Laparoscopic Occlusion Compared With Embolization of Uterine Vessels

A Randomized Controlled Trial

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OBJECTIVE: To compare clinical outcome 6 months after treatment with bilateral laparoscopic occlusion of the uterine artery versus uterine leiomyoma embolization.

METHODS: Sixty-six premenopausal women with symptomatic uterine leiomyomata were randomized to treatment with either laparoscopic occlusion of uterine arteries or uterine leiomyoma embolization. The primary outcome was reduction of blood loss from pretreatment to 6 months postoperatively, measured by a Pictorial Bleeding Assessment Chart. Secondary outcomes included patients' own assessment of symptom reduction, postoperative pain assessed using visual analog scales, ketobemidone used postoperatively, complications, secondary interventions, and failures.

RESULTS: Fifty-eight women were included; 6-month follow-up data were available for 28 participants in each group. The percentage reduction in Pictorial Bleeding Assessment Chart scores did not differ between the treatment groups (52% after uterine leiomyoma embolization and 53% after laparoscopy, $P=.96$). The study had 52% power to detect a 20% difference on the Pictorial Bleeding Assessment Chart. Fewer participants in the group treated with uterine leiomyoma embolization complained of heavy bleeding after 6 months (4% compared with 21%, $P=.044$). The postoperative use of ketobemidone was higher after uterine leiomyoma embolization (46 mg compared with 12 mg, $P<.001$).

CONCLUSION: Both laparoscopic occlusion of uterine vessels and embolizaton of uterine leiomyoma improved clinical symptoms in the majority of patients. Participants with the laparoscopic procedure had less postoperative pain but heavier menstrual bleeding 6 months after treatment. A larger study and longer follow-up is necessary before a definite conclusion can be made regarding the most effective treatment.

CLINICAL TRIAL REGISTRATION: ClinicalTrials.gov, http://www.clinicaltrials.gov, NCT 00277680

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LEVEL OF EVIDENCE: I

Hysterectomy is the most common treatment for symptomatic leiomyomata. The demand for alternative treatments has increased during the last decade, both by patients and by physicians looking for less invasive procedures. Uterine leiomyoma embolization has become one such alternative procedure, and laparoscopic occlusion of uterine vessels is suggested as another. Since Ravina et al[1] published the first report on arterial embolization as a treatment for uterine leiomyomata in 1995, observational studies have reported relief of excessive menstrual bleeding or pressure in 80–90% of patients.[2–10] These studies have also shown a reduction in leiomyoma and uterus size 3–12 months after the procedure, as measured by ultrasonography or magnetic resonance imaging (MRI). Similar relief of symptoms and reduction of the uterus and leiomyoma size were reported in 2001 in a 7- to 12-month follow-up of 87 patients after laparoscopic bipolar coagulation of uterine vessels.[11] Smaller studies with a follow-up as long as 36 months postprocedure[12,13] have confirmed the results of bilateral laparoscopic occlusion of uterine arteries.

In a preliminary nonrandomized study, the authors reported reduction in menstrual bleeding and

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reduction of leiomyoma volume after both uterine leiomyoma embolization and laparoscopic occlusion of uterine vessels.[14] In the present randomized study, the clinical outcome of these two methods is compared. The reduction in bleeding after 6 months, as measured by the Pictorial Bleeding Assessment Chart, was the primary outcome variable. The Pictorial Bleeding Assessment Chart is a validated[15] and recommended[16] standard assessment method for evaluating uterine leiomyoma embolization. Secondary outcome measures were patients' own assessment of menstrual bleeding and pressure symptom reduction, postoperative pain and nausea registration on visual analog scales, the amount of ketobemidone used postoperatively, recovery time, complications, secondary interventions, and failures.

