESSION OF ORIGINAL PAPERS 2.3
Chair: Mariusz Dąbrowski

P33
ASSESSMENT OF AWARENESS AND ADDITIONAL RISK PARAMETERS OF NOCTURNAL HYPOGLYCAEMIA IN PATIENTS WITH LONG-TERM TYPE 1 DIABETES

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Introduction: Hypoglycemia is one of the main limiting factor in the glycemic management of type 1 diabetes mellitus. Hypoglycemia unawareness, which is one of the main risk factors for severe hypoglycemia, seems to be a major problem for patients with long-term type 1 diabetes. Evaluation of selected parameters of the AGP report, HbA_{1c} and hypoglycemia awareness based on the results of the Gold questionnaire as indicators of the risk of nocturnal hypoglycemia.

Material and methods: 77 patients (42 female, 35 male, mean age 47.5 years, ±9.3) with type 1 diabetes present for at least 20 years (mean 30.2 years, ±7) and without diagnosed macrovascular complications. Each patient underwent blinded, continuous glucose monitoring with the Dexcom G6, assessment of HbA_{1c} using the laboratory method, and an interview including the assessment of hypoglycemia symptoms according to the Gold Score questionnaire (1 – full awareness of hypoglycemia, 7 – unawareness of hypoglycemia). Selected parameters of the AGP report were analyzed – average blood glucose, TIR, TBR, CV, and the time of night hypoglycaemia was extracted based on the data from the report.

Results: The mean HbA_{1c} in the study group was 7.61% ±1.23. The median score according to the Gold Score questionnaire was 2.5 (mode 2). Nocturnal hypoglycaemia ≤ 70 mg/dl and ≤ 54 mg/dl correlated linearly with CV variability (r = 0.489 and 0.491, p = 0.00, respectively) and negatively with rtCGM average glucose (r = –0.628, r = –0.425, p = 0.00, respectively) and HbA_{1c} (r = –0.285, p = 0.01, r = –0.378, p = 0.00, respectively). In addition, a linear correlation was found between the time spent in hypoglycemia at night ≤ 70 mg/dl and TIR (r = 0.426, p = 0.00), but no correlation was found between TBR and time spent in hypoglycemia at night ≤ 54 mg/dl and ≤ 70 mg/dl with awareness of the symptoms of hypoglycemia assessed by the Gold questionnaire.

Conclusions: There is a significant lack of relationship between the awareness of hypoglycemia symptoms and the time spent in hypoglycemia including nocturnal hypoglycemia in patients with long-term type 1 diabetes. In diagnosing the risk of nocturnal hypoglycaemia in these patients, the parameters obtained using rtCGM – CV, TIR, mean glycaemia may be helpful.

P34
ANALYSIS OF THE EFFECT OF PARENTAL ANTHROPOMETRIC PARAMETERS ON THE BIRTH WEIGHT OF NEWBORNS OF PATIENTS WITH TYPE 1 DIABETES TREATED WITH A PERSONAL INSULIN PUMP

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Introduction: Pregnancy complicated by diabetes is associated with an increased risk of pregnancy complications, including, above all, accelerated fetal growth. The results of the trials indicate that this is mainly related to the metabolic control of diabetes, but also other factors have an impact on the above phenomenon. The aim of the study was to evaluate the influence of parental anthropometric factors on birth weight of newborns in the population of women with type 1 diabetes treated with a personal insulin pump.

Material and methods: The study included 93 patients with T1DM treated with personal insulin pump. Data on medical history, parental anthropometric parameters, metabolic control, daily dose of insulin (DDI) and obstetric outcomes were analyzed.

Results: The mean age of the patients was 31.2 ±4.3 years, duration of diabetes 15.9 ±7.43 years, and pre-pregnancy HbA_{1c} 7.12 ±1.28% (54 ±9.7 mmol/mol). The mean weight of mothers was 65.8 ±11.0 kg, body mass index (BMI) was 23.8 (95% CI: 23.0–24.6) kg/m^2, and their birth weight was 3294 ±468 g. Fathers' current body weight was 87.9 ±12.4 kg, BMI 27.3 (95% CI: 26.6–28.0) kg/m^2, and their birth weight was 3316 ±598 g. The incidence of LGA was 43%. Parental anthropometric parameters were analyzed depending on the presence of LGA. Women who gave birth to children with LGA had a higher birth weight (3432 ±530 vs. 3173 ±447g; $p = 0.013$), and fathers a higher current body weight (91.0 ±11.5 vs. 85.2 ±12.7 kg; $p = 0.03$) and BMI 28.1 (95% CI: 27.1–29.1) vs. 26.7 (95% CI: 25.7–27.4) kg/m^2; $p = 0$ .04). Pre-pregnancy DDI, gestational DDI increase, gestational weight gain, HbA_{1c} before pregnancy and in each trimester did not differ between the groups of women who gave birth to children with LGA or with normal birth weight ($p > 0.05$). Maternal birth weight correlated with neonatal birth weight ($r = 0.22$, $p = 0.03$) and the occurrence of LGA ($r = 0.26$, $p = 0.01$). The analysis of paternal parameters showed that the current body weight and BMI correlated with the occurrence of LGA ($r = 0.235$; $p = 0.03$ and $r = 0.250$; $p = 0.019$, respectively; $p = 0.02$). There was no correlation between other parental anthropometric parameters and obstetric outcomes.

Conclusions: The anthropometric factors of both parents, both actual and concerning their birth weight, may be related to fetal growth and should not be omitted in the analysis of their child's birth parameters.

P35
DPP-4 INHIBITOR IN NEWLY DIAGNOSED TYPE 1 DIABETES

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Introduction: DPP-4 inhibitors have been used in the treatment of type 2 diabetes for several years. However, due to their pleiotropic effects, including the impact on the immune system, they have also been studied, especially sitagliptin, in the treatment of type 1 diabetes (T1DM). Aim of this case study is to present a patient with newly diagnosed T1DM, in whom the DPP-4 inhibitor sitagliptin was added to the standard therapy.

Material and methods: Male, born 1983, reported for the first visit in September 2020. Family history: father treated for T1DM for > 55 years. Symptoms of hyperglycaemia appeared soon after suffering from mononucleosis. T1DM was confirmed by the presence of anti-GAD antibodies. I prescribed the patient fast-acting insulin aspart in small doses before meals. Due to C-peptide level within the normal range, I additionally proposed sitagliptin (off-label) 1x100 mg due to its protective effect on β-cells shown in some studies, to which the patient agreed.

Results: At the first visit, body weight 100 kg, height 177 cm, BMI 31.9 kg/m^2, HbA_{1c} 7.9%, anti-GAD antibodies 948.1 IU/ml, C-peptide 2.63 ng/ml. Blood glucose normalized quickly with low insulin requirements (average 9–12 IU/day), HbA_{1c} decreased to the range of 5.7–6.1%. In July 2021, vitiligo was diagnosed. Body weight decreased to 95.5 kg. After a year, control C-peptide was 1.48 ng/ml. I added 750 mg of metformin XR. The patient followed a more restrictive diet and after another year weight decreased to 91.5 kg. HbA_1c at this time was 5.8–6.1%, with no severe and rare mild, symptomatic hypoglycemia. C-peptide in November 2022 was 2.28 ng/ml. HbA_{1c} was 6.1% at last visit on February 2023. The patient wanted to continue therapy. He declined from using proposed isCGM.

