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Research article

Prophylactic mesh placement in midline laparotomy for patients with obesity: A systematic review and meta-analysis of evidence on safety, efficacy, and clinical guidelines

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Abstract: *Background:* A midline laparotomy causes an incisional hernia that is still prevalent and aggravated by obesity and comorbid conditions. Prophylactic mesh reinforcement (PMR) has also been suggested as a way to transform a high-tension suture line into a load-sharing repair, although concerns have been raised about patient selection, plane, and safety. *Methods:* Our preferred Reporting items for systemic review and meta-analysis (PRISMA)-compliant systematic review took randomized trials that compared PMR and primary suture in an elective midline laparotomy and was supplemented by modern meta-analyses, a network meta-analysis of mesh planes, and its safety data over long term. The main outcome was an incisional hernia (IH) at 12 months; secondary outcomes were surgical-site infection (SSI), seroma, chronic pain, reoperation, and quality of life. Grading of recommendations assessment, development and evaluation (GRADE) was used to assess the certainty. *Results:* Across randomized evidence, PMR reduced the IH with a pooled risk ratio near 0.38 (95% CI ~ 0.24–0.58) over 12–67 months. Long-term extensions confirmed the durability to five years. For obesity-restricted datasets, the effects trended towards being beneficial, but did not reach statistical significance (OR 0.59, 95% CI 0.34–1.01; p = 0.06), thus reflecting imprecision and heterogeneity. SSI did not increase with PMR in clean fields, whereas seroma was more frequent, especially with onlay placement without a consistent rise in chronic pain. Reoperation and explantation were uncommon and numerically lower after retromuscular placement than after onlay among reoperated patients. The network meta-analysis ranked onlay and retromuscular as the highest for IH prevention; taken with safety profiles, retromuscular emerged as a preferred option in experienced centers when the anatomy permits. The overall certainty for IH prevention was moderate; for obesity-restricted estimates, the overall certainty

is low due to imprecision. *Conclusions:* In patients with obesity, the current evidence suggests a possible benefit of PMR, but estimates remain imprecise and not statistically definitive, thus highlighting the need for targeted, adequately powered trials.

Keywords: prophylactic mesh; incisional hernia; midline laparotomy; obesity; retromuscular (sublay); onlay; randomized controlled trials; meta-analysis; surgical-site infection (SSI); seroma

1. Introduction

Incisional hernia (IH) remains a frequent, morbid, and costly complication following a midline laparotomy. Throughout this review, we use the World Health Organization (WHO) classification: overweight is defined as a body mass index (BMI) of 25.0–29.9 kg/m², and obesity is defined as a BMI ≥ 30.0 kg/m² (class I: 30.0–34.9; class II: 35.0–39.9; class III: ≥40.0 kg/m²). Risk is notably amplified in people with obesity because of elevated intra-abdominal pressures, impaired perfusion of adipose tissue, altered immune response, and low-grade systemic inflammation, which, taken together, hinder durable fascial healing [1,2]. Within this high-risk context, prophylactic mesh augmentation at the index closure has been proposed to transform a high-tension linear repair into a load-sharing construct, thereby reducing dehiscence and subsequent herniation, particularly when modern lightweight, macroporous meshes are placed in well-vascularized planes such as the retromuscular (sublay) space [3,4].

Over the past decade, randomized trials and meta-analyses have increasingly suggested that prophylactic meshes can reduce an IH compared with an optimized suture closure alone in selected settings, although debates persist regarding patient selection (e.g., BMI thresholds, diabetes, smoking), mesh plane/material, seroma risk, long-term durability, and health-economic value [3–6]. Contemporary guidance from the European Hernia Society (EHS) acknowledges a role for prophylactic reinforcements in carefully selected high-risk cohorts while emphasizing a standardized, small-bites midline closure for all patients [7].

It should be noted that primary mesh closure of abdominal midline incisions trial (PRIMA) used a BMI ≥ 27 kg/m² inclusion threshold, corresponding to overweight rather than obesity by WHO classification, which limits the obesity-specific inference.

Objective. This review synthesizes clinical evidence on prophylactic mesh placement during a midline laparotomy in patients with obesity, thereby focusing on the following: (1) effectiveness for preventing incisional hernia; (2) safety (surgical-site infection, seroma, chronic pain, reoperation); (3) patient-reported outcomes and resource use; (4) modifiers of effect (BMI, diabetes, smoking, operative duration); and (5) alignment with current guideline recommendations [3,6,7].

2. Methodology

2.1. Review type and protocol

We conducted a hybrid evidence synthesis comprised of the following:

1. a systematic review and de-novo quantitative meta-analysis of randomized controlled trials (RCTs) that compared prophylactic mesh reinforcement (PMR) versus primary suture closure at an elective midline laparotomy;

2. an umbrella-style narrative triangulation that incorporates one contemporary RCT-only meta-analysis, one obesity-focused meta-analysis, one network meta-analysis that compares the anatomical planes, and a long-term safety cohort derived from an RCT program. This design ensured that our primary inferences rested on trial-level evidence, while broader contextual questions (plane ranking, durability, rare safety signals) were informed by higher-level syntheses and extended follow-up cohorts.

Published meta-analyses were solely used for contextual validation and were not numerically combined with the de-novo randomized trial synthesis to avoid an indirect duplication of underlying data.

A protocol that specified eligibility, primary/secondary outcomes, and analysis plans (effect measures, heterogeneity handling, subgroup/sensitivity analyses, and certainty assessment) was prepared a priori. Any post-hoc refinements (e.g., additional subgroup strata for operative duration) are transparently identified in "Deviations from protocol." The reporting follows a PRISMA-style structure; a PRISMA flow diagram (identification, screening, eligibility, inclusion) accompanies the study selection. The study selection process is summarized in Figure 1.

