Hernia (2020) 24:85–92
https://doi.org/10.1007/s10029-019-02025-4

ORIGINAL ARTICLE

Safety and efficacy of prophylactic resorbable biosynthetic mesh following midline laparotomy in clean/contemned field: preliminary results of a randomized double blind prospective trial

F. Pizza[1] · D. D'Antonio[1] · M. Arcopinto[2] · C. Dell'Isola[3] · A. Marvaso[1]

Received: 30 May 2019 / Accepted: 4 August 2019 / Published online: 20 August 2019

Abstract

Background Incisional hernia (IH) is one of the most common sequelae of laparotomy.

Materials and methods We present a double-blind randomized study examining feasibility, safety and incisional hernia rate using a prophylactic Bio-A biosynthetic stripe (Gore) in a sub-lay position after midline laparotomy in patients undergoing operations in clean-contaminated and contaminated field. One hundred patients who underwent a midline laparotomy of at least 10 cm in a clean-contaminated and contaminated field were considered. Patients were divided into two groups: [Group A closed in double layer using PDS 0 with WL/SL of 1:4; Group B closure in double layer using PDS 0 and sub-lay positioning a 3 cm-wide BIO A (Gore) strip extended for the entire length of the incision]. The primary objective of the study was to identify IH rate in the two groups at 1- and 2-year follow-up. Secondary objective was to identify any differences in the two groups in terms of post-operative pain, morbidity and mortality.

Results Out of a total of 100 patients included in the study, a 2-year follow-up was possible for 47 patients in group A and 45 in group B. The incidence of IH was 11/47 in group A (22%) and 3/45 in group B (6%) [$p < 0.01$]. Furthermore, no statistically significant difference was noted about post-operative morbidity and pain related to the wall closure method.

Conclusions The prophylactic use of a BIO-A biosynthetic stripe (Gore) showed a statistically significant reduction in the incisional hernia rate in patients who underwent clean-contaminated and contaminated surgery.

Keywords Incisional hernia · Resorb able mesh · Prophylactic mesh

Introduction

Incisional hernia (IH) is one of the most frequent postoperative complications in abdominal surgery causing significant morbidity and even mortality [1, 2]. The risk of developing an incisional hernia following primary elective midline laparotomy is reported to be between 5 and 20% [3]. Risk factors for developing IH are both patient and surgery related. Patient factors include diabetes, smoking, obesity, chronic corticosteroids' use and connective tissue disorders, included the presence of an abdominal aortic aneurysm [4]. Surgery-related factors include type of laparotomy, type of surgery, wounds classification, suture material used to close the laparotomy and the suture length to wound length (SL/WL) ratio [5].

In patients carrying aortic abdominal aneurysm and/or obesity and/or contaminated wounds, incidence rises up to 39% [6, 7]. Besides the negative impact of incisional hernia regarding the patients' quality of life, the direct costs of hernia repair and indirect cost (sick leave) are an important burden for the health care system [8]. Although guidelines exist about elective laparotomy closure [9], no recommendation can be found in scientific literature about emergent laparotomy closure, especially in contaminated wounds [10, 11].

Several groups started working to find out if a prophylactic mesh placement could decrease incisional hernia occurrence. The published papers have been analysed in two systemic reviews [12], concluding that the use of a prophylactic non-absorbable mesh could reduce IH rate [13]. On the other side, surgeons are mostly reluctant to implant permanent

✉ F. Pizza
francesco_pizza@libero.it

[1] ASL Napoli 2 Nord, Via Lupoli, 27, 80027 Frattamaggiore, Naples, Italy

[2] AORN "A. Cardarelli", Naples, Italy

[3] AORN Azienda Dei Colli "A. Cotugno", Naples, Italy

material even in patients undergoing a contaminated ventral hernia repair because of the increased risk of postoperative infections, bowel adhesions, mesh extrusion and/or erosion, fistula formation, seroma development and pain [14, 15].

Recently, a retrospective study by Carbonell et al. investigated open ventral hernia repairs performed with a polypropylene mesh in the retro-rectus position in clean-contaminated and contaminated fields reporting a 30-day surgical site infection rate of 7.1 and 19.0%, respectively [16]. The most appropriate mesh for hernia repair in clean-contaminated and contaminated fields is not as clear [17].

