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ORIGINAL ARTICLE

Preventing hysterectomies for dysfunctional uterine bleeding with the HTA™: a survival analysis

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Abstract A questionnaire was sent to 121 women with dysfunctional uterine bleeding who had been treated with the HTA™. Prior to treatment the women had received advice about the failure rate of the HTA™. There was a 68% (82) response rate, of which 11% (9/82) of patients had a hysterectomy. Of these patients 7.3% (6/82) were performed for persistent pelvic pain and 1.2% (1/82) for irregular vaginal bleeding. The projected Kaplan-Meier survival rate for the device over a 5-year period was 89%. The amenorrhoea rate was 42.7% and the oligomenorrhoea rate was 81.7%. The HTA™ is an effective form of treatment for DUB and the majority of women are likely to avoid a hysterectomy at 5 years.

Keywords Hydrothermal ablation · Hysterectomy · Survival analysis

Introduction

The HydroThermal ablator (HTA™) is a second generation endometrial ablation device used to treat women with dysfunctional uterine bleeding (DUB). The reported success rates range from 77–88% [1, 2]. However, a hysterectomy may have to be performed following treatment with the HTA™ for a variety of reasons. Previous studies have reported rates ranging from 1–7.1% [1–3] over a 12 month follow-up period. Long term outcome data following second generation endometrial ablation procedures is limited, but follow-up studies on patients who underwent first generation endometrial ablation-resection indicate that the rate of hysterectomy can vary between 5–21% and that it increases with time [4–7]. In order to overcome these limitations and determine the proportion of women who can be expected to avoid a hysterectomy after an HTA™ procedure over a 5 year period, a survival analysis on a cohort of patients was carried out. The indications for hysterectomy, and the patient's menstrual status were also quantified.

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Methods

One hundred and twenty one women with a history of menorrhagia, without intra-uterine pathology, were recruited for the study at a district general hospital. Patients were eligible if they had a uterine cavity (excluding the cervical length) measuring between 6 and 10 cm in length at hysteroscopy or on transvaginal ultrasound scan. The patients were aged between 26 and 52 years (mean age 43.4 years). They were excluded if there was intra-uterine pathology or endometrial and cervical abnormalities on histological and cytological examination. Intra-mural and extra-uterine pelvic disease were considered a relative contraindication. Histories of previous caesarean section(s) or clotting abnormalities were not considered a contraindication.

The HTA™ device consists of an insulated polycarbonated sheath (7.8 mm/24 F), which accepts a 3 mm hysteroscope and a microprocessor controlled heater. The sheath is positioned inside the uterus to give a panoramic view of the cavity. Gravity determines the maximum hydrostatic pressure (50 mmHg) and a pump recirculates the fluid. The heater raises the saline temperature to 90°C and the treatment cycle lasts for 10 min.

All 121 patients had HTA™ performed to treat the DUB in a "One Stop" Clinic for abnormal uterine bleeding. They had received both verbal advice and patient information leaflets about the side effects of the HTA™ prior to the operation. A postal questionnaire was sent to all the women. The date of treatment with the device, and the patient's age was recorded. The patients were asked if they had a hysterectomy performed. If they had, they specified the time after HTA this had occurred, and the reason for performing a hysterectomy. If they had not had a hysterectomy, the patients were asked to specify whether they still had periods. Those women who still had a menstrual bleed (more than spotting) were asked to specify whether it was lighter, heavier or unchanged compared to their periods before the device was inserted.

Statistical analysis

Data for analysis was recorded on Microsoft Excel software. The survival analysis was undertaken in SPSS version 12.0. Survival probabilities by Kaplan Meier method for censored data were plotted.