Conclusions: In case of this patient with a positive family history of T1DM, use of sitagliptin in combination with mealtime insulin showed a protective effect on β-cells. Fasting C-peptide concentration decreased only mildly over the period of over 2 years and still remains within the normal range. Previous studies of the effectiveness of such therapy gave divergent results, but the DPP-4 inhibitor has been used at different stages of T1DM. This single observation indicates that in a person with newly diagnosed T1DM and preserved β-cell function, the use of sitagliptin in combination with insulin may allow, probably due to the immunomodulating effect of the DPP-4 inhibitor, long-term maintenance of β-cell secretion.

P36
POLYURIA AND POLYDIPSIA IN A PATIENT WITH TYPE 1 DIABETES AS A SYMPTOM OF TYPE 3 APS

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Introduction: The incidence of autoimmune diseases is increasing and currently problem concerns 3–5% of the general population. Nearly half are autoimmune endocrinopathies. Autoimmune polyendocrine syndromes (APS) are rare syndromes. Type 3 APS includes autoimmune thyroid disease, type 1 diabetes, and other autoimmune diseases (excluding Addison's disease and hypoparathyroidism). To present a case of a patient with type 1 diabetes mellitus and chronic autoimmune thyroiditis, diagnosed de novo with central diabetes insipidus and secondary adrenal insufficiency.

Material and methods: Medical data were collected during several hospitalizations.

A 23-year-old female patient with a long-term history of type 1 diabetes was admitted to the hospital due to persistent weakness. The patient reported fatigue, polydipsia and polyuria. Symptoms were independent of glycemic control and have been present for the last year. Patient had the history of chronic thyroiditis (increased ATPO and ATG titers) – not requiring L-thyroxine substitution. Five months before hospitalization, the patient temporarily received thyrostatics due to symptoms of hyperthyroidism (lack of medical documentation). Treatment was discontinued after a few weeks due to overt hypothyroidism with a TSH of 51.9 IU/ul.

Results: After expanding the diagnostics at the Clinic (imaging and laboratory tests), the results indicated the phase of hoshitoxicosis. Due to the lower value of urine specific gravity test, low urine osmolality in the morning samples and increased plasma osmolality, a water deprivation test was performed, confirming the diagnosis of central diabetes insipidus. In the MRI of the pituitary gland, asymmetry of the stalk was found. Desmopressin supplementation (2x60µg) was recommended, which resulted in disappearance of symptoms and normalization of laboratory test results. After a few weeks, another hospitalization. The symptoms returned in the form of polydipsia with polyuria and vomiting not related to meals. In laboratory results: good glycemic control, no features of ketoacidosis. Tendency to hypoglycemia. On the basis of the clinical picture, the results of hormonal tests and functional tests of the hypothalamic-pituitary-adrenal axis – secondary adrenal insufficiency was diagnosed. Substitution treatment with hydrocortisone was started and the dose of desmopressin was increased by 60 µg/day. After treatment modification, significant clinical and laboratory improvement was achieved.

Conclusions: The presented case confirms the need for monitoring of patients diagnosed with an autoimmune disease that can occur in APS syndromes. Patients with type 1 diabetes complaining of polydipsia and polyuria with proper glycemic control should have extended diagnostics to include other less common causes of the above-mentioned ailments.

POSTER SESSION OF ORIGINAL PAPERS 2.4
Chair: Marta Wróbel

P37
LOWER MEAN SACCADIC VELOCITY, BUT NOT LATENCY OR AMPLITUDE, IN PATIENTS WITH TYPE 1 DIABETES

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Introduction: Diabetic neuropathy is a heterogeneous group of conditions that affects the nervous system. The early recognition and appropriate management of the condition in diabetic patient is of great importance. Screening for symptoms and signs of diabetic neuropathy is critical in clinical practice, as it gives chance to detect the earliest stages of neuropathy, enabling early intervention. The saccadic or eye movement system is the ocular motor system that allows the eyes to rapidly fixate a target on the fovea. Saccadic eye movement examination may prove to be a promising new screening method for asymptomatic diabetic neuropathy. The primary goal of the study was an assessment of the saccadic eye movement examination as a novel method of screening for diabetic neuropathy in diabetic women with type 1 diabetes mellitus (T1DM).

Material and methods: In this study we assessed the saccadic latency, duration, amplitude, mean and peak velocity using Saccadometer Advanced system in diabetic women with T1DM and compared them to healthy controls. We excluded patients with diagnosed diabetic neuropathy and retinopathy.

Results: We analyzed data of 18 healthy and 19 type 1 diabetic women. The mean age was 26.5 ±4.6 years, the mean duration of diabetes was 9.9 ±7.6 years. In patients with T1DM significantly lower mean saccade velocity was observed (median 202.5, IQR 176.8–217.8 ms vs. 221.5, IQR 206.8–230.8 ms; $p = 0.05$). There were no differences in saccadic latency, amplitude and peak velocity between T1DM and healthy women.

Conclusions: In the studied population, among the quantitative parameters of saccadic eye movements, mean saccadic velocity differentiated subjects with T1DM from the healthy ones. Saccadic eye movement examination may be a promising, simple and objective method for diabetes neuropathy screening. More studies are needed to assess its effectiveness in patients with neuropathy and retinopathy.

P38
EFFECTS OF INTRODUCING MORE LIBERAL 1-HOUR POSTPRANDIAL GLYCEMIC TARGET IN WOMEN WITH GESTATIONAL MELLITUS – A SINGLE-CENTER COHORT STUDY

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Introduction: Improperly treated gestational diabetes mellitus (GDM) can pose a risk of developing complications for the mother and infant. Dietary and lifestyle advice is a first-choice treatment, and when glycemic targets are not met, insulin therapy is administered. Clinical practice guideline recommendations on the glycemic targets to use for women with GDM vary, as the paucity of high-quality evidence exists. In 2017 Diabetes Poland introduced more liberal glycemic goals, changing the 1-hour postprandial glycemic target to < 7.8 mmol/l (140 mg/dl) instead < 6.7 mmol/l (120 mg/dl). The effects of this move have not been yet evaluated. We aimed to assess the impact of changing the postprandial glycemic target on administered treatment and pregnancy outcomes of GDM patients treated in the 2015 to 2019 time period.

Material and methods: We performed a retrospective analysis of 1046 GDM patients admitted to the outpatient clinic at the University Hospital of Krakow, Poland between 2015 and 2019. We compared the insulin use rate, type of insulin therapy administered (basal insulin only, basal with boluses or boluses only) and pregnancy outcomes between the women admitted in the time period 2015–2016 (before the change of 1-hour postprandial glycemic target) and 2018–2019 (after the change). We collected data from 1046 women treated between 2014 and 2019. 385 patients were admitted between 2015 and 2016 (PRE group) and 661 between 2018 and 2019 (POST group). The mean age was 31.4 ±4.7 years.

