Thermal balloon ablation versus endometrial resection for treatment of abnormal uterine bleeding

Dear Sir,

Gervaise and colleagues recently reported on a comparison of thermal balloon ablation versus endometrial resection for the treatment of abnormal uterine bleeding (Gervaise et al., 1999). We have some concerns about their methods.

Taking into account the non-randomized character of their study, it is of importance to know the indications for both interventions under study. While excessive menstrual blood loss was the indication for treatment, nothing is mentioned on the indication for either balloon ablation or endometrial resection. This is worrisome, since the authors fail to take into account pre-operative bleeding patterns in the comparison of baseline characteristics. The imbalance in menopausal status indicates that the two groups are not comparable as the authors want us to believe.

Another concern is that for no obvious reason, patients in the balloon group have been contacted three times at follow-up, whereas patients in the resection group have been contacted...
only once. Given the single follow-up moment, it remains unclear how ‘time to failure’ is registered in the resection group.

A third point of concern is the definition of end-points. In the absence of measurement of patients’ quality of life or patients’ valuation of treatment effect, the authors use amenorrhoea and hypomenorrhoea as measure of success. Although significant differences are not reported, the percentages of amenorrhoea and hypomenorrhoea are lower after balloon ablation as compared to endometrial resection. Combination of these two endpoints leads to a relative risk of 0.68 in favour of endometrial resection (95% confidence limits 0.51 to 0.90). On the disappearance of dysmenorrhoea, announced as a secondary end-point in the methods, no results are reported at all. Taking into account these concerns, we feel that the data provided in the study of Gervaise et al. (1999) do not allow the conclusion of the authors that uterine balloon ablation appears to be as efficacious as endometrial resection for the treatment of abnormal uterine bleeding.

References

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Dear Sir,

The study we have reported recently (Gervaise et al., 1999), compared the clinical efficacy and safety of a thermal balloon system with the reference treatment of dysfunctional uterine bleeding, hysteroscopic endometrial resection.

This study was non-randomized, but the indications of both interventions were strictly similar, in terms of age, normality and depth of the uterine cavity and number of pads per cycle used. About the menopausal status, all post-menopausal women were taking substitutive hormone therapy which in our opinion has the same meaning in terms of functional excessive bleeding. Furthermore, the Cox proportional hazards model was applied in order to analyse the simultaneous relationships between event failure and possible co-variates, and to study the influence of prognostic factors on the appearance of failure. Menopausal status (and parity) were forced into the Cox model in order to ensure that their possible confounding effects were controlled, and the multivariate analyses have shown that the menopausal status was not a factor associated with failure.

The choice between the two procedures was surgeon-dependent. For both groups of patients, the procedure was done by the French referent surgeon for the technique: H.Fernandez for the thermal uterine balloon system, and J.Hamou for the hysteroscopic endometrial resection.

With reference to the follow-up, the thermal uterine balloon system which is a new surgical technique, needed a frequent follow-up to evaluate efficacy and safety. This follow-up was done by phone-contact using a check-list, to record the date of failure. Since endometrial resection is a well-known surgical procedure, only one phone-contact in this group gave us enough information. Although two different frequencies of follow-up were used, the fact is that no patients were lost to follow-up.

Concerning the end-points, it appears that amenorrhoea and hypomenorrhoea were not significantly different between the two techniques. It is true that combination of these two endpoints leads to a relative risk in favour of endometrial resection. However, we defined clinical failure as persistent menorrhagia. We consider that eumenorrhoea is a good result for these women suffering excessive uterine bleeding, and this endpoint was in favour of thermal balloon system (p < 0.001). These treatments are not supposed to create amenorrhoea, as did the Elit laser system in 68% of cases (Donnez et al., 1999). About the disappearance of dysmenorrhoea, our results are similar with those obtained by Meyer et al. (1998) with no statistical difference between thermal balloon system and endometrial resection.

In summary, with the criteria we defined, our comparative study is statistically valid, and allows us to conclude that thermal uterine balloon system appears to be as efficacious as endometrial resection for the treatment of dysfunctional uterine bleeding.

References


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