

**Documentation of specific mesh implant at the time of midurethral sling surgery in women
with stress incontinence**

Nadine C. Kassis MD¹, Jennifer C. Thompson MD², Anne M. Scheidler³, Douglass S. Hale MD¹

*1 Indiana University Health/Methodist Hospital, Urogynecology Associates, Indianapolis,
Indiana*

2 Indiana University, Department of Obstetrics and Gynecology, Indianapolis, Indiana

3 Indiana University, School of Medicine, Indianapolis, Indiana

Corresponding Author: Nadine C. Kassis, MD

Urogynecology Associates

1633 N. Capitol Avenue, Suite 436

Indianapolis, IN 46032

Phone: 317-962-6603, Fax: 317-962-2049

Email: nkassis@iupui.edu

Funding: None

Disclosures: Dr. Douglass S. Hale is an investigator with Allergan and Pelvalon. The remaining authors have no relevant financial disclosures.

Presented at the American Urogynecologic Society 34th Annual Scientific Meeting, October 16-19, 2013, Las Vegas, Nevada

Objective: We aimed to assess documentation completeness of the operative record for mesh implanted at the time of midurethral sling surgery and to identify modifiable predictors of documentation completeness.

Methods: A retrospective cross-sectional study of women with stress incontinence that underwent midurethral sling placement between 1/2009 and 12/2011 was conducted. Data from the dictated operative note and nursing operative record were extracted to determine if the specific mesh implanted during surgery was documented. The primary outcome was the rate of documentation of mesh implanted in the physician's dictated operative note and in the nursing record. Logistic regression was used to determine if any characteristics were associated with the rate of documentation.

Results: There were 816 surgeries involving the implantation of a midurethral sling during the study period. A Urogynecologist dictated 71% of the operative notes. The rate of documentation completeness for mesh implanted in the physician's note was 10%. The rate of documentation completeness for mesh implanted in the nursing operative record was 92%. Documentation of mesh implanted in the physician's note was not significantly associated with level of training, specialty, or year of surgery.

Conclusion: Documentation completeness for specific mesh implant in the physician's note is low, independent of specialty and level of training. Nursing documentation practices are more rigorous. Post-market surveillance, currently mandated by the FDA, may not be feasible if only the physician's note is available or if nursing practices are inconsistent. Development of documentation guidelines for physicians would improve feasibility of surveillance.

Introduction: Stress urinary incontinence (SUI) is a common problem affecting 15-50% of community-dwelling women (1,2). While initial treatment is often nonsurgical, surgery is offered to women with persistent symptoms. An estimated 4 to 10% of women in the United States undergo surgery to restore urinary continence (3). Surgical treatment frequently involves the placement of a synthetic midurethral sling. According to the Food and Drug Administration (FDA), in 2010 approximately 260,000 women underwent surgery to treat SUI and over 80% involved transvaginal mesh (4). Multiple products exist for SUI, all of which received FDA approval as Class II devices under the 510(K) Premarket Notification Program. In 2011, the FDA issued a Safety Communication to inform clinicians and patients that complications related to urogynecologic mesh are not rare (5). In 2012, the FDA mandated continued analysis of the literature, surveillance of adverse events, and further research on safety and effectiveness of surgical mesh including post-market (“522”) studies by manufacturers. Although they focused on vaginal mesh for prolapse, continued surveillance of midurethral slings was also specified. The specific mesh implant used must be completely and accurately documented, either within the physician’s note or the nursing record, to effectively conduct this mandated reporting and research.

We aimed to assess documentation completeness of the operative record for the specific mesh implanted at the time of midurethral sling surgery and to identify modifiable predictors of documentation completeness. This will help determine if post-market surveillance utilizing institution based medical records is feasible given current practice and documentation patterns.

Materials and Methods: A retrospective cross-sectional study of women presenting with stress incontinence that underwent midurethral sling placement at one of six Indiana University Health hospitals was conducted between January 1st 2009 and December 31st 2011. This study was

approved by the Institutional Review Board at Indiana University. Eligible subjects were identified by querying the Indiana University Health electronic medical record for surgical procedure name. Although the Indiana University Health system includes 17 adult hospitals, the surgical records of just 6 of these 17 hospitals were available for electronic querying. As such, only surgeries conducted at these 6 facilities were included in our analysis. All women with SUI who underwent midurethral sling placement during our study period were eligible for inclusion. Any subjects in whom the surgeon's operative note or the nursing operative record was not available for electronic review, or in whom a midurethral sling was not actually implanted, were excluded. Each eligible subject's operative note and nursing operative record was then individually reviewed. Data was extracted to determine if the specific urogynecologic mesh implanted at the time of surgery had been appropriately documented in each of these records. A strict definition was applied for documentation completeness requiring identification of both the manufacturer name as well as the product name of the specific mesh implanted. For instance, reporting "Boston Scientific Advantage" and "AMS Monarc" would qualify as complete documentation for the specific mesh implanted, while "TVT", "TOT", and "tension free vaginal tape" would not.

