Review Article

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Meta-Analysis of Primary Mesh Augmentation as Prophylactic Measure to Prevent Incisional Hernia

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Key Words
Incisional hernia · Primary mesh augmentation · Abdominal wall closure · Primary suture

Abstract
Background: Incisional hernia (IH) remains one of the most frequent postoperative complications after abdominal surgery. As a consequence, primary mesh augmentation (PMA), a technique to strengthen the abdominal wall, has been gaining popularity. This meta-analysis was conducted to evaluate the prophylactic effect of PMA on the incidence of IH compared to primary suture (PS). ***Methods:*** A meta-analysis was conducted according to the PRISMA guidelines. Randomized controlled trials (RCTs) comparing PMA and PS for closing the abdominal wall after surgery were included. ***Results:*** Out of 576 papers, 5 RCTs were selected comprising 346 patients. IH occurred significantly less in the PMA group (RR 0.25, 95% CI 0.12–0.52, I^2 0%; $p < 0.001$). No difference could be observed with regard to wound infection (RR 0.86, 95% CI 0.39–1.91, I^2 0%; $p = 0.71$) or seroma (RR 1.22, 95% CI 0.64–2.33, I^2 0%; $p = 0.55$). A trend was observed for chronic pain in favor of the PS group (RR 5.95, 95% CI 0.74–48.03, I^2 0%; $p = 0.09$). ***Conclusion:*** The use of PMA for abdominal wall closure is associated with significantly lower incidence of IH compared to PS.

Introduction

Since the beginning of the surgical profession, the optimal technique for abdominal wall closure has been investigated in many studies in an attempt to prevent incisional hernia (IH) and fascial dehiscence. Unfortunately, the introduction of the mass closure technique, continuous sutures, slowly absorbable sutures, suture length to wound length ratio (SL:WL) of 4:1 and small stitch length have not resulted in acceptable IH rates [1–5]. On the contrary, IH remains one of the most frequent postoperative complications after abdominal surgery with incidences in the general population of 5.2–20% [1, 6, 7].

Risk factors for the development of IH, such as abdominal aortic aneurysm (AAA) and obesity, can increase the incidence of IH up to 35% [8–12]. It is generally thought that patients with AAA are suffering from a connective tissue disorder, and are more prone to develop IH and inguinal hernia [13–15]. It is also believed that obese patients have a higher intra-abdominal pressure causing higher tension on the abdominal wall suture closure compared to patients without obesity. High tension on the suture should be avoided, as it weakens the wound, impairs collagen synthesis and increases the rate of infection and the incidence of IH [16–19]. Other factors that influence wound healing negatively are malignancy, dia-

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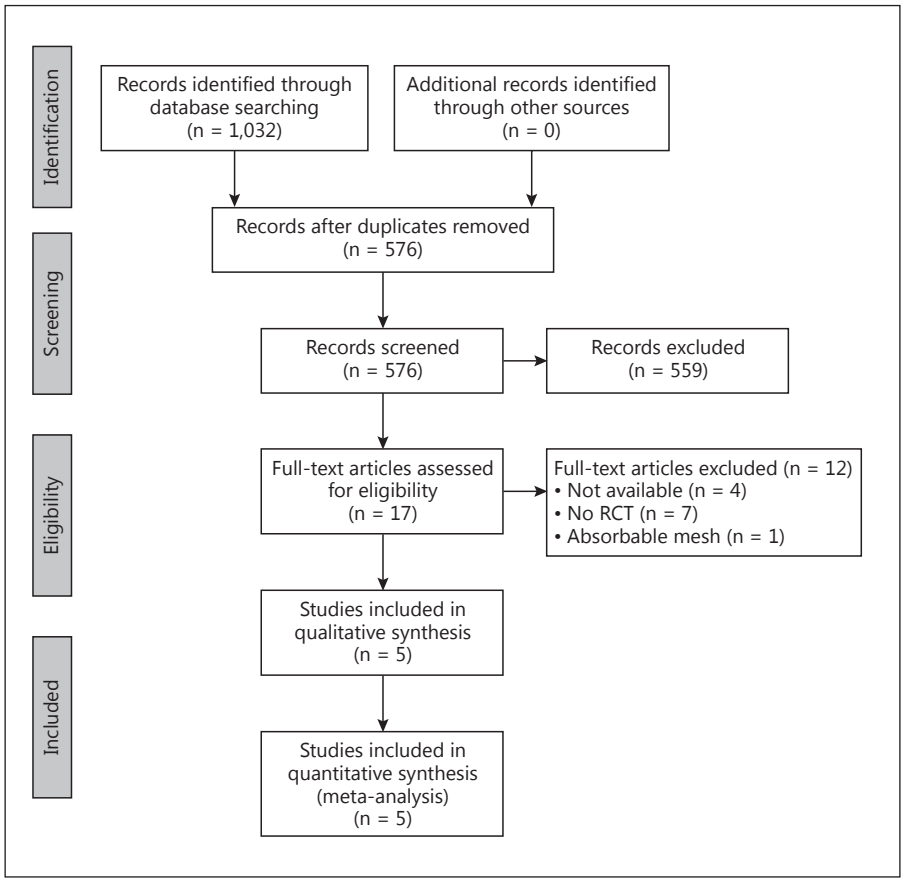

