



Prognostic factors for the success of endometrial ablation in the treatment of menorrhagia with special reference to previous cesarean section

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ABSTRACT

Objective: To assess whether, among other prognostic factors, a history of Cesarean section is associated with endometrial ablation failure in the treatment of menorrhagia.

Study design We compared women who had failed ablation to women who had successful ablation for menorrhagia in a case–control study. Failed ablation was defined as the need for hysterectomy due to persistent heavy menstrual bleeding after ablation. Successful ablation was defined as an ablation for menorrhagia not needing hysterectomy and the woman being satisfied with the result. Both cases and controls were identified from the surgery registration in the Máxima Medical Center between January 1999 and January 2009. Cases were women that had an endometrial ablation and a hysterectomy, whereas controls only had an endometrial ablation. From the medical files we collected for each patient clinical history, including the presence of a previous Cesarean section, baseline characteristics at the moment of initial ablation, data of the ablation technique and follow-up status. We used univariable and multivariable logistic regression to estimate the risk of failure of endometrial ablation.

Results: We compared 76 cases to 76 controls. Among the cases, 12 women had had a previous Cesarean section versus 15 in the control group (15.8% versus 19.7%; odds ratio (OR) 0.76; 95% CI 0.3–1.8). Factors predictive for failure of ablation were dysmenorrhea (OR 3.0; 95% CI 1.5–6.1), having a submucous myoma (OR 3.2; 95% CI 1.5–6.8) and uterine depth (per cm OR 1.3; 95% CI 1.0–1.6). Presence of intermenstrual bleeding, sterilization and age were not associated with failure of ablation.

Conclusion: A previous Cesarean delivery is not associated with an increased risk of failure of endometrial ablation, but dysmenorrhea, a submucous myoma and longer uterine depth are. This should be incorporated in the counseling of women considering endometrial ablation.

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1. Introduction

Dysfunctional uterine bleeding is a frequent problem in premenopausal women, and one in 20 women suffer from menorrhagia [1,2]. Menorrhagia has consequences for the general wellbeing of women. Although a hysterectomy guarantees amenorrhea in all women, it is expensive and has a significant impact on health-related quality of life immediately after surgery [3,4]. The treatment of dysfunctional uterine bleeding by destroying the endometrium without removal of the uterus has become common practice. Compared with hysterectomy, transcervical

endometrial ablation techniques initially show similar efficacy with lower costs and fewer complications [4,5].

These beneficial outcomes, however, seem to diminish with time, as 12% of the women require hysterectomy within two years and 30% within four years after ablation [4,5]. Nevertheless, most women choose endometrial ablation rather than hysterectomy as therapy for menorrhagia [6]. Despite the willingness to accept potential risk of treatment failure, counseling of women with menorrhagia, who needed surgical treatment, could be improved by predicting the probability of success in each particular case.

Due to the rise in Cesarean sections in the last decade more and more women who will undergo endometrial ablation have had a previous Cesarean section. Data are lacking, however, on the association between a previous Cesarean section and the success of an endometrial ablation.

The objective of this study was to assess if, among other potential prognostic factors, a Cesarean section could determine the outcome of endometrial ablation in women with menorrhagia.

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2. Materials and methods

We performed a retrospective case–control study in the Maxima Medical Center (MMC). The MMC is a teaching hospital with 500 beds in the south of The Netherlands. We studied women who had undergone an endometrial ablation between January 1999 and March 2009 for menorrhagia. In our center, endometrial ablation for menorrhagia has been carried out since 1994.

In the study period we performed several randomized clinical trials (RCTs) evaluating balloon ablation; Novasure[®] and Hydrothermal ablation (HTA). At present, Novasure[®] is the treatment of choice due to the results of the RCTs [7–9].

In this study, we defined cases, i.e. women in whom ablation has failed, as women who underwent a hysterectomy for persistent menorrhagia after an ablation in the period January 1999 until March 2009. Controls were women who had had an ablation without any reintervention. We identified our cases and controls from the electronic operation room planning system. For each included case patient, the next woman with a successful comparable ablation procedure scheduled directly after the index procedure was selected as a control patient. Subsequently we checked in the medical records of the selected control patients whether the endometrial ablation had indeed been successful or not. An endometrial ablation was considered to be successful if the patient was satisfied without a reintervention. Information on satisfaction was obtained from the medical chart and by contacting the patient by telephone.

We only included patients with dysfunctional uterine bleeding who had cavity investigation by a saline infusion sonography and/or a hysteroscopy. Submucous myomas, as observed on ultrasound or at pre-endometrial ablation hysteroscopy, were defined as partial protrusion of a myoma into the cavity. Only women with submucous myomas smaller than 2 cm, or not disturbing the endometrial cavity, could undergo endometrial ablation. Exclusion criteria were malignancy of the uterus or cervix, presence of intrauterine adhesions after assessment by hysteroscopy, and uterine depth more than 12 cm. The use of oral contraceptives, antiprostaglandins and anticoagulants in the previous 3 months before the ablation was not an exclusion criterion.

