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ORIGINAL ARTICLE

The two-year outcome of the I-Stop TOMS™ transobturator sling in the treatment of male stress urinary incontinence in a single centre and prediction of outcome



Traitement de l'incontinence urinaire masculine par bandelette transobturatrice I-StopTOMS™, évaluation monocentrique avec deux ans de suivi

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KEYWORDS

Male urinary incontinence;
 Male sling;
 Transobturator sling;
 Prostatectomy

Summary

Purpose. – The aim of this study was to present the results of the 2 year outcome of I-Stop TOMS™ transobturator sling for post-prostatectomy (UIPP) minor to moderate male urinary incontinence treatment.

Materials and methods. – A prospective, single center study, including 26 patients with minor to moderate IUPP and operated on using a suburethral sling (MS) TOMS™ (four arms) was performed. UIPP assessment was made preoperatively and 1 year postoperatively, using validated questionnaires (SF36 and ICIQ), number of pads daily, and the 24 hours Pad-test (LPT). Telephone follow-up evaluation was performed in 21 patients over a 2 years period following surgery.

Results. – Radical prostatectomy was performed 48.4 months earlier and average patient age was 67.3 years. Preoperatively, the mean number of pads used daily was 2.3 with an average weight loss of 207.1 grams at LPT. At 1 year, ICIQ and SF36 scores significantly improved. Weight loss in the LPT as well as the number of pads significantly decreased ($P < 0.05$). At 1 year, 13 patients were cured, 12 were improved, one reached improvement criteria, and 96.2% using a pad daily maximum. With more than a 2 year follow-up, 10/21 patients were dry, nine improved and two failed, and 90.5% using 0 to 1 pad per day.

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MOTS CLÉS

Incontinence urinaire masculine ;
Bandelette homme ;
Bandelette transobturatrice ;
Prostatectomy

Conclusions. – The transobturator TOMS™ male sling is a simple and well-tolerated procedure permitting a significant improvement of UIPP, with 50% of patients achieving complete continence at 1 year postoperatively, these good results continued beyond 2 years.

Level of evidence. – 4.

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Résumé

But. – Le but était de rapporter avec deux ans de suivi les résultats du traitement de l'incontinence urinaire masculine mineure à modérée (IUPP) par bandelette transobturatrice I-StopTOMS™.

Matériel. – L'étude prospective monocentrique a porté sur 26 patients ayant une IUPP et opérés de bandelette transobturatrice I-StopTOMS™ quatre bras, ayant au minimum un an de recul. L'analyse a porté sur la continence, le nombre de garnitures, le poids des fuites/jour, les questionnaires SF 36 et ICIQ. Pour 21 patients ayant un recul minimum de deux ans, l'analyse des mêmes paramètres a été réalisée par évaluation téléphonique.

Résultats. – Le délai entre la prostatectomie et la pose de bandelette était de 48,4 mois, l'âge moyen des patients de 67,3 ans. Le nombre moyen de garnitures était de 2,3 et le pad-test de 24 h. de 207 g. À un an, les scores SF 36 et ICIQ étaient significativement améliorés, de même le pad-test et le nombre de garnitures, 13/26 patients étaient guéris, 12 étaient améliorés, et 96 % des patients avaient 0 à 1 garniture par jour. À deux ans, 10/21 patients étaient guéris, neuf améliorés, deux en échec, et 90,5 % des patients avaient 0 à 1 garniture par jour.

Conclusion. – La bandelette transobturatrice I-StopTOMS™ est une procédure simple qui permet une amélioration significative de IUPP mineure à modérée, avec 50 % de patients ayant une continence complète à un et deux ans, et pour 90 % des patients une amélioration significative avec 0 à 1 garniture par jour.

Niveau de preuve. – 4.

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Introduction

The incidence of urinary incontinence post-prostatectomy (UIPP) varies from 10 to 87% [1,2]. It affects the patient's quality of life (QOL) even when only one pad is used per day [3].

