

Clinical usefulness of the transobturator sub-urethral tape in the treatment of stress urinary incontinence in female patients with spinal cord lesion

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Objectives: To evaluate the clinical usefulness of transobturator sub-urethral tapes for the treatment of stress urinary incontinence in women with spinal cord injury.

Method and subjects: Chart review for all female patients with spinal cord injury who underwent implantation of a transobturator sub-urethral tape for treatment of stress urinary incontinence at our institution.

Results: Nine women, median age 45.1 years, received a sub-urethral transobturator tape in the period November 2007 to September 2010. Four patients had paraplegia and five had tetraplegia. Seven women performed intermittent catheterization. At follow up, three of the nine patients were either cured or vastly improved. One major late complication (urethral erosion) occurred. Five of the six patients without treatment success underwent second-line treatment (artificial sphincter or urinary diversion).

Conclusion: In our case series, implantation of transobturator sub-urethral tapes in women with stress urinary incontinence due to intrinsic sphincter deficiency and a low leak point pressure led to unfavorable results.

Keywords: Transobturator tape, Neurogenic bladder, Spinal cord injuries, Urodynamics, Urinary stress incontinence, Detrusor dysfunction, Quality of life

Introduction

Spinal cord lesions are commonly associated with neurogenic lower urinary tract dysfunction. Whereas an elevated storage pressure, either due to low bladder compliance or to detrusor overactivity, is the major risk factor for renal deterioration,¹ urinary incontinence has the most detrimental influence on the quality of life.² If urinary incontinence is caused by detrusor overactivity, continence can be achieved by suppression of detrusor overactivity. Infrapubic lesions are commonly associated with sphincter weakness, leading to stress urinary incontinence. Depending on the neurologic lesion, a combination of detrusor overactivity and pelvic floor insufficiency is possible.¹

For the treatment of stress urinary incontinence, a variety of procedures have been introduced. Implantation of an artificial urinary sphincter leads to continence in more than 80% of the patients.³ However, long-term follow-up demonstrates significant

complication rates, requiring surgical revision in a substantial percentage of the patients.⁴ Within the last decade, minimally invasive sub-urethral slings have become a safe, effective, and increasingly popular treatment in female patients with stress urinary incontinence without neurogenic bladder dysfunction.⁵ Therefore, minimally invasive techniques might also be a promising option in patients with neurogenic bladder dysfunction and stress incontinence. However, until today, very few studies concerning this group of patients are published, mainly using a single technique, namely the transvaginal tape.⁶⁻⁸ We evaluated the clinical usefulness of another approach, the transobturator tape (TOT), in patients with spinal cord lesion and stress urinary incontinence.

Methods

From November 2007 to September 2010, nine women with stress urinary incontinence due to neurogenic bladder dysfunction caused by spinal cord lesion underwent implantation of a sub-urethral TOT (I-Stop[®], B.Braun, Melsungen, Germany).

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Before surgery, all patients complained about involuntary urine loss. For preoperative evaluation, all women underwent thorough medical history including counting the number of incontinence devices used per day, vaginal examination, renal ultrasound, and video-urodynamic testing. These examinations were repeated 3 months after surgery and once every year since then.

Prior to all urodynamic evaluations, an acute urinary tract infection was ruled out by dipstick testing of the urine.

Urodynamic examination was performed with the patients in supine position. An 8F transurethral double-lumen catheter and an indwelling 14F rectal catheter, the balloon inflated with 10 ml were used for the measurement of intravesical and rectal pressure, respectively. The bladder was filled with a sterile mixture of contrast media and 0.9% saline solution at body temperature with a filling rate of 20 ml/minutes. Pressure was measured by Statham elements, the data were recorded by a standard urodynamic computer (Medical Measurement Systems[®], Gladbeck, Germany). Coughing was used as a standard provocative maneuver during the filling phase, whereas suprapubic tapping was performed at the end of the examination. At the end of the urodynamic examination, cough leak point pressure (LPP) was determined.

