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REVIEW PAPER

A classification of complications in urogynecology

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Abstract

The frequency of female pelvic floor reconstruction surgery with synthetic materials has been systematically rising for the last 30 years. Nowadays, they are widely used in urogynecology with a high cure rate, and a statistically significant better outcome compared to classical vaginal repair procedures. This type of operation progressed in some areas from an indication for recurrent prolapse to that of using them in primary procedures. Nevertheless, implantation of synthetic material is associated with the occurrence of specific complications and side-effects. The number and type of complications varies, depending on the study, reaching as much as 10% in some centers. The International Continence Society (ICS) and International Urogynecological Association (IUGA) have introduced an interesting tool for the evaluation of complications related directly to the insertion of prostheses and grafts in the female pelvic floor. The purpose of this classification is to describe possible complications with numbers and letters which together form a code containing comprehensive information about the complication. This article presents the clinical and practical aspects of this classification and first comments about its usability. The presented classification may serve as a tool for the development of national and international registries of urogynecological procedures that would be a great source of information on the number and type of operations performed, their effectiveness and potential complications.

Key words: classification, urogynecology, pelvic organ prolapse, synthetic material, complications.

Introduction

Epidemiological studies show that 11% of women in the United States will undergo surgery for pelvic organ prolapse (POP) or urinary incontinence [1, 2]. This is due to the fact that POP occurs in up to 50% of parous women, although only 10-20% of them will have symptoms [3]. It has been calculated that the probability of POP surgery increases in proportion to age and in the population of young women (20-29 year-old) is 4 per 100 000 women, but in the seventh decade of life it increases to approximately 340 per 100 000 [4]. Traditional methods of POP surgery are not very effective in preventing recurrence, which happens in 33-45% of cases after the primary operation [3]. The number of female pelvic floor reconstruction procedures with synthetic materials has been systematically rising for the past 30 years [5-8]. In 2005, the first transvaginal prolapse kit for POP repair was introduced; its purpose was to increase the effectiveness of proper pelvic floor restoration of the anatomy and functionality of the female pelvic floor [1]. This type of operation progressed in some areas from an indication for recurrent prolapse to that of using them in primary procedures [5]. The Food and Drug Administration (FDA) has published data showing that in 2010 about 300 000 women in the United States underwent surgical procedures for POP, and approximately 260 000 underwent surgery for stress urinary incontinence (SUI). The presented study shows that in one out of three POP procedures, synthetic mesh was used and 75% of those procedures were carried out transvaginally. More than 80% of SUI procedures involved a transvaginal mid-urethral sling [9]. On the market today there are a large number of different surgical kits for pelvic floor reconstruction surgery, as well as SUI treatment [10]. Many years of experience already gained by doctors in urogynecological centers allows the performance of such operations in a way which minimizes the risk of complications, and guarantees good anatomical and functional results. Nevertheless, the implantation of synthetic material is associated with the occurrence of specific complications and side-effects [1, 6]. The number and type of complications varies, depending on the study, reaching as much as 10% in some centers [1]. These reports led the FDA to release in 2008 and 2011 a Public Health Notification regarding the complications of vaginal mesh following sling surgery and prolapse repair, drawing attention to the potential dangers associated with the use of synthetic materials [7, 11]. It must be borne in mind that complications also occur after native tissue repairs, but using synthetic materials and specially de-

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signed kits only adds to the new complication profile, e.g. injuries during passing the trocar and reaction of the body to the prosthesis (inflammation, infection, rejection) [5].

At present, urogynecologists are divided between those who see no clear benefit from mesh surgery and those who perform these procedures frequently and successfully, touting its benefits [11]. To avoid disappointment after the operation and its outcome, patients should be precisely informed about the benefits, risks, and possible consequences of corrective surgery. The International Continence Society (ICS) and International Urogynecological Association (IUGA) have introduced an interesting tool for the evaluation of complications related directly to the insertion of prostheses and grafts in the female pelvic floor [5].

Classification

The purpose of this classification is to describe possible complications with numbers and letters which together form a code containing comprehensive information about the problem, without the need for additional descriptions. This system consists of three components – category (C), time (T) and site (S) – for which the detailed specification is given in Table I.

