



Selección de Resúmenes de Menopausia

Semana del 1 al 7 de Junio 2016

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Eur J Obstet Gynecol Reprod Biol. 2016 May 26;203:82-88. doi: 10.1016/j.ejogrb. [Epub ahead of print]

Efficacy, tolerability and safety of a new medical device, Monurelle Biogel® vaginal gel, in the treatment of vaginal dryness: a randomized clinical trial in women of reproductive age.

Nappi RE, Benedetto C, Campolo F, Martella S, Tosti C, Cianci A, Caruso S, Guaschino S, Grimaldi E, et al.

OBJECTIVE: To prove the efficacy, tolerability and safety of Monurelle Biogel® (ZP-025) vaginal gel, which contains a purified, dialyzed, lyophilized bovine colostrum, in women of reproductive age suffering from vaginal dryness. **DESIGN:** Randomized clinical trial (RCT) (Z7213M01). **SETTING:** Five University Gynaecological Units. **PATIENTS:** Ninety-five subjects were allocated at random to receive either ZP-025 (n=48) for about 23 intermenstrual days (1 or 2 times/daily intra-vaginally) or no treatment (lubricants on demand were allowed). **MAIN OUTCOME MEASURES:** Change of Verbal Rating Scale (VRS) total and single score for vaginal symptoms, Vaginal Health Index (VHI) score, Female Sexual Function index (FSFI) and Female Sexual Distress Scale-revised (FSDS-R) scores.

RESULTS: A total number of 85 subjects was evaluable for primary analyses. Symptoms (VRS) of vaginal discomfort improved significantly already after 11 days, as compared to the control arm ($p < 0.0001$). The mean VHI score was also significantly higher in ZP-025 group ($p < 0.001$) at the end of the study. The analysis of covariance with the baseline value as covariate carried out on the FSFI Total Score showed a statistically significant difference in favour of the ZP-025 arm ($p < 0.032$). A shift from presence to absence of sexual distress (≤ 11 points) was more prominent in the ZP-025 arm [10 subjects (40%) in the ZP-025 arm ($p < 0.0001$) and 6 subjects (21.4%) in the control arm ($p = 0.01$)]. Women reported a compliance rate of 100% for one ZP-025 application/day. Local tolerability of ZP-025 was excellent or good in 82.9% of the subjects. **CONCLUSIONS:** The present multicentre RCT supports the use of Monurelle Biogel® in women of reproductive age reporting symptoms of vaginal dryness. A positive impact on vaginal health and sexual function was also evident.

Breast J. 2016 Jun 4. doi: 10.1111/tbj.12620. [Epub ahead of print]

Assessing the Relationship of Mammographic Breast Density and Proliferative Breast Disease.

Lewis MC, Irshad A, Ackerman S, Cluver A, Pavic D, Spruill L, Ralston J, Leddy RJ.

Increased breast density and a history of benign breast biopsy are both considered risk factors for developing breast cancer. Understanding the specifics of these risk factors and their relationship to each other can lead to a better understanding of a patient's propensity for breast cancer development and improved surveillance strategies. We included 245 women who underwent a benign breast biopsy without atypia between October 2011 and June 2013. Biopsies were performed for suspicious calcifications as well as masses and architectural distortion. Lesions biopsied were divided into two groups: calcified and noncalcified lesions. The patient's breast density was assessed on most recent mammogram and was classified using the American College of Radiology BI-RADS density categories. Based on histologic diagnosis, each case was classified as proliferative or nonproliferative breast disease. The median age of the cohort (n = 245) was 55 years (range, 40-84 years). There were 162 (66%) postmenopausal women in the study. A core biopsy was performed for calcifications in 33.5% cases and for noncalcified lesions in 58% cases. In patients with dense breast tissue, an underlying proliferative histology was found significantly more frequently with calcifications (66.7%) as opposed to noncalcified lesions (35.9%) (RR = 2.3 (1.3-4.0); $\chi^2 = 8.7$; $p = 0.003$). In nondense breast patients, there was no significant difference (RR = 1.1 (0.7-1.8); $\chi^2 = 0.1$; $p = 0.738$). In the postmenopausal group, women with dense breasts had proliferative histology significantly more frequently than women with nondense breasts (55.3% versus 38.3%; $p < 0.05$), regardless of the underlying lesion type. Postmenopausal women with dense breasts who underwent a breast biopsy with benign histology had a significantly higher likelihood of having proliferative breast disease, regardless of underlying lesion type. Women with dense breasts also showed proliferative histology significantly more often for calcifications as opposed to noncalcified lesions.

