Hysteroscopic transcervical endometrial resection versus thermal destruction for menorrhagia: A prospective randomized trial on satisfaction rate

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OBJECTIVE: The purpose of this study was to compare the satisfaction rate and the effectiveness of transcervical hysteroscopic endometrial resection and thermal destruction of the endometrium in the treatment of menorrhagia.

STUDY DESIGN: A prospective randomized trial with 2 years of follow-up was carried out in the Department of Gynecology of the University of Naples. Eighty-two patients who were affected by menorrhagia that was unresponsive to medical treatment were respectively randomized to transcervical hysteroscopic endometrial resection or to thermal destruction of the endometrium. Satisfaction rate, operative time, discharge time, complication rate, reintervention rate, and resumption of normal activity were evaluated in each group.

RESULTS: The satisfaction rate was significantly higher in the thermal destruction group. Operative time was significantly shorter in the thermal destruction group (24 ± 4 minutes vs 37 ± 6 minutes). Intraoperative blood loss was significantly lower in the thermal destruction group (7.2 ± 2.8 mL vs 89 ± 38 mL). Reintervention rates were higher in the transcervical hysteroscopic endometrial resection group, although postoperative pain was not significantly different between the two groups. Discharge time, complication rate, and resumption of normal activity were not significantly different between the two groups.

CONCLUSION: Thermal destruction of the endometrium for the treatment of menorrhagia should be considered an effective therapeutic option because of its acceptability among patients, shorter operative time, and lower blood loss. (Am J Obstet Gynecol 2002;187:545-50.)

Key words: Hysteroscopic transcervical endometrial resection, thermal destruction, satisfaction rate

Menorrhagia is a common gynecologic complaint and frequently needs a surgical treatment.[1] Hysterectomy is the most common surgical procedure used in those cases that are unresponsive to medical treatments, despite the diffusion of minimal-access hysteroscopic procedures as alternatives.[2] In these last years, there has been a prompt increase in the number of minimally invasive procedures for the treatment of these conditions, from different types of laparoscopic hysterectomies to several techniques of endometrial destruction. Five randomized controlled trials[3-7] compared hysterectomy and hysteroscopic transcervical endometrial resection (HTER); findings from all the trials concluded that hysteroscopic surgical procedures are associated with lower postoperative morbidity, faster return to normal activities, and significant cost advantage. However, it is associated with a high reintervention rate (22%), although hysterectomy is more effective in relieving menstrual symptoms and is associated with a greater satisfaction rate.[8]

On the other hand, all methods of hysteroscopic endometrial ablation need a liquid medium for the distension of the uterine cavity. This solution may enter the circulation with the risk of intravasation.[9-11] Moreover, it should be noted that these minimal-access procedures are strictly practicer dependent and that many gynecologists have not developed the necessary hysteroscopic skill.

Thermal destruction (TD), carried out with different methods, is one of the most recent types of endometrial destruction.

Recently, a new silicon balloon device for the TD of the endometrium (Cavaterm, Wallsten Medical SA, Morges, Switzerland) has been introduced[12] that has given significant results in the few studies reported so far.[12-14]

A recent multicenter, prospective, randomized study compared hysteroscopic endometrial resection and thermal ablation of endometrium and reported the percent-

Table I. Characteristics of the patients who were treated with HTER or TD

Characteristic	HTER	TD
Patients (No.)	42	40
Age (y ± SD)	43.2 ± 3.5	42.6 ± 4.4
Body mass index (kg/m² ± SD)	28.3 ± 1.4	29.8 ± 1.9
Parity (No. ± SD)	1.8 ± 1.0	1.9 ± 0.7
Uterine dimensions (mL)	315 ± 43	295 ± 58
Irregular periods (No.)	26 (61.9%)	24 (60%)
Length of period, >7 d (No.)	33 (78.5%)	34 (85%)
Cycle <24 d (No.)	30 (71.4%)	30 (75%)
Dysmenorrhea (No.)	16 (38.0%)	17 (42.5%)
Premenstrual symptoms (No.)*	32 (76.1%)	27 (64.2%)
Pelvic pain (No.)	9 (21.4%)	9 (22.5%)
Duration of symptoms (y ± SD)	3.3 ± 1.1	3.5 ± 0.9

There were no significant differences between HTER and TD groups.
*Bloating, breast discomfort, irritability, and headache.

Table II. Operative data of patients who were treated with HTER or TD

Characteristic	HTER (n = 42)	TD (n = 40)
Operative time (min ± SD)	37 ± 6*	24 ± 4*
Estimated intraoperative blood loss (mL ± SD)	89 ± 38*	7.2 ± 2.8*
Intraoperative complications (No.)		
Fluid overload	5	—
Cervical tear	1	—
Conversion to hysterectomy	2	—
Postoperative pain: visual analog scale (±SD)	3.8 ± 0.6	3.2 ± 0.7

*HTER versus TD: $P < .01$.

age of success of the two operative techniques in terms of patients who had amenorrhea or normal bleeding after 1 year, 2 years, and 3 years of follow-up.[15]

We considered that a prospective randomized study to compare TD using the Cavaterm device and HTER by electrosurgery would be useful, in terms of intraoperative and postoperative outcomes. Satisfaction rate was considered the main outcome measure.

