

Review

The International Urogynecological Association/International Continence Society classification of complications of prosthesis and graft insertion: Pros and cons and the review of the literature

Yassa and Doğan. The IUGA/ICS classification of complications of prosthesis and graft insertion

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Abstract

International Urogynecological Association (IUGA) and the International Continence Society (ICS) and the Joint IUGA/ICS Working Group on Complications Terminology constituted a standardized terminology and classification of complications related to the use of prosthesis in female pelvic floor surgeries. It has been mainly purposed to globally standardize the complications and related definitions in order to obtain factual rates and to enable comparisons and surgical audits. Although this unique classification has frequently been cited in the literature, some concerns has been raised against its complexity of use and inter and -intra observer variability. This review aimed to discuss the rationale behind the IUGA/ICS complication classification system, underline the opposing views and provide the Turkish version of online calculator facilitating the universal coding to increase the utility.

Keywords: Calculator, complications terminology, female pelvic floor surgeries, graft, prosthesis

Introduction

International Urogynecological Association (IUGA) and the International Continence Society (ICS) and the Joint IUGA/ICS Working Group on Complications Terminology constituted a standardized terminology and classification of complications related to the use of prosthesis in female pelvic floor surgeries.¹ This classification system is the first attempt to systematically classify the related complications. It has been mainly purposed to globally standardize the complications and related definitions in order to obtain factual rates and to enable comparisons and surgical audits. Although this unique classification currently had over 150 citations (<https://citations.springer.com/item?doi=10.1007/s00192-010-1324-9>, data received at 11/02/2019), some concerns has been raised against its complexity of use and inter and -intra observer variability.^{2,3} This non-systematic review aimed to discuss the rationale behind the IUGA/ICS complication classification system, underline the opposing views and provide the Turkish version of online calculator facilitating the universal coding to increase the utility (Supplement).

Rationale

Mid-urethral sling is the gold standard and the most common surgical procedure to treat the stress urinary incontinence with a proven superiority over the other surgical procedures.⁴ Although mid-urethral slings exhibited a good safety and effectivity profile, a safety concern is raised globally against the vaginal use of mesh, particularly to treat pelvic organ prolapse. The use of synthetic mesh has statistically decreased between 2011 and 2013 after the second FDA Public Health Notification while the number of mesh revision surgeries increased by almost three-fold from 2007 to 2013.⁵

A recent meta-analysis consisting of 28 RCTs and 15,855 patients showed that patients received mid-urethral sling had higher overall and objective cure rates than those underwent Burch colposuspension.⁴ The latest Cochrane systematic review assessing the mid-urethral slings for stress urinary incontinence determined that major complications such as nerve, bowel or major vascular injuries, pelvic haematoma, necrotizing fasciitis, ischiorectal abscess and death are found to be uncommon in mid-urethral slings.⁶ Bladder perforation, reoperation, urinary retention, pelvic haematoma, infection, vaginal tape erosion/extrusion and groin pain occurred in 3.9%, 2.4%, 1.6%, 1.9%, 0.7%, 1.5% and 0.4% of women underwent to retropubic tape procedure,

respectively. Those rates were 0.4%, 2.2%, 0.5%, 0.5%, 0.6%, 0.4% and 1.6% for transobturator tapes.⁶ Another large population-based retrospective series consisting of 95,057 women was recently published.⁷ Women who had their first mid-urethral sling procedure to treat stress urinary incontinence were included and followed for 5.5 (interquartile range, 3.2-7.5 years) years. They found that the rate of mesh sling removal was 1.4% at 1 year, 2.7% at 5 years and 3.3% at 9 years. The rate of any reoperation including all was found to be 2.6%, 5.5% and 6.9% at 1, 5 and 9 years, respectively. In contrary, the recent largest study of vaginal mesh to treat stress urinary incontinence including 92,246 women followed over an 8-year period revealed that peri-operative and 30-day complication rates were found to be 2.4% and 9.8% of all patients faced within 5 years of the initial mesh surgery.⁸