MATERIALS AND METHODS

The study was performed at the Department of Obstetrics and Gynecology and at the Department of Radiology, Ullevål University Hospital, Oslo. It was approved by the Regional Committee for Medical Research Ethics, Eastern Norway. Sixty-six premenopausal women referred to the university clinic for uterine leiomyomas and menorrhagia or bulk symptoms between December 2000 and December 2004 were included in this randomized, nonblinded trial. The preliminary treatment results from the first 27 randomized patients have been reported previously together with the results of patients not participating in the randomized study.[14] Inclusion criteria were the women's own interpretation of increased amounts of bleeding, pressure symptoms, and an expressed desire not to have a hysterectomy. Exclusion criteria were suspicion of malignancy, subserous leiomyomata that could easily be removed by laparoscopic surgery, known adenomyosis, and uterus size exceeding the umbilical level. Submucous leiomyomata with a diameter of less than 3.5 cm situated completely intracavitarily or with an intramural extension of more than 50% were considered more suitable for hysteroscopic resection and were therefore excluded. Larger submucous leiomyomata were not excluded. In addition, women wishing to have children were excluded, as well as those with contraindications for surgery. All eligible patients attended a consultation by a gynecologist (K.H. or O.I.), which included a gynecological examination, ultrasonography, a cervical smear, and endometrial biopsy. An MRI procedure was performed preoperatively. The patients were informed about the possible risks and benefits of both treatments. After agreeing to participate, patients signed a written informed consent form before randomization took place. Randomization of 1:1 was undertaken in a total of seven blocks of 10 patients each, using sealed envelopes. Five envelopes in each block of 10 were assigned to laparoscopic treatment and five to uterine leiomyoma embolization. The envelopes in each block were closed, mixed, and then numbered. Treatment was decided by drawing the next available envelope in ascending numerical order.

One dose of cefalotin 2 g and metronidazol 1.5 g was given before the procedures as infection prophylaxis. Before admission, the patients were informed of a standardized protocol of 2 days of hospital care and 14 days of sick leave.

Interventional radiologists performed the embolization procedure. The right femoral artery was punctured and the uterine arteries intubated with a 4F Cobra catheter or a microcatheter. In all cases, both arteries were embolized with 355- to 500-micron polyvinyl alcohol particles.

The laparoscopic bilateral occlusion of the uterine arteries was carried out by using the lateral approach to the origin of the uterine artery from the internal iliac artery. In all cases, the uterine artery was closed with two to three endoclips on each side. The uteroovarial ligaments were also coagulated bilaterally with bipolar forceps. Additional surgery was performed on six patients; one patient underwent adhesiolysis, and five women had tubal sterilization performed simultaneously. Both the embolization and laparoscopic techniques used have been described in detail previously.[14]

A validated bleeding chart, Pictorial Bleeding Assessment Chart,[15] was filled in by the participants during the last menstrual period before treatment, as well as in advance of each outpatient appointment. The participants were encouraged to use the same type of sanitary pads or tampons during the study period. The change in Pictorial Bleeding Assessment Chart score from baseline to 6 months after treatment was the primary outcome measure. The percentage change in Pictorial Bleeding Assessment Chart score for each individual was calculated and the changes compared to minimize possible bias generated by women using different types of sanitary pads and tampons. One of the authors (K.H.) surveyed the study participants in relation to their present leiomyoma-related symptoms before treatment and after 1 month, 3 months, and 6 months, respectively.

A standardized questionnaire was used at all appointments. The amount of bleeding was rated as "little," "moderate," "heavy," or "very heavy." Pressure symptoms, including voiding problems, were

recorded as "yes" or "no." Participants were asked to grade changes in amount of bleeding and pressure symptoms as better, worse, or unchanged. Total relief of symptoms at the 6-month follow-up was defined as little or moderate bleeding and no bulk symptoms. Clinical failure was defined as persisting symptoms requiring secondary treatment or no improvement at the 6-month follow-up. Patients still complaining of heavy bleeding, although improved and with insufficient bleeding to prompt further treatment, were not classified as clinical failures.

Postoperative pain and nausea during the hospital stay were recorded on a visual analog scale score ranging from 0 to 100 mm. Patients were asked to fill in the level of pain and nausea they experienced every 4 hours during the first 24 hours in the hospital and every 6 hours during the next 24 hours or until leaving the hospital. The analgesic regime consisted of nonsteroidal anti-inflammatory drugs and a paracetamol-codeine combination in fixed doses, as well as patient controlled ketobemidone in variable doses. The amount of ketobemidone used during the hospital stay was recorded.

