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THERAPEUTICS AND CLINICAL TRIALS

DAPAGLIFLOZIN'S EFFECT ON SERUM HOMOCYSTEINE IN PATIENTS WITH HYPERTENSION COMPLIACTED WITH INSULIN RESISTANCE

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Objective: Most patients with hypertension complicate with insulin resistance (IR), which is one of risk factors of hypertension and can increase the level of serum homocysteine (hcy) by affecting hcy metabolic enzyme and insulin. Investigations in recent years have shown that hcy is an independent risk factor of cardiovascular diseases. At present, folic acid is the main drug used to reduce hcy, but its effection for hcy has obvious individual difference, which is closely related to individual genes. Moreover, folic acid (FA) is mostly used in patients with hcy beyond 15 μmol/l, but hcy beyond 10 μmol/l has had an adverse effect for cardiovascular system. Animal studies have shown that dapagliflozin can improve insulin resistance. Therefore, whether it can reduce hcy has become a new direction.

Design and method: This study is a retrospective case-control study. Patients with highly serum hcy and hypertension complicated with insulin resistance are divided into two groups: dapagliflozin group and FA group. Before and after 12 weeks of treatment, the changes in serum hcy and IR index are measured and compared.

Results: (1) The IR index and serum hcy levels are clearly lower in the dapagliflozin group after therapy, and the changement of IR index and the level of serum hcy has a significant relativity. (2) The IR index reduction is more noticeable in the dapagliflozin group than in FA group. (3) In dapagliflozin group, the standard deviation (SD) of serum hcy is lower than in the FA group.

Conclusions: Dapagliflozin can reduce the serum hcy level of patients with hypertension and insulin resistance in a certain extent, also having an important effection in reducing IR. The lowering of serum hcy in the dapagliflozin group is more balanced than in the FA group. Dapagliflozin could be a viable option for these patients.

EPLERENONE VS IRBESARTAN AS FIRST LINE THERAPY IN OBESE HYPERTENSIVE PATIENTS: PRELIMINARY RESULTS FROM HEBRO STUDY

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Objective: Obesity is significantly associated with adverse cardiovascular outcomes. The relationship between obesity and hypertension is well described with obese patients having two times the incidence of developing increased blood pressure (BP). However, little is known about the impact of aldosterone blockade using eplerenone on hypertensive obese patients as first line therapy. The aim of this study was to compare the efficacy between eplerenone and irbesartan in obese hypertensive subjects.

Design and method: A prospective, randomized, open-labeled, multicenter trial enrolled 54 hypertensive patients aged 30 to 75 years old, with obesity [body mass index BMI > or = 30 kg/m2)], evaluated by home BP, office BP and ambulatory BP measurements. Subjects randomly received 25 mg eplerenone twice daily or 150 mg irbesartan every morning. The primary endpoint were systolic and diastolic BP after 2 months of follow up.

Results: In 54 hypertensive obese patients [53.7% women, mean age 55.8 ± 10.9 years, BMI 34.6 ± 3.1 kg/m2, mean office BP 146.4 ± 9.7/91.8 ± 9.8 mmHg and mean ABP 140.9 ± 7.9/84.6 ± 8.2 mmHg] there was no significant difference in the reduction of systolic ABP between irbesartan and eplerenone (11 ± 14.8 vs. 7 ± 14.7, p = 0.11), nor in the reduction of diastolic ABP (5 ± 8.3 vs. 3.8 ± 9.7, p = 0.13). Moreover, there was no difference in the reduction of OBP in irbesartan group (12 ± 11.3 vs. 9.4 ± 12.7, p = 0.14) in comparison with eplerenone group (7.1 ± 8.7 vs. 2.8 ± 8.7, p = 0.11). Also, there was no statistical significant change in renal function parameters and electrolytes levels in both groups

Conclusions: this study suggests that eplerenone does not differ in efficacy and safety compared to irbesartan, an established angiotensin receptor antagonist, as first line therapy in obese hypertensive patients.

