Outcome of uterine embolization and hysterectomy for leiomyomas: Results of a multicenter study

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Objective: The purpose of this study was to estimate the outcomes of uterine embolization and hysterectomy for uterine leiomyomas.

Study design: This was a multicenter prospective study of patients who were treated with embolization (n = 102 patients) and hysterectomy (n = 50 patients) for leiomyomas. Changes in symptoms, complications, and quality of life were measured. The data analysis included linear and logistic regression, the Student t and paired t test, Fisher’s exact test, and chi-squared test.

Results: For patients who underwent embolization, there were marked reductions in blood loss scores (P < .001) and menorrhagia questionnaire scores (P < .001) compared with baseline. At 12 months, a larger proportion of the patients who had undergone hysterectomy experienced improved pelvic pain (P = .021). Both groups had marked improvement in other symptoms and quality of life scores, with no difference between groups. Complications were more frequent in patients who underwent hysterectomy (50% vs 27.5%; P = .01).

Conclusion: Both procedures substantially improved symptoms for most patients, with an advantage for hysterectomy at 12 months for pelvic pain. Serious complications were infrequent in both groups.

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KEY WORDS
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Embolization
Hysterectomy
Quality of life

Since the initial report of uterine embolization for leiomyomas,1 there have been numerous case series that have reported on the outcome of this therapy.2–8 Little is yet known regarding the relative effectiveness and safety of embolization and standard leiomyoma therapies. A small randomized study that compared hysterectomy and embolization has been published recently,9 but the primary outcome measure was length of stay. That study evaluated only 40 patients who underwent embolization and 20 patients who underwent hysterectomy and was thus unable to determine relative safety. Another small study that compared the long-term outcome
of myomectomy and embolization was published, but this study compared 2 different patient groups retrospectively and therefore provides limited conclusions. Beyond embolization, there are few comparative studies for any leiomyoma therapies, and there is a need for additional data for patients and physicians to make appropriate choices.

To better characterize the outcome of these 2 therapies, we undertook a multicenter study of the outcome from embolization and hysterectomy in patients who were treated as contemporaneous cohorts. We present here the results of that study.

Material and methods

This phase II study was developed as part of a 510(k) Premarket Notification to the Food and Drug Administration (FDA) for the embolic material, tris-acryl gelatin microspheres (Embossphere Microspheres; Biosphere Medical, Inc, Rockland, Mass) used in the study. Each of the participating centers obtained approval of the protocol from the institutional review board, and each patient gave informed consent to participate at the time of enrollment. Patients were not paid at enrollment but received a small payment (up to $50) for the completion of follow-up questionnaires. Study sample size was based on an estimate of anticipated adverse events of both procedures, but a power analysis was not performed, because there were no a priori data to estimate outcomes based on the use of the measures in this study.

There were 11 participating centers. Five of these centers enrolled patients who underwent embolization only; 4 centers enrolled patients who underwent hysterectomy only, and 2 centers enrolled both patients who underwent embolization and patients who underwent hysterectomy.

All patients who were included in the study were between 30 and 50 years, inclusive, with symptomatic leiomyomas.

For patients who underwent embolization, submucosal leiomyomas with >50% of their diameter within the uterine cavity (suitable for hysteroscopic resection) or dominant pedunculated serosal leiomyoma (suitable for simple abdominal myomectomy) was excluded. Either pelvic ultrasound or magnetic resonance imaging was completed to determine the extent of leiomyomas, with the largest single leiomyoma defined as the dominant. All measurements before and after the procedure were made with the use of the formula for a prolate ellipse (length × depth × width × 0.5233) as described by Orsini et al.

