

MINIMALLY INVASIVE PROCEDURES FOR URETHRAL INCONTINENCE: IS THERE A ROLE FOR LAPAROSCOPY?

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ABSTRACT

This article focuses on the minimally invasive surgical approaches for the treatment of stress urinary incontinence (SUI). The role of laparoscopic suspension is reviewed and compared with other minimally invasive techniques, such as the pubovaginal sling procedure and injection of the urethral bulking agents.

The role of laparoscopic Burch colposuspension remains ill defined in 2002. Once this minimally invasive technique is shown to duplicate the success rate of the open Burch procedure, it could be offered as a first-line therapy to patients with SUI. At this time, the pubovaginal sling (PVS) offers the best long-term results with acceptable low complication rates of urinary retention, urgency, and sling erosion or infection. These complications are rarely seen with the laparoscopic repair but the incidence of bladder injuries is higher. The PVS operation can be performed as a salvage procedure, in obese patients, and concomitant with cystocele and rectocele repair whereas data for laparoscopy in these conditions are lacking. Until the long-term efficacy of the laparoscopic repair is clearly defined, offering it to patients as a minimally invasive therapy denies them of procedures with superior efficacy.

Key words: stress urinary incontinence; surgical treatment; laparoscopy, prostheses and implants
Int Braz J Urol. 2002; 28: 403-12

INTRODUCTION

In the United States, 15 billion dollars are spent annually for the treatment of urinary incontinence (1). The prevalence of incontinence is 20% in women older than 40 years old (2), 40% in ambulatory elderly women (3), and up to 50% in nursing home residents (4). Unfortunately, less than half of the patients with incontinence discuss their condition with health care providers (5).

Incontinence is the involuntary loss of urine. It may be due to bladder abnormalities, such as detrusor overactivity, or urethral dysfunction. The 2 types of urethral dysfunction are urethral hypermobility and intrinsic sphincter deficiency (ISD). The weakness of pelvic floor support with re-

sulting rotational descent of the bladder neck and proximal urethra during Valsalva maneuvers are the main causes of incontinence in women with hypermobility. ISD is characterized by decreased urethral resistance due to lack of internal sphincter mechanism. Neurological conditions, previous pelvic surgery, hypoestrogenic states, and aging process are some of the causes of ISD.

Urethral continence is believed to be multifactorial, including tone and contraction of smooth and striated muscles, viscoelastic properties of extracellular matrix (proteoglycans, glycoproteins, collagen, and elastin), structural support of the posterior urethra, transmission of abdominal pressure to the bladder and urethra, apposition of urethral lumen, and neurological control. A defect of any of the above

properties may lead to incontinence. Lack of estrogen can decrease coaptation of the urethral lumen. Loss of structural support of posterior urethra can also lead to urethral hypermobility and incontinence (6). Others believe that unequal transmission of abdominal pressure to the bladder and urethra can cause incontinence when the bladder pressure exceeds that of the urethra (7). We have demonstrated that the endopelvic fascia and skin of women with stress urinary incontinence secrete more elastase and collagenase than control subjects (8). This may result in decreased amounts of extracellular matrix of the pelvic floor leading to the development of SUI. In addition, we showed that the increased level of the proteolytic enzymes in the skin and plasma of women with SUI suggests a systemic process not limited to the endopelvic fascia. Other investigators believe that there is radiological evidence to support that the anterior and posterior walls of the bladder neck and proximal urethra pull apart from each other with increased abdominal pressure leading to incontinence (9).

A multitude of surgical and non-surgical treatment modalities has been described to correct SUI. In the published review of the American Urological Association Guidelines, the open Burch and sling procedures had the best results up to 48 months of follow-up (10). Minimally invasive approaches to correct SUI have followed the path from open surgery to needle suspension to bioinjectibles and to possible drug therapy. The needle suspension procedure while initially popular, failed in the long-term follow-up (11). Minimally invasive modifications of the pubovaginal sling and the laparoscopic approach to replace Burch colposuspension are reviewed here for the current state of the art.

PUBOVAGINAL SLING

The gold standard of treatment for SUI due to ISD is the pubovaginal sling (PVS) procedure. Von Giordano was the first person to describe the procedure in 1907 (12). In 1910, Goebell was the first to use the pyramidalis muscle (13). Many modifications were introduced, but PVS lost popularity due to extensive retropubic dissections and complications.

