

Reporting and grading of complications after mid-urethral sling surgeries: Could the “Clavien-Dindo Classification” be adopted?

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Abstract

Background: To construct a modified model for reporting and grading of postoperative complications after the mid-urethral sling (MUS) procedure based on the Clavien-Dindo classification. In addition, complications of three different types of MUS were compared.

Materials and methods: A PubMed search for postoperative complication after MUS was carried out for the period between January 1990 and July 2018. Reported complications were stratified in a plate form designed in accordance with grades of the Clavien-Dindo classification. Then, the proposed model was applied on reported complications in 160 females who underwent three different procedures of MUS (transvaginal tape [TVT], transobturator tape [TOT], and autologous fascial sling) with a minimum follow-up of 24 months.

Results: The mean \pm SD age at time of surgery was 46 ± 7 years. TVT was carried out in 75 (47%) patients, TOT in 40 (25%), and fascial sling in 45 (28%). The total number of complications was 62 in 43 (26.8%) patients. The vast majority of complications were Grade I and Grade II 19 (12%) and 21 (13%) out of 160 patients, respectively. Transient postoperative voiding difficulty (Grade II) and de novo urgency (Grade II) were the most prevalent complications in the fascial sling method (15.4% for each), whereas transient thigh pain (Grade II) was the most frequently reported complication after TOT (10%). Life-threatening vascular injury (Grade IV-a) was a serious complication in TVT cases.

Conclusions: Postoperative complications of the MUS could be graded according to Clavien's classification. The vast majority of complications were Graded I or II. TVT can cause serious life-threatening complications.

Keywords: Complications; Fascial sling; Mid-urethral sling; Stress urinary incontinence; Transobturator tape; Transvaginal tape

1. Introduction

After their efficacy was proven, mid-urethral slings (MUS) are currently considered to be the procedure of choice in management of female stress urinary incontinence (SUI).^[1–3] However, there is a lack of consensus in the urogynecological community about an ideal postoperative measure that can efficiently evaluate such procedures.^[4] It seems that evaluation of safety is an easy task by reporting any encountered adverse effect during or after surgical treatment of SUI. However, conclusive assessments about safety remain limited by the lack of consensus on how to define complications and to stratify them by severity. Currently, there is a growing awareness about sling-related complications, malpractice litigations, and associated patients' concerns. This forced many synthetic sling manufacturers to withdraw their

products from the market. Simultaneously, many pelvic surgeons have reduced the utilization of synthetic slings and increased the utilization of autologous slings.^[5] In this context, standardization of terminology about postoperative complications after native tissue female pelvic surgery was published.^[6] The ultimate goal of that step was to provide a standardized method of data reporting. Although complications were coded, the grading of severity was far from sufficient in that report.

The Clavien-Dindo classification is a validated therapy-based classification system in which postoperative adverse effects are ranked by severity.^[7] Currently, it is considered as the standardized method of choice for grading postoperative adverse effects. It has been adopted by hundreds of publications in different fields of surgery as a method of reporting and evaluating postoperative complication. It is considered as a classic model of reporting safety of complications following procedures dealing with the treatment of the lower urinary tract.^[8] In the urogynecology field, the Clavien-Dindo's model was previously used in reporting sporadic complications following apical prolapse repair^[9] and MUS.^[10] Because of the specific nature of complications following MUS, there is a real need for a standardized model for grading complications. In this study, we proposed a model for grading of adverse effect of MUS in line with the original Clavien-Dindo's model. In addition, we evaluated adverse events of 3 different procedures of MUS by using Clavien-Dindo's grading system.

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Table 1
Grading of MUS complications.

Grade	Event
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions <ul style="list-style-type: none"> • Superficial wound infection • Nausea, vomiting, low grade fever • Prolonged catheterization (up to 1 week) either due to intraoperative injury or postoperative urine retention.
Grade II	Requiring pharmacological treatment with drugs other than such allowed for Grade I complications. Blood transfusions and total parenteral nutrition are also included <ul style="list-style-type: none"> • Hemorrhage requiring blood transfusion • De novo urgency • Urinary tract infection • Erosions/extrusions conservatively treated • Thigh /groin pain conservatively treated • Urine retention treated by transient clean intermittent catheterization • Dyspareunia not affecting sexual activity
Grade III	Requiring surgical, endoscopic, or radiological intervention
Grade IIIa	Intervention not under general anesthesia <ul style="list-style-type: none"> • Erosions/extrusions surgically treated • Thigh/groin pain treated by tape excision • Urine retention treated by tape excision
Grade IIIb	Intervention under general anesthesia
Grade IV	Life-threatening complication (including <i>central nervous system</i> complications) requiring intermediate care/intensive care unit management
Grade IVa	Single organ dysfunction <ul style="list-style-type: none"> • Dyspareunia affecting sexual activity • Irreparable bladder injury • Persistent thigh pain; not resolved after removal of tape
Grade IVb	Multiorgan dysfunction <ul style="list-style-type: none"> • Hemorrhage causing shock, intensive care unit admission ± exploration • Bowel perforation
Grade V	Death of a patient

