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Use of prophylactic mesh during initial stoma creation to prevent parastomal herniation: a systematic review and meta-analysis of randomised controlled trials

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ABSTRACT

Background

Parastomal hernia (PSH) is a common complication following stoma creation. Previous reviews found mesh reinforcement during initial stoma creation beneficial in reducing PSH incidence. Since then, several multicentre randomised controlled trials (RCTs) produced widely ranging results rendering previous findings debatable. This current review assessed whether combining the latest larger multicentre RCTs would alter the previous findings.

Methods

The Cochrane Library, MEDLINE and Embase were searched from the respective dates of inception until 15 January 2021. RCTs were included if they compared mesh with no mesh during initial stoma creation in adult patients to prevent PSH. Included RCTs were summarised narratively and meta-analysed to estimate the relative risk (RR) of PSH incidence (primary analysis), peristomal complications and PSH repair (secondary analyses). Several subgroup analyses were performed, including mesh type (synthetic/biologic), surgical technique (open/laparoscopic) and mesh position (sublay/intraperitoneal).

Results

Thirteen RCTs were included in the primary meta-analysis (1,070 patients); PSH incidence was reduced in patients with mesh compared with patients without mesh at maximal follow-up (RR=0.54 [95% CI: 0.39–0.77]; I^2=67%; p<0.01). The number of PSH repairs was fewer in patients who had mesh (RR=0.63 [0.35–1.14]; I^2=6%; p=0.39), with no difference in peristomal complications (RR=0.96 [0.55–1.70]; I^2=0%; p=0.71), comparing with no mesh. Subgroup analyses suggested that placing synthetic mesh using an open, sublay technique might be more beneficial.

Conclusions

Prophylactic mesh reinforcement during initial stoma creation reduces PSH incidence and potentially its repair, without an increase in peristomal complications. However, substantial heterogeneity among included RCTs limits confidence in the results.

What does this paper add to the literature?

We meta-analysed a larger body of evidence to assess the efficacy of mesh during initial stoma creation to prevent PSH. We performed secondary analyses such as the rates of peristomal complications and PSH repair. We also performed various subgroup analyses of PSH incidence by mesh type, surgical technique, and mesh position.

INTRODUCTION

Parastomal hernia (PSH) is a common complication after stoma creation. The European Hernia Society has defined PSH as "an abnormal protrusion of the contents of the abdominal cavity through the abdominal wall defect created during placement of a colostomy, ileostomy or ileal conduit stoma" [1]. Although the exact incidence of PSH has not been fully established, estimates range between 20% and 50%, depending on the length of follow-up, stoma type and diagnostic method [2-6]. Symptoms of PSH can adversely affect patients' health-related quality of life [7-10]. PSH can cause pain, stoma appliance leakage and peristomal skin irritation [11,12], and can lead to unplanned hospital admissions due to bowel obstruction, strangulation or perforation [6,13]. The psychosocial impact of PSH may be significant, limiting patients' social interaction, intimacy and return to work [10,14].

More than 120,000 people in the UK have a stoma and around 20,000 new stomas are formed every year [15] and a similar population prevalence of intestinal stomas is evident in other northern European countries and the USA [16]. The incidence of PSH is highest within the first 2 years after initial surgery, but is common up to 5 years [17]. The risk of PSH development is life-long, with some authors regarding it as an inevitability [18,19]. Patients with a symptomatic PSH can be treated either conservatively or surgically. However, the optimal technique for PSH repair is unknown, complications are common, and the rate of recurrence remains high [3,14,20]. Despite advances in surgical techniques and stoma care, the proportion of patients with symptoms of PSH has remained largely unchanged over the past 20 to 30 years [21].

The high prevalence of PSH and difficulties in its treatment highlight the importance of primary prevention. Consequently, there has been notable interest in the use of prophylactic mesh at the time of initial stoma creation to prevent PSH [13,22-24]. There are several options available to surgeons including mesh type (synthetic or biologic), surgical technique (open or laparoscopic) and mesh placement (sublay or intraperitoneal) [14,23], but with no clear consensus [3,14,25,26]. Based on promising results from several early RCTs, the European Hernia Society recommended the use of non-absorbable synthetic mesh during construction of a permanent end colostomy [27]. However, this recommendation has not been widely adopted in everyday practice [28], mainly due to concerns about long-term mesh-related complications such as infection, erosion and fistulation [29,30].

Five meta-analyses [11,31-34] of early RCTs reported significant reductions in PSH incidence in patients who underwent a mesh placement at the time of initial stoma creation compared with no mesh at maximal follow-up: odds ratios (ORs) [95% CI] were 0.21 [0.11–0.38] (569 patients) [33], 0.24 [0.12–0.50] (649 patients) [32] and 0.24 [0.10–0.58] (410 patients) [34], while relative risks (RRs) were 0.34 [0.18–0.65] (432 patients) [31] and 0.40 [0.21–0.75] (430 patients) [11]. However, the RR estimate of 0.92 from the largest multicentre RCT (232 patients) did not show any significant difference between the mesh and no mesh groups at 12 months follow-up [5]. In contrast, a Cochrane review and meta-analysis of 10 RCTs (771 patients) published in 2018 reported that the use of prophylactic mesh results in lower incidence of PSH compared with no mesh at maximal follow-up (RR=0.53 [0.43–0.66]) [13]. However, the Cochrane review did not analyse the incidence of PSH by synthetic and biologic mesh types, and it is unclear why they used a fixed-effects model for their primary analysis despite the presence of substantial heterogeneity (I^2=69%).

