MP 4.01.12  Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids

Medical Policy

Section  
OB/Gyn/Reproduction

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Description

Uterine fibroids are one of the most common conditions affecting women in the reproductive years; symptoms include menorrhagia, pelvic pressure, or pain. Hysterectomy and various myomectomy procedures are considered the gold standard treatment. However, there has been longstanding research interest in developing minimally invasive alternatives that include endometrial ablation (for submucosal fibroids), uterine artery embolization, and various techniques to induce myolysis. A variety of energy sources have been used for myolysis, including Nd:YAG lasers, bipolar electrodes, cryotherapy, or radiofrequency ablation. Typically, patients are pretreated with a 2- to 6-month course of depot GnRH agonists to shrink fibroids prior to the procedure. In general, the procedures involve the insertion of probes multiple times into the fibroid. When activated, the various energy sources induce devascularization and ultimately ablation of the target tissue.

Most frequently, myolysis is performed as a laparoscopic procedure, but, more recently, percutaneous approaches using magnetic resonance imaging (MRI) guidance have been reported. The MRI can provide both the guidance for insertion of the probe and real-time thermal imaging maps of the treated area. It can also be used to carry out in vivo monitoring of thermal changes in the tissues. Previously, in laparoscopic procedures, thermal damage could only be assessed visually by observing a blanching of the serosa, which may be too late to avoid serosal damage. It is thought that MRI monitoring of thermal damage within the fibroid may reduce the risk of serosal damage and subsequent adhesions.

Note: MRI-guided focused ultrasound therapy, a transcutaneous procedure, is addressed separately in policy 7.01.109.

Policy

Laparoscopic and percutaneous techniques of myolysis as a treatment of uterine fibroids are considered investigational.
Policy Guidelines

There is no specific CPT code for laparoscopic or percutaneous lysis of uterine fibroids. The following codes might be used for a laparoscopic procedure:

- 58578: Unlisted laparoscopy procedure, uterus
- 58999: Unlisted procedure, female genital system

For percutaneous procedures, the following code would likely be used to describe the MRI imaging component of the procedure:

- 77022: Magnetic resonance guidance for, and monitoring of, visceral tissue ablation

Rationale

In 2002, the American College of Obstetricians and Gynecologists (ACOG) published a review on the management of uterine fibroids. (1) This review was performed as an Evidence-based Practice Center report for the Agency for Healthcare Research and Quality. Ultimately the authors sought to use this review to form the basis of guidelines regarding the role of various treatment options, including hysterectomy, myomectomy, and uterine artery embolization. While this review did not directly report on techniques of myolysis, the report did comment on the quality of literature in general regarding the treatment of uterine fibroids. Specifically:

- There is almost no high-quality evidence on which to base treatment strategies.
- There are no randomized trials to support the superiority of one treatment over the other, including established treatments such as myomectomy or newer procedures such as uterine artery embolization.
- Inconsistency in reporting severity of symptoms, uterine anatomy, and response to therapy prevented comparisons between studies and prevented the performance of a meta-analysis.
- Efforts to standardize treatment or determine the most "appropriate" management, such as expert panel recommendations, clinical pathways, or use of review criteria are presumably based on the same literature reviewed. It is unclear how management strategies based on these efforts can be more "evidence-based" than individual patient or clinical opinion when the evidence is not interpretable.
- Rectifying the limitations in the reported literature should be a major research priority.

The published literature regarding techniques of myolysis is limited and of similar poor quality, even though some techniques, such as Nd:YAG laser myolysis have been available since the early 1990s. There are no controlled trials comparing myolysis to either hysterectomy or myomectomy, and the available case series often lack pertinent information such as uterine size, number, and size of fibroids, location of fibroids (i.e., either subserosal, intramural, or submucosal), and recurrence rates. These factors relate to the technical feasibility of the procedure and patient selection criteria. Reporting of patient outcomes is inconsistent or absent. Data on each of the laparoscopic myolysis techniques is summarized below:
Laparoscopic Procedures