Adverse events were also recorded for each patient during the hospital stay and during outpatient visits after 1 month, 3 months, and 6 months. All subsequent surgical and medical interventions, as well as readmission to the hospital or prolonged hospitalization, were recorded as adverse events.

Randomized patients who did not receive treatment were excluded from the analyses, as described by Fergusson et al.[17] The efficacy variables were subsequently analyzed using two different statistical approaches: intention to treat and per protocol. Intention-to-treat analyses included all patients who received the initial treatment. In the per protocol evaluation, patients receiving additional treatment during the study period were excluded. The results of intention-to-treat analyses are reported unless stated otherwise. Data from two patients with only a 3-month follow-up (Fig. 1) were included in the final evaluation, together with the 6-month follow-up of the other patients.

The proposed sample size for the present study was based on the assumption that a 20% difference in Pictorial Bleeding Assessment Chart score between the groups would be of clinical significance. Based on a within-group standard deviation of 27 for the percentage change in Pictorial Bleeding Assessment Chart score, 30 patients were needed for each treatment group to define a statistically significant difference between the groups with a significance level of .05 and a power of 80%. Sixty-six participants were enrolled to make allowances for a drop-out rate of 10%.

Statistical analyses were performed with SPSS 12.0 (SPSS Institute Inc, Chicago IL), and the data are presented as mean values for normal distributed data and as median values for skewed data. A two-sided *t* test was used for comparisons of a continuous variable in two patient groups if the variable in question did not have a markedly skewed distribution. If the distribution was markedly skewed, a two-sided Wilcoxon-Mann-Whitney test was used. A χ^2 test or Fisher exact test was used when comparing categorical variables. A significance level of .05 was used for all tests.

RESULTS

Of the 66 patients randomized and included in the study, 58 patients received treatment, 29 with uterine leiomyoma embolization and 29 with bilateral laparoscopic occlusion of uterine vessels. Twenty-eight participants in each group completed the 6-month trial (Fig. 1). The two groups were similar with respect to age, body mass index, parity, and baseline symptoms (Table 1).

There was no significant difference in Pictorial Bleeding Assessment Chart reduction between the treatment groups 6-months after treatment (P=.96). At the 3-month follow-up, the subjects treated by uterine leiomyoma embolization had a mean Pictorial Bleeding Assessment Chart reduction of 45%, as opposed to 47% for those treated by laparoscopy. Six months after uterine leiomyoma embolization, the reduction was 52%, and the corresponding reduction for laparoscopic treatment was 53%. Excluding participants who received secondary treatment during the study period, the percentage change in Pictorial Bleeding Assessment Chart scores showed a 50% reduction after uterine leiomyoma embolization and 56% reduction after laparoscopic treatment (P=.57). Bleeding reduction was reported among 26 (90%) women after uterine leiomyoma embolization, whereas 25 (86%) women in the laparoscopic group reported favorable results. The number of patients reporting reduced menstrual bleeding, reduction of pressure symptoms, or total relief of all symptoms after treatment did not differ significantly between the two treatment groups (Table 2).

Clinical failure was seen in two (7%) subjects after uterine leiomyoma embolization and in six (21%) subjects after laparoscopic occlusion. There was no statistical difference between the groups (P=.13). However, there were seven women still reporting heavy or very heavy bleeding 6 months after treat-