It has been argued that RCTs designed for long-term follow-up possess limited information about whether there was hidden cache of serious adverse effects that might have been set against the benefits of curing incontinence.⁶ Many reporting system belong to the major registries were characterized with passive surveillance system limited by the inclusion of the potential submission of incomplete or inaccurate data, under-reporting of events, lack of denominator data and the lack of report timeliness.⁶

Due to the inconsistent and increasing reports of complication rates The International Urogynecological Association (IUGA) and International Continence Society (ICS) proposed a well-detailed but inclusive classification system of the complications related to the use of all type of prosthesis including meshes, implants, tapes and grafts in female pelvic floor surgery.¹

Classification system and coding

The IUGA/ICS system has been developed to cover all possible physical complications including trocar-related insertion complications and healing abnormalities. The classification system depends on three main factors; Category (numeric) and division (letter), Time (numeric+letter) and Site (numeric+letter), respectively and all together is called as 'CTS' system. "Category" refers to the general description of the complication such as the degree or extent of erosion (according to former usage), affected site or the condition of the patient. "Division" refers to four common major complication type: A-Asymptomatic, B-Symptomatic, C-Infection, D-Abscess. "Time" describes the duration between the surgery and clinically diagnosed complication. "Site" describes the localization of the complication. One can obtain a code of 3 letters and 3 numerals after classification (*e.g.* 2B/T3/S1) (Figure 1). The only sub-group reflects the "pain" according to the vaginal examination and/or anamnesis. Pain adds a lower case next to the division (*e.g.* 2Bc/T3/S1, if patient expresses pain during sexual intercourse).

One of the main prominent features in newly proposed joint terminology is that the term of "erosion" is not favoured. Mesh inherently interacts with adjacent tissue. Therefore, it is replaced by terms of vaginal epithelium separation, exposure, extrusion, contraction, prominence and sinus tract formation. Additional new terms include compromise, perforation and dehiscence.¹ While exposure can simply be described as visible or palpable mesh through separated epithelium (mainly vaginal wall) in earlier period, extrusion represents a subsequent delayed process that mesh protrudes gradually out of a body structure or adjacent tissue such as vagina, bladder and urethra. Perforation frequently refers to perioperative events. In addition, the classification system has dynamic characteristics. Naturally, multiple complications may occur in the same patient at the same time or over a period of time and all should be reported separately.¹

The boundaries of the CTS system include not covering the urinary tract infections, functional issues (*e.g.* voiding dysfunction), intraperitoneal adhesions and prion or viral infection of a xenograft. Secondly, recurrences are not situated in the CTS system because a recurrence is not counted as a complication. That exclusions might be due to the fact that those not-included complications may not be directly related to the insertion of prosthesis. Lastly, complications linked to the bulking agents are also not included.

Literature and opposing views

Petri and Ashok assessed the applicability of IUGA-ICS classification by retrospectively analysing 359 cases who encountered with a surgical management due to a complication directly related to insertion of a synthetic sling and classifying each complication according to the new IUGA-ICS classification with online calculator (<https://www.ics.org/complication>). Although they found that the new classification system has good general applicability, it was inadequate to classify over active bladder (OAB) which was accounted as the most common complication with a rate of 54% (n=193). Lower urinary tract obstruction requiring resection or cutting the sling was the second commonest complication with 48% of all (n=174). That complication was classified 4B, however authors could not state the "Site". Except those two, the CTS system was beneficial in classifying most of the rare and common complications. Along with including OAB and sub-classifying 4B, Petri and Ashok also recommended some other rare complications to be labelled as miscellaneous such as dyspareunia of the partner, urine loss during intercourse and foreign body sensation in the vagina.

