Original article

Prospective study on 185 females with urinary incontinence treated by an outside-in transobturator suburethral sling

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Abstract: Objectives To assess the placement and efficacy of a low elasticity TOT (Aris) in the long term and to compare it with the other techniques. *Patients and methods:* This is a prospective study. Between 2004 and 2008, 185 patients were included. They were suffering from pure or mixed stress urinary incontinence. All the slings were implanted by the same surgeon according to the same original surgical technique described in 2001. The patients underwent regular clinical follow-up. Outcomes assessed include the efficacy on SUI and urgency, de novo dysuria and urgency, per and post-op complications, the impact of sphincter deficiency and bladder instability. The average median follow-up of our patients is 23 months. *Results:* The long-term results on continence are 91.2% at over 36 months. There is no degradation of the efficacy over time. A rigorous surgical technique minimizes the risk of complications. The urinary urgency is cured or improved in 74.3% of cases in the long-term. Lower level efficacy of the transobturator sling in the case of sphincter deficiency is confirmed. The de novo dysuria rate is 4.4%. *Conclusion:* This study confirms the efficacy, reproducibility, and the safety of the transobturator technique.

Key words: Female Stress Urinary Incontinence; Transobturator Tape (TOT); Hypo elasticity; Urinary Urgency.

INTRODUCTION

In 2001 we described and published information on the first group of patients treated for stress urinary incontinence by the implantation of a transobturator sling to treat stress urinary incontinence (SUI).[1] The initial objective of the transobturator sling was to use synthetic tape to reproduce the suburethral fascia described by Delancey.[2] In 1998, we used suburethral slings sutured to the obturator external muscle, at the level of the tendinous arch on both sides of the urethra. In 1999 we used the "tension-free" suspension proposed by Petros et Ulmsten[3] with a passage through the obturator hole to maintain the sling in place. In 2003, anatomical work led by Delmas led us to definitively privilege the outside-in technique which anatomically speaking presents less of a risk of a pudendal nerve and obturator lesion.[4,5] From the very beginning of experimentation with the transobturator route, it seemed preferable to us to use low elasticity synthetic mesh to facilitate suburethral adjustment and to avoid using the sheaths that are required for the insertion of the elastic slings. To meet the low elasticity criterion, the first transobturator slings were made of hot-welded monofilament polypropylene. This mesh proved to carry a high risk of infection and vaginal erosion.[6-8] In 2004, we abandoned the use of hot-welded mesh in favour of a macroporous, knitted, polypropylene mesh with reduced elasticity, low grammage and good shape memory (no cupping), the ARIS® Transobturator Sling (Coloplast Corp.).

In this article we will report on the first group of patients treated for SUI using TOT/ARIS, operated on by the same surgeon.

MATERIALS AND METHODS

Between 2004 and 2008, 305 patients were enrolled in a prospective study of the TOT-ARIS sling device. All patients had pure or mixed SUI, positive cough stress test results, and had failed perineal re-education. Patients were excluded from the study if they had previously undergone related surgery (hysterectomy or prolapse treatment). Based on the above criteria, 185 patients were included in the study. The slings were all implanted according to the same original technique described in 20011 and modified in 2005.[9]

Patients were seen pre-operatively, at 3 months, at 1 year and then every year post-implant. Follow-up over 36 months was available for 68 patients. All the patients have been clinically evaluated using the Measurement of Urinary Handicap (Table 1) in the pre-operative phase and during all subsequent outpatient visits. Pre-operative Urodynamic Assessment (PUA) was systematic. The sling used was the ARIS® Transobturator Sling (Table 2). The ancillary equipment was a re-steriliziable Emmet needle with a foam tip. The majority of the patients were operated on under spinal anaesthesia (82%), more rarely under a general anaesthetic and exceptionally, under a local anaesthetic (n=1).

