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REVIEW

Adjuvant materials in anterior vaginal wall prolapse surgery: a systematic review of effectiveness and complications

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Abstract The objective of this study is to assess the objective recurrence and complications of adjuvant materials in the treatment of anterior vaginal wall prolapse. The inclusion criteria were randomised controlled trials (RCTs) using adjuvant materials versus standard surgery for anterior vaginal wall prolapse. The main outcome measures were objective recurrence and complications. Ten RCTs (1,087 patients) were included in the systematic review. Meta-analysis showed a lower risk of objective recurrence after 1 year in the patients having an anterior repair with a biological adjuvant material (odds ratio 0.56; 95% confidence interval 0.34–0.92) and absorbable synthetic adjuvant material (odds ratio 0.44; 95% confidence interval 0.21–0.89). The evidence for the use of biological adjuvant materials in anterior vaginal wall prolapse surgery shows trends towards reduction of objective recurrence at 12 months.

Keywords Cystocele · Meshes · Prolapse · Repair · Vaginal wall

Introduction

It is estimated that the lifetime risk of having prolapse or incontinence surgery by age 80 is 11.1% and the risk of having a second operation is about 29.2% [1]. Implanted adjuvant materials (grafts) are being used with increasing frequency by pelvic reconstructive surgeons [2]. It seems logical that reinforcing with stronger material rather than re-using the same weak connective tissue that failed will strengthen the repair.

Outside the field of urogynaecology, the use of adjuvant materials in incisional hernia has been explored. In cases of small incisional hernias, the recurrence rates were 67% in suture repair compared to 17% with adjuvant material repair over an 81-month follow-up [3].

An ideal adjuvant material is one that is biocompatible, chemically and physically inert, non-carcinogenic, mechanically strong, non-allergenic, non-modified by body tissue, resistant to infection and inexpensive [4]. Adjuvant materials can be classified by material type, weave and pore size and may be biological or synthetic. Biological adjuvant materials (grafts) are in the form of allograft, autografts and xenografts. Autografts are taken from the patient themselves (e.g. fascia lata from the thigh). Allografts are taken from a similar species while xenografts are taken from another species (e.g. porcine dermis or small intestine submucosa). Synthetic adjuvant materials may be classified as absorbable and non-absorbable and the pore size classified as macro-porous (>75 μm) and micro-porous (<75 μm) [4]. The pore size and weave of mesh may be important in whether the body can mount an immune response against bacteria [1].

Currently, there is a dearth of robust data to support the use of adjuvant material in prolapse surgery and most of the data available are from the manufacturer, which can cause bias. In addition, the existent data that are published are in the form of case series; with its inherent biases, there may be little incentive for companies to produce randomised controlled data due to financial drive to get a product onto the market.

In vaginal surgery, the most common site for recurrence is in the anterior vaginal wall with reported failure rates

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ranging from 20% to 40% [5]. We can assume that the factors that cause a prolapse in the first instance are also the cause of the recurrence. However, factors such as grade of the prolapse, type of surgery, experience of the surgeon and age of the patient at first repair can also play a part [6].

The objectives of this review were to determine the efficacy of the use of adjuvant material in surgical treatment of anterior vaginal wall prolapse in randomised controlled trials (RCTs) and to explore the rates of adverse events. Because of the more recent RCT data included, this review is more up to date, when compared to the one in the Cochrane library [7]. Furthermore, this review looks at anterior repairs using biological and synthetic grafts as separate entities.

Materials and methods

A prospective peer-reviewed protocol for this review was prepared a priori as per published guidelines. The components of the protocol consisted of the following: identifying the review questions, the search strategy including search terms, the study selection criteria, study quality assessment checklist and data extraction and synthesis [8].

Sources

All reports which describe (or might describe) RCTs and quasi-randomised trials of the use of adjuvant materials in anterior vaginal wall prolapse surgery were obtained. The databases searched included Cochrane Incontinence Group Trials Register (September 2007), CENTRAL (The Cochrane Library, Issue 3, 2007), MEDLINE (1966 to September 2007), EMBASE (1980 to September 2007), CINAHL (1982 to September 2007) and the National Library of Health.

The following keywords were used for the search as text words or subject headings using OVID software: 'pelvic organ prolapse AND cystocele AND anterior colporrhaphy AND mesh.' We also hand-searched the bibliographies of all relevant reviews and primary studies to identify articles not captured by electronic searches. In addition, a hand search of conference proceedings of the International Continence Society and International Urogynaecological Association (2004–2007) was performed. In most cases, the first or corresponding authors of included trials were contacted for additional information. Attempts were made to contact the authors of seven abstracts [10, 12, 23, 24, 26, 28, 29]. Three authors responded and provided the complete transcripts of the study [10, 12, 24]. In cases where the same article has been published as an abstract, complete article or presented at a meeting, then reference would be made to the published completed article in this text [9–13].

