Prediction of unsuccessful endometrial ablation

Gynecological Surgery

ORIGINAL ARTICLE Open Access

Prediction of unsuccessful endometrial ablation: a retrospective study

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Abstract

Background: Endometrial ablation (EA) is a frequently used treatment for abnormal uterine bleeding, mainly due to the low risks, low costs and short recovery time associated with the procedure. On the short term, it seems successful, long-term follow-up however, shows decreasing patient satisfaction as well as treament efficacy. There even is a post-ablation hysterectomy rate up to 21%. Multiple factors seem to` influence the outcome of EA. Due to dissimilarities in and variety of these factors, it has not been possible so far to predict the success rate of EA based on pre-operative factors. Therefore, the aim of this study is to develop two prediction models to help counsel patients for failure of EA or necessity of surgical re-intervention within 2 years after EA.

Methods: We designed a retrospective two-centred cohort study in Catharina Hospital, Eindhoven and Elkerliek Hospital, Helmond, both non-university teaching hospitals in the Netherlands. The study population consisted of 446 pre-menopausal women who underwent EA for abnormal uterine bleeding, with a minimum follow-up time of 2 years. Multivariate logistic regression analysis was used to create the prediction models.

Results: The mean age of the patients was 43.8 years (range 20–55), 97.3% had complaints of menorrhagia, 57.4% of dysmenorrhoea and 61.0% had complaints of intermittent or irregular bleeding. 18.8% of patients still needed a hysterectomy after EA. The risk of re-intervention was significantly greater in women with menstrual duration > 7 days or a previous caesarean section, while pre-operative menorrhagia was significantly associated with success of EA. Younger age, parity ≥ 5 and dysmenorrhea were significant multivariate predictors in both models. These predictors were used to develop prediction models, which had a C-index of 0.71 and 0.68 respectively.

Conclusion: We propose two multivariate models to predict the chance of failure and surgical re-intervention within 2 years after EA. Due to the permanent character of EA, the increasing number of post-operative failure and re-interventions, these prediction models could be useful for both the doctor and patient and may contribute to the shared decision-making.

Keywords: Prediction model, Endometrial ablation, Abnormal uterine bleeding, Patient counselling.

Article

The use of EA as treatment for abnormal uterine bleeding is rapidly increasing. This surgical outpatient procedure offers a minimally invasive alternative for hysterectomy in case non-surgical treatment is not effective. The success of EA is mainly based on the short recovery time, low risks and low costs associated with the procedure. [1–5] In contrast to the short-term success, long-term follow-up shows decreasing patient satisfaction as well as treatment efficacy [6–13]. A common complaint of patients after EA is pain (20–23%), which often leads to re-interventions [7, 8]. Besides the occurrence, persistence or aggravation of pain, another reason for re-intervention can be persisting bleeding disturbances [7, 10]. Retrospective cohort data reveal a post-ablation hysterectomy rate up to 21% [6, 8–10, 12, 14–16].

Several factors influencing failure of EA have been reported. It has been shown that the probability of success increases with older age at the time of

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Partly presented as abstract at:- The 24th Annual International Congress of the European Society of Gynaecological Endoscopy, Budapest Hungary 2015- The 26th Annual International Congress of the European Society of Gynaecological Endoscopy, Antalya Turkey 2017- The 46th global congress of the American Association of Gynaecologic Laparoscopists, Washington D.C. United States 2017
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intervention. [6, 8–12, 14, 17, 18] Prior studies demonstrated different negative influencing factors, such as the duration of pre-operative menstruation, dysmenorrhea, the position of the uterus and the thickness of the endometrium [6, 7, 9–13, 15, 19, 20].

However, due to dissimilarities in and variety of the factors previously described, it has not been possible so far to predict the success rate of EA based on pre-operative factors. Patient counselling is therefore difficult.

The aim of this study was to develop two prediction models to counsel patients for failure of EA and for surgical re-intervention within 2 years. In addition, we established the hysterectomy rate, the additional treatment rate and the patient satisfaction after EA.