Category (C)

The system includes seven main categories coded with numbers which describe the affected organ, system, or severity of complication. The authors distinguish between complications of the vaginal wall (divided into three different categories depending on the extent of mucosal injury), urinary tract, gastrointestinal system (rectum or colon), skin and musculoskeletal system, and a separate category for systemic risk. Each number is accompanied by one of the letters A, B, C, D, which provide information on whether the complication is asymptomatic (A), symptomatic (B), or associated with infection (C) or the presence of an abscess (D). In this way, the description of the complication is coded

Tab. I. ICS/IUGA joint classification of complications related directly to insertion of prostheses and grafts in female pelvic floor surgery [5]

	Category			
	A (asymptomatic)	**B (symptomatic)**	**C (infection)**	**D (abscess)**
1: vaginal – no epithelial separation, includes prominence, mesh fiber palpation or contraction	1A: abnormal prosthesis or graft finding on clinical examination	1B: symptomatic e.g. unusual pain/discomfort, dyspareunia (either partner), bleeding	1C: infection (suspected or actual)	1D: abscess
2: vaginal – smaller ≤ 1 cm exposure	2A: asymptomatic	2B: symptomatic	2C: infection	2D: abscess
3: vaginal – larger > 1 cm 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 or graft perforation, fistula, calculus	4A: small intra-operative defect, e.g. bladder perforation	4B: other lower urinary tract complication or urinary retention	4C: ureteric or upper urinary tract complication	4D: abscess
5: rectal or bowel – compromise or perforation including prosthesis perforation and fistula	5A: small intra-operative 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 (including hematoma)	7B: major degree of resuscitation or intensive care	7C: mortality (additional complication – no site applicable – S0)	
	Time			
T1: intra-operative to 48 h	T2: 48 h – 2 months	T3: 2 months – 12 months	T4: over 12 months	
	Site			
S1: vaginal – area of suture line	S2: vaginal – away from area of suture line	S3: bladder, bowel	S4: skin or musculoskeletal site	S5: intra-abdominal

by a single number and a single letter which give a total of 26 categories. It is possible to code additional information about pain associated with the complication and situations in which it occurs. This can be accomplished by adding a small letter to the code (Table II). The designation for category – the number with appropriate letter/letters – appears at the beginning of the code.

Time (T)

The complication is diagnosed during surgery or at a follow-up visit. Classification distinguishes four time intervals. The first period is for intra-operative injuries or complications occurring within 48 hours after surgery, and is usually associated with the introduction of synthetic materials (trocar injury). The second period is the range between 48 hours and 2 months after the operation, and is usually connected with inappropriate healing of the wound or infection. The third period is between 2 and 12 months after surgery, and the fourth is more than 12 months after the procedure and is associated with late impaired wound healing and mesh contraction. The designation for time – letter T with the appropriate number – is at the second position of the code.

Tab. II. Subclassification of complication categories to specify the presence of pain (by the patient only, not the partner) associated with the abnormal finding and the grade in terms of the presence and severity of symptoms [5]

Grade of pain	Symptoms
a	Asymptomatic or no pain
b	Provoked pain only (during vaginal examination)
c	Pain during intercourse
d	Pain during physical activities
e	Spontaneous pain

Tab. III. Examples how to use system in practice

Case no.	Age	Surgery	Symptoms	Time interval	Findings during examination	Code	Figure
1	50	TVT	continuous urine leakage spotting vaginal discharge	3 months	vesico-vaginal fistula on the anterior wall of the vagina	4B, T3, S3	Fig. 1
2	54	Prolift anterior	dysuria recurrent urinary tract infections	6 weeks	the front left arm of the mesh was visualized in the bladder	4B, T2, S3	Fig. 2
3	68	TOT	nodule in the right inguinal area	14 months	small abscess in the place of sling insertion	6D, T4, S4	Fig. 3
4	62	Prolift anterior	recurrent infections of the vagina pain	24 months	a stone-like change in the line of a suture on anterior wall of the vagina	3Bd, T4, S1	Fig. 4

