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Radiofrequency induced endometrial ablation: an update

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Objective To test the safety and efficiency of radiofrequency endometrial ablation as a nonhysteroscopic treatment of dysfunctional uterine bleeding.

Design A multicentre trial.

Setting Nineteen clinics in six countries.

Methods From February 1990 to December 1994, 1280 women were treated with radiofrequency endometrial ablation. Inclusion criteria were: menorrhagia, age 30–55 years, a completed family, a wish to retain the uterus, no hypergonadotropic state indicating an approaching menopause, a normal sized uterus, normal cervical cytology, normal adnexa, no prolapse, no intrauterine abnormalities, and no history of a bleeding disorder. Treatment was performed according to a standard operating protocol.

Results Either amenorrhoea or a satisfactory improvement of menstruation was obtained in 78.5% of 944 women followed for six months or more. The design of the equipment has been thoroughly revised and improved during the last four years. The complications encountered were mostly related to the handling of radiofrequency and sometimes due to failures in following the safety protocol.

Conclusions Although the technology is complicated, the treatment is simple, fast and effective. The complications have often been unpredictable. Despite the improvements made during this period, safety must be further enhanced to develop the original concept into an established technique.

INTRODUCTION

The number of hysterectomies performed for menorrhagia remains large. For dysfunctional bleeding alone an estimated 25,000 hysterectomies are performed yearly in the United Kingdom^{1,2}. In the Netherlands this number is around 8000 per year³.

Hysteroscopic methods of endometrial ablation are being performed increasingly as an alternative to hysterectomy. It is estimated that around 40% to 60% of patients with menorrhagia might benefit from this form of treatment^{4,5}. The techniques used require substantial skill and experience in order to be performed safely^{6,7}. In specialised centres success rates are good: amenorrhoea is reported in 30% to 60%, while a satisfactory reduction in the amount and/or duration of menses is obtained in a further 35% to 65%^{8–10}.

Long term effects in either Nd:YAG laser ablation, endometrial resection or rollerball coagulation are largely unknown. Published studies reported in the literature have addressed the distorted uterine cavity due to fibrosis¹¹ and the small risk of new symptoms such as haematometra, pyometra, endometriosis and abdominal pain¹⁰. There is a generally lasting effect, although longer term studies are needed¹². The risk of endometrial

carcinoma appears to be low and in cases of abnormal bleeding, standard diagnostic procedures can be carried out¹³. Infertility remains uncertain as pregnancies after endometrial ablation have been reported⁶.

The use of radiofrequency for thermal destruction of tissue was introduced as a treatment of prostatic hypertrophy¹⁴. Phipps *et al.* reported on radiofrequency endometrial ablation in 1990¹⁵. After the initial experiments, it was concluded that the uterus as small, hollow and richly vascularised organ with a relatively thick protective muscular wall provides an ideal setting for this modality. Hyperthermia is induced by a rapid oscillation of charged particles in the tissue directly around an intrauterine probe, which is connected with a purpose-built radiofrequency source, the MENOSTAT (Rocket Medical, Watford, UK). The emitted frequency is 27.12 MHz. A belt electrode around the patient's waist ensures a closed circuit by way of a return cable to the radiofrequency source (Fig. 1). The endometrial surface is heated to 62–65°C. The temperature in the basal layer (providing the endometrium is only a few millimetres thick) rises sufficiently to ablate all of the endometrium, while the temperature decreases rapidly with the square of the distance from the probe¹⁵. There is virtually no generation of heat on the outer uterine surface and a normal body temperature is maintained in bladder and bowel. The procedure is simple and does not require distension fluids. It can be performed under

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either general anaesthesia or under epidural/spinal anaesthesia. The duration of treatment is about 20 minutes during which the slightly curved probe is rotated in a step-wise fashion to ensure even endometrial contact. Severe uterine cramping lasts approximately six hours. Discharge from the hospital is possible 8 to 24 hours after the intervention. A seven-day oral course of antibiotic prophylaxis is prescribed. A watery, bloodstained vaginal discharge occurs for a period of four to six weeks. Normal activity is resumed during the week after the procedure.

