Incidence and Risk Factors for Clinical Failure of Uterine Leiomyoma Embolization

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OBJECTIVE: To estimate the incidence of clinical failure after uterine leiomyoma embolization and identify possible risk factors.

METHODS: One hundred seventy-six consecutive women undergoing uterine leiomyoma embolization were followed prospectively for a median of 48 months (range 12–84 months) to estimate the occurrence of clinical failure, defined as persistence or recurrence of leiomyoma symptoms, and any subsequent invasive treatment. Cumulative failure and reintervention rates were estimated by survival analysis and log-rank tests according to baseline patient characteristics. Multivariable Cox proportional hazards analysis was performed to adjust for confounders.

RESULTS: Overall, there were 18 failures at a median of 36 months (range 3–84 months). The cumulative failure rate increased steadily over time, 3% at 1 year, 7% at 3 years, 14% at 5 years, and 18% at 7 years. Of the 18 failures, 11 had reintervention, including six hysterectomies, four myomectomies, and one repeat uterine leiomyoma embolization, at a median of 56 months (range 15–84 months). The cumulative reintervention rate was 0 at 1 year, 3% at 3 years, 7% at 5 years, and 15% at 7 years. Women aged 40 years or younger had a higher failure risk (hazard ratio [HR] 5.89, 95% confidence interval [CI] 2.50–20.02, P=.023) compared with older women. A history of previous myomectomy was also associated with an increased failure risk (HR 3.79, 95% CI 2.07–13.23, P=.037).

CONCLUSION: The 7-year cumulative rates of clinical failure and reintervention after uterine leiomyoma embolization were 18% (95% CI 8.2–27.8) and 15% (95% CI 5.2–24.8), respectively. The failure risk was higher for younger patients and for those with a prior myomectomy.

LEVEL OF EVIDENCE: III

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Uterine leiomyoma embolization is now an established alternative to hysterectomy and myomectomy for treating symptomatic uterine leiomyomas. Several large series demonstrated rates of symptom control ranging from 85% to 95% at short- and midterm follow-up.[1–4] Nevertheless, the reported incidence of failure of symptom control, and therefore the need for additional therapy, ranges from 9% to 23% after approximately 2 years.[5–8] Longer-term studies with follow-up periods ranging from 3 to 6 years reported treatment failure and subsequent invasive treatment in 13–28% of patients.[3,9–17]

The currently available data regarding the effect of baseline patients' characteristics on the likelihood of failure after leiomyoma embolization are relatively few and inconsistent.[5,7–8,11–12,14,18–21] In particular, no previous long-term studies have prospectively assessed the incidence of treatment failure in relation to demographic, anthropometric, and health characteristics at the time of treatment. If specific risk factors for failure can be identified for women considering uterine leiomyoma embolization compared with surgery, a better informed choice could be made.

The aim of this long-term prospective study was to estimate the incidence of failure after uterine leiomyoma embolization in relation to baseline variables in a cohort of women undergoing the procedure at our institution.

MATERIALS AND METHODS

The study included 176 consecutive women treated with uterine leiomyoma embolization between Janu-

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ary 2001 and December 2010. All were first seen at the local outpatient gynecology clinic and referred by the attending gynecologist based on the following criteria: 1) clinical and ultrasonographic diagnosis of single or multiple uterine leiomyomas; 2) leiomyoma-related symptoms (menorrhagia, bulk-related symptoms, pain) severe enough to warrant major surgery (hysterectomy or abdominal myomectomy); and 3) women wishing to avoid surgery.

As part of our multidisciplinary team approach, all potential candidates for the procedure were thoroughly evaluated by a gynecologist experienced with this treatment modality before consultation with the interventional radiologist. Gynecologic assessment included a Pap smear, cervical cultures for sexually transmitted diseases, evaluation for bacterial vaginosis and trichomonas, and diagnostic hysteroscopy with endometrial biopsy.