Fig. 1. PRISMA 2009 flow diagram.

betes, steroid use, surgical site infection, smoking and malnutrition [20–23].

It has been shown that IH has a negative effect on patients' quality of life and reduces the body image [24]. In the United States, a total of 400,000 patients are treated for IH each year [25]. Mesh repair can significantly reduce the risk of IH recurrence. However, IH mesh repair still has a 10-year cumulative recurrence rate of 32%, and cumulative reoperation rates have been reported as high as 23% [25]. Considering the impact of IH on patients' quality of life and body image in addition to the high recurrence rates, research should therefore focus on prevention of IH.

In 1995, a Belgian research group was the first to publish results focusing on primary mesh augmentation (PMA) as a means to reduce the incidence of IH [26]. Since 1995, a number of articles, including randomized controlled trials (RCTs), have been published on this subject. However, in these trials a variation of different patient groups, meshes and augmentation techniques are used. Therefore, a systematic review and meta-analysis of RCTs were conducted to evaluate the effectiveness of PMA on IH incidence, the operation time, length of hospital stay and rate of postoperative complications such as infection, seroma, hematoma and chronic pain.

Methods

Data Sources, Searches and Selection Criteria

A systematic search of MEDLINE, Embase, Web of Science and the Cochrane library was performed for articles published between January 1990 and October 2012. All aspects of the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement were followed [27].

No formal protocol was created for this meta-analysis; however, the actions undertaken during the review process are described in this section. Manual reference checks of accepted papers in recent reviews and papers included were performed to supplement the electronic searches. The search syntax included key words corresponding to the target population (adults), interventions (elective abdominal surgery) and target condition (IH). De-

tails of the search syntax are listed in the appendix. Language restrictions were not used for the initial search in order to investigate potential language bias as demonstrated in the flow diagram (fig. 1). Subsequently, the exclusion criteria of article type (nonrandomized) and nonadult participants were applied and duplicates were removed. Studies were evaluated for inclusion independently by 2 reviewers (B.G., L.T.) based on title and abstract and finally were evaluated independently based on the full text.

Studies were included if they met the following criteria: (1) participants: adult patients who underwent elective abdominal wall surgery; (2) interventions: abdominal wall closure with primary suture (PS) or nonabsorbable PMA; (3) outcome measures: IH, and (4) types of studies: RCTs. A random check was performed by the senior author (J.F.L.). Any discrepancies in inclusion were resolved by discussion between the reviewers and the senior author (J.F.L.).

Data Extraction and Management

Two reviewers (B.G., L.T.) extracted all required data from each study included independently using a standardized form which covered: (1) study characteristics (study design, year of publication, study location, study period, level of evidence and risks of bias); (2) baseline characteristics of each study [type of intervention, number of patients, age, sex, body mass index (BMI), type of sutures, type of mesh, mesh location, and duration of follow-up]; (3) type of intervention (abdominal wall surgery: PS vs. nonabsorbable PMA), and (4) surgery-related factors (reported incidence of IH and postoperative complications). Disagreements were resolved by consensus.

Assessment of Study Quality

The level of evidence of each paper was established according to the Oxford Centre for Evidence-Based Medicine Level of Evidence scale [28]. The methodological quality of the included studies was assessed according to the criteria specified by the Cochrane Collaboration and risks of bias summary figures were generated [29].