In 2015, Miklos *et al* analysed the mesh complications among women who had undergone pelvic floor reconstructive surgery with mesh including sub-urethral mesh slings, transvaginal synthetic mesh and

Sacrocolpexy in their multi-centre retrospective study.⁹ A total of 445 patients were included from three tertiary urogynecological referral centers. Unlike Petri and Ashok, all of the complications that mainly consist of complicated and often recurrent cases were possible to be classified by the IUGA-ICS classification system in their study.

Tunitsky *et al* retrospectively analysed 1236 patients and identified 133 eligible patients presenting after pelvic organ prolapse or incontinence surgery with 195 mesh-related complications in their study to assess inter-rater reliability of the IUGA-ICS classification.² The complications were classified by 2 independent reviewers with using the ICS/IUGA classification system. They observed low agreement at 44.09% on vaginal complications (categories of 1A-3D), high agreement on urologic (96.1%, categories of 4A-4C) and bowel complications (100%, categories of 5A-5C). Authors claimed that 2.2% of the complications could not be classified into any organ/severity categories and “Site” of the complications could not be located in 38% of the complications due to the lack of clarity of the IUGA-ICS classification. Interestingly, they also observed low agreement on “complication time” and “complication site” between the two independent reviewers with 47.6% and 29.7%, respectively. Tunitsky *et al* suggested that the complications might be classified by symptom and intervention rather than the physical findings. For example, they argued that Category 5 that was designated for bowel complications does not cover defecatory dysfunctions. Although that proposal will probably increase the complexity of the classification system, we believe that Tunitsky *et al* might get a point particularly in pelvic organ prolapse surgeries but not necessarily in anti-incontinence procedures.^{10, 11} We were able to explain all the complications with using the CTS system after insertion of old and new generation mid-urethral slings to treat urinary stress incontinence.

The feasibility and the difference of the complication system in between prolapse and anti-incontinence surgeries was assessed in a single-centre retrospective study with using a wide range of surgical kits.¹² The most frequent complications varied with the type of the surgery which were found to be the bladder outlet obstruction for vaginal sling-plasty and pain for prolapse surgery. The affected site was also differed between each other meanwhile the time remained statistically similar. The authors commented that using the CTS code may provide a quick overview of patients’ major findings in a more general way, however, the complication classification system needs to be evolved in a way to cover the functional disorders (*e.g.* urgency, constipation and dyschezia) since 17.32% (n=31/179) of the patients were presented with only functional problems in their study.

Following assertion of poor inter-rater reliability of the IUGA-ICS classification, Gowda *et al* had similar results in their study that stratifies interobserver reliability by stage of training.³ It should be noted that authors stated their study as underpowered and with sampling bias. As a response to the studies showing the poor interrater and interobserver reliability, the original authors run the hypothesis of the poor reproducibility is because of the unperfect study designs and the reliability can be strengthened by an optimized training prior to use of the CTS IGAU/ICS complication classification system.¹³ Haylen *et al* achieved an excellent interobserver reliability (93%) with no significant differences among 39 respondents after giving structured instructions supported by photos and quizzes even though the participants were under time pressure and without access to the online calculator.

Batalden *et al* assessed the retrospective applicability of IUGA/ICS classification system.¹⁴ Authors only included complications with mesh erosion and the newly expanded definitions consisting of contraction, prominence, separation, exposure, extrusion, perforation, dehiscence and sinus tract formation. They observed that the classification did not predict the treatment or outcome of the complication and 30% of the mesh erosions could not retrospectively coded with the CTS system. However, it was mainly due to missing information that did not exist in the clinical documentation or operative reports.