GENDER AS A RISK FACTOR FOR CARDIOVASCULAR EVENTS IN PATIENTS WITH HYPERTENSIVE CRISES AFTER 12-MONTH FOLLOW-UP: A GREEK REGISTRY

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Objective: Currently, epidemiological data on prognosis of patients with hypertensive crises (HC) are limited. The purpose of our study was to register the prevalence and clinical characteristics of patients with hypertensive urgencies (HU) and emergencies (HE) admitting to the emergency department (ED) and during hospitalization and a 12-month follow-up to record new end points in a Greek tertiary hospital.

Design and method: The study population included patients reporting to the ED with acute rise in blood pressure (BP) (systolic BP> or = 180mmHg and/or diastolic BP> or = 120mmHg), categorizing as HE and HU depending on the presence or absence of acute hypertension-mediated target organ damage, respectively. In all patients the demographic and clinical information were registered for 12 consecutive months. In addition, there was a 12-month follow-up for new events.

Results: Out of 38,589 patients assessed in the ED during a period of 12 months, 353(0.91%) had HC, out of whom 256(72.5%) had HU and 97(27.5%) had HE. The mean age of the HE patients was 73 ± 12years, 51.5% were males and 86.4% had a history of hypertension. During the study period 3 HE patients did not complete the follow-up. After stratification of HE population by gender, we created two subgroups, males and females, and analyzed the composite end point involving deaths or hospitalizations by cardiovascular causality. Men reported more composite events than women (21 vs 11 events, p = 0.042, HR for males 2.2, 95% CI 1.03–4.6). Cox regression models were adjusted for age, gender, cardiovascular disease, chronic kidney disease and diabetes mellitus.

Conclusions: The results indicate male gender as an independent risk factor for deaths or hospitalizations caused by cardiovascular disease in patients with HE. Our registry highlights the commitment for a more intensive follow-up of HE patients, especially for men, and underlines the need for further research in this pathological entity.

STATINS, BUT NOT PCSK9 INHIBITORS, REDUCE THE ADIPOKINE CHEMERIN IN FAMILIAL HYPERCHOLESTEROLEMIA: FOCUS ON LIPOPROTEIN SUBFRACTIONS

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Objective: Familial hypercholesterolemia (FH) is characterized by severe elevations in circulating LDL-cholesterol, and an increase in the risk of dyslipidemia-related cardiovascular disease (CVD). Chemerin, as a newly identified adipokine, is considered as an additional risk factor for CVD. Here we investigated whether it can be modified by cholesterol-lowering therapy.

Design and method: Lipoprotein subfractions were isolated by density gradient ultracentrifugation. Lipids and chemerin concentrations were determined both before and after cholesterol lowering with either a statin (atorvastatin, simvastatin, rosuvastatin, or fluvastatin) or a PCSK9 inhibitor (PCSK9i; alirocumab or evolocumab).

Results: At baseline chemerin levels were 113 ± 46 (statin group) and 95 ± 44 (PCSK9i group) ng/ml, while triglyceride (TG) levels were 1.9 ± 1.6 and 2.6 ±

1.7 mmol/ml, high-density lipoprotein cholesterol (HDL-c) levels were 1.3 ± 0.4 and 1.2 ± 0.4 mmol/ml, and low-density lipoprotein cholesterol (LDL-c) levels were 5.7 ± 1.5 and 4.9 ± 1.4 mmol/ml (P = ns for difference between 2 groups). Chemerin correlated positively with triglycerides (r = 0.45, P < 0.005) and negatively with HDL-c (r = -0.33, P < 0.01). Both statins and PCSK9i reduced LDL-c (by 41 and 62%, P < 0.0001), triglycerides (by 13 and 19%, P < 0.01), and increased HDL-c (by 8 and 23%, P < 0.01), but only statins additionally reduced chemerin (by 35%, P < 0.005). The lipoprotein subfraction profile revealed that chemerin accumulated particularly in the HDL3 fraction (containing > 60% of all chemerin in lipoprotein subfractions), with approximately 30% being present in the HDL2 fraction, and approximately 3% in the LDL fraction. Statins reduced HDL3-c and HDL3-TG, and the level of chemerin bound to all subfractions. PCSK9i reduced HDL3-c but did not affect HDL3-TG or the level of chemerin bound to HDL3 and HDL2.