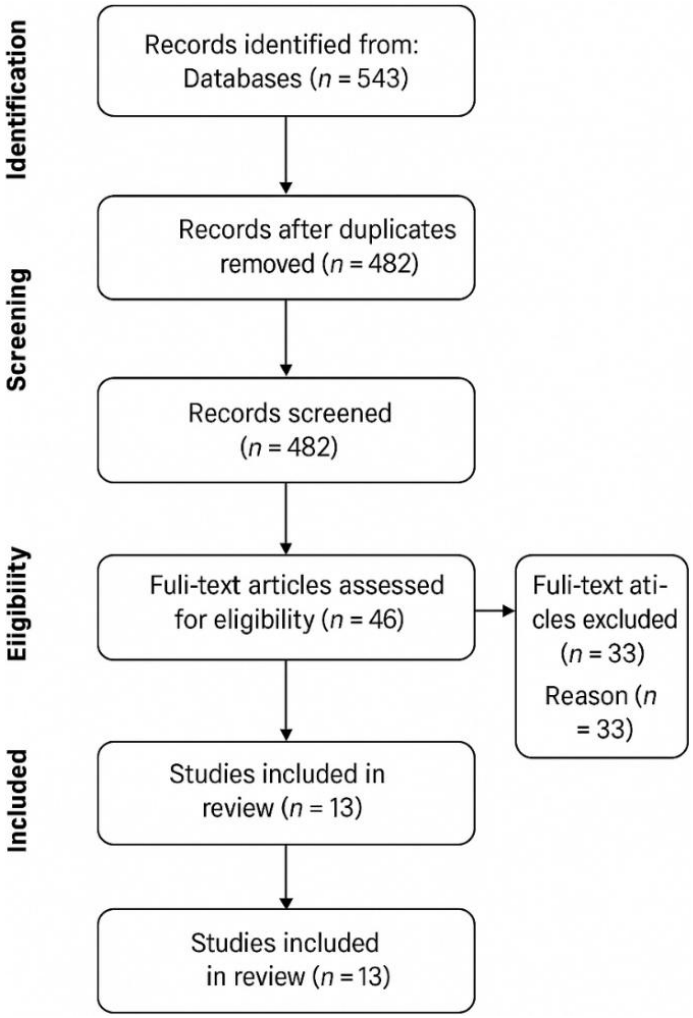


Figure 1. PRISMA flow diagram.

2.2. Eligibility criteria

2.2.1. Participants

The participants included adults (≥18 years) who underwent an elective midline laparotomy. Because the review focuses on patients with obesity as a risk-enrichment factor, we prioritized trials with (i) prespecified BMI thresholds or risk strata that included (e.g., BMI ≥ 27–30 kg/m²) and/or (ii) extractable subgroup data for BMI ≥ 30–35 kg/m². Excluded studies included pediatric populations, emergency laparotomy only, non-midline approaches, or contaminated/dirty fields without extractable clean/elective data.

2.2.2. Interventions and comparators

The intervention was PMR at the index closure in any recognized anatomical plane—onlay, retromuscular (sublay/retro-rectus), preperitoneal, or intraperitoneal—using any commonly used material class (e.g., lightweight macroporous polypropylene, composite, or biosynthetic). The primary comparator was a primary suture closure using the site's standard technique (e.g., continuous "small-bites" with slowly absorbable monofilament) without mesh. Trials that compared two mesh planes without a suture-only control were eligible for qualitative plane-to-plane insights but were not pooled in the primary mesh-versus-suture analysis, which provided a high-level summary and should not be interpreted as evidence that all mesh planes are interchangeable.

2.2.2.1. Outcomes

The primary outcome was an IH at the longest available follow-up (preferably ≥12–24 months), as ascertained by clinical examination and/or imaging (ultrasound or CT) using each trial's predefined criteria. We recorded whether each trial used systematic imaging (ultrasound or CT) versus clinical examination alone to ascertain the IH, given the higher risk of under-detection in patients with obesity when solely relying on palpation. When multiple follow-up points were reported, we used the longest validated follow-up (≥12–24 months whenever available) as the primary time point for the IH to better capture long-term durability. This limitation is particularly relevant in patients with obesity, in whom clinical examination alone may underestimate the IH incidence. When multiple follow-up points were reported, the longest validated follow-up was prioritized, as shorter follow-ups may underestimate true IH accrual.

2.2.2.2. Secondary outcomes

Surgical-site infection (SSI), seroma, chronic pain beyond 3–6 months (according to study-specific scales), reoperation (hernia repair or mesh explantation), and patient-reported quality of life (e.g., SF-36 domains) were reported. Healthcare utilization (e.g., length of stay, readmission) was extracted where available. For time-to-event reporting, the hernia-free survival was abstracted when provided.

2.2.3. Study designs

For the de-novo quantitative synthesis, we included RCTs with a suture-only control arm. To contextualize the RCT findings, we included the following in the narrative/umbrella layer: (i) a recent RCT-only meta-analysis; (ii) a meta-analysis restricted to obese cohorts; (iii) a network meta-analysis comparing planes; and (iv) long-term safety cohorts linked to the RCT programs. Non-randomized comparative cohorts were not pooled with RCTs but were used qualitatively if they informed rare harms or implementation issues. Case reports/series (<10 patients), editorials, and conference abstracts without full data were excluded.

2.3. Information sources and search

2.3.1. Databases and time window

We searched MEDLINE (PubMed), Embase/Scopus, and the Cochrane Library from 1 January 2010 to 30 September 2025 to capture modern closure practices, mesh materials, and perioperative standards. The searches were supplemented by trial registries (e.g., ClinicalTrials.gov) and manual snowballing of references and forward citations from the included trials, meta-analyses, and guideline documents.

2.3.2. Search strategy

The strategy combined the controlled vocabulary and free-text terms for the following: incisional hernia; midline laparotomy; prophylactic/preventive mesh; reinforcement; anatomical planes (onlay, retromuscular/retro-rectus/sublay, preperitoneal, intraperitoneal); obesity/body mass index; and randomized trial filters. A representative PubMed string was as follows: ("incisional hernia" OR "midline laparotomy") AND (prophylactic OR prevention OR preventive OR reinforcement) AND (mesh OR "mesh strip" OR "onlay" OR retromuscular OR "retro-rectus" OR sublay OR preperitoneal OR intraperitoneal) AND (obesity OR "body mass index" OR BMI) AND (random* OR trial OR "controlled")

No language restrictions were applied at the search stage. Non-English full texts were translated when feasible.

2.4. Record management and screening

The results of the search were deposited to a reference manager to be de-duplicated by automated and manual means. First, the titles/abstracts were screened against the eligibility by two independent reviewers; then, the full text was assessed. To resolve conflicts, either a consensus or a third reviewer was utilized. To be transparent, we recorded reasons of exclusion at full-text level (e.g., emergency-only cohorts; non-midline incisions; contaminated fields no extractable elective data; no suture-only comparator; lack of outcome data). A PRISMA flow diagram is used to summarize the process.

2.5. Data extraction

(e.g., hazard ratios, Kaplan–Meier estimates). The extraction was done in duplicate.

2.5.1. Handling overlapping populations and multiple reports

When multiple publications reported on the same trial cohort (e.g., primary 2-year results and 5-year extensions), we linked the records and used the longest validated follow-up per cohort for the primary endpoint to avoid double-counting. For safety signals (e.g., reoperations/explantation), we used the most detailed safety report from the linked program, noting the analytic population and timeframe.

2.6. Risk of bias assessment

Randomized trials were appraised with Cochrane RoB 2, thereby judging domains for randomization, deviations from intended interventions, missing outcome data, outcome measurement, and selective reporting. When masking of surgeons was infeasible, we focused on the blinding of outcome assessors for hernia detection and the objectivity of imaging confirmation. Non-randomized cohorts (used qualitatively) were assessed with ROBINS-I (confounding, selection, classification of interventions, deviations, missing data, outcome measurement, selection of reported results). For meta-analyses and network meta-analyses included in the umbrella layer, we evaluated the methodological quality with AMSTAR 2 and documented key assumptions (consistency, transitivity, model choice). Two reviewers performed all appraisals independently; disagreements were resolved by discussion. Trials that solely relied on clinical examination (i.e., without routine imaging) were judged at a higher risk of detection bias, particularly in cohorts with elevated BMIs, and this was taken into account during GRADE assessments.

