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MID-TERM EFFICACY AND SATISFACTION OF ALTIS® ADJUSTABLE SINGLE INCISION SLING FOR FEMALE STRESS URINARY INCONTINENCE: A POOLED DATA

Hypothesis / aims of study

Transobturator midurethral synthetic slings (TOMUSS) are currently considered as a standard surgical treatment for stress urinary incontinence (SUI) with similar results when compared to pubovaginal fascial slings. However, TOMUSS composed of potential complications related to its passage through obturator fossa and the length of the material used. The third generation single incision slings proposed some solutions facing these concerns. They are available on the market since 2006. Controversies were reported about their short-term efficacy results especially when the TVT-Secur data were initially included. Altis has been proven safe and effective with a median follow-up of 12 months1. The aims of this study are to evaluate the mid-term efficacy and satisfaction of Altis adjustable single incision sling and whether there are differences in the academic or community settings for treament of SUI in women.

Study design, materials and methods

This retrospective ethical board approved review was conducted at 2 canadian centers (one academic and one community hospital). Female patients with SUI who were at least 18 years of age and had failed conservative therapy were included. Patients were excluded if they had an active urogenital infection, pelvic organ prolapse ≥ stage 2 by Baden Walker classification, required a concomitant pelvic floor procedure, had a previous surgical SUI treatment, or were pregnant or planning on being pregnant.
Patients were evaluated pre-operatively, and post-operatively at 3 and 6 months, then yearly for a total of five years as routinely done in their respective centers. Follow-up consisted of a questionnaire, a gynaecological exam, as well as objective and subjective measures. Objective outcomes consisted of 24-hr pad weight test (PWT) and pad use, and cough stress testing (CST). Subjective measures consisted of the Urogenital Distress Inventory-Short Form (UDI-6), Incontinence Impact Questionnaire-Short Form (IIQ-7), and Patient Global Impression of Improvement (PGI-I) questionnaire.

Results

Between 2009 and 2013, 94 patients were implanted with the Altis sling (49 in the academic and 45 in the community hospital). The mean patient age was 60.3 ± 11.6 years. The majority of patients had mixed urinary incontinence (MUI) (68.1%, 64/94), while 31.9% (30/94) had SUI alone. Patients were followed for an average of 43.2 ± 4.5 months Interim analysis of data was done in August 2015. By this time, 18 patients were lost to follow-up, leaving 76 patients for assessment (table 1).
Median number of pad use decreased from 2.5 (1.5, 3.5 IQR) at baseline to 0.0 (0.0, 1.0 IQR) ($p<0.0001$). The median 24-hr PWT decreased from 20.4 gm (13.5, 74.6 IQR) at BL to 0.0 (0.0, 5.0 IQR) ($p<0.0001$). Positive cough stress test was present in 100% of patients pre-operatively and was reduced to 17% (13 patients) at 3 years. Fifty-one patients (66.2%, 51/77) were considered dry (not wearing pad at all).

Patient assessment of their condition verified the objective outcomes. The median reductions in UDI-6 and IIQ-7 scores was 5.0 (2.5, 9.0 IQR) ($p<0.0001$) and 12.0 (6.0, 16.0 IQR) ($p<0.0001$), respectively. 92% (70 patients) indicated that their incontinence condition was *very much better* or *much better* based on the PGI-I questionnaire. No patients indicated that their condition worsened after receiving a sling implant (table 2).

There were no reports of mesh erosion, migration, or foreign body reaction through 36 months. Three patients (3.9%, 3/77) experienced urinary retention shortly after surgery that resolved within one week of the procedure without reintervention. There is no difference for the efficacy, satisfaction and complications between academic and community hospital.

Concluding message

The Altis Single Incision Sling System appears to be safe and effective for treatement of SUI with high patient subjective satisfaction.

TABLE. 1 ***Demographic characteristics***

AGE (years) :	
Mean±SD	60.3±11.6
BMI (kg/m^2):	
Mean±SD	28.9±4.7
Incontinence type :	
Mixed incontinence	64 (68.1%)
SUI alone	30 (31.9%)
Procedure duration (min):	
Mean±SD	29.1±18.5
Median (IQR)	25.0 (20.75, 30.0)
Follow-up time (months)	
Mean±SD	43.2±7.5
Median (range)	44.0 (37.0, 49.3)

TABLE 2 ***Objective and subjective outcomes***

	Baseline(n=94)	36 months (n=77)
24-Hr pad wt (gm) :		
Mean±SD	44.4±49.9	
Mean reduction±SD	Not applicable	Not applicable
Median (IQR)	20.4(13.5,74.6)	0.0 (0.0, 5.0)
Negative CST (%):	0(0)	64(83.1)
Numbers of pad use:		
Median (IQR)	2.5 (1.5, 3.5)	0.0 (0.0,1.0)
Median reduction (IQR)	Not applicable	2.0 (1.00, 3.25)
UDI-6 score:		
Mean±SD	16.2±3.2	9.9±4.7
Mean reduction±SD	Not applicable	5.5±5.5
Median (IQR)	16.0(14.0,18.0)	0.8(6.0,14.0)
Median reduction (IQR)	Not applicable	5.0 (2.5, 9.0)
SUI score from UDI-6 :		
Mean±SD	3.8±0.4	1.5±0.9
Mean reduction±SD	Not applicable	2.2±1.0
Median (IQR)	4.0 (4.0,4.0)	1.0(1.0,2.0)
Median reduction (IQR)	Not applicable	3.0 (1.0, 3.0)
IIQ-7 score :		
Mean±SD	20.2±5.2	8.5±4.1
Mean reduction±SD	Not applicable	11.0±6.0
Median (IQR)	20.0(18.0,24.0)	7.0(7.0,7.0)
Median reduction (IQR)	Not applicable	12.0 (6.0, 16.0)
SUI score from IIQ-7:		
Mean±SD	9.0±2.7	3.6±1.7
Mean reduction±SD	Not applicable	5.5±2.7
Median (IQR)	9.0(7.5, 11.5)	3.0(3.0,3.0)
Median reduction (IQR)	Not applicable	6.0 (4.0, 8.0)
PGI-1 (%)		
Very much better	Not applicable	65(84.4)
Much better	Not applicable	5(6.5)
A little better	Not applicable	3(3.9)
Unchanged	Not applicable	4(5.2)
A little worse	Not applicable	0(0)
Much worse	Not applicable	0(0)
Very much worse	Not applicable	0(0)

References

1. 1. Dias J1, Xambre L, Costa L, Costa P, Ferraz L. Short-term outcomes of Altis single-incision sling procedure for stress urinary incontinence: a prospective single-center study. Int Urogynecol J. 2014 Aug;25(8):1089-95. doi: 10.1007/s00192-014-2355-4. Epub 2014 Mar 6

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