Prevention of incisional hernia with prophylactic onlay and sublay mesh reinforcement vs. primary suture only in midline laparotomies (PRIMA): long-term outcomes of a multicentre, double-blind, randomised controlled trial

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Summary

Background Incisional hernia occurs approximately in 40% of high-risk patients after midline laparotomy. Prophylactic mesh placement has shown promising results, but long-term outcomes are needed. The present study aimed to assess the long-term incisional hernia rates of the previously conducted PRIMA trial with radiological follow-up.

Methods In the PRIMA trial, patients with increased risk of incisional hernia formation (AAA or BMI ≥27 kg/m^2) were randomised in a 1:2:2 ratio to primary suture, onlay mesh or sublay mesh closure in three different countries in eleven institutions. Incisional hernia during follow-up was diagnosed by any of: CT, ultrasound and physical examination, or during surgery. Assessors and patients were blinded until 2-year follow-up. Time-to-event analysis according to intention-to-treat principle was performed with the Kaplan–Meier method and Cox proportional hazard models. Trial registration: NCT00761475 (ClinicalTrials.gov).

Findings Between 2009 and 2012, 480 patients were randomized: 107 primary suture, 188 onlay mesh and 185 sublay mesh. Five-year incisional hernia rates were 53.4% (95% CI: 40.4–64.8), 24.7% (95% CI: 12.7–38.8), 29.8% (95% CI: 17.9–42.6), respectively. Compared to primary suture, onlay mesh (HR: 0.390, 95% CI: 0.248–0.614, p < 0.001) and sublay mesh (HR: 0.485, 95% CI: 0.309–0.761, p = 0.002) were associated with a significantly lower risk of incisional hernia development.

Interpretation Prophylactic mesh placement remained effective in reducing incisional hernia occurrence after midline laparotomy in high-risk patients during long-term follow-up. Hernia rates in the primary suture group were higher than previously anticipated.

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Keywords: Incisional hernia; Prophylactic mesh; Onlay; Sublay; Primary suture

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Research in context

Evidence before this study

The benefit of prophylactic mesh closure after midline laparotomy in high risk patients has been established in several RCTs and meta-analyses. However, most trials report short-term outcomes (i.e., <2 years) and limited means of radiological follow-up. This might lead to an underestimation of the incisional hernia rate. Therefore, long-term outcomes with radiological confirmation is essential to adequately assess the performance of a prophylactic mesh.

A literature search up to March, 2023, with the keywords "incisional hernia", "prophylactic mesh", "long-term" was performed by LMvdD and DS. The search was not restricted by language. Two researchers (DS & LMvdD) reviewed all records independently. Prospective randomised controlled trials that enrolled patients aged 18 years or older undergoing midline laparotomy for all indications were included, with any type of mesh and mesh position, with more than two-year follow-up. Three randomised controlled trials with high heterogeneity were included. Incisional hernia rates in the prophylactic mesh groups was lower, but only in one study standardized radiological follow-up was used.

Added value of this study

Compared with other long-term studies, the long-term study of the PRIMA trial included significantly more patients. Additionally, the PRIMA trial compared onlay and sublay mesh closure vs. primary suture in high-risk patients. Also, a multitude of surgical specialties participated in the PRIMA, reflecting daily practice. Finally, the present study used radiological follow-up for accurate diagnosis of incisional hernia. This long-term analysis of the PRIMA trial found a high rate of incisional hernia in the primary suture group and a significantly lower incisional hernia rate in both mesh groups indicating the value of a prophylactic mesh in the long-term.

Implications of all the available evidence

The long-term follow-up of the PRIMA trial provides explicit evidence in favour of prophylactic mesh reinforcement for prevention of incisional hernia in high-risk patients undergoing elective midline laparotomy. Since closure by onlay or sublay mesh is equally effective, onlay mesh placement may be a useful technique for surgeons who do not routinely perform a retrorectus dissection.