2. Materials and methods

A PubMed search for postoperative surgical complications after MUS procedures was carried out using key words “MUS,” “transvaginal tape (TVT),” “transobturator tape (TOT),” “fascial sling,” “stress urinary incontinence,” and “complications.” Reported complications in 784 publications were identified and graded into 5 categories for model construction in accordance with the Clavien-Dindo classification (Table 1).

The data files of 160 patients who underwent 3 different techniques (TVT, TOT, and autologous fascial graft) for surgical treatments of SUI in our institution were retrospectively reviewed. All patients had completed at least 24 months follow-up. Patients’ demographics, clinical, and preoperative urodynamic data were compared. Follow-up data were prospectively registered and updated according to prospective protocols.^[10,11]

All women were seen during 1 week at the outpatient clinic to check wound status. A vaginal examination, stress test and urinalysis were regularly done at 3 months. At 6 months, a voiding pressure flow test was carried out and the Urinary Distress Inventory, Short Form (UDI-6), and Incontinence Impact Questionnaire, Short Form (IIQ-7) were taken. The stress test, vaginal examination, and pad test were repeated at 12, 18, and 24 months. Patients were then checked annually thereafter by analysis of new lower urinary tract symptoms, urinalysis, noninvasive flowmetry, and postvoid residual urine (PVR). The recorded complications up to 2 years follow-up were graded and compared.

Continuous data were expressed by mean ± SD. One-way ANOVA, Post-Hoc, and Kruskal–Wallis tests were used to compare continuous variables according to normality. The Chi-square test was utilized to compare categorical variables. Statistical significance was considered when $p < 0.05$. All statistical analyses were done by using SPSS[®], version 19 (IBM SPSS).

3. Results

The mean ± SD age at time of surgery was 46 ± 7 years. TVT was carried out in 75 (47%) patients, TOT in 40 (25%), and fascial sling in 45 (28%) patients. Concomitant prolapse repair with fascial plication was carried out in 20 (12.5%) patients. No difference was detected with regard to patients’ demographics, clinical data, and abdominal leak point pressure among the 3 groups (Table 2).

Recorded complications were from Grade I to Grade IV-b. No mortality cases (Grade V) were reported. The total number of complications was 62 in 43 (26.8%) patients. There were 7 patients who had more than 1 complication. When complications were adjusted per each procedure, the highest rate was in the fascial graft followed by TOT and TVT (46.5%, 22.5%, and 18.6%, respectively, $p=0.006$). The vast majority of complications were Grade I and Grade II (19 [12%] and 21 [13%] out of 160 patients, respectively).

De novo urgency (Grade II), the most frequently reported complication, was detected in 14 patients. Postoperative urine retention or high PVR > 100 mL necessitating re-fixation and

Table 2

Patients' characteristics and baseline parameters.

	TVT <i>n</i> =75	TOT <i>n</i> =40	Fascial sling <i>n</i> =45	<i>p</i>
Age, years	46±7	46±7	45±7	0.9*
Gravidity	4.8±2	4.4±2	4.8±3	0.4**
Parity	4.4±2	4±1.5	4.3±2	0.5**
Body mass index, kg/m ²	34±5	31±6	33±5	0.3*
Abdominal leak point pressure, cmH ₂ O	78±24	81±33	81±34	0.8*
SUI grade				0.5***
1	19 (25%)	14 (35%)	17 (38%)	
2	36 (59%)	18 (45%)	15 (32%)	
3	20 (26%)	8 (20%)	13 (30%)	

TOT = transobturator tape; TVT = transvaginal tape.

* One-way ANOVA test.

** Kruskal–Wallis test.

*** Chi-square test.

prolongation of urethral catheterization was encountered in 15 patients. In 11 patients a urethral catheter was left for an extra 1 to 2 weeks until PVR was <100mL (Grade I). In 4 patients, urethral dilatation was carried out (Grade II). None needed removal of the sling.

The highest grade of complication was reported in 1 patient in the TVT group. The patient presented with a drop in the hemoglobin level and signs of hemorrhagic shock (Grade IV-b). A pelvic hematoma was detected by noncontrast spiral CT. The patient was managed by blood transfusion and hemostatics (Table 3).