METHODS

Between February 1990 and December 1994, 1280 patients were treated with radiofrequency endometrial ablation. During that period the technology was gradually introduced in a number of centres, some of which stopped the treatment after a short trial period. At the end of December 1994, 12 clinics in five countries were currently using the method. Inclusion criteria were as for other methods of endometrial ablation, namely: menorrhagia, age 30 to 55 years, no further desire for pregnancy, a wish to retain the uterus, no hypergonadotropic state indicating an approaching menopause (FSH < 15 IU/L), uterus not enlarged (length < 12 cm), normal cervical cytology, normal adnexa, no prolapse, no intrauterine pathology such as polyps, submucous fibroids or endometrial pathology and no history of a bleeding disorder. Menorrhagia was not quantified but it was defined from subjective criteria such as loss of blood clots, heavy bleeding with the need of extra protection at night or with interference of daytime activities. A history of menstrual periods of more than eight days and recurrent iron deficient anaemia were also noted as important criteria. Some patients were included because of medical problems such as gross obesity or cardiovascular disease.

Before the intervention, an abdominal ultrasound scan was performed in each patient and hysteroscopy with biopsy or curettage to confirm the presence of a regular uterine cavity and to exclude endometrial pathology. Informed consent was obtained from all patients and the importance of contraception after the procedure was stressed. In most hospitals the agreement of an ethical committee had been obtained.

Although initially in a small group of patients no medication before treatment was given¹⁶, pretreatment was found to be advantageous. With this, endometrial ablation can be scheduled independently of the menstrual cycle. Moreover, in radiofrequency endometrial ablation cell-destructive heat is only generated as far as a few millimetres from the probe; a thin or atrophic endometrium should increase the likelihood of destruction of the basal layer.