BMC Womens Health. 2016 Jun 3;16(1):28.

A community-based cross-sectional study for relationship of frequency of vegetables intake and osteoporosis in a Chinese postmenopausal women sample.

Liu N, Zeng F, Zhang K, Tang Z.

BACKGROUND: The main purpose of this study was to explore the associations between frequency of vegetables intake and osteoporosis (OP) in Chinese postmenopausal women. **METHODS:** We conducted a large-scale, community-based, cross-sectional study to investigate the associations by using self-report questionnaire to access frequency of vegetables intake. The total of 1903 participants was available to data analysis in this study. Multiple regression models to include frequency of vegetables variable were performed to investigate the relationships for OP, after controlling for confounding factors. **RESULTS:** Multiple regression analysis indicated that the frequency of vegetables intake was independently and significantly associated with OP ($P < 0.1$ for model 1 and model 2). The postmenopausal women with high frequency of vegetables intake had a higher prevalence of OP. **CONCLUSION:** The findings indicated that frequency of vegetables intake was independently and significantly associated with OP. The prevalence of OP was more frequent in Chinese postmenopausal women preferring vegetables food habits.

Stroke. 2016 Jun 2. pii: STROKEAHA.116.013052. [Epub ahead of print]

Postmenopausal Hormone Therapy and Risk of Stroke: Impact of the Route of Estrogen Administration and Type of Progestogen.

Canonica M, Carcaillon L, Plu-Bureau G, Oger E, Singh-Manoux A, Tubert-Bitter P, Elbaz A, Scarabin PY.

BACKGROUND AND PURPOSE: The benefit/risk analysis of hormone therapy in postmenopausal women is not straightforward and depends on cardiovascular disease. Evidence supports the safety of transdermal estrogens and the importance of progestogens for thrombotic risk. However, the differential association of oral and transdermal estrogens with stroke remains poorly investigated. Furthermore, there are no data regarding the impact of progestogens. **METHODS:** We set up a nested case-control study of ischemic stroke (IS) within all French women aged 51 to 62 years between 2009 and 2011 without personal history of cardiovascular disease or contraindication to hormone therapy. Participants were identified using the French National Health Insurance database, which includes complete drug claims for the past 3 years and French National hospital data. We identified 3144 hospitalized IS cases who were matched for age and zip code to 12 158 controls. Conditional logistic regression was used to estimate odds ratios (OR) and 95% confidence intervals (95% CI). **RESULTS:** Compared with nonusers, the adjusted ORs of IS were 1.58 (95% CI, 1.01-2.49) in oral estrogen users and 0.83 (0.56-1.24) in transdermal estrogens users ($P < 0.01$). There was no association of IS with use of progesterone (OR, 0.78; 95% CI, 0.49-1.26), pregnanes (OR, 1.00; 95% CI, 0.60-1.67), and nortestosterones (OR, 1.26; 95% CI, 0.62-2.58), whereas norpregnanes increased IS risk (OR, 2.25; 95% CI, 1.05-4.81). **CONCLUSIONS:** Both route of estrogen administration and progestogens were important determinants of IS. Our findings suggest that transdermal estrogens might be the safest option for short-term hormone therapy use.

BMJ. 2016 May 31;353:i2610. doi: 10.1136/bmj.i2610.

Migraine and risk of cardiovascular disease in women: prospective cohort study.

Kurth T, Winter AC, Eliassen AH, Dushkes R, Mukamal KJ, Rimm EB, Willett WC, Manson JE, Rexrode KM.