Introduction

Incisional hernia is a frequent complication after abdominal surgery. It occurs in approximately 15% of patients in the overall population after midline laparotomy.[1] High body mass index (BMI) and a history of abdominal aortic aneurysm (AAA) are reported to increase the risk of developing an incisional hernia up to approximately 40%.[2,3] Complaints associated with incisional hernia are pain, a decreased patient bodily image and impaired quality of life. In the worst case, incarceration may require emergency surgery.[4,5] The likelihood of incisional hernia development after midline laparotomy can be reduced by closure of the fascia following a 4:1 suture length to wound length ratio with the small bites (i.e., 5 mm by 5 mm) technique, as well as prophylactic mesh reinforcement of the midline.[3,6,7]

Long-term outcomes after prophylactic mesh placement are scarce. Studies reporting on long-term outcomes are mainly based on observational studies, with limited patient numbers or methodological shortcomings.[8,9] The long-term follow-up of a randomized controlled trial (RCT) by Burger et al. showed that incisional hernia recurrence continued until ten years of follow-up.[10] This warrants studies on long-term outcomes of RCTs comparing suture repair vs. prophylactic mesh reinforcement.

The primary aim of the current study was to assess the incisional hernia rate after extended follow-up of a RCT that compared prophylactic onlay mesh, prophylactic sublay mesh and primary sutured closure of midline laparotomies (the PRIMA trial). Incisional hernia occurrence was measured by physical examination in combination with ultrasound imaging or by computed tomography (CT). Secondary outcomes comprised frequency of incisional hernia repair and mesh explantations.

Methods

Study design

The trial design as well as the two-year follow-up of the PRIMA trial have been reported previously.[3,10] In brief: between March 2009 and December 2012, eleven centres from three different countries (Austria, Germany and the Netherlands) included and randomized patients in a 1:2:2 ratio from different surgical specialties (i.e., vascular, gastro-intestinal, hepatobiliary and pancreatic, urological and gynecological) between large bite primary suture, onlay mesh, and sublay mesh for closure of elective midline laparotomies. Randomization was stratified by centre and indication of operation. Adult patients with a high risk of developing an incisional hernia were included. High risk was defined as a BMI of 27 kg/m^2 or higher or patients with AAA as primary diagnosis. Exclusion criteria were an emergency procedure, history of incisional hernia, inclusion in any other trial, immune suppression therapy within two weeks prior to surgery and pregnancy.

For the current study, medical records of all patients who were previously included in the PRIMA trial were first retrospectively screened to determine their health status from March 2019 to January 2022. Patient files

were also used to identify CT scans that were performed as routine patient care, which were then re-assessed by radiologists blinded for treatment allocation. Any abdominal surgery after index laparotomy was registered, and surgical reports were checked for diagnosis of incisional hernia, or whether incisional hernia repair was performed. All patients who were alive and had no prior diagnosis of incisional hernia were contacted by the local investigator to invite them to the outpatient clinic for completing clinical data, additional physical examination and abdominal wall ultrasound examination. Ultrasound was performed by a radiologist from the local medical institution or a trained local investigator. Current study was reported according to the CONSORT guidelines for randomized controlled trials (Supplemental File 1).

The study protocol for this long-term trial update was submitted to the medical ethics committee of the Erasmus University Medical Centre in Rotterdam. A waiver for additional formal ethical approval was obtained, because patients were not subjected to new interventions. The local institutional review boards approved the study protocol. Informed consent was obtained for every patient who agreed on visiting the hospital. This trial was registered at ClinicalTrials.gov (NCT00761475).

Data collection

The coordinating investigators (LMvdD, DS and YY) arranged data collection, review of abdominal CT scans and outpatient clinic consultations including ultrasound examination with all local investigators from the Dutch centres. The German and Austrian data collection (i.e., CT scan review and outpatient consultation) was performed by the local investigators.

Outcomes

The primary outcome was incisional hernia based on any of: CT, ultrasound and physical examination with the diagnosis of incisional hernia (during outpatient visit as part of this update) or subsequent abdominal surgery following index laparotomy. Patients were censored at last date of abdominal wall evaluation, consisting of either CT-scan (for routine clinical care), physical examination, or repeat abdominal surgery. Therefore, all patients were censored before possible time of death. If patients reached their endpoint (i.e., incisional hernia) follow-up was ceased. Incisional hernia was defined according to the European Hernia Society: 'any abdominal wall gap with or without bulge in the area of a postoperative scar perceptible or palpable by clinical examination or imaging'.[11] Location of incisional hernia, and length and width during radiological examination were recorded. Secondary outcomes were frequency of incisional hernia repair, mesh explantation (graded according to the article by Van den Dop et al.[12]), and long-term mesh-related complications.