4. Discussion

Recent recommendations in general surgical and urological communities suggested that standardized registering and recording the severity of complications should become a standard step in clinical practice and in the surgical literature to adequately compare the quality of care and the results of clinical trials.^[12,13] In this context, the modified Clavien-Dindo classification for the severity of surgical complications has many advantages in that it helps in uniform reporting of negative outcomes, for longitudinal follow-up of cases, allows easy comparisons and collection of

results in multi-center trials, and when adequate meta-analysis is considered. In a prospective cross-sectional survey, the Clavien-Dindo classification was found to be true and to similarly reflect the perception of patients, practicing nurses, and physicians toward postoperative complications.^[14] Therefore, it was suggested to serve as the basis to assess the outcome in many surgical procedures.^[12]

Consequently, the Clavien-Dindo classification has gained much popularity in urology practice. The Clavien-Dindo classification was adopted for reporting of complications following kidney transplantation,^[15] radical cystectomy,^[16] radical prostatectomy,^[17] trans-vesical prostatectomy,^[18] radical nephrectomy, open and laproscopic partial nephrectomy,^[19] laparoscopic and open adrenalectomy,^[20] ureteroscopy,^[21] and percutaneous nephrostomy.^[22] However, the classification system has not yet been used in the urogynecology literature.

Complications after MUS have a unique nature. This may be the possible cause that hinders using the Clavien-Dindo classification. In the current study, we proposed a model for ranking of complications following MUS that was in accordance with the philosophy of the Clavien-Dindo classification. This philosophy is based on grading of severity according to the type of management offered to each complication. In this current plate

Table 3

Percentage and grading of reported complications per sling type.

Grade	TVT <i>n</i> =75	TOT <i>n</i> =40	AFS <i>n</i> =45
I			
Wound infection, <i>n</i> (%)	0	0	1 (2.2)
Prolong catheter for bladder perforation, <i>n</i> (%)	3 (4)	1 (2.5)	3 (6.6)
Prolong catheter for retention, <i>n</i> (%)	3 (4)	1 (2.5)	7 (15.4)
II			
Suprapubic/thigh pain, <i>n</i> (%)	0	4 (10)	1 (2.2)
De novo urgency, <i>n</i> (%)	6 (8)	1 (2.5)	7 (15.4)
Vaginal erosion, <i>n</i> (%)	1 (1.3)	0	0
Dyspareunia, <i>n</i> (%)	0	0	1 (2.2)
IIIa			
Urine retention needs dilatation, <i>n</i> (%)	0	2 (5)	1 (2.2)
IVb			
Bleeding, <i>n</i> (%)	1 (1.3)	0	0
Total, <i>n</i> (%)	14 (18.6)	9 (22.5)	21 (46.5)

AFS = autologous fascial sling; TOT = transobturator tape; TVT = transvaginal tape.

form, events such as low grade fever, nausea, and vomiting have been graded as “Grade I.” This matches their universal ranking in the literature of different surgical fields. Likewise, stage “Grade V” for mortality. According to the original classification, “Grade III-b” is defined as when intervention for correction of a complication is done under general anesthesia. Therefore, we did not specify complications for “Grade III-b” because any complication with Grade I or II could be upgraded to III-b on that basis.

One of the advantages of this model is the flexibility of grading. Thus, according to the provided plate form, ranking of one specific complication could be up-graded according to its severity. For example, ranking of voiding difficulty starts with “Grade I” if it is transient and urethral catheter is needed for an extra few days. If an extra step is required, such as temporary self-catheterization, the severity is then ranked as “Grade II.” If surgical intervention is needed to correct such a complication, grading becomes “Grade III-a or III-b.” Similarly, ranking of hematoma starts from Grade I if only hemostatics are required. It rises to Grade II in case of blood transfusion. Likewise, other complications, for example, vaginal injuries or mesh erosions are ranked as “Grade II” if local vaginal antiseptics or estrogen cream solves the problem or ranked as “Grade III” if correction is done under anesthesia.

For neurological complication, we followed similar ranking used for grading of orthopedic complications based on the Clavien-Dindo system.^[23] Therefore, groin/thigh pain that is more common in TOT is ranked Grade II in transient pain that is resolved by analgesics. If tape removal is judged as the only solution for pain relief, the grading then is Grade III-a. If pain persists after tape removal “persistent neoupraxia,” the condition is Grade “IV-a.” A serious complication such as bowel perforation is very rare after TVT (<1%), yet, it could result in mortality.^[24] Thus, it is ranked as “Grade IV” if it is properly managed or “Grade V” if it leads to mortality.