Conclusions: Circulating chemerin occurs in different lipoprotein subfractions, accumulating particularly in the HDL3 fraction. Statins, but not PCSK9i, lowers chemerin, possibly by interfering with its levels across lipoprotein subfractions. This may represent a novel cardiovascular protective function of statins.

OBSERVATIONAL PROSPECTIVE STUDY OF AZILSARTAN MEDOXOMIL/ CHLORTALIDONE COMPARED WITH IRBESARTAN/ HYDROCHLOROTHIAZIDE COMBINATION THERAPY IN OBESE HYPERTENSIVES (PUZZLE)

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Objective: Attainment of blood pressure (BP) control is important to successful management of arterial hypertension (AH). It is more difficult to reach recommended BP goals in obese hypertensives. Combination of ARB and thiazide diuretics is recommended. Azilsartan medoxomil/chlorthalidone (AZL-C) is potent and currently the only fixed combination of ARB and thiazide-like diuretic used for AH. The objective of this study was to evaluate influence of AZL-C on office, 24-hour brachial, central blood pressure and aortic stiffness parameters compared with irbesartan/hydrochlorothiazide (IRB-H).

Design and method: We included 94 patients 35–55 years old with I-II grade AH and obesity at high cardiovascular risk. Patients with symptomatic organ damage, intolerance of ARB, thiazide diuretics, secondary AH were exluded. All patients underwent phisical exam, office, ambulatory BP measurement with arterial stiffness analysis on inclusion, during 1, 3 and 6 months visit. After inclusion 47 patients received AZL-C dose 40/12.5 or 40/25 mg, 47 patients received IRB-H dose 150/12.5 or 300/25 mg. The study was approved by local ethic committee and registered on clinicaltrials.gov (NCT03006796).

Results: On 1 month visit 37(79%) patients reached office BP goals in AZL-C group vs 32(68%) in IRB-H, finally the proportion was 45(96%) vs 41(87%). After 3 months significantly more patients received higher doses of IRB-H: 18(38%) vs 9(19%) in AZL-C group. The mean office systolic/diastolic BP on the final visit was 126,4/84,5 in AZL-C vs 132,7/89,9 mmHg in IRB-H group. The mean ambulatory SBP/DBP was 124,6/77,6 in AZL-C vs 127,4/81,7 mmHg in IRB-H group. After 6 months the mean ambulatory central SBP and aortic augmentation index reduced in both groups, more significantly in AZL-C patients: from 129,4 to 115,3 vs. from 129,5 to 117,6 mmHg in IRB-H group; from 26% to 17% vs. from 28% to 21% in IRB-H. There were no changes in ambulatory PWV in both groups, which may be due to the variability of this parameter during the day.

Conclusions: Both fixed combinations of ARB and diuretic are safe and effective treatment of AH in obese patients, but long-term treatment with AZL-C allows to achieve more stable peripheral and central BP decrease.

THE ASSOCIATION BETWEEN ANTIHYPERTENSIVE TREATMENT AND SERIOUS ADVERSE EVENTS BY AGE AND FRAILTY: AN OBSERVATIONAL COHORT STUDY OF 3.8 MILLION PATIENTS FOLLOWED UP FOR 10 YEARS

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Objective: Antihypertensives are effective at reducing the risk of cardiovascular disease, but limited data exist quantifying their association with serious adverse events (SAEs), particularly in older people with frailty. This study examined this association using data from a large database of electronic health records.

Design and method: This was a retrospective observational cohort study, utilising data from the Clinical Practice Research Datalink in England. Patients were eligible if they were aged 40 years or older, with a systolic blood pressure reading between 130–179 mmHg and not previously prescribed antihypertensive treatment. Outcomes were defined as hospitalisation or death within 10 years due to hypotension, syncope, falls, fractures, acute kidney injury (AKI), electrolyte abnormalities and gout. The association between antihypertensive treatment and SAEs was examined by cox regression, using propensity score adjustment to adjust for confounding. Subgroup analyses were undertaken by age and frailty.