Since the Cochrane review, new evidence has emerged from two European multicentre RCTs [35,36], which found no significant difference between the mesh and no mesh groups; the RRs were 0.78 (121 patients at 12 months) [35] and 0.99 (135 patients at 24 months) [36]. Furthermore, a long-term follow-up of an earlier RCT [37] reported a radiological PSH in 9/19 patients in the mesh group and 7/12 in the no mesh group at 60 months (RR=0.81) [38]. New widely ranging evidence justifies an updated systematic review and meta-analysis with a larger sample size to help assess the true effect of mesh prophylaxis.

The primary objective of this study was to perform a systematic review and meta-analysis of all eligible RCTs to assess whether the addition of the most recent multicentre RCTs would alter the previous findings that mesh reinforcement during initial stoma creation reduces the risk of PSH formation. Secondary analyses included the rates of PSH repair, peristomal complications, PSH incidence up to 24 months, and PSH incidence detected by a combination of clinical examination and computed tomography (CT) scan.

METHODS

Study design

This review conforms to the AMSTAR 2 checklist [39] and also complies with the PRISMA checklist [40]. A review protocol was produced and set out the process to address the study objectives. The protocol is registered at PROSPERO (CRD42021232555).

Search strategy

The Ovid MEDLINE, Ovid Embase and Cochrane Central Register of Controlled Trials (CENTRAL) databases were searched from the respective dates of inception until 15 January 2021, using a combination of MeSH and text terms such as ‘enterostomy’, ‘colostomy’, ‘ileostomy’, ‘parastomal hernia’ and ‘mesh’. The search strategies used were identical to the Cochrane review [13] (Appendix).

Inclusion criteria

RCTs were identified as being eligible for inclusion if they compared the use of prophylactic mesh (synthetic or biologic) against no mesh at the time of initial stoma creation (colostomy or ileostomy) in adult patients (≥18 years) to prevent PSH, irrespective of sample size, surgical technique or publication language. Systematic reviews of RCTs offer the clearest evidence for the benefits of a healthcare intervention. Similar to the Cochrane review [13], cluster RCTs, quasi-randomised trials and non-RCTs were not considered for inclusion in this review.

Study selection and data extraction

Two authors (SM and NR) independently screened and assessed all retrieved articles for relevance and agreed the final list of RCTs that met the inclusion criteria. Using a data extraction table, SM and NR extracted the relevant data from all included RCTs. Any discrepancies in the study selection and/or data extraction were resolved by consensus. The types of data extracted included study details (e.g. author, sample size and follow-up duration), patient characteristics (e.g. age, gender and indication for surgery),

intervention attributes (e.g. mesh type, surgical technique and mesh position), PSH incidence, peristomal complications and PSH repair.

Quality assessment of included RCTs

Two authors (SM and WH) independently used the Cochrane risk-of-bias tool [41] to assess the risk of bias associated with all included RCTs using the "low", "unclear" or "high" risk-of-bias grading levels. Any disagreement was resolved by consensus after discussion.

Outcome measures

The primary outcome was PSH incidence at maximal follow-up. Secondary outcomes included the rates of PSH repair, peristomal complications defined as infection, necrosis and/or stenosis within 30 days postoperatively, PSH incidence up to 24 months, and PSH incidence detected by a combination of clinical examination and CT scan.

Subgroup analyses included PSH incidence by mesh type (synthetic or biologic), surgical technique (open or laparoscopic), mesh position (sublay or intraperitoneal), disease pathology (cancer only or both cancer and benign), centre (single or multicentre), study follow-up duration (12 or 24 months) and stoma type (end colostomy only).

In a sensitivity analysis, the RCT by Târcoveanu et al [42] was excluded from the primary meta-analysis since it was deemed to be at high risk of bias across several domains. In another sensitivity analysis, the RCT by Jänes et al [43] was excluded from the primary meta-analysis since it was the only RCT with a follow-up period of 60 months. In the final sensitivity analysis, the two largest RCTs [5,36] with low risk of detection bias (blinding of outcome assessment) were pooled together.

Statistical analysis

Eligible RCTs were meta-analysed to pool effect estimates for all analyses. Overall pooled effect for each analysis was expressed as an RR with 95% CI using the Mantel-Haenszel model. Statistical heterogeneity was assessed using the widely applied I^2 statistic to estimate the percentage of variation among RCTs that is due to heterogeneity rather than chance [44]. The random-effects model was used to account for the expected clinical heterogeneity in the study populations and study designs. The results of the meta-analyses were presented graphically as forest plots. As recommended by the Cochrane Collaboration [45], publication bias was assessed using a funnel plot if more than 10 RCTs were included in a meta-analysis. All statistical analyses were performed using the statistical software package R.

RESULTS

A total of 351 records were retrieved from three databases: 76 from Ovid MEDLINE, 106 from Ovid Embase and 169 from CENTRAL (Cochrane Library). Of which, 121 duplicate records were removed. After screening the titles and abstracts, 25 articles were selected for full-text review. Based on the inclusion criteria, 15 articles [2,4,5,35-38,42,43,46-51] were included at this stage (excluded articles and reasons for their exclusion are provided in Table A1 in Appendix). Two [38,43] of these 15 articles reported longer-term PSH

outcomes of earlier RCTs [4,37]. Finally, a total of 13 RCTs [2,5,35-37,42,43,46-51] were included in the narrative and quantitative analyses; a flowchart is shown in Figure 1. Mäkäräinen-Uhlbäck et al [38] reported PSH outcomes at 60 months follow-up from the RCT that originally reported PSH outcomes at 12 months by Vierimaa et al [37]. As 50% of the patients either died or were lost to follow-up at 60 months, PSH outcomes at 12 months were included in the narrative and quantitative analyses instead. The sources of funding for the RCTs included in this review are shown in Table A2 in Appendix.

