Ectopic low submuscular pressure regulating balloon placement with transfascial fixation for artificial urinary sphincter

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Introduction: *To present our novel low submuscular (LSM) pressure regulating balloon (PRB) placement for artificial urinary sphincter (AUS) technique as an alternative to standard approaches with patient-reported satisfaction outcomes.*

Material and methods: *A retrospective review was conducted on patients who underwent an AUS implantation using the LSM PRB placement with transfascial fixation technique from July 2019 to August 2020. Preoperative characteristics were collected. Patients then conducted a postoperative phone interview using an adapted questionnaire to assess satisfaction of device and PRB concealment.*

Results: *During the study period, nine patients had undergone AUS placement using the LSM technique by a single surgeon at our private institution. Eight of the nine patients had undergone a radical prostatectomy while the ninth patient developed stress urinary incontinence after radiation treatment for prostate cancer. All patients were 'very satisfied' with PRB placement and concealment with no patients endorsing PRB complications. The majority of patients (78%) were satisfied with the device. One patient was able to palpate the PRB while another patient endorsed mild soreness around the PRB. No surgical revisions were required and there were no surgical complications such as bowel obstruction, herniations, bladder erosions, or vascular injuries.*

Conclusion: *LSM placement of AUS PRB with transfascial fixation offers an improved technique for balloon placement with decreased risk for complications. This can be performed as a safe, alternative approach to current standard techniques with a high degree of patient satisfaction.*

Key Words: artificial urinary sphincter, urination, technique

Introduction

Discourse surrounding the optimum placement of artificial urinary sphincter (AUS) pressure regulating balloons (PRB) and inflatable penile prosthesis (IPP) reservoirs to treat urinary incontinence and erectile dysfunction has undergone significant change over the last two decades. Early reservoirs were valve-less, thus an increase in abdominal pressure could lead to inappropriate inflation of the prosthetic device. Placement of the PRBs and reservoirs into spaces such as the peritoneal cavity or the Space of Retzius was required to avoid such a complication.[1] For decades, the PRBs and IPP reservoirs were inserted into the Space of Retzius via a puncture through the transversalis fascia, putting vulnerable structures such as the bladder, bowel and pelvic vessels at risk of damage.[2-10] The introduction of a reservoir with "lock-out valves" by Mentor Corporation in 1998 allowed

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for exploration into "ectopic" reservoir placements. A number of different ectopic approaches were tried throughout the 2000s and early 2010s, led by Wilson and Perito who introduced placement of the reservoir in positions anterior and posterior to the transversalis fascia.[11-14] In 2013, Morey introduced the high submuscular technique, which places the reservoir between the rectus abdominus and the transversalis fascia in a position anterior to the locations described by Wilson and Perito.[15] This method of placement along with Morey's "Five-Step" technique described in 2020 have greatly reduced the risk of herniation as well as complications involving the underlying viscera.[16]

We hope to further improve on these developments by introducing the low submuscular (LSM) placement of the AUS PRB. In this paper, we present the reported outcomes from the initial nine patients who have undergone low submuscular PRB placement.

Materials and methods

Institutional Review Board approval was obtained prior to project initiation. A retrospective review was conducted on patients who had undergone an AMS 800 (American Medical Systems, Minnesota, MA, USA) AUS PRB placement using the low submuscular with transfascial fixation technique between July 2019 and August 2020 by a single surgeon. Data collected included age, BMI, patient comorbidities (including diabetes mellitus, hypertension, sleep apnea, hyperlipidemia, and smoking), prior surgical history, history of radiation, and date of AUS placement.

Extensive preoperative evaluation was performed at time of clinic visit to optimize surgical results. Patients were counseled on the device and dexterity assessed to ensure feasibility of usage. Past surgical history was reviewed in detail to ensure there was no compromise of the inguinal canal that may affect low submuscular PRB placement.

Postoperatively, patients conducted a telephone interview to assess satisfaction with the device both anatomically and functionally. Patients were asked a total of 17 questions that were adapted from the validated questionnaire Brinkman et al employed to assess inflatable penile prosthesis satisfaction.[17]

Low submuscular with transfascial fixation surgical technique

Once the bulbar urethra has been dissected circumferentially and the AUS has been placed around the urethra via a perineal incision, the PRB is ready for placement. A midline incision is made along the median raphe and the external inguinal ring is first identified and an S-retractor is placed inside the ring and elevated. Next ring forceps are used to develop a space below the rectus muscle and above the transversalis fascia. The space is directed towards the umbilicus midway between the external inguinal ring and the umbilicus. A Babcock clamp is employed to grasp the medial aspect of the inguinal ring, Figure 1a. A right angle is then passed in an out-to-in fashion through the fascia below the Babcock clamp, Figure 1b. The PRB tubing is grasped and brought through the fascia, Figure 1c. A 61-70 cm H_20 pressure PRB is placed submuscular in the previous developed space and filled with approximately 24 cc of normal saline. The fascia is thus used to anchor the balloon and tubing in place. The tubing is then connected to complete placement.

