Public Statement:

Uterine nerve ablation or presacral neurectomy are two laparoscopic surgical approaches that have been investigated as techniques to interrupt the majority of the cervical sensory nerve fibers in patients with dysmenorrhea. These procedures have not been clearly demonstrated to improve health outcomes, and they are not covered.

Medical Policy Statement:

Laparoscopic nerve ablation or presacral neurectomy for the treatment of primary or secondary dysmenorrhea is considered investigational and is not covered.

Background:

A literature search identified 6 randomized controlled trials focusing on either presacral neurectomy or laparoscopic uterine nerve ablation (LUNA). Five of these trials were published prior to 1999 and were reviewed in a Cochrane report. An additional randomized study was published in 2003. The trials vary in patient populations (i.e. primary vs. secondary dysmenorrheal) and control groups used. In the case of secondary dysmenorrhea, conservative surgical therapy was performed with or without LUNA or presacral neurectomy. The primary outcome in all the reviewed trials was pain relief, which was measured and reported in a variety of ways. The following summarizes the results from the Cochrane review and the additional published randomized trial.

Primary Dysmenorrhea

- LUNA vs. Diagnostic Laparoscopy Only
The Cochrane review only identified one small randomized trial that included 10 patients in the treatment group compared to 11 in the control group. The study reported that LUNA is associated with greater pain relief as measured with a 5 point pain scale at both 6 and 12 months, but that pain relief may decrease over time.

- **LUNA vs. Presacral Neurectomy**
The only randomized study in this group was a 1996 study by Chen and colleagues that randomized 68 patients to undergo either LUNA or presacral neurectomy. The procedure was considered a success if there was at least a 50% reduction in pain. While there was no significant difference in the two procedures at 6 months, at greater than 6 months, presacral neurectomy was associated with improved pain relief compared to LUNA. However, the incidence of adverse effects was greater with presacral neurectomy; specifically 94% of patients randomized to presacral neurectomy reported constipation.

**Secondary Dysmenorrhea**

- **LUNA + Conservative Surgical Therapy vs. Conservative Surgical Therapy Alone**
The Cochrane review identified two randomized trials in this category, both of which reported that there was no significant improvement in pain relief by adding LUNA to conservative laser ablative therapy for endometriosis.

- **Presacral Neurectomy + Conservative Surgical Therapy vs. Conservative Surgical Therapy Alone**
The Cochrane review identified one randomized study of 71 patients that reported that there was no significant difference in pain relief between presacral neurectomy group and the control group. In 2003, Zullo and colleagues reported the results of a trial that randomized 147 women with dysmenorrhea associated with endometriosis to undergo ablation of endometriosis deposits either with or without presacral neurectomy. The primary outcome was the cure rate, defined as the percentage of patients who reported an absence of dysmenorrhea or dysmenorrhea that did not require medical treatment. At six and 12 months the cure rate for the treatment and control group was 87.3% vs. 60.3% and 85.7% vs. 57.1%, respectively. While there was no difference in short term complications between the two groups, at 12 months, 14.3% of the presacral neurectomy group reported constipation compared to none in the control group. While the results of this trial conflict with those reported by Candiani, the Candiani trial of 71 may have been underpowered to detect a significant difference.

**Summary**

There is inadequate published data to permit scientific conclusions regarding laparoscopic uterine ablation (LUNA) or presacral neurectomy in patients with primary dysmenorrhea. For patients with secondary dysmenorrhea, data suggests that the addition of LUNA to conservative surgical therapy does not result in improved pain control. In contrast, the results of a randomized study of 147 women suggests that...
presacral neurectomy in conjunction with conservative surgical therapy is associated with increased pain control and cure rate. In 2002, a group of authors published a consensus statement regarding the management of chronic pelvic pain and endometriosis. The consensus process included a review of the literature, development of clinical recommendations, which were then discussed during a 2 day consensus meeting. The final treatment algorithms and recommendation statements were approved by unanimous or near-unanimous (>95%) votes. This consensus group offered the following recommendation regarding LUNA and presacral neurectomy.

"Patients with dysmenorrhea who have not responded to medical therapy may be offered presacral neurectomy at laparotomy, or if the operator is adequately experienced, via laparoscopy. Available evidence suggests that laparoscopic uterine nerve ablation does not benefit women with chronic pelvic pain associated with endometriosis."

In 2009, an additional randomized, multicenter, controlled trial from the U.K. was published comparing LUNA to a control intervention (Daniels, 2009). The study included women who had chronic pelvic pain lasting longer than 6 months and who had not been diagnosed with moderate-to-severe endometriosis or major pelvic inflammatory disease. Forty-five percent of the sample had some type of visible pathology; 17% minimal endometriosis and 20% had adhesions. LUNA after diagnostic laparoscopy (n=243) was compared to diagnostic laparoscopy alone (n=244) for women with primary dysmenorrhea. Patients were blinded to treatment group; at the end of the study, 122 in a subsample of 211 women (58%) correctly guessed their treatment group. The primary outcome was patient-rated pain using a 10 cm visual analog scale (VAS). Patients were asked about 3 types of pain (noncyclical pain, dysmenorrhea, and dyspareunia). At 12-month follow-up, pain data were missing for 51 women (21%) in the LUNA group and 48 (20%) women in the control group; an additional 5 women in the LUNA group and 4 women in the control group withdrew consent during the first year of follow-up. Analysis was intention to treat. At 12 months, there was no significant difference between groups in any of the types of pain or in the worst pain level of any type. There was also no significant difference between groups in any of the pain outcomes when the difference in pain was measured over all timepoints (outcomes were assessed at 3 and 6 months and 1, 2, 3, and 5 years). The median time in the study was 69 months; 72% of women had at least 5 years of follow-up. Note that actual VAS scores for each group were not reported but were represented on figures. Advantages of this study include longer-term follow-up, blinding of subjective outcomes and randomization after inspection of the pelvis to ensure eligibility.

References:


Application to Products

This policy applies to ARBenefits. Consult ARBenefits Summary Plan Description (SPD) for additional information.

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