Methods

This retrospective two-centred cohort study included patients with EA for complaints of abnormal uterine bleeding in two non-university teaching hospitals in the Netherlands (the Catharina Hospital in Eindhoven and the Elkerliek Hospital in Helmond). In both hospitals, similar ablation techniques were used between 2004 and 2013, namely Cavatherm® (Veldana Medical SA, Morges, Switzerland), Thermablate® EAS (Idoman, Ireland) and Gynecare Thermachoice® (Ethicon, Sommerville, US). Previous research showed that these techniques were equal in effectivity [13, 21]. The study was approved by the local medical ethical review board. All patients gave informed consent.

Patients

Patients were identified in the Electronic Patient Care System using the following search terms: endometrial ablation, balloon-coagulation endometrium, coagulation uterus and endoresection: hysteroscopic extensive. The retrieved cases were verified by means of chart review.

Patients were excluded if they were post-menopausal at the time of treatment, if they had or were suspected of having an endometrial malignancy or if they had uterine cavity deformations (anomalies, fibroids, adenomyosis or a polyp).

Follow-up period after EA was at least 2 years, since earlier research showed that most re-interventions took place in this post-operative 2-year period [8, 15, 20–24]. Follow-up ended on the day of hysterectomy, in case of death or on April 15, 2015.

Data extraction

Two researchers extracted all the data from individual patient files. Patients were requested to complete a questionnaire concerning follow-up information. In case of non-response, patients were contacted by letter again and ultimately by telephone. The questionnaire comprised questions based on significant factors previously published [6, 9–15, 17–20]. Charts and patient responses were used to obtain post-procedural information on menstrual pattern, patient satisfaction, additional treatment and pathology results in case a hysterectomy was performed.

Abnormal blood loss as procedure outcome was defined by a combination of intermittent or irregular bleeding and heavy menstrual bleeding (HMB) following EA. Treatment prior to EA was defined as any treatment for abnormal uterine bleeding performed prior to surgery. Satisfaction was evaluated on a four-point scale (1: very satisfied, 2: satisfied, 3: dissatisfied, 4: very dissatisfied). During analysis, we combined the answers scoring 1 and 2 points as 'satisfied' and those scoring 3 and 4 points as 'dissatisfied'.

Outcomes

The primary aim of this study was to identify significant predictors of failure of EA and surgical re-intervention within 2 years after EA by constructing a prediction model for each outcome. Failure was defined as pelvic pain, abnormal blood loss or dissatisfaction after the procedure. Secondary outcomes of this study were hysterectomy rate, patient satisfaction and percentage of additional treatment after EA, for example hormonal treatment, re-ablation or endometrial resection.

Statistical analysis

Statistical analysis was performed using the statistical package IBM SPSS statistics, software version 21.0 (IBM Corp., Armonk, NY, USA). Continuous variables were presented as mean and standard deviation or median and minimum-maximum, depending on normality. Categorical variables were reported as frequencies.

Univariable logistic regression analysis was used to determine which predictive factors were significant. Corresponding odds ratios (OR) and 95% confidence intervals (CI) were given.

Predictive factors with a p value <.10 were used in the multivariable analysis. A manual selection process was done by progressively excluding the variable with the highest p value.

The p value of 0.10 was chosen because, as Steyerberg et al. stated, an incorrect exclusion of a variable would be far more detrimental than considering to put in a factor too many [25, 26].

Possible interaction between the significant predictors in the model was tested using interaction terms. Furthermore, multicollinearity was tested.

The overall fit of the model was tested using the C-index (area under the curve). A value of 1.0 for the C-index implies a perfectly produced model, where every prediction made with the variables in the model is true. However, a value of 0.5 implies that the model gives information that is equal to that given by the probability on its own. Values over 0.7 indicate a good model, whereas values over 0.8 indicate a strong model [27, 28].

The regression model was internally validated with bootstrap resampling ($n = 5000$) [29–33]. Regression coefficients of the model were multiplied by the shrinkage factor to correct for over-optimism of the original model.

Results

In this study, 762 patients were identified. After examination of patient records, 33 patients were excluded; 30 patients did not completely fulfil the inclusion criteria (e.g. malignancy, cavity deformations) and 3 patients had an incomplete ablation procedure.

The remaining 729 participants were contacted, of whom 283 did not respond despite our best efforts. This resulted in 446 included patients, which represents a response rate of 61% (Fig. 1).

The baseline patient characteristics are listed in Table 1. The mean age of the patients at the time of EA was 43.8 years (SD ± 5.5, range 20–55). The mean BMI was 26.5 kg/m^2 (SD ± 4.7). A mean number of parity of 2.2 (SD ± 1.0) was observed; 13.7% of the women had undergone a previous caesarean section.