Some other authors proposed the implant of biological meshes (BM) in contaminated and dirty wounds, but their high costs mostly limit their use. Moreover, data about long-term durability of biologic grafts used in case of complex abdominal wall reconstruction are not clearly defined [18]. On the other hand, a synthetic rapid absorbable mesh-like polyglactin (Vicryl®) has been used for decades for infected IH. However, the recurrence rate following their implantation was high (> 60% in most reports) [19] and a definitive repair often required a second procedure, responsible for prolonged recovery, additional morbidity and costs and decreased quality of life [20].

Long-term absorbable synthetic materials, so-called biosynthetic meshes (BSM), have recently been proposed instead of the biological ones in cases of abdominal wall reconstructions in contaminated fields [17]. BSM may, actually, offer advantages when challenged with bacterial colonization during complex abdominal wall reconstruction [17].

The GORE BIO-A Tissue Reinforcement is a BSM composed of a bio-absorbable polyglycolide-trimethylene carbonate copolymer, which is gradually absorbed by the body.

The aim of the present study was to analyse the feasibility, safety and IH rate using a prophylactic sublay biosynthetic BIO-A (GORE) mesh in order to prevent incisional hernia following midline laparotomy in clean-contaminated and contaminated wounds. The study was designed as a double-blind randomized controlled trial comparing the running suture alone to the running suture reinforced with biosynthetic mesh (BIOA) in sub lay position.

Methods

Aim

The aim of the present study was to evaluate the effectiveness of IH prevention in patients undergoing laparotomy for clean-contaminated and contaminated surgery. The classification of wound contamination was assigned according to the likelihood and degree of wound contamination at the time of the operation, as stated in the Centre for Disease Control and Prevention (CDC) wound classification (Grade II–III) [21]. A double-blind, randomized, controlled trial will compare the running suture alone versus the running suture, reinforced with biosynthetic mesh (BIO-A) in a sub lay fashion. The primary outcome will be IH rate at 6, 12 and 24 months postoperatively. Secondary outcome measures will cover relevant postoperative complications (Clavien-Dindo) at 30 days and post-operative pain at 1 and 12 months with VAS score [22].

Study design

The study is a double blinded randomized trial, comparing the widely recommended midline laparotomy closure using a running, slowly absorbable suture to closure with the aid of a biosynthetic sub-lay mesh (BIO-A) in patients undergoing midline laparotomy for clean-contaminated and contaminated surgery. From January 2016 to June 2017, a series of 100 patients were included. All patients were operated in a single surgical Unit, located in Lacco Ameno (Naples) at the only Hospital of the island. All patients undergoing elective and emergent 'open' midline laparotomy for abdominal surgery in clean-contaminated and contaminated fields were included. All patients subscribed an informed consent. Authorization was requested from the local regional Ethics Committee. Exclusion criteria were as follows: age < 18 years; life expectancy < 24 months (as estimated by the operating surgeon), pregnancy, immunosuppressant therapy within 2 weeks before surgery, clean and dirty wounds, wound length < 10 cm. Patients were randomized into two groups (Group A, receiving primary closure; Group B, receiving mesh supported closure in a sub lay fashion). Randomization was obtained just before abdominal wall closure through number (1–100) extraction by OR nurse (Group A vs Group B). All patients enrolled in the study were followed up by sending a letter to their General Practitioner. Outpatient clinic controls were done by surgeons/surgical residents/GP blinded for the procedure.

Technical details

Group A: primary closure of midline laparotomy

The midline fascia is closed using a double-layer running slowly absorbable suture. (PDS, USP 0, Needle HRT30, 150 cm). Above arcuate line, posterior layer was performed suturing peritoneum and posterior rectus sheath; below arcuate line posterior layer was performed suturing peritoneum and trasversalis fascia. Anterior layer was performed suturing anterior rectus sheath. Suture length to wound length ratio was 4:1 as recommended (not routinely measured).

Subcutaneous tissue and skin are closed according to the first surgeon's preference.