The primary outcome was to assess the rate of documentation completeness for specific mesh implanted in the physician's dictated operative note and in the nursing operative record. In the records in which a specific mesh implant was dually identified in both the physician's operative note and in the nursing operative record, we were able to calculate concordance and discordance rates. Secondary variables collected included rates of documentation of product code (a unique identifier assigned by the manufacturer to distinguish a specific product) and lot number (which pinpoints where and when the product was produced and provides traceability),

indication for surgery, use of concomitant cystoscopy, and actual product implanted. Clinical characteristics such as year of surgery, institution, surgical specialty and level of training of dictating surgeon were collected as possible predictors of documentation completeness.

Statistical analysis was conducted using SPSS 20.0 software. Descriptive statistics were performed. Categorical variables are reported as frequencies and percentages while continuous variables are reported as means with standard deviations. Logistic regression was used to determine if the year of surgery, institution, surgical specialty, or level of training of the dictating surgeon were independent predictors of documentation completeness for the specific implant in both the physician and nursing records using separate models. Generalized estimating equation (GEE) methodology assuming compound symmetry correlation structure was used to account for the correlation of subjects from the same dictating physician. The Chi-square likelihood ratio test was used. Odds ratios and 95% confidence intervals were calculated. $P \leq 0.05$ was considered statistically significant.

Results: There were 816 surgeries involving the implantation of a midurethral sling during the study period. 55% (n=448) of the surgeries were performed at a single institution, 27% (n=219) were performed at a second institution, and the remaining 18% (149) were performed at the remaining 4 institutions. 71% (n=584) of the operative notes were dictated by a Urogynecologist, 17% (n=136) by an Obstetrician Gynecologist, and 12% (n=96) by a Urologist. 38% (n=308) of the operative notes were dictated by an attending physician, 60% (n=492) by a fellow, and 2% (n=16) by a resident. The average age of our subjects was 56 years (SD 12.8). A documented indication for midurethral sling implantation such as “stress incontinence”, “urodynamic stress incontinence” or “stress predominant mixed incontinence” was noted in 95% of cases. Concomitant cystoscopy was documented in 96% of cases.

The rate of documentation completeness for the specific mesh implanted in the physician's dictated operative note was 10% (n=84). Only 4.5% had both a manufacturer and product name documented under the "Procedures" heading of the of the physician's operative note and only 1.7% had both a manufacturer and product name documented in the body of the physician's operative note. Thus careful review of the entire physician's dictated operative note was required to obtain even the low rate of documentation completeness (10%) described above. The rate of documentation completeness for the specific mesh implanted in the nursing operative record was 92% (n=748). A product number and lot number were documented in 98% of cases in the nursing operative record. There was 11% (n=8) discordance or disagreement in the 68 records in which a specific mesh implant was identified in both the physician's operative note and the nursing operative record. In 6 of these 8 cases, the discordance resulted from inaccurate documentation of product name in the physician's dictated note. The most frequent product implanted was the Gynecare TVT™ Retropubic sling, 57% (n=420), followed by the AMS Monarc™ trans-obturator sling, 23% (n=166).

The dictating physician's level of training (Attending vs. Fellow/Resident, P=0.145), surgical specialty (Urogynecology vs. Obstetrics and Gynecology vs. Urology, P=0.720), and year of surgery (2009 vs. 2011, P=0.419) were not predictors of documentation completeness for the specific mesh implanted in the physician's dictated operative note.

However, year of surgery did predict the rate of documentation completeness for the specific mesh implant in the nursing operative record (P<0.001) with an 86% documentation rate in 2009 and a 96% documentation rate in 2011. Institution also predicted the rate of documentation completeness for the specific mesh implant in the nursing operative record (P=0.005), with documentation rates ranging from 73% to 95%. In addition, year of surgery

($P=0.009$, OR 2.52, 95% CI 1.2-5.03) and institution ($P=0.011$) remained independent predictors of the rate of documentation completeness for the specific mesh implant in the nursing operative record when both were included as explanatory variables in a single logistic regression model.

Discussion: Documentation completeness for the specific mesh implanted at the time of surgery in the physician's operative note is low upon review of more than 800 midurethral sling surgeries performed at 6 institutions by over 30 surgeons. This was independent of surgical specialty and level of training of the dictating physician. Nursing documentation practices in our health system are more rigorous with a higher rate of documentation completeness in the nursing operative record. This was institution dependent, with a wide range of documentation rates. In addition, rates of documentation improved over the course of our study period. The high rate of documentation completeness in the nursing record may be related to specific guidelines and training that nurses within our system receive regarding surgical implants. Nurses are required to document the name, product and lot number of any surgical implant. In addition, they use a templated electronic medical record containing prompts and fields for documentation of permanent implants. While this may differ between systems, physicians have no specific guidelines for documentation of surgical implants. They also often dictate operative reports rather than using templated electronic records. Finally, it is likely that nursing documentation occurs during the surgery, in the operating room, with ready availability of implant packaging, while surgeon documentation often occurs outside of the operating room.