Both patients who underwent hysterectomy and patients who underwent embolization had the following parameters recorded for comparison at baseline: age, ethnic origin, previous pregnancies, previous live births, previous leiomyoma treatments, number of leiomyomas (1, 2, or ≥3), the uterine volume, dominant leiomyoma volume, and its location in the uterus. Each patient of both groups also completed a self-assessment of menstrual flow (ranging from no periods to extremely heavy) a menorrhagia questionnaire, and a short form 12 (SF-12), a general health-related quality of life questionnaire. The presence of leiomyoma-related pelvic pain, pressure, and urinary dysfunction was also recorded. Each patient completed a self-assessment of health status on a scale of 1 to 100, with a higher number indicating better health. A serum hemoglobin level was also obtained from each patient. Each patient who underwent embolization also completed a menstrual pictorial blood loss assessment chart during a menstrual period prior to the procedure.

Uterine artery embolization

Bilateral embolization was performed in each patient. Embolization was performed through 5F, 4F, or micro catheters at the operator’s discretion. Embosphere microspheres, which ranged in size from 500 to 700 microns to 900 to 1200 microns, were used in each case. The preferred end point of embolization was devascularization of the leiomyomas, with the occlusion of the circumferential vessels that supplied them. The main uterine arteries typically were left patent, with sluggish forward flow remaining at the completion of the procedure, which was the accepted end point of embolization with this product.

Hysterectomy

Hysterectomy was performed in the standard manner as either a transabdominal, laparoscopic, or combined laparoscopic and vaginal procedures. There were no total vaginal hysterectomies. General anesthesia was used in all cases.

Follow-up

Routine postprocedure or postoperative care was provided. Length of stay and all in-hospital adverse events were recorded. Both study groups were assessed at identical time intervals for follow-up; each patient was seen for an office visit within 1 to 3 weeks, 3 months, and 6 months after treatment. Patient status at 12 months was determined by mailed questionnaires, with telephone follow-up for those patients who did not respond immediately. The primary evaluations for efficacy of embolization were conducted at 3, 6, and 12 months after treatment. At these intervals, each patient who underwent embolization completed a menorrhagia
questionnaire, pelvic imaging, a symptom questionnaire, the SF-12 questionnaire, and a self-assessment of health status and patient satisfaction. A blood loss chart was obtained at 3 and 6 months.

The patients who underwent hysterectomy completed a follow-up evaluation form, a symptom questionnaire, the SF-12 questionnaire, and a self-assessment of health status. Pelvic pain, pelvic discomfort, and urinary symptoms, and patient satisfaction were assessed at 6 and 12 months after treatment to allow for complete recovery before measurement.

The symptom questionnaire asked patients to rate the degree of change on a 7-point scale in menstrual bleeding (patients who underwent embolization only), pelvic pain, pelvic discomfort, urinary dysfunction, and satisfaction with the outcome. This questionnaire, which is not a validated instrument, is similar to those questionnaires that were used in previously reported studies. The menorrhagia questionnaire, pictorial blood loss assessment chart, and SF-12 have been validated.

Each patient who underwent embolization had follow-up imaging at 3 and 6 months, with the same imaging modality (either ultrasound or magnetic resonance imaging) as that used at baseline, with measurements made in the same manner as baseline.

Adverse events were recorded prospectively at each follow-up point and between follow-up visits as they occurred during the 1-year follow-up interval. Each complication was graded with the use of the classification for symptom severity that was developed by the Society of Cardiovascular and Interventional Radiology (SCVIR) as reported recently. Limited definitions are presented in Table I. Class A and B complications are considered minor, and complications that are classified C through F are major. Complications were also classified by type with a set of perioperative morbidity measures that were derived from American College of Obstetricians and Gynecologists (ACOG) quality indicators. These have been used previously by Sawin et al in a study that compared the complications of hysterectomy and myomectomy for leiomyomas and thus allow for the potential for comparison of complications by type. The definitions for these also are presented in Table I.