Study selection

The inclusion criteria were prospective RCTs comparing anterior vaginal wall repair with and without adjuvant material. The main outcomes assessed were objective recurrence, dyspareunia, voiding difficulties, adjuvant material erosions and prolapse symptoms. Two authors (PL and RF) performed the selection of trials for inclusion after employing the search strategy described previously.

All assessments of the quality of trials and data extraction were performed independently by two authors (PL and RF) using forms designed according to Cochrane guidelines. Data on characteristics of the study participants including details of inclusion criteria, interventions, methods used to measure success (or definitions of cure/failure) and adverse events were extracted. Wherever there were two or more publications by the same author on same topic, we assessed the quality of data from both and used the most up-to-date or larger dataset for meta-analysis. The following quality criteria and methodological details were assessed: method of randomisation; quality of allocation concealment until randomisation, sample size, proportion of women lost to follow-up and whether an intention-to-treat analysis and a power calculation were done.

Statistical analyses were performed according to the statistical guidelines of the Cochrane Collaboration [14]. Data from intention-to-treat analyses were used where available. For the dichotomous data, results of each study were expressed as Peto odds ratio (OR) with 95% confidence intervals (CI) and combined for meta-analysis using the Peto-modified Mantel–Haenszel method [15]. The outcome of recurrence and other adverse events were a negative consequence; therefore, higher odds were considered to be detrimental. Conversely, lower odds ratio meant that risk of adverse event including recurrence was lower in the adjuvant material (experimental) group. Heterogeneity was assessed by P value and I^2 test [16].

Results

Figure 1 summarises the trial flow for identifying the potentially relevant RCTs involving the use of adjuvant material in the treatment for prolapse surgery. There were two studies that looked at the use of adjuvant material in both anterior and posterior vaginal prolapse and these studies were excluded as the data could not be teased out [20, 21]. Ten RCTs containing 1,087 women in total were included in the review (details given in Table 1) [9, 10, 12, 13, 17–29]. The surgical techniques in all the studies were described and performed using "standard or traditional techniques" and these were clarified in five studies [10, 13, 22, 25, 27]. The primary outcome in all trials was cure–

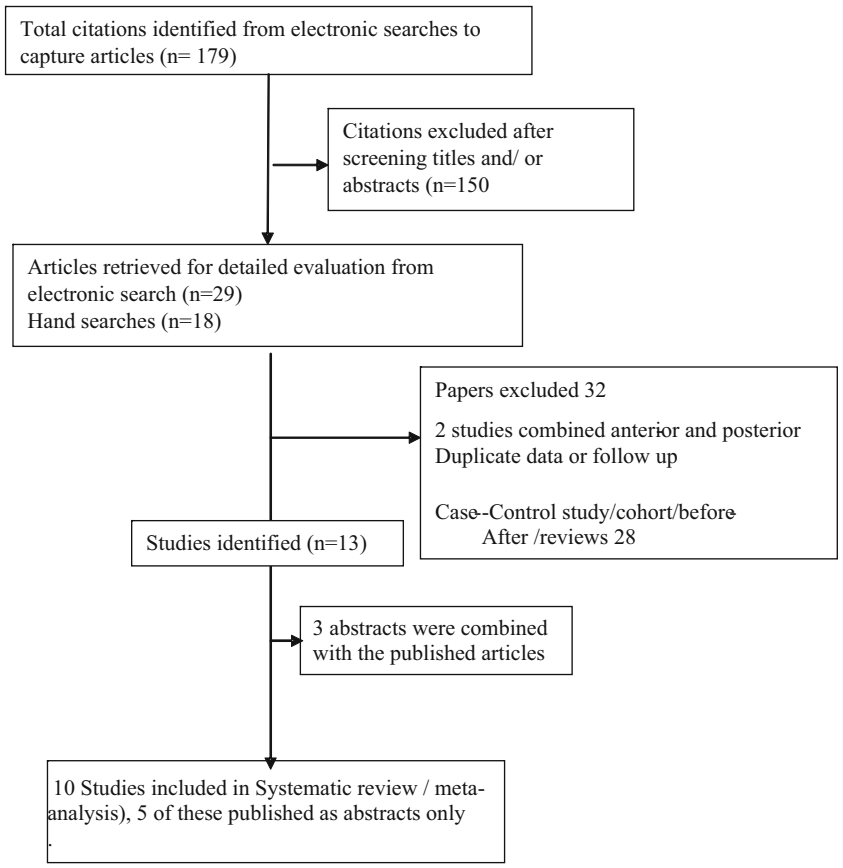

Fig. 1 Study selection process for systematic review of the use of adjuvant material in anterior vaginal wall repair