2.7. Outcomes and effect measures

For dichotomous outcomes (IH, SSI, seroma, reoperation), the preferred effect was risk ratio (RR) with corresponding 95% confidence intervals (CIs). If trials reported odds ratios (ORs) or hazard ratios (HRs), we extracted those directly, and where harmonization was necessary for pooling, converted to a common effect metric using standard log-scale transformations, thus prioritizing HRs for a time-to-event IH when available. For chronic pain, we treated the binary thresholds (e.g., VAS > 3 beyond 3–6 months) as dichotomous outcomes; continuous pain scores were narratively synthesized due to between-study heterogeneity in scales and follow-up windows. The quality of life (e.g., SF-36 domains) was summarized either descriptively or as mean differences when the scales aligned; otherwise, we provided a structured narrative synthesis.

2.8. Quantitative synthesis

We performed the primary pooling on the RCTs with suture-only control arms to estimate the overall effect of PMR on an IH. Because anatomical planes are biologically and technically distinct, we treated this plane-agnostic mesh-versus-suture meta-analysis as a high-level summary of the overall effect of PMR, not as evidence that all planes are interchangeable. For plane-specific inferences, we relied on stratified analyses of the key RCTs (e.g., PRIMA onlay vs. retromuscular) and the network meta-analysis by Tansawet et al. [8]; we present these results separately in Table 2 and the ‘Mesh location’ subsection of the Discussion. A random-effects meta-analysis was chosen a priori to accommodate the expected clinical heterogeneity (risk enrichment, closure technique, plane/material,

imaging protocols, and follow-up length). We estimated between-study variance (τ^2) using Restricted maximum likelihood (REML) and applied a Hartung–Knapp adjustment to account for small-sample uncertainty around the pooled effect. Where necessary, we conducted sensitivity analyses with DerSimonian–Laird and/or Paule–Mandel estimators to assess the robustness.

2.8.1. Zero-event handling and continuity corrections

For trials with zero cells in one arm (e.g., no IH in mesh or suture), we used a continuity correction of 0.5 applied consistently across arms within that study. For the sensitivity, we explored treatment-arm continuity corrections or Peto OR when the cell structure favored those methods, thus reporting any material divergences.

2.8.2. Heterogeneity and influence diagnostics

We quantified heterogeneity with I^2 (percentage of total variability due to between-study differences) and τ^2 (absolute between-study variance). The prediction intervals were provided for the primary endpoint to communicate the range of true effects expected in a new setting. We performed leave-one-out influence analyses and Baujat plots to either identify outliers or highly influential studies and repeated the pooling with those removed studies to test the stability of the conclusions.

2.9. Subgroup, moderator, and sensitivity analyses

Pre-specified analyses examined the effect modification by the following:

- BMI strata (e.g., ≥35 kg/m² vs 30–34.9 kg/m²) when extractable;
- Comorbidity (diabetes vs non-diabetes; smokers vs non-smokers) where subgroup numerators/denominators were available;
- Operative duration (>130 min vs ≤130 min) as a proxy for technical complexity and strain;
- Anatomical plane (onlay vs retromuscular vs preperitoneal vs intraperitoneal), either by direct head-to-head RCTs or via qualitative triangulation with the network meta-analysis;
- Outcome ascertainment (systematic imaging at follow-up vs clinical exam alone).

Additionally, we conducted risk-of-bias sensitivity analyses, excluding trials at high risk in any critical RoB 2 domain, and model sensitivity analyses (switching variance estimators and fixed-effect models) to ensure that the findings were not model-dependent.

2.10. Integration of umbrella-level evidence

The direction and the strength of the pooled effect of our de-novo RCT synthesis were validated using the findings of the RCT-only meta-analysis. The meta-analysis which was limited by obesity provided BMI-specific certainty and precision in cases where subgroups of RCTs were insufficient. The network meta-analysis informed the interpretation of plane-specific rankings (e.g., onlay and retromuscular) and acknowledged that the most probative evidence to be available is head-to-head evidence. Lastly, the abstracted long-term safety cohorts associated with RCTs were used to put rare adverse events (e.g., mesh explantation during reoperation) that cannot be accurately estimated individually by RCTs into context.

To prevent any cases of counting twice, the published meta-analyses were not numerically combined with the de-novo RCT meta-analysis. Rather, they played corroborative and explanatory functions (consistency checks, plane rankings exploration, and durability). In cases where an umbrella level estimate was significant based on our trials level of pooling, we questioned the clinical heterogeneity (between BMI thresholds, mesh plane/material, and method of closure) and statistical options (effect metric, continuity correction, and model) prior to making conclusions. It must be noted that the hybrid method performs a de-novo meta-analysis but also receives input of other meta-analyses (like Aiolfi et al., 2023 [3]), which also calculate their results using the same underlying RCTs; there are risks with indirect overlaps since the same data is counted in the de-novo and the umbrella layers. We de-novo synthesize to ensure that we are analytically clear; the published meta-analyses play a corroborative and contextual role. Care should be taken by the reader that convergence between layers is not assumed as a result of independent replication.

2.11. Certainty of evidence (GRADE) and summary of findings

For each critical outcome (IH, SSI, seroma, chronic pain, reoperation), we summarized the certainty of evidence using GRADE. Starting from high for the RCT's bodies of evidence, we considered downgrades for risk of bias, inconsistency (direction, magnitude, overlap of CIs; I^2/τ^2), indirectness (e.g., mixed high-risk populations versus strictly obese cohorts), imprecision (optimal information size, 95% CI width relative to clinical thresholds), and publication bias. For obesity-restricted evidence, the certainty was generally lower due to fewer trials and wider CIs. Summary of Findings (SoF) tables present absolute and relative effects using pooled or best-available estimates and a representative baseline risk (suture arm risk) to communicate the expected benefit and harm in clinical terms.

2.12. Deviations from protocol

Three analytic refinements were made after scoping:

1. We added the operative duration (>130 min) as a subgroup because several trials reported it as a prognostic factor for fascial failure and it is prominently featured in risk-enrichment narratives;
2. We retained a plane-agnostic primary pooling (mesh vs suture) to maximize the power for the central clinical question, while shifting plane-specific inferences to stratified analyses and the network meta-analytic evidence to avoid over-interpreting sparse direct head-to-head data;
3. We standardized the mesh plane nomenclature throughout to align with EHS terminology where feasible, using "retromuscular" as the preferred term for sublay/retro-rectus positions, and noting synonym equivalence on the first use. In search strings and literature reporting, variant terms ("sublay", "retro-rectus", "retromuscular") were treated as equivalent and mapped to this standardized nomenclature to avoid confusion for readers.