Data analysis

Baseline demographics and baseline questionnaire data were compared between the patients who underwent embolization and patients who underwent hysterectomy with the use of the Student t test, Fisher’s exact, and chi-square tests. At each follow-up interval, the change over time was evaluated for all continuous variables with the use of the Student t test and paired t test, and Fisher’s exact test was used for ordinal variables. Trends over time were calculated by repeated measures analysis of variance for SF-12 scores and for menstrual bleeding scores (patients who underwent embolization only). The SF-12 scores were also analyzed on the basis of quartile to assess whether those scores that were in a given baseline quartile had an outcome that was different from those scores in other quartiles. Logistic regression analysis was used to determine whether uterine size, previous therapies, age, race, or treatment group predicted outcome for bulk symptoms. Linear regression was used to analyze whether those same baseline factors impacted the outcome for physical and mental summary SF-12 scores. The assessment of overall health status was analyzed with the Kruskal-Wallis test.

Complications were graded, and mean incidence values with exact confidence intervals were calculated. Logistic regression analysis was used to determine whether complications were predicted by any baseline characteristics. The analysis was completed for early complications (≤30 days), late complications (>30 days), and severity of complications on the basis of the SCVIR classification.

For all comparisons, a probability value of ≤.05 was considered to be statistically significant. All data was analyzed using SAS software (version 8; SAS Institute Inc, Cary NC).

Results

One hundred two patients were treated with embolization, and 50 patients were treated with hysterectomy. Table II presents the baseline demographic data and shows that there were significant differences between the 2 groups. Although there was no difference in age, patients who underwent embolization were more likely to have been black, to have had previous medical or surgical treatment for their leiomyomas, and to have had more numerous leiomyomas. The embolization group had a mean uterine volume nearly twice that of the hysterectomy group. Table III presents the symptom severity and questionnaire data for both groups. Although the baseline menorrhagia scores were similar between the 2 groups, patients who underwent embolization had lower mean hemoglobin levels and a greater likelihood of having moderately or extremely heavy bleeding by self-assessment.

The embolization procedure was of shorter duration than hysterectomy (mean embolization time, 57.9 minutes; mean hysterectomy time, 93.6 minutes; P < .001). The hysterectomy procedures included 40 abdominal hysterectomies, 2 laparoscopically assisted vaginal hysterectomies, and 8 laparoscopic hysterectomies. There were no total vaginal hysterectomies. The mean hospital stay was 0.83 days for embolization and 2.3 days for hysterectomy (P < .001), and patients who underwent
embolization returned to work in a shorter period of time (embolization [mean, 10.7 days] vs hysterectomy [mean, 32.5 days]; P < .001).

Hysterectomy controlled menstrual bleeding completely in all but 3 patients. These 3 patients had continued light cyclic menstrual bleeding after supracervical hysterectomy, which was presumed to be the result of retained endometrial tissue. The hysterectomy group had no further analysis of menstrual bleeding after the procedure because none of the menstrual measures in use had been validated in women without menstrual bleeding. The results for bleeding outcome for patients who underwent embolization are presented in Table IV. At 3 months, the mean percentage of reduction in pictorial blood loss score was 55.6% (paired data; P < .001), decreased from 435.6 to 161.1, which is within the normal range for this instrument. The reduction was maintained at 6 months (mean score, 140.6; 58.1% reduction;
The menorrhagia questionnaire had a similar proportional percent reduction in paired data at 3 months (46.8%; \(P < .001\)), 6 months (56.6%; \(P < .001\)), and 12 months (61.3%; \(P < .001\)). Repeated measures analysis of variance detected no baseline characteristics that influenced bleeding outcome but noted a significant trend toward improvement over time.

For symptoms other than menstrual bleeding at 6 months, there was no difference between the 2 groups in the proportion of patients with improvement in pelvic