RESULTS

Our results are summarized in Tables 3, 4 and 5. Table 3 presents the pre-operative condition of the patients and tables 4 and 5 present patient follow-up. The average median follow-up of our patients is 23 months. For 68 patients follow-up has been demonstrated for greater than 36 months. Stress urinary incontinence (SUI) was cured (MUH=0) in 85.3% of cases and was improved in 91.2% of cases. Six patients required tightening of the sling by surgical plication at a distance from their first operation and all of them were continent after the plication operation (MUH=0). Patients suffering from sphincter deficiency (urethral pressure (UP) < 30 cmH_2O) were cured after 3 months in 71.4% of cases, whereas patients with a UP > 30 cmH2O were cured in 89.8 % of cases. At over 36 months, 55.5% of the patients with sphincter deficiency were cured, compared with 84.1% in the absence of sphincter deficiency.

Pre-operatively, 90 patients suffered from mixed urinary incontinence (MUI) and 19 from an SUI combined with urinary urgency without leakage. Among the urinary urgency patients in the pre-operative phase, with (urge urinary incontinence (UUI)) or without leakage, urinary urgency was cured in 51.4% of cases, improved in 22.9% and unchanged in 25.7% of cases. No urinary urgency was worsened by the surgery.

At 3 months, 11.3% of the patients suffered from de novo urinary urgency (of which half were with leakage, thus, 5.6% of those with de novo UUI). At 36 months, the total amounted to 17.6% of de novo urinary urgency (of which half were with leakage, in other words 8% of UUI de no-

TABLE 1. – Mhu scale.

Score	**0**	**1**	**2**	**3**	**4**
Urgency (Deadline of safety)	No Urgency	10-15 minutes	5-10 Minutes	2-5 minutes	< 2 minutes
Urge Urinary incontinence (number of leakage)	No UUI	Once a month	Several time a month	Several time a week	Several time a day
Day time frequency (number of hours between two voids)	> 2	1,5-2	1	0,5	< 0,5
Night time frequency	0-1	2	3-4	5-6	>6
Stress urinary incontinence	No SUI	Violent effort (sports...)	Average effort (cough, sneeze, laughter...)	Low effort (walking...)	Lesser effort
Other incontinence/enuresis	No other incontinence	Once a month	Once a week	Several time a week	Once a day
Dysuria	No Dysuria	Terminal dribble	Straining	Feeling of incomplete emptying	Catheterisme

TABLE 2. – Physical characteristics of the aris® sling.

Materiel	Knitted monofilament polypropylene
Weight	78g /m2
Thickness	0,3mm
Diameter of the fibres	80µm
Size of the mesh	550*170 µm
Elasticity	7,5%
Resistance	55N
Maximum elongation %	72%
Sheath	NO
Particles released	<0,3%

TABLE 3. – Pre-operative condition of patients.

	Number	**Average**	**%**
Number of patients	185		
Patient characteristics Ages		59.09 (31-89)	
Weight (Kg)		70.9	
BMI		27.2	
Height (cm)		162	
Parity		2.2	
ATCD hysterectomy	28		15
ATCD cure prolapsus	11		6
ATCD cure of SUI	9		4.8
Gesture associated with the TOT	0		0
Symptoms			
SUI alone	77		41.6
SUI with urge urinary incontinence without leakage	90		48.6
Mixed UI	18		9.8
SUI MUH 1	5		2.6
SUI MUH 2	31		16.7
SUI MUH 3	142		76.6
SUI MUH 4	8		4.2
Clinical Dysuria	31		16.7
Diurnal overactive bladder (>8 urinations)	38		20.5
Nocturnal overactive bladder (>2 urinations)	59		31,9
Pre-operative PUA			
Qmax< 15ml/s	12/182		6.6
Qmax> 15ml/s	170/182		93.4
RPM≥ 75 ml	5/179		2.8
Closing pressure Urethral < 30 cmH_2O	17/177		9.6

vo). Of the patients with urinary urgency seen past 36 months, 5.8% had not urinary urgency at 3 months. Hence, their urinary urgency de novo appeared at a later stage.