Laser and Bipolar Needles

The largest experience using Nd:YAG laser myolysis has been reported by Goldfarb, who published the results of a case series of 75 patients. (2) All the patients presented with symptomatic fibroids 5-10 cm in diameter. Symptoms included pelvic pain, pressure, dyspareunia, and recurrent menorrhagia. The Nd:YAG laser was inserted into the fibroid multiple times; for example, 75 to 100 punctures were used to coagulate a 5-cm fibroid. Based on assessment by endovaginal ultrasound, the fibroids regressed in size and, after 6 to 14 months of follow-up, the size remained stable. No patient experienced significant complications. Nisolle and colleagues reported on a case series of 48 women who were apparently offered myolysis instead of myomectomy if they had completed childbearing. Although the report states that 28 of the 48 had more than 2 fibroids, it is not clear if all fibroids were treated in each patient, and if not, how the treated fibroids were selected. (3) The authors reported that maximal decrease in fibroid size had occurred by 6 months. However, there is no report of associated patient symptoms. Several authors have reported pelvic adhesions as a complication, presumably due to thermal damage to the serosal surface. In addition, the Nd:YAG laser produces a significant amount of smoke, which can obscure visibility. Interest has shifted to using bipolar electrodes. (4, 5) In a case series, Goldfarb reported the outcomes of 300 women with symptomatic fibroids no larger than 10 cm who underwent either myolysis using either Nd:YAG or bipolar needles. (6) The author reported that the coagulating effect of the bipolar needle devascularized the fibroids, and the resulting shrinkage was comparable with that produced by Nd:YAG laser.

Chapman reported on a case series of 300 patients who underwent myolysis using a low power energy source, a procedure referred to as interstitial laser photoacoagulation. (7) Some patients underwent combined laparoscopic and hysteroscopic procedures. The author reported that the procedure was associated with an improvement in menorrhagia, abdominal pain, and bladder discomfort, but there is no description of how these outcomes were assessed and at what length of duration. Visvanathan and colleagues reported on a small case series of 24 symptomatic patients who were treated with low power laser energy; shrinkage was reported in 23 of 24 lesions, with clinical benefit reported in 13 patients. (8) The authors concluded that fibroids greater than 6 cm in diameter responded poorly to treatment.

Cryomyolysis

Cryomyolysis is a technique in which a cryoprobe is inserted into the center of a fibroid. Freezing temperatures of -180 degrees centigrade create an “iceball” within the fibroid. Several freeze/thaw cycles are typically used. Zreik and colleagues presented their preliminary experience with 14 patients, while Zupi and colleagues presented their initial experience with 20 patients. (9, 10) In both of these small case series, the authors reported that patients had symptom resolution. In the Zreik study, patients were given GnRH agonist before the procedure; cryomyolysis maintained or slightly reduced the post-GnRH uterine size. In contrast, in the Zupi study, GnRH was not used, and cryomyolysis was associated with a 25% reduction in fibroid size. Zupi subsequently reported the 1-year follow-up of these patients. (11) Mean shrinkage in fibroid size continued until 9 months after surgery, to a mean volume reduction of 60%. Patients reported absence of symptoms. Interpretation of these studies is limited due to their small size.

Radiofrequency Ablation
Two small studies of laparoscopic radiofrequency ablation were identified. Milic and colleagues reported on a case series of 4 patients (12), while Bergamini and colleagues reported on a case series of 18 patients. (13) Both studies reported improvement in patient symptoms from 1 to 12 months after the procedure. Interpretation of these studies is limited due to their small size.

**MRI-Guided Percutaneous Procedures**

As noted in the Description section, the availability of open interventional MRI scanners permits both vertical and horizontal MRI image guidance and thermal monitoring of percutaneous myolysis procedures. Hindley and colleagues reported on a case series of 66 patients with symptomatic fibroids who were treated with MRI-guided percutaneous Nd:YAG laser myolysis. (14) Outcome measures included assessment of fibroid size and responses to a menorrhagia questionnaire. The mean reduction in fibroid size was 31%. Compared to a control group of those undergoing hysterectomy, the total outcome score was less in those undergoing percutaneous myolysis but the quality of life score was similar. Although not entirely clear, it appears that treatment was targeted to only the largest fibroid in each patient. The study does not provide details on the number and location of fibroids. It should also be noted that MRI guidance was provided with a high field (0.5T) open machine, which is not available in most institutions. Cowan and colleagues reported on a small case series of 9 patients undergoing MRI-guided percutaneous cryomyolysis. (15) MRI-guided focused ultrasound therapy, a transcutaneous procedure, is considered separately in policy No. 7.01.109.

