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Closure of Abdominal Wall - Status Quo

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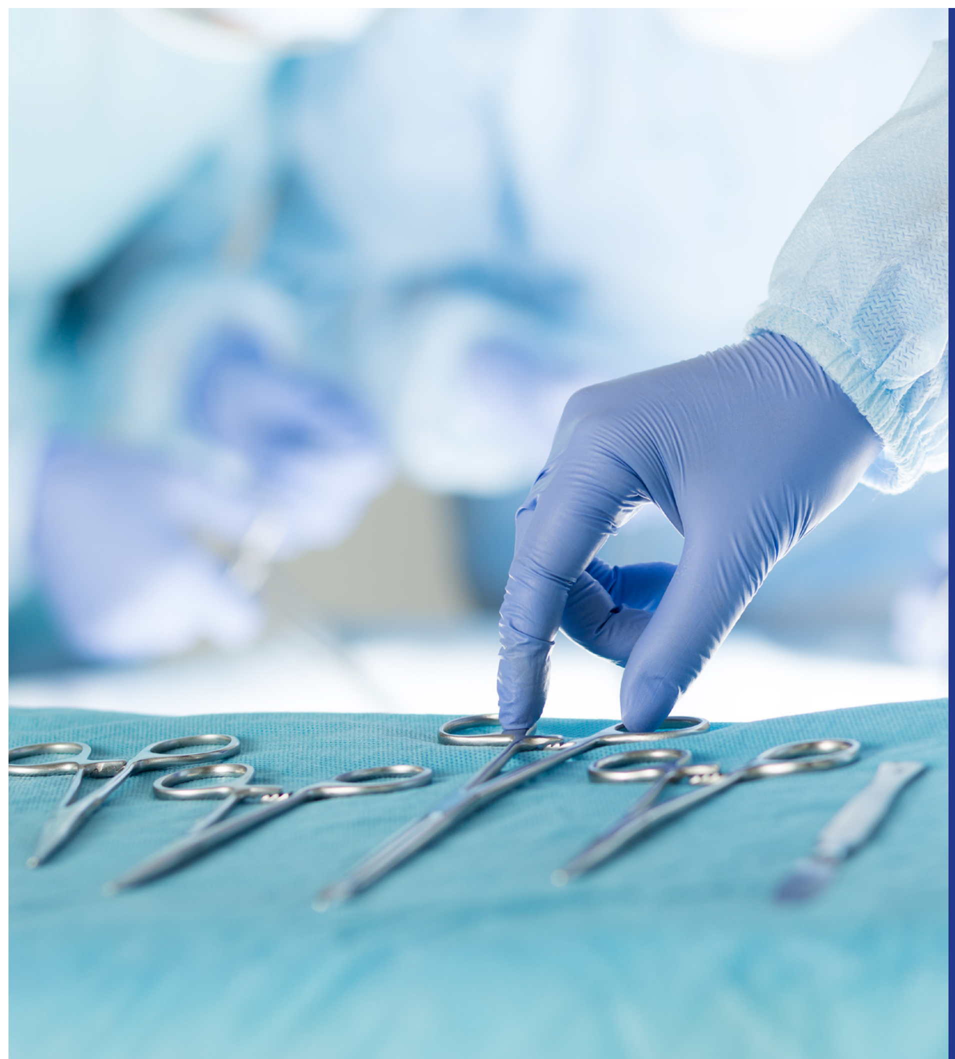

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Editorial: Closure of abdominal wall - status Quo

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Editorial on the Special Issue
Closure of abdominal wall - status Quo

Incisional hernia (IH) remains one of the most frequent complications following midline laparotomy, with an overall prevalence of approximately 10% and markedly higher rates in high-risk populations. Despite advances in surgical technique, prevention strategies are not uniformly implemented, particularly in emergency settings where patient-related risk factors are compounded.

Recent evidence highlights the importance of risk stratification. Surgical site infection and reoperation represent the most significant contributors to IH development, supporting a targeted and individualized preventive approach. Prophylactic mesh reinforcement has consistently demonstrated a reduction in IH incidence across meta-analyses; however, its clinical adoption remains limited due to increased risks of seroma and surgical site infection, as well as heterogeneity in study design and patient populations. Notably, randomized data in emergency laparotomy settings remain inconclusive, emphasizing the need for further investigation in high-risk cohorts.

Technical aspects of abdominal wall closure continue to play a central role. The small-stitch technique and meticulous tissue handling are key principles, with emerging technologies suggesting potential benefits in reducing tissue trauma and standardizing closure. In complex abdominal wall reconstruction, innovative approaches such as intraoperative fascial traction may facilitate high rates of primary fascial closure while reducing the need for extensive component separation.

Overall, a multimodal and risk-adapted strategy integrating optimized closure techniques, selective mesh reinforcement, and advanced reconstructive concepts appears essential. Future research should focus on high-quality randomized trials, standardized methodologies, and patient-centered outcomes to refine prevention strategies and improve clinical implementation.

Author contributions

RF contributed substantially to the conceptualization of the manuscript, literature review, drafting and critical revision of the manuscript, and approved the final version for publication. NH contributed to manuscript preparation, critical revision, and approval of the final manuscript. All authors contributed to the article and approved the submitted version.

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A Comparison of Tissue Handling Forces Between a Novel Suturing Device for Standardised Abdominal Wall Closure and Manual Needle-Driver Suturing

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Introduction: Suturing is a fundamental component of surgical procedures, wherein training emphasises the significance of gentle tissue handling. The suturing process involves the pressure exerted by the forceps onto the tissue, as well as the medial traction force applied to stabilise the tissue during the needle bite. This study examined the forces involved in tissue handling during suturing, comparing a novel suturing device for standardised abdominal closure with two sizes of curved suture needles (NDS).

Methods: A model was developed to measure suturing forces. The study introduction comprised both a written letter and an oral explanation. Participants performed 10x3 needle pull-throughs, using a large needle (36 mm, LN) and a small needle (26 mm, SN). Maximum forceps pressure and maximum medial traction forces were recorded. Additionally, needle pull-through time and the area under the curve (AUC) were calculated for both forceps pressure and medial traction pressure.

Results: The study involved 20 specialists, ten scrub nurses, and five surgical trainees. Of these participants, 22 were female, the average glove size was 6.9, and two were left-handed. The use of SutureTOOL resulted in significantly less force exerted with forceps ($p < 0.001$) when compared to NDS, and a shorter needle pull-through time ($p < 0.001$). No differences were observed in maximum traction force; however, the medial traction force AUC was lower for SutureTOOL and SN compared to LN ($p = 0.025$).

Conclusion: The study revealed that SutureTOOL required less forceps pressure and exerted either less or comparable traction force to perform needle pull-throughs, compared to traditional methods. We conclude that this innovative suturing technology did not increase the forces measured in the model. However, the impact on abdominal wall related complications requires further study.

Keywords: surgeon skill, suture forces, suturing technique, abdominal wall closure, surgical training

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INTRODUCTION

Suturing plays a crucial role in most surgical procedures. In training surgeons, a key emphasis is placed on manipulating tissue as gently as possible to minimise damage and enhance healing [1]. Attention to detail is essential throughout the surgical process, including the placement of the incision, minimal tissue manipulation during surgery, and the application of meticulous closure techniques [2].

Suturing involves the transmission of various forces to the tissue, which can be broadly categorized as follows: First, as the suture needle penetrates the tissue, the forceps apply counter-tension to stabilise it. Second, the interaction between the forceps and the advancing needle generates a horizontal force, leading to medial traction. Third, the tension exerted by the suture thread itself in the approximation of the tissue.

These forces are partly influenced by the friction between the suture and the tissue. Friction can be reduced by shortening the needle, using a smaller diameter needle, polishing the material, and applying a coating [3, 4]. Friction increases with the thickness of the suture thread and when multifilament sutures are used [5]. A fundamental issue with the curved suture needle is the difficulty in achieving a perfect circular suturing pathway while manoeuvring the needle with a needle holder, as the needle becomes buried in the tissue [6]. Surgeons also tend to waver the tip of the curved needle while attempting to reach the intended target [7]. Accuracy in following the intended suture pathway improves, and the force required to advance the needle is reduced when the needle-driver grasps the needle closer to the tip rather than at the non-sharp end [8]. Another method to reduce the force involved in suturing is palm grip suturing. The Frimand needle holder has been shown to reduce surgical stress by 62% compared to conventional needle-driver suturing [9].

In clinical practice, the majority of surgeons often complete laparotomy closure using large-bore sutures (USP 1, 43%–58%, and USP 0, 15%–28%) alongside large needles (LNs) (30–48 mm) [10, 11]. However, this practice does not align with guidelines that recommend the small-bites closure technique, for which the use of a small suture needle is essential [12–14].

When a tissue is manipulated or stabilised, the grasper or forceps exerts a crushing force on it. This crushing force is related to the histologically identified trauma to the tissue [15].

A novel suturing device, SutureTOOL, has been developed to facilitate rapid and standardised abdominal wall closure. The device transports a straight, double-pointed needle between two arms along a track that runs perpendicular to the fascia. This contrasts with the tangential needle track used when suturing with a curved needle, potentially influencing the forces exerted on the fascia during suturing.

The aim of this study was to compare suturing forces using the SutureTOOL with those from manual needle-driver suturing, which was tested using two different sizes of a standard suture needle.

METHODS

This was an experimental study comparing suturing forces between three different suture needles. Primary endpoint was forceps pressure required to stabilize the tissue. Secondary endpoints included medial traction force and needle pass-through time. The suturing needles assessed included a straight needle, used with the SutureTOOL (Suturion AB, Lund, Sweden), and two different sizes of semi-circular needles (**Figure 1**). Ethical approval was not necessary for this study.

SutureTOOL Suturing

SutureTOOL is a handheld suture applicator developed by the first author in collaboration with Lund University (Lund, Sweden). This device is detailed in prior studies [16, 17]. It features a handle and a straight, double-pointed needle with a centrally attached thread (**Figure 2**). When the device is compressed, the needle transfers between the jaws, enabling the advancement of the suture thread through tissue.

Needle-Driver Suturing

The manual needle-driver suturing technique (NDS) utilised a standard semi-circular suture needle and a manual needle-driver (Mayo-Hegar 16 cm, Stille AB, Sweden). Two sizes of curved suture needles were employed: a LN (PDS II Suture 2-0, CT-1 needle, Ethicon, Somerville, NJ, USA) and a small needle (SN) (PDS II Suture 2-0, CT-2 needle, Ethicon, Somerville, NJ, USA) (**Figures 1b,c**). Suture threads were cut close to the needle to enable individual measurement of multiple needle pass-throughs. A new suture needle was used for each participant.

Theoretical Model for Suturing With Straight and Curved Needles

Suturing with the SutureTOOL and a straight needle requires a single stabilising grasp for each tissue bite, with the suture track remaining perpendicular to the tissue (**Figure 3a**). In contrast, the NDS is controlled by the surgeon's hand and necessitates two stabilising grasps per bite, alongside repositioning of the needle in the needle-driver. The entry of the suture track is tangential to the tissue surface, possibly resulting in a longer track compared to that of a straight needle (**Figure 3b**).

Study Model

The first author developed a technical model designed to measure suturing forces by continuously recording both forceps pressure and medial traction force. A medical student conducted the tests independently of the other authors.

Forceps Pressure

A 4.5 kg load cell (FX29K0-100A-0010-L, TE Connectivity, Berwyn, Pennsylvania, United States) was installed on a 15 cm 3 × 4 claw forceps (Stille, Stille Surgical AB, Solna, Sweden) at the thumb position (**Figure 4c**). The load cell was connected to a microcomputer (Arduino Nano), and data were transferred and converted into an Excel data file using Serial Plot (Hasan Yavuz Özderya, Hackaday.io). The load cell was calibrated to record ten measurements per second. Before engagement, it transmitted values of approximately 1000 units. The maximum load capacity was 15,000 units, corresponding to 4,536 g.

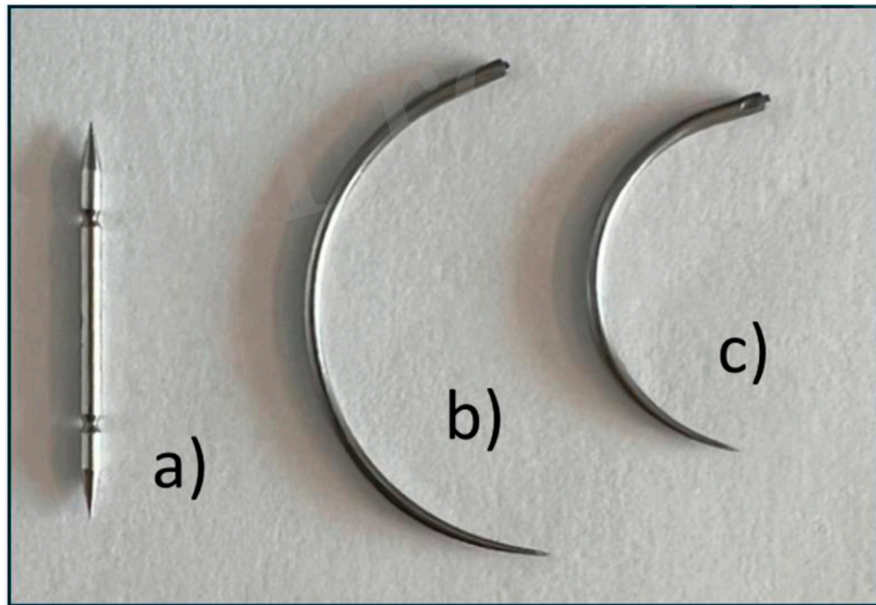

FIGURE 1 | Devices used in this study. **(a)** SutureTOOL double pointed needle, length 20 mm. **(b)** Large semi-circular needle, length 36 mm. **(c)** Small semi-circular needle, length 26 mm. All needles are taper-pointed.

FIGURE 2 | The SutureTOOL. The SutureTOOL handle **(a)** and SutureTOOL double-pointed needle **(b)**. When the device is compressed, the needle is transferred between the jaws and propels the suture thread through the tissue.

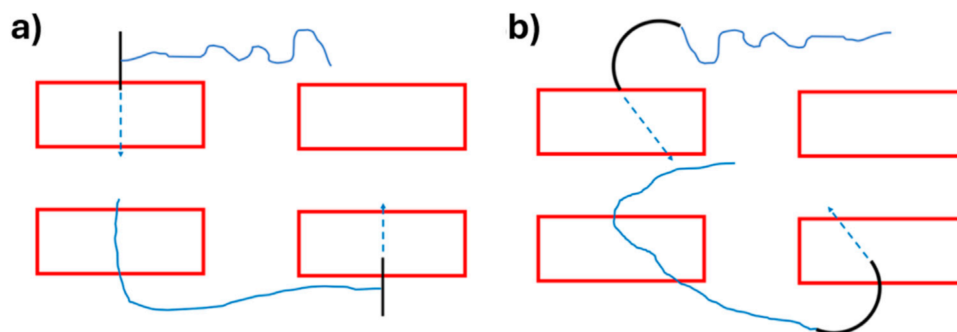

FIGURE 3 | Suture tracks with **(a)** Suture-TOOL suturing with a straight needle **(b)** suturing with a curved needle.

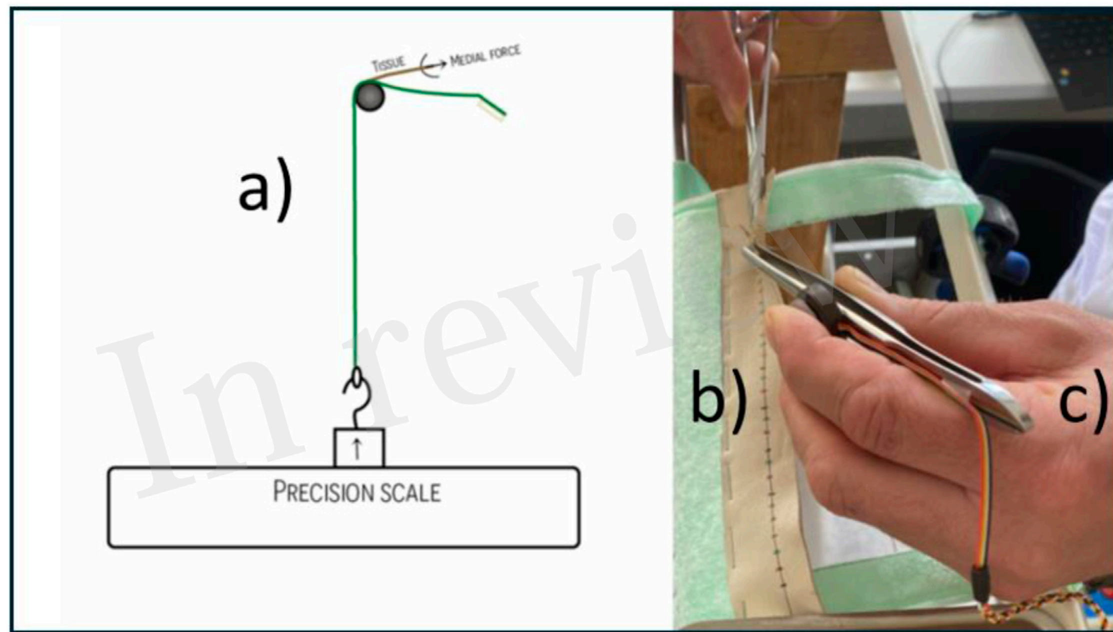

FIGURE 4 | A model to measure suturing forces. **(a)** Suture pad attached to a precision scale. **(b)** Lamb skin suture pad cross-marked for the individual needle pass-throughs. **(c)** Standard forceps with an attached load cell to measure stabilising pressure.

Medial Traction Force

The medial traction force was directed from the suturing pad to a precision scale (Model WLC 6/C1/R, Radwag Wagi Elektroniczne, Radom, Poland). Using a precision scale was previously described by Frimand Rönnow [9]. Data were transferred and converted into an Excel data file using Pomair Win (Vetek AB, Väddö, Sweden). The precision scale was configured to record five measurements per second (**Figure 4a**). The scale provided values in grams, requiring no additional transformation.

Suturing Pad

A 3 × 25 cm piece of lamb leather served as the suturing pad. Each pad displayed 30 cross-marks in green, blue, and red, spaced at 5 mm intervals along a line located 5 mm from the edge of the pad (**Figure 4b**). The pad was mounted on a stance specifically developed to measure suturing forces. A new suturing pad was used for each participant.

Data Analysis

Forceps pressure data and median traction data were adjusted to a baseline of zero and filtered to eliminate signal noise between recorded waves. The duration and maximum amplitude of each individual wave was measured. The AUC for each wave was calculated by summing the amplitudes and multiplying by the measurement interval.

Wave duration, maximum amplitude, and AUC were calculated for the SutureTOOL, LN, and SN. For each participant, a mean value was determined. The data was reported as mean and standard deviation (SD).

The data were analysed using SPSS Statistics for Windows, version 26.001 (SPSS Inc., Chicago, Ill., USA), employing the analysis of variance (ANOVA) procedure. The significance level was set at 5%. For *post hoc* analysis, the Bonferroni adjustment was applied. Data analysis was performed by co-author PR. PR have no financial interest in the investigational device.

Participants and Instructions

Specialists in operating specialities, scrub nurses, and surgical trainees were invited to participate and were assigned according to their schedule availability. Participant characteristics collected included age, sex, years in training, subspecialty, glove size, and whether the participant was a nurse or surgeon. The introduction to the study provided both oral and written instructions. Before the test began, participants received brief training on both SutureTOOL and NDS suturing using a separate training model. Individual training time was recorded for SutureTOOL and NDS. Participants performed ten needle pull-throughs with each technique–SutureTOOL and NDS–using LN and SN. Forceps pressure and traction force were recorded for each needle pull-through. The needle pull-through time, as well as maximum force and AUC forces, were calculated. Needle pull-through time was recorded from the first to the last step in the sequences outlined in **Figure 5**.

