Original article

Argus-T sling in the treatment of male urinary incontinence: short-term evaluation in 182 patients

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Abstract: We evaluated short-term results of patients undergoing to positioning of Argus-T sling for the treatment of post-prostatectomy stress urinary incontinence (SUI). *Materials and Methods:* 182 patients were treated with Argus-T sling at four institutions from June 2008 to March 2013. The preoperative evaluation included medical history, pad count (1-2 pads: mild SUI; 3-5 pads: moderate SUI; >5 pads: severe SUI), VAS on continence, QoL score scale, physical examination, cystoscopy and urodynamic evaluation. Postoperative evaluation was performed four weeks postoperatively, and late follow-up (FU) was achieved in April 2013. We considered a satisfactory result cured (no pads) and or improved (1-2 pads per day). *Results:* 21 (11.8%), 96 (52.7%) and 65 patients (35.7%) were affected by mild, moderate and severe incontinence respectively. At the median FU of 22 months the overall satisfactory rate was 86.2%. Satisfactory results were 95% in mild incontinence, 78% in moderate incontinence and 70% in severe incontinence. In cured and improved patients we observed a statistically amelioration of QoL ($p<0.0001$). Sling regulation was necessary in 42.9% of cases while its removal occurred in 9.3% of cases. Postoperative complications were reported in 14.3% of patients. In patients with previous radiotherapy we observed a satisfactory result in 61.2% of cases. *Conclusions:* This study represents the first report that shows short-term results of Argus-T positioning in a large population. This device seems to offer good outcomes in patients with mild and moderate SUI while in case of previous radiotherapy it is associated with a low possibility to recover a satisfactory continence.

Key words: Sling; Urinary incontinence; Male urinary incontinence; Prostatectomy; Radical prostatectomy.

INTRODUCTION

It is well known that male stress urinary incontinence (SUI) is generally due to radical prostatectomy (RP) or in some cases to transurethral resection of prostate (TURP)[1]. In this setting several authors reported that up to 1-40% of patients who undergo prostatectomy are affected by persistent post-prostatectomy incontinence (PPI)[2,3].

As well defined in these cases the surgical treatment should be considered only 6-12 months after the radical prostatectomy and in presence of a permanent condition of SUI[4-5]. Indeed in this period it is useful employ a conservative therapy, such as lifestyle interventions, pelvic floor muscle training and biodfeedback[6].

In this way the artificial urinary sphincter (AUS) has been to offer long-term durable results in terms of continence and at present is the gold standard continence procedure[7,8]. However in recent years the use of slings is growing strongly and Argus-T adjustable male sling with transobturator approach seems to be attractive for the intrinsic characteristics of the material composition, for the easiness of the surgical implant and finally for its ability to modulate the urethral compression post-operatively. The literature on Argus-T is still lacking and to our knowledge there are only few reports with low number of patients. In this setting[9,10] in which the social continence rate reported is about 62-77%.

In this way we retrospectively evaluated the data in the short-term in a large cohort of patients regarding the efficacy, complication rate and quality of life in patients undergoing to the positioning of Argus-T male sling for the treatment of mild, moderate and severe SUI.

MATERIAL AND METHODS

Patients

The records of 182 patients treated with the Argus-T sling at 4 institutions since June 2008 to March 2013 were evaluated.

Eligible patients had SUI as a result of radical prostatectomy, transurethral resection of the prostate (TURP) and of previous failure of AUS, ProACT, urethral constrictor and other male slings. We considered eligible all patients affected by persistent SUI at least 6-12 months after the surgery. The patients quantified their SUI as mild 1-2 pads per 24 hours, moderate as 3-5 pads per 24 hours and severe more than 5 pads per 24 hours. We excluded all those affected by detrusor overactivity.

We also included patients underwent previous adjuvant radiotherapy after prostatectomy.

Pre-operative evaluation

The evaluation of male patients with SUI before the surgical procedure included medical history, pad count, VAS measurements on continence (scale of 1-severe incontinence to 10-dry) and a QoL score (scale of 1-poorest to 10-best)[11]. All patients were evaluated preoperatively with physical examination and cystoscopy. We performed urodynamic evaluation in all patients and we excluded the ones affected by overactivity.

