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ORIGINAL SCIENTIFIC REPORT

Prophylactic Intraperitoneal Onlay Mesh Following Midline Laparotomy—Long-Term Results of a Randomized Controlled Trial

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Abstract

Objectives Incisional hernia, a serious complication after laparotomy, is associated with high morbidity and costs. This trial examines the value of prophylactic intraperitoneal onlay mesh to reduce the risk of incisional hernia after a median follow-up time of 5.3 years.

Methods We conducted a parallel group, open-label, single center, randomized controlled trial (NCT01003067). After midline incision, the participants were either allocated to abdominal wall closure according to Everett with a PDS-loop running suture reinforced by an intraperitoneal composite mesh strip (Group *A*) or the same procedure without the additional mesh strip (Group *B*).

Results A total of 276 patients were randomized (Group *A* = 131; Group *B* = 136). Follow-up data after a median of 5.3 years after surgery were available from 183 patients (Group *A* = 95; Group *B* = 88). Incisional hernia was diagnosed in 25/95 (26%) patients in Group *A* and in 46/88 (52%) patients in Group *B* (risk ratio 0.52; 95% CI 0.36–0.77; $p < 0.001$). Eighteen patients with asymptomatic incisional hernia went for watchful waiting instead of hernia repair and remained free of symptoms after of a median follow-up of 5.1 years. Between the second- and fifth-year follow-up period, no complication associated with the mesh could be detected.

Conclusion The use of a composite mesh in intraperitoneal onlay position significantly reduces the risk of incisional hernia during a 5-year follow-up period.

Trial registration number Ref. NCT01003067 (clinicaltrials.gov).

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Introduction

The burden of incisional hernia after midline laparotomy has raised the question if a prophylactic mesh placement during abdominal wall closure is of benefit.

The reported rate of incisional hernia after midline incision varies from 4.2% up to a calculated risk of 73% [1–5]. The impact on quality of life [6] and annual health care costs of $3.2 billion in the USA [7] alone has motivated various groups to research ways to decrease the rate of incisional hernia by optimizing the technique of abdominal wall closure.

The use of prophylactic mesh placement after midline laparotomy is of great interest with promising results in a multitude of randomized controlled trials [8–19]. However, these studies are difficult to compare due to differences in the location of the mesh, mesh type, suture material and mesh fixation [20]. Standard technique regarding preparation of the mesh and its placement in onlay and sublay position incur additional operating time. The major advantage of this randomized controlled trial is that this selective method of using a composite mesh as an intraperitoneal onlay mesh (IPOM) generates no additional time needed for dissection or placement. The short-term results regarding the feasibility and safety of this technique and effect on hernia reduction after 2 years have already been published [21].

Methods

This single center, non-blinded, parallel group, randomized, controlled, trial recruited patients from June 2008–May 2013. The trial design and methodology were reported in detail in a previous publication [21].

Patients undergoing median laparotomy were either randomly allocated to abdominal wall closure with a PDS-loop running suture and an additional IPOM (Group *A*) or to Group *B* which included the same procedure without the additional IPOM (Group *B*). The allocation ratio was 1:1.

Study participants

Prior to surgery, all patients with a planned median laparotomy were screened for eligibility. Written informed consent was attained from all participants. Exclusion criteria were current pregnancy, intestinal perforation, substance abuse, life expectancy < 5 years due to advanced cancer, documented mesh material allergy, a planned second laparotomy, age below 18 years and severely handicap patients. A previous laparotomy was not an exclusion criterion. Patient characteristics were collected with a case reporting form.