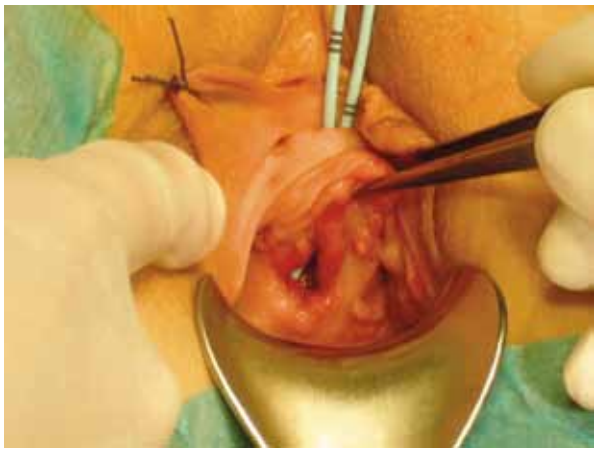

Fig. 1. Vesico-vaginal fistula on the anterior wall of the vagina

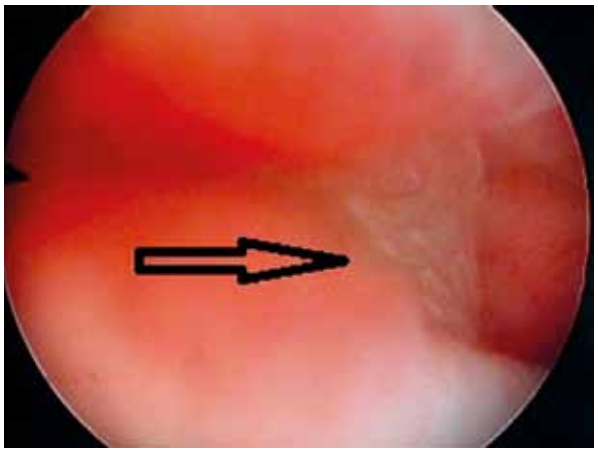

Fig. 2. Arrow indicates front left arm of the mesh in the bladder (cystoscopy)

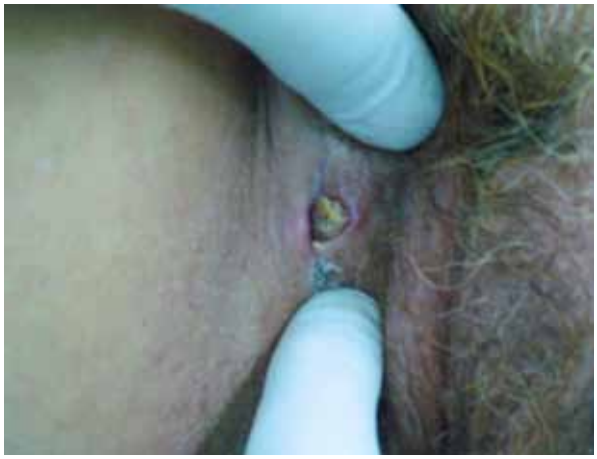

Fig. 3. Abscess in the right inguinal area in the place of sling insertion

Site (S)

This code provides information about current sites where prostheses or graft complications have been noted. The system distinguishes five locations and provides an additional code to describe a situation where it is not possible to identify the location. The designation for the site – letter S with the appropriate number – is at the third position of the code.

The authors also give some additional guidelines. In the case of patients who have more complications, or complications occur in different periods of time, they should be reported with a separate set of codes. If there is progression of a complication over time, the highest category should be used. The authors also indicate that the described system does not allow coding of the type of mesh used, urinary tract infections or voiding dysfunction, migration of bulking agents or viral infection (very rare cases) [5].

