27th

Congress of the Federation of the International Danube Symposia on Diabetes Mellitus

ABSTRACT BOOK

MDT
MAGYAR DIABETES TÁRSASÁG
HUNGARIAN DIABETES ASSOCIATION

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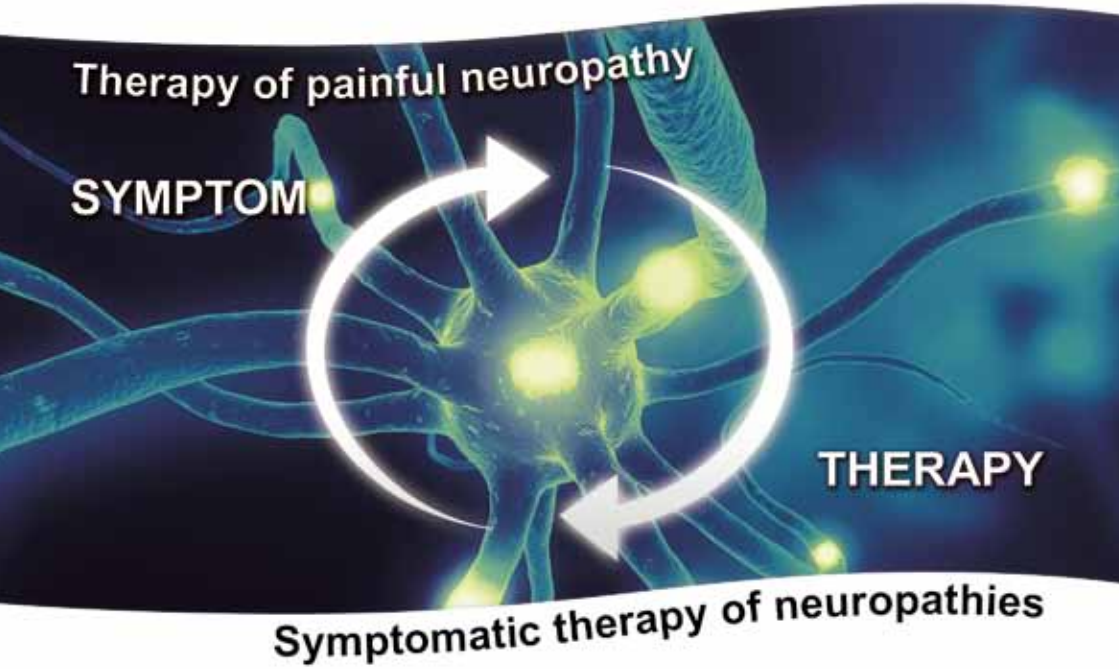
ZENTRALEUROPÄISCHE
DIABETESGESELLSCHAFT

Budapest, Hungary,
28 – 30 June 2012

Wörwag – Neuropathy Specialist

Gabagamma

gabapentin 300 mg, 400 mg, 600 mg



Symptomatic therapy of neuropathies

Gabagamma 300 mg, 400 mg, 600 mg
Active ingredient: gabapentin 300 mg, 400 mg, 600 mg, Film-coated tablet

Therapeutic Indication: Epilepsy:Gabapentin is indicated as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults and children aged 6 years and above.Gabapentin is indicated as monotherapy in the treatment of partial seizures with and without secondary generalization in adults and adolescents aged 12 years and above.Treatment of peripheral neuropathic pain:Gabapentin is indicated for the treatment of peripheral neuropathic pain such as painful diabetic neuropathy and post-herpetic neuralgia in adults. **Dosage:** For all indications a titration scheme for the initiation of therapy, which is recommended for adults and adolescents aged 12 years and above: Day 1: 300 mg once a day, Day 2: 300 mg two times a day, Day 3: 300 mg three times a day. Epilepsy: Please refer to the complete summary of product characteristics. Peripheral neuropathic pain: Adults The therapy may be initiated by titrating the dose as described in Table 1. Alternatively, the starting dose is 900 mg/day given as three equally divided doses. Thereafter, based on individual patient response and tolerability, the dose can be further increased in 300 mg/day increments every 2-3 days up to a maximum dose of 3600 mg/day. Slower titration of gabapentin dosage may be appropriate for individual patients. The minimum time to reach a dose of 1800 mg/day is one week, to reach 2400 mg/day is a total of 2 weeks, and to reach 3600 mg/day is a total of 3 weeks. **Contraindications** Hypersensitivity to the active substance, soya, peanut or to any of the other excipients. **Interactions:** No interaction between gabapentin and phenobarbital, phenytoin, valproic acid, or carbamazepine has been observed. Coadministration of gabapentin with oral contraceptives containing norethindrone and/or ethinyl estradiol, does not influence the steady-state pharmacokinetics of either component. Coadministration of gabapentin with antacids containing aluminium and magnesium, reduces gabapentin bioavailability up to 24%. It is recommended that Gabapentin be taken at the earliest two hours following antacid administration. Renal excretion of gabapentin is unaltered by probenecid.A slight decrease in renal excretion of gabapentin that is observed when it is coadministered with cimetidine is not expected to be of clinical importance. **Undesirable effects:** Very Common: Viral infection, fatigue, fever. Common: Pneumonia, respiratory infection, urinary tract infection, infection, otitis media, leucopenia, anorexia, increased appetite, hostility, confusion and emotional lability, depression, anxiety, nervousness, thinking abnormal, convulsions, hyperkinesias, dysarthria, amnesia, tremor, insomnia, headache, sensations such as paresthesia, hypaesthesia, coordination abnormal, nystagmus, increased, decreased, or absent reflexes, visual disturbances such as amblyopia, diplopia, vertigo, hypertension, vasodilatation, dyspnoea, bronchitis, pharyngitis, cough, rhinitis, vomiting, nausea, dental abnormalities, gingivitis, diarrhea, abdominal pain, dyspepsia, constipation, dry mouth or throat, flatulence, facial oedema, purpura most often described as bruises resulting from physical trauma, rash, pruritus, acne, arthralgia, myalgia, back pain, twitching, impotence, peripheral oedema, abnormal gait, asthenia, pain, malaise, flu syndrome, elevated liver function tests, accidental injury, fracture, abrasion. **Date of Revision of the Text:** 06/2011 **Prescription Status:** Only available from pharmacists. Please refer to the complete summary of product characteristics for your country as variations may exist.

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gaba04.2012.05.24.

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BYETTA + basal insulin: a smart partnership.

The addition of BYETTA is now approved for patients with type 2 diabetes inadequately controlled on an existing regimen of basal insulin.[1] BYETTA complements basal insulin's control of FPG with additional postprandial control.[2] Compared with titrated basal insulin alone, BYETTA + basal insulin resulted in greater HbA_{1c} reduction, no increased risk of hypoglycaemia, potential for weight loss* instead of weight gain, and less increase in insulin dose to achieve FPG <5.6 mmol/L.[2]

*** BYETTA is not indicated for the management of obesity, and weight change was a secondary endpoint in clinical trials.**

BYETTA 5µg and 10µg solution for injection, prefilled pen Abbreviated Summary of product characteristics
Each dose contains 5 or 10 micrograms (µg) exenatide in 20 or 40 microlitres (µl) (respectively), (0.25 mg exenatide per ml). Each pre-filled pen contains 60 doses of sterile preserved solution. **Therapeutic indications:** BYETTA is indicated for treatment of type 2 diabetes mellitus in combination with metformin, sulphonylureas, thiazolidinediones, metformin and a sulphonylurea, metformin and a thiazolidinedione in adults who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies. BYETTA is also indicated as adjunctive therapy to basal insulin with or without metformin and/or pioglitazone in adults who have not achieved adequate glycaemic control with these agents. **Posology and method of administration:** BYETTA therapy should be initiated at 5 µg exenatide per dose administered twice daily (BID) for at least one month in order to improve tolerability. The dose of exenatide can then be increased to 10 µg BID to further improve glycaemic control. Doses higher than 10 µg BID are not recommended. BYETTA can be administered at any time within the 60-minute period before the morning and evening meal (or two main meals of the day, approximately 6 hours or more apart). BYETTA should not be administered after a meal. If an injection is missed, the treatment should be continued with the next scheduled dose. BYETTA is recommended for use in patients with type 2 diabetes mellitus who are already receiving metformin, a sulphonylurea , pioglitazone and/or a basal insulin. One can continue to use BYETTA when a basal insulin is added to existing therapy. When BYETTA is added to existing metformin and/or pioglitazone therapy, the current dose of metformin and/or pioglitazone can be continued as no increased risk of hypoglycaemia is anticipated, compared to metformin or pioglitazone alone. When BYETTA is added to sulphonylurea therapy, a reduction in the dose of sulphonylurea should be considered to reduce the risk of hypoglycaemia. When BYETTA is used in combination with basal insulin, the dose of basal insulin should be evaluated. In patients at increased risk of hypoglycaemia consider reducing the dose of basal insulin. The dose of BYETTA does not need to be adjusted on a day-by-day basis depending on selfmonitored glycaemia. However, blood glucose self-monitoring may become necessary to adjust the dose of sulphonylureas or the dose of basal insulin. BYETTA should be used with caution and dose escalation from 5 µg to 10 µg should proceed conservatively in patients >70 years. The clinical experience in patients >75 years is very limited. No dosage adjustment of BYETTA is necessary in patients with mild renal impairment creatinine clearance:50-80 ml/min). In patients with moderate renal impairment (creatinine clearance:30-50 ml/min), dose escalation from 5 µg to 10 µg should proceed conservatively. BYETTA is not recommended for use in patients with end-stage renal disease or severe renal impairment (creatinine clearance <30 ml/min). No dosage adjustment of BYETTA is necessary in patients with hepatic impairment. The safety and effectiveness of exenatide have not been established in patients under 18 years of age. Each dose should be administered as a subcutaneous injection in the thigh, abdomen, or upper arm. BYETTA and basal insulin must be administered as two separate injections. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Special warnings and precautions for use:** BYETTA should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. BYETTA must not be administered by intravenous or intramuscular injection. BYETTA is not recommended for use in patients with end-stage renal disease or severe renal impairment (creatinine clearance <30 ml/min). BYETTA has not been studied in patients with severe gastrointestinal disease, including gastroparesis, therefore, the use of BYETTA is not recommended in patients with severe gastrointestinal disease. The concurrent use of BYETTA with D-phenylalanine derivatives (meglitinides), alpha-glucosidase inhibitors, dipeptidyl peptidase-4 inhibitors or other GLP-1 receptor agonists has not been studied and cannot be recommended. If pancreatitis is suspected, BYETTA and other potentially suspect medicinal products should be discontinued. Treatment with BYETTA should not be resumed after pancreatitis has been diagnosed. This medicinal product contains metacresol, which may cause allergic reactions. **Interaction with other medicinal products:** Gastroresistant formulations containing substances sensitive for degradation in the stomach, such as proton pump inhibitors, should be taken at least 1 hour before or more than 4 hours after BYETTA injection. INR should be closely monitored during initiation and dose increase of BYETTA therapy in patients on warfarin and/or cumarol derivatives. **Fertility pregnancy and lactation:** If a patient wishes to become pregnant, or pregnancy occurs, treatment with BYETTA should be discontinued. BYETTA should not be used during pregnancy or if breast feeding. **Undesirable effects and Adverse reactions** (Adverse reactions reported in long term phase 3 controlled studies and spontaneous adverse reactions) Patient frequencies are defined as: very common (≥1/10): Hypoglycaemia (with sulphonylurea with or without metformin), Nausea, Vomiting, Diarrhoea; common (≥1/100 to <1/10): Decreased appetite, Headache, Dizziness, Dyspepsia, Abdominal pain, Gastroesophageal reflux disease, Abdominal distension, Hyperhidrosis, Feeling jittery, Asthenia, Injection site reactions; Weight decreased uncommon (≥1/1,000 to <1/100): Dysgeusia, Eructation, Constipation, Flatulence rare(≥1/10,000 to <1/1,000): Dehydration, generally associated with nausea, vomiting and/or diarrhea, Somnolence, Acute pancreatitis, Alopecia, Macular and popular Rash, Pruritus, and/or urticaria, Angioneurotic oedema, Altered renal function, including acute renal failure, worsened chronic renal failure, renal impairment, increased serum creatinine. very rare (<1/10,000) Anaphylactic reaction, necrotising or hemorrhagic pancreatitis and/or death. Frequency not known: INR increased with concomitant warfarin, some reports associated with bleeding. In the three placebo-controlled trials 38 % of patients had low titre antiexenatide antibodies at 30 weeks. An additional 6 % of patients had higher titre antibodies at 30 weeks. About half of this 6 % had no apparent glycaemic response to BYETTA. Patients who develop antibodies to exenatide tend to have more injection site reactions (for example: redness of skin and itching), but otherwise similar rates and types of adverse events as those with no antiexenatide antibodies. When BYETTA was used in combination with basal insulin therapy the incidence and types of other adverse events observed were similar to those seen in the controlled clinical trials with exenatide as monotherapy, with metformin and/or sulphonylurea or a thiazolidinedione, with or without metformin. Pack size of 1 pen, injection needles are not included. Marketing Authorisation Number: EU/1/06/362/001-2, EU/1/06/362/003-4, date: 20th of November 2006. Date of SmPC: 22. March 2012. In Hungary: Prescription only medicine by Internist/Diabetologist. In Hungary: Price: 24993 Ft, Patient co-pay with 70% reimbursement: 7498 Ft. For more information please read the Summary of Product Characteristic. Lilly Hungária Kft. 1075 HUNGARY, Budapest, Madách u. 13–14.

References: 1. BYETTA Summary of Product Characteristics. 2. Buse JB, Bergenstal RM, Glass LC, et al. Use of twice-daily exenatide in basal insulin-treated patients with type 2 diabetes: a randomized, controlled trial. *Ann Intern Med.* 2011;154:103-112.

