

Prospective evaluation of endometrial ablation with Thermablate®

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Introduction

Abnormal menstrual bleeding, menorrhagia, is a common complaint in premenopausal women. The Thermablate Endometrial Ablation System (TEAS) is one of the newest endometrial ablation devices to treat excessive uterine bleeding in an outpatient setting (Figure 1). During a Thermablate endometrial ablation treatment, a soft balloon is inserted into the uterus. The balloon is then inflated with a heated sterile fluid and expanded to fit the size and shape of the uterus (Figure 2). The treatment lasts less than 2.5 minutes, during which time the majority of the endometrium of the uterus is destroyed.

Aim of the study: This study was designed to evaluate the acceptability and efficacy of the TEAS.



Figure 1: Thermablate Endometrial Ablation System



Figure 2: Soft balloon inserted into the uterus

Methods

This prospective cohort study was performed in a teaching hospital. Women with menorrhagia were treated with the TEAS after former conservative, mostly hormonal, therapy failed. Excluded were women with submucosal fibroids, polyps, desire to preserve fertility and suspicion of endometrial malignancy. Main outcome was satisfaction and effect of the TEAS, measured by questionnaires at 3, 6 or 12 months and recording additional therapies during follow up. These additional therapies were divided according to invasiveness (surgical vs. non-surgical treatment).

Statistical analysis: Data were analyzed with Predictive Analytics Software (PASW) Statistic 18 (Statistical Package for Social Sciences (SPSS) for Windows Release 18.0 SPSS inc., Chicago, IL, USA). $p < 0.05$ was considered statistically significant.

Results

A total of 249 women were included. The majority (92%) of these women were treated at the outpatient clinic. Reduction of menstrual bleeding was reported by 82% and complete amenorrhea was achieved in 18% of the women. 194 (78%) women were satisfied with the procedure and 210 (84%) would recommend it to a friend.

Age

After a mean follow up of 13 months (range 2-46), 55 women (22%) required additional surgical treatment, of whom 31 women underwent a surgical endometrial ablation and 24 women a hysterectomy. These 55 women were significantly younger compared to women who did not require additional surgical treatment (43 vs. 45 years, $p = 0.02$).

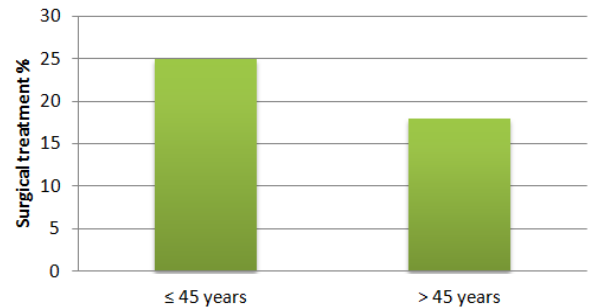


Figure 4: Percentage of women acquiring additional surgical treatment in relation to age

Dysmenorrhea

26% of the women with dysmenorrhea before treatment with the TEAS was not satisfied instead of only 10% of the women without dysmenorrhea ($p = 0.11$).

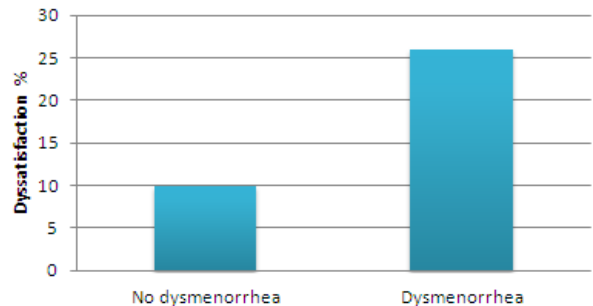


Figure 3: Percentage of women who were not satisfied after treatment with the TEAS correlated to dysmenorrhea before treatment

Conclusion

Overall satisfaction and effectiveness in combination with the simple performance makes the TEAS a successful outpatient procedure in women with excessive menstrual bleeding.

Discussion

- Further studies should focus on long term efficacy.
- Predictors of success should be more investigated.