Results

A cohort of 121 women were sent a questionnaire. There was a 68% (82/121) response rate. Of these patients 11% (9/82) had a subsequent hysterectomy. The reasons for hysterectomy were pelvic pain 66.6% (6/9), irregular vaginal bleeding 11.1% (1/9), and 22.2% (2/9) were women had a hysterectomy for unrelated reasons (ovarian cysts). All the women who had hysterectomies for pelvic pain had reported debilitating dysmenorroea prior to the HTA procedure, and subsequent histological examination of excised specimens demonstrated adenomyosis or intra mural fibroids. There were no serious intra operative complications in this series.

Menstrual status

The current menstrual status of patients is shown in Table 1. In those women who had not had a hysterectomy the amenorrhoea rate was 42.7% (35/82) and the success rate

Table 1 Menstrual status at the time of follow-up

Condition	Number of cases	Percentage (%)
No difference	15	18.3%
Successful	67	81.7%
Amenorrhoea	35	42.7%
Oligomenorrhoea	32	39.0%

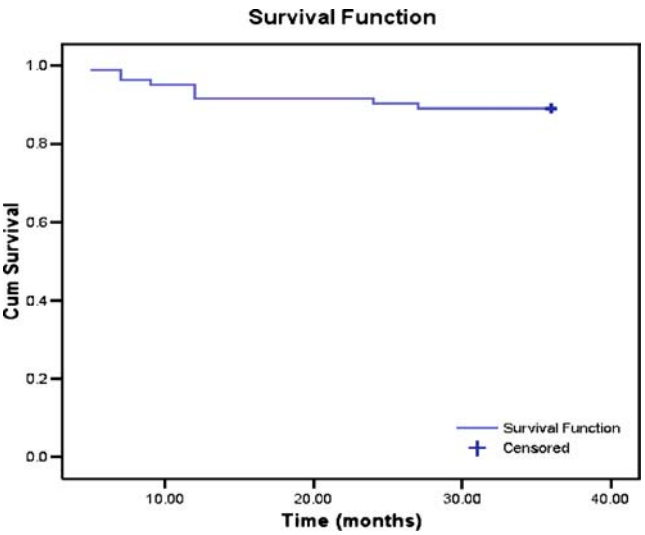

Fig. 1 A survival analysis (Kaplan-Meier plot for censored data). The cumulative survival (avoidance of hysterectomy) over time

was 81.7% (67/82). The median age of patients in the hysterectomy group was similar to the patients who did not need hysterectomy (43 yr) (Fig. 1). The median age of patients who were amenorrhoic post procedure was 46 yrs compared to 43 yrs in the group who were not amenorrhoic Fig. 2. These differences were not significant.

Hysterectomy rates

The hysterectomy rate within the first six months following HTA was 2.4% and the survival rate was 97.5%. At 36 months the hysterectomy rate had increased to 3.8% with a 96% survival rate. The projected survival rate by the Kaplan-Meier method for censored data is shown in Fig. 3. This demonstrates that "avoidance of a hysterectomy" over 5 years is projected to occur in 89% of patients.

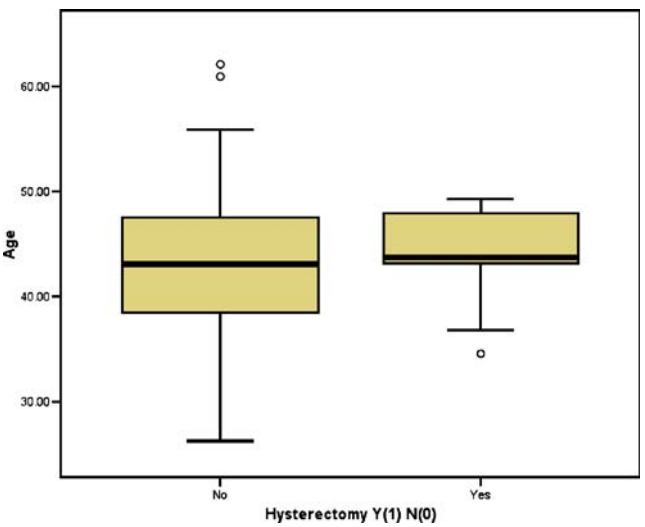

Fig. 2 The age difference between women who did and did not have hysterectomies following HTA