Data analyses

Data was analyzed according to the intention-to-treat principle. Comparisons between primary suture, onlay mesh and sublay mesh were made, leading to a pairwise comparison at an alpha of 0.017 (0.05/3) according to Bonferroni's correction for multiple testing, this is in concordance with the original (two year) analysis, since the same treatment arms are investigated.

The primary endpoint was studied as time-to-event variable to account for loss to follow-up of included patients (censoring). The cumulative percentage of incisional hernia diagnoses at five-year follow-up was estimated with Kaplan–Meier analyses. The primary outcome was compared between the primary suture, onlay mesh and sublay mesh groups using Cox proportional hazard analyses. Two group levels were added to account for clustering of patients in hospitals and according to operation type. The proportional hazard assumption was assessed visually with Schoenfeld residuals plots.

The incisional hernia occurrence after onlay, sublay or sutured closure was studied with univariable and multivariable mixed effects analyses. Since performing covariate adjustment in RCTs can lead to substantial increase in power, analyses were adjusted for predefined variables age, sex, smoking, BMI, AAA, chronic obstructive pulmonary disease (COPD), cardiovascular diseases, American Association of Anesthesiologists (ASA) classification, and steroid use.[13] The variables adjusted for were consisted with the 2-year analysis. Secondary outcomes were presented as absolute numbers and percentages without formal statistical testing as the study was not powered to study these outcomes.

Analyses were performed with R Statistical Software (version 3.4.0; R Foundation for Statistical Computing, Vienna, Austria).

Role of funding source

The industries that funded this study had no part in study design, data collection, data analysis, data interpretation or writing of the manuscript.

Results

A study flowchart is depicted in Fig. 1. A total of 498 patients were enrolled in the original study. After exclusion, 480 patients were randomized to either the onlay mesh group, sublay mesh group or primary suture group, and stratified according to operation type consisting of vascular, upper gastrointestinal, lower gastrointestinal, hepatobiliary, gynaecological and urological (Table 1). After two-year follow-up, 341 patients (primary suture: 62, onlay mesh: 146 and sublay mesh: 133) were still alive, had not been diagnosed with incisional hernia and were screened for long-term follow-up.