Results: There was no change in the frequency of prescription of any insulin therapy (50.9% vs. 55.8%, $p = 0.124$). Prandial insulin was prescribed more frequently in the PRE group (39.0% vs. 23.3%, $p < 0.001$). Basal insulin-only model was used more frequently in the POST group (29.5% vs. 10.2%, $p < 0.001$), whereas basal insulin with boluses and boluses only models were prescribed less frequently in the POST group (21.7% vs. 33.3% and 1.6% vs. 5.6%, $p < 0.001$, respectively). In the POST group, the delivery occurred slightly earlier (38.5 ±1.4 vs. 39.1 ±1.8 weeks, $p = 0.041$) and caesarian sections were performed more frequently (55.1% vs. 44.9%, $p = 0.007$). There were no differences in the frequency of preterm births, mean birth weight, the prevalence of small for gestational age births and macrosomia.

Conclusions: More liberal glycemic targets in women with GDM, compared to tighter targets, led to shifts in types of insulin therapy, often limited only to basal insulin, with less frequent use of prandial insulin. The change of glycemic targets did not change the prevalence unfavorable pregnancy outcomes.

P39
5 X Z SCHEME AS A NURSING SCREENING PROCEDURE FOR DIABETIC PERIPHERAL NEUROPATHY

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Introduction: Diabetic neuropathy is the most common chronic complication of diabetes, which significantly reduces the quality of life. It is also a risk factor for the development of diabetic foot syndrome with ulceration. At the same time, this complication seems to be the most abstract for diabetes patients. Despite the recommendations of the Polish Diabetes Association for an annual touch sensation test using a 10 g monofilament, many patients have never had such test performed. The evaluation should be performed at 5 years since the diagnosis of diabetes type 1 and at the time of the diagnosis of diabetes type 2 because neuropathy can develop at the stage of prediabetes. The longer the duration of diabetes, the greater the risk of developing neuropathy, so early detection is essential. About 50% of cases of diabetic neuropathy are initially asymptomatic and are detected during the clinical examination. Therefore, diabetic neuropathy should be actively searched for in all diabetes patients. The aim of this paper is to present the "5xZ" procedure, which can be used by nurses in hospital, outpatient clinic and primary healthcare

Material and methods: The premise for creating the "5xZ" scheme was the fact that there is no tool that would facilitate nursing screening procedure for diabetic peripheral neuropathy . Based on my own experience in working with diabetes patients, I created the project entitled "5xZ" scheme for nurses.

Description of the "5xZ" scheme:

1. Zapytaj – ASK – interview the patient.
2. Zobacz – VIEW – look carefully at patient's feet.
3. Zbadaj – TEST – perform a diabetic foot exam.
4. Zostaw informację – PASS THE INFORMTION ON – provide the patient with information about the foot exam results.
5. Zaleć – RECOMMEND – provide the patient with recommendations for primary and secondary prevention of neuropathy and ulceration.

An appropriate instruction was prepared for each of the five points of the diagram.

Results: The "5xZ" scheme was tested in the Diabetology Department of the District Hospital in Płońsk, among patients with type 1 and type 2 diabetes. In the basic version, which involves performing a foot examination using a monofilament, the procedure takes little time, i.e. from 5 to 15 minutes, depending on recommendations that should be given to the patient.

Conclusions: The "5xZ" scheme is a simple tool to be used in nursing practice, which can contribute to the early detection of distal neuropathy.

P40
COMORBIDITY OF RENAL CYSTIC SYNDROME AND DIABETES WITH MEGACYSTIS IN THE FETUS

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Introduction: Renal cysts and diabetes mellitus (RCAD) is an autosomal dominant multisystem syndrome with significant phenotypic heterogeneity. It is characterized by non-diabetic kidney disease, resulting from abnormal kidney development, and early-onset diabetes, which is consistent with the diagnosis of maturity-onset diabetes of the young (MODY). The aim of this paper is to present the possibility of coexistence of the kidney cysts and diabetes syndrome with a malformation such as megacystis, a congenital abnormality of the urinary bladder arising as a consequence of a fetal urethral defect.

Material and methods: A 24-year-old female patient was referred to the department because of abnormalities on first trimester ultrasound (11 weeks + 6 days). The examination revealed a megacystis with a diameter of 12 mm. In the next ultrasound in the second trimester (18 weeks + 0 days), shortening of the nasal bone and bilateral pyelectasias were also observed. The diagnosis was further investigated using a microarray analysis test.

Results: The aCGH analysis revealed a deletion of a fragment of the long arm of chromosome 17, located within band 17q12. Deletions in the 17q12 region, including the HNF18 gene, are associated with the clinical features of RCAD.

Conclusions: On the basis of the presented case, it is shown that genetic diagnosis should support prenatal testing in order to make a correct diagnosis.

P41
PATIENT WITH OVERLAPPING TYPE 1, TYPE 2 AND SECONDARY DIABETES

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Introduction: Diabetes is a group of metabolic diseases, the common symptom of which is hyperglycemia, caused by defect of insulin action or secretion. It is possible for a patient to have different types of diabetes. Those kinds can manifest at different sequences and different ages of patients, also proceeding in an acute state and leading to a life-threatening condition. Presenting a case of a 75-year-old woman with overlapping type 2, type 1 and secondary diabetes.

Material and methods: Presents a case of a 75-year-old woman admitted to the hospital because of hyperglycemia and ketoacidosis, for whom 40 years earlier type 2 diabetes was diagnosed. The unstable course of the disease, significant insulin sensitivity and a severe decrease of insulin demand after a few days of hospitalization extended the diagnostics scope and the original diagnosis was corrected. When the patient was admitted, an intravenous infusion of insulin started under glycemic control. Insulin therapy with insulin lispro and isophane was attempted after the metabolic acidosis subsided and the daily demand for insulin reached 46U. It was unsuccessful due to high morning glycaemia. Third time was successful, when the patient's daily need for insulin decreased to 7.2U it was possible to switch dosage of insulin from intravenous to subcutaneous as insulin lispro and glargine were used. Such a significant decrease of daily need for insulin led to the suspicion of a "honeymoon period" which is typical for type 1 diabetes. Diagnostics was expanded – additional laboratory tests showed high levels of anti-GAD antibodies, undetectable levels of C-peptide and low levels of amylase and lipase. Pancreatic elastase and stool tests were within limits. Abdominal computed tomography showed an atrophic pancreas. The screening test of antinuclear antibodies gave a positive result. During further long-term hospitalization (complicated by infection with Clostridium difficile), an increase of daily insulin need was ca. 40 units per day on the day of hospital discharge, with acceptable glycemic levels, which happened one week after the infection symptoms stopped.

Results: Type 1 diabetes may be suspected in a patient with long-term type 2 diabetes, with secondary diabetes due to pancreas damage caused by an autoimmune pancreatitis.

Conclusions: In the case of an atypical process of the disease, high insulin sensitivity, unstable course of diabetes, sudden decrease in insulin demand, it is worth considering the possibility of development of type 2 diabetes, type 1 and/or secondary diabetes and correction of original diagnosis.