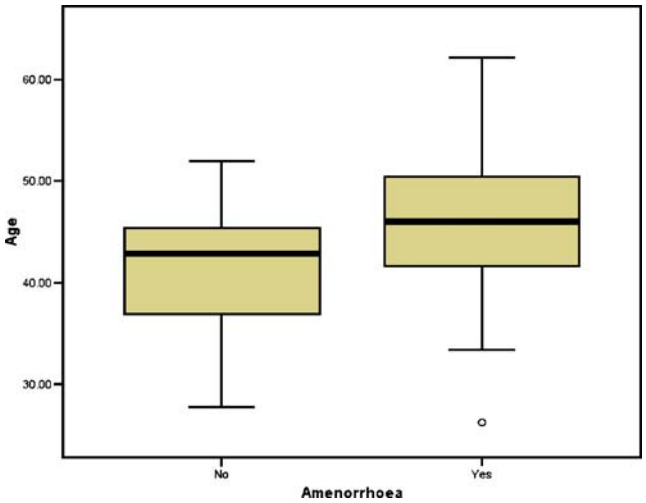

Fig. 3 The age difference between women who were amenorrhoeic and those who still experienced menstrual bleeding following HTA

Discussion

Hysteroscopic endometrial ablation using free heated saline with the HTA™ device has been described previously [8]. The technique has NICE approval [9], and it has been validated in a RCT [1]. In this study the technique had an amenorrhoea rate of 42.7% and a success rate of 81.7% compared to 53% and 94% in a RCT [1]. This provides further evidence that HTA is an effective form of treatment for women with DUB. One in 20 women aged 30–49 years consult their general practitioners each year with this complaint. Once referred to a gynaecologist 60% of these women will have a hysterectomy within 5 years and half of all women who have a hysterectomy for this reason have a normal uterus removed [10]. In response to this the Royal College of Obstetricians and Gynaecologists (RCOG) has developed guidelines for the management of DUB with the intention of decreasing the hysterectomy rate [11]. Despite these guidelines there is evidence that endometrial ablation techniques have not decreased the hysterectomy rate for the treatment of DUB. The ratio of hysterectomy to endometrial ablation for DUB was 3:1 in 1992/3, but by 1995/6 it had increased to 4:1 [12]. This trend may simply be a result of adding an alternative operative technique for the management of DUB, but it may also be explained by treatment failures following endometrial ablation which result in women undergoing a subsequent hysterectomy. Table 2 shows the hysterectomy rates after first generation procedures. These range from 5–25% over a mean follow-up time of 4 yr (range 1–6.5 yr). Long term follow-up data on the outcome of second generation devices is even more limited because of their relatively shorter duration of use (Table 3). In order to overcome these limitations, a survival analysis was used to calculate the projected hysterectomy rate in women undergoing an HTA procedure. This demonstrated that 89% of women would be expected to avoid a hysterectomy over a 5 yr period following an HTA procedure which is comparable to the best rates for first generation devices over a similar period of time (Table 1).

One of the features of HTA which distinguishes it from other second generation devices is that it allows the operator

Table 2 Hysterectomy rates following first generation endometrial ablation procedures

Author	Procedure	No. patients	Hysterectomy rate (%)	Time (yr)
Comino and Torrejon [6]	TCRE	16/89	18	6
Bhattacharya et al. [14]	TCRE	52/372	14	1
Cooper et al. [15]	TRCE	66/263	25	5
Loffer [13]	Rollerball	14/214	6.5	3
Paskowitz [4]	Rollerball	10/200	5	5
Phillips et al. [7]	Laser	160/762	21	6.5
Bhattacharya et al. [14]	Laser	19/372	5	1