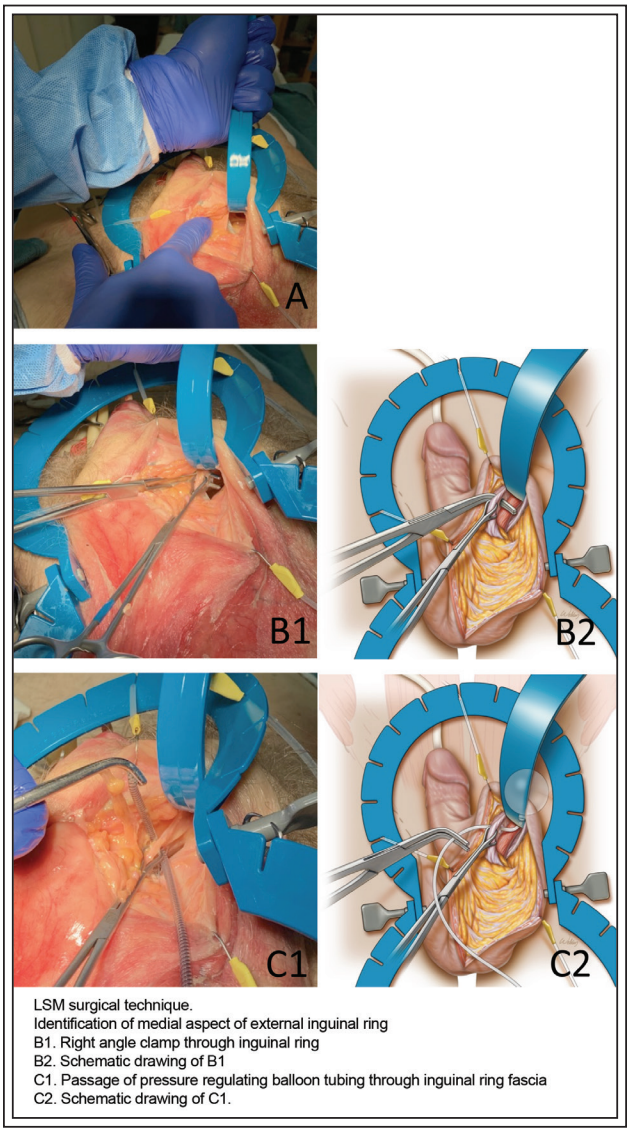

Figure 1. LSM surgical technique.

TABLE 1. **Patient characteristics**

Patient demographics	LSM (n = 9)
Age	77.6 (65-90)
Body mass index	26.59 (19.49-32.69)
Smoking	6 (67%)
Diabetes mellitus	2 (22%)
Hypertension	5 (56%)
Obstructive sleep apnea	3 (33%)
Hyperlipidemia	4 (44%)
History of prior incontinence procedure	4 (44%)
History of post-prostatectomy radiation	2 (22%)
On post-RALP incontinence medications	2 (22%)

LSM = low submuscular

Results

During the 1-year time period, nine patients underwent AUS surgery with low submuscular balloon placement. Eight of the nine patients had undergone a radical prostatectomy while the ninth patient developed stress urinary incontinence after radiation treatment for prostate cancer. Four patients (44%) had undergone prior lower urinary tract procedures which include male sling (n = 1), direct visual internal urethrotomy (DVIU, n = 1), prior AUS (n = 1), and one patient who underwent DVIU then male sling. Two patients (25%) required radiation after their prostatectomy. Patient characteristics are given in Table 1. The mean follow up was 5.8 ± 2.8 months with a range of 3-11 months. The average surgical time was 99 ± 17 minutes. All patients had a drain placed perioperatively and were admitted under 'Observation' for less than 24 hours. The device was activated approximately 6 weeks postoperatively.

Among the nine patients, seven (78%) were satisfied with the AUS device and would recommend it to others with urinary incontinence. All patients were 'very satisfied' with PRB placement and concealment with one patient able to palpate the balloon. Only one patient was able to feel the reservoir and one patient reported mild soreness around site of placement, Table 2. There were no complications from surgery such as herniation, vascular injury, bladder erosion, or bowel injury.

TABLE 2. **AUS satisfaction questionnaire results**

Survey question	**Patient response**
1) Overall satisfaction with LSM AUS (Likert scale1-5)	4/5 (satisfied)
2) Percentage who would undergo LSM AUS again	78% (7/9)
3) Percentage who would recommend an LSM AUS to a friend	78% (7/9)
4) Reported ease of operating mechanism (Likert scale 1-5)	4.7/5 (very satisfied)
5) Satisfaction with how natural the PRB feels (Likert scale 1-5)	4.7/5 (very satisfied)
6) Percentage who leaked prior to surgery	100%
7) Average number of pads used per day preoperation	6.4 (2.5-15)
8) Rated annoyance with leakage prior to surgery (Likert scale 1-5)	1.2/5 (very dissatisfied)
9) Percentage who leak after surgery	78% (7/9)
10) Average number of pads used per day by those who leak postoperation	1.2 (0-2.5)
11) Rated annoyance with leakage after surgery (Likert scale 1-5)	3.9/5 (satisfied)
12) Percentage who can feel the PRB	11.1% (1/9)
13) Percentage who reported being bothered by their PRB	0%
14) Overall satisfaction with PRB concealment (Likert scale 1-5)	5/5 (very satisfied)
15) Percentage who report being able to see their PRB	0%
16) Percentage reporting pain from the PRB	11.1% (1/9)
17) How bad is the pain from the PRB (Likert scale 1-5)	2/5 (n =1)