<Figure 1>

Characteristics of included RCTs

The study, patient and clinical characteristics of all 13 RCTs are summarised in Table 1. These RCTs were published between the years 2008 and 2021. The sample size across the RCTs varied between 20 [47] and 232 [5] patients. All RCTs except one [46] were published in Europe. Eight of the 13 RCTs were multicentre studies. Most study participants were men. The mean age ranged between 43 [47] and 72 [49] years (mesh group) and between 50 [47] and 72 [35] years (no mesh group), while body mass index ranged between 24.6 [48] and 26.8 [2] kg/m^2 (mesh group) and between 24.7 [35,46] and 27.5 [49] kg/m^2 (no mesh group).

The study follow-up period was 12 months in 6 RCTs, 24 months in 3 RCTs and 60 months in 1 RCT (Table 1). All RCTs included patients with cancer as an indication for primary surgery; 7 RCTs also included patients with other benign indications. Ten RCTs included patients with an end colostomy only, 1 RCT [46] included patients either with an end colostomy (63%) or end ileostomy (37%), 1 RCT [42] included patients with an end or loop colostomy and 1 RCT [47] did not report the stoma type. Synthetic mesh was the intervention in 11 RCTs and biologic mesh in 2 RCTs [46,47]. Mesh was placed either in sublay (9 RCTs), intraperitoneal (3 RCTs) or preperitoneal (1 RCT) position. Open surgery was performed in 7 RCTs, laparoscopic in 3 RCTs and open or laparoscopic in 3 RCTs. PSH incidence was confirmed by a combination of clinical examination and radiological imaging in 10 RCTs (8 RCTs used CT scan and 2 RCTs [42,47] used ultrasonography), by CT scan only in 2 RCTs [49,50] and clinical examination alone in the remaining 1 RCT [43].

<Table 1>

Risk of bias assessment

The risk of bias associated with each RCT is summarised in Table 2. Most RCTs were deemed to be at low risk of selection (random sequence generation and allocation concealment), attrition (incomplete outcome data) and reporting (selective reporting) bias. Performance bias (blinding of participants and personnel) was unclear in most RCTs (n=11), while it was high in 1 RCT [42] and low in another RCT [36]. Five RCTs [2,35,37,42,47] were assigned with high risk of detection bias (blinding of outcome assessment) and 2 RCTs [46,48] were graded as unclear. Across all domains, 7 of the 13 RCTs were mostly judged to be at low risk of bias, while 1 RCT [42] was judged at high risk of bias.

<Table 2>

PSH incidence at maximal follow-up

Meta-analysing the results of 13 RCTs showed that the incidence of PSH was significantly lower in the prophylactic mesh group (137/536; 26%) compared with the no mesh group (222/534; 42%) at maximal follow-up, but with a high degree of variation in findings between RCTs (RR=0.54 [95% CI: 0.39–0.77]; I^2=67%; p<0.01; Figure 2). The overall incidence of PSH across all RCTs was approximately 34% (359/1,070).

<Figure 2>

The funnel plot in Figure 3 suggests that publication bias may be present as smaller studies reported better outcomes for mesh (i.e. smaller risk ratios) whereas the largest studies reported risk ratios close to one.

<Figure 3>

Surgical repair of PSH

PSH repair rates were low and varied across RCTs. Pooling the results of 10 RCTs, the number of PSH repairs was fewer in patients who had mesh (20/474; 4%) compared with no mesh (35/476; 7%) at maximal follow-up (RR=0.63 [0.35–1.14]; I^2=6%; p=0.39; Figure 4).

<Figure 4>

Peristomal complications

Rates of peristomal complications, including infection, necrosis and/or stenosis, within 30 days postoperatively were very low across RCTs. The meta-analysis of 12 RCTs comparing the use of mesh (24/498; 5%) at stoma creation with no mesh (24/520; 5%) found no difference in the risk of any peristomal complication (RR=0.96 [0.55–1.70]; I^2=0%; p=0.71; Figure 5).

<Figure 5>

PSH incidence up to 24 months

Combining the results of 11 RCTs showed that PSH incidence was lower in the prophylactic mesh group (127/477; 27%) compared with the no mesh group (186/481; 39%) up to 24 months of follow-up (RR=0.65 [0.48–0.89]; I^2=56%; p=0.01; Figure 6).

<Figure 6>

PSH incidence by clinical examination and CT scan

Combining the results of 8 RCTs, the incidence of PSH, detected by a combination of clinical examination and CT scan, was reduced in patients with mesh than without mesh (RR=0.71 [0.51–0.99]; I^2=58%; p=0.02; Figure 7). The treatment effect of mesh in other subgroups was not estimated because only 1 RCT [43]

used clinical examination alone, 2 RCTs [49,50] used CT scan only and the remaining 2 RCTs combined clinical examination with ultrasonography [42,47].

<Figure 7>

Subgroup analyses

Results from the subgroup analyses are shown in Table 3; forest plots are shown in Figures A1–A12 (Appendix). The relative risk of PSH (mesh vs no mesh) differed between RCTs depending on surgical technique (open 0.26 vs laparoscopic 0.62) and number of centres (single centre 0.29 vs multicentre 0.67), while differences were less evident on disease pathology (cancer 0.48 vs cancer/benign 0.59), mesh position (sublay 0.50 vs intraperitoneal 0.62) and study follow-up duration (12 months 0.73 vs 24 months 0.61). However, the effects were similar between RCTs using different mesh type (synthetic 0.54 vs biologic 0.55).

<Table 3>

As for the subgroup by stoma type, the use of mesh compared with no mesh significantly reduced the incidence of PSH in patients with end colostomy only (RR=0.56 [0.39–0.80]; I^2=72%; p<0.01; Figure A13 in Appendix). An analysis for patients with end ileostomy was not viable because only 1 RCT [46] included some patients (37%) who had end ileostomy.