RESULTS

The participants comprised 20 specialists, ten scrub nurses, and five surgical trainees. Of these, 22 were female, with a mean glove

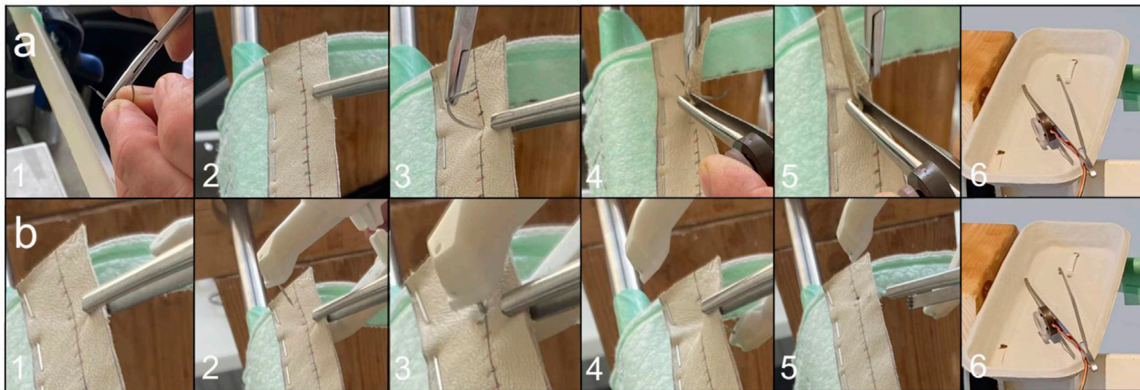

FIGURE 5 | Sequence of a needle pull-through with **(a)** NDS and **(b)** SutureTOOL. **(a)** NDS: 1. Positioning the needle in the needle-driver 2. Grasping the suture pad 3. Penetrating the pad with the curved needle 4. Pushing the needle 5. Pulling the needle through the pad 6. The forceps is placed in the tray. **(b)** SutureTOOL: 1. Grasping the suture pad 2. Positioning the SutureTOOL 3. Compressing the device 4. The straight needle is pulled through the tissue pad by releasing the compression of the SutureTOOL 5. The needle is released from the pad 6. The forceps is placed in the tray.

TABLE 1 | Test outcomes.

Outcome	SutureTOOL (n = 35)	NDS		*p*
		LN (n = 35)	SN (n = 35)	
Maximum forceps pressure, g	944 (421.9)	1072 (454.3)	1128 (501.6)	p < 0.001
Forceps pressure AUC, gs	1314 (936.8)	1831 (772.9)	1702 (832.2)	p < 0.001
Maximum traction force, g	60 (56.8)	62 (44.8)	54 (49.8)	p = 0.105
Traction force AUC, gs	140 (234.3)	172 (161.3)	139 (160.4)	p = 0.025
Needle-pull through time, s	3.4 (2.15)	4.4 (2.12)	3.9 (1.90)	p < 0.001

Values are mean, standard deviation within brackets. NDS, needle-driver suturing. LN, large needle (CT1). SN, small needle (CT2). g, grams. gs, gram times seconds. AUC, area under curve. P value depicts the difference between groups according to ANOVA, prior to post hoc analysis.

size of 6.9, and two participants were left-handed. The training duration was 4 min and 5 s for SutureTOOL and 2 min and 19 s for NDS. SutureTOOL resulted in less pressure force than NDS (p < 0.001) and a shorter needle pull-through time (p < 0.001). Although no differences were found in maximum traction force, the medial traction force AUC was lower for both SutureTOOL and SN compared to LN (p = 0.025). Test outcomes are detailed in **Table 1**, and typical recordings are presented in **Figure 6**. Key metrics from ANOVA are depicted in **Figure 7**.

DISCUSSION

To our knowledge, this is the first study to compare forceps pressure force and medial traction force during suturing with a straight needle and two sizes of NDS needles. The results demonstrated that SutureTOOL required less forceps force compared to both sizes of NDS needles, and it also required lower medial traction force compared to the larger LN needle. These findings are important, as SutureTOOL represents a novel technique for fascia approximation after laparotomy. The forces necessary to stabilise and apply traction to tissue can potentially cause damage. Excessive medial traction force may tear the fascia, increasing the risk of impaired wound healing and incisional hernia formation. The device must not exert greater traction force than the current gold standard, NDS [1]. Although the exact crushing force that fascia can tolerate is unknown, surgeons should adhere to the precautionary principle. Rodrigues et al. investigated the relationship between tractive forces and tissue damage in different porcine abdominal organs [1]. Authors found that fascia and aorta had the highest tolerance, while uterus and fallopian tube had the lowest. Fascia was damaged at a median tractive force of roughly 11.5 N. The maximum mean traction force in this study was 62 g and the highest recorded value was 440 g, which corresponds to 0.6 N and 4.3 N respectively. Assuming the findings are comparable, the forces recorded in the study was less than at risk of rupturing the fascia.

The medial traction force was lower for SutureTOOL and SN compared to LN. LNs are commonly used for laparotomy closure following open surgery, despite the recommendation for smaller needles to facilitate the small-bites closure technique [10, 11, 14]. A major disadvantage of LNs is their use of unnecessarily large-bore suture threads, which result in higher tissue friction [5]. Several clinical trials have demonstrated that a suture bore of USP 2/0 is sufficient for the small-bites closure technique [18–20]. Small needles offer the advantage of taking smaller tissue bites and encourage the

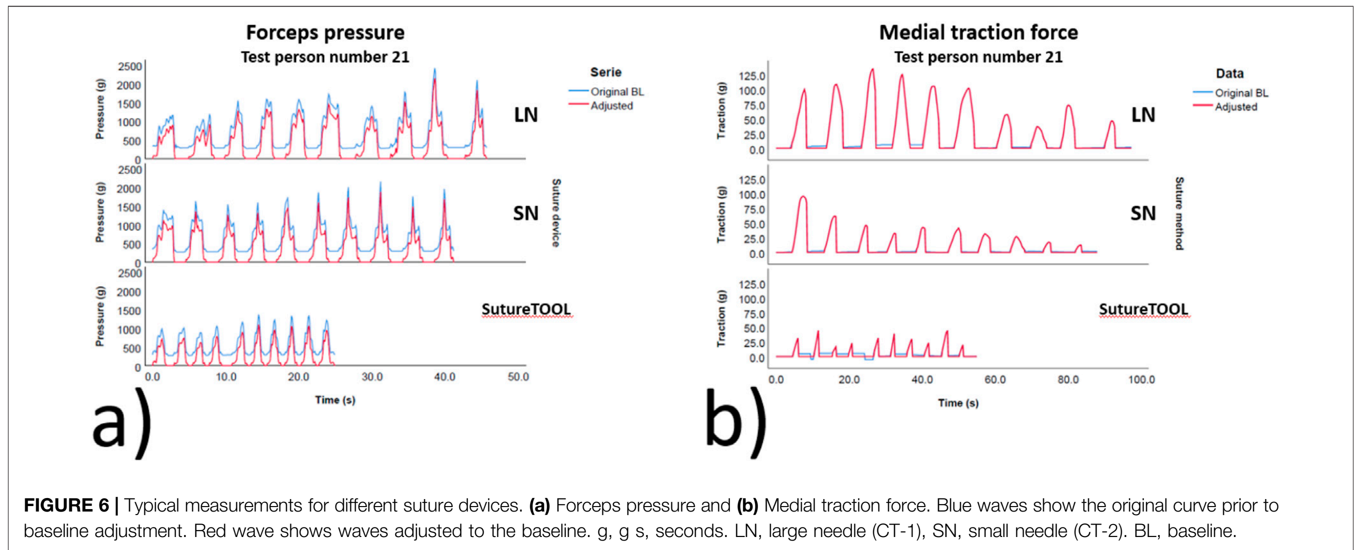

FIGURE 6 | Typical measurements for different suture devices. **(a)** Forceps pressure and **(b)** Medial traction force. Blue waves show the original curve prior to baseline adjustment. Red wave shows waves adjusted to the baseline. g, g s, seconds. LN, large needle (CT-1), SN, small needle (CT-2). BL, baseline.

ANOVA

a) Maximum forceps pressure (g)

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	6084701.323	2	3042350.661	14.325	0.000
Within Groups	221086696.9	1041	212379.152		
Total	227171398.2	1043			

ANOVA

b) Maximum forceps pressure AUC (gs)

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	4996395527	2	2498197763	34.682	0.000
Within Groups	7.498E+10	1041	72031277.53		
Total	7.998E+10	1043			

ANOVA

c) Maximum traction force (g)

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	11607.382	2	5803.691	2.263	0.105
Within Groups	2634056.537	1027	2564.807		
Total	2645663.918	1029			

ANOVA

d) Maximum traction force AUC (gs)

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	260232.875	2	130116.438	3.685	0.025
Within Groups	36261658.47	1027	35308.333		
Total	36521891.35	1029			

ANOVA

e) Needle pull-through time (s)

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	92.225	2	46.112	14.349	0.000
Within Groups	3300.298	1027	3.214		
Total	3392.523	1029			

FIGURE 7 | ANOVA table for mean adjusted data **(a)** Maximum forceps pressure **(b)** Maximum forceps pressure AUC **(c)** Maximum traction force **(d)** Maximum traction force AUC **(e)** Needle pull-through time. g, grams. df, degrees of freedom. F, F-statistic. Sig., significance level.

surgeon to limit the bite to the midline aponeurosis exclusively. The study indicates that small needles reduce the amount of force imposed on tissue, which can be beneficial for wound healing.

Incision closure time has previously been shown to be shorter with SutureTOOL, with 95%–100% adherence to the small-bites closure technique demonstrated in animal tissue models, cadaver models, and clinical trials [16, 17, 21]. In this study, the pull-through time with SutureTOOL was shorter compared to LN and SN. Laparotomy closure using the small-bites technique after open surgery can take 18–30 min [18, 22]. Reducing small-bite closure time is crucial for implementing this technique, as some surgeons consider the extra time required an obstacle [23]. A reduction in laparotomy closure time also provides an opportunity to reallocate limited surgical resources to more patients.

Many surgical tasks rely heavily on individual proficiency. Seki introduced the term *surgeotechnology* to underscore the importance of teaching and assessing basic surgical skills, such as suturing and knot tying, which can significantly impact patient outcomes [7]. Conway demonstrated considerable variation among surgeons when estimating the distance for suture placement [24]. In a study by von Trotha regarding knot tying, the final tension varied from 0.19 to 10 N among 118 surgeons, highlighting the substantial differences in this fundamental skill [25].

Several limitations of the study need to be addressed. The lamb patches were cut from a single sample of leather, why the

individual patches were considered comparable in strength. Lamb skin is probably tougher to penetrate compared to human fascia due to it being tanned and lacks lubrication and an exaggeration of the measured forces would be expected. The clinical relevance of the study is not predictable by the findings. The aim was to assess if the straight needle, as being part of a novel fascia closure method, imposed more forces compared to the standard curved needles. The study found comparable forces among the studied needles in the model and the potential difference in tissue damage and healing needs to be addressed in future clinical studies.

Another limitation of the study is the limited training. The scrub nurses have less experience in suturing and the overall results would probably have benefited from performing the study after formal training and proficiency examination.

The SutureTOOL propels the straight needle between its arms perpendicularly, unlike the NDS, where the needle is passed through tissue tangentially. Furthermore, the surgeon does not need to manipulate the needle to reach the target, as the SutureTOOL includes a guide for placing small bites with high accuracy [21]. According to Seki, handling a curved needle in tissue involves wavering the needle tip, which may potentially harm the tissue [7]. Although the clinical relevance of this wavering is unknown, it would be worthwhile to compare the passage accuracy through tissue of the SutureTOOL and NDS in a future study.

Surgical procedures are often lengthy and strenuous. The risk of complications rises with extended operating times, and there is a correlation with surgeon fatigue [26, 27]. The SutureTOOL requires fewer steps to place the suture line, and adherence to small-bite techniques is high. The next steps involve studying adherence to the small-bites closure technique and comparing surgical site occurrences between the SutureTOOL and NDS in settings involving patients undergoing long operations, such as debulking or transplantation surgery.

CONCLUSION

The study demonstrated that SutureTOOL required less forceps pressure and exerted equal or reduced traction force for needle pull-throughs compared to traditional suturing methods. We conclude that this innovative suturing technology did not increase the forces measured in the model. However, the impact on abdominal wall related complications requires further study.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

AUTHOR CONTRIBUTIONS

Conceptualization: GB and EL. Data curation: EL, PR, and ME. Formal analysis: GB, PR, and ME. Investigation: GB and EL. Methodology: GB, EL, PR, and ME. Project administration: GB and EL. Supervision: PR and ME. Validation: GB, PR, and ME. Visualization: GB, EL, and PR. Writing – original draft: GB, EL, PR, and ME. Writing – review and editing: GB, EL, PR, and ME. All authors contributed to the article and approved the submitted version.

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CONFLICT OF INTEREST

GB is the inventor, founder, and shareholder of Suturion AB, located in Lund, Sweden.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Efficacy and Safety of Prophylactic Mesh Reinforcement for the Prevention of Incisional Hernia: An Umbrella Review of Meta-Analyses

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Introduction: Incisional hernia (IH) is a frequent and expensive complication of laparotomy, occurring in up to 50% of high-risk patients. Although prophylactic mesh placement has been proposed as an effective preventive strategy of IH, its adoption remains limited due to concerns about mesh-related complications and the heterogeneity and variable quality of the available evidence. This umbrella meta-analysis aimed to synthesize the existing evidence to evaluate the efficacy and safety of prophylactic mesh reinforcement for IH prevention.

Methods: A systematic search of multiple databases was performed until June 2025 to identify meta-analyses comparing the use of prophylactic meshes versus primary closure in adults undergoing laparotomy. Methodological quality was assessed with the AMSTAR-2, and the data were reanalyzed with random or fixed effects models. Heterogeneity (I^2), study overlap (CCA), publication bias, and robustness of the results were evaluated.

Results: Twenty-one meta-analyses were included. Prophylactic mesh reinforcement was associated with a significant reduction in the odds of incisional hernia (OR = 0.29; 95% CI: 0.22–0.38); this effect was consistent across different surgical settings. Mesh use was also associated with an increased risk of surgical site infection (OR = 1.17; 95% CI: 1.04–1.30) and seroma formation (OR = 2.31; 95% CI: 1.99–2.67). No significant differences were observed in abdominal wound dehiscence or hematoma. Overall, the evidence demonstrated a large and consistent effect, although substantial heterogeneity and signs of publication bias were present.

Conclusion: Prophylactic mesh reinforcement is associated with a reduced likelihood of incisional hernia but an increased risk of seroma and surgical site infection. Its use should be considered selectively in high-risk patients, balancing potential benefits against known

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complications. Further studies are needed to optimize patient selection and evaluate strategies to reduce mesh-related adverse outcomes, as well as to assess cost-effectiveness and quality-of-life outcomes.

Keywords: abdominal wound dehiscence, incisional hernia prevention, midline laparotomy, prophylactic mesh, umbrella review

INTRODUCTION

Incisional hernia (IH) is the most significant complication of laparotomy, with an incidence of 10%–30% in elective surgeries and up to 50% in high-risk patients [1, 2]. The development of this condition entails high healthcare costs and the need for frequent reoperations [3]. The significant clinical and economic burden associated with this complication calls for the use of preventive strategies. Currently, these efforts are focused on optimizing abdominal wall closure techniques and on the selective use of prophylactic mesh, for which multiple clinical trials have already been published [1].

The meshes applied in the abdominal wall (both for the prophylactic and direct management of IH) mainly function by increasing the tensile strength of the fascia. This resistance must be sufficient to counteract the forces that are exerted on the abdominal wall during activities daily life. Generally, most commercially available meshes exceed the tensile strength required to withstand these physiological forces [4]. However, mechanical failure has been reported to be associated not only with the properties of the material but also with patient risk factors, such as increased intra-abdominal pressure (due, e.g., to obesity), weakness of the connective tissue (as occurs when an aneurysm is present in the abdominal aorta) or the presence of surgical site infections. These conditions can compromise mesh performance and are related to failure to prevent hernia development or recurrence [5].

Although prophylactic mesh placement has been shown in several studies to significantly reduce the incidence of IH compared with primary closure [6], most surgeons do not use it for this purpose. Additionally, only 45% of surgeons claim to be familiar with the literature and use the meshes for this purpose [7]. The main reason for not using these meshes is a fear of infections or other associated complications, reflecting uncertainty regarding morbidity and appropriate patient selection, despite several meta-analyses reporting no overall increase in major complications [7, 8].

Although global evidence indicates a benefit from the use of prophylactic mesh, guidelines such as those of the European Hernia Society (EHS) recommend caution prior to its application, given that the quality of the evidence is low and the strength of the recommendations is weak. This caution is not only related to the heterogeneity and variable quality of the available evidence, but also to concerns regarding mesh-related morbidity and the lack of clear patient-level risk stratification to identify those most likely to benefit. Specifically, the indications for prophylactic mesh use have been evaluated in very different clinical settings (emergency surgery, obese patients, and aortic aneurysms, among others), and the mesh positions, materials and placement techniques differ among the studies. This variability has prevented the implementation of universal and widely applicable recommendations [9, 10].

Although multiple meta-analyses have addressed specific populations and scenarios, no integrative synthesis has systematically compared and ranked the evidence on the use of prophylactic meshes in laparotomy. An umbrella meta-analysis represents the most appropriate methodology for addressing this gap in the field, as it allows the results of different meta-analyses to be reanalyzed uniformly while evaluating the robustness of the findings, quantifying study overlap and classifying the strength of the evidence [11]. Therefore, the objective of this study was to perform an umbrella meta-analysis of the meta-analyses that have been published on this topic, in order to evaluate their effectiveness and safety in the prevention of IH. The findings of this review could provide a solid basis for the development of clinical practice guidelines and international consensus, as they would represent one of the highest levels of evidence in the methodological hierarchy.

METHODS

Protocol and Registration

An umbrella meta-analysis was performed and reported in accordance with corresponding guidelines, including the Preferred Reporting Items for Overviews of Reviews (PRIOR) [12] and Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [13]. This study was registered with the hospital research and research ethics committees of the hospital (registration numbers: CEI/HRAEB/004/2025 and CEI-002-2025) and in the International Registry for Prospective Systematic Evaluation (PROSPERO, registration number: CRD420251125560) [14].

Search Strategy

A systematic search of the English-language literature was performed in the PubMed, The Cochrane Library, SCOPUS, ScienceDirect, and Google Scholar databases from inception to June 30, 2025.

A combination of controlled terms (MeSH) and free terms was used to maximize the sensitivity of the search strategy. Similarly, the bibliographic references of the included studies were manually reviewed to identify relevant articles that may have been missed in the automated search. The search terms included ("Incisional Hernia" [tiab] OR "Abdominal Wall Hernia" [tiab]) AND ("Mesh" [tiab] OR "Prophylactic Mesh" [tiab] OR "Mesh Reinforcement" [tiab]) AND ("Laparotomy" [Mesh] OR

"Abdominal Surgery" [tiab] OR "Midline Laparotomy" [tiab]) AND ("Systematic Review" [Publication Type] OR "Meta-Analysis" [Publication Type] OR "systematic review" [tiab] OR "meta-analysis" [tiab]) (**Supplementary Table A**).

Inclusion Criteria

This umbrella meta-analysis included only systematic reviews with meta-analyses that provided pooled estimates of at least one of the main outcomes. Studies that met the following PICO criteria were eligible: P (population), adult patients undergoing laparotomy in different surgical settings (including elective, emergency, high risk, abdominal aortic aneurysm, and bariatric surgery, among others); I (intervention), prophylactic mesh placement during laparotomy closure, regardless of the placement plane (onlay, sublay, preperitoneal, or retromuscular) or the type of material used (permanent synthetic, absorbable, or biological); C (comparator), conventional primary closure without the use of a prophylactic mesh; and O (outcomes), including primary outcomes (incidence of IH) and secondary outcomes (mesh-related complications such as SSIs, seroma, chronic pain, and reoperation). Only meta-analyses that presented the full text available in English were included.

Exclusion Criteria

Narrative reviews, scoping reviews or systematic reviews without quantitative meta-analyses; original articles, editorials, letters to the editor or experimental studies in animals; studies that were exclusively performed in the pediatric population, adolescents or pregnant women; and meta-analyses that exclusively compared different mesh placement techniques without including a primary closure group.

Selection of Studies and Quality Assessment

Two investigators independently performed the study selection and data extraction processes. The titles and abstracts were subsequently reviewed for preliminary study selection. Finally, a complete reading of the selected texts was performed to determine their eligibility according to the previously defined inclusion and exclusion criteria. Disagreements were resolved via discussion between the investigators; if disagreements persisted, a third evaluator was consulted to make the final decision. The information extracted from each study included the name of the first author, year of publication, country of origin, type of surgery, sample size, follow-up, number of IH patients and reported complications.

Assessment of Methodological Quality

The methodological quality of the included systematic reviews was assessed independently by two researchers with the AMSTAR (A MeaSurement Tool to Assess systematic Reviews) 2 tool [15]. This tool is specifically designed to evaluate systematic reviews through 16 items encompassing critical domains. The tool classifies the confidence in the results of each review as follows: high confidence, which indicates no critical weaknesses; moderate confidence, which indicates one critical weakness; low confidence, which indicates more than one critical weakness; and critically low confidence, which indicates a relatively large number of critical weaknesses. In this umbrella meta-analysis, only systematic reviews classified as moderate to high quality according to the AMSTAR 2 were included.

Statistical Analysis

The data were extracted from the included meta-analyses and reanalyzed to guarantee a uniform methodology in the calculation of the risk estimates. Statistical analysis was performed in R Studio (version 1.4.1106) with the R programming language (version 4.3.0) and the metaumbrella package, as well as functions from the meta and metafor packages. The measures of association (OR) were log transformed and subsequently reported in their original metrics via the corresponding exponential.