Interventions

Late-absorbable monofilament polydioxanone loop sutures (PDS II size 1; Ethicon^{TM} by Johnson and Johnson^{TM}, New Brunswick, NJ, USA) were used for abdominal wall closure in both groups with a suture distance of 10 cm. A single-layer continuous suture taking all layers of the abdominal wall apart from subcutaneous fat and skin (peritoneum, posterior rectus sheath, rectus muscle and anterior rectus sheath) was the chosen as the closure technique. As per Jenkins rule [22], a new stitch was placed every one cm with a minimum distance to the midline of one centimeter. The thread to incision length ratio was 4:1. The laparotomy length was measured prior to closure of the abdominal wall. In Group *A*, a 7.5-cm-wide Parietex^{TM} composite mesh (Covidien^{TM}, Dublin, Ireland) was additionally used. Parietex^{TM} is a special 3D mesh with a visceral side containing absorbable, hydrophilic film and the abdominal wall facing side consisting of porcine collagen, polyethylene glycol and glycerol. This specially engineered product is designed to minimize adhesions and visceral erosion. This works by selectively choosing the treated surface to face the abdominal cavity [23]. The abdominal wall was closed with an all layer continuous suture using the same technique in both groups. In addition, the mesh strip was grasped by the PDS loop and fixed in the midline. The edges of the mesh strip overlapped the line of the incision by 4 cm, each toward the chest and the pubic symphysis. This sort of mesh strip is currently not available; therefore, a 20 × 15 cm Parietex^{TM} composite mesh was divided longitudinally into two equal parts, and the resulting parts were sutured together using three single stitches (SurgiproTM, size 4–0; CovidienTM). The abdominal wall closure was finished with a subcutaneous continuous suture using absorbable material (Vicryl^{TM}, size 3–0; Ethicon^{TM}). A skin stapler was used to close the skin (Proximate^{TM}; Ethicon^{TM}). This above-mentioned study protocol was carried out by all surgeons of the department and by residents under supervision. The principle investigator of the study trained all involved surgeons on how to implant the mesh strip.

Outcomes

Intraoperative findings were collected using an operative case reporting form. This included: study group, midline incision length, mesh strip length, numbers of PDS loops used for the closure of the fascia and classification of the wound contamination. A postoperative case reporting form was used for complications occurring after surgery. The primary endpoint was the incidence of incisional hernia (definition below) 2 years after midline laparotomy. Secondary endpoints were feasibility and safety of the mesh

implantation (sepsis, infection, seroma and bowel injury), postoperative pain, and the rate of incisional hernias at the 5-year follow-up. Postoperative clinical examinations occurred at 6 weeks, 2 years and 5 years. Abdominal wall ultrasound was performed at 2 and 5 years. Pain was documented using a visual analogue scale (VAS) from 0 to 10 cm.

Definition of incisional hernia

Any visible and/or palpable "blowout" within a distance of 3 cm from the midline abdominal scar was defined as an incisional hernia. The sonographic criteria of an incisional hernia were a visible gap within the abdominal wall and/or tissue moving through the abdominal wall during Valsalva maneuver and/or a detectable "blowout." The definitive diagnosis of incisional hernia was either clinical criteria, ultrasound criteria or both. The study did not distinguish between single and multiple incisional hernias.

Randomization and masking

A total of 280 sealed envelopes (140 in group *A* and 140 in group *B*) were placed in a box and numbered sequentially from 1 to 280. Randomization took place during surgery just before abdominal closure. At this point, an envelope would be chosen in consecutive order. Randomization was not carried through in cases when an exclusion criterion was only discovered during surgery (i.e., intestinal perforation).

Statistical methods

Pearson's Chi-square test or Fisher's exact test were used for categorical and continuous data, respectively, and Mann–Whitney *U* test for ordinal data. Time-to-event analysis was not done because patients were controlled at specific time points (6 weeks, 2 years, 5 years). The p value was considered significant at 0.05. Statistical analysis was performed using Stata version 10.1 (StataCorp; College Station, TX, USA). The study was approved by the ethical committee of Basel and Baselland (EKBB Ref-No. 364/07) and registered at www.ClinicalTrials.gov (Ref-No. NCT01003067).

Role of the funding source

The sponsors were not involved in the study design, data collection, data analysis, data interpretation or writing of the manuscript.

