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LACTOBACILLUS PARACASEI B21060, ARABINO GALATTANO AND XILOOLIGOSACCHARIDES: SYMBIOTIC CANDIDATES TO REDUCE CHOLESTEROL LEVELS

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Introduction: Elevated blood cholesterol is an important risk factor associated with atherosclerosis and coronary heart disease. Probiotics have been proposed for the treatment of dyslipidemia.

Aim: To evaluate efficacy, tolerability and safety of a new symbiotic formulation containing a combination of probiotic (*Lactobacillus paracasei* B21060) and prebiotics (arabinogalactano, xilooligosaccharides) and amine (L-glutamine) in the early treatment of children affected by familial hypercholesterolemia (FH).

Methods: FH subjects, aged 6–12 years, consecutively observed at a Tertiary Center for Pediatric Nutrition were randomly allocated to two groups of intervention for 6 months: active group, received a low saturated fats diet plus the symbiotic (2.5×10^9 cfu, bid) for 6 months; control group, received low saturated fats diet alone. All children received written indications for low saturated fats diet. The plasmatic lipid profile was assessed by peripheral blood sampling at T0 and T1.

Results: 40 FH children were enrolled (20 in active group: 8 male, median age 8.4 yrs, BMI 17.6; 20 in control group: 8 male, median age 7.5 years, BMI 17.0. All subjects

completed the study. At T1 a reduction of C-LDL, total cholesterol, LDL/HDL ratio was observed in both groups, but the differences were significant only in active group (median value (IQR) C-LDL: 221 (55) vs 192 (33), $p < 0.01$; total cholesterol: 280 (31) vs 260 (43), $p < 0.05$; LDL/HDL: 4.0 (1.5) vs 3.5 (1.3), $p < 0.05$). The symbiotic preparation was well accepted by the children, the adherence was $>90\%$, no side effects were observed.

Conclusions: The symbiotic containing *Lactobacillus paracasei* B21060 is able to significantly reduce main laboratory biomarkers in children with FH. The treatment was well accepted and tolerated by patients. Our results open the light on new opportunity for the early treatment of pediatric FH. Further studies are advocated to better define the mechanism of action and the potential of a long term use of this new strategy.

ANALYSIS OF THE INFLUENCE OF BASELINE DIABETES DURATION (DD) ON BLOOD PRESSURE RESPONSES TO LIRAGLUTIDE

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Introduction: Across the phase 3 ‘Liraglutide Effect and Action in Diabetes’ (LEAD)1–6 and liraglutide vs sitagliptin (Lira-DPP-4i) trials, once-daily liraglutide (LIRA) consistently reduced systolic blood pressure. In a sub-analysis of LEAD trials, significantly greater reductions in SBP were observed with LIRA in patients aged ≤ 65 vs >65 years. Since diabetes duration (DD) was 3–4 years longer in the groups >65 years, this

observation raised concerns that DD may influence SBP responses to LIRA.

Aim: To evaluate the effect of DD on changes in SBP and DBP with LIRA vs placebo in LEAD-1-6 and Lira-DPP-4i.

Methods: Linear regression analyses of pooled 26–28-week data from LEAD-1-6 and Lira-DPP-4i were carried out to estimate the slope for SBP and DBP changes from randomisation vs DD. Data used were for the intention-to-treat population, last observation carried forward (LIRA 1.2 mg, $n = 1,117$; LIRA 1.8 mg, $n = 1,581$; placebo, $n = 524$). The statistical model used assumed equal residual variance across trials and included baseline SBP/DBP values, DD and age as continuous covariates. For pooled data, the model also included a categorical trial effect.

Results: DD ranged from <1 to >40 years (mean for the pooled study population: ~ 8 years). There were no statistically significant relationships between DD and changes in SBP (pooled estimate [95 % CI]: LIRA 1.2 mg: -0.05 [$-0.20, 0.10$]; LIRA 1.8 mg: -0.05 [$-0.16, 0.06$]; placebo: -0.08 [$-0.30, 0.14$]) or DBP (LIRA 1.2 mg: 0.01 [$-0.08, 0.10$]; LIRA 1.8 mg: -0.05 [$-0.12, 0.02$]; placebo: -0.04 [$-0.18, 0.09$]) observed with LIRA or placebo. Non-significant trends toward larger reductions in SBP and DBP with greater DD were evident, except for DBP with LIRA 1.2 mg.

Conclusion: DD did not appear to affect the SBP and DBP responses to LIRA observed in the LEAD-1-6 and Lira-DPP-4i trials. These findings suggest that the blood pressure-lowering effects of LIRA are not limited to those with shorter DD.

MYOCARDIAL PERFORMANCE IN BREAST CANCER SURVIVORS ATHLETES

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Introduction: The upper limbs edema in breast cancer survivors is a frequent side effect, often controlled with sport activity as Dragon Boat. Few information are available on the cardiovascular performance when this sport is regularly practiced.

Aim: To evaluate in a group of survivors breast cancer women (BC), the effects of Dragon Boat sport on the myocardial performance during 4 years of follow up.

Methods: Since 2006–2010, one year after the diagnosis of breast cancer, a group of 55 women, previously treated with adjuvant therapy without evidence of metastasis, has been consecutively enrolled in a Dragon Boat competitive

team. They were yearly submitted to an ergometric test, and to an 2D echocardiographic exam (MayLab 50-ESA-OTE) to evaluate the hemodynamic, morphological and functional cardiac parameters. All data have been matched with a group of 36 healthy women (HW).

Results: Both groups have maintained a normal systolic function during all the period, despite the CMi and BMI and EF values were higher in HW. At the onset of the study, the diastolic function of the BC group turns out to be compatible with an initial diastolic dysfunction, if compared with the HW group. After 4 years of sport Dragon Boat activity, the diastolic parameters resulted to be improved in both, but specially in BC group (A peak: from 68.5 ± 15.1 to 50 ± 14.1 cm/s with $p < 0.05$; E': from 9.3 ± 2 to 11.89 ± 1.7 cm/s with $p < 0.001$). The data obtained from the ergometric test showed in both normal values despite in HW group, the data were significantly higher than in BC (Double Product $23,870 \pm 3,190$ in HW vs BC $22,785.8 \pm 276$ with $p < 0.005$).

Conclusions: The results obtained demonstrate significant improvement of the diastolic function in BC survivors after four years of Dragon Boat sport training with an excellent effort's tolerance. Competitive sport activity, does not seem to have any negative impact on the myocardial performance in patients previously treated with chemotherapy.

CARDIOVASCULAR FITNESS ASSESSMENT IN RENAL ORGAN TRANSPLANTS

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Introduction: Regular physical exercise is a new method to reduce the metabolic syndrome in presence of solid transplantations.

Aim: To assess the benefits of a supervised exercise training program, in renal solid organ recipients.

Methods: By the informed consent, six renal transplant recipients patients, were submitted to supervised aerobic exercise program, whose intensity, duration and frequency were established after a cardiopulmonary exercise test. An echocardiographic exam, skin fold, bio impedance analysis, and test of strength for the lower limbs (leg press for the quadriceps and calf) and higher limb (arm curl, French press and lateral lift) were also performed. The exercises consisted in 30 min of aerobic training at the intensity of aerobic threshold and 2 sets of 20 repetitions at 35 % of the maximum load for each resistance exercise.

Results: All the echocardiographic parameters are normal (LVDd 48.0 ± 3.6 mm; LVSd 30.0 ± 5.4 mm; CMI 116.8 ± 21.7 m/m²; EF 62.0 ± 3.2 %; E 85.2 ± 15.2 peck cm/s; DT 212.7 ± 58.0 cm/s). These values will then be updated every six months to adapt the program that will end after 1 year of training.

Conclusion: Cardiovascular fitness assessment after renal transplantation is an essential requirement to start with an aerobic and resistance exercise program. The Physical Exercise is a promising tool in this special category despite the eventual long term positive impact is not yet demonstrated.

The results is shown in attachments table.

Table 1 Anthropometrics, hydration and functional parameters recorded during the first evaluation in patients with renal organ transplant before to start the exercise program

	Mean
Age (years)	47.3 \pm 11.5
Time from transplant (years)	4.8 \pm 2.1
Height (m)	1.7 \pm 0.1
Weight (kg)	65.6 \pm 6.9
BMI (kg/m ²)	23.4 \pm 2.5
Skin fold	
Triceps (mm)	15.0 \pm 4.3
Pectoral (mm)	14.0 \pm 6.3
Subscapula (mm)	17.3 \pm 5.3
Midaxilla (mm)	14.8 \pm 7.1
Abdomen (mm)	22.3 \pm 9.6
Suprailiac (mm)	10.3 \pm 4.8
Quadriceps (mm)	17.5 \pm 10.7
Body fat (%)	17.0 \pm 7.6
Bio impedance	
Rz (ohm)	556.8 \pm 113.4
Xc (ohm)	52.7 \pm 17.1
PA (°)	5.4 \pm 1.0
TBW (L)	37.2 \pm 6.0
ECW (L)	18.3 \pm 3.5
ICW (L)	18.9 \pm 3.5
Aerobic threshold	
ml O ₂ /kg/min	14.8 \pm 6.4
Heart rate (bpm)	111.2 \pm 27.2
Load (W)	66.7 \pm 12.9
VO ₂ peak	
ml O ₂ /kg/min	19.9 \pm 7.3
Heart rate max (bpm)	127.7 \pm 30.7
Load (W)	95.8 \pm 18.8
Leg press (quadriceps)	
Right (kg)	43.2 \pm 23.0
Left (kg)	39.7 \pm 19.3
Leg press (calf)	

Table 1 continued

	Mean
Right (kg)	39.3 \pm 21.0
Left (kg)	45.4 \pm 22.1
Arm curl	
Right (kg)	7.4 \pm 1.2
Left (kg)	8.1 \pm 3.7
French press	
Right (kg)	5.0 \pm 1.6
Left (kg)	4.9 \pm 1.8
Lateral rise	
Right and left (kg)	3.4 \pm 0.8

CARDIOVASCULAR PERFORMANCE AFTER 5 MONTHS OF EXERCISE AS PRESCRIPTION PROGRAM: A 6 MIN WALKING TEST AND ECHOCARDIOGRAPHIC FOR FUNCTIONAL ASSESSMENT

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Introduction: Exercise as Prescription represents a therapy in many chronic diseases. More recently the employment of the 6 Minute Walking Test (6MWT) for a regular evaluation has been spread.