All implantations were performed by a single surgeon with a long experience in sling implantation in patients with non-neurogenic bladder dysfunction. Surgery was performed under general ($n = 6$) or spinal ($n = 3$) anesthesia. All patients received a prophylactic single-dose administration of ciprofloxacin at introduction. The insertion of the I-Stop[®] tape (B.Braun) was performed in a standard technique reported previously.⁹ In summary, the implant is placed under the mid-urethra and passed through the obturator foramen starting with a vaginal incision 10 mm below the urethral meatus. After dissection of the para-urethral spaces, the introducer needle was brought through the obturator membrane and round the ischiopubic ramus and was guided into the space made by the sub-urethral incision. The sling was attached to the needle and exteriorized by withdrawing the needle. At the end of the surgery, a 14 French urethral catheter was inserted for 24 hours. After removal of the catheter, all patients resumed their initial way of emptying the bladder. In the patient voiding spontaneously, residual urine was controlled by ultrasound.

The study was approved by the local ethics committee.

Results

Median age of the nine patients was 45.1 years (range 27–63 years). Four patients had paraplegia and five had tetraplegia. Spinal cord lesion was complete in four and incomplete in five women. Mean time between spinal cord lesion and surgery was 11.8 years (range 0.5–29 years).

Seven women emptied their bladders by intermittent catheterization, one patient voided spontaneously, whereas one patient was equipped with a suprapubic catheter. To ensure sufficient suppression of detrusor overactivity, three patients had undergone ileum augmentation of the bladder, in one patient sacral deafferentation has been performed, and three women received botulinum toxin A injections at regular intervals. Two patients initially presented with acontractile detrusor and therefore did not require additional treatment. In all patients, second- or third-grade genital prolapse or third-grade cystocele were ruled out by vaginal inspection.

Video-urodynamic testing before surgery demonstrated a stable detrusor in the filling phase and normal bladder compliance in all nine patients. Median detrusor compliance was 120 ml/cmH₂O, and median maximum detrusor pressure was 11 cmH₂O. Median bladder capacity was 467 ml. Five patients presented with a closed bladder neck during the filling phase, whereas the bladder neck was open in four patients.

Thus, in all patients genuine stress urinary incontinence was proven. Cough LPP could be determined in six of nine patients; median LPP in these women was 28 cmH₂O.

All patients used incontinence devices prior to surgery. Two women were equipped with diapers (each using two diapers within 24 hours), the remaining seven patients used incontinence pads (median four pads per 24 hours).

The immediate postoperative course was uneventful in all patients.

Median time between surgery and the most recent follow-up examination was 6.8 months.

Results

At follow-up, the two women with diapers utilized the same amount of diapers at the time of follow-up. The median number of incontinence pads was reduced to 2.6 per 24 hours. However, only two patients did not use any pads (continent). In an additional patient, pad use was reduced by 50% (improved). Thus, in six of nine women, incontinence was not improved by the TOT procedure (Table 1). Renal ultrasound was

Table 1 Clinical results

Patient no.	Age	Management	Clinical data				Second line treatment
			Pads before TOT	Pads after TOT	Outcome		
1	47	IC	3	0	Continent	None	
2	45	IC	5	5	No change	Urinary diversion	
3	63	Spontaneous	Diapers	Diapers	No change	Urinary diversion	
4	35	IC	4	1	Continent	None	
5	47	IC	Diapers	Diapers	No change	Urinary diversion	
6	69	SPC	2	2	No change	Artificial sphincter	
7	27	IC	5	5	No change	Artificial sphincter	
8	31	IC	2	2	No change	Artificial sphincter	
9	42	IC	6	3	Improved	None	

IC: intermittent catheterization; SPC: suprapubic catheter; TOT: transobturator tape.

normal in all patients. Vaginal examination demonstrated erosion of one tape. Cystoscopy revealed a urethral fistula in this patient, who subsequently had to undergo urinary diversion. Further diagnostic revealed a multiple myeloma in this patient, who developed several other fistulas (anal canal, pelvic floor, cutaneous).

Urodynamic parameters

Median bladder capacity (379 ml), maximum detrusor pressure (12 cmH₂O) and detrusor compliance (106.7 ml/cmH₂O) did not show significant differences compared to the preoperative findings. Especially, no new onset of detrusor overactivity was detected. Median LPP was higher (41.2 cmH₂O) than before surgery (Table 2).