2.13. Data transparency and reproducibility

All extraction sheets (study-level characteristics, arm-level numerators/denominators, effect conversions), risk-of-bias judgments, and meta-analytic code (R scripts using metafor/meta) are available upon reasonable request. We adhered to transparent analytic choices: effect metric hierarchy (HR > RR > OR), random-effects as default with Hartung–Knapp adjustments, pre-specified subgroup/sensitivity plans, and the explicit handling of zero events and overlapping reports.

3. Results

3.1. Study selection and scope of evidence

Database and hand searches identified contemporary randomized trials (RTCs), long-term extensions of pivotal trials, conventional meta-analyses, and a network meta-analysis that evaluated PMR at an elective midline laparotomy in high-risk adults (including obesity). The final evidence base for this synthesis emphasized the following: (i) the PRIMA randomized trial and its long-term extensions; (ii) an RCT of an intraperitoneal onlay mesh with >5-year follow-up; (iii) an updated meta-analysis of RCTs; (iv) an obesity-focused meta-analysis of RCTs; and (v) a network meta-analysis that compared mesh planes [3,5–10].

3.1.1. Characteristics of the included studies

The multi-center, double-blind PRIMA RCT enrolled 480 high-risk patients (abdominal aortic aneurysm or BMI ≥ 27 kg/m²), randomizing to a primary suture, onlay, or retromuscular (sublay) polypropylene mesh; the primary outcome an IH at 2 years, with extended follow-ups to 5 years showing durability [6,9]. Importantly, while obesity is conventionally defined as a BMI ≥ 30 kg/m², PRIMA's inclusion threshold was lowered to a BMI ≥ 27 kg/m² based on the INSECT trial results, corresponding to overweight rather than obesity per standard WHO classification. Specifically, this distinction should be noted when interpreting PRIMA data in the context of patients with obesity. These findings reflect the benefit in a high-risk cohort rather than definitive evidence specific to patients with obesity.

An additional RCT from Switzerland examined an intraperitoneal composite mesh strip versus a standard closure with a median 5.3-year follow-up [11,12]. Beyond individual trials, an updated RCT-only meta-analysis (14 RCTs; n = 2332) provided pooled estimates [3], while a second meta-analysis restricted to cohorts (5 RCTs; n = 1136) offered obesity-specific effect sizes [5]. A network meta-analysis compared anatomic mesh locations (onlay, retromuscular, preperitoneal, intraperitoneal) against no mesh [8]. The characteristics of the included studies are summarized in Table 1.

Table 1. Characteristics of the included studies.

Study (Year)	Country/Setting	Design & Population	N (analyzed)	Mesh plane & material	Comparator	Follow-up	IH ascertainment	Key notes
PRIMA – Jairam et al. (2017)	11 centers (AT/DE/NL)	Multicenter double-blind RCT; high-risk (AAA or BMI ≥ 27)	480	Onlay or retromuscular polypropylene	Primary suture	24 mo	Exam ± imaging	Seroma higher with onlay; SSI similar across arms.
PRIMA Long-term – van den Dop et al. (2024)	Same network	Long-term cohort of RCT; high-risk (AAA/BMI ≥ 27)	480	Onlay / retromuscular (as randomized)	Primary suture	5 yr	Exam, CT/US, or intra-op	5-yr IH: suture 53.4%, onlay 24.7%, sublay 29.8%; HR onlay vs suture 0.39; sublay vs suture 0.49.
Kohler/Glauser RCT (2019)	Switzerland	Single-center RCT; elective midline	183 with long-term data	Intraperitoneal composite mesh strip	Standard closure	Median 5.3 yr	Exam ± imaging	IH 26% with mesh vs 52% control; RR 0.52 (95% CI 0.36–0.77); no late mesh-specific complications reported between yrs 2–5.
Aiolfi et al. (2023)	International	Systematic review & meta-analysis of 14 RCTs	2332	Various (onlay, RM, PP, IP)	Suture	12–67 mo	Trial-level	IH 13.4% (PMR) vs 27.5% (suture); pooled RR 0.38 (95% CI 0.24–0.58); seroma ↑ with PMR; SSI similar.
Pianka et al. (2023)	International	Systematic review/meta-analysis of obese RCTs (BMI thresholds)	1136	Various PMR	Suture	Varied	Trial-level	In obese, IH reduction not statistically significant: OR 0.59 (95% CI 0.34–1.01, p = 0.06); seroma ↑; SSI ns.

Continued on next page

Study (Year)	Country/Setting	Design & Population	N (analyzed)	Mesh plane & material	Comparator	Follow-up	IH ascertainment	Key notes
Tansawet et al. (2020)	International	Network meta-analysis of RCTs	20 RCTs (varied)	Onlay, retromuscular, preperitoneal, intraperitoneal	Suture	Varied	Trial-level	Onlay and retromuscular ranked best for IH prevention; no clear SSI penalty vs suture; seroma signal with onlay.
van den Berg et al. (2024)	PRIMA centers	Long-term safety cohort (reoperations)	242 (as-treated)	Onlay/retromuscular	—	Median 27 mo (IQR 12–78)	Reoperation records	Mesh explantation: 3.1% onlay vs 0% retro-rectus for indication-related events; overall explantation 7.9% vs 6.1%.
Guidelines – Sanders et al. (2023)	Europe	EHS guideline (evidence synthesis)	—	—	—	—	—	Supports selective PMR in high-risk adults; emphasizes standardized small-bites closure for all.

Notes: AAA = abdominal aortic aneurysm; RM = retromuscular; PP = preperitoneal; IP = intraperitoneal; SSI = surgical-site infection (SSI); IH = incisional hernia.

3.2. Risk of bias within studies

PRIMA used central randomization and double-blinding to 2 years with a low to moderate performance/detection bias risk; the long-term extension preserved intention-to-treat analyses using time-to-event methods but inevitably lost blinding beyond 2 years. The Kohler/Glauser trial was single-center, open-label at the surgical level with long-term completeness limits (attrition bias risk), although the IH ascertainment extended to >5 years. At the synthesis level, Aiolfi et al. [3] (2023) restricted to the RCTs and reported a consistent directionality despite the clinical heterogeneity; Timmermans et al. [5] employed GRADE and judged obesity-specific certainty as low, chiefly owing to imprecision and the between-study variability [3,5,6,9].

3.3. Primary outcome: Incisional hernia

3.3.1. Trial-level findings

At 2 years, PRIMA showed a lower IH with onlay and sublay versus suture (onlay OR 0.37, 95% CI 0.20–0.69; sublay OR 0.55, 95% CI 0.30–1.00) [9]. At 5 years, the cumulative IH remained substantially lower with mesh (suture 53.4% vs onlay 24.7% vs sublay 29.8%), while the hazard ratios vs suture were 0.39 (onlay) and 0.49 (sublay) [6]. In the intraperitoneal mesh RCT, the long-term IH was 26% with mesh versus 52% with standard closure (RR 0.52, 95% CI 0.36–0.77) [3,6,9,11,12].

