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The World Congress on Clinical Trials in Diabetes

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Cardiovascular Outcome Studies

OC1
Evolution of the magnitude of stroke at the teaching hospital of Bobo-Dioulasso
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Background
Strokes are more and more frequent in the world, particularly in Africa. The evolution of their magnitude remains still poorly documented in the context of Burkina Faso, particularly in Bobo-Dioulasso. That is why this study was conducted to clarify the epidemiology of stroke and its risk factors in order to raise the alarm.

Objective
Investigate the evolution of the magnitude of stroke and its risk factors at the Teaching Hospital of Bobo-Dioulasso between 2009 and 2013.

Methods
It was a descriptive transversal type, retrospective collection, covering the period from January 1st 2009 to December 31st 2013. It focused on the medical records of adults admitted to hospital for stroke (with confirmed cases) or without brain scanner confirmation (not confirmed cases).

Results
The number of the included cases was 967. The average age was 61.06 years more or less 14.35 years, with a sex ratio of 1.58.
They were on average 05.55% of admissions annually within the services involved in their care. Their number and their proportion among admissions have increased in overall during the period. Confirmed cases represented 34.23% of all the cases, with 38.37% of hemorrhagic strokes.
When they had been well-documented, the risk factors such as high-blood pressure, smoking and diabetes were found respectively in 75.80, 22.46 and 07.46% of all cases. The frequency of arterial hypertension and diabetes had an overall growing trend also.

Conclusion
Strokes are more and more frequent in Bobo-Dioulasso, just like its main risk factors high blood pressure and diabetes. It is urgent to prevent the latter in order to reduce the extent of the stroke.

Keywords: stroke, magnitude, Bobo-Dioulasso

DOI: 10.1530/endoabs.43.OC1

OC2
HyperapoB and dysfunctional white adipose tissue; relation to risk factors for type 2 diabetes in humans
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Background
Elevated plasma concentrations of apoB-lipoproteins (i.e. hyperapoB) is an independent predictor of type 2 diabetes (T2D) in humans; however underlying mechanisms remain unclear. Chronic reduction in the function of white adipose tissue (WAT) promotes T2D. We reported that differentiation of preadipocytes is independent predictor of type 2 diabetes (T2D) in humans; however underlying mechanisms remain unclear. Chronic reduction in the function of white adipose tissue (WAT) promotes T2D. We reported that differentiation of preadipocytes

Objective
Determine the effects of combined acute and chronic aerobic resistance exercises on HbA1c, cardiovascular and immune functions in type 2 diabetic condition.

Methods
Twenty-four (ten males and 14 females) consenting patients (aged 52–73 years) with type 2 diabetes were consecutively recruited at Diocesan Hospital Amichi, in an experimental study. Seven participants (Acute Exercise Group - AEG) received one bout of combined (15 min) moderate intensity aerobic (using bicycle ergometer) and (15 min) resistance exercises (using 40–60% resistance at 1-repetitive maximum), ten repetitions per set, and three sets per session. Five participants completed 8 weeks of the same (Chronic Exercise Group – CEG) protocol, thrice weekly. Blood meals were taken before-after experiment, and analyzed. Data were tested for normality with Shapiro-Wilk test, and analysed with student t-test and Pearson correlation coefficient, at 95% confidence interval.

Results
Baseline versus post-treatment values of diastolic blood pressure (DBP), for both groups, were significantly elevated, but with a large effect size, in only the CEG. HbA1c and NO level, cardio-vascular, and immune functions in acute versus chronic exercise conditions, in T2D conditions.

Conclusions
Acute combined aerobic and resistance exercises may enhance immune function, and insulin action at the skeletal muscles. However, its chronic application might induce vaso-dilatation and reduce peripheral resistance to stabilize the blood pressure, and is of clinical significance.

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OC4
Antihyperglycemic drugs use and new-onset atrial fibrillation in elderly patients: a population-based longitudinal cohort study
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Background
Antihyperglycemic drugs have been linked to new-onset atrial fibrillation (NAF); however, the effect of different class antihyperglycemic drugs on the development of NAF in elderly patients with diabetes mellitus (DM) has not been well studied. Objectives
We investigated the association between different class antihyperglycemic drugs and NAF in elderly patients.

Methods
This was a retrospective cohort study performed using database of National Health Insurance Program in Taiwan from January 2000 to December 2011. Prescriptions for antihyperglycemic drug before the index date were retrieved from a prescription database. A total of 1931 participants aged 65 and older who were newly diagnosed with atrial fibrillation from 2005 to 2011 were assigned to the NAF group, whereas 7724 sex-matched, age-matched, diabetes duration-matched, and propensity score-matched randomly selected participants without NAF served as the non-NAF group. The multivariable logistic regression model was used to estimate the odds ratios (ORs) and 95% confidence interval (CI) of NAF associated with different class antihyperglycemic agent use. Non-users served as the reference group.

Results
The overall risk of NAF was netural effect (OR, 0.93; 95% CI, 0.83–1.04) between NAF and non-NAF group. The risk of NAF after adjusting for sex, age, comorbidities, and concurrent medication was higher among users of insulins (OR, 1.58; 95% CI, 1.37–1.82) than among non-users. Patients who took dipeptidyl peptidase four inhibitors (OR, 0.65; 95% CI, 0.45–0.93) was at lower risk of developing NAF than non-users. Metformins, acarboses, glinides, sulfonylureas and thiazolidinediones were not associated with risk of NAF.

Conclusion
In this population, dipeptidyl peptidase four inhibitors are at lower risk of NAF. Insulins was associated with a significant increase in the risk of NAF during long-term follow-up.

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OC5
Diabetes and blood pressure rhythm abnormalities
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Background
The absence of blood pressure dip during sleep is a common disorder in patients on dialysis, especially those with diabetes. Non-dipping is clinically significant as a predictor of cardiovascular events and an overview of the situation is possible only during ambulatory blood pressure monitoring (AMP), especially during sleep. Objective
Inversion of nighttime blood pressure is an indication of worse outcomes.

Methods
During our study, we examined 89 patients on hemodialysis (HD), of which 38 had diabetes and 51 did not. Hypertension was defined according to the guidelines of the European Society for Hypertension (ESH). The control group were 89 patients in the clinic for hypertension who were not dialysis patients, of which 35 had diabetes and 54 did not.

Results
Among the group of patients undergoing hemodialysis, 72% had unregulated blood pressure. In the second group of patients who were not hemodialysis patients, 60% had unregulated blood pressure. Among the dialysis population, 71% had an inversion of blood pressure during nighttime, as opposed to 35% in the control group. In the control group, a nightly increase in blood pressure had 26% of diabetic patients and only 7% of patients who did not suffer from diabetes. Hemodialysis patients had higher median blood pressure, higher mean arterial pressure and higher pulse pressure. According to outcome, there were significant differences – none of the non-HD patients had died, nor did they have severe complications. In the HD group, 48 patients did not have complications, 24 had severe complications and 15 patients died.

Conclusion
HD patients with diabetes have a greater increase in blood pressure at night, have more complications and lethal outcomes compared to non-HD patients with diabetes. Causes are numerous, and diabetes is not the only factor of blood pressure inversion at night.

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OC6
Nootkatone from Cyperus rotundus Protects Against Ischemia-reperfusion Mediated Acute Myocardial Injury in the Rat
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Background
Myocardial infarction is a common type of ischemic heart disease, which is the leading cause of disease-related death worldwide. In the ischemic heart, cardiac damage is initiated by a diminished blood supply, and swift restoration of blood supply is imperative to minimize cardiac injury. However, reperfusion itself can induce additional injury in the form of cardiac dysfunction, reperfusion arrhythmia, and by exacerbating myocardial infarction. Objective
The up-regulation of heme oxygenase-1 (HO-1) has been reported to protect from I/R injury, and nootkatone, a pharmacologically active ingredient found in the rhizomes of Cyperus rotundus, has been reported to induce HO-1 in immune cells. The aim of the present study was to determine whether the protective effect of nootkatone against myocardial ischemia-reperfusion (I/R) injury is due to its antioxidant and anti-inflammatory effects.

Methods and results
Adult male rats were subjected to 30 min of ischemia and 24 h of reperfusion. Rats were randomized to receive vehicle or nootkatone (5 or 10 mg/kg) 1 h before reperfusion. Infarct sizes were measured and myocardial functions assessed. Nootkatone at 10 mg/kg i.p., significantly reduced infarct sizes vs an I/R control group and ameliorated I/R-induced myocardial dysfunction by increasing the first derivative (± dp/dt) of left ventricular pressure and by decreasing infarct size.

Conclusion
The study suggests nootkatone protects hearts from I/R injury by reducing oxidative stress and the expressions of inflammatory mediators.

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OC7
The effect of eye mask on sleep quality in patients of coronary care unit
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Objectives
Patients in coronary care unit (CCU) are at risk of sleep deprivation. This study investigated effects of eye mask on sleep quality in patients of CCU in Southeast of Iran by a crossover design.

Methods
Using Verran and Snyder-Halpern Sleep Scale (VSH Sleep Scale), quality sleep of 60 patients with and without usage of eye mask were evaluated. This tool consists of 16 items that includes three main sleep sub scales: disturbance, effectiveness, and supplementation. Results
In total, 34, 22 and four out of 60 patients were admitted to CCU due to myocardial infarction (MI), chest pain and angina pectoris, respectively. Mean time of patients’ nocturnal sleep was 6.6 ± 1.1 h. Using eye mask have statistically significantly increased the quality of sleep in subscales disturbance and effectiveness (P < 0.05).

Conclusion
In general, the use of eye mask is an easy and cheap method to improve the quality of sleep in CCU patients.

Keywords: heart diseases, sleep, sleep deprivation.

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OC8

Bromocriptine shifts the blood pressure circadian rhythm in type 2 DM and stage 4 of chronic kidney disease patients: A post hoc study
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Background
Type 2 DM and chronic renal disease CKD are conditions associated with severe hypertension, loss of the blood pressure circadian rhythm (CR) and sympathetic nervous system (SNS) hyperactivity, suggesting a deficient dopaminergic modulation that could be reversed with dopamine agonists such as bromocriptine (BEC).

Objective
The objective of this study was to evaluate the effect of bromocriptine in the blood pressure CR in patients with type 2 DM and stage IV of CKD.

Material and methods
The data were obtained from a previous controlled clinical trial. 28 patients were included. 14 received 2.5 mg BEC tablets three times a day during six months and 14 received placebo (PBO). Blood pressure was measured by 24 h ambulatory blood pressure monitoring. The CR was identified by the method of Cosinor. The CR was characterized by the equation $PA = M + acos(2π/T + φ)$, with the following parameters: 1) phase; 2) mesor (M), 24 h mean blood pressure; 3) amplitude (A) and; 4) time period (T = 24 h, 12 h). Comparisons time to time were performed with student T test. A general linear model was used to analyzed the differences between and intragroup.

Results
Daytime and nighttime blood pressure improved significantly in the BEC group compared to PBO. The mesor mean arterial pressure decreased in the BEC group and increased in the PBO group. 100.9 mmHg (BEC) vs 106.24 mmHG (PBO) P<0.05.

Conclusions
BEC decreased blood pressure, increased and shifted the amplitude to the early hours of the morning.

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OC9

Years of Life Gained by Multifactorial Intervention in Patients with Type 2 Diabetes and Microalbuminuria – 21 Years Follow-Up on the Steno-2 Study
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Aims
To study the potential long-term impact of a 7.8 years intensified, multifactorial intervention in patients with type 2 diabetes mellitus and microalbuminuria in terms of gained years of life and years free from incident cardiovascular disease.