Sensitivity analyses

Excluding the RCT by Târcoveanu et al [42] from the primary meta-analysis barely changed the relative effect estimate of mesh against no mesh (RR=0.56 [0.40–0.79]; I^2=67%; p<0.01; Figure A14 in Appendix), compared with the primary meta-analysis. Excluding the RCT by Jänes et al [43] from the primary meta-analysis yielded a slightly higher RR of 0.62 [0.45–0.83] (I^2=58%; p<0.01; Figure A15 in Appendix). Combining the two largest multicentre RCTs [5,36] with blinded outcome assessment produced an RR of 0.95 [0.73–1.25] (I^2=0%; p<0.77; Figure A16 in Appendix), which indicates no significant difference in treatment effect between the mesh and no mesh groups.

DISCUSSION

PSH is a common stoma-related complication that is difficult to treat, and primary prevention has been the focus of research. Mesh prophylaxis during initial stoma creation has been hypothesised to prevent or delay PSH. The effectiveness of mesh has been examined in several small and moderately sized RCTs between the years 2008 and 2021.

Summary of key findings

This current review and meta-analysis, which has included all recent larger multicentre RCTs (n=3) [5,35,36], has synthesised data from 13 RCTs (1,070 patients) and found a reduced risk of PSH incidence in patients with mesh than without mesh at maximal follow-up; RR of 0.54 [0.39–0.77]. This estimate was less pronounced than those reported in previous meta-analyses with fewer RCTs [11,13,31-34]. Potential

publication bias was observed; several early small RCTs found large effects but later, larger RCTs reported results consistent with no effect.

Other reviews

The use of mesh at index stoma creation to prevent PSH has been extensively investigated in several RCTs which have generated many systematic reviews and meta-analyses of varying quality [52]. The recent publication of the three large RCTs [5,35,36] that have failed to demonstrate any benefit of prophylactic mesh has led to further evidence syntheses.

Based on a pooled mean RR estimate of 0.73 [0.51–1.07], one recent review concluded that "the use of a mesh shouldn't be recommended" for the prevention of PSH [53]. This conclusion was based on 7 RCTs (including 692 patients with an end colostomy only) reporting PSH outcomes at 12 months. An acknowledged limitation of their review is that they used PSH rates at one year as the primary endpoint, which led to the exclusion of several RCTs [42,43,46,48] from their review and hence late occurrences of PSH. The most recent review found that prophylactic synthetic mesh reduced the rate of both clinical (OR=0.27 [0.12–0.61]; 8 RCTs including 739 patients) and radiological (OR=0.39 [0.24–0.65]; 9 RCTs including 823 patients) PSH at maximal follow-up, but the effect disappeared when only RCTs with low risk of bias were included [54]. This current review included 13 RCTs that investigated the use of both synthetic and biologic meshes.

Mesh types and surgical techniques

To date, no RCTs have compared synthetic with biologic mesh; only 2 RCTs [46,47] compared biologic with no mesh. The relative risk in RCTs of synthetic vs no mesh (0.54 [0.37–0.77]) was similar to the relative risk (0.55 [0.14–2.12]) in RCTs of biologic vs no mesh. However, biologic mesh remains much more costly [22,25,26] and, although potentially more resistant to infection than synthetic mesh, there is currently insufficient trial evidence, particularly head-to-head comparisons with synthetic mesh, to support its use to prevent PSH.

Other subgroup analyses suggested that placing a mesh using an open, sublay technique might be more beneficial, which is in concordance with previous findings [13,34]. However, it is important to emphasise that our subgroup analyses represent observational (i.e. non-randomised) comparisons of results between RCTs. There remains a relative lack of evidence to assess the effectiveness of mesh prophylaxis in specific contexts, such as around end ileostomies or around end colostomies in an intraperitoneal position (during laparoscopic surgery). The impact of minimally invasive surgical techniques on the likelihood of PSH development are poorly understood but the reduction in intra-abdominal adhesions noted with laparoscopic approaches may be a contributing factor to the higher incidence of PSH [55]. Potential risks of placing a mesh at an intraperitoneal position may include intestinal obstruction [31], bowel adhesion or erosion [20]. However, as none of the RCTs were designed to address such issues, it remains unknown whether true differences exist for different surgical techniques and mesh positions. Further studies are needed to understand better the influence of various surgical factors on the risk of PSH.

Mesh complications and safety

Secondary analyses suggested that mesh prophylaxis may potentially reduce the risk of requiring a PSH repair, without an increase in peristomal complications within 30 days postoperatively of the index stoma creation. Despite interest in the adoption of mesh prophylaxis in practice, concerns persist among some surgeons about the perceived risk of mesh-related infections [30]. A review of surgical techniques for PSH repair reported a 2.3% overall risk of mesh-related infections [20]. However, this outcome was not analysed herein due to sparse data; most RCTs did not report this outcome. Only 1 RCT [51] reported mesh infection (3 out of 27), but infection resolved quickly with non-operative management. Mesh-related infections may not be apparent in RCTs with short follow-up [56], but 2 RCTs [38,43] did not report any mesh-related infections even after 60 months of follow-up.

