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MINISLING COMPLICATIONS CAN BE MAJOR

Hypothesis / aims of study
Single incision minislings (SIMS) have been advocated to avoid the complications of transobturator and retropubic MUS. We reviewed a series of SIMS complications and their outcome after transvaginal removal at a tertiary care center.

Study design, materials and methods
Following IRB approval, a prospective database of consecutive women who underwent SIMS removal for complications was reviewed. Excluded were patients with less than 6 months follow-up, or with a neurogenic bladder. Extracted data included patient demographics, type of SIMS, presenting symptoms, and outcomes, including secondary procedures. Additional testing, including urodynamic testing, and/or imaging was selectively obtained. An ideal outcome or cure was defined as continent, pain-free, sexually active if active pre-operatively, and not requiring additional medical or surgical therapy. Outcome resolution was also evaluated for each major presenting symptom using patient's self-report.

Results
From 1/2007 to 9/2013, 17/23 met inclusion criteria and were included in this final analysis with a mean age of 57±12, mean parity of 2,5 (1-4) and mean BMI of 29.8 ± 7.7 (17-41). Excluded were: follow-up < 6 months (3), lost to follow-up (2) and deceased (1). Prior to SIMS removal, 7/17 women were sexually active and 7 had prior anti-incontinence procedures, including 4 women who had a SIMS placed after a mid-urethral sling and 1 woman who had a Mini-Arc sling removed and replaced by another one. Five women had a history of vaginal prolapse repairs with synthetic mesh. Presenting symptoms were urethral pain from urethral erosion (2), vaginal extrusion (2), dyspareunia (10), pelvic pain (11), incontinence (14), chronic urinary tract infections (4), obstructive symptoms (5) and retention (1) with 76% presenting with more than one complaint. Urodynamic studies (UDS) were performed in (6), voiding cystourethrogram (VCUG) in (11), pelvic MRI in (4), cystoscopy in (6) and trans-labial ultrasound in (1). Mean interval time between SIMS insertion and removal was 29 ± 21 months (range: 4-60). Type of SIMs included Mini-Arc™ (American Medical Systems, Minnetonka, MN, USA) (11), Solyx™ (Boston Scientific Corp; Natick, MA, USA) (4), and TVT-Secur™ (Gynecare; Ethicon Inc., Somerville, NJ, USA) (2). SIMS removal was done vaginally with the intent of removing the majority of the device or the entire device.

At a mean follow-up of 17 ± 9 (range: 7-44) months, 6 (35%) women were cured. Among the 11 women presenting with a pelvic pain component, 6 had resolution of pain, 2 improved and 3 had persistent pain. After SIMS removal, 6 of 7 women who were sexually active beforehand resumed sexual activity. Dyspareunia persisted in 3 women who did not have a concurrent mesh placement. Eight of 14 presenting with incontinence had cure or improvement. Five underwent urethral bulking agents after SIMS removal. Obstruction resolved in 3 of 5. One woman with urethral erosion treated with holmium laser still had incontinence but no more erosion, while the other also had resolution of erosion after holmium laser treatment but dyspareunia for which she underwent subsequent SIMS removal.

Interpretation of results
To our knowledge this is the first series of SIMS complications and their management, with a minimum 6 months follow-up. Even minimally invasive procedures can produce complications which can be difficult to manage. Over one third of women did well ultimately; but some experienced irreversible outcomes like pain, dyspareunia, incontinence, or voiding dysfunction despite SIMS removal.

Concluding message
Beyond the current debate on SIMS efficacy and its role in the armamentarium of anti-incontinence procedures, this series outlines concerns regarding several complications with these minimally invasive procedures not dissimilar to what has been reported in the past with other sub-urethral synthetic tapes. Therefore, caution is required and patient counselling is important.

Pt	Age	Primary complaint	Type of mesh	Additional Investigations					1st surgery	Additional procedures	F/u (months)
				UDS	VCUG	MRI	Cys	US			
1	66	IE	S	1	1	0	0	0	TR, C		27
2	42	D	M	0	0	0	0	0	TR		11
3	78	I	M	0	1	0	0	0	TR	Inj	11
4*	55	D	M	1	1	1	0	0	TR		13
5	66	P	M	0	1	0	1	0	TR	Inj	44
6	68	I	M	0	1	0	1	0	TR, Sling	Inj	18
7**	58	E	M	0	0	0	1	0	TR, Hol		25
8	67	P	M	0	1	0	1	0	TR		9
9	61	IE	M	1	1	1	0	0	TR		13
10	41	D	M	1	1	0	0	0	TR, C	Dil	19
11*	41	D	S	0	0	0	0	0	TR	Inj	30
12	68	IE	S	1	0	1	0	0	TR		7
13*	66	E	M	0	0	0	1	0	Hol	TR, Sling	12
14	46	D	T	0	1	0	0	0	TR	Inj	14
15*	48	D	S	1	1	1	0	1	TR, PMR		12
16	52	IE	T	0	1	0	1	0	TR, Dil		12
17	45	D	M	0	1	1	0	0	TR, PMR		20

IE: incomplete emptying
D: dyspareunia
I: Incontinence
P: vaginal/pelvic pain
E: urethral pain from erosion
S: Solyx™ (Boston Scientific Corp; Natick, MA, USA)
M: Mini- Arc™ (American Medical Systems, Minnetonka, MN, USA)
T: TVT-Secur ™(Gynecare; Ethicon Inc., Somerville, NJ, USA)
Cys: cystoscopy
US: trans-labial ultrasound
TR: tape removal
C: cystocele repair
Inj: urethral injection of bulking agent
Sling: Rectus fascia sling
Hol: Holmium laser vaporization
PMR: mesh removal from posterior vaginal wall
Dil: urethral dilatation
*women who had a SIMS placed after a prior midurethral sling
** woman who had a Mini-arc removed and replaced by another one

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