Methods
The original intervention (mean treatment duration 7.8 years) involved 160 patients with type 2 diabetes and microalbuminuria that were randomly assigned to either conventional therapy or intensified, multifactorial treatment including both behavioral and pharmacological approaches. After 7.8 years the study continued as an observational follow-up with all patients receiving treatment as for the original intensive-therapy group. The primary end-point of this follow-up 21.2 years after intervention start was difference in median survival time between the original treatment groups with and without incident cardiovascular disease.

Results
38 intensive-therapy patients vs 55 conventional-therapy patients died during follow-up (hazard ratio 0.55 [0.36, 0.83, P=0.005]). The patients in the intensive-therapy group survived for a median of 7.9 years longer than the conventional-therapy group patients. Median time before first cardiovascular event after randomization was 8.1 years longer in the intensive-therapy group (P=0.001).

The hazard for all microvascular complications was decreased in the intensive-therapy group (hazard ratios 0.52–0.67, except for peripheral neuropathy (hazard ratio 1.12).

Conclusions
At 21.2 years of follow up of 7.8 years of intensified, multifactorial, target driven treatment of type 2 diabetes with microalbuminuria, we demonstrate a median of 7.9 years of gain of life. The increase in life span is matched by the time free from incident cardiovascular disease.

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OC10

Efficacy, outcome and safety of SGLT2-I in patients with type II diabetes meta analysis review
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Background
SGLT2-I is a promising new class of diabetes pharmacotherapy, it targets blood glucose lowering in both postprandial and fasting states. It offers minimal risk of hypoglycemic events and demonstrates modest effects on blood pressure and weight.

Objective
Meta-analysis review of SGLT2-I outcome, safety and efficacy RCT.

Methods
Medline, EMBASE & CENTRAL were searched until August 2015, double blind study IND were included.

Table 1 Mean A1c reduction in RCT of SGLT2 inhibitors.

<table>
<thead>
<tr>
<th>Study</th>
<th>IND</th>
<th>Duration (Weeks)</th>
<th>Baseline A1c</th>
<th>Change in A1c (%±s.d.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterlidi et al.</td>
<td>Canagliflozin 300 mg</td>
<td>26</td>
<td>8%</td>
<td>−1.03</td>
</tr>
<tr>
<td></td>
<td>Canagliflozin 100 mg</td>
<td>26</td>
<td>8%</td>
<td>−0.77</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>26</td>
<td>8%</td>
<td>+0.14</td>
</tr>
<tr>
<td>Haring et al.</td>
<td>Empagliflozin 10 mg + Metformin</td>
<td>24</td>
<td>7.90%</td>
<td>−0.7±0.05</td>
</tr>
<tr>
<td></td>
<td>Empagliflozin 25 mg + Metformin</td>
<td>24</td>
<td>7.90%</td>
<td>−0.77±0.05</td>
</tr>
<tr>
<td>Ferrannini et al.</td>
<td>Empagliflozin 5 mg + Metformin</td>
<td>12</td>
<td>7.90%</td>
<td>−0.6</td>
</tr>
<tr>
<td></td>
<td>Empagliflozin 10 mg + Metformin</td>
<td>12</td>
<td>7.90%</td>
<td>−0.5</td>
</tr>
<tr>
<td></td>
<td>Empagliflozin 25 mg + Metformin</td>
<td>12</td>
<td>7.90%</td>
<td>−0.6</td>
</tr>
<tr>
<td></td>
<td>Placebo + Metformin</td>
<td>12</td>
<td>7.90%</td>
<td>+0.1</td>
</tr>
</tbody>
</table>

Note: P<0.001 vs Placebo

Results and Conclusions Outcome Table SGLT2-I

Potential AE
Genitourinary Infections, Bone Fractures, Diabetic Ketonacidosis, Long term safety not established

Cardiovascular Outcomes
Reduction in CV death in patients with known ASCVD, Unclear benefit in primary prevention

Hypoglycaemic Event Risk
Low

Weight Loss (kg) | 1.5–3.0
SBP Reduction (mmHg) | 3–5

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Managing cardiometabolic risk in type 2 diabetes care
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Background
Cardiometabolic risk (CMR) refers to risk factors that increase the likelihood of experiencing vascular events or developing diabetes. This concept encompasses traditional risk factors, such as hypertension, dyslipidemia, smoking. Abnormal glucose metabolism is a risk factor for cardiovascular disease (CVD) and, in some individuals, may progress to meet the threshold for the diagnosis of diabetes. CVD is the leading cause of death in the worldwide, and nearly one quarter of deaths caused by CVD are considered to be preventable.

Aim
The aim of this review is to provide evidence-based recommendations for preventing the development of cardiovascular disease in patients with type 2 diabetes.

Methods
Akdeniz University electronic databases center including MEDLINE, CINAHL and PUBMED e.g. were searched studies published in English within the last five years with key words such as 'cardiovascular disease in patients with type 2 diabetes', 'evidence-based recommendations and cardiovascular disease' and 'evidence-based recommendations in patients with type 2 diabetes'. Randomized control studies, systematic reviews, international guideline and meta-analyses were reviewed for evidence-based recommendations for preventing the development of cardiovascular disease in patients with type 2 diabetes.

Table 1 Evidence-based recommendations for preventing the development of cardiovascular disease in patients with type 2 diabetes

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Evidence-Based</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. In all patients with diabetes, cardiovascular risk factors should be systematically assessed at least annually.</td>
<td>(Evidence-based (B))</td>
</tr>
<tr>
<td>2. Blood pressure should be measured at every routine visit</td>
<td>(Evidence-based (B))</td>
</tr>
<tr>
<td>3. People with diabetes and hypertension should be treated to a systolic blood pressure goal of &lt; 140 mmHg and a diastolic blood pressure goal of &lt; 80 mmHg</td>
<td>(Evidence-based (A)).</td>
</tr>
<tr>
<td>4. Patients with blood pressure &gt; 120/80 mmHg should be advised on lifestyle changes to reduce blood pressure (Evidence-based (A)).</td>
<td></td>
</tr>
<tr>
<td>• Weight loss, if over weight or obese.</td>
<td></td>
</tr>
<tr>
<td>• Improve diet quality, including salt restriction (&lt;2.000 mg/day),</td>
<td></td>
</tr>
<tr>
<td>• Increasing potassium intake,</td>
<td></td>
</tr>
<tr>
<td>• Regular exercise (3–5 d/wk; 30–60 min/d)</td>
<td></td>
</tr>
<tr>
<td>• Caloric restriction,</td>
<td></td>
</tr>
<tr>
<td>• Reduction of saturated fat, trans fat. and cholesterol intake,</td>
<td></td>
</tr>
<tr>
<td>• Increase of omega-3 fatty acids, viscous fiber, and plant stanols/sterols intake.</td>
<td></td>
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<tr>
<td>• Smoking cessation counseling.</td>
<td></td>
</tr>
<tr>
<td>5. For patients with diabetes at risk for cardiovascular disease, diets high in fruits, vegetables, whole grains, and nuts may reduce the risk (Evidence-based (C)).</td>
<td></td>
</tr>
<tr>
<td>6. Patients with confirmed office-based blood pressure &gt; 140/90 mmHg should, in addition to lifestyle therapy, have prompt initiation and timely subsequent titration of pharmacological therapy to achieve blood pressure goals (Evidence-based (A)).</td>
<td></td>
</tr>
<tr>
<td>7. Pharmacological therapy for patients with diabetes and hypertension should comprise a regimen that includes either an ACE inhibitor or an angiotensin receptor blocker but not both. If one class is not tolerated, the other should be substituted (Evidence-based (C)).</td>
<td></td>
</tr>
<tr>
<td>8. If ACE inhibitors, angiotensin receptor blockers, or diuretics are used, serum creatinine/estimated glomerular filtration rate and serum potassium levels should be monitored (Evidence-based (E)).</td>
<td></td>
</tr>
<tr>
<td>9. Consider aspirin therapy (75–162 mg/day) as a primary prevention strategy in those with type 2 diabetes who are at increased cardiovascular risk (Evidence-based (C)).</td>
<td></td>
</tr>
<tr>
<td>10. Prescribe aspirin therapy (75–162 mg/dag) for all adult patients with type 2 diabetes and evidence of cardiovascular disease (Evidence-based (A)).</td>
<td></td>
</tr>
<tr>
<td>11. Use aspirin therapy (75–162 mg/dag) as a secondary prevention strategy in those with diabetes with history of CVD (Evidence-based (A)).</td>
<td></td>
</tr>
<tr>
<td>12. Statins are first line agents in primary and secondary prevention of CVD regardless of HDL-C or TG level.</td>
<td></td>
</tr>
<tr>
<td>13. Statin Therapy (Aged 40–80 years) is recommended for all patients aged 40–80 years with diabetes and total cholesterol (TC)&gt;135, regardless of baseline LDL (Evidence-based (A)).</td>
<td></td>
</tr>
<tr>
<td>14. For patients of all ages with diabetes and atherosclerotic cardiovascular disease, high-intensity statin therapy should be added to lifestyle therapy (Evidence-based (A)).</td>
<td></td>
</tr>
</tbody>
</table>

OC12
Interleukins 6 and 8 and abdominal fat depots are distinct correlates of lipid moieties in healthy pre- and postmenopausal women
Johannes Veldhuis 1, Roy Dyer 2, Sergey Trushin 1,2, Olga Bondar 2, Ravinder Singh 3 & George Klee 4
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Purpose
Available data associate lipid concentrations in men with BMI, anabolic steroids, age, and certain cytokines. Data are less clear in women, especially across the full adult lifespan, and when segmented by pre- and postmenopausal status.

Methods
Subjects: 120 healthy women in Olmsted County, MN, USA, a stable well studied clinical population. Dependent variables: measurements of 10-hr fasting high-density lipoprotein cholesterol (HDL-C), total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C) and triglycerides (TG). Independent variables: testosterone, estrone, estradiol, 5-alpha-dihydrotestosterone (DHT) and sex-hormone binding globulin (SHBG, by mass spectrometry); insulin, glucose, and albumin; abdominal visceral, subcutaneous and total abdominal fat (AVF, SCF, and TA respectively); body mass index (BMI) and waist circumference; and vitamin D. Data were analyzed using linear-regression analysis.

Results
Lifetime data: HDL-C was correlated jointly with age (P=0.0001, positively), AVF (P=0.0001, negatively), and IL-6 (0.0063, negatively), together explaining 28.1% of its variance (P=2.3×10^9, negatively). TC was associated positively with multivariate age only (P=0.0115), AVF (P=0.0001), and IL-6 (P=0.0016) all positively (P=1.6×10^9, 38.9% of variance). Non-HDL-C and LDL-C were correlated positively with both TAF and IL-8 (P=2.0×10^6, 16.9% of variance; and P=0.0001, 9.4% of variance, respectively). Pre- vs postmenopausal comparisons identified specific relationships that were stronger in pre- than postmenopausal individuals, and vice versa. Age was a stronger correlate of LDL-C, IL-6 of TG and HDL; and SHBG and TAF both of non-HDL-C in pre- than postmenopausal women. Conversely, SHBG, AVF, IL-8, adiponecin were stronger correlates of TG; AVF and testosterone of HDL-C; and age of both non-HDL and LDL in post-than premenopausal women.