### Table II  Demographic data

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Embolization</th>
<th>Hysterectomy</th>
<th>(P) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>102</td>
<td>50</td>
<td>.264 (Student (t) test)</td>
</tr>
<tr>
<td>Age (y)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>42.6 ± 4.0</td>
<td>41.6 ± 5.3</td>
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</tr>
<tr>
<td>Minimum/maximum</td>
<td>33/50</td>
<td>31/50</td>
<td></td>
</tr>
<tr>
<td>Ethnic origin (n)</td>
<td></td>
<td></td>
<td>.264 (Student (t) test)</td>
</tr>
<tr>
<td>Asian/Pacific Island</td>
<td>1 (1%)</td>
<td>2 (4%)</td>
<td>&lt;.001 (Fisher’s exact test)</td>
</tr>
<tr>
<td>Black</td>
<td>61 (60%)</td>
<td>9 (18%)</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>7 (7%)</td>
<td>8 (16%)</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>31 (30%)</td>
<td>31 (62%)</td>
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</tr>
<tr>
<td>Other</td>
<td>2 (2%)</td>
<td>0 (0%)</td>
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</tr>
<tr>
<td>Previous pregnancies (n)</td>
<td></td>
<td></td>
<td>.615 (chi-squared test)</td>
</tr>
<tr>
<td>0</td>
<td>19 (19%)</td>
<td>8 (16%)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>24 (24%)</td>
<td>9 (18%)</td>
<td></td>
</tr>
<tr>
<td>(≥2)</td>
<td>59 (58%)</td>
<td>33 (66%)</td>
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</tr>
<tr>
<td>Previous live births</td>
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<td>.025 (chi-squared test)</td>
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<td>0</td>
<td>44 (43%)</td>
<td>11 (22%)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>20 (20%)</td>
<td>10 (20%)</td>
<td></td>
</tr>
<tr>
<td>(≥2)</td>
<td>38 (37%)</td>
<td>29 (58%)</td>
<td></td>
</tr>
<tr>
<td>Previous leiomyoma treatment (n)</td>
<td></td>
<td></td>
<td>.308 (chi-squared test)</td>
</tr>
<tr>
<td>None</td>
<td>53 (52%)</td>
<td>35 (70%)</td>
<td></td>
</tr>
<tr>
<td>Gonadotropin-releasing hormone agonist</td>
<td>9 (9%)</td>
<td>2 (4%)</td>
<td>.341 (chi-squared test)</td>
</tr>
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<td>Oral contraceptive</td>
<td>25 (25%)</td>
<td>5 (10%)</td>
<td>.050 (chi-squared test)</td>
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<tr>
<td>Other hormone therapy</td>
<td>5 (5%)</td>
<td>5 (10%)</td>
<td>.298 (chi-squared test)</td>
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<tr>
<td>Myomectomy</td>
<td>19 (19%)</td>
<td>4 (8%)</td>
<td>.097 (chi-squared test)</td>
</tr>
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<td>Curettage</td>
<td>16 (16%)</td>
<td>1 (2%)</td>
<td>.012 (chi-squared test)</td>
</tr>
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<td>Hysteroscopy</td>
<td>13 (13%)</td>
<td>2 (4%)</td>
<td>.146 (chi-squared test)</td>
</tr>
<tr>
<td>Other invasive</td>
<td>5 (5%)</td>
<td>3 (6%)</td>
<td>.719 (chi-squared test)</td>
</tr>
<tr>
<td>Leiomyoma (n)</td>
<td></td>
<td></td>
<td>.021 (chi-squared test)</td>
</tr>
<tr>
<td>1</td>
<td>27 (26%)</td>
<td>20 (40%)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>33 (32%)</td>
<td>19 (38%)</td>
<td></td>
</tr>
<tr>
<td>(≥3)</td>
<td>42 (41%)</td>
<td>10 (20%)</td>
<td></td>
</tr>
<tr>
<td>No response</td>
<td>0 (0%)</td>
<td>1 (2%)</td>
<td></td>
</tr>
<tr>
<td>Uterine volume</td>
<td></td>
<td></td>
<td>&lt;.001 (Student (t) test)</td>
</tr>
<tr>
<td>N</td>
<td>100</td>
<td>47</td>
<td></td>
</tr>
<tr>
<td>Mean ± SD (mL)</td>
<td>689.4 ± 466.1</td>
<td>389.2 ± 521.2</td>
<td></td>
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<tr>
<td>Minimum/maximum (mL)</td>
<td>185.6/3076.3</td>
<td>91.8/3415.1</td>
<td></td>
</tr>
<tr>
<td>Dominant leiomyoma volume</td>
<td></td>
<td></td>
<td>.330 (Student (t) test)</td>
</tr>
<tr>
<td>N</td>
<td>93</td>
<td>42</td>
<td></td>
</tr>
<tr>
<td>Mean ± SD (mL)</td>
<td>146.8 ± 158.5</td>
<td>90.6 ± 354.8</td>
<td></td>
</tr>
<tr>
<td>Minimum/maximum (mL)</td>
<td>5.1/776.8</td>
<td>3.2/2322.3</td>
<td></td>
</tr>
<tr>
<td>Type of dominant leiomyoma (n)*</td>
<td></td>
<td></td>
<td>.072 (Fisher’s exact test)</td>
</tr>
<tr>
<td>Intramural</td>
<td>61 (60%)</td>
<td>32 (64%)</td>
<td>.724 (chi-squared test)</td>
</tr>
<tr>
<td>Subserosal</td>
<td>19 (19%)</td>
<td>8 (16%)</td>
<td>.823 (chi-squared test)</td>
</tr>
<tr>
<td>Submucosal</td>
<td>17 (17%)</td>
<td>13 (26%)</td>
<td>.197 (chi-squared test)</td>
</tr>
<tr>
<td>Transmural</td>
<td>11 (11%)</td>
<td>1 (2%)</td>
<td>.108 (chi-squared test)</td>
</tr>
<tr>
<td>Pedunculated</td>
<td>2 (2%)</td>
<td>4 (8%)</td>
<td>.072 (Fisher’s exact test)</td>
</tr>
</tbody>
</table>