HUDBT00068a, 12. June, 2012
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Byetta® exenatide injection

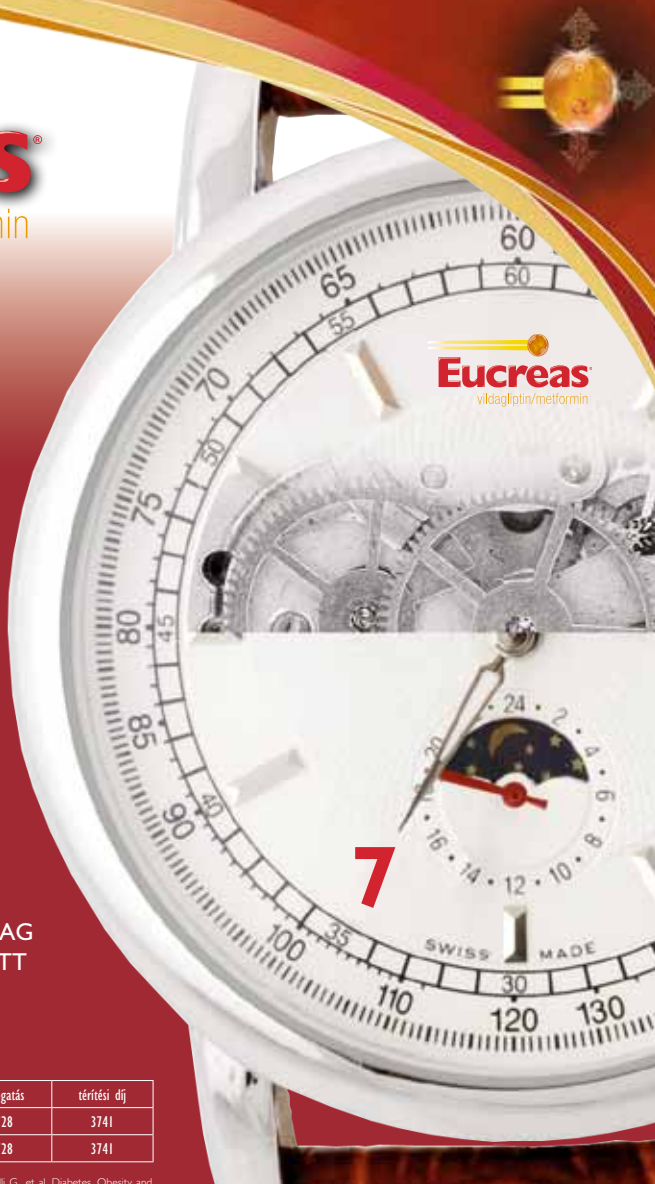
Eucreas®

vildagliptin/metformin

Hatékony glikémiás kontroll,[1,2,3,4] kellő időben[5]

GLIMEPIRIDHEZ HASONLÓ GLIKÉMIÁS HATÉKONYSÁG TESTSÚLYNÖVEKEDÉS NÉLKÜL ÉS SZIGNIFIKÁNSAN KEVESEBB HIPOGLIKÉMIA ELŐFORDULÁSA MELLETT[1]

PIOGLITAZON KEZELÉSHEZ HASONLÓ GLIKÉMIÁS HATÉKONYSÁG[2], SZÍVELÉGEDETLENSÉG, TESTSÚLYNÖVEKEDÉS – ÉS HÚGYHÓLYAG CARCINOMA KISMÉRTÉKBEN FOKOZOTT KOCKÁZATA NÉLKÜL[6,7]



2009. 09. 01-től érvényes árak[8]	termelői ár	bruttó fogy. ár	támogatás	térítési díj
Eucreas 50 mg/850 mg 60x	10 500	12 469	8728	3741
Eucreas 50 mg/1000 mg 60x	10 500	12 469	8728	3741

IRODALOM: 1. Ferranini et al. Diabetes, Obesity and Metabolism, 11, 2009, 157–166. **2.** Bolli G., et al. Diabetes, Obesity and Metabolism, 11: 589–595, 2009. **3.** Rosenstock J., et al. Diabetes Care 30:217–223, 2007. **4.** Bosi et al. Diabetes Care 30:890-895;2007. **5.** www.oep.hu, Eü 70. 1. pont. **6.** Actos alkalmazási előírás. **7.** Competact alkalmazási előírás. **8.** www.oep.hu.

Eucreas® 50 mg / 850 mg filmtabletta Eucreas® 50 mg / 1000 mg filmtabletta Vildagliptin / metformin-hidroklorid: 50 mg / 850 mg, 50 mg / 1000 mg filmtabletta. **Terápiás javallatok:** Azoknak a 2-es típusú cukorbetegségben szenvedő betegeknek a kezelésére javallt, akiknél a monoterápiában alkalmazott metformin maximális tolerált orális adagjával nem sikerült a vércukorszintet megfelelően beállítani, vagy akiket már különálló tablettákban adott vildagliptin és metformin kombinációval kezelnek. **Adagolás és alkalmazás:** A 100 mg-nál magasabb vildagliptin adagok nem javasoltak. Az Eucreas-t vagy az 50 mg/850 mg-os vagy az 50 mg/1000 mg-os hatáserősségű tabletta napi kétszeri szedésével lehet elkezdeni. A javasolt napi adag 100 mg vildagliptin és 2000 mg metformin-hidroklorid. A vildagliptint és metformint különálló tablettákban kapó betegek átállíthatók Eucreas-ra. Nincs klinikai tapasztalat vildagliptint és metformint, valamint más antidiabetikumot is tartalmazó hármas kombinációval. Az Eucreas nem javasolt 75 évnél idősebb, vagy gyermekkorú (< 18 év) betegeknek. **Ellenjavallatok:** A készítmény hatóanyagaival vagy bármely segédanyagával szembeni túlérzékenység. Veseelégtelenség vagy vesemőködési zavar. Akut vagy krónikus metabolikus acidosis, beleértve a diabétészes ketoacidózist kómával vagy anélkül. Olyan akut vagy krónikus kórképek, amelyek szöveti hipoxiát idézhetnek elő, mint például: keringési vagy légzési elégtelenség, friss szívinfarktus, sokk. Májkárosodás. Akut alkohol intoxikáció, alkoholizmus. Szoptatás. **Különleges figyelmeztetések és az alkalmazással kapcsolatos óvintézkedések:** Nem alkalmazható 1-es típusú cukorbetegségben szenvedő betegeknél. Fennállhat a laktát-acidózis kockázata. A vesemőködést ellenőrzni kell. Elővigyázatosság szükséges olyan gyógyszerek együttadása esetén amelyek befolyásolhatják a vesemőködést vagy a metformin-hidroklorid hatását A májkárosodásban szenvedő betegeket beleértve azokat a betegeket is, akiknél a kezelés előtt az ALT vagy az AST szintje meghaladja a normálérték felső határának 3-szorosát nem szabad Eucreas-szal kezelni. A kezelés megkezdése előtt májfunkciós vizsgálatokat kell végezni, majd a kezelés első évében háromhavonta, ezt követően időszakosan. Amennyiben az AST vagy az ALT értéke tartósan meghaladja a normálérték felső határának háromszorosát, az Eucreas-kezelés megszakítása javasolt. Azoknál a betegeknél, akiknél sárgaság vagy májmúködési zavarra utaló egyéb tünet alakul ki, az Eucreas adását abba kell hagyni. Az Eucreas-kezelés abbahagyását és a májfunkciós vizsgálatok eredményeinek normalizálódását követően az Eucreas-kezelést nem szabad újra elkezdeni. Nem javasolt gyermekek és serdülők számára (< 18 év). A New York Heart Association (NYHA) I-II-es funkcionális stádiumú pangásos szívelégtelenségben szenvedő betegeknek fokozott óvatossággal alkalmazandó. NYHA III-as -IV-es stádiumú betegeknél alkalmazása nem ajánlott. Szívelégtelenségben szenvedő betegeknél ellenjavallt. A cukorbetegek rutinszerű gondozásával összhangban, a bőrbetegségek, mint például a hólyag-, vagy fekélyképződés ellenőrzése javasolt. A kezelést időlegesen fel kell függeszteni: jódozott kontrasztanyagok intravaszkuláris alkalmazása, és műtéti beavatkozás esetén. Az Eucreas-t a terhesség ideje alatt nem szabad alkalmazni. Vannak a forgalomba hozatali körvetően akut pancreatitiről szóló spontán beszámolók.

Gyógyszerkölcsönhatások és egyéb interakciók: *A vildagliptin* esetében alacsony a gyógyszerkölcsönhatások valószínúsége. A vildagliptin nem mutatott klinikailag releváns farmakokinetikai interakciókat kombinációban adott orális antidiabetikumokkal (gliburid, pioglitazon, metformin), amlodipinnel, digoxinnal, ramiprillel, szimvasztatinnal, warfarinnal vagy valzartánnal. Más orális antidiabetikumokhoz hasonlóan, a vildagliptin hipoglikémiás hatását csökkenthetik bizonyos hatóanyagok, így pl. tiazidok, kortikoszteroidok, a pajzsmirigyre ható gyógyszerek és szimpatomimetikumok. *Interakciók metformin hidrokloriddal - Nem javasolt kombináció:* alkohol, kationos hatóanyagok (pl. cimetidin), jódozott kontrasztanyagok. *Elővigyázatosságot igénylő kombináció:* a glükokortikoidok, béta-2-agonisták, diuretikumok, ACE inhibitorok. **Nemkívánatos hatások, mellékhatások:** A nemkívánatos események többsége enyhe és átmeneti volt, és nem igényelték a kezelés felfüggesztését. *Vildagliptin:* angioödémáról, májmúködési zavarról (beleértve a hepatitist is) ritkán számoltak be. Metforminnal kombinálva – Gyakori: fejfájás, tremor, szédülés, hányinger – Nem gyakori: fáradtság. Monoterápia esetén gyakori: szédülés, nem gyakori: fejfájás, székrekedés, arthralgia, perifériás ödéma. Nagyon ritka: nasopharyngitis, felső légúti fertőzés. A *metformin* összetevő ismert mellékhatásai: nagyon gyakori: hányinger, hányás, hasmenés, hasi fájdalom és étvágytalanság, gyakori: fémes íz érzése, nagyon ritka: csökkent B12-vitamin felszívódás, laktát-acidózis, májfunkciós vizsgálatok kóros eredményei vagy hepatitis, bőrreakciók, mint például erythema, pruritus és urticaria.

Megjegyzés: A forgalomba hozatali engedély kiadásának/megújításának dátuma, száma(i): 2007.11.14.; EU/1/07/425/001–018. A támogatásban, vagy az árakban bekövetkező változások a www.oep.hu honlapon, vagy az Egészségbiztosítási Közlönyben érhetők el. Bővebb információért kérjük, hogy olvassa el a gyógyszer alkalmazási előírását (Eucreas-H-W5164, 2011. 11. 24.)! Forgalomba hozatali engedély jogosultjának magyarországi képviselője: Novartis Hungária Kft., H-1114 Budapest, Bartók Béla u. 43-47. A dokumentum lezárásának dátuma: 2012. 03. 28.

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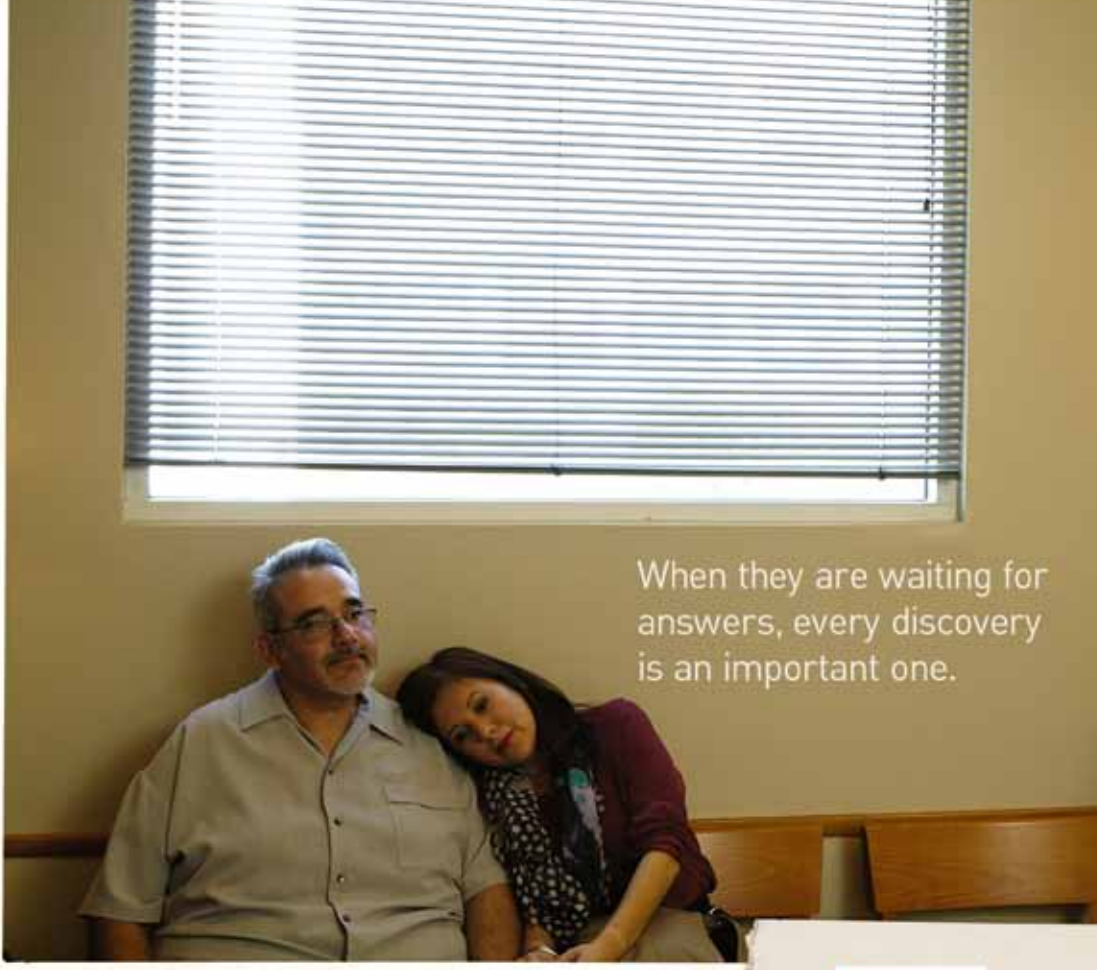

We understand that people with diabetes are waiting for new solutions every day. We also know many of those answers will come from discoveries made by scientists like you.

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Because one of the best ways we can make a difference in the everyday lives of patients and the healthcare professionals who help them is to support the people who make the discoveries possible.

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SELECTED ORAL PRESENTATION

CURRENT ISSUES IN THE LABORATORY DIAGNOSTICS OF DIABETES MELLITUS: STANDARDIZATION AND THE USE OF POINT OF CARE TESTING (POCT) FOR HbA1c

Gy. Ábel[1] and **M. Umemoto**[2]

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[2] Reference Material Institute for Clinical Chemistry Standards, Kawasaki, Japan

Introduction: Since its inclusion among the diagnostic criteria, HbA1c has been increasingly used for screening and monitoring of diabetes world-wide. The accuracy and portability of HbA1c results largely depend on the international standardization and harmonization of the methods used. With the advent of POCT technologies, it is imperative that clinicians understand the impact of the quality of HbA1c results on patient care and become well informed on the performance and limitations of the various testing methods and platforms.

Objectives: 1) Review the HbA1c standardization efforts of the National Glycohemoglobin Standardization Program (USA), the International Federation of Clinical Chemistry, and the Japanese Diabetes Association. 2) Compare various central laboratory and POCT methods used for the measurement of HbA1c, and provide guidance on the performance of these systems.

Materials and Methods: In a U.S. study (n=49), two POCT systems that were reported as best in class (Clin. Chem. 2010; 56:44–52), and the Tosoh AIA-PACK immunoassay system were compared to a certified HPLC method (Bio-Rad Variant Turbo). In a parallel study in Japan (n=40), an enzymatic method (Sekisui, Tokyo, Japan), and the Banalyst POCT (Ushio/ROHM, Kyoto, Japan) were compared to the Tosoh 8020 HPLC reference method.