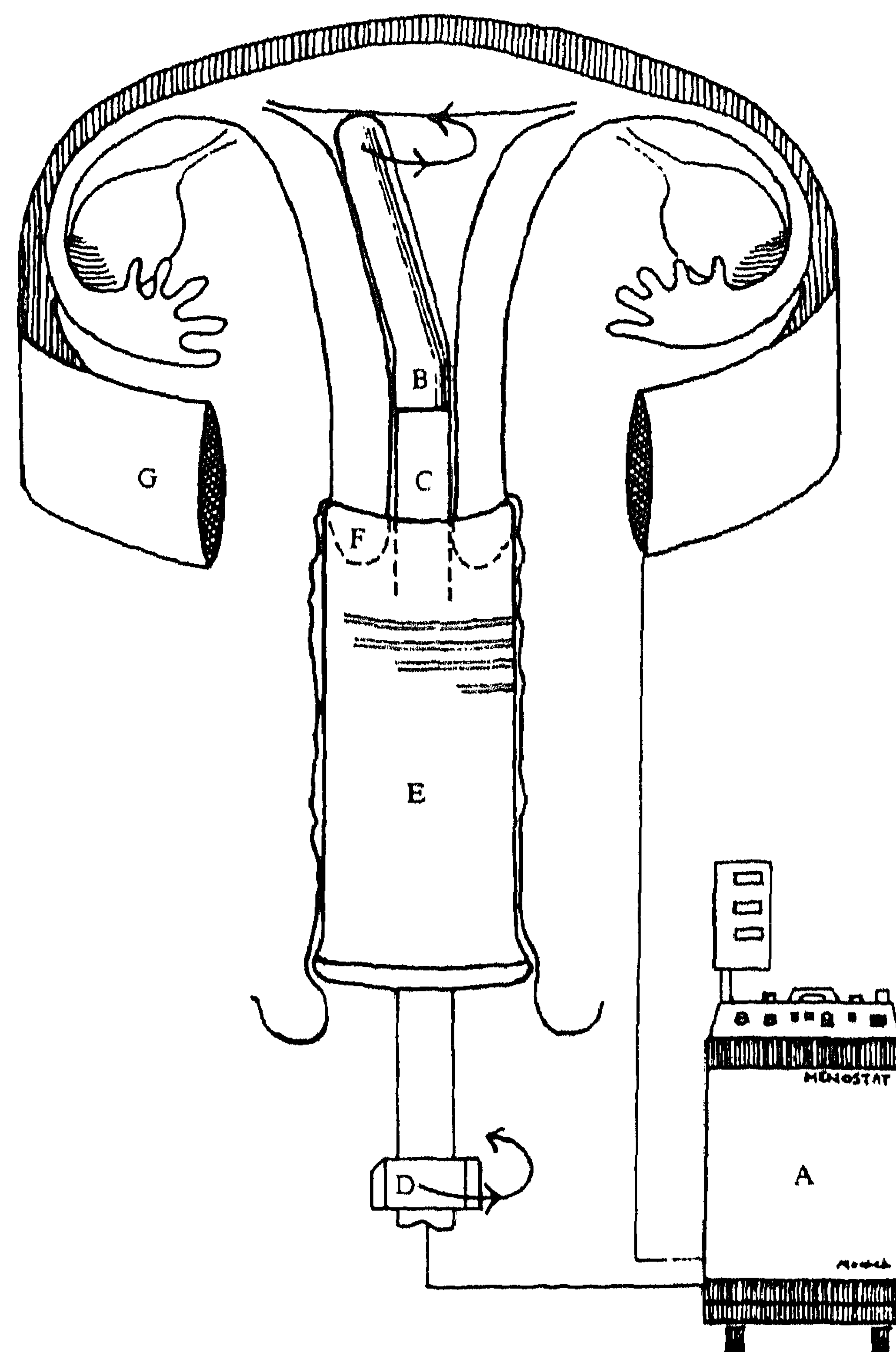


Fig. 1. Schematic representation of equipment used in radiofrequency induced endometrial ablation. (Reproduced with kind permission from *Ned Tijdschr Geneesk* 1993; 137: 1776–1780.)

A	Radiofrequency source with operating panel and display pod.
B	Metal part of probe in uterine cavity.
C	Insulated part of probe.
D	Knob to rotate probe 360° during procedure.
E	Protective vaginal guard.
F	Cervix fixated in guard by means of 2 stay sutures.
G	Belt electrode around patients lower abdomen.

All patients had endometrial thinning: in most clinics Danazol 400 mg twice daily for four weeks was used immediately preceding treatment. In a small number of clinics GnRH analogues were given for a period of four to six weeks before treatment. Differences in outcome with regard to the different pretreatment regimes have been reported³.

The intervention was performed under general anaesthesia. In a few clinics however, a spinal or epidural anaesthesia was offered and sometimes preferred (60% of the patients treated in Nijmegen). The disposable belt electrode and the electrocardiogram electrodes were placed according to the British working protocol and safety regulations. Just before endometrial destruction was undertaken, the size of the disposable applicator (small, medium, large) was chosen by deducing the cervical length (measured by a thin hooked probe or

Table 1. Menostat centres and results (1990–1994). Only patients with follow up given and not lost to follow up have been included in the total results (marked in bold). UK = United Kingdom; NL = The Netherlands; SA = South Africa; AUS = Australia; E = Spain; DK = Denmark.

Hospital	Period of treatment	No. treated	Follow up at 6–58 months	Amenorrhoea	Hypomenorrhoea	Dissatisfied	Lost to follow up
Bath (UK)	11/91–12/94	183	174	18	99	52	5
Carmarthen (UK)	4/93–12/94	31	23	7	11	5	
Glasgow (UK)	1/91–12/94	66	65	18	28	18	1
Manchester (UK)	4/90–12/91	83	82	7	44	30	1
Nuneaton (UK)	9/92–12/94	77	77	28*	40	9	
Paisley (UK)	1/93–12/93	17	17	0	10	7	
Rotherham (UK)	9/90–6/91	13	13	1	3	8	1
Watford (UK)	2/90–12/92	103	99	37*	36	22	4
Delft (NL)	6/93–12/94	29	23	8	10	4	1
Groningen (NL)	11/93–12/94	51	43	2	32	9	
Leiden (NL)	11/91–12/94	68	65	14	48	3	
Nijmegen (NL)	2/91–12/94	193	170	20	126	24	
Cramerview (SA)		147†					
Durban (SA)	4/93–12/94	75	75	10	60	5	
Johannesburg (SA)	8/93–12/94	13†					
Pretoria (SA)	8/93–12/94	43	29	5	9	6	9
Sydney (AUS)	11/92–12/93	63†					
Barcelona (E)	10/93–6/94	11	11	9	1	1	
Glostrop (DK)	8/94–12/94	14	0	—	—	—	—
TOTAL		1280	966	184	557	203	22

*Amenorrhoea or spotting. †No further results given.

by a small balloon catheter) from the uterine length (measured by sound). The radiofrequency source was operated by specially trained theatre personnel.