Group B: sub-lay mesh supported closure

A 4-cm space is created between posterior rectus sheath and rectus muscle, widening 2 cm at each side of midline. Both posterior rectus sheath edges are sutured using a running slowly absorbable suture (PDS 0, USP1, Needle HRT30, 150 cm, B.). Above arcuate line, posterior layer was performed suturing peritoneum and posterior rectus sheath; below arcuate line posterior layer was performed suturing peritoneum and Trasversalis fascia. Anterior layer was performed suturing anterior rectus sheath. A suture length to wound length ratio of 4:1 is recommended (not routinely measured). A 3-cm BIO-A Mesh strip was placed between the posterior rectus sheath and the rectus muscle with an overlap of 1.5 cm at each side, sutureless. Being maximum BIO-A length available on European medical market is 20 cm, two stripes were designed in laparotomies > 20 cm. The midline anterior rectus sheath was closed using a running slowly absorbable suture (PDS0, USP1, Needle HRT30, 150 cm), covering the mesh. A suture length to wound length ratio of 4:1 is recommended (not routinely measured). Sub- cutaneous tissue and skin closure was up to the surgeon preference.

Endpoints

Primary endpoint was hernia recurrence rate. Patients were postoperatively examined at 30 days, 6, 12 and 24 months. Both clinical examination and ultrasound imaging were performed in all patients at follow-up. Physicians were blind about which Group (A or B) the patients had been placed. Incisional hernia was clinically defined as any visible or palpable "blowout" in the midline abdominal scar. The ultrasonic criteria of incisional hernia were a visible gap within the abdominal wall and/or "tissue moving through the abdominal wall by Valsalva manoeuvre'' and/or a detectable "blowout''. Incisional hernia was diagnosed if clinical criteria and/or ultrasound criteria were fulfilled [21]. The study was not designed to discriminate single or multiple defects. At 6, 12 and 24 months ultrasound imaging was performed to examine the midline for all patients with symptomatic or asymptomatic or clinically not detectable incisional hernia, providing any valuable information about incisional hernia onset. Size and location of all ultrasound detected incisional hernias were registered, as well as any other patient's complaint. The study will be completed at 2 years' follow-up. Secondary endpoints included incidence of wound events. Wound events were classified as surgical site infections according to CDC criteria (superficial, deep or organ space) [23]. Surgical site events were reported according to the Ventral Hernia Working Group definitions. Actions for wound events were categorized as follows: antibiotics only, bedside wound interventions, percutaneous manoeuvres or surgical debridement. Postoperative pain was recorded according to visual analogue scale (VAS) from 0 to 10 [24]. VAS score was measured at 1 and 6, 12 months.

Statistical analysis

Variables' description and statistical analysis were performed using the Statistical Package for the Social Sciences (SPSS) program (version 18.0 for Windows). Quantitative variables were expressed as mean and standard deviation; categorical variables as absolute numbers and percentages. The intention-to-treat analysis included all randomized patients. Statistical analysis of quantitative variables for independent groups was performed using the Student *t*-parametric test or the nonparametric Mann–Whitney *U* test. Proportions were compared with the Chi-square test. The identification of IH during the follow-up was analysed using the Kaplan–Meier estimation method and the log-rank test. Statistical significance was set at $p < 0.05$.

Results

From January 2016 to July 2017, a total of 100 patients were randomly allocated as follows: 50 patients to Group A (without mesh) and 50 patients to Group B (with mesh). All patients received the planned procedure. Pre-operative and operative data are reported in Tables 1 and 2. There were no statistically significant differences in terms of age, sex, CDC class, length of laparotomy and comorbidity in two Groups. Early results were obtained at 1-year follow-up. One patient in Group A and one patient in Group B missed consultation or did not want to be re-examined. Three patients were re-operated for complications not related to abdominal wall closure (1 in both Groups for abscess, 1 for anastomotic leak in Group B). In Group B, access to the abdominal cavity was not impaired by the mesh. One patient of Group B died before the first-year follow-up for cardiac arrhythmia. These patients were excluded. Ninety-five patients attended the 1-year follow-up consultation (Group A = 48, Group B = 47), undergoing both clinical examination and abdominal wall ultrasound.

Ninety-two patients attended the 2-year follow-up consultation (Group A = 47, Group B = 45), undergoing both clinical examination and abdominal wall ultrasound.

