

SAFETY AND EFFICACY OF MIRENA IN MENORRHAGIA : 10 YEARS RESULTS OF VUOKKO-STUDY

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Heavy menstrual bleeding is a common complaint, which causes much inconvenience as well as physical, mental, and emotional problems to many women. It has a prominent effect on the health-related quality of life (HRQoL). The increasing health care costs are world wide phenomenon and there is an obvious need for strategies which result in net cost savings. Vuokko -study was conducted to compare multifactorially the cost-effectiveness of the most effective treatment modalities in menorrhagia, LNG-IUS and hysterectomy, between 1994-2008. Overall, 236 women aged 35 to 49 years who were menstruating, had completed their family size, and were eligible for both treatments were randomized to either receive a LNG-IUS (n=119) or undergo hysterectomy (n=117). The follow-up visits took place six months and 12 months after the treatment, and again five and ten years after the randomization.

The one-year follow-up data was published in Lancet (1) and five-year data in JAMA (2). After 5 years of follow-up the groups did not differ substantially in terms of HRQoL or psychosocial well-being (anxiety, depression and sexual function). Although 42% of women assigned to the LNG-IUS group subsequently underwent hysterectomy, the overall direct and indirect costs after 5 years were still approximately 40% lower in the LNG-IUS group.

After 10 years of follow-up, 221 women (94%) were analysed for the primary outcomes (mean age 53 years). In LNG-IUS-group 36% had the IUS in situ, 46% were hysterectomised and 15% were without IUS. In hysterectomy group 94% of the women were hysterectomised and one had IUS. The preliminary results analyzed by intention to treat suggest that the health-related quality of life measured by EQ-5 VAS (0-100) is significantly better in LNG-IUS group (74 vs 64). No differences were found in psychosocial well-being (anxiety, or depression). There were no differences between the study arms in terms of weight or acne. Previously we showed that after 12 months hysterectomized women had higher FSH levels and more hot flushes (3). The 10-year results are in line with this suggesting higher estrogen therapy rate in women with hysterectomy than with LNG-IUS (59% vs 28%). Urinary problems seem to be associated with hysterectomy. Women with hysterectomy had more urinary infections, problems with emptying the bladder and stress urinary incontinence. More about this topic will be presented by Dr Heliövaara-Peippo in this congress. Although 46% of the women assigned to the LNG-IUS group eventually underwent hysterectomy, the costs in the LNG-IUS group remained significantly lower than costs in the hysterectomy group.

The preliminary 10-year results of Vuokko study show that LNG-IUS is a good alternative option to hysterectomy in the treatment of menorrhagia. Although half of the women assigned to the LNG-IUS group eventually underwent hysterectomy, the costs remain significantly lower than in hysterectomy group. The transition from menorrhagia to menopause seems to be well tolerated and associated with a favourable bleeding pattern.

References

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