Between February 1990 and December 1994 a number of modifications with regard to the generating equipment and the patient delivery systems were made to increase safety and efficiency. The most important changes from the original concept include:

- Improved insulation of the wire connecting the radiofrequency source with the intrauterine probe. The desired intrauterine temperatures can now be obtained with 50–200 Watts instead of 250–500 W (June 1991).
- The vaginal speculum (Fig. 1) which serves as thermal guard for bladder and rectum has been fitted with two anchors for cervical stay sutures. With these the cervix is firmly pulled into the distal end of the speculum to ensure that no vaginal tissue can come into contact with the intrauterine probe (September 1991).
- The belt electrode is now attached to a double ended earth cable. Possible resonance in the belt electrode which could result in heating at the tail of the belt and in localised burns of the patient's abdomen is now avoided (September 1992).
- Possible radiofrequency induced heating of the pulse oximeter attached to the patient during the procedure is avoided by a common mode choke. This consists of a ferrite ring core through which the pulse oximeter cable is wound a few times (September 1993).

- A disposable measuring sound of 10 mm in diameter has been produced by the equipment suppliers. This greatly facilitates the choice of adequate probe size (January 1994).
- A small vaginal speculum has been produced by the equipment suppliers in case a small cervix is present (April 1994).
- An extra small probe has been manufactured. Pretreatment with GnRH analogues sometimes produces substantial shrinking of the uterine cavity. As treatment of the cervical canal should be avoided, the extra small probe should be used where uterine length is < 7 cm (April 1994).

All these alterations have been published in regular updatings of the operating protocol, which were sent to all the users.

RESULTS

An overview of the centres which participated in the trial and the number of patients treated in each centre is given in Table 1. The mean duration of the procedure was 20 minutes (range 15–28). This was dependent on the interval necessary to reach the ideal intrauterine temperature (62–65°C). The follow up period was 6 to 58 months. Median follow up was 32 months. Success defined as either amenorrhoea or a greatly reduced menstruation and/or a shortened menstrual period (hypomenorrhoea) was 78.5%. In most of the patients

Table 2. Complications to radiofrequency endometrial ablation in 19 centres from 1 February 1990 to 31 December 1994 ($n = 1280$).

Complication	No.
Superficial skin burns	10
Uterine perforation during dilatation	3
Haematometra	2
Pelvic inflammation	4
Vesico-vaginal fistula	5
Burn right index finger	1
Thermal injury of bowel	1
Thermal injury of cervix/anterior fornix	1

who required further therapy because of an unsatisfactory result (21.5%), a hysterectomy was performed.

In the Nijmegen group, amenorrhoeic patients strictly included those with neither bloodloss nor any bloodstained discharge. Five out of six patients, who were not completely satisfied with only a slight improvement reported a satisfactory result after a second procedure. The 24 patients, who were not satisfied and who had subsequently requested a hysterectomy, were operated on 6 to 12 months after radiofrequency endometrial ablation. Pathology reports confirmed the presence of small fibroids ($n = 6$), adenomyosis ($n = 8$), an incompletely treated endometrium ($n = 3$), an intact endometrium ($n = 4$) and no endometrium detected in three patients. In this group of 170 patients the results were reassessed in November 1996. Reassessing the Nijmegen results in November 1996 showed little difference with 21 amenorrhoeic patients, 123 hypomenorrhoeic and 26 dissatisfied.

Three patients who were amenorrhoeic had restarted regular but improved periods. Two patients required a hysterectomy 2.5 and 5 years after radiofrequency endometrial ablation due to abdominal pain. At surgery endometriosis was found. Finally, six previously hypomenorrhoeic women had reached the menopause and were now amenorrhoeic.