The de novo dysuria rate (MUH stages 2 to 4) amounted to 3.3% at 3 months and 4.4% at over 36 months. The patients cured of their stress incontinence (MUH=0) and who had no de novo dysuria accounted for 96.8% at 3 months and 96.6% at 36 months.

There were no per-operative complications and no immediate revision surgery was performed. There were 23 immediate post-operative complications. Intermittent catheterization (Clavien II) involved a total of 16 patients. For 14 of them, the catheterization was necessary for less than 10 days. For 2 patients, catheterization continued for 3 and 24 months respectively and was then stopped. Two patients suffered from EVA>3 (Clavien I) post-operative pain. The same two patients continue to suffer from chronic pelvic pain. Four patients suffered from urinary tract infections and one patient suffered from pyelonephritis (Clavien II). There were no cases of late onset serious complications (urethral or vaginal erosion).

DISCUSSION

The per and post-operative complications rate in our group of patients is lower than that of the literature (table 6).

Anatomic surgical descriptive studies[5] have already demonstrated the theoretical low risk of the passage of the sling during the course of its implantation. The absence of bladder wounds is to be found in the literature, apart from in the Porena[10] group that presents a rate of 1.33%. The anatomical study[5] shows that there is a minimal distance of 15 mm between the upper edge of the ischiopubic branch and the insertion of the levator ani muscle on the internal obturator muscle on which the bladder rests. The needle must go in under the obturator insertion of the levator ani muscle in order to not harm the bladder. If the needle is passed in contact with the ischiopubic branch and if when it leaves the bone contact it directly meets the finger introduced into the vaginal incision in the sub-pubic lateral ure-

TABLE 4. – Results at 3 and at 36 months.

	Follow-up at 3 months		**Follow-up at > 36 months**	
	Number	**%**	**Number**	**%**
Number	177		68	
Satisfaction				
Very satisfied	142	80.3	43	63
Satisfied	30	17	18	26.6
Unchanged	5	2.7	4	5.8
Regrets	0	0	3	4.2
Stress Continence				
MUH 0	155	87.5	58	85.3
MUH 1	9	5.1	2	3
MUH 2	8	4.5	3	4.4
MUH 3	5	2.8	5	7.3
MUH 4	0	0	0	0
Not improved	5	2.8	6	8.8
Worsened	0	0	0	0
Dysuria				
Clinical dysuria patients	8		3	
De novo	6	3.3	3	4.4
Held back	1	0.5	0	0
Intermittent catheterisation	2	1.1	0	0
Overactive Bladder				
Over active bladder patients	10	5.6	5	7.3

** Percentage in relation to the population seen again that was suffering from urge urinary incontinence in the pre-operative phases.*

thral muscle, the needle's journey will be perineal and anatomically, there will be no risk of a bladder lesion.

There was virtually no immediate or delayed (1.1%) post-operative pain. In the literature, secondary pain from out/in TOTs is rare. The study that reports on the most is the Wang[11] study with 12.9% post-operative pain, compared with 0.8% in the David-Montefiore[12] group. The post-operative pain rates in the TVT-O groups are higher, up to over 24 %[13] and 16% for Laurikainen.[14] The lower incidence in the out/in pathway can find its explanation in the anatomical surgical study. Indeed, Delmas, Spinosa and Riedere showed in 2005 that the out/in pathway minimizes the risk of a pudendal nerve and obturator lesion with a shorter journey that is closer to the ischiopubic branch.[15] The type of synthetic prosthesis could also play a role in post-operative pain. For some, prosthetic rehabilitation could be the cause of pain. This has been described for hernia prostheses.[16]

There was no occurrence of urethral or vaginal erosion. It has been demonstrated that the macroporous, knitted, polypropylene mesh prostheses are more effective at preventing vaginal erosion.[17] Clinical trials on the other types of slings (e.g. multifilament polypropylene) report erosion rates and notably vaginal erosion rates that are higher.[18-20] The use of monofilament prostheses does not eliminate the risk.[21]

In our group, the UI cure rate is 87.5% (155/177) at 3 months and 85.3% (58/68) at over 36 months. The improvement rate is 97.2% at 3 months and 91.2% at over 36 months.