Material and methods

The study design was approved by the Ethics Committee of Federico II University of Naples. All patients who were referred to the Department of Obstetrics and Gynecology of University of Naples because of menorrhagia and who were unresponsive to medical treatment were invited to participate in the study.

Inclusion criteria were women aged below 50 years who weighed <100 kg not desiring pregnancy; a documented history of at least 3 months of failed medical therapy; documented evidence of normal endometrial histologic condition and Papanicolaou smear within the previous 12 months; the absence of an uterine size of >12 weeks of pregnancy; the absence of submucosal fibroids, adnexal masses, or endometriosis; the absence of uterovaginal prolapse and severe urinary symptoms; and the absence of severe intercurrent illness.

Patients were thoroughly counseled about TD and HTER before they were asked to give their informed consent for randomization. They were advised that both techniques might not induce a complete amenorrhea and that, if menses resumed after HTER or TD, contraceptive measures should be used. Patients were randomly assigned to TD or HTER by means of a computer-generated randomization number sequence.

From May 1998 to June 1999, 105 eligible patients gave written consent to the trial, but 9 women (5 assigned to the HTER and 4 to the TD group) withdrew before knowing the random assignment and 14 women refused the allocated treatment (8 in the HTER group and 6 in the TD group). Therefore, there were 42 HTER (group 1) and 40 TD (group 2) treatments. Thirty-eight patients who were assigned to the HTER group and 37 patients who were assigned to TD group were followed up for 1 year after the procedure; 33 and 35 patients, respectively, were followed up for 2 years.

Complete medical, gynecologic, and drug histories were taken. All patients underwent a clinical examination with esocervical and endocervical smear, a pelvic and vaginal ultrasonography, a diagnostic hysteroscopy with endometrial sampling, and a complete hematochemical evaluation.

Patients who were randomized to the HTER group were pretreated with a depot formulation of a go-

Table III. Postoperative details of patients who were treated with HTER or TD

Characteristic	HTER (n = 42)	TD (n = 40)
Discharge time (d ± SD)	1.3 ± 0.6	1.0 ± 0.4
Complications (No.)		
Fever	2	1
Urinary infection and/or retention	1	0
Hemorrhage	4	5
Blood transfusions	—	2
Postoperative pain (score ± SD)		
At discharge	1.5 ± 0.6*	1.9 ± 0.3
At 3 d	0.5 ± 0.2	0.4 ± 0.1
At 7 d	0	0
Vaginal bleeding (d ± SD)	7.8 ± 2.1†	5.2 ± 1.8†
Normal domestic activities (d ± SD)	6.2 ± 3.3	4.1 ± 2.6
Return to work (wk ± SD)	0.9 ± 0.3	0.7 ± 0.1
Resumption of sexual activity (d ± SD)	9.8 ± 0.7	9.6 ± 0.6

*HTER group versus TD group: $P < .01$.
†HTER group versus TD group: $P < .05$.

nadotropin-releasing hormone-α (Enantone 3.75; Takeda, Rome, Italy) 6 and 2 weeks before endometrial resection.[16] Patients who were randomized to the TD group were not pretreated. Medical treatment to thin endometrium before TD was not administered in this group because no drugs were approved in Italy for this purpose at the time of the study.

All procedures used spinal anesthesia by staff who were proficient both in HTER and in TD. An accurate record of operating time, intraoperative blood loss, and intraoperative and postoperative complications were kept.

Standard techniques were used for both HTER and TD. Briefly, HTER was performed by means of a rigid resectoscope that was equipped with a 12-degree fore-oblique telescope and a loop electrode that were introduced into the uterine cavity after a dilatation up to Hegar probe (No. 9 ½). The cavity was distended with a nonconductive hypo-osmolar solution of 2.7% sorbitol and 0.54% mannitol that was instilled under manometric control, with a pressure of 100 to 120 mm Hg that was generated by a pneumatic cuff and a vacuum of 30 mm Hg to 0 that was applied for suction. After careful inspection of the cavity, the endometrium was resected with pure cutting waveform unipolar current. The mucosa of the cornual areas was then treated in a radial fashion with a ball electrode, starting from the tubal osthia and withdrawing the electrode toward the surgeon very slowly. Vaporization was completed on the fundus and the remaining cavity down the isthmus.