Primary endpoint results are summarized in Table 3. Incidence of IH in the two Groups (A vs B) was significantly different ($p < 0.05$) at 6, 12 and 24 months (12% vs 2%, 20% vs 6%, 22% vs 6%). At 12 months, 10 patients in group A developed a IH, in 7/10 of cases (70%) it was

Table 1 Preoperative data

	Group A ($n=50$)	Group B ($n=50$)	p
Sex, male–female (%)	36–62 (48%)	41–59 (52%)	> 0.05
Age, mean (range), years	56 (22–86)	58 (29–88)	> 0.05
BMI, mean (range), kg/m^2	27 (18–38)	28 (17–35)	> 0.05
Active smoking, *n* (%)	11 (22%)	13 (26%)	> 0.05
Diabetes, *n* (%)	9 (18%)	8 (16%)	> 0.05
Cardiac disease, *n* (%)	11 (22%)	13 (26%)	> 0.05
COPD, *n* (%)	11 (22%)	15 (30%)	> 0.05
Previous radiotherapy or chemotherapy, *n* (%)	3 (6%)	2 (4%)	> 0.05
Previous abdominal operations, *n* (%)	2 (4%)	8 (16%)	> 0.05
Other abdominal hernias, *n* (%)	4(8%)	2 (4%)	> 0.05
CCS chronic use, *n* (%)	2 (4%)	1 (2%)	> 0.05
Length of laparotomy, mean (range) cm	26 (18–27)	25 (20–29)	> 0.05

Table 2 Peri-operative outcomes

	Group A	Group B	p
Clean-contaminated wound (CDC class II), *n* (%)	30 (60)	28 (56)	$p > 0.05$
Contaminated wound (CDC class III), *n* (%)	20 (40)	22 (44)	$p > 0.05$
Length of laparotomy, mean (range), cm	26 (18–27)	25 (20–29)	$p > 0.05$
Operation time (for abdominal wall closure), mean (range), min	14 (8–18)	22 (14–27)	$p > 0.05$
Emergency surgery, *n* (%)	22 (44)	31 (62)	$p < 0.05$

Table 3 Incidence of incisional hernia (IH) at 6, 12 and 24 months follow-up, found either by clinical exam or ultrasounds (US)

	Group A	Group B	p
IH (6 months), *n* (%)	6/50 (12%)	1/50 (2%)	$p < 0.05$
IH (12 months), *n* (%)	10/49 (20%)	3/48 (6%)	$p < 0.05$
IH (24 months), *n* (%)	11/47 (22%)	3/45 (6%)	$p < 0.05$
Among those patients with IH			
Clinical IH (12 months), *n* (%)	7/10 (70%)	1/3 (33%)	$p < 0.05$
US IH (12 months), *n* (%)	3/10 (33%)	2/3 (66%)	$p < 0.05$
Clinical IH (24 months), *n* (%)	11/11 (100%)	2/3 (66%)	$p < 0.05$
US IH (24 months), *n* (%)	0/11 (0%)	1/3 (33%)	$p < 0.05$

diagnosed by clinical examination only and in 3/10 (30%) of cases with US support. In group B 3 patients developed IH at 12 months and it was clinically evident in one case (33%) and diagnosed with US support in the other two cases (66%). At 2-year follow-up, all patients in group A diagnosed with IH showed a clinically evident bulging, while clinically detectable hernia was present in two out of three patients (66%) in group B.

Results regarding morbidity and mortality at 6 weeks after surgery are reported in Table 4. There were no statistically significant differences in both Groups (A vs B) in terms of seroma (6% vs 4%), hematoma (4% vs 2%) and superficial (4% vs 4%) and deep infections (2% vs 2%). In

Table 4 Postoperative wound events and surgical site infections

	Group A (50)	Group B (50)	p
Seroma, *n* (%)	3 (6)	2 (4)	> 0.05
Hematoma, *n* (%)	2 (4)	1 (2)	> 0.05
Superficial incisional infections, *n* (%)	2 (4)	2 (4)	> 0.05
Deep incisional infections, *n* (%)	1 (2)	1 (2)	> 0.05
Wound dehiscence, *n* (%)	0 (0)	0 (0)	> 0.05
Blood transfusion, *n* (%)	6 (12)	4 (8)	> 0.05
Re-operation (within 30 days), *n* (%)	2 (4)	2 (4)	> 0.05
Death (30-day mortality), *n* (%)	0 (0)	0 (0)	> 0.05

Group B, no mesh had to be removed during follow-up. In both groups, patients complained of marginal postoperative pain after 6 weeks (VAS in Group A 1.1 vs 1.2 in Group B) and 1 year (VAS in Group A 0.22 vs. 0.24 in Group B). During the study period, 5 patients (3 of group A and 2 of group B with additional mesh) had to be re-operated for several reasons after 12 months follow-up. In these patients no differences about were found in adhesions. At 24 months follow-up, no patients in both Groups underwent surgery for IH because patients will.

