Summary & Conclusion
SUMMARY

The present study was carried out at Department of Obstetrics & Gynaecology, M.L.B. Medical college, Jhansi with an aim to study the effect of hormone replacement therapy versus Raloxifene therapy on postmenopausal symptoms, lipid profile, bone mineral density and endometrial biopsy in subjects with natural or surgical menopause, having postmenopausal symptoms.

50 subjects were selected for the study and divided into 2 groups.

**Group - I** Included 25 subjects who were given oral conjugated equine estrogen (Premarin) 0.625 mg per day.

**Group - II** Included 25 subjects who were given Tab. Raloxifene (selective estrogen receptor modulator) 60mg per day along with oral calcium preparation 500mg/day.

History of individual post menopausal symptoms were taken in detail to judge the severity of symptoms and efficacy of both the therapies on different symptoms. These patients underwent thorough general and systemic examination to rule out any dysfunction and to rule out any absolute contra indications. Such patients were excluded from the study specific investigations such as serum lipid profile, bone
mineral density and endometrial biopsy were done at the start of the therapy and then to evaluate the effect of two drugs, lipid profile was repeated at 3 and 6 months. Bone mineral density and Endometrial biopsy were repeated at 6 months.

The following points were observed: -

(a) The mean age of subjects in group I and II was 42.56 ± 3.16 years and 44.20 ± 3.82 years, respectively.

(b) The mean age of attainment of menopause in group I & II was 40.2 ± 3.2 years and 41.7 ± 1.7 years, respectively.

(c) Mean age of attainment of natural menopause was 43.32 ± 2.05 years and mean age of attainment of surgical menopause was 39.32 ± 1.21 years.

(d) Majority of subjects 56% in group I and 52% in group II had surgical menopause.

(e) Vasomotor symptoms like hot flushes (80% in group I and 72% in group II) was commonest symptom followed by palpitation and depressive symptoms (64% in group I and 52% in group II), sweating and psychosomatic symptoms like insomnia, dizziness, headache, nervousness; dyspareunia (8% in group I and 2% in group II), backache and joint pain.

(f) There was marked improvement in hot flushes, sweating, nervousness and palpitations in group I during and after the therapy whereas there was no significant
improvement in these symptoms in group II. There was slight improvement in symptoms like joint pain, backache etc. in group II.

\( g \) HDL is a cardioprotective lipoprotein and in present study. 9.31% increase in HDL level was noted after 6 months in group I, which was statistically significant whereas increase of only 1.23% was noted in group II which was statistically insignificant.

\( h \) In group I subjects, level of LDL-C decreased by 7.72% and this decrease was statistically significant. Almost similar decrease of 7.95% was noted in subjects of group II and was statistically significant.

\( i \) Statistically significant decrease of 7.96% was observed in the levels of STC in group I after 6 months. A decrease of 7.54% was noted in group II and was also statistically significant.

\( j \) Conjugated equine estrogen administered for 6 months in group I caused a decrease of 3.11% in level of STG which was statistically significant. There was an increase in STG of 0.45% after 6 months of therapy in group II which was statistically insignificant.

\( k \) On comparing the mean values of bone mineral density in both the groups, there was significant increase of 2.5% in group I and 2.19% in group II.

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It was also observed that 44% subjects showed osteopenia in group I at the start of therapy, which was reduced to 12% after 6 months of therapy. In group II, 48% subjects showed osteopenia which was reduced to 16% after 6 months of therapy.

The present study also compared the effect of both the drugs on the endometrium. At the start of therapy, maximum number of subjects in both the groups i.e., 72% in group I and 91% in group II showed no estrogenic effects on endometrial biopsy. At the end of 6 months moderate to marked estrogenic effects were noted in 81% of subjects in group I versus 0% in group II.

Major side effects noted among both the groups were vaginal bleeding, breast pain, leg cramps and hot flushes. Incidence of vaginal bleeding (36%) and breast pain (32%) was much higher among the subjects of group I. Whereas that of hot flushes was higher in group II i.e. 32% as compared to 4% in group I.

But these hot flushes experienced by subjects of group II were mild and tolerable. They were more severe, earlier during the therapy becoming milder later on.

In terms of cardiovascular risk, the optimal lipid profile includes elevated HDL levels and reduced LDL levels, serum total cholesterol levels and serum triglyceride level. In our study, HRT shows such effects
But Raloxifene does not increase HDL which is cardioprotective.

In terms of bone mineral density, Raloxifene as well as HRT do increase the BMD in osteopenic subjects, thus reducing the risk of fractures & osteoporosis.

As far as effect on endometrium is concerned, HRT causes estrogenic effects on endometrium, so increasing the risk for endometrial malignancies. But Raloxifene does not cause estrogenic effects on endometrium so it proves to be safer in terms of malignancies.
CONCLUSION

From the present study, it can be concluded that selective estrogen receptor modulator, Raloxifene has not been proved to be as effective as conjugated equine estrogen for controlling post menopausal symptoms but it is well tolerated. Both the therapies have beneficial effects on lipid profile. Although Raloxifene reduced LDL cholesterol and serum total cholesterol, yet no significant changes in HDL cholesterol and triglycerides have been observed, hence confirmation of effect on these factors is still required. The apparently reduced risk of coronary artery disease cannot be attributed with certainty to hormone replacement therapy and raloxifene. It may instead have been caused by healthier life style and medical characteristic of women studied with the possibility that healthier women were selected for the study. Conjugated equine estrogen as well as raloxifene improve the bone mineral density of, osteopenic post menopausal subjects so both might prove to be beneficial in the treatment and prevention of osteoporosis. Raloxifene does not cause proliferation of endometrium, hence it does not predispose to development of uterine malignancy.

Hence the present study concludes that Raloxifene and premarin both are lipid friendly (cardio protective) and have positive effect on BMD. Raloxifene also has favourable effect
on endometrium but at the same time it can not be used as 1st line treatment of post menopausal symptoms for which premarin still remains the drug of choice.