The TD procedure was preceded by a dilatation of the cervix until to Hegar probe (No. 9). The Cavaterm device and its use was previously described.[12,13] Briefly, a silicon balloon with self-regulating heating element was introduced into the uterine cavity and filled with 15 mg/mL (0.2 mol/L) of hypotonic glycine solution, with a pump that induced a circulation of the fluid in the catheter until a stabilized pressure at 160 to 180 mm Hg was ob-

tained, to distribute the heat from the central element to the balloon surface. Net destruction time (the number of minutes the device must be kept in place) was 15 minutes.[12,13] The temperature of the balloon surface was 80°C, set by the manufacturer that yielded an operative temperature of 75°C.

After the operation, the patients were asked to record their degree of pain by means of a visual analog scale (1 = no pain; 2 = slight pain; 3 = tolerable pain; 4 = severe pain; 5 = not tolerable pain). At discharge, pain was re-evaluated, and the patients were asked to record their pain for a week, the duration of vaginal bleeding, and the dates of return to normal activities, to intercourse, to sexual activity, and to work.

The follow-up visits were performed at 3 months and 1 and 2 years after the operation (longer term follow-up is currently in progress). The patients were asked for pain and bleeding symptoms, and the satisfaction rate questionnaire was given to all of them to be filled out. Specifically, for the satisfaction rate evaluation, women had to answer the following question: "How do you think the improvement of your health state is after the procedure (HTER or TD)?" Women had to choice among four different assessments of satisfaction (excellent, good, moderate, and no improvement).

The statistical analysis was performed with the use of a commercial software program (STATISTICA for Windows [Microsoft Corporation, Redmond, Wash], Statsoft, Inc, Tulsa, Okla). Differences in age, parity, and body mass index between groups were compared with the use of the two-tailed Student t test for unpaired data. Preoperative basal values were compared with the postoperative values in each group with a Student t test for paired data. Postoperative details and postoperative pain score and satisfaction profile between the two groups were compared with the use of the χ^2 test. Operative time differences, estimated blood loss, duration of symptoms, and

Table IV. Satisfaction rate of patients who were treated with HTER or TD

Patient assessment of satisfaction	HTER (n = 42)		TD (n = 40)	
	No.	%	No.	%
At 3 mo*				
Excellent	21†	50	27†	67.5
Good	12	28.5	13	32.5
Moderate	9	21.4	0	
No improvement	0		0	
At 1 y‡				
Excellent	12†	31.5	20†	54.0
Good	12	31.5	10	27.0
Moderate	10	26.3	5	13.5
No improvement	4	10.5	2	5.4
At 2 y§				
Excellent	2†	6.0	16†	45.7
Good	18	54.5	12	34.2
Moderate	3	9.0	5	14.2
No improvement	10	30.3	2	5.7

*HTER, 42 patients; TD, 40 patients.
†HTER versus TD: $P < .001$.
‡HTER, 38 patients; TD, 37 patients.
§HTER, 33 patients; TD, 35 patients.

mean discharge time were compared with the use of the Wilcoxon rank sum test. A probability value of <.05 was defined as statistically significant.

Results

One hundred five patients gave written consent to the trial, but only 82 patients entered into the study, of whom 42 women were treated by HTER and 40 women were treated by TD. Overall, 33 patients from the HTER group and 35 patients from the TD group completed the trial.

There were no differences in terms of age, parity, body mass index, uterine dimensions, preoperative hemoglobin, symptom patterns, and duration of symptoms between the 2 groups (Table I).

Operative data are reported in Table II. The operative time was significantly lower in the TD group (24 ± 4 minutes) in comparison with the HTER group (37 ± 6 minutes; $P < .01$). Intraoperative blood loss was higher in the HTER group (89 ± 38 mL) in comparison with TD group (7.2 ± 2.8 mL, $P < .01$). Intraoperative complications and postoperative pain, immediately after the operation, were not different between the two groups (Table II). Two women in the HTER group (2/42; 4.7%) underwent laparotomic hysterectomy for a severe uterine perforation.

Postoperative details are resumed in Table III. Discharge time and postoperative complications were not significantly different between groups. The degree of pain was significantly lower in the HTER group at discharge, although no pain differences were noted between groups at 3 and 7 days after the operation (Table III). Two patients from TD group with a preoperative low hemoglobin level underwent blood transfusion because their bleeding continued for 5 and 7 days, respectively, after the operation. Vaginal bleeding was significantly

lower for the TD group compared with the HTER group ($P < .05$). Women who were included in the TD group returned to normal domestic activities and to work in a shorter time. No differences were found in the resumption of sexual activity between two groups.