The ARGUS-T Device

The Argus-T device includes a silicone cushion that is long 3.2-4.5 cm and large 2.9-3.5 cm along its antero-posterior axis. It is also connected to 2 silicone columns made of multiple cone-like sections and 2 silicone rings/washers. The rings are positioned on the columns to regulate the tension of the silicone cushion on the bulbar urethra. The coned structure of the columns allows regulation of sling tension by tightening or releasing the 2 silicone rings[10].

The surgical procedure

Implantation of the male sling

The surgical technique is the same well described by Romano et al[10] with some changes, as follows. Patients were previously treated with antibiotic prophylaxis (500mg vancomycin 4 times in 24h and 3mg/kg/die gentamicin in 72h) intravenously. Then they were operated upon under spinal or general anesthesia. With the patient in lithotomy position, it is prepared the suprapubic and the perineal areas and it is

positioned an 18 Ch Foley catheter. Then it is executed a 6cm median perineal incision and the tissues are dissected until the bulbocavernous muscle is seen. It is left in situ and the urethra is not mobilized from the central tendon. It unsticks the lateral borders until the bilateral identification of perineal aponeurosis and then it detaches this to the muscle fibers in order to access to the obturator foramen.

In correspondence of the inguinal fold it is executed a bilateral small incision below the insertion of the adductor magnus muscle. Finally it is made a last transverse suprapubic incision until the exposure of the muscle rectus fascia. Hence it is introduced the helical needle bilaterally with a movement "out-in" from the lateral entries until the perineal one. During this procedure the operator had to perforate the obturator aponeurosis so with an opposite movement it is possible to allocate the columns laterally (transobturator approach) and the cushion on the ventral surface of the bulbar urethra. Then the washers are introduced on the end of the columns bilaterally so the operator can adjust the tension of the sling.

At this point it is executed a cystoscopy to control and possibly to correct the tension. The regulation is obtained with the identification of "retrograde leak point pressure" at level 0 (normally it is 30-40cmH_2O). Then this procedure can identify any urethral trauma related to the needle crossing. When the tension of the sling is achieved the cushion is fixed to the muscle bulbocavernous. Finally the end of the columns are positioned crosswise deep the suprapubic subcutaneous fat and both wounds were closed in layers. The Foley catheter is repositioned at the end of the procedure and it is removed about 48 hours after the surgery.

Revision procedures

A revision procedure was performed on all patients with persistent SUI after implantation of the device. Patients were operated upon under spinal or general anesthesia and there was injected antibiotic prophylaxis (500mg vancomycin 4 times in 24h and 3mg/kg/die gentamicin in 72h) intravenously.

Suprapubic and inguinal incisions were opened and the sling tightened by pulling the coned columns through the washers over 1 or 2 cones bilaterally. Cystoscopy was performed as previously described. During the retrograde urethromanometry we aimed for an optimal retrograde leak point pressure (between 40 and 50 cm H_2O), generally 10 cm H2O higher than the previous condition.

Postoperative evaluation

Postoperative evaluation was performed 4 weeks postoperatively and late FU was achieved in April 2013.

Moreover we evaluated as satisfactory result the patients cured (no pads) and or improved (1-2 pads per day).

Patients were asked to fill out VAS measurements (1 to 10) on continence and QoL.

Complications and revision procedures were registered.

Data analysis

All statistical analyses were conducted using SAS version 9.3 software (SAS Institute, Inc., NC). Preoperative and postoperative results were compared using the paired samples t-test. Statistical significance were considered when $p \leq 0.05$ (two-tails.).

RESULTS

Patient characteristics

Between June 2008 and March 2013 an amount of 182 patients affected by SUI were treated with surgical procedure of positioning of sling Argus-T according to a transobturator approach. The median age of them is 71 years (range 50-86 years) and the median follow-up is 22 months (range 1-59 months) (Tab. 1).

TABLE 1. – Clinical characteristics of 182 patients with SUI pre-operative and post-operative Argus-T positioning.