Discussion

The first outcome of this double-blind randomized study was the incidence of IH. Early results after 12 months showed statistically significant differences between two groups. Group B with mesh had a lesser rate of IH than Group A (6% vs 20%). Furthermore, IH was detected not only by clinical examination but also by ultrasound, for the known increased sensitivity of ultrasound compared to clinical examination to detect mostly asymptomatic hernias [25], so in the present study, clinical suspected hernias were always verified by ultrasound. The clinical diagnosis in the first year of follow-up showed an underestimation of incisional hernia cases compared to the clinical/ultrasonography combination, which we believe must be taken into account. At 2-year follow-up the incisional hernia cases were all clinically evident in group A, 2/3 in group B.

Data from our study show no significant differences in postoperative mortality and morbidity between two groups. No higher infection rate, seroma and/or hematoma within the first 6 weeks postoperatively was found between reinforcement with prophylactic and control group. The two cases of deep infections (1 in Group A and 1 in Group B) were managed with antibiotic therapy alone. The incidence of mesh infection in the present study was lower than the rates of mesh infection reported for mesh implantation in ventral hernia repair with different material and mesh positions [26, 27]. Furthermore, the implant of the BIOA-stripe was minimally time-consuming and no special equipment was required. No adverse events during mesh implantation such as bowel lesion were reported. Longer operation times for prophylactic mesh implantation were reported in other studies using a sub-lay-technique [28], being, anyway, significantly different just in one of them [13]. A trend towards increased chronic pain after mesh implantation has been reported in the past [29]. However, in the present study, no difference in postoperative pain was measured between Groups A and B at 6 weeks and 1 year postoperatively using VAS. The cost issue of a prophylactic mesh is the last point of debate. Whilst biosynthetic meshes are not as expensive as their biological counterparts, they do represent an increased cost over primary suture closure.

Incisional hernia (IH) is a common complication following laparotomy, affecting 5–20% of midline laparotomies [3, 30]. Complications include bowel obstruction, strangulation, and perforation sometimes necessitating emergency surgery. Even in the absence of these severe complications, IH has a negative impact on quality of life and, when repair is possible, recurrence rates are high, up to 22% with mesh repair [31]. If risk factors for IH development are primary patient related, abdominal wall closure technique has a considerable weight [5]. The European Hernia Society published guidelines about abdominal wall incisions closure [32] in 2015. The closure of elective midline incisions using a single running suture technique and avoiding rapidly absorbable sutures is strongly recommended. In the same paper, the use of a slowly absorbable monofilament suture in a single-layer aponeurotic closure technique without separately closing the peritoneum is also suggested. As well, the same guidelines recommend the 'small bite technique' with a suture to wound length (SL/WL) ratio of at least 4:1. Regardless these technical recommendations, incidence of Incisional Hernia remains high, mostly increased in obesity/vascular/ostomy surgery. These latter categories of patients might benefit from prophylactic mesh reinforcement of the abdominal wall, significantly decreasing the incidence of IH as reported in several papers and guidelines. The results of the "PRIMA" trial [33] showed a significant reduction of IH rate using a permanent mesh reinforcement. Meta-analyses [34] also found significant decrease of IH rate following prophylactic mesh placement. Timmermans et al. [35] also reported same results using a prophylactic mesh; however, its routine use could not be recommended due to insufficient data about mesh-related complication rate. In the present study, we focused our attention on clean-contaminated and contaminated wounds (Grade II/III of CDC) as a risk factor for IH rate; surgeons actually are reluctant to implant a permanent synthetic mesh in a so thorny situation. Some Authors report that the grade according to CDC is the main risk factor to develop a wound infection. Several reports [1–3] stressed how bacteria inherently colonize all surgical wounds, but not all such contaminations lead to infection. In clean-contaminated, contaminated and dirty surgical procedures, the polymicrobial aerobic and anaerobic flora closely resemble the normal endogenous microflora of gastrointestinal (GI) tract, being the most frequently pathogens found. The contaminating pathogens in GI surgery include gram-negative bacilli (e.g. *Escherichia coli*) and gram-positive microbes, such as enterococci and anaerobic organisms. A classification scheme has been proposed in several studies to predict the probability of a wound to become infected [36, 37]. Besides, Gilson et al. showed how wound infections are the most important single factor for IH occurrence

