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Review

Sacrocolpopexy for pelvic organ prolapse: evidence-based review and recommendations

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ABSTRACT

Sacrocolpopexy is considered a reference operation for pelvic organ prolapse repair but its indications and technical aspects are not standardized. A faculty of urogynecology surgeons critically evaluated the peer-reviewed literature published until September 2015 aiming to produce evidence-based recommendations. PubMed, MEDLINE, and the Cochrane Library were searched for randomized controlled trials published in English language. The modified Oxford data grading system was used to access quality of evidence and grade recommendations. The Delphi process was implemented when no data was available. Thirteen randomized, controlled trials were identified, that provided levels 1 to 3 of evidence on various aspects of sacrocolpopexy. Sacrocolpopexy is the preferred procedure for vaginal apical prolapse (Grade A), monofilament polypropylene mesh is the graft of choice and the laparoscopic approach is the preferred technique (Grade B). Grade B recommendation supports the performance of concomitant procedures at the time of sacrocolpopexy. Grade C recommendation suggests either permanent or delayed sutures for securing the mesh to the vagina, permanent tackers or sutures for securing the mesh to the sacral promontory and closing the peritoneum over the mesh. A Delphi process Grade C recommendation supports proceeding with sacrocolpopexy after uncomplicated, intraoperative bladder or small bowel injuries. There is insufficient or conflicting data on hysterectomy (total or subtotal) or uterus preservation during sacrocolpopexy (Grade D). Sacrocolpopexy remains an excellent option for vaginal apical prolapse repair. The issue of uterine preservation or excision during the procedure requires further clarification. Variations exist in the performance of most technical aspects of the procedure.

Contents

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Introduction

Sacrocolpopexy, first described in 1962 by Lane [1], has long been a preferred by many surgeons procedure for the management of apical vaginal prolapse, even though vaginal approaches, with or without use of mesh grafts, represent an alternative [2]. Following the Food and Drug Administration (FDA) public health notification regarding transvaginal synthetic mesh repair of vaginal prolapse in 2008 [3], updated in 2011 [4], there has been a significant increase in uptake of sacrocolpopexy, especially of minimally invasive techniques, performed in the United States of America [5]. While robust data supports efficacy of sacrocolpopexy in general, there are significant variations in indications for, and in nearly every technical aspect of the procedure that is commonly referred to as sacrocolpopexy (SCP) or abdominal sacrocolpopexy (ASC).

In 2014, an international faculty of seven, high-volume, urogynecology surgeons critically evaluated the available peer-reviewed literature aiming to produce evidence-based recommendations on indications and technical issues regarding sacrocolpopexy. The literature review was updated in September 2015.

Methods

The panel for this review, convened in March 2014, comprised of seven high-volume urogynecology surgeons from 5 countries; Australia, Canada, Ireland, Italy and USA. During panel deliberations 10 questions emerged as the most important regarding indications for and technical approach to sacrocolpopexy (Appendix A). In order to provide answers and recommendations the group searched the literature published until March 2014 initially, and the literature review was updated in September 2015. PubMed, MEDLINE, the Cochrane Library and ClinicalTrials.gov were searched using the terms sacrocolpopexy, open, abdominal sacrocolpopexy, laparoscopic, robotic assisted, vault prolapse, apical prolapse and prolapse repair. Relevant article reference lists were manually searched for further studies. Only randomized or quasi-randomized controlled trials published in peer reviewed, English-language, journals were included.

Evidence from the included studies was critically evaluated under the modified Oxford grading system [6]. Data were categorized to a Level of Evidence (LoE) from 1, the highest, to 4, the lowest. Once a LoE was assigned, recommendations were possible including, depending on the quality of findings, Grade A (consistent level 1 evidence), Grade B (consistent level 2 and/or 3 studies, or "majority evidence" from RCT's), Grade C (level 4 studies or "majority of evidence" from level 2/3 studies or Delphi processed expert opinion) and Grade D ("no recommendation possible" when the evidence is inadequate or conflicting) recommendations. The Delphi process [7] was implemented when no evidence relating to one specific question was available in the literature. When more than 75% of the panel reached consensus, the notion was carried and awarded a Grade C recommendation with the acknowledgment of "Delphi process expert opinion".