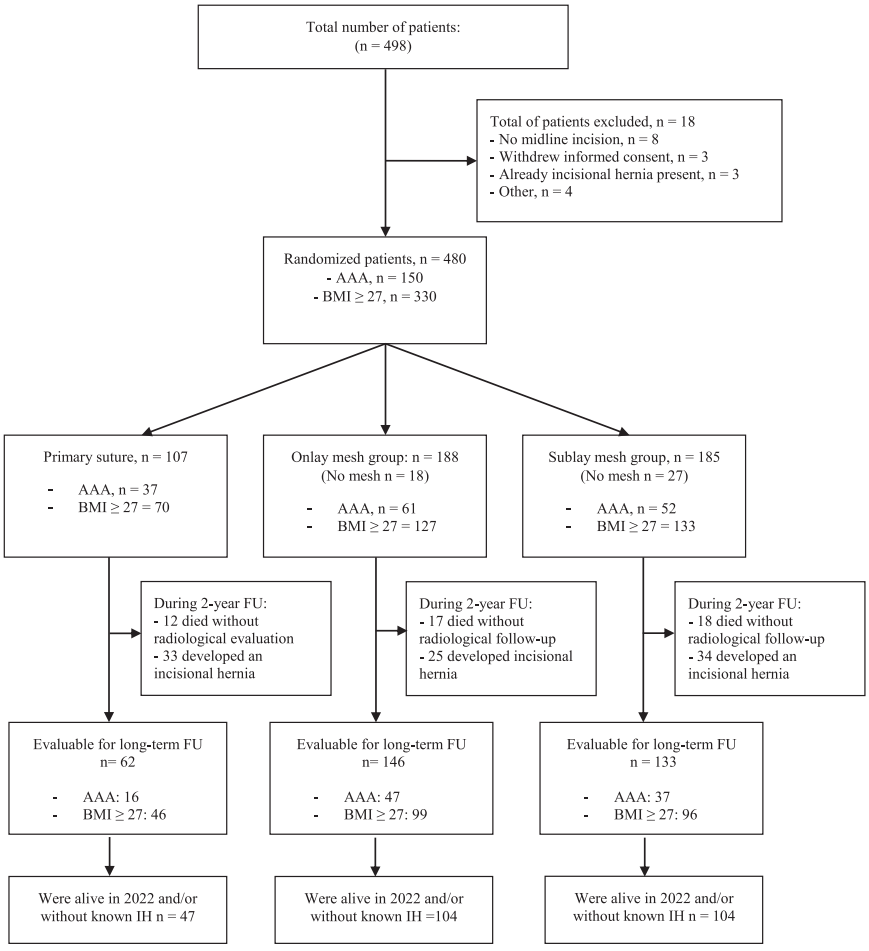

Fig. 1: Study flow diagram.

Ten of the eleven hospitals were willing to participate in the extended follow-up study. The two-year data of the remaining hospital was also included in the current analysis. Between 2019 and 2022, 255 patients (primary suture: 47, onlay mesh: 104, sublay mesh: 104) were still alive and/or without a known incisional hernia. Additional long-term data was acquired for 142 of these 255 patients. The preoperative patient characteristics are depicted in Table 1.

Primary outcome

The primary outcome was assessed in the overall population of 480 patients with a median follow-up of 24 months (IQR 11–49), with a minimum of 0.5 months and maximum of 138 months. The cumulative percentage of incisional hernia diagnoses at five-year follow-up was 53.4% (95% CI: 40.4–64.8) for the primary suture group vs. 24.7% (95% CI: 12.7–38.8) and 29.8% (95% CI: 17.9–42.6) for the onlay and sublay mesh closure groups, respectively (Fig. 2). These numbers considerably increased after the two-year follow-up (30% vs. 13% and 18%).

When adjusted for potentially confounding factors, a significant hazard reduction was found independently for both onlay mesh closure (HR: 0.39, 95% CI: 0.25–0.61, $p < 0.001$) and sublay mesh closure (HR: 0.49, 95% CI: 0.31–0.76, $p = 0.0017$) compared to primary suture closure. Unadjusted analyses in the onlay closure group showed a HR of 0.44 (95% CI: 0.28–0.68), and in the sublay closure group a HR of 0.52 (95% CI: 0.34–0.80) compared to primary suture closure. The complete time-to event models are detailed in the Supplemental Table S1. The proportional hazard assumptions were satisfied in both onlay and sublay groups. Figures of the Schoenfeld residuals can be found in Supplemental Files 1 and 2.

Deviations from the intended mesh groups allocation were reported in 45/480 (10%) patients. In the onlay group, 18/188 (10%) patients did not receive a mesh and in the sublay group 27/185 (15%) patients did

	Total	Primary suture	Onlay mesh	Sublay mesh
Men	292 (61)	68 (64)	116 (62)	108 (58)
Women	188 (39)	39 (36)	72 (38)	77 (420)
Age (years)	64.5 (11.2)	65.2 (10.5)	64.2 (12.3)	64.4 (10.4)
BMI (kg/m^2)	30.6 (5.3)	29.8 (4.4)	30.8 (5.9)	30.8 (5.2)
Smoking	102 (21)	17 (16)	41 (22)	44 (24)
Diabetes mellitus	94 (20)	19 (18)	36 (19)	39 (21)
COPD	52 (11)	9 (8)	24 (13)	19 (10)
ASA				
I	44 (9)	10 (9)	21 (11)	13 (7)
II	234 (49)	55 (51)	90 (48)	89 (48)
III	150 (31)	35 (33)	54 (29)	61 (33)
IV	6 (1)	1 (1)	3 (2)	2 (1)
Unspecified	46 (10)	6 (6)	20 (11)	20 (11)
Previous midline incision	21 (40)	3 (3)	10 (5)	8 (4)
Other hernia	50 (10)	13 (12)	19 (10)	18 (10)
Type of operation				
Vascular	159 (33)	39 (36)	64 (34)	56 (30)
Upper gastrointestinal	65 (14)	18 (17)	22 (12)	25 (14)
Lower gastrointestinal	162 (34)	29 (27)	67 (36)	66 (36)
HPB	21 (4)	3 (3)	8 (4)	10 (5)
Gyn	66 (14)	15 (14)	24 (13)	27 (15)
Uro	7 (1)	3 (3)	3 (2)	1 (<1)

Data are number of patients (%) or mean (SD). BMI = body-mass index; COPD = chronic obstructive pulmonary disease; ASA = American Society of Anesthesiologists.