Aim: To verify the role of the 6MWT in predicting the progressive improvement of the heart performance.

Methods: Eleven hypertensive patients, were enrolled for this study. At the beginning (T0) and after 5 months (T5) of exercise program, at least three times a week at moderate intensity, a 6MWT was carried out to evaluate: meters (m), Peak Heart Rate (PHR), Peak Respiratory Rate (PRR), Systolic and Diastolic blood pressure (SBP, DBP). In the same session an Echocardiographic exam was performed.

Results: all data are expressed as mean and standard deviation. After 5 months there was a trend:

- the distance in 6 min was in T0: 567.27 ± 66.65 m in T5: 599.09 ± 81.42 m ($p \leq 0.05$),
- PHR was in T0: 134.36 ± 12.13 b/min in T5: 136.00 ± 10.30 b/min ($p = 0.74$),
- PRR resulted in T0: 30.00 ± 4.38 r/min in T5: 31.45 ± 4.95 r/min ($p = 0.47$),

- SBP was in T0: 137.73 ± 14.89 mmHg in T5: 143.64 ± 12.67 mmHg ($p = 0.33$),
- DBP mean values were in T0: 75.27 ± 7.80 mmHg in T5: 70.91 ± 5.84 mmHg ($p = 0.15$). The CMI resulted to significantly ($p < 0.05$) increased after 5 months of regular exercise

Conclusions: exercise as prescription improves the effort tolerance showed by the HR response at the peak of the exercise, with an increase of CMI parameter. The 6 MWT seems to be a sensible test much more than echo parameters whose modifications need a longer period of observation. Otherwise the pulmonary response to the exercise does not seem to be apparently easily estimated in presence of exercise program at moderate intensity.

EXERCISE PRESCRIPTION PROGRAM TO REDUCE CARDIOVASCULAR RISK FACTORS: COMPARISON BETWEEN CANCER AND HYPERTENSIVE PATIENTS

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Introduction: Despite the positive effects of the exercise therapy in patients with chronic disease has been well demonstrated, however the global response and any possible differences among different kinds of diseases, after a short period of an unsupervised program, it has not yet well investigated.

Aim: To verify the effects of fast walking associated to a resistance exercise to improve the cardiovascular risk factor.

Methods: Two groups of subjects (10 cancer survivorship and 19 hypertensive) were submitted to an evaluation of exercise tolerance with 6-Minute Walking Test (6MWT), assessing heart rate, respiratory rate, systolic and diastolic blood pressure at rest and at the end of the 6MWT. Bio-impedance measure the distribution of the Intra and Extracellular water, the Sit & Reach Test evaluated the flexibility, Handgrip and 30" Chair Test for muscular strength. From the 6MWT data, the intensity and duration of exercise was established per each patients. The exams were performed at the beginning and after 3 month of regular physical exercise.

Results: Main findings of the study are reported in Table 1. A significant reduction of anthropometric parameters it has been observed in the hypertensive population. A significant improvement in water distribution was also observed. A predominant improvement of the cardiovascular parameters was on the contrary observed in cancer group.

Conclusion: A combined aerobic and resistance exercise program can induce a predominant modification of the cardiovascular risk factors in a hypertensive population. On the contrary it is more evident in a population affected of cancer, the improvement of the exercise tolerance and the flexibility parameters more frequently related to the muscles fatigue. The same program seems to be therefore adequate for both, despite in presence of different kind of chronic disease and with apparent different risk factors. Further studies will be anyway necessary to investigate the main cause of this diverse sensibility.

Table 1 Parameters recorded during the two visits in cancer patients and in patients with hypertension at the beginning of the program and after 3 months of physical exercise therapy

	Cancer T0	Cancer T3	p value	Hypertensive T0	Hypertensive T3	p value
Height (cm)	165.5 ± 12.0	165.5 ± 12.0	NS	163.5 ± 10.0	163.5 ± 10.0	NS
Weight (kg)	82.2 ± 23.5	80.6 ± 21.6	NS	77.9 ± 16.6	76.2 ± 15.8	<0.00
BMI (kg/m ²)	30.3 ± 10.3	29.8 ± 9.7	NS	29.2 ± 6.8	27.4 ± 4.4	<0.00
Abdominal (cm)	92.4 ± 19.2	90.9 ± 17.3	NS	92.5 ± 14.1	92.1 ± 12.8	<0.05
Waist (cm)	109.2 ± 21.1	110.5 ± 19.2	NS	101.1 ± 8.6	101.0 ± 8.5	NS
Abd/waist	0.8 ± 0.1	0.8 ± 0.1	NS	0.9 ± 0.1	0.9 ± 0.1	NS
RZ (ohm)	542.7 ± 91.2	569.7 ± 104.1	<0.05	520.5 ± 82.8	513.4 ± 86.0	NS
XC (ohm)	59.9 ± 10.5	61.4 ± 11.6	NS	58.1 ± 17.6	55.9 ± 12.3	NS
Phase Angle (°)	6.4 ± 1.1	6.2 ± 0.7	NS	6.4 ± 1.4	6.2 ± 1.1	NS
Total Body Water (Lt)	38.1 ± 8.2	37.0 ± 7.9	<0.04	39.9 ± 8.6	38.1 ± 8.1	NS
Extra Cellular Water (Lt)	16.9 ± 3.9	16.7 ± 3.8	NS	17.5 ± 3.7	17.2 ± 3.9	<0.05
Intra Cellular Water (Lt)	21.2 ± 4.9	20.3 ± 4.6	NS	20.9 ± 4.8	21.9 ± 4.2	NS
Rest Metabolic Rate (kcal)	1521.1 ± 152.8	1525.0 ± 182.7	NS	1536.4 ± 187.5	1556.1 ± 174.5	NS
Rest HR (bpm)	77.1 ± 9.2	74.0 ± 12.4	NS	76.3 ± 12.1	71.2 ± 9.9	NS

Table 1 continued

	Cancer T0	Cancer T3	p value	Hypertensive T0	Hypertensive T3	p value
Heart Rate 6'WT (bpm)	137.4 ± 12.9	131.5 ± 15.2	NS	126.9 ± 18.2	127.9 ± 15.3	NS
Respiratory Rate 6'WT (bpm)	30.0 ± 6.7	29.0 ± 5.3	NS	42.5 ± 19.6	39.5 ± 9.1	NS
rest SBP (mmhg)	121.7 ± 8.7	118.3 ± 13.2	NS	128.3 ± 7.5	126.9 ± 12.5	NS
rest DBP (mmhg)	76.4 ± 6.5	72.2 ± 7.1	<0.05	82.0 ± 7.1	78.1 ± 9.9	NS
SBP 6'WT (mmhg)	141.7 ± 10.9	135.3 ± 7.1	NS	153.8 ± 8.3	141.8 ± 12.0	NS
DBP 6'WT (mmhg)	73.7 ± 6.3	70.6 ± 6.8	NS	75.6 ± 8.6	72.5 ± 6.4	NS
Mt 6' WT (m)	487.8 ± 116.0	525.6 ± 117.3	<0.05	590.0 ± 67.3	575.4 ± 56.9	NS
CR10 Scale	5.7 ± 3.3	4.9 ± 2.9	NS	3.0 ± 2.1	2.7 ± 2.1	NS
Sit & Reach (cm)	0.4 ± 7.4	4.1 ± 6.1	<0.05	-5.2 ± 8.3	-6.2 ± 6.5	NS
Chair Test (rip)	11.8 ± 2.2	14.1 ± 3.9	NS	16.6 ± 3.4	16.4 ± 2.8	NS
Hand Grip dx (kg)	29.3 ± 17.2	27.5 ± 5.1	NS	36.3 ± 10.2	33.8 ± 11.6	NS
Hand Grip sx (kg)	30.5 ± 13.4	27.2 ± 5.6	NS	34.0 ± 9.1	33.2 ± 11.9	NS

RESISTANCE AND AEROBIC EXERCISES IN CANCER PATIENTS: PHYSICAL CAPACITY AND QUALITY OF LIFE OUTCOMES

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Introduction: Physical Exercise (PE) is normally used in patients with cancer to reduce the fatigue. The effects of a combination aerobic and resistance training, after a short period, it has not been well investigated.

Aim: To verify the effects of fast walking and resistance exercise, to improve the cardiovascular and body composition parameters in cancer patients.

Methods: A group of ten cancer survivors (breast and colon) were submitted to a mixed PE program composed in a week by three times of fast walking and two times of resistance exercise. Before to start, they were all evaluated for exercise tolerance and anthropometrics parameters, the exams performed were: 6-Minute Walking Test (6MWT), heart rate, Respiratory Rate, systolic and diastolic blood pressure (DBP) at rest and at the end of the 6MWT, the idration evaluation by bioimpedance, the Sit and Reach test for flexibility (S&R), the HandGrip and 30'' Chair Test for strenght of upper and lower limbs. These exams were performed at the beginning and after 3 months of exercises.

Results: The anthropometrics and idration parameters showed a trend toward a reduction (waist circumference T0: 92.4 ± 19.2, T3: 90.9 ± 17.3 cm, p < 0.05; total water T0: 38.1 ± 8.2, T3: 37.0 ± 7.9 L p < 0.05). 6MWT data shows an improve of the distance covered (T0: 487.8 ± 116.0 m, T3: 525.6 ± 117.3 m, p < 0.05), the DBP at rest is lower (T0: 76.4 ± 7.1, 72.2 ± 7.1 mmHg,

p < 0.05). The flexibility is significantly improved (S&R T0: 0.4 ± 7.4, T3: 4.1 ± 6.1 cm, p < 0.005).