Menorrhagia was present in 97.3% of patients, 61% had complaints of intermittent or irregular bleeding and 57.4% had complaints of dysmenorrhea. In 39.4% of patients, the duration of the menstruation was longer than 7 days (Table 1).

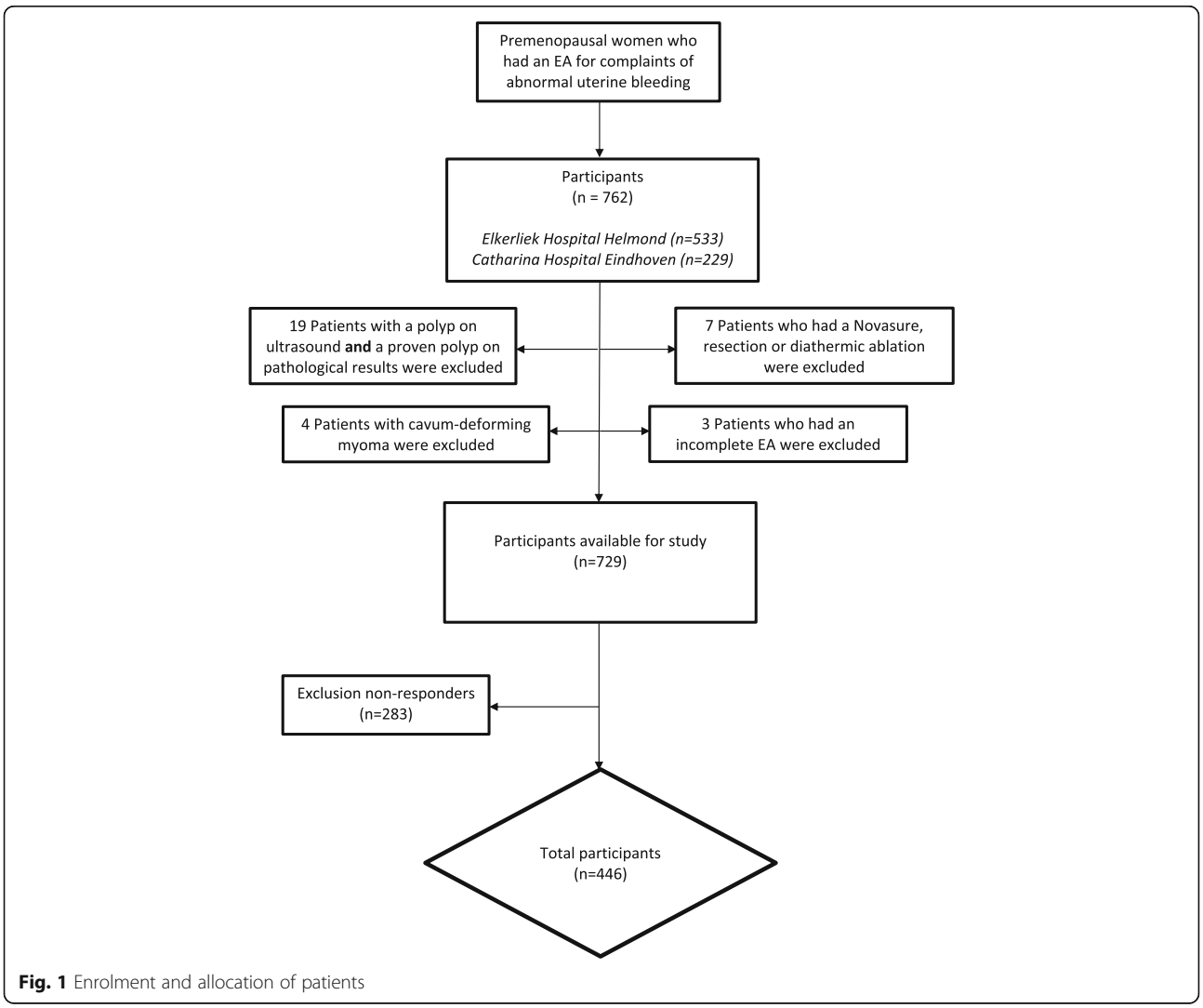

Fig. 1 Enrolment and allocation of patients

Table 1 Baseline patient characteristics ($N = 446$)