recurrence. There was a wide variation in the method used to report cure. Outcomes were assessed at various time periods following surgery between 3 and 24 months. The studies also reported a range of other adverse events, the most common being erosions and dyspareunia reported in five and three studies, respectively [10, 13, 22–24, 29]. Biological adjuvant materials were used in four RCTs [10, 24–26] and synthetic adjuvant materials were used in the experimental group in six studies [13, 22, 23, 27–29]. Amongst the synthetic adjuvant materials used, two studies used absorbable material [22, 27]. The ten studies compared the use of adjuvant material in anterior repairs with standard anterior repairs [10, 13, 22–28]. All the studies included in the meta-analysis were primary repairs [10, 24, 25].

As shown in Fig. 2, the included studies were of varying quality with some studies published as abstracts only. Three trials reported adequate concealment prior to allocation [10, 13, 22]. There was an adequate description of the method of randomisation in seven studies [10, 13, 22, 24, 25, 27, 28]. Intention-to-treat analysis was reported in seven studies while power calculation was done in five studies. In two trials, the follow-up was inadequate (more than 15% of randomised participants withdrew or were lost to follow-up) [22, 23].

Figure 3 provides a summary of the results of the meta-analyses.

In this review, recurrence was defined as Ba greater than or equal to −1. The outcome measured in the meta-analysis was recurrence at 12 months and only three studies using biological adjuvant materials (450 patients) and one study using absorbable synthetic adjuvant material (143 patients) qualified. Three studies assessed recurrence in less than 12 months [23, 26, 29] while the other studies defined recurrence differently [13, 22, 28].

On meta-analyses, there was a lower recurrence in the group who had an anterior repair with a biological adjuvant material (odds ratio 0.56; 95% confidence interval 0.34–0.92) and polyglactin adjuvant material (OR 0.44; 95% CI 0.21–0.89). A meta-analysis of non-absorbable synthetic adjuvant material could not be performed.

Figure 4 quantifies the risks of various complications by the type of adjuvant material. We looked at studies reporting their erosion rates for patients undergoing anterior repairs only. The erosion rates amongst studies using non-absorbable and absorbable synthetic adjuvant material were 14% (21/150) and 2.9% (1/35), respectively, whilst amongst the studies with biological adjuvant material it was 0.67%(1/150). Only one study looked at re-operation rate for prolapse and this rate was 1% in both the adjuvant

Table 1 Details of the studies included in the systematic review of effectiveness of adjuvant material in anterior vaginal wall prolapse

Year published or year presented	Author, location, duration of study	Participants	Methods	Interventions (experimental versus control)	Outcomes	Notes	Complications
Biological adjuvant materials							
IUGA 2006 abstract 013/ *Journal of Urology* 2007/ abstract 1374 AUA 2007	Meschia M et al. [9, 10], Italy, Mar 2003–June 2004; Kocjancic E et al. [11]	206 patients randomised (106 and 100 in E and C group, respectively); inclusion criteria: anterior wall prolapse > stage II; no difference in demographic and clinical characteristics; vaginal hysterectomy and McCall culdoplasty was done in 186 patients; posterior repair done in 133 patients; follow-up 6 and 12 months	Allocation concealment: opaque envelopes; randomisation method: computer-generated; blinding: not done; power calculation: yes; ITT analysis: yes; FU> 85%—yes	E: anterior repair + Pelvicol; Pelvicol; C: anterior repair	Detailed urogynaecological history and pelvic examination; recurrence as defined as anatomical outcome at point Ba>−1; at 1-year follow-up Pelvicol group 7/98, without Pelvicol 20/103	IUGA abstract (oral presentation) plus published article	No intra op complications; mean blood loss 151±112 vs. 167±96 ml; dyspareunia amongst sexually active patients 7/47 vs. 5/48; prolapse sensation 9/98 vs. 13/103; overactive bladder 15/98 vs. 18/103; rejection of graft 1/103
IUGA 2006 abstract 011	Guerette NL et al. [24]	94 randomised (47 in E and C groups); inclusion criteria age>18 years, second-degree midline cystocele; exclusion criteria: presence of a vaginal epithelial ulceration or infection, previous pelvic organ prolapse surgery using an implant, known allergy to bovine material, severe vaginal atrophy, previously shortened vaginal length (total vaginal length<6 cm), future desire for pregnancy, an isolated paravaginal defect, less than second-degree cystocele with vaginal vault support corrected; no differences in demographic variables; concomitant procedures were done	Allocation concealment: not mentioned; randomisation method: sealed envelopes; blinding: not stated; power calculation: no; ITT analysis: yes; FU> 85%—yes	E: anterior colporrhaphy with collagen matrix graft; bovine pericardium matrix; C: traditional anterior colporrhaphy	POP-Q data were used as baseline; peri-operative and post-operative complications were recorded and analyses were done at 3 and 12 months; peri-operative complications were similar; healing abnormalities did not differ at 3, 6 and 12 months; recurrence as defined as Ba at or equal to −1; at 12 months: eight in each group; at 6 months: 5/47 vs. 7/47; at level of Ba 0 or greater; at 12 months: 2/47 vs. 5/47; at 6 months: 1/47 vs. 3/47	IUGA abstract (oral presentation) + complete article provided by author	No erosions at 12 months; granulation tissue 0/47 vs. 1/47
AMJOG 2005	Gandhi S et al. [25],	162 women were enrolled; 154 were randomised (76	Allocation concealment: not mentioned;	E: anterior colporrhaphy with fascia patch;	Patients had pelvic examinations based on		New onset slow stream 2/20 vs. 5/23; New onset of

