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Sacrocolpopexy with polyvinylidene fluoride mesh for pelvic organ prolapse: Mid term comparative outcomes with polypropylene mesh

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ABSTRACT

Objective: The aim of this study was to compare the surgical, anatomical, and functional outcomes of sacrocolpopexy (SCP) using polyvinylidene fluoride (PVDF) mesh versus SCP using the standard polypropylene (PP) mesh.
Study design: This was a retrospective single centre case-control study including female patients who underwent laparoscopic or abdominal SCP for POP with either PP (Cousin Biotech®) or PVDF (DynaMesh®-PRS) mesh between March 2005 and May 2015. Anatomical outcomes were assessed by the Pelvic Organ Prolapse Quantification (POP-Q) system. Functional outcomes included voiding and storage urinary symptoms (VS and SS, respectively), urgency and stress urinary incontinence (UUI and SUI) and sexual dysfunction (SD). Symptoms and their impact on patients' quality of life (QoL) were assessed using validated questionnaires as Incontinence Impact Questionnaire (IIQ-7), Urinary Distress Inventory (UDI-6) and Female Sexual Function Index (FSFI). Global patient perception of improvement (PGI-I questionnaire) and mesh erosion rates were also recorded.
Results: Of the 166 patients enrolled, 136 could be included in the analysis: 73 in the PP group and 63 in the PVDF group. The mean follow-up was 94± 17.31 months for the PP and 25.6± 13.8 months for the PVDF group. There were no statistically significant differences in patient demographics and preoperative clinical characteristics. Postoperative anatomical correction were not significantly different between the two groups. The PVDF group showed superior results in term of storage symptoms (PVDF = 0% versus PP = 8.2%; p = 0.02) and lower rate of sexual dysfunction (PVDF = 0% versus PP = 16,4%; p = 0.001). Only 1 patient in PP group and 2 in PVDF group (p = 0.47) presented a mesh exposure. There was no statistical difference in PGI-I scores (PP = 1.5 ± 1.0 vs PVDF = 1.8 ± 0.5; p = 0.40).
Conclusions: Our findings suggest that both meshes can be safely and effectively used with good anatomical outcomes. Interestingly, PVDF use was associated with significantly less storage symptoms and sexual dysfunction.

Introduction

Pelvic organ prolapse (POP),defined by the joint International Urogynecological Association (IUGA) and International Continence Society (ICS) as 'the descent of one or more of the pelvic organs (uterus, vagina, bladder or bowel) through the genital hiatus'[1], is a highly prevalent condition worldwide with significant impact on the physiological, psychological and sociological health of women. It is estimated to affect approximately 50% of parous and 5.8% of non-parous women between the ages of 20 and 59 [2].

Given the impact of POP, development of uniform and effective treatment strategies are of the utmost importance. Options available for treatment are conservative, mechanical or surgical interventions. Following failure of conservative management,

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reconstructive surgeryis considered to be the most effective and durable treatment for POP. Sacrocolpopexy (SCP) is considered the "gold standard" for Vaginal Vault Prolapse (VVP) repair, with good anatomic and functional outcomes at long term [3]. However, the need for reoperation is reported [4] and the causes of these failures are a source of significant debate, leading to investigation into possible biological factors that may predispose patients to fail. However the development of new surgical technologies and of biologically compatible meshes is ongoing with the aim of achieving better outcomes.

Pelvic reconstructive surgeons have followed in the footsteps of general surgeons who use mesh for abdominal wall hernias and have used mesh to augment advanced POP repairs [5].Although the use of mesh material led to a significant reduction of recurrence rates, the implantation of alloplastic mesh material sometimes is associated with serious mesh infection [6–8], chronic pain [9], or adhesion formation with erosion of adjacent organs and consecutive fistula formation [10,11].

Apart from predetermined characteristics like strength and elasticity it is the specific tissue response to the mesh material that defines the suitability of a polymer [11]. Most of the synthetic meshes used for surgical treatment of POP are constructed of polypropylene (PP), a polymer known for its initial inflammatory and consecutive fibrotic reaction [12]. The non-degradable polymer polyvinylidene fluoride (PVDF) was initially described in 2002 by *Klinge* et al. [13]. Small studies have shown that this polymer has better biocompatibility, reduced bacterial adherence, and more durable tensile properties than PP [14].However, long-term clinical data showing superior outcomes when using PVDF meshes for POP surgery are lacking.

The aim of this study was to compare the surgical, anatomical, and functional outcomes of SCP using PVDF mesh versus SCP using the standard PP mesh.

