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Complications of synthetic slings used in female stress urinary incontinence and applicability of the new IUGA-ICS classification

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ABSTRACT

Objectives: To analyze different complications of synthetic suburethral slings, and to apply the new "IUGA-ICS classification of complications directly related to the insertion of prosthesis (meshes, implants, tapes) and grafts in female pelvic floor surgery" to the list of complications, check its applicability, and give suggestions regarding possible improvements.
Study design: This study is an analysis of complications of synthetic suburethral slings. Data on type of complication, time interval between the insertion of the prosthesis and the onset of symptoms of complication, type and nature of prosthesis, and management process were documented. Additional descriptions of the sling position in relation to lower urinary tract, shrinkage or prominence of the prosthesis, and intra-operative nature of the prosthetic material were collected for analysis.
Results: From the year 2003 to 2010, 376 women with complications of synthetic suburethral slings were managed surgically and the data were analyzed. Overactive bladder (OAB) at 54%, lower urinary tract obstruction (48%), vaginal exposure (19%), and pain (14%) were the most frequent complications. Infection, fistulae, urinary tract penetration, and groin/thigh pain were other complications. The new IUGA-ICS classification could be applied to most of the types of complications, a notable exception being de novo development of overactive bladder. Also category 4B of IUGA-ICS classifications encompasses a wide clinical variety of complications and may need reconsideration.
Conclusion: De novo OAB seems to be the commonest complication of synthetic suburethral slings, followed by obstruction, vaginal exposure, and long term pain. The new IUGA-ICS classification on complications has good general applicability; some minor changes may be useful in the future.

1. Introduction

The introduction of the tension-free vaginal tape (TVT) and its many modifications has been a revolution in anti-incontinence surgery. The widespread use of such materials has resulted in typical complications known with other anti-incontinence procedures, but also in unique problems new for the pelvic floor surgeon.

In order to provide necessary information to patients and to minimize the rate of complications, it is important to be aware of all possible types of complications and reasons for complications. This paper is an analysis of various complications surgically managed at a tertiary referral center. With the intention of improving the safety of use of prostheses in pelvic floor surgery, the International Urogynecology Association (IUGA) and International Continence Society (ICS) have come up with a joint terminology and classification of complications directly related to the use of prosthesis (IUGA-ICS classification) [1]. (Details on this classification can be obtained at the web page http://www.icsoffice.org/complication.) In this study we attempt to apply the new IUGA-ICS terminology for the list of complications to assess its applicability, to test its pros and cons, and to suggest possible modifications.

2. Materials and methods

As this study is a compilation and analysis of complication profiles of patients referred for surgical management in a tertiary referral center, ethical review and approval are not deemed necessary. The inclusion criteria for the study were any case of complication directly related to insertion of synthetic slings in female stress urinary incontinence (SUI) surgery and requiring surgical management. From the year 2003 to 2010, 376 cases of complications were managed surgically: 17 patients were excluded because of concomitant use of vaginal meshes or incomplete follow-up. Data on parity, weight, type of complication,

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time interval between insertion of the prosthesis and the onset of symptoms of complication, type and nature of the prosthesis, and the management process were documented. In order to find possible reasons for the complications, additional data on presence or absence of paravaginal defects, position of the prosthesis in relation to the lower urinary tract (e.g., under the urethra, extension to bladder neck), shrinkage or prominence of the prosthesis (clinically palpable), and intra-operative nature of the prosthetic material (like the presence of over correction or excess tension – as evidenced by sudden retraction of cut edges of sling, and banding or thickening of sling material) were collected for analysis. Our study included only those women in whom obstruction persisted for more than eight weeks and required revision of sling/mesh for the relief of obstruction. In addition, introital ultrasonography was performed to assess the position, size, and contraction of the sling material. Cystourethroscopy was performed in all patients and the results were documented. An attempt was made to classify each complication according to the IUGA-ICS classification by assigning category, site, and time (CTS) coding. (http://www.icsoffice.org/complication).

3. Results

Between the years 2003 and 2010, 376 cases directly related to complication of synthetic slings in female SUI were surgically managed. Of these, 17 cases were excluded because of concomitant use of vaginal meshes or incomplete follow-up. Hence, analysis was performed for the remaining 359 cases. The age of the patients ranged from 26 years to 94 years with an average of 63.20 years and mean parity was 2. The different types of slings encountered in this study are shown in Table 1. As shown in Table 1, the synthetic slings were of differing material, texture, and weaving properties, although the monofilament polypropylene tape constitute the largest group. In seven patients we were not able to identify the exact type of the sling seen during re-operation for complications. The time interval between the insertion of prosthesis and onset of complication varied from the immediate post-operative period up to 18 years (Fig. 1). It is to be noted that most of the complications were seen between one and five years and very late complications could be documented even 18 years after implantation of the prosthesis (nylon slings). Some women developed multiple complications at different time intervals. Information on the weight of patients with complications is presented in Fig. 2.