Conclusion: The combination of resistance and aerobic exercises determine a significant improvement, in a short time, of the principal parameters strongly related with the cardiovascular risks factors and the quality of life. The two kinds of exercise are easily accepted on behalf of the subjects investigated, inducing a larger adhesion to the exercise program in the cancer survivors population.

LIFESTYLE AND EATING HABITS ANALYSIS OF A WORKING BUSINESS COMMUNITY

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Introduction: The analysis of the lifestyle is one of the most important aspects in terms of prevention of many chronic diseases. The questionnaires are one of the most direct and used methods for a first investigation for discovery sedentary and poor dietary habits.

Aim: To highlight the prevalence of some incorrect aspects of lifestyle and the prevalence of chronic diseases in a working community.

Methods: It was investigated a sample from a working community of a pharmaceutical company in Tuscany. We used questionnaires translated into Italian language whose content was extracted from validated models in the international literature: INRAN for eating habits and Physical Activity Stages of Change for tendency to exercise.

Results: 95 subjects, 58 female (F) and 37 male (M) aged 42.0 ± 0.7 years, completed the questionnaire. Only 12 %

were smokers, the prevalence of chronic diseases was 35 % (67 % F and 33 % M). The active population was 75 % of the whole group, only 25 % were sedentary. The percentage of the gender into the active subjects was similar. In 51 % of cases physical activity was regularly practiced more than once a week, while 13 % did it only once. For eating habits, food intolerances were in 8 %, the choice of food is in prevalence for consumption of fruits, cereals and dairy products, low consumption of fish and alcohol. The meat consumption was in the average. The perception of their general quality of life is at the highest level, in 70 % of the community the score reached is in the range from 60–90 %.

Conclusion: The lifestyle's questionnaires represent now a valid system for the evaluation of risk factors closely related to cardiovascular risks. Questionnaires can be used for their positive implications for the educational role on the general population. The results obtained confirm the sensitivity of the working realities to undergo to these investigations.

SHORT AND LONG TERM OF A 3-MONTH KETOGENIC DIET ON CARDIOVASCULAR RISK PROFILE IN THE SETTING OF CLINICAL PRACTICE

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Introduction: Ketogenic diets have been shown in the short-term to promote weight loss, and to improve some metabolic parameters of obese patients, in highly specialized obesity clinics.

Aim: To test the short and long-term effects of a 3-month ketogenic diet on the cardiovascular disease risk profile of overweight-obese patients in the setting of general practice.

Methods: We consecutively recruited 377 subjects (M: 22 %, W: 78 %; mean age: 46 ± 10 years, mean BMI: 31 ± 3). They were instructed to follow a 3-month ketogenic diet, and then to gradually recover to a balanced diet with a follow-up visit at 6 and 12 months. Changes in studied parameters was evaluated by ANOVA for repeated measures.

Results: After three months, there was a significant improvement in body weight (-7.6 ± 5.6 kg), BMI (-2.8 ± 2.3 kg/m²), Waist circumference (-7.1 ± 4.4 cm), Index of Central Obesity (-0.04 ± 0.02), and % of fat (-3.8 ± 3.8) (all, $p < 0.01$), that further improved at 6 months ($p < 0.05$), and then remained constant till 12 months. FPG

(-8.7 ± 15.3 mg/dL), HbA1c (-0.2 ± 0.7 %), LDL-C (-19.4 ± 31.2 mg/dL), TG (-23.4 ± 61.2 mg/dL), gGT (-4.0 ± 11.4 mg/dL) and SBP (-10.5 ± 12.8 mmHg), DBP (-2.2 ± 6.2 mmHg), PP (-8.4 ± 12.6 mmHg) improved after 3 months and the stabilized till 12 months. HDL-C ($+1.8 \pm 11.7$ mg/dL), and SUA (-0.4 ± 2.9 mg/dL) only improved after 6 months ($p < 0.05$) and then stabilized till the end of the study. No significant change in renal parameters or electrolytes changes was observed beyond a mild by significant decrease in calcemia ($p < 0.05$). The long term body weight loss was higher in those subjects experiencing a ketonuria in the first period of diet, and was directly related to the baseline body fat mass and inversely to the patient age.

Conclusions: A 3-month ketogenic diet safely improve a large number of anthropometric and cardiometabolic parameters in the setting of general practice and these effects seems to be maintained on the long-term after diet normalization.

BERBERINE AND MONACOLIN EFFECTS ON WOMEN WITH OESTROGESTIN-INDUCED HYPERCHOLESTEROLEMIA

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Introduction: One of the most frequent side effect of oral contraceptives use is a stable alteration of the lipid profile. This could be even more relevant in women affected by polycystic ovary syndrome (PCOS).

Aim: To investigate the possible beneficial effect of a largely tested low-dosed combined lipid-lowering nutraceutical on dyslipidemias induced by oestrogestins prescribed to young women for different indications.

Methods: We prospectively enrolled 84 patients in primary cardiovascular disease prevention, with low estimated cardiovascular disease risk (< 5 % according to the ESC/EAS guidelines), and LDL-C increased above normal value (LDL-C > 130 mg/dL) after the use of at least two different oral oestrogestins treatments. Forty-four women were prescribed oral oestrogestins for PCOS, while 40 for pure contraception. The tested nutraceutical contained berberine 500 mg/tab and monacolins 3 mg/tab was prescribed to all enrolled patients, associated the previously prescribed standard lipid-lowering diet.

Results: After three months of nutraceutical treatment, we observed a significant improvement in BMI (-1.5 ± 0.8 %, $p < 0.001$), FPG (-6.9 ± 5.8 %, $p < 0.001$), HOMA index

($-3.5 \pm 5.6 \%$, $p < 0.001$), TC ($-20.1 \pm 6.6 \%$, $p < 0.001$), LDL-C ($-25.3 \pm 8.9 \%$, $p < 0.001$), HDL-C ($+14.1 \pm 2.2 \%$, $p < 0.001$), TG ($-29.9 \pm 25.2 \%$, $p < 0.001$) and hsCRP ($-2.5 \pm 2.4 \%$, $p = 0.019$). Similar results have been obtained even repeating the analysis by subgroups, beyond hsCRP that significantly improved in PCOS patients compared to both the baseline and the non-PCOS group.

Conclusion: It appears that the tested combined lipid-lowering nutraceutical is able to equally improve lipid metabolism in oral contraceptive induced cholesterolemic women affected or not by PCOS.

FACTORS ASSOCIATED WITH 2-YEAR PERSISTENCE IN FULLY NON REIMBURSED LIPID-LOWERING TREATMENTS (STATINS AND NUTRACEUTICALS)

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Introduction: Long-term persistence on lipid-lowering treatment is usually low in clinical practice. The lack of treatment reimbursement is one of the main predictors of non-persistence in therapy.

Aim: To evaluate the main factors associated with long-term persistence in lipid-lowering treatment among patients without right to drug reimbursement.

Methods: We retrospectively evaluated the clinical charts of moderately hypercholesterolemic subjects visited each 6 months over at least 2 years during a 6-year period in the outpatient lipid clinics of the University of Bologna, in primary prevention for cardiovascular disease, without right to reimbursement of lipid-lowering treatments based on the Italian regulation. We selected 628 subjects (M: 307; F: 311, mean age 59 ± 9 years old), to whom we firstly prescribed a statin (N. 397) or different kind of lipid-lowering nutraceuticals (N. 231), mainly containing red yeast rice more or less associated to other active components. Then, depending of their will, patients took brand statin (N. 194) or generic statins (N. 203), without significant differences among genders.

Results: In our cohort of patients, the main determinants of long-term persistence in therapy are female sex, family history of early cardiovascular disease, baseline LDL-C and treatment with nutraceuticals versus statins.

Persistence appears not to be influenced by patient age, smoking habit, adverse events during treatment, and estimated cardiovascular risk. The target LDL-C < 115 mg/dL was reached by the 76 % of patients on statins (without significant differences between generic and brand statins) and by the 67 % of those on nutraceuticals ($p < 0.05$).

Conclusion: On the basis of our data, it seems that the use of lipid-lowering nutraceuticals is associated to a higher long-term persistence in therapy than full paid statins, while the use of brand statins a higher persistence in therapy than generic drugs, independently from the cost of the treatment.

SERUM URIC ACID RELATES WITH EJECTION FRACTION IN ELDERLY OUTPATIENTS AFFECTED BY HYPERTENSION RELATED CHRONIC HEART FAILURE

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Introduction: An increasing body of evidence suggest that serum uric acid (SUA) is a cardiovascular disease risk factor, however only preliminary data support the hypothesis that it could be also involved in the prognosis of chronic heart failure.

Aim: To evaluate the relationship between SUA and left ventricular ejection fraction (EF) in a large cohort of outpatients affected by hypertension related heart failure.

Methods: For this study, from the general cohort of patients followed by the heart failure outpatient clinic of the Bologna University Hospital, we consecutively selected 487 outpatients affected by hypertension related heart failure (M = 291, 59.8 %; F = 196, 40.2 %; mean age: 72 ± 11 years old).

Results: In an univariate analysis SUA appears to have an inverse strong relationship with EF: $B = -4.392$, 95 % CI -5.427 to -3.357 , $p < 0.001$). When including in a multivariate analysis age, BMI, medium arterial pressure (MAP), heart rate, haemoglobin, fasting plasma glucose, LDL-cholesterol, HDL-cholesterol, and creatinine, the model best predicting FE included only SUA ($B = -3.005$, 95 % CI -4.386 to -1.623 , $p < 0.001$) and MAP ($B = 0.241$, 95 % CI 0.047 – 0.435 , $p = 0.015$). Repeating the analysis by sex, we confirmed that SUA was a significant strong predictor of EF in men, but not in women (where MAP and BMI were the best predictors). Repeating the analysis on the basis of the obesity level, we did not

find any difference in the ability of SUA to predict EF in slim patients as in obese ones.

Conclusion: SUA seems to be inversely related to EF in elderly patients affected by heart failure, after correction for a large number of clinical variables, especially in men.

