Tibolone in the treatment of psychosomatic symptoms in menopause

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Summary

The purpose of this study was to investigate the value of tibolone in the treatment of psychosomatic symptoms in menopause. Forty-two menopausal women (aged 46-63, mean 53.9) with nightly perspiration, vasomotor flushes, disturbance of libido, dyspnea and other psychosomatic symptoms were assigned to one of two treatment groups for three months: 1st group) 21 users of tibolone; 2nd group) 21 users of placebo. At the end of the trial disturbance of libido was observed in 4 (19.0%) cases tin the 1st group and 11 (52.4%) cases in the 2nd ($p<0.05$) and nightly perspiration was observed in 3 cases (14.3%) in the 1st group and 9 cases (42.9%) in the 2nd ($p<0.05$). Although vasomotor flushes were observed in only 3 (14.3%) cases in the 1st group and 7 cases (33.3%) in the 2nd group, this difference was not significant ($p>0.05$). There was no significant effect of tibolone or placebo in dyspnea, vertigo and headache. From the results it can be concluded that tibolone can have a beneficial effect on some psychosomatic symptoms in postmenopausal women.

Introduction

The characteristic menopausal changes are raised pituitary gonadotropins (FSH and LH) and estrogen deficiency. As the ovaries involute, which is the primary change, levels of circulating estrogen fall and this may be associated with the onset of menopausal symptoms. As the pituitary tries to stimulate the failing ovaries, marked rises occur in FSH and LH levels. These rises provide a very good marker for the menopausal state, but lower or middle range values are less conclusive.

Which menopausal women should be prescribed hormone replacement therapy and in what form? What benefits and what side-effects are to be expected? And for how long should it be continued? [1].

All of these questions should be addressed in modern gynecology. Many women are happy to pass through menopause without treatment but others have severe symptoms that cry out for help. Long-term estrogen deficiency is, however, a cause of major morbidity, predisposing to osteoporosis and cardiovascular disease and long-term hormone replacement needs to be considered for those most at risk of these two diseases [2]. Unfortunately, there is at present no simple way (screening) of identifying those women at higher risk.

There is some evidence that hormone replacement therapy can benefit the mental functioning of menopausal women who do not have very serious psychological or psychiatric problems. The purpose of our study was to investigate the value of tibolone in the treatment of psychosomatic symptoms in menopause.

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Material and Methods

Forty-two menopausal women (aged 46-63, mean 53.9) with nightly perspiration, vasomotor flushes, disturbance of libido, dyspnea and other psychosomatic symptoms were assigned to one of two treatment groups: 1st group) 21 users of tibolone; 2nd group) 21 users of placebo. Women were treated for three months. X-ray and laboratory tests were normal in the cases examined.

Results

At the end of this trial the most frequent psychosomatic symptoms were as follows:

Nightly perspiration was reported in 3 cases (14.3%) in the 1st and 9 cases (42.9%) in the 2nd group. Total Chi-Square, with DF=1, is 4.2 and p=0.0404 (Chi-Square with continuity correction factor = 2.917).

Vasomotor flushes were reported in 3 cases (14.3%) in the 1st and 7 cases (33.3%) in the 2nd group. Total Chi-Square, with DF=1, is 2.1 and p=0.1473 (Chi-Square with continuity correction factor = 1.181).

Disturbance of libido was reported in 4 (19.0%) and 11 (52.4%) cases, respectively. Total Chi-Square, with DF=1, is 5.081 and p=0.0242 (Chi-Square with continuity correction factor = 3.733). At the end of therapy there was no significant effect of tibolone or placebo on dyspnea, vertigo and headache.

Discussion

Only women who have had a hysterectomy should be given estrogen alone and some suggest that a progestogen should be added even in that group. Whether this

should be administerd cyclically or continuously has to be decided on an individual basis.

Oral therapy is easy but estrogen absorbed from the gut passes to the portal circulation and thus into the liver. In that way, it alters the functioning of the liver and coagulation factors, lipids and lipoproteins may be changed.

One gram of conjugated equine estrogens applied topically in the vagina is about equivalent to 0.625 mg taken orally, in its effect on the endometrium.

On the other hand, estradiol absorbed transdermally is delivered directly into the circulation, bypasses the liver, and is therefore not exposed to the side-effects mentioned-above in oral therapy. Diffusion of estradiol from a transdermal patch delivers an amount of estradiol (μg/24 hours), depending on the size of the patch, i.e. the surface area applied to the skin. Plasma estradiol levels fall rapidly after a patch is removed.

High FSH levels, which are characteristic in menopause, show a dose-dependent diminution in response to estradiol given orally or transdermally.

Tibolone is a relatively new regiment with beneficial effects in menopause and without the side-effects of hormone therapy.

Tibolone is effective in preventing postmenopausal bone loss and can also, at least transiently, increase vertebral mineral density in climacteric and postmenopausal women.

The regimen is also effective in sexual function and has a beneficial effect on menopausal flushes [3, 4].

Postmenopausal women responded to tibolone with measurable improvement in mood in double-blind cross-over studies with tibolone and palcebo [5, 6]. Many different changes have been reported in the physiology of sexual responses after the menopause. These changes reflect a decrease in blood flow and a change in peripheral nerve function. After the menopause, the majority of woman experience some problem with sexual function associated with vaginal dryness, pain on intercourse, loss of organism response and decreased sexual desire. The final result of all of the above is the decreased sexual activity. We saw a beneficial effect of tibolone in the disturbances of libido and the women of the tibolone group reported a beneficial effect of the regimen on sexual desire, sensitivity, frequency of orgasm and intensity of orgasm. Finally, we found a beneficial effect of tibolone in vasomotor flushes and nightly perspiration.

Conclusion

From the results it can be concluded that tibolone can have a beneficial effect on some psychosomatic symptoms in postmenopausal women.

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