Table 1: **Baseline characteristics.**

not receive a mesh. Of these 45 patients, 22 (48.9%) developed an incisional hernia.

Secondary outcomes

The cumulative proportion of patients diagnosed with incisional hernia for the subgroups of patients with a BMI ≥27 or AAA is presented in Fig. 3. For the subgroup of patients with a BML ≥27, the cumulative percentage of incisional hernia diagnoses at five-year follow-up was 48.0% (95% CI: 29.2–64.6) for the primary suture group vs. 19.7% (95% CI: 6.9–37.4) and 29.8% (95% CI: 15.7–45.2) for the onlay and sublay mesh closure groups, respectively (Fig. 3, left panel). Incisional hernia rates in both subgroups are mentioned in Table 2.

For the subgroup of patients with AAA, the cumulative percentage of incisional hernia diagnoses at five-year follow-up was 62% (95% CI: 45.4–75.1) for the primary suture group vs. 31% (95% CI: 11.1–53.6) and 31% (95% CI: 10.8–53.4) for the onlay and sublay mesh closure groups, respectively (Fig. 3, right panel).

After extended follow-up, hernia repair was performed in 31 of 119 patients (26.1%) who were diagnosed with incisional hernia: 7/39 after primary suture, 12/40 after onlay mesh, and 12/40 after sublay mesh (Table 3). Mesh explantations were performed in 48 patients, with redo surgery unrelated to the mesh being the most recorded reason: 14/44 (31.8%).

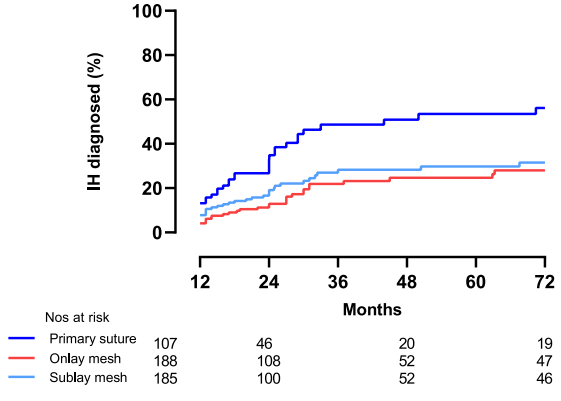

Fig. 2: Cumulative incisional hernia rate in primary suture, onlay mesh and sublay mesh group.

Discussion

The present analysis of the PRIMA trial based on extended follow-up demonstrates the effectiveness of onlay and sublay prophylactic mesh placement in preventing incisional hernia after midline laparotomy in both AAA patients and patients with a BMI ≥27 compared to primary suture closure with radiological verification. Prophylactic mesh placement remained effective over time, halving the hernia rate as compared to primary suture. Onlay and sublay mesh

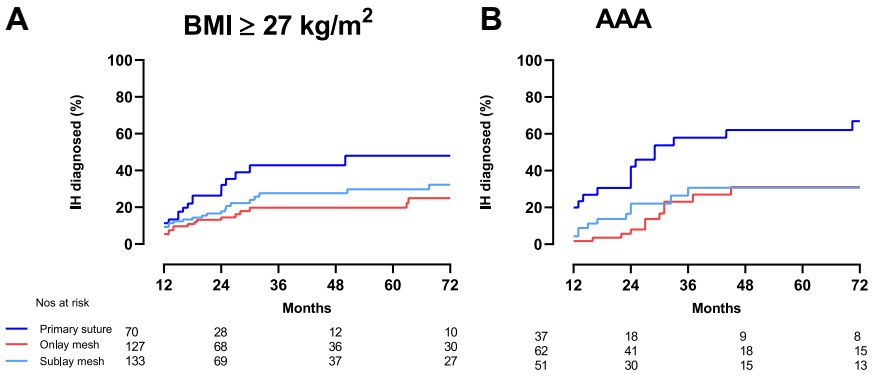

Fig. 3: Cumulative incisional hernia rate in patients with BMI ≥27 and AAA.