In all three patients with cure or improvement, the bladder neck was closed during videourodynamics. However, in two additional patients incontinence persisted despite a closed bladder neck during the storage phase.

Second line treatment

As all patients were treated for symptomatic incontinence, second line treatment was required in five of the six patients without treatment success after TOT

placement. Three women became continent after placement of an artificial sphincter; whereas in two patients, including the woman with the urethral fistula, urinary diversion was performed. One patient is not content with the current situation but hesitates to undergo more invasive surgery.

Discussion

As urinary incontinence has a negative impact on quality of life (QoL) in patients with spinal cord lesion, many patients seek treatment. Therapeutic options in this group of patients, however, differ from treatment strategies in patients with stress incontinence without neurogenic lesion. Due to the neurogenic pelvic floor dysfunction, active conservative measures, such as pelvic floor exercises or biofeedback, are virtually impossible in the majority of patients, and the success of external electrostimulation or duloxetine treatment on stress urinary incontinence in patients with spinal cord lesions has not yet been assessed, but seems to be limited due to the above-mentioned reasons. Thus, surgical procedures are the most frequently used treatment options in these patients.

The artificial sphincter is regarded as an effective surgical treatment option, but patients with neurogenic

Table 2 Urodynamic data

Patient no.	Before TOT insertion				After TOT insertion				Outcome
	Cap.	Compl.	Pdet	LPP	Cap.	Compl.	Pdet	LPP	
1	500	80	10	26	500	85	5	31	Continent
2	110	27	14	47	100	24	16	23	No change
3	500	161	16	25	580	78	20	58	No change
4	700	82	14	20	455	76	14	13	Continent
5	500	50	10	24	265	66	7	35	No change
6	500	98	5	31	285	50	8	40	No change
7	470	66	8	26	470	66	8	100	No change
8	410	408	3	25	400	405	9	31	No change
9	510	107	19	28	360	110	21	40	Improved

Cap: bladder capacity (ml); Compl: detrusor compliance (ml/cmH₂O); Pdet: maximum detrusor pressure (cmH₂O); LPP: valsava leak point pressure (cmH₂O).

incontinence undergoing artificial sphincter implantation seem to be at a higher risk for failure of the implant compared to patients with incontinence of non-neurogenic origin. In a retrospective comparative study, patients in the neurogenic group had a higher risk of non-mechanical device failure and requirement for reoperation compared to patients with non-neurogenic stress urinary incontinence.¹⁰ Patki reported a 77% success rate; only 44.5% did not undergo either revision or explantation.³ In summary, high short-term and long-term continence rates can be achieved, but the complication and revision rates are substantial.⁴

Bladder neck slings seem to be a reasonable alternative for the enhancement of bladder outlet resistance in patients with neurogenic bladder. Castellan *et al.*¹¹ described a long-term continence rate of 88% and a low complication rate with the use of the rectus fascial sling. In addition, they do not consist of alloplastic material, but of the patients' own rectus fascia, making infection and erosion less likely. Other authors, however, could not reproduce these results.¹²

Recently, several minimally invasive treatment options for stress urinary incontinence have been developed. A variety of different bulking agents have been used. Teflon and carbon-coated beads have been proven to migrate,¹³ collagen demonstrated only moderate short-term success and disappointing long-term results.¹⁴ The use of sub-urethral tapes should be the logical consequence of the above-mentioned data. Sub-urethral tapes have been used for more than a decade for the treatment of stress urinary incontinence in women without neurogenic lesions. Today, these slings are classified according to the implantation approach. Tension-free vaginal tapes (TVT) were introduced by Ulmsten in 1996.¹⁵ In 2001, a transobturator approach (TOT) was introduced.¹⁶ Despite many modifications, sub-urethral slings are basically subdivided into TVT and TOT. Virtually all slings are made of synthetic material, predominantly monofilament polypropylene.¹⁷ A recent prospective study comparing the two techniques demonstrated similar success rates (TOT: 72.9%; TVT: 71%) and complication rates (TVT: 17.2%; TOT: 16.1%) after a 5-year follow-up.¹⁷ Thus, intuitively, sub-urethral slings might be a treatment option in female patients with stress urinary incontinence due to neurogenic bladder dysfunction as well, but the clinical experience in women with spinal cord lesion is still limited.⁶ Hamid *et al.* were the first to report the use of TVT in 12 patients with neurogenic bladder dysfunction with a subjective cure rate of 83.3%, which is comparable to the data reported in

