CLINICAL ACTIVITY OF ISOFLAVONES + BERBERINE IN MENOPAUSAL PATIENTS WITH BORDERLINE DYSLIPIDAEMIA: PREVENTION IN THE MENOPAUSE.

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Introduction
Preventive treatment in menopause should consider both osteoporotic and cardiovascular (CV) risk: due to oestrogen failure, the mean total cholesterol (Tot-C) is 220mg/dl and 35% of cases are borderline (Tot-C 200-239mg/dl).

Beside lifestyle changes, it is rational to use food supplements to control the lipid profile.

A combination of nutraceuticals (EL) based on berberine (a natural extract which reduces Tot-C and TG), soy isoflavones and L. sporogenes was compared with the same formulation without berberine (E) in menopausal women with borderline dyslipidaemia.

Methods
Women with menopausal symptoms and borderline hypercholesterolaemia (Tot-C <260mg/dl) were treated with 1 tablet/day of E containing isoflavones 60mg+lactobacilli+vitamin D3+calcium (Estromineral, Rottapharm-Madaus) or EL (berberine 500mg+E, Estromineral Lipid) in addition to a low-fat diet for 3 months in a randomised, controlled multicentre study.

Assessments at baseline and at 3 months.

Results
In 59 gynaecological centres, 535 women were treated (287 EL and 248 E) mean age 53.8 years and BMI 25.4 kg/m2, in menopause for 3.8 years and 6.7% had previously used HRT. At start, lipid profile and menopausal symptoms were similar in the two groups.

At the end of treatment, EL significantly improved the lipid profile compared with E: -9.2% vs -4.9% for Tot-C, -16.7% vs -9.9% for LDL-C, -13.3% vs -6.3% for TG. BMI, body weight and waist circumference decreased but without statistical significance.

All menopausal symptoms fell significantly versus the baseline with both treatments (p< 0.0001).

Non-serious unexpected events: 3 cases with EL (dyspepsia, gastralgia and erythema) and 1 case with E (gastralgia).

Conclusions
EL significantly improved lipid profile in menopausal women and has the potential for risk prevention in the menopause. Isoflavones efficacy on menopausal symptoms is confirmed.