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Vaginal administration of testosterone in Pentravan® and itseffect on inflammatory and metabolic parameters in menopausal women with sexual dysfunction

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Testosterone deficiency during menopause is associated with increasedsubclinical inflammation, which may be the underlying cause of a variety of clinical conditions that may occur during ageing. In addition to its sexual enhancing effects in both men and women,testosterone also exerts a potent antiinflammatory effect through the blockade of NF-Kappa B translocation to the cell nucleus, thus halting the activation of several genes involved in the inflammatory cascade. One clinical issue is how to replace bioidentical testosterone in women,using a non oral route, thus circumventing the problem of the first passage through the liver. One promising route in women is through the vaginal mucosa.

Material and Methods: This is an open clinical observational study to evaluate the absorption of vaginally administered testosterone and its effects on metabolic parameters related to inflammation. Forty-two menopausal patients with symptoms of androgen deficiency were enrolled for this investigation between January and November 2013. Testosterone was administered vaginally at the dose of 3 mg in Pentravan® (Fagron, The Netherlands). Serum levels of testosterone, c-reactive protein (CRP), SHBG, glucose, total cholesterol, high-density lipoprotein (HDL) cholesterol,thyroid-stimulating hormone (TSH) and liver enzymes were measured in all patients prior to their admission of the study.To evaluate testosterone absorption, blood was drawn 3, 12 and 24 hours after vaginal insertion of 1 ml of a Pentravan® emulsion containing 3 mg of testosterone. For patients who completed 3 months of testosterone therapy, the same blood chemistry determinations were repeated after 12 hours of fasting and then compared to pretreatment values.

Results: There was no statistically significant difference in baseline testosterone levels between the groups of women whose blood was drawn at 3, 12 or 24 hours after vaginal insertion of testosterone; therefore, these women were pooled together for analysis. Serum testosterone levels increased significantly ($p<0.0001$) inthe first 3 hours following vaginal administration, from13±8ng/dl at baselineto 338±235ng/dl at 3 hours.This rise in testosterone was followed by a rapid decrease inmeanblood levels to67±8 ng/dland 21±11 ng/dlat12 and 24 hours, respectively,following vaginal administration. This pulse-like increase in testosterone lasted less than 24 hours and resulted in no untoward androgenic side effects. At 24 hours,testosterone levels were not significantly different from pre-insertion levels. This transient, pulse-like rise effectively improved libido and the sensation of well-being in 40/42 patients. Fasting glucose levels decreased significantly from 95 to 88 mg/dl after three months of vaginal testosterone use ($p=0.01$). Similar decreases occurredin blood levelsofC - reactive protein (from 2 mg/L at baseline to 0.9 mg/L after 3 months of use; $p=0.01$), TSH (from 3.5mIU/mlto 2.4 mIU/ml; $p=0.002$),total cholesterol (from 204to 178mg/dl; $p=0.005$) and LDL cholesterol(from 124to 107 mg/dl; $p=0.02$).Liver enzymes, SHBG and estradiol blood levels, on the other hand, were not significantly affected by treatment.

Discussion: These results indicate that vaginal administration of testosterone is effective for the treatment of the symptoms of androgen deficiency and is associated with a decrease in blood inflammatory markers. Hepatic function, on the other hand,remains unchanged during treatment.Testosterone is readily absorbed through the vaginal mucosa,causing a pulse-like increase in serum levels that lasts less than 24 hours.Ageing is inversely associated with a decrease in free testosterone and an increase in fat mass, which has a boosting effect on inflammation, thus enhancing the risk of postmenopausal women of developing the metabolicsyndrome.The findings of the present studyon the vaginal administration of bio-identical testosterone in Pentravan® showed that the same antiinflammatory effects of testosterone are alsomaintained in menopausal women with symptoms of androgen deficiency without any significant increase in adverse events.

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