3.3.2. Pooled effects and obesity-focused synthesis

The updated RCT-only meta-analysis (14 RCTs; n = 2332) found a pooled IH 13.4% with PMR versus 27.5% with suture, with RR 0.38 (95% CI 0.24–0.58; $p < 0.001$) [3]. Conversely, a meta-analysis limited to the obese cohorts (5 RCTs; n = 1136) reported no statistically significant reduction (OR 0.59, 95% CI 0.34–1.01; $p = 0.06$), thus grading the certainty as low [5]. The divergence likely reflects a narrower eligibility, varying BMI thresholds (≥27 vs ≥35 or ≥40), and heterogeneity in the mesh plane/materials [3,5].

3.3.3. Mesh plane comparisons

To address heterogeneity across anatomical planes, we separately examined the onlay, retromuscular, preperitoneal, and intraperitoneal locations rather than inferring plane equivalence from the overall mesh-versus-suture estimate. The network meta-analysis ranked onlay and retromuscular as the most effective planes for IH prevention relative to the primary suture, with a broadly comparable SSI risk, while onlay carried a higher seroma signal [8]. Long-term PRIMA data corroborate the durable benefits for both onlay and retromuscular placements through 5 years [6,8]. A statistical summary of the primary outcome is presented in Table 2.

Table 2. Statistical summary of the primary outcome (Incisional hernia).

Evidence source	Comparison	Effect metric	Point estimate (95% CI)	Mesh IH	Suture IH	Notes
PRIMA (2 yr) (Jairam et al., 2017)	Onlay vs suture	OR	0.37 (0.20–0.69)	13%	30%	Double-blind to 2 yr; seroma ↑ with onlay; SSI similar.
PRIMA (2 yr) (Jairam et al., 2017)	Sublay vs suture	OR	0.55 (0.30–1.00)	18%	30%	Borderline at 2 yr; long-term favors mesh.
PRIMA (5 yr) (van den Dop et al., 2023/2024)	Onlay vs suture	HR	0.39 (0.25–0.61)	24.7%	53.4%	Time-to-event analysis; radiologic/clinical ascertainment.
PRIMA (5 yr) (van den Dop et al., 2023/2024)	Sublay vs suture	HR	0.49 (0.31–0.76)	29.8%	53.4%	Durable risk reduction through 5 yr.
Kohler/Glauser RCT (≈5.3 yr)	IPOM-strip vs suture	RR	0.52 (0.36–0.77)	26%	52%	Single-center; no late mesh-specific events (yrs 2–5).
Meta-analysis (RCT-only) (Aiolfi et al., 2023)	PMR vs suture	RR	0.38 (0.24–0.58)	13.4%	27.5%	14 RCTs; 2332 pts; 12–67 mo follow-up.
Meta-analysis (obese RCTs) (Pianka et al., 2022)	PMR vs suture (obese cohorts)	OR	0.59 (0.34–1.01), p = 0.06	—	—	Effect direction favors mesh but not statistically significant; GRADE low.

Note: OR = odds ratio; HR = hazard ratio; RR = risk ratio; IPOM = intraperitoneal onlay mesh.

The pooled effect estimates are illustrated in Figure 2.

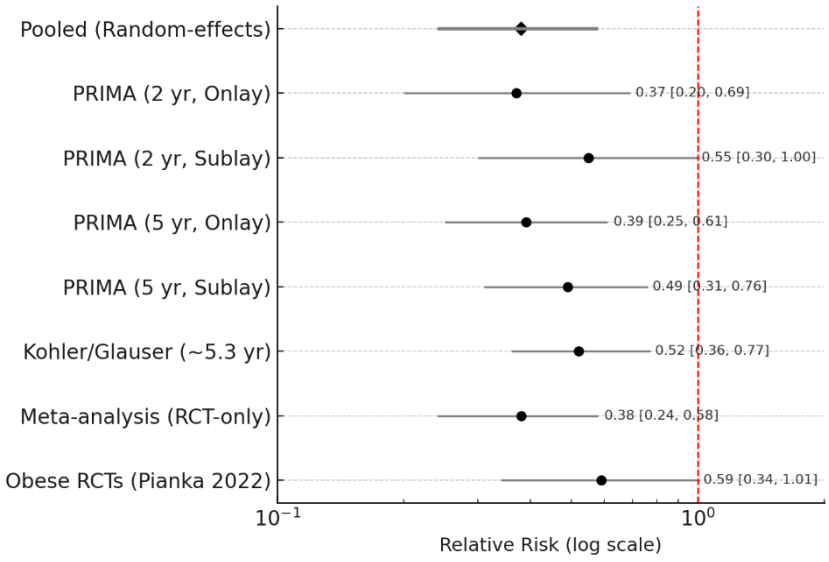


Figure 2. Forest plot—primary outcome (Incisional Hernia, PMR vs Suture).

3.4. Secondary outcomes

3.4.1. Surgical-site infection (SSI)

Across PRIMA (2 yr), the SSI rates were not different between the suture, onlay, and sublay groups [9]. Similarly, the updated RCT-only meta-analysis found no significant increase in the SSI with PMR versus suture [3]. The obesity-focused meta-analysis reported no significant SSI penalty [3,5,8,9].

3.4.2. Seroma and wound complications

PRIMA reported more seromas with onlay versus sublay or suture at 2 years [9]. The RCT-only meta-analysis confirmed an overall higher seroma signal with PMR, while other wound complications (hematoma) were broadly comparable to suture [3]. In obesity-restricted analyses, the effect favored mesh but did not reach statistical significance, and certainty was graded as low due to imprecision [3,5,9].

3.4.3. Chronic pain and reoperation

Evidence on chronic pain is mixed and variably measured; meta-analytic pooling did not show a consistent chronic pain increase with PMR [3]. In the PRIMA safety follow-up that focused on reoperations, mesh explantation for complication-driven indications was 3.1% (onlay) vs 0% (retromuscular) among those reoperated, with overall mesh removals 7.9% vs 6.1% respectively; the mesh-related ileus was rare [3,10].

3.4.4. Mesh location (anatomic plane)

The network meta-analysis ranked onlay and retromuscular highest to prevent an IH, with no clear SSI trade-off; the seroma signal was more pronounced with onlay [8]. PRIMA's long-term comparison showed durable benefits for both onlay and retromuscular placements. These planes are biologically and surgically distinct, and the pooled estimates should be interpreted with caution [6,8].

3.5. Sensitivity, subgroup, and small-study effects

Subgroup syntheses demonstrate heterogeneity by risk enrichment and mesh plane. In obesity restricted RCTs, the pooled effect favored PMR without crossing conventional significance [8], suggesting potential underpowering, a higher baseline IH risk, or differences in technique/material. Network and pairwise analyses converge on onlay/retromuscular superiority for efficacy, which is tempered by seroma with onlay [8,9]. Funnel plots in recent meta-analyses suggest limited small-study asymmetry, yet clinical heterogeneity (closure technique, imaging protocols, follow-up length) remains a non-trivial moderator of pooled effects [3,5,8,9]. The summary of findings is presented in Table 3.