Results: The Siemens DCA Vantage, Afinion, and Banalyst POCTs, and the Sekisui enzymatic method showed excellent correlation with the HPLC reference methods (regression slopes: 1.00, 1.02, 0.98, 0.99; Y-intercepts 0.07, -0.18, 0.19, 0.13; and R2 values 92.7, 85.6, 99.7, and 99.8%, respectively). The correlation of the Tosoh immunoassay with HPLC was less impressive (slope: 0.89, Y-intercept 0.16, and R2 =83.5%).

Conclusion: The best enzymatic and POCT methods gave satisfactory results and can be used for monitoring HbA1c. Caveat: POCT methods are not acceptable for making the diagnosis of diabetes mellitus, and expensive.

RELATIONSHIP BETWEEN INSULIN RESISTANCE AND SOME COAGULATION AND FIBRINOLYTIC PARAMETERS IN SUBJECTS WITH METABOLIC SYNDROME

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Background: Insulin resistance syndrome has been shown to be associated with many coagulation and fibrinolytic proteins and these associations suggest that some coagulation and fibrinolytic proteins have a role in atherothrombotic disorders.

Aim: This study was conducted to determine the levels of some of the haemostatic parameters in subjects having metabolic syndrome and to correlate these values with the anthropometric and metabolic variables associated with this syndrome.

Subjects and methods: The study included 46 obese non diabetic subjects of whom 28 subjects (group1) fulfilled the ATP III criteria of the metabolic syndrome and 18 subjects (group2) did not have metabolic syndrome as well as 14 lean subjects (group 3) of matched age and sex as a control group. Clinical and laboratory evaluation of the study groups stressed on anthropometric measurements (weight, height, body mass index, waist circumference, and sagittal abdominal diameter), blood pressure, and laboratory measurements of fasting plasma glucose, fasting insulin, serum lipids, tissue plasminogen activator (t-PA), antithrombin III activity (ATIII), protein C and von Willebrand factor (vWf) antigen.

Results: There was significant increase in the concentrations of t-PA and vWf antigens in subjects having metabolic syndrome (group 1) in comparison to the other groups while there were non-significant changes in the levels of protein C antigen and AT III activity. Both t-PA and vWf showed significant correlation with HOMA-IR as a measure of insulin sensitivity. The t-PA showed also significant correlation with most of the variables of metabolic syndrome including waist circumference, BMI, systolic blood pressure, fasting plasma glucose, fasting insulin, and HDL cholesterol. On the other hand, vWf showed significant correlations with fasting plasma glucose, fasting insulin and sagital abdominal diameter, with non-significant correlations with the other variables.

Conclusion: Haemostatic and fibrinolytic parameters should be included in the features and characterization of the insulin resistance syndrome. t-PA and vWf antigens concentrations were increased in subjects with metabolic syndrome and correlated with the HOMA-IR measure of insulin sensitivity. Taking into consideration that both t-PA and vWf are mainly released from vascular endothelium, these findings could be an indicator of endothelial dysfunction in that group of subjects.

POSTER NR. 24.

THE ROLE OF ECHOCARDIOGRAPHY IN THE EARLY DIAGNOSIS OF HEART DAMAGE CAUSED BY DIABETES

Zs. Ádám[2], P. Hajós[1], A. Czégeni[1], A. Polyák[1], P. Dabrónaki[2], Z. László[2] and G. Winkler[1]
[1] St. John's Hospital and North-Buda United Institutions, 2nd Dept. Intern., Budapest, Hungary
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Introduction: Diabetic macroangiopathy (CHD) and microangiopathy (diabetic cardiomyopathy) are both common cardiac complications. Echocardiography (Echo) plays an important role in their discovery.

Objectives: Early detection of cardiac complications in complaints-free T2DM patients by using new Echo techniques, such as Tissue Doppler Imaging (TDI) and Speckle Tracking Imaging (STI).

Methods: To measure systolic, diastolic and segmental heart function, we have done M mode, 2D imaging, flow Doppler, TDI, STI strain examinations with automated function imaging (AFI) software.

We examined 111 people with echocardiography. The mean age was 56.5. 93 patients had T2DM, they were divided into 2 groups. Newly diagnosed T2DM, within one year of diagnoses (DMA) and long term T2DM, for over 5 years (DMB). We created an (N) subgroup out of diabetic patients at whom we could verify autonom cardiac neuropathy. The metabolic state of the patients was of an acceptable level. The control group (K) consisted of 18 healthy people.

Results: We found cardiac complications in 49% of the patients with T2DM. Systolic left ventricle dysfunction in K, DMA, DMB and N was 0%, 0%, 15.1%, 0%. We found left ventricle diastolic dysfunction in the same groups, in the same order in 11.1%, 35%, 56.2%, 52.9%. Heart failure was found in 14% of the examined diabetic patients. Segmental wall motion could be found in 5 cases.

Conclusion: We found that new echocardiography methods has an important role in the early discovery of heart disease complications accompanied by diabetes.

EVALUATION OF CARDIOVASCULAR AUTONOMIC NERVE FUNCTION IN PATIENTS WITH PREDIABETES AND NEWLY-DIAGNOSED TYPE 2 DIABETES

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Objectives: The aim of the present study was to evaluate cardiovascular autonomic nerve function (CAF) in patients at different stages of glucose intolerance - prediabetes (impaired fasting glucose and impaired glucose tolerance) and newly-diagnosed type 2 diabetes (NDD).

Methods: A total of 87 subjects,of mean age 49.7±16.0 years and mean BMI 31.9±6.2 kg/m^2, divided in 3 groups - 28 with normal glucose tolerance (NGT), 34 with prediabetes and 25 with NDD, were involved in a cross-sectional study. Glucose tolerance was studied during OGTT, applying 2006 WHO criteria. CAF was assessed by ANSAR 3.0 measuring the balance between sympaticus and parasympaticus using deep breathing (E/I ratio), valsalva and standing from a seated position (30:15 ratio) tests.

Results: The groups with prediabetes and NDD presented with significant deterioration in CAF. Abnormal E/I ratio was observed in 35% of subjects with prediabetes, 33% of NDD and 4.5% of NGT group. 30:15 ratio was impaired in 30% of prediabetes, 33% of NDD and 13.6% of NGT group. Abnormal Valsalva test was found in 55% of prediabetes group, 33% of NDD and 45% of NGT group. Abnormalities in all three tests were established in 4.5% of NGT group, in 10% of prediabetes group and in 16.7% of NDD group.

Conclusion: Our results demonstrate that CAF is altered even at the early stages of glucose intolerance - prediabetes and NDD. Cardiovascular autonomic dysfunction worsens with the progression from NGT to prediabetes and NDD.

POSTER NR. 11.

OBESITY DOES NOT PROTECT AGAINST BONE FRACTURES

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Introduction: Low BMI is one of the main determinants of low bone mass according to previous results and it was found to be associated with low-energy fractures as an independent risk factor. Obesity strongly associated with a higher BMD, however the fracture risk was found to be increased among type 2 diabetes patients. Our aim was to investigate whether obesity, without diabetes can affect fractures in postmenopausal women.

Patients and Methods: A total of 100 postmenopausal women (mean age: 61.8 yr) without known diabetes was enrolled into our study. Potential participants with secondary causes of osteoporosis or those on medication likely to affect skeletal metabolism were excluded. Bone mineral density (BMD, g/cm2) was measured for all patients at lumbar 2–4 vertebrae, left femoral neck [XR-46, Norland, Fort Atkinson, Wis] and at the radius of the nondominant side (P-DEXA, Norland) by the dual-energy X-ray absorptiometry method (DXA). Broadband ultrasound attenuation of the heel (BUA, dB/MHz), speed of sound (SOS, m/s), quantitative ultrasound index (QUI, CV%: 1.85) and estimated calcaneal BMD and it's T-score were assessed by the quantitative ultrasound (QUS) method (Sahara bone sonometer, Hologic, Waltham, Mass.). According to the World Health Organization (WHO) guidelines, BMD measurements were categorized as normal (T-score 1.0 or above), osteopenia (Tscore between -1.0 and -2.5), or osteoporosis (T-score 2.5 or below). Diagnosis of osteopenia or osteoporosis was set up if T-score values were lower than -1.0 or ≤2.5 at one or more measured sites. Distal forearm, hip and validated (by morphometry) vertebral fractures with clinical symptoms that resulted from mild to moderate trauma and had occurred within the past 10 years, and were confirmed by medical record were considered to be lowenergy fractures. The patients were asked about skeletal pain, especially about back pain, by means of a questionnaire.

Results: Overweight and obesity (25 kg/m2≤BMI) were common among the women (76%). 52% of patients suffered from osteoporosis, 30% had osteopenia, and only 18% of the examineed subjects had normal bone mineral density. The rate of prevalent low-energy fractures was 13%. The femoral neck BMD positively correlated with BMI, with a higher number of fractured patients found with higher BMD. 9 out of the 13 fractured patients were overweighted or obes. Neither DXA, nor QUS values were able to predict bone fractures acording to regression analysis. However, QUS at the heel, with respect to SOS values, showed an ability to discriminate between women with or without fractures. No statistically significant differences were observed in age, BMI, and age at menopause between fractured and non-fractured subjects.

Conclusion: In conclusion, we found a relatively high prevalence of low-energy fractures among overweighted or obes postmenopausal women. It is possible that obesity itself has the negative effect on bone fracture risk, not the deteriorate effect of diabetes cause the increased fracture rate.

Keywords: Bone mineral density, Fractures, Obesity

SERUM DIPEPTIDYL PEPTIDASE-4 ACTIVITY IN INSULIN RESISTANT PATIENTS WITH NON-ALCOHOLIC FATTY LIVER DISEASE: A NOVEL LIVER DISEASE BIOMARKER

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Background: In a cross-sectional study we assessed the fasting serum DPP-4 enzymatic activity (sDPP-4), the insulin resistance index (HOMA2-IR) in gliptin naïve patients with type 2 diabetes and in non-alcoholic fatty liver disease (NAFLD) and in controls (CNTRL). Recently it was reported that higher sCD26 levels were associated with a worse response to only 50mg daily sitagliptin and baseline sCD26 has been inversely correlated with the improvement observed in HbA1c levels.

Methods and Findings: sDPP-4 was measured by kinetic assay in 39 NAFLD (F/M:19/20, mean age: 47.42 yrs) and 82 type 2 diabetes (F/M:48/34, 62.8 yrs) patients and 26 (F/M:14/12, 35.3 yrs) controls. Definition of T2D group as patients with type 2 diabetes but without clinically obvious liver disease created non-overlapping study groups. Patients in T2D and NAFLD groups were similarly obese. 75 g CH OGTT in 39 NAFLD patients: 24-NGT, 4- prediabetes, 11-type 2 diabetes. HOMA2-IR: CNTRL: 1.44; T2D-group: 2.62 ($p = 0.046$ vs CNTRL); NAFLD(NGTonly): 3.23 ($p = 0.0013$ vs CNTRL); NAFLD(IFG/IGT/type 2 diabetes): 3.82 ($p<0.001$ vs CNTRL, $p = 0.049$ vs 2TD group). sDPP-4 activity was higher in NAFLD both with NGT (mean:33.08U/L) and abnormal glucose metabolism (30.38U/L) than in CNTRL (25.89U/L, $p<0.001$ and $p = 0.013$) or in T2D groups (23.97U/L, $p<0.001$ and $p = 0.004$). Correlations in NAFLD among sDPP-4 and ALT: $r = 0.4637$,$p = 0.0038$ and γGT: $r = 0.4991$,$p = 0.0017$ and HOMA2-IR: $r = 0.5295$,$p = 0.0026$ and among HOMA2-IR and ALT: $r = 0.4340$,$p = 0.0147$ and γGT: $r = 0.4128$,$p = 0.0210$.

Conclusions: In addition that the high sDPP-4 activities were correlated with gGT, ALAT liver tests and also with HOMA2-IR, but not with the fasting plasma glucose or HbA1C in NAFLD suggesting that sDPP-4 activity should be considered as a novel liver disease biomarker, our data together with the results form the comprehensive proteomic profiling of the human adipocyte secretome (DPP-4 as a novel adipokine hormone) suggests that the visceral fat pathology that goes hand-in-hand with the intrahepatic lipid accumulation might be identified as having an essential role.

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POSTER NR. 27.

CLINICAL AND EPIDEMIOLOGICAL FEATURES OF A COMBINATION OF HYPERTENSION AND OBESITY IN PATIENTS WITH DIABETES MELLITUS IN THE POPULATION

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Introduction: Among the risk factors of arterial hypertension (AH), the largest place takes obesity. The prevalence of obesity is rising rapidly and is projected to 2010 will suffer from obesity 150 million adults (Lobstein T., 2006). Among the adult population overweight and obesity annually accounts for about 80% of type 2 diabetes mellitus, 35% of ischemic heart disease and 55% of cases of arterial hypertension, as well as more than a million deaths and 12 million years of life of poor health (James WPT et al., 2004).

Aim of research – to study clinical and epidemiological features of the prevalence of hypertension and obesity as major components of the metabolic syndrome among patients with diabetes mellitus on the regional level

Materials and methods: According to the Regional Registry of diabetes mellitus studied the prevalence of hypertension and obesity in 6949 patients with diabetes type 1 and 2, including 5275 women and 1674 men. Identified groups and the parameters of the relative risk for major components of the metabolic syndrome.

Results of research: It is established, that the highest prevalence of type 2 DM accounts for a female sub-population, amounting to 1819.5 per 100 thousand population, which is higher than among men in 3.3 times. Sex and age dynamics of the prevalence of type 1 DM showed, that statistically significant differences occur only in the age group 65-69 years and 80 years of age due to the excess rate among women is 2.5 times., And the assessment of the dynamics in patients with type 2 DM of statistically significant differences observed, beginning with the age group 45-49 years, reaching a maximum in the older age groups. The analysis revealed several patterns indicating a high level dependence of AH from type of DM, and the trigger is a degree of obesity. Among patients with type 1 DM incidence of 1 degree of AH among men 15%, women 11%, 2 degree – 13% of men, women – 20%, 3 degree - men – 3%, women – 7%, isolated systolic AH – among men 9%, women – 15%. Among patients with type 2 DM frequency of 1 degree hypertension is 18% among men and women – 16%, 2 degree – 28% of men, women – 27%, 3 degree – male – 14%, women – 20%, isolated systolic AH – among 15% of men, women – 20%. The peculiarity of the prevalence of obesity is the presence of obesity 2 and 3 degree in patients with type 2 DM regardless of sex. The first degree of obesity was 7% among men with type 1 DM and with type 2 diabetes – 26.1%. Among women, this indicator is respectively 16.0 and 30.5%. Second degree – 1.2% and 9.4% in men and 2.9% and 12.7% in women, respectively, for type 1 and 2 diabetes mellitus. Third Degree – 0.3% and 2.6% in men and 0.9% and 6.3% – in women, respectively, for type 1 and 2 diabetes mellitus. The calculations indicate the presence of pronounced relative risk of obesity 2 and 3 degree in patients with type 2 diabetes mellitus, regardless of gender and women at the isolated systolic AH. The data presented necessitate revision of the protocol, patients with 2-3 degree arterial hypertension and isolated arterial hypertension in patients with obesity 2 and 3 degrees.