Concern regarding the long-term safety of implanted medical devices generally has become prominent over the past decade and surgical mesh is no exception [57]. Although much of the focus has been on transvaginal mesh placement for pelvic organ prolapse, similar concerns have been raised regarding mesh used in hernia repair by independent inquiries [57] which have resulted in changes to licensing by regulatory authorities [58]. Long-term safety issues relating to bowel obstruction, mesh erosion and fistulation, chronic pain, stiffness, chronic infection and nonhealing wound may occur following surgery [59]. A registry-based cohort study including all elective incisional hernia repairs in Denmark reported a 5-year risk of long-term adverse events of 4.9% (142/2,876) for patients with mesh and 0.8% (3/366) for patients without mesh [59]. A follow up duration of “10 years or more” has been advocated by NICE for the establishment of the effectiveness and safety of mesh in the pelvis [60] and this is likely to be relevant for mesh implanted elsewhere in the body. None of the RCTs have, as yet, reported long-term safety in adequate detail.

Limitations

This review is limited by methodological and clinical differences across included RCTs, which resulted in a high level of heterogeneity (I^2=67%) in the primary meta-analysis. The variation in trial findings might be due to the lack of a harmonised definition of PSH or method of assessment, lack of blinding of outcome assessors in some RCTs, or publication bias. In this regard, it is notable that our meta-analysis which was restricted to the two largest RCTs [5,36] with blinded outcome assessment reported similar effects and could not exclude no treatment effect for mesh. Another potential source of variation was disparity in the duration of follow-up across RCTs (ranged from 12 to 60 months). However, it is unlikely that this changed the overall effect of mesh compared to no mesh since 77% of included RCTs used 12 to 24 months of follow-up. The difference in the RR estimate of PSH incidence up to 24 months (0.65) was small compared to the primary analysis at maximal follow-up (0.54). This review is also limited in that not all RCTs reported or clearly defined peristomal complications, but, in those that did, patients with mesh had no more complications than patients without mesh.

The included RCTs all have methodological limitations that are worthy of further discussion. All the RCTs had PSH occurrence as the primary outcome measure of mesh prophylaxis, but it is not clear whether this is appropriate and may be another example of the quantitative fallacy that is widely recognised as a

problem in clinical trials [61]. Public and patient involvement in study design is now acknowledged by many funders as being of paramount importance in ensuring that the questions that matter to patients are answered, but its absence is conspicuous in the context of PSH research. Since the indication for elective PSH repair is to improve quality of life, it is notable that only one RCT has reported data relating to this outcome [9]. Patient reported outcome measures relating to PSH symptoms have not been detailed in the RCTs, but this may be because the available tools were lacking or were only published after the studies were planned and were recruiting [62]. PSH is treated as a binary outcome in the RCTs – it is either present or it is not – but this negates the nuance of the clinical entity for which several classification systems now exist [1,63]. Reporting standards for abdominal wall hernia exist especially with regards to time to hernia development [64] but have rarely been used in the context of PSH prophylaxis with evaluation of PSH occurrence at a set time point the most frequently used metric. Combined, these issues mean that it is impossible for us to know whether the use of prophylactic mesh may result in smaller, less symptomatic, PSH that occur longer after index stoma creation, or which are less likely to need surgical repair.

CONCLUSIONS

This current review suggests that the use of mesh during initial stoma creation reduces the incidence of PSH and potentially its repair, without an increase in peristomal complications. Biologic mesh is much more costly [22,25,26] and there is no evidence that it is better than synthetic mesh at reducing the risk of PSH. Synthetic mesh reinforcement at the time of definitive end colostomy using an open, sublay technique might be more beneficial. However, the presence of substantial heterogeneity among included RCTs limits confidence in the results; individual patient data meta-analyses could be initiated by seeking patient level data from all RCTs to assess the effect of mesh on all outcomes. Future research endeavours should also consider focusing on specific patient groups, quality of life and determining priorities for further research [65] in reducing uncertainty about the risk of mesh-related complications.

Data availability statement

The data that supports the findings of this study are available within the article.

Authorship and contributions

SM: Study concept and design; Drafting of study protocol; Study selection and appraisal; Data extraction; Risk of bias assessment; All statistical analyses; Drafting of manuscript.

WH: Study concept and design; Review of study protocol; Risk of bias assessment; Review of manuscript.

NR: Study selection and appraisal; Data extraction; Review of manuscript.

BR: Study concept and design; Review of study protocol; Review of manuscript.

NS: Study concept and design; Review of study protocol; Review of manuscript.

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Table 1. Characteristics of included RCTs