Conclusion
Our data delineate correlations of TAF and IL-8 (both positively) with non-HDL-C and LDL-C in healthy women across the full age range of 21–79 year along with even more specific associations in pre- and postmenopausal individuals.
Design a Clinical Program for Success

OC13
Additive benefits of environmental enrichment and voluntary exercise on cognition and motor coordination in diabetic mice

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Long-term diabetes is associated with accelerated ageing of the brain as evidenced by impairment of cognitive function as well as motor performance. The aim of this study was to investigate the effects of voluntary daily exercise and environmental enrichment on spatial memory and learning, as well as motor coordination and learning, in diabetic mice. Briefly, BALB/C mice (20–25 g) received 55 mg/kg streptozotocin i.p. daily for 5 days. Diabetes was confirmed by measurement of random blood glucose. Diabetic mice were randomly assigned to one of the following groups for 12 weeks duration: i) social isolation; ii) environmental enrichment; iii) environmental enrichment and voluntary daily exercise. A 4th group consisted of normal controls with environmental enrichment and voluntary daily exercise. At the end of 12 weeks blood glucose measurements were repeated and animals were assessed by the Morris Water Maze and the Rotarod for cognitive and motor performance respectively. Exercise per se did not have a significant additional benefit on learning and memory compared to environmental enrichment alone, in diabetic mice. In diabetics, motor learning was impaired with isolation but enhanced with environmental enrichment and exercise. After week 12 there were no differences in blood glucose when comparing between diabetic groups. In conclusion, environmental enrichment confers significant benefits on cognition and motor performance and the latter effect can be enhanced by adding exercise. The effects of enrichment on motor learning are worthy of further investigation as regards the mechanism and whether or not such benefits would translate to other motor activities.

DO: 10.1530/endoabs.43.OC13

OC14
A patient focused monogenic diabetes clinical program for the primary care physician

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Background
Monogenic diabetes is a rare form of diabetes which accounts for 5% of all diabetes cases. This is caused by a single gene mutation mostly inherited from an autosomal dominant pattern. The two types of monogenic diabetes are Neonatal monogenic diabetes (NMD) and Maturity-onset diabetes of the young (MODY).

Accurate diagnosis of monogenic diabetes remains to be a great challenge for most clinicians due to its overlapping clinical features from other forms of diabetes.

Objectives
It is our primary objective to design a clinical tool that serves as a guide in the management of monogenic diabetes. Our secondary objective is to design a patient focused approach in clinical management and early diagnosis.

Methods

Table 1 Characteristics of monogenic diabetes

<table>
<thead>
<tr>
<th></th>
<th>NMD</th>
<th>MODY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>0–6 months</td>
<td>6 months to &lt;25 years old</td>
</tr>
<tr>
<td>Family history</td>
<td>Positive, Low birth weight,</td>
<td>Positive, Non-obese, non-</td>
</tr>
<tr>
<td>Risk factors</td>
<td>DEND syndrome</td>
<td>hypertensive, Low risk ethnic group</td>
</tr>
<tr>
<td>Glycemic pattern</td>
<td>Acute general hyper-</td>
<td>FBS of 5.5–6 mmol/l</td>
</tr>
<tr>
<td>l-cell antibodies</td>
<td>glycermia</td>
<td></td>
</tr>
<tr>
<td>Gene mutation (most common)</td>
<td>KCNJ11, ABC8, Chr 6q24</td>
<td>GCK, HNF1A, HNF4A genes</td>
</tr>
</tbody>
</table>

Table 2 Clinical management of monogenic Diabetes

<table>
<thead>
<tr>
<th></th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDM</td>
<td>Sulfonylureas</td>
</tr>
<tr>
<td>MODY</td>
<td>Diet and lifestyle modification, medication not required, some may respond to Sulfonylureas</td>
</tr>
</tbody>
</table>

Conclusion
It is our recommendation that primary care physicians should use this tool as to differentiate clinical characteristics of monogenic diabetes from other forms of diabetes. Genetic testing serves as a confirmatory tool in the diagnosis and defines the appropriate treatment plan for the patient. Performing a screening test based on the American Diabetes Association guidelines, coupled with educating and counselling the patient/family should be part of a standard of care for early and accurate management of diabetes.

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OC15
Prevalence of depressive and anxiety symptoms in youth with type 1 diabetes – a systematic review and meta-analysis

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Background
There is a complex interaction between psychosocial factors and type 1 diabetes (T1D) resulting in compromised diabetes management and suboptimal glycemic control. Individuals with T1D are at increased risk of developing depression and anxiety. Screening for psychosocial risk factors from diagnosis of T1D has been recommended. International standard is integrated care by a multidisciplinary team.

Objective
We performed a systematic review and meta-analysis to update the evidence base in this area.

Methods
We searched EMBASE, MEDLINE, The Cochrane Library, and PsyCINFO in April 2014 and updated our searches in May 2015. We focused on signs of depression and anxiety in youth with T1D and the association with glycemic control and diabetes management. When possible, we pooled data to estimate summary effects.

Results
Our searches identified 14 publications investigating the correlation of anxiety and depression with T1D in children and adolescents: eight cross-sectional studies, five cohort studies, and one case-control study. Using the Children’s Depression Inventory (CDI), the pooled prevalence of depressive symptoms was 30.04%, 95% CI [16.33; 43.74]. There were correlations between symptom levels and glycemic control as well as three-way interactions between HbA1c, blood glucose monitoring frequency or diabetes-specific stress and depression. Symptoms of anxiety were reported for up to 32% of patients. A negative impact on glycemic control was demonstrated.

Conclusion
Our analyses confirmed a high prevalence of signs of depression and anxiety in youth with T1D confirming the need for early screening for psychological comorbidity and regular psychosocial assessment from diagnosis of T1D. Future prospective studies and randomized controlled trials are needed to further explore the interaction of signs of depression and anxiety with glycemic control and diabetes management and develop evidence-based treatment models.

DO: 10.1530/endoabs.43.OC15
OC16

Effects of hesperidin supplementation on glycometabolic control, lipid profile and inflammatory factors in patients with type 2 diabetes: a randomized, double-blind and placebo-controlled clinical trial

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Background
Diabetes mellitus is a common chronic disease and a major public health problem globally. The management of this disease through antioxidative and anti-inflammatory agents specially flavonoids, as an adjunct therapy, is of interest and attention.

Objectives
This study was conducted to investigate the effects of hesperidin (a common constituent of citrus fruits) supplementation on indices of glycometabolic control, insulin resistance, lipid profile, and inflammatory markers in patients with type 2 diabetes.

Methods
Following approval by Ethics Committee of Iran University of Medical Sciences for Human Studies 45 patients with type 2 diabetes were recruited in a randomized double-blind controlled clinical trial design. Subjects consumed 500 mg/d hesperidin supplement in the intervention group (n=23) and 500 mg/d placebo in the control group (n=22), for 8 weeks. 10 cc blood samples and three days dietary Information were obtained at the baseline and the end of the study. The levels of fasting blood glucose (FBG), insulin, hemoglobin A1c (HbA1c), total cholesterol (TC), triglyceride (TG), high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, insulin resistance, inflammatory factors IL6 and hs-CRP were measured and compared within and between treatment group. Statistical analyses were conducted with SPSS software by using independent t and paired t test.

Results
Hesperidin supplementation led to significant decrease in FBG and glycated hemoglobin (HbA1c) (P=0.034 and 0.028, respectively). A significant increase in serum insulin (P=0.018) and decrease in TC (P=0.049) were also observed in the hesperidin group, whereas no significant changes occurred in the placebo group. Inflammatory factors, high-sensitivity C-reactive protein (hs-CRP) and interleukin-6 (IL-6) were not significantly changed in the hesperidin group compared to the control group.

Conclusions
Hesperidin supplementation lowered the plasma level of TC and improved glycometabolic control and insulin resistance in patients with type 2 diabetes.

Keywords: Hesperidin, glycometabolic control, insulin resistance, lipid profile, inflammatory markers, type 2 diabetes

OC18

Concordance of diabetes clinicians’ decision making – face-to-face versus telemedicine clinics: a feasibility trial

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Background
A feasibility trial was conducted to determine the potential for telemedicine to replace alternate diabetes review appointments in the care of those with gestational diabetes (GDM). One of the aims of this study was to access concordance of clinical decision making between diabetes clinic visits and telemedicine review sessions.

Methods
50 women with GDM were randomised to usual care (n=26) or usual care plus telemedicine (n=24). Telemedicine entailed weekly blood pressure and weight measurements and transmission of this data, along with blood glucose readings, for review by the health care team. The management decisions made for the intervention group at each clinic and telemedicine review were recorded under one of 6 categories. Recall bias was minimised by conducting the telemedicine review 2 days before the clinic review. It was not possible to ensure the same clinician performed both the telemedicine and corresponding clinic review making it necessary to measure inter-rater (between clinician) and intra-rater (within the same clinician) agreement. 20 vignettes, short clinical scenarios, were developed based on information which would be available at telemedicine or clinic review. Each clinician was asked to record a management decision for these vignettes (measuring inter-rater agreement) and to repeat this after a number of weeks (measuring intra-rater agreement).

Cohen’s kappa was used to quantify the proportion of agreement in excess of the amount of agreement that would be expected by chance.

Results
Cohen’s kappa was 0.54 for telemedicine and face-to-face review, indicating moderate or fair to good agreement in terms of the management decisions made. This compared to 0.65 (substantial or fair to good agreement) for inter-rater agreement and 0.44, (indicating moderate or fair to good agreement) to 0.77 (indicating substantial or excellent agreement) for intra-rater agreement.

Conclusion
Telemedicine allows clinicians to make comparable management decisions as diabetes clinic review.

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OC19
Development of an electronic clinical decision support system: “mWellcare – an Integrated mHealth System for Prevention and Care of Chronic Diseases”
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Background
Diabetes and hypertension are among leading causes of premature adult deaths in India. Innovative approaches such as electronic clinical decision support systems (DSS) could play major role in improving quality and access to diabetes and hypertension care at primary care settings.

Objective
The main objective of this study is to develop an innovative tablet-computer based DSS namely “m-WELLCare”, and other essential support healthcare processes for facilitating evidence-based diabetes and hypertension care at primary care.

Methods
A multidisciplinary team of researchers, clinicians, administrators and software experts used mixed methods to design and develop the mWellcare in six iterative steps: 1) Literature review and expert consultation; 2) Needs assessment; 3) Adapting the clinical management guideline to local context; 4) Validation of clinical algorithms 5) Identifying support healthcare processes and 6) Field testing of the mWellcare at five Community Health Centers in India.

Results
The above steps provided inputs for designing core-features of the DSS which include: Computation of personalized evidence-based management plan for diabetes, hypertension and co-morbid conditions (depression and alcohol use disorder); 1) Literature review and expert consultation; 2) Needs assessment; 3) Adapting the clinical management guideline to local context; 4) Validation of clinical algorithms 5) Identifying support healthcare processes and 6) Field testing of the mWellcare at five Community Health Centers in India.

Conclusion
Development of electronic DSS for diabetes and hypertension care for the use at resource poor settings is a complex process. Learning from this study can serve as resource for developing similar applications for decision support enabled interventions.

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OC20
Selected adipokines in patients with type 2 diabetes: relationship to markers of vascular damage
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13rd Department of Internal Medicine, Faculty of Medicine and Dentistry Palacky University, University Hospital Olomouc, Olomouc, Czech Republic; 2Department of Clinical Biochemistry, University Hospital Olomouc, Olomouc, Czech Republic.

Introduction
Adiponectin, adipocyte fatty acid-binding protein (A-FABP), fibroblast growth factor 21 (FGF-21), C1q/TNF-related protein 9 (CTR9) and allograft inflammatory factor-1 (AIF-1) belong to the proteins produced by adipocyte tissue, which differently contribute to oxidative stress, chronic inflammation, insulin resistance and endothelial damage. The aim of this pilot study was to compare their levels in patients with diabetes and in healthy individuals and determine their relationship to cardiovascular risk factors and indicators of vascular damage.

Methods
Fifty-four patients with type 2 diabetes (32 men, 22 women) and 21 healthy controls (8 men, 13 women) were included in the study. Besides adiponectin, lipids, anthropological parameters, indicators of insulin resistance and of renal damage also markers of endothelial dysfunction – von Willebrand factor (vWF), plasminogen activator inhibitor-1 (PAI-1), tissue plasminogen activator (t-PA) and arterial stiffness parameters – augmentation index and pulse wave velocity were tested.