Results

Until May 2018, we were able to follow-up 183 patients (Group *A*: 95; Group *B*: 88) after a median of 5.3 years (interquartile range [IQR] 5.0–5.75). Details of the inclusion, exclusion and follow-up of patients are summarized in the Consort flow diagram (Fig. 1). All patients underwent ultrasound during the planned follow-ups. Time to follow-up was 5.3 years (IQR 5.0–5.8) in group *A* and 5.3 years (IQR 5.0–5.7) in group *B*. In group *A,* the rate of incisional hernia was 27.4% ($n = 26$) vs. 52.3% ($n = 46$) in group *B*. The risk ratio was 0.52 (95% CI 0.36–0.77; $p < 0.001$). As outlined in Fig. 1, during the follow-up from 2 to 5 years, only two patients underwent relaparotomy. The indication for this in the participants from group *A* was slow transit constipation 4 years after the index procedure, which led to a subtotal colectomy. The participant in group *B* had a left hemihepatectomy 3 years after the index operation due to liver metastasis. Neither patient had an incisional hernia before relaparotomy. Therefore, even in these two cases, during the interval from the 2- to 5-year follow-up, no additional complication with the prophylactic mesh occurred.

After the 2-year follow-up, we detected 58 patients with incisional hernia. Out of these, 22 patients (38%) were managed with a watch and wait approach. All patients were free of pain (VAS 0) at this time. Two patients died during follow-up, and two patients were lost to follow-up. Subsequently, 18 patients were available for follow-up after a median of 61 months (IQR 56–68). In the interim, none of the patients had a hernia repair or symptoms requiring a surgical intervention.

Discussion

The European Hernia Society (EHS) recommend efforts to prevent incisional hernias whenever possible [24]. Here, we present data from the long-term follow-up of the first randomized controlled trial designed to evaluate the use of an intraperitoneal composite onlay mesh to prevent post-laparotomy incisional hernias. After a median follow-up of 5.3 years, we demonstrate a significant reduction in incisional hernias by using a mesh strip in intraperitoneal onlay position. The results concerning the feasibility as well as the efficacy and safety after 2 years have already been published [21]. The procedure itself did not prolong the overall time of surgery [21].

A multitude of studies have investigated the benefit of prophylactic mesh implantation and are summarized in different reviews [20, 25]. The follow-up in these studies varies from 13 to 48 months. The variability regarding the

