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CLINICAL APPLICATION OF THE IUGA/ICS CLASSIFICATION SYSTEM FOR MESH-RELATED COMPLICATIONS

Hypothesis / aims of study
The use of synthetic mesh in female pelvic surgery has risen dramatically leading to an increase in mesh-related complications. The IUGA/ICS classification system was created to enhance awareness of prosthetic and graft related complications in female pelvic surgery and to develop a registry of complications to inform surgeons, patients, and industry [1]. To encompass a vast array of clinical scenarios, a Category, Time, and Site (CTS) Classification was developed: *Category*—describes both the involved organ and degree of involvement with a *pain grade* sub-domain; *Time*—describes the interval from index surgery to presentation of the complication; *Site*—describes the location of the complication.
Assessment of the clinical utility of the CTS classification system is of utmost importance. We hypothesized that the system's complexity would pose challenges in daily clinical practice. Our objectives were: 1) to assess the usability of the IUGA/ICS CTS classification system for mesh erosions in clinical practice; 2) to evaluate the association of the classification system with treatment and outcome of mesh erosion; 3) to evaluate the association of a patient's symptoms with treatment and outcome of mesh erosion.

Study design, materials and methods
We performed a retrospective analysis of mesh erosions in patients who presented to a tertiary care center after surgery for pelvic organ prolapse (POP) or urinary incontinence (UI) with synthetic mesh (heretofore called index surgery). Subjects were identified using ICD-9 codes for complications of urogenital implants, prostheses, or grafts (996.30, 996.65, or 996.76) from 11/2007-11/2012. We included subjects with mesh erosion from synthetic mesh slings for UI, vaginal mesh placed using a mesh-kit, hand-cut vaginal mesh, and sacro- colpopexy or cervicopexy using synthetic mesh. The medical records of eligible subjects were reviewed and demographic data, medical history, information about the index surgery, complications after mesh placement, and treatment of the mesh erosions were collected.
Given the vast array of code assignments within the IUGA/ICS classification system, we analyzed each domain (*Category*, *Time*, *Site*) and sub-domain (*pain grade*) of the system. We evaluated the association between a subject's CTS classification and the decision to pursue conservative management (observation, vaginal estrogen, pelvic floor physical therapy, or office excision) or surgical management for treatment of the mesh erosion. When subjects were treated with multiple modalities, they were grouped with the most invasive. We also evaluated the association between CTS classification and a subject's final outcome after treatment. Final outcome was divided into two categories: persistence of symptoms (patient unsatisfied) and resolution of all/most symptoms (patient satisfied). Expanding beyond the CTS classification system, we next evaluated a spectrum of related symptoms in patients with mesh erosion. The *symptom groups* were asymptomatic, bleeding, voiding or defecatory dysfunction, infection, recurrent prolapse, and pain. These *symptom groups* were analyzed for association with management and outcome.
Study data were managed using REDCap electronic data capture tools. We analyzed data using chi-squared test, student's t-test, and logistic regression where applicable using SPSS-20 software.

Results
A total of 149 patients were identified and 74 subjects were eligible. The most common reasons for exclusion were mesh-complications without erosion or complications from other devices (e.g. IUD). Mean age was 59 years (SD±12), median parity was 2 (range 0-5), 82% were menopausal. The subjects were healthy overall: mean BMI was 27 kg/m^2 (SD±5), 88% were ASA Class 2, 2/74 used tobacco, and 2/74 were immunocompromised. 80% (59/74) of subjects had no history of urogynecologic surgery prior to index surgery. Index surgery included POP surgery in 36% (27/74), UI surgery in 34% (25/74), and combined POP/UI surgery in 30% (22/74). Most of the mesh placed was Type I (82%, 61/74); the remainder were Type II, III, IV, or unknown. Mesh erosions were treated surgically in 65% (48/74).
Using the IUGA/ICS classification system, 70% (52/74) were able to be fully indexed. The missing information that precluded classification was *Category* in 86% (19/22), *Time* in 23% (5/22), *Site* in 45% (10/22) and more than one variable was missing in 27% (6/22).
We found no association between CTS classification and management choice, specifically *Category* (p=0.4), *pain grade* (p=0.2), *Time* (p=0.7), or *Site* (p=0.9). Furthermore, there was no association between CTS classification and final outcome, specifically *Category* (p=0.06), *pain grade* (p=0.08), *Time* (p=0.2), or *Site* (p=0.1).
The six *symptom groups* (asymptomatic, bleeding, voiding/defecatory dysfunction, infection, recurrent prolapse, pain) were associated with management choice (p=0.005). Furthermore, these *symptom groups* were associated with final outcome (p=0.03). Patients who were asymptomatic were significantly more likely to pursue conservative management (p=0.03) and have satisfactory outcome (p=0.03). Patients reporting voiding or defecatory dysfunction were more likely to pursue surgical management (p=0.02). Logistic regression confirmed these associations.

Interpretation of results
We found that the majority of mesh erosions could be coded using the IUGA/ICS classification system, however CTS classification domains were neither associated with treatment nor outcome. Patient symptoms were, however, associated with both treatment and outcome.
Even though the IUGA/ICS classification system is considerably more encompassing than other available surgical complication classifications systems (e.g. Dindo, TVM, Accordion), it does not account for common complications specific to mesh use in female pelvic surgery, most notably voiding dysfunction and bleeding. With the increasing use of Type I mesh for pelvic surgery,

the majority of erosions, at least as seen in our cohort, range from asymptomatic to distressing but not life threatening. This may be the underlying reason we found the patient's symptoms to drive intervention and affect her perception of outcome.

Our cohort was drawn from ICD-9 rather than CPT codes, providing a useful guide to management decisions and counseling regarding outcomes for the physician encountering a mesh complication in the office setting. Limitations of our study are inherent in its retrospective nature, including small sample size and partial data collection that preceded publication of the IUGA/ICS classification system.

Concluding message

The IUGA/ICS classification system for mesh-related complications is expansive and encompasses a vast array of clinical scenarios. However, the complexity of the system precluded classification in 30% of patients with mesh erosion in a tertiary care center with fellowship trained urogynecologists. In our study, the classification system was not associated with treatment or outcome but patient symptoms were associated with both. Continuing research is needed to hone the clinical relevance of this mesh classification system.

References

1. Haylen BT, Freeman RM, Webb R, et al. An IUGA/ICS Joint Terminology and Classification of the Complications Related Directly to the Insertion of Prostheses (Mesh, Implants, Tapes) and Grafts in Female Pelvic Surgery. Neurology and Urodynamics 30:2-12 (2011).

Disclosures