[8]. Riou et al. found that Grade II/III is a significant risk factor for IH [36], while Cohen et al. [38] showed how a bowel resection influenced a wound dehiscence and so the IH rate. Carbonell et al. [16] reported primary outcomes of surgical site infection, surgical site occurrence, need for mesh removal and hernia recurrence in 100 patients with II–III CDC class wounds undergoing ventral hernia repair with retro-rectus mesh placement. The overall incidence of surgical site occurrence was 31%, higher in the contaminated than in the clean-contaminated cases. The 30-day surgical site infection rate was 14%. Mesh removal was required in four patients. Some evidence suggests that the use of foreign materials, like prosthetic meshes, could decrease the infection threshold. With this in mind, the possibility of mesh infection, potentially resulting in readmissions, reoperations, mesh explant and, eventually, hernia recurrence, represents a major warning to mesh placement after clean-contaminated and contaminated surgery [38]. Data from the National Surgical Quality Improvement Program (NSQIP) on 33,832 patients with ventral hernia repair using mesh in clean-contaminated and contaminated surgical fields compared to clean cases showed a significantly higher odds ratio (OR) of having one or more postoperative occurrences with OR 3.56 [3.25–3.89] and 5.05 [1.78–12.41], respectively [37]. There was a significantly increased OR for superficial surgical site infections (SSI) (OR 2.53), deep SSI (OR 3.09) and wound disruption (OR 4.41) for clean-contaminated cases compared to clean cases [36].

Biologic mesh is often recommended in a contaminated setting. The use of biologic mesh has, anyway, not proven to be superior to permanent synthetic mesh in resisting infection [7, 20, 21]. In long-term analysis, recurrence rates after biologic mesh repair are significantly greater than most series using synthetic mesh [38] although reported results are highly variable. The systematic review by Atema et al. showed no benefit of biologic over synthetic mesh for repair of potentially contaminated hernias with comparable surgical site complication rates [38]. Overall surgical complication rate was 50% and mesh removal rate was 1% [38]. The systematic review by Cross et al. [39] comprised 16 studies with 554 patients with contaminated surgical fields. The overall infection rate was 25%. The authors concluded that caution should be used when using biologic mesh products in infected fields, because there is a paucity of controlled studies and none of the meshes have US Food and Drug Administration approval for their use in infected fields [39]. However, the prophylactic use of biological mesh is not yet recommended. An alternative to biologic mesh in clean-contaminated and contaminated ventral hernia repairs is absorbable synthetic meshes. In the present study, we used a BIO A (GORE) mesh: the prospective advantages of lower costs versus biological mesh, informed consent in certain religious or cultural groups, and ability to be iterative in generational improvements in mesh constructs based on outcome studies comparing allogeneic or xenogeneic mesh makes its use very appealing [17]. The location of the mesh is another matter of debate. Whereas some authors promote the use of the mesh in pre-fascial situation (onlay), others support the retro-muscular, pre-peritoneal or even intraperitoneal space [8, 10, 12]. Although a retro-muscular dissection is needed as in a Rives procedure for ventral hernia repair, we chose the sub-lay position because the surgical technique is quite more common and much simpler to perform. Just to be clear, in a previous RCT on obesity we decided to put the mesh retro-muscularly resulting, anyway, in a lower incidence of ventral hernia [15]. The mean time of the procedure was increased of an average time of 17 min in our series, with no added morbidity.

Hobart et al. (2017) during "International Symposium on Prevention of Incisional Hernias Analysis of the USA" showed that approximately 1.9 million patients underwent open surgery in 2013, and this population exhibited a relevant and substantial comorbidity burden as evidenced by the high prevalence of obesity, pulmonary disease and diabetes. Based on a simple calculation, approximately 600,000 patients per year undergoing open surgery are at a markedly increased risk of developing an incisional hernia. Fischer et al. [40] conducted a cost analysis study: they found the use of a prophylactic mesh after laparotomy to be more cost effective. Our study has several limitations reported as follows. The wound length was not measured if > 10 cm, potentially influencing main and secondary outcomes. Another source of potential bias could be the inclusion of both elective and emergency cases.