Data Analysis

To pool data and calculate a pooled mean for each patient level outcome, a random effects model was used, which takes into account both the variance between studies and the variance within a study [30]. Risk ratios or mean differences with 95% confidence intervals were calculated to evaluate the statistical difference between outcomes following PS or PMA. Statistical heterogeneity was assessed for incidence of IH, mesh infection, wound infection, seroma, operation time and hematoma by calculating the Q statistics and the I^2 statistic.

Selective dissemination of evidence was assessed by plotting each outcome measure of each study against precision (1/standard error) in a plot with p value contours. Funnel plot asymmetry, specifically with an apparent lack of studies in high p value areas of the plot, can be indicative of publication bias [31]. In addition, the individual study effects on the results were examined by removing each study one at a time to determine whether removing a particular study would change the significance of the pooled effect. Two-sided $p \leq 0.05$ was considered statistically significant. Analyses were performed using Review Manager software (RevMan, 5.0.25; The Nordic Cochrane Centre, Copenhagen, Denmark).

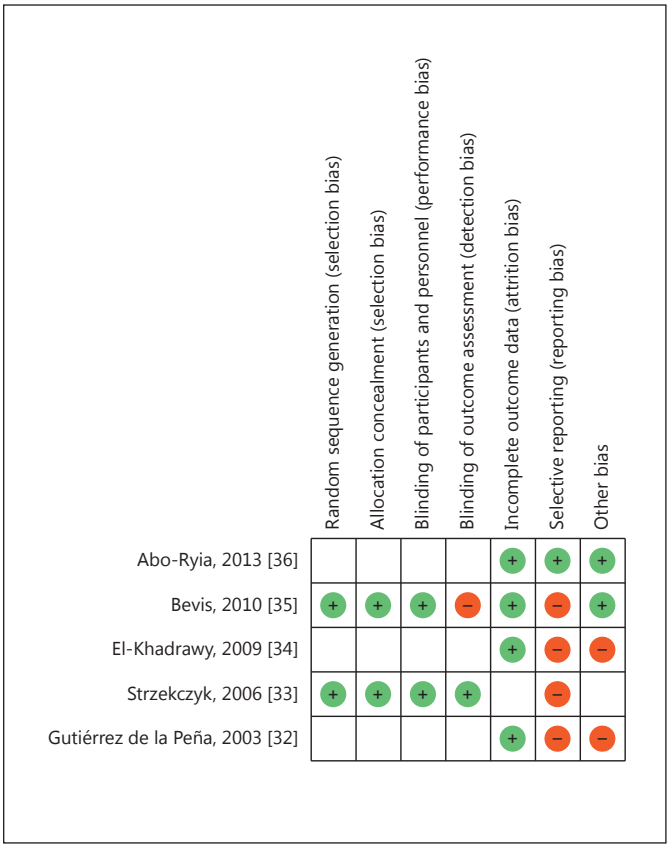

Fig. 2. Summary of risk of bias assessment.

Results

Search and Study Characteristics

Of 576 papers found after the initial search, 5 fell within the scope of the study, i.e. 5 RCTs comparing abdominal wall closure with nonabsorbable PMA and with PS in patients who underwent elective abdominal surgery. The PRISMA flow diagram for systematic reviews is presented in figure 1. Two studies included provided level 1b evidence and 3 studies provided level 2b evidence on the Oxford Level of Evidence Scale. The evaluation of risks of bias is demonstrated in figure 2. No studies were excluded after assessing the quality of the papers included.

The meta-analysis was performed using these 5 RCTs comprising 346 patients. Three techniques often used in IH repair (onlay, sublay and preperitoneal) were used for PMA in the included RCTs. None of the deaths reported in the studies included were related to the mesh placement. Study characteristics and baseline characteristics of patients are given in table 1. The total number of complications per treatment group reported in each study is presented in table 2.