The complications encountered in the total group of 1280 patients treated with radiofrequency endometrial ablation are listed in Table 2.

Minor complications in this group consisted mostly of superficial burns ($n = 10$) of the abdominal skin (belt electrode) buttock (return cable) chest (wrongly placed or faulty electrocardiogram electrodes) or sacral area (faulty cable). The actions taken to avoid these accidents varied from the retraining of theatre personnel to the redesigning of equipment (belt electrode). All superficial burns have healed spontaneously. Other minor complications which have possibly been under-reported were:

- Uterine perforation during dilatation ($n = 3$). In these cases the procedure was cancelled and rescheduled four to six weeks later.
- Haematometra ($n = 2$). Mild damage of the cervical canal is possible because of the use of too large a probe. Sounding of the cervical canal was sufficient to empty the uterine cavity.
- Pelvic inflammatory disease ($n = 4$). These patients were treated with antibiotics without any sequelae. One patient required a hysterectomy because of persistent abdominal pain.

The major complications in this group of 1280 patients comprised four types of accidents.

1. Vesicovaginal fistulae ($n = 5$). Two of these cases from the experimental period, when no vaginal guard was used, have been reported^{15,16}. A third patient had a history of three caesarean sections and evidence of adhesions between the base of the bladder and the lower uterine segment. In two further cases the operating protocol was not completely observed: the probe was allowed to slip down the endocervical canal. All fistulae have been repaired and the patients are well.
2. A right index finger burn caused by a nonapproved pulse-oximeter. The device had a low resistance path to earth. The patient lost the distal phalanx of her right index finger.
3. Thermal injury of the bowel. A patient with generalised peritonitis three days after routine radiofrequency endometrial ablation was found on laparotomy to have a false passage through the anterior wall of her retroverted uterus. Although the bowel had not perforated, thermal injury was caused to a small part of the rectosigmoid and the terminal ileum. These were excised and a hysterectomy was performed. The patient is now fit and well.
4. Thermal damage to the cervix and anterior fornix. During radiofrequency endometrial ablation it was noted that a small cervix and uterine cavity (6.5 cm sound length) were present. The intrauterine temperature rose quickly to 67°C. Two weeks after the procedure the patient was admitted with a grossly swollen cervix and a small necrotic area of the anterior fornix. She recovered after bedrest and antibiotic therapy. The cervix has now a scarred appearance, but no haematometra is present.

DISCUSSION

The use of radiofrequency for medical purposes is relatively new: radiofrequency endometrial ablation requires special instruction and training for all personnel involved to become familiar with the technology, protocol and safety regulations. The equipment

suppliers have given ample time and energy to achieve this in each centre. Teething problems have been experienced by most centres which adopted the procedure, particularly between 1990 and 1993.

There is a grey area where technological shortcomings, unfamiliarity with the effects of radiofrequency and safety aspects are intermingled. The technology however, could only be improved after extensive clinical experience and immediate feedback to the manufacturers, who have promptly improved the equipment to decrease the potential risk or taken steps to improve training. Only recently stray field strength during radiofrequency endometrial ablation has been shown not to be hazardous to the surgeon¹⁶.

The results in terms of the amenorrhoea/hypomenorrhoea ratio reflects the blind nature of the procedure; no guarantee can be given that all of the cavity is treated. On the other hand, most patients with reduced periods are satisfied with the reduced blood loss. The presence of a smooth cavity, confirmed by preoperative hysteroscopy and the administration of medication for endometrial 'thinning' appear to be desirable conditions for this nonhysteroscopic intervention³.

Hysteroscopic assessment some time after radiofrequency endometrial ablation has shown that endometrium is replaced by fibrous tissue, but no intra-uterine synechiae appear to form¹⁷. This finding is confirmed in 19 patients, who underwent a hysteroscopy at least one year after radiofrequency endometrial ablation at Nijmegen University Hospital. Generally an increased resistance was met during dilatation of the cervical canal. The uterine cavity was narrower than usual but no adhesions as in Asherman syndrome were found. The tubal ostia frequently could not be visualised. The strong reflection of light confirmed the absence of endometrium but the demarcation between possible islands of intact endometrium and fibrotic areas was not clear.