Results
Compared with healthy controls, type 2 diabetics had significantly higher levels of A-FABP [50.0 (38.1–68.6) vs 28.6 (23.6–32.9) mg/l, P = 0.001] and lower levels of adiponectin [5.9 (4.3–9.0) vs 11.3 (8.7–14.8) mg/l, P = 0.001]. Differences in other adipokines were not statistically significant. Adiponectin correlated negatively with vWF levels (r = -0.29, P = 0.05) and PAI-1 (r = -0.35, P = 0.01), A-FABP positively with vWF (r = 0.45, P = 0.01) PAI-1 (r = 0.46, P = 0.01) and augmentation index (r = 0.39, P = 0.01). The levels of FGF-21 correlated only with PAI-1 (r = 0.27, P = 0.05).

Conclusion
Patients with type 2 diabetes have significantly higher levels of A-FABP and lower levels of adiponectin. The levels of these adipokines correlate with indicators of vascular damage and could thus directly contribute to cardiovascular risk individuals with diabetes. Supported by grants IGA_LF_2016_014 a MZ CR – RVO (FNIO 00098982) – IP 87-54.

DOI: 10.1530/endoabs.43.OC20

OC21
Patient preference for using computers, smartphones, and internet to participate in diabetes clinical trials
Khurana Laura1, Ellen M Durand1, Sarah Tressel Gary1, Antonio V Otero2, Chris Hall1, Kelsey Berry2, Christopher J Evans1 & Susan M Dallabrida1
1Clinical Science & Consulting, ERT, USA; 2Research, Endpoint Outcomes, USA.

Background
Patient engagement and adherence are critical to the success of clinical trials. Electronic patient-reported outcomes (ePROs) are increasingly used to evaluate diabetes clinical trial endpoints. This study characterized how subjects prefer to use various types of technology to report ePROs in a clinical trial. Considering patient preference during diabetes trial design may reduce patient burden and improve patient engagement.

Methods
102 subjects with type 2 diabetes were surveyed regarding their preferences for using computers, smartphones, and internet in clinical trials.

Results
Subjects were diverse in age, sex, ethnicity, and technology use. 66% reported having a computer at home, 53% reported using the internet daily, and 48% reported owning a smartphone. Subjects reported that they would be willing to participate in a clinical trial using the internet for up to 1 month (19%), 2–6 months (25%), 1–2 years (17%), or 5+ years (18%). Similarly, subjects were willing to participate in a clinical trial using a smartphone for up to 1 month (19%), 2–6 months (29%), 1–2 years (11%), or 5+ years (18%). When asked what time of day they would prefer to complete a daily electronic diary, subjects preferred 8pm-midnight (32%), 8am-noon (19%) or noon-4pm (15%). Subjects thought it would be necessary (16%) or helpful (74%) to have an audible alarm to remind them to record their symptoms. In a multi-select question, subjects preferred to report their symptoms once a day for a clinical trial using a paper form (55%), an interactive voice system (51%), or a web-based form on the internet (49%).

Conclusions
Diabetes subjects are willing to use computers, smartphones, and internet in a clinical trial setting. Trial sponsors should consider patient preferences for specific technology features to reduce patient burden and improve engagement and adherence when using ePRO assessments.

DOI: 10.1530/endoabs.43.OC21

OC22
Patient preference for display of electronic patient-reported outcomes in diabetes clinical trials: wording emphasis, question format, and navigation button placement
Khurana Laura1, Ellen M Durand1, Sarah Tressel Gary1, Antonio V Otero1, Chris Hall1, Aising Ryan2, Christopher J Evans1 & Susan M Dallabrida1
1Clinical Science & Consulting, ERT, USA; 2Research, Endpoint Outcomes, USA.

Background
Electronic patient-reported outcomes (ePROs) are a reliable method for collecting patient data in diabetes clinical trials and offer many advantages over paper
collection; however, it is essential to consider patient preference and ease of use when employing this technology. Improving the usability of ePRO in clinical trials could ultimately reduce subject burden and improve subject engagement.

Methods
102 subjects with type 2 diabetes were surveyed regarding their preferences for ePRO display.

Results
When presented with options for showing emphasis in a sentence, subjects thought that underlining best drew attention to emphasized words (37%), followed by capitalized (27%) or italicized (19%) lettering. Subjects were shown screens of a multi-select question formatted to read left to right (question to the left of the answers) or top to bottom (question above the answers). 38% could read and understand the screens equally. Of those with a preference, 76% preferred the top to bottom format. Subjects were shown screens of a tablet computer ePRO device with either one question per screen or several multi-select questions per screen in a matrix format. 55% preferred one question per screen because it was easier to read (65%), 45% preferred the multiple questions per screen because it was faster to complete (50%). Subjects were shown two screens with “back” and “next” navigation buttons at either the top or bottom of the screen. 34% thought it was equally easy to find the buttons; of those with a preference, 64% preferred them at the bottom of the screen.

Conclusions
When possible, questionnaire designers should consider these results to incorporate patient preference into the design of ePRO instruments; potentially reducing subject burden and increasing patient engagement in diabetes clinical trials.

DOI: 10.1530/endob.43.OC22

OC24
Gestational diabetes mellitus, Diagnostic, Surveillance and Management Plan A Recommendation for Prenatal Care follow-up in a community set up, Houston Texas USA
Mukunda Singh, Marvin D Dao & Thyu Pham
Research, Clinical Trial Network, Houston, TX, USA.

A comprehensive pregestational prenatal monitoring and early detection of diabetes amongst pregnant patients is the cornerstone of the updated ADA recommendation 2016 in Diabetes Care. It is our main objective to lay out an attainable management plan for early diagnosis, and management of gestational diabetic in a community clinic. The plan includes implementation of family planning and effective contraception for known women with previous gestational diabetes, as primary preventive measure. This plan consists of reeducation and reinforcement of gestational diabetes awareness and also of monitoring the following targeted A1C as per recommendation of a target of 6–6.5% (42–48 mmol/mol), although depending on hypoglycemia risk the target may be relaxed or restricted. Glyburide in gestational diabetes mellitus was deemphasized based on new data suggesting that it may be inferior to insulin and metformin in accordance with the ADA recommendation. In conclusion consistent and regular reeducation, blood A1c, FPG, RBG monitoring, diet, weight monitoring, and adherence to medication compliance, and highlighted emphasis on the updated ADA recommendation was noted to be effective and shows achievable targets to community patients afflicted with gestational diabetes.

DOI: 10.1530/endob.43.OC24

OC23
Adapting DESMOND, a structured education programme for the self-management of Type 2 diabetes, for adults with intellectual disabilities
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Background
People with intellectual disability (ID) are living longer and more likely to develop Type 2 diabetes (T2D). It is recognised in many westernised countries that better self-management of T2D can improve the persons’ health and quality of life: one such programme is DESMOND. However, such programmes have not been adapted for adults with ID.

Objective
This poster focuses upon adapting DESMOND. There were two objectives, firstly, to explore whether the psychological and educational learning theories underpinning DESMOND can also be utilised for adults with ID. Secondly, what changes need to be made to the DESMOND programme to make it accessible to adults with an ID?

Methods
This study involved the delivery of two iterations of the DESMOND education programme to 15 adults with ID and T2D, and 7 family/paid carers, over a 7 week period. Evaluation of the two iterations of the DESMOND programme was obtained via video recordings, focus groups with the participants, their carers, the educators and independent observers.

Results
The adaptation process of the DESMOND focused upon extending the delivery time, defining core concepts, using pictorial representation (i.e. visual, photos, pictures, symbols), repetitious learning/interactive sessions, development of skills (self-efficacy), education/support of carers, health action plans/goal setting, and celebration and fun. If the appropriate reasonable adjustments are made and supported developed then the four psychological and educational theories that underpin DESMOND can also be used for this population.

Conclusion
Overall, the findings of this study suggest that DESMOND was successfully modified for adults with mild to moderate ID in promoting diabetes self-management care. Although this population has a greater dependency upon carers to support them to translate the messages of DESMOND into everyday life in order to decrease their HbA1c, reduce weight, maintain a healthy diet, exercise more and ensure medication compliance. This is a promising study.

DOI: 10.1530/endob.43.OC23

OC25
Dietary mistakes as a cause of new treatment modalities lower efficacy
Katerina Stechova, Pavliina Pithova & Milan Kvapil
Internal Department, University Hospital Motol, Prague, Czech Republic.

Background
By using new treatment modalities in DM1 patients (glucose sensors, insulin pumps) we quite often do not reach optimal results.

Objective
As a part of the project developing software for smartphones (a self-learning diabetes management advisory tool) we provided in insulin pump users detail diet and RT-CGM records analysis. As the main cause of postprandial hyperglycaemia in our DM1 patients we identified dietary mistakes. Moreover diet of our patients was often unhealthy. We decided to obtain real insight into DM1 patient diet in a larger cohort because dietary mistakes may interfere with new treatment approaches.

Methods
In this study 30 DM1 patients (15/15 F/M; 20/30 already suffering from chronic diabetic complications) were involved (median, range): age 41 years (23–55), DM1 duration 20 years (4–25), 15 used CSII, 15 MDI, insulin dose 0.6 IU/kg (0.4–1), BMI 25.3 (21.2–34.8), HbA1c 66 mmol/mol (48–89) IFCC. They were instructed to document one week all food and drinks by smartphone camera and to record a log book including weight of all food. Their diet was analysed by professional nutritional software (NutriPro EXPERT). Notice - all patients underwent standard intensified diabetic education within last two years.

Results
(median, range) in % of recommended daily value: Energy intake:115% (94– 160%), total carbohydrates 103% (66–113%), mono- and oligosaccharides 130% (93–166%), proteins 98% (70–130%), total fat 140% (120-201%), saturates 135% (115–186%), cholesterol 98% (94–110%), fiber 74% (66–103%), Na 117% (104–150%), Fe 72% (60–93%), Ca 83% (66–93%), vit. C 100% (80–121%), vit.D 54% (35–83%). Pump users made mistakes more often (P<0.01). Patients did not consider their diet as unhealthy. Generally they considered only total carbohydrate content as important.

Conclusion
Prior analysis of any new DM1 treatment modality patient’s compliance and knowledge (including diet) must be checked and re-educated if necessary. Supported by the Czech Ministry of Health Project No.15-25710A(P08 panel).

DOI: 10.1530/endob.43.OC25
Background

Carpal Tunnel syndrome (CTS) was reported in 2.6 to 20% in diabetic patient’s population that may be as results of repeated undetected trauma, metabolic changes, and accumulation of fluid or edema within the confined space of the carpal tunnel and/or diabetic Cheirourthropathy. Manual therapy is prescribed as a conservative treatment for CTS.

Objective

The aim of this study was to compare the effects of two manual therapy methods including (1) techniques for opening the surrounding space of the nerve and (2) neuromobilization techniques on diabetic patients with CTS.

Methods

20 diabetic patients with CTS participated in this Randomized clinical Trial which assigned into two groups, namely mobilization for mechanical interface techniques had significant and probably equal effects on subjective clinical changes, and accumulation of fluid or edema within the confined space of the carpal tunnel and/or diabetic Cheirourthropathy. Manual therapy is prescribed as a conservative treatment for CTS.

Objective

Transition of diabetes care from adolescents to adulthood remains a challenging field due to many social, demographic, and economic factors. During the transition phase, strong emphasis should be placed on encouraging teens to assume self-care and self-management of their diabetes through guided practice of physical and practical skills needed once they transition to adult care.

Objectives

The UT Health Pediatric Endocrinology team created an evidence-based plan to transition adolescent diabetic patients, starting at age 16.5, to adult care. This plan includes (i) identifying and maximizing skills for successful self-management of diabetes, (ii) coordination of transitioning care, (iii) identifying barriers to transition, (iv) creating a plan to help and encourage they continue receiving healthcare, (v) locating and facilitating an appointment with an adult physician, (vi) providing discharge prescriptions and supplies, (vii) providing school nurse orders, and (viii) follow up phone calls after discharge.