	July 1999–Nov 2002	and 78 in the E and C groups, respectively); patients had concomitant surgery; inclusion criteria: all women with anterior vaginal wall prolapse to the hymen and beyond; follow-up: 1 year	randomisation method: computer-generated; blinding: not stated; power calc.: done; ITT analysis: yes; FU>85%—yes	cadaveric fascia lata (Tutoplast); C: standard anterior colporrhaphy	POP-Q findings; recurrence was defined as anterior descent to Ba≥−1 at 1 year: 16/76 vs. 13/78; recurrence defined as at the level of the hymen and beyond 8/76 vs. 13/78		post-void fullness 2/20 vs. 6/24
IUGA 2005 abstract 110	Hviid UH et al. [26]	39 patients enrolled (19 and. 20 in the E and C groups, respectively); no demographic differences in the two groups	Allocation concealment: not mentioned; randomisation method: not mentioned; blinding: not stated; power calculation: no; ITT analysis: no; FU>85%—yes	E: anterior colporrhaphy with adjuvant material; Pelvicol; C: anterior colporrhaphy without adjuvant material	Recurrence at 3 months 0/10 vs. 0/12; Average op time 38 vs. 28 min	IUGA abstract; poster presentation	
Synthetic adjuvant materials (non-absorbable)							
IUGA 2007 abstract 086	Nguyen JN et al. [29]	63 women enrolled; 31 and 32 in the E and C groups, respectively; inclusion criteria: stage 2 or greater anterior prolapse; age, parity, BMI, previous prolapse surgery, menopause status, severity of anterior vaginal prolapse, operative procedures were similar between the two groups; 6-month follow-up	Allocation concealment: not mentioned; randomisation method: not mentioned; blinding: not stated; power calculation: not mentioned; ITT analysis: yes; FU>85%—yes	E: anterior colporrhaphy with adjuvant material; Perigee versus C: anterior colporrhaphy without adjuvant material	Anatomical outcome optimal if Ba and Aa at stage 0 17/31 vs. 10/32; anatomical outcome Aa and Ba at stage 1 13/31 vs.15/32; anatomical outcome Aa and Ba at stage 2 or more 1/31 vs. 7/32; PFDI20, PFIQ7 and PISQ12 questionnaires	Abstract only; oral presentation	Dyspareunia 2/31 vs. 4/25 post-operative
IUGA 2007 abstract 265	Al-Nazer MA et al. [28], 2003–2005	40 patients enrolled (20 in E and C groups, respectively); follow-up 6 weeks, 3, 6 and 12 months	Allocation concealment: not mentioned; randomisation method: computer-generated; blinding: not stated; power calculation: not mentioned; ITT analysis: yes; FU>85%—yes	E: anterior colporrhaphy with adjuvant material; Gynemesh versus C: anterior colporrhaphy without adjuvant material	More significant improvement in prolapse, urinary and sexual symptoms in the mesh group (E); cure rates as determined by points Aa, Ba, Ap, Bp were 19/20 (E) versus 17/20 (C)	Abstract only; poster presentation	Details of findings not given
IUGA 2006 abstract 146 Obs and Gyn 2007	Hiltunen R et al. [12, 13], April 2003 to May 2005	201 patients recruited and randomised (105 and 97 in E and C groups, respectively); inclusion criteria grade II or more cystocele; no statistical difference in demographic studies and POP-Q scores between the two groups	Allocation concealment: done opaque envelope in one centre; randomisation method: computer-generated; blinding: done; power calculation: yes; ITT analysis: no; FU>85%—yes	E: anterior colporrhaphy with mesh; low-weight polypropylene adjuvant material; C: anterior colporrhaphy without adjuvant material	Evaluation using POP-Q score; at 12 months patients followed up: E 104, C 96	Contains information from abstract from IUGA 2006 (oral presentation) as well as published data	Post-operative infection: 1/105 vs. 4/97; mesh erosion 18/104 (12 months); at 12 months: de novo stress incontinence 15/104 vs. 9/96; recurrent cystocele (at least stage 2 by POP-Q) at 12 months 7/104 vs. 37/96; Requiring re-operation for