Discussion

Complications connected with mesh procedures are being increasingly recognized due to the growing frequency of surgery for POP and SUI with synthetic materials. There is a lack of validated data about the real number of complications due to inconsistent terminology and underreporting of those types of complications [7]. To provide an accurate risk and benefit rating more data are needed regarding the nature, management and morbidity of mesh-related complications [12]. The first step towards this goal was collaboration between the IUGA and ICS, which resulted in the development of the described classification. This Joint Report recognized that the increasing number of prostheses and grafts involved in female pelvic floor surgery needs clarification of terminology used by urogynecologists [5]. The report contains definitions for all urogynecological terminology which prevents misunderstandings during coding

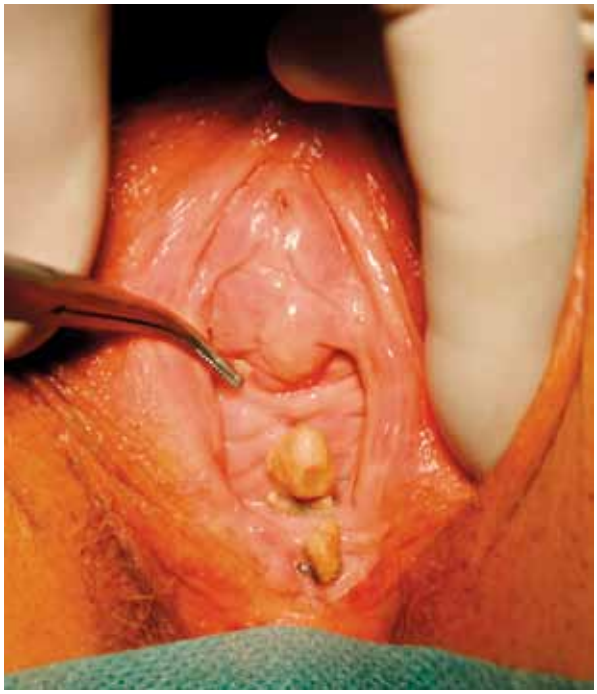

Fig. 4. Stone-like change in the line of a suture on anterior wall of the vagina

complications. Two publications were found in the literature in which the authors used this system in practice [1, 12]. The ICS/IUGA system was used for the first time by Firoozi *et al*. in reporting a contemporary series of mesh complications secondary to commercially available mesh kits. The authors found that the system is comprehensive and useful for specialists, but also indicated the need for further testing and implementation in other outcome studies [1]. On the other hand, Tunitsky *et al*. compared this new ICS/IUGA system with 3 other available classifications (TVM, Accordion, Dindo *et al*.). They performed a retrospective analysis of complications after mesh implantation for POP or SUI in 133 patients. These complications were classified by 2 independent reviewers who underwent extensive training in the use of all 4 systems; the collected data were then compared and inter-rater reliability assessed. It was demonstrated that the ICS/IUGA system has poor inter-rater reliability compared to the other systems. The authors suggested that this was due to the use of terminology and definitions that have not been accepted by a urogynecologist, which is the cause of different individual interpretations [12]. They claim that this system is too complex, but at the same time does not give the possibility to code several important complications, e.g. dyspareunia, pelvic pain without concomitant vaginal erosion, and bowel dysfunction. Lack of possibility to graduate the severity of complications, and the problem of coding multiple complications, may result in low utility in clinical practice. The authors recommend the development of 2 separate systems for meshes and

slings as the complications are often different and difficult to compare. They suggest that the system based on symptoms and management would be more helpful for clinicians and patients in planning the therapeutic process, as well as for investigators preparing research for estimating the safety of these devices [12].

Conclusions

The classification designed jointly by the IUGA and ICS was created to standardize and unify reports about complications after operations for POP with biological or synthetic materials for all urogynecological centers worldwide. Potential complications are a part of the therapeutic process, it can therefore be helpful to use this tool in clinical practice, surgical audits, or for scientific purposes. This system has, of course, some limitations, but taking into account the diversity of urogynecological procedures and habits in different centers, it is not possible to create an ideal system that is simple, universal and intuitive to use, and which also gives unlimited possibilities to communicate the problems. Perhaps the presented classification may serve as a tool for the development of national and international registries of urogynecological procedures that would be a great source of information on the number and type of operations performed, their effectiveness and potential complications. It can serve to improve knowledge and communication between physicians, scientists, nurses and physiotherapists. The introduction of this system into practice could answer the question about its usability.

Disclosure

Authors report no conflicts of interest.

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