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Skrócona informacja o leku JARDIANCE®

Nazwa produktu leczniczego, dawka i postać farmaceutyczna: Jardiance® 10 mg, 25 mg tabletki powlekane. Każda tabletka zawiera 10 mg empagliflozyny lub 25 mg empagliflozyny. Jardiance® 10 mg okrągła tabletka powlekana barwy bladożółtej, obustronnie wypukła, o średnicy 9,1 mm ze ściętą ostro krawędzią, z wytłoczonym symbolem „S10" na jednej stronie oraz logo Boehringer Ingelheim na drugiej. Każda tabletka zawiera ilość laktozy jednowodnej odpowiadającą 154,3 mg laktozy bezwodnej. Jardiance® 25 mg owalna, bladożółta, obustronnie wypukła tabletka powlekana z wytłoczonym symbolem „S25" na jednej stronie oraz logo Boehringer Ingelheim na drugiej (długość tabletki: 11,1 mm, szerokość: 5,6 mm). Każda tabletka zawiera ilość laktozy jednowodnej odpowiadającą 107,4 mg laktozy bezwodnej. **Wskazania do stosowania:** Cukrzyca typu 2 Produkt leczniczy Jardiance® jest wskazany do stosowania w leczeniu dorosłych z niewystarczająco kontrolowaną cukrzycą typu 2 łącznie z dietą i aktywnością fizyczną: w monoterapii, kiedy nie można stosować metforminy z powodu jej nietolerancji, w skojarzeniu z innymi produktami leczniczymi stosowanymi w leczeniu cukrzycy. Wyniki badań dotyczące różnych skojarzeń, wpływu na kontrolę glikemii i zdarzenia sercowo-naczyniowe oraz badane populacje, patrz punkt Specjalne ostrzeżenia i środki ostrożności dotyczące stosowania. Niewydolność serca Produkt leczniczy Jardiance® jest wskazany do stosowania u dorosłych w leczeniu objawowej przewlekłej niewydolności serca. **Dawkowanie i sposób podawania:** Dawkowanie Cukrzyca typu 2 Zalecana dawka początkowa wynosi 10 mg empagliflozyny raz na dobę w monoterapii oraz w terapii skojarzonej z innymi produktami leczniczymi stosowanymi w leczeniu cukrzycy. U pacjentów tolerujących dawkę 10 mg empagliflozyny raz na dobę z wartością eGFR ≥ 60 ml/min/1,73 m^2 i wymagających ściślejszej kontroli glikemii, dawkę można zwiększyć do 25 mg raz na dobę. Maksymalna dawka dobowa wynosi 25 mg. Niewydolność serca Zalecana dawka to 10 mg empagliflozyny raz na dobę. Wszystkie wskazania Podczas stosowania empagliflozyny w skojarzeniu z pochodną sulfonylomocznika lub z insuliną, konieczne może być zmniejszenie dawki pochodnej sulfonylomocznika lub insuliny, aby zmniejszyć ryzyko wystąpienia hipoglikemii. W razie pominięcia dawki pacjent powinien ją zażyć niezwłocznie po przypomnieniu sobie o tym; nie należy jednak przyjmować podwójnej dawki tego samego dnia. *Szczególne grupy pacjentów Upośledzenie czynności nerek* U pacjentów z cukrzycą typu 2 skuteczność empagliflozyny w kontrolowaniu glikemii zależy od czynności nerek. Aby zmniejszyć ryzyko sercowo-naczyniowe, u pacjentów z wartością eGFR poniżej 60 ml/min/1,73 m^2 dodatkowo do standardowego leczenia należy stosować 10 mg empagliflozyny raz na dobę (patrz Tabela 1). Ze względu na to, że skuteczność empagliflozyny w zmniejszaniu glikemii jest mniejsza u pacjentów z umiarkowanym uszkodzeniem nerek i prawdopodobnie nieobecna u pacjentów z ciężkim uszkodzeniem nerek, jeśli konieczna jest dalsza kontrola glikemii, należy rozważyć zastosowanie innych produktów leczniczych obniżających stężenie glukozy. Patrz tabela 1, aby uzyskać informacje dotyczące dostosowywania dawki w zależności od wartości eGFR lub CrCl. Tabela 1: Zalecenia dotyczące dostosowywania dawki[a]

Wskazanie	eGFR [ml/min/1,73 m^2] lub CrCL [ml/min]	Całkowita dawka dobowa
Cukrzyca typu 2	≥60	Rozpocząć od dawki 10 mg empagliflozyny. U pacjentów tolerujących dawkę 10 mg empagliflozyny i wymagających dodatkowej kontroli glikemii dawkę można zwiększyć do 25 mg empagliflozyny.
	45 do <60	Rozpocząć od dawki 10 mg empagliflozyny.[b] Kontynuować stosowanie dawki 10 mg empagliflozyny u pacjentów, którzy już przyjmują produkt leczniczy Jardiance®.
	30 do <45[b]	Rozpocząć od dawki 10 mg empagliflozyny. Kontynuować stosowanie dawki 10 mg empagliflozyny u pacjentów, którzy już przyjmują produkt leczniczy Jardiance®.
	<30	Nie zaleca się stosowania empagliflozyny.
Niewydolność serca (z cukrzycą typu 2 lub bez cukrzycy typu 2)	≥20	Zalecana dawka dobowa to 10 mg empagliflozyny.
	<20	Ze względu na ograniczone doświadczenie nie zaleca się stosowania empagliflozyny.

[a] Patrz punkty Specjalne ostrzeżenia i środki ostrożności dotyczące stosowania, Działania niepożądane [b] Pacjenci z cukrzycą typu 2 i z potwierdzoną chorobą sercowo-naczyniową