Statistical heterogeneity was assessed by using the I^2 statistic and the Cochran Q test. Heterogeneity was considered to be low when I^2 was <50% and high when I^2 was >50%. In addition, τ^2 was calculated as an estimator of the variance between studies. Depending on the degree of heterogeneity, a fixed-effects or random-effects model (DerSimonian–Laird method) was applied. Similarly, 95% prediction intervals (95% PIs) were calculated for each association to estimate the expected variability of the effects in future studies. Forest plots were constructed to visualize the main associations in terms of outcomes and clinical contexts.

The robustness of the findings was evaluated via sensitivity analysis by sequentially eliminating each included meta-analysis (via the leave-one-out method) and recalculating the global estimate. A result was considered to be robust when the exclusion of an individual study did not substantially modify the magnitude, direction or statistical significance of the effect. Publication bias was assessed by using Egger's regression (considered to be significant if $p < 0.10$ in analyses with ≥10 studies).

The overlap of the primary studies between meta-analyses was quantified with the corrected covered area (CCA) index, which was calculated with the following formula:

$$CCA = \frac{N - r}{(r^{*}c) - r}$$

where N is the total number of primary study citations (counting duplicates), r is the number of unique primary studies, and c is the number of included meta-analyses. The interpretation was categorized as follows: 0%–5% (slight overlap), 6%–10% (moderate overlap), 11%–15% (high overlap), and >15% (very high overlap) [16]. Finally, the strength of the evidence was classified according to the criteria proposed by Ioannidis and Fusar-Poli, with the evidence being stratified as strong, highly suggestive, suggestive, weak or not significant [17].

RESULTS

Study Selection

After searching the different databases, a total of 802 records related to the topic were identified. Following the removal of 618 duplicate articles, 184 records remained for screening. After

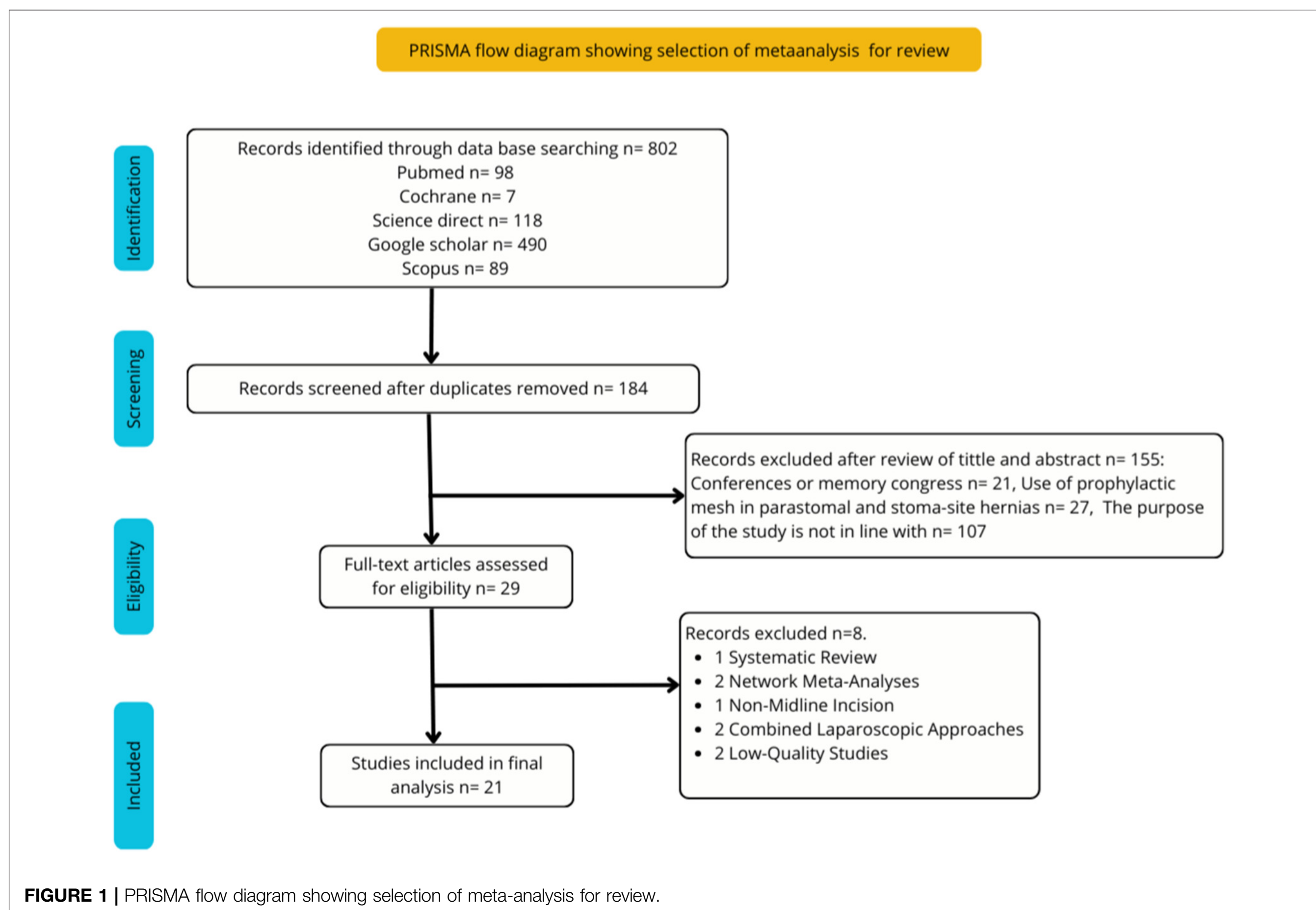

FIGURE 1 | PRISMA flow diagram showing selection of meta-analysis for review.

title and abstract review, 155 articles were excluded for not meeting the inclusion criteria. Consequently, 29 full-text articles were assessed for eligibility. Of these, 8 meta-analyses were excluded after full-text evaluation due to methodological or conceptual reasons, including low methodological quality according to AMSTAR-2 [2], network meta-analysis design [2], non-midline incisions [1], or combined laparoscopic approaches [2]. Finally, 21 meta-analyses were included in the umbrella meta-analysis [1–3, 5, 18–34]. The detailed study selection process and reasons for exclusion are presented in **Figure 1**.

Study Characteristics

The included studies were published by researchers in multiple countries, including the United Kingdom [6], the United States [5], the Netherlands [3], Brazil [2], Italy [2], and Germany, Canada and Egypt (one study each). In terms of the type of surgery, 10 studies involved general surgery (elective and emergency), 3 studies involved elective surgery alone, 3 studies involved emergency surgery alone, 3 studies involved abdominal aortic aneurysm surgeries, and 2 studies involved bariatric surgery. **Table 1** describes the characteristics of the studies. All studies with adequate methodological quality were evaluated via the AMSTAR 2 scale (**Supplementary Table B**).

Efficacy: IH and AWD

Incisional Hernia

The umbrella meta-analysis revealed that the use of a prophylactic mesh reduces the risk of IH compared with primary closure. The global estimate yielded an OR of 0.29 (95% CI: 0.22–0.38), which corresponds to a relative risk reduction of approximately 71% (**Figure 2**). The sensitivity analysis by type of surgery revealed that the effect was maintained in elective and emergency procedures as well as in specific populations (including bariatric and AAA surgery patients). Comparisons between meta-analyses with ≥10 studies and those with <10 studies did not reveal changes in the direction or magnitude of the effect (**Table 2**).

The overall heterogeneity was high ($I^2 = 81.5\%$). The funnel plot showed asymmetry, and the results of the Egger test were significant ($p = 0.008$), thus suggesting publication bias (**Supplementary Figure A**). The leave-one-out analysis confirmed that the results were stable; specifically, after each meta-analysis was sequentially excluded, the OR remained between 0.30 and 0.42, thus excluding the greatest influence of an individual study (**Supplementary Figure B**).

Overlap analysis of the primary studies included in the meta-analyses revealed a CCA index of 0.18, indicating a moderate degree of overlap [35]. Thirty-eight unique studies were identified as the basis of the available evidence.

Global analysis of excess significance revealed that the number of studies with observed positive results (n = 20) was greater than

TABLE 1 | Characteristics of the included studies.

Author(Year)	Country	Patients included	Studies included	Type of patient	AMSTAR 2 rating	Follow up mean
Abbas et al. [18]	Egypt	2,233	15	Elective	MOD	39
Aiolfi et al. [19]	Italy	2,332	14	General	HIGH	32
Olavarría et al. [20]	USA	1,768	15	General	MOD-HIGH	24
Albendary et al. [21]	UK	817	6	Emergency	HIGH	11
Jairam et al. [5]	USA	1,815	12	General	HIGH	32
Hew et al. [22]	UK	487	5	AAA	HIGH	43
Bhangu et al. [23]	UK	588	7	General	MOD	28
Pianka et al. [24]	Germany	1,136	5	Bariatric	HIGH	32
Borab et al. [25]	USA	2,114	14	Elective	HIGH	28
Burns et al. [26]	UK	288	2	Emergency	MOD-HIGH	16
Chou et al. [3]	USA	2,900	19	General	HIGH	29
Dasari et al. [2]	USA	1,095	7	Bariatric	HIGH	17
Frassini et al. [27]	Italy	2,659	16	General	HIGH	33
Indrakusuma [1]	Netherlands	388	4	AAA	HIGH	30
Nachiappan et al. [28]	UK	1,219	9	Elective	HIGH	32
Hassan et al. [30]	Canada	916	7	General	MOD-HIGH	27
Timmermans et al. [31]	Netherlands	346	5	General	HIGH	34
Marcolin et al. [32]	Brazil	464	4	Emergency	HIGH	15
Valerio-Alves et al. [33]	Brazil	2,108	15	General	HIGH	24
Payne et al. [29]	UK	727	8	General	MOD-HIGH	33
van der Berg et al. [34]	Netherlands	493	5	AAA	MOD-HIGH	24

Type of patient. General: refers to meta-analyses that included both elective and emergency patients. AMSTAR 2 Rating: MOD: Moderate Quality, HIGH: High Quality, MOD-HIGH: moderate-high quality. AAA: Abdominal Aortic Aneurysm

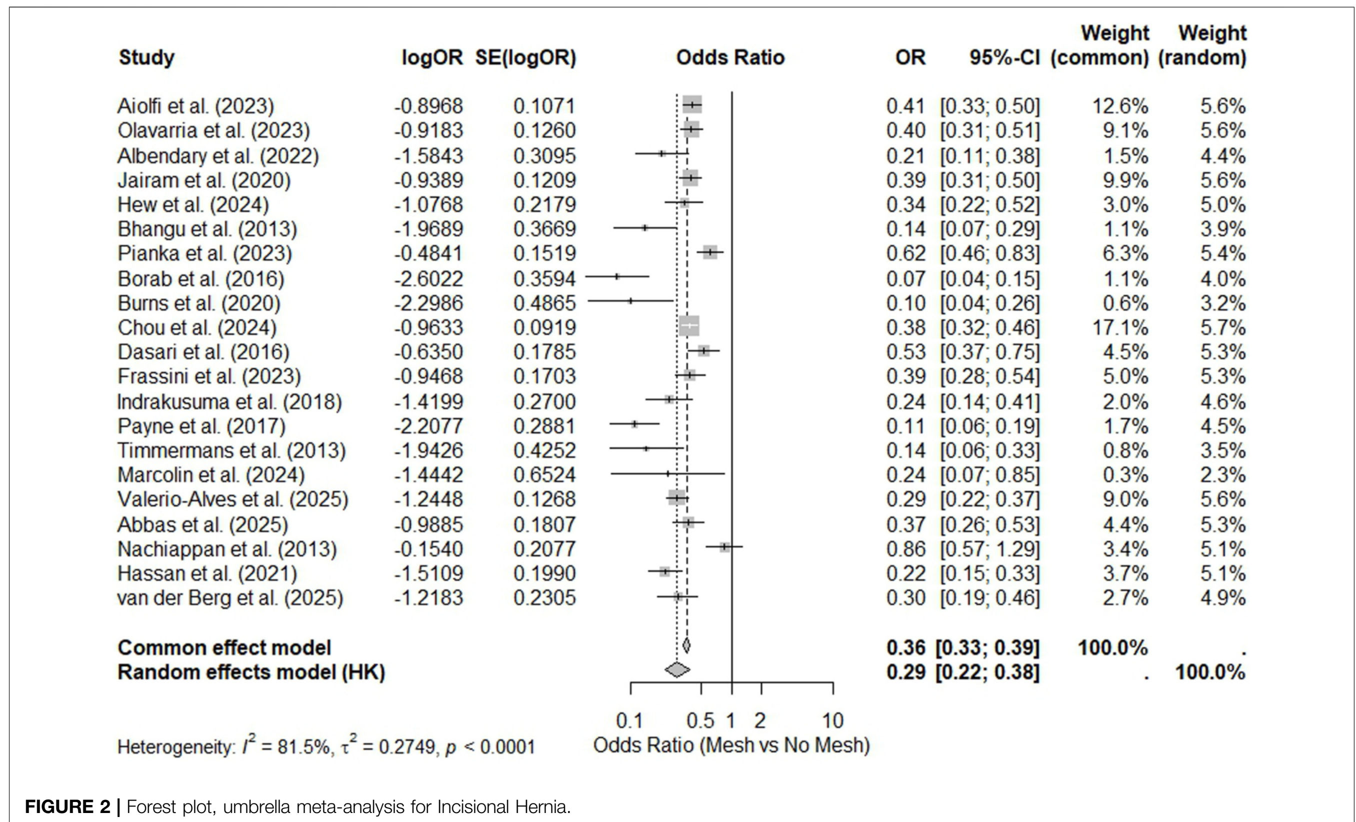

FIGURE 2 | Forest plot, umbrella meta-analysis for Incisional Hernia.

expected according to the mean statistical power (16.9). This corresponds to an excess significance of 14.9% (p = 0.018), which indicates the possible presence of publication bias or overreporting. In the subgroup analyses (including AAA, bariatric, elective, emergency and general surgical subgroups), no excess of significance was identified (p > 0.05).

TABLE 2 | Sensitivity analysis by surgery type and >10 articles.

Surgery type	Studies (n)	I^2 (%)	p (Heterogeneity)	Model	OR	95% CI
1. By surgery type						
General	10	77.3	<0.0001	Random effects	0.29	0.22–0.38
Emergency	3	0	<0.41	Fixed effects	0.18	0.11–0.28
Elective	3	91.2	<0.001	Random effects	0.58	0.46–0.73
AAA	3	0	0.61	Fixed effects	0.3	0.23–0.39
Bariatric	2	0	0.51	Fixed effects	0.58	0.46–0.73
2. By > or <10 articles						
>10	8	72.5	<0.0006	Random effects	0.33	0.23–0.49
<10	13	85.4	<0.0001	Random effects	0.27	0.18–0.40

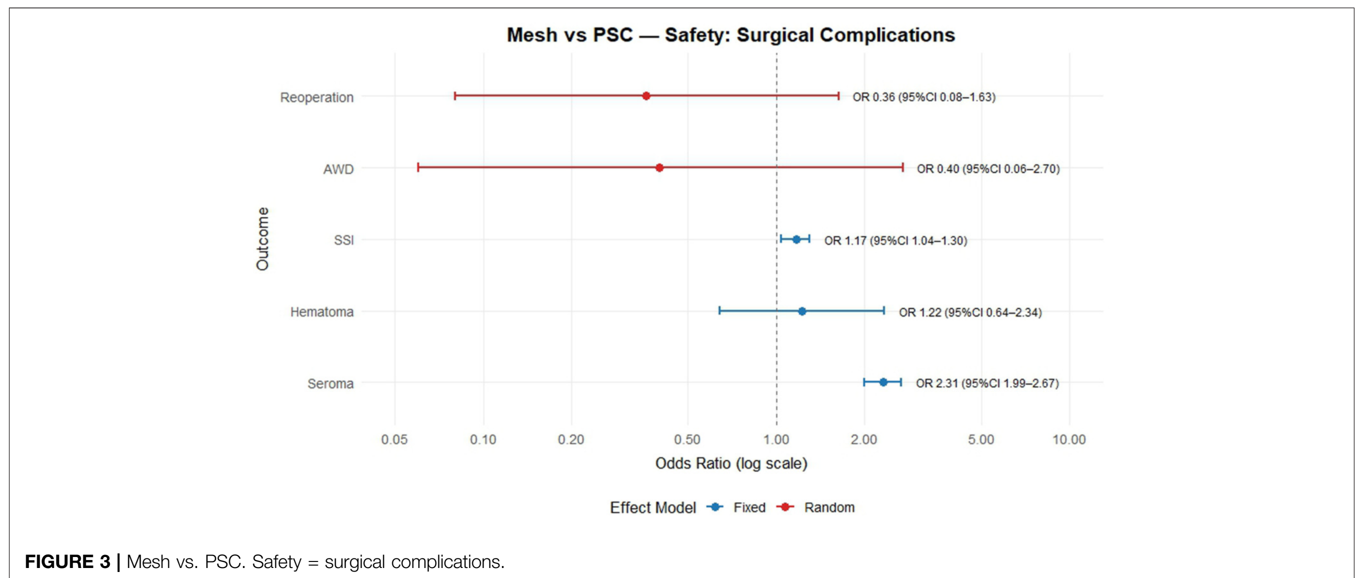

FIGURE 3 | Mesh vs. PSC. Safety = surgical complications.

The 95% prediction interval was calculated, which estimates the expected range for the effect size of an individual future study from the same study population. The obtained interval (0.22–0.37) indicates that, with 95% confidence, the *odds ratio* of a new study would be observed within this range. Since the entire interval is well below 1.0, the protective effect of the prophylactic mesh was considered to be robust and consistently beneficial for preventing IH in various clinical settings.

Despite the consistent direction of effect observed across the included meta-analyses, the overall certainty of the evidence is downgraded by substantial heterogeneity, signals of publication bias, and the presence of excess significance. These methodological features reflect limitations inherent to the available meta-analytical evidence and should be considered when interpreting the magnitude and generalizability of the pooled estimates at the umbrella review level.

Classification of the Evidence

According to the Ioannidis criteria, the evidence for preventing incisional hernias with prophylactic meshes does not meet the Class I requirements due to high heterogeneity and the presence of publication bias. However, the magnitude of the effect, the stability of the sensitivity analysis results, and the large number of patients (25,286) suggest a level of evidence approaching *Class II–III (high to suggestive)*.

Abdominal Wound Dehiscence (AWD)

Only 5 meta-analyses discussed the prevention of abdominal wound dehiscence (23.8%) none of which identified a significant difference between the mesh and primary closure (OR = 0.4; 95% CI: 0.06–2.7) (**Figure 3**).

Safety: SSI, Seroma, Hematoma and Reoperation

In the safety analysis (which included four main outcomes), sixteen studies (76%) reported on surgical site infection (SSI) with moderate heterogeneity (I^2 = 37.0%; $p < 0.06$), and the corresponding fixed-effects model yielded an OR of 1.17 (95% CI: 1.04–1.30). Seroma was evaluated in fourteen studies (71.4%) exhibiting similar heterogeneity (I^2 = 36.9%; $p < 0.08$), and the fixed-effects model yielded an OR of 2.31 (95% CI: 1.99–2.67). Three studies (14.2%) that evaluated hematoma did not

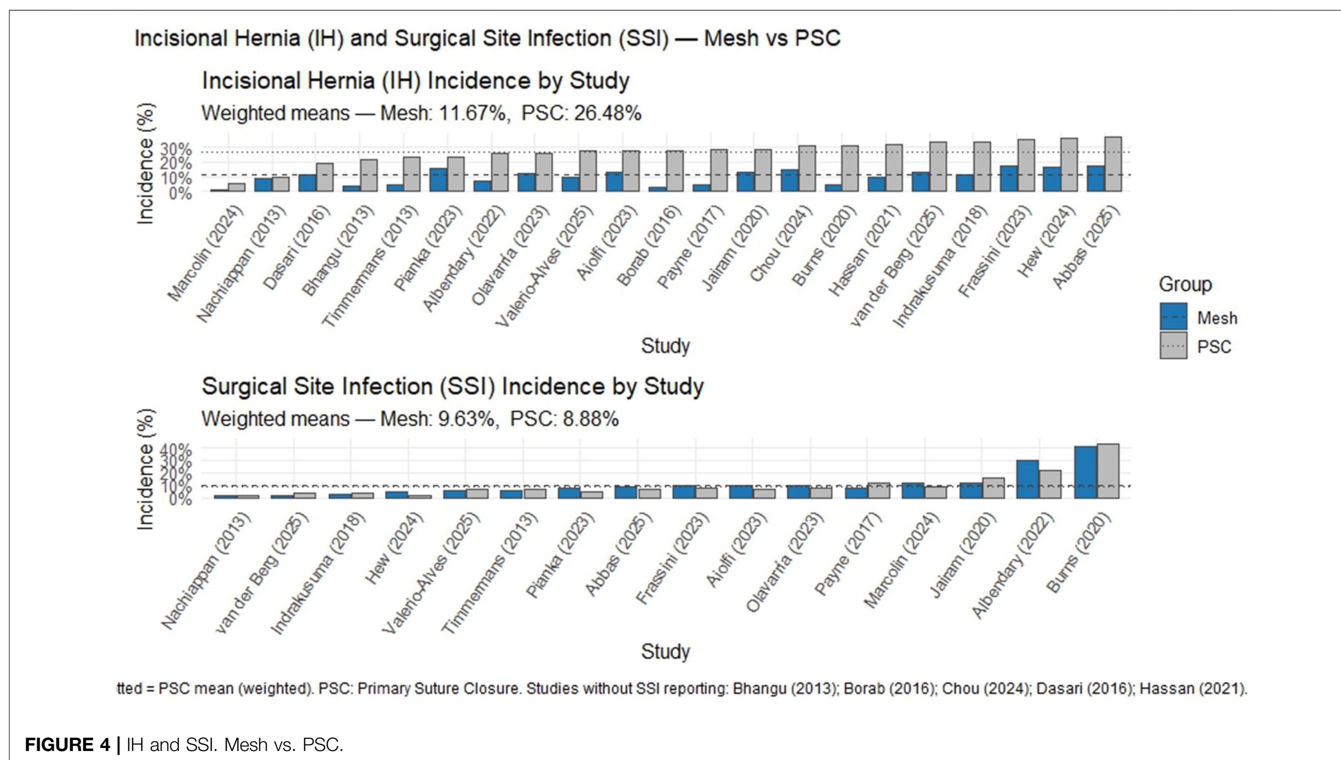

FIGURE 4 | IH and SSI. Mesh vs. PSC.

demonstrate evidence of heterogeneity (I^2 = 0%; p = 0.69), and the OR was 1.22 (95% CI: 0.64–2.34) according to a fixed-effects model. Finally, five studies (23.8%) reported on reoperation with considerable heterogeneity (I^2 = 61.3%; p < 0.03), and a random-effects model yielded an OR of 0.36 (95% CI: 0.08–1.63) (**Figure 3**).