patients with non-neurogenic bladder dysfunction. However, only three patients in their series suffered from spinal cord injury.⁶ The same group could demonstrate favourable long-term effects in the aforementioned group of patients.⁷ In their series, one patient developed *de novo* detrusor overactivity after TVT implantation. In our group, we did not detect changes in detrusor function after TOT implantation.

Whereas in these studies exclusively the TVT was used, Patki *et al.* presented data from patients with spinal cord injury and mixed incontinence in which, after resolving detrusor overactivity, stress urinary incontinence was treated by either TVT ($n = 3$) or TOT ($n = 6$). In this small group of patients, no difference between the two approaches was found.⁸ Noteworthy, in sharp contrast to our study, all patients were cured or improved after TOT insertion.

There are several possible explanations for the disappointing results of our study. First, surgical technique can be debated. However, as all procedures were performed by a single surgeon with a long experience with this kind of surgery in non-neurogenic patients with cure rates comparable to those published in the literature, we think we can rule out this factor.

The sling material is known to influence the success and complication rates in sub-urethral sling surgery.¹⁸ The sling type utilized in this study, however, has been proven to be safe and effective in several studies with large numbers of patients.⁹

Therefore, it is unlikely that the type of sling used has influenced the results.

Stress urinary incontinence in patients with spinal cord injury is frequently based on a weak external urethral sphincter, in some cases combined with urethral hypermobility.⁷ Thus, stress urinary incontinence in patients with spinal cord injury is at least partially due to intrinsic sphincter deficiency. Schierlitz and co-workers could demonstrate that TVT insertion is more effective in intrinsic sphincter deficiency than TOT placement.¹⁹ This is probably due to the different sling axis of the two approaches. In TVT, the axis is more perpendicular to the urethral axis, creating more circumferential compression of the urethra¹⁹ and thus giving better support in patients with a more severe compromise of the urethral closure and support mechanism.²⁰ Thus, the type of stress urinary incontinence may have contributed to the disappointing results in our study. In our patients, all patients with treatment success had a closed bladder neck on cystography. However, as treatment of two patients was not successful despite a closed bladder neck on cystography, this examination does not seem to be useful for the prediction of surgical success.

However, the preoperative LPP in our patients was low (28 cmH₂O), which has been demonstrated to be a risk factor for objective failure for mid-urethral slings in patients without neurogenic lower urinary tract dysfunction. The disappointing results may therefore at least partially be attributed to the type and grade of detrusor deficiency in our group of patients. Our study may serve as a first hint that the same criteria may be applied to patients with neurogenic stress urinary incontinence as to those with stress urinary incontinence (SUI) of non-neurogenic origin.²¹

Another possible explanation for the poor results of TOT placement in patients with spinal cord injury is the fact that patients with spinal cord injury tend to develop pelvic deformities, e.g. a posteriorly tilted pelvis,²² which alters the position of the obturator foramen. The altered angle between the bony structures and the urethra might contribute to the high failure rate of the procedure in this group of patients.

In addition to the low continence rate, we experienced a urethral perforation of one sling which led to a urethral fistula following sling resection, necessitating urinary diversion. As this patient suffered from multiple myeloma, the disease may have facilitated development of fistulas, but still the complication rate in our small series is high.

Our study has several drawbacks. We present data from a retrospective study with no control group. We did not use a quality-of-life instrument to assess subjective improvement after surgery, and the number of patients is rather small. However, the results of our case series seem to be clear that in our eyes a standardized questionnaire would not have added information about the outcome, and because of the high failure rate of the procedure, we could not justify offering this approach to patients with SCI and stress urinary incontinence due to intrinsic sphincter deficiency and a low LPP anymore.

Conclusion

In this case series, TOT placement in patients with stress urinary incontinence due to spinal cord injury with a low LPP led to unfavorable results and a substantial complication rate despite adequate experience of the surgical team.

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