W przypadku leczenia niewydolności serca u pacjentów z cukrzycą typu 2 lub bez cukrzycy typu 2 stosowanie dawki 10 mg empagliflozyny można rozpocząć lub kontynuować leczenie do wartości eGFR równej 20 ml/min/1,73 m^2 lub wartości CrCl równej 20 ml/min. Nie należy stosować empagliflozyny u pacjentów ze schyłkową niewydolnością nerek (SNN), ani u pacjentów dializowanych. Nie ma wystarczających danych, aby uzasadnić stosowanie w tej grupie pacjentów. *Upośledzenie czynności wątroby* Nie ma konieczności dostosowania dawki u pacjentów z upośledzeniem czynności wątroby. U pacjentów z ciężkim upośledzeniem czynności wątroby ekspozycja na empagliflozynę jest zwiększona. Doświadczenie w leczeniu pacjentów z ciężkim upośledzeniem czynności wątroby jest ograniczone, w związku z czym nie zaleca się stosowania empagliflozyny w tej populacji pacjentów. *Pacjenci w podeszłym wieku* Nie ma konieczności dostosowania dawki w zależności od wieku pacjenta. U pacjentów w wieku 75 lat i starszych należy wziąć pod uwagę zwiększone ryzyko zmniejszenia objętości płynów. *Dzieci i młodzież* Nie określono dotychczas bezpieczeństwa stosowania ani skuteczności empagliflozyny u dzieci i młodzieży. Dane nie są dostępne. Sposób podawania Tabletki mogą być przyjmowane jednocześnie z posiłkiem lub niezależnie od niego. Tabletki należy połykać w całości popijając wodą. **Przeciwwskazania:** Nadwrażliwość na substancję czynną lub na którąkolwiek substancję pomocniczą wymienioną w punkcie Wykaz substancji pomocniczych ChPL. **Specjalne ostrzeżenia i środki ostrożności dotyczące stosowania:** Kwasica ketonowa U pacjentów z cukrzycą leczonych inhibitorami SGLT2, w tym empagliflozyną, zgłaszano rzadkie przypadki kwasicy ketonowej, w tym przypadki zagrażające życiu i zakończone zgonem. W niektórych przypadkach obraz kliniczny był nietypowy, tylko z umiarkowanym zwiększeniem stężenia glukozy we krwi, poniżej 14 mmol/l (250 mg/dl). Nie wiadomo, czy zastosowanie większych dawek empagliflozyny zwiększa ryzyko kwasicy ketonowej. Należy uwzględnić ryzyko kwasicy ketonowej w razie wystąpienia niespecyficznych objawów, takich jak: nudności, wymioty, jadłowstręt, ból brzucha, silne pragnienie, zaburzenia oddychania, splątanie, niezwykłe zmęczenie lub senność. W razie wystąpienia takich objawów należy niezwłocznie zbadać pacjentów, czy nie występuje u nich kwasica ketonowa, niezależnie od stężenia glukozy we krwi. Należy natychmiast przerwać leczenie empagliflozyną u pacjentów z podejrzeniem lub rozpoznaniem kwasicy ketonowej. Należy przerwać leczenie u pacjentów hospitalizowanych z powodu dużych zabiegów chirurgicznych lub ostrych ciężkich chorób. U tych pacjentów zaleca się monitorowanie stężeń ciał ketonowych. Preferowane jest oznaczanie stężenia ciał ketonowych we krwi, niż w moczu. Leczenie empagliflozyną można wznowić, gdy stężenie ciał ketonowych będzie prawidłowe, a stan pacjenta ustabilizuje się. Przed rozpoczęciem leczenia empagliflozyną należy rozważyć czynniki w wywiadzie predysponujące pacjenta do kwasicy ketonowej. Do pacjentów ze zwiększonym ryzykiem kwasicy ketonowej zalicza się osoby z małą rezerwą czynnościową komórek beta (np. pacjenci z cukrzycą typu 2 i małym stężeniem peptydu C lub późno ujawniającą się cukrzycą autoimmunologiczną dorosłych – ang. latent autoimmune diabetes in adults – LADA lub pacjenci z zapaleniem trzustki w wywiadzie), pacjentów ze stanami prowadzącymi do ograniczenia przyjmowania pożywienia lub z ciężkim odwodnieniem pacjentów, którym zmniejszono dawkę insuliny oraz pacjentów ze zwiększonym zapotrzebowaniem na insulinę z powodu ostrej choroby, zabiegu chirurgicznego lub nadużywania alkoholu. U tych pacjentów należy ostrożnie stosować inhibitory SGLT2. Nie zaleca się wznawiania leczenia inhibitorem SGLT2 u pacjentów, u których wcześniej wystąpiła kwasica ketonowa podczas stosowania inhibitora SGLT2, chyba że zidentyfikowano i usunięto inną wyraźną przyczynę. Produktu leczniczego Jardiance® nie należy stosować u pacjentów z cukrzycą typu 1. Dane z programu badań klinicznych u pacjentów z cukrzycą typu 1 wykazały zwiększone, częste występowanie kwasicy ketonowej u pacjentów leczonych empagliflozyną w dawce 10 mg i 25 mg jako uzupełnienie insuliny w porównaniu z placebo. Niewydolność nerek We wskazaniu cukrzyca typu 2 u pacjentów z wartością eGFR poniżej 60 ml/min/1,73 m^2 lub CrCl <60 ml/min dawka dobowa empagliflozyny jest ograniczona do 10 mg. Nie zaleca się stosowania empagliflozyny w przypadku wartości eGFR poniżej 30 ml/min/1,73 m^2 lub CrCl poniżej 30 ml/min. We wskazaniu niewydolność serca nie zaleca się stosowania produktu leczniczego Jardiance®, u pacjentów z wartością eGFR <20 ml/min/1,73 m^2. Nie należy stosować empagliflozyny u pacjentów ze schyłkową niewydolnością nerek (SNN) ani u pacjentów dializowanych. Nie ma wystarczających danych, aby uzasadnić stosowanie w tej grupie pacjentów. Monitorowanie czynności nerek Zaleca się ocenę czynności nerek w następujący sposób: przed rozpoczęciem leczenia empagliflozyną i okresowo podczas leczenia, tzn. co najmniej raz na rok; przed rozpoczęciem leczenia jakimkolwiek innym jednocześnie stosowanym produktem leczniczym, który może mieć niekorzystny wpływ na czynność nerek. Ryzyko zmniejszenia objętości płynów Z uwagi na mechanizm działania inhibitorów SGLT2, diureza osmotyczna towarzysząca glukozurii może spowodować nieznaczne zmniejszenie ciśnienia krwi. W związku z tym należy zachować ostrożność u pacjentów, dla których taki spadek ciśnienia krwi spowodowany przez empagliflozynę mógłby stanowić zagrożenie, takich jak pacjenci z rozpoznaną chorobą układu krążenia, pacjenci stosujący leczenie przeciwnadciśnieniowe z epizodami niedociśnienia w wywiadzie lub pacjenci w wieku 75 i więcej lat. W przypadku stanów, które mogą prowadzić do utraty płynów przez organizm (np. choroba przewodu pokarmowego) zaleca się dokładne monitorowanie stanu nawodnienia (np. badanie przedmiotowe, pomiar ciśnienia krwi, testy laboratoryjne włącznie z oznaczeniem hematokrytu) i stężenia elektrolitów u pacjentów przyjmujących empagliflozynę. Należy rozważyć tymczasowe wstrzymanie leczenia empagliflozyną do czasu wyrównania utraty płynów. Pacjenci w podeszłym wieku