Characteristic *	Value**
Age (years)	43.8 ± 5.5
Body mass index (kg/m^2)	26.5 ± 4.7
Dysmenorrhea	57.4%
Follow-up time (days)	1693.8 ± 871.9
Duration of menstruation > 7 days ($n = 429$)	39.4%
Intermittent or irregular bleeding	61.0%
Length of the uterus (cm) ($n = 402$)	9.1 ± 1.1
Menorrhagia	97.3%
Parity (no.)	2.2 ± 1.0
Previous caesarean section	13.7%
Smoking ($n = 445$)	21.6%
Sterilisation ($n = 444$)	26.1%
Uterus position ($n = 296$)	
Anteverted	72.3%
Retroverted	23.6%
Midposition	4.1%

*$n = 446$ unless otherwise mentioned
**Mean ± SD or a percentage

Re-intervention model

In the study group, 11.9% ($n = 53$) of the patients needed a surgical re-intervention within 2 years after EA. Univariate analyses showed that the following pre-operative variables were significantly associated with a higher probability of getting a surgical re-intervention within 2 years after EA ($p < .05$): age (OR 0.93, 95% CI 0.89–0.98), dysmenorrhea (OR 2.83, 95% CI 1.44–5.55), length of menstruation > 7 days (OR 1.87, 95% CI 1.04–3.37), parity ≥ 5 (OR 5.84, 95% CI 1.27–26.83), previous caesarean section (OR 2.98, 95% CI 1.52–5.83) and pre-treatment (OR 0.40, 95% CI 0.16–0.95) (Table 2). These pre-operative variables were included in the multivariate analyses.

In the final prediction model after multivariate analysis, the following pre-operative variables were significant: age (OR 0.95, 95% CI 0.90–1.00), dysmenorrhea (OR 2.48, 95% CI 1.21–5.07), length of menstruation > 7 days (OR 2.05, 95% CI 1.10–3.82), previous caesarean section (OR 2.21, 95% CI 1.05–4.64) and parity ≥ 5 (OR 7.63, 95% CI 1.51–38.46) (Table 2). The C-index of the model was 0.71.

No two-way interaction and multicollinearity between the variables was detected.

The shrinkage factor of 0.823 was used to correct the model.

Table 2 Pre-operative predictors of re-intervention after endometrial ablation

	Univariate analysis			Multivariate analysis			
Variable	Odds ratio	95% CI	*p* value	Odds ratio	95% CI	*p* value	*β*
Age (years)	0.93	0.89–0.98	<.01	0.95	0.90–1.00	.06	− 0.052
Body mass index (kg/m^2)	0.99	0.93–1.05	.68				
Dysmenorrhea	2.83	1.44–5.55	<.01	2.48	1.21–5.07	.01	0.097
Duration of menstruation > 7 days	1.87	1.04–3.37	.04	2.05	1.10–3.82	.02	0.718
Intermittent or irregular bleeding	1.56	0.84–2.89	.16				
Menorrhagia	0.67	0.14–3.12	.61				
Myomas	0.67	0.30–1.48	.33				
Parity (no.)	0.88	0.66–1.17	.38				
Parity ≥ 5	5.84	1.27–26.83	.02	7.63	1.51–38.46	.01	2.032
Pre-treatment*	0.40	0.16–0.95	.04	0.49	0.20–1.22	.13	–
Previous caesarean section	2.98	1.52–5.83	<.01	2.21	1.05–4.64	.04	0.794
Smoking	1.36	0.70–2.62	.36				
Sterilisation	1.59	0.86–2.94	.14				
Total endometrial thickness							
Thin, 0–3 mm	0.64	0.18–2.29	.49				
Normal, 4–12 mm	1.00	–	–				
Thick, > 13 mm	0.96	0.36–2.58	.93				
Uterine cavity length of the uterus (cm)	1.16	0.88–1.54	.29				
Uterus position							
Anteverted	1.00	–	–				
Retroverted	1.23	0.54–2.79	.63				
Midposition	2.77	0.70–10.96	.15				