Characteristics	N. (%)
Pre-operative	
Age (years)	
Median (range)	71 (50-86)
Follow-up (months)	
Median (range)	22 (1-59)
Type of radical prostatectomy	
Open	109 (59.9)
Laparoscopic	49 (26.9)
Robotic	3 (1.7)
TURP	21 (11.5)
Adjuvant radiotherapy	
No	133 (73.1)
Yes	49 (26.9)
Previous urinary device	
No	160 (87.9)
Artificial urinary sphincter	2 (1.1)
Other male sling	6 (3.3)
Pro ACT	12 (6.6)
Urethral constrictor	2 (1.1)
Vesico-urethral anastomosis stenosis	
No	154 (84.6)
Yes	15 (15.4)
Post-operative	
Number of regulations of Argus-T	
0	104 (57.1)
1	55 (30.2)
2	15 (8.2)
≥3	8 (4.5)
Type of complications	
No	87 (47.8)
Hyper-continence	16 (8.8)
Infections	9 (5.0)
Urethral erosion	1 (0.5)
Removal Argus-T	
No	165 (90.7)
Yes	17 (9.3)

21/182 patients (11.6%) were affected by mild incontinence (1-2 pads per day), 96/182 of them (52.7%) were affected by moderate incontinence (3-5 pads per day) and 65/182 of them (35.7%) were affected by severe incontinence (more than 5 pads per day).

Most of people were become incontinent after radical prostatectomy (161/182 patients, 88.4%), while the other ones after TURP (21/182 patients, 11.6%).

49/182 patients (26.9%) received previous adjuvant radiotherapy. Then some patients underwent to a previous surgery for SUI: 2/182 of them (1.1%) were treated with AUS, 6/182 of them (3.3%) with other kind of sling, 12/182 of them (6.6%) with ProACT and 2/182 of them (1.1%) with urethral constrictor.

At cystoscopy 28/182 patients (15%) showed vesico-urethral anastomosis stricture.

Operative outcomes and revisions

At the median follow-up of 22 months, the overall satisfactory rate was 86.2% (157/182 patients) of which 60/182 patients (33%) were cured and 97/182 patients (53.2%) were improved.

Also we observed that the reduction of number daily pads after the surgery and the improvement of the QoL (identified on the specific questionnaires) were statistically significant ($p < 0.0001$) after an analysis with T-student test (Tab. 2).

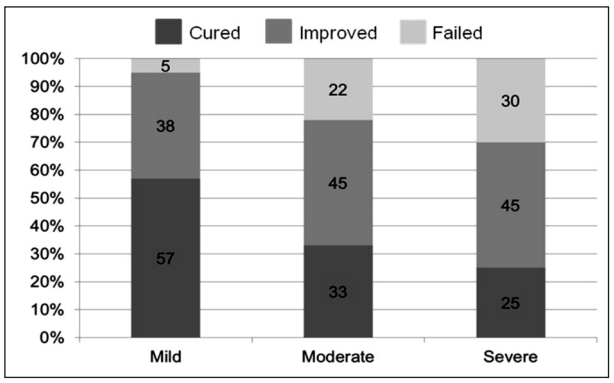

Figure 1. – Success rate by incontinence degree of 182 patients with SUI after Argus-T positioning.

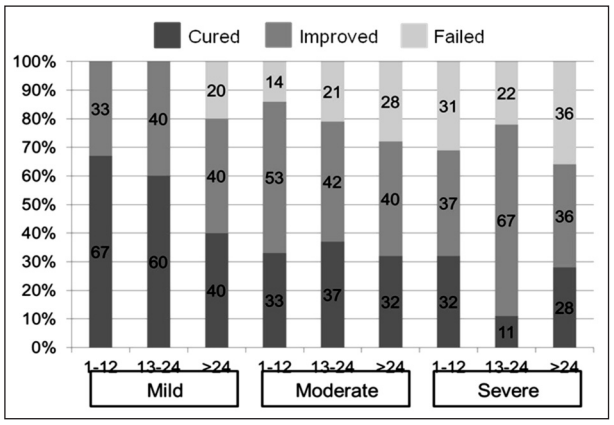

Figure 2. – Success rate by months of follow-up and incontinence degree of 182 patients with SUI after Argus-T positioning.