Exclusion criteria were submucosal leiomyomas suitable for hysteroscopic resection, pedunculated subserosal leiomyomas with a stalk less than 50% of the maximal leiomyoma diameter, desire to improve fertility, suspected pelvic malignancy, any active pelvic infection, coexisting tubo-ovarian pathology, diffuse adenomyosis, and gonadotropin-releasing hormone agonist therapy during the 6 months preceding the enrollment. There were no exclusions by uterus size or number of leiomyomas.

Patients were counseled by the gynecologist and interventional radiologist about the possible risks and complications of, and alternatives to, the procedure. Each patient gave written informed consent and volunteered to participate in the follow-up examinations. The study was approved by the institutional review board of the Catholic University of Sacred Heart (Rome, Italy).

Baseline demographic, anthropometric, and health characteristics were recorded for each patient. Presenting symptoms were recorded using a self-administered written questionnaire that inquired about the nature and severity (mild, moderate, severe) of symptoms. Each patient had a transabdominal and transvaginal Doppler ultrasonography. All scans were performed by a single, highly experienced ultrasound operator using Esaote Technos equipment with color and power Doppler capability. Abdominal probes were 3.5 mHz. Transvaginal probes were 5.0 to 9.0 mHz. Dimensions of the uterus, number of leiomyomas, and dimensions, location, and degree of vascularity (marked, moderate, or absent) of the largest (dominant) leiomyoma were estimated. Uterine and dominant leiomyoma volumes were calculated using the formula for a prolate ellipse (width×length×depth×0.5233). If further information about leiomyoma location, size, number, and vascularity was required, magnetic resonance imaging was performed.

All procedures were performed by one interventional radiologist in a standardized fashion.[22–24] Polyvinyl alcohol particles (Contour) sized 355–500 micrometers were used in all cases. Only if an anastomosis with the ovarian artery was observed were 500–700 micrometers polyvinyl alcohol particles used to prevent migration of particles into the ovarian artery. The embolization end point was occlusion of the perileiomyoma plexus with sluggish flow remaining in the main uterine artery. No ovarian arteries were embolized. The postprocedural care protocol has been described previously.[22–24]

Follow-up included clinical and ultrasonographic examinations at 1, 3, 6, 12 ,18, and 24 months and then yearly up to 7 years after embolization. At each interval, uterine volume and the volume, location, and vascularity of the dominant leiomyoma were established using the same ultrasonographic methods as used before treatment. The same operator performed all preprocedural and postprocedural scans during the study period. Throughout follow-up, each patient was always examined by the same gynecologist who also administered a written questionnaire concerning changes in leiomyoma symptoms compared with baseline. Symptom change was categorized as worsened, unchanged, slightly improved, markedly improved, or resolved. Any recurrence of initially controlled symptoms was recorded. If a woman reported no change or worsening of symptoms or return of initially controlled symptoms, she was defined a clinical failure, and treatment options were discussed, including medical, surgical, and interventional techniques. Patients were censored when they had an additional invasive procedure (hysterectomy, myomectomy, or repeat uterine leiomyoma embolization) for unresolved leiomyoma symptoms or at the time of the last available follow-up. Interventions done for indications other than leiomyomas were not counted as clinical failures.

The primary outcome measure was the cumulative failure rate in relation to baseline variables. Secondary outcome was the cumulative rate of surgical or endovascular reintervention.

Data were analyzed using SPSS 17.0 statistical software. Quantitative and qualitative data were expressed as means, standard deviations, medians, and ranges and as frequency and percentage, respectively. Cumulative rates of treatment failure and reintervention were estimated by Kaplan-Meier survival analysis and compared

by log-rank tests according to baseline variables. The variables evaluated were: age, body mass index, parity, smoking status, medical comorbidity (cardiovascular, respiratory, thyroid, diabetes, other), previous medical treatment (any form), previous gonadotropin-releasing hormone agonist therapy, previous myomectomy (abdominal, laparoscopic, hysteroscopic), leiomyoma symptoms, uterine volume, number of leiomyomas, dominant leiomyoma volume and location (subserosal, intramural-subserosal, intramural-submucosal, or intramural), and concomitant adenomyosis. Subgroups for each variable were determined by category for categoric variables and by the median value for numerical variables. Cox regression (full model) analysis of possible predictors for failure followed by a stepwise variable selection was performed to adjust for confounders. A probability value of less than 5% ($P<.05$) was considered statistically significant.