TABLE 5. – Results at 3 and at 36 months.

	Follow-up at 3 months		**Follow-up at > 36 months**	
Urge Urinary Incontinence				
Number of patients seen again among those who had urinary urgency in pre-operative	107		35	
Urinary Urgency	70	39.5	29	42.6
Cured	57	32.2; 53.3*	18	26.4; 51.4*
Improved	23	13; 21.5*	8	11.8; 22.9*
Leakage			7	10.3
Without			1	1.47
Remained asymptomatic	50	29.4	19	27.9
Identical to pre-operative phase	21	11.9; 19.6*	9	13.1; 25.7*
Leakage	17	9.6; 15.9*	8	11.7; 22.9*
Without leakage	4	2.2; 3.7*	1	1.4; 2.9*
De novo	18	11.3	12	17.6
Leakage	11	6.2	6	8.8
Without leakage	9	5.1	6	8.8
De novo/ status the same at 3 months			4	5.8
Worsened	3.3; 6	5.6*	0	0;0*
Leakage	5	2.8; 4.7*	0	0;0*
Without leakage	1	0.5; 0.9*	0	0;0*
Tightened since the last surgery	0		1	
Neuromod	0		0	
Complications				
Urinary infections (cystitis)	30		13	
Slings felt at vaginal level during clinical examination	6			
Pain/ Dyspareunia	2		1	
Intermittent catheterisation	2	1.1	0	0
Other	0		0	
Clavien I	8	20	13	7
Clavien II	32	80	1	93
Clavien III	0		0	
Clavien IV	0		0	
Clavien V	0		0	

** Percentage in relation to the population seen again that was suffering from urge urinary incontinence in the pre-operative phases.*

There is no statistically significant difference between the cure rates at 3 months and at over 36 months (p=0.9), nor between the improvement rates (p=0.75) and hence there is no degradation of the UI results over time. These rates are similar to those found in the literature (Table 7).

For our patients, sphincter deficiency was one of the factors that led to failure of the TOT. At 3 months and after 36

TABLE 6. – Per and post-operative complications in the literature.

Group	Number of patients	Haematoma Haemorrhage	Bladder wounds %	Vaginal wounds %	Urinary retention %	Analogical visual scale >3
Castaings T. et Delorme E. 2010	185	0	0	0	0.5	1
TOT						
Barry C. et al. 2008[36]	80	40	0			
Paick JS. Et al. 2007[33]	212		0		6.6	
Porena M. et al. 2007[10]	75		1.33	5.33		
Wang AC. et al. 2006[11]	31	117	0	12.9		12.9
David-Montefiore L. et al. 2006[12]		46	0	0	0	1
Mellier G. et al.2004[37]	94		0			
TVTO						
Zullo MA. Et al. 2007[38]	37	40	0	0	0	
Lee KS. Et al. 2007[39]	60	31	0		13.3	
Andonian S. et al. 2007[19]	78		0		7.8	3.9
Laurikainen E. et al. 2007[14]	131	131				16
TVT						
Barry C. et al. 2008[36]	107	64	8.5			
Zullo MA. Et al. 2007[38]	35	39	5.7	2.7	2.7	
Lee KS. Et al. 2007[39]	60	40	3.3		10	
Paick JS. Et al. 2007[33]	252		4.8		15.1	
Porena M. et al. 2007[10]	73		2.7	0		
Andonian S. et al. 2007[19]	80		13.8		7.5	6.3
Laurikainen E. et al. 2007[14]	136					1.5
Wang AC. et al. 2006[11]	29	125	3.4	0		0
David-Montefiore L. et al. 2006[12]		42		9.5	10.9	2
Mellier[37] G. et al. 2004	99		10			

TABLE 7. – Continence results for the SUIS in the literature.