Bontje *et al* specifically assessed the complications of patients who consecutively underwent vaginal prolapse repair using the mesh.¹⁵ Authors were able to code 43 complication from 39 patients out of 107 (36.45%). They stated that the classification system was found to be generally successful but only needs to expand the coverage such as the need of reoperation, the duration of the impact of the complication, severity of bleeding. In a small scaled retrospective study with 57 patients, Hammett *et al* drew attention to the rate of the resolution of symptoms after the mesh removal.¹⁶ They showed that the complete resolution or improvement rate was found to be 57.3% with using the IUGA/ICS classification system

Conclusion

IUGA/ICS complication classification system is one of its kind and the first universal classification coding system facilitating the standardized data accumulation and surgical audit specifically for the vaginal prosthesis. The system can be enriched and strengthened by covering the urinary functional problems. Although gaining a prompt and deep insight into the CTS system seems difficult, the online calculator can accurately simplify the classification. We believe that the complications' classification system should be increasingly used to achieve an objective and internationally agreement. This may allow to standardized documentation that leads to a more accurate assessment of complications and their severity.

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CATEGORY

General Description	A (Asymptomatic)	B (Symptomatic)	C (Infection)	D (Abscess)
1 Vaginal: no epithelial separation Include prominence (e.g. due to wrinkling or folding), mesh fibre palpation or contraction (shrinkage)	1A: Abnormal prosthesis or graft finding on clinical examination	1B: Symptomatic e.g. unusual discomfort / pain; dyspareunia (either partner); bleeding	1C: Infection (suspected or actual)	1D = Abscess
2 Vaginal: smaller ≤ 1cm exposure	2A: Asymptomatic	2B: Symptomatic	2C: Infection	2D = Abscess
3 Vaginal: larger >1cm exposure, or any extrusion	3A: Asymptomatic 1-3Aa if no prosthesis or graft related pain	3B: Symptomatic 1-3B (b-e) if prosthesis or graft related pain	3C: Infection 1-3C /1-3D (b-e) if prosthesis or graft related pain	3D = Abscess
4 Urinary Tract: compromise or perforation Including prosthesis (graft) perforation, fistula and calculus	4A: Small intraoperative defect e.g. bladder perforation	4B: Other lower urinary tract complication or urinary retention	4C: Ureteric or upper urinary tract complication	
5 Rectal or Bowel: compromise or perforation including prosthesis (graft) perforation and fistula	5A: Small intraoperative defect (rectal or bowel)	5B: Rectal injury or compromise	5C: Small or Large bowel injury or compromise	5D = Abscess
6 Skin and / or musculoskeletal: complications including discharge pain lump or sinus tract formation	6A: Asymptomatic, abnormal finding on clinical examination	6B: Symptomatic e.g. discharge, pain or lump	6C: Infection e.g. sinus tract formation	6D = Abscess
7 Patient: compromise including hematoma or systemic compromise	7A: Bleeding complication including haematoma	7B: Major degree of resuscitation or intensive care*	7C: Mortality * *(additional complication - no site applicable - S 0)	

TIME (clinically diagnosed)

T1: Intraoperative to 48 hours	T2: 48 hours to 2 months	T3: 2 months to 12 months	T4: over 12 months
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SITE

S1: Vaginal: area of suture line	S2: Vaginal: away from area of suture line	S3: Trocar passage Exception: Intra-abdominal (S5)	S4: other skin or musculoskeletal site	S5: Intra-abdominal
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- N.B.**
- Multiple complications may occur in the same patient. There may be early and late complications in the same patient. i.e. All complications to be listed. Tables of complications may often be procedure specific.
 - The highest final category for any single complication should be used if there is a change over time. (patient 888)
 - Urinary tract infections and functional issues (apart from 4B) have not been included.

CODE - **T** - **S**



Uncorrected Proof

Supplement

ICS/IUGA Protez-Greft Komplikasyon Sınıflandırılması*

<https://www.ics.org/complication>

KATEGORİ

1 – Vajinal: Epitelyal ayrılma yok

Vajinal çıkıntılar (buruşma veya katlanma gibi), meş lifinin palpasyonu veya kontraksiyonu (büzüşmesi) dahil.