Table 1. Study and baseline characteristics

Study and reference (first author)	Study period	Ox LoE	n	Suture: PMA	Age, years	Male	BMI	SL/WL ratio	Type of mesh	Mesh position	Mesh (overlap)	Type of surgery	Follow-up, months
Bevis [35]	2003–2007	1b	80	43 37	73 (59–89)[a]	77 (96)	–	4:1	PP	sublay	7.5 × 30 cm mesh	AAA	25.4
Abo-Ryia [36]	2004–2006	2b	64	32 32	36.9±11.3[b] 38.5±10.8[b]	7 (21.8) 6 (18.8)	51.4±10.5[b] 52.2±9.1[b]	–	PP	pre-peritoneal	5 cm[c] × 4 cm[d] overlap	RYGB/ VBG/VSG	48
Strzelczyk [33]	2002–2005	1b	74	38 36	38.9±11.8[b] 39.4±12.3[b]	47 (64)	46.8±7.6[b] 46.2±7.1[b]	–	PP	sublay	4 cm[c] × 2 cm[d] overlap	RYGB	28
El-Khadrawy [34]	2000–2002	2b	40	20 20	47.7±14.8[b]	18 (45)	–	4:1	PP	pre-peritoneal	2 cm[c] × ?[d] overlap	Misc	36
Gutiérrez de la Peña [32]	–	2b	88	44 44	64.3 (42–83)[a]	67 (59)	–	–	PP	onlay	3 cm[c] × 3 cm[d] overlap	Misc	36

[a] Median (range); [b] mean ± SD; [c] lateral; [d] caudal and cranial. Figures in parentheses indicate percentages unless otherwise specified.

Ox LoE = Oxford level of evidence; SL/WL ratio = suture length to wound length ratio; PP = polypropylene; RYGB = Roux-en-Y gastric bypass; VBG = vertical banded gastroplasty; VSG = vertical sleeve gastrectomy; Misc = miscellaneous.

Table 2. Classification of wound-related complications

Study and reference (first author)	Type of intervention	Total number of complications	Hematoma	Seroma	Incisional hernia	Wound infection	Mesh infection	Complete dehiscence	Reoperation	Mesh removal
Bevis [35]	PS	20	–	0	16	2	–	–	2	–
	PMA	12	–	2	5	2	0	–	2	1
Abo-Ryia [36]	PS	12	–	5	9	5	–	0	–	–
	PMA	12	–	6	1	5	–	0	–	–
Strzelczyk [33]	PS	13	–	3	3	4	–	1	–	–
	PMA	8	–	4	1	2	–	0	–	–
El-Khadrawy [34]	PS	12	–	4	8	0	–	0	–	–
	PMA	5	–	5	0	0	–	0	–	–
Gutiérrez de la Peña [32]	PS	11	2	3	5	1	–	0	–	–
	PMA	5	3	1	0	1	–	0	–	0

Outcome Parameters

Five studies (n = 346 patients) investigated pooled occurrence of IH and were included in the meta-analysis [32–36]. IH occurred significantly less in the PMA group (RR 0.25, 95% CI 0.12–0.52, I^2 0%; p < 0.001; fig. 3).

Five studies (n = 346 patients) investigated pooled occurrence of wound infection and were included in the meta-analysis [32–35]. There was no statistically significant difference in the occurrence of wound infection between the PMA group and the PS group (RR 0.86, 95% CI 0.39–1.91, I^2 0%; p = 0.71; fig. 4).

Five studies (n = 346 patients) investigating pooled occurrence of seroma were included in the meta-analysis [32–35]. There was no statistically significant difference in the occurrence of seroma between the PMA and PS groups (RR 1.22, 95% CI 0.64–2.33, I^2 0%; p = 0.55; fig. 5).

Two studies (n = 128 patients) investigated pooled chronic pain and were included in the meta-analysis [32, 34]. There was no statistically significant difference in chronic pain between PMA and sutured abdominal closure; however, a trend was visible (RR 5.95, 95% CI 0.74–48.03, I^2 0%; p = 0.09; fig. 6).

Four studies reported data regarding fascial dehiscence; however, as the numbers were so low and definitions differed throughout most studies, these results could not be pooled. Gutiérrez de la Peña et al. [32] and Strzelczyk et al. [33] describe that no eviscerations or wound dehiscence were observed in their study. El-Khadrawy et al. [34] describes that 1 (5%) complete