Satisfaction rate was significantly higher in the TD group (Table IV). Each satisfaction rate questionnaire (at 3 months, 1 year, and 2 years) gave high percentages of women who considered their health state excellent or good, never lower than 60%. More particularly, the number of women who considered their state to be excellent was higher in the TD group during the follow-up period. Furthermore, we reported a significant difference between women who considered their state to be excellent or good between the two groups (HTER vs TD) during the follow-up period (50% excellent + 28.5% good = 78.5% vs 67.5% excellent + 32.5% good = 100% at 3 months follow-up; 31.5% excellent + 31.5% good = 63% vs 54.0% excellent + 27.0% good = 81% at 1 year follow-up; 6.0% excellent + 54.5% good = 60.5% vs 45.7% excellent + 34.2% good = 79.9% at 2 years follow-up). Our data show that the percentage of women who considered their health state to be excellent or good remained significantly high during the follow-up period for the TD group (100%-79.9%), although this percentage was significantly lower for the HTER group (78.5%-60.5%, Table IV).

The clinical follow-up of patients is reported in Table V. The percentage of reoperation rate was significantly lower for the TD group in comparison with the HTER group at 1 year and 2 years (5.4% vs 10.5 at 1 year and 5.7% vs 15.1% at 2 years).

Bleeding recurrence was significantly lower for the TD group in comparison with the HTER group (5.4% vs 15.7% at 1 year and 8.5% vs 24.2% at 2 years). No differ-

Table V. Follow-up of patients who were treated with HTER or TD

	HTER (n = 42)			TD (n = 40)		
	3 Mo (n = 42)	1 Y (n = 38)	2 Y (n = 33)	3 Mo (n = 40)	1 Y (n = 37)	2 Y (n = 35)
Reoperation rate (No.)*	0	4 (10.5%)†	5 (15.1%)†	0	2 (5.4%)†	2 (5.7%)†
Bleeding recurrence (No.)*	3 (7.1%)	6 (15.7%)†	8 (24.2%)†	1 (2.5%)	2 (5.4%)†	3 (8.5%)†
Pain recurrence (No.)*	1 (2.3%)	7 (18.4%)†	9 (27.2%)†	0	1 (2.7%)†	2 (5.7%)†
Urinary incontinence (No.)*	—	—	3 (9.0%)	—	—	2 (5.7%)
Cervical pathologic result: CIN grade 1 (No.)*	—	—	1 (3.0%)	—	—	1 (2.8%)

*Rates are specific percentages for each follow-up step.
†HTER versus TD: $P < .01$.

ences between the two groups were found in pain recurrence at 3 months, although after 1 and 2 years, the percentage of pain recurrence was significantly lower for the TD group in comparison with the HTER group (2.7% vs 18.4% at 1 year and 5.7% vs 27.2% at 2 years). Finally, no significant difference was found between the two groups when the number of women with urinary incontinence and cervical pathologic condition were evaluated at 2 years.

Comment

This trial was designed to evaluate the advantages and the disadvantages of HTER, when compared with the least invasive type of TD. In this regard, we considered the main outcome measure to be the satisfaction rate of the patients. Most patients who undergo ablation consider satisfaction to be the subjective reduction of bleeding symptoms.[17-22] Five previous randomized controlled trials[3-7] that compared traditional hysterectomy (abdominal and/or vaginal) and HTER concluded that hysteroscopic operation is associated with lower postoperative morbidity, a faster return to normal activities, and a significant cost advantage. Hysterectomy is more effective in the relief of menstrual symptoms, has a greater satisfaction rate, and is associated with a dramatically lower reoperation rate.

Our data clearly show that the satisfaction rate at 3 months, 1 year, and 2 years follow-up is significantly higher after TD than after HTER.

Some authors reported different data about the efficacy of the two techniques. A recent multicenter, prospective randomized study has compared HTER and TD of endometrium and reported the percentage of success of the two operative techniques as the percentage of patients who had amenorrhea or normal bleeding after these procedures at 1 year, 2 years, and 3 years.[15] In this study, although the percentage of success was higher for the HTER group in comparison with the TD group at 1 and 2 years, this percentage was higher for the TD group at 3 years.

We underlined the patients' satisfaction more than the clinical outcomes, but our data concerning the clinical

characteristics (preoperative and postoperative details) clearly demonstrated that TD of endometrium is associated with a lower number of short- and long-time complications in comparison with hysteroscopic endometrial resection, including postsurgical resumption of menorrhagia.

Finally, the operating time for TD, including the time necessary to administer spinal anesthesia, was significantly lower in comparison with HTER. This is in accord with many studies that described the operative data of the two techniques that were previously described.[3-8,12-14]

Moreover, our trial reports a comparable rate of intraoperative complications, similar discharge time, and return to normal activities between the two groups.

In conclusion, the TD procedure avoids the potential risks of fluid overload and electrolyte disturbance that are intrinsic to hysteroscopic procedures. Moreover, endometrial ablation with thermal balloon is as effective as hysteroscopic electrosurgical, but it permits a lower operative time, a lower intraoperative blood loss, and a higher satisfaction rate among patients at 2 years.

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