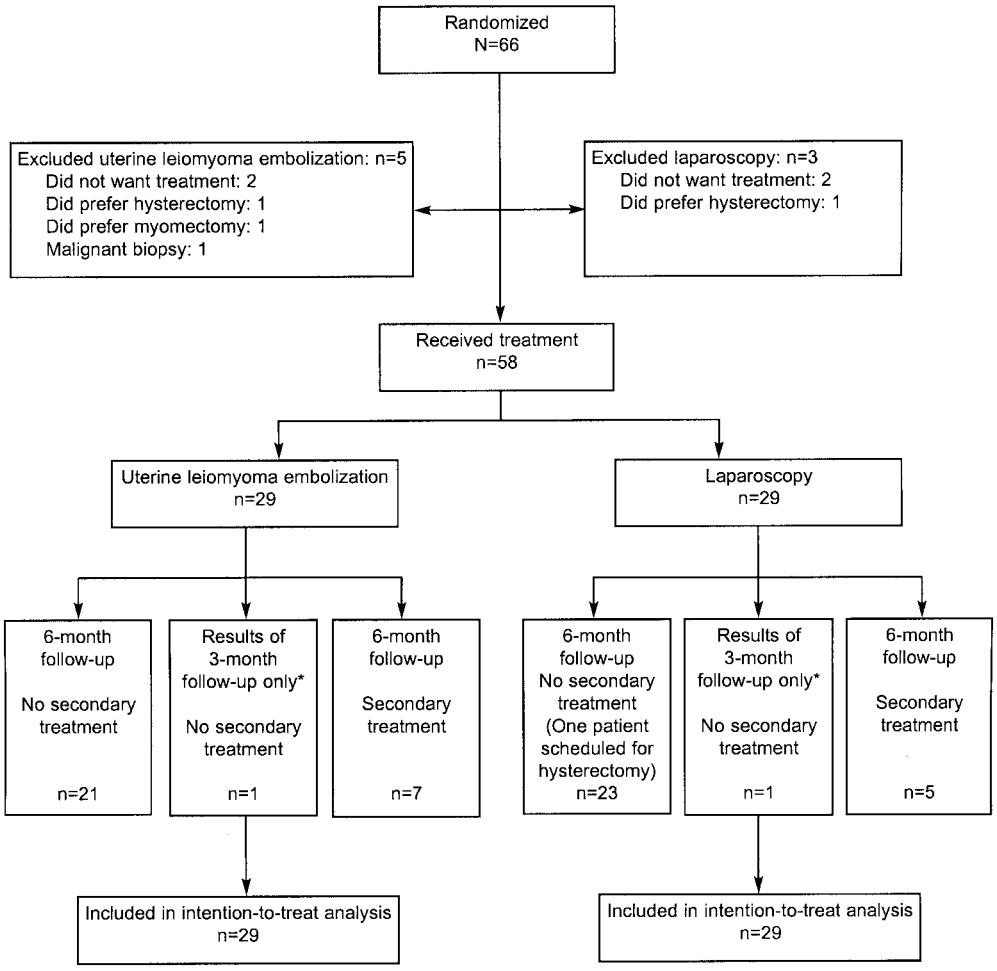

Fig. 1. Study participants flow diagram.
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Table 1. Baseline Parameters

	ULE (n=29)	Laparoscopy (n=29)	*P*
Age (y)	42.5±4.3	43.3±5.2	.51
Body mass index (kg/m^2)	23.0 (19.3–37.3)	23.5 (20.2–39.2)	.85
Number of nullipara	11	11	1.0
Number of patients with menorrhagia	29	28	
PBAC score	358 (63–1,257)	317 (108–1,200)	.89
Number of patients with bulk symptoms including voiding problems	24	20	.22
Number of patients with both menorrhagia and pressure symptoms	24	19	.13
Preoperative hemoglobin (g/100 mL)	11.6±1.5	11.7±1.6	.82
Preoperative uterine volume (mL)*	598 (171–1,276)	557 (128–1,921)	.65
Preoperative volume of largest leiomyoma (mL)*	257 (35–530)	137 (6–847)	.33

ULE, uterine leiomyoma embolization; PBAC, Pictorial Bleeding Assessment Chart.
Data are expressed as mean±standard deviation or median (range).
* Magnetic resonance imaging measurements.

ment, one (4%) after uterine leiomyoma embolization and six (21%) after laparoscopic treatment. The difference in the intention-to-treat analysis with regard to the number of patients who reported heavy bleeding was statistically significant (*P*=.044). Three of these patients, one in the uterine leiomyoma embolization

Table 2. Clinical Outcome After Treatment

	ULE (n=29)	Laparoscopy (n=29)	*P*
Bleeding reduction	26	25	.69
Reduction of pressure symptoms	20	17	.88
Total relief of pressure	16	9	.15
All symptoms completely resolved	20	15	.18
Satisfaction rate*	27	24	.23
Clinical failure†			
Hysterectomy	1	1	1.00
Transcervical resection for menorrhagia	0	3‡	.24
UFE	0	2‡	.49
Levonorgestrel IUD	1	0	1.00
No symptom improvement, but no additional treatment	0	1	1.00