Table 3 Hysterectomy following second generation endometrial ablation procedures

Author	Procedure	No. patients	Hysterectomy rate (%)	Time (yr)
Perlitz et al. [3]	HTA	1/14	7.1	1.5
Botacini et al. [2]	HTA	1/26	3.8	1
Corson [1]	HTA	2/187	1.1	1
Cooper et al. [15]	MEA	42/263	16	5
Loffer [13]	Thermachoice	8/214	3.7	3
Baskett et al. [16]	NovaSure	10/146	6.8	4

Table 4 Cost analysis of hysterectomy vs HTA

Operating differences	TAH (A)	HTA (B)	Cost difference per case (B-A)
Disposable kit	0	£395	+395
Theatre time	£252[a]	£112[b]	−140
Bed days	£970[c]	£0	−970
Total	£1225	£507	Saving £718

[a] calculated on the basis of 2 hysterectomies per theatre list (£504/2=£252)
[b] calculated on the basis of 4.5 HTAs per theatre list (£504/4.5=£112)
[c] calculated on the basis of 5 days in hospital per hysterectomy patient (5×£194=£970)

to directly visualize the uterine cavity during the treatment which in turn promotes patient safety. In our series there were no intra operative complications and very few were reported in the RCT [1] or cohort studies [2, 3]. Age was not found to be significantly different between the group of women who became ammoenorrhoeic, or in the women who had subsequent hysterectomies. However, the device has the potential to be used on large, irregular uterine cavities with submucous fibroids, polyps, and septae because it relies on freely circulating fluid. This particular feature means that the surgeon can potentially treat a wider range of patients with the HTA compared to other second generation devices. In this series 67% (6/9) of patients who had a subsequent hysterectomy did so because of pelvic pain. All of these women reported debilitating dysmenorroea prior to the HTA procedure, and subsequent histological examination of excised specimens demonstrated adenomyosis or intra mural fibroids. Previous studies have also concluded that adenomyosis may be a risk factor for failed endometrial ablation [17, 18]. This study has demonstrated that counseling of women with irregular uterine cavities or known intra mural pathology where pre operative pelvic pain is a presenting feature needs to include discussion of the higher hysterectomy rate.

Besides being a clinically effective device, HTA also has economical advantages and this study can be used to demonstrate this. In our unit the average bed stay following hysterectomy is 5 days and 90 min of theatre time (2 TAH/3 hr list) is allocated per patient. National figures demonstrate that 42% of hysterectomies are performed for DUB [10, 11]. In the case of HTA™ the average bed stay is 0 days and 40 min of theatre time (4.5 HTA's/3 hr list) is allocated per patient. This study has demonstrated a survival rate (avoidance of hysterectomy) of 89%, that is, 11% of women who have an HTA will go on to have a hysterectomy over the subsequent 5 years. Therefore, for every 100 hysterectomies performed in our unit, 42 are for DUB and we would expect an additional 4.6 to have subsequent hysterectomies, leaving 37.4 patients who have to have a successful HTA procedure.

On the basis of these figures the number of bed days saved/year/100 hysterectomies is 37.4 (no. successful HTA's)×5 (length of hospital stay)=187. The number of operating lists saved/year/100 hysterectomies can also be calculated. Patients who avoid a hysterectomy (37.4) would require 19 operating lists (rate: 2 per 3 hrs) while 37.4 HTA's requires 8 operating lists (rate: 4.5 per 3 hrs). Therefore 11 operating lists can be saved/year/100 hysterectomies. This survival analysis also allows us to predict direct savings in terms of costs.

The HTA™ disposable procedure kits cost approximately £395. The capital equipment is provided on loan. The average cost of a theatre session is £504, while the average cost of a surgical bed day is £194. Table 4 sets out the calculation of cost saving per HTA case (£718). If this cost saving is multiplied by the number of HTA procedures, 37.5 (no. HTA's)×£718 (cost difference per case), the total savings/year/100 hysterectomies=£26,925.