Severe incontinence is treated by implanting an artificial sphincter (AS), which today remains the gold standard, but slight or moderate incontinence may be treated with periurethral injections, periurethral adjustable continence therapy (ACT) balloons or suburethral male slings (MS) in order to improve the continence with a minimal invasive surgery. The aim of this study was to evaluate the results of the TOMS™ bulbar-transobturator suburethral male sling with four arms to treat slight to moderate UIPP at 1 year then 2 years follow-up and to search predictive factors of success.

Material and methods**Structure of the study**

A prospective single centre study in a series of 26 patients operated on by the same surgeon was reported. Patients gave their informed written consent to be included in the study, which was approved by the local Ethics Committee.

Inclusion criteria were: slight to moderate UIPP; urinary physiotherapy failure; prostatectomy more than 1 year previously. Exclusion criteria were: sign of recurrence on PSA,

radiotherapy, neurological disease, urethral or anastomotic stenosis confirmed by urethroscopy or urethrography, detrusor overactivity with leak from bladder contraction, chronic urinary retention or current urinary infection.

Slight incontinence was defined as one to two pads per day, moderate incontinence as three to four pads, severe as equal or more than five pads.

Data collection

The data collected were: patient's age; RP-MS time (delay in months between radical prostatectomy and MS); UD (urodynamics recording bladder compliance, maximum bladder capacity, maximum urethral closure pressure, and detrusor activity); uroflowmetry (recording maximum flow rate, urine volume and post-urination volume obtained from a bladder scan); ICIQ questionnaire score: based on three questions concerning the leakage and Quality of life affected by leakage, the total value varying from 0 (no incontinence) to 21 (major incontinence); SF36 questionnaire Score: specific score on urinary incontinence and QOL. The total value obtained varied from 0 (major incontinence) to 500 (no incontinence); number of pads per day; 24 hour Long Pad-Test (LPT) according to ICS recommendations [4]; occurrence of early postoperative complications; Index of satisfaction based on two questions, each had four items i.e. very satisfied, satisfied, dissatisfied and very dissatisfied. The two questions were "What do you feel about the surgery performed?" and "What is your opinion about your

condition after the operation compared to your previous condition?"; A Visual Analogic pain scale (VAS) range 0 to 10.

The timetable for data collection was before surgery; during hospital stay; at 30, 90, 180 and 360 days after surgery. A telephone interview was added more than 2 years postoperatively using the same evaluation based on the ICIQ questionnaire plus a specific questionnaire i.e.: do you suffer from urine leakage: yes or no? How many pads do you use per day on average?

Surgical technique

The technique was previously described by Grise et al. [5]. The shape of the tape is a rectangle with four arms extension (two on each side). Its structure is made of polypropylene monofilaments organized into a macroporous mesh.

Patient classification results:

- group A: patient cured: if the following four criteria were number of pads 0 or 1; LPT 0 g; SF36 score 500; ICIQ score 0;
- group B: patient improved: if the following four criteria were reached i.e. number of pads reduced by more than 50%, or equal to 0 or 1; LPT reduced by more than 50%; improved SF36 or ICIQ score;
- group C: patient failure. It could be either a patient slightly better (number of pads reduced by less than 50%, or equal to 0 or 2 or more; LPT reduced by less than 50%; SF36 score improved; ICIQ score improved) or a patient complete failure.

Statistical analysis

The preoperative and one-year postoperative characteristics were compared using the Wilcoxon, or the Friedman test, non-parametric Rank test on related series. The preoperative characteristics of cured and non-cured patients were compared with the Mann-Whitney non-parametric Rank test. Analyses and graphical representations (boxplot and stripchart) were performed using R-2.14.0 software for Windows.

Results

Descriptive analysis of the preoperative population

Radical prostatectomy was performed 48.4 months (12–156) earlier and average patient age was 67.3 years (54–80). Preoperatively, the mean number of pads used daily was 2.3 (1–4) with an average weight loss of 207.1 g (24–1100) at LPT.

Characteristics of the hospital stay

In 24 of the 26 patients (92.3%): no postoperative complications were reported. One patient presented with a small haematoma near the site of the incision, while another patient experienced pain conducting to 24 hours-delayed discharge from hospital. Postoperative pain was evaluated at 2 [range 0–7] on a VAS. The index of satisfaction was very

satisfied or satisfied for 25 patients (96.1%) but one patient was dissatisfied due to the persistence of incontinence.