Author (Year)	Randomised sample size	Centre (Country)	Mean age (years)/ Mean BMI (kg/m²)/ Gender ratio (M:F)	Study follow-up in months	Indication for surgery	Stoma type	Mesh type	Surgical technique	Mesh position	PSH detection
Brandsma et al (2017) [2]	150 (mesh 72)	Multicentre (Netherlands)	63.0/ 26.5/ 48:28[b] (no mesh) 63.5/ 26.8/ 43:29 (mesh)	12	Cancer (88%)/ Benign (12%)	End colostomy only	Synthetic	Open	Sublay	Clinical, CT
Correa Marinez et al (2021) [35]	137[a] (mesh 63)	Multicentre (Sweden/Denmark)	72.0/ 24.7/ 43:31 (no mesh) 68.0/ 26.3/ 42:21 (mesh)	12	Cancer (84%)/ Benign (16%)	End colostomy only	Synthetic	Open/ Laparoscopic	Sublay	Clinical, CT
Fleshman et al (2014) [46]	113 (mesh 55)	Multicentre (USA)	59.1/ 24.7/ 29:29 (no mesh) 60.3/ 26.2/ 30:25 (mesh)	24	Cancer (47%)/ Benign (53%)	End colostomy (63%) End ileostomy (37%)	Biologic	Open/ Laparoscopic	Sublay	Clinical, CT
Hammond et al (2008) [47]	20 (mesh 10)	Single centre (UK)	50.0/ 26.3/ 4:6 (no mesh) 42.6/ 26.3/ 3:7 (mesh)	12	Cancer (15%)/ Benign (85%)	NR	Biologic	Open	Preperitoneal	Clinical, US
Jänes et al (2009) [43]	54 (mesh 27)	Single centre (Sweden)	71.0/ 27.0/ 16:11 (no mesh) 70.0/ 26.0/ 15:12 (mesh)	60	Cancer (87%)/ Benign (13%)	End colostomy only	Synthetic	Open	Sublay	Clinical
Lambrecht et al (2015) [48]	58 (mesh 32)	Multicentre (Norway)	63.0/ 25.5/ 21:5 (no mesh) 64.0/ 24.6/ 22:10 (mesh)	40	Cancer	End colostomy only	Synthetic	Open	Sublay	Clinical, CT
López-Cano et al (2012) [49]	36 (mesh 19)	Single centre (Spain)	65.9/ 27.5/ 7:10 (no mesh) 72.2/ 26.3/ 11:8 (mesh)	12	Cancer	End colostomy only	Synthetic	Laparoscopic	Intraperitoneal	CT
López-Cano et al (2016) [50]	52 (mesh 24)	Multicentre (Spain)	67.3/ 26.9/ 16:8[c] (no mesh) 70.5/ 25.3/ 21:3 (mesh)	26	Cancer	End colostomy only	Synthetic	Laparoscopic	Intraperitoneal	CT
Odensten et al (2019) [5]	232 (mesh 114)	Multicentre (Sweden)	69.9/ 26.3/ 62:56 (no mesh) 69.7/ 26.1/ 74:40 (mesh)	12	Cancer (91%)/ Benign (9%)	End colostomy only	Synthetic	Open	Sublay	Clinical, CT
Prudhomme et al (2021) [36]	199 (mesh 98)	Multicentre (France)	70.5/ 24.8/ 57:44 (no mesh) 67.2/ 25.6/ 57:41 (mesh)	24	Cancer (86%)/ Benign (14%)	End colostomy only	Synthetic	Open/ Laparoscopic	Sublay	Clinical, CT
Serra-Aracil et al (2009) [51]	54 (mesh 27)	Single centre (Spain)	67.2/ 27.3/ 16:8[d] (no mesh) 67.5/ 25.6/ 19:5[e] (mesh)	29	Cancer	End colostomy only	Synthetic	Open	Sublay	Clinical, CT
Târcoveanu et al (2014) [42]	42 (mesh 20)	Single centre (Romania)	66.7/ NR/ 18:24[f] (no mesh & mesh combined)	24	Cancer	End/loop colostomy only	Synthetic	Open	Sublay	Clinical, US
Vierimaa et al (2015) [37]	70 (mesh 35)	Multicentre (Finland)	65.1/ 25.4/ 19:16 (no mesh) 67.1/ 26.2/ 18:17 (mesh)	12	Cancer	End colostomy only	Synthetic	Laparoscopic	Intraperitoneal	Clinical, CT

PSH (parastomal hernia); CT (computed tomography); US (ultrasonography); NR (not reported)

[a] Patients in the circular incision group were not counted

[b] Patients without mesh (n=78); M:F gender ratio has been reported as 48:28 (identity of 2 other patients is unknown)

[c] Patients without mesh (n=28); M:F gender ratio has been reported as 16:8 (identity of 4 other patients is unknown)

[d] Patients without mesh (n=27); M:F gender ratio has been reported as 16:8 (identity of 3 other patients is unknown)

[e] Patients with mesh (n=27); M:F gender ratio has been reported as 19:5 (identity of 3 other patients is unknown)

[f] Estimated based on the reported M:F gender ratio of 11:15

Table 2. Risk of bias assessment for the included RCTs

	Selection bias		Performance bias	Detection bias	Attrition bias	Reporting bias
	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting
Brandsma et al (2017) [2]	Low	Low	Unclear	High	Low	Low
Correa Marinez et al (2021) [35]	Low	Low	Unclear	High	Low	Low
Fleshman et al (2014) [46]	Low	Low	Unclear	Unclear	Low	Low
Hammond et al (2008) [47]	Low	Unclear	Unclear	High	Low	Low
Jänes et al (2009) [43]	Low	Low	Unclear	Low	High	Low
Lambrecht et al (2015) [48]	Low	Low	Unclear	Unclear	Low	Low
López-Cano et al (2012) [49]	Low	Low	Unclear	Low	Low	Low
López-Cano et al (2016) [50]	Low	Low	Unclear	Low	Low	Low
Odensten et al (2019) [5]	Low	Unclear	Unclear	Low	Low	Low
Prudhomme et al (2021) [36]	Low	Low	Low	Low	Low	Low
Serra-Aracil et al (2009) [51]	Unclear	Low	Unclear	Low	Low	Low
Târcoveanu et al (2014) [42]	Unclear	Unclear	High	High	High	Low
Vierimaa et al (2015) [37]	Low	Low	Unclear	High	Low	Low

Table 3. Meta-analysed results from various subgroup analyses

Subgroup analysis		No. of RCTs	Mesh group (n/N)	No mesh group (n/N)	Relative risk (95% CI)	Heterogeneity (I^2)	*p*-value
Mesh type	Synthetic	11	132/477	212/471	0.54 (0.37–0.77)	71%	<0.01
	Biologic	2	5/59	10/63	0.55 (0.14–2.12)	19%	0.27
Surgical technique	Open	7	46/282	105/277	0.26 (0.10–0.63)	77%	<0.01
	Laparoscopic	3	33/77	50/76	0.62 (0.37–1.04)	63%	0.07
Mesh position	Sublay	9	104/449	169/448	0.50 (0.31–0.80)	73%	<0.01
	Intraperitoneal	3	33/77	50/76	0.62 (0.37–1.04)	63%	0.07
Disease pathology	Cancer	6	41/156	80/151	0.48 (0.28–0.81)	63%	0.02
	Cancer/benign	7	96/380	142/383	0.59 (0.37–0.96)	70%	<0.01
Centre	Single	5	17/102	56/102	0.29 (0.12–0.70)	61%	0.03
	Multi	8	120/434	166/432	0.67 (0.47–0.96)	63%	<0.01
Study duration	12 months	7[a]	108/383	143/378	0.73 (0.52–1.03)	60%	0.02
	24 months	4[b]	41/163	59/168	0.61 (0.30–1.25)	61%	0.05