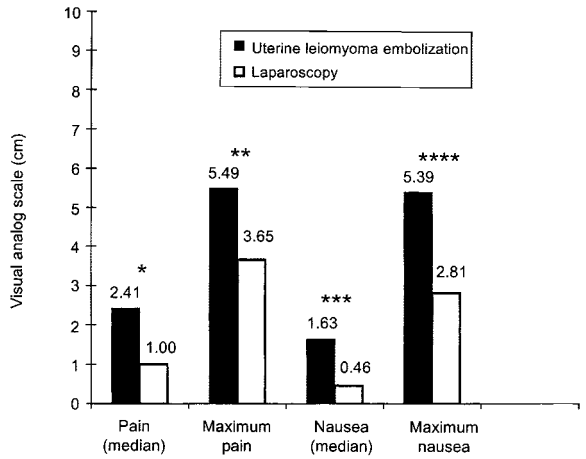
ULE, uterine leiomyoma embolization; IUD, intrauterine device.
Intention-to-treat analysis; data are expressed as numbers of patients.
* Partly or totally satisfied.
† Persistent symptoms requiring secondary therapy or no improvement at 6-month follow- up.
‡ One patient received both transcervical resection and ULE during the study period.

group and two in the laparoscopy group, did not meet the definition of clinical failure. All three participants reported improvement of symptoms, together with reductions in their Pictorial Bleeding Assessment Chart score between 32% and 78%, and received no additional treatment during the study period. If these three participants had been added to the group of patients deemed clinical failures, there would have been three (10%) patients after uterine leiomyoma embolization and eight (28%) after laparoscopy with unfavorable results 6 months after treatment (*P*=.094).

Significantly more pain and nausea were observed after uterine leiomyoma embolization than after laparoscopy (Fig. 2). The median amount of ketobemidone used after the embolization procedure was four times higher than after laparoscopic surgery: 46 mg compared with 12 mg (*P*<.001)

Only minor in-hospital adverse events were observed (Table 3). The patients were scheduled to stay for up to 48 hours in the department after treatment. The duration of hospitalization varied significantly, with an average of 57 (range 24–108) hours after uterine leiomyoma embolization and 46 (24–72) hours after laparoscopic occlusion (*P*=.001).

Twenty-two patients noticed increased vaginal discharge during the postoperative period. No significant differences were observed in the proportion of women with vaginal discharge extending to 7 days (Table 3), although four patients, all of whom had undergone uterine leiomyoma embolization, experienced the problem for longer than 30 days. Two of these were still suffering continuous discharge at their 6-month follow-ups. Extended sick leave did not



	SEM for median pain	SEM for maximum pain	SEM for median nausea	SEM for maximum nausea
Uterine leiomyoma embolization	0.27	0.44	0.27	0.63
Laparoscopy	0.27	0.53	0.30	0.68

Fig. 2. Pain and nausea recorded on a visual analog scale score the first 48 hours after treatment. The scale ranged from 0 to 10 cm. SEM, standard error of the mean. * *P*=.026 (Mann-Whitney); ** *P*=.010 (Student *t* test); *** *P*=.003 (Mann-Whitney); **** *P*=.007 (Student *t* test).

Hald. Laparoscopic Occlusion of Uterine Vessels. Obstet Gynecol 2007.

differ between the groups, however. The median sick leave duration was 21 days after both treatment modalities.

Amenorrhea occurred during the study period in one patient. This participant underwent uterine leiomyoma embolization at the age of 51 years. In

Table 3. Adverse Events After Treatment

	UFE (n=29)	Laparoscopy (n=29)	*P*
During hospitalization			
Superficial bleeding	1	1	1.00
Urine tract infection	1	0	1.00
Adverse drug effect	2	2	1.00
After discharge from hospital			
Thromboembolism	0	1*	1.00
Temporary muscle weakness	0	2	.49
Buttock claudication	0	1	1.00
Expulsion of leiomyomata†	5	1	.19
Vaginal discharge more than 7 days	10	4	.12

ULE, uterine leiomyoma embolization.
* Pulmonal embolism.
† Expulsion or sloughing necessitating secondary surgery.

spite of preclimacterial follicle-stimulating hormone (FSH) values before treatment, FSH showed postmenopausal values 3 and 6 months after treatment.