Results of male slings 1 year after surgery

As regards the ICIQ score, 14 patients (54% [CI95: 33%–73%]) had an ICIQ score evaluated at 0 1 year after surgery, whereas the 12 others all had an improved score (46% [CI95: 27%–67%]). The median ICIQ score changed from 14.5 [11–18] preoperatively to 0 [0–12] 1 year after surgery. The difference was statistically significant ($P < 0.001$).

SF36 scores showed that 13 patients (50% [CI95: 30%–70%]) obtained the maximum score of 500, while the 13 others (50% [CI95: 30%–70%]) had an improved score. Between D0 and D360, there was a significant improvement in the median SF36 score, which changed from 83 [range 0–167] preoperatively to 425 [range 83–500] 1 year after the operation ($P < 0.001$).

As regards results of the LPT, 15 patients (58% [CI95: 37%–77%]) obtained a nil final weight, while the 11 others (42% [CI95: 23%–63%]) all had a lower urinary loss weight. The median LPT changed from 207 g [24–1100] preoperatively to 22.5 g [0–200] 1 year after surgery. The difference was statistically significant ($P < 0.001$).

Number of pads (Fig. 1): all patients reduced their number of pads, with 15 patients (58% [CI95: 37%–77%]) no longer using any pads, 10 patients (39% [CI95: 20%–59%]) only using one, and one patient (4% [CI95: 0%–20%]) using three pads per day. The median number of pads used varied from 2 [1–4] to 0 [0–3] 1 year after surgery.

Results of male slings 2 years after surgery

Twenty-one patients were evaluated at more than 2 years post-surgery, with a median period 35 months (24–48). Concerning daily number of pads used (Fig. 1): 12 patients used respectively 0 pads (57% [CI95: 34%–78%]), seven patients used one pad per day (33% [CI95: 15%–57%]), one two pads (5% [CI95: 0%–24%]), one three pads (5% [CI95: 0%–24%]). Daily use of pads compared with the number used prior to surgery decreased significantly (2 [range 1–4]; $P < 0.001$), but there was no difference when compared to 1 year.

Concerning ICIQ score: 10 patients (48% [CI95: 26%–70%]) had a score 0, 11 patients (52% [CI95: 30%–74%]) had a better score than before surgery and five patients among these (24% [CI95: 8%–47%]) had a worse score than at the 1 year evaluation.

The median ICIQ score was 2 [0–15], significantly lower than the preoperative score (which was 14 [11–18]; $P < 0.001$). There was no significant difference from the score obtained at 1 year.

Group results at 1 and 2 years after surgery

At 1 year: 13 patients were cured (group A) (50% [CI95: 29.9–70.1]), 12 patients were improved (group B) (46.2% [CI95: 26.6–66.6]), one patient was slightly better but considered as failure (group C) (3.8% [CI95: 0–19.6]) and 0 patients had complete failure (0% [CI95: 0–13.2]).

At 2 year: 10 patients (47.6% [CI95: 25.7%–70.2%]) were cured (no leakage, 0 pads and ICIQ score of 0), nine patients (42.8% [CI 95: 21.8%–66.0%]) were improved (leakage with