LONG-TERM PREDICTORS OF IMPAIRED FASTING GLUCOSE AND TYPE 2 DIABETES IN SUBJECTS WITH FAMILY HISTORY OF TYPE 2 DIABETES: A 12-YEARS FOLLOW-UP OF THE BRISIGHELLA HEART STUDY HISTORICAL COHORT

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Introduction: Data coming from 174 sources representing 130 countries show that in 2013 382 million people had diabetes and this number is expected to rise to 592 million by 2035, mainly because of increasing aging, obesity and sedentarity, in both developing and developed countries. Among risk factors, family history of T2DM is a strong predictors of incident disease, and, even if not modifiable, it could be very useful to easily detect people at high risk.

Aim: To identify and quantify the role of different risk factors in the long-term development of IFG and T2DM in a rural Italian population sample with family history of T2DM.

Methods: We selected a sample of 1,271 adult subjects from among those 1,851 consecutively visited during four consecutive Brisighella Heart Study surveys (1996–2008), then selecting those ones with a family history of T2DM. Thus, we obtained a final sample including 545 subjects and for which a full clinical and ematochemistry data set was available.

Results: The Cox-regression model better predicting the incident IFG and T2DM included age, gender, FPG, TG and SUA. The model best predicting the incident IFG status alone (without T2DM) is very similar to that predicting both IFG and T2DM, including the same predictors. Finally, the model best predicting T2DM (excluding IFG) simply includes FPG, BMI and ALT/AST ratio. Repeating the Cox-regression analysis using BMI as a covariate, TG appears to be also a significant predictor of T2DM (HR 1.018, 95 % CI 1.009–1.041, $p = 0.013$).

Conclusion: In a sample of subjects with a family history of diabetes the best long-term predictors of IFG are age, gender, FPG, TG and SUA, while those of T2DM are FPG and BMI.

SERUM URIC ACID AND MARKERS OF LDL-OXIDATION IN A LARGE SAMPLE OF OVERALL HEALTHY SUBJECTS: DATA FROM THE BRISIGHELLA HEART STUDY

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Introduction: Serum uric acid (SUA), an inexpensive and standardized marker of systemic oxidative stress, has been recently associated to the risk to develop atherosclerosis-related cardiovascular events.

Aim: To evaluate the eventual relationship between SUA, oxidized LDLs and LDL susceptibility to oxidation in a relatively large sample of non-smokers healthy subjects.

Methods: We selected from the general database of the Brisighella Heart Study a sample of 354 non-smokers and non-pharmacologically treated young subjects (age included between 20 and 55 years), in primary prevention for cardiovascular disease, without known allergic nor rheumatological disease (including gout), not assuming antioxidant dietary supplements, visited during the 2008 population survey. A full set of clinical and ematochemistry parameters has been evaluated together with oxidative susceptibility of LDL and oxidized LDL dosage level.

Results: In the multivariate analysis, the LDL lag phase was inversely related to apo B ($B = -0.166$, 95 % CI -0.259 to -0.073 , $p = 0.001$) and FPG ($B = -0.254$, 95 % CI -0.471 to -0.037 , $p = 0.022$). The propagation phase was directly related to age ($B = 0.117$, 95 % CI 0.025 – 0.209 , $p = 0.013$) and inversely to TG ($B = -0.021$, 95 % CI -0.038 to -0.004 , $p = 0.015$). The dienes level was directly related to LDL-C ($B = 0.685$, 95 % CI 0.347 – 1.023 , $p < 0.001$), SUA ($B = 2.201$, 95 % CI 1.117 – 5.285 , $p < 0.001$) and ApoB ($B = 0.717$, 95 % CI 0.404 – 1.031 , $p < 0.001$) level. The oxLDL level was directly related to apo B ($B = 0.077$, 95 % CI 0.015 – 0.139 , $p = 0.016$), TG ($B = 0.050$, 95 % CI 0.032 – 0.069 , $p < 0.001$), LDL-C ($B = 0.102$, 95 % CI 0.052 – 0.153 , $p < 0.001$) and SUA ($B = 1.106$, 95 % CI 0.405 – 1.807 , $p = 0.002$).

Conclusion: In a sample of healthy subjects SUA is a significant predictor of ox-LDL and dienes level, but not of LDL lag phase and propagation phase.

NAFLD AND CARDIO- CEREBROVASCULAR EVENTS: CAUSE AND EFFECT OR JUST FELLOW PASSENGERS?

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Introduction: The nonalcoholic fatty liver disease (NAFLD) is present in up to one third of the general population and in most of the patients with cardio- metabolic risk factors such as type 2 diabetes, abdominal obesity and other components of the metabolic syndrome. Currently, the importance of NAFLD and its relationship with the metabolic syndrome is increasingly recognized, and this finding has stimulated interest in the possible role of NAFLD in the development of cardiovascular and cerebrovascular disease. The incidence of NAFLD on vascular risk is of particular attention because of the strong spread of the disease and the need to use simple and precise strategies for screening and surveillance in the years to an increasing number of patients.

Aim: To evaluate the association between FL and cardio-cerebrovascular disease in a large population of hospitalized patients with diabetes type 2.

Methods: In 546 type 2 diabetes patients, hospitalized at least twice in recent years, we assessed glycemic control, hepatic enzymes, lipids, and the presence or absence of previous vascular accident.

Results: The presence of FL was estimated using the index of steatosis (FLI >60, probability >78 % presence of FL; FLI <20 probability >91 % without FL), obviously not with the ultrasound too operator dependent. The diagnosis of vascular disease with previous accident was acquired because of certain documented medical history and/or confirmed by appropriate investigations during hospitalization.

Conclusion: The index of steatosis (FLI) is a practical and effective method and can be used in place of ultrasound too operator dependent. In our population of type 2 diabetics the risk of developing vascular events associated with high values of FLI (T0: OR = 0.364; IC 0.189–0.702; p = 0.002; T1: OR = 0.344; IC = 0.187–0.633; p = 0.0001).

IS THE INDEX OF STEATOSIS A PREDICTOR OF ISCHEMIC HEART DISEASE IN ELDERLY DIABETICS?

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Introduction: Elderly patients with hepatosteatois (FL) have a high risk of developing diabetes and cardiovascular disease. **Aim:** To evaluate the association between fatty liver (FL) and previous coronary heart disease (CHD) in a large population of hospitalized patients with type 2 diabetes.

Methods: In 845 elderly subjects with type 2 diabetes (age >70 years), hospitalized in the past 5 years, we assessed glycemic control, hepatic enzymes, lipids, and the presence or absence of previous AMI.

Results: The presence of FL was estimated using the index of steatosis (FLI >60, probability >78 % presence of FL; FLI <20 probability >91 % without FL), obviously not with the ultrasound examination too operator dependent. The population was divided into three groups based on the index of steatosis: G0: FLI <20 (n = 40); G1: FLI >60 (n = 544), G2: intermediate group (n = 261). We had based the diagnosis of CVD with previous AMI on clinical history documented or confirmed by appropriate investigations during hospitalization.

Conclusions: The index of steatosis (FLI) is a practical and effective method, it can be used in place of ultrasound too operator dependent in the diagnosis of hepatosteatois. Moreover, in our population of elderly type 2 diabetics CVD is highly associated with values of FLI (OR 56.835; IC 17.172 to 188.110 IC, p < 0.0001).

THE EFFECTS OF PROBIOTICS SUPPLEMENTATION ON ANTIOXIDANT ACTIVITY IN CHILDREN AFFECTED BY PRIMARY HYPERLIPIDEMIA

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Introduction: Probiotics, as dietetic supplement, exert various biological roles on human health, one of the most

debated being the antioxidant activity. This capacity may provide vascular defense against oxidative stress, implicated in the atherosclerosis progression.

Aim: To evaluate the effects of probiotic strains *Bifidobacterium lactis* BS05 and *Lactobacillus acidophilus* LA06 on the production of reduced glutathione (GSH) and superoxide dismutase (SOD), antioxidant parameters, in children affected by primary hyperlipidemia.

Methods: A double-blind, randomized, placebo-controlled trial was performed on 44 hypercholesterolemic children, 10.4 ± 2.8 years old. They were randomized to receive probiotics or placebo for 6 months. Subjects were submitted to biochemical analyses at baseline, after 3 months and at the end of the treatment. Oxidized LDL (Ox-LDL), were tested by enzyme linked immunosorbant assay (Mercodia AB, Uppsala, Sweden) and glutathione levels (GSH and total glutathione) by Biovision GSH Assay kit (Biovision). Lipid profile (TC, HDL-C, TG) was assessed by automatic analyzer (Olympus AU 2700, Japan) and LDL-C were calculated. Statistical analyses were performed using the SPSS 20.0.

Results: Lipid profile levels (mean \pm SD [mg/dl]): baseline TC 242.5 ± 60 , HDL-C 57.2 ± 13.9 , TG 92.8 ± 33.8 , LDL-C 167.6 ± 60.6 ; after probiotics TC 227.7 ± 47.0 , HDL-C 56.0 ± 11.8 , TG 93.2 ± 28.6 , LDL-C 153.4 ± 47.5) showed significant TC reduced compared to baseline after 3 months while, when comparing active treatment and placebo, decrease were not significant. Ox-LDL and GSH were respectively 71.2 ± 25.5 U/L and 27.1 ± 6.5 ng/ μ L in basal conditions and decreased to 63.2 ± 20.7 U/L and 21.8 ± 5.3 ng/ μ L after probiotic treatment. These decrease were significant intra-group but results were not significant compared with the placebo ones.

Conclusions: The effects of *Bifidobacterium lactis* BS05 and *Lactobacillus acidophilus* LA06 supplementation in children affected by primary hyperlipidemia are contrasting and the positive results showed after 3 months of probiotics treatment are not confirmed at the end of the study. Apo A and HDL-c levels ameliorate after active treatment; these results are an important points that need to be further investigated.

OXIDATIVE STRESS IN CHILDREN AFFECTED BY PRIMARY HYPERCHOLESTEROLEMIA

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Introduction: Oxidative stress is implicated in the pathogenesis of endothelial dysfunction and atherosclerosis progression. This event cascade may start in childhood and is correlated with hypercholesterolemia. Data on Oxidized

LDL (Ox-LDL), a marker of oxidative stress, are poorly checked in children besides controversial.