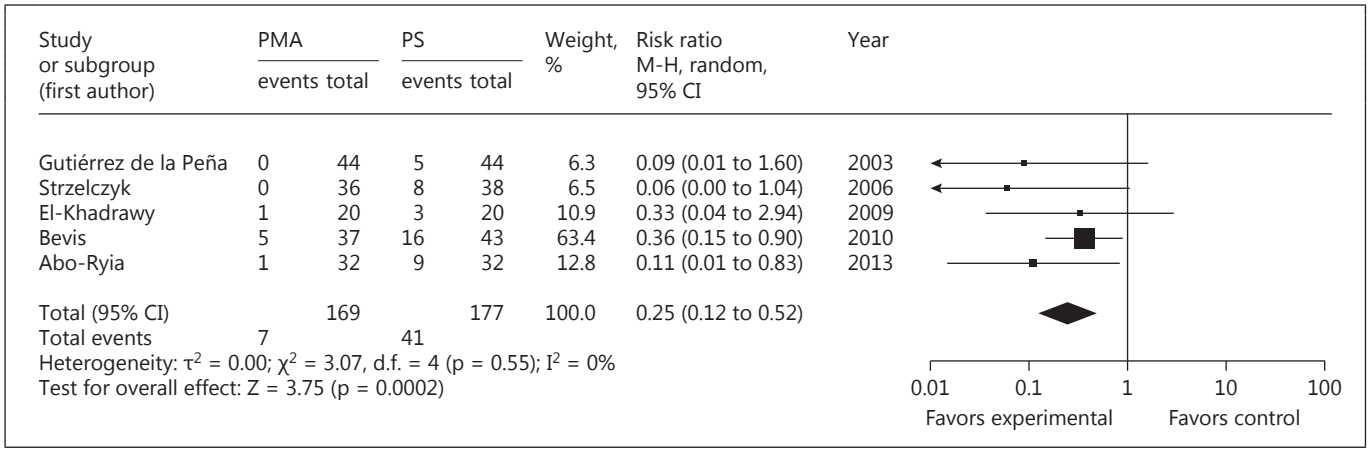

Fig. 3. Incisional hernia.

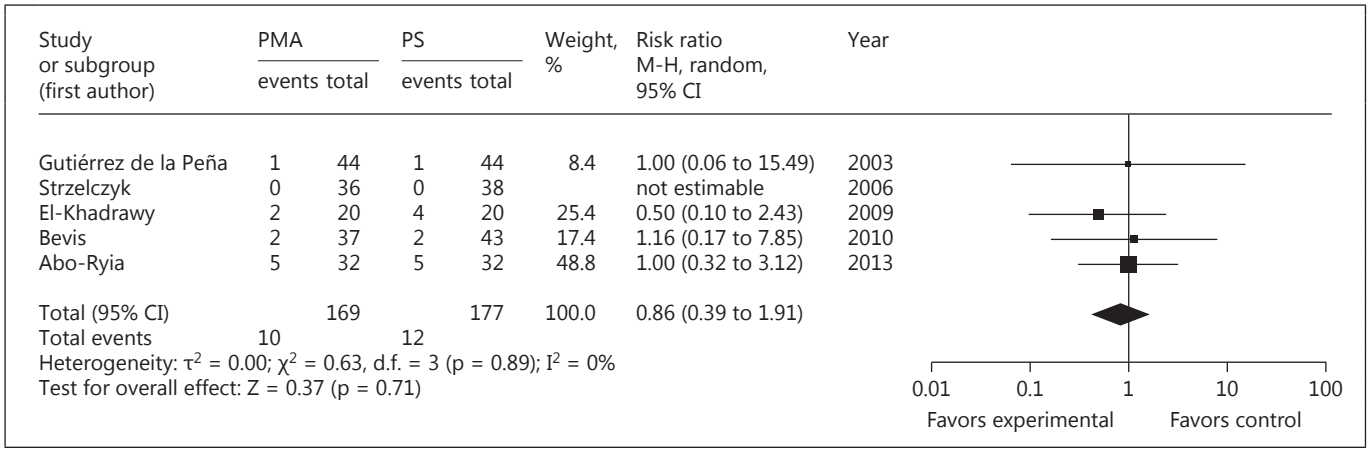

Fig. 4. Infection.