Other Outcomes

Because no meta-analysis specifically reported on the type of mesh, placement space, or other important variables such as cost, quality of life, or postoperative pain (although several primary studies did), this analysis was not performed.

DISCUSSION

This umbrella meta-analysis, considered the highest level of methodological synthesis, evaluated the efficacy (in terms of preventing IH and AWD) and safety (in terms of the occurrences of surgical site infection, hematoma and seroma) of the use of prophylactic meshes. Our findings indicate that the use of meshes significantly reduces the incidence of IH (OR = 0.29; RRR ≈71%); this effect was consistent across multiple surgical contexts, including elective, emergency, AAA and bariatric procedures.

Despite identifying high heterogeneity and evidence of possible publication bias, we consider these results to be results for three reasons: first, the stability of the effect size in the sensitivity analysis (OR = 0.30–0.42), second, an interval of consistently protective prediction (0.22–0.37) that anticipates favorable results in future studies, and third, a moderate study overlap (CCA = 0.18) that indicates a diverse but complementary evidence base.

These results demonstrate a consistent association between prophylactic mesh use and a reduced incidence of IH, although its impact on AWD could not be conclusively established. The global evidence was classified as Class II–III (high or suggestive) according to the Ioannidis criteria, thus reflecting methodological limitations inherent in the available literature; however, the magnitude of the effect, its cross-sectional consistency and the consolidated sample size (n = 25,286) support a selective role for prophylactic meshes in clinical practice, thereby suggesting active surveillance of possible biases in future publications.

Another fundamental aspect of this analysis is related to the safety of mesh placement. In our study, the use of prophylactic meshes was associated with a statistically significant increase in the risk of surgical site infection (OR≈1.17) and seroma (OR≈2.31) (**Figure 4**). Previous studies have analyzed this relationship by reporting the number needed to treat for net effect (NNTnet), which quantitatively integrates efficacy (including the prevention of incisional hernia) and safety (including SSO) in a single metric. In the study by Lozada et al. [8], the NNT for benefits (NNTB) was 7.57, thus indicating that approximately 8 patients should be treated with a mesh to prevent one incisional hernia, whereas the number needed to elicit harm (NNTH) was −14.3, indicating that for every 14 patients treated, one patient would experience an additional adverse event attributable to the use of the mesh. Critically, the resulting NNTnet was 5, which indicates that for

every 5 patients treated with a prophylactic mesh, a net benefit would be obtained from one event (including the prevention of an incisional hernia that exceeds the occurrence of a complication). These findings support the notion that despite the increased risk of complications, the benefit-risk balance may be favorable in carefully selected high-risk patients, thereby reinforcing a context-dependent safety and efficacy profile rather than a universal preventive strategy.

An additional aspect to consider is the economic feasibility of mesh prophylaxis. Although this meta-analysis could not directly evaluate this factor because of the lack of reporting of economic data in the included primary studies, a cost-benefit analysis performed by Sheikh et al. regarding stoma closure [36] revealed that the profitability of this intervention critically depends on the type of utilized mesh. This study revealed that the use of biological meshes substantially increases costs, whereas the implementation of synthetic meshes significantly reduces costs, thereby maintaining the clinical benefits of prevention. These findings suggest that the selection of prosthetic material is a determining factor for the economic sustainability of this preventive strategy.

Although our meta-analysis could not directly assess the effect of mesh position because of the limited information reported in the primary meta-analyses, the current evidence suggests that the onlay and retromuscular planes are the most effective positions for preventing IH. The network meta-analyses of Aiolfi et al. and Tansawet et al. [37, 38] revealed that these positions exhibit the lowest probability of hernia without increasing complications such as seroma, hematoma or infection. The onlay position is particularly advantageous in contexts with limited experience in retrorectal dissection because of its lower technical complexity. In addition, this position offers the possibility of an easier and safer removal of the mesh, if necessary, thus preserving the other anatomical spaces for an eventual correction of incisional hernia in the future.

Regarding the relationship between the effectiveness of the mesh in preventing IH and its association with an increased risk of SSI, the question arises as to what other measures associated with the use of meshes could be beneficial. Although the meta-analysis by McGeehan et al. [39] did not demonstrate a significant reduction in SSI with the implementation of bundles in emergency surgery, when considering our findings, we propose that future research should evaluate the incorporation of the mesh within a specific and multimodal bundle to determine whether this strategy can reduce the risk of infection without compromising its effectiveness in preventing hernias.

Our study revealed that the use of prophylactic meshes increases the risk of infections (SSIs) and seromas. On this basis, the risks and benefits of this technique should be carefully considered. As described by Krpata et al. [40, 41], the preventive use of mesh leads to an ethical dilemma, wherein all of the treated patients are exposed to the risks of implantation with foreign material (with a complication rate close to 5.6%) to avoid hernias that may only form in some patients. This dilemma is even more relevant given safter and effective alternatives to mesh use, such as the small bites closure technique [42] or the reinforced tension line (RTL) technique [43], which reduce the formation of hernias without increasing the risk of infection. Therefore, the focus in future studies should not be simply “whether a mesh should be used” but to correctly identify those patients exhibiting such a high risk of hernia that the benefits of mesh use clearly outweigh its proven risks.

Among the limitations of the study, high heterogeneity was observed, which was associated with the use of different surgical techniques, mesh types and populations. A risk of publication bias was also identified, which could lead to an overestimation of the actual benefits. Moreover, the analysis was unable to assess crucial outcomes such as chronic pain, quality of life or costs, which limits the overall assessment of the benefit-risk balance. Finally, the significant increase in local complications such as infections (SSIs) and seromas represents a critical clinical disadvantage that must be weighed against the reduction in hernias.

CONCLUSION

The use of prophylactic mesh is associated with a significant reduction in the incidence of incisional hernia (OR = 0.29), consistent relative effect across surgical contexts), supporting a preventive role rather than confirming definitive efficacy. This benefit must be interpreted alongside an increase in local complications such as seroma formation and surgical site infection, which warrants equal consideration and careful risk–benefit assessment at the individual patient level.

The global evidence demonstrated a moderate-to-suggestive level of certainty (Class II–III, according to the Ioannidis criteria), which was supported by a broad evidence base; however, considerable heterogeneity and signs of publication bias were observed. Accordingly, prophylactic mesh should not be regarded as a universal preventive strategy, and future efforts should focus on refined risk stratification of high-risk patients, evaluation of safer technical approaches, and studies addressing cost-effectiveness and quality-of-life outcomes to better define its role in incisional hernia prevention.

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EL, and GM conducted the experiments, EL and LF-V-M wrote the manuscript. All authors contributed to the article and approved the submitted version.

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SUPPLEMENTARY MATERIAL

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REVIEW
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Intraoperative Fascial Traction - From Concept to Comprehensive Application

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Intraoperative Fascial Traction (IFT) represents a promising alternative technique for complex abdominal wall reconstruction in large ventral hernias, particularly those exceeding 10 cm in width. Developed by Swiss and German surgeons and introduced clinically in 2021, IFT achieves fascial closure without extensive muscle component separation. Multiple studies demonstrate closure rates of 79%–96% for defects below 19 cm, though rates decline significantly for larger defects. Preoperative botulinum toxin A (BTA) administration and transversus abdominis muscle release (TAR) are often combined with IFT. The paper discusses the Hamburg algorithm 2.0 as it provides a structured treatment approach based on defect width, recommending IFT as a first-line intervention for defects up to 15 cm and incorporating additional component separation for larger hernias. Controlled fascial traction allows standardised treatment and can lead to higher fascial closure and lower recurrence rates.

Keywords: abdominal wall reconstruction, fascial traction, fasciotens, IFT, ventral hernia repair

INTRODUCTION

It is generally accepted that two key principles guide modern ventral hernia repair: 1. The hernia repair should be augmented by a mesh in retrorectus, retromuscular or preperitoneal position and 2. The fascial defect should be closed primarily by suture and bridging should be avoided [1].

Around the millennium, the Dutch working group of Hans Jeekel from Rotterdam showed that a mesh augmented incisional hernia repair is superior to direct suture repair in terms of recurrence rates [2, 3]. Later, other Randomised Controlled Trials demonstrated that a mesh in sublay position has significantly lower recurrence and seroma rates as mesh augmentation in Onlay position [4, 5]. Regarding fascial closure, it was shown that a bridging of the anterior rectus sheath (ARS) has drastically increased risk of recurrence [6, 7].

Naturally, it is relatively easy to follow these key principles in smaller hernias. The more challenging cases are summarised as complex abdominal wall hernias. Although the term is not standardised, it often involves a hernia width above 10 cm or significant loss of domain [8]. Those cases require extensive reconstruction of the abdominal wall, referred to as complex abdominal wall repair (CAWR). For this purpose, component separation techniques such as anterior component separation (ACS) and transversus abdominis muscle release (TAR) have been available for many years and have proven to be very valuable [1, 9–11]. Nevertheless, apart from being surgically demanding, they have in common that the aponeurosis or muscle fibres of one or more of the lateral abdominal wall muscles are deliberately severed. Looking for alternatives to restore the abdominal wall and to achieve fascial closure without extensive preparation, Eucker et al from Switzerland

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TABLE 1 | Subgroup analysis in relation to hernia defect width based on Niebuhr et al., Springer Hernia [20]. *SSO* surgical site occurrences, *SSI* surgical site infections, *TAR* transversus abdominis muscle release.

	Subgroup 1	Subgroup 2	Subgroup 3
Number of patients (total number = 143)	45	61	37
Defect width [cm]	8 - >15	15–19	>19
Lateral or additional lateral defect rate	4/45 (8.9%)	7/61 (11.5%)	4/37 (10.8%)
Closure rate	43/45 (95.6%	48/61 (78.7%)	12/37 (32.4%)
TAR rate	7/45 (15.6%)	18/61 (29.5%)	18/37 (48.6%)
Intraoperative complication rate	0/45 (0%)	2/61 (3.3%)	3/37 (8.1%)
SSO	11/45 (24.4%)	17/61 (27.9%)	15/37 (40.5%)
SSI	4/45 (8.9%)	6/61 (9.8%)	9/37 (24.3%)
Re-operation	5/45 (11.1%)	10/61 (16.4%)	7/37 (18.9%)

started using fascial traction for CAWR in 2012 and published their first case series in 2017 [12]. At the same time the conceptualization of vertical fascial traction using an external device was developed by Lill from Germany, first proven in an animal model and afterwards used for open abdomen treatment [13, 14]. After fusing the concepts, intraoperative fascial traction (IFT) was introduced as a new technique in CAWR and the first case series was published in 2021 by Niebuhr et al. showing promising results [15].

LITERATURE REVIEW

Since the introduction of the concept by Eucker et al. in 2017 several publications have shown the outcomes of IFT. The first paper on abdominal wall expander system (AWEX) including 10 patients with a median hernia width of 12.0 cm reported a closure rate of 60% and a mean reduction of fascia-to-fascia distance of 8.5 cm [12]. In 2022 follow-up data on AWEX were published including 33 cases. Median hernia width in this cohort was 13.0 cm. Complete fascial closure was achieved in 20 cases (60.6%) and 1 recurrence (3%) after a median follow-up of 29 months was reported [16]. Also showing promising data, performing AWEX using a non-standardised, "self-built" mechanism seems to lead to a relatively low closure rate. In 2021, first results were published for large incisional hernia repair using fasciotens® Abdomen (Fasciotens GmbH, Germany) which was initially developed for open abdomen treatment allowing to apply controlled, reproducible and quantifiable traction. A total of 21 patients with a mean intraoperative measured defect width of 17.3 cm were included in this prospective observational trial. 13 patients were pretreated with Botulinum Toxin A (BTA). An overall closure rate of 100% and Surgical Site Occurrence (SSO) rate of 19% was reported [15]. The results were confirmed in a retrospective analysis of 50 cases showing a closure rate of 90% and SSO rate of 12% [17]. Most recently, Woeste et al. published the results of a follow-up of 100 patients treated with IFT [18]. The mean follow-up time was 19.6 months in this cohort. BTA was administered preoperatively in 87% of the cases and TAR was added in 28%. On average, the defect size was 15.8 cm and fascial closure was achieved in 94% of all cases. The SSO rate was 33%, however 54.5% were seromas. Having a relatively small mean mesh width of 22.6 cm, a recurrence rate of only 2% was reported, which may emphasise the importance of ARS closure.

The clinical effect of IFT in terms of medialisation of the lateral abdominal wall was also confirmed in a cadaver study [19]. Retrorectus dissection was first carried out in a total of four fresh frozen specimens. Subsequently, IFT was applied for 30 min. The mean medial advancement was 10.5 cm, which is in line with clinical findings [15, 17, 20]. In 2024, we reported on 143 cases treated at the Hamburg Hernia Centre [20]. All patients in this cohort received Botulinum Toxin A 4 weeks prior to surgery and IFT was also used in all cases. The mean hernia width was 16.9 cm and 68.5% of the patients had a transverse hernia size above 15 cm. The patient cohort was divided into subgroups as shown in **Table 1**. It shows that closure rates of 95% can be achieved for cases up to 15 cm of hernia width. However, closure rates decline especially above 19 cm and bridging becomes more likely even with higher TAR rates (48.6% in subgroup 3).

HAMBURG ALGORITHM 2.0

Based on the results an initial Hamburg algorithm for CAWR was presented. Since then, we have further adapted the algorithm following our ongoing clinical experience and feedback from conferences and discussions with colleagues. We now propose an approach based on the subgroups for the treatment of ventral hernias in order to address the raising complexity associated with an increase in defect width (see **Figure 1**). It is important to note that the defect width is only one criterion for the complexity of a hernia and that each patient requires a tailored approach. The decision-making process depends on whether ARS closure can be achieved after each step of the algorithm. The elements of the algorithm will be discussed in detail below.

Subgroup 1/2 – Hernia Width Below 19 cm

The analysis of 143 patients treated with BTA and IFT has shown that anterior sheath closure rates of 96% for defects with a transverse diameter below 15 cm and 79% for defects below 19 cm in width can be achieved [20]. The procedure for these patients therefore initially consists of peritoneal flap preparation and retromuscular dissection according to Rives-Stoppa [21]. If

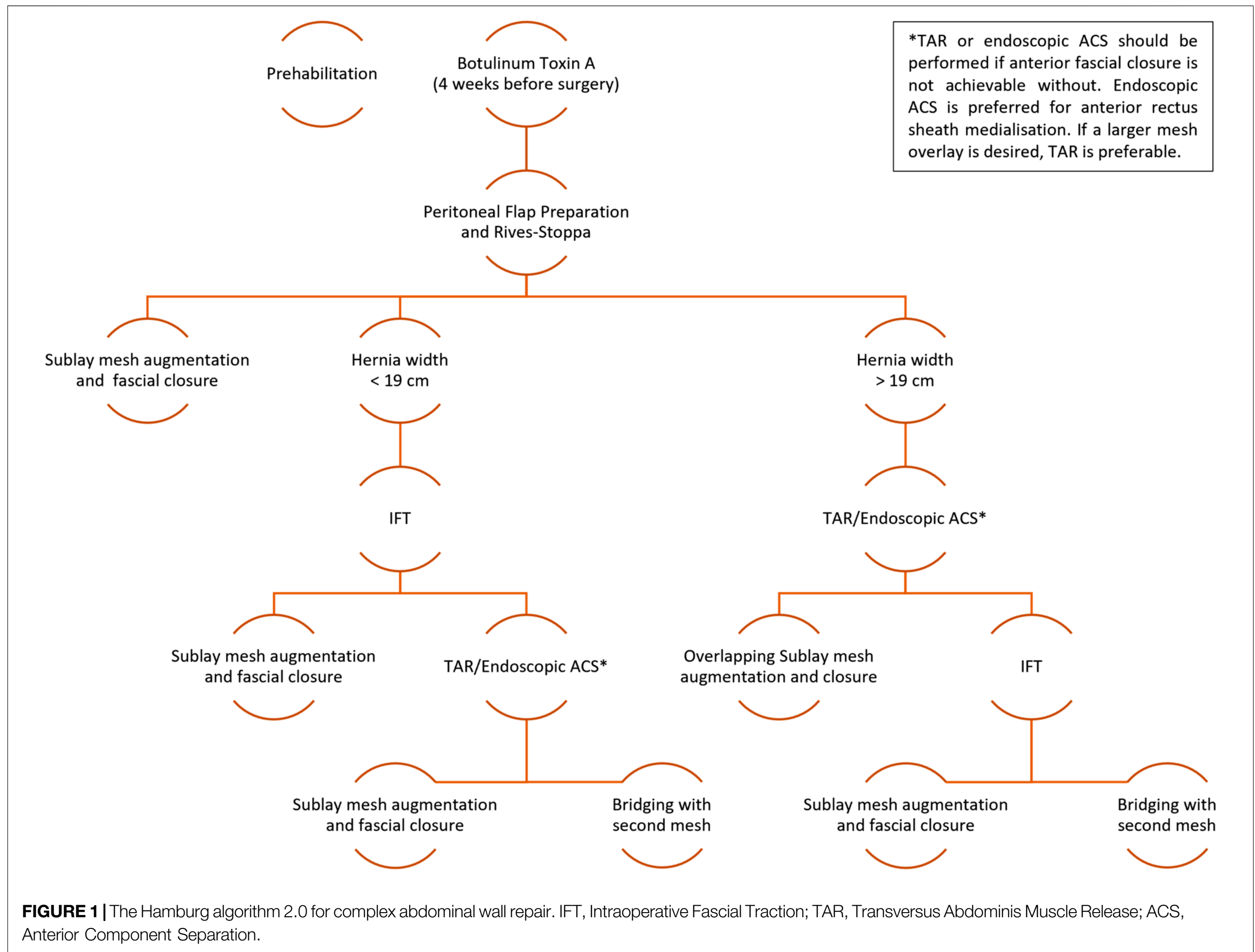

FIGURE 1 | The Hamburg algorithm 2.0 for complex abdominal wall repair. IFT, Intraoperative Fascial Traction; TAR, Transversus Abdominis Muscle Release; ACS, Anterior Component Separation.

the anterior layer of the rectus sheath can be closed under moderate tension, IFT is not performed. If fascial closure is not possible, IFT will be carried out. Only if closure is still not possible afterwards component separation is added. In rare cases peritoneal flap closure or mesh bridging should be considered [22].

Subgroup 3 - Hernia Width Above 19 cm

The patient cohort having a defect width above 19 cm showed a relatively low complete closure rate of around 32% [20]. Therefore, TAR or ACS is performed in these patients before IFT is applied. If closure is still not possible afterwards, peritoneal flap closure or mesh bridging should be considered [22].

DISCUSSION

Indication

In our own experience, IFT achieves a different range in terms of medialisation of the lateral abdominal wall in a (naturally) heterogeneous patient population. The EHS classification for ventral hernias has strongly helped to standardise hernia characteristics, but every CAWR surgeon knows that each complex hernia is different and needs an individualised treatment plan [1, 23]. Therefore, although it can generally be said that IFT is used in the vast majority of cases for ventral hernias with a diameter above 10 cm, it is difficult to predict the definitive length gain preoperatively. Nevertheless, its use does not have to be determined in advance of the operation; rather, it should be used on demand, namely, at the moment when low-tension closure of the ARS after Rives-Stoppa preparation appears difficult. Additionally, IFT should be considered in any case of CAWR with visceroabdominal disproportion which is often the case in Loss of Domain (LOD) hernias. Hence, it has also been previously used in flank and massive scrotal hernias.