*Any form of treatment (medicamentous or surgical) prior to the EA

The final model after application of the shrinkage factor is as follows:

$$y = \frac{1}{1 + e^{-(-0.896-(\text{age}\times 0.046)+(\text{dysmenorrhea (yes=1 no=0)}\times 0.008)+(\text{parity}\geq 5\ \text{(yes=1 no=0)}\times 1.781)+(\text{duration of menstruation}>7\ \text{(yes=1 no=0)}\times 0.629)+(\text{previous caesarean section (yes=1 no=0)}\times 0.700))}}$$

Failure model

In the study group, 35.8% ($n = 160$) of the EA failed. Univariate analyses showed that the following pre-operative variables were significantly associated with a higher probability of failure of EA ($p < .05$): age (OR 0.93, 95% CI 0.89–0.96), dysmenorrhea (OR 2.14, 95% CI 1.42–3.23), menorrhagia (OR 0.27, 95% CI 0.08–0.91) and parity ≥ 5 (OR 11.17, 95% CI 1.33–93.60) (Table 3). The pre-operative variables with a p value $p < .10$ were also included in the multivariate analyses; these were total endometrial thickness and pre-treatment.

In the final prediction model after multivariate analyses, the following pre-operative variables were significant: age (OR 0.93, 95% CI 0.90–0.97), dysmenorrhea (OR 2.11, 95% CI 1.37–3.26), menorrhagia (OR 0.21, 95% CI 0.06–0.77) and parity≥ 5 (OR 11.19, 95% CI 1.30–96.51) (Table 3). The C-index of the model was 0.68.

No two-way interaction and multicollinearity between the variables was detected.

The shrinkage factor of 0.904 was used to correct the model.

The final model is as follows:

$$y = \frac{1}{1 + e^{-(3.485-(\text{age}\times 0.063)+(\text{dysmenorrhea (yes=1 no=0)}\times 0.677)+(\text{parity}\geq 5\ \text{(yes=1 no=0)}\times 2.183)-(\text{menorraghia (yes=1 no=0)}\times 1.400))}}$$

Other results

Our results showed that 82.6% ($n = 368$) of patients were satisfied with the outcome of EA, and 86.8% ($n = 387$) of patients would recommend EA to a friend.

Of the satisfied group, 14.6% ($n = 54$) of patients had a new medical therapy or a surgical re-intervention. Furthermore, 32.7% ($n = 146$) of the total population had an additional treatment after EA, varying from hormonal to surgical intervention.

The hysterectomy rate was 18.8% ($n = 83$), and 61% ($n = 51$) of this group had surgery within 2 years after EA. A total of 22.9% ($n = 102$) of the study population had additional surgical treatment, 52% ($n = 53$) of whom within 2 years after EA. Besides the number of smokers, there was no significant difference between the baseline data and the hysterectomy rates between the responders and the non-responders.

Discussion

Main findings

This study identified predictors for the outcome of EA as a treatment of abnormal uterine bleeding; this resulted in two prediction models, one for the probability of a surgical re-intervention within 2 years after EA (C-index 0.71) and one for the probability of failure of EA (C-index 0.68).

Explaining the models

The significant factors seem to be in line with the previously published literature. [6, 11–15, 17–20]

An EA procedure at a younger age increases the risk of failure due to the longer interval until menopause. This increased time interval can also increase the risk of new complaints or re-intervention. In our model, age was used as a continuum, so the probability can be calculated more specifically based on the exact age of the individual patient.

The significant factor of high parity (≥ 5) is probably due to a larger multiparous uterine cavity, which is less congruent with an optimal fit of the ablation devices. However, we did not find a univariate significant difference in uterine cavity length.

Previous caesarean section as a significant negative risk factor can possibly be explained due to abnormal bleeding caused by uterine scar defects. It is possible that the device cannot make complete contact with the entire surface, especially in the inner part of the niche, leading to incomplete EA due to residual active endometrium [34]. Furthermore, in our models, pre-operative dysmenorrhea is associated with higher risk of failure and surgical re-intervention.