OBJECTIVE: To evaluate the association between migraine and incident cardiovascular disease and cardiovascular mortality in women. **DESIGN:** Prospective cohort study among Nurses' Health Study II participants, with follow-up from 1989 and through June 2011. **SETTING:** Cohort of female nurses in United States. **PARTICIPANTS:** 115 541 women aged 25-42 years at baseline and free of angina and cardiovascular disease. Cumulative follow-up rates were more than 90%. **MAIN OUTCOME MEASURES:** The primary outcome of the study was major cardiovascular disease, a combined endpoint of myocardial infarction, stroke, or fatal cardiovascular disease. Secondary outcome measures included individual endpoints of myocardial infarction, stroke, angina/coronary revascularization procedures, and cardiovascular mortality. **RESULTS:** 17 531 (15.2%) women reported a physician's diagnosis of

migraine. Over 20 years of follow-up, 1329 major cardiovascular disease events occurred and 223 women died from cardiovascular disease. After adjustment for potential confounding factors, migraine was associated with an increased risk for major cardiovascular disease (hazard ratio 1.50, 95% confidence interval 1.33 to 1.69), myocardial infarction (1.39, 1.18 to 1.64), stroke (1.62, 1.37 to 1.92), and angina/coronary revascularization procedures (1.73, 1.29 to 2.32), compared with women without migraine. Furthermore, migraine was associated with a significantly increased risk for cardiovascular disease mortality (hazard ratio 1.37, 1.02 to 1.83). Associations were similar across subgroups of women, including by age (<50/≥50), smoking status (current/past/never), hypertension (yes/no), postmenopausal hormone therapy (current/not current), and oral contraceptive use (current/not current). **CONCLUSIONS:** Results of this large, prospective cohort study in women with more than 20 years of follow-up indicate a consistent link between migraine and cardiovascular disease events, including cardiovascular mortality. Women with migraine should be evaluated for their vascular risk. Future targeted research is warranted to identify preventive strategies to reduce the risk of future cardiovascular disease among patients with migraine.

J Clin Endocrinol Metab. 2016 May 31;jc20161726. [Epub ahead of print]

Association between insulin resistance and bone structure in non-diabetic postmenopausal women.

Shanbhogue VV, Finkelstein JS, Bouxsein ML, Yu EW.

CONTEXT: The clinical consequences of insulin resistance and hyperinsulinemia on bone remain largely unknown.

OBJECTIVE: To evaluate the effect of insulin resistance on peripheral bone geometry, volumetric bone mineral density (vBMD), bone microarchitecture and estimated bone strength. **DESIGN, SETTING AND PARTICIPANTS:** This cross-sectional study included 146 postmenopausal, non-diabetic Caucasian women (mean age 60.3 ± 2.7 years) who were participating in the Study of Women's Health Across the Nation (SWAN). **INTERVENTIONS:** None **Main outcome measures:** High-resolution peripheral quantitative computed tomography was used to assess bone density and microstructure at the distal radius and tibia. Fasting insulin and glucose was measured and insulin resistance was estimated using homeostasis model assessment of insulin resistance (HOMA-IR) with higher values indicating greater insulin resistance. **RESULTS:** There was a negative association between HOMA-IR and bone size and a positive association between HOMA-IR and total vBMD, trabecular vBMD, trabecular thickness and cortical thickness at the radius and tibia. These relationships remained even after adjusting for body weight and other potential covariates (e.g., time since menopause, cigarette smoking, physical activity, prior use of osteoporosis medications or glucocorticoids).

CONCLUSIONS: In non-diabetic, postmenopausal women, insulin resistance was associated with smaller bone size, greater volumetric bone mineral density and generally favorable bone microarchitecture at weight bearing and non-weight bearing skeletal sites. These associations were independent of body weight and other potential covariates, suggesting that hyperinsulinemia directly effects bone structure independent of obesity and may explain, in part, the higher trabecular bone density and favorable trabecular microarchitecture seen in individuals with type 2 diabetes mellitus.