In the current study, we found the highest rate of complications in the autologous fascial sling group (46.5%) and nearly equal rates in TOT (22.5%) and TVT (18.6%). This might be considered higher than reported data in the literature of multi-center studies.^[25,26] A qualitative summation of complications may be an explanation. Long-term follow-up in the current study compared with other reports is another explanation. Furthermore, when comparing the complication rates published from different centers, certain minor complications may or may not be omitted. Interestingly, a similar observation of reporting higher rates of complications when the Clavien-Dindo classification was utilized was highlighted in many reports on other urological procedures.^[15,22] Such bias leads to the problem of under reporting of complications, which is still a major defect in scientific publications.

In contrast, when it comes to complication, it is not a matter of “frequency of complication,” rather it is a matter of “grade.” Therefore, despite that the highest rate of complications was found in the fascial sling group, the most serious and highest grade was found in the TVT group.

In summary, a novel model for reporting of complications after MUS is proposed. The proposed model was utilized to compare 3 different types of slings; TVT, TOT, and autologous fascial. A point of strength in the comparative section in our study is a prospective collection of data. Prospective registration has shown to be more superior to morbidity and mortality rounds. Therefore, it was suggested as a standard by different authors.^[12,13]

In contrast, the current study had some potential limitations. The model does not take into account scenarios when more than 1 complication happens in the same patient. In this situation, either summation of grades or ranking according to highest grade may be a viable option. A third solution is that each complication could be counted as a separate case and the number of cases with more than 1 complication is announced as previously reported in other surgical scenarios.^[15] We think that the third option would provide more precise reporting. Another limitation is failure of treatment. However, this event is not considered as a complication in all relevant literature. Certainly, the current model did not undergo tests of reliability and validity that should be a point of investigation following this preliminary report. Therefore, we applied it to already published data that involved 160 patients.^[11,12] We tried to make a correlation between the current proposed scale and the International Continence Society/ International Urogynecological Association classification for complications.^[6] It is comprised of 3 domains: category, site, and time classification. Although this way seems to be more precise, it is more complicated and seems to be difficult for application. We have already linked it to the terminology section supplied. However, we failed to find a suitable form for achieving correlation with category and site classification sections due to differences in concepts. Finally, one considerable point is to popularize this grading system. Since, the Clavien-Dindo classification is not well known to gynecologists involved in urogynecology, it might need a lot of education in this environment to implement this scale among urogynecologists.

5. Conclusions

The proposed model can provide an easily available tool that may facilitate standardized reporting and grading of complication of mid-urethral slings. Although the autologous fascial graft had the highest incidence of complications, more serious complications were reported with TVT.

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None.

Statement of ethics

The study was conducted after gaining local ethical committee and IRB approval.

Conflict of interest statement

No conflict of interest has been declared by the author.

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Author contributions

AS: Draft, conduction of surgeries, data collection and analysis.
BW: Conduction of surgeries. Data collection and analysis.

References

- [1] El-Hefnawy AS, Wadie BS. Severe stress urinary incontinence: objective analysis of risk factors. *Maturitas* 2011;68(4):374–377.