McGuire & Lytton reintroduced the PVS in 1978 using autologous rectus fascia (14). In that series, at a mean follow-up of 2.3 years 41 out of 52 patients (80%) were cured with operation alone and another 11% were cured with operation and medication. Blaivas & Jacobs later modified the procedure in 1991 and an overall success rate of 91% was reported (15). However, the PVS was performed as a salvage procedure after other continence procedures had failed. Now, the PVS procedure is indicated as the primary treatment of incontinence due to ISD. It can be performed under general or regional anesthesia, in less than 2 hours, and as an ambulatory or overnight stay basis.

The choice of sling material includes autologous, allograft, and synthetic materials. The rectus fascia, fascia lata, vaginal wall, and a number of other tissues have been used as autologous sling material. Harvesting of fascia lata requires a separate thigh incision but larger strips of more uniform fascia can be obtained compared to rectus fascia, especially if patient had previous abdominal surgery. Cure rates of up to 98% have been reported using fascia lata (16). Anterior vaginal wall slings have achieved 90-94% cure rates with a mean follow-up of 24 months; however, longer follow-up is lacking (17,18). Autologous fascia is less costly and less prone to infection and erosion than other material, however, larger or separate incisions, longer operative time, and more post-operative pain are observed when autologous fascia is used. Use of cadaveric fascia lata as sling material was first reported in 1996 (19). Long-term safety and efficacy of allografts have been well documented in the orthopedic literature (20). The risk of HIV transmission from allografts is estimated to be 1 in 1,667,600 (21). A recent study demonstrated that intact DNA was present in freeze-dried, gamma-irradiated cadaveric fascia lata and acellular cadaveric dermis (22). However, the infectious potential of this finding remains unknown. Allografts are available in different sizes and eliminate the need for harvesting. Similar continence rates have been achieved with autologous and allograft material but the operative time, post-operative pain, and hospital stay have been significantly shorter when allografts are used (23,24).

Some of the synthetic sling materials include polyethylene (Mersilene), polytetrafluoroethylene (Gore-Tex), polypropylene (Marlex), polyester with bovine collagen matrix (ProteGen), Teflon, and Silastic. Similar to allografts, synthetic materials decrease operative time and eliminate the need for tissue harvesting. In addition, they cannot be degraded by enzymatic reactions (25). Earlier series reported high rate of erosions, infections, and sling removal (26,27). A cure rate of 82% was reported in those series. In a recent prospective study, an antimicrobial mesh was compared with vaginal wall sling. At a mean follow-up of 22 months, SUI was cured in 95% of the mesh group and 70% of those with vaginal wall sling. De novo urge incontinence developed in 12.5% of the mesh and 14.3% of the vaginal wall sling group. No tissue erosions or infections were reported (28). In another investigation, 94% cure rate was reported after a minimum of 2 years of follow-up using autologous or synthetic material and a bone-anchoring system to support sutures to the pelvic bone (29). We use a polypropylene mesh sling with bone anchors. Report of our preliminary results showed that 91.4% of the patients were dry at a mean follow-up 8.4 months without any infections or erosions (30). When these patients were followed-up for a mean of 52 months (longest 66 months), 70% of the 50 patients were completely dry, 20% rarely leaked urine, 2% leaked a moderate amount, and 8% failed the procedure. No infections or erosions occurred but bone anchors were removed in one patient due to pain (unpublished data).

In 1996, Ulmsten et al. reported the initial experience with tension-free vaginal tape (TVT) procedure (31). A polypropylene mesh is placed at the level of mid-urethra through a small vaginal incision under local anesthesia as an outpatient procedure. The longest follow-up result reported showed that at a median follow-up of 56 months, out of 90 patients 85% were cured, 11% were significantly improved, and 4% failed (32). Similar results were reported after a mean follow-up of 4 years when TVT procedure was performed for ISD. Seventy four percent were cured, 12% were improved, and 14% failed. Failure was more common in those with leak point pressure of < 10 cm H₂O (33). Other investigators have also

shown that TVT may not be as effective in those with ISD. In a study of 319 patients in which 43 (13%) had urethral pressure of < 20 cm H₂O, post-operative leakage after a median follow-up of 7 months was significantly more than those with urethral leak pressure of > 20 cm H₂O. However, patient satisfaction was the same between the 2 groups (34). Another prospective, multi-center study demonstrated that after 2 years of follow-up, objective continence rate was 37% for patients with ISD and 95% for those with SUI types I and II ($p = 0.0006$) after TVT procedure. However, subjective evaluation did not reveal any differences in continence rates (35). It was assumed that the position of the tape at the mid-urethral level (not the bladder neck) might be the cause of failure to restore continence. Therefore, patients with ISD should be informed regarding the lower success rate of TVT prior to the procedure.