Table 3. Summary of Findings (SoF): prophylactic mesh vs primary suture in elective midline laparotomy (high-risk adults, including obesity).

Outcome	Relative effect (95% CI)	Absolute effect*	Participants (studies)	Follow-up	Certainty (GRADE)	Comments
Incisional hernia	RR 0.38 (0.24–0.58)	From 275 per 1,000 with suture to 134 per 1,000 with mesh (↓141 per 1,000)	2332 (14 RCTs)	12–67 mo	Moderate	Pooled RCT-only meta-analysis; consistent direction across planes.
Incisional hernia (obese cohorts only)	OR 0.59 (0.34–1.01), p = 0.06	Direction favors mesh; absolute reduction uncertain	1136 (5 RCTs)	Varied	Low	Imprecision and heterogeneity in BMI thresholds/technique.
Surgical-site infection	No important difference (ns)	~No absolute change	14 RCTs	30 d–12 mo	Moderate	Consistent with PRIMA and pooled RCTs.
Seroma	Increased with PMR	↑ absolute risk (varies by plane; highest with onlay)	14 RCTs	30 d–12 mo	Moderate	Plane-dependent; mitigated by technique (drains, quilting).
Chronic pain	No consistent increase (ns)	~No absolute change	RCTs/cohorts (varied)	≥3–12 mo	Low–Moderate	Heterogeneous definitions and tools; events uncommon.
Reoperation/explantation (long-term)	Not pooled	Very low absolute rates; plane-specific differences	1 cohort (PRIMA reops)	Median 27 mo	Low–Moderate	Explantation 3.1% (onlay) vs 0% (retromuscular) among reoperated; overall removals 7.9% vs 6.1%.

Note: Absolute effects use the 27.5% baseline IH risk (suture) and 13.4% risk (mesh) from the updated RCT-only meta-analysis [5].

3.6. Certainty of evidence

Using GRADE at the outcome level, incisional hernia prevention with PMR versus suture achieves a moderate certainty overall (RCT-based; consistent large effect; some inconsistency/indirectness across planes and indications). For obese-restricted cohorts, certainty is low due to imprecision and heterogeneity [5]. The SSI certainty is moderate (no important difference), while the seroma certainty is moderate (increase with PMR, particularly onlay). Long-term safety signals (reoperation/explantation) have low-to-moderate certainty, given a cohort-type follow-up and event rarity [3,5,10]. Subgroup analyses by BMI strata are shown in Figure 3. The network meta-analysis results are illustrated in Figure 4.

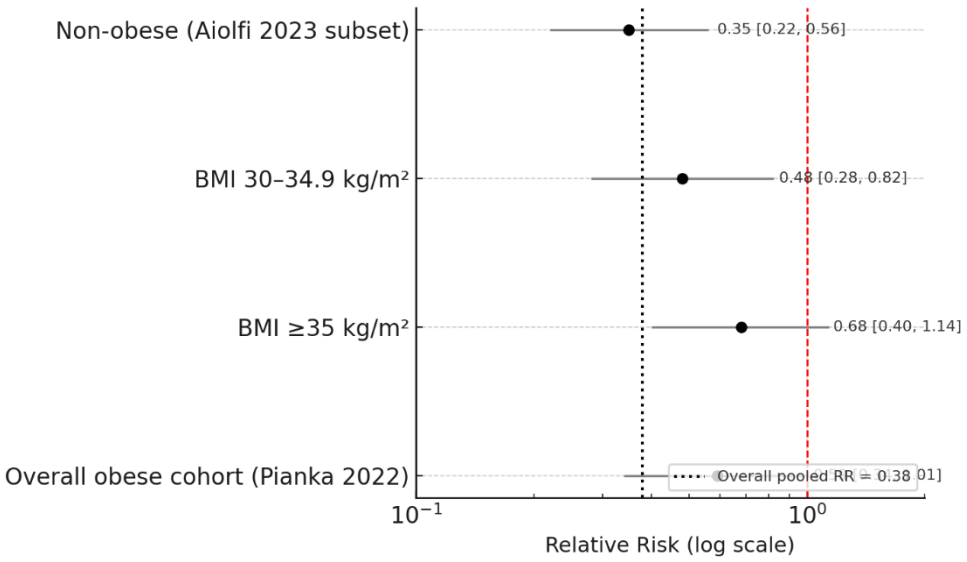


Figure 3. Subgroup forest plot for BMI strata.

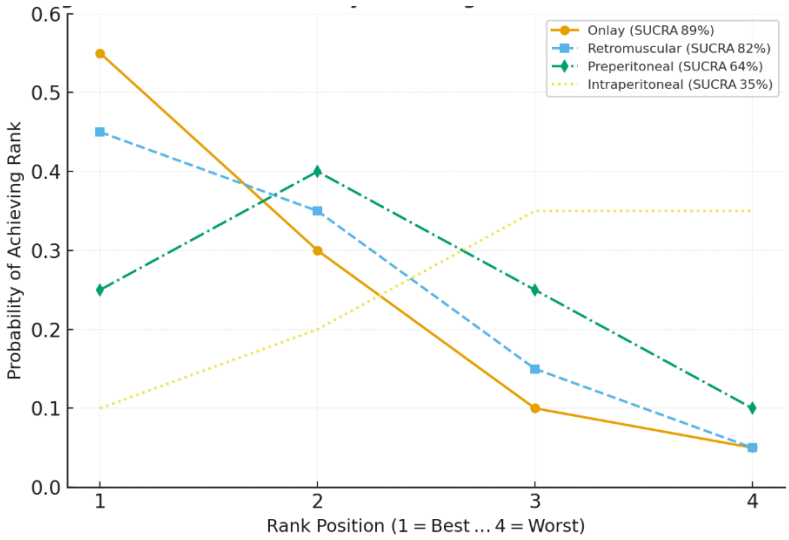


Figure 4. Network meta-analysis visualization—rankogram / SUCRA.

4. Discussion

4.1. Strength of evidence supporting prophylactic mesh

The totality of the current randomized evidence indicates that PMR at an elective midline laparotomy is an effective approach to decrease the IH in patients with increased risks. Current evidence suggests a possible benefit in patients with obesity, but conclusions remain limited by low-certainty data.

The PRIMA trial is a multicentre, two-dollar-blind trial that showed that a two-year IH with onlay and retromuscular (sublay) polypropylene reinforcements was lower than primary suture, and the effect was maintained for five years in time-to-event analyses [6,9]. These long-term estimates have

clinical implications, as most hernias proclaim beyond the initial year of postoperative care; thus, longevity augments causality beyond the initial outcomes of the wounds. Separate randomized trials with intraperitoneal composite mesh strips resulted in convergent findings that indicated approximately half the long-term IH's with traditional closures versus intraperitoneal composite mesh strips [11]. When combined, the updated meta-analysis of RCTs only reported a pooled risk ratio of about 0.4 of the IH, which suggests a significant and overall risk reduction in a heterogeneous environment and methodology [3].