Materials and methods

Study design

This was a single centre case-control study including female patients who underwent laparoscopic or abdominal SCP for POP with either PP (Cousin Biotech®) or PVDF (DynaMesh®-PRS) mesh at a tertiary care academic Institution (Department of Urology, University of Perugia) between March 2005 and May 2015. Data were prospectively collected and retrospectively analyzed. The local ethics committee approved the study (Protocol N° 2707/16). Inclusion criteria were women with symptomatic stage III or IV vaginal prolapse, according to the Pelvic Organ Prolapse – quantification system (POP-q) with at least 24 months follow-up [15].

Mesh characteristics and surgical procedure

PP mesh is a monofilament polymer with pore size $1{,}7 \times 1{,}7$ mm, surface mass 39 ± 3 g/m^2, thickness $0{,}38 \pm 0{,}02$ mm, minimum thread resistance100 N (for 5 cm), minimal porosity 20 μm, minimum thread resistance 100 N (for 5 cm) [16]. PVDF mesh is a monofilament polymer with pore size 1.1 mm*1.3 mm, reactive surface 2.2/1.9 m^2/m^2, maximum stability 44/58 N/cm, elasticity at 16 N/cm 14/13(%), textile porosity 68/71 (%), effective porosity 62/68 (%), effective porosity at 2.5 N/cm 62/68 (%) [17]. All surgical procedures were performed by two senior surgeons (E.C., A. Z.) according to a previously described surgical technique [18]. The anterior vaginal wall was dissected from the bladder down to the bladder neck, while the posterior vaginal wall was prepared down to the levator ani plane. Two rectangular polypropylene meshes were attached with four polyglycolic 1-0 sutures to the anterior and posterior vaginal wall respectively. The meshes were fixed to sacral periosteum with one or two non-absorbable 2.0 sutures, avoiding tension. The procedures were similar for both abdominal and laparoscopic approach. No concomitant vaginal or anti-incontinence procedures were performed.

Assessment

All patients were assessed by a focused urogynecologic history. Urinary symptoms were recorded according to ICS (International Continence Society) criteria and stratified as stress, urgency and mixed urinary incontinence, and voiding and storage symptoms [1]. Voiding symptoms include hesitancy, slow and/or interrupted stream, straining to void, spraying (splitting) of urinary stream, feeling of incomplete (bladder) emptying, need to immediately re-void, position-dependent micturition, dysuria and post-micturition leakage. Storage symptoms include increased daytime urinary frequency, nocturia, urgency and overactive bladder syndrome. Physical examination was performed with the patient in the gynaecologic and standing positions, at rest and under maximum straining with a full bladder [1].

POP was classified with the POP-Q classification [15]. Before and after prolapse reduction all patients underwent a stress test while supine at maximum physiological bladder capacity. Any patients with urinary incontinence or a positive stress test (occult incontinence) were considered wet. All patients underwent abdominal and pelvic ultrasound, and urodynamic assessment in compliance with ICS standards.

The validated short forms of the IIQ-7 (Incontinence Impact Questionnaire) [19] and UDI-6 (Urinary Distress Inventory) questionnaires [20], and FSFI (Female Sexual Function Index) [21] were administered preoperatively and postoperatively.

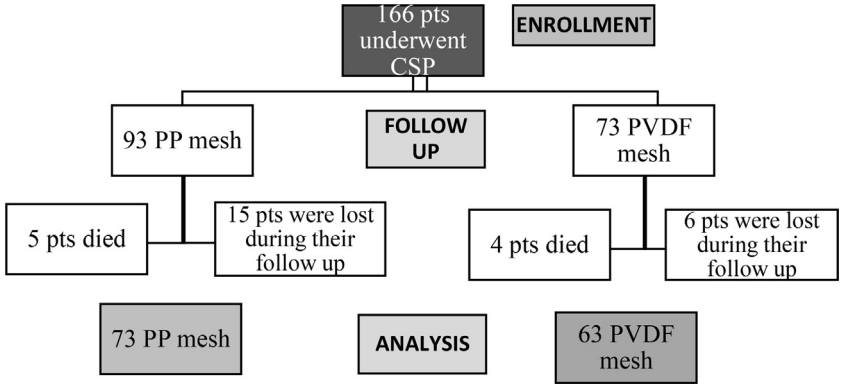

Fig. 1. Flow diagram of study recruitment process CSP: sacrocolpopexy, PP: polypropylene, PVDF: polyvinylidene fluoride.