* More than 1 type indicated for some patients.
pain (embolization [83%] vs hysterectomy [88%]; $P = .478$), pelvic discomfort (embolization [80%] vs hysterectomy [80%]; $P = 1.0$), or urinary dysfunction (embolization [75%] vs hysterectomy [73%]; $P = .841$). By 12 months after treatment, a greater proportion of patients who had hysterectomy had improved pelvic pain (embolization [84%] vs hysterectomy [98%]; $P = .021$).

There was a trend toward a greater proportion of patients who underwent hysterectomy having improved pelvic pressure (embolization [83%] vs hysterectomy [95%]; $P = .055$). There was no difference in urinary symptoms (embolization [80%] vs hysterectomy [79%]; $P = .819$) at 12 months. Logistic regression analysis of the impact of baseline characteristics on the outcome detected no characteristics that influenced outcome for pelvic pain, pelvic pressure, or urinary dysfunction.

Table V presents the data from the SF-12 quality of life questionnaire. Both procedures demonstrate marked improvement in both physical and mental summary scores, with no differences in the mean values for embolization or hysterectomy scores at any of the follow-up intervals. Quartile analysis of these scores also did not show any difference between the 2 therapies. For both, the SF-12 scores had greater improvement among patients in the quartile with the lowest baseline score; with each higher quartile, the degree of change from baseline to 6 months decreased. Thus, the group with the highest baseline scores had the least degree of change at 6 months.

Both procedures also improved patient self-assessment of overall health status. With paired data, the mean value for embolization rose from 71.1 to 83.6; the baseline mean value (67.5) for hysterectomy increased to 86.1. Both of these changes are statistically significant and were maintained at the 6-month and 12-month intervals. Neither procedure had an advantage in overall health self-assessment when compared with the other at 3 months ($P = 0-.26$), 6 months
(P = 0.52), or 12 months (P = 0.67) with the Kruskal-Wallis test.

For the embolization group, mean uterine volume decreased by 26% (paired data; P < .001) at 3 months and 33.1% (paired data; P < .001) at 6 months. The dominant leiomyoma volume decreased by a mean of 45.8% (paired data; P < .001) at 3 months and by a mean of 54.0% (paired data; P < .001) at 6 months. Imaging was not done at the 12-month interval.