2 – Vajinal: ≤ 1 cm ekspozür (exposure)

3 – Vajinal: > 1 cm ekspozür (veya herhangi ekstrüzyon olması)

4 – Üriner trakt:

Herhangi bir kötüleşme veya perforasyon. Perforasyon, fistül ve taş (kalkül) dahil.

5 – Rektum veya bağırsak:

Herhangi bir kötüleşme veya perforasyon. Greft perforasyonu ve fistül dahil.

6 – Cilt ve / veya kas-iskelet:

Akıntı, ağrı, şişkinlik (topaklaşma) veya sinüs traktı oluşumu

7 – Hastada kötüye gidiş

Hematom veya sistemik kötüleşme dahil.

BÖLÜM (Kategori 1 için)

A – Anormal protez (meş veya greft)

Klinik muayenede meşe dair herhangi bir anormallik

B – Semptomatik

Örn. Alışılmadık rahatsızlık hissi/ağrı; dispareni (partnerde de olabilir); kanama

C – Enfeksiyon varlığı veya şüphesi

D – Apse

BÖLÜM (Kategori 2 ve 3 için)

A – Asemptomatik

B – Semptomatik

C – Enfeksiyon

D – Apse

BÖLÜM (Kategori 4 için)

A – Küçük intraoperatif defekt

Örn. Mesane perforasyonu

B – Alt üriner trakt

Diğer alt üriner trakt komplikasyonu veya üriner retansiyon

C – Üretere veya üst üriner trakta ait

BÖLÜM (Kategori 5 için)

A – Küçük intraoperatif defekt

(Rektal veya bağırsak)

B – Rektal hasar veya kötüleşme

C – Küçük veya büyük bağırsak hasarı veya kötüleşme

D – Apse

BÖLÜM (Kategori 6 için)

A – Asemptomatik

Klinik muayenede anormal bulgu

B – Semptomatik

Örn. Akıntı, ağrı veya şişkinlik (topaklaşma)

C – Enfeksiyon

Örn. Sinüs traktı oluşumu

D – Apse

BÖLÜM (Kategori 7 için)

A – Kanama

Hematom dahil

B – Majör resüsitasyon veya yoğun bakım ihtiyacı

C – Mortalite

AĞRI

Sınıflandırılmayan

A – Asemptomatik veya ağrı yok

B – Uyarılma ile ağrı

(Vajinal muayene esnasında)

C – Cinsel aktivite sırasında ağrı

D – Fiziksel aktivite sırasında ağrı

E – Spontan ağrı

SÜRE

T1: İntraoperatif – 48 saat

T2: 48 saat – 2 ay

T3: 2 – 12 ay

T4: > 12 ay

YER

S1 – Vajinal: Sütür hattı boyunca

S2 – Vajinal: Sütür hattı alanından farklı bölgede

S3 – Trokar geçiş hattında (batın içi hariç)

S4 – Diğer cilt veya kas-iskelet alanları

S5 – Batın içi

NOTLAR

1. Aynı hastada birden fazla farklı komplikasyonlar görülebilir. Aynı hastada erken ve geç komplikasyonlar görülebilir. Bütün komplikasyonlar belirtilmelidir. Komplikasyonlar tablosu uygulanan prosedüre spesifik olmalıdır.
2. Bir komplikasyona ait zaman içinde bir değişiklik görülürse en büyük final kategorisi not edilmelidir.
3. Üriner trakt enfeksiyonları ve fonksiyonel problemler (4B haricindeki) dahil edilmemiştir.

TANIMLAR

- Çıkıntı : Yüzeyden dışarı uzanma (Örn. Epitelyal ayrılma olmadan buruşma veya katlanma sebebiyle)
- Kontraksiyon : Büzüşme veya boyutta küçülme
- Exposure: : Açığa çıkması, görülebilir veya ulaşılabılır hale gelmesi (Örn. Meş ekstrüzyonu)
- Extrusion : Bir vücut parçası veya doku boyunca parça halinde dışarı çıkması, yürümesi

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