Conclusion: Diagnosing patients with type 2 diabetes mellitus of moderate and severe arterial hypertension combined with obesity 2, 3 degrees brings them into the category of high risk. These patients are in need of cardinal clinical events. The rehabilitation of patients with obesity and arterial hypertension should be based on mechanisms of influence on the risk factors and behavioral reactions.

POSTER NR. 14.

OCCURRENCE OF MICRO- AND MACROVASCULAR COMPLICATIONS IN TYPE-2 DIABETIC PATIENTS ON EARLY INSULIN TREATMENT

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Introduction: There are several guidelines and algorythms regarding the therapy of type-2 diabetes. Some guidelines consider early insulin treatment after the diagnosis of diabetes mellitus depending on the glycaemic status of the patient (HbA1C≥ 10%). In most cases, lifestyle changes along with OHA monotherapy (usually metformin) is the preferred first-line treatment. In other cases, however, patients' metabolic state cannot be improved with oral antidiabetic agents alone, necessitating insulin administration.

Objectives: 109 type-2 diabetic individuals with initial insulin administration were found by searching the digital medical documentation of the hospital between 01.07.2009 and 01.07.2011. Retrospective analysis of the latter patients was carried out.

Methods: The focus of our investigation included initial insulin regimen, additional OHA therapy, gender, age (41 females, 68 males, 54,82+/-13,74 years), metabolic parameters (PPBG level 20,6+/-8,13 mmol/l, HgbA1c 11,42+/-1,95% serum total cholesterol 5,93+/-1,64 mmol/l, serum triglyceride 4,3+/-5,14 mmol/l, BMI (29,77+/-6,76 kg/m2), waist circumference (107,1+/-15,31 cm), the occurrence of micro- and macrovascular complications.

Results: At the point of diagnosis, 65 patients (59,6%) had evidence of vascular complications. In 42 individuals (38,5%) microangiopathy was detected (nephropathy in 40 cases, retinopathy in 3 cases). Macroangiopathy occurred in 37 patients (33,9%, 23 coronary heart disease, 14 cerebrovascular disease, 7 peripheral artery disease). 12 patients showed symptoms of neuropathy (11%).

Conclusion: The high occurrence of vascular complications suggests a long duration of disease, which draws attention to the delay in the diagnosis of type-2 diabetes, underlining the importance of early screening in high-risk populations.

EDUCATION AND SELF-MONITORING OF BLOOD GLUCOSE: CORNERSTONES OF DIABETES CARE

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Diabetes is a chronic and progressive disorder that impacts upon almost every aspect of life. The number of people with diabetes is continuously growing and diabetes is associated with a high mortality rate. Diabetes education is a critical element of care of people with diabetes in order to improve clinical outcomes. The therapeutic patient education is a planned and structured program that is comprehensive in scope, flexible in content, responsive to an individual's clinical and psychological needs, and adaptable to patients' educational and cultural background. The diabetes educator should control the implementation of education and should evaluate the patient's knowledge. The educator should be trained for care of patients with chronic diseases and for education of patients with diabetes mellitus.

POSTER NR. 34.

HEALTH POLICY DECISION MAKING IN DIABETOLOGY: FACTS AND TASKS IN HUNGARY

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Introduction: It is necessary to allocate available resources of healthcare system to sectors where the losses of health capital are significant, and the costs of care are high for both, the health care system and the patients as well. The care of diabetes mellitus belongs to these areas.

Objectives: To assess the direct healthcare expenditures spent on diabetes in order to characterize the disease burden and to perform further health economics analyses.

Methods: Dataset of diabetes patients were derived from the database of the National Health Insurance Fund Administration (NHIF) for 2008. Patients with diabetes mellitus were divided into two groups according to obtaining inpatient or outpatient care. Groups receiving exclusively outpatient care according to the antidiabetic treatment were classified as 1) taking only oral antidiabetics (OAD), 2) taking only insulin, and 3) combined OAD and insulin users. The statistical figures of health insurance costs related to the cost items and the age-groups were determined in the sub-groups. Data of the patients with or without complications were analysed separately, and the loss of health capital were also examined, and the costs for the first two years in the group with complications.

Results: The annual health insurance expenditure for the 521,546 OAD/insulin patients was 335,000 Hungarian Forints (HUF) per patient. The costs were almost doubled for complicated cases (633,000 HUF). 242,000 HUF were spent for OAD-users with no complications, whereas the healthcare costs of the insulin group were 449,000 HUF per annum. Half of the expenses (53%) was paid for the reimbursement of pharmaceuticals (26% for OAD and insulin) and the quarter of the costs (27%) was covered for inpatient care. The direct health costs of the diabetes exceeded 0.65% of the national Gross Domestic Product (GDP) and reached 13% of the total public health care budget of the NHIF. The loss of health capital was 35.6% in blindness, 34.6% in amputation due to diabetic foot ulcer, while it was 21.3% following stroke. The expenditures of the inpatient care and the medication has been multiplied during the occurrence of complications.

Conclusion: The healthcare of diabetes, particularly the treatment of complications, represents major health expenses. Considering the burden of disease that manifests in premature mortality, reduction in quality of life, and high cost, and the epidemiological trends, diabetes mellitus should be a public health priority in Hungary. A National Diabetes Programme would be essential for the treatment and for a sustainable system. To calculate the effects of health policy programs and public interventions in diabetes mellitus, an open access health economic model would be highly beneficial.

HIGHER FASTING GLUCOSE EVEN WITHIN THE NORMAL RANGE IS AN INDEPENDENT RISK FACTOR FOR SENSORY NEUROPATHY IN PATIENTS WITH ESSENTIAL HYPERTENSION

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Objectives: We aimed to assess prevalence and risk factors for neuropathy in patients with essential hypertension.

Materials and Methods: Seventy-two patients with essential hypertension and 31 age-matched healthy control subjects were examined. Five standard cardiovascular reflex tests and heart rate variability (HRV) analysis were performed to define autonomic function. HRV was characterized by HRV triangular index (HRVTI) and frequency domain method. Sensory nerve function was assessed by current perception threshold (CPT), using Neurometer®.

Results: 87% of patients had autonomic dysfunction; the prevalence of sensory neuropathy was 15%. Elevation of fasting glucose within the normal limits correlated with higher CPT values at testing median nerve (2000 Hz: $p=0.002$; 250 Hz: $p=0.03$; 5 Hz: $p=0.01$). Classifying patients into subgroups by fasting glucose (< 5.2; 5.2-5.5; 5.6-6.0 mmol/l) CPT values increased as glycaemia worsened even after adjustment for other cardiovascular risk factors (ANCOVA: N. medianus 2000 Hz: $p=0.003$; 5 Hz: $p=0.002$). Sensory nerve dysfunction was also related to weight, elevated 24-hour-mean blood pressure, and triglycerides (all $p<0.05$). Compared to healthy controls, hypertensive patients had lower heart rate response to deep breathing ($p<0.0001$), standing and Valsalva manoeuvre, lower HRVTI (all $p<0.05$), lower total power ($p=0.01$), and low frequency power ($p<0.01$). Autonomic dysfunction was independently associated with age ($p<0.001$), weight ($p<0.05$), and female sex ($p=0.001$).

Conclusion: Neuropathy is a frequent complication of essential hypertension. Sensory neuropathy was independently associated with higher fasting glucose levels, just as with weight, higher 24-hour-mean blood pressure and triglycerides. Age, weight and female sex were independent determinants of autonomic impairment.

POSTER NR. 21.

EVALUATION OF COMPLICATING EFFECT OF DIABETES MELLITUS IN PATIENTS WITH ISCHEMIC STROKE

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Introduction: High levels of mortality and disability due to stroke dictates the need to study the prevalence of pathogenic factors contributing to its emergence. According to various population registers, the proportion of ischemic stroke is 70-90% among all types of stroke. To one of the most important risk factors leading to stroke is diabetes mellitus (DM). Diabetes increases the risk of stroke 2-fold, worsens its course and increase the number of deaths with due to stroke.

Aim of research – study of prevalence and complicating effect of diabetes mellitus in patients with ischemic stroke (IS), taking into account gender and age differences among the urban population of East Kazakhstan.

Materials and methods: By the method of continuous sampling analyzed 2272 case histories of patients with ischemic stroke admitted to the Emergency Care Hospital of Semey of the East Kazakhstan region. Thus, 45.1% were men and women – 54.9%. All the patients were divided into five age groups. Investigated the prevalence of diabetes among the survivors and the dead. Assessing the impact of diabetes mellitus on the prognosis of stroke is presented in the form of aggravation index, determined by the ratio of prevalence of pathogenetic factors among the deceased to the same value among the survivors.

Results of research: The average age of men was – 62.6, and women – 69.8 years. Among all patients with diabetes mellitus, almost 2 times more frequently in women than in men (12.9 and 6.8% respectively). In group up to 40 years diabetes has not been registered in both men and women. In the other age groups revealed a significant prevalence of diabetes mellitus in women. So in the group 40-49 years the prevalence of the disease in women was more than 4 times higher than among men (6.9 and 1.7% respectively), while in the group 50-59 years – 1.4 times (17.1 and 10.9% respectively). The maximum incidence of the disease in women was noted in the group 60-69 years, where every fourth patient suffered from these diseases, accounting, respectively, 24.8% versus 9.9% in men. In the group older than 70 years noted the prevalence of diabetes in women is 1.6 times (17.1 and 10.9% respectively). The highest prevalence of diabetes in men found in the group 50-59 years (11.6%). In general, men in the age group 60-69 years, 70 years and older indexes were almost on the same level, respectively, 9.9 and 10.9%.

Comparative analysis of the prevalence of diabetes among the dead and the survivors allowed to determine the severity of the complicating effect on the prognosis of the disease. It turned out that the dominance of diabetes among the dead was significantly increased complicating effect, as women and men in all age groups, except for the group 40-49 years for men, where due to the thin amount of cases of diabetes (1.7%) data were beyond statistical significance. Despite the significant prevalence of diabetes among women, complicating effect on the outcome of the disease was more significant in men. It is established that the index weights for women in the groups 40-49, 50-59, 60-69, 70 years and older was respectively 3.9, 1.6, 1.7 and 1.3, and men in groups of 50-59, 60-69, 70 years and older – 2.6, 2.1 and 2.5, respectively.

Conclusion: The dominance of diabetes mellitus in ischemic stroke among women in general, and in all age groups, from 40 years of age and older, as well as the complicating effect of diabetes mellitus on the outcome of stroke at all ages of both gender groups, with a more significant adverse effects on male requires to take into account this fact in the treatment and prevention of this type of stroke.

POSTER NR. 6.

DEVELOPMENT OF THE CLASSIC THERAPEUTIC PARADIGM FOR PAIN IN DIABETIC POLYNEUROPATHY

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Introduction: We present some contemporaneous theories of pain and therapeutic concepts of analgesia, including drug and physical analgesia. We mentioned different natural and preformed physical modalities, with effectiveness in clinical practice.

Objectives: Comparative evaluation of drug, physical and combined analgesia on pain in diabetic polyneuropathy patients.

Material and methods: A total of 105 in-patients with diabetic polyneuropathy are observed and investigated. The investigation was conducted with consideration of Declaration of Helsinki, and was approved by the appropriate institutional review boards and ethics commissions. All patients gave written informed consent. Group 1 received only drug therapy – infiltrations with corticosteroids, Milgamma N and local anesthetic. Patients of group 3 received only physical modalities [rehabilitation programme including transcutaneous electroneurostimulation, exercises, massages, sea lye compresses). In group 2 we applied drugs and physical analgesia techniques. For statistical evaluation we used t-test (ANOVA) and Wilcoxon rank test (non parametrical correlation analysis), performed using SPSS package. The treatment difference was considered to be statistically significant if the p value was <0.05.

Results: The comparative analysis of results shows a significant improvement of the symptoms of the polyneuropathy patients, concerning pain relief, depression, etc. The drug analgesia in group 1 is fast, but short. The efficacy in group 3 is slow, but stable, and durable. We observed best results in group 2. We expose our own conception of pathogenetic mechanisms of physical analgesia.

Conclusion: We could recommend the complex program for treatment of pain in diabetic polyneuropathy.

DEVELOPMENT OF THE CLASSICAL THERAPEUTICAL PARADIGM IN NEUROPATHIC PAIN: FROM DRUGS TO PHYSICAL ANALGESIA

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Introduction: We present some contemporaneous theories of pain and therapeutic concepts of analgesia, including drug and physical analgesia. We mentioned different natural and preformed physical modalities, with effectiveness in clinical practice.

Goal: Comparative evaluation of drug, physical and combined analgesia on the peripheral radicular pain.

Material and methods: During last years a total of 105 in-patients with a spondylogenic radiculopathy are observed and investigated. Patients are randomized to three treatment groups of 35 each one. The investigation was conducted in accordance with consideration for the protection of patients, as outlined in the Declaration of Helsinki, and was approved by the appropriate institutional review boards and ethics commissions. All patients gave written informed consent before undergoing any examination or study procedure. Groups 1 received only drug therapy – paravertebral infiltrations with cortico-steroids, Milgamma N and local anesthetic. Patients of group 3 received only physical modalities [complex rehabilitation programme including transcutaneous electroneurostimulation (TENS), exercises, massages, sea lye compresses distally). In group 2 we applied drug and physical analgesia techniques.

For statistical evaluation we used t-test (ANOVA) and Wilcoxon rank test (non parametrical correlation analysis), performed using SPSS package. The treatment difference was considered to be statistically significant if the p value was < 0.05.

The comparative ANALYSIS of RESULTS shows a significant improvement of the symptoms of the patients, concerning pain relief (visualized by the analysis of results of Visual analogue scale), radiculopathy (Lassegue's sign), depression (scale of Zung). The drug analgesia in group 1 is fast, but short. The efficacy in group 3 is slow, but stable, and durable. We observed best results in group 2. We expose our own conception of pathogenetic mechanisms of physical analgesia.

Discussion: The drug therapy is efficient but with short duration. The physical analgesia initiates its effect slowly, but their results are stable. Best efficacy was observed in case of combination of medication with physical modalities – in the beginning due to non-steroidal anti-inflammatory drug, toward the moment of effective «input» of physical modalities.

Conclusion: We could recommend the complex program for treatment of the paravertebral pain.

Key words: physical modalities, steroids, neuropathic pain, analgesia

POSTER NR. 32.

ASSOCIATIONS OF GLYOXALASE I GENE POLYMORPHISMS rs1130534 AND rs1049346 WITH REDUCED ENZYME ACTIVITY

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Introduction: A large body of evidence suggests that advanced glycation endproducts (AGEs) are important pathogenetic mediators of diabetic complications. Glyoxalase I (GLO1) is a part of enzymatic defense system that prevents accumulation of AGE precursors.

Objectives: The aim of our study was to determine whether single nucleotide polymorphisms (SNP)in GLO1 gene influence enzyme activity and the prevalence of diabetic microvascular complications.