Table 1. Baseline Patient Characteristics

Characteristic	Success Group (n=158)	Failure Group (n=18)
Age at procedure (y)		
Younger than 35	10	4
35–39	23	5
40–44	45	6
45–49	55	3
50 or older	25	0
Body mass index (kg/m^2)		
Lower than 20	20	0
20–24	90	13
25–29	39	3
30 or higher	9	2
Parity		
0	68	10
1 or more	90	8
Smoking status		
Former or current smoker	92	11
Never smoker	66	7
Medical comorbidity		
Yes	34	1
No	124	17
Concomitant adenomyosis		
Yes	7	4
No	151	14
Previous medical therapy		
Any form	67	9
Gonadotropin-releasing hormone agonist	22	7
Previous surgical treatment		
Hysteroscopic myomectomy	20	2
Laparoscopic myomectomy	3	0
Laparotomic myomectomy	20	8
Presenting symptoms		
Menorrhagia	138	16
Pain	115	12
Bulk-related complaints	133	15
Iron deficiency anemia	64	7
Number of leiomyomas		
1	43	4
2–4	63	8
5 or more	52	6
Location of the dominant leiomyoma		
Subserosal	13	2
Intramural–subserosal	38	6
Intramural–submucosal	26	2
Transmural	81	8
Dominant leiomyoma volume (cm^3)	114.75 (10.20–1, 456.0)	167.45 (23.06–509.50)
Uterine volume (cm^3)	282.90 (70.57–3, 142.0)	355.45 (85.80–1, 369.0)

Data are n or median (range).

RESULTS

The median age of the study population was 43.5 years (range 26.1–53.4 years), and median body mass index (calculated as weight (kg)/[height (m)]^2) was 23.0 (range 18–38). All women were white and premenopausal. Most of them (86.4%) had multiple symptoms, 11 (6.2%) presented with menorrhagia alone, 10 (5.7%) with only bulk-related symptoms, and two (1.1%) with pelvic pain alone. The median number of leiomyomas was three (range 1–20). All leiomyomas were markedly or moderately vascular on preprocedural Doppler ultrasonography.

Embolization was performed bilaterally in 175 women and unilaterally in one woman because of aplasia of one uterine artery. There were no intraprocedural or postprocedural complications.

Patients were followed for a median of 48 months (range 12–84 months). All had at least 1 year of follow-up, 102 (57.9%) had at least 3 years follow-up, and 56 (31.8%) had more than 6 years follow-up. Three patients (1.7%) of the original cohort were lost to follow-up over the study period: one died of pre-existing cardiomyopathy at 65 months and the other two refused to continue participation after the 36-month visit. All three patients were symptom-free at their last available follow-up.

Of the total 176 patients treated, 158 had relief from their leiomyoma symptoms (success group), whereas 18 others experienced treatment failure (failure group). The baseline characteristics of the two groups are summarized in Table 1. All failures were women who experienced return of initially controlled leiomyoma symptoms after a median of 36 months (range 3–84 months), resulting in a cumulative failure rate according to Kaplan-Meier analysis of 18% (95% confidence interval [CI] 8.2–27.8) after 7 years (Fig. 1). Recurrent symptoms were menorrhagia alone in nine women, bulk-related symptoms alone in one, pelvic pain alone in one, and multiple symptoms in seven. Imaging follow-up showed: 1) reappearance of leiomyoma vascularity and subsequent leiomyoma regrowth despite an initial reduction in volume in four patients who had failure by 1 year, of whom one was the single patient having unilateral embolization, and in three failures occurring during the second year; 2) progressive uterine and leiomyoma volume reduction with no evidence of leiomyoma perfusion in one failure occurring within 1 year and in 3 failures occurring between 3 and 5 years; and 3) presence of new leiomyomas (six submucosal and one intramural), 2–5 cm in diameter, in seven women who had failure between 5 and 7 years.

