Levator ani midurethral support to treat stress urinary incontinence: description of technique and proof-of-concept

Lai-Yet Lam[1], Janice Santos-Cortes[2], and Timothy O'Rourke[3]

[1]Albert Einstein College of Medicine
[2]Mount Sinai Medical Center
[3]Brown University Warren Alpert Medical School

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Abstract

This proof-of-concept investigation reports the results of eight patients who, after declining mesh midurethral slings, were treated for stress urinary incontinence with levator ani midurethral support, a single vaginal incision technique. Seven patients had good subjective outcomes at 22 to 33 months. One patient had good subjective outcome for 14 months, followed by stress urinary incontinence recurrence. The peri-operative complications were temporary urinary retention at hospital discharge and urinary tract infection. Patients reported having no long-term complications. Results of this preliminary investigation suggest that this technique may be a reasonable alternative to other surgical procedures for stress urinary incontinence.

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The surgeries using the levator ani midurethral support technique were performed at the Rhode Island Hospital, Brown University, Providence, Rhode Island, USA. Dr. Lam was in the Division of Gynecology, Department of Surgery. Dr. Santos was in the Division of Urology, Department of Surgery. Dr. Lam and Dr. Santos are no longer at Brown University. Dr. O'Rourke is finishing his residency at Brown University in the Division of Urology, Department of Surgery.

Co-authors' current addresses

Lai-Yet Lam, MD

Division of General Obstetrics and Gynecology

Department of Obstetrics & Gynecology and Women's Health

Albert Einstein College of Medicine

Montefiore Medical Center

1695 Eastchester Road

Bronx, NY 10461, USA

Janice Santos-Cortes, MD

Columbia University's Division of Urology

Mount Sinai Medical Center

4302 Alton Road

Simon Bldg., Suite 540

Miami Beach, FL, 33140, USA

Timothy O'Rourke, MD

Division of Urology

Department of Surgery

Residency Program

The Warren Alpert Medical School of Brown University

2 Dudley Street, Suite 174

Providence, RI 02905, USA

Corresponding author : Lai-Yet Lam, MD.: 1695 Eastchester Road, Bronx, NY 10461, USA Telephone number: +1 917-273-5311, email: lalam@montefiore.org

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Abstract

This proof-of-concept investigation reports the results of eight patients who, after declining mesh midurethral slings, were treated for stress urinary incontinence with levator ani midurethral support, a single vaginal incision technique. Seven patients had good subjective outcomes at 22 to 33 months. One patient had good subjective outcome for 14 months, followed by stress urinary incontinence recurrence. The peri-operative complications were temporary urinary retention at hospital discharge and urinary tract infection. Patients reported having no long-term complications. Results of this preliminary investigation suggest that this technique may be a reasonable alternative to other surgical procedures for stress urinary incontinence.

Introduction

Stress urinary incontinence (SUI) is reported to affect between 25% and 45% of women.[1] The standard surgical treatment for SUI in the United States is placement of a mesh midurethral sling (MUS).[2,3] A minimally invasive procedure is needed for women who decline MUS or when MUS is unavailable. The lead author developed levator ani midurethral support (LAMS) for the treatment of SUI. In addition to treating SUI, MUS was found to prevent de novo urinary incontinence for patients undergoing pelvic organ prolapse (POP) surgery.[4] As an alternative to MUS, LAMS was initially performed concomitantly with POP surgeries, utilizing the same incision as for the anterior repair, to treat pre-operative SUI and prevent post-operative de novo urinary incontinence.[5] These patients had good outcomes.[5] The peri-operative complications were urinary retention at hospital discharge and urinary tract infection. A photograph of LAMS before anterior repair in a patient with POP, without previous surgery, is shown in Figure 1. Subsequently, patients with SUI who declined MUS were offered the option of Burch colposuspension, fascia sling, urethral bulking injection or LAMS. The LAMS technique and its subjective outcomes are detailed here.

Technique

After we obtained informed consent, patients were prescribed nightly vaginal estrogen cream for 2 weeks to facilitate dissection. They were taken to the operating room, given a prophylactic antibiotic, placed in

the lithotomy position, put under general anaesthesia, and prepped and draped in the usual manner. 1% Lidocaine with 1/100,000 epinephrine was injected on the midline of the anterior vaginal epithelium from 0.5 cm to approximately 4 cm below the urethral meatus. An incision was made on the hydro-dissected vaginal epithelium, which was separated from the underlying vesicovaginal fascia sharply and bluntly. The vaginal epithelium was separated as far laterally as possible and the retropubic space was created at least 2-3 cm cephalad, allowing space to place serial plication sutures at the level of the midurethra. A 0-Vicryl® suture on a UR-6 needle was placed in a down-to-up manner, posterior to anterior, on the vesicovaginal fascia as laterally and deeply as possible on the patient's left side to include the puborectalis, the most medial part of the levator ani muscle. A strong pull on the suture allowed the surgeon to determine that the anchoring suture had included the puborectalis muscle. The same suture was brought to the right side, placed in an up-to-down manner, anterior to posterior, again as laterally and deeply as possible to include the contralateral puborectalis muscle (Figure 2). After a strong pull was performed, the suture ends of the resulting inverted U shape were tied, bringing the puborectalis muscle from the two sides together to support the midurethra. After the suture was tied, a more lateral portion of the muscle was then accessible. A second suture was used to make another inverted U plication. This was repeated a third time to ensure good support of the midurethra with the puborectalis muscles in apposition at the midline (Figure 3). Dissection and plication can be technically challenging if the patient has significant scar tissue. Sometimes the puborectalis muscles from either side did not meet in the midline, resulting in a small suture bridge between the two sides (Figure 4).