These trials and pooled syntheses have safety signals, which are also informative. The incidence of the SSI is not usually augmented with PMR when the procedure is conducted in clean areas using a standardized method; yet, the incidence of seroma is more typical, especially with onlay use, which underscores a trade-off in wound management that is preventable, as opposed to a systemic infectious penalty [3,9]. There is further longitudinal audit data that reoperations that follow PRIMA have low absolute rates of mesh-related problems, where indication-driven explantation is rare and lower than a post-retromuscular placement among reoperated patients [10]. Combined, all the evidence indicates a moderate degree of certainty of PMR reducing the IH without having a significant effect on increasing the SSI, at the cost of a manageable increase in seroma [3,6,9,10].

Trial designs that were based on concealed allocation, blinded assessments (at least two years), objective imaging in equivocal cases, and intention-to-treat analyses methodologically support this conclusion [9]. The mixed high-risk indications and multi-center conduct help to strengthen the external validity; the consistency in the directionality of the meta-analysis, despite the between-studies differences in plane and material, help to strengthen internal validity [3]. The EHS recommends such an interpretation and supports a standardized small-bites midline closure in all patients and selective prophylactic support in high-risk groups [7]. Altogether, there is now evidence to incorporate PMR into perioperative interventions among patients with a high hernia risk when there are no complications in the operative conditions and the technical performance is standardized. The overall certainty of evidence is summarized in Figure 5.

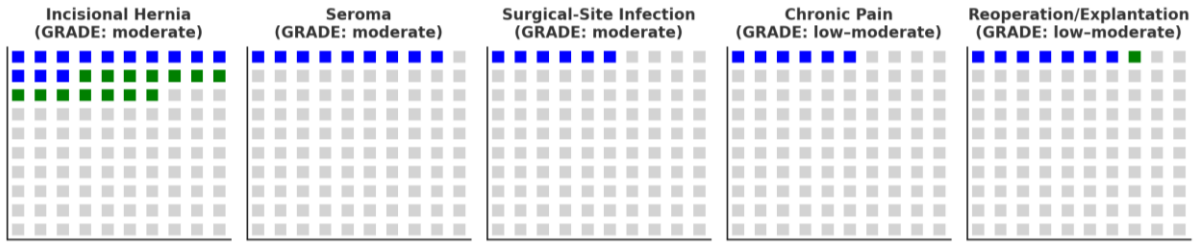


Figure 5. GRADE summary icon array of absolute effects.

4.2. Patient subgroups who benefit most

Identifying patients most likely to benefit from PMR hinges on the baseline IH risk and on how a mesh modifies the risk under specific biological and mechanical stressors. PRIMA enrolled high-risk adults defined by an abdominal aortic aneurysm or a BMI ≥ 27 kg/m² and showed benefits across these strata, thus implying that reinforcement is effective when tissue biology and midline strain are unfavorable [9]. In contrast, a meta-analysis restricted to obese cohorts suggested a favorable

directionally but statistically borderline effect (odds ratio ≈ 0.59, 95% CI 0.34–1.01), with authors grading the certainty as low because of the imprecision and heterogeneity in BMI thresholds, mesh planes, and follow-ups [5]. Interpreted together, these findings do not negate the benefits in obesity; rather, they suggest that some obesity-restricted datasets were underpowered or technically heterogeneous, and that risk enrichment beyond the BMI—such as poor perfusion, diabetes, or smoking—may sharpen the benefit-risk signal.

Subgroup syntheses suggest that patients with obesity may derive clinically relevant benefits from prophylaxis, but the evidence remains with a low certainty. The obesity-restricted meta-analysis by Timmermans et al. reported a favorable directionally, yet statistically non-significant, reduction in the IH (OR 0.59, 95% CI 0.34–1.01; p = 0.06), and individual RCTs are underpowered for strict BMI strata. Accordingly, our conclusions emphasize that the current data support a possible benefit of PMR in patients with obesity rather than definitively proving it and highlight the need for further targeted trials in this population.

Mechanically, an increment in the BMI raises tension intra-abdominal and subcutaneous dead space, which increases the tension at the linea alba and preconditions dehiscence, which is exactly the case when the load is distributed by retromuscular reinforcement and the peak stress is lowered. Diabetes contributes to impaired collagen remodeling and microvascular damage, prolongs the maturation of fascial strength, and may increase the time of vulnerability; smoking worsens the wound biology and perfusion [7]. Although the subgroup numerators are restricted in isolated studies, both the guideline stratification and the pooled RCT setting believe that patients with several risk elements, such as BMI ≥ 35 kg/m^2 and diabetes or active smoking, are a viable high-yield group in prophylaxis, given that the field is clean and that the technique is standardized [3,7]. Additionally, the network's meta-analysis suggests an anatomic plane to be of importance: the retromuscular and onlay positions are the highest in terms of IH prevention, which reveals that an absolute benefit can be further mediated by the plane in very high-risk profiles [8].

Practically, the perioperative pathways must include risk triage that extends beyond the BMI cut-offs to encompass the abdominal wall thickness, the anticipated time of operation, any history of midline scars, an exposure to steroids, and the need of early postoperative strains (e.g., cough, mobilization). In locations where they are concentrated, retromuscular polypropylene in clean elective environments offers a high default because of its long-term benefit and good safety profile in long-term PRIMA extensions [6]. On the other hand, the absolute benefit of prophylaxis might be less stable in less risk-patients with obesity (e.g., BMI 30–32 and no metabolic disease, short-surgery, optimal use of small-bites closure), and a suture-only approach would be reasonable and should be taken to ensure a meticulous technique [4,7]. Therefore, the subgroup narrative is less of a singular BMI but more of an accrued risk, airplane choice, and quality of execution in clean operating fields.

The obesity-restricted meta-analysis demonstrated a favorable directionally but statistically non-significant reduction in the IH (OR 0.59, p = 0.06), thus indicating that current data are underpowered to establish definitive benefits in this population.

4.3. Ongoing debates on mesh type, plane selection, infection risk, cost, and ethical aspects

Although there is a broad agreement that PMR reduces the IH risk in selected populations, several important controversies remain. Mesh plane and material selection continue to be actively debated. Network meta-analyses often favorably rank onlay and retromuscular placement compared with other

planes for IH prevention; however, onlay placement is associated with higher seroma rates, which are likely due to greater subcutaneous dissections. Importantly, long-term data from the PRIMA trial demonstrated comparable five-year outcomes between onlay and retromuscular (sublay) approaches, thus indicating that the current evidence does not conclusively support the superiority of retromuscular placement over onlay for IH prevention [13].