The main complications of TVT procedure are voiding difficulty, bladder perforation, and de novo urgency. A large study showed that urinary retention occurred in 2.8% (17 out of 600 patients) lasting more than one week post-operatively. All 17 patients underwent transvaginal release of TVT and 16 remained dry after release (36). Bladder perforation and de novo urge incontinence occur in 6-11% and 25%, respectively (37,38).

In summary, the PVS procedure shows excellent long-term success rate for the treatment of SUI. Urinary retention, de novo urgency, and a small risk of erosion and infection remain as complications of this procedure. However, the PVS should be the standard against which all other minimally invasive therapies for incontinence are examined.

LAPAROSCOPIC BURCH COLPOSUSPENSION

Although numerous treatment options are available for patients with SUI, the open Burch procedure has stood the test of time (39-41). Vaginal approaches, on the other hand, continue to undergo a series of modifications in search for the most durable, biocompatible support material. As a natural extension of the success of laparoscopy in other areas, laparoscopic Burch colposuspension was introduced

by Vancaille & Scheussler in 1991 to provide patients with an alternative treatment option associated with less morbidity (42). Laparoscopic pelvic surgery provides better visualization, shorter hospital stay, better cosmetics, less postoperative pain, and faster recovery to normal daily activity. However, despite the renewed interest in the application of laparoscopic technique in the management of SUI, a dichotomy of opinion remains regarding its long-term efficacy. Laparoscopic colposuspension is historically regarded as having good, short-term success rate of over 90% (43-48) but this rate declines with longer follow-up to 59%-68% (Table-1) (49-50). This is in contrast to the open Burch procedure, which is associated with a 10-year success rate of at least 81.6% (51). Although the laparoscopic approach is arguably more cost-effective and less morbid than the open procedure originally described by Burch in 1961, laparoscopic Burch is not recommended for recurrent SUI (40,52-54). The wide range of success rates reported by some of the most skilled laparoscopists has led many to scrutinize this technique. This may be partly related to the difference in the definition of success rate after incontinence surgery, limited follow-up, and lack of standardized suturing technique.

Laparoscopic Burch colposuspension has been described using the transperitoneal or extraperitoneal approach, using 3 to 5 trocars. The extraperitoneal route is favored by most authors

(40,52,55,56) and is similar to the technique described by Burch (39). In this approach, the space of Retzius is rapidly dissected using a balloon, or without a balloon by finger and pneumodissection with CO₂ (40,43). This in turn reduces the operative time, and helps minimize the cost (40,52). The extraperitoneal approach also avoids intraperitoneal pelvic adhesions, minimizes the risk of intra-abdominal injury, and is associated with a shorter learning curve. The main disadvantage of extraperitoneal laparoscopic colposuspension is the risk of increased absorption of CO₂ leading to pneumomediastinum and pneumothorax (41,57). On the other hand, the transperitoneal approach is suitable for patients undergoing concomitant pelvic surgery (47-49,58,59). The operative time with this technique may be prolonged due to the need to take down adhesions, mobilize the bladder, and difficulty in retracting intra-abdominal organs. The gasless approach has also been described (60). A pilot study by Flax has shown the gasless approach to be feasible and easier than the traditional approach leading to lower conversion rates, simpler suture tying, and decreased operative time.

One of the factors that affects the learning curve and determines the success rate of laparoscopic colposuspension, is the intuition one has to develop in determining suture tension while approximating the Cooper's ligament to the pubocervical fascia. Because of the relative lack of tactile feedback with

Table 1 - Contemporary series of laparoscopic Burch colposuspension.

Series	Year	Patients (No.)	Success Rate (%)	Follow-Up (months)
Liu (47)	1993	58	94.8	6-22
Liu, Paek (48)	1993	107	97.2	3.27
Nezhat (43)	1994	62	100	8-30
McDougall (50)	1994	56	59	23
Cooper (41)	1996	113	87	8.4
Radomski (52)	1996	46	85	17.3
Lobel (49)	1997	35	68.6	34
Pelosi (46)	1998	10	100	20
Sadi (63)	1998	70	91.4	15.9
Jacome (45)	1999	51	94	24
Lee (44)	2001	166	90.7	36

Table 2 - Comparison of open versus laparoscopic Burch colposuspension.