Results

We reviewed transition process of 2 years. Out of 138 patients (99 type 1 and 39 type 2 diabetes) who started the transition process, only 81 patients (59%) completed the process and were formally discharged from clinic. The remaining patients (41%) are still in the transition phase and currently being seen in clinic.

We were able to make follow up appointments with adult endocrinologist for 55 patients (68%) but only 40 patients documented presence for this follow up (49%).

Conclusion

The transition of diabetes care faced many obstacles including:
1- Patients’ psychological factors
2- Financial and health insurance factors including access to diabetes care
3- Communication factors to provide feedback about adult care obtained.

Keywords: Diabetes, CTS, Manual therapy

DOI: 10.1530/endoabs.43.OC28
and compliance with therapy. Psychological factors (depression, anxiety) play a major role in pediatric diabetes compliance. Access to psychological support may not be always attainable. The effect of improved access can be evaluated by comparing HgbA1c values before and after psychological support.

Objective
Patients who visit with a psychologist during their routine clinic visits for diabetes have an improved HgbA1c in follow-up after this intervention.

Methods
A clinical psychologist was present in clinic for three months allowing immediate access to psychological intervention. Charts were retrospectively reviewed and non-identifying information was collected including age, time since diagnosis, race, gender, HgbA1c before and after the intervention, reason for referral, and topics of discussion as documented by the psychologist. The data was described using medians (with interquartile ranges) and frequencies (with percentages). Stratified and non-stratified univariable comparisons were made using the Friedman test. Multivariable regression comparisons utilized generalized linear mixed models. Statistical significance was assumed at a type 1 error rate of 5%.

Results
Data was collected on 41 patients. HgbA1c values were 9.9% (8.7–11.8) and 10.3% (8.7–12.7) before and after psychological intervention, respectively. Values were higher in African Americans than in non-Hispanic whites ($P=0.005$). There was no difference in HgbA1c values before and after psychological intervention with a median difference of 0.3 (~0.9–1).

Conclusions
There was no significant change in HgbA1c values after a one-time clinical psychological intervention. Some individual patients may have benefited, but a larger dataset is needed to assess this subgroup while considering the reason for the psychology consult. 

DOE: 10.1530/endoonsubs.43.OC29

GCP Learning and Best Practice

OC30
Contribution to a Better Understanding of Aspects of Type 2 Diabetes Mellitus Treatment in the Elderly. What is the optimal target serum concentration of HbA1c?
Jiří Nakládal & Hana Matějková Kubešová
Department of Internal Medicine, Geriatrics and General Practice, Faculty Hospital and Medical Faculty of Masaryk University Brno, Brno, Czech Republic.

Background
The prevalence of type 2 diabetes mellitus is very high among elderly people and can larser the cognitive decline and the loss of independence, if not treated adequately. Another topic not clearly explained yet is the relationship between vitamin D and type 2 diabetes mellitus.

Objective
The aim of our work is to reveal relationship between diabetes control and self-sufficiency and to determine the possible impact of the current levels of vitamin D in elderly hospitalized patients.

Methods
We studied retrospectively the group of hospitalized patients of age 65+ with type 2 diabetes mellitus. Each patient included into our study was assessed according to Comprehensive Geriatric Assessment tool. The serum levels of glycated hemoglobin (HbA1c), C-peptide fasting and after breakfast and vitamin D were determined. Data were analyzed by descriptive statistical methods, Student’s T-Test and regression analysis.

_results_
Altogether 77 patients (average age 82.7±7.08 years, median 84 years, 56 women, 21 men) fulfilled the inclusion criteria. The average HbA1c serum concentration was 50.5±12.5, median 47 mmol/mol and decreased with age. The average fasting and after breakfast C-peptide serum level was 1222.1±997.1 resp. 2340.0±1535.3 pmol/l. Vitamin D serum levels ranged from unmeasurable values to 100 nmol/l with average 23.3±19.7 nmol/l and median 17 nmol/l and decreased with age. Seniors with vitamin D serum level below 10 nmol/l showed significantly lower C-peptide serum levels – fasting and after breakfast ($P=0.033$; $P=0.027$). Despite it we have found significant positive correlation between vitamin D serum level and HbA1c ($r=0.257$, $P=0.05$). The curve of HbA1c and parameters of self-sufficiency dependence was “J” shaped with optimal HbA1c levels between 50 and 70 nmol/mol.

Conclusions
Sufficient vitamin D serum levels were connected with higher insulin secretion and better self-sufficiency parameters. Optimal HbA1c serum concentration was between 50 and 70 nmol/l from self-sufficiency parameters point of view.

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Meta-Analysis of Phase 2 / 3 Studies

OC31
Do mobile phone applications improve glycemic control in the self-management of diabetes: A systematic review, meta-analysis and GRADE of 14 RCTs
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Background
Diabetes mobile phone applications (hereafter referred to as diabetes apps) are a promising tool for self-management. Due to the ubiquitous, low cost, interactive and dynamic health promotion, and there is potential for a cost-effective intervention in diabetes self-care. However, there is uncertainty of the clinical effectiveness.

Objectives
To investigate the effect of mobile phone applications on glycemic control in the self-management of diabetes.

Methods
Relevant studies that were published between 1996 to June 1st, 2015 were searched from five databases. Randomized controlled trials that evaluated diabetes apps were included. We conducted a systematic review with meta-analysis and GRADE of the evidence.

Results
1360 participants from 14 studies were included and quality assessed. Whilst there may have been clinical diversity, all type 2 diabetes studies reported a reduction in HbA1c. The mean reduction in participants using an app compared to control was 0.49% (95% CI 0.30%–0.68%; $I^2=10%$), with a moderate GRADE of evidence. Subgroup analyses indicated that younger patients were more likely to benefit from the use of diabetes apps and the effect size was enhanced with healthcare professional feedback. There was inadequate data to describe the effectiveness of apps for type 1 diabetes.

Conclusions
Apps may be an effective adjuvant intervention to the standard self-management for patients with type 2 diabetes. It is likely to be cost-effective at the population level. The functionality and use of this technology needs to be standardized, but policy and guidance is anticipated to improve diabetes self-management care and reduce healthcare cost.

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OC32
Cohort Analysis of Randomized Clinical Trials on long acting GLP-1 receptor agonists versus DPP4 inhibitors
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Background
Oral semaglutide GLP1 receptor agonist is coformulated for better absorption compared to prior injectable semaglutide. Phase 2 open label, dose escalation randomized clinical trials of semaglutide and liraglutide investigating the dose-response relationship between the two. DPP-4 inhibitor produces a smaller glycemic reduction and minimal weight reduction through effect of endogenous
GLP-1 receptor activity, while GLP-1RAs yield greater efficacy related to the pharmacological levels of these agonists stimulating GLP-1 receptor activity. DOI: 10.1530/endoabs.43.OC32

OC33

Daytime napping, daytime sleepiness and the risk of metabolic diseases: dose-response meta-analysis
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Background
Adequate sleep is important for good health, but it is not always easy to achieve because of social factors. Daytime napping is widely prevalent around the world. We recently published a meta-analysis, in which a J-shaped relationship was identified between naptime and cardiovascular diseases.

Objective
In this research, we also performed a meta-analysis to investigate the association between daytime sleepiness or napping and the risk of metabolic diseases, and to quantify the potential dose-response relation.

Methods
We searched electronic databases for articles published up to December 2015. The adjusted relative risk and 95% confidence interval were calculated with the random effect model. Dose-response relations were also evaluated by using restricted cubic spline models.

Results
About 300,000 Asian and Western subjects were selected. Pooled analysis revealed that excessive daytime sleepiness and a longer nap (60 min/day) each significantly increased the risk of type 2 diabetes by about 50% compared with the absence of these factors. In contrast, a shorter nap (60 min/day) did not increase the risk of diabetes (P=0.07). Nap time was not associated with an increased risk of obesity.

A dose-response meta-analysis using the cubic spline model showed a J-shaped relationship between naptime and the risk of diabetes or metabolic syndrome, with no effect of napping up to about 40 minutes/day followed by a sharp increase in the risk at longer times.

Conclusion
Nap time and diabetes or metabolic syndrome may be associated via a J-curve relation. Further studies are needed to confirm the efficacy of a short nap.

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OC34

Exercise Prescription in Diabetic Patients type 2
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Sedentary life is one of the main risk factors in diabetes type 2. Exercise and physical activities are very effective in prevention and treatment of diabetic patients. During exercise, muscles uptake more glucose from blood, insulin affects better and glucose is entered easily into the muscular cells. Diabetic Patients can use exercises in order to weight loss, blood glucose control, increasing body capabilities in insulin usage, decreasing body need to drug and insulin injections, heart and vessels health, decreasing blood pressure and decreasing blood lipids. Also, exercise can decrease the level of anxiety and depression, and improve the quality of sleep. Studies showed that increased exercise and physical activities are very effective in prevention of diabetes in patients at risk.

Diabetic Patients can use a variety of exercise activities including increased ADL, aerobic activities, resistance training and stretching exercises. It is recommended to select an exercise type that you enjoy it. Aerobic exercise for 30 minutes or more, 3–5 times weekly, with intensity of 40-60% VO2 max and also resistance exercises for 2–3 times weekly with intensity of 30–50% RM is recommended. In generally, Aerobic exercise such as walking, cycling and swimming are most appropriate activity for diabetic patients. Diabetic Patients with heart disease should be consulting with their physician before initiation of exercise program. If the blood sugar is higher than 250 mg/dl or lower than 100 mg/dl, do not exercise. If the signs of depressed blood sugar are happened during exercise (shivering, sweet, tachycardia) the patient should eat sweet things (cubes of sugar, chocolate, candy, juices). Exercise should be performed at a given hours and regularly in days, for example after snack time and before dinner time. The patient and trainer should be aware of possible diabetic’s complications including hypoglycemia, hyperglycemia, damage to retina, diabetic foot ulcers.

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OC35

Correction of liver damage in the metabolic syndrome
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In recent years non-alcoholic fatty liver disease (NAFLD) has been ascribed to conditions associated with the metabolic syndrome (MS). The high probability of an unfavorable course of NAFLD combined with MS symptoms dictates the need to search for some therapeutic approaches in the treatment of patients, given the similarity of the development mechanisms of both MS and NAFLD, i.e., the insulin-resistance. One of the drugs that reduces insulin resistance is Subetto (Subetto, NPF Materia Medica Holding, Russia), that provides antibodies to the C-terminal fragment of the beta-subunit of the insulin receptor and the endothelial NO synthase.
A prospective clinically controlled study was carried out performed, in which 20 men (average age: 40.05 ± 1.25 years) with ultrasound signs of NAFLD and a verified MS were examined. The research was carried out in accordance with the Declaration of Helsinki. The research lasted 3 months, during which all patients took the drug Subetto 3 times a day after meals. At baseline and after 3 months of treatment a physical examination was performed, together with the evaluation of carbohydrate metabolism (including determination of insulin and calculation of insulin resistance index HOMA-R) and the content of aspartate transaminase (AST) and alanine transaminase (ALT). Ultrasound examination of the liver was done on the scanner ClearVue 550. The results were processed according to the methods of variation statistics.
During the treatment with Subetto, 75% of the patients returned to normal levels of fasting plasma glucose, and the postprandial blood glucose levels decreased from 7.60 ± 0.16 to 6.75 ± 0.21 mmol/l. A decrease in the concentration of basal insulin by 28.7% (P<0.05) was recorded, which resulted in a significant reduction of HOMA-R index from 2.42 ± 0.01 to 1.49 ± 0.01. The number of patients with insulin resistance decreased from 100% to 40%.
Evaluation of the cytolytic syndrome showed significant reduction in the ALT activity (from 48.16 ± 5.16 to 30.39 ± 4.09 U/L, P<0.01) and AST (from 39.74 ± 3.03 to 29.35 ± 4.09 U/L, P<0.01), which is indicative of improvement of the functional state of the liver among the patients with NAFLD.