The three global endometrial ablation methods which were used in MMC during the study period were radio-frequency ablation (Novasure[®]), hydrothermal ablation (HTA) and balloon ablation (Thermachoice). All three procedures were performed in the operating room under regional or general anesthesia. After 2005 the Novasure[®] was also performed in an outpatient setting under local anesthesia. Women who chose the procedure at the outpatient clinic were advised to use an oral nonsteroidal anti-inflammatory drug as a painkiller 12 h and 1 h before the procedure. At the beginning a paracervical block with Ultracaine or Prilocaine 1% with or without adrenaline was placed.

The aim of the analysis was to relate potential prognostic factors available before the start of treatment to the occurrence of an adverse outcome. Apart from previous Cesarean section, the case subjects were compared with the control subjects with regard to the occurrence of clinical signs and symptoms, abnormal laboratory tests, medical history and preoperative characteristics. The position of the uterus was assessed by bimanual examination and confirmed during hysteroscopy. Dysmenorrhea, intermenstrual bleeding and an irregular menstrual cycle were recorded as either present or absent and the duration of menstruation was recorded in days.

All data were obtained from the patients' medical records. In the cases and controls in which we were not sure about whether a Cesarean delivery had been performed, we contacted the patient. Beside Cesarean delivery we also collected data on preoperative characteristics, medical history and main factors

about dysfunctional uterine bleeding. Age was categorized by using two threshold values; one of 40 years and one of 45 years. A 4 mm threshold for endometrial thickness was selected [7].

Each potential prognostic variable was first evaluated in a univariable logistic regression model. Subsequently variables with a P value ≤ 0.05 were evaluated in a multivariable logistic regression model. Odds ratios (ORs) and 95% confidence intervals (CI) were presented. All data were analyzed using SPSS 17.0 for Windows.

3. Results

We identified 890 women who had an endometrial ablation in the MMC between January 1999 and March 2009. Of these 890 women, 76 had had a hysterectomy after their endometrial ablation as treatment for menorrhagia, and therefore were considered as having experienced the ablation as unsuccessful. These patients were compared to 76 women who had an ablation with a satisfying result. Of the 152 women 110 had a Novasure[®], 36 the HTA and the other 6 the Thermachoice.

Table 1 shows the clinical characteristics of both the cases and controls. There were a few differences between case and control subjects. Duration of menstruation, intermenstrual bleeding and an age above the 45 years differed significantly (respectively: $P = 0.03$, $P = 0.03$ and $P = 0.03$). In the case subjects, the mean number of months between the endometrial ablation and the hysterectomy was 12.6 months. The mean follow-up of the controls was 54.7 months.

Twelve of the 76 case subjects had had a Cesarean section, as compared with 15 of the 76 control subjects (OR 0.76; 95% CI 0.3–1.8). Table 1 also shows the results of the other potential prognostic factors. Age above 45 years reduced the risk of an adverse outcome (OR 0.47; 95% CI 0.24–0.92). On the other hand, the risk of an adverse outcome increased when women had dysmenorrhea (OR 3.0; 95% CI 1.5–6.1), intermenstrual bleeding (OR 2.1; 95% CI 1.1–4.1) a submucous myoma (OR 3.2; 95% CI 1.5–6.8) or a sterilization in their medical history (OR 2.2; 95% CI 1.1–4.2). A uterus in retroversion increased the risk of failure of treatment (OR 2.1; 95% CI 0.90–4.8), whereas endometrial thickness was not associated with the risk of an adverse outcome (OR 1.02; 95% CI 0.94–1.1).

Beside the univariable results, Table 1 also shows the results of the multivariable logistic regression analysis. Dysmenorrhea, uterine depth and a submucous myoma decreased the chance of a successful outcome. All these three associations were statistically significant. However, sterilization, intermenstrual bleeding and age above 45 years associated with an increased risk in the univariable analysis, had limited impact on the multivariable analysis (respectively: $P = 0.26$, $P = 0.20$ and $P = 0.06$).

4. Comment

In this case–control study, we assessed prognostic failures for endometrial ablation in women suffering from menorrhagia. We found that a previous Cesarean section did not affect the success rate of endometrial ablation, but dysmenorrhea (before treatment), uterine depth, and a submucous myoma increased the risk of treatment failure. On the other hand we showed that sterilization, intermenstrual bleeding and age equal or above 45 years had also a positive effect on the treatment outcome, although this effect was limited in the multivariable analysis. These results are generally in agreement with results of other studies evaluating the outcome of various sorts of endometrial ablation techniques [4,10–13].

The main limitation of our study was its retrospective nature. This resulted in partly precluding some objective pre-operative

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