Around 20% of patients require further therapy after radiofrequency endometrial ablation. Most often, because of an insufficient improvement of menstrual blood loss, a hysterectomy is performed. The pathology report in 8/24 patients who required a hysterectomy after radiofrequency endometrial ablation at Nijmegen University Hospital, suggests that adenomyosis is a frequent cause of persistent menorrhagia. Two further patients have required a hysterectomy 2.5 and 5 years after radiofrequency endometrial ablation because of abdominal pain due to endometriosis.

Nearly all centres have been puzzled by the complications encountered. The effects of radiofrequency are not easily understood: its direct actions are not visible. The (skin) burns at a distance from the intra-uterine probe were mainly encountered during the early years of radiofrequency endometrial ablation: these

complications are now well controlled and they should be avoided if safety regulations are strictly followed. No further difficulties with pulse oximeters are to be expected. In cooperation with the United Kingdom Department of Health the equipment suppliers have introduced a new radiofrequency transmission system which reduced environmental losses to less than 10%. Tests on monitoring devices were performed and those deemed to be safe are included on an approved equipment list (January 1992). The burns that have resulted from the action of the probe because of heat generated deeper than the expected few millimetres are more difficult to control and also more dangerous. They appear to be dependent on uterine bloodflow and local circulatory changes after pelvic surgery¹⁷.

The major complications are spread out evenly over this period of nearly five years of use of radiofrequency endometrial ablation. They do not seem to be related to the amount of experience with the technique.

Two further complications at Nijmegen University Hospital in 1995 have prompted the Dutch Health Inspectorate to discontinue radiofrequency endometrial ablation treatments in the Netherlands until further investigations have been carried out. These complications consisted of a fundal transmural necrosis of 1 cm diameter in an otherwise technically flawless procedure and a vesicovaginal fistula in an obese patient who had a Stamey-Pereira bladder suspension operation six months prior to radiofrequency endometrial ablation. The first patient required a hysterectomy because of persistent abdominal pain. In the latter patient the fistula was closed three months after radiofrequency endometrial ablation.

In cases of previous pelvic surgery it is advisable to determine the position of the bladder in relation to the lower uterine segment by vaginal ultrasound examination. The separation of these structures should not be less than 10 mm in view of the depth of penetration of the radiofrequency induced hyperthermia¹⁵. In addition, the operating protocol was amended to include a specific warning to alert the surgeon that the probe must lie in the endometrial cavity. A smooth rotation of the disposable measuring sound can help to establish this. Alternatively, an abdominal ultrasound examination prior to the start of the procedure will ascertain a correct position of the probe.

Thermal damage of the cervix caused by too large a probe should be avoided with the use of the extra small probe. The intrauterine temperature should not exceed 65°C and in a small uterus it is possibly best to aim for 62°C. Where there is a small cervix, the small vaginal speculum should be used to prevent damage to the vaginal wall.

Every new medical technology carries risks. The concept of a nonhysteroscopic, nonconductive heat

source to ablate endometrium appears an improvement compared with other methods of endometrial destruction which have their own complications. For patients with major renal or cardiovascular disease, the avoidance of the need for uterine fluid distension may well be an advantage. However, as endometrial ablation is an elective procedure where women would like to minimise morbidity related to previous procedures such as with hysterectomy, this procedure should be as safe as possible. Considerable efforts should go into the rethinking of radiofrequency endometrial ablation and its safety aspects.

In addition, other disadvantages remain: preoperative endometrial histology and endometrial thinning are necessary. Radiofrequency endometrial ablation does not seem to be feasible under local anaesthesia as an office procedure¹⁸. Postoperative pain is temporary but substantial and probably related to a large amount of prostaglandines and serotonin like substances released from the damaged tissues. As an unknown part of the myometrium is destroyed, a more selective ablation would be the ideal. Finally, more studies are needed to elucidate the role of the frequency chosen and the importance of the dispersion and penetration of the heat generated in the tissue with regard to its water or fat content and to its blood circulation.

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