	n	No of events	HR	95% CI	p
All patients					
Onlay vs. suture	295	82	0.39	(0.25–0.61)	<0.0001
Sublay vs. suture	292	85	0.49	(0.31–0.76)	0.0017
			Hernia rate (%)[a]		
BMI ≥27 kg/m²					
Primary suture	70		48.0	(29.2–64.6)	
Onlay mesh	127		19.7	(6.9–37.4)	
Sublay mesh	133		29.8	(15.7–45.2)	
AAA					
Primary suture	37		62.1	(45.4–75.1)	
Onlay mesh	61		31.0	(11.1–53.6)	
Sublay mesh	52		30.7	(10.8–53.4)	

[a]Cumulative proportion of patients with incisional hernia at 5-year follow-up.

Table 2: **Multivariable cox regression for incisional hernia after mesh or suture closure of all patients, and descriptive outcomes for subgroups BMI ≥27 and AAA.**

	Total n = 480	Primary suture n = 107	Onlay mesh n = 188	Sublay mesh n = 185
Hernia repair surgery in diagnosed incisional hernia	31/119 (26%)	7/39 (18%)	12/40 (30%)	12/40 (30%)
Mesh explantation			20	24
Burst abdomen			4	5
Related to an infectious complication			9	3
Incisional hernia surgery			2	7
Redo surgery unrelated to the mesh			5	9

Table 3: **Hernia surgery and mesh explantations.**

reinforcement seemed equally effective in reducing the risk for incisional hernia.

The rate of incisional hernia in both prophylactic mesh groups kept increasing as time passed. The rate of incisional hernia after the initial two-year follow-up continued to increase, although most events occurred within the first three years after surgery. Thereafter, incisional hernia rate seemed to increase less, although this period of follow-up was less reliable due to low numbers at risk. The finding of high rates of incisional hernia after suture repair is in line with the findings of Burger et al.,[10] who found an incisional hernia recurrence rate of 67% at ten years after primary suture closure. Although incisional hernia surgeries were investigated and the midline fascia was already compromised at time of surgery, the high rate of recurrence after suture repair is appreciable. These findings indicate that incisional hernia continues to

develop during a longer period of time than previously anticipated, although most events will occur in the first three years. Studies focusing on treatment or prevention of incisional hernia could use two-year follow-up to evaluate treatment strategy, but should inform patients that their risk for developing an incisional hernia continues to after two years.

Although significantly effective, the results with mesh reinforcement might be further improved by a combined technique with closure of the fascia by small bites technique.[6] At the time (before 2009) the trial was constructed, only few studies mentioned this technique for closure of the midline, and therefore the small bites technique was not incorporated in the study protocol. This might have been a significant contributor to the incisional hernia rate in the study groups. Another technical factor that should be considered is the mesh overlap of 3 cm, whereas a 5 cm overlap is advised in hernia surgery as formulated by the 2010 Ventral Hernia Working Group recommendations.[14] However, the midline fascia is closed with lower tension during a primary laparotomy than in hernia surgery, the tissue is healthy, no hernia sac has been resected, the tissue has not been compromised by scarring from previous surgery and it may not have lost its strength. Furthermore, smaller overlap might minimize seroma formation and wound complication by reducing mesh surface.[15] New trials should focus on the combination of small bites suturing with mesh enforcement.[16]

Potentially, the fixation of the mesh using fibrin glue as used in the PRIMA trial did not properly keep the mesh in place, and the mesh might have displaced during increased intra-abdominal pressure (e.g., postoperative ileus). In the PRIMAAT trial, the prophylactic mesh was fixed with stitches in the retro-rectus space using a total overlap of 7.5 cm.[17] None of the patients developed an incisional hernia after five years, although ultrasound or CT was used in only 35.3% in the mesh group.[17] Furthermore, participants of the PRIMAAT trial were all abdominal wall surgeons, whereas the PRIMA trial included a plethora of surgical specialists, more accurately reflecting daily practice. Furthermore, due to deviations in treatment allocation, a number of patients allocated to the onlay or sublay group never received a mesh as per discretion of the operating surgeon. This causes for an overestimation of the incisional hernia rate in the mesh groups. However, the hernia rate is likely an accurate representation if widespread implementation of the technique is established, as in daily clinical practice deviations will likely occur.