Methods: The study included 125 nondiabetic control subjects, 101 patients with type 1 and 100 patients with type 2 diabetes genotyped for three common SNP (rs2736654 A111E, rs1130534 G124G and rs1049346 5'UTR) in the GLO1 gene.The activity of GLO1 in blood samples was assessed and late complications such as neuropathy, retinopathy or nephropathy were recorded.

Results: Obtained results showed significant association of rs1130534 G124G and rs1049346 5'UTR with enzyme activity decreased in minor allele homozygotes to 25.2±10.0 U/gHb (p=0.001) and 27.2±8.0 U/g Hb ($p=2.6*10^{-5}$), respectively. Haplotype analysis supported this evidence – carriers of both minor alleles had enzyme activity of 21.8±4.3 U/g Hb vs.33.0±7.0 U/g Hb in wild type carriers with rs2736654 A111E being effect modulator as haplotypes with wild type in this position showed stronger difference and significant association. No association with recorded complications of diabetes was observed.

Conclusion: Our study provides evidence that the presence of the minor T allele at rs1049346 and rs1130534 in GLO1 gene is significantly associated with reduced enzyme activity.Further studies are necessary in order to understand relations of these SNPs with diabetes late complications.

HYPERTENSION AND SENSORY NERVE DYSFUNCTION IN LONG-STANDING AND NEWLY DIAGNOSED TYPE 1 DIABETES MELLITUS: IS THERE A RELATIONSHIP?

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Aim of our study was to assess the connection between hypertension and peripheral sensory neuropathy in patients with long-standing and newly diagnosed Type 1 diabetes mellitus (T1DM).

Our study involved 32 patients with long-standing (mean age: 37,8 ± 12,7 years), 40 patients with newly diagnosed T1DM (mean age: 34,7 ± 11,3 years) and 25 healthy volunteers (mean age: 38,3 ± 12,8 years). According to medical history, 8 long-standing T1DM patients had hypertension.

24-hour blood pressure monitoring was performed by Meditech ABPM04 device. Sensory nerve function was assessed by the Neurometer. Current perception threshold (CPT) was measured on median and peroneal nerves at three frequencies.

Higher CPT values indicating hypaesthesia were found in hypertensive subjects compared to those with normotension ($p<0,01$ for median at 250 kHz and for peroneal nerve at 5 Hz; $p<0,05$ for median nerve at 5Hz). Analyzing the impact of hypertension and microalbuminuria on sensory nerve function separately, hypertension was independently associated with elevated CPT values: $p<0,01$; $p<0,05$ and $p<0,05$ for 2kHz, 250Hz and 5Hz on median nerves, respectively.

In the newly diagnosed T1DM patients the CPT values on median nerve at 5Hz correlated significantly with higher casual systolic blood pressure values ($r=0,399$; $p=0,01$). This association was independent of other risk factors.

The decrease of systolic blood pressure after standing correlated significantly negatively with CPT values on the peroneal nerve at 2 kHz ($r=-0,344$, $p=0,032$), at 250 Hz ($r=-0,389$, $p=0,014$) and at 5Hz ($r=-0,327$, $p=0,042$).

Sensory loss is independently associated with hypertension in long-standing and newly diagnosed T1DM as well. Patients with elevated blood pressure and orthostatic hypotension but no symptoms are also suggested to be screened for sensory impairment. Our data may support the role of vascular factors in developing peripheral neuropathy.

POSTER NR. 17.

ACUTE INTERSTITIAL NEPHRITIS ACCOMPANYING METFORMIN THERAPY

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Background: metformin is a safe drug with favourable side-effect spectrum when administered according to the indication list. We present a rare side-effect (interstitial nephritis), which has been described previously only in few cases.

Case report: the case of a 29-year-old woman is presented, who because of preeclampsia underwent caesarean delivery on the 39th week of gestation in April 2008. A considerable weight gain (25,0 kg) was observed during the pregnancy. After the delivery an endocrinological check-up was performed, insulin resistency, insulin mediated ovarial dysfunction and polycystic ovarium syndrome was diagnosed, metformin (MET) treatment was begun. In March 2009 the patient complained on joint pain (knees and PIP/DIP joints) and constitutional symptoms (mainly weakness). Lab tests showed impaired renal function (urea: 10,7 mmol/l, creatinine:116 umol/l), anemia (hemoglobin:106 g/l), thrombocytosis, proteinuria (P) and microscopic haematuria (MH) with elevated blood cell sedimentation (100 mm/h). The antinuclear antibody was positive in a small titer (1:40) with a granular pattern but other immunoserologic tests were negative. To exclude systemic autoimmune disease as the background of the permanent P and MH, a renal biopsy was performed, and acute interstitial nephritis could be verified. As no other causative agent could be identified, MET as the cause of the damage was assumed. MET was stopped and a short course of steroid was administered. (methylprednisolone16 mg/day). Methylprednisolon was tapered and stopped after 2 months, the lab tests became normal, and the complaints resolved. The patient became pregnant in October 2009 but on the 8th it ended as a miscarriage. In July 2010 she became pregnant again. The kidney function was normal during the pregnancy but from the second trimester hypertension was recognized and methyldopa treatment had to be started. Iron was administered due to (iron deficiency) anaemia. On week 39 she delivered a healthy baby.

Conclusion: during metformin treatment a special attention is required considering renal function. When P and/or MH occurs, as rare but serious side-effect, acute interstitial nephritis also has to be excluded. When diagnosed early, also this can be cured succesfully.

EFFECT OF HOME BASED EXERCISE PROGRAM WITH TYPE 2 DIABETES MELLITUS ON THE EXERCISE CAPACITY AND QUALITY OF LIFE

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Introduction: The role of home based exercise program in the type 2 diabetes mellitus (T2DM) is less clear.

Objectives: The aim of this study was to investigate the effect of home based exercise program on exercise capacity and quality of life with T2DM for 3 months five times per a week.

Methods: Twenty subjects (mean age 50.1 ±7.44 year) with T2DM were recruited. Subjects were randomized to each of 2 groups; a home based exercise group (group I (n=10); calisthenic exercises, walking and resistive exercise and nonhomebased exercise group(group II (n=9); only walking). Health related quality of life was evaluated by Nottingham Health Profile (NHP), functional capacity was evaluated by 6 minute walk test.

Results: When the 2 groups were compared after exercise program, NHP emotional score significantly decreased in group I (P=0.046), there was no statistically change in group II (P> 0.05). There were no statistically significant differences in the walking distance (P>0.05) between groups after exercise program. The resting heart rate in the 6 minute walk test (P=0.038), NHP pain score (P=0.012) emotional reaction score (P=0.023) and total score of NHP (P=0.05) decreased statistically in group I, there were no statistically change in group II (P>0.05) after exercise program than before.

Conclusion: Our finding indicate that home based exercise programmes improves exercise capacity and quality of life but a lot of similar studies should be performed with more cases in the future.

SELECTED ORAL PRESENTATION

MICROCAPSULES FOR IMMUNOPROTECTION OF TRANSPLANTED ISLETS IN DIABETES

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Introduction: A diabetes treatment by encapsulated islets of Langerhans in a semipermeable membrane is seen as the future immunosuppression-free therapy. This principle, however, has not resulted in broadly accepted biomaterials for clinics yet due to several reasons. Biocompatibility with respect to humans is understood as one of the most critical issues to be resolved in steps toward clinical trials.

Objectives: The objective is to identify suitable polymeric microcapsules aimed at encapsulation of islets in terms of both functionality and safety. This work combines the design of microcapsules with immunological approach represented by the human whole blood assay.

Methods: Polyelectrolyte complex-based microcapsules were prepared from sodium alginate, cellulose sulfate and poly(methylene-co-guanidine) hydrochloride. Surface of microcapsules was coated either by cellulose sulfate, or heparin, or photo-sensitive biomimetic copolymer. Human whole blood anticoagulated with lepirudine was used to measure complement, cytokines and leukocyte up-regulation by microcapsules.

Results: Microcapsules successfully tested in vivo in baboons with the absence of fibrotic overgrowth activated complement in human whole blood assay. Therefore several modification steps to encapsulation protocol in terms of selecting polymers and varying the type of final coat were employed. These steps resulted in significantly reduced stimulation of complement, which in several cases was at the level of control.

Conclusion: The biocompatibility of microcapsules toward the clinical trials can be reliably supported by the human whole blood assay linking the microcapsule design with stimulation of, importantly, the human immune system.

POLYCYSTIC OVARIAN SYNDROME AND VENTRICULAR REPOLARIZATION: IS THERE A RELATIONSHIP?

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Introduction: Cardiovascular consequences of polycystic ovarian syndrome (PCOS) have been investigated intensively. The aim of this study was to evaluate the alterations of repolarization characterized by conventional ECG parameters in PCOS.

Patients and methods: 25 PCOS patients (age: 30.8±1.0 years, BMI: 32.3±1.8 kg/m^2, blood glucose: 4.7±0.1 mmol/l, HbA1c: 5.6±0.1%, serum insulin: 15.4±2.8 mU/l, HOMA-IR: 3.26±0.57, serum testosterone: 1.74±0.15 nmol/l; mean±SEM) and 25 healthy controls (age: 30.8±2.0 years, BMI: 22.9±0.7 kg/m^2, blood glucose: 4.6±0.1 mmol/l, HbA1c: 5.4±0.1%, serum insulin: 8.2±1.2 mU/l, HOMA-IR: 3.74±0.25, serum testosterone: 0.77±0.08 nmol/l) were enrolled into the study. ECGs were recorded and analyzed off-line. The repolarization was characterized by QT and corrected QT (QTc) intervals. The spatial and temporal repolarization inhomogenity were specified by QT dispersion (QTd) and short-term QT interval variability (QTV), respectively. Autonomic function was assessed by means of cardiovascular reflex tests.

Results: QT and QTc intervals revealed shortening in PCOS compared to the control group (QT: 377±6.2 ms *vs* 398±4.8 ms, p=0.017, QTc: 416±3.7 ms *vs* 430±3.2 ms, p=0.005; PCOS *vs* kontroll). Comparison of the two groups indicated no difference in the QTd (30.4±1.76 ms *vs* 29.7±1.81 ms, p=0.764). The QTV, however, was enhanced in the PCOS patients relative to those for the control group (4.27±0.29 ms *vs* 3.14±0.25, p=0.00003). The autonomic function was similar in both groups.

Conclusions: In PCOS homogeneous shortening of QT interval was detected. The change of repolarization time may reflect the effect of the higher testosterone level. The increased short-term QT variability may be indicative of attenuated repolarization reserve.

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POSTER NR. 33.

GLUCOMEN®DAY CONTINUOUS GLUCOSE MONITOR: ASSESSMENT OF SAFETY AND ACCURACY PERFORMANCE IN TYPE-1-DIABETIC PATIENTS

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Introduction: Continuous subcutaneous glucose monitoring (CGM) gives full pictures of daily glucose excursions allowing better adjustment of insulin therapy in diabetes.

Objectives: The aim of the present study was to assess both safety and accuracy of the newly-developed microdialysis based GlucoMen®Day system (A. Menarini Diagnostics)

Material and Methods: In twenty type-1-diabetic patients (9 female, age 41±11 years, diabetes duration 21±10) years, BMI 24.4±3.0kg/m2, HbA1c 7.6±0.7%) the GlucoMen®Day system was investigated over 5 consecutive days with alternating in-patient visits (around meal/insulin challenges) and home study phases. During in-patient visits, arterialised-venous blood samples were analysed using a Super GL glucose analyser; at home the patients performed capillary glucose measurements five times per day using a study-specific glucometer. The CGM signal was calibrated against capillary reference data using two calibration points on the first study day and one calibration point/day for the remaining study period.

Results: All patients tolerated the GlucoMen®Day system well. One subject was withdrawn due to a defect in the monitoring setup. Overall, a total of 1678 hours of useful CGM profiles was collected (88±15h per patient). Over the 5-days study period, 843 capillary and 349 venous reference glucose data were obtained. 98.6% of the CGM/reference data pairs fell within the A+B zones of the Clarke Error Grid Analysis. Median Absolute Relative Error and Median Absolute Rate Deviation were 10.5% and 0.81 mg/dL/min, respectively.

Conclusion: The GlucoMen®Day system was able to accurately track the changes in glycemia in type-1-diabetic patients both in daily life as well as during insulin/glucose challenges.

THE EFFICACY OF GLICLAZIDE MR AS THE FIRST OR SECOND LINE THERAPY IN PATIENTS WITH TYPE 2 DIABETES MELLITUS IN UKRAINE

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Introduction: Diabetes mellitus represents the major problem for the medicine and society in Ukraine taken into the consideration the high prevalence of the disease, the late diagnosis of patients with type 2 diabetes and the difficulties in achieving the good metabolic control in the majority of the patients.

Objective: The aim of this study was to investigate the possibility of the achieving the good metabolic control by prescribing Gliclazide in the large cohort of patients with type 2 diabetes mellitus previously untreated or treated with sulphonylurea or metformin.

Materials and Methods: We enrolled 664 patients with type 2 diabetes mellitus aged 58.5±9.35 year, BMI – 30.3±4.80 kg/m^2, diabetes duration – 3.3±3.8 year (data are presented as mean ± SD). Patients were divided into 3 groups – those who did not take any antihyperglycemic medications (339 patients, aged 58.3±9.72 year), patients who were treated by sulphonylurea (184 patients, aged 59.8±9.01 year) and those who were on metformin (141 patients, aged 57.2±8.93 year). All those patients were prescribed Gliclazide MR (modified release, one pill contains 60 mg) in the dose of 60-90 mg once daily as the monotherapy in the first group of patients, as the change from previously prescribed sulphonylurea in the second group or in addition to metformin in the third group. The dose of Gliclazide MR was adjusted up to 120 mg qd based on the fasting glucose levels every 2 weeks and the final assessment was performed after 3 months of the treatment.

Results: All patients in all three groups had high basal HbA1c levels – 9.38±1.99 %, 9.33±1.62% and 9.41±1.62% in those patients who were drug-naïve, on sulphonylurea or metformin, respectively. We found that prescription of Gliclazide MR led to the significant drop of HbA1c levels in all 3 groups of patients studied. In those patients who were drug-naïve we observed the decrease of HbA1by 2.32% till 7.06%, $p<0.001$ compared to the basal value. In the second group of patients HbA1c decreased by 1.87% till 7.46%, $p<0.001$ and in those treated with metformin addition of Gliclazide MR resulted in the drop of HbA1c by 2.0% till 7.42%, $p<0.001$. For the entire cohort of patients studied the goal levels of HbA1c below 7.0% were achieved in 52.8% cases. In all groups of patients the majority of patients required Gliclazide MR in the dose of 120 mg qd.

Conclusion: We may conclude that intensive antihyperglycemic treatment with the prescription of Gliclazide MR resulted in the significant improvement of the glucose control in the large cohort of patients in Ukraine.

POSTER NR. 10.