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Subetto also positively affected the size of the liver: the vertical side level size of the right lobe of the liver decreased from 159.90±3.62 to 150.20±2.79 mm and cranio-caudal size of the left lobe - from 83.80±8.37 mm to 78.60±5.74 mm (P<0.05). For patients with NAFLD and MS, treatment with Subetto (Subetta, NPF Materica Medica Holding, Russia) contributed to a relief of the key manifestations of metabolic disorders, coupled with a decrease of the severity of the cytolytic syndrome, a reduction of the aminotransferase activity, and a decrease in liver size. In addition, a high compliance to the treatment among the patients was reported.

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**OC36**

The effect of empowering on self-care and coping strategies with type 1 Diabetes

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**Background**

Diabetes mellitus has become a serious problem worldwide. Effects of diabetes stress, in addition to the physical complications had mental complications that make its treatment difficult. Concept of empowerment, enabling patients to make informed decisions and play an active role in planning and decision-making in health-related activities.

**Aim**

To determine the effect of empowering on self-care and coping strategies with type 1 diabetes.

**Methods**

This before-and-after experimental study was performed on one group of 40 diabetic. Patients referred to diabetes clinic of Mashhad Persian 1391 that they were randomly sampling in two groups. Program empowering in intervention group during the 60 min and 6 session. But the control group did not receive any intervention. Research tools included a questionnaire to assess knowledge; copi.pg strategies questionnaire Tabin, glucose and insulin were measured by two check list. Data were analyzed by SPSS version 11.5 using independent t-test and paired t-test.

**Results**

Findings showed that self-care program on empowering (knowledge, skills insulin injections, measuring of blood glu ose) in diabetic patients and has a positive impact. The two groups did not Have statistically significant intervention variables. It also detected the empowerment program increase the use effective coping strategies (problem-solving, change perceptions, social relations, expression of feelings), and reduce the use of ineffective coping strategies (avoid the problems, vain thoughts, social withdrawal, self-criticism). In conclusion the results show the effectiveness of empowerment to improve self-care and also promote effective coping strategies: problem-solving, change perceptions, social relations, expression of feelings, and reduce the use of ineffective coping strategies: avoid the problems, vain thoughts, social withdrawal, and self-criticism.

**Keywords:** type 1 diabetes, self-care, empowerment

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**OC37**

Building a clinical research network to support clinical trials in diabetes in Northern Ireland

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**Background**

The Northern Ireland Clinical Research Network (NICRN) is a regional research platform, established in 2008 to support clinical trials. NICRN comprises 10 groups, one of which is diabetes and all are supported by government funding.

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Objective

To outline the development and achievements of this research network.

**Methods**

The organisational structure is built around a hub and spoke design. The network is managed via a coordinating centre with spokes reaching into the 5 Health and Social Care Trusts covering NI. Performance targets are agreed to enable the development of a high quality portfolio around the number of studies adopted, minimum recruitment to target, the % of commercial involvement and the proportion of clinical trials.

**Results**

In 2014/15, the group was involved in 14 active studies running across 26 sites; comprising 7 investigations actively recruiting, 5 in follow-up (recruitment completed), 2 recently closed. Five studies were adopted during 2014/15.

The breakdown of the studies is: 6 CTIMP, 2 CT, 4 using questionnaire/ interview or mixed method design, 1 study was a basic science and 1 was limited to tissue samples. Of the 14 active studies, 8 had commercial involvement and the remainder were funded through research councils, charities and R&D sources. Research nurses (4.1 WTE, Band 6) have been recruited and trained, the EDGE management system has been adopted, electronic case record access agreed and a network committee including diabetologists, dietitians, nurses, a patient representative and a member of Diabetes UK (Charity) established and convened quarterly.

The individual representing the views of people with diabetes is also a member of the Diabetes UK lay research group and communicates the views of this wider group. Training of lay members is available.

**Conclusion**

The metrics indicate that this network is enabling NI to contribute to high quality clinical research in diabetes.

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**OC38**

The growing burden of diabetes on the State of Texas: The fiscal cost and associated factors

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The primary objective of this study is to examine the monetary and associated costs of diabetes in the state of Texas and the factors involved. The growing rates of obesity and associated diabetes continue to be a burden on the healthcare system. Data gathered from state records is reviewed and summarized by investigators to determine the fiscal cost of managing diabetes medically from the state and Medicaid/medicare, and also the associated costs of patients diagnosed with diabetes, such as lost time from work and cost for diabetes education, for example. The rate of incidence and prevalence of diabetes is also examined for possible association with the rising costs of diabetes. In conclusion diabetes is an increasing burden annually on the state and federal government with direct correlation to rates of obesity, education, and demographic.

**Primary Objective**

To examine the monetary and associated costs of diabetes in the state of Texas and the factors involved.

**Secondary Objective**

To examine the associated risk factors or contributing factors which affect growing incidence of diabetes.

**Research design**

Data collection and review of state department information with extrapolation of projected expenditures and the contributing factors.

**Methodology**

Data on projected diabetic spending in the state of Texas. Include demographics and population throughout the state for those diagnosed with diabetes along with the prevalence and incidence of the disease. Examine comorbid conditions which could increase spending on the diabetic patient.

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**OC39**
The effect of diet education program on glycemic and lipid profile among fasting type 2 diabetes

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**Background**
This study aimed to investigate the effect of nutritional education program based on health belief model, on the glucose and lipid profile, weight changes and frequency of hypoglycemia and hyperglycemia in type 2 diabetic patients who fast in Ramadan.

**Methods**
Based on inclusion criteria, 53 type 2 diabetic patients were referred to diabetes clinic of Endocrinology and Metabolism Research Institute, Tehran and who tended to be fast during Ramadan were enrolled and randomly assigned into 2 groups, intervention (n=26) and control (n=27). A week before Ramadan, the intervention group was educated based on the health belief model. Data on demography, health belief model components, knowledge, physical activity and anthropometric assessments were collected through face to face interview before and after Ramadan. Fasting blood samples were collected in the weeks before and after Ramadan. Both groups were asked to register food record and blood glucose two days per week (at least 3 times per day) and the number of hypoglycemia or hyperglycemia during Ramadan.

**Results**
Education in the intervention group significantly increased health believes model components such as perceived severity, perceived benefits, perceived barriers, and self-efficacy compared to control group. There was a significant difference in knowledge scores for fasting condition, blood glucose control, scores and medication, nutrition and physical activity between the two groups. There was shown no statistically significant difference in the biochemical markers between two groups and in each group. In both groups, BMI and physical activity showed a significant decrease at the end of the study compared to baseline. Calorie and macronutrient intake in the two groups did not change significantly during the study.

**Conclusion**
Focusing Ramadan education would increase the patient’s knowledge and empower them to proper management of diabetes, making changes to lifestyle and prevention of complications of fasting.

**Keywords:** Diet, Education, Glycemic, Lipids profile, fasting, Type 2 diabetes

**DOI:** 10.1530/endoabs.43.OC39

**OC40**
"Why me...? Why now? Why Diabetes?": Exploring reactions to receiving a diagnosis of type 2 diabetes mellitus

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**Background**
Receiving a diagnosis of a chronic disease such as diabetes mellitus can be a distressing and life-altering event. However, reactions to the receipt of this "bad news" can be varied and are not always negative. Further research, particularly with non-Western populations, is required to explore patients’ differing reactions to their diagnosis.

**Objective**
The objective of the study was to explore adult men and women’s reactions to diagnosis and the possible factors affecting these reactions.

**Design**
A qualitative interview design was adopted.

**Methods**
In-depth, semi-structured, face-to-face interviews were conducted, audio-recorded and transcribed. Qualitative content analysis (informed by the principles of frame-work analysis) was performed; all authors participated in the discussion of the findings, and consensus was obtained for each identified theme.

**Settings**
The study was conducted at the Diabetes Association of Iran. The association offers wide-ranging, specialized, multidisciplinary services six-days-a-week, for outpatients who are referred by a doctor or nurse specializing in diabetes.

**Participants**
Twenty participants (11 men and 9 women) with type 2 diabetes referred to the Diabetes Association of Iran (to receive consulting services in the fields of nutrition, psychology and health care) were recruited via purposive (maximum-variation) sampling.

**Results**
Four themes emerged from the study: emotional responses, cognitive responses, behavioral responses and contextual factors. A complex interplay between the themes was identified.

**Conclusions**
Emotional responses to receiving diagnosis of diabetes can be varied and affect the ways in which people think about and react to their diagnosis in terms of behavior change. Family may play a key role in how people initially respond to their diagnosis and should be considered in future research and interventions to support the psychological needs of adults diagnosed with type 2 diabetes mellitus. The results of this study can be utilized by healthcare professionals when planning care programs to support patients to manage the disease.

**DOI:** 10.1530/endoabs.43.OC40

**OC41**
Non-invasive lower limb small arterial measures co-segregate strongly with foot complications in people with diabetes

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**Aim**
In diabetes, non-invasive lower-limb assessments including continuous wave Doppler (CWD), ankle-brachial index (ABI) and toe-brachial index (TBI) are recommended to assess vascular status due to increased risk of ulceration and amputation associated vascular pathology. How well these measurements can identify those at risk of these complications is unknown. The aim of this study was to investigate the relationship between a history of foot complication and non-invasive vascular assessments in people with diabetes.

**Methods**
Bilateral ABIs, TBIs and CWDs were performed in 100 consenting adults with diabetes (54% type 2; age 64.9 ± 11.3 years; 55% men; diabetes duration 8.8 ± 7.9 years; 21% on insulin therapy; 15% with a foot complication history including ulceration or amputation). Correlations were performed between known risk factors for, and documented history of, foot complications. Regression analysis was used to determine the effect of each vascular measurement on the likelihood of a previous foot complication.

**Results**
By logistic regression, the likelihood of foot complications history was highest in those with TBI 0.6 (OR = 10.17, P < 0.002); longer diabetes duration (OR = 1.08, P = 0.012) and higher HbA1c (OR = 1.05, P = 0.045). ABI (OR = 3.31, P = 0.783) and CWD (OR = 1.299, P = 0.264) did not independently predict a history of foot complications.

**Conclusions**
Likelihood of foot complication presence in this population was ten times higher when the TBI was 0.6, whereas such clinical risk profiling was not shown by other non-invasive measures. Prioritising TBI as a measure of lower limb microvascular disease may be useful to prospectively identify those at risk of diabetic foot complications.

**DOI:** 10.1530/endoabs.43.OC41
Conducting randomised control trials in diabetes with adults with an intellectual disability: a systematic review

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Background
Between 1-2% of the population have an intellectual disability (ID), within this group the rate of diabetes is approximately 12%: three times higher than the non-disabled population. Although pharmacological therapy is frequently prescribed for this population, there is a lack of evidence underpinning these interventions. Likewise, there is a paucity of evidence regarding the different behavioural self-management programmes for people with ID.

Conducting randomised control trials (RCTs) is a complex process. However, conducting RCTs with hard-to-reach populations poses additional methodological and clinical challenges. In order to address the sparse evidence base of these pharmacological and behavioural interventions, more RCTs are needed.

Objective
This poster has two objectives. Firstly, to highlight the methodological barriers to conducting diabetes RCTs with people with ID. Secondly, to identify strategies to overcome methodological barriers faced in undertaking RCTs with hard-to-reach populations.

Methods
A systematic review of the ID RCT literature, spanning 15 yrs, was conducted exploring the frequency of trials for people with diabetes, the methodological challenges inherent in conducting this research and strategies to overcome them.