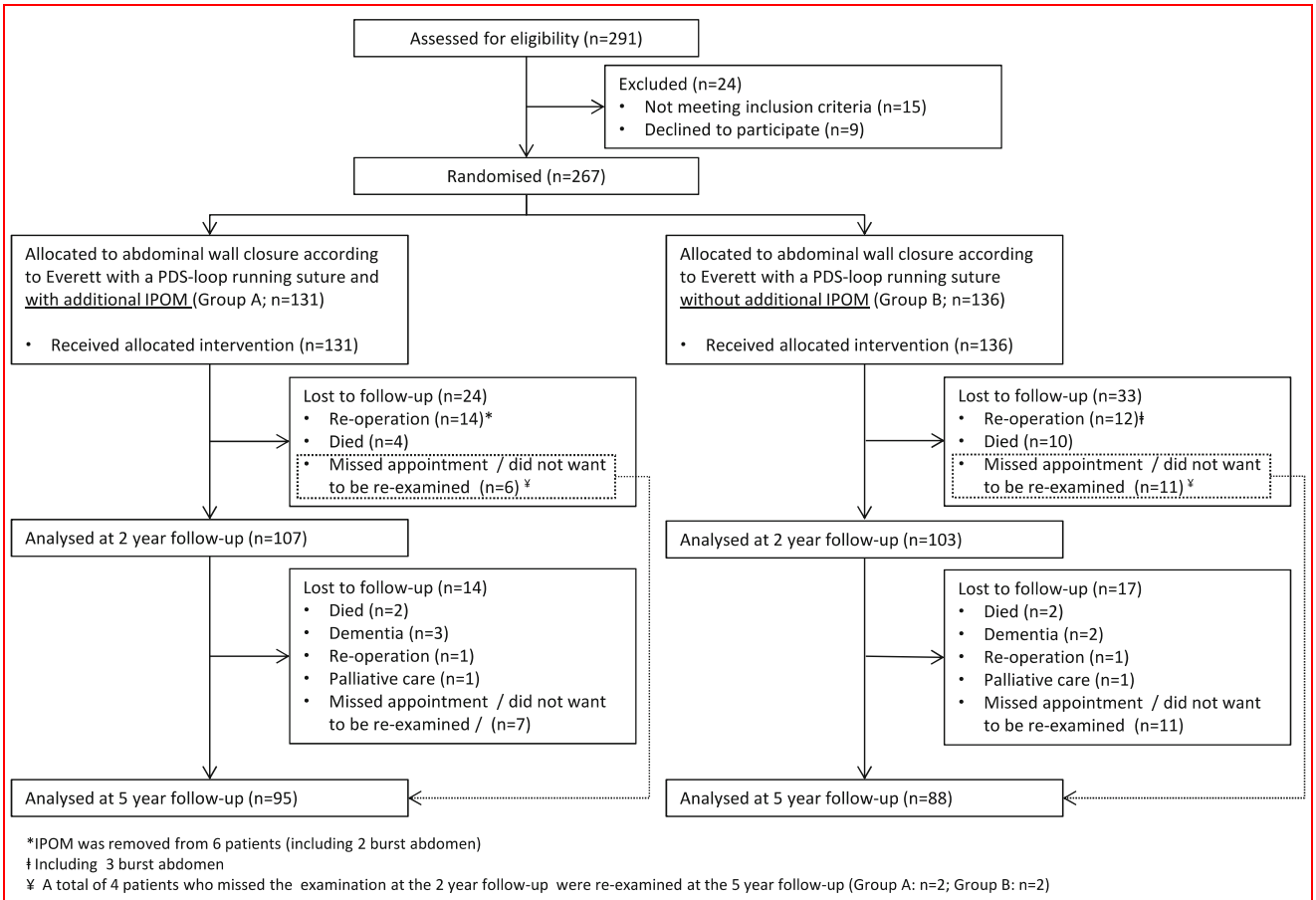

Fig. 1 Consort flow diagram

type of mesh used and mesh position is high. This, in turn, does not give surgeons a clear position on the best procedure to prevent this complication. The recently published data from the PRIMA study reported a higher rate of seroma in onlay position compared to sublay position and primary fascial closure, however, without a significantly higher rate of infections [18]. After a 2-year follow-up period, the onlay position reduced the risk of incisional hernia significantly compared to sublay position and primary fascial closure [19].

The rate of incisional hernia in our study seems quite high with 52 versus 27%. However, there are limited data with similar median follow-up time to compare with. Alnassar et al. presented a 5-year incidence of incisional hernia of 69.1% after vascular repair in a prospective series [26]. It has to be mentioned that in the above-mentioned study the participants were already at a high risk of incisional hernia.

To date, comparable results from randomized controlled trials after a 5-year follow-up are lacking. After a 2-year follow-up period, the PRIMA study reported a rate of incisional hernia of 30% after primary fascial closure and a rate of 18% and 13% after mesh reinforcement in sublay and onlay positions, respectively [19]. All of our patients underwent radiological examination in contrast to only 59% in the PRIMA study, which was surprising since ultrasound increases the rate of detection [27]. The STITCH study reported a rate of incisional hernia at 21% after 1 year of follow-up in the large bites group [28]. This technique is comparable to our technique with bites of 1 cm and intersuture spacing of 1 cm. In this study, 24% of the patients underwent a physical examination with a hernia detection rate of 3%. If we consider a reported relative increase in more than 60% during 2 years of follow-up [29], our findings are to be expected.

Regarding complications associated with the mesh, we previously published short-term results with no significant difference in postoperative morbidity and mortality [21]. However, six meshes were removed during the 6-week follow-up period due to burst abdomen ($n = 2$), mesh infection leading to the formation of a sinus tract ($n = 2$), bowel perforation not related to the implanted mesh ($n = 1$) and retroperitoneal infection ($n = 1$). Table 1 shows all perioperative complications. In the interim, no new complications related to the mesh such as fistulas have been observed. These finding support the feasibility and safety