COMPARISON OF BONE MINERAL DENSITY AND ULTRASOUND PARAMETERS IN PATIENTS WITH POLYCYSTIC OVARIAN SYNDROME AND TYPE 2 DIABETIC WOMEN

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Introduction: Skeletal health inpatients with patients with polycystic ovarian syndrome and T2DM is an area of interest and controversy. Quantitative ultrasound anddual-energy X-ray absorptiometry techniques are helpful in detecting bonedeficits in patients.

Objectives: The aim of the study was to compare the bone mineral density measurements and quantitative ultrasound parameters between the patients with polycystic ovarian syndrome and the body mass index matched type 2 diabetic women.

Methods: Ten women with PCOS were weight-matched to 17 women with T2DM. Lumbar spine bone mineral density (BMD), femoral neck BMD were measured by DXA. The QUS examination consisted of measuring the attenuation (BUA) and the speed of the ultrasound (SOS) transversing the calcanei. Differences between the groups were analyzed by Student's t-test. Correlation analysis was also performed between QUS and BMD measurements in both groups.

Results: Patients with T2DM had higher BMD in the lumbar spine than patients with PCOS (1,09g/cm2 vs 0.992 g/cm2, p=0.04), but we found no statistically significant differences in the femoral neck density. QUS measurements showed similar values in both groups: BUA (70.3 dB/Mhz vs 68.7 dB/Mhz, p=0.378), SOS (1531 m/s vs1532 m/s, p=0.578). There was a moderate and significant positive relationship between SOS and BMD measurements in both groups.

Conclusion: Differences in bone mass as measured by DXA and QUS in PCOS and T2DM women do not change in parallel. Our results indicate that QUS can provide useful information in the skeletal assessment of patients with PCOS and T2DM.

POSSIBILITY OF THE PAIN SYNDROME RELIEF IN SENSOMOTOR DIABETIC NEUROPATHY

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Introduction: The neuropathic pain is a typical manifestation of a sensomotor form of diabetic neuropathy (DN). Therapeutic possibilities of the pain syndrome relief in DN include the using of the anticonvulsive drug gabapentin.

Objectives: To estimate the efficacy of gabapentin (Gabagamma) in patients with neuropathic pain due to sensomotor form of DN.

Methods: The study group included 22 patients with DN and evident pain syndrome; the intensity of pain according to visual analogue scale (VAS) was >4points. All patients received Gabagamma during 4 weeks; initial dosage 300mg/day was titrated to 1500mg/day. An intensity of pain during a day and night (VAS), an intensity of convulsive syndrome and dysesthesiae according to 3-point scale, indices of neuropathic symptomatic count (NSC) and neuropathic dysfunctional count (NDC) were used as primary end-points. Secondary end-points included a subjective assessment of treatment efficacy according to the questionnaire MOSSF-36.

Results: After treatment with Gabagamma neuropathic pain syndrome measured by VAS significantly decreased from 7.2±0.8 to 5.1±2.1 during a day; from 7.6±2.8 to 4.5±2.2 during a night. Convulsions' intensity reduced from 1.8±0.7 to 1.1±0.4; dysesthesiae from 2.4±0.5 to 1.5±0.5. NSC decreased from 4.3±1.3 to 3.5±1.2; NDC from 14.3±5.3 to 12.9±5.8. Analysis of secondary end-points has shown positive dynamics of indices in 80% of patients. Patients pointed to less suppressed daily activity and improved emotional state.

Conclusion: Significant improvement of primary and secondary end-points after 4 week of therapy allowed concluding that Gabagamma is an effective drug for amelioration of the neuropathic pain in patients with DN.

POSTER NR. 5.

IMPAIRED GLUCOSE TOLERANCE ASSOCIATED NEURAL DYSFUNCTION: ARE CARDIOVASCULAR RISK FACTORS OF IMPORTANCE?

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Introduction: It is well known that cardiovascular risks factors have a role in the development of neuropathy in patients with diabetes mellitus. We have already proved that autonomic and sensory neuropathy can be also demonstrated in impaired glucose tolerance. The aim of our study was to evaluate whether traditional cardiovascular risk factors are associated with the presence of neuropathy in patients with IGT.

Objectives: We examined 75 patients with IGT (age: 58.67±11.05 years, fasting blood glucose 5.63±0.58 mmol/l; 120 min blood glucose: 8.74±0.96 mmol/l; HbA_{1c}: 6.03±0.30 %; x±SD).

Methods: Cardiovascular autonomic neuropathy was detected by standard cardiovascular reflex tests while heart rate variability (HRV) was characterized by the triangle index (HRV_{ti}). Sensory function was assessed by using Neurometer R device, Medoc equipment, and Rydel-Seiffer calibrated tuning fork.

Results: Autonomic neuropathy was demonstrated in 43 patients with IGT, while sensory neuropathy was proved in 49 cases. No significant differences were found assessing traditional cardiovascular risk factors comparing IGT patients with and without sensory neuropathy (systolic blood pressure:125.9±12.3 vs. 126.6±11.1 mmHg, p=0.57; diastolic blood pressure: 75.2±7.4 vs. 75.0±5.5 mmHg, p=0.89; BMI: 29.5±4.3 vs. 30.8±5.4 kg/m^2, p=0.48; serum total cholesterol: 4.8±1.0 vs. 5.4±1.3 mmol/l, p=0,07; triglycerides: 1.5±1.1 vs. 1.5±0.7 mmol/l, p=0,31; HDL-cholesterol: 1.4±0.4 vs. 1.4±0.4 mmol/l, p=0,32; smoking: 0.18±0.4 vs. 0.24±0.4, p=0,57;). The same observation has been confirmed comparing IGT subjects with and without autonomic neuropathy.

Conclusion: Our data suggested that rather glucose intolerance itself than cardiovascular risk factors might contribute the development of neuropathy among patients with impaired glucose tolerance.

DIABETIC EYE AND FOOT CARE PROJECT IN MOLDOVA

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Introduction: Today Moldova is going through a very difficult period of economical and political crisis. In spite of efforts made by government, access to qualified diabetes care is limited and inadequate.

Objectives: The aim of the project is to improve prevention, diagnosis and treatment of diabetic eye and foot complications in all districts of Moldova.

Methods: Project was initiated in 2011 by Association for Study of Chronic Diseases and funded by WDF.

Project has 3 phases (1 phase=1year). 1st phase: Establishment of the Centre of Diabetes Complications in Chisinau, which was equipped to provide complete eye and foot care services. Educational materials were elaborated. 2nd phase: Training of healthcare providers. A mobile unit was launched to conduct training and mass screening of diabetes in rural areas. 576 doctors will be trained at camps held in each of the 36 districts. 3rd phase: Screening. 2-3 times a month a team of two ophthalmologists and two surgeons will conduct screening, reaching the remote areas of the country. It is estimated that 7,000 consultations will be conducted by the mobile unit. With the support from the MoH awareness activities are performed throughout the project period. A patient database was established serving as monitoring and research tool.

Conclusion: "Diabetic Eye and Foot Care" project: 1. Improves prevention and treatment of eye and foot diabetes complications and access to them by diabetic patients; 2. Establishes a diabetes training system for health care providers; 3. Provides education and awareness raising activities.

SELECTED ORAL PRESENTATION

EARLY, TEMPORARY INSULIN THERAPY IN PATIENTS WITH NEWLY DIAGNOSED TYPE-2 DIABETES MELLITUS

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Introduction: In some cases, when certain concomitant conditions are present so that the patients' metabolic state cannot be improved with oral antidiabetic agents, early insulin administration is required. Some patients show significant improvement of ß-cell function, allowing the insulin therapy to be suspended within a few months.

Objectives: 109 type-2 diabetic individuals treated with initial insulin administration were found by searching the digital medical documentation. In 13 cases, the necessity of insulin therapy proved to be temporary. A retrospective analysis of the latter patients' data was carried out.

Methods: The focus of our investigation included initial insulin-regimen, concomitant OHA-therapy, gender, age (4 females, 9 males, 51,76+/-12,43 years), metabolic parameters (FBG 10,42+/-1,71 mmol/l, PPBG 19,21+/-6,03 mmol/l, HgbA1c 10,54+/1,13% serum total cholesterol 6+/-1,07 mmol/l, serum triglyceride 3,52+/-0,7 mmol/l, BMI (31,72+/-7,89 kg/m2), waist circumference (107,69+/-1,13 cm), the occurrence of vascular complications.

Results: Human premixed preparations and human ICT regimens were administered in 2 and 11 cases, while additional metformin therapy in 8 patients. At the point of interruption of insulin therapy 9 patients were treated with OHA-s, while in 4 cases dietary restrictions alone provided normoglycaemia. The duration of insulin therapy was 6,46+/-3,4 months. We found that additional metformin therapy increased the likelihood of temporary insulin treatment.

Conclusion: Vascular complications were less frequent compared to the individuals on permanent insulin therapy, which suggests a shorter duration of disease. Patients with temporary insulin treatment showed disciplined behaviour in terms of both lifestyle changes and adherence to medication.

MICROCAPSULES FOR IMMUNOPROTECTION OF TRANSPLANTED ISLETS IN DIABETES TREATMENT: STEPS TOWARD THE CLINICS

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Introduction: A diabetes treatment by encapsulated islets of Langerhans in a semipermeable membrane is seen as the future immunosuppression-free therapy. This principle, however, has not resulted in broadly accepted biomaterials for clinics yet due to several reasons. Biocompatibility with respect to humans is understood as one of the most critical issues to be resolved in steps toward clinical trials.

Objectives: The objective is to identify suitable polymeric microcapsules aimed at encapsulation of islets in terms of both functionality and safety. This work combines the design of microcapsules with immunological approach represented by the human whole blood assay.

Methods: Polyelectrolyte complex-based microcapsules were prepared from sodium alginate, cellulose sulfate and poly(methylene-co-guanidine) hydrochloride. Surface of microcapsules was coated either by cellulose sulfate, or heparin, or photo-sensitive biomimetic copolymer. Human whole blood anticoagulated with lepirudine was used to measure complement, cytokines and leukocyte up-regulation by microcapsules.

Results: Microcapsules successfully tested in vivo in baboons with the absence of fibrotic overgrowth activated complement in human whole blood assay. Therefore several modification steps to encapsulation protocol in terms of selecting polymers and varying the type of final coat were employed. These steps resulted in significantly reduced stimulation of complement, which in several cases was at the level of control.

Conclusion: The biocompatibility of microcapsules toward the clinical trials can be reliably supported by the human whole blood assay linking the microcapsule design with stimulation of, importantly, the human immune system.

SELECTED ORAL PRESENTATION

THE METABOLIC SYNDROME SIGNIFICANTLY AFFECTS THE ASSOCIATION BETWEEN RESTING HEART RATE AND ALL CAUSE AS WELL AS CARDIOVASCULAR MORTALITY

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Introduction: Epidemiological studies suggest that the resting heart rate(RHR) is an independent predictor of cardiovascular and all cause mortality. However, the power of the RHR to predict cardiovascular events in patients with the metabolic syndrome (MetS) is not known.

Methods: We prospectively investigated the relationship between RHR and cardiovascular events in 756 consecutive patients undergoing coronary angiography for the evaluation of coronary artery disease (CAD) over a follow-up period of 7.1±0.1 years. The (MetS) was defined according to NCEP-ATPIII criteria.

Results: In the total study population, all cause and cardiovascular mortality were increased with an increasing RHR (standardised adjusted HRs 1.03[1.01-1.04];p=0.001 and 1.15[1.03-1.47];p=0.001, respectively). From our patients, 357(47.2%) had the MetS and 399 didn't have it. Among patients without the MetS, a higher baseline RHR indicated a significantly higher risk of total mortality (HR=1.14[111–1.16],p=0.001) and cardiovascular mortality (HR=1.13[1.12–1.16],p=0.001) after multivariate adjustment. The RHR didn't significantly affect total mortality (p=0.120) or cardiovascular mortality (p=0.244) in patients with the MetS. Interaction terms RHRxMetS were significant for total and cardiovascular mortality (p=0.027 and p=0.037, respectively), indicating that the respective risks conferred by a high RHR were significantly higher in patients without the MetS than in patients with MetS.

Conclusion: Among angiographically characterized coronary patients, the MetS status significantly affects the association of the RHR with total and cardiovascular mortality: RHR is a strong predictor of both total and cardiovascular mortality among subjects without the MetS, but not among MetS patients.

SERUM OMENTIN IS NEITHER ASSOCIATED WITH THE METABOLIC SYNDROME NOR WITH ANGIOGRAPHICALLY DETERMINED CORONARY ARTERY DISEASE

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Introduction: Some recent small studies have decribed associations of the new adipocytokine omentin with the metabolic syndrome (MetS) and with cardiovascular disease. However, data still are very scarce.

Materials and Methods: We therefore measured serum omentin in 395 patients undergoing coronary angiography for the evaluation of established or suspected stable CAD; the MetS was defined according to NCEP-ATPIII criteria; significant CAD was diagnosed when coronary stenoses ≥50% were present.

Results: Omentin was positively correlated with age (r=0.170; p <0.001) but did not show significant correlations with waist circumference, fasting glucose, HDL cholesterol, triglycerides, systolic blood pressure, or diastolic blood pressure; it was similar in MetS patients (n=118) as in subjects without the MetS (15±21 vs. 14±15 ng/ml; p=0.460). Omentin also did not differ significantly between patients with significant CAD (n=190) and those without significant CAD (14±19 vs. 15±15 ng/ml; p=0.233). When both, MetS and CAD status were considered, chemerin similar in MetS patients as in subjects without the MetS both among those who had significant CAD (15±13 vs. 15±13 ng/ml; p=0.482) and among those who did not have significant CAD (16±30 vs. 14±15 ng/ml; p=0.876); it further did not differ significantly between patients with significant CAD and subjects without significant CAD among MetS patients (p=0.321) nor among subjects without MetS (p=0.452).

Conclusion: We conclude that omentin is neither associated with the MetS nor with angiographically determined CAD. Omentin therefore does not appear to be a useful marker of cardiometabolic disease.

POSTER NR. 23.

ANGIOPOIETIN-LIKE 4 IS ELEVATED IN TYPE 2 DIABETES BUT IS NOT ASSOCIATED WITH ANGIOGRAPHICALLY DETERMINED CORONARY ARTERY DISEASE

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Introduction: Angiopoietin-like 4 (ANGPTL4, fasting-induced adipose factor), a protein inhibitor of lipoprotein lipase, is synthesized and secreted during fasting in adipose tissue and the liver. Its associations with metabolic syndrome traits are uncertain, and it is not known whether it is associated with type 2 diabetes (T2DM) or coronary artery disease (CAD).

Materials and Methods: We therefore measured serum ANGPTL4 in 493 patients undergoing coronary angiography for the evaluation of established or suspected stable CAD; significant CAD was diagnosed when coronary stenoses ≥50% were present.

Results: ANGPTL4 was significantly positively correlated with age ($r=0.177$; $p<0.001$) and fasting glucose ($r=0.112$; $p=0.013$) but was not correlated with waist circumference, triglycerides, HDL cholesterol, systolic blood pressure or diastolic blood pressure. ANGPTL4 was significantly higher in patients with T2DM (n=115) than in non-diabetic subjects (28±32 vs. 25±38; $p=0.032$); however, it was not significantly different between patients with significant CAD (n=246) and individuals without significant CAD ($p=0.112$).