	Laparoscopy (ref. 55)	Open (ref. 55)	Laparoscopy (ref. 64)	Open (ref. 64)	Laparoscopy (ref. 58)	Open (ref. 58)
Patients (No.)	70	87	34	40	36	36
Follow-Up (months)	12.9	16.3	18	18	17	46
Success Rate (%)	91.4	92	87.9	85	80	75
Surgery Time (min)	49.2	62.6	70.18	53	89	42
Hospital Stay	14 hours	2.7 days	36 hours	76 hours	3 days	6.7 days
Recovery Period	1.6 weeks	4.7 weeks	8.5 days	31.5 days	15 days	21 days
Complications (%)	15.8	33.3	33	40	14	28

laparoscopic surgery, the technique warrants that the urologist must overcome this portion of the learning curve outside the operating room. Tying of the knots can be performed with intracorporeal free-hand technique, using the Endostitch device (US Surgical Corporation, Norwalk, CT, USA), or by using an extracorporeal knot pusher (48). The type of suture used to elevate the bladder neck also varies. Although Burch proposed an absorbable suture in his initial report, some have used non-absorbable sutures to minimize recurrence (41,58). The use of curved needle, straight needle, and Stamey's needle has been described with laparoscopic Burch colposuspension (49). Broken needles at the time of laparoscopy, though rarely reported, can be very frustrating (61). In all cases, however, emphasis is placed on the degree of tension placed on the suture rather than the type of needle or suture utilized.

Finally, the number of sutures placed on each side of the urethra has been studied in a prospective, randomized study by Persson & Wolner-Hanssen (62). One hundred and sixty-one women were randomized to receive one (78) or 2 (83) sutures. At one-year follow-up, the objective cure rate was 83% for the two-suture group. Therefore, placement of 2 sutures at the bladder neck is recommended.

There have been numerous reports confirming the feasibility of laparoscopic Burch colposuspension (41,43-47,49,52,63). Review of 10 series (1993-2001) shows that the laparoscopic approach is associated with less postoperative analgesic use, shorter hospital stay, and rapid recovery

(Table-2). However, durable long-term results that compare with the open retropubic technique have yet to be demonstrated. Comparative studies between the open and laparoscopic approach have been reported (55,58,64). Miannay and associates reported on an age, stage, and associated procedures-matched retrospective analysis of 72 patients (58). With a mean follow-up of 17 and 46 months for the laparoscopic and open groups, respectively, the cure rate after one and 2 years was similar in both groups. Similarly, Saidi et al. (55) retrospectively compared laparoscopic colposuspension with open Burch in 157 patients. The short-term cure rate at 12-16 months was comparable to the open procedure (91.4% vs. 91.8%), and complication rate was lower for the laparoscopic group (15.8% vs. 33.3%). On the other hand, reports by McDougall & Portis on 56 patients with SUI have demonstrated poor outcome with this procedure. At an average follow-up of 23 months, the success rate was only 59%. If preoperative abdominal leak point pressure was less than 90 mmHg, the success rate was 25% after 30 months of follow-up (50).

The only randomized, prospective study comparing open Burch to the laparoscopic approach found a lower success rate with the laparoscopic approach, which was statistically significant (65). Most recently, Brenner reported his experience with 36 laparoscopic Burch colposuspensions and 42 suburethral sling procedures (59). The Burch procedure was for primary incontinence while the suburethral sling was done for secondary cases. Although follow-up was limited (15 months for laparoscopy and 11 months for sling), the

sling group had higher success rate than the laparoscopic group (93% vs. 83%).

The complication rate related to the laparoscopic approach is higher than the open procedure (5-8% vs. 8-22%) (66). The most common intraoperative complication is lower urinary tract injury. Bladder injury, which occurs at an incidence of 2.17-18%, is common in patients with prior pelvic surgery (40,41,48,55,59,66,67). Bladder catheter drainage during surgery and meticulous dissection help prevent most bladder injuries. In the majority of cases, these injuries can be managed laparoscopically obviating the need to convert to an open procedure (52). Conversion rates, especially in the earlier stages of learning, can be as high as 26% (52). Rare cases of partial ureteral obstruction have been reported (48,68). The development of overactive bladder after laparoscopic Burch colposuspension is a well-recognized phenomenon (40,41,43,48,58,64,69). It occurs at an incidence of 2.8%-8% and has been attributed to extensive dissection of the bladder (43,48,69). The high incidence of rectocele (11-30%) and enterocele (1-5.7%) has led many to obliterate the cul-de-sac, and perform enterocele and rectocele repair, as well as vaginal wall suspension at the time of colposuspension (40,43,48,49). Furthermore, the incidence of postoperative permanent or transient urinary retention is low (1.8%) (48). Granulation tissue at the vagina from suture protruding through vaginal mucosa, and small bowel obstruction through a peritoneal defect have been reported as complications of the laparoscopic approach (49,70). Osteitis pubis has not been reported with the laparoscopic Burch procedure (71).