Conclusion

Prophylactic strip mesh reinforcement of midline abdominal wall, using bio-absorbable (BIO-A) mesh in the retro-muscular position at the time of laparotomy, is safe. The effects of stripe of BIO A may be effective to reduce the incidence of IH, although longer term follow-up is required. Because of its structure, the BioA support results relatively easy to implant with very few stiches, or even, no suture to host tissue following its placement. These features, together with infection resistance and in 6/7 months' complete reabsorbtion, make the BioA Gore tissue reinforcement a very appealing product for a prophylactic purpose in clean-contaminated and contaminated fields. The production of a dedicated strip by the company (GORE) could lower the costs of the product and make it even easier to use this mesh for a prophylactic purpose. The present paper could contribute to the literature in the field demonstrating the safety of BIO-A

mesh use in contaminated fields and its effectiveness in IH prevention if used prophylactically.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval This study was approved by the research ethics board of the ASL NApoli 2 Nord, Naples.

Human and animal rights All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This article does not contain any studies with animals performed by any of the authors.

Informed consent Informed consent was obtained from all individual participants included in the study.

References

1. Adotey JM (2006) Incisional hernia a review. Niger J Med 15:34–43
2. Carlson MA, Ludwig KA, Condon RE (1995) Ventral hernia and other complications of 1,000 midline incisions. S Med J 88:450–453
3. Van't Riet M, Steyerberg EW, Nellensteyn J, Bonjer HJ, Jeekel J, Friedman DW (2002) Meta-analysis of techniques for closure of midline abdominal incisions. Br J Surg 89(11):1350–1356
4. Payne R, Aldwinckle J, Ward SM et al (2016) Analysis of randomised trials comparing the use of prophylactic mesh to standard midline closure in the reduction of incisional hernia. Hernia 17:1653–1654
5. Diener MK, Voss S, Jensen K et al (2010) Elective midline laparotomy closure: the inline systematic review and meta-analysis. Ann Surg 251:843–856
6. Mudge M, Hughes LE (1985) Incisional hernia: a 10 year prospective study of incidence and attitudes. Br J Surg 72:70–71
7. Wadstrom J, Gerdin B (1990) Closure of the abdominal wall; how and why? clinical review. Acta Chir Scand 156:75–82
8. Gillion JF, Sanders D, Miserez M et al (2016) The economic burden of incisional ventral hernia repair: a multicentric cost analysis. Hernia 20:819–830
9. Diener MK, Voss S, Jensen K et al (2010) Elective midline laparotomy closure: the INLINE systematic review and metaanalysis. Ann Surg 251:843–856
10. Muysoms FE, Antoniou SA, Bury K et al (2015) European Hernia Society guidelines on the closure of abdominal wall incisions. Hernia 19:1–24
11. Veljkovic R, Protic M, Gluhovic A et al (2010) Prospective clinical trial of factors predicting the early development of incisional hernia after midline laparotomy. J Am Coll Surg 210:210–219
12. Nachiappan S, Markar S, Karthikesalingam A et al (2013) Prophylactic mesh placement in high-risk patients undergoing electivelaparotomy: a systematic review. World J Surg 37:1861–1871
13. Muysoms FE, Detry O, Vierendeels T et al (2016) Prevention of incisional hernias by prophylactic mesh-augmented reinforcement of midline laparotomies for abdominal aortic aneurysm treatment: a randomized controlled trial. Ann Surg 263:638–645
14. Park AE, Roth JS, Kavic SM (2006) Abdominal wall hernia. Curr Probl Surg. 43:326–375
15. Ventral Hernia Working Group, Breuing K, Butler CE, Ferzoco S et al (2010) Incisional ventral hernias: review of the literature and recommendations regarding the grading and technique of repair. Surgery 148:544
16. Carbonell AM, Criss CN, Cobb WS, Novitsky YW, Rosen MJ (2013) Outcomes of synthetic mesh in contaminated ventral hernia repairs. J Am Coll Surg 217(6):991–998
17. Rosen MJ, Bauer J, Harmaty M et al (2015) Multicenter, prospective, longitudinal study of the recurrence, surgical site infection, and quality of life after contaminated ventral hernia repair using biosynthetic absorbable mesh: the COBRA study. Ann Surg 265:205
18. Rosen M, DeNotoK G (2013) Butler DEvaluation of surgical outcomes of retro-rectus versus intraperitoneal reinforcement with bio-prosthetic mesh in the repair of contaminated ventral hernias. Hernia 17(31–3):5
19. Renard Y, de Mestier L, Henriques J et al (2019) Absorbable polyglactin vs. non-cross-linked porcine biological mesh for the surgical treatment of infected incisional hernia. J Gastrointest Surg. https://doi.org/10.1007/s11605-018-04095-8
20. Bondre IL, Holihan JL, Askenasy EP, Greenberg JA, Keith JN, Martindale RG et al (2016) Suture, synthetic, or biologic in contaminated ventral hernia repair. J Surg Res 200:488–494
21. Todd B, New CDC (2017) Guideline for the Prevention of Surgical Site Infection. Am J Nurs 117(8):17
22. Clavien PA, Barkun J, de Oliveira ML, Vauthey JN, Dindo D, Schulick RD, de Santibañes E, Pekolj J, Slankamenac K, Bassi C, Graf R, Vonlanthen R, Padbury R, Cameron JL, Makuuchi M (2009) Ann Surg 250(2):187–196
23. Mangram AJ, Horan TC, Pearson ML et al (1999) Guideline for prevention of surgical site infection, Hospital Infection Control Practices Advisory Committee. Infect Control Hosp Epidemiol 20:250–278
24. Brosi P, Glauser P, Speich B et al (2017) Prophylactic intraperitoneal onlay mesh reinforcement reduces the risk of incisional hernia, two-year results of a randomized clinical trial. World J Surg 42:1687–1694
25. Bloemen A, van Dooren P, Huizinga BF et al (2012) Comparison of ultrasonography and physical examination in the diagnosis of incisional hernia in a prospective study. Hernia 16:53–57
26. Leber GE, Garb JL, Alexander AI et al (1998) Long-term complications associated with prosthetic repair of incisional hernias. Arch Surg 133:378–382
27. Berrevoet F, Vanlander A, Sainz-Barriga M et al (2013) Infected large pore meshes may be salvaged by topical negative pressure therapy. Hernia 17:67–73
28. Bevis PM, Windhaber RA, Lear PA et al (2010) Randomized clinical trial of mesh versus sutured wound closure after open abdominal aortic aneurysm surgery. Br J Surg 97:1497–1502
29. Bhangu A, Fitzgerald JE, Singh P et al (2013) Systematic review and meta-analysis of prophylactic mesh placement for prevention of incisional hernia following midline laparotomy. Hernia 17:445–455
30. Friedman DW, Boyd CD, Norton P, Greco RS, Boyarsky AH, Mackenzie JW et al (1993) Increases in type III collagen gene expression and protein synthesis in patients with inguinal hernias. Ann Surg 218(6):754–760
31. Fortelny RH (2018) Abdominal wall closure in elective midline laparotomy: the current recommendations. Front Surg 5:34