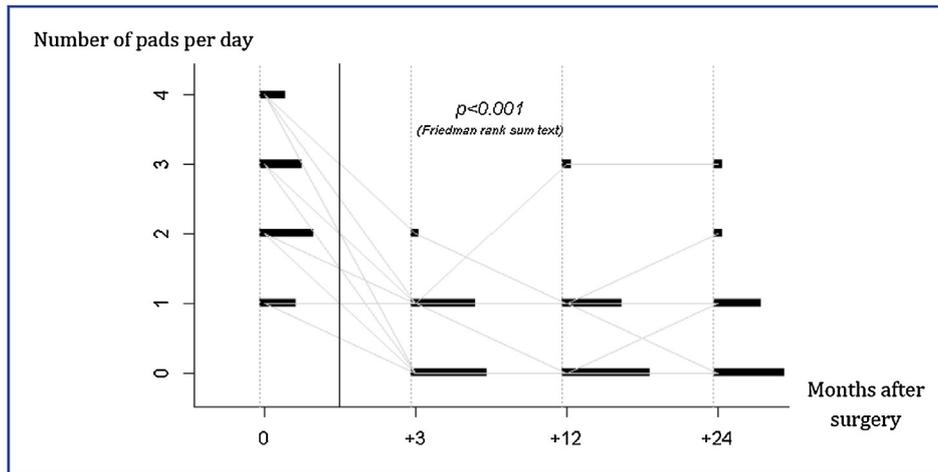


Figure 1. Results on continence according to pad per day during the follow-up period.

the use of a single pad per day and an improved ICIQ score), two patients (9.5% [CI95: 1.2%–30.3%]) experienced treatment failure (leakage with the use of two or more pads). The results are summarized on Fig. 2.

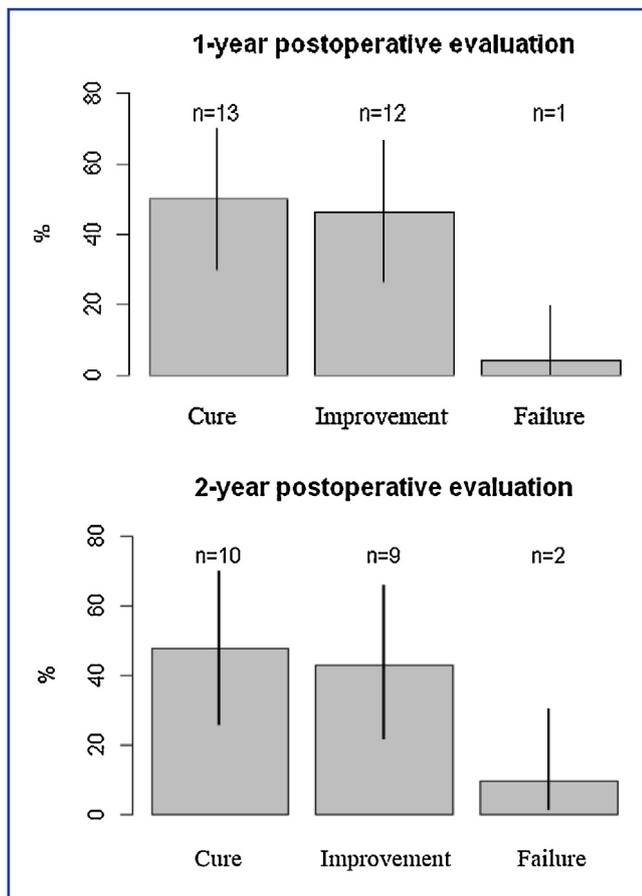


Figure 2. Results on continence according to % of the total number of patients and to classification in completely dry (A), improved (B), failure (C).

Predictive factors of success

In order to identify factors predictive of success, two groups were considered: a completely dry group (group A), and a no dry group (group B and C). All the preoperative data were successively tested, in order to search for a significant difference between the success group and the failure group, defined as $P < 0.05$. (Mann-Whitney-Rank test). The only predictive of success factor was a low LPT, with a median of 50 gm in the completely dry group as compared to 200 g in the non-dry group ($P = 0.024$).

Discussion

Our series has shown that half of the patients with slight or moderate post-prostatectomy incontinence may be cured and that more than 90% had 0 to 1 pad per day, these good results were similar at 1 and 2 years.

A comparison of our continence results with those described in the literature is difficult due to the variable definition of success, which has not been standardized. If success is defined by the wearing of a maximum daily 0 to 1 pad, our series showed a 96.2% success rate 1 year after surgery and a 90.5% success rate after 2 years (median elapsed time of 35 months). In comparison, the artificial sphincter series [6,7] ranged from 75 to 90%, those with balloons [8] ranged from 52 to 81%, those with other slings varied widely from 40% to 96% [9]. The good results in our series are probably explained by our patient selection excluding severe incontinence and radiated patients. In fact, only one predictive factor of success in the multivariate analysis was a 50 g LPT score in the completely dry group versus 200 g in the non-dry group which underlines the importance to select patients based on LPT in order to propose a MS versus an artificial sphincter. A correlation of success (very much or much improved) or failure, based on LPT and Patient Global Impression of Improvement questionnaire, was also reported by Fisher et al. [10] with respectively 22.5 g versus 350 g.