Results: A total of 3,834,056 patients, aged 57 ± 12 years, were eligible for the study. Of these, 484,187 (12.6%) were prescribed antihypertensive medication in the 12 months prior to the index date. Over a median follow-up of 7.1 years, antihypertensives were associated with an increased risk of hypotension (HR 1.32, 95%CI 1.29–1.35), syncope (HR 1.20, 95%CI 1.17–1.22), falls (HR 1.23, 95%CI 1.21–1.26), AKI (HR 1.44, 95%CI 1.41–1.47), electrolyte abnormalities (HR 1.42, 95%CI 1.43–1.48) and gout (HR 1.32, 95%CI 1.46–1.52). The absolute risk of SAEs with treatment was very low, ranging from four syncope events to twelve AKI events per 10,000 patients treated per year. In older patients and those with severe frailty, this risk was increased up to 116–120 events per 10,000 patients treated per year.

Conclusions: Antihypertensive treatment is associated with an increased risk of SAEs, but the absolute risk of harm is very low. However, in older patients and those with severe frailty, this absolute risk is increased and physicians should take this risk into consideration when making prescribing decisions.

THE OPEN-LABEL MULTICENTRAL STUDY OF ANTIHYPERTENSIVE FIXED-DOSE COMBINATION EFFECTIVENESS IN UKRAINE

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Objective: The aim of this study was to evaluate the effectiveness of new 2- or 3-component fixed-dose combinations (FDC) with Olmesartan in comparison with general clinical practice antihypertensive treatment.

Design and method: 72 physicians were involved in the multicenter open-label study. They included patients with uncontrolled systolic (SBP)/diastolic(DBP) blood pressure in spite of at least one-month therapy and without exclusion criteria. The one group(n = 604) was treated by Olmesartan/HTC or Olmesatan/HTC/Amlodipin (with up-titration). The other group(n = 311) was treated according to general clinical practice. The physicians were asked to use the FDC more frequently. The follow-up period was 3 months.

Results: There were included 1055 patients (59.9 ± 0.5 yr), but only 915 (SBP/DBP–164.9 ± 4.2/93.3 ± 0.3mmHg) were examined at 3 month, the others were lost of follow up. 62.5% at baseline and 94% at the end were on FDC therapy. Baseline 56.7% missed the pills vs 9% at the end of study (P < 0.001). The main reasons were forgetfulness, consideration of not need taking due to BP normalization, not convenient regime, unwilling - 35.5, 30.9, 10.7 and 12.4% at baseline vs 8.1, 0.3,1.4 and 1.4% at the end of study (P < 0.001). 48.6% at baseline vs 9.5% at the end considered the missing of one or more pills could not influence on treatment results and 35.4 vs 3.4% receptively considered they take a lot of pills. Baseline in the group of non-FDC treatment the not-compliant, partly compliant, compliant patients consist 68.1, 11.3 and 20.8% vs 63.4, 18.5 and 18.1% (NS) in the group of FDC therapy. At the end of study there were 59.7, 6,5 and 33.9 vs 17.7, 25.9 and 58 % respectively (P < 0.05). δ SBP/DBP was -48/23, 44/21 and 28/14 mmHg (P < 0.001/0.039) in Olmesartan 2-, 3-component FDC and in other therapy groups. The target BP (<140/90mmHg) was achieved in 83.5% of Olmesartan FDC group vs 71.2% (P < 0.05) in other therapy group.

Conclusions: Only 62.5% of hypertensive patients are on FDC therapy in Ukraine. More frequently use of FDC was associated with improving patient compliance. The 2- or 3-component Olmesartan based FDCs were more effective in BP decreasing than routine antihypertensive therapy.

META-ANALYSIS OF THE EFFECT OF DUAL GIP AND GLP-1 RECEPTOR AGONISTS ON BLOOD PRESSURE LEVELS IN PATIENTS WITH TYPE 2 DIABETES MELLITUS

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Objective: Hypertension and type 2 diabetes mellitus (T2DM) are common comorbidities, with hypertension being twice as frequent in patients with T2DM compared to those without. Blood pressure (BP) control is of utmost importance for subjects with T2DM, in order to minimize the risk for development of cardiovascular and chronic kidney disease. High on treatment BP levels also cor-