Prehabilitation

Thorough preoperative assessment and planning are key to reducing postoperative risk for complications and recurrence. In addition to the clinical examination, a CT or MRI scan of the abdomen should be performed at rest and during the Valsalva manoeuvre in order to assess the extent of the hernia and plan the

operation. Several risk factors have been identified to negatively influence postoperative outcomes. It is very important to perform an individual risk assessment with each patient and to identify potential improvement. To visualise the risk, the CeDAR (Carolinas Equation for Determining Associated Risks) app, which is available for free in the Apple and Android App Store, can be used. Additionally, the colleagues from the York Abdominal Wall Unit have developed a range of leaflets and easy to understand guidance documents for patients to help prepare for the surgery (available for free on the website: https://www.yorkhospitals.nhs.uk/our-services/organdonation/a-z-of-services/abdominal-wall-reconstruction/).

Prehabilitation covers a wide range of factors and influencing variables, with BMI, smoking and diabetes among the most influential. A BMI below 30 kg/m^2 should be aimed for as it significantly decreases the risk for SSO and recurrence [24, 25]. However, each patient needs a realistic and individual goal for weight loss in order to achieve a lasting effect in the best-case scenario. The same applies to nicotine cessation. Smoking has a significant impact on SSO, wound infections and recurrence rates and therefore patients should stop at least 4 weeks prior to surgery [26, 27]. As is widely known, diabetes has a strong influence on wound morbidities and infections [28]. As CAWR is associated with extensive preparation and large wound areas, strict preoperative control of diabetes is recommended.

Botulinum Toxin A

Administration of Botulinum Toxin A in the lateral abdominal wall muscles to achieve temporary muscle relaxation was first described in 2009 [29]. Different dosages and number of administration points have been described [29–31]. Hernia defect width reduction was reported to be between approx. 4–6 cm [31]. In our practice BTA is mainly used in cases above 10 cm in width. However, it should be noted that BTA administration in the abdominal wall is an off-label use. The FDA issued a mandated black box warning already back in 2009 concerning the risk of botulism-like symptoms such as muscle weakness, dysphagia and aspiration which can be life-threatening [32–34]. Therefore, the use of BTA should be weighed carefully and especially patients with lung disease should be treated very cautiously with BTA [35].

Peritoneal Flap and Rives-Stoppa

We strongly believe that the retrorectus dissection according to Rives and Stoppa is the foundation of every (midline) CAWR [21]. The technique is elementary and should be understood by every AWR surgeon. Therefore, we will not go into detail about the procedure itself and refer to detailed descriptions elsewhere. [36, 37]. If possible, the hernia sac should always be preserved until complete fascial closure of both rectus sheaths is achieved. We usually perform the preparation of the hernia sac according to the peritoneal flap technique [22]. Contrary to the initial description of the technique, in our approach, we leave 2/3 of the hernia sac on the PRS on one side and 1/3 on the ARS on the contralateral side. Performing IFT usually requires narrower bridging on the ARS if complete fascial closure is not possible. In the majority of cases a complete ARS closure is achievable. In these cases, the hernia sac attached to the ARS is resected.

Intraoperative Fascial Traction

Applying IFT does not only involve fascial traction but also a certain approach to restoring the abdominal wall. Part of the flap is regularly used to “bridge” the posterior rectus sheath (PSR) if low-tension direct closure is not possible. Early biomechanical research has shown that the PSR is less resistant to pressure forces and more prone to bursting [38]. Therefore, we see it as less important for abdominal wall strength and the main goal should be a reliable layer between the abdominal organs and the augmenting mesh in sublay position. Before applying IFT, the mesh can already be placed. The fixation of the mesh is an ongoing debate that should be done according to house standards. In our practice the mesh is normally only fixated cranially and caudally with one stitch.

After mesh placement, the prosthetic and the (preperitoneal) landing zone are covered with several (2–4) moist abdominal cloths. The traction forces which are applied by an external device (fasciotens® Hernia, Fasciotens GmbH, Germany) are distributed on the fascia by using polyfilamentel USP 2 sutures. 6 sutures per side are anchored in the ARS in a U-shape manner. After placing the sutures, they are crossed to mimic a diagonal directed traction. The sutures are connected to the suture holder of the device and fascial traction is carried out. Normally traction forces of approx. 14 kg are applied which can gradually be increased to about 18 kg. IFT should be maintained for about 30 min and traction sutures should be individually retightened every 2 minutes. Otherwise, traction forces cannot be distributed sufficiently on the fascia. It is very important to have complete muscle relaxation during IFT. The muscle tone works as an antagonist and can lead to a poor outcome. After IFT, sutures are disconnected from the external device and uncrossed. The abdominal cloths are removed and ARS closure is carried out according to the concept of small steps–small bites [39–41].

Eucker et al. have shown that promising results can also be achieved using the AWEX system based on a self-built mechanism. However, using an external device which allows quantifiable traction seems to lead to higher closure rates as shown in the literature review section. It should also be considered that quantifiable and reproducible traction helps to standardise treatment and to compare outcomes. It can also reassure patients and might prevent medicolegal consequences in case of complications or misfunction. Following that, even when self-built, surgeons should follow standardisation and at least measure the applied traction forces.

Component Separation

Any type of CS might be added according to the patient’s needs as outlined above. It should be considered especially in the case of TAR for what purpose it is performed (mesh overlap, additional lateral defect, closure of the PRS). Studies have shown that TAR is less effective in terms of ARS medialisation compared to ACS [42, 43]. Therefore, ACS still plays a role when it comes to anterior fascial closure. To reduce the risk of SSO, a minimally invasive approach has proven useful [44, 45].

Sublay Mesh Augmentation

There is an ongoing debate regarding mesh size and overlap in CAWR. Some still recommend a 5 cm overlap in all directions although the data showing an advantage were derived from laparoscopic IPOM procedures without fascial closure [46]. A recent report from the Danish national patients registry showed that a 10–15 cm mesh width in open ventral hernia repair seems to have favourable outcomes in terms of long-term recurrence rates [47]. They also mention that “overlap” is not an appropriate term if the hernia gap is closed and the midline is restored (as it was done in all cases of the aforementioned study). Hence, if the fascial defect is closed, a smaller mesh covering only the retrorectus space might be sufficient. Supporting this, the follow-up published by Woeste et al. regarding CAWR using IFT showed a relatively low recurrence rate of only 2% in 100 patients. Interestingly, the mean mesh width in this cohort was 22.6 cm and a recurrence was found in one patient without TAR and in one patient treated with an additional TAR [18].

Anterior Rectus Sheath Closure

Although IFT can facilitate fascial closure and has shown closure rates above 90% even in large defects, it is noteworthy that the decision to restore the midline or to pursue a direct fascial closure should be taken with caution. In our practice, we have seen cases of elevated intra-abdominal pressure (IAP) directly after surgery but never faced a subsequent abdominal compartment syndrome. Therefore, some colleagues perform intraoperative measurement of IAP [48]. In order to streamline intraoperative decision-making, close communication with the anaesthetists is necessary regarding peak inspiratory pressure (PIP), particularly while performing IFT. Colleagues from Portugal have shown, that an increased PIP after fascial closure can lead to a postoperative abdominal compartment syndrome [49]. Following their algorithm, we have found PIP variations between 1 and 3 mmHg tolerable, variations above 4 mmHg should be closely monitored (admission to ICU postoperatively). The paper states that only PIP variations above 10 mmHg should lead to bridging. However, we recommend being more cautious and might performing bridging even at lower values. The data so far only present small numbers. Therefore, no general recommendations can be made, and the proposed ranges should only be used as a decision-making aid. If bridging is unavoidable, we normally use a second synthetic mesh as an inlay bridging (ARS). To avoid exposure of the mesh in case of subcutaneous infection or seroma, it is helpful to cover the mesh with residual hernia sac in the style of the peritoneal flap technique [22].

Limitations

The algorithm presented here is primarily based on single-centre data from a specialised hernia centre. In order to create a simple guideline, hernia width was used as the primary decision criterion. Of course, other factors such as BMI, loss of domain, scarring processes and muscular compliance also play an important role and can influence the surgical procedure. Although initial long-term data is available, further studies with longer follow-up are necessary. In addition, there is currently a lack of prospective comparative studies to identify the advantages and disadvantages of IFT in comparison to other CAWR techniques.

Conclusion

IFT is a promising technique in CAWR to facilitate fascial closure and restoration of the abdominal wall without extensive preparation as with component separation techniques. Naturally, there are limits and restrictions on its use and every patient with a complex hernia needs a tailored approach and should be treated individually. The achievable medialisation of the abdominal wall differs among patients and is influenced by the anatomy and condition of the lateral abdominal wall. Therefore, IFT is one tool in the CAWR surgeon’s toolbox and should only be used by experienced and dedicated AWR units.

AUTHOR CONTRIBUTIONS

HN conceived the article and was responsible for preparing and writing the manuscript. CW and SB assisted with literature research and conception and contributed to the references. HD, WR, GW, and FK contributed to the writing of the manuscript. All authors contributed to the article and approved the submitted version.

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Authors CW and SB were employed by Fasciotens GmbH. HN and GW have performed financially compensated workshops for P. J. Dahlhausen und Co. mbH for complex hernia repair with IFT and Dynamesh meshes.

The remaining author(s) declared that this work was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

GENERATIVE AI STATEMENT

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Prophylactic Retrorectus Mesh Versus Small-Stitch Closure After Emergency Midline Laparotomy: 2-Year Results of a Randomized Controlled Trial

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Introduction: Incisional hernias (IH) are common complications following emergency midline laparotomies. Mesh reinforcement has shown efficacy in preventing incisional hernias in elective surgeries, but evidence remains limited for emergency midline incisions. This study aimed to evaluate the safety and effectiveness of retrorectus placement of a self-gripping polyester mesh in preventing incisional hernia after emergency midline laparotomy, as measured by the incidence of IH, postoperative complications, quality of life, and health economic outcomes.

Methods: In this multicenter randomized controlled trial, adult patients undergoing emergency midline laparotomy were randomized to receive either prophylactic retrorectus mesh or standard 4:1 small-stitch fascial closure using a slowly absorbable monofilament suture. The primary outcome was the radiological/clinical IH rate within 2 years after the surgery. Secondary outcomes were complications, reoperations, quality of life, and health-economic measures. Blinding was maintained for patients, outcome assessors, and radiologists. Due to difficulties in recruitment, the study was prematurely terminated prior to reaching the aimed number of patients.

Results: Out of 925 patients screened, 109 were randomized, and 72 received the allocated intervention. At 2-year's follow-up, one (4%) asymptomatic incisional hernia was detected in the control group compared to none in mesh group. In the mesh group, three (9%) patients experienced mesh-related complications: one (5%) retrorectus hematoma, one (5%) internal hernia and one (5%) postoperative seroma. One (5%) additional patient in the mesh group developed a fistula requiring mesh removal. No significant differences were found in early postoperative complications or quality of life between groups.

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Conclusion: Retrorectus mesh reinforcement did not reduce the incidence of incisional hernia compared to standard small-stitch closure in this trial. However, mesh-related complications were observed. Due to recruitment challenges and limited sample size, definitive conclusions cannot be drawn.

Clinical Trial Registration: https://clinicaltrials.gov/study/NCT04311788?term=preemer&rank=1, NCT04311788.

Keywords: incisional hernia, emergency laparotomy, midline laparotomy, incisional hernia prevention, randomized controlled trial

INTRODUCTION

Emergency midline laparotomy is a risk factor for incisional hernia (IH), with up to 33% IH rate [1–4]. However, the guidelines do not provide any recommendations on midline closure after emergency laparotomy [5]. In elective setting, the recommended technique for midline fascial closure is the small stitch method, using a slowly absorbable monofilament suture with a suture-to-wound length ratio of at least 4:1 [5]. The same method can also be applied to close emergency midline laparotomy incisions to help prevent IH and fascial dehiscence [4, 6–8]. Additionally, prophylactic mesh augmentation in midline laparotomies has been both effective and safe for IH prevention after elective midline laparotomy [5, 9].

IH prevention after emergency midline laparotomy has been rarely studied. Ulutas et al. have published results of randomized controlled trial (RCT) using onlay mesh to prevent IH [6]. In the study, the preventive mesh decreased the IH rate significantly when compared to suture closure with small stitch technique (4% vs. 27%), without predisposing patients to increased risk of severe complications [6]. In another RCT, retrorectus mesh decreased the IH rate compared to small stitch closure (6% vs. 21%) [8].

The Preemer trial was designed as a multicenter RCT comparing retrorectus mesh-augmented closure with the conventional small-stitch 4:1 continuous fascial closure using a slowly absorbable monofilament suture for the prevention of incisional hernia after emergency midline laparotomy. In both groups, the fascia was closed in a continuous 4:1 manner using a slowly absorbable monofilament suture. The hypothesis was that the mesh prevents IHs compared to controls without increasing the risk of complications.

METHODS

Trial Design

The PREEMER study was a multicenter, parallel-group, patient- and assessor-blinded, randomized controlled superiority trial conducted at Oulu, Helsinki, and Turku University Hospitals, as well as at the Central Hospital of Seinäjoki in Finland. The study aimed to determine whether prophylactic mesh reinforcement in emergency midline laparotomy closure is superior to standard primary closure in preventing incisional hernia without increasing postoperative complications.

The study protocol was published previously [10], and the trial was registered at ClinicalTrials.gov before enrollment started (NCT04311788). Eligible patients were recruited between 22 April 2020, and 10 October 2022. After receiving both oral and written information and providing written informed consent, patients were enrolled in the trial.

Participants were followed up at 30 days postoperatively, either by phone interview or at an outpatient clinic, to assess recovery. Clinical and radiological evaluations were performed 2 years after surgery to detect incisional hernias. Quality of life was assessed using the RAND-36, Activities Assessment Scale (AAS), and PROMIS questionnaires at both follow-up points.

Participants

Inclusion criteria was midline emergency laparotomy for any abdominal indication. Conversion from laparoscopy to laparotomy was accepted provided there was a written consent received prior the operation. Exclusion criteria were as follows:

- Previous ventral hernia repair with mesh in the midline
- World Health Organization (WHO) class of physical activity 3–4 (rest time greater than 50 per cent of day in bed) [11].
- Relaparotomy within 30 days of previous abdominal surgery
- Indication for laparotomy is hernia-related
- Pregnant or suspected pregnancy
- Patient is <18 years old
- Metastatic malignancy of any origin
- Patients living geographically distant and/or unwilling to return for follow-ups
- No informed consent provided
- Patient participates in other RCT (non-gastrointestinal trials were accepted)
- Planned or existing ostomy

Additionally, there were intra-operative exclusion criteria applied for both randomization groups as follows:

- Abdomen was left open
- Second-look laparotomy was planned
- Inability to keep the mesh securely out of the peritoneal cavity or close the anterior fascia
- Intra-abdominal non-curable malignancy diagnosed during the operation
- ≥2 cm hernia in midline

Intervention

Onlay mesh placement has been associated with increased risk of seroma [9]. To avoid that complication in contaminated surgical site, we decided to use the retrorectus space for mesh, despite the likelihood of being more technically challenging and time consuming. A 8 cm-wide self-gripping polyester mesh (Progrip™, Medtronic, Sofradim Production, France) was chosen as the mesh has an indication for hernia prevention and does not need additional suturing.

In the control group, fascial closure was performed using the 4:1 small stitch technique with a continuous slowly absorbable monofilament suture in one layer.

In the mesh group, the posterior rectus sheath was opened extending the retrorectus opening both cranial and caudal to incision. The posterior layer was closed using continuous slowly absorbable monofilament suture with the 4:1 small stitch technique. An 8 cm-wide mesh was then applied over the closed posterior sheath, with gripping material directing posteriorly. The length of the mesh was cut to extend over the edges of incision. The anterior rectus sheath was closed using the slowly absorbable monofilament suture and 4:1 small stitch technique.

A step-by-step photographic guide of the surgical technique was provided to all participating centers to standardize the procedure.

Outcomes

The primary outcome was the occurrence of incisional hernia (IH) detected either clinically or radiologically during the 2-year follow-up period.

The secondary outcomes included:

- Comprehensive Complication Index (CCI) within 30 days after surgery
- Surgical site infection (SSI) within 30 days of follow-up
- Fascial dehiscence within 30 days from surgery
- IH rate at 5 years
- IH repair rate within 2 and 5 years from surgery
- Reoperations due to mesh or hernia within 2 and 5 years
- Quality of life (QOL) assessed using the RAND-36, Activities Assessment Scale (AAS), and PROMIS questionnaires at 30 days, 2 years, and 5 years
- Health-economic exploratory measures, including
  a. Time to create the retrorectus space and insert the mesh
  b. Length of hospital stay
  c. Material costs of abdominal closure
  d. Duration of patient sick leave
  e. Direct hospital costs due to recurrence or reoperation

Patients who were retired or stay-at-home caregivers were excluded from the sick leave assessment, as its duration could not be reliably estimated.

Adverse events and harms were systematically recorded and evaluated throughout hospitalization and during follow-up visits. All postoperative complications, including SSIs, seromas, hematomas, wound dehiscence, mesh-related complications, and deaths, were documented and graded according to the Clavien–Dindo classification, and summarized using CCI. The patients were clinically assessed during hospitalization by a surgeon who had not performed the operation, in order to maintain blinding.

A definition by the European Hernia Society for IH was applied [12]. A surgical site infection (SSI) was defined and documented according to the Centers for Disease Control and Prevention (CDC) criteria [13]. The RAND-36 is a validated quality-of-life instrument available in both official languages of Finland (Finnish and Swedish). The AAS and PROMIS questionnaires were selected to assess activity levels and functional outcomes, although they are not validated in the target languages. The results of all quality-of-life instruments were compared between randomized groups at 30-day and 2-year follow-up points.

Blinding

Study participants were blinded to their randomized group throughout the entire follow-up period. The surgeon responsible for evaluating outcomes during hospital stay, and at the 30-day, 2-year, as well as the radiologist interpreting imaging, were also be blinded to group allocation. To preserve blinding, the medical records included only the statement, "Fascial closure was performed according to randomized group," without disclosing which group the patient was assigned to.

The randomization number assigned to each patient was recorded in the medical files. Sealed envelopes labeled with the randomization numbers and containing the actual allocation group were accessible at all times, in case group information was required, for example, due to complications. If blinding was unintentionally broken, such event was documented.

Sample Size Calculation and Statistical Analysis

The sample size calculation was based on an expected incisional hernia rate of 10% in the mesh group and 25% in the control group, as suggested by earlier studies [1–4]. Using a significance level (α) of 0.05 and a power of 80%, a minimum of 97 patients per group was required. With an anticipated dropout rate of 20%, the final target was 122 patients per group. The sample size calculation pertained only to the primary outcome, while the secondary outcomes were interpreted as hypothesis-generating.

Randomization was stratified to control for possible confounding factors. Stratification was based on body mass index (BMI less than 30 kg/m^2 vs. 30 kg/m^2 or higher), previous midline laparotomy (yes or no), conversion from laparoscopic to open surgery (yes or no), and age (below or above 65 years). Within each stratum, block randomization was performed using random permuted blocks of varying sizes (2, 4, 6, or 8). A separate randomization list was created for each participating center. Patients were randomly assigned in a 1:1 ratio to either the mesh or control group using a computer-generated list compiled by a biostatistician independent of clinical care.

The study data was stored in a secure electronic database that also included a built-in randomization software. The randomization result was visible only to the investigator who performed the randomization.

