IUGA/ICS terminology and classification of complications of prosthesis and graft insertion–rereading will revalidate

TO THE EDITORS: As representative authors of the title document,[1] we believe the authors of a recent multicategory critique[2] might have most of their criticisms answered by a careful rereading of the document.[1] Despite significant methodologic difficulties involving the interrater reliability validation study contained within the article,[2] a positive data reinterpretation is also possible.

The study observers[2] have not been clearly identified. The retrospective observations are on variably notated medical records, whereas the IUGA/ICS Classification is designed for prospective "live" use with full clinical information. For example, the presence/size/timing or diagnosis and/or site of a mesh exposure, the category of most disagreement, may not have been clearly recorded, ideally with pictorial evidence.

Reinterpretation of the data from Table 3[2] would suggest that 77% (40/52) of the instances of noncorrelation in the vaginal complication categories were due to record issues rather than the "clarity" of the assessment tool. If corrected and added to the 43% (39/91) where correlation occurred, a very acceptable 87% (79/91) interrater reliability is possible.

As indicated, most of the answers to the multicategory criticisms, almost all unrelated to validation study, can be found within the title document.[1]

Category 1 criticism–Terminology and definitions: a terminology document will define terminology, eg, the reason for a 1 cm cutoff for (smaller/larger) mesh exposures is clearly explained.[1]

Category 2 criticism–Inability to categorize complications: category 1B[1] clearly covers the scenario of pain without mesh exposure with the pain subclassification (a-e) available to distinguish the type of pain. The authors[2] cite the IUGA/ICS Classification as "too complex in attempting to optimize the coverage of all possible (physical) complications" yet criticizes it for not additionally including functional (eg, bowel) disorders or recurrent urinary tract infection, the latter not necessarily related to the prosthesis or graft insertion.

Category 3 criticism–Lack of consistency with scale: the authors[2] state "the IUGA/ICS classification system does not allow gradation of the severity and this may be a barrier to its utility." Even the most cursory appraisal of the IUGA/ICS CTS Classification Table (Table 2 in Reference 1 and included in the critique) would note a clear increase in severity of complications across, and in general, down the table. The authors[2] pose the self-evident question, allegedly not answered by the IUGA/ICS Classification, "should the presence of multiple complications increase the degree of severity." The IUGA/ICS Classification[1] clearly deals with multiple and changing complications.

Authors of the IUGA/ICS Classification system for prostheses and grafts[1] and the recently published native tissue female pelvic floor surgical equivalent[3] encourage studies using the system including constructive criticisms related specifically to the results of well-performed prospective validation studies. Retrospectively, unclear data and a misreading of the title document[1] represent, we believe, multiple weaknesses in the current study[2] and the accompanying critique. ■

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REPLY

We greatly appreciate the interest Dr Haylen and colleagues have shown in our recent article evaluating the interrater reliability of the International Continence Society/International Urogynecological Association (ICS/IUGA) classification system for mesh-related complications. We are surprised by Haylen et al's assertion that the classification system is not appropriate for retrospective use and was "designed for prospective 'live' use with full clinical information" because it's clearly stated in the Preface of their most recent article they list "medical records and surgical audits" as among the possible applications of the system.[1] If indeed the intent of the ICS/IUGA Standardization Committee is that the system only be used in a prospective fashion with optimal data collection, then: (1) the classification system should be amended to make this explicit and (2) the applicability of the system will be severely limited as

it would preclude its use by government agencies and academic centers with large administrative databases and for the majority of surgical studies submitted for peer review publication.

Dr Haylen and colleagues attempt to reinterpret our reliability data by eliminating noncorrelation based on medical record issues suggesting that once these are eliminated, the agreement is "very acceptable." Unfortunately, it is not clear what assumptions they made and we are not able to duplicate their calculations. As noted in Table 3 of our paper, disagreement between reviewers because of insufficient information in the medical record was noted in only 16 patients (12%) and eliminating them does not appreciably improve the reliability measures (kappa for vaginal category .34).

One of our criticisms that Haylen et al disagreed with was that the IUGA/ICS classification system does not allow the gradation of severity. To illustrate this point we offer an example. A patient experiencing urinary retention after a sling is categorized as 4B. However, it requires a minimal intervention of a simple sling lysis, with moderate burden to the patient. In contrast, another patient may be suffering from vaginal constriction and dyspareunia, and undergo numerous interventions in the effort to correct this, yet still may remain debilitated by chronic pain. Despite a much greater burden, this patient would be categorized as 1B.

We very much appreciate the significant efforts that these authors have made to develop a tool that has such clinical need. Unfortunately, our data suggest that the system has poor interrater reliability. We strongly encourage careful validity and reliability testing of this and any similar classification system before wide-spread adoption. ■

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Validity of intraoperative evaluation of myometrial invasion and preoperative grading in endometrial cancer

TO THE EDITORS: We read with great interest the recent analysis of systematic lymphadenectomy in endometrial cancer (EC) that was reported by Bendifallah et al.[1] This study suggests that omission of systematic pelvic lymphadenectomy in women undergoing primary surgery for presumed stage I with grade I or II EC has no impact on disease outcome and overall survival.

However, intraoperative identification of lymph node involvement and precise disease stage in patients with EC is somewhat problematic. In a retrospective analysis of 128 patients with EC, we observed only a fair agreement between preoperative and postoperative evaluation of myometrial invasion (quadratic-weighted Cohen kappa, 0.30; 95% confidence interval, 0.12–0.48; $P = .0006$). The sensitivity, specificity, and positive and negative predictive values of intraoperative frozen section for the detection of ≥50% myometrial invasion were 76.3%, 96.4%, 95.7%, and 79.1%, respectively. This, in turn, can be translated as almost 20% of patients assumed to have early disease stage actually have advanced disease with possible pelvic/paraaortic lymph node involvement. Skip metastasis is also another concern in the staging and decision of systematic lymphadenectomy in these patients. Of patients, 16% have only isolated paraaortic lymph node involvement.[2]

Preoperative tumor grading with intraoperative assessment of depth of myometrial invasion and histologic subtype has been reported to correlate poorly with final pathologic grade. A higher grade on final pathologic assessment will be diagnosed in 25% of patients with preoperative grade 1 disease and 3% will be diagnosed as nonendometrioid or grade III disease.[3] The risk of underestimating the grade during intraoperative assessment in patients with grade 2 disease has been reported as approximately 29%, as well. Clinically relevant upstaging occurs in 18% of patients.[4]

In contrast to the authors' conclusion, we think that decision-making on systematic lymphadenectomy in patients with EC according to preoperative grade and intraoperative myometrial invasion may put a considerable number of patients with presumed early-stage disease at risk of incomplete surgery and adjuvant therapy. ■

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