Aim: To evaluate the Ox-LDL status in children affected by primary hypercholesterolemia.

Methods: 44 hypercholesterolemic children (10.4 ± 2.8 years, BMI 21 ± 1.9) and 20 normocholesterolemic children (sex and age matched) afferring to our department, were included in the study. On the basis of international criteria they were affected by Familial Hypercholesterolemia (FH) ($n^{\circ}14$), Familial Combined Hyperlipidemia (FCH) ($n^{\circ}15$) or Undefined Autosomal Dominant Hypercholesterolemia ($n^{\circ}15$), when they did not show the characteristics for FH or FCH. Blood collection was performed on fasting state, when healthy since at least one month. Samples were stored at -80°C , until processed. Lipid profile parameters (TC, HDL-C, TG) were assessed by automatic analyzer (Olympus AU 2700, Japan), LDL-C were calculated and OxLDL tested by enzyme linked immunosorbant assay (ELISA) (Mercodia AB, Uppsala, Sweden). Statistical analyses were performed using the SPSS 20.0 software (SPSS Inc, Chicago, IL, USA).

Results: Lipid profile parameters in dyslipidemic and normocholesterolemic children were: TC 234 ± 52.8 mg/dl, HDL-C 54 ± 13 mg/dl, TG 91 (42–195), LDL-C 162 ± 51.8 mg/dl in the former group and TC 167.4 ± 8.8 mg/dl, HDL-C 59 ± 4.6 mg/dl, TG 49 (34–82), LDL-C 100.8 ± 13.6 mg/dl in the latter group. The Ox-LDL level measurement resulted 67.97 ± 20.2 U/l in dyslipidemic children and 42.7 ± 5.2 U/l in normocholesterolemic children, this difference being statistically significant ($p = 0.0001$).

Conclusion: Increased Ox-LDL levels in children confirm an early exposure to oxidative stress that is detectable when primary dyslipidemia occur. These results underline the relevance of an early diagnosis to establish a primary prevention approach aimed to prevent the oxidative process.

ABSENCE OF AN ASSOCIATION BETWEEN SHORT-TERM BLOOD PRESSURE VARIABILITY AND MILD RENAL DYSFUNCTION IN ESSENTIAL HYPERTENSIVE PATIENTS

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Introduction: Studies investigating the prognostic implications of short-term blood pressure (BP) variability (STBPV), expressed a standard deviation (SD) and

assessed by noninvasive 24-h ambulatory BP monitoring (ABPM), yielded conflicting results. In last years further indices of STBPV have been proposed. Among these, the 24-h BP average real variability (ARV) seems to be associated with an increased cardiovascular risk more closely than the SD. Little is known about the association between mild renal dysfunction (MRD) and STBPV, and particularly between 24-h BP ARV and MRD.

Aim: To analyse, in a group of essential hypertensives, the relationships between MRD and STBPV, expressed as SD of day and night-time BP and as 24-h BP ARV and between these latter, 24-h albumin excretion rate (AER) and estimated glomerular filtration rate (eGFR).

Methods: We enrolled 178 untreated essential hypertensives, with and eGFR >60 ml/min/1.73 m². All the patients underwent 24-h ABPM. BP readings were performed automatically at 15 min intervals during the day and at 20 min intervals during night-time resting. Moreover, 24-h AER was determined and eGFR calculated using the CKD-EPI equation. Subjects belonging to the I and II stages of the KDIGO classification of chronic kidney diseases (CKD) were considered as having MRD.

Results: No significant difference was found between subjects with MRD (n = 43) and those without it, regarding all the indices of STBPV examined, except for SD of daytime diastolic BP that was higher (p 0.02) in patients with MRD. However, this difference lost statistical significance after adjustment for age, average daytime diastolic BP, waist circumference and triglycerides. Among the STBPV indices studied, only SD of daytime systolic BP showed a weak (p = 0.03) inverse correlation with eGFR, that disappeared after adjustment for age, gender and average systolic daytime BP in multiple regression analysis. Both 24-h systolic and diastolic ARV did not show significant correlations neither with 24-h AER nor with eGFR.

Conclusions: Our results seem to suggest that in essential hypertensive patients, STBPV, even when expressed by 24-h ARV, does not influence early renal abnormalities.

SMOKING AND OTHER RISK FACTORS IN HEART FAILURE PATIENTS-RESULTS FROM CRO-HF REGISTRY

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Introduction: Cardiovascular risk factors are very important in development of heart failure (HF).

Aim: To analyse the frequency of smoking and other risk factors in patients with HF.

Results: A total of 2,203 in-hospital HF patients from CRO-HF Registry were analyzed: 1,028 (46.7 %) females (f) and 1,175 (53.3 %) males (m); median age was 76 years. Preserved left ventricular systolic function (LVEF ≥ 50 %) was recorded in 37.8 % patients. History of hypertension (AH) was recorded in 67.5 % patients, diabetes mellitus (DM) in 34.4 %, myocardial infarction in 22.7 %, renal insufficiency in 19.2 %, COPD in 17.3 %, and cerebrovascular disease in 16.5 % patients. Atrial fibrillation (AF) or undulation (AU) was noted in 53.7 % patients. Active smoking habit had 11.1 % patients and 15.6 % patients were former smokers. Males were frequently active smokers (14.8 %) as well as former smokers (24.9 %), than females (active 6.4 %, former 3.9 %). COPD had 30.6 % active smokers and 24.8 % former smokers. According to body mass index (BMI), overweight was 46.3 % patients and obese-25 %. Lower levels of haemoglobin was recorded in 51.9 % patients, higher levels of creatinine in 46.8 %, ALT in 29.8 %, cholesterol in 32.7 %, triglycerides in 31.9 %, uric acid in 79.3 % and hyperglycaemia in 99.8 % patients. Females had higher values of ALT (f 33 %, m 27 %, P = 0.012), cholesterol (f 36.8 %, m 29.1 %, P = 0.009), triglycerides (f 36.1 %, m 28.3 %, P = 0.014), and uric acid (f 82.9 %, m 76.4 %, P = 0.007). Opposite to expectation, males had lower haemoglobin levels (m 58 %, f 44.8 %, P \leq 0.001). The frequent precipitating factors of HF were hypertension (55.5 % patients), arrhythmia (51.3 %), valvular heart disease (32.8 %), acute coronary syndrome-ACS (19.7 %), and infections (19.6 %). In-hospital mortality rate was 13.8 %.

Conclusion: Active or former smokers were one third of our patients. Overweight or obese was almost 71.3 % of HF patients. The frequent “triggers” of HF were hypertension, arrhythmia, ACS, and infections. Nevertheless, the most important underline diseases of HF were hypertension, diabetes mellitus, myocardial infarction, renal insufficiency and COPD.

PREVENTION OF CHILDHOOD OVERWEIGHT AND OBESITY

Laura Perez Torre, María Mohiño Rondán

Introduction: Obesity is a disease characterized by accumulating neutral fat in the adipose tissue, higher than 20 % of the body weight of a person depending on his height, age and sex. Its etiology is multifactorial, since it has metabolic, genetic, psychosocial and environmental factors. Childhood obesity is a risk factor linked to the increasing

number of cardiovascular diseases in adulthood, along with others such as smoking, hypertension, sedentary lifestyle or hypercholesterolemia. Therefore, childhood obesity is one of the most serious problems in the twenty-first century, it affects high, medium and low income countries all over the world. Overweight, obesity, and derived diseases are mostly preventable, so prevention has to be prioritized.

Aim: To formulate appropriate guidelines to prevent overweight and obesity in childhood.

Method: To prevent childhood obesity, it is essential to promote a healthy diet as well as regular physical activity. It is necessary that these measures are supported from the family and school environment.

- With regard to infants, keep exclusive breastfeeding until at least the first 4 months.
- Do not oblige children in caloric intake, relying on the child's ability to regulate his own intake.
- With regard to children and adolescents, it is essential to emphasize the importance of a full and healthy breakfast.
- Encourage the intake of fruits and vegetables
- Reduce the intake of packaged food, which is calorie-dense and micronutrient-poor.
- Control exposure to television to avoid marketing practices.
- Avoid soft drinks or sugary beverages.
- Try to eat with family, as well as to promote having five meals a day.
- Promote activities that combat the sedentary lifestyle and reduce those that promote it.
- Promote the use of bicycles or walk to move from one place to another.
- Find time for family outdoor activities.

Results: Population awareness about the importance of a correct diet in the early ages, to avoid the establishment of unhealthy habits and weight gain, which is so hardly reversible.

Conclusion: Prevention is the best option to curb the childhood obesity epidemic. This is intended to achieve caloric balance which is maintained throughout life.

VARICOSE VEIN PREVENTION FOR HEALTH CARE WORKERS

María Mohiño Rondán, Laura Perez Torre

Introduction: Varicose veins are altered leg veins that are enlarged and deformed, both at a superficial level (under the skin) and at a deep level (inside leg muscles). In addition to a family willingness to have them, factors promoting the development of varicose veins are:

- Obesity
- Several pregnancies
- Standing for a long time while working
- A sedentary lifestyle
- The use of contraceptives
- Thrombosis or injuries in leg veins

The lower limb varicose veins have a high prevalence over population and, particularly, over the workers that are standing for a long time, such as healthcare workers.

Aim: To prevent varicose veins in healthcare workers.

Method:

- Do exercise for at least half an hour a day: walking, swimming, cycling.
- Cold water baths after working day.
- Daily massage on legs, always upwards.
- Use compression stockings, put them on before working day.
- Prevent overweight and avoid alcohol and smoking.
- Do not use tight clothes or high-heeled shoes.
- Raise legs slightly while sleeping.

Results: Decreasing emergence and development of varicose veins.

Conclusion: No medicines avoid the emergence and development of varicose veins, so the only way to prevent their emergence and development is by preventive attitudes.