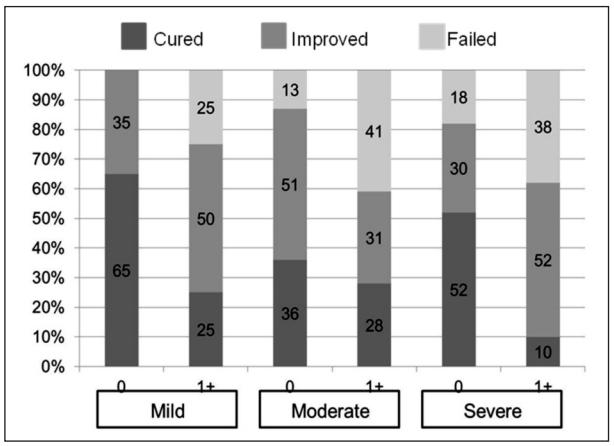

Figure 3. – Success rate by months of follow-up and incontinence degree of 182 patients with SUI after Argus-T positioning.

According the incontinence degree, we observed interesting results, as follows. 12/21 patients (57%) with mild incontinence were cured while 8/21 patients (38%) were improved. Moreover patients with moderate incontinence showed satisfactory results in 78% (33% cured and 45% improved). Finally patients with severe incontinence were cured in 25% (16/65 patients) and improved 45% (29/65 patients) (Fig. 1).

In particular, the outcomes were inversely proportional compared to the time of follow-up regardless of incontinence degree, as described in Fig. 2. We also observed the same link with the QoL score scale the VAS continence scale (data not shown).

Table 2. – Mean and standard deviation (±SD) of number of pad/die, VAS continence scale and QoL score scale of 182 patients with SUI before and after Argus-T positioning.

	Argus-T positioning		
	Before Mean (±SD)*	After Mean (±SD)*	p-value**
Number of pad/die	4.9 (±2.5)	1.6 (±1.9)	<0.0001
VAS continence scale	3.4 (±2.2)	7.5 (±2.9)	<0.0001
QoL score scale	2.9 (±1.9)	7.5 (±3.1)	<0.0001

*SD=standard deviation. **T-student pairs test

Table 3. – Clinical characteristics of 182 patients with SUI previous Argus-T positioning by adjuvant radiotherapy.

Characteristics	Adjuvant radiotherapy	
	No (N. 133)	Yes (N. 49)
Type of radical prostatectomy		
Open	80 (60.2)	29 (59.2)
Laparoscopic	35 (26.3)	14 (28.6)
Robotic	2 (1.5)	1 (2.0)
TURP	16 (12.0)	5 (10.2)
Previous urinary device		
No	114 (85.7)	46 (93.9)
Artificial urinary sphincter	2 (1.5)	--
Other male sling	5 (3.8)	1 (2.0)
Pro ACT	10 (7.5)	2 (4.1)
Urethral constrictor	2 (1.5)	--
Vesico-urethral anastomosis stenosis		
No	112 (84.2)	42 (85.7)
Yes	21 (15.8)	7 (14.3)
Number of Argus-T regulations (1)		
0	82 (61.6)	22 (44.9)
1	39 (29.3)	16 (32.7)
2	9 (6.8)	6 (12.2)
≥3	3 (2.3)	5 (10.2)1
Type of post-operative complications (2)		
No	72 (54.1)	15 (30.6)
Residual incontinence	43 (32.3)	26 (53.1)
Hyper-continence	13 (9.8)	3 (6.1)
Infections	4 (3.0)	5 (10.2)
Urethral erosion	1 (0.8)	-2
Removal Argus-T (3)		
No	126 (94.7)	39 (79.6)
Yes	7 (5.3)	10 (20.4)3

1,2,3 In comparison of the "No adjuvant radiotherapy" the p-value of the chi-square test were: p=0.04, p=0.01 and p=0.002 respectively.

In 30.2% of patients (55/182) it was necessary to perform a single regulation while in 12.6% of patients (23/182) at least two regulations (Tab. 1). The regulation of Argus-T was associated with worse outcomes regardless the incontinence degree, as described in Fig. 3.