Table 1 (continued)

Year published or year presented	Author, location, duration of study	Participants	Methods	Interventions (experimental versus control)	Outcomes	Notes	Complications
							prolapse 1 year later 1/104 vs. 1/96; at 12 months: persistent difficulty emptying their bladder 8/81 vs. 8/70; pelvic pressure: new onset 1/104 vs. 3/96; persistent pelvic pressure 3/79 vs. 7/70; Info from IUGA abstract: patients sexually active in each group: 49 vs. 42; dyspareunia 0/49 vs. 2/42; intercourse more uncomfortable 18/49 vs. 14/42
IUGA 2006 abstract 292	Ali S et al. [23], Singapore	108 patients (54 in each group); inclusion criteria grade 3 or 4 cystourethrocele; the group's demographic features were similar in the two groups	Allocation concealment: not mentioned; randomisation method: not mentioned; blinding: not stated; power calculation: no; ITT analysis: no; FU>85%—no	E: anterior colporrhaphy with polypropylene adjuvant material; Gynemesh; C: anterior colporrhaphy without adjuvant material	Evaluated pre- and post-operative using the Baden–Walker classification (failure defined as grade 2 or worse); no statistical difference in duration of operation and type of anaesthesia; at 6-month follow-up rate 46/54 vs. 43/54; success at 6 months 43/46 versus 38/43	Abstract only; poster presentation	Recurrence at 6 months 3/46 vs. 5/43; mesh erosion 3/46
Synthetic adjuvant materials (absorbable)							
AMJOG 1999	Weber M et al. [22], USA, June 1996 to May 1999	114 randomly assigned to three groups; five patients were excluded; C 1 39; C 2 35; E 35; 26 patients did not return for follow-up	Allocation concealment: opaque envelopes; randomisation method: computer-generated; blinding: not done; power calculation: yes; ITT analysis: yes; FU>85%—no	Treatment: E: having standard ant colporrhaphy with polyglactin adjuvant material; Polyglactin adjuvant material; C: having standard ant; other: colporrhaphy group 2 having a unilateral ant colporrhaphy	Physical examination before and after the examination; questionnaires about urinary symptoms and sexual function; 6 months, 1 and 2 years after operation; physical examination: satisfactory or optimal anatomical results: C 1 10/33, C 2 11/24, E 11/26		1/39 patient C 1 had a post-operative haemorrhage requiring blood transfusion; 1/35 patient from C 2 had a pulmonary embolism; 1/35 patient from E had a mesh erosion

AMJOG 1999	Sand P et al. [27], USA, Sep 1995 to April 1999	160 patients; 80 subjects in each group (E and C groups); at 1 year—follow-up available on 73 vs. 70; inclusion criteria: cystocele up to hymen ring; no difference in age, weight, smoking status, parity, menopausal status, and hormone replacement status; abdominal hysterectomy was done in 24 patients receiving mesh and in 13 who were not receiving mesh; follow-up: 12 weeks and 1 year post-operative	Allocation concealment: not stated; randomisation method: computer-generated; blinding: not stated; power calculation: yes; ITT analysis: yes; FU>85%—yes	E: anterior repair with adjuvant material; Polyglactin adjuvant material; C: standard ant repair	Assessed by pelvic examination (Baden–Walker classification): at 1 year, success 55/73 vs. 40/70

ITT Intention to treat, *E* experimental group, *C* control group, *POP-Q* pelvic organ prolapse quantification score. *VAS* visual analogue scale, *IUGA* International Urogynecological Association, *AUA* American Urological Association, *AMJOG* American Journal of Obstetrics and Gynecology, *FU* follow-up

material and the control group [13]. The number needed to treat with biological adjuvant material to prevent recurrence at 12 months post-operatively was 13 (95% CI 6.5–85.3) and with absorbable synthetic adjuvant material was six (95% CI 3.0–33.8). As there were only three studies in the meta-analysis, the funnel plot or other tests for publication bias were not performed [30].