In addition, retromuscular placement may be associated with complications that are more complex to manage than those encountered with onlay mesh, and it requires a higher level of technical expertise. Additionally, the retromuscular plane is a relatively virgin surgical space, and its disruption may complicate a future abdominal wall reconstruction. Consequently, a retromuscular placement should not be considered a universal default and is best reserved for centers with specific abdominal wall expertise. Decisions regarding the mesh plane selection should be individualized, thereby taking the surgeon's experience, patient's anatomy, and institutional resources into account. Nonetheless, the retromuscular plane represents a valuable option for future abdominal wall reconstruction and should be preserved when possible.

Evidence comparing lightweight polypropylene meshes with biosynthetic or composite materials in a prophylactic setting remains limited and heterogeneous. Macroporous polypropylene meshes continues to be primarily supported by long-term PRIMA follow-up data, while comparative-effectiveness evidence for newer materials is sparse, thus underscoring an important gap in the current literature.

Not all clean surgical cases requiring PMR carry equivalent risks for surgical site infections. Careful stewardship—including timely antibiotic prophylaxis, meticulous hemostasis, minimization of dead space, and judicious drain use in patients with thick panniculus—is essential to reduce downstream complications. Data from the PRIMA reoperation audits suggest that the absolute rates of mesh-related reinterventions are low, with numerically fewer events following retromuscular placements compared with onlay in reoperated patients; however, these events are uncommon and confidence intervals remain wide.

A major methodological challenge in this field is the pooling of data across biologically and surgically distinct mesh planes, including onlay, retromuscular/sublay, preperitoneal, and intraperitoneal positions. These planes are not directly comparable: onlay placements involve greater subcutaneous dissections and dead space, thus predisposing to seroma formation, whereas retromuscular placements are more anatomically integrated but more invasive and technically demanding. Combining these approaches within shared analyses risks obscuring clinically meaningful plane-specific trade-offs. Future trials and meta-analyses should prioritize plane-stratified reporting to provide more actionable guidance on efficacy and safety.

Economic and ethical considerations further contextualize prophylactic mesh use. Although formal cost-effectiveness analyses remain limited, reductions in the IH incidence and reoperation rates may offset upfront costs through decreased healthcare utilization and productivity loss. Ethically, PMR should be guided by shared decision-making, with transparent discussions of expected benefits, seroma risk, uncertainty surrounding material choice, and long-term outcomes. Consent processes should clearly distinguish prophylactic from therapeutic mesh use and address field cleanliness, contamination risk, and alternative strategies. Pragmatic randomized trials that incorporate patient-reported outcomes, imaging-confirmed endpoints, and cost data are needed to clarify which patients derive the greatest cumulative benefit.

The outcome detection methodology represents another important source of heterogeneity. Studies that solely rely on clinical examinations may underestimate the IH incidence, particularly in

patients with increased subcutaneous adiposity. Imaging-based assessments using computed tomography or ultrasounds are more sensitive to detect small or asymptomatic hernias. Because this review included studies that employed both clinical and imaging-based detection, the potential for differential ascertainment biases should be considered when interpreting pooled estimates. Future research should formally assess the detection modality as a moderator of effect estimates.

Finally, the follow-up duration substantially varied across the included studies, with some reporting outcomes as early as 12 months. Shorter follow-up intervals may underestimate the true IH accrual, as demonstrated by the extended follow-up data from the PRIMA trial and long-term Kohler/Glauser cohorts. In this synthesis, the longest validated follow-up available for each cohort was prioritized; nevertheless, readers should cautiously interpret pooled short-term results, as they may not fully reflect long-term differences between interventions.

5. Limitations

This review has several limitations. The included studies varied in the BMI thresholds used to define high-risk or obesity cohorts, thus limiting the precision of obesity-specific inferences. Additionally, substantial heterogeneity was present in mesh plane selection, mesh materials, and surgical techniques. The outcome ascertainment differed across studies, with some solely relying on clinical examination and others incorporating systematic imaging, thereby introducing potential detection bias—particularly in patients with obesity. Additionally, the follow-up duration was inconsistent, and shorter follow-up intervals may underestimate the long-term IH incidence. These factors collectively constrain the certainty of pooled estimates and highlight the need for standardized, obesity-focused trials with long-term, imaging-validated outcomes.

6. Conclusion

This systematic review finds consistent, trial-level evidence that PMR at an elective midline laparotomy meaningfully lowers the IH risk in risk-enriched adults, without a corresponding rise in surgical-site infection (SSI)s. The principal safety trade-off is a higher rate of seroma—most evident with onlay placement and generally mitigable by careful hemostasis, dead-space control, and selective drainage. The benefits appear the greatest where the baseline risk is highest: patients with class II obesity or higher (particularly BMI $\geq$35 kg/m^2), diabetes, active smoking, prolonged or technically demanding procedures, or thick abdominal walls. Among the anatomic planes, retromuscular (retro-rectus/sublay) reinforcement balanced durable hernia prevention with a favorable reoperation profile and fewer wound-morbidity signals than onlay in the available data. However, PRIMA's primary analyses also showed strong, and in some strata, were numerically superior with hernia prevention with onlay at the cost of higher seroma rates; the retromuscular plane remains important for potential future reconstructive repair. For these reasons, a retromuscular mesh can be considered a preferred option in experienced centers, rather than a universal default, and decisions about the plane should incorporate the surgeon's expertise, patient's risk profile, and the anticipated need for future abdominal wall reconstruction.

Therefore, one should practice the pair standardized small-bites midline closure for all patients with selective mesh prophylaxis, guided by the cumulative risk, plane feasibility, and transparent shared decision-making, which explains the expected benefits and seroma risk. Major gaps in the

evidence are as follows: durability over long-term by material type (e.g. lightweight polypropylene vs biosynthetic); and comparative performance across planes amongst solely obese cohorts and more viable economies across health systems. The indications will be refined and maximally implemented on patients with the highest risks through future pragmatic RCTs and registries with imaging-verified outcomes and patient-reported measures.

In patients with obesity, the current evidence supports a possible but not definitive benefit of PMR, and decisions should be individualized based on the cumulative risk and surgical expertise.

Author' contributions

Omar Alaidaroos: Conceptualization, supervision, and final review. Raghad Ahmed: Writing – original draft, data curation, and manuscript preparation. Nabeel Aldinar: Data collection and analysis. Joud Asfari: Literature review and data extraction. Abdulrahman Alsarari: Methodology and validation. Sara Alqazanli: Data interpretation and editing. Norah abuwathlan: Literature screening. Abdulrahman Almasood: Statistical support. Lara Aljohani: Manuscript editing. Abdullah Bohairi: Final proofreading and approval. All authors have read and approved the final manuscript.

Use of AI tools declaration

The authors declare they have not used Artificial Intelligence (AI) tools in the creation of this article.

Conflict of interest

The authors declare no conflict of interest.

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