- [2] Rac G, Younger A, Clemens JQ, et al. Stress urinary incontinence surgery trends in academic female pelvic medicine and reconstructive surgery urology practice in the setting of the food and drug administration public health notifications. *Neurourol Urodyn* 2017;36(4):1155–1160.
- [3] Linder BJ, Elliott DS. Synthetic midurethral slings roles, outcomes, and complications. *Urol Clin North Am* 2019;46(1):17–30.
- [4] Haliloglu B, Rizk DE. Subjective versus objective measurement of surgical outcomes of treatment of female stress urinary incontinence: it is not just black and white. *Int Urogynecol J* 2010;21(7):761–762.
- [5] Mahdy A, Ghoniem GM. Autologous rectus fascia sling for treatment of stress urinary incontinence in women: a review of the literature. *Neurourol Urodyn* 2019;38(suppl 4):S51–S58.
- [6] Haylen BT, Freeman RM, Lee J, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint terminology and classification of the complications related to native tissue female pelvic floor surgery. *Int Urogynecol J* 2012;23(5):515–526.
- [7] Clavien PA, Barkun J, de Oliveira ML, et al. The Clavien-Dindo classification of surgical complications: five-year experience. *Ann Surg* 2009;250(2):187–196.
- [8] Gilling PJ, Barber N, Bidair M, et al. Randomized controlled trial of aquablation versus transurethral resection of the prostate in benign prostatic hyperplasia: one-year outcomes. *Urology* 2019;125:169–173.
- [9] Robinson BL, Parnell BA, Sandbulte JT, Geller EJ, Connolly A, Matthews CA. Robotic versus vaginal urogynecologic surgery: a retrospective cohort study of perioperative complications in elderly women. *Female Pelvic Med Reconstr Surg* 2013;19(4):230–237.
- [10] El-Hefnawy AS, Wadie BS, El Mekresh M, Nabeeh A, Bazeed MA. TOT for treatment of stress urinary incontinence: how should we assess its equivalence with TVT? *Int Urogynecol J* 2010;21(8):947–953.
- [11] Wadie BS, Mansour A, El-Hefnawy AS, Nabeeh A, Khair AA. Minimum 2-year follow-up of mid-urethral slings, effect on quality of life, incontinence impact and sexual function. *Int Urogynecol J* 2010;21(12):1485–1490.
- [12] Baccaglioni W, Medina L, Azhar RA, Sotelo RJ. Complications of robotic surgery in urological diseases: are we using standardized methodology to report complications? *Curr Opin Urol* 2019;29(1):19–24.
- [13] Mitropoulos D, Artibani W, Graefen M, Remzi M, Rouprêt M, Truss M. European Association of Urology Guidelines Panel. Reporting and grading of complications after urologic surgical procedures: an ad hoc EAU guidelines panel assessment and recommendations. *Eur Urol* 2012;61(2):341–349.
- [14] Slankamenac K, Graf R, Puhan MA, Clavien PA. Perception of surgical complications among patients, nurses and physicians: a prospective cross-sectional survey. *Patient Saf Surg* 2011;5(1):30.
- [15] Harraz AM, Shokeir AA, Soliman SA, et al. Toward a standardized system for reporting surgical outcome of pediatric and adolescent live donor renal allotransplantation. *J Urol* 2012;187(3):1041–1046.
- [16] Pavone C, Candela L, Fontana D, Simonato A. Postoperative complications and 90 day mortality in radical cystectomy in high-risk patients: a monocentric retrospective observational study. *Urologia* 2018;85(3):111–117.
- [17] Porcaro AB, Siracusano S, Bizzotto L, et al. Is a drain needed after robotic radical prostatectomy with or without pelvic lymph node dissection? Results of a single center randomized clinical trial. *J Endourol* 2019;doi: 10.1089/end.2018.0176.
- [18] Oranusi CK, Nwofor A, Oranusi IO. Complication rates of open transvesical prostatectomy according to the Clavien-Dindo classification system. *Niger J Clin Pract* 2012;15(1):34–37.
- [19] Heinze A, Larcher A, Umari P, et al. Assessing perioperative, functional and oncological outcomes of patients with imperative versus elective indications for robot-assisted partial nephrectomy: results from a high-volume center. *Int J Urol* 2018;25(9):826–831.
- [20] Eichhorn-Wharry LI, Talpos GB, Rubinfeld I. Laparoscopic versus open adrenalectomy: another look at outcome using the Clavien classification system. *Surgery* 2012;152(6):1090–1095.
- [21] Mager R, Kurosch M, Höfner T, Frees S, Haferkamp A, Neisius A. Clinical outcomes and costs of reusable and single-use flexible ureterorenoscopes: a prospective cohort study. *Urolithiasis* 2018;46(6):587–593.
- [22] Güler A, Erbin A, Ucpinar B, Savun M, Sarilar O, Akbulut MF. Comparison of miniaturized percutaneous nephrolithotomy and standard percutaneous nephrolithotomy for the treatment of large kidney stones: a randomized prospective study. *Urolithiasis* 2019;47(3):289–295.
- [23] Sink EL, Leunig M, Zaltz I, Gilbert JC, Clohisy J. Reliability of a complication classification system for orthopaedic surgery. *Clin Orthop Relat Res* 2012;470(8):2220–2226.
- [24] Daneshgari F, Kong W, Swartz M. Complications of mid urethral slings: important outcomes for future clinical trials. *J Urol* 2008;180(5):1890–1897.
- [25] Albo ME, Richter HE, Brubaker L, et al. Burch colposuspension versus fascial sling to reduce urinary stress incontinence. *N Engl J Med* 2007;356(21):2143–2155.
- [26] Brubaker L, Norton PA, Albo ME, et al. Adverse events over two years after retropubic or transobturator midurethral sling surgery: findings from the Trial of Midurethral Slings (TOMUS) study. *Am J Obstet Gynecol* 2011;205(5):498.e1–6.

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