Discussion

Women who had anterior vaginal wall repair with adjuvant material had a lower risk of recurrence of prolapse at 1 year post-operatively compared to patients undergoing standard repair. The confidence intervals are wide and there was insufficient data to suggest any difference in the risk of dyspareunia, voiding difficulties and recurrent prolapse symptoms in the two groups.

There are several strengths of this review. The search was thorough and systematic. Two reviewers independently did the study selection and data extraction to minimise errors. We adhered to the QUOROM checklist while reporting the meta-analyses [31]. There were also no language restrictions in the literature search; however, all the articles and abstracts retrieved were in English. The data for biological and synthetic adjuvant material were sub-grouped to assess whether there was any significant difference in the recurrence rates.

There was no uniformity in reporting of the outcomes in the intervention studies of prolapse repairs. All studies used the endpoints of the recurrence of prolapse, dyspareunia post-operatively and the incidence of erosions but the method of assessing the outcomes varied as did the definitions of subjective and objective success of the operations. Some studies used reference point at Ba<−2 while others used Ba<−1 to define objective cure. The subjective cure rates are of prime importance to patients and clinicians [32]. Only two RCTs reported data on subjective improvement by means of validated questionnaires or visual analogue scales [22, 29].

Interestingly, despite the widespread interest in the use of adjuvant material in surgery, there has only been one RCT of synthetic adjuvant material in the published literature since 2001 [13]. There were however three studies that were published as abstracts for international meetings [23, 28, 29]. This might represent a greater inclination to use biological adjuvant material for trial purposes. Five of the RCTs were in the form of abstracts and not yet published as complete articles [23, 24, 26, 28, 29]. There was no significant difference in the complications such as voiding difficulties, dyspareunia and prolapse symptoms following the use of both synthetic and biological adjuvant material when compared to standard anterior

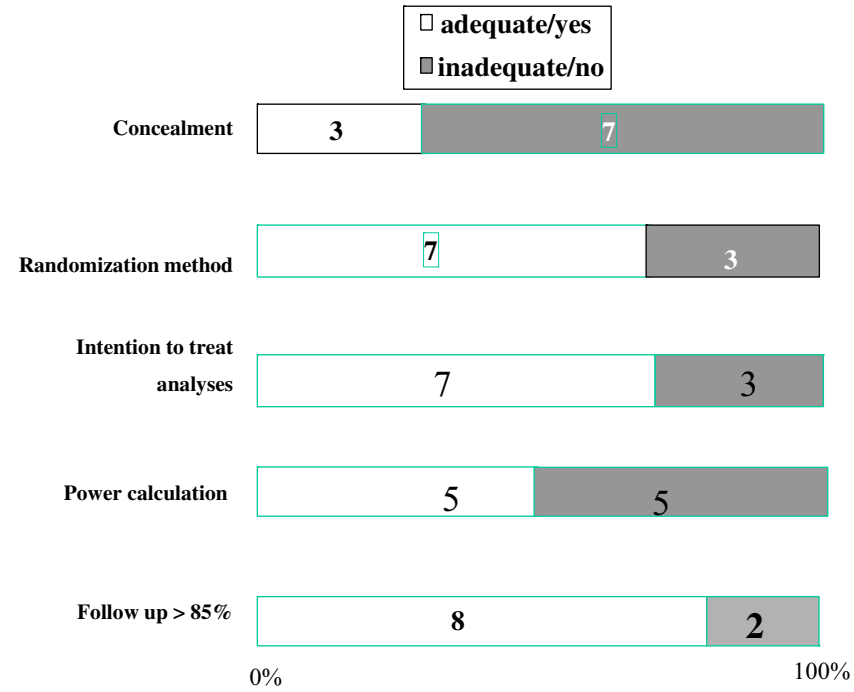

Fig. 2 Methodological quality of studies included in the systematic review of effectiveness and complications of adjuvant material in anterior vaginal wall prolapse surgery

repairs. This could be due to the small number of subjects included in these studies and therefore the need for larger studies. There have been reports of retrovesical haematoma, erosion into the bladder and vesicovaginal fistula after the use of anterior vaginal adjuvant material [33, 34]. There was also a wide range of adjuvant material used, from biological adjuvant material like Pelvicol and fascia lata to non-absorbable and absorbable synthetic adjuvant material