Regardless of therapy, most patients were moderately or very satisfied with the symptom outcome (embolization [89%] vs hysterectomy [94%] at 3 months; embolization [88%] vs hysterectomy [94%] at 6 months, and embolization [90%] vs hysterectomy [97%] at 12 months). None of these differences were statistically significant.

Complications were substantially more likely to occur in the patients who underwent hysterectomy than patients who underwent embolization. Among the 102 patients who underwent embolization, 28 patients had at least 1 complication (27.5%; 95% CI, 19.1, 37.2); 25 of 50 patients who underwent hysterectomy had at least 1 complication (50%; 95% CI, 35.5, 64.5; P = .01). The most common complication in either group during the 1-year follow-up interval was vaginitis (5% in patients who underwent embolization; 10% of patients who underwent hysterectomy; P = .30); most complications were minor, such as drug reactions or urinary tract infections. There was no difference in the frequency of complications within 30 days of the procedure (17.6% for embolization; 28% for hysterectomy; P = .15).

However, complications that occurred after 30 days were significantly higher for patients who underwent hysterectomy (32% vs 12.7%; P = .01). The severity of complications by SCVIR class is provided in the upper portion of Table I. There were no deaths and few serious complications in either group, but among the more severe complications (classes C, D, E, and F), there was a trend toward greater frequency among patients who underwent hysterectomy compared with patients who underwent embolization (12% vs 3.9%; P = .08). When complications that fit ACOG descriptors were compared, overall morbidity for the hysterectomy group was greater than the embolization group (34% vs 14.7%; P = .01).

The most serious complications among the patients who underwent hysterectomy were pneumonia, bowel injury, vaginal cuff herniation, and recurrent bleeding from the vaginal stump. The latter 3 complications required reoperation. One patient was readmitted for 3 days for dehydration (class D), and another patient required evaluation with colonoscopy on 2 occasions for possible bowel obstruction. For the patients who underwent embolization, there were 4 episodes of leiomyoma passage that occurred in 3 patients who underwent embolization in the follow-up interval. Only 1 patient required intervention, initially curettage, but followed by a hysterectomy 3 weeks later after recurrence. This was the only hysterectomy for a complication among the patients who underwent embolization. There were 2 other SCVIR class C complications in the embolization group: 1 patient with an emergency room visit for

<table>
<thead>
<tr>
<th>Table IV</th>
<th>Bleeding outcome for patients who underwent embolization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pictorial blood loss assessment score (paired data)*</td>
<td>Pretreatment 3-Mo follow up Reduction: Pretreatment to 3 mo (%) 6-Mo follow up Reduction: Pretreatment to 6 mo (%) 12-Mo follow up Reduction: Pretreatment to 12 mo (%)</td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>435.6 ± 286.5 161.1 ± 133.3</td>
</tr>
<tr>
<td>Minimum/maximum (paired Student t test)</td>
<td>150-1777 9-830</td>
</tr>
<tr>
<td>Menorrhagia questionnaire score (paired data)†</td>
<td>47.2 ± 13.8 23.3 ± 11.2</td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>143.8/33.3 7.1/61.9</td>
</tr>
<tr>
<td>Minimum/maximum (paired Student t test)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>P value (sign test)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

* N=76. † N=68.
nausea and 1 patient for whom the embolization initially failed and who was readmitted for re-embolization, which was ultimately successful.

Among patients who underwent embolization, 6 patients (age range, 38-48 years) had not had a menstrual period by 3 months after the procedure. Of these, all patients resumed menstrual cycles, except 1 patient (age, 46 years) who had persisting amenorrhea at 1 year after treatment. At 12 months, an additional 6 patients (age range, 45-47 years) had amenorrhea.

Baseline variables (other than treatment) did not predict the frequency of minor complications within 30 days of the procedure or major complications during the entire follow-up period. These results are presented in Table VI. Both older age \((P = .014)\) and the absence of previous leiomyoma therapies \((P = .030)\) predicted a greater likelihood of minor complications that occurred after 30 days.