Table 1 Perioperative complications

	Group *A* (with additional IPOM)	Group *B* (without additional IPOM)	*p* value
Minor complications			
Hematoma	3 (2.3%)	3 (2.2%)	n.s.
Seroma	2 (1.5%)	2 (1.5%)	n.s.
Subcutanous infect	4 (3.1%)	1 (0.7%)	n.s.
Major complications			
Bowel perforation	0 (0%)	1 (0.7%)	n.s.
Intraabdominal abscess	2 (1.5%)	1 (0.7%)	n.s.
Anastomotic leackage	3 (2.3%)	1 (0.7%)	n.s.
Burst abdomen	2 (1.5%)	3 (2.2%)	n.s.
Reoperation (within 30 days)[a]	4 (3.1%)	6 (4.4%)	n.s.
Death (30-day Mortality)[a]	2 (1.5%)	2 (1.5%)	n.s.

n.s. not significant

[a]Identical to reoperation and death within 6 weeks

of our technique. As a limitation, 15% of the patients were lost to follow-up. The missing data on mesh related complications in this population cannot be discounted. The possibility of intestinal erosion due to the mesh after the 5-year follow-up period must be considered, in particular, when our results are compared to other techniques such as onlay mesh for hernia prevention.

In the current study, 38% (22/58) of patients with an incisional hernia after a 2-year follow-up period were asymptomatic and did not undergo hernia repair [21]. This rate is comparable to the results of a systemic review by Bosanquet et al. [5]. Out of this group, 18 patients with incisional hernia were detected after 2 years and were managed with a wait-and-watch approach. None of these patients required hernia repair during a median follow-up of 61 months. All patients remained free of symptoms. The indication for hernia repair in asymptomatic patients is still under debate. The guidelines of the International Endohernia Society give no recommendations regarding a wait-and-watch approach due to lack of valid data [30]. Thus far, there are no data regarding the natural course of asymptomatic incisional hernias in general. Incarceration or strangulation is the indication in 3–5% of the cases of incisional hernia repair [31, 32]. If the patient is oligosymptomatic, then the repair of incisional hernia does not improve regarding pain [32].

Currently, high-quality data where a wait-and-watch approach has been implemented are only available for inguinal hernia repair. Long-term follow-up data of two randomized controlled trials reported a rate of incarceration of 2.4% and 2.5% after a median follow-up of 7.5–10 years [33, 34]. Delay of the hernia repair does not negatively influence the outcome and is cost-effective [35, 36].

The AWARE study, an ongoing randomized control trial recruiting patients with incisional hernias, is anticipated to publish its results soon which will give the surgical community more information on this debate [37]. These data are highly awaited, especially if we consider the morbidity rates in laparoscopic incisional hernia repair with iatrogenic bowel lesions at 1.8% to 6% [38–40]. A systemic review and meta-analysis of 4 RCT's already showed the benefit of prophylactic mesh reinforcement after abdominal aortic aneurysm repair via midline laparotomy. Moreover, the aforementioned analysis also showed no significant difference in reoperation for incisional hernia [41]. These results emphasize the need for valid data with long-term follow-up regarding the necessity for hernia repair in asymptomatic incisional hernia. Possibly, routine ultrasound screening for the detection of incisional hernia may be proven irrelevant.

A limitation in our study is the lack of additional information regarding the size of the incisional hernia, because we only recorded "yes or no" as an outcome parameter. We assumed the size would guide further management especially in regard to a watchful waiting policy.

Also, Deerenberg et al. published data in 2015 regarding the advantage of small bites vs large bites. This was published after our recruitment phase and was not consistent with our study protocol where we chose to take large bites as the advantage of small bites was at this point in time still unknown.

Additionally, we fixed the mesh in the midline and not on the edges. We can assume that some IH are favored by mesh dislocation but we do not have data about the mesh position in reoperated patients.

Conclusion

The use of a non-absorbable intraperitoneal mesh strip in intraperitoneal onlay position to prevent incisional hernia reduces the risk of incisional hernia significantly after 5 years of follow-up.

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Compliance with ethical standards

Conflict of interest Philippe M. Glauser, MD, Philippe Brosi, MD, Benjamin Speich, PhD, Samuel A. Käser A., MD, Andres Heigl, MD, Robert Rosenberg, MD, and Christoph A. Maurer, MD have no conflicts of interest or financial ties to disclose.

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