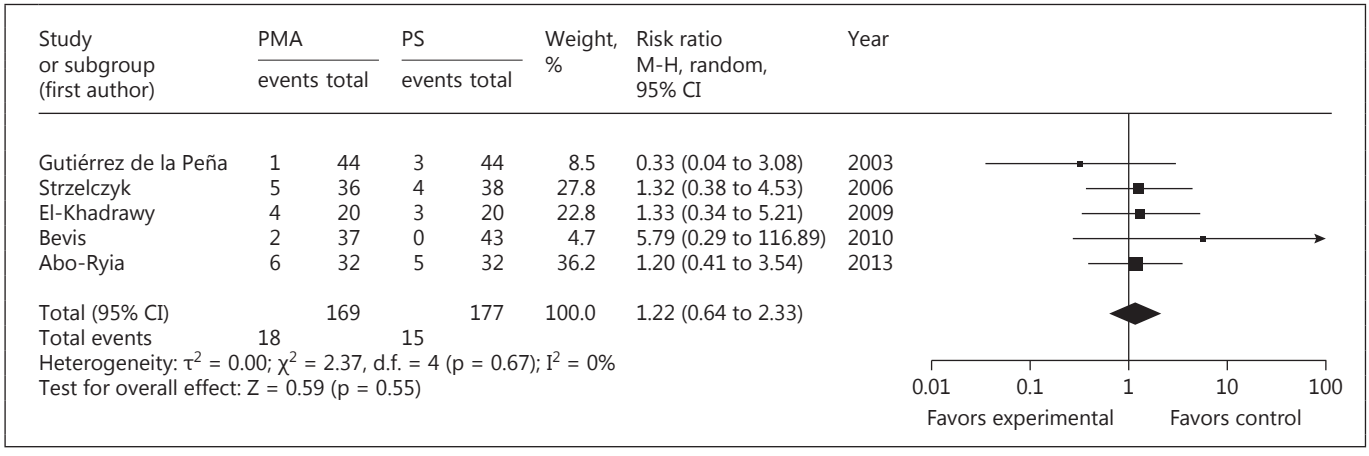

Fig. 5. Seroma.

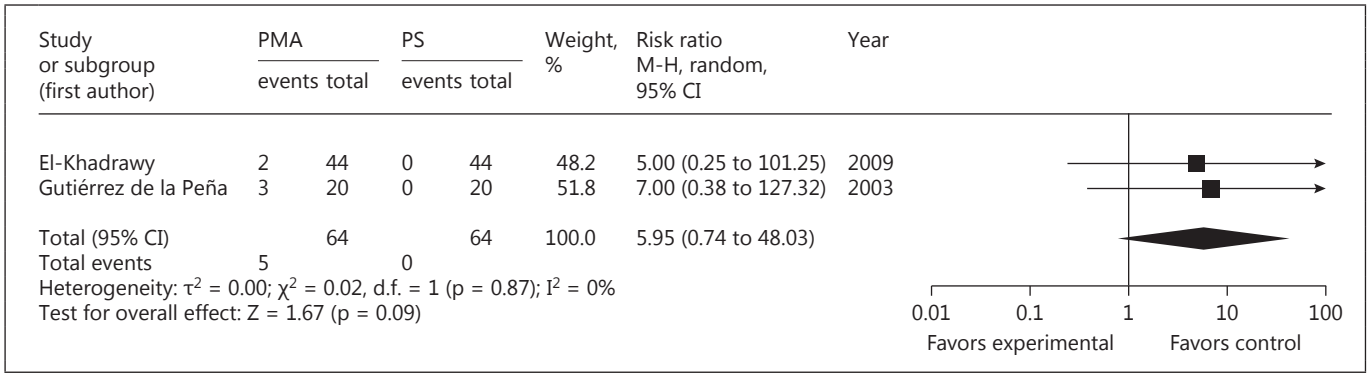

Fig. 6. Chronic pain.

wound disruption was observed in the PS compared to none in the PMA, and 2 (10%) partial wound disruptions were observed in the PS group compared to 1 (5%) in the PMA group. Abo-Ryia et al. [36] describe 2 partial dehiscences in the PS group compared to 1 in the PMA group; this was not statistically significant.

Two studies reported data on operation time [35, 36]; however, as the study by Bevis et al. [35] did not report standard deviations, these results could not be pooled. Bevis et al. [35] reported no statistically significant difference in median duration of operation (min) between the PMA group and the PS group (150 min, range 90–225 vs. 140 min, range 90–300; p = 0.59). Abo-Ryia et al. [36] also discovered no statistically significant difference in mean duration of their operations between the PMA group and the PS group (vertical banded gastroplasty: 81.2 min, SD 7 vs. 76.2 min, SD 9; Roux-en-Y gastric bypass: 151 min, SD 9 vs. 144.9 min, SD 9; vertical sleeve gastrectomy: 123.5 min, SD 8 vs. 115.1 min, SD 5).