The primary outcome, defined as the incidence of incisional hernia within 2 years, was compared between groups using a 95% confidence interval for the difference. Categorical variables, including the primary endpoint, were analyzed

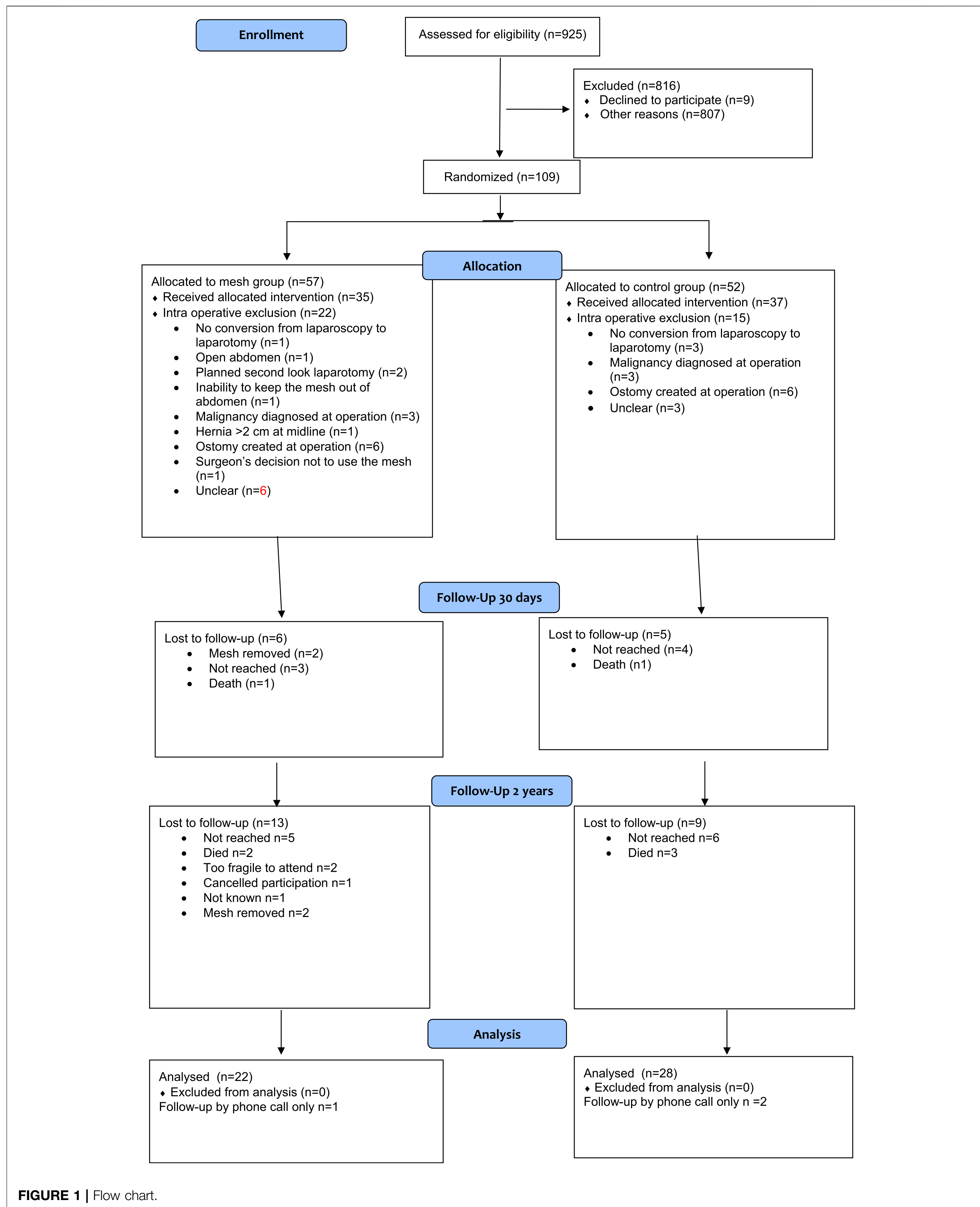

FIGURE 1 | Flow chart.

using the chi-squared test or Fisher's exact test. Continuous variables were compared using the Student's t-test or Welch's test, depending on whether the assumption of homogeneity of variance holds. The results for the above mentioned analyses were presented as difference between groups with 95% confidence interval (95% CI). Analyses were performed according to ITT principle.

Repeated measures data was analyzed using linear mixed model (LMM) using patients as random effect and time, group and time × group interaction as fixed effects. The results for the LMM were presented as difference between means with 95% CI.

As previous research on synthetic mesh utilized as prophylaxis at emergency midline laparotomy was scarce, an analysis of the complications and risks was planned for safety reasons after 30 patients would have been randomized to each group and reached 30 days' follow-up.

Statistical analyses was conducted using IBM SPSS Statistics (Version 24.0) and SAS (Version 9.4).

RESULTS

The Preemer study faced problems in patient recruitment. The patient number was non achievable, and the enrollment was prematurely terminated. As the original patient number was evidently non achievable, the enrollment was prematurely terminated. Between April 2020 and October 2022, a total of 925 patients undergoing emergency midline laparotomy were screened at the participating hospitals. Out of that patient population, 109 patients were randomized (**Figure 1**). After randomization, 35 patients in the mesh group and 37 patients in the control group received the allocated intervention (**Table 1**). The details of surgical procedures, including contamination classifications, are presented in **Table 2**. One patient was re-operated for a seroma during primary stay, with mesh removal during the on-call hours (**Table 3**). There were no differences in the length of hospital stay or complications during the index stay. No fascial dehiscense were observed in either group. There was one (1/35, 3%) deep surgical site infection in mesh group compared to two (2/37, 6%) in control group (p = 0.513).

At the 30-day follow-up, 29 patients in the mesh group and 32 patients in the control group were successfully contacted and interviewed regarding their recovery by phone call or visit to outpatient clinic (**Table 3**). During the 30 days' follow-up, one patient (1/29, 3%) in the mesh group had been readmitted due to retrorectus hematoma that was later drained (Clavien-Dindo Complications class 3a). There was no difference in the Comprehensive Complications Index between the groups. There were two deaths, one in both groups. To our knowledge, the deaths were not related to mesh. Notably, some patients who could not be reached at the 30-day follow-up were later reached at the 2-year follow-up.

By the 2-year follow-up point, 22 patients in the mesh group and 28 in the control group were clinically evaluated (**Table 4**). In the control group, 1/22 (4%) patient had a clinically detectable incisional hernia, which was also visible on ultrasound, although the hernia was asymptomatic. A patient (5%) in the mesh-group who did not attend the clinical follow-up but had been diagnosed with an abdominal wall infection with an enterocutaneous fistula and had a mesh removal (Clavien-Dindo classification 3b). Additionally, one (5%) patient experienced an internal hernia, requiring emergency laparotomy when a loop of intestine herniated between the mesh and the peritoneum (Clavien-Dindo Classification 3b).

The time required to open the retrorectus space, close the posterior layer and apply the mesh was 20.9 ± 10.2 (range 8–53 min, SD 10.0). The average cost for the mesh was 235€. Additionally, there were in total 3 complications in mesh group

TABLE 1 | Patient demographics.

	Mesh group (n = 35)	Control group (n = 37)
Sex		
Female	12 (34)	25 (68)
Male	23 (66)	12 (32)
BMI	27.0 ± 4.8	25.7 ± 4.9
Age	66.9 ± 14.7	68.7 ± 13.5
Smoking status		
Yes	3 (9)	3 (8)
No	28 (80)	29 (78)
Previously	3 (9)	3 (8)
ASA		
1	4 (11)	3 (8)
2	12 (34)	10 (27)
3	16 (46)	18 (49)
4	3 (9)	5 (14)
5	0	1 (3)
Laboratory results		
Creatine	84.7 ± 47.6	83.2 ± 37.6
Albumine	29.4 ± 6.6	32.2 ± 6.1
Cardiovascular disease	4 (11)	4 (11)
Congestive heart failure	1 (3)	3 (8)
COPD	7 (20)	5 (14)
ASO	6 (17)	7 (19)
Celebrovascular disease	3 (9)	2 (5)
DM	7 (20)	6 (16)
DM with end organ damage	2 (6)	3 (8)
Renal disease	3 (9)	2 (5)
Prior malignancy	2 (6)	2 (5)
WHO scale of activity		
1	22 (63)	26 (70)
2	12 (34)	7 (19)
3	1 (3)	4 (11)
Medications affecting healing		
Corticosteroid	5 (14)	4 (11)
Immunosupression	2 (6)	1 (3)
Biological medication	1 (3)	1 (3)
Previous incision		
Upper midline	1 (3)	3 (8)
Midline	1 (3)	4 (11)
Lower midline	3 (9)	8 (22)
Right subcostal	0	1 (3)
Bilateral subcostal	1 (3)	0
McBurney	4 (11)	1 (3)
Phannenstiel	2 (6)	3 (8)
Other	4 (11)	3 (8)
Previous hernia		
Umbilical	5 (14)	1 (3)
Inguinal	2 (6)	0

Nominal variables are reported as counts and percentages (in parentheses); continuous variables are reported as means and standard deviations. BMI, body mass index; ASA, american society of anesthesiologists physical status classification; COPD, chronic obstructive pulmonary disease; ASO, arteriosclerosis obliterans; DM, diabetes mellitus; WHO, world health organization.

TABLE 2 | Operation details.

	Mesh group (n = 35)	Control group (n = 37)	P value	Difference (95% CI)
Operation time (min)	103.7 ± 36.5	96.1 ± 52.4	0.236	
Contamination class			0.578	
1 Clean	1 (3)	2 (5)		
2 Clean-Contaminated	22 (63)	25 (68)		
3 Contaminated	6 (17)	4 (11)		
4 Dirty/Infected	6 (17)	6 (16)		
Primary operation			0.200	
Small bowel resection	16 (46)	13 (35)		
Colon resection	6 (17)	9 (24)		
Division of adhesive band in intestinal obstruction	6 (17)	5 (14)		
Adhesiolysis	2 (6)	6 (16)		
Explorative laparotomy	3 (9)	0		
Cholecystectomy	0	1 (3)		
Gastric or duodenal ulcer suturing	1 (3)	2 (5)		
Small bowel suturing	0	1 (3)		
Vaginal suturing	1 (3)	0		
Length of the midline incision (cm)	16.1 ± 4.6	16.9 ± 4.5	0.243	
Length of suture material used (cm)	77.1 ± 27.0	75.0 ± 28.6	0.371	2.1 (−15.6 to 11.1)
Suture material to wound length ratio	4.9 ± 1.7	4.5 ± 1.5	0.130	
Blood loss (cc)	100.2 ± 109.9	81.6 ± 102.1	0.246	
Time to create the retrorectus space and apply the mesh (min)	20.9 ± 10.2	n/a		
The average cost of mesh per patient (€)	235	n/a		
Length of stay (days)	6.5 ± 3.6	6.1 ± 2.3	0.390	0.4 (−2.8 to 1.1)

Nominal variables are reported as counts and percentages (in parentheses); continuous variables are reported as means and standard deviations.
CI, confidence interval; IH, incisional hernia, cm cm, cc cubic centimeters.

TABLE 3 | 30 days′ follow-up.

	Mesh group (n = 29)	Control group (n = 32)	P value	Difference (95% CI)
Type of follow-up			0.548	
Visit	10 (38)	9 (28)		
Call	19 (66)	23 (72)		
Complications				
Fascial dehiscense	0	0	n/a	
Superficial SSI (C-D 3b)	1 (3)	0	0.491	3.6 (−8.5–17.7)
Deep SSI	1 (3)	2 (6)	0.513	−3.3 (−18.7 to 11.7)
Clavien-dindo Classification 2	1 (3)	1 (3)	0.667	0.1 (−13.9–14.5)
Clavien-dindo Classification 3a	0	1 (3)	0.491	−3.4 (−17.2 to 8.9)
Mesh related complications	0	0		
Mesh removed during hospital stay	1 (3)	n/a		
Place of further care			0.232	
Home	23 (82)	24 (83)		
Healthcare center	2 (7)	5 (17)		
Other hospital	1 (3)	0		
Other	2 (7)	0		
Returned to previous level of activity	25 (76)	26 (81)	0.432	−0.4 (−18.2 to 17.1)
Returned to work	12 (41)	12 (38)	0.562	1.5 (−22.8–25.5)
Length of sick leave	36.6 ± 9.7	45.0 ± 18.5	0.268	−8.4 (−30.4–46.9)
Wound status			0.366	
Healed	28 (97)	31 (97)		
Open less than 2 cm	0	1 (3)		
Open more than 2 cm	1 (3)	0		
Readmission to hospital	3	2 (6)	0.468	3.8 (−12.8–21.0)
Hematoma, COPD worsening	1 (3)	0		3.6 (−8.5–17.7)
Fever	2 (7)	0		7.1 (−5.6–22.6)
Pulmonary embolism	0	1 (3)		−3.4 (−17.2 to 8.9)
Deep SSI	0	1 (3)		−3.4 (−17.2 to 8.9)
CCI	23,9 ± 4,8	22.0 ± 2.2	0.151	1.9 (−5.7 to 1.9)

Nominal variables are reported as counts and percentages (in parentheses); continuous variables are reported as means and standard deviations.
SSI, surgical site infection, C-D Clavien-Dindo Classification, COPD, Chronic Obstructive Pulmonary Disease; CCI, comprehensive complication index.

TABLE 4 | 2 years' follow-up.

	Mesh group (n = 22)	Control group (n = 28)	P value	Difference (95% CI)
Sex			0.053	26.9 (−0.6–49.6)
Female	9 (41)	19 (68)		
Male	13 (55)	9 (32)		
Age	66.4 ± 15.0	70.4 ± 14.3	0.168	
Follow-up time (months)	26.3 ± 3.6	26.3 ± 2.9	0.460	
Operation since index surgery	1 (5)	1 (4)	0.691	1.0 (−13.7–18.5)
IH at clinical evaluation	0	1 (4)	0.560	−3.6 (−17.7 to 11.6)
IH at ultrasound	0	1 (4)	0.560	−3.6 (−17.7 to 11.6)
Blinding of the patient maintained			0.493	
Yes	20 (91)	26 (93)		−1.9 (−21.4 to 14.9)
No	1 (5)	0		
Not known	1 (5)	2 (7)		
Blinding of the surgeon evaluating the patient maintained			0.439	
Yes	18 (82)	21 (75)		6.8 (−17.0–28.2)
No	4 (18)	5 (18)		
Not known	0	2 (7)		

Nominal variables are reported as counts and percentages (in parentheses); continuous variables are reported as means and standard deviations.

requiring further procedures. The length of sick leave was similar between the groups. There was no difference in quality of life between the groups (**Supplementary Material**).

DISCUSSION

This randomized controlled trial found no difference in the rate of incisional hernia between patients who received retrorectus mesh and those whose fascia was closed with a standard 4:1 small-stitch technique. These results are in contrast with earlier studies involving both emergency and elective midline laparotomies, in which prophylactic mesh has significantly reduced incisional hernia rates [2, 5–8]. However, the IH rate was significantly lower in control group closed with 4:1 small stitch closure in this study, compared to significantly higher IH rates previously reported [1–8].

During the 2-year follow-up, two patients experienced complications directly attributable to the creation of the retrorectus space. These types of mesh related complications have not been commonly reported in earlier trials.

The increased costs in the mesh group were the time required to apply the mesh and the cost of the mesh. The mesh cost 235€ on average per patient. Additionally, there were additional procedures required in the mesh group causing more costs. As the rate of IH was very low, the mesh use did not lead to savings in healthcare.

The trial was prematurely terminated due to significant challenges in patient recruitment. This reflects not only difficulties to recruit the emergency patients and the still existing hesitations to use the mesh in contaminated surgical site despite the evidence, but also the shift from emergency midline laparotomies to laparoscopies. Consequently, the small sample size limits the generalizability of the findings and precludes firm conclusions. Furthermore, a large proportion of patients were excluded intraoperatively or lost to follow-up, underscoring the difficulties of conducting high quality randomized controlled trials in emergency surgical settings.

The results of this trial leave more questions than give answers. Further trials are needed to comparing small stitch technique to mesh prevention, possibly concentrating on patients with increased risk of IH in addition to emergency laparotomy alone. The retrorectus placement of the mesh may carry an increased risk for complications.

DATA AVAILABILITY STATEMENT

The datasets generated and/or analyzed during the current study are not publicly available due to Finnish laws on privacy protection but are available from the corresponding author on reasonable request. Requests to access the datasets should be directed to Elisa EM, elisa.makarainen@pohde.fi.

ETHICS STATEMENT

The studies involving humans were approved by Pohjois-Pohjanmaan hyvinvointialueen eettinen toimikunta. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study. Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

AUTHOR CONTRIBUTIONS

EM: Conceptualization, data curation, formal analysis, methodology, software, supervision, writing – original draft, writing – review and editing. MT: Conceptualization, methodology, writing – review and editing. VS: Conceptualization, methodology, writing – review and editing. PM: Conceptualization, methodology, writing – review and editing. AL: Conceptualization, methodology, writing – review and editing. MA: Conceptualization, methodology, writing – review and

editing. JS: Conceptualization, methodology, writing – review and editing. TP: Data curation, writing – review and editing. HL: Data curation, writing – review and editing. HM: Data curation, writing – review and editing. EL: Data curation, writing – review and editing. MN: Data curation, writing – review and editing. PO: Conceptualization, formal analysis, methodology, software, supervision, writing – original draft, writing – review and editing. FM: Conceptualization, methodology, writing – review and editing. TR: Conceptualization, data curation, formal analysis, methodology, supervision, writing – original draft, writing – review and editing. All authors contributed to the article and approved the submitted version.

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CONFLICT OF INTEREST

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontierspartnerships.org/articles/10.3389/jaws.2025.15500/full#supplementary-material

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Systematic Review and Meta-Analysis of the Prevalence and Risk Factors Associated With the Occurrence of Incisional Hernia in Patients Undergoing Midline Laparotomy

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Introduction: Incisional hernia (IH) is the main long-term complication after midline laparotomy and has significant clinical and economic effects. Although multiple risk factors for IH formation have been proposed, their ranking and clinical relevance have not been clearly established. This meta-analysis aimed to estimate the prevalence of IH and rank the associated risk factors, considering both their statistical significance and their clinical impact.

Methods: This meta-analysis was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and registered in PROSPERO (CRD420251107739). Observational (cohort and cross-sectional) studies evaluating patients undergoing midline laparotomy with follow-up for IH were included. Clinical trials and studies involving a laparoscopic approach were excluded. The global prevalence of IH was calculated, and random effects models were used to identify risk factors associated with the occurrence of IH, whose associations are reported as hazard ratios (HRs) and 95% confidence intervals.

Results: Twenty studies (n = 790,800 patients) were included, among whom the overall prevalence of IH was 10.1% (95% CI: 7%–15%). Only 10 studies analyzed relevant risk factors. The factors with the greatest clinical impact were reoperation during hospitalization (HR = 4.09) and surgical site infection (HR = 2.96). Other significant factors included emergency surgery, colon surgery, stoma creation, diabetes, and liver disease. Factors such as sex, obesity, or hypertension were not significantly associated with IH formation.

Conclusions: Perioperative factors are key determinants of the occurrence of IH. The identification of such factors would allow prioritization of preventive interventions, such as the application of prophylactic meshes, especially in high-risk patients. Standardized prospective studies are needed to validate these findings.

Keywords: prevalence, incisional hernia, meta-analyses, midline laparotomy, risk factor

INTRODUCTION

The main complication after midline laparotomy is incisional hernia (IH), with an prevalence of 12.8% at 23.8 months of follow-up [1, 2], although values of up to 69% have been reported in high-risk groups [3]. This prevalence is related to the study population evaluated, the type of incision made, and the methods of follow-up and with which the hernia is diagnosed [3–5].

IH not only results in morbidity associated with chronic pain, functional limitations and deterioration in quality of life but is also associated with a substantial economic burden related to the need for reinterventions [6]. In the United States, the cost of care for this complication is 4 billion dollars per year; a cost reduction of 32 million dollars has been estimated for every 1% decrease in the prevalence of IH [7]. Taken together, these data justify efforts to prevent the occurrence of this complication [2].

There is no single determining risk factor for the occurrence of IH, and the effects of each of the factors are cumulative; hence, not all patients have the same risk of developing an IH [2, 8]. Although preventative efforts have focused on optimizing the surgical technique used to close the incision or the use of prophylactic meshes [3], IH nevertheless occurs more frequently in patients with predisposing factors such as obesity [9], surgical site infection [10], malnutrition, the use of immunosuppressants and chronic diseases such as liver disease. More concerningly, several of these factors are unmodifiable, at least in emergency surgery settings [11].

Despite the multiple studies that have addressed factors associated with the development of IH and developed predictive scores, the results have been heterogeneous and sometimes contradictory. This inconsistency refers to the variation in reported clinical significance for the same factor. For instance, regarding male gender, Ganesh et al. [12] report finding no association, whereas Rios-Diaz et al. [13] report male gender as a statistically significant risk factor. Similarly, for Body Mass Index (BMI), Ganesh et al. [12] identify a significant risk for BMI >25 kg/m^2, whereas Tecce et al. [14] report significance only for BMI >30 kg/m^2, finding no association for BMI <30 kg/m^2. Some predictive models have shown clinical utility, but their applicability is limited by the lack of external validation, the inclusion of postoperative variables that are unavailable at the time of surgical decision-making, and the lack of stratification by type of patient or procedure [15].

The evidence on IH risk arises from heterogeneous study populations that combine different surgical approaches. Given the fundamental anatomical and pathophysiological differences between a full-length midline fascial incision and minimal-access port sites (which involve distinct risk profiles, prevention strategies, and even clinical guidelines), a synthesis focused specifically on open midline laparotomy is warranted. This approach ensures methodological homogeneity and provides clinically actionable evidence for the high-risk patient population that requires this specific surgical access, often in settings of emergency, complexity, or contraindication to minimally invasive techniques.