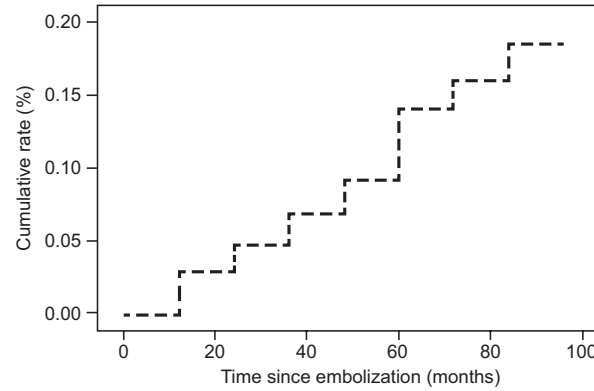

Fig. 1. Cumulative failure rate after uterine leiomyoma embolization.

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Univariable analysis revealed age 40 years or younger (P=.001), previous abdominal myomectomy (P=.001), and prior gonadotropin-releasing hormone agonist therapy (P=.033) as significant risk factors for failure (Table 2). After controlling for confounding factors in multivariable analysis, only being aged 40 years or younger (hazard ratio 5.89, 95% CI 2.50–20.02, P=.023) and a history of previous myomectomy (hazard ratio 3.79, 95% CI 2.07–13.23, P=.037) remained significant predictors of failure. The difference in mean age between women who had failure (38.2±5.1 years) or did not fail uterine leiomyoma embolization (43.4±5.7 years) was significant (P<.001).

Of the 18 failures, 11 underwent reintervention after a median of 56 months (range 15–84 months), resulting in a cumulative rate of 15% (95% CI 5.2–24.8) after 7 years (Fig. 2). Details of reinterventions are shown in Table 3. No unexpected pathology was found on postsurgical histopathology; the four patients with histopathologic findings of concomitant adenomyosis had this condition detected preprocedurally.

Of the 18 patients in the failure group, nine had additional hormonal therapy (oral progestins or estroprogestins, levonorgestrel intrauterine device) to deal with recurrent leiomyoma symptoms. In this subgroup, three ended up having surgery after failed hormonal therapy and were included in the reintervention analysis. One patient, who was treated at age 47 years and reported recurrent pain after 3 years, declined any further treatment because of her impending menopause. Over the follow-up period, 42 (23.9%) patients entered menopause. Median time to menopause was 26 months (range 4–84 months), and the median menopausal age was 50.5 years (range 45–56 years).

Table 2. Risk Factors for Clinical Failure After Uterine Leiomyoma Embolization

Variable	No. of Patients	No. of Failures	*P*	χ^2
Age at procedure (y)				
40 or younger	46	10	.001	10.907
Older than 40	130	8		
Body mass index (kg/m^2)				
Lower than 25	123	13	.664	0.182
25 or higher	53	5		
Parity				
0	78	10	.495	1.462
1 or more	98	8		
Smokers				
No	73	7	.792	0.070
Yes	103	11		
Medical comorbidity				
No	141	17	.120	2.429
Yes	35	1		
Ultrasonography-diagnosed concomitant adenomyosis				
No	165	14	.514	0.410
Yes	11	4		
Previous medical therapy (any form)				
No	100	9	.797	0.071
Yes	76	9		
Previous gonadotropin-releasing hormone agonist treatment				
No	147	11	.033	4.377
Yes	29	7		
Previous abdominal myomectomy				
No	148	10	.001	10.290
Yes	28	8		
Previous hysteroscopic myomectomy				
No	154	16	.812	0.060
Yes	22	2		
Menorrhagia				
No	22	2	.643	0.227
Yes	154	16		
Pelvic pain				
No	49	6	.723	0.128
Yes	127	12		
Bulk-related symptoms				
No	28	3	.695	0.161
Yes	148	15		
Number of leiomyomas				
1	47	4		
2–4	71	8	.911	0.186
5 or more	58	6		
Location of dominant leiomyoma				
Subserosal	15	2		
Intramural–subserosal	44	6	.486	1.527
Intramural–submucosal	28	2		
Transmural	89	8		
Dominant leiomyoma volume (cm^3)				
Less than 218	88	12	.186	1.707
218 or greater	88	6		
Uterine volume (cm^3)				
287 or less	88	6	.241	1.331
Greater than 287	88	12		