Conclusion

In this series the amenorrhoea rate following HTA was 42.7% and the success rate was 81.7%. Survival analysis demonstrates that up to 89% of women can expect to avoid a hysterectomy over a 5 year period. Using this data it can be seen that the use of HTA will reduce the overall unit cost of treating DUB. Therefore, HTA is both a clinically and economically effective alternative to hysterectomy in women with DUB.

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Conflict of interest statement Mr. K.D. Jones acts as a preceptor and proctor for Boston Scientific.

References

1. Corson SL (2001) A multicentre evaluation of endometrial ablation by hydro ThermalAblator and rollerball for treatment of menorrhagia. J Am Assoc Gynecol Laparosc 8(3):359–367
2. Botacini das Dores G, Richart RM, Nicolau SM, Focchi GR, Cordeiro VC (1999) Evaluation of hydro thermaAblator for endometrial destruction in patients with menorrhagia. J Am Assoc Gynecol Laparosc 6:275–316
3. Perlitz Y, Rahav D, ben-Ami D (2001) Endometrial ablation using hysteroscopic instillation of hot saline solution in the uterus. Eur J Obstet Gynecol Reprod Biol 99:90–92
4. Paskowitz RA (1995) Rollerball ablation of the endometrium. J Reprod Med 40:333–336
5. Comino R, Torrejon R, Sanchez-Ortega I (2002) Long term results of endometrial ablation-resection. J Am Assoc Gynecol Laparosc 9:268–271
6. Comino R, Torrejon R (2004) Hysterectomy after endometrial ablation-resection. J Am Assoc Gynecol Laparosc 11:495–499
7. Phillips G, Chien PF, Garry R (1998) Risk of hysterectomy after 1000 consecutive laser ablations. Br J Obstet Gynaecol 105:897–903
8. Weisberg M, Goldrath MH, Berman J, Greenstein A, Krotec JW, Fronio L (2000) Hysteroscopic endometrial ablation using free heated saline for the treatment of menorrhagia. J Am Assoc Gynecol Laparosc 7:311–316
9. NICE (2004) Interventional procedural guidance 51. Ref no. 496, NICE, London
10. Seth A, Stabinsky ME, Breen JL (1998) Modern treatment of menorrhagia attributed to dysfunctional uterine bleeding. Obstet Gynaecol Surv 54(1):61–72
11. RCOG (1999) The management of menorrahgia in secondary care. Evidence-based clinical guideline no. 5. http://www.rcog.org.uk/guidelines/menorrhagiasc.html. Accessed 22 August 2006
12. Bridgman SA, Dunn KM (2000) Has endometrial ablation replaced hysterectomy for the treatment of dysfunctional uterine bleeding? National figures. BJOG 107:531–534

13. Loffer FD (2001) Three year comparison of thermal balloon and rollerball ablation in treatment of menorrhagia. J Am Assoc Gynecol Laparosc 8:48–54
14. Bhattacharya S, Cameron IM, Parkin De, Abramovich DR, Mollison J, Pinion SB, Alexander DA, Grant A, Kitchener HC (1997) A pragmatic randomized comparison of transcervical resection of the endometrium with endometrial laser ablation for the treatment of menorrhagia. Br J Obstet Gynaecol 104:601–607
15. Cooper KG, Bain C, Lawrie L, Parkin DE (2005) Randomised comparison of microwave endometrial ablation with transcervical resection of the endometrium; follow up at a minimum of five years. BJOG 112:470–475
16. Baskett TF, Clough H, Scott TA (2005) NovaSure bipolar radiofrequency endometrial ablation: report of 200 cases. J Obstet Gynaecol Can 27:473–476
17. Quemere MP, Cravello L, Roger V, d'Ercole C, Blanc B (1999) Impact of adenomyosis on results of endometrial ablation. Contraception Fertile Sex 27:357–363
18. Wortman M, Daggett A (2001) Retrospective surgery in the management of patients who fail endometrial ablation and resection. J Am Assoc Gynecol Laparosc 8:272–277