Results
No diabetes pharmacological or behavioural RCTs were conducted with an ID population. The review highlighted a number of methodological challenges identified from trials in other areas with those with ID including identification/recruitment, consent, capacity and the use of proxy informants. A number of creative and effective strategies for addressing these methodological challenges were identified.

Conclusions
Whilst the RCT literature within the fields of diabetes and ID are growing separately, this poster offers guidance on how to overcome a range of methodological challenges faced by trialists, thereby enhancing opportunities to include people with ID and other hard-to-reach populations in future trials. This review will inform methodology underpinning diabetes pharmacological and behavioural trials with ID and potentially other hard-to-reach populations.

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Pediatric Investigational Plan (PIP)

The Effect of Family-centered Care on Management of Blood Glucose Levels in Adolescents with Diabetes
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Background
Responsibility for diabetes management tasks must shift from caregivers to adolescents as adolescents grow older. Also, family-centered care is a way to provide efficient care for them at home. This study aimed to identify the effect of family-centered care on management of blood glucose levels in adolescents with type 1 diabetes mellitus (T1DM). This is a Pre-experimental study with a pre- and post-test design. The participants consisted of forty adolescents with T1DM, aged between 10-14 years, with their caregivers who were selected through simple random sampling from Hamadan Diabetes Research Center in Iran in 2013. The sample was divided into four similar groups. Educational sessions were conducted for each group for 30-40 minutes. Data collection tools were “supervisory behaviors of caregiver” (SBC), “management behaviors of adolescents” (MBA) questionnaires, and the “blood glucose levels record sheet”. Data were analyzed using SPSS 19 and based on descriptive statistics, Kolmogorov-Smirnov, paired t-test and Pearson coefficient.

Results
There was a significant difference between the subjects’ MBA and SBC mean scores before (110.17±26.6) and after (134.6±1.28) intervention in four domains: “blood glucose testing”, “insulin therapy”, “meal plan” and “physical activity” (P<0.001). There were significant differences between the mean levels of recorded blood glucose during a week before and after intervention and between the mean levels of Glycated Hemoglobin level (HbA1c) before (8.4±1.12) and three months after (7.78±1.2) it (P<0.001). Pearson coefficient showed a positive relationship between the SBCs with MBA before and after the intervention (P<0.001). Empowering adolescents with T1DM and their caregivers in home-centered care could improve diabetic adolescents’ management of blood glucose levels and reduce their HbA1C levels. Therefore, family-centered care could provide for better regime adherence at home.

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Regulatory Trends in Diabetes

Effect of curcumin supplementation on anthropometric measurements in patients with type 2 diabetes
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Objective
Curcumin is the main natural polyphenol found in the rhizome of Curcuma longa (turmeric). Experimental evidence supports the activity of curcumin in promoting weight loss. This double blind randomized, controlled study aims to evaluate the effect of curcumin on anthropometric measurements in patients with type 2 diabetes.

Methods
About 44 subjects were randomly assigned to receive either curcumin or placebo capsules for 10 weeks. The patients in the curcumin group (n=22) received 500 mg curcumin capsules three times daily, whereas the placebo group (n=22) received matching placebo capsules.
received same dose of the placebo. At baseline and the end of week 10 anthropometric measurements (weight, height, waist and hip circumferences) were determined according to standard protocol. The questioners of general characteristics and 24-hour food recall were completed by interview.

Result
The mean nutrient and fiber intake, drug intake and physical activity of patients did not change during the study. This study showed a significant reduction in weight in curcumin compared to control group ($P=0.04$) after 10 weeks of intervention. No significant difference was observed in waist circumference between two groups at the end of the study.

Conclusion
This study suggests that daily administration of 1500 mg curcumin has positive effect on weight loss in patients with type 2 diabetes.

Keywords: curcumin, turmeric, weight reduction, weight loss, diabetes

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OC46

**The role of plant natural products in diabetes drug discovery and development: A report with focus on Nigerian biodiversity**

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**Background**
Diabetes mellitus (DM) is a metabolic disorder resulting from a defect in insulin secretion, insulin action, or both. Insulin deficiency in turn leads to chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism. DM affects most of the people in both developed and developing countries. The treatment of diabetes with conventional drugs is very expensive and chances of side effects are high.

Plant natural products have a proven global history of treating diseases and ailments. These medicinal plants have been used since ancient times in various parts of the world where access to modern medicine is limited. Medicinal plants play an important role in the management of DM especially in developing countries where resources are meagre.

**Objective**
The specific objective of this article is to provide a comprehensive report on on-going global efforts to discover and develop more efficacious anti-diabetic drugs with no side effect from various medicinal plants found within Nigerian’s rich flora, which have been shown to display potent hypoglycaemic activity.

**Methods**
Different researchers in different fields (chemistry, biochemistry and molecular biology) have employed technological developments in separation methods, hyphenated technique and high throughput assays to drive the drug discovery processes.

**Conclusion**
Natural products identified from medicinal plants give an exciting opportunity for the development of new therapeutic agents for the treatment of DM. Most prevalent among natural products are flavonoids, terpenoids cardiac glycoside, alkaloids and steroids. Despite considerable progress in the development of synthetic drugs, the discovery of phytochemistry as an alternative therapy is progressing.

Keywords: Medicinal plants, Natural products, Diabetes mellitus, Antioxidant activity, Anti-hyperglycaemic activity Drug discovery and development

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OC47

Abstract unavailable.

OC48

**Effects of Telemedicine Intervention on Exercise Capacity and Quality of Life in Patients with Type 2 Diabetes Mellitus**

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**Background**
Exercise training has become an important adjunct therapy for both the prevention and management of type II diabetes mellitus. Interest in telemedicine is increasing as a potentially innovative and sustainable intervention approach to diabetes management. Telemedicine can facilitate the achievement of individualized treatment goals by training patients to manage their own disease.

**Objective**
To evaluate the effect of telemedicine on exercise capacity and quality of life in patients with type II diabetes mellitus.

**Methods**
Twenty patients with type II diabetes mellitus randomized to either telemedicine treatment group ($n=12$; HbA1C% $=7.3 \pm 0.8$, mean age $=55.3 \pm 11.2$ years, BMI $=33.6 \pm 5.2$ kg/m$^2$) or a control group ($n=8$; HbA1C% $=8.8 \pm 7.9$, mean age $=50.2 \pm 13.8$ years, BMI $=26.0 \pm 2.3$ kg/m$^2$). Treatment procedure consists of callisthenic exercises at home by internet based video conferences, 3 days a week for 6 weeks and supervised by a physiotherapist and the patients kept a diary. Disease education performed to all participants at the beginning of the study. Exercise capacity was evaluated by Six Minutes Walk Test (6MWT) and quality of life was assessed by Short Form 36 (SF-36).

**Results**
SF-36: physical functioning ($P=0.01$), physical role functioning ($P=0.01$), emotional role functioning ($P=0.02$) sub parameters and 6MWT walking distance ($P=0.00$) were significantly improved after the training in the treatment group while no improvement was obtained in the control group. The change in physical functioning ($P=0.00$) and physical role functioning ($P=0.02$) scores significantly differed between two groups.

**Conclusion**
Telemedicine intervention may be appropriate for type II diabetes mellitus who has activity limitation and may be useful for those who cannot participate in other form of exercises. Studies are limited and more trials that include cost evaluation are required.

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OC49

**Modulating effects of omega-3 fatty acids and pioglitazone combination on insulin resistance through toll-like receptor 4 in type 2 diabetes mellitus**

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Background
Toll-like receptor 4 (TLR-4) plays an important role in innate immunity. Changes in the reduction-oxidation balance of tissues can lead to a pro-inflammatory state and insulin resistance typically seen in diabetes. An action thought to be mediated by TLRs. Omega-3 fatty acids and peroxisome proliferator activated receptor gamma (PPAR-γ) agonists as pioglitazone are currently used for decreasing inflammation in diabetes.

**Aim**
The aim of this study is to investigate the potential anti-diabetic effects of combining omega-3 fatty acid with the insulin sensitizer “pioglitazone” in a rat model of type 2 diabetes, and the modulating effects on TLR-4.

**Method**
Type 2 diabetes was induced in male Sprague-Dowley rats by combination of high fat diet and low dose streptozotocin (35 mg/kg). Diabetic rats were treated with omega-3 fatty acids (10%W/W diet), pioglitazone (20 mg/kg), and their combination for a period of 4 weeks.

**Results**
Omega-3 fatty acids and combination therapy significantly decreased TLR-4 activation, compared to diabetic group ($P=0.05$). Omega-3 fatty acids, pioglitazone, and combination therapy showed significant decrease in TLR-4 mRNA expression. Omega-3 fatty acids, pioglitazone and their combination significantly lowered hepatic malondialdehyde, total cholesterol and triglycerides levels, compared to diabetic group. Pioglitazone and combination significantly decreased blood glucose levels and improved insulin resistance.

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In this study, an antibacterial electrospun nanofibers for wound dressing application was successfully prepared from polyvinyl alcohol (PVA), Pluronic F127 (Plur), polyelectrolyte (PEI) blend solution with titanium dioxide nanoparticles (TiO2NPs). PVA–Plur–PEI nanofibers containing various ratios of TiO2NPs were obtained. The formation and presence of TiO2 in the PVA–Plur–PEI/TiO2 composite was confirmed by X-ray diffraction (XRD), Transmission electron microscopy (TEM), Fourier transform infrared (FTIR), thermal gravimetric analysis (TGA), mechanical measurement, and antibacterial activity were undertaken in order to characterize the PVA–Plur–PEI/TiO2 nanofiber morphology and properties. The PVA–Plur–PEI nanofibers had a mean diameter of 220 nm, and PVA–Plur–PEI/TiO2 nanofibers had 255 nm. Moreover, the antimicrobial properties of the composite were studied by zone inhibition against Gram-negative bacteria, and the result indicates high antibacterial activity. Results of this antibacterial testing suggest that PVA–Plur–PEI/TiO2 nanofiber may be effective in topical antibacterial treatment in wound care; thus, they are very promising in the application of wound dressings.

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**OC51**

**Effects of curcumin supplementation on BMI and blood pressure in patients with type 2 diabetes**

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**Objective**

Diabetes and hypertension frequently occur together. Obesity, inflammation, oxidative stress, and insulin resistance are thought to be the main risk factors for them. Several spices have been shown to exhibit activity against hypertension and obesity through antioxidant and anti-inflammatory mechanisms. Among them curcumin has shown to be non-toxic and exhibits various bio-logical activities such as anti-oxidant and anti-inflammatory effects. This study was designed to indicate the effects of curcumin supplementation on blood pressure and BMI in patients with type 2 diabetes.

**Methods**

Forty patients with type 2 diabetes were supplemented triple daily for 10 week with either a curcumin (1500 mg/day) or a placebo capsule. Systolic blood pressure (SBP) and diastolic blood pressure (DBP) were measured twice in a sitting position on the right arm after 15 min of rest and the mean of the two measurements was considered as the subject’s blood pressure. In addition anthropometric measurements (weight, height, waist and hip circumferences) were determined and BMI was computed at the baseline and 10 weeks later. The results of this study indicates that a 10-week period supplementation has no effect on BMI and systolic and DBP in patients with type 2 diabetes. Keywords: curcumin, turmeric, systolic blood pressure, diabetes, obesity

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**OC52**

Abstract unavailable.

**OC53**

Abstract unavailable.

**OC54**

**Insomnia in adults with Type 2 diabetes: Baseline data from the Diabetes Sleep Treatment Trial**

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**Purpose**

Previous studies have established that obstructive sleep apnea (OSA) frequently co-exists in persons with type 2 diabetes (T2DM) with negative effects on glycemic control and functional outcomes. However, there is limited data about the effect of insomnia or co-morbid OSA and insomnia among those with T2DM. We compared glucose control, functional outcomes, sleep quality, and daytime sleepiness among 4 groups of participants with T2DM: (i) OSA, (ii) insomnia, (iii) OSA + insomnia, and (iv) normal sleep.