[a] Jänes et al (2009) [43] reported PSH incidence at 60 months follow-up from the RCT that originally reported PSH incidence at 12 months (mesh 0/27; no mesh 8/27) by Jänes et al (2004) [4]

[b] The RCT by López-Cano et al (2016) [50] was included assuming that PSH incidence at 26 months follow-up was the same at 24 months

Figure 1. Flowchart of the identification and inclusion process of RCTs in the narrative and quantitative analyses

Figure 2. Forest plot of the risk of parastomal herniation after initial stoma creation at maximal follow-up

Figure 3. Funnel plot for assessing publication bias

Figure 4. Forest plot of the risk of PSH requiring surgical repair

Figure 5. Forest plot of the risk of peristomal complications within 30 days of initial stoma creation

Figure 6. Forest plot of the risk of parastomal herniation after initial stoma creation (up to 24 months)

Figure 7. Forest plot of the risk of parastomal herniation after initial stoma creation (clinical examination and CT scan)

Figure 1. Flowchart of the identification and inclusion process of RCTs in the narrative and quantitative analyses

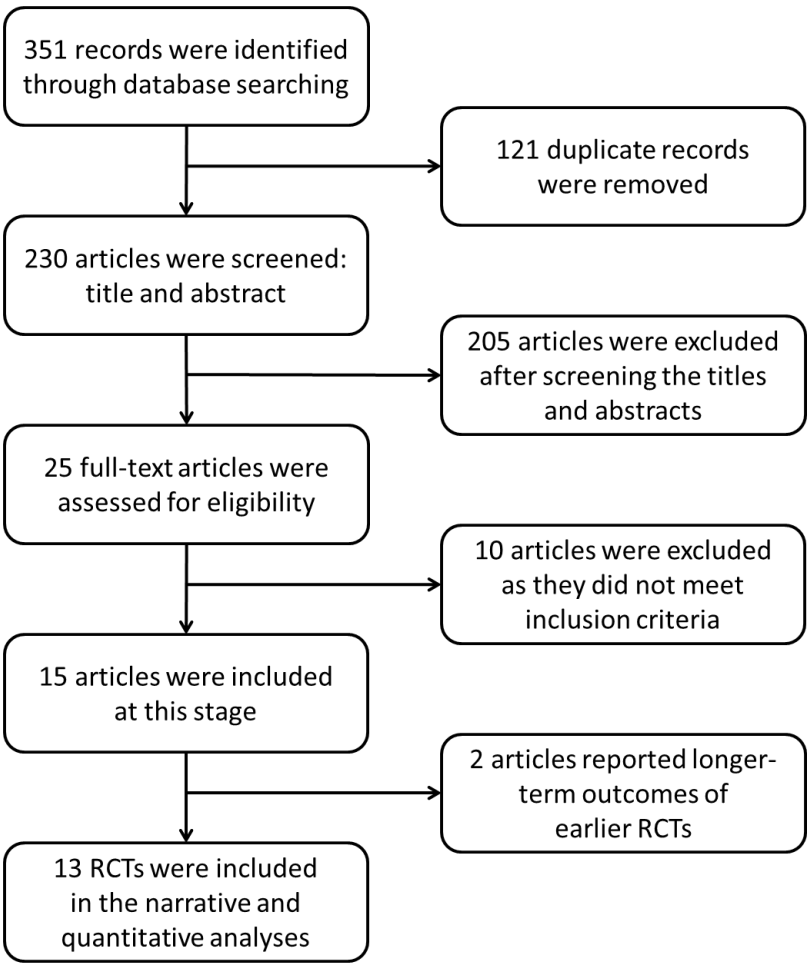

Figure 2. Forest plot of the risk of parastomal herniation after initial stoma creation at maximal follow-up