32. Muysoms FE, Antoniou SA, Bury K, Campanelli G, Conze J, Cuccurullo D et al (2015) European Hernia Society guidelines on the closure of abdominal wall incisions. Hernia 19(1):1–24
33. Jairam AP, Timmermans L, Eker HH, Pierik R, van Klaveren D, Steyerberg EW et al (2017) Prevention of incisional hernia with prophylactic onlay and sublay mesh reinforcement versus primary suture only in midline laparotomies (PRIMA): 2-year follow-up of a multicentre, double-blind, randomised controlled trial. Lancet 390(10094):567–576
34. Wang X-C, Zhang D, Yang Z-X et al (2017) Mesh reinforcement for the prevention of incisional hernia formation: a systematic review and meta-analysis of randomized controlled trials. J Surg Res 209:17–29
35. Timmermans L, de Goede B, Eker HH et al (2013) Meta-analysis of primary mesh augmentation as prophylactic measure to prevent incisional hernia. Dig Surg 30:401–409
36. Cruse P, Foord R (1980) The epidemiology of wound infection. A ten-year prospective study of 62,939 wounds. Surg Clin N Am 60:27–40
37. Olson M, O'Connor M, Schwartz M (1984) A 5-year prospective study of 20,193 wounds at the Minneapolis VA Medical Center. Ann Surg 199:253–259
38. Birindelli A, Sartelli M, Di Saverio S et al (2017) update of the WSES guidelines for emergency repair of complicated abdominal wall hernias. World J Emerg Surg 12:37
39. Cross AJ, Buchwald PL, Frizelle FA, Eglinton TW (2017) Meta-analysis of prophylactic mesh to prevent parastomal hernia. Br J Surg 104(3):179–186
40. Fischer JP, Basta MN, Krishnan NM, Wink JD, Kovach SJ (2016) A cost-utility assessment of mesh selection in clean-contaminated ventral hernia repair. Plast Reconstr Surg 137(2):647–659