Experience

From March 2019 to February 2020, all women with SUI were offered MUS. Women who declined MUS were offered the option of Burch colposuspension, fascia sling, urethral bulking injection or LAMS. Nine women chose LAMS.

Four of the nine women previously had total MUS removal and SUI recurrence. Three women did not have prior surgery for SUI. Two women came for MUS removal. After we obtained informed consent, LAMS was performed on these nine patients. Urodynamic tests, unnecessary before surgery for SUI, were not performed unless there were other indications.[6] Patient demographic data, case summaries and outcomes are listed in Table 1. Approximately 2 years after LAMS, the Patient Global Impression of Improvement (PGI-I) questionnaire, which specifically addressed SUI, was answered by phone interview and verified with a signed mail-in paper copy to assess patients' subjective outcomes.[7] On the PGI-I questionnaire, patients' self-reported responses to their SUI treatment were selected from the following: very much better, much better, a little better, no change, a little worse, much worse, very much worse. In addition, de novo dyspareunia, de novo pelvic pain, de novo urgency incontinence and subsequent surgery for SUI were assessed. We defined good subjective outcome as PGI-I results of much better or very much better. Nine of the nine patients answered the questionnaire by phone. We excluded from assessment one patient who did not return the signed paper questionnaire, even though she reported a good subjective outcome over the phone.

Seven patients reported that their SUI was much or very much better with a good subjective outcome at the time that the written questionnaire was answered, 22 to 33 months after LAMS. One patient reported that her SUI was much better with LAMS for 14 months, but then recurred. This result was confirmed by her medical record.

Patients 1, 4 and 7 had declined MUS and had no previous surgery for SUI.

Patient 2 had total MUS removal because of hispareunia and vaginal exposure within 3 months of MUS placement. She is the patient whose SUI recurred 14 months after LAMS.

Patient 3 had a good subjective outcome even with extensive scarring from previous surgeries by outside uro-gynaecologists. In a span of 5 years, she had MUS placed serially three times and removed because of vaginal exposure. This was followed by a rectus fascia sling with severe wound infection requiring wound exploration and wound vacuum-assisted closure. She was referred to us 5 years after her last surgery. Initially, a bulking agent was used but was ineffective. She opted for LAMS even after she was informed that it might

not be successful because of her previous surgeries. A suture bridge (Figure 4) resulted at the end of LAMS because the scarring prevented apposition of the levator ani muscle.

The vaginal epithelium of Patient 5 disintegrated as a result of the MUS. The MUS was totally removed within 3 weeks of placement, with SUI recurrence. She returned 2 years later for SUI and POP treatment. The MUS in Patient 6 was totally removed because of pelvic pain but then SUI recurred. She returned 7 years later for SUI and POP treatment.

Patient 8 came for total MUS removal 3 years after MUS placement by an outside uro-gynaecologist because of dyspareunia, hispareunia and recurrent urinary tract infection. Although there was no mesh exposure, the mesh could be palpated as a hard rod underneath the midurethra. The MUS was totally removed and LAMS was performed concomitantly without complication.

Four patients had urinary retention at hospital discharge lasting 1 to 3 weeks. One of these four patients also had a urinary tract infection. There were no other immediate peri-operative complications such as bleeding or urethral, bladder, visceral or nerve injury. Patients reported that they had no long-term complications such as de novo dyspareunia, de novo pelvic pain or de novo urgency incontinence. No subsequent surgeries for SUI were performed.

Discussion

When patients decline MUS or when it is unavailable, non-mesh options are being used, such as an autologous fascia sling (fascia sling on a string), Burch colposuspension or urethral bulking injections.[8-12] Use of an autologous fascia sling involves harvesting of either rectus fascia or fascia lata and is a more extensive procedure.[8,9] Burch colposuspension requires either a mini abdominal incision or a laparoscopy.[10-11] The efficacy of urethral bulking injections for treating SUI ranges from 32.7% to 83.6%.[12]

LAMS and Kelly plication are both native tissue plication techniques with a single vaginal incision; however, there are four major differences[13]: (1) LAMS uses the levator ani muscle for support, whereas Kelly plication uses the vesicovaginal fascia; (2) in LAMS, the plication is done as laterally and deeply as possible to include the levator ani muscle and one must ensure the inclusion of the muscle, whereas in Kelly plication, a paraurethral plication is performed; (3) the location of plication is different, with LAMS at the midurethra and Kelly plication at the bladder neck; and (4) LAMS uses triple plication, whereas Kelly uses single plication.