Conclusion: We conclude that ANGPTL4 is positively correlated with fasting glucose and elevated in T2DM but is not significantly associated with angiographically determined CAD.

CHEMERIN IS ASSOCIATED WITH THE METABOLIC SYNDROME BUT IS NOT LINKED TO ANGIOGRAPHICALLY DETERMINED CORONARY ARTERY DISEASE

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Introduction: The adipocytokine chemerin has been suggested to be linked to insulin resistance and to the metabolic syndrome (MetS). Its association with coronary artery disease (CAD) is unclear. Is chemerin associated with both angiographically determined CAD and with the MetS?

Materials and Methods: We measured serum chemerin in 498 patients undergoing coronary angiography for the evaluation of established CAD; the MetS was defined according to NCEP-ATPIII criteria; significant CAD was diagnosed when coronary stenoses ≥50% were present.

Results: Chemerin was higher in MetS patients (n=150) than in subjects without the MetS (184±77 vs. 150±62 ng/ml; $p<0.001$). It didn't differ significantly between patients with CAD (n=250) and those without significant CAD ($p=0.327$). When both, MetS and CAD status were considered, chemerin was higher in MetS patients among those who had significant CAD (182±80 vs. 152±60 ng/ml; $p=0.002$) and among those who did not have significant CAD (187±73 vs. 148±63 ng/ml; $p<0.001$); it didn't differ significantly between patients with significant CAD and subjects without significant CAD among MetS patients ($p=0.248$) nor among subjects without MetS ($p=0.263$). Analysis of covariance (ANCOVA) showed that from the NCEP-ATPIII metabolic syndrome traits a large waist circumference as well as elevated trigylcerides were independent predictors of elevated serum chemerin ($F=12.5$; $p<0.001$ and $F=8.5$; $p=0.004$).

Conclusion: Chemerin is significantly associated with the MetS but not with angiographically determined CAD. The association of chemerin with the MetS is carried by its association with visceral obesity and elevated triglycerides.

POSTER NR. 29.

KEY ROLE OF LOW HDL CHOLESTEROL FOR THE ASSOCIATION OF THE METABOLIC SYNDROME WITH INFLAMMATION IN PATIENTS WITH PERIPHERAL ARTERIAL DISEASE

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Introduction: The association of the metabolic syndrome (MetS) and of the individual MetS stigmata with inflammation in patients with peripheral arterial disease (PAD) has not been investigated yet.

Methods: We enrolled 410 consecutive patients who underwent routine duplex sonography for the evaluation of suspected or established PAD Fontain stages I-III and in whom PAD was verified sonographically. According to National Cholesterol Education Programme Adult Treatment Panel III criteria, the MetS was defined in the presence of at least 3 out of the 5 quantitatively defined criteria large waist circumference, low HDL cholesterol, high triglycerides, high blood pressure, and elevated fasting glucose.

Results: In univariate analyses, CRP was higher in patients with the MetS (n=200) than in those who didn't have the MetS (0.94±1.88vs.0.56±1.18mg/dl;p=0.001), and also was higher in patients who fulfilled the large waist (0.93±1.93vs.0.59±1.16mg/dl;p =0.009) and the low HDL criteria (1.10±1.66vs.0.61±1.52mg/dl;p<0.001) than in those who did not. After adjustment for gender, smoking, BMI and LDL cholesterol by means of ANCOVA only the low HDL cholesterol criterion (F=6.06;p=0.014) remained significantly associated with CRP. The significant and independent association of low HDL with CRP was confirmed after additional adjustment for all other MetS traits (F=7.76;p=0.006).

Conclusion: Among patients with sonographically proven PAD, low HDL cholesterol drives the association between the MetS and subclinical inflammation. This observation is well in line with the paramount role of low HDL cholesterol as a marker of cardiovascular risk.

LIPID PARAMETERS IN ACUTE CORONARY SYNDROMES VERSUS STABLE CORONARY ARTERY DISEASE IN SUBJECTS WITH AND WITHOUT METABOLIC SYNDROME

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Introduction: Differences in lipid parameters between patients with acute coronary syndromes (ACS) and patients with stable coronary artery disease (CAD) are unclear and are addressed in the present study.

Methods: We enrolled 582 patients with angiographically proven stable CAD (of whom 37.2% had the diagnosis of the MetS according to NCEP-ATPIII criteria and 182 patients with ACS (of whom 33.9% had MetS according to NCEP ATPIII criteria).

Results: When compared to patients with stable CAD, HDL-c and apolipoprotein A1 were significantly lower in patients with ACS among subjects with the MetS (38±9mg/dl vs.48±13mg/dl;p<0.001 and 139±30mg/dl vs.14±25 mg/dl;p<0.001, respectively) as well as among subjects without the MetS (52.4±17mg/dlvs.60.3±15mg/dl;p=0.001 and 147.3±31mg/dl vs.157.2±26mg/dl;p=0.003, respectively). Analysis of covariance (ANCOVA) adjusting for age, gender, smoking, BMI, and hypertension confirmed an independent impact of the ACS state on these lipid parameters both among patients with the MetS and among subjects without MetS. Total cholesterol, LDL-c and apolipoprotein B neither in subjects with the MetS (182±41mg/dl vs.197±48mg/dl;p=0.583vs.120±43mg/dl vs. 130±42mg/dl;p=0.884 and 84±23mg/dl vs.83±24mg/dl;p=0.834) nor among subjects without MetS (191±50mg/dlvs.193±47mg/dl;p=0.583vs.124±42mg/dlvs.124±45 mg/dl;p=0.884 and 84±23mg/dlvs.83±24mg/dl;p=0.834), differed significantly between ACS and stable CAD patients. There were no significant differences in triglycerides between patients with ACS and patients with stable CAD, neither among subjects with the MetS (187±85mg/dl vs.184±99mg/dl;p=0.160) nor among subjects without the MetS (114±49 mg/dl vs. 111±67mg/dl;p=0.891).

Conclusion: Both among patients with the MetS and among non-MetS individuals, HDL-c and apolipoprotein A1 are lower in the ACS state than with stable CAD.

POSTER NR. 31.

JAK3 TAG SINGLE NUCLEOTIDE POLYMORPHISM RS3212780 IS SIGNIFICANTLY ASSOCIATED WITH DIABETES-RELATED METABOLIC PHENOTYPES

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Introduction: Janus kinase (JAK) 3 is involved in cytokine receptor-mediated intracellular signal transduction. Inhibition of JAK3 protects beta-cells from cytokine toxicity and has been shown to delay the onset of diabetes in the mouse model. The influence of JAK3 single nucleotide polymorphisms (SNPs) on diabetes risk or on diabetes-related metabolic traits is unknown.

Materials and Methods: We therefore investigated the association of JAK3 tagging SNP rs3212780 (C>T) with metabolic phenotypes and type 2 diabetes (T2DM) in a cohort of coronary patients including 1220 non-diabetic subjects and 375 patients with T2DM, totally comprising 1595 individuals.

Results: Among non-diabetic subjects SNP rs3212780 was significantly associated with HbA1c (CC: 5.8±0.4, CT: 5.7±0.4, TT: 5.6±0.4%; p=0.001), fasting glucose (CC: 5.4±0.7, CT: 5.3±0.7, TT: 5.5±1.1 mmol/L; p=0.010), and HDL-cholesterol (CC: 55±17, CT: 55±16, TT: 51±16 mg/dL; p=0.009), as well as with total cholesterol (CC: 212±44, CT: 206±46, TT: 196±48 mg/dL; p=0.002) and LDL-cholesterol (CC: 134±37, CT: 131±40, TT: 124±42 mg/dL; p=0.013). In patients with T2DM, the JAK3 variant was significantly associated with fasting glucose (CC: 8.3±2.7, CT: 8.7±2.8, TT: 7.4±1.9 mmol/L; p=0.036). The association between SNP rs3212780 and T2DM did not reach statistical significance (allelic odds ratio=1.18 [0.98-1.40]; p=0.076).

Conclusion: We conclude that JAK3 tagging SNP rs3212780 is significantly associated with phenotypes conferring an increased cardiometabolic risk, at least in non-diabetic coronary patients. The association between rs3212780 and the risk of T2DM warrants further investigation.

DIAGNOSIS OF THE GESTATIONAL DIABETES MELLITUS: WHO VS. IADPSG CRITERIA

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Inroduction: The International Association of Diabetes and Pregnancy Study Groups (IADPSG) suggested new criteria for diagnosis of diabetes in pregnancy. Novel blood glucose cut-off values and a new standard arrangement are recommended for the oral glucose-tolerance test (OGTT).

Objects: Comparison of diabetes screening in pregnancy (GDM) according to the World Health Organisation (WHO) and IADPSG criteria interms of prevalence of macrosomy and other pregnancy outcome measurements.

Methods: 733 women underwent between the 24-28th gestational weeks a 2-hour 75-g OGTTevaluated according to the WHO (0., 120. min) and IADPSG criteria (0., 60. and 120. min blood glucose values). Women shown to have any alterations by each of the screening methods were referred to complex pregnancy care. Pregnancy outcomes were analysed in both groups and compared to normal pregnants.

Results: 545 pregnants were normoglycaemic according to both criteria. According to the WHO classification 96 participants, additionally based on IADPSG criteria 92 women were diagnosed as GDM. (All diabetic mothers considering WHO criteria had diabetes also according to IADPSG criteria.) Pre-pregnancy body mass index and the weight gain during pregnancy was higher in the IADPSG group. Preterm birth was observed in 4.8% among the controls, whereas it was 6.3 (WHO-group) and 6.5% (IADPSG-group). There were no differences in perinatal outcomes including the prevalence of macrosomy.

Conclusion: A higher GDM rate was diagnosed according to the IADPSG screening criteria as compared to those of WHO. Consequently, a potentially higher number of adverse pregnancy outcomes might be prevented by complex pregnancy care.

POSTER NR. 16.

INDEPENDENT ASSOCIATION BETWEEN VITAMIN D LEVELS AND INSULIN SENSITIVITY AND b-CELL FUNCTION AMONG WOMEN WITH PRIOR GDM

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Aims: Accumulating evidence suggests that vitamin D (VD) deficiency might play a role in the development of type 2 diabetes and insulin resistance. Since women with prior GDM have a substantially increased risk of incident diabetes at a young age, we aimed to compare VD levels between prior GDM women and controls and to investigate the association between insulin sensitivity (IS) / b-cell function (BCF) and VD levels.

Methods: A retrospective cohort study of women who had been diagnosed with GDM (WHO criteria 1997, n=87, age: 34.8±4.4 [mean±SD] yrs, BMI: 25.9±5.9 kg/m^2) and of a matched healthy female control group (n=45, age: 33.8±3.6 ys, BMI: 24.3±4.4 kg/m^2) all of whom had had a prior pregnancy without any diagnosis of diabetes 3.2±0.6 yrs after delivery. Smoking, leisure-time physical activity, height, weight, waist circumference, and blood-pressure were assessed. HbA1c, blood lipids, liver enzymes, and serum 25(OH)-D-vitamin levels were assessed. Glucose tolerance was determined by a 75g oGTT. Serum glucose and insulin were determined during the oGTT. IS and BCF were estimated by the HOMA2 calculator and by Insulinogenic Index (II).

Results: VD levels were similar in prior GDM and control women (27.2±13.1 vs. 26.9±9.8 ng/l, P NS) as well as between glucose intolerant and normal glucose tolerant women (24.6±10.2 vs. 28.1±12.6 ng/l, P NS) at follow-up. There was a positive association between IS (measured either by HOMA or fasting insulin) and VD levels even after adjustment for waist circumference (standardized coefficient 0.19, P<0.05). According to a multiple regression with backward elimination HOMA IS was independently related to fasting glucose waist, gGT, triglycerides, age, and vitamin D levels (r^2=0.43 for the model). HOMA BCF tended to be negatively associated with VD levels even after adjustment for waist circumference (standardized coefficient -0.15, P<0.1). According to a multiple regression model the independent determinants of BCF were gGT, waist, triglycerides, age, and vitamin D levels (r^2=0.26 for the model). Vitamin D levels were not related to II.

Conclusions: While neither prior GDM nor current glucose intolerance was associated with decreased levels of VD, we found an independent association between IS, BCF and VD levels suggesting that low levels of VD may be a cause or a consequence of insulin resistance and (a compensatory) increased insulin secretion. Longitudinal investigations are warranted to prove or dysprove these hypotheses.

PREVALENCE OF PREDIABETES AMONG PATIENTS WITH PERIPHERAL ARTERIAL DISEASE AND NO HISTORY OF DIABETES

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Introduction: Atherosclerotic arterial disease manifests as coronary, cerebrovascular or peripheral arterial disease (PAD). It is well establisdhed that large proportion of patients suffering myocardial infarction or stroke have unknown abnormal glucose metabolism. There are few studies reporting data on the prevalence of dysglycemia in PAD patients, and there are no such data available in Hungary.

Objectives: We wanted to examine prevalence of abnormal glucose metabolism in Hungarian PAD patients without known diabetes using fasting plasma glucose (FPG) data and OGTT.

Methods: Between January 1 and June 10, 2009 at our department of vascular surgery 565 PAD patients were treated of whom 188 had known diabetes (33%) at admission. During this period we performed OGTT in 96 consecutive PAD patients (80 men, 16 women, mean age 62±10 years) without known diabetes.

Results: From our PAD patients without previously known diabetes 46 (48%) had abnormal glucose metabolism: 10 (10%) had diabetes 26 (27%) had impared glucose tolerance (IGT), 7 (7%) had impared fasting glucose (IFG), and 3 (3%) had IFG+IGT. Most (74%) of the abnormalities could have only been diagnosed with OGTT.

Conclusion: We diagnosed abnormal glucose metabolism in large proportion (48%) of our 96 consecutive PAD patients with no previous diagnosis of diabetes. Prevalence of unknown prediabetes was very high (36%). Compared to FPG OGTT was a more effective tool for diagnosing IGT and diabetes. Routine screening with OGTT for abnormal glucose metabolism is reasonable in PAD patients with FPG<7mmol/l.

POSTER NR. 12.

ASSESSMENT OF THE POSSIBLE ROLE OF ALPHA- AND BETA DEFENSINS IN THE PATHOGENESIS OF DIABETIC COMPLICATIONS

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Introduction: Defensins are involved in inflammatory and proatherogenic processes, their possible role in the pathogenesis of diabetic micro- and macroangiopathy is assumed.

Objectives: The aim of this study was to analyse the genetic characteristics and the plasma levels of alpha- and beta-defensins in diabetic patients.

Methods: 98 type 1 and 135 type 2 diabetic patients and 221 controls were tested. ELISA, real-time PCR, Taq-Man based real-time PCR and Custom TaqMan® single nucleotide polymorphism (SNP) genotyping were applied.