Additional treatment during the first 6 months after the initial surgery was necessary in 13 patients, in seven (24%) after uterine leiomyoma embolization, and in six (21%) after laparoscopy. Two participants in the uterine leiomyoma embolization group and five in the laparoscopy group needed further treatment for persistent menorrhagia (*P*=.42). Among the 13 participants who underwent further invasive therapy, satisfactory symptomatic improvement occurred in 11 women. The remaining two patients, both primarily treated with laparoscopy, received a transcervical resection of leiomyomata because of continuous menorrhagia. This did not result in satisfactory bleeding reduction, however. One of these patients demonstrated closure of the uterine artery on one side only with angiography and achieved satisfactory bleeding relief after subsequent unilateral embolization. The other patient refused further treatment.

The most serious adverse event, pulmonary embolism, occurred in one patient who was readmitted to the hospital 1 week after laparoscopic bilateral occlusion (Table 3). After leaving the hospital, two participants complained of temporary adductor muscle weakness after laparoscopy, which spontaneously resolved during the first 6 months after treatment. One woman had symptoms of claudication from the right buttock and persistent menorrhagia after laparoscopic surgery. An angiographic examination revealed bilateral occlusion of the hypogastric arteries, and both arteries were recanalized with balloon angioplasty. The angioplasty was followed by immediate bilateral embolization, and the symptoms of both claudication and menorrhagia resolved. In addition, three participants complained of prolonged pain and intermittent fever 3–12 weeks after treatment, two after uterine leiomyoma embolization and one after laparoscopic occlusion. None of these patients needed antibiotics or readmission to the hospital.

DISCUSSION

The primary goal of the present study was to compare the improvement in bleeding patterns between uterine leiomyoma embolization and laparoscopic occlusion. No significant difference in symptom reduction was found between the two treatment options 6 months after treatment, neither by calculating the percentage reduction in Pictorial Bleeding Assessment Chart nor by self-reported reduction in amount of bleeding.

In the literature, there is one additional study using Pictorial Bleeding Assessment Chart reduction as an efficacy measure in studies evaluating uterine leiomyoma embolization or laparoscopic occlusion of uterine vessels. In a comparative study between radiological embolization and hysterectomy, Pictorial Bleeding Assessment Chart reduction in 76 patients treated by embolization was found to be 55.6% after 3 months and 58.1% after 6 months, which is slightly better than in this study.[18]

The patients' own assessment of symptom relief is more commonly used as an outcome parameter than the Pictorial Bleeding Assessment Chart, even though there is a lack of uniformity in defining degree of improvement. Notwithstanding these limitations, the present findings, based on the patients own assessment 6 months after uterine leiomyoma embolization, are similar to those of other studies.[2,3,5,6,8] The reduction of menstrual bleeding and bulk symptoms in 90% and 83% of the patients, respectively, after uterine leiomyoma embolization in this study is in accordance with the short-term results of the two largest prospective single-center studies evaluating uterine leiomyoma embolization to date, which reported improvements in menorrhagia in 89% of patients after 6 months and in 84% after 16 months, respectively.[6,8] Furthermore, the reduction in the amount of bleeding in 93% and in bulk symptoms in 85% of the patients after bilateral laparoscopic occlusion in this study is similar to that of other studies, which report improvement of these symptoms in about 90% of the participants.[11–13]

In contrast to the lack of difference between the two treatment groups with regard to the percentage reduction of Pictorial Bleeding Assessment Chart scores, significantly more participants reported heavy or very heavy bleeding 6 months after laparoscopic

treatment. One possible explanation for this discrepancy might be differences in assessment of bleeding. In addition, some patients had a very high initial Pictorial Bleeding Assessment Chart score, and even with substantial improvement of both subjective assessment and percentage reduction of Pictorial Bleeding Assessment Chart, there was still heavy bleeding present. The validation of Pictorial Bleeding Assessment Chart[15] was performed using standardized sanitary pads and tampons. The women in our study used their own regular sanitary pads and tampons, and this could possibly generate bias in the results, even though the percentage reduction in Pictorial Blood Assessment Chart for each patient was used to reduce this bias. According to the power calculation before the study, the standard deviation for the percentage change in Pictorial Bleeding Assessment Chart from baseline to 6 months after treatment was not expected to be higher than 27. However, the standard deviation for this parameter was actually found to be 37. With the actual standard deviation, it may be shown that the power of detecting a 20% difference between the treatment groups for this variable is 52%. Thus, even though similar results were found in regard to this variable, there might be undetected differences in efficacy between the two methods.