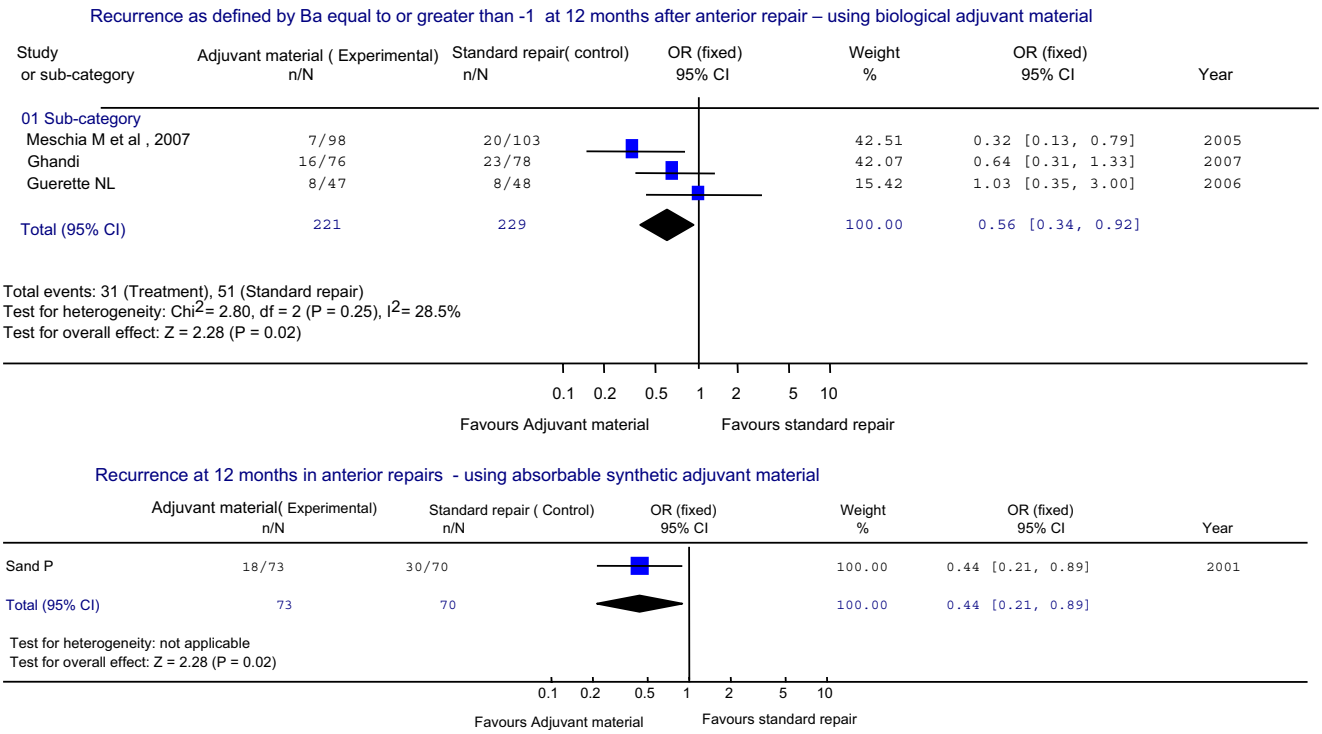

Fig. 3 Meta-analysis of recurrence of prolapse 1 year following surgery using adjuvant material versus a standard anterior repair

