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European Association of Urology

Review – Incontinence

Consensus Statement of the European Urology Association and the European Urogynaecological Association on the Use of Implanted Materials for Treating Pelvic Organ Prolapse and Stress Urinary Incontinence

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Abstract

Context: Surgical nonautologous meshes have been used for several decades to repair abdominal wall herniae. Implantable materials have been adopted for the treatment of female and male stress urinary incontinence (SUI) and female pelvic organ prolapse (POP).
Objective: A consensus review of existing data based on published meta-analyses and reviews.
Evidence acquisition: This document summarises the deliberations of a consensus group meeting convened by the European Association of Urology (EAU) and the European Urogynecological Association, to explore the current evidence relating to

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the use of polypropylene (PP) materials used for the treatment of SUI and POP, with reference to the 2016 EAU guidelines (European Association of Urology 2016), the European Commission's SCENIHR report on the use of surgical meshes (SCENIHR 2015), other available high-quality evidence, guidelines, and national recommendations.
Evidence synthesis: Current data suggest that the use of nonautologous durable materials in surgery has well-established benefits but significant risks, which are specific to the condition and location they are used for. Various graft-related complications have been described—such as infection, chronic pain including dyspareunia, exposure in the vagina, shrinkage, erosion into other organs of xenografts, synthetic PP tapes (used in SUI), and meshes (used in POP)—which differ from the complications seen with abdominal herniae.
Conclusions: When considering surgery for SUI, it is essential to evaluate the available options, which may include synthetic midurethral slings (MUSs) using PP tapes, bulking agents, colposuspension, and autologous sling surgery. The use of synthetic MUSs for surgical treatment of SUI in both male and female patients has good efficacy and acceptable morbidity. Synthetic mesh for POP should be used only in complex cases with recurrent prolapse in the same compartment and restricted to those surgeons with appropriate training who are working in multidisciplinary referral centres.
Patient summary: Synthetic slings can be safely used in the surgical treatment of stress incontinence in both male and female patients. Patients need to be aware of the alternative therapy and potential risks and complications of this therapy. Synthetic mesh for treating prolapse should be used only in complex cases with recurrent prolapse in specialist referral centres.

1. Introduction

If lifestyle interventions, pelvic floor muscle training (PFMT), pessary treatment, and drug therapy for stress urinary incontinence (SUI) and pelvic organ prolapse (POP) are unsuccessful, the surgeon may have to decide whether to use a surgical approach. For SUI and POP surgery, biological grafts derived from either xenograft or allograft materials and autologous tissue are alternatives to synthetic tapes/meshes. Current evidence would not support the use of nonautologous biological materials, whether of human or animal origin. Nonabsorbable synthetic polypropylene (PP) tapes/meshes have widely been used and other materials to a lesser extent. Aspects that need to be carefully considered are the filamentous structure (mono- or multifilament) and its pore size, surface area, textile properties, and type of polymer used. Postimplantation changes linked to biomechanics and host response are likely to influence the clinical outcomes, but implantation techniques, surgeon experience, and patient risk factors are equally important contributing factors.

Patient stratification based on careful assessment according to contemporary guidelines is essential, as are adequate identification of the patient's goals and expectations, counselling of patients, collaborative decision making, and appropriate surgeon experience and expertise. The group highlights that the ultimate aim of any surgical treatment for non-life–threatening conditions is to improve the patient's quality of life.

In view of current controversies relating to the use of implanted materials for SUI and POP, and the lack of clear guidelines for the use of biomaterials, the European Association of Urology (EAU) and European Urogynecological Association (EUGA) convened this expert group to discuss the evidence relating to current practice in this area of functional urology and urogynaecology. The conclusions from the group are presented in this consensus statement.

2. The clinical problem

Pelvic floor dysfunction is a major health problem for many women, and SUI affects an estimated one in three women and POP affects an estimated one in nine women [1]. It is strongly linked to childbearing [2], obesity, and advancing age, and it is not surprising that there has been an increase in the lifetime risk that a woman will undergo a surgery for SUI and POP, from 11% in 1997 to 19–20% at present [3,4]. A Norwegian study [5] reported the percentage of patients with SUI to be approximately half of all women with incontinence, with the remainder characterised as urgency (11%) and mixed incontinence (36%). In a large observational cohort study, anatomical prolapse stage 2 or higher was observed in more than one of two women 12 yr after first delivery [6]. In another study, 24% of prolapses protruded beyond the hymen, a point where most women become symptomatic [7]. The lifetime risk for parous women to undergo at least one surgical treatment for either SUI or POP is 1:10 [8]. With surgical repair using native tissue there is a failure rate for primary repair of POP of approximately 17–20% in 10 yr [9]. This has resulted in the adoption of mesh-augmented prolapse repair.

POP is less commonly seen in male patients, and SUI is usually seen only as a consequence of surgery on the prostate—usually after radical prostatectomy for prostate cancer, where percentages up to 31% are reported [10], or intervention albeit far less commonly for benign prostatic obstruction.

3. Treatment of SUI in women

PFMT/physiotherapy is usually considered to be an effective treatment for mild to moderate SUI in the short to medium term and certainly is more effective than no treatment. One large multicentre randomised controlled trial (RCT) compared PFMT/physiotherapy and synthetic midurethral-sling

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