Table 3 Pre-operative predictors of failure of endometrial ablation

	Univariate analysis			Multivariate analysis			
Variable	Odds ratio	95% CI	*p* value	Odds ratio	95% CI	*p* value	*β*
Age (years)	0.93	0.89–0.96	<.01	0.93	0.90–0.97	<.01	− 0.070
Body mass index (kg/m^2)	0.99	0.95–1.03	.61				
Dysmenorrhea	2.14	1.42–3.23	<.01	2.11	1.37–3.26	<.01	0.749
Duration of menstruation > 7 days	1.26	0.84–1.89	.27				
Intermittent or irregular bleeding	1.22	0.82–1.83	.33				
Menorrhagia	0.27	0.08–0.91	.03	0.21	0.06–0.77	.02	− 1.544
Myomas	0.92	0.56–1.49	.72				
Parity (no.)	0.88	0.73–1.07	.22				
Parity ≥ 5	11.17	1.33–93.60	.03	11.19	1.30–96.51	.03	2.415
Pre-treatment	0.63	0.39–1.03	.07	0.74	0.37–1.47	.39	–
Previous caesarean section	1.57	0.90–2.72	.11				
Smoking	0.73	0.45–1.18	.20				
Sterilisation	1.30	0.84–2.01	.24				
TED							
Thin, 0–3 mm	0.94	0.47–1.85	.85	1.11	0.54–2.30	.78	–
Normal, 4–12 mm	1.00	–	–				
Thick, > 13 mm	0.55	0.29–1.07	.08	0.56	0.27–1.16	.12	–
Uterine cavity length (cm)	1.07	0.89–1.28	.49				
Uterus position							
Anteverted	1.00	–	–				
Retroverted	1.40	0.79–2.46	.25				
Midposition	1.51	0.46–4.95	.49				

*Any form of treatment (medicamentous or surgical) prior to the EA

Adenomyosis has been suggested to be a factor influencing the increased occurrence of (post-ablation) pelvic pain [35–38]. Pain is a subjective outcome measure. On the one hand, the level of pain can be explained by the coping mechanism of the patient; on the other hand, if a patient experiences many pre-operative complaints, the cause can be multifactorial (e.g. coping, dysmenorrhea, adenomyosis, endometriosis [37–41].

Performing ablation in patients with a certain extent of uterine pathology (fibroids, adenomyosis) can be seen as a risk for success of therapy [2, 34, 41, 42]. However, sensitivity and specificity of the diagnostic tools for determining these myometrial diseases are still low.As expected, thin endometrium is a positive predictor for ablation success due to the increased chance of complete penetration of heat during the EA. In multivariate analysis, however, this no longer was a significant factor.

Menorrhagia, defined as the subjective estimation of heavy bleeding (e.g. increased blood clots, overall bleeding quantity), is a patient characteristic that seems to fit the success profile for EA. This can be explained by the primary expected effect of EA: reduction of endometrial surface and subsequent bleeding.

Furthermore, we observed that pre-treatment leads to a univariate outcome of significantly higher risk of failure or re-intervention. Multiple treatments prior to EA can be an indication of the complexity of the underlying cause of the uterine disorder.

Examples of using the models

In clinical practice, the models can be used to estimate the risk of failure for individual patients. For instance, a 38-year-old patient, para 5, with a previous caesarean section, a menstrual duration of more than 7 days and complaints of dysmenorrhea and menorrhagia, has 93% chance of failure of EA and 62% chance of surgical re-intervention within 2 years after EA.

On the other hand, a 48-year-old woman, para 2, with no previous caesarean section, a menstrual duration shorter than 7 days and complaints of menorrhagia but no dysmenorrhea, has a chance of 28% failure of EA and 4% chance of surgical re-intervention within 2 years after EA (Table 4).

Table 4 Clinical example

Variable	Patient 1	Patient 2	Patient 3	Patient 4
Age (years)	38	42	45	48
Dysmenorrhea	Yes	No	Yes	No
Duration of menstruation > 7 days	Yes	No	Yes	No
Menorrhagia	Yes	Yes	Yes	Yes
Parity ≥ 5	Yes	No	No	No
Previous caesarean section	Yes	No	Yes	No
Chance of failure of EA (%)	93%	84%	50%	28%
Chance of getting a surgical re-intervention < 2 years after EA (%)	62%	26%	17%	4%

Other results

In accordance with the literature, our results show that most re-interventions take place within 2 years after EA [8, 15, 20–24].

Our study showed that 82.6% ($n = 368$) of patients were satisfied with EA, and 86.8% ($n = 387$) would recommend it to a friend. The discrepancy between the satisfaction and the percentage of re-interventions can be explained by the fact that many patients stated that they first wanted to try a minimally invasive therapy, instead of having a major surgery such as a hysterectomy. If the EA failed for them, they would still recommend the treatment to others, to possibly avoid a more invasive treatment.