Wpływ empagliflozyny na wydalanie glukozy z moczem związany jest z diurezą osmotyczną, co może mieć wpływ na stan nawodnienia. Pacjenci w wieku 75 i więcej lat mogą być w większym stopniu zagrożeni wystąpieniem zmniejszenia objętości płynów. Większa liczba takich pacjentów leczonych empagliflozyną miała działania niepożądane związane ze zmniejszeniem objętości płynów w porównaniu z pacjentami otrzymującymi placebo. W związku z tym należy zwracać szczególną uwagę na przyjmowaną objętość płynów w razie jednoczesnego podawania z produktami leczniczymi mogącymi prowadzić do zmniejszenia objętości płynów (np. leki moczopędne, inhibitory ACE). Powikłane zakażenia dróg moczowych U pacjentów otrzymujących empagliflozynę zgłaszano przypadki powikłanych zakażeń dróg moczowych, w tym odmiedniczkowe zapalenie nerek i posocznicę moczopochodną. Należy rozważyć tymczasowe wstrzymanie leczenia empagliflozyną u pacjentów z powikłanym zakażeniem dróg moczowych. Martwicze zapalenie powięzi krocza (zgorzel Fourniera) Zgłaszano przypadki martwiczego zapalenia powięzi krocza (znanego także jako zgorzel Fourniera) u pacjentów płci żeńskiej i męskiej z cukrzycą przyjmujących inhibitory SGLT2. Jest to rzadkie, ale ciężkie i mogące zagrażać życiu zdarzenie, które wymaga pilnej interwencji chirurgicznej i antybiotykoterapii. Pacjentom należy zalecić, aby zgłosili się do lekarza, jeśli wystąpi u nich zespół objawów, takich jak ból, wrażliwość na dotyk, rumień lub obrzęk w okolicy zewnętrznych narządów płciowych lub krocza, z jednoczesną gorączką lub uczuciem rozbicia. Należy pamiętać o tym, że martwicze zapalenie powięzi może być poprzedzone zakażeniem narządów układu moczowo-płciowego lub ropniem krocza. Jeśli podejrzewa się wystąpienie zgorzeli Fourniera, należy przerwać stosowanie produktu Jardiance® i niezwłocznie rozpocząć leczenie (w tym antybiotykoterapię oraz chirurgiczne opracowanie zmian chorobowych). Amputacje w obrębie kończyn dolnych W długoterminowych badaniach klinicznych innego inhibitora SGLT2 zaobserwowano zwiększoną częstość przypadków amputacji w obrębie kończyn dolnych (szczególnie palucha). Nie wiadomo, czy jest to „efekt klasy leków". Podobnie jak w przypadku wszystkich chorych na cukrzycę, ważna jest edukacja pacjentów dotycząca profilaktycznej pielęgnacji stóp. Uszkodzenie wątroby W badaniach klinicznych obejmujących empagliflozynę zgłaszano przypadki uszkodzenia wątroby. Nie ustalono związku przyczynowo-skutkowego pomiędzy empagliflozyną a uszkodzeniem wątroby. Zwiększenie wartości hematokrytu Obserwowano zwiększenie wartości hematokrytu podczas leczenia empagliflozyną. Przewlekła choroba nerek Istnieje doświadczenie dotyczące stosowania empagliflozyny w leczeniu cukrzycy u pacjentów z przewlekłą chorobą nerek (eGFR ≥30 ml/min/1,73 m^2) z albuminurią i bez albuminurii. Leczenie empagliflozyną może być bardziej skuteczne u pacjentów z albuminurią. Choroba naciekowa lub kardiomiopatia takotsubo Nie prowadzono specyficznych badań u pacjentów z chorobą naciekową lub kardiomiopatią takotsubo. Z tego powodu nie określono skuteczności u tych pacjentów. Laboratoryjna analiza moczu Z uwagi na mechanizm działania produktu Jardiance®, pacjenci przyjmujący go będą mieć dodatni wynik testu na zawartość glukozy w moczu. Wpływ na badanie stężenia 1,5-anhydroglucitolu (1,5-AG) Nie zaleca się monitorowania kontroli glikemii za pośrednictwem badania stężenia 1,5-AG, ponieważ oznaczanie stężenia 1,5-AG nie jest miarodajne w ocenie kontroli glikemii u pacjentów przyjmujących inhibitory SGLT2. Zaleca się stosowanie innych metod monitorowania kontroli glikemii. Laktoza Tabletki produktu leczniczego zawierają laktozę. Produkt leczniczy nie powinien być stosowany u pacjentów z rzadko występującą dziedziczną nietolerancją galaktozy, brakiem laktazy lub zespołem złego wchłaniania glukozy-galaktozy. Sód Każda tabletka zawiera mniej niż 1 mmol (23 mg) sodu, to znaczy lek uznaje się za „wolny od sodu". **Działania niepożądane:** Podsumowanie profilu bezpieczeństwa *Cukrzyca typu 2* Łącznie 15 582 pacjentów z cukrzycą typu 2 wzięło udział w badaniach klinicznych oceniających bezpieczeństwo stosowania empagliflozyny, z czego 10 004 pacjentów otrzymywało empagliflozynę w monoterapii lub w skojarzeniu z metforminą, pochodną sulfonylomocznika, pioglitazonem, inhibitorami DPP-4 lub insuliną. W 6 badaniach przeprowadzonych z kontrolą placebo trwających od 18 do 24 tygodni wzięło udział 3 534 pacjentów, z których 1 183 otrzymywało placebo, a 2 351 – empagliflozynę. Ogólna częstość występowania zdarzeń niepożądanych u pacjentów leczonych empagliflozyną była podobna do częstości w grupie otrzymującej placebo. Najczęściej obserwowanym działaniem niepożądanym była hipoglikemia przy stosowaniu w skojarzeniu z pochodną sulfonylomocznika lub insuliną. *Niewydolność serca* Do badań EMPEROR włączono pacjentów z niewydolnością serca i zredukowaną frakcją wyrzutową (N=3 726) lub zachowaną frakcją wyrzutową (N=5 985), którzy otrzymywali leczenie 10 mg empagliflozyny lub placebo. U około połowy pacjentów występowała cukrzyca typu 2. Najczęściej zgłaszanym działaniem niepożądanym łącznie w badaniach EMPEROR-Reduced i EMPEROR-Preserved było zmniejszenie objętości płynów (10 mg empagliflozyny: 11,4%; placebo: 9,7%). Ogólny profil bezpieczeństwa stosowania empagliflozyny był zasadniczo spójny w badanych wskazaniach. Wykaz działań niepożądanych w postaci tabeli W poniższej tabeli przedstawiono działania niepożądane – sklasyfikowane według grup układowo-narządowych oraz według preferowanych terminów MedDRA – zgłaszane u pacjentów, którzy otrzymali empagliflozynę w badaniach prowadzonych z kontrolą placebo (Tabela 2). Działania niepożądane są wymienione według bezwzględnej częstości występowania. Częstość występowania zdefiniowana jest następująco: bardzo często (≥ 1/10); często (≥ 1/100 do < 1/10); niezbyt często (≥ 1/1 000 do < 1/100); rzadko (≥ 1/10 000 do < 1/1 000), bardzo rzadko (< 1/10 000), nieznana (częstość nie może być określona na podstawie dostępnych danych). Tabela 2: Wykaz działań niepożądanych (MedDRA) obserwowanych w badaniach prowadzonych z kontrolą placebo i zgłoszonych po wprowadzeniu produktu do obrotu, w postaci tabeli

