157

Saussine C[1], Delorme E[2], Roumeguère T[3], Serment G[4], Gunnemann A[5], Deutsch V[6], de Tayrac R[7], Ballanger P[8], Grise P[9], Monneins F[10], Costa P[7], Droupy S[11]

1. *Hôpital Civil de Strasbourg,* ***2.*** *Clinique Sainte-Marie,* ***3.*** *Hôpital Erasme,* ***4.*** *Hôpital Salvator,* ***5.*** *Urologische Klinik,* ***6.*** *Hôpital Bichat,* ***7.*** *Hôpital Carémeau,* ***8.*** *Centre Hospitalier Universitaire de Bordeaux – Hôpital Pellegrin,* ***9.*** *Centre Hospitalier Universitaire de Rouen - Charles Nicole,* ***10.*** *Centre Hospitalier de Gonesse,* ***11.*** *Hôpital de Bicêtre*

EFFICACY AND SAFETY OF A TRANSOBTURATOR POLYPROPYLENE SLING FOR FEMALE STRESS URINARY INCONTINENCE

Hypothesis / Aims of Study

The aim of this ongoing observational registry is to investigate the efficacy and safety of a low elasticity polypropylene transobturator midurethral sling for the surgical treatment of female stress urinary incontinence (SUI) in a large patient population.

Study Design, Materials and Methods

Patients who underwent the transobturator outside-in procedure as described by E. Delorme[1], with a monofilament polypropylene, light weight, macroporous midurethral sling (Aris®, Coloplast, Denmark) were prospectively followed at 11 centers in France, Belgium and Germany starting in July 2004. Inclusion criteria were: SUI, urethral hypermobility with or without previous surgery, and with or without associated prolapse. Patients were followed through 24 months post-procedure.

The pre-operative evaluation included medical history, gynecological examination, and urodynamic testing. Peri- and post-operative complications were recorded. Post-operative evaluations were performed in person and included physician assessment through gynecological examination, (optional) and urodynamic testing. If a patient was unavailable for in person follow-up, phone interviews were completed to collect partial data. Treatment failure was defined as the first follow-up (after a 75-day healing period) at which the physician's assessment determined the patient to be consistently non-improved or worse.

Baseline urodynamics were compared to 24-month urodynamics using paired t-tests. Baseline stage of incontinence was compared to 24-month using paired X^2 tests (McNemar's test). Effectiveness was analyzed as time-to-failure data using a Kaplan-Meier survival analysis. Kaplan-Meier is a standard method in clinical medicine for estimating the proportion of patients with events over time because it accommodates patients who are lost to follow-up without biasing the estimated proportions. Cured was defined by answers of "cured" or "improved" through physician assessment and failure was defined as answer of "not improved" or "worse". Safety was analyzed as the rate of various adverse events per month of device experience.

Results

The study included 668 patients implanted, 557 of whom had follow-up after a 75-day healing period. Sixty-one patients were censored due to leaving the study prior to the 75-day healing period; however, none of patients left the study due to the treatment. The 557 patients had an average follow-up time of 2.7 years (range: .2 – 5.0). A total of 453 patients had at least 12 months of follow-up; 390 had at least 24 months. Table 1 shows the demographic and clinical characteristics of the study participants at baseline, and the comparison of urodynamics and incontinence at 24 months to that at baseline. The Kaplan-Meier analysis of effectiveness is shown in Figure 1. At 12 and 24 months, 97% and 95%, of the patients, respectively, were improved or cured.

The peri-operative device- and procedure-related complication rates were: hemorrhage 0.9%; perforation of an organ 4.3%; urinary retention/PVR>100ml 1.8%; tape release 1.1%; and moderate-to-severe pain 5.2%. There were a total of 18,061 device months of experience. Follow-up complication rates per month include: dysuria or dyspareunia 0.4%; urinary retention 0.05%; erosion or tape extrusion 0.06%; and infection 1.1%.