**Summary**

Data are inadequate to permit scientific conclusions regarding various laparoscopic or percutaneous myolysis techniques. The published case series inconsistently report relevant criteria such as fibroid size, location, and associated symptoms. The gold standard technique is hysterectomy, while myomectomy may be considered the gold standard for a uterine-sparing procedure. It is hoped that hysterectomy-sparing procedures will preserve fertility. However, the published articles of myolysis techniques primarily include only women who have completed childbearing. In 2001, ACOG published an updated version of its 1994 Clinical Management Guidelines on surgical alternative to hysterectomy in the management of leiomyomas. (16) The listed alternatives included myomectomy, laparoscopic myomectomy, and various hysteroscopic procedures. Uterine artery embolization was listed as a procedure under development. The guidelines did not include any discussion of percutaneous or laparoscopic techniques for lysis of uterine fibroids.

**2005 Update**

The literature search performed for the period of 2004 through March 2005 did not identify any additional published literature that would prompt reconsideration of the policy statement, which remains unchanged.

**2006 Update**

The literature search performed for the period of 2005 through April 2006 did not identify any additional published literature that would prompt reconsideration of the policy statement, which remains unchanged. The discussion on radiofrequency ablation and reference numbers 11–13 were added.
2007 Update
A search of the MEDLINE database for the period of May 2006 through September 2007 identified several case series utilizing radiofrequency ablation. Ghezzi and colleagues published 1- to 3-year follow-up of 25 consecutive patients; preliminary results from 18 of these procedures were reviewed above. (13, 17) The median diameter of the dominant (assessed) myoma was 5.3 cm (range, 3.0 to 8.6). One of the women (4%) required a hysterectomy before one year and was censored from subsequent follow-up. For the remaining patients (n=24) there was a 78% reduction in myoma volume at one-year follow-up, with significant improvement in symptoms (from 44 to 7) and quality of life (QOL, from 63 to 100) scores. Follow-up at 2 (n=18) and 3 (n=9) years showed continued reduction (84%) in myoma volume, and maintenance of improvements in symptoms (0) and QOL (100). Another study reported 6-month results for 35 patients treated with combined radiofrequency ablation and uterine artery embolization for large (> 5 cm in diameter) subserosal and/or intramural symptomatic leiomyomas. (18) There was an average 57% reduction in myoma volume with a 40-point improvement in symptom severity. No significant morbidity was observed in either series. The published results suggest that radiofrequency ablation is being actively investigated as an alternative to surgery for symptomatic uterine myomas. However, due to the risk of recurrence with this type of procedure, longer follow-up with a larger number of patients is needed. Evidence remains insufficient to alter the conclusions reached above; the policy statement is unchanged.

2008 Update
A search of the MEDLINE database for the period of October 2007 through November 2008 identified 2 feasibility and safety studies utilizing percutaneous sonographically guided radiofrequency ablation (RFA) for medium-sized (19) and large (20) symptomatic uterine leiomyoma (fibroids) after uterine artery embolization. The authors concluded that percutaneous sonographically guided radiofrequency ablation alone is a feasible and efficient procedure in the management of medium-sized uterine myomas, and as adjunctive therapy to uterine artery embolization (UAE) under moderate sedation appears safe without significant morbidity in the treatment of large uterine leiomyoma. However, these results are to be considered preliminary. Further studies are needed to assess the efficacy and potential benefit of percutaneous RFA as a primary or an adjunctive treatment to UAE for symptomatic leiomyoma.

In August 2008, the American College of Obstetricians and Gynecologists issued a Practice Bulletin titled “Alternatives to Hysterectomy in the Management of Leiomyomas” which replaces Practice Bulletin Number 16, May 2000 and Committee Opinion Number 293, February 2004. This Bulletin contains no recommendations regarding myolysis utilizing laparoscopic or percutaneous techniques. (21)

In summary, the current data are inadequate to permit scientific conclusions regarding various laparoscopic or percutaneous myolysis techniques. The issues identified with the 2007 update still remain; those are a need to have well-designed, long-term, randomized controlled trials with larger patient populations to provide evidence for long-term (durable) clinical outcomes and to establish the appropriate patient selection criteria. The policy statement is unchanged and remains investigational due to insufficient evidence to evaluate the impact on health outcomes.

References:


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<th>Codes</th>
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<th>Description</th>
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<td>Uterine leiomyomata code range</td>
</tr>
</tbody>
</table>

**Index**

Bipolar Electrodes, Treatment of Uterine Fibroids  
Fibroids, Uterus, Laparoscopic and Percutaneous Treatment  
Laser, Laparoscopic Treatment of Uterine Fibroids  
MRI Guided Percutaneous Treatment of Uterine Fibroids  
Uterine Fibroids, Laparoscopic Techniques of Myolysis