The objective of this study was to quantitatively evaluate the relative impact of relevant risk factors on the prevalence of IH after midline laparotomy through a meta-analysis of cohort studies to identify the specific magnitude of the effect of each factor. This analysis will establish a hierarchy of risk factors, providing solid evidence to guide clinical decision-making while also identifying the actual prevalence of IH associated with midline laparotomy.

The rationale for establishing this hierarchy is to move beyond a mere list of associations and create a clear, actionable framework for clinical practice. By stratifying risk, the findings can directly guide the intensity of preventive strategies: from mandating advanced measures like prophylactic mesh for high-risk patients to optimizing standard care for others. This approach personalizes management, prevents intervention fatigue, and focuses resources where they offer the greatest benefit.

METHODS

A meta-analysis was conducted and reported in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines [16]. The study was registered with the hospital research and research ethics committees of the hospital, with registration numbers CEI/HRAEB/002/2025 and CEI-001-2025 and in the International Registry for Prospective Systematic Evaluations in PROSPERO (registration number: CRD420251107739) [17].

Study Objectives

This meta-analysis had two primary objectives, formulated as specific research questions:

1. Research Question 1 (Risk Factors): What is the hierarchy of risk factors based on the magnitude of their effect, associated with the development of IH after midline laparotomy?
2. Research Question 2 (prevalence): What is the pooled cumulative prevalence of IH in adult patients after midline laparotomy?

Eligibility Criteria (PEO Framework)

The eligibility criteria were structured according to the PEO framework (Population, Exposure, Outcome), which is the

recommended format for systematic reviews addressing questions of risk factors and prevalence.

Population (P): Adult patients (>18 years) undergo midline laparotomy. Exposure (E): For the synthesis of risk factors, the "exposure" was defined as any pre-, intra-, or postoperative patient characteristic or surgical variable (e.g., demographics, comorbidities, technical factors). For the synthesis of prevalence, the "exposure" was the index surgical event (midline laparotomy). Outcome (O): The primary outcome was the diagnosis of an IH during the postoperative follow-up period, confirmed clinically or radiologically [18].

Inclusion and Exclusion Criteria

Inclusion Criteria

Study population: Patients who underwent midline laparotomy, regardless of surgical indication (urgent or elective), with postoperative follow-up for the detection of IH. *Type of study*: Cohort observational studies (prospective or retrospective) and cross-sectional studies were included. *Study content*: Studies that clearly reported the prevalence of IH as well as the associated risk factors for the condition (demographic, clinical, nutritional or technical). Language: Studies published in English with available full text.

Exclusion Criteria

Studies focused on other types of surgical approach (exclusively laparoscopic or robotic) or another type of incision (transverse, paramedian). Studies including patients with a preexisting IH before the first surgery. Studies that did not report relevant data on the prevalence of IH or its risk factors. Nonprimary publications such as narrative reviews, systematic reviews, previous meta-analyses, conference abstracts, letters to the editor, clinical guidelines, theses or institutional reports.

Data Sources and Search Terms

A systematic search was carried out in the following databases for studies published in English between 1 January 2000, and 30 June 2025: PubMed, The Cochrane Library, SCOPUS, ScienceDirect, ProQuest and Google Scholar.

A combination of controlled terms (MeSH) and free terms was used to maximize the sensitivity of the search strategy. In addition, the bibliographic references of the included studies were manually reviewed to identify relevant articles that may have been omitted in the automated search. The search terms included: "Incisional Hernia," "Risk Factor," "Influencing Factor," "Associated Factor," "Laparotomy," and "Abdominal Surgery." The full search strategy is described in Annex 1, **Supplementary Table A**.

Selection of Studies and Quality Assessment

Two investigators independently (L.A.M.C. and H.V.A.) conducted the study selection and data extraction process. The titles and abstracts were subsequently reviewed for preliminary study selection. Finally, the selected texts were read completely to determine their eligibility according to the previously defined inclusion and exclusion criteria. Disagreements were resolved by discussion among the investigators, and if they persisted, a third evaluator (L.A.F.V.M) was consulted to make the final decision. Information extracted from each study included the name of the first author, year of publication, country of origin, type of study, characteristics of the participants, total sample size, number of patients with IH and reported risk factors.

The risk of bias in the studies included was assessed independently by two investigators (E.R.J.S. and H.A.R.). For non-randomized cohort studies, the investigators used the Risk Of Bias In Non-randomized Studies – of Interventions (ROBINS-I) tool. This tool evaluates bias across seven domains: bias due to confounding, participant selection, classification of interventions, deviations from intended interventions, missing data, measurement of outcomes, and selection of the reported result. Each study received an overall judgment of Low, Moderate, Serious, or Critical risk of bias (**Supplementary Figure SA,B**) [19, 20].

Data Extraction and Management

Data extraction was performed using a form developed in Microsoft Excel, applied independently by two investigators. The extracted data was organized into the following categories:

Study and Population Characteristics: Including author, year, design, sample size, number of incisional hernia (IH) cases, and prevalence (columns 1-7, **Table 1**).

Definitions: The operational definition of IH and the follow-up method were synthesized narratively.

Data for Meta-Analysis: For prevalence, data on cases and sample size from **Table 1** were used. For risk factors, raw data were extracted (number of patients with/without IH who had each factor), constructing 2 × 2 tables, as the Hazard Ratio (HR) was not uniformly reported. For continuous variables, the mean and standard deviation were extracted as reported by the primary studies. For age, the cutoff of ≥65 years was applied in analyses where studies dichotomized this variable. For BMI, the WHO definition for obesity (≥30 kg/m^2) was used as the standard cutoff in our synthesis. We did not test the distribution of these variables, as individual patient data was not available.

Discrepancies were resolved by consensus or, when necessary, by a senior third investigator. The synthesis for each risk factor was performed using only the subset of studies that reported the necessary raw data for that specific factor; therefore, the number of studies (k) varied across factors. Finally, the data was organized in the R environment (version 4.3.0) for analysis.

Main Outcomes

Primary Outcome: The strength of association between potential risk factors and the occurrence of incisional hernia (IH), measured as the Hazard Ratio (HR) with its 95% confidence interval. The definition of IH (e.g., clinical diagnosis, imaging confirmation, or surgical repair) was based on the criteria reported in each primary study and was recorded during the data extraction process.

Secondary Outcome: The cumulative prevalence of IH after midline laparotomy, calculated as the proportion of patients who developed a hernia relative to the total surgical cohort.

TABLE 1 | Characteristics of the studies included (n = 20).

Author, Year	Country	Study type	IH/Simple size	Prevalence (95% CI)	Follow-up (months)	Risk of Bias (ROBINS-I)
Ganesh et al. [12]	India	Cross-sectional	18/100	18 (11–26)	8	7/9 High Quality*
Fink et al. [4]	Germany	Prospective cohort	173/775	22.3(19.4–25.3)	36	7.5/9 High Quality
Rios-Diaz et al. [13]	USA	Retrospective cohort	3127/35666	8.7(8.4–9.06)	67	9/9 High Quality
Veljkovic et al. [9]	USA	Prospective cohort	81/522	15.5(12.4–18.6)	7	8/9 High Quality
Walming et al. [10]	Sweden	Retrospective cohort	166/1621	10.2(8.7–11.7)	12	8.5/9 High Quality
Basta et al. [21]	USA	Retrospective cohort	42/497	8.4 (6–10.9)	28.3	8.5/9 High Quality
Basta et al. [22]	USA	Retrospective cohort	1398/19902	7 (6.66–7.38)	57.9	8/9 High Quality
Ortega-Deballon et al. [23]	France	Retrospective cohort	22944/672429	3.4(3.3–3.5)	60	9/9 High Quality
Cherla et al. [24]	USA	Retrospective cohort	114/247	46.2(39.9–52.3)	21.4	9/9 High Quality
Moas et al. [25]	USA	Retrospective cohort	109/570	19.1(15.9–22.3)	24	8/9 High Quality
Tecce et al. [14]	USA	Retrospective cohort	59/852	6.9(5.2–8.6)	35.5	9/9 High Quality
Franchi et al. [26]	Italy	Retrospective cohort	77/455	16.9(9.5–24.2)	120	8/9 High Quality
Lozada et al. [17]	Mexico	Retrospective cohort	161/789	20.4(17.5–23.2)	24	7/9 High Quality
Fisher et al. [27]	USA	Retrospective cohort	436/12373	3.5 (3.1–3.8)	32.2	9/9 High Quality
Goodenough et al. [28]	USA	Prospective cohort	93/625	14.8(12–17.6)	41	8/9 High Quality
Weissler et al. [29]	USA	Retrospective cohort	2563/30741	8.3(8–8.6)	24	9/9 High Quality
Höer et al. [30]	Germany	Retrospective cohort	128/2983	4.2(3.5–5)	120	8/9 High Quality
Tansawet et al. [11]	Thailand	Retrospective cohort	101/5431	1.8(1.5–2.2)	23.4	9/9 High Quality
Adell-Carceller et al. [31]	Spain	Retrospective cohort	43/295	10.2(8.7–11.7)	37.5	8/9 High Quality
Itatsu et al. [32]	Japan	Retrospective cohort	318/3927	8.1(7.2–8.9)	24	8/9 High Quality

Evaluated using the scale proposed by the Agency for Healthcare Research and Quality (AHRQ), the remaining studies were assessed with the Newcastle-Ottawa Scale (NOS).

Statistical Analysis

A meta-analysis was conducted to estimate the cumulative prevalence of IH after midline laparotomy and to identify the risk factors associated with its formation. Hazard Ratios (HRs) with their 95% confidence intervals (CIs) were calculated for all risk factors, irrespective of whether they were continuous (e.g., age) or categorical (e.g., presence of diabetes) variables. The effect sizes were synthesized using a random-effects model (Der Simonian and Laird method) to incorporate the anticipated variability between studies. Heterogeneity among the included studies was assessed using the Cochrane Q statistic and the Higgins and Thompson I^2 index. Substantial heterogeneity was considered present if $I^2 \geq 50\%$ alongside a p-value ≤0.05 for the Q statistic. Sensitivity analyses were conducted to assess the robustness of the pooled estimates. First, we performed a leave-one-out analysis by sequentially excluding each study. Second, we compared the results from our primary random-effects model with those obtained from a fixed-effects model. Subgroup analyses were carried out to explore possible sources of heterogeneity, such as differences in the population or methodological characteristics of the included studies. To evaluate the existence of publication bias, a funnel plot was generated, and Egger's test was performed. $P < 0.05$ was considered to indicate statistical significance. All the statistical analyses were performed in the R Studio environment (version 1.4.1106) using the R language (version 4.3.0) with the meta, metafor, dmetar and metasens packages.

RESULTS

Study Selection

Following a search of the abovementioned databases, a total of 1,116 articles related to the topic were found. A total of 370 duplicate articles were removed, followed by 625 following the initial review. Among the 101 articles assessed for eligibility, 20 were included in the quantitative synthesis for the cumulative prevalence of IH. Of these, 10 studies provided data in an extractable format suitable for the meta-analysis of risk factors [4, 9–14, 21–33]. The study selection flowchart is shown in **Figure 1**.

Study Characteristics

The countries of origin of the included studies were as follows: the United States [10], Germany [2], India, France, Italy, Mexico, Sweden, Spain, Japan and Thailand (one study each) (**Figure 2**). The methodologies of the studies were distributed as follows: 16 retrospective cohort studies, 3 prospective cohort studies and 1 cross-sectional study. The risk of bias assessment for the cohort studies, conducted using the ROBINS-I tool, indicated that most studies (n = 16) were judged to be at moderate risk of bias. Three studies [3] were assessed as having a low risk of bias, and one study [1] was judged to be at high risk of bias. A detailed summary is provided in **Supplementary Table C**.

Prevalence Meta-Analysis

In total, 790,800 patients who underwent laparotomy were included in the analysis, of whom 32,151 developed IH. The mean prevalence was 10.1% (95% CI 7%–15%), with a range of 1.8%–46.2%, and the mean follow-up was 39.6 months (**Figure 3**). The general characteristics of the included studies are presented in **Table 1**.

Sensitivity Analysis and Publication Bias

A sensitivity analysis was performed by sequentially excluding studies (the "*leave-one-out*" method). This analysis revealed that the pooled prevalence remained stable, with values that ranged between −2.4 and −2.1 on the logit scale (equivalent to ~8.2%–

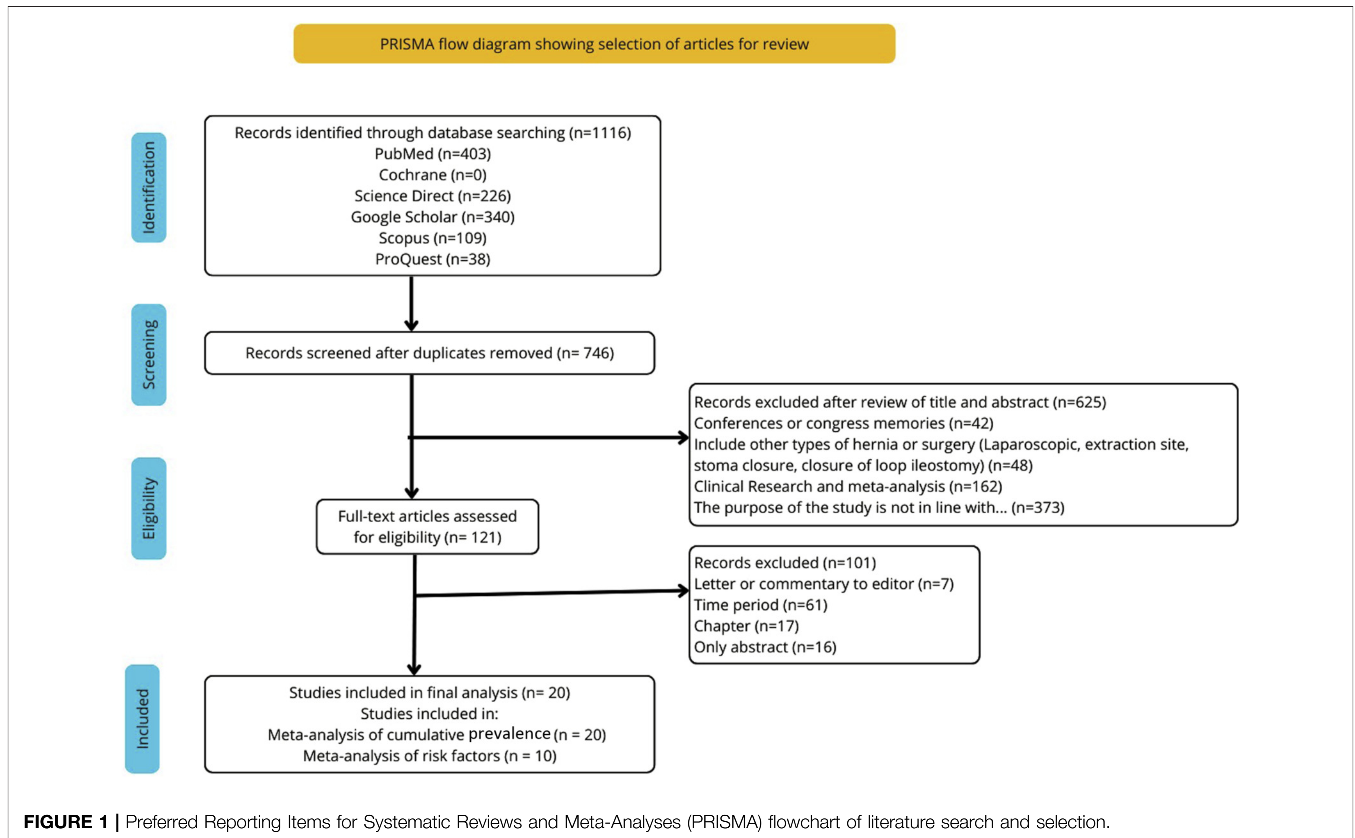

FIGURE 1 | Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart of literature search and selection.

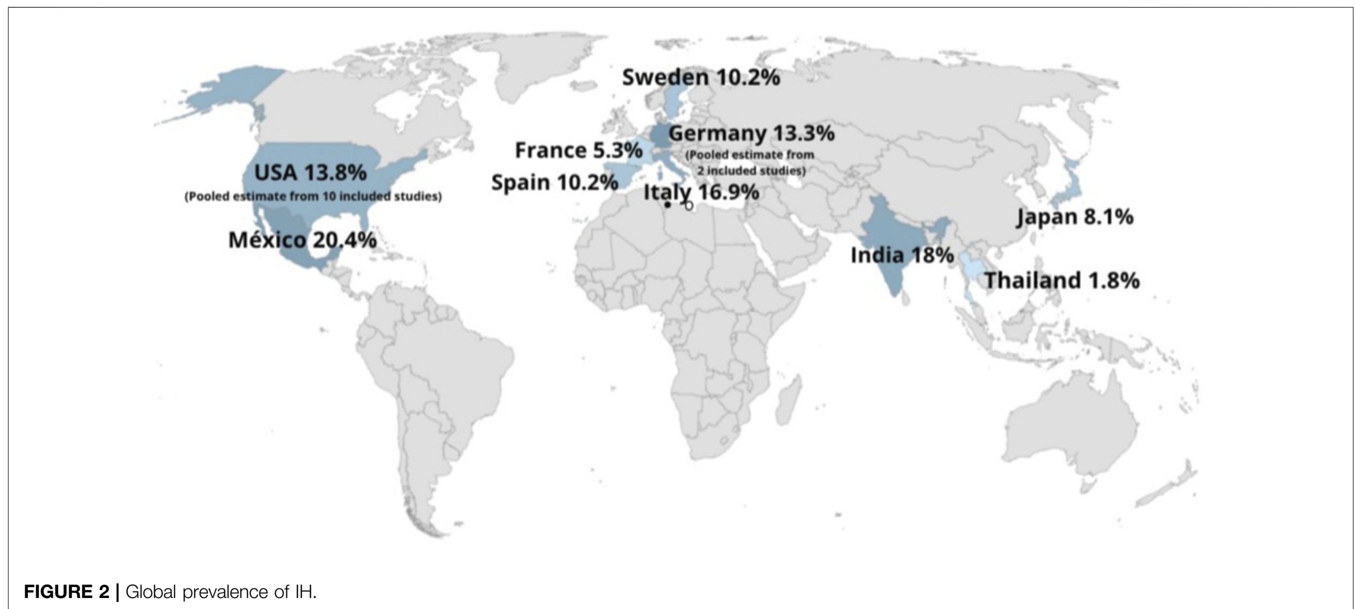

FIGURE 2 | Global prevalence of IH.

11.3% on the natural scale); this value was not significantly different from the original estimate (−2.2 logit; 95% CI: [−2.3, −2.1]). The exclusion of any one study substantially altered the results (i.e., all confidence intervals overlapped with the original value), suggesting that the conclusions of the meta-analysis are robust and do not depend on a particular study (Annex 1, **Supplementary Figure SA**). The analysis revealed the presence of publication bias (p = 0.002) and high heterogeneity, suggesting that the results should be interpreted with caution. Although the direction of the effect was consistent, the variability

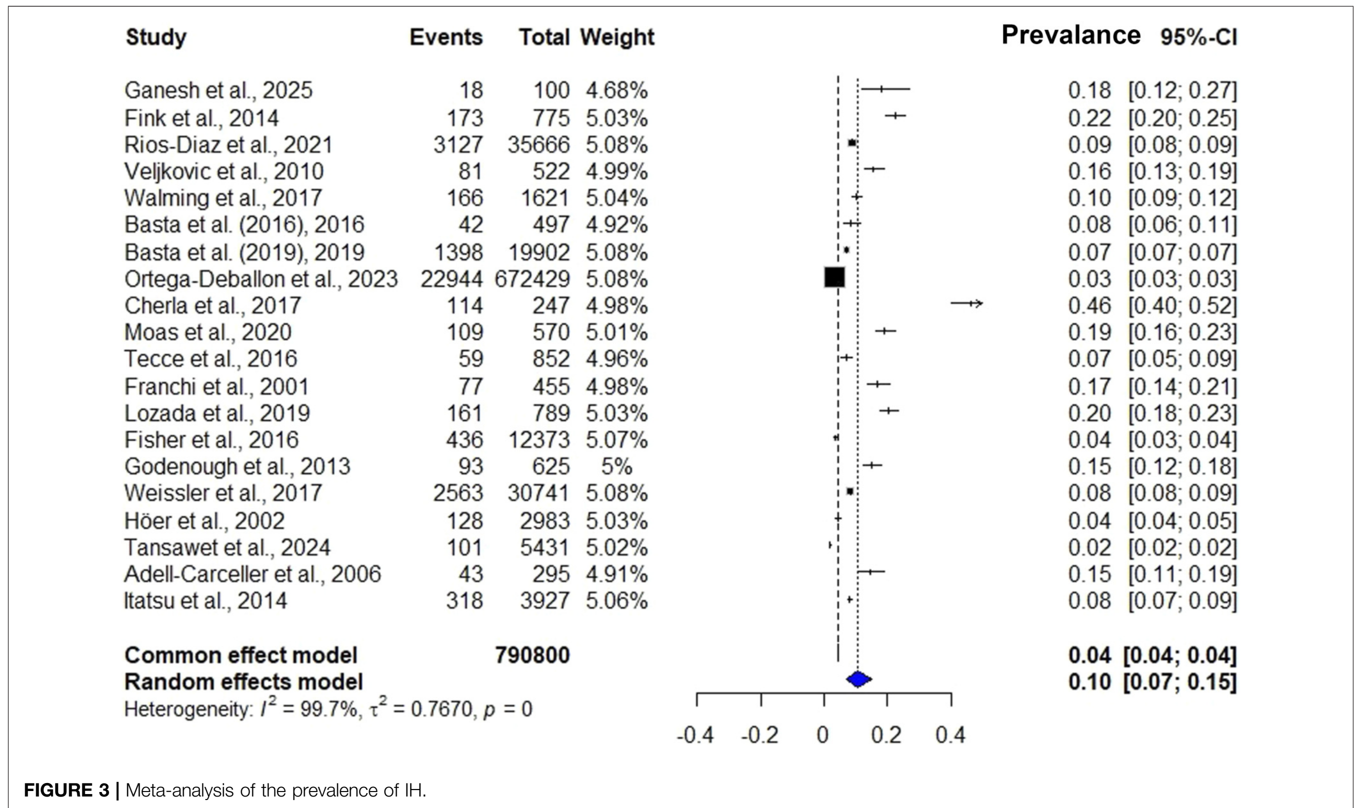

FIGURE 3 | Meta-analysis of the prevalence of IH.