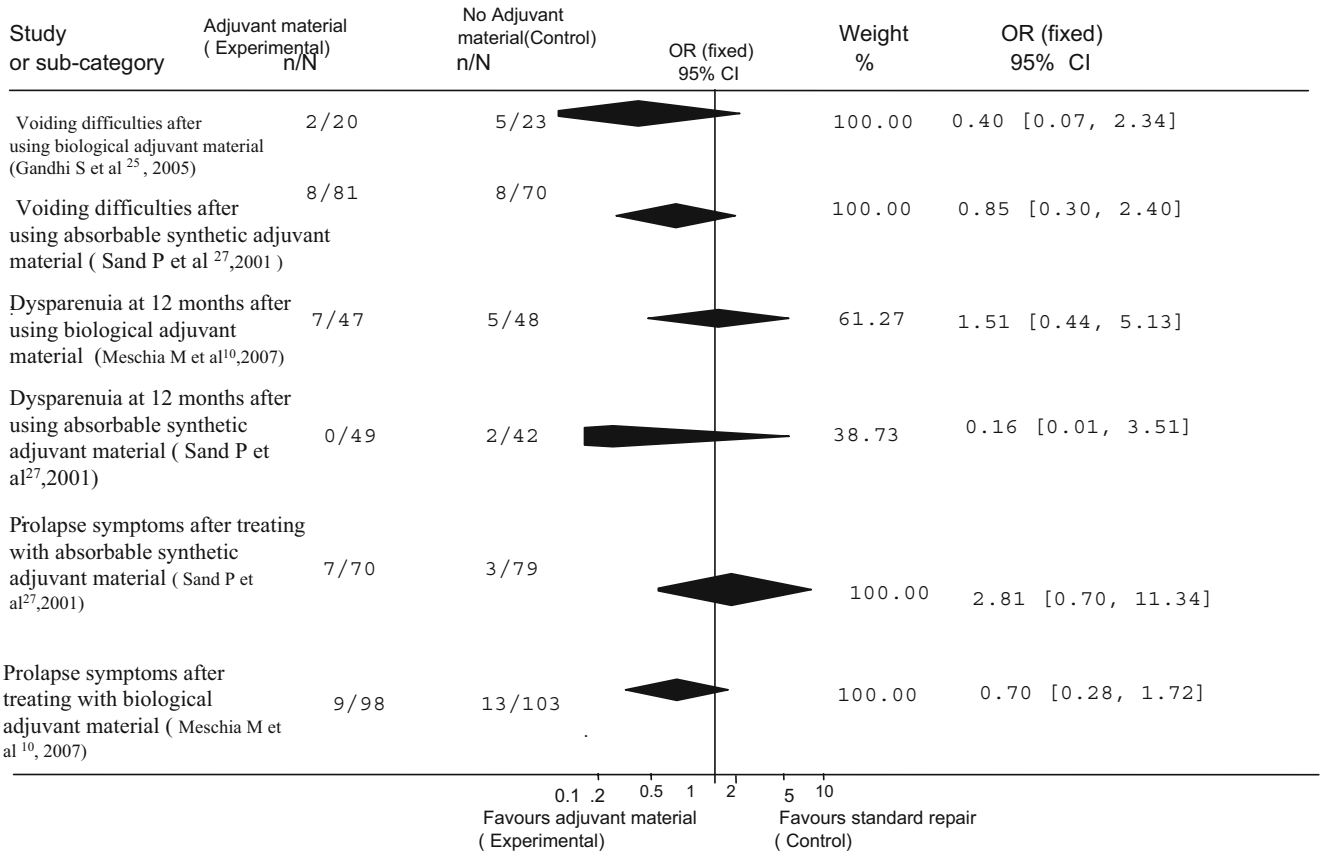

Fig. 4 Risk of complications following the use of adjuvant material in anterior vaginal wall prolapse surgery

such as polypropylene or polyglactin. This along with different definitions of recurrence might explain heterogeneity amongst the studies.

One must remember that it is a relatively new operation, so there should be appropriate clinical governance procedures in place. The reduced risk of recurrence may appear to make the use of adjuvant material in repair preferable in women with recurrent prolapse but needs to be investigated specifically in this subgroup of patients.

There were insufficient data to suggest any difference in re-operation rate for prolapse in the two groups. Patients suffering erosions may need to have second operation but some can be treated conservatively (for example with estrogen cream). With the erosion of 11.9% amongst adjuvant material, one has to take this into consideration when calculating the economic benefit of using adjuvant material. The publication bias could not be assessed meaningfully as there were only three studies included in the meta-analysis.

Patients should be counselled that long-term data on effectiveness and adverse events are still awaited. If clinicians are to perform adjuvant material procedures, then data should ideally be collected for audit purposes. In the UK, there is the British Society of Urogynaecology database (URL: www.rcog.org.uk/bsug) to enable the best chance of collection of robust observational data at a national level.

To help resolve the issue of medium- to long-term effectiveness and complications, clinicians may initiate good quality and adequately powered trials with long-term follow-up or participate in ongoing robustly designed multicentre trials. The main issues are sample size and trial methodology. An individual patient data meta-analysis may address the uncertainty by combining raw data from various studies included in this review as well as the data from ongoing studies.

This review shows the need for more methodologically sound and sufficiently powered RCTs with a longer follow-up before meshes can be introduced widely into clinical

practice. The need also for more standardised outcomes to be measured cannot be over-emphasised.

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Conflicts of interest Mr. Toozs-Hobson has recruited for an RCT using SurgiSIS mesh in recurrent pelvic floor prolapse.

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