Otherwise this study demonstrated a worse percentage of success in patients previously treated with radiotherapy: in fact only the 61.2% of patients (30/49) obtained a satisfactory result while in 38.8% of patients (19/49) the treatment failed showing that the outcomes were inversely proportional to the incontinence degree (Fig. 4). The group with previous radiant treatment was associated to high percentage of sling regulation or sling removal and post-operative complications (p=0.04, p=0.002, p=0.01) (Tab. 3). Nevertheless, these patients showed a significant reduction of daily pad number and an improvement on their QoL (p<0.0001) (Tab. 4).

TABLE 4. – Mean and standard deviation (±SD) of number of pad/die, VAS continence scale and QoL score scale of 182 patients before and after Argus-T positioning by previous adjuvant radiotherapy.

	Argus-T positioning		
	Before Mean (±SD)*	After Mean (±SD)*	p-value**
Number of pad/die			
Adjuvant radiotherapy			
No	5.9 (±2.7)	2.6 (±2.2)	<0.0001
Yes	4.5 (±2.3)	1.3 (±1.6)	<0.0001
VAS continence scale			
Adjuvant radiotherapy			
No	2.7 (±1.8)	6.0 (±3.5)	<0.0001
Yes	3.7 (±2.3)	8.1 (±2.5)	<0.0001
QoL score scale			
Adjuvant radiotherapy			
No	2.2 (±1.2)	5.9 (±3.6)	<0.0001
Yes	3.1 (±2.0)	8.2 (±2.7)	<0.0001

*SD=standard deviation. **T-student pairs test.

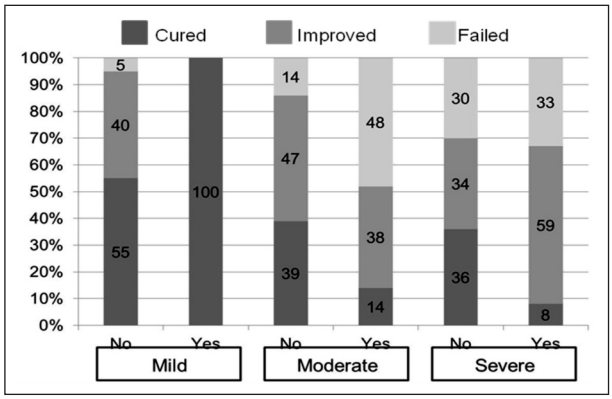

Figure 4. – Success rate by adjuvant radiotherapy and incontinence degree of 182 patients with SUI.

Complications

None complication was occurred during the intra-operative period while we observed in 26/182 patients (14.2%) a post-operative complication, such as infection (9/182 patients, 4.9%), urethral erosion (1/182 patients, 0.5%) and hypercontinence (16/182 patients, 8.8%). In some of them it was necessary to remove the device. The overall removal rate was 9.3% (17/182 patients) (Tab. 1).

Patients reported at least one complication were associated with worse outcomes regardless the incontinence degree, as described in Fig. 5.

DISCUSSION

Nevertheless mini-invasive approaches, as robotic and laparoscopic surgery, stress urinary incontinence (SUI) after radical prostatectomy represents an important post-operative complication causing remarkable troubles on QoL of these patients[1,12].

Percentage of PPI at 24 months after surgical operation ranges between 1 to 40% of patients underwent RP[2,3].

It is known that SUI is caused by a reduced urethral resistance to abdominal pressure secondary to the intrinsic sphincter deficiency[14-16].

According to the international guidelines, the surgical treatment of SUI should be offered only after the failure of conservative therapy and with a stability of the continence status for at least 12 months[4,6].

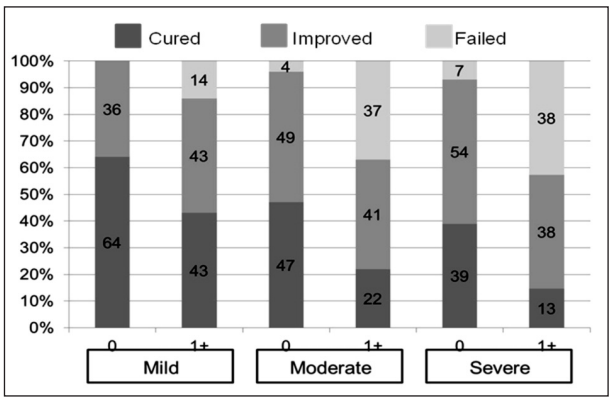

Figure 5. – Success rate by post-operative complications and incontinence degree.

