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THE IUGA/ICS CLASSIFICATION OF SYNTHETIC MESH COMPLICATIONS IN FEMALE PELVIC FLOOR RECONSTRUCTIVE SURGERY: A MULTICENTER STUDY

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Abstract:
Introduction: Reports of prostheses related complications are increasing in the field of female pelvic floor reconstructive surgery. The IUGA/ICS (International Urogynecological Association/ International Continence Society) created the uniform classification system in order to systematically report mesh complications in a standardized manner[1].
Objectives: Our objective was to analyze the utility of the IUGA/ICS prosthesis related complications classification and to report on sling and transvaginal mesh related complications.
Methods: This was a retrospective chart review of all patients who underwent surgical removal of sling, transvaginal synthetic mesh and sacrocolpepexy for mesh related complications from 2011 to 2013 at three tertiary referral centers in the Southeast United States. The IUGA/ICS classification system for prostheses complications was used to report complications. We included all women who underwent reconstructive pelvic surgery using synthetic mesh for prolapse or urine incontinence and subsequent synthetic mesh removal due to complications. The database was queried to identify potential subjects. Data was analyzed by using chi-square test for categorical data, and Student's t-test and Wilcoxon Rank Sum test for continuous data. The measure of effect was determined by logistic regression analysis.
Results: We identified 445 patients with mesh complications who subsequently underwent mesh removal laparoscopicaly, via groin dissection and/or transvaginally. Of those identified, 178 (40%) had transvaginal mesh inserted for treating pelvic organ prolapsed (POP), 373 (83.8%) had a midurethral sling, and 38 (8.5%) had sacrocolpopexy. There were 506 pieces of synthetic mesh removed and 587 prostheses related complications classified. The mean age was 53.8±11.2 year and parity 2.5±1.2. The majority of patients were Caucasian (82.0%), postmenopausal (72.8%), sexually active (52.1%), and insured (76.4%). 82.9% had previous hysterectomy and 92.6% had previously been seen by a different physician(s). Twenty-five percent were current smokes. Twenty-eight percent had a previous mesh revision or removal.
The most common presenting chief complaint was pain (68.6%) with or without intercourse. Only 3.7% of patients had viscus organ erosion or vaginal extrusion as their presenting chief complaint. According to the IUGA/ICS classification, 59.7% were classified into category 1 (no vaginal epithelial separation). The most common category was pain related (1Be --32.5%) followed by dyspareunia (1Bc --14.7%). Most patients presented with mesh related complications over a year after insertion (T4). The most common affected site (S2) was away from the suture line (49%) (Table 1). Sling group was 20% more likely to have pain than POP group (OR 1.2, 95% 0.8- 1.6). Comparing sling and mesh for POP complications classification, mesh for POP group had higher erosion/extrusion (less than 1 cm exposure 17.6%vs. 11.1%, p=0.024, more than 1 cm exposure25.6% vs. 6.9%, p<0.001) and more likely to occur at the area of the suture line (36.1% vs. 15.0%, p<0.001) than the sling group. However, the sling group had more complications in category 1 (vaginal no separation 68.0% vs. 48.4%, p<0.001) and category 6 (skin and musculoskeletal 7.5% vs. 3.6%, p=0.047).
Conclusion: Based on these results surgeons should be aware that patients with mesh complications are routinely

presenting more than one year after the initial surgery. Surgeons should note that while vaginal extrusion is a common complication of slings and transvaginal POP mesh it is more common in the latter. However most of the time the patient's chief complaint is not an objective find (i.e.--erosion or extrusion) but more commonly a patient's subjective complaint (i.e.pain). If the patient had a sling and is complaining of pain it might be beneficial to focus ones exam away from the suture line (i.e. paraurethrally) and not necessarily suburethrally. The IUGA/ICS classification of mesh complication is a pragmatic system to report and analyze mesh complications.

References:

1. Int Urogynecol J. 2011 Nov;22(11):1429-35.

Table 1- IUGA/ICS classification of complications related directly to the insertion of prosthesis in female pelvic reconstructive surgery (506 mesh removed, 587 complication classified), n (%)

Classification	Overall (n=587)	Comparing sling and mesh for POP		
		Sling (n=337)	POP (n=250)	P-value
Category				
1. Vaginal: no epithelial separation	349 (59.66)	227 (67.96)	121 (48.40)	<0.001
2. Vaginal: smaller ≤1 cm exposure	81 (13.82)	37 (11.08)	44 (17.60)	0.024
3. Vaginal: larger > 1 cm exposure, or any extrusion	87 (14.86)	23 (6.89)	64 (25.60)	<0.001
4. Urinary tract: compromise or perforation including prosthesis (graft) perforation and fistula	27 (4.61)	19 (5.69)	8 (3.20)	0.157
5. Rectal or bowel: compromise or perforation including prosthesis (graft) perforation and fistula	6 (1.03)	2 (0.60)	4 (1.60)	0.235
6.Skin or musculoskeletal: complications including discharge pain lump or sinus tract formation	34 (5.81)	25 (7.49)	9 (3.60)	0.047
7. Patient: compromise including hematoma or systemic compromise	1 (0.17)	1 (0.30)	0 (0)	0.387
Time (Clinical diagnosed)				
T1: Intraoperative to 48 hours	1 (0.17)	1 (0.30)	0 (0)	1.000*
T2: 48 hours to 2 months	14 (2.39)	8 (2.40)	6 (2.40)	0.997
T3: 2 months to 12 months	61 (10.43)	31 (9.28)	30 (12.00)	0.288
T4: over 12 months	509 (87.01)	294 (88.02)	214 (85.60)	0.389
Site				
S1: vaginal: area of suture line	140 (23.97)	50 (14.97)	90 (36.14)	<0.001
S2: vaginal: away from suture line	286 (48.97)	176 (52.69)	109 (43.78)	0.033
S3: Trocar passage	34 (5.82)	20 (5.99)	14 (5.62)	0.852
S4: other skin or musculoskeletal site	82 (14.04)	60 (17.96)	22 (8.84)	0.002
S5: Intra-abdominal	42 (7.19)	28 (8.38)	14 (5.62)	0.202

*Fisher's exact test

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Category (Complete): Surgical Complications ; Pelvic Organ Prolapse ; Urinary Incontinence: Assessment (includes Urodynamics)

Keyword (Complete): mesh complication ; IUGA/ICS mesh classification ; mesh removal

Additional Questions (Complete):

***Was study presented/published previously?**: No

***This study was NOT previously presented at an International Meeting**: Confirmed

***Was work supported by industry?** : No

***Level of support :** Not Applicable

***Was consent obtained from patients?**: Not Applicable

All authors have reviewed the abstract as submitted and have confirmed approval: Confirm

***Is the presenter a Fellow?**: No

If not accepted for oral presentation, would you participate in the informal paper session offered to fellows?: No

Does this study have IRB or Ethical Committee Approval?: Yes

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