Results

Thirteen randomized, controlled trials (RCTs) [8–20] that evaluated different sacrocolpopexy techniques against one another, or to other procedures, primarily in terms of efficacy and/or complications, were identified. Data deriving from these studies, which provided evidence relevant to the 10 research questions of this review, are presented in Tables 1 and 2. Table 1 lists data on population size, randomization options, concomitant procedures, bowel complications and mesh erosion rates. Table 2 lists data from the same thirteen studies relevant to type and configuration of mesh, methods of fixation of mesh to the vagina and sacrum as well as closing the peritoneum over the mesh or not. Evidence and recommendations for each of the 10 review questions are reported hereunder.

1) How the efficacy of sacrocolpopexy compares to that of alternative, apical vaginal suspension procedures?

The 2013 Cochrane review [2] on the surgical management of pelvic organ prolapse reported on 5 [8–12] of the 13 RCTs included in this review that compared abdominal sacrocolpopexy with vaginal sacrospinous colpopexy [8–10], apical transvaginal mesh [11] and high uterosacral vault suspension (HUVS) [12], at that time published as congress abstract.

On meta-analysis of the three studies comparing ASC and vaginal sacrospinous colpopexy, the authors found that ASC was associated with a lower risk of subjective failure, a lower rate of recurrent vault prolapse as well as less urinary stress incontinence and dyspareunia, compared to the vaginal sacrospinous colpopexy. However, for ASC operating and recovery time was longer and cost was higher, compared to sacrospinous colpopexy.

Maher et al. [11] compared laparoscopic sacrocolpopexy (LSC, $n = 53$) to total vaginal mesh (TVM, $n = 55$) and found that the LSC took significantly longer to perform than the TVM but was associated with reduced blood loss and reduced inpatient days, and resulted in quicker return to activities of daily living, compared to TVM. The rate of recurrent prolapse and reoperation were significantly lower and satisfaction rate higher after the LSC compared to the TVM.

Rondini et al. [12], in their peer reviewed publication, compared ASC ($n = 54$) and HUVS ($n = 56$) and found a reduced rate of prolapse and a lower rate or reoperation at 1 year in the ASC group. Improvement with regards to prolapse symptoms, quality of life, and sexual function was comparable between procedures. The operating time and hospital stay were less with the vaginal procedure (HUVS), as were postoperative complications.

In a single RCT, with primary objective the impact of surgery on urogenital function, Roovers et al. [21] compared vaginal hysterectomy plus uterosacral colpopexy to the abdominal sacrocolpopexy with uterus preservation. In terms of efficacy they reported that, at one year, there was a lower rate of reoperation in the vaginal hysterectomy plus uterosacral colpopexy group (one of 41 patients versus 9 of 41 patients).

Based on the above evidence, sacrocolpopexy offers higher correction rates and may be preferred for apical vaginal prolapse (Grade A recommendation). However, surgeons need to recognize that the vaginal approach is associated with reduced morbidity and that sacrocolpopexy may not be suitable for all patients including the frail and those with significant medical and surgical comorbidities.

2) Perform hysterectomy or preserve the uterus during sacrocolpopexy?

In the RTCs that compared sacrocolpopexy to alternative procedures, both women with post-hysterectomy prolapse and women with uterine prolapse were included. In these studies of the total 192 patients undergoing sacrocolpopexy 41 had a concomitant hysterectomy. Unfortunately, a comparison of outcomes between subjects with and without concomitant hysterectomy could not be determined from these manuscripts.

Gutman and Maher [22] evaluated eleven, non-randomized, studies that reported the rate of mesh exposure in women undergoing sacrocolpopexy with uterus preservation ($n = 339$) and women having sacrocolpopexy with hysterectomy ($n = 129$). Sacrocolpopexy with uterus perseveration (laparoscopic or open) was quicker to perform and as effective as sacrocolpopexy with hysterectomy. Moreover the mesh exposure rate was nearly six