In this way, the AUS offers long-term durable results in terms of social continence (73-90% at 5 years and 80-90% at 10 years) and at present it is the gold standard continence procedure[7,8] in this setting.

However in recent years the use of slings is growing strongly due to high costs of AUS that causes about 37% of post-operative complications, such as mechanical failure, erosion and or infections[17].

These issues induced several urologists to choice the sling procedure that seems to assure satisfactory results in the short-term[18,19].

In particular, according to the National Institute for Health and Clinical Excellence (NICE) in the UK the best candidates to receive a surgical treatment with male sling are the patients with mild and or moderate SUI[2].

In this way, Argus-T adjustable male sling with transobturator approach seems to be attractive for the intrinsic characteristics of the material composition, for the easiness of the surgical implant and finally for its ability to modulate the urethral compression post-operatively.

Overall results with this device showed a continence rate between 62% and 100% after a short follow-up[9,10,19] even if this variability is due to differences on continence definition.

In particular in our study, that at present represents the largest clinical series with this device, emerges a satisfactory result in 86.2% of clinical cases at 22 months of follow-up, as also confirmed by others with low clinical series[9,10,20]. In this context, our outcomes are overlapping with those published on AdVance by Bauer et al in the short-term[9].

According to the incontinence degree, our data revealed that success rate was worse in the group with severe SUI in comparison with the group with mild and moderate SUI. These results are also confirmed by Romano with a cure rate of 100% in subjects with mild and moderate SUI while 71% in severe SUI[10]. The lower efficacy of Argus-T in presence of severe incontinence confirms what it was previously described in Literature[9,13,18] where AUS remains the "gold standard" while the ideal candidates for male sling are patients with mild and moderate SUI.

At the same conclusions arrived Rehder[21] with AdVance that described a continence rate of 71% in patients with severe SUI compared to 79% in patients with lower incontinence degree.

In this context our study suggests that severe SUI has lower possibility of recovery after sling procedure.

Regarding the complication rate, at present, there are no data in Literature showing intra-operative complications with Argus-T while in the post-operative period the patients reported troubles in 15.8-19.1% of cases[22,23] as urgency de novo, hypercontinence, urethral erosion, perineal pain or infections with an high risk of sling removal in these three last conditions.

In our data we reported post-operative complications in a percentage of 14.3% and most of them were hypercontinence rather than infections. In 9.3% of patients was necessary to remove the device, especially after sling infection (7/17, 41%) and, generally, in our series patients affected by one or more complications obtained worse success rate.

Although the greatest problem on the indication for the sling procedure is related to the previous radiotherapy and in this regard many studies tried to identify predictive factors of success for male sling[12,21,24-27] and so to select ideal candidates for this surgical procedure. In particular, some Authors reported that age and adjuvant radiotherapy are not predictive factor of success[9,13]. This issue is still controversial and in our experience the patients with previous radiotherapy showed a worse outcome in comparison with patients without radiotherapy. This aspect could be related to the fibrosis of pelvic floor induced by radiation activity causing an ineffective cushion effect of the sling pad on the pelvic floor with particular reference to the sphincter complex.

On the base of our experience, we suggest that patients with previous radiotherapy should be not ideal candidates for surgical treatment of their PPI with Argus-T device.

In fact, our data showed that adiuvant radiotherapy was associated with higher number of regulation or removal of ARGUS-T ($p= 0.04$ and $p= 0.002$) and post-operative complications ($p= 0.01$).

Instead as regarding the QoL of these patients we observed a linear correlation between with the latter and the daily pads use after Argus-T. In fact the VAS continence scale and the QoL score scale showed an overall improvement of QoL in these patients about 100% after Argus-T positioning, even if this trend does not remain in the long-term in all groups of patients underwent radiotherapy.