Results: Alpha-defensin was higher (type 1 vs control: 29030±5650 vs 11940±2960 pg/ml, $p<0.001$; type 2 vs control: 29800±6010 vs 11940±2960 pg/ml, $p<0.001$, mean±SEM). The highest alpha-defensin was found in nephropathy (49200±1300 pg/ml vs. 23500±900 pg/ml; with vs without, $p<0.05$), neuropathy (36500±4900 pg/ml vs 25700±3500 pg/ml; with vs without; $p<0.05$) or cardiovascular complications (45600±1450 pg/ml vs 24500±2500 pg/ml; with vs without, $p<0.05$). Two SNPs of beta-defensin 1 (G20A and G52A) did not differ from the controls, while the frequency of the GG genotype in the SNP of C-44G allele was lower than the controls (2.5% vs 9.5%, $p<0.01$). This was more pronounced in neuropathy or nephropathy (1.2% vs 9,5%, $p<0.01$ and 1.5% vs 9.5%, $p<0.01$). The CC genotype of C-44G SNP was more frequent (65% vs 50%, $p<0.05$).

Conclusion: Diabetic patients had increased alpha-defensin levels, the highest values were observed in micro- or macrovascular complications. The presence of certain alleles of beta-defensin 1 seems to be protective against nephropathy or neuropathy. Both alpha- and beta-defensins might have a role in the pathogenesis of diabetic complications.

THE EFFECT OF THE OBSTRUCTIVE SLEEP APNEA ON THE NIGHT-TIME GLUCOSE VARIABILITY IN PATIENTS WITH THE METABOLIC SYNDROME

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Introduction: Obstructive sleep apnea (OSA) is often accompanied by metabolic syndrome (MetSyn). OSA increases the sympathetic activity, through which it can also influence the carbohydrate metabolism.

Objects: To analyse the connection between the apneaseverity and the night-time glucose variability, using the continuous glucosemonitoring system (CGMS).

Methods: Thirty-eight patients with theMetSyn (ATP III) from the diabetes outpatient clinic of the 1st Department of Internal Medicine at Semmelweis University, Budapest. 26 male; age: 60±14 (mean±SD) yrs; HbA1c: 7.1±1.2%; Body Mass Index: 33±7 kg/m^2. All patientsunderwent overnight polysomnography. OSA severity was defined with theapnea-hypopnoea index (AHI). Respiratory disturbance index (RDI) was alsomeasured. During the polysomnography intersticial glucose values were assessedusing CGMS.

Results: Eleven patients had severe, nine moderate and eightmild OSA, while 10 patients had an AHI of less than 5. In the moderate-severe OSAgroup the daily insulin dose was higher (54±57 vs. 19±31 IU; p=0.035), the average of the CGMS glucose values was lower (6.3±1.6 vs. 5.6±0.8; p=0.038), but the standard deviation (SD) (0.51±0.2 vs. 0.79±0.5; p=0.032) and theamplitude (2.1±0.7 vs. 3.2±1.7; p=0.028) of the CGMS data were also higher vs.normal-mild OSA group. We found a moderate positive correlation between RDI andboth the SD (r=0.367; p=0.039) and the amplitude (r=0,365; p=0,04) of the glucose values.

Conclusion: The severity of OSA is associated with thenight-time glucose variability in patients with the MetSyn. Higher glucosevariability may increase the oxidative stress that can worsen the cardiovascularoutcomes of patients with the MetSyn comorbid OSA.

POSTER NR. 34.

HEALTH POLICY DECISION MAKING IN DIABETOLOGY: FACTS AND TASKS IN HUNGARY

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Introduction: It is necessary to allocate available resources of healthcare system to sectors where the losses of health capital are significant, and the costs of care are high for both, the health care systemand the patients as well. The care of diabetes mellitus belongs to these areas.

Objectives: To assess the direct healthcare expenditures spent on diabetes in order to characterize the disease burden and to perform further health economics analyses.

Methods: Dataset of diabetes patients were derived from the database of the National Health Insurance Fund Administration (NHIF) for 2008. Patients with diabetes mellitus were divided into two groups according to obtaining inpatient or outpatient care. Groups receiving exclusively outpatient care according to the antidiabetic treatment were classified as 1) taking only oral antidiabetics (OAD), 2) taking only insulin, and 3) combined OAD and insulin users. The statistical figures of health insurance costs related to the cost items and the age-groups were determined in the sub-groups. Data of the patients with or without complications were analysed separately, and the loss of health capital were also examined, and the costs for the first two years in the group with complications.

Results: The annual health insurance expenditure for the 521,546 OAD/insulin patients was 335,000 Hungarian Forints (HUF) per patient. The costs were almost doubled for complicated cases (633,000 HUF). 242,000 HUF were spent for OAD-users with no complications, whereas the healthcare costs of the insulin group were 449,000 HUF per annum. Half of the expenses (53%) was paid for the reimbursement of pharmaceuticals (26% for OAD and insulin) and the quarter of the costs (27%) was covered for inpatient care. The direct health costs of the diabetes exceeded 0.65% of the national Gross Domestic Product (GDP) and reached 13% of the total public health care budget of the NHIF. The loss of health capital was 35.6% in blindness, 34.6% in amputation due to diabetic foot ulcer, while it was 21.3% following stroke. The expenditures of the inpatient care and the medication has been multiplied during the occurrence of complications.

Conclusion: The healthcare of diabetes, particularly the treatment of complications, represents major health expenses. Considering the burden of disease that manifests in premature mortality, reduction in quality of life, and high cost, and the epidemiological trends, diabetes mellitus should be a public health priority in Hungary. A National Diabetes Programme would be essential for the treatment and for a sustainable system. To calculate the effects of health policy programs and public interventions in diabetes mellitus, an open access health economic model would be highly beneficial.

DEVELOPMENT OF THE CLASSICAL THERAPEUTICAL PARADIGM IN NEUROPATHIC PAIN: FROM DRUGS TO PHYSICAL ANALGESIA

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Introduction: We present some contemporaneous theories of pain and therapeutic concepts of analgesia, including drug and physical analgesia. We mentioned different natural and preformed physical modalities, with effectiveness in clinical practice.

Goal: Comparative evaluation of drug, physical and combined analgesia on the peripheral radicular pain.

Material and methods: During last years a total of 105 in-patients with a spondylogenic radiculopathy are observed and investigated. Patients are randomized to three treatment groups of 35 each one. The investigation was conducted in accordance with consideration for the protection of patients, as outlined in the Declaration of Helsinki, and was approved by the appropriate institutional review boards and ethics commissions. All patients gave written informed consent before undergoing any examination or study procedure. Groups 1 received only drug therapy – paravertebral infiltrations with cortico-steroids, Milgamma N and local anesthetic. Patients of group 3 received only physical modalities [complex rehabilitation programme including transcutaneous electroneurostimulation (TENS), exercises, massages, sea lye compresses distally). In group 2 we applied drug and physical analgesia techniques.

For statistical evaluation we used t-test (ANOVA) and Wilcoxon rank test (non parametrical correlation analysis), performed using SPSS package. The treatment difference was considered to be statistically significant if the p value was < 0.05.

The comparative ANALYSIS of RESULTS shows a significant improvement of the symptoms of the patients, concerning pain relief (visualized by the analysis of results of Visual analogue scale), radiculopathy (Lassegue's sign), depression (scale of Zung). The drug analgesia in group 1 is fast, but short. The efficacy in group 3 is slow, but stable, and durable. We observed best results in group 2. We expose our own conception of pathogenetic mechanisms of physical analgesia.

Discussion: The drug therapy is efficient but with short duration. The physical analgesia initiates its effect slowly, but their results are stable. Best efficacy was observed in case of combination of medication with physical modalities – in the beginning due to non-steroidal anti-inflammatory drug, toward the moment of effective «input» of physical modalities.

Conclusion: We could recommend the complex program for treatment of the paravertebral pain.

Key words: physical modalities, steroids, neuropathic pain, analgesia

NOTES

NOTES

For your patients with type 2 diabetes on monotherapy when HbA_{1c} levels begin to rise above 7%

Onglyza®
Abbreviated Prescribing Information
Presentations. 2.5 mg and 5 mg film-coated tablets. Each tablet contains 2.5 mg or 5 mg saxagliptin (as hydrochloride). **Therapeutic indications.** *Add-on combination therapy:* Onglyza is indicated in adult patients with type 2 diabetes mellitus to improve glycaemic control: in combination with metformin, when metformin alone, with diet and exercise, does not provide adequate glycaemic control; in combination with a sulphonylurea, when the sulphonylurea alone, with diet and exercise, does not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate; in combination with a thiazolidinedione, when the thiazolidinedione alone with diet and exercise, does not provide adequate glycaemic control in patients for whom use of a thiazolidinedione is considered appropriate; in combination with insulin (with or without metformin), when this regimen alone, with diet and exercise, does not provide adequate glycaemic control. **Posology and method of administration.** *Add-on combination therapy:* the recommended dose of Onglyza is 5 mg once daily as add-on combination therapy with metformin, a thiazolidinedione or a sulphonylurea. The safety and efficacy of saxagliptin as triple oral therapy in combination with metformin and a thiazolidinedione, or with metformin and a sulphonylurea, has not been established. *Renal impairment:* no dose adjustment is recommended for patients with mild renal impairment. The dose of Onglyza should be reduced to 2.5 mg once daily in patients with moderate or severe renal impairment. The experience in patients with severe renal impairment is very limited. Therefore, saxagliptin should be used with caution in this population. Onglyza is not recommended for patients with end-stage renal disease (ESRD) requiring haemodialysis (see section 4.4). Because the dose of Onglyza should be limited to 2.5 mg based upon renal function, assessment of renal function is recommended prior to initiation of Onglyza, and, in keeping with routine care, renal assessment should be done periodically thereafter (see sections 4.4 and 5.2). *Hepatic impairment:* no dose adjustment is necessary for patients with mild or moderate hepatic impairment (see section 5.2). Saxagliptin should be used with caution in patients with moderate hepatic impairment, and is not recommended for use in patients with severe hepatic impairment (see section 4.4). *Elderly (≥65 years):* no dose adjustment is recommended based solely on age. Experience in patients aged 75 years and older is very limited and caution should be exercised when treating this population (see also sections 4.4, 5.1 and 5.2). *Paediatric population:* Onglyza is not recommended for use in children and adolescents due to lack of data on safety and efficacy. *Method of administration:* Onglyza can be taken with or without a meal at any time of the day. If a dose is missed, it should be taken as soon as the patient remembers. A double dose should not be taken on the same day. **Contraindications.** Hypersensitivity to the active substance or to any of the excipients, or a history of hypersensitivity to any DPP-4 inhibitor. **Warnings & Precautions.** *General:* Onglyza should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. *Use with medicinal products known to cause hypoglycaemia such as sulphonylurea or insulin:* a lower dose of sulphonylurea or insulin may be required to reduce the risk of hypoglycaemia when used in combination with Onglyza. *Pancreatitis:* from post-marketing experience there have been spontaneous reports of acute pancreatitis. Resolution has been observed after discontinuation of saxagliptin. *Hypersensitivity reactions:* from post-marketing experience , there have been spontaneously reported adverse reactions of serious hypersensitivity reactions (anaphylactic reaction, anaphylactic shock and angioedema; see section 4.8). If these conditions are suspected, discontinue Onglyza, assess for other potential causes for the event, and institute alternative treatment for diabetes. *Skin disorders:* ulcerative and necrotic skin lesions have been reported in extremities of monkeys in non-clinical toxicology studies (see section 5.3). Although skin lesions were not observed at an increased incidence in clinical trials, there is limited experience in patients with diabetic skin complications. Post-marketing reports of rash have been described in the DPP-4 inhibitor class. Rash is also noted as an adverse event (AE) for Onglyza (section 4.8). Therefore, in keeping with routine care of the diabetic patient, monitoring for skin disorders, such as blistering, ulceration or rash, is recommended. *Cardiac failure:* experience in NYHA class I-II is limited, and there is no experience in clinical studies with saxagliptin in NYHA class III-IV. *Immunocompromised patients:* immunocompromised patients, such as patients who have undergone organ transplantation or patients diagnosed with human immunodeficiency syndrome, have not been studied in the Onglyza clinical programme. Therefore, the efficacy and safety profile of saxagliptin in these patients has not been established. *Use with potent CYP3A4 inducers:* using CYP3A4 inducers like carbamazepine, dexamethasone, phenobarbital, phenytoin and rifampicin may reduce the glycaemic-lowering effect of Onglyza (see section 4.5). *Lactose:* the tablets contain lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. **Pregnancy and lactation.** *Pregnancy:* there are no data from the use of saxagliptin in pregnant women. Studies in animals have shown reproductive toxicity at high doses (see section 5.3). The potential risk for humans is unknown. Onglyza should not be used during pregnancy unless clearly necessary. *Lactation:* it is unknown whether saxagliptin is excreted in human breast milk. Animal studies have shown excretion of saxagliptin and/or metabolite in milk. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy to the woman. **Undesirable effects.** Please refer to section 4.8 of SPC for complete information on side effects. There were 4,148 patients with type 2 diabetes, including 3,021 patients treated with Onglyza, randomised in six double-blind, controlled clinical safety and efficacy studies conducted to evaluate the effects of saxagliptin on glycaemic control. In a pooled analysis, the overall incidence of adverse events in patients treated with saxagliptin 5 mg was similar to placebo. Discontinuation of therapy due to adverse events was higher in patients who received saxagliptin 5 mg as compared with placebo (3.3% as compared with 1.8%). Adverse reactions reported (regardless of investigator assessment of causality) in ≥5% of patients treated with saxagliptin 5 mg and more commonly than in patients treated with placebo or that were reported in ≥2% of patients treated with saxagliptin 5 mg and ≥1% more frequently compared with placebo are listed below. Saxagliptin with metformin: *common (≥1/100 to <1/10):* upper respiratory infection, urinary tract infection, gastroenteritis, sinusitis, nasopharyngitis, headache, vomiting. Saxagliptin with a sulphonylurea (glibenclamide): *very common (≥1/10):* hypoglycaemia. There was no statistically significant difference compared with placebo. The incidence of confirmed hypoglycaemia was uncommon for Onglyza 5 mg (0.8%) and placebo (0.7%); common *(≥1/100 to <1/10):* upper respiratory infection, urinary tract infection, gastroenteritis, sinusitis, headache, vomiting. Saxagliptin with a thiazolidinedione: common *(≥1/100 to <1/10):* upper respiratory infection, urinary tract infection, gastroenteritis, sinusitis, headache, vomiting, peripheral oedema. Saxagliptin with insulin (with or without metformin): *common (≥1/100 to <1/10):* hypoglycaemia. *Laboratory tests:* across clinical studies, the incidence of laboratory adverse events was similar in patients treated with saxagliptin 5 mg compared with patients treated with placebo. *Legal classification:* on medical prescription. **Marketing Authorisation Number:** EU/1/09/545/001-010. **Marketing Authorisation Holder:** Bristol-Myers Squibb/AstraZeneca EEIG, Bristol-Myers Squibb House, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex, UB8 1DH, United Kingdom. For more information please read the summary of product characteristics.

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Date of SmPC: 22-Dec-2011

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