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Presentation Title: A PROSPECTIVE PARALLEL COHORT, MULTI-CENTER STUDY OF THE SOLYX™ SINGLE INCISION SLING SYSTEM VS. THE OBTRYX™ II SLING SYSTEM FOR THE TREATMENT OF WOMEN WITH STRESS URINARY INCONTINENCE: 3 YEAR RESULTS

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Objective

Determine if single incision sling (SIS) is non-inferior (NI) to transobturator sling (TMUS) in efficacy and safety.

Methods

Participants underwent sling per the study protocol. Prior to study, investigators participated in a training session to standardize technique. Patients were followed for 36 months to compare efficacy and adverse events for noninferiority (NI). Inclusion criteria included stress predominant urinary incontinence per the MESA and positive cough stress test. Patients were required to undergo urodynamic evaluation, have a negative urine culture, and a PVR ≤150cc. Participants were not eligible if they had undergone prior SUI surgery or had a mesh extrusion. Study sites were assigned to a cohort group (either SIS or TMUS) based on documented competency with the cohort device. Concomitant prolapse repair was allowed. The primary endpoint was treatment success defined by a composite of objective measure (negative cough stress test) and any subjective self-reported improvement in SUI using the Patient Global Impression of Improvement (PGI-I) at 36 months. Secondary endpoints included adverse events and indication for reoperation or retreatment. NI margin of 15% and 10% was prespecified for the primary efficacy and safety, respectively. Propensity score stratification was used to balance key risk factors between the treatment groups and were used for the primary endpoint assessment. Data analysis was performed using both intent-to-treat (ITT) and per protocol (PP) methods.

Results

No evidence of imbalance in baseline characteristics was observed between groups after propensity score stratification in the 281 subjects. Estimated blood loss in mL (72.3±92 vs. 73.1±63.9), time to spontaneous void in days (1.1±2 vs. 0.8±2.8), and time to discharge in days (0.7±0.7 vs. 0.6±0.6) were similar between SIS and TMUS, respectively. SIS group was NI to the TMUS group in composite treatment success with both ITT and PP analyses. At 36 months, ITT analysis showed treatment success of 90.4% in the SIS group and 88.9% in the TMUS group (P = 0.93), Figure 1. At 36 months, mesh related complications were similar between groups (mesh exposure: 2.8% vs. 4.3%, P = 0.54; mesh erosion: 0.0% vs. 0.7%, P = 0.50). SAE including pain during intercourse (0.7% vs. 0%, P = 1.00), pelvic pain (0.7% vs. 0%, P = 1.00), and urinary retention (2.8% vs. 4.3%, P =0.54) were similar between groups, Figure 2.

	Treatment Arm		Propensity Adjusted Treatment Difference	
Visit	**Single Incision Sling**	**Transobturator Sling**	**Estimate [90% CI]**	**p-value**
6 Months	91.6% (109/119)	90.7% (117/129)	0.5% [-5.1% , 6.1%]	0.882
12 Months	86.8% (92/106)	91.7% (111/121)	-4.6% [-11.4% , 2.2%]	0.268
18 Months	92.9% (105/113)	91.4% (106/116)	2.1% [-4.4% , 8.6%]	0.591
24 Months	90.7% (98/108)	88.2% (97/110)	2.9% [-4.6% , 10.3%]	0.526
36 Months	90.4% (94/104)	88.9% (96/108)	-0.4% [-8.2% , 7.4%]	0.933

Figure 1: Composite Treatment Success, All Time Points, Available Cases from Intent-to-Treat Subjects (N=281)

	Single Incision Intent-to-Treat Subjects (N=141)		Obturator Intent-to-Treat Subjects (N=140)		
Adverse Events (coded with MedDRA Preferred Term)	**Events**	**Proportion of Subjects with ≥1 Events**	**Events**	**Proportion of Subjects with ≥1 Events**	**p-value**
Device extrusion (mesh exposure)	4	2.8% (4/141)	6	4.3% (6/140)	0.541
Dyspareunia	1	0.7% (1/141)	0	0.0% (0/140)	1.000
Medical device site reaction (mesh erosion)	0	0.0% (0/141)	1	0.7% (1/140)	0.498
Pelvic Pain	1	0.7% (1/141)	0	0.0% (0/140)	1.000
Urinary retention	4	2.8% (4/141)	6	4.3% (6/140)	0.541

Figure 2: Summary of Selected Adverse Events - MedDRA Outcome, Intent-to-Treat Subjects (N=281)

Conclusions

This study provides a long-term NI analysis between single incision sling and traditional TMUS. SIS is not inferior to TMUS for long-term treatment success of stress urinary incontinence (SUI). The rates of SAE following SIS are not inferior to SAE following TMUS. This suggests longer term efficacy and safety data on SIS, and may support more minimally invasive surgery for SUI.

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