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Title Abbrev:	Clin Exp Obstet Gynecol
Citation:	1985;12(1-2):1-2
Article:	Benefits of vaginal estriol cream combined with cl
Author:	Blum M
NLM Unique ID:	7802110 Verify: PubMed
PubMed UI:	3987021
ISSN:	0390-6663 (Print)
Publisher:	S.O.G., Padova
Copyright:	Copyright Compliance Guidelines
Authorization:	barb
Need By:	N/A
Maximum Cost:	**$15.00**
Patron Name:	Glaser, Rebecca - TN: 77513
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BENEFITS OF VAGINAL ESTRIOL CREAM COMBINED WITH CLONIDINE HCL FOR MENOPAUSAL SYNDROME TREATMENT

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Summary: In a group of 25 post menopausal women mean age 57.2 years, treatment with Estriol vagina cream (Ovestin ® cream from Organon - Holland) gives rise (but within normal limits) to cholesterol, triglicerides and HDL - cholesterol, the protective facor against M. I. A rise in glycohemoglobin (HbA_1C) statistical significant was noted, as a sign of slight glucose intolerance, but in no case was there a diabetic pattern. Vaginal Estriol cream was able to prevent osteoporosis. After a few weeks of treatment urinary calcium/creatinine ratio decreased.

In the light of our own findings, Ovestin ® being a weak estrogen does not induce endometrial proliferation or breakthrough bleeding and does not modify the blood biochemistry, and can be recommended for postmenopausal syndrome even in familial hyperlipidemia diabetes, and for prevention of osteoporosis.

Key words: menopausal syndrome, vaginal estriol cream, blood biochemistry, urinary CA : CR ratio.

A generally accepted consensus today is that Estrogen therapy for post-menopausal women is an important part of preventive medicine (1) and that risk factors of these treatmtents can be avoided using the best accepted Estrogen in a suitable dose and method of administration.

The aim of the present paper is to show the benefits of an Estriol vaginal cream, as a restorer of normal psychological and sexual life, without disturbing basic metabolisms, but preventing osteoporosis.

MATERIAL AND METHOD

Twentyfive post menopausal women entered our study. Mean age 57.2 years, with a mean weight of 67.82 kg (a slight overweight according to the Metropolitan Life Insurance Co. tables). The reason for treatment were typical menopausal symptoms linked with genito-urinary atrophy and vasomotor symptoms. In our study we used Ovestin® cream from Organon-Holland (1 g containing 0.5 mg Estriol). Dosage: a daily application of 0.5 g cream at bedtime for two weeks, following this by one application twice a week for four months.

All our patients were in good health. Before and after 4 months of treatment we performed measurements of cholesterol by the method of Huang (2) normal ranges are 150-280 mg %. Tryglycerides by the method of Giegel (3), normal ranges 60-160 mg % and HDL-cholesterol using a commercial kit. Normal ranges 40-50 mg %. Glycohemoglobin (HbA_1C) served us as indicator for glucose tolerance. The test described by Blum (4) *et al.* in previous papers is easy to perform in every laboratory by a kit. Normal ranges are 5.5% to 7.5%. For bone mineral metabolism we examined the urinary calcium/creatinine ratio in fasting state. According to Nordin *et al.* (5) the urinary calcium in fasting state represents mainly the calcium coming from bones.

RESULTS

No adverse reactions such as local irritation, spotting or breast tenderness were recorded. Urinary and vaginal symptoms improved significantly with disappearance of urinary-frequency urgency. Vaginal dryness and dyspareunia, with a mood improvement and restoration of sexual drive. Less effective were vaginal estriol cream for vasomotor instability.

Addition of Clonnirit ® (Clonidine Hcl from Rafa - Jerusalem) tablets of 25 mgr twice daily to the topical Estriol vaginal treatment, was able to relieve hot flushes, profuse sweating and sleep disturbances.

Blood biochemistry was slightly affected. Taking into consideration the lipid profile, and glucose tolerance, but values remain in normal or high normal levels.

Cholesterol rises from 206.4 mg% to 223.3 ($P<0.01$), Triglycerides from 115.5 to 136.1 ($P<0.01$), HDL Cholesterol (the protective cholesterol from 45.0 to 45.6 ($P<0.01$).

As for urinary calcium/creatinine ratio, we noted a clear lowering from 0.25 ± 0.09 before to 0.19 ± 0.08 during 4 months of treatment, statistically significant, $T=35.5$, $P<0.01$. In other words, vaginal estriol cream was able to stop calcium loss and prevent osteoporosis.

DISCUSSION

After natural or surgical menopause, women are deficient in their estrogenic hormone. The symptoms of this estrogen deficiency are hot flushes, profuse sweating, insomnia, genito-urinary atrophy, dysparunia, urinary disturbances, increased risk of coronary heart disease and a non symptomatic osteoroporosis that increases the risk of fractures.

Using substitution therapy by Estriol vaginal cream, a relief of most of the symptoms was achieved with no adverse side effects (local or general).

As to the influence on blood biochemistry, treatment with Ovestin ® vaginal cream gives a rise in cholesterol triglycerides, but values remain within normal limits. At the same time, the treatment gives a statistical rise to HDL-cholesterol, the protective factor against M.I.

In our study we replaced the tedious and equivocal GTT by the simple glycohemoglobin (HbA_1C) test. Known as HbA_1C, a part of the minor Hbs, they are a postsynthetic transformation of the native HbAo, formed when glucose is slowly non-enzymatically and irreversibly linked to HbAo.

Treatment with Estriol cream did not raise the HbA_1C level significantly Glycohemoglobin although increased remained in normal range. The role of estrogen in the process of bone absorbtion and formation is still controversial. There are no estrogen receptors in bone and estrogen does not appear to stimulate osteoblastic activity. However, in the light of clinical data estrogen with physical excercises, dietary calcium and vitamin D, is recommended in all menopausal women. Estriol cream used by us had a clear effect on urinary calcium/creatinine ratio ($P<0.01$) Estrogen substitution has been associated with many types of adverse reaction, one of the being hypertension. Certain side effects of estrogen therapy are caused by unphysiologic nature of the oral method of administration as a result of increased renin substrat ([6]).

By using the vaginal route, and bypassing the liver most adverse effects are excluded.

Vaginal estriol cream has no contraindications in our opinion, even in diabetics or women suffiering from familial hyperlipidemia. Treatment with estriol vaginal cream had only a slight therapeutic effect on vasomotor instability. When insomnia, profuse sweating, and hot flushes were the cardinal symptoms, we needed to add clonidine Hcl.

ACKNOWLEDGEMENT

The Author is indebted to Mrs. Ruth Don from the Research Dept. of The Sick Fund, for help in statistical analysis.

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