An argument against onlay mesh closure was the fear for mesh related infections with this mesh position. Also mentioned in a recently published PRIMA article, the rate of mesh explantations were higher in the onlay group.[12] Furthermore, when assessing hernia repair surgery, the onlay mesh position has been associated with an increased risk for infectious complications.[18] However, the overall low rate of mesh infections may fairly outweigh the beneficial effect on incisional hernia prevention as shown in this follow-up study. Due to its technical simplicity, onlay prophylactic mesh placement may still be the preferred mesh closure technique for surgeons who do not routinely perform a retrorectus dissection (e.g., vascular surgeons, urologists, gynaecologists). Compelling surgeons to adhere solely to sublay mesh position could negatively influence the support for prophylactic mesh placement.

Doubt still exists whether prophylactic mesh use outweighs potential complications in the long-term.[19] In a long-term study on prophylactic mesh placement by Glauser et al. and Carro-Tarrago et al. no mesh-related complications were reported between two and five years.[9,20] Twenty-eight percent of the patients included in the original PRIMA trial had died before long-term follow-up could be conducted. The population of patients undergoing midline laparotomy often have a limited life-expectancy due to the underlying disease and may present with significant comorbidity. Prevention in this frail population is imperative since incisional hernia repair surgery may be hazardous or not feasible.

The main limitation of the current follow-up study is the percentage of patients lost to follow-up. Many patients died or did not routinely come to the hospital for check-ups of the abdominal wall. Therefore, we cannot link all abdominal CT scans with clinical examinations. Nevertheless, valuable data was gathered on a substantial subset of patients with radiological follow-up. The lower numbers at risk during long-term follow-up from three years onwards limits accuracy of these estimates, and the protective effect of the prophylactic mesh might have decreased after these three years. Additionally, since only 18 patients were excluded, pre-inclusion selection of patients may have occurred, which cannot be quantified. Patients with incisional hernia may be more likely to participate in study follow-up, causing selective loss to follow-up; if true, this would mean the estimated incidence rates underestimate the true rates. The randomized design means these effects should not have been differential by group. Finally, based on these results its unknown how prophylactic mesh reinforcement would compare to a small bites technique in high-risk patients or if a combination of small bites closure with mesh prophylaxis would further improve results.

In conclusion, the present update of the PRIMA trial demonstrates that significantly fewer incisional hernias occurred in the prophylactic mesh groups compared to the primary suture group after extended follow-up. Incisional hernia in the suture group appears to occur after a longer period of time and to higher rates than previously described in literature. Due to its technical simplicity, onlay mesh placement could be the preferred prophylactic mesh closure technique for surgeons who do not routinely perform a retrorectus dissection.

Contributors

LMD: Inclusion and follow-up, acquisition of data, analysis of data, interpretation of data, manuscript drafting and rewriting, final approval for manuscript. DS: Inclusion and follow-up acquisition of data, analysis of data, interpretation of data, manuscript drafting and rewriting. YY: Inclusion and follow-up acquisition of data, analysis of data, manuscript revision. AW: Inclusion and follow-up acquisition of data, analysis of data, interpretation of data. DvK: Inclusion and follow-up, interpretation of data, statistical revisions. RP: acquisition of data, interpretation of data, manuscript revision. DR: acquisition of data, interpretation of data, manuscript revision. LT: acquisition of data, interpretation of data, manuscript revision. RF: Conception and design of study acquisition of data, interpretation of data, manuscript revision. AM: Conception and design of study acquisition of data, interpretation of data, manuscript revision. GK: Conception and design of study, interpretation of data final approval of manuscript. PT: interpretation of data, revision of the manuscript, final approval of manuscript. JF: Conception and design of study, interpretation of data, revision of the manuscript, final approval of manuscript. JJ: Conception and design of study, interpretation of data, revision of the manuscript, final approval of manuscript.

Data sharing statement

Deidentified individual participant data collected in the PRIMA trial can be made available upon reasonable request. The corresponding author (LM) will review the request. The PRIMA investigators will be asked to approve all research performed with the shared data.

Declaration of interests

None of the authors declare conflict of interest.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.lanepe.2023.100787.

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