These findings raise questions about the feasibility of FDA mandated post-market surveillance of urogynecologic mesh devices within the current system. In their Guidance document (6), the FDA suggests that surveillance should be conducted and references the use of secondary data sets, registries and tracking systems which allow for analysis of outcomes. The

document cautions “In these instances, it is important to ensure that variables of interest are included in the data set.” In addition, the Committee Opinion released by the American College of Obstetricians and Gynecologists and the American Urogynecologic Society (AUGS) on the Vaginal Placement of Synthetic Mesh for Pelvic Organ Prolapse emphasizes the importance of continued surveillance with support of “continued audit and review of outcomes, as well as the development of a registry for surveillance...” (7). Many patients present to tertiary centers with mesh complications, and the ability to report to an adverse event registry becomes significantly hampered by lack of specific implant data.

Our findings are similar to those seen by Dr. Ballard and colleagues (8). Using a health information exchange containing data from 20 hospital systems, they were able to review over 2000 cases in which a urogynecologic mesh device was placed transvaginally. They identified the specific device used for the treatment of SUI in only 28% of cases, consistent with the low documentation rate in our study. On the other hand, they were able to identify the specific mesh device used for the treatment of prolapse in 86% of cases, a much higher rate of documentation completeness. Nursing documentation practices were not assessed. In their discussion, the authors recommend the inclusion of a unique device code in the medical record to allow for more automated and accurate surveillance.

Recent cardiac literature has demonstrated success with automated surveillance using device registry data. In one study evaluating 70,000 procedures, automated surveillance of the device registry was able to detect low-frequency safety signals arising from complications related to new cardiac devices (9). The Pelvic Floor Disorders Outcome Registry, currently under development by AUGS, will be crucial in providing much needed information about the effectiveness and safety associated with implantation of urogynecologic mesh, given this

previous experience. While device registries rely on voluntary reporting, entry into the registry at time of the index surgery will allow for accurate data collection and will facilitate automated surveillance for adverse events and efficacy.

All of the surgeries reviewed in our analysis were performed within a single system. This may limit the generalizability of our findings. However, 6 institutions and 30 surgeons were included in this analysis. In addition, we chose to be rigorous with the definition of “documentation completeness” requiring both manufacturer and product name. We did so because there are more than 20 slings currently being marketed. Additionally, we have noted a trend for describing any retropubic sling as a “TVT” even though TVT is a trademarked product name. Requiring only a product name would have resulted in higher documentation completeness rates but would have misrepresented accuracy.

Adverse event reporting, utilizing data from electronic medical records, may not be presently feasible if only the physician’s note is available or if nursing practices are not consistent across systems. Improved documentation is required so that accurate information about outcomes following mesh implantation can be used to drive healthcare decision making. Development of documentation guidelines for physicians, requiring identification of implants by both manufacturer and product name, and by product and lot number, would likely improve documentation rates and the feasibility of post-market surveillance. Continued support for the development of a national urogynecologic registry is vital.

References:

1. Melville JL, Katon W, Delaney K, Newton K. Urinary incontinence in US women: a population-based study. *Arch Intern Med* 2005;165:537-42.
2. Thom D. Variation in estimates of urinary incontinence prevalence in the community: effects of differences in definition, population characteristics, and study type. *J Am Geriatr Soc* 1998;46:473-80.
3. Thom DH, Nygaard IE, Calhoun EA. Urologic Diseases in America Project: urinary incontinence in women — national trends in hospitalizations, office visits, treatment and economic impact. *J Urol* 2005;173:1295-301.
4. Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse. FDA Center for Devices and Radiological Health. July 2011. Accessed at <http://www.fda.gov/downloads/MedicalDevices/Safety/AlertsandNotices/UCM262760.pdf> on 01/15/2013.
5. FDA Safety Communication: UPDATE on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse. FDA Center for Devices and Radiological Health. July 2011. Accessed at: <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm> on 01/15/2013.
6. Guidance for Industry and FDA Staff: Postmarket Surveillance under Section 522 of the Federal Food, Drug and Cosmetic Act. FDA Center for Devices and Radiological Health. April 2006. Accessed at: <http://www.fda.gov/cdrh/osb/guidance/316.pdf> on 02/05/2013.
7. Committee Opinion Number 513: Vaginal Placement of Synthetic Mesh for Pelvic Organ Prolapse. The American College of Obstetricians and Gynecologists and the American Urogynecologic Society. *Obstet Gynecol* 2011;118(6):1459-1464.

8. Ballard J, Rosenman M, Weiner M. Harnessing a Health Information Exchange to Identify Surgical Device Adverse Events for Urogynecologic Mesh. AMIA Annu Symp Proc. 2012;1109-18. Epub 2012 Nov 3.
9. Resnic FS, Gross TP, Marinac-Dabic D et al. Automated surveillance to detect post-procedure safety signals of approved cardiovascular devices. JAMA 2010;304(18):2019-27.