EFFECT OF OLMESARTAN ON METABOLIC AND HEMODYNAMIC PARAMETERS IN A GROUP OF NEWLY DIAGNOSED HYPERTENSIVE PATIENTS WITH NORMAL GLUCOSE TOLERANCE

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Introduction: It's well known that insulin resistance (IR) represents a risk factor for the onset and progression of subclinical organ damage. It's also known that the modulation of the renin-angiotensin system plays a key role in the intracellular insulin signaling, as demonstrated by our group. Recently, our group has shown, in a large population of newly diagnosed hypertensive patients, that normal glucose tolerant subjects (NGT) with 1-h post-load glucose levels ≥ 155 (NGT ≥ 155), compared with NGT with 1-h post-load glucose < 155 (NGT < 155), show a worse diastolic function, higher left ventricular mass, intima-media

thickness and vascular stiffness, as well as a reduction of estimated glomerular filtration rate, all predicting factors for subsequent cardiovascular events.

Aim: To evaluate the effect of olmesartan on 1-h post-load plasma glucose and insulin sensitivity, assessed by Matsuda index, in a group of NGT ≥ 155 .

Methods: We enrolled 24 patients (16 males and 8 females), mean age 46 ± 8 years, that underwent OGTT at time 0 and after 6 months of treatment with olmesartan 20 mg/daily. Patients also underwent ambulatory monitoring of blood pressure at baseline and after 6 months.

Results: As expected, drug treatment significantly reduced systolic (137.4 ± 9.2 vs 120.4 ± 8.6 , $P < 0.0001$) and diastolic (84.2 ± 5.2 vs 71.2 ± 5.6 , $P < 0.0001$) blood pressure. Olmesartan also induced a significant reduction of plasma insulin at baseline (17.3 ± 12.0 vs 9.8 ± 5.5 , $P = 0.003$), 1 h (117.1 ± 51.5 vs 84.7 ± 50.4 , $P < 0.0001$) and 2 h (84.0 ± 75.5 vs 55.4 ± 42.5 , $P = 0.002$), blood glucose at 1 h (176.8 ± 31.3 vs 136.0 ± 41.5 , $P < 0.0001$) and 2 h (139.0 ± 32.8 vs 107.6 ± 25.3 , $P < 0.0001$) and the Matsuda index (52.0 ± 22.2 vs 66.6 ± 32.9 , $P = 0.011$).

Conclusions: Our data confirm the protective effect of olmesartan on blood pressure demonstrating a significant improvement in all metabolic parameters examined.

SYMPATHO-VAGAL IMBALANCE DURING ORAL GLUCOSE TOLERANCE TEST IN NEWLY DIAGNOSED HYPERTENSIVES

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Introduction: The autonomic nervous system influences the Heart Rate Variability (HRV) that reflects the sympatho-vagal balance. In patients with cardiovascular risk factors the reduction of HRV, due to an increase of sympathetic activity, is an independent predictor for clinical events. Recently, many evidences suggest that 1-h post-load plasma glucose ≥ 155 mg/dl is able to identify normoglycose tolerant (NGT) subjects at high risk for type 2 diabetes (T2D) and development of subclinical organ damage.

Aim: To evaluate the variability of sympatho-vagal balance, by HRV analysis, in a group of never-treated hypertensives during oral glucose tolerance test (OGTT).

Methods: We enrolled 92 never-treated hypertensive subjects (56 women, 36 men), aged 55 ± 9.8 years. During OGTT, the patients underwent to short-term recordings to

evaluate the HRV in the time domain, particularly the standard deviation of NN intervals (SDNN) at 0, 30, 60, 90 and 120 min. Insulin sensitivity was assessed by Matsuda index.

Results: According to OGTT, we divided the population in 4 groups: (1) NGT with 1-h post-load plasma glucose < 155 mg/dl ($n = 38$), (2) NGT with 1-h plasma glucose ≥ 155 mg/dl ($n = 18$), (3) impaired glucose tolerance (IGT, $n = 20$) and (4) T2D ($n = 16$). There were no significant differences among groups for gender, age, systolic and diastolic blood pressure, total cholesterol and triglyceride. From the first to fourth group, there was a progressive increase of fasting and post-load glucose and insulin, parallel to Matsuda index reduction. The values of SDNN were significantly reduced during OGTT in all groups. Moreover, HRV was significantly different between groups from 60 minutes to the end of the test. In particular, in group 2, 3 and 4, SDNN was significantly lower than group 1.

Conclusions: A different glucose tolerance status induces significant HRV variations and SDNN modification. Particularly, NGT ≥ 155 mg/dl show sympathetic hyperactivity with a sympatho-vagal profile similar to IGT and T2D.

ACETYLSALICYLIC ACID PROMOTES OXIDATIVE STRESS AND ENDOTHELIAL DYSFUNCTION IN THE PRIMARY PREVENTION OF THE DIABETIC PATIENT

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Introduction: Acetylsalicylic acid (ASA) utilized at low doses for secondary prevention, is able to reduce the appearance of new cardiovascular (CV) events in patients affected by coronary artery disease, peripheral artery disease and diabetes mellitus (DM). DM represents one of the most important CV risk factors, so much that diabetic patients are considered at a high CV risk, similar to those who have already had a major CV event. Therefore, it has been proposed the use of ASA for patients with DM also in primary prevention.

Aim and methods: In this study, we evaluated in 12 newly diagnosed diabetic patients, in primary prevention, the impact of treatment with ASA (100 mg/daily) on oxidative stress and vascular function, testing the hypothesis that ASA, through the inhibition of COX1 enzyme, promotes an alternative signaling pathway that stimulates the

production of 8-isoprostane, a well-known substance with pro-oxidant and pro-thrombotic properties.

Results: As expected, after 4 weeks of treatment, the ASA resulted in a significant reduction in plasma thromboxane-A2 (8.4 ± 0.6 vs 7.1 ± 0.4 pg/ml; $P < 0.05$), as a consequence of COX1 inhibition. By contrast, ASA caused the increase of plasma (from 165 ± 8 to 194 ± 7 μ g/ml, $P < 0.05$) and urine (from 68 ± 11 to 113 ± 7 μ g/ml, $P < 0.05$) 8-isoprostane and plasma levels of NOX2 (from 8.5 ± 0.8 to 9.7 ± 0.4 ng/ml, $P < 0.05$). The promotion of this pro-oxidant pathway resulted in a reduction of the endothelium-dependent vasodilation, measured by a semi-plethysmographic method (reduction of RHI from 1.68 ± 0.88 to 1.31 ± 0.92 , $P < 0.0001$). The pharmacological wash-out reverted all parameters to basal condition.

Conclusions: Present data suggest that ASA utilization for primary prevention in diabetic patients causes a significant increase of oxidative stress burden impairing the vascular function.

EFFECTS OF ORAL SUPPLEMENTATION WITH ESSENTIAL AMINOACIDS ON HEMODYNAMIC PARAMETERS AND VASCULAR STIFFNESS IN ESSENTIAL HYPERTENSION

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Introduction: Essential aminoacids (AAs) are able to improve the cardio-metabolic profile in subjects with chronic disease, such as heart failure, chronic obstruction pneumopathy disease and type-2 diabetes. These effects are related to the increase of the insulin-mediated nitric-oxide production in endothelium with a subsequent improvement of insulin sensitivity and endothelial function. Moreover, the endothelial dysfunction, that represents the first step in atherosclerotic process, is closely related to arterial stiffness (AS), that represents a strong indicator of subclinical organ damage.

Aim: To evaluate the effects of oral supplementation with AAs on hemodynamic parameters and AS in hypertensive patients.

Methods: We enrolled 15 newly diagnosed hypertensive patients (10 males and 5 females, mean age of 56.3 ± 10.2 years). All patients underwent evaluations of anthropometric and biochemical parameters, blood pressure, hemodynamic and AS parameters at baseline, after 3 months of conventional anti-hypertensive therapy, and after

2 months of oral supplementation with a preconstituted mix of AAs (4 g/die—Aminotrofic[®]) in addition to conventional therapy. Pulse wave velocity (PWV) and its central hemodynamic correlates were obtained by a validated system (SphygmocorTM). Data were processed by repeated measures ANOVA, paired t-test and chi-square test when appropriated.

Results: 3 months of anti-hypertensive therapy was able to reduce the central systolic and diastolic blood pressure. 2 months of AAs oral supplementation lead to a significant improvement of AS in addition to that obtained with the conventional therapy. Moreover EAAS supplementation reduced the central blood pressure parameters.

Conclusion: The oral supplementation with AAs is able to improve the AS in uncomplicated hypertensive patients. AAs supplementation seems to have a positive effect on hemodynamic profile that is additive to that obtained with the anti-hypertensive drugs.

FAMILIAL HYPERCHOLESTEROLEMIA: GENETIC SCREENING IN PAEDIATRIC PATIENTS

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Introduction: Familial hypercholesterolemia (FH) is a severe monogenic hyperlipidemia leading to very high levels of LDL cholesterol, associated with increased cardiovascular risk and in some cases with the presence of tendinous

xanthomatosis. The early identification of FH patients can be useful for establishment of an adequate therapy and the prevention of cardiovascular accidents.

Aim: To perform a genetic screening in a paediatric population.

Methods: 68 unrelated patients under 16 years were enrolled in different Italian clinics, of which 62 were clinically diagnosed as possible and 6 as definite FH based on the Simon Broome criteria. The LDLR gene was amplified by PCR and directly sequenced. MLPA was performed to identify large rearrangements.

Results: The screening in the LDLR gene revealed mutations in 49/68 unrelated FH patients (mutation rate 72 %). Three patients are compound heterozygotes (4 %) and 46 are heterozygotes (68 %). The mutation found are 30 missense, 8 splicing, 4 nonsense, 1 duplication, 1 small deletion and 2 large deletions. We identified 2 new variants in LDLR gene in the exon 8 and exon 9 respectively. The presence of the variant was excluded in 160 chromosomes from healthy subjects. Four algorithms (SIFT, PolyPhen, a PMut and Mutation tasting) were used to predict the effect of the novel variants. Among heterozygote patients the presence of a radical mutation (splicing, nonsense, duplication and deletion) leads to higher values of LDL cholesterol (264 ± 42 mg/dL) respect to carriers of missense mutations (221 ± 53 mg/dL) with $p = 0.001$.