Table 1: Demographic and Clinical Characteristics of Study Participants

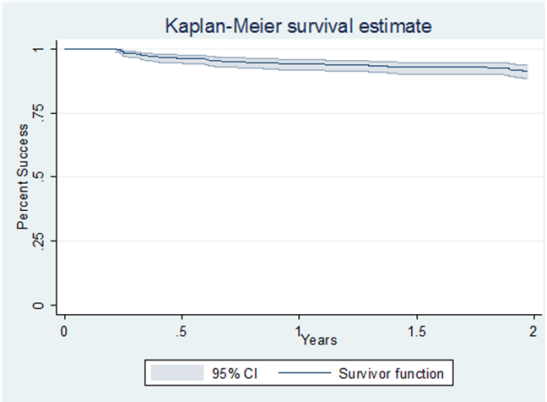
Characteristic	Baseline		24 Months		Paired N	p
	N	Mean or Percent (SD)	N	Mean or Percent (SD)		
Age	557	59.0 (12.5)				
BMI	502	26.7 (4.96)				
Parity	512	2.39 (1.48)				
Menopause	536					
Yes	358	66.8%				
Prior Surgery for Incontinence	543					
Yes	56	10.3%				
Type of Incontinence	551					
Stress	263	47.7%				
Urge	83	15.1%				
Mixed	205	37.2%				
Associated Prolapse	539		NA			
Yes	319	59.2%				
Uroflometry*						
Urine volume (ml)	491	366 (170)	308	342 (216)	290	0.016
Q max (ml/s)	490	27.9 (13.2)	308	25.0 (11.8)	287	<0.001
Voiding duration (s)	394	35.2 (26.8)	272	35.7 (23.2)	231	0.010
Post-void residual (ml)	483	14.2 (45.6)	327	20.1 (43.0)	304	0.169
Urethral closing pressure	465	52.1 (25.5)	NA			
Max cystometric capacity (ml)	487	373 (130)	NA			
Volume at first urge to void (ml)	480	201 (101)	NA			

* Used most recent observation to 24m (last observation carried forward)

Interpretation of results

This large, multicenter registry has permitted the analysis of both short- and mid-term results of the surgical treatment of incontinence with the Aris sling. At 24 months, patients showed clinically significant improvement in incontinence by their physician's assessment. The last-observation-carried forward analysis avoided bias caused by the absence of data from patients with treatment failures. The physician's assessment was confirmed by the urodynamic data, although these data were only available in a subset of patients, not an unusual circumstance for a registry study. Complication rates were low both peri-operatively and during follow-up. Patients who discontinued registry participation were included in this analysis to their last follow-up. Some were lost to follow-up; others were treatment failures. This enabled us to analyze the effectiveness of the treatment using Kaplan-Meier survival analysis. The results showed that the treatment is highly effective, with 95% of the patients remaining cured or improved after 2 years.

Figure 1: Time-to-Procedure Failure



Concluding message

The transobturator midurethral sling for SUI is an effective, safe, and durable treatment.

References

1. Delorme E. Transobturator urethral suspension: a minimally invasive procedure to treat female stress urinary incontinence. Prog Urol 2001; 11:1306-13013.

Specify source of funding or grant	**Coloplast, Corp.**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require eithics committee approval because	**the European Directive 2001/20/EC provides that non interventional medical device studies can be conducted without signed consent forms; however, a patient information form was provided by investigators to patients stating de-identified data may be used for research and publication purposes. This letter provided patients with a right to refuse. Data have been captured in a database using unique identifiers only.**
Was the Declaration of Helsinki followed?	**No**
This study did not follow the Declaration of Helsinki in the sense that	**a protocol wasn't developed & informed consent wasn't obtained; however, a letter of information was sent to patients stating potential use of the data & providing an option to decline. Data from physician medical records was used in a database collecting de-identified data. It was collected based on non-interventional methodology per EU Dir 2001/20/EC where the device was implanted in accordance with the marketing authorisation & no assignment of the patient occurred to a clinical strategy.**
Was informed consent obtained from the patients?	**No**