As stated in previous literature, satisfaction is a difficult and subjective concept and therefore an outcome that is less reliable as an objective parameter for success [43–48].

Strengths and limitations

The two-centred aspect of the study ensures its representativeness. Furthermore, two researchers reviewed the charts, and if unclear answers were given, the patients were contacted by telephone to filter out wrong or misinterpreted data.

The models were developed with the data of 446 patients, who responded to our questionnaire. The hysterectomy rate in this group does not differ significantly from that of the non-responder group. The chance of selection bias therefore is minimal, although this cannot be completely ruled out.

The most important limitation of this retrospective study is the acquisition of data from patient charts with a non-validated questionnaire.

Besides the calculated probability of failure and re-intervention within 2 years, there still is a chance of having a re-intervention after this time; this cannot be calculated with the models.

An external validation of the prediction models is needed; this is currently being performed, using retrospective data of similar patient groups in two non-university teaching hospitals in the Netherlands. Furthermore, we are currently performing a study to investigate the impact of the models (and their corresponding individual percentages) in the decision of both the patients and doctors. The influence of costs of the treatment has not been added, although this may influence the choice of the patient or doctor. Therefore, this option has been added to a follow-up questionnaire of this study.

We are aware of the fact that some of the devices in the study are no longer used or have been updated; therefore, in the external validation, Novasure® and Thermachoice III® will be added.

Previous research however showed that these techniques were similar effective [13, 21].

Interpretation in light of other evidence

When comparing existing literature concerning the success rates of EA, there seems to be some inconsistency in the importance of variables, especially when multivariate analyses were performed. Bongers et al. reported that dysmenorrhoea seems less important in predicting the outcome of EA in relation to other variables when performing multivariate analyses [9]. In contrast to this study, the multivariate prediction model produced by El Nashar et al. showed young age, high parity, history of sterilisation and pre-operative dysmenorrhea as significant prognostic factors for failure of EA. [6]

To illustrate the discrepancies in literature, a case-control study by Peeters et al. reported that the outcome is not predicted by age and sterilisation, but by pre-operative dysmenorrhea, submucous myomas and large-sized uteri. [19]

El Nashar et al. created a model to predict 'failure' of EA. Failure in this model was defined as bleeding or pain following EA, with the necessitating of having a hysterectomy or re-ablation. In this model, age as a continuum was not used [6]. Comparing outcomes of our study on re-intervention and complaints, we observed different significant variables predicting the two types of failure of EA. Therefore, we made two prediction models, so patients can be counselled for the chance of failure and for the risk of re-intervention. In this way, they can decide what is most important to them. The models still need external validation.

Conclusion

Proper patient selection is the key for failure or re-intervention of EA. Therefore, we propose two multivariate models to predict the chance of failure and surgical re-intervention within 2 years after EA. Due to the permanent character of EA, the increasing number of post-operative failure and re-interventions, these prediction models could be useful for both the doctor and patient and may contribute to the shared decision-making.

Significant factors in these models are age, dysmenorrhea, duration of menstruation > 7 days, menorrhagia, parity and previous caesarean section.

External validation of the models is being performed; furthermore, we are performing a study to see the impact of the models in the decision of both the patients and the doctor.

Acknowledgements
The authors thank the patients for completing the questionnaires and for consenting to participate in our study.

Funding
None

Availability of data and materials
The datasets generated and analysed during the current study are not publicly available due to privacy, but they are available from the corresponding author on a reasonable request.

Authors' contributions
KS contributed to the project development, data management, data analysis, and manuscript writing/editing. DM contributed to the project development, data collection, and manuscript editing. SH contributed to the data analysis and manuscript editing. TG contributed to the data collection and manuscript editing. SW contributed to the data collection and manuscript editing. BS contributed to the project development and manuscript editing. All authors read and approved the final manuscript.

Ethics approval
The ethical board in the Catharina hospital and in the Elkerliek hospital concluded that ethics approval was not necessary for this study.

Consent for publication
Not applicable

Competing interests
B.C. Schoot received fees from Medtronic on an hourly basis for lectures on hysteroscopic morcellation. The fees were donated to a foundation that promotes research in obstetrics and gynaecology. The remaining authors have no competing interests.

Publisher's Note

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Received: 18 December 2018 Accepted: 12 March 2019
Published online: 01 May 2019

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