In contrast to our study most authors reported results with only one-year follow-up. Our results, over 2 years for 21 patients, were: 18 wearing the same number of pads, two deteriorated and one improved. This stability of results over time could be due to a tough transobturator attachment of the sling and a large surface over the bulbar urethra. Concerning moderate deterioration in two patients, one could assume a possible loosening of the attachment or sliding of the sling to a posterior location between the urethra and the rectum. As regards the improved patient, this may be explained by a retraction from fibrosis around the sling or a late improvement of the sphincter. Nevertheless, a long follow-up over 5 or 10 years would be necessary for a better evaluation.

We must also underline the single centre single-surgeon nature of our study with a surgeon above the learning curve and experienced with the previous TOMS™ with two arms. The results after 1 year in a series with 2-arm TOMS™ showed only 30% dry patients, 30% improved patients and 40% failure [11]. Therefore, the MS was modified from two to four arms. This was reported on a TOMS™ multicenter series [5] on 104 patients at 1 year follow-up i.e; 59.4% of patients dry and 20.3% improved. Our results are in accordance with this series.

A comparative study [9] of two MS techniques, between bone anchor MS and transobturator TOMS MS, showed a significant decrease in pad usage in the TOMS group and a better improvement on PGI, although this was a retrospective study it confirms the favorable outcome of the transobturator sling.

There is no strict consensus concerning the choice between various techniques, even if minimal invasive techniques are preferred for minor incontinence and artificial sphincter for severe incontinence and radiated patients. In moderate incontinence, the physician and the patient may discuss between the two techniques. After implantation of an AS, the patient satisfaction varies between 85 and 95% [6,7], however this surgery is invasive, with a revision rate of 40 to 64% at 10 years [12]. In a recent study asking patients what would be their choice between a MS and an artificial sphincter, a large majority opted for the MS [13].

The TOMS™ male sling could be compared favourably to other mini-invasive techniques in regards to safety. The non-invasive nature of the transobturator route has been established on large series in women and demonstrated in an anatomical study on men [14]. The Pro-ACT® balloons procedure may reach 66% continence rate in non radiated patients [8] but numerous complications were reported i.e. bladder or urethral perforations, rupture of the balloon, urine retention, urethral or bladder erosion. The bulbar and anchored InVance® MS produced good results concerning continence rate but has been discontinued due to infection (2 to 10%), acute urine retention (3 to 4%), perineal pain (4 to 22%), and an explantation rate of approximately 10% [15]. The bulbo-membranous transobturator MS Advance® was originally proposed in order to improve tolerance, however some complications have still been reported i.e. urinary retention up to 20% but only few patients with perineal pain [16–18]. Similarly to the TOMS™ location on bulbar urethra, the series involving the bulbar-transobturator Gynemesh PS® tape showed minor complications such as retention, superficial infection or chronic pain [19]. In order to make

postoperative adjustments of the tension, adjustable MS has been used [20] however the amount of inserted biomaterial is possibly a factor to explain the infection complications leading to sling explantation.

In the final analysis, the positive results of TOMS™ MS need to be confirmed by a longer-term study. Nevertheless, the study does confirm the good results and good tolerance in selected patients with no radiation and minor or moderate incontinence. Comparative studies between the various techniques available, based on comparable cohorts and identical assessment criteria are warranted.

Conclusion

In the reported series of TOMS™ transobturator MS, 50% of patients obtained a full continence and 90% used no more than one pad per day at 1 year after surgery. These good results were maintained at 2 years. This biomaterial is an attractive option for minor and moderate post-prostatectomy incontinence.

Disclosure of interest

Philippe Grise was a invited speaker for Medtronic®, Astellas®, CL medical®, and is a consultant for Astellas® and Coloplast®. No conflict of interest for the other authors.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at [doi:10.1016/j.purol.2013.08.308](https://doi.org/10.1016/j.purol.2013.08.308).

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