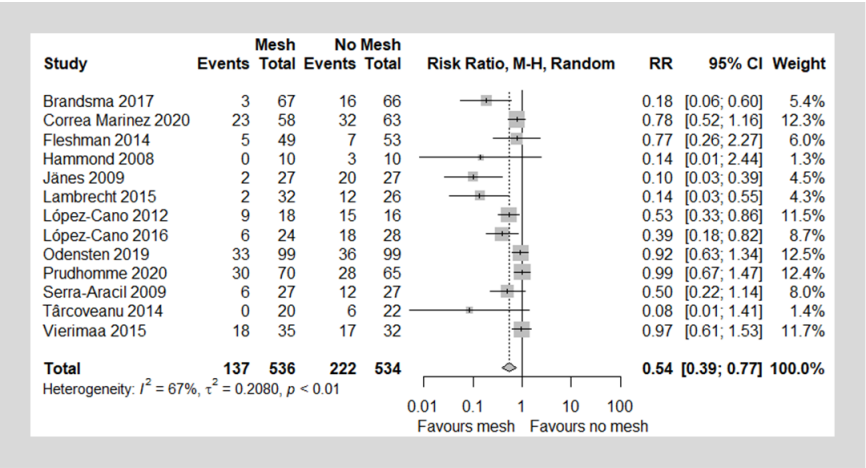

Figure 3. Funnel plot for assessing publication bias

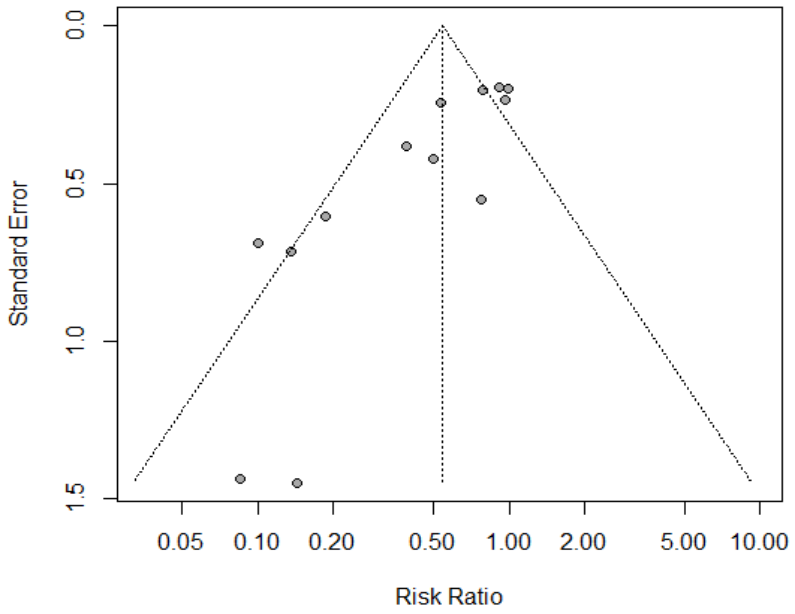

Figure 4. Forest plot of the risk of PSH requiring surgical repair

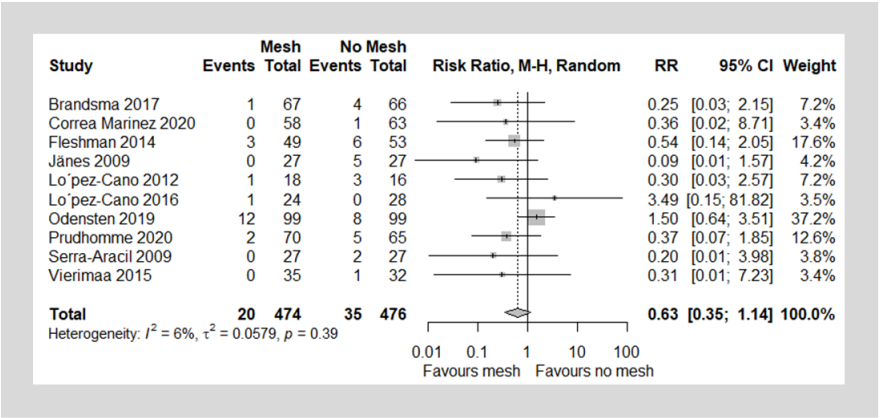

Figure 5. Forest plot of the risk of peristomal complications within 30 days of initial stoma creation

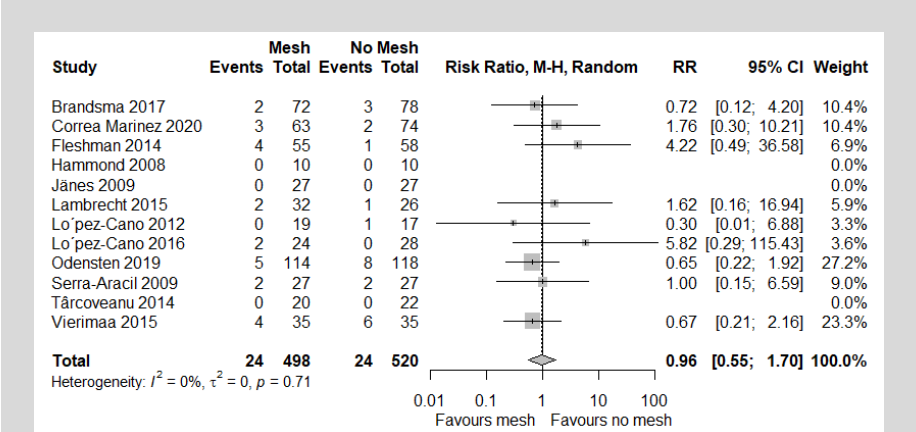

Figure 6. Forest plot of the risk of parastomal herniation after initial stoma creation (up to 24 months)

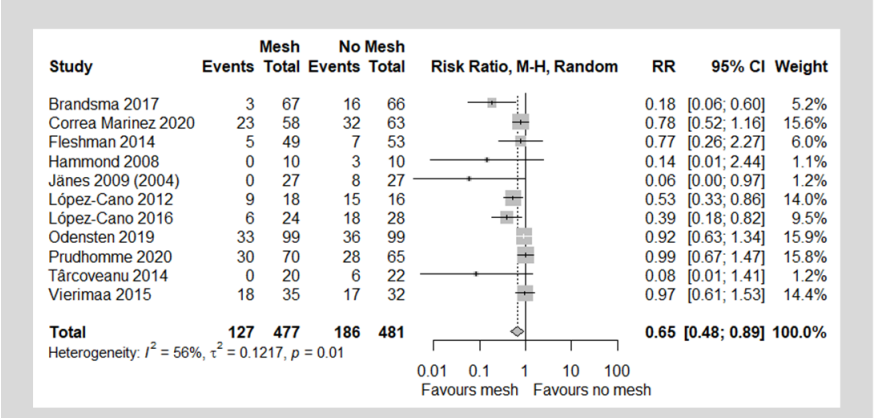

Figure 7. Forest plot of the risk of parastomal herniation after initial stoma creation (clinical examination and CT scan)