Conclusions: The mutation rate in our paediatric population is 72 %, although their diagnosis was predominantly not definite because the lack of xanthomatosis due to the young age. Two new variations were identified, suggesting the whole screening of LDLR gene. Carriers of radical mutations showed a severe lipid phenotype since childhood suggesting a strict follow up and an early initiation of therapy.

EXPRESSION OF ADIPONECTIN RECEPTORS IN HUMAN CAROTID ATHEROSCLEROTIC PLAQUES

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Introduction: Adiponectin is a protein secreted by the adipose tissue with pleiotropic effects on metabolism. This adipokine play different anti-atherogenic action, such as the improvement of endothelial function and anti-inflammatory status in arterial walls. Two receptors ubiquitously expressed, AdipoR1 and AdipoR2, are involved in its action which. In obesity a mechanism of adiponectin resistance was demonstrated.

Aim: To verify if adiponectin-resistance occurs in human atherosclerotic plaques.

Methods: RNA from 49 carotid atherosclerotic plaques (advanced lesions), their respective adjacent regions (with a low grade lesions) and 7 healthy arteries (iliac and mesenteric) was extracted, reverse-transcribed and used for real-time PCR by specific TaqMan assays (Applied Biosystems). In vitro experiments for gene regulation studies were performed on primary Human Aortic Endothelial Cells and Smooth Muscle Cells (Lonza) co-cultured with the macrophage cell line THP-1.

Results: Expression levels of AdipoR1 were lower in advanced plaques as well as in their respective adjacent regions than in healthy arteries ($p = 0.020$ and $p = 0.001$ respectively). AdipoR2 levels gradually decreased from healthy arteries to plaque adjacent regions and to advanced plaques (all comparisons $p < 0.0001$). In both cell types, expression of AdipoR1 was not affected by the co-culture with THP-1. The presence of THP-1 decreased AdipoR2 expression in Smooth Muscle Cells ($p = 0.040$), whereas a not statistically significant decrease was observed in Endothelial Cells.

Conclusions: We demonstrated a decreased expression of adiponectin receptors in initial and advanced plaques, suggesting a mechanism of adiponectin-resistance during atherosclerotic process. A local adiponectin-resistance could be a main cause of the lack of atheroprotective effects mediated by adiponectin. Presence of macrophages could be a contributory cause of AdipoR2 decrease.

RELATIONSHIP BETWEEN ANTIHYPERTENSIVE THERAPY AND TARGET BLOOD PRESSURE IN HYPERTENSIVE PATIENTS IN DRUG THERAPY

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Aim: To examine the relationship between antihypertensive drug therapy, monotherapy or combination therapy, and the achievement of target blood pressure in 100 patients with hypertension, at Hypertension Center in Vito Fazzi Hospital of Lecce.

Methods: Were observed 100 consecutive patients at Hypertension Center through the analysis of home BP, office BP and ABPM for the past three years, and defined the status “to target BP or less” of the same, according to the guidelines ESH/ESC July, 2013. Was also considered the condition of mono- or polypharmacy patients on antihypertensive treatment at our center.

Results: From this study it was found that 81 % of patients tested is a target blood pressure. 12.34 % of patients in the target takes only one active ingredient (monotherapy); 87, 65 % combination therapy (polypharmacy). 19 % of patients, however, are not at target blood pressure. Of these, 15.80 % are treated by monotherapy drug, 81.21 % with combination therapy. For active employees see the attached table.

Conclusions: This study shows that 81 % of 100 examined patients is to target blood pressure through a combination therapy evidently more effective than monotherapy in the majority of them. Of the patients not at target blood pressure (19 % of the total), 87, 65 % are being treated with combination therapy with 3 or more medications, including a diuretic at full dosage (condition of hypertension refractory to drug therapy). Combination therapy is, therefore, more effective than monotherapy in achieving target blood pressure and the percentage of patients refractory to treatment agrees with the percentages known in the literature.

Figure 1

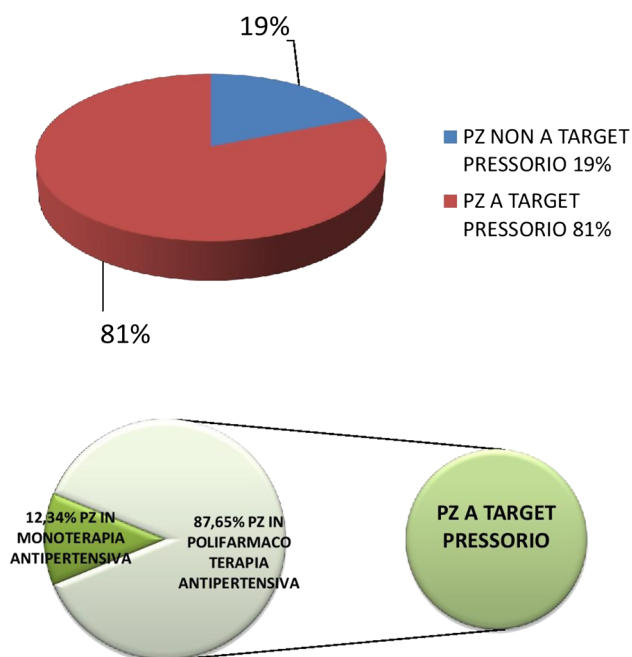
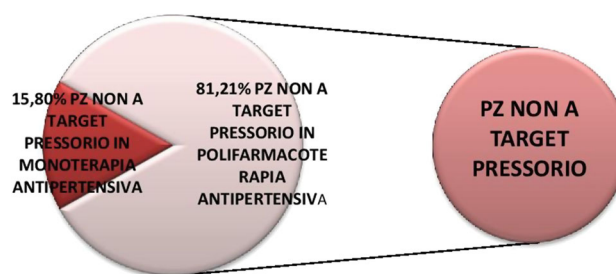


Figure 2



IL-18, STRONG PREDICTOR OF CARDIOVASCULAR DISEASE AND CARDIAC ORGAN DAMAGE

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Introduction: In hypertension, development of arterial and cardiac damage (TOD) is closely associated with cardiovascular (CV) morbidity. Inflammatory activation plays an important role in determination of cardiovascular status too. In particular, Interleukin-18 (IL-18) can predict the development of CV disease and death and it seems to be related to plaque vulnerability and atherosclerosis disease.

Aim: To investigate if IL-18 could be involved in both arterial and heart TOD development in the population of our study.

Methods: We performed both arterial and cardiac study (carotid-femoral pulse wave velocity (PWV), common carotid intima-media thickness (IMT) and standard echocardiography) and we measured systemic inflammatory markers (IL-18; interleukin 6, IL-6; serum-amyloid A, SAA; C-reactive protein, CRP) in 568 well-controlled HTs (age 55.1±13.0 years, BP=138/84±22/13 mmHg, means ±SD) without manifest cardiovascular disease.

Results: IL-18 expression was higher in our hypertensive patients with evidence of organ damage, left ventricular hypertrophy (LVMI >115 in male/95 in female, g/m²) (236.7 vs 268.3 pg/mL, p = 0.0012) and high PWV (>12 m/s) (245.7 vs 267 pg/mL, p = 0.0473), while no gap was found for the other inflammatory markers. IL-18 level was correlated with both LVMI and PWV (LVMI:

$r = 0,185$, $p < 0.0001$; PWV: $r = 0,124$, $p = 0,003$), but multivariable analysis adjusting for age, systolic and diastolic arterial pressure (SBP, DBP) and BMI showed independent association of IL-18 level only with LVMI (linear regression: $\beta = 0.0658$, $p < 0.0001$). No connection has been observed between IL-18 and IMT.

Conclusions: IL-18 level is increased in HTs with arterial and cardiac damage and it's independently associated only with LVMI, taken as a surrogate of cardiac TOD. This finding points out the relevant role of IL-18 on cardiac damage development and underlines the contribution of specific pattern of inflammation markers to the pathophysiology of heart and arterial disease. The EU-MASCARA project has received funding from the European Community's Seventh Framework Programme (FP7/2007-2013) under Grant Agreement no 278249.

PSYCHOLOGICAL CHARACTERISTICS AND TOTAL CARDIOVASCULAR RISK RELATIONSHIP IN A COHORT OF 345 CONSECUTIVE HYPERTENSIVE PATIENTS

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Introduction: Health psychology gave strong attention to cardiovascular disease (CVD). Psychological models aim to assess the relationships between CVD and dispositional characteristics (e.g. neuroticism, optimism) and theories on factors influencing behavioural changes (e.g. resilience, self-efficacy beliefs) had been made; but scanty data are available in hypertensive patients (HT).

Aim: To investigate possible associations between cardiovascular risk factors and subclinical organ damage and psychological characteristics in a population of Hypertensive patient.

Methods: We enrolled 345 consecutive HT outpatients (55 ± 11 years, 57 % males). Medical history, in particular CV risk factors, and presence of subclinical organ damage (LVMI, microalbuminuria, right IMT, cf PWV) were detected to define each patient CV risk. Afterwards, trained researchers submitted individually questionnaires for measuring type D personality (negative affectivity and social withdrawal), resiliency factors (optimism, self-

efficacy, self-esteem), anxiety, depression. Then we correlated variables obtained and adjusted for age and sex.

Results: Average BP values were well controlled ($135 \pm 18/82.5 \pm 11$ mmHg), BMI showed overweight (27 ± 4 g/m²), cfPWV and LVMI were borderline (10.5 ± 2.5 m/s; 110.3 ± 25.8 g/m²), EF was preserved (62 ± 5 %), average total and LDL cholesterol were high (201 ± 33 and 123 ± 30 mg/dl) while rIMT and microalbuminuria were in the normal range (0.73 ± 0.17 mm, 13.6 ± 30.5 mg/24 h). In our population, type D personality was associated with total number of risk factors ($r = 0.12$, $p = 0.04$), higher BMI ($r = 0.11$, $p = 0.05$), and inversely correlated with EF ($r = -0.13$, $p = 0.04$); resiliency factors (self-efficacy and optimism) were inversely correlated with total risk factors number ($r = -0.16$, $p = 0.004$), FC ($r = -0.12$, $p = 0.038$) and directly with EF ($r = 0.16$, $p = 0.008$); anxiety and depression were both associated with the total number of risk factors ($r = 0.15$, $p = 0.009$ and $r = 0.18$, $p = 0.001$ respectively), while depression was associated also with higher BMI ($r = 0.14$, $p = 0.015$). Furthermore, the only organ damage correlated with considered psychological variables was PWV with depression ($r = 0.12$, $p = 0.02$).