One study reported data regarding operating time and thus no pooled assessment could be calculated. Strzelczyk et al. [33] reported no statistically significant difference in mean duration of hospitalization (days) between the PMA group and the PS group (8.4 days, SD 3.2 vs. 10.3 days, SD 5.9; p = 0.09).

Inspection of funnel plots revealed no indications for publication bias. However, due to the limited number of studies no formal tests of funnel plot asymmetry were performed. Further sensitivity analyses were performed for all outcomes by removing each study with Oxford level of evidence scale lower than 1b and each study which scored mediocre on the evaluation of risk of bias; this did not change the significance level of any of the risk ratios.

During the analysis, we observed no statistical heterogeneity; however, it had already been decided to use a random effects model beforehand due to the clinical diversity of the included trials.

Discussion

This meta-analysis shows that the use of PMA for abdominal wall closure is associated with significantly lower incidence of IH compared to PS. No significant differences could be observed for postoperative complications, such as infections and seroma, between the two groups. However, this study did observe a trend of increased chronic pain in favor of the PS group. Furthermore, data regarding postoperative hematoma formation, duration of hospital stay and operation time could not be pooled, because it was reported only once in the studies included.

Study Characteristics

All studies included had a relatively long follow-up period which is essential for investigating IH as it is known that IH can still occur after 10 years [6, 7, 25]. Other characteristics of the studies included differed in some aspects. In three studies [32, 34, 36], no description of blinding was described, and it is likely that the personnel were not blinded during follow-up. Bevis et al. [35] describe that patients were blinded but that surgeons during follow-up had access to full patient notes. All three studies are at risk for detection bias. Only in the study of Strzelczyk et al. [33] were the surgeons blinded for the randomization results during follow-up.

The study by Bevis et al. [35] was the only study that performed a power analysis prior to the start of trial. Unfortunately, they were not able to reach the number of patients calculated, and thus the study remained underpowered.

Patient Characteristics

Three of the included studies [33, 35, 36] had clearly defined study groups, only including patients with AAA or morbid obesity. Both risk factors increase the risk of IH significantly and have an incidence rate of over 30%. The other 2 studies [32, 34] included patients according to a predefined list of risk factors (hepatic cirrhosis, jaundice, renal impairment, malignancy, cardiac disease, chest problems, previous abdominal incisions, steroid therapy, old age, respiratory failure, clear malnutrition, obesity, habitual smoker) [32, 34]. Patients needed one or more of these risk factors in order to be eligible for inclusion. Although these characteristics are known risk factors for the development of IH or impaired wound healing, the actual increase in risk by these factors is often not known.

All studies focused on the use of PMA in midline laparotomy patients. However, the study of Gutiérrez de la Peña et al. [32] included more than one type of incision. Except for midline laparotomy, this study also included some paramedian incisions. Paramedian incisions, however, are known to have a lower incidence of IH compared to the traditional midline laparotomy [37].

It has been demonstrated that the use of ultrasonography or other additional radiological tests will yield a higher number of IH diagnosis [38]. Only one study [33] performed standard ultrasonography during follow-up. Three studies [32, 35, 36] performed additional radiological testing in cases of doubt after physical examination. El-Khadrawy et al. [34] did not perform additional testing [38]. The combination of not regular use of ultrasound, the patient study groups, and inclusion of paramedian incisions might explain the relatively low incidence of IH found in 2 studies [32, 34].

PMA Techniques

One RCT was not included in the meta-analysis [39]. In this study, an absorbable mesh (Vicryl) was used for PMA, and as we were interested in long-term protection, this study was excluded.

Not all studies used the same type of PMA. The studies included used the onlay [32], sublay [33, 35] or preperitoneal techniques [34, 36]. The onlay technique (mesh placed on the anterior rectus fascia) is somewhat different compared with the sublay (mesh placed on the posterior rectus fascia and peritoneum) and preperitoneal (mesh placed on the peritoneum) mesh positions. The onlay technique is generally easier, quicker to perform but might also facilitate seroma formation [40, 41]. This was, however, not observed in the study by Gutiérrez de la Peña et al. [32]. In this study, no evaluation regarding superiority of the different techniques could be calculated. In addition, the current literature on IH repair is still indecisive as to which of the techniques is superior [40, 41]. Ideally, a meta-analysis of exactly the same types of surgery is preferable, reducing intervention heterogeneity. However, we hypothesize that the concept of PMA is similar with regard to the different techniques, and thus a meta-analysis can be performed. In addition, removing the study using the onlay technique did not alter the results of the meta-analysis.