**Methods**

This study was a secondary analysis of baseline data from the Diabetes Sleep Treatment Trial (R01-DK096028). Measures evaluated OSA severity (Apnea-Link Plus to determine apnea + hypopnea index [AHI]; AHI ≥ 10 = OSA), insomnia severity (Insomnia Severity Index [ISI]; scores ≥ 15 = clinical/moderate insomnia), sleep quality (Pittsburgh Sleep Quality Index [PSQI]; global score5 ≥ 10 = poor sleep quality), functional outcomes (Functional Outcomes of Sleep Questionnaire [FOSQ]; normal ≥ 18), and excessive daytime sleepiness (Eighth Sleepiness Scale [ESS]; ESS ≥ 10 = excessive sleepiness). Clinical evaluations with A1C and height /weight measurements for body mass index (BMI kg/m2) were obtained. Descriptive statistics and *apriori* planned comparisons of (insomnia, insomnia + OSA) versus (Normal, OSA) were conducted on the targeted outcomes with statistical significance set at *P* ≤ 0.05.
OC55
“Energetic balance” appreciation as a complementary feedback for insulin delivery monitoring in glucose metabolism disorders
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Background

Hoping to avoid repeated hypoglycaemia and yo-yo phenomena, alternative feedback was proposed based on the body “energetic balance” evolution checking. A device (ADD-CIT – Apparatus for Diagnosis of Diabetes and Complex Insulin Therapy) measuring the differences between core and superficial temperatures (Dt) evolution and programming insulin delivery was proposed and first-tested (PDT, 2015).

Objective

The present work aims at the ADD-CIT evaluation in decompensating diabetic patients.

Methods

About 148 patients with DM-1 disease – before kidney-pancreas transplantation (32), in critical situations (58) or decompensating (39) were included after informed consent. Besides current clinical analysis, blood glucose and lactate were determined once every hour during the ADD-CIT sessions. As a comparison evolution of similar patients (19) treated as usually was considered. Results

In 95% of the cases insulin delivery monitored by Dt evolution was efficient: blood glucose mean fall varying from 30+/−5% up to 48+/−18% (20%+/−5% in control) followed by stabilisation at an acceptable level was obtained within 3–4 hours. Mean insulin amount/hour remained between 2 and 10 UI. Hypoglycaemia (72 mg/dl) was relatively less frequent in the ADD-CIT groups, than in control. Hypoglycaemia episodes could be predicted by a Dt fall while blood glucose was still normal or even elevated. That has allowed earlier and more adequate correction. No side effect of ADD-CIT use could be noted. Blood glucose was still normal or even elevated. That has allowed earlier and more adequate correction. No side effect of ADD-CIT use could be noted.

Conclusion

In 93% of the cases insulin delivery monitored by Dt evolution was efficient: blood glucose mean fall varying from 30+/−5% up to 48+/−18% (20%+/−5% in control) followed by stabilisation at an acceptable level was obtained within 3–4 hours. Mean insulin amount/hour remained between 2 and 10 UI. Hypoglycaemia (72 mg/dl) was relatively less frequent in the ADD-CIT groups, than in control. Hypoglycaemia episodes could be predicted by a Dt fall while blood glucose was still normal or even elevated. That has allowed earlier and more adequate correction. No side effect of ADD-CIT use could be noted. Blood glucose was still normal or even elevated. That has allowed earlier and more adequate correction. No side effect of ADD-CIT use could be noted.

OC56
The use of modified hyperinsulimnic hypoglycaemic glucose clamp to evaluate the accuracy of blood glucose monitoring systems in T1DM patients
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Background and aims

The ISO guideline 15197 lays out the system accuracy (SA) and user performance (UP) evaluation requirements for BGMS for self-testing in managing diabetes mellitus. They require the measurement of blood glucose to be tested across a spectrum of glucose ranges to demonstrate accuracy, including within the hypoglycemic range. Fulfilling the requirements for accuracy evaluations at the hypoglycemic range can be challenging. The aim of the study was to show that a modified hyperinsulinemic glucose clamp can be used to fast-track the evaluation of new BGMSs in hypoglycemic ranges for regulatory purposes.

Materials and methods

Nineteen patients with type 1 Diabetes participated in a hypoglycemic clamp to evaluate the SA and UP of a BGMS within the hypoglycemic range (63–75 mg/dl). Demographic data of study population was: age 30±1.7 years; duration of diabetes 13.1±1.7 years; mean HbA1c 6.46±3.36 mmol/mol). Patients had no pre-existing significant microvascular or macrovascular complications of diabetes and had been performing self-monitoring since diagnosis. During the hypoglycemic glucose clamp blood glucose levels were maintained in a stable non dynamic state during which the BGMSs were investigated for UP and SA was confirmed by an industry standard reference instrument (YSI 2300).

Results

About 19/19 patients successfully completed the hypoglycemic glucose clamp. 18 patients met the UP ISO requirements (±15 mg/dl of the average values of the reference measurement procedure at glucose concentrations 100 mg/dl) one subject did not meet these requirements (16.2 mg/dl) due to patient application error. 15 of the 15 subjects evaluated for SA met the ISO requirements (±15 mg/dl of the results of the reference measurement procedure at glucose concentrations 75 mg/dl).

Conclusion

These results demonstrate that the modified hyperinsulimnic hypoglycemic glucose clamp is a safe, robust and reliable method of evaluating the accuracy of BGMSs at levels of hypoglycemia for regulatory purposes.

References


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would pull apart the ends of the transverse arch of the foot, thereby increasing the AI. This experience might be more adverse in the less dominant foot considering the observed relationship between the left AI and STJ motions, which should be closely monitored in patients with diabetes.

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OC58
ALMS1 acts as a critical molecular switch that controls Insulin-stimulated glucose transport in adipocytes
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Background
ALMS1 is a 461kDa protein that, when mutated, causes Alström syndrome (AS). AS is a rare autosomal recessive disorder characterized by childhood obesity and early-onset insulin-resistant diabetes, amongst other features. Studies using primary human adipocytes revealed that ALMS1 is critical for insulin-regulated glucose transport. The predominance for insulin resistance and T2DM in AS children seems to reflect a hitherto uncharacterized role of ALMS1 in the insulin signaling pathway, rather than just being secondary to obesity.

Objective
We sought to characterize the effect of ALMS1 inactivation on insulin signaling and glucose transport in ALMS1-deprived primary human adipocytes.

Methods
In order to knock down ALMS1, we used human white visceral adipocytes and used a lentiviral-mediated RNA-interference. To characterize the effect of this protein we performed qPCR, western blot, immunofluorescence microscopy and protein identification by mass spectrometry. To evaluate the insulin-dependent glucose uptake, we used C57BL/6 transgenic mice, with an Alms f/f, adiponectin-knockout and glucose transport in ALMS1-deprived primary human adipocytes.

Results
Our data demonstrate that in absence of insulin, ALMS1 is linked to zPKC, regulating the swelling and plasma membrane integration of GLUT4 secretory vesicles (GSVs). In response to insulin, ALMS1 is no longer bound to TBC1D4, concomitantly releasing zPKC and thereby allowing zPKC to activate the GSVs/ATPase, triggering GSVs membrane fusion. Subsequently, we demonstrated that in primary human adipocytes artificial release of zPKC from its ALMS1 binding site activated glucose absorption in absence of insulin.

Conclusion
These findings represent a novel exploitable pathway for drug development in order to treat hyperglycemia and glucose intolerance.

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OC59
Human cartilage glycoprotein39 (HC-gp39) stands up for “Madam Diabetes”-a peasant French woman: An update
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Diabetes remains a major public health burden worldwide. The causes of Diabetes have not been fully understood and there is to date no cure for Diabetes. Accumulating evidence, however, supports the notion that interplay between HC-gp39 and adipocytes could be fundamental in understanding the pathobiology of type 2 Diabetes and help to develop novel therapeutic strategies to arrest metabolic dysfunction. HC-gp39 is an inflammation-associated chitinase-like protein, found in vertebrates as well as invertebrates. HC-gp39 has been reported to be implicated in almost all human pathological conditions. It is believed to play particularly critical role in both the genesis and the clinical outcome of diabetes, respectively. HC-gp39 working in concert with Toll-like receptor 4 and a set of adaptor proteins may impact on the activity of the DNA-binding components with concomitant perturbation of mitochondrial activity leading to impairment of age-related insulin production in human Islets. Additionally, HC-gp39 has been suggested to impact upon autophagy execution machinery. Autophagy is controlled by complex signaling pathways, including those used by insulin, whereby phosphatidylinositol 3 kinase (PI3K) plays important role. Hence, high serum levels of HC-gp39 resulting from disordered expression of HC-gp39 might lead to the destruction of the beta-cells of the pancreas. Furthermore, Pannexin1 has been reported to contribute significantly to metabolic homeostasis through its role in controlled ATP-release from the adipocytes, suggesting that factors in a position to regulate Pannexin 1 channel activity may be of enormous importance for the management of type 2 diabetes. Src Kinase phosporylation of Pannexin1 was suggested to mediate NMDA-receptor activation of the channel. Now, high serum levels of HC-gp39 resulting in perturbation of the activation of Src Kinase via disruption of the binding activity of 85 KDa regulatory subunit of PI3K) would negatively impact on the Src Kinase phosphorylation of Pannexin1 mediated NmDA-receptor activation of the channel resulting in preventing ATP release and eventually leading to disruption of insulin metabolism.

The above considerations, coupled with recently emerging notion that HC-gp39 may interact with tumor Suppressor Candidate 5 (TUSC5) an important regulator of insulin action in adipocytes, make a case suggesting an exceptionally clinically relevant mechanism for HC-gp39 in this pathology and implies an important role for HC-gp39 in controlling metabolic homeostasis.

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OC60
Glucose transporters and C peptide role in diabetes control a preclinical review of literature
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Background
C-peptide therapy ameliorates sensory nerve function in T1DM neuropathy. Prolonged GLUT-4 translocation and delayed counter regulation can induce hypoglycemia. GLUT-2 protein is the primary hepatic liver transporter related to hepatic glucose regulation and it also plays a role on glucose sensing by pancreatic beta cells, via hepatoporal sensors controlling the autonomic nervous system and stimulates glucagon secretion.

Objective
To discuss the role of isoforms GLUT 2, GLUT 4 and C peptide in the control of diabetes based on analyses of published scientific literatures.

Methods
Review of relevant preclinical and published clinical trial literature on GLUT 2, GLUT 4 and C peptide was completed. Results are analyzed in relation to its role in T1DM or T2DM. Authorship and journal citation observed.

Results
A randomized and placebo controlled study on C-peptide with 139 participants with mean age of 30.6 years. Eighty six percent has neurological impairment. C peptide treatment for 6 months among T1DM participants. GLUT 2 serves as a specific molecule which is required on glucose metabolism and play a role on pancreatic beta cell glucose sensing mechanism. Analyses of cultured hepatocytes treated with high glucose (25 mmol/L) shows that glucose plays a major role in GLUT2 gene upregulation. Comparison of T1DM mice versus normal control mice and the effect of exercise in GLUT 4 shows in mean ± SE, that T1DM group demonstrates a sudden dropping of glucose with exercise stimulus at hour 3 post prandial versus the control on steady state all throughout hour 5.

Conclusions
C-peptide treatment improves sensory nerve function in early stage type 1 diabetic neuropathy. GLUT2 plays a role in primary hepatic regulation and pancreatic beta cells. Exercise induced hypoglycemia in T1DM by prolonging GLUT 4 translocation.

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