It can be seen from Table 2 that slightly more than half of all complications seen in this study were either de novo development or worsening of symptoms of overactive bladder (OAB). The next common complication seen in the study was development of lower urinary tract obstruction, which accounted for 48% of all complications. Vaginal exposures accounted for almost 19% and

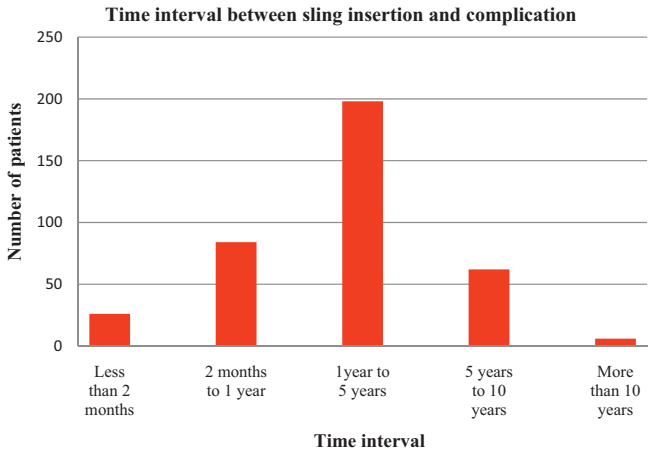

Fig. 1. Time interval between sling insertion and seeking of treatment for complication.

pain at the operation site (groin or thigh pain in the case of the transobturator route, and vaginal or pelvic in others) accounted for 14% of complications. Another observation was that 30 out of 285 (10%) patients with TVT (by the retropubic route) presented with long term pain compared to 25 out of 74 (34%) of patients undergoing sling surgery by the trans-obturator route. Dyspareunia was seen in 6% of women with complications. Infection of sling material accounted for 10% of complications.

Other less common, but serious, complications were urethral and bladder penetration, genitourinary fistulae, necrotizing fasciitis, injury to the small intestine, and serious post-operative hematomas requiring transfusion. Two thirds (12 out of 17) of patients with urethral/bladder base penetration had a body weight of more than 80 kg and their average body weight was 83 kg (range 60–105 kg). Partner dyspareunia was the presenting complaint in seven cases and in the five of them the husbands suffered penile injury. Of the seven women with partner dyspareunia, six had vaginal exposure of the prosthetic material and one woman had prominence of the prosthetic material without vaginal exposure. Other rare complications included feeling of a foreign body during bicycling and sitting, and urine loss during intercourse. In our series only 127 patients (35%) out of 359 patients with sling complications had isolated symptoms. This means that around two thirds of patients with complications present with more than one coexisting condition (e.g., de novo urgency and vaginal exposure, obstruction and pain).

In our study possible reasons for complications included abnormal positioning of slings (either at the bladder neck or too distally), use of slings in patients with paravaginal defects,

Table 1
Types of suburethral slings.

Types of synthetic slings	$n = 376$
TVT	260
TOT	49
Anterior IVS	20
Nylon sling	13
TVT-O	10
Obtape	4
Marlex	3
I-stop	3
Reemax	3
Sparc	2
Urethral surrounding tape	2
Unknown slings	7

TVT: tension-free vaginal tape, TOT: transobturator tape, IVS: intra vaginal sling plasty, SPARC: suprapubic arc.

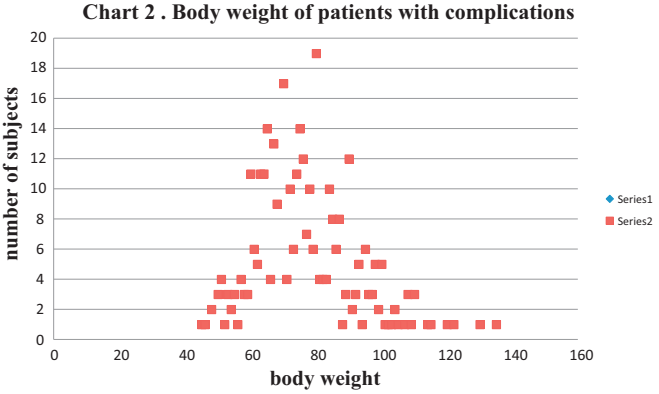

Fig. 2. Body weight of patients with complications.