Conclusions: Data collected can be useful to realise tailored programs of primary prevention in treated HT patients. We also obtain evidence of the ability of PWV to describe the current state of the cardiovascular system and its strictly association even with psychological profile.

ANNEXIN A5 MAY HAVE A PROTECTIVE ROLE IN ARTERIAL STIFFNESS AND ATHEROSCLEROTIC VASCULAR PROGRESSION IN TREATED HYPERTENSIVE PATIENTS

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Introduction: It's well known that exists a relationship between annexin A5 (AnxA5) and atherosclerotic cardiovascular disease: AnxA5 plays a role in attenuating vascular inflammation and improving vessel wall function and plaque integrity.

Aim: We investigate the possible relation of AnxA5 with arterial stiffness, assessed by cf-Pulse Wave Velocity (PWV), marker of vascular organ damage.

Methods: We recruit 175 consecutive hypertensive patients with fairly controlled BP values (HT) and 175 healthy controls (C). First, we analyse AnxA5 possible relationship with different cardiovascular variables (age; heart rate, HR; systolic and diastolic blood pressure, SBP and DBP; BMI and PWV) in the whole population (Pearson R). Then we compared AnxA5 levels in patients with (OD, n 193) and without (NOD, n 155) vascular organ damage (i.e. $PWV \geq 10$ m/s) (T student). Afterwards, we divided, always on the basis of the presence of organ damage, both HT and C obtaining four groups (HTOD, n 110; HTNOD, n 35; COD, n 57; CNOD, n 114); in which we compared AnxA5 concentrations (ANOVA).

Results: Analysing whole population (n = 350, 55 ± 15 years), we found a correlation between AnxA5 levels and PWV (p 0.04, r 0.10), SBP (p 0.03, r 0.11), HR (p 0.01, r 0.13) and age (p 0.01, r 0.13), while no relationship was found with DBP and BMI. AnxA5 plasma levels were higher in OD than in NOD (12.5 ± 9.7 vs 10.1 ± 7.46 ng/mL, p-value 0.005) and in both HTNOD and HTOD compared with CNOD (14.2 ± 10.9 and 13.2 ± 10.2 vs 8.8 ± 7.31 , p < 0.05) too, even after adjusting for age.

Conclusions: Our preliminary data show that AnxA5 levels have a relationship with arterial stiffness in hypertensive and healthy subjects. We can speculate that AnxA5 can be over expressed in well-controlled hypertensive patients in order to counteract incipient aortic stiffness, that is indicative of initial atherosclerotic disease. This work has received funding from the European Community's Seventh Framework Programme (FP7/2007-2013) under Grant Agreement no 278249.

EFFECTS OF BIOENTERICS INTRAGASTRIC BALLOON (BIB) ON GLUCOSE TOLERANCE, INSULIN SENSITIVITY AND ENTERO-HORMONAL AXIS

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Introduction: BioEnterics IntraGastric Balloon (BIB) is the less invasive, temporary and safe surgical procedure to

obtain a weight loss. Several evidences have demonstrated an improvement in insulin sensitivity and incretin axis in obese patients following treatment with different bariatric surgery procedures but there are few data on the effect of BIB on insulin sensitivity and modifications of entero-hormonal axis.

Aim: To evaluate whether BIB was able to lead an improvement of metabolic parameters, insulin sensitivity and modifications of entero-hormonal axis in obese subjects.

Methods: We evaluated ten obese subjects underwent to BIB. At baseline and after 6 months from BIB placement, the subjects underwent a complete anthropometrical evaluation and a 75 g oral glucose tolerance test (OGTT) to 5 h. To estimate insulin sensitivity, the Matsuda index was used. After OGTT, 2 patients showed a type 2 diabetes, 2 an impaired glucose tolerance, the remaining patients had normal glucose tolerance.

Results: After 6 months from BIB placement in all the patients a 12 % mean reduction in the body weight was observed. The BIB was able to induce an improvement of glucose tolerance. In fact, all the patients showed a significant reduction in fasting glucose (118 ± 31 vs 91 ± 4 mg/dl, $P < 0.01$) and glucose 2 h during OGTT (198 ± 86 vs 117 ± 16 mg/dl, $P < 0.0001$). In addition, the patients exhibited also a reduction of fasting insulin (88 ± 36 vs 27 ± 16 mU/l, $P < 0.001$), insulin 2 h during OGTT (236 ± 95 vs 69 ± 24 mU/l, $P < 0.001$) and an improvement of insulin sensitivity (11 ± 8 vs 43 ± 11 , $P < 0.001$). Moreover, the patients showed a reduction in both basal and during OGTT GLP-1 levels (18 ± 4 vs 8.5 ± 2 pm/l, $P < 0.001$ and 12 ± 4 vs 7 ± 3 pm/l, $P = 0.005$, respectively) and an increase in both basal and during OGTT glucagon levels.

Conclusions: Our data indicate that BIB is able to induce an improvement of tolerance glucose, an improvement of insulin sensitivity and a modification of entero-hormonal axis.

METABOLIC PROFILE IN OBESE PATIENTS WITH AND WITHOUT BINGE EATING DISORDER

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Introduction: Binge Eating disorder (BED) is characterized by recurrent episodes of binge eating, associated with

loss of control as well as significant distress in the absence of regular compensatory weight-reducing behaviors. BED is associated with a poorer response to weight loss therapy. **Aim:** We evaluated whether obese patients with BED had different metabolic profile compared obese non-BED patients.

Methods: We evaluated fifty obese patients. All patients underwent anthropometrical evaluation. After a 12-h fasting, a 75 g oral glucose tolerant test (OGTT) to 5 h was performed with sampling for plasma glucose, insulin and C-peptide. The insulin resistance was evaluated by HOMA-IR. All patients answered to the Binge Eating Scale (BES). It is an easily administered scale, with adequate internal consistency and validity, that assesses symptoms of binge eating. All obese participants have been subsequently interviewed by a psychiatrist to confirm the diagnosis of BED.

Results: The patients was divided into two groups: obese non-BED patients (n = 21) and obese-BED patients (n = 29). Age, sex and BMI did not differ between the two groups. High percentages of hyperphagia were evident in both groups but obese-BED patients exhibited significantly higher rates of bingeing (50 vs 0 %, $P < 0.001$), emotional eating (75 vs 16 %, $P < 0.01$), sweet-eating (78 vs 33 %, $P = 0.003$) and craving for carbohydrates (84 vs 23 %, $P < 0.01$). In addition, obese-BED patients showed a lower fasting glucose levels (96 ± 12 vs 100 ± 25 mg/dl), a lower area under the curve (AUC) of glucose during OGTT (255 ± 42 vs 299 ± 48 mg/dl h), a higher basal insulin levels (33 ± 16 vs 24 ± 12 mU/l), a higher AUC of insulin during OGTT (9.2 ± 7 vs 5.7 ± 4 , $P = 0.02$) and increased insulin resistance evaluated by HOMA-IR (9.2 ± 7 vs 5.7 ± 4 , $P = 0.02$) when compared with obese non-BED patients.

Conclusion: Although preliminary, our data demonstrated that obese-BED patients have a different metabolic profile when compared with obese non-BED patients.

EFFECT OF BOTH LIRAGLUTIDE AND SITAGLIPTIN ON LEFT VENTRICULAR EJECTION FRACTION AND FUNCTIONAL STATUS IN DIABETIC PATIENTS WITH CHRONIC HEART FAILURE

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Introduction: Increasing evidence suggests that there is a strong association between type 2 diabetes (T2DM) and heart failure. It is unknown whether treatment with GLP-1R agonists is able to have beneficial effects on cardiac function beyond their effect on glucose control.

Aim: To compare the efficacy of Liraglutide, Sitagliptin and insulin Glargine as adjunct treatments to standard therapy on ventricular function in post-ischemic T2DM patients with class NYHA II/III heart failure and/or a left ventricular ejection fraction (LVEF) ≤ 45 %.

Methods: The participants (n = 32) were treated with standard therapy for chronic heart failure and with metformin and/or sulfonylurea for at least 3 months with suboptimal glucose control (HbA1c ≥ 7.0 and < 10 %). The participants were randomized to receive 1.8 mg Liraglutide, 100 mg Sitagliptin or insulin Glargine in addition to metformin and/or sulfonylurea. The participants underwent a laboratory determinations, electrocardiogram, echocardiogram, Minnesota Living with Heart Failure questionnaire and 6 min Walk Test.

Results: 24 out 32 subjects enrolled completed the study. Treatment with Liraglutide was associated with an improvement in LVEF compared with baseline (46 ± 2 vs 40 ± 1.9 %, $P < 0.001$). On the contrary, treatment with Sitagliptin or insulin Glargine was associated with no changes in the LVEF. Both end-diastolic and end-systolic left ventricular volumes (270 ± 30 vs 244 ± 27 and 124 ± 16 vs 119 ± 14 , respectively) were reduced in Liraglutide-treated patients but not in the patients treated with Sitagliptin or insulin Glargine. Liraglutide treatment was also associated with an improvement of functional capacity and an improvement of quality of life. Treatment with either Liraglutide or Sitagliptin was associated with a reduction in left ventricular mass (334 ± 30 vs 302 ± 26 and 348 ± 31 vs 315 ± 30 , $P < 0.05$ and $P < 0.05$ respectively).

Conclusions: The data suggest that treatment with Liraglutide is associated with improvement of cardiac function and functional capacity in post-ischemic T2DM patients with heart failure