CONCLUSION

In conclusion, PPI represents a considerable social problematic for this kind of patients.

This paper represents the first that shows functional outcomes after Argus-T positioning in a large population.

Nevertheless the lacking of results in Literature on long-term results, Argus-T sling seems to offer good outcomes at short-term, especially in patients affected by mild and or moderate SUI while adjuvant radiotherapy is associated to low possibility of recovery of the continence.

This issue is contrast with latest published works that suggest the radiotherapy is not a negative predictive factor for slings procedure.

DISCLOSURE STATEMENTS

We declare no conflict of interest and informed consent was obtained by all patients.

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Multidisciplinary Colorectal Editorial Comment

To improve the integration among the three segments of the pelvic floor, some of the articles published in *Pelviperineology* are commented on by **Urologists, Gynecologists, Proctologists/Colo Rectal Surgeons** or **other Specialists**, with their critical opinion and a teaching purpose. Differences, similarities and possible relationships between the data presented and what is known in the three fields of competence are stressed, or the absence of any analogy is indicated. The discussion is not a peer review, it concerns concepts, ideas, theories, not the methodology of the presentation.

The definitions of **urinary and fecal incontinence** are similar: ability to hold urine and feces and to eliminate them when and where desired. An interdisciplinary perspective may analyze similarities and differences between the two functions in physiological and pathological conditions. In the **female** the **Integral Theory** highlights the interactions among them, the pelvic ligaments working for both. In the **male** we are often still in the dark excluding some specific muscular or neurological lesions. Maintaining or recovering fecal continence continues to be a challenge for the colorectal surgeon who is facing many failures. Surgery in the rear is much less favorable compared to urology, it deserves anyway to be discussed.

As in the anus, in the urethra the sphincter complex is composed of an inner smooth muscle and an outer rhabdosphincter of skeletal muscle. The latter is most marked around the membranous urethra and gradually less distinct toward the bladder; the former has its main part at the vesical orifice and is thinner in its further course in the urethra; the smooth muscle is primarily concerned with continence at rest (in the anus as well). The rhabdosphincter has a double genitourinary function, namely active continence during stress conditions and antegrade semen propulsion. Stress urinary incontinence is caused by a reduced urethral resistance to abdominal pressure secondary to the intrinsic sphincter deficiency, and the majority of male incontinence is secondary to sphincter weakness following prostatic surgery. With the growing number of operations for prostate cancer, incidence of male incontinence is increasing, hence, management of male incontinence is of great interest to urologists with various conservative not invasive therapies (for early postoperative and mild incontinence) and surgical approaches. The **artificial urinary sphincter** is still labeled as the gold standard despite the introduction of several more minimally invasive alternative treatments. However, as yet there is no consensus on the optimal timing and best modality for managing these patients, and well designed clinical trials are needed. The rather expensive **artificial anal sphincter** has been implanted as well, but results have been disappointing both in patients with anatomic sphincters damage and with idiopathic fecal incontinence. The authors of this article propose a transobturator adjustable sling in males with mild or moderate SUI with a short term good outcome the worst results being observed after adjuvant radiotherapy. A similar surgical alternative with an anal sling based on the success of tension-free suburethral tapes used to treat SUI has been described by Haverfield (*A pilot study: The anal sphincter support procedure for the treatment of anal incontinence, Pelviperineology 2007; 26: 108-112*) supporting the external anal sphincter with a circlage tape prosthesis. La Torre's procedure tries to create an elastic structure supporting the pelvic diaphragm placing tension free along puborectalis muscles's line a prosthetic biological mesh *(Use of anal sling in the treatment of fecal incontinence; Pelviperineology 2013; 32: 9-13*). Results have not been better than with the artificial sphincter or the so-called dynamic graciloplasty. Among the numerous factors involved in fecal incontinence (cerebral conditions, rectal compliance, peristalsis, quality of stools, anal canal sensitivity), none individually appears crucial to achieving a cure so that, after the failure of conservative therapy, surgical management of fecal incontinence in order to claim fair outcome is limited to the reconstruction by the overlapping technique, and the best results in the treatment of fecal incontinence resistant to rehabilitation, seem to be obtained by the sacral neurostimulation.

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