	Number of patients	Average duration of follow-up (months)	Cure rate %
TVT-O			
Waltregny, 2008[40]	102	36	88.4
Collinet, 2008[41]	984	2	90
Neuman, 2007[42]	300	14	97.3
TOT			
Deval, 2006[43]	129	17	89.9
Roumeguere, 2005[44]	120	12	80
Spinosa, 2005[15]	117	16	92.3
Costa, 2004[45]	183	7	80.5
Delorme, 2001[1]	32	17	90.6

months, there is a statistically significant difference in recovery between those patients with a UP<30 cmH_2O and those with a UP>30 cmH_2O (At 3 months, p=0.016; after 36 months, p=0.0068). These results are corroborated by Clemons JL[22] and Guerette NL[23] who find similar results to ours. For us the TOT is not the gold standard for UI with sphincter deficiency. The results diverge in the literature: Cetinel B[24] and Meschia M 25 do not find sphincter deficiency to be a predictive factor for efficacy.

The cure rate for urinary urgency patients is on average in the literature slightly higher than 50% with an aggravation rate of 10%; however, the studies report recurrence of urinary urgency over time. [26-32] In our group, at 3 months, 53.3% of the patients were cured of their urinary urgency symptoms and 21.5% had improved, hence an efficacy of 74.8%. For patients with over 36 months follow-up, 51.4% were cured and 22.9% had improved, in other words, an efficacy rate of 74.3%. No patient saw a worsening in her symptoms and the efficacy on urinary urgency symptoms remained stable. At the end of our follow-up, we observed a non-negligible rate (17.6%) of de novo urinary urgency, half of which was with urinary leakage.

For Duckett J.R[27] and Choe, J.H[30] the presence of uninhibited contractions at the pre-operative urodynamic assessment is not a risk of failure of the SUI on the urge urinary incontinence symptoms. For Paick J.S.[33] and Laurikainen E.,[28] he presence of bladder instability at the time of the pre-operative urodynamic assessment is a factor for failure. The comparison of the efficacy of our SUIs treatment on the urinary urgency symptoms according to the presence or absence of pre-operative bladder instability did not give rise to any significant differences, neither at 3 months (p=0.56), nor at over 36 months (p=0.70). However, we did not propose the implantation of a sub-urethral sling for those patients suffering from sphincter instability with strong contractions at 15 cm of water.

In our group, the de novo dysuria rate amounted to 3.3% at 3 months and 4.4% at over 36 months. In Latthe's34 meta analysis, the average de novo dysuria rate for TVT-Os is 5.5%, for Monarc® TOTs, 2.9% and for the other TOTs,

2.5%. For the TVTs the average rate is 9.2%. The transobturator route appears to be less impactful regarding dysuria than the retropubic route. The meta-analysis does not reveal any difference regarding post-operative dysuria between elastic slings (TVT-O and Monarc® TOT) and TOT low elasticity slings (elasticity: <10% vs 30%). Nevertheless, the Krauth35 study is in favor of the low elasticity slings (1.5% of post-operative dysuria at 1 year). The efficacy of low level elasticity slings on dysuria remains to be confirmed by other studies.

CONCLUSION

A rigorous out/in TOT surgical technique that relies on sound knowledge of the pelvic anatomy is the best way to prevent per-operative complications as our group shows (a single center experience). Erosion prevention is conditioned by the type of sling used, but also by the technical quality of the surgical gesture. The long and short-term results of our group are in line with those of the literature. SUI is cured in approximately 90% of cases and these results are stable over time. Urge urinary incontinence is cured in 50% of cases. Recurrence of incontinence by de novo urge urinary incontinence occurs in 8.9% of cases. Further study is needed to show a statistically significant reduction of post-operative dysuria followed by the implantation of reduced elasticity slings.

ABBREVIATIONS

SUI, stress urinary incontinence;
TOT, transobturator tape
PUA, Pre-operative Urodynamic Assessment
MUH, Measurement of Urinary Handicap
UP, urethral pressure
UUI, urge urinary incontinence

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