Discussion

A brief history of reservoir/balloon placement

Although IPP/AUS placement is considered an elective procedure, retropubic placement of the PRB could potentially be associated with a number of rare yet serious complications in patients with and without a history of pelvic surgery. Incision and reflection of the peritoneum during robotic assisted laparoscopic prostatectomy (RALP) disrupts the Space of Retzius. Therefore, post-RALP PRB placement into this space can put intraperitoneal structures at risk of damage.[15,18] Patients without a history of pelvic surgery are at risk for complications as well, with documented incidents involving bladder perforation and erosion, bowel erosion, vascular compromise, and urethral obstruction.[2-10,19,20]

The introduction of reservoirs with lockout valves allowed for new experimentation with reservoir placement.[1] In 2001, Wilson et al described a new technique for IPP reservoir placement that no longer required puncturing of the transversalis fascia nor a second abdominal counter-incision to place the reservoir in the Space of Retzius. In Wilson's method, the reservoir was to be placed between the transversalis fascia and the rectus abdominus superior to the external inguinal ring. This location was termed "ectopic", as it differed from the traditional Space of Retzius placement for which IPP reservoirs were FDA approved at the time.[1,11] Wilson would go on to establish the efficacy and decrease in palpability of AUS PRBs placed ectopically in 2005.[12] Perito later improved on Wilson's technique by suggesting the use of a nasal speculum to create the pocket needed for ectopic reservoir placement. The nasal speculum could be used to create pockets posterior to the transversalis fascia (between fascia and peritoneum) in patients without a history of pelvic surgery, or anterior to the transversalis fascia in patients with a history of pelvic surgery. Nasal speculum use also allowed for a more cephalad reservoir placement that decreased palpability and likelihood of reservoir herniation.[1,13,14] While promising, the popularity of Wilson's technique with implanters was ultimately limited because it required blunt dissection using the surgeon's finger that was often difficult and painful for the surgeons. Additionally, reservoirs were frequently palpable and susceptible to herniation into the scrotum.[1,15]

Over the last decade, there have been two major developments in IPP/AUS reservoir/ balloon placement. A flat, pancake-shaped reservoir expressly designed to decrease palpability after ectopic placement was first introduced by AMS in 2010. Coloplast soon followed with their Cloverleaf Reservoir which could assume a flat shape when partially filled.[1] In 2013, Morey et al introduced an alternative "high submuscular" placement of reservoirs and balloons that used a Foerster clamp to create a pocket between the rectus abdominus and the transversalis fascia 6-8 inches cephalad to the external inguinal ring. This position, superior to Wilson's ectopic location, decreases the risk of herniation and eradicates the need to suture the external ring closed.[15] With the development of Morey's high submuscular placement, the complexity of the patient's anatomy or surgical history was no longer a factor in the placement of AUS balloons or IPP reservoirs.

Low submuscular balloon placement

Most surgeons place the PRB under the rectus muscle and above the transversalis fascia via a counter incision. One concern of placing the PRB in this exact same location through the external ring was the risk of herniation of the PRB due to its small size. The low submuscular PRB placement does not require a counter-incision and at the same time mitigates the risk of herniation of the PRB with the transfascial fixation. By essentially anchoring the PRB through the fascia, the risk of herniation is significantly decreased. We find it to be easier and safer than placing the PRB in the Space of Retzius. To this point, none of the patients reported being able to see their AUS balloon or being bothered by its palpability. None of the patients experienced balloon herniation or any other complication of the procedure other than soreness. Although our sample size is small, this technique has not shown any decrease in efficacy or malfunction of the AUS. This approach is an acceptable alternative to traditional PRB placement and offers a potentially decreased risk of complication and with a high rate of patient satisfaction.

Many surgeons have historically made a midline lower abdominal counter incision to place the reservoir or balloon. This involves placing the PRB under the rectus muscle and then bringing the tubing out through the fascia. The technique we describe with the LSM placement of the PRB with transfascial fixation allows for the same placement of the PRB with less morbidity and decreased operative time.

Future directions

The authors of this study recognize the small sample size of the study involved. No complications involving the balloon (herniations, infections, erosions etc.) have occurred as a result of our procedure, but new complications may arise as we move further from

the surgical date. Our experience using the low submuscular placement with transfascial fixation of the IPP reservoir, is forthcoming.

Conclusion

We herein describe an alternative technique for AUS pressure regulating balloon placement which increases the ease of placement and decreases the risk of complications, the morbidity of a counter incision, and operative time. The LSM placement with transfascial fixation of the AUS PRB offers an alternative approach to current techniques with a high degree of patient satisfaction. □

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