There are several possible explanations for the slightly less favorable results after the laparoscopic treatment. Angiographic and surgical studies have shown numerous anatomical variations of the uterine arteries.[19,20] It is thus possible to occlude the wrong artery in laparoscopy or to overlook one artery in cases where there are two instead of one single artery on one side. The protocol did not include angiographic examination after surgery. However, in one patient experiencing failure after laparoscopy, an angiographic examination was carried out after primary surgery as preparation for uterine leiomyoma embolization as secondary treatment. The reason for the failure was found to be insufficient occlusion of the uterine artery at one side.

The collateral arterial supply to the uterus in general could explain smaller amounts of pain after surgical uterine artery occlusion, in spite of ischemia and infarction of leiomyomata. Because embolization is a more distal occlusion reducing collateral flow, increased uterine ischemia can be expected, resulting in increased pain and potentially increased efficacy compared with proximal surgical occlusion. Concerns have been expressed among interventional radiologists that leiomyomata that are not completely infarcted will have the potential to regrow.[21] In two prospective studies, 16%[22] and 20%[23] recurrence was found 5–7 years after embolization. If smaller amounts of pain after laparoscopy were caused by less ischemia and thus incomplete infarction of leiomyomata, one would expect even more recurrences with time after laparoscopic occlusion.

In the current study, only one case of amenorrhea was seen after uterine leiomyoma embolization and none after laparoscopic occlusion. In the literature, the reported amenorrhea rate after uterine leiomyoma embolization is 2–14%.[5,6,8–10,18] In women younger than 45 years, the incidence is up to 3%.[8] In this study, the uteroovarial anastomotic sites were cauterized in addition to division of the uterine arteries to avoid collateral perfusion to leiomyomata. This additional procedure during surgery might increase the risk of ovarian failure. However, it is not known whether occlusion of the collateral vessels from the ovaries to the uterus is important for the clinical reduction in leiomyoma symptoms.

The proportion of patients requiring secondary surgery was above 20% in both treatment groups in our study. This proportion is larger than in other studies reporting outcomes after uterine leiomyoma embolization or laparoscopic occlusion. In two larger studies, subsequent interventions or readmission occurred in 10.5% after 21 months[6] and in 7.5% after 17 months,[8] respectively. In both of these studies, the main indications for secondary surgery were similar to those in this study: continuous menorrhagia or symptoms related to leiomyoma expulsion. Patient selection is probably most significant for beneficial results, and more careful selection might reduce the number of cases of secondary surgery caused by persistent menorrhagia or expulsion of leiomyomata.

Surgery-related complications were seen only after laparoscopy, with temporary affection of the obturator nerve in two patients and claudication symptoms in one patient after bilateral occlusion of the hypogastric arteries. Usually there are enough collaterals for a sufficient blood supply to the pelvis after closing the hypogastric artery,[24] but in the latter case, the procedure caused ischemia and pain, which was later resolved by angiographic intervention. These complications illustrate the importance of close attention being paid to the integrity of other organs, especially nerves and vessels, when surgery is performed in this area.

Based on this study, both laparoscopic occlusion of the uterine vessel and embolization appear to improve symptoms associated with uterine leiomyomata in the majority of patients. However, a definite conclusion regarding the most effective treatment is

hampered by a low study power. The laparoscopic procedure resulted in less postoperative pain and nausea and shorter hospital stays, although significantly more participants experienced heavy menstrual bleeding 6 months after laparoscopic occlusion, indicating a more favorable effect after uterine leiomyoma embolization. In the light of these results and bearing in mind the significant risk of surgical complications and lack of long-term results, the laparoscopic procedure for leiomyoma treatment should be confined to clinical trials in centers with appropriate expertise in laparoscopic surgery.

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