Klasyfikacja układów i narządów	Bardzo często	Często	Niezbyt często	Rzadko	Bardzo rzadko
Zakażenia i zarażenia pasożytnicze		kandydoza pochwy, zapalenie pochwy i sromu, zapalenie żołędzi i inne zakażenia narządów płciowych[a] zakażenie dróg moczowych (w tym odmiedniczkowe zapalenie nerek i posocznica moczopochodna)[a]		martwicze zapalenie powięzi krocza (zgorzel Fourniera)*	
Zaburzenia metabolizmu i odżywiania	hipoglikemia (przy stosowaniu w skojarzeniu z pochodną sulfonylomocznika lub insuliną)[a]	pragnienie	cukrzycowa kwasica ketonowa*		
Zaburzenia żołądka i jelit		zaparcie			
Zaburzenia skóry i tkanki podskórnej		świąd (uogólniony) wysypka	pokrzywka obrzęk naczynioruchowy		
Zaburzenia naczyniowe	zmniejszenie objętości płynów[a]				
Zaburzenia nerek i dróg moczowych		zwiększone oddawanie moczu[a]	dyzuria		cewkowo-śródmiąższowe zapalenie nerek
Badania diagnostyczne		zwiększenie stężenia lipidów w surowicy[a]	zwiększenie stężenia kreatyniny we krwi i (lub) zmniejszenie współczynnika filtracji kłębuszkowej[a] zwiększenie hematokrytu[a]		