Similarly, linear regression of SF-12 scores at 6 months after therapy did not identify any baseline factors that predicted better outcome other than baseline SF-12 physical and mental summary scores. Thus, a higher baseline SF-12 score predicted a higher score 6 months after therapy.

**Comment**

Although numerous case series are now available that report the outcome from embolization, it is important for any intervention to be evaluated in the context of other accepted therapies. This study was intended to assess embolization in the context of hysterectomy, which is the definitive therapy for leiomyomas. We chose to estimate the outcomes in 2 groups of patients who underwent either embolization or hysterectomy in the same

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**Table V** SF-12 scores, physical, and mental/embolization and hysterectomy (paired data)

<table>
<thead>
<tr>
<th></th>
<th>Pretreatment</th>
<th>3 Mo follow up</th>
<th>Increase: Pretreatment to 3 mo (%)</th>
<th>6-Mo follow up</th>
<th>Increase: Pretreatment to 6 mo (%)</th>
<th>12-Mo follow up</th>
<th>Increase: Pretreatment to 12 mo (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Embolization</strong> SF-12 score (physical)*</td>
<td>Mean ± SD</td>
<td>Minimum/maximum</td>
<td>P value</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>45.1 ± 8.2</td>
<td>26.0/61.6</td>
<td>−29.7/111.1</td>
<td>19.5 ± 25.6</td>
<td>32.9/62.6</td>
<td>22.3 ± 25.7</td>
<td>23.1/64.1</td>
</tr>
<tr>
<td>Minimum/maximum</td>
<td>52.3 ± 6.0</td>
<td>22.3/58.5</td>
<td></td>
<td>53.4 ± 5.0</td>
<td>29.1/95.5</td>
<td>53.6 ± 6.1</td>
<td>23.1/95.5</td>
</tr>
</tbody>
</table>

**Hysterectomy** SF-12 score (physical)** | Mean ± SD    | Minimum/maximum | P value                           |               |                                  |                |                                  |
| Mean ± SD           | 43.0 ± 9.9   | 25.8/66.2       | −18.0/72.2                        | 22.3 ± 25.6   | 29.5/60.2                        | 26.0 ± 34.0   | 30.5/57.7                        | 25.4 ± 32.7   |
| Minimum/maximum     | 50.7 ± 6.6   | 36.7/62.1       |                                   | 51.6 ± 7.5    | 39.0/100.5                       | 51.4 ± 6.9    | 36.6/94.1                        | 36.4/94.1     |

**SF-12 score (mental)** | Mean ± SD    | Minimum/maximum | P value                           |               |                                  |                |                                  |
| Mean ± SD           | 40.6 ± 11.1  | 19.6/55.9       | −31.7/170.5                       | 38.4 ± 52.8   | 17.9/62.1                        | 32.3 ± 51.3   | 23.5/62.3                        | 39.1 ± 60.2   |
| Minimum/maximum     | 51.7 ± 10.5  | 21.6/62.9       |                                   | 49.7 ± 11.8   | 17.9/62.1                        | 51.1 ± 11.2   | 46.3/217.4                       | 46.3/217.4    |

* N = 76.  
** N = 30.
time interval, using the same baseline and outcome measures. The intent was to obtain contemporaneous data that might be useful in putting the safety and effectiveness of each therapy in the context of the outcomes of the other. In addition, we attempted to estimate the effectiveness of embolization in controlling menorrhagia using standard measures of menstrual bleeding.

Clearly, control of menstrual bleeding is self-evident after hysterectomy, despite the occasional patient with continued light bleeding after supracervical hysterectomy. If the goal of therapy is to stop menstrual bleeding, then hysterectomy is effective. However, the intent of uterine embolization is not to stop menstrual bleeding but to normalize it. Thus in this particular aspect of outcome, these procedures cannot be compared easily. We focused rather on attempting to measure the degree of bleeding after embolization using the validated measures that are available. The bleeding scores for both the menorrhagia questionnaire and the blood loss chart of the patients who underwent embolization revealed a marked improvement on average.