Postoperative Complications

In all studies included, the *postoperative* complications which were routinely described were represented by IH, infection and seroma. However, 3 studies did not mention hematoma [33–35], 1 did not mention fascial dehiscence [35], and 3 did not mention possible mesh explantation [33, 34, 36]. It seems strange not to mention mesh removal, considering 25% meshes had to be extracted in a previous PMA cohort study [42]. Two studies reported data on chronic pain in favor of the PS group; however, this was not statistically significant [32, 34]. In addition, these studies lacked information on how the chronic pain was assessed and which scale was used. Therefore, a good interpretation of the intensity of the pain was not possible. Furthermore, no clear definitions were described for any of the postoperative complications.

In addition to all postoperative complications, it will be interesting to get more insight into long-term mesh-related complications such as fistula and late infection. These complications are not discussed in the included papers but are known to occur in IH surgery. Also, in cases of re-laparotomies, the question whether PMA will make getting access to the abdomen more difficult, increasing the chance of enterotomy, is very important and needs to be addressed in other trials [43, 44].

Conclusion

Despite continuous research regarding abdominal wall closure, the incidence of IH remains unacceptably high, especially in patients who have one or more risk fac-

tors for the development of IH. However, in an attempt to reduce this incidence, new surgical techniques were developed to reduce the incidence of IH to an acceptable proportion. This study shows that the use of PMA for abdominal wall closure is associated with significantly lower incidence of IH compared to PS. No significant differences could be observed in postoperative complications, such as infections and seroma. Thus, PMA seems to be an effective and safe method for the prevention of IH in high-risk groups. However, the quality of the available RCTs was in some cases low, and important outcome measures, such as mesh removal, hematoma, fistula, postoperative pain, operation duration, hospital stay, enterotomy during relaparotomy, quality of life, and cost-effectiveness were not reported in all studies included. Other large high-quality RCTs should be performed to evaluate these shortcomings.

Appendix

Search String

Embase

('surgical mesh'/de OR prosthesis/de OR (mesh OR prosthe* OR implant*):ab,ti) AND (prophylaxis/de OR prevention/de OR (prophyla* OR prevent*):ab,ti) AND ('incisional hernia'/de OR 'abdominal wall hernia'/de OR ((incision* OR scar* OR cicatri* OR postoperat* OR surg* OR operat* OR ventral* OR abdom*) NEAR/3 (herni*)):ab,ti)

MEDLINE in OvidSP

('surgical mesh'/ OR 'Prostheses and Implants'/ OR (mesh OR prosthe* OR implant*).ab,ti.) AND ('prevention and control'.xs. OR 'Primary Prevention'/ OR (prophyla* OR prevent*).ab,ti.) AND ('Hernia, Ventral'/ OR ((incision* OR scar* OR cicatri* OR postoperat* OR surg* OR operat* OR ventral* OR abdom*) ADJ3 (herni*)).ab,ti.)

Cochrane Central

((mesh OR prosthe* OR implant*):ab,ti) AND ((prophyla* OR prevent*):ab,ti) AND (((incision* OR scar* OR cicatri* OR postoperat* OR surg* OR operat* OR ventral* OR abdom*) NEAR/3 (herni*)):ab,ti)

Web of Science

TS = (((mesh OR prosthe* OR implant*) NEAR/3 (prophyla* OR prevent*)) AND (((incision* OR scar* OR cicatri* OR postoperat* OR surg* OR operat* OR ventral* OR abdom*) NEAR/3 (herni*))))

PubMed

((mesh[tiab] OR prosthe*[tiab] OR implant*[tiab])) AND ((prophyla*[tiab] OR prevent*[tiab])) AND (((incision*[tiab] OR scar*[tiab] OR cicatri*[tiab] OR postoperat*[tiab] OR surger*[tiab] OR surgic*[tiab] OR operation*[tiab] OR operative*[tiab] OR ventral*[tiab] OR abdom*[tiab]) AND (herni*[tiab]))) AND publisher[sb]

Acknowledgments

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