TABLE 2 | Pooled prevalence estimates with subgroup analyses.

1. By geographic region

Region	Studies (n)	I^2 (%)	p (Heterogeneity)	Model	Prevalence (%)	95% CI
Asia	3	76.6	<0.001	Random effects	10.4	7.0–13.9
North America	11	94.2	<0.001	Random effects	9.8	6.3–13.3
Europe	5	91.2	<0.001	Random effects	13.4	7.8–19.1

2. By study design

Study type	Studies (n)	I^2 (%)	P (heterogeneity)	Model	Prevalence (%)	95% CI
Prospective	3	85.4	<0.001	Random effects	15.2	8.7–21.7
Retrospective	16	93.1	<0.001	Random effects	9.5	7.2–11.8

The North American subgroup comprises studies from the United States and Mexico. The single cross-sectional study was omitted from subgroup comparisons due to insufficient sample size.

between studies limits the generalizability of the estimates (Annex 1, **Supplementary Figure B**).

Sensitivity Analysis by Region and Type of Study

A subanalysis was performed by geographic region, revealing the highest prevalence in Europe (13.4%), followed by Asia (10.4%) and North America (9.8%). In terms of the type of study, a higher prevalence was found among prospective studies (15.2%) than among retrospective studies (9.5%). All these analyses involved studies with >50% heterogeneity and thus were interpreted with a random effects model (**Table 2**).

Meta-Analysis of Risk Factors

The meta-analysis of prevalence included all 20 available studies. However, for the analysis of risk factors, 10 studies were excluded: three because they did not compare groups with and without IH [4, 26, 31] and seven because, although they reported general prevalence by surgical approach (and thus were included in the meta-analysis of prevalence), they did not provide separate data for the analysis of risk factors by the type of surgical approach [11, 21, 22, 24, 27, 28, 32]. Studies with mixed approaches were excluded because the objective of this study was to evaluate patients undergoing midline laparotomy.

TABLE 3 | Results of meta-analysis of risk factors for incisional hernia.

Risk factor	Publications	Effect model	Meta-analysis results	Heterogeneity
			HR (CI95%)	I^2/p
Demographic factors				
Sex male	6	Random effects model	0.9 (0.48–1.69)	98%/<0.0001
Age	5	Random effects model	1.11 (1.06–1.15)	96%/<0.0001
Age >65	7	Fixed effects model	1.28 (1.26–1.30)	0%/0.69
BMI >30	8	Random effects model	1.34 (0.98–1.85)	
Comorbidities				
Diabetes	7	Random effects model	1.63 (1.11–2.41)	96%/<0.0001
Smoking	4	Random effects model	1.4 (1.12–1.74)	70.5%/0.01
Hypertension	3	Random effects model	1.18 (0.95–1.48)	85.4%/0.001
Chronic Pulmonary disease	6	Fixed effects model	1.3 (1.2–1.36)	0%/0.52
Chronic heart failure	5	Random effects model	1.06 (0.72–1.57)	96.9%/<0.0001
Anemia	5	Random effects model	1 (0.84–1.20)	72.5%/0.0058
Cancer	4	Random effects model	1.38 (0.99–1.93)	88.5%/<0.0001
Liver disease	5	Random effects model	1.76 (1.5–2.06)	59.4%/0.043
Kidney failure	6	Fixed effects model	1.2 (1.14–1.27)	1.1%/0.4
Perioperative factors				
Emergency surgery	3	Fixed effects model	1.6 (1.1–2.16)	31.4%/0.23
Colon surgery	4	Random effects model	1.55 (1.35–1.79)	90.1%/<0.0001
Previous surgery	4	Fixed effects model	1.52 (1.23–1.88)	36.5%/0.19
Reoperation during hospitalization	4	Random effects model	4.09 (1.92–8.7)	98.7%/<0.0001
Ostomy	4	Fixed effects model	1.53 (1.35–2.16)	29.4%/0.23
Surgical site infection	7	Random effects model	2.96 (1.76–4.9)	90.3%/<0.0001
Surgical site ocurrence	3	Random effects model	1.57 (1.27–1.95)	69.6%/0.037

BMI: Body mass index. I^2: percentage of heterogeneity. p: p value. HR: Hazard ratio. CI: confidence interval.

Among the ten included studies, 76 variables related to the occurrence of IH were identified. Of these, 35 were excluded because they did not meet the inclusion criteria (for example, cost and type of hospital), and 21 were excluded because they were reported in only one or two studies, which made it impossible to meta-analyze them (e.g., cough and use of steroids). Finally, 20 variables were considered for analysis (**Supplementary Table B**). The variables included were grouped into three categories: demographic factors, comorbidities, and perioperative factors.

Demographic factors: Sex: No statistically significant differences were found between men and women. Age: The association between age and IH risk was analyzed separately based on how the data were reported in the primary studies. In studies reporting age as a continuous variable (mean and standard deviation), a significant positive association was found (HR = 1.11; 95% CI: 1.06–1.15). Similarly, in studies that dichotomized age using a cutoff of ≥65 years, older age was significantly associated with a higher risk of IH (HR = 1.28; 95% CI: 1.26–1.30). Thus, regardless of the analytical approach, increased age was consistently identified as a significant risk factor for IH.

Body mass index (BMI): Studies reported BMI continuously or with different cutoff points (≥25 or ≥30 kg/m^2). For this analysis, a cutoff point of ≥30 kg/m^2 was chosen to define obesity, but the association with the incidence of IH was not significant.

Comorbidities: In the analysis of comorbidities associated with the presence of IH, diabetes (HR = 1.63; 95% CI: 1.11–2.41), smoking (HR = 1.40; 95% CI: 1.12–1.74), chronic lung disease (HR = 1.30; 95% CI: 1.20–1.36), liver disease (HR = 1.76; 95% CI: 1.50–2.06) and kidney failure (HR = 1.20; 95% CI: 1.14–1.27) were significantly associated with an increased risk of developing IH.

In contrast, the presence of hypertension (HR = 1.18; 95% CI: 0.95–1.48), chronic heart failure (HR = 1.06; 95% CI: 0.72–1.57), or anemia (HR = 1.00; 95% CI: 0.84–1.20) or a diagnosis of cancer (HR = 1.38; 95% CI: 0.99–1.93) was not significantly associated with the occurrence of IH.

Perioperative factors included emergency surgery (HR = 1.60; 95% CI: 1.10–2.16)), colon surgery (HR = 1.55; 95% CI: 1.35–1.79), a history of previous surgery (HR = 1.52; 95% CI: 1.23–1.88), reoperation during hospitalization (HR = 4.09; 95% CI: 1.92–8.70), creation of a stoma during surgery (HR = 1.53; 95% CI: 1.35–2.16), the presence of surgical site infection (HR = 2.96; 95% CI: 1.78–4.90) and surgical site ocurrence (including infection) (HR = 1.57; 95% CI: 1.27–1.95). All these factors were significantly associated with the development of IH; the ones with the greatest impact were reoperation during hospitalization and the presence of surgical site infection (**Table 3**; **Figure 4**).

DISCUSSION

The European Hernia Society (EHS) guidelines for abdominal wall closure, published in 2015 and updated in 2022, report an prevalence of IH of 12.8% [2, 3] on the basis of the results of a meta-analysis by Bosanquet et al. (2015) [1]. However, that study presents several methodological biases that must be considered. First, 48% of the studies included were clinical trials, a design that is not ideal for estimating prevalence, since it is limited by the

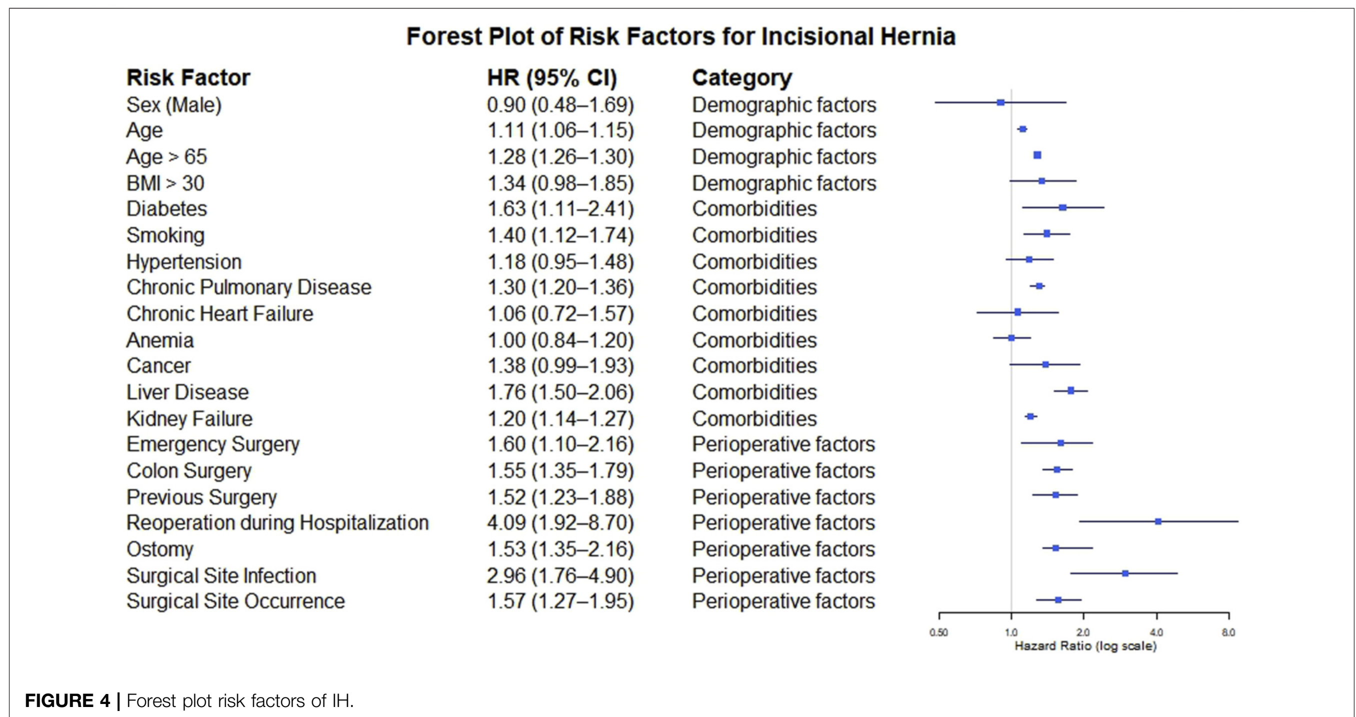

FIGURE 4 | Forest plot risk factors of IH.

population defined by the inclusion criteria (for example, patients with obesity or aortic aneurysm, which does not represent the general population) [34, 35].

Second, 44% of the clinical trials included involved use of a laparoscopic approach. Pooling data from both open and laparoscopic procedures introduces substantial clinical heterogeneity and potential confounding, since the prevalence of IH differs substantially between these approaches, a fact recognized by the EHS guidelines, which state that laparoscopy reduces IH risk. Therefore, the aggregated prevalence reported by Bosanquet et al. may not accurately reflect the risk specific to open surgery. In contrast, by design, our meta-analysis focused exclusively on open midline laparotomy, and by excluding studies involving laparoscopic approaches, our pooled prevalence estimate is specific to the open midline laparotomy population. Consequently, our pooled prevalence estimate (10.1%) provides a more precise and directly applicable measure of risk for the specific patient population undergoing open abdominal surgery.

Finally, 38% of the included studies were conducted in the 1980s and 1990s, when both the imaging methods and the surgical techniques used substantially differed from those currently in use, which could have led to overestimations of the reported prevalence.

In this study, we reported an prevalence of IH of 10.1% at 39.6 months of follow-up. Only data from cohort and cross-sectional studies were analyzed; clinical trials and studies involving laparoscopic approaches were excluded. Consequently, our estimate specifically reflects the risk in patients undergoing open surgery. However, two important factors should be noted in the evaluation of this result: 1. Among the included studies, some involved diagnoses obtained from the patients' files, while in others, patients who underwent IH repair were identified during the study period. Consequently, one potential bias is related to the fact that 16%–44% of patients with IH are usually asymptomatic [24, 36]; additionally, it has been reported that among patients with hernia, only 6.6%–20% end up undergoing surgical repair [26, 32, 37]. 2. Analyses of retrospective and prospective studies yielded incidence values of 9.5% vs. 15.2%, respectively; in the prospective studies, if physical examinations or imaging studies were performed to corroborate the presence of IH, performing imaging studies increased the number of patients identified with IH by up to 40% [24, 38].

One of the main objectives of this study was to rank the risk factors associated with the development of IH on the basis of not only their statistical significance but also their real clinical impact. In this sense, although the associations for multiple variables reached statistical significance ($p < 0.05$), the magnitude of the effect, measured with the HR, allowed us to determine the differences in the clinical impact of these factors. The factors with the highest risk (HR >2.0) included reoperation during hospitalization (HR = 4.09) and surgical site infection (HR = 2.96). Factors that imparted moderate–high risk (HR 1.5–2.0) included liver disease (HR = 1.76), diabetes (HR = 1.63), emergency surgery (HR = 1.60), surgical site complications (HR = 1.57), colon surgery (HR = 1.55), stoma creation (HR = 1.53) and a history of previous surgery (HR = 1.52). Factors that imparted moderate–low risk (HR 1.2–1.5) included smoking (HR = 1.40), chronic lung disease (HR = 1.30), kidney failure (HR = 1.20) and age ≥65 years (HR = 1.28). Finally, there was no significant association between sex,

BMI ≥30 kg/m^2, hypertension (HR = 1.18), chronic heart failure (HR = 1.06), anemia (HR = 1.00) or cancer (HR = 1.38) and IH development.

The literature mentions that an HR >1.5 is usually considered the threshold of clinical relevance, since it represents a substantial increase in risk that justifies intervention. In contrast, an HR between 1.1 and 1.2, although potentially statistically significant, implies only a 10%–20% increase in risk, which rarely merits changes in clinical practice. In this study, factors such as age ≥65 years (HR = 1.28) and kidney failure (HR = 1.20) fell into this category and thus had limited clinical significance. In contrast, a hazard ratio (HR) >1.5 (and especially >2.0), such as that for reoperation and surgical infection, identified the variable as a priority target around which preventive strategies could be developed. This distinction is crucial to avoid over intervention based on marginal associations and focus resources on factors that truly impact the risk of IH [39, 40].

The impact of surgical site infection on the occurrence of IH is significant. Infections can compromise the integrity of the surgical wound and weaken the tissue and fascia at the incision site, which can lead to poor healing. In addition, surgical site infections can prolong hospitalization time, increase the need for additional surgical interventions to treat hernia and infection, and increase healthcare costs [41, 42]. This association is highly relevant, yet it has been underutilized in risk prediction. Few existing scales for predicting IH incorporate SSI as a predictor, and those that do often treat it simply as a dichotomous variable. Given that SSI emerged as the strongest risk factor in our analysis and considering that validated scales already exist to predict SSI, integrating these SSI prediction tools into existing or novel IH risk scores could significantly improve their predictive performance [43].

This meta-analysis presents several relevant strengths. The inclusion of studies from different regions and a cumulative sample of almost 800,000 patients (including more than 32,000 cases of incisional hernia), allows the estimation of the prevalence of IH in patients undergoing midline laparotomy with high precision. Only observational studies (multiple cohort and one cross-sectional study) were analyzed, none of which mixed experimental designs or different surgical approaches, which improves the clinical applicability of the results. In addition, the sensitivity analysis demonstrated the robustness of the estimates, and the protocol was registered in PROSPERO according to the PRISMA guidelines.

This review has limitations inherent to its design and the included studies. First, the assessment using the ROBINS-I tool indicated that potential selection bias (D2) was present across studies, as illustrated in **Supplementary Appendix 3**, which may affect the generalizability of our pooled estimates. Second, our evaluation of publication bias using Egger's test yielded a statistically significant result (p = 0.002), and the accompanying funnel plot (**Supplementary Figure SB**) showed asymmetry, suggesting a potential underrepresentation of smaller studies with null or negative findings. Although we employed a comprehensive search strategy, this asymmetry indicates that the overall effect size should be interpreted with caution, as the meta-analytic estimate might lead to an overestimation of the true effect.

This study also has several limitations. One of these is the high heterogeneity among studies, which can be attributed to differences in definitions, diagnostic methods, and designs. Another important limitation is the relatively short mean follow-up of 39.6 months across the included studies, as IH can develop later than this period. Only ten of the twenty included studies contributed data for the risk factor analysis, which restricted the number of evaluable variables. Among the 76 initially identified factors, only 20 could be analyzed in an aggregate manner. Most of the studies were retrospective in nature, which is associated with a high risk of bias, and publication bias was evident. Some clinically relevant factors could not be included because of a lack of consistent data between studies. A major and modifiable limitation is the absence of data on fascial closure technique (e.g., suture-to-wound length ratio, stitch size), a critical peri-operative variable known to profoundly influence IH risk, which was not reported in the observational studies we synthesized.

These limitations reinforce the need for multinational prospective studies, with standardized protocols that validate the identified factors and allow exploration of other factors that have not yet been analyzed in sufficient depth.

CONCLUSIONS

This study revealed that IH after midline laparotomy is a frequent complication, with an estimated prevalence of 10.1%. Perioperative factors, especially in-hospital reoperation and surgical site infection, showed the greatest clinical relevance, surpassing even multiple comorbidities in terms of the imposed risk. The ranking of these factors according to their clinical impact could allow a more precise development of prevention strategies. The findings of this study underscore the need for standardized prospective studies that validate and complement this evidence to improve decision-making in abdominal surgery.

AUTHOR CONTRIBUTIONS

EL, LM-d-C, LFV-M, HV, EJ, HR, RR, MM, CP, and TP: Study conception and design, Acquisition of data and Analysis and interpretation of data. LFV-M and EL: Analysis and interpretation of data and drafting of manuscript and all authors: Critical revision of manuscript. All authors contributed to the article and approved the submitted version.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontierspartnerships.org/articles/10.3389/jaws.2026.15439/full#supplementary-material

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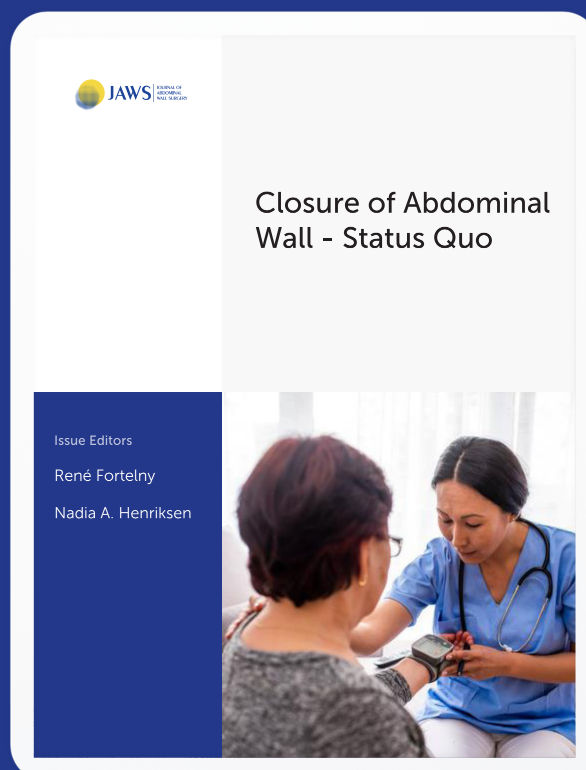

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