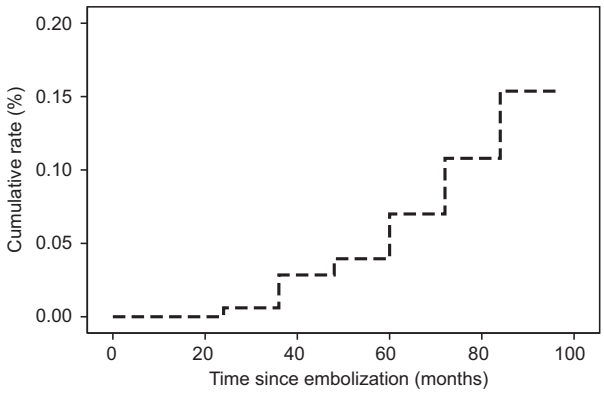

Fig. 2. Cumulative reintervention rate after uterine leiomyoma embolization.

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DISCUSSION

In this long-term prospective study of a large cohort of women undergoing uterine leiomyoma embolization, we estimated the probability of treatment failure in relation to baseline variables. Because the primary indication for leiomyoma treatment is the symptoms they cause, we chose to define failure of uterine leiomyoma embolization based on the patient's subjective assessment of persistence or recurrence of the original leiomyoma symptoms.

Results indicate that the 7-year cumulative rates of treatment failure and reintervention were 18% and 15%, respectively. We also identified age 40 years or younger and a history of prior myomectomy at baseline as factors associated with the failure risk.

The rate of short-, mid-, and long-term failure of uterine leiomyoma embolization in our study was lower than results from earlier long-term studies,[3,9–17] which reported failure rates ranging from 4.2%[9] to 10.5%[6] at 1 year, from 6.5%[9] to 23.5%[7] at 2 years, from 12.7%[9] to 14.4%[12] at 3 years, and from 12.7%[9] to 28.4%[15] over the course of 5 years.

The inherent difficulty in quantification of leiomyoma-related disease and individual study variations in length of follow-up and definition of treatment failure (symptom persistence, or recurrence, or need for additional surgery) make results difficult to compare between different study cohorts. We do believe, however, there are additional explanations for our results differing from those of others. First, in contrast to other studies that were retrospective[11,13] with follow-up data obtained by chart reviews, mailed questionnaires, or telephone interviews, our study was prospective with outcome data gathered by systematic clinical and ultrasonographic evaluation. This allowed us to determine the exact timing of failures and reinterventions together with the reasons for interventions. Second, while most previous studies reported only crude failure rates,[3,10,14,15] our study accounted for disparity in length of follow-up by analyzing the cumulative probability of failure calculated by survival analysis. Third, our technical failure rate, with bilateral embolization not performed in only one patient, was much lower than in earlier trials reporting lower success rates.[11,15] Finally, while in most earlier studies preprocedure patient selection was mainly based on imaging findings and clinical outcomes were assessed only by means of returned questionnaires or telephone interviews,[3,9,12,14,16,17] in our study, screening and selection of patients and long-term monitoring of clinical outcomes were per-

Table 3. Reinterventions by Time Since Uterine Leiomyoma Embolization and Indications

Patient Age (y)	Time to Failure (mo)	Type of Reintervention	Time to Reintervention (mo)	Indication for Reintervention	Pathology Report
35	3	Hysterectomy	60	Recurrent menorrhagia, pain, and bulk symptoms	Coexisting adenomyosis
44	6	Hysterectomy	32	Recurrent menorrhagia	Coexisting adenomyosis
40	12	Myomectomy	25	Recurrent menorrhagia	Coexisting adenomyosis
46	12	Hysterectomy	15	Recurrent menorrhagia and pain	Coexisting adenomyosis
26	24	Myomectomy	33	Recurrent menorrhagia	Leiomyoma
36	36	Myomectomy	46	Recurrent menorrhagia	Leiomyoma
34	36	Uterine leiomyoma embolization	80	Recurrent menorrhagia	—
35	43	Hysterectomy	84	Recurrent menorrhagia	Leiomyomas
35	48	Hysterectomy	72	Recurrent bulk symptoms	Leiomyomas
43	50	Myomectomy	56	Recurrent menorrhagia and bulk symptoms	Leiomyoma
33	60	Hysterectomy	72	Recurrent menorrhagia	Leiomyomas