Neither procedure had a short-term advantage in controlling pelvic pain, discomfort, or urinary frequency. By 12 months after treatment, pelvic pain was improved more likely with hysterectomy, and there was a trend in the same direction for pelvic pressure, yet >80% of patients who were treated with embolization were improved in these symptoms. With the use of broader means to assess health status, health-related quality of life and patient self-assessment of health status showed dramatic improvements for patients who were treated with both therapies, with no difference detected in the degree of improvement. Patient satisfaction also did not differ between the 2 groups.

Analysis of baseline factors by logistic regression did not predict complications other than the type of therapy. Linear regression of quality of life scores also did not identify any baseline factors (other than baseline HR quality of life scores) to explain the improvement at 6 months. Those patients with better baseline scores were more likely to have better scores at 6 months. At the same time, the quartile analysis of these scores revealed that patients with lower scores at baseline were more likely to have a larger improvement than patients with higher scores. This can be explained when one considers that patients with very severe symptoms at baseline had tremendous improvement but still were less likely to have a very high score after therapy than patients with high score to start. This held true whether the therapy was embolization or hysterectomy.

The embolic material that was used in this series of patients has been reported to be effective in the past in smaller studies. The FDA cleared it for use in the treatment of hypervascular tumors and arteriovenous malformations in 2000. This study confirms the clinical effectiveness of embolization with this material; the FDA cleared the use of Embosphere microspheres in November 2002 for uterine embolization for leiomyomas, in part on the basis of the data presented here.

In this study, there were few severe complications, none of which was life-threatening. However, complications were significantly more likely to occur in the hysterectomy group, which perhaps reflects the more extensive nature of the procedure. The morbidity rates that we reported are very similar to those rates that were reported previously after embolization and hysterectomy.18

The results of this study should be interpreted with caution, because its power to detect differences between the groups is not known. It is possible that differences could be detected with a larger sample size. This study was also not intended to determine the long-term sequelae of either procedure. For example, for patients who underwent embolization, we did not study the likelihood of leiomyoma recurrence, the development of new leiomyomas, or the impact of other uterine diseases on those patients who did not undergo hysterectomy. Similarly, potential late sequelae of hysterectomy were also not examined. Further study is also needed to compare embolization to other uterine-sparing therapies, such as myomectomy.

Although it appears self-evident that the goal of stopping menstrual bleeding is better achieved with hysterectomy, menstrual bleeding is improved markedly in most patients after uterine embolization. On the basis of the data presented, both uterine embolization and hysterectomy improved nonbleeding symptoms for most patients, with patients who underwent hysterectomy more likely to have improved pelvic pain at 12 months. Although patients who underwent embolization had fewer complications, serious complications are rare with either procedure.

Table VI Results of logistic regression of perioperative complications that were based on baseline variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Parameter estimate</th>
<th>SE</th>
<th>P value</th>
<th>Odds ratio</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment group</td>
<td>0.149</td>
<td>0.262</td>
<td>0.570</td>
<td>1.347</td>
<td>0.482 - 3.767</td>
</tr>
<tr>
<td>Uterine volume</td>
<td>-0.001</td>
<td>0.001</td>
<td>0.302</td>
<td>0.999</td>
<td>0.998 - 1.001</td>
</tr>
<tr>
<td>Previous therapies</td>
<td>-0.321</td>
<td>0.461</td>
<td>0.486</td>
<td>0.725</td>
<td>0.294 - 1.792</td>
</tr>
<tr>
<td>Age</td>
<td>0.025</td>
<td>0.049</td>
<td>0.618</td>
<td>1.025</td>
<td>0.930 - 1.129</td>
</tr>
<tr>
<td>Race</td>
<td>-0.595</td>
<td>0.498</td>
<td>0.232</td>
<td>0.552</td>
<td>0.208 - 1.464</td>
</tr>
</tbody>
</table>
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References