[a] patrz dodatkowe informacje podane poniżej * patrz punkt Specjalne ostrzeżenia i środki ostrożności dotyczące stosowania

Opis wybranych działań niepożądanych *Hipoglikemia* Częstość występowania hipoglikemii zależała od leczenia podstawowego stosowanego w poszczególnych badaniach i była podobna jak po zastosowaniu placebo u pacjentów stosujących empagliflozynę w monoterapii, jako leczenie skojarzone z metforminą, jako leczenie skojarzone z pioglitazonem w skojarzeniu z metforminą lub bez niej, jako leczenie skojarzone z linagliptyną i metforminą, jako leczenie dodane do terapii standardowej oraz w razie stosowania skojarzenia empagliflozyny z metforminą u nieleczonych uprzednio pacjentów w porównaniu z pacjentami leczonymi osobnymi lekami empagliflozyną i metforminą. Zwiększoną częstość zaobserwowano w przypadku stosowania jako leczenie skojarzone z metforminą i pochodnymi sulfonylomocznika (10 mg empagliflozyny: 16,1%; 25 mg empagliflozyny: 11,5%; placebo: 8,4%), jako leczenie skojarzone z insuliną podstawową w skojarzeniu z metforminą lub bez niej oraz w skojarzeniu z pochodną sulfonylomocznika lub bez niego (10 mg empagliflozyny: 19,5%; 25 mg empagliflozyny: 28,4%; placebo: 20,6% w ciągu pierwszych 18 tygodni leczenia, gdy nie można było dostosowywać dawki insuliny; 10 mg i 25 mg empagliflozyny: 36,1%; placebo: 35,3% w ciągu 78 tygodni badania) i jako leczenie skojarzone z insuliną MDI w skojarzeniu z metforminą lub bez niej (empagliflozyna 10 mg: 39,8%, empagliflozyna 25 mg: 41,3%, placebo: 37,2% podczas pierwszych 18 tygodni leczenia, gdy nie można było dostosować dawki insuliny; empagliflozyna 10 mg: 51,1%, empagliflozyna 25 mg: 57,7%, placebo: 58% w ciągu 52 tygodni badania). W badaniach niewydolności serca EMPEROR obserwowano podobną częstość występowania hipoglikemii podczas stosowania w skojarzeniu z sulfonylomocznikiem lub insuliną (10 mg empagliflozyny: 6,5%; placebo: 6,7%). *Ciężka hipoglikemia (zdarzenia wymagające interwencji)* Nie zaobserwowano zwiększenia częstości występowania ciężkiej hipoglikemii przy stosowaniu empagliflozyny w porównaniu do placebo, w monoterapii, w leczeniu skojarzonym z metforminą, w leczeniu skojarzonym z metforminą i pochodną sulfonylomocznika, w leczeniu skojarzonym z pioglitazonem w skojarzeniu z metforminą lub bez niej, w leczeniu skojarzonym z linagliptyną i metforminą, jako leczenie dodane do terapii standardowej oraz w razie stosowania skojarzenia empagliflozyny z metforminą u nieleczonych uprzednio pacjentów w porównaniu z pacjentami leczonymi osobnymi lekami empagliflozyną i metforminą. Zwiększoną częstość zaobserwowano w przypadku stosowania jako leczenie skojarzone z insuliną podstawową w skojarzeniu z metforminą lub bez niej oraz w skojarzeniu z pochodną sulfonylomocznika lub bez niego (10 mg empagliflozyny: 0%; 25 mg empagliflozyny: 1,3%; placebo: 0% w ciągu pierwszych 18 tygodni leczenia, gdy nie można było dostosowywać dawki insuliny; 10 mg empagliflozyny: 0%; 25 mg empagliflozyny: 1,3%; placebo: 0% w ciągu 78 tygodni badania) i jako leczenie skojarzone z insuliną MDI w skojarzeniu z metforminą lub bez niej (empagliflozyna 10 mg: 0,5%, empagliflozyna 25 mg: 0,5%, placebo: 0,5% podczas pierwszych 18 tygodni leczenia, gdy nie można było dostosować dawki insuliny; empagliflozyna 10 mg: 1,6%, empagliflozyna 25 mg: 0,5%, placebo: 1,6% w ciągu 52 tygodni badania). W badaniach dotyczących niewydolności serca EMPEROR ciężką hipoglikemię obserwowano z podobną częstością występowania u pacjentów z cukrzycą podczas leczenia empagliflozyną i placebo w skojarzeniu z sulfonylomocznikiem lub insuliną (10 mg empagliflozyny: 2,2%, placebo: 1,9%). *Kandydoza pochwy, zapalenie pochwy i sromu, zapalenie żołędzi i inne zakażenia narządów płciowych* Kandydoza pochwy, zapalenie pochwy i sromu, zapalenie żołędzi i inne zakażenia narządów płciowych były obserwowane częściej u pacjentów leczonych empagliflozyną (10 mg empagliflozyny: 4,0%; 25 mg empagliflozyny: 3,9%) w porównaniu z pacjentami otrzymującymi placebo (1,0%). Zakażenia takie obserwowano częściej u kobiet leczonych empagliflozyną w porównaniu z placebo. Różnica ta była mniej wyraźna w przypadku mężczyzn. Zakażenia narządów płciowych miały nasilenie łagodne lub umiarkowane. W badaniach dotyczących niewydolności serca EMPEROR częstość występowania tego typu zakażeń była większa u pacjentów z cukrzycą (10 mg empagliflozyny: 2,3%; placebo: 0,8%) niż u pacjentów bez cukrzycy (10 mg empagliflozyny: 1,7%; placebo: 0,7%) w trakcie leczenia empagliflozyną w porównaniu z placebo. *Zwiększone oddawanie moczu* Zwiększone oddawanie moczu (obejmujące określone wcześniej takie terminy jak częstomocz, wielomocz i oddawanie moczu w nocy) były obserwowane częściej u pacjentów leczonych empagliflozyną (10 mg empagliflozyny: 3,5%; 25 mg empagliflozyny: 3,3%) w porównaniu z pacjentami otrzymującymi placebo (1,4%). Zwiększone oddawanie moczu miało przeważnie nasilenie łagodne lub umiarkowane. Obserwowana częstość oddawania moczu w nocy była podobna dla empagliflozyny i dla placebo (< 1%). W badaniach niewydolności serca EMPEROR zwiększone oddawanie moczu obserwowano z podobną częstością występowania u pacjentów leczonych empagliflozyną i placebo (10 mg empagliflozyny: 0,9%, placebo 0,5%). *Zakażenie dróg moczowych* Ogólna częstość występowania zakażeń dróg moczowych zgłaszanych jako zdarzenie niepożądane była podobna u pacjentów otrzymujących 25 mg empagliflozyny i placebo (7,0% i 7,2%), i wyższa u pacjentów otrzymujących 10 mg empagliflozyny (8,8%). Podobnie jak w przypadku placebo, zakażenia dróg moczowych były zgłaszane częściej u pacjentów leczonych empagliflozyną z przewlekłymi lub nawracającymi zakażeniami dróg moczowych w wywiadzie. Nasilenie (łagodne, umiarkowane, ciężkie) zakażenia dróg moczowych było podobne u pacjentów otrzymujących empagliflozynę i placebo. Zakażenia dróg moczowych były zgłaszane częściej u kobiet leczonych empagliflozyną w porównaniu z placebo; nie było takiej różnicy w przypadku mężczyzn. *Zmniejszenie objętości płynów* Ogólna częstość występowania zmniejszenia objętości płynów (obejmującego określone wcześniej takie terminy jak spadek ciśnienia krwi (określony ambulatoryjnie), spadek skurczowego ciśnienia krwi, odwodnienie, niedociśnienie, hipowolemia, hipotonia ortostatyczna oraz omdlenie) była podobna u pacjentów otrzymujących empagliflozynę (10 mg empagliflozyny: 0,6%; 25 mg empagliflozyny: 0,4%) i placebo (0,3%). Częstość występowania zmniejszenia objętości płynów była zwiększona u pacjentów w wieku 75 lat i starszych leczonych empagliflozyną (10 mg empagliflozyny: 2,3%; 25 mg empagliflozyny: 4,3%) w porównaniu z pacjentami otrzymującymi placebo (2,1%). *Zwiększenie stężenia kreatyniny we krwi i (lub) obniżenie współczynnika filtracji kłębuszkowej* Ogólna częstość występowania przypadków zwiększenia stężenia kreatyniny we krwi i obniżenie współczynnika filtracji kłębuszkowej była podobna u pacjentów otrzymujących empagliflozynę lub placebo (zwiększenie stężenia kreatyniny: empagliflozyna 10 mg 0,6%, empagliflozyna 25 mg 0,1%, placebo 0,5%; zmniejszenie szybkości filtracji kłębuszkowej: empagliflozyna 10 mg 0,1%, empagliflozyna 25 mg 0%, placebo 0,3%). Występujące początkowo zwiększenie stężenia kreatyniny we krwi i (lub) obniżenie współczynnika filtracji kłębuszkowej u pacjentów leczonych empagliflozyną jako terapią uzupełniającą leczenie metforminą zwykle ustępowało w trakcie ciągłego leczenia lub było odwracalne po zakończeniu leczenia tym lekiem. Konsekwentnie w badaniu EMPA-REG OUTCOME u pacjentów leczonych empagliflozyną obserwowano występujący początkowo spadek eGFR (średnia: 3 ml/min/1,73 m^2). Następnie wartość eGFR utrzymywała się w czasie trwania leczenia. Średnia wartość eGFR powracała do wartości początkowej po zakończeniu leczenia, co sugeruje, że w patogenezie tych zmian czynnościowych nerek mogą odgrywać rolę ostre zmiany hemodynamiczne. *Zwiększenie stężenia lipidów w surowicy* Średnie zwiększenie procentowe od punktu początkowego dla 10 mg i 25 mg empagliflozyny w porównaniu z placebo wynosiło odpowiednio dla cholesterolu całkowitego 4,9% i 5,7% w porównaniu z 3,5%; dla cholesterolu HDL 3,3% i 3,6% w porównaniu z 0,4 %; dla cholesterolu LDL 9,5% i 10,0% w porównaniu z 7,5%; dla triglicerydów 9,2% i 9,9% w porównaniu z 10,5%. *Zwiększenie wartości hematokrytu* Średnia zmiana wartości hematokrytu od punktu początkowego wynosiła odpowiednio 3,4% i 3,6% dla 10 mg i 25 mg empagliflozyny w porównaniu z 0,1% dla placebo. W badaniu EMPA-REG Outcome wartości hematokrytu powróciły do wartości wyjściowych po 30-dniowym okresie kontroli po zakończeniu leczenia. Zgłaszanie podejrzewanych działań niepożądanych Po dopuszczeniu produktu leczniczego do obrotu istotne jest zgłaszanie podejrzewanych działań niepożądanych. Umożliwia to nieprzerwane monitorowanie stosunku korzyści do ryzyka stosowania produktu leczniczego. Osoby należące do fachowego personelu medycznego powinny zgłaszać wszelkie podejrzewane działania niepożądane za pośrednictwem Departamentu Monitorowania Niepożądanych Działań Produktów Leczniczych Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych: Al. Jerozolimskie 181C, 02-222 Warszawa, tel.: +48 22 49-21-301, faks: +48 22 49-21-309, strona internetowa: https://smz.ezdrowie.gov.pl. Działania niepożądane można zgłaszać również podmiotowi odpowiedzialnemu. **Podmiot odpowiedzialny:** Boehringer Ingelheim International GmbH, Binger Str. 173, 55216 Ingelheim am Rhein, Niemcy. **Numery pozwoleń na dopuszczenie do obrotu:** Jardiance® 10 mg tabletki powlekane: EU/1/14/930/013 (28 tabletek), Jardiance® 10 mg tabletki powlekane: EU/1/14/930/014 (30 tabletek) wydane przez Komisję Wspólnot Europejskich. **Data zatwierdzenia lub częściowej zmiany tekstu ChPL:** 21 lipca 2022 **Kategoria dostępności:** Produkt leczniczy wydawany na receptę – Rp. **Cena urzędowa detaliczna:** Jardiance® 10 mg x 28 tabl. – 170,38 zł. Wysokość dopłaty pacjenta: 54,00 zł we wskazaniach: <1>Cukrzyca typu 2 u pacjentów leczonych co najmniej dwoma lekami hipoglikemizującymi, z HbA1c ≥ 7,5% oraz bardzo wysokim ryzykiem sercowo-naczyniowym rozumianym jako: 1)potwierdzona choroba sercowo-naczyniowa, lub 2)uszkodzenie innych narządów objawiające się poprzez: białkomocz lub przerost lewej komory lub retinopatię, lub 3) obecność 3 lub więcej głównych czynników ryzyka spośród wymienionych poniżej: -wiek ≥ 55 lat dla mężczyzn, ≥60 lat dla kobiet, -dyslipidemia, -nadciśnienie tętnicze, -palenie tytoniu, -otyłość; <2>Przewlekła niewydolność serca u dorosłych pacjentów z obniżoną frakcją wyrzutową lewej komory serca (LVEF≤40%) oraz utrzymującymi się objawami choroby w klasie II-IV NYHA pomimo zastosowania terapii opartej na ACEi (lub ARB/ARNi) i lekach z grupy betaadrenolityków oraz jeśli wskazane antagonistach receptora mineralokortykoidów – na podstawie obwieszczenia Ministra Zdrowia z dnia 21 grudnia 2022 r. w sprawie wykazu refundowanych leków, środków spożywczych specjalnego przeznaczenia żywieniowego oraz wyrobów medycznych na 1 stycznia 2023 r. (DZ. URZ. Min. Zdr. 2022.132).

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