This limited proof-of-concept investigation of eight women who declined MUS showed that SUI patients treated with LAMS had good subjective outcomes with or without previous SUI surgeries. Five patients had LAMS alone. Two patients, who initially presented with SUI without POP, had previous total MUS removal with SUI recurrence. Years later, these patients presented with persisting SUI and POP. POP surgery with concomitant MUS is often used to treat pre-existing symptomatic SUI.[14] In these two patients, LAMS was performed concomitantly with POP surgery and they had good subjective outcomes of their SUI. One patient had total MUS removal and concomitant LAMS. Total MUS removal is followed by recurrent SUI in 48.7% of patients.[15] After total MUS removal and concomitant LAMS, this patient did not have SUI recurrence. For these eight patients, the complications were urinary retention at hospital discharge (four patients) and urinary tract infection (one of the four patients). Urinary retention at hospital discharge was reported to be 42.6% in a large study of MUS concomitant with POP surgery, and 96.3% resolved within 6 weeks.[4] In this small investigation, half of the patients had urinary retention at hospital discharge and all resolved within 3 weeks. These eight patients reported that they had no long-term complications.

Conclusion

The results of this preliminary investigation suggests that LAMS may be a reasonable alternative to other surgical procedures for treating SUI. To demonstrate that LAMS may be a feasible surgical alternative to offer patients with SUI, a prospective multi-site, multi-surgeon study is necessary. Short-term and long-term outcomes should be assessed, as well as peri-operative and long-term complications.

Table Captions

Table 1. Patient demographics, case histories and procedure outcomes

Figure Captions

Figure 1. Photograph of levator ani midurethral support (LAMS)

Figure 2. Schematic of levator ani midurethral support (LAMS) technique showing first plication, frontal view

Figure 3. Schematic of levator ani midurethral support (LAMS) technique after three plication passes made and suture ends tied. (A) Frontal view. (B) Axial view.

Figure 4. Schematic of levator ani midurethral support (LAMS) technique after three plication passes made and suture ends tied, with dense tissue scarring and a suture bridge. (A) Frontal view. (B) Axial view.

Disclosure of interests

None declared. Completed disclosure of interest forms are available to view online as supporting information.

Contribution to authorship

LL developed the surgical technique. LL and JS were the principal surgeons who performed the operations with TO as assisting surgeon. LL wrote this article with the assistance of TO in reviewing patients' medical records. TO and JS contributed to editing and reviewing the manuscript. All authors have read and agreed to the published version of the manuscript.

Details of ethics approval

This study was reviewed for ethical compliance by the Advarra Institutional Review Board and received exempt determination on 28 April 2022 (Reference number is Pro00062321). Written consent was obtained from each patient, including the patient with the photograph, for the publication of material about them.

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Data availability statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available because of privacy or ethical restrictions.

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Figure 1

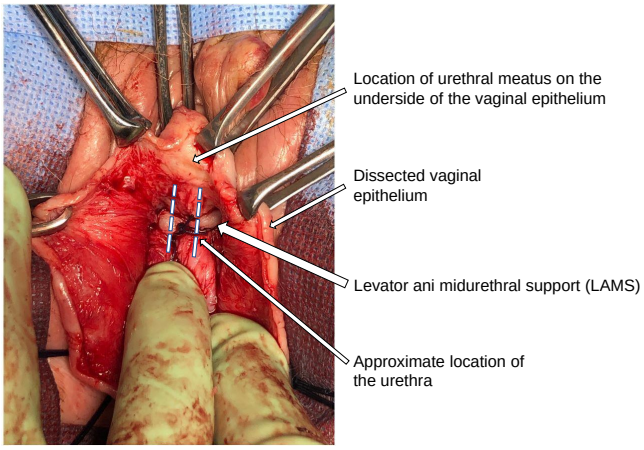
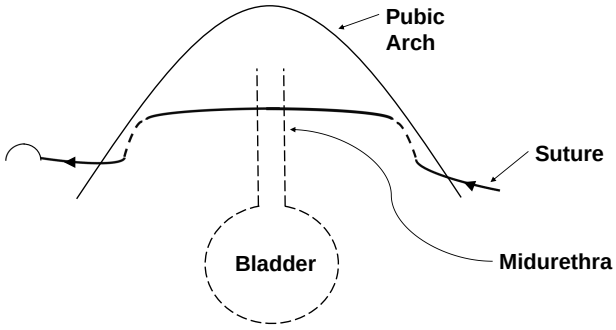


Figure 2 Frontal View



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