formed by an experienced gynecologist. This might have contributed to prevent failures related to a wrong clinical indication (undiagnosed additional endometrial, tubo-ovarian, or pelvic pathology)[7,11,18,19] or an inadequate assessment of causes other than leiomyomas for symptoms that may occur after embolization.[4,5,9]

Development of new leiomyomas, regrowth of incompletely infarcted leiomyomas, and concurrent adenomyosis all have been reported as potential causes of treatment failure.[18,25,26] In line with these reports, seven (38.8%) failures in our study had ultrasonographically detected new leiomyomas, and seven (38.8%) exhibited reappearance of leiomyoma perfusion and subsequent leiomyoma regrowth, suggesting insufficient initial devascularization. Additionally, four of the seven women with evidence of leiomyoma regrowth had a preprocedural diagnosis of coexisting adenomyosis, which was subsequently confirmed by postsurgical histopathology. It is noteworthy, however, that we were unable to identify a likely cause for four (22.2%) failures. These patients had clinical failure despite a technically successful procedure and the evidence of progressive leiomyoma shrinkage on serial ultrasonographic scans. A possible explanation is that, as noted by others,[7,27] reduction in leiomyoma volumes after uterine leiomyoma embolization does not necessarily correlate with symptom improvement. However, the possibility that our imaging modality was not accurate enough in detecting underlying causes of failure such as residual leiomyoma perfusion or undiagnosed adenomyosis[26,28] cannot be ruled out.

In this study, women aged 40 years or younger appeared to be six times more likely to fail embolization than older patients. This finding contrasts with results from most earlier reports[5,7,11,12,14,18–21] but agrees with the findings of previous studies on abdominal myomectomy.[29–31] The relationship between age and failure risk might be related to the underlying biology: women presenting clinically significant leiomyomas at a young age are probably more at risk than the others of having a more active leiomyoma disease and thus recurrence after embolization as well as after myomectomy. An alternative explanation is that younger patients have more time until menopause to fail uterine leiomyoma embolization.

We also found that women with a history of prior myomectomy were 3.9 times more likely to fail treatment than those without such a history. This was the opposite relationship from that reported in an earlier study[32] but was consistent with others.[5,33] A possible explanation is that a history of prior myomectomy means that the myometrial disease is more aggressive. Alternatively, considering the greater frequency of ovarian artery collateral supply to leiomyomas reported in women who have undergone prior pelvic surgery,[34] one can speculate that this patient subgroup may be at higher risk of incomplete embolization.

There are limitations to this study. First, the number of failures after uterine leiomyoma embolization was small. This led to wide CIs for the estimates of Cox regression analysis. However, even the lower bound of the CIs predicted an approximately twofold higher failure risk for patients aged 40 years or younger and those with prior myomectomy. Using a larger number of patients could possibly narrow the CIs. Second, our study population did not include black women, who are known to be at particularly high risk for leiomyomas compared with white women.[35] Thus, if black women were involved in our study, different outcomes might have been observed. Third, there is no clear consensus about the most effective embolic agents to use in uterine leiomyoma embolization.[36] In our study, polyvinyl alcohol particles were used. Perhaps the use of other embolic agents may result in different results.

In conclusion, this study adds evidence that uterine leiomyoma embolization is quite effective even in the long term with a relatively low cumulative probability of failure by 7 years. The key finding in this study is that patient age and gynecologic history must be considered in clinical decision-making. It is important to discuss with younger women and with those with a history of myomectomy the higher risk of treatment failure. These subgroups of patients may find it an acceptable risk, particularly if they want to avoid, or have previously failed, surgery.

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