URETHRAL BULKING AGENTS

Periurethral bulking agents are alternative forms of minimally invasive therapy for urinary incontinence due to ISD. The bulking agents serve to increase the coaptation of the urethral mucosa and help prevent involuntary loss of urine during periods of increased abdominal pressure. Delivery of the bulking agent can be accomplished via the transurethral or periurethral route under local anesthesia and as an outpatient procedure (72). Most studies evaluating the

efficacy of bulking agents for the treatment of ISD have demonstrated that the success rate drops after 6 months due to distant migration or local degradation of the bioinjectable particles. Currently, there are two Food and Drug Administration (FDA)-approved periurethral bulking agents in the United States, collagen and Durasphere (Carbon Medical Technologies, Inc., St. Paul, Minnesota, USA). Experience with Teflon as an injectable agent, as well as Durasphere, has been disappointing due to reported cases of particle migration (73). Durasphere is a carbon-coated bead that was approved by FDA in 1999 for the treatment of incontinence due to ISD. The success rate associated with this agent is limited. Pannek et al. have recently reported their experience in 7 men and 11 women with ISD (73). Their results demonstrated that the success rate drops from 76% at 6 months to 33% at 12 months. Furthermore, at 6 months, migration of the beads was noted into the distant lymph nodes and urethral mucosa. More recently, Lightner et al. have reported the only multi-center, randomized, controlled, double-blind study comparing Durasphere to bovine collagen in the treatment of ISD (74). In this study, an average of 4.83 ml of Durasphere and 6.23 ml of collagen were injected. At 12 months of follow-up, the 2 agents produced similar results in terms of improving incontinence. Improvement rates with Durasphere and bovine collagen at 12 months were 80.3% and 69.1% ($p = 0.162$), respectively. Currently, experience with Durasphere is limited and more investigation is required before offering it to patients with ISD as the first line of therapy.

The use of collagen for the treatment of ISD has gained widespread popularity since it was FDA-approved in 1993 (72,75-78). Contigen (C.R. Bard, Covington, GA, USA) has been demonstrated to be safe, durable, and efficacious. The reported success rate with injectable collagen varies from 88% - 100%. Like all the injectable agents, the success rate declines with longer follow-up (13%) (75). Richardson et al. reported their results with collagen for the treatment of ISD in 42 women (78). The mean amount of collagen injected per patient was 28.3 ml. The greatest improvement in incontinence was noted after 17.2 ml was injected. At a mean follow-up of 42 months, 83% were greatly improved. Similarly, Cross et al. reported

their experience with collagen in 139 women with ISD (77). Seventy-two percent of patients improved after 2 or fewer injections, whereas 11% required booster injections more than 6 months after the initial treatment. Complications, in this series, were rare. Elsergany et al. investigated the relationship between the grade of incontinence and success of injection and found no difference between the 2 factors (76). At a mean follow up of 18 months, an overall success rate of 81.8% was reported. Finally, Groutz et al. showed that using strict criteria the cure rate of collagen injection was only 13% (75). Clearly, the short-term success rate with collagen is favorable, and overall morbidity is low. Uncommon complications due to collagen injection include formation of urethral diverticulum, permanent urinary retention, abscess formation, delayed hypersensitivity, and systemic arthralgia (79-82).

The use of autologous fat is an attractive treatment option. Fat may be readily harvested by liposuction from the abdomen or thigh. Autologous fat has not been shown to be more efficacious than the other bulking agents (83,84). Comparative studies evaluating collagen and autologous fat have demonstrated that autologous fat is not as efficacious and durable as collagen in improving urinary incontinence (85). Although the use of autologous fat may be cost-effective, it requires numerous injections to sustain continence. The possibility of pulmonary fat embolism has made this agent less popular (82).

CONCLUSIONS

The role of laparoscopic Burch colposuspension remains ill defined in 2002. Most authors echo the need for more prospective, multi-center, randomized studies comparing open to laparoscopic Burch colposuspension to better define the role of laparoscopy in the management of SUI. More standardized suturing techniques and methods of measuring the suture tension intraoperatively will contribute to better results. Once this minimally invasive technique is shown to duplicate the success rate of the open Burch procedure, it could be offered as a first-line therapy to patients with SUI. At this time, the PVS offers the best long-term results with accept-

able low complication rates of urinary retention, urgency, and sling erosion or infection. These complications are rarely seen with the laparoscopic repair but the incidence of bladder injuries is higher. The PVS operation can be performed as a salvage procedure, in obese patients, and concomitant with cystocele and rectocele repair whereas data for laparoscopy in these conditions are lacking. Until the long-term efficacy of the laparoscopic repair is clearly defined, offering it to patients as a minimally invasive therapy denies them of procedures with superior efficacy.

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Received: April 17, 2002

Accepted: May 24, 2002