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Prevention of Incisional Hernia in Midline Laparotomy with an Onlay Mesh: A Randomized Clinical Trial

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Abstract
Objective Our objective was to evaluate the prevention of incisional hernia (IH) during the postoperative period of a midline laparotomy during elective surgery.
Material and methods A controlled, prospective, randomized, and blind study was carried out. The patients in group A (mesh) were fitted with a polypropylene mesh, to reinforce the standard abdominal wall closure. The patients in group B (non-mesh) underwent a standard abdominal wall closure and were not fitted with the mesh.
Results In group A, 2/80 his were diagnosed, whereas in group B the number was 30/80. The Kaplan–Meier survival curves show that the likelihood of IH at 12 months is 1.5 % in group A compared with 35.9 % in group B ($p < 0.0001$), which means that the differences are statistically significant.
Conclusion Fitting a prophylactic supra-aponeurotic mesh prevents IH independently of other factors.

Introduction

Incisional hernias (IHs) are a common complication after a midline laparotomy during abdominal surgery. This type of hernia represents an important surgical problem because of the significant amount of healthcare and financial resources that it takes up and because of the negative effect it has on the patient's quality of life [1]. Despite this, there is still no safe technique for closing the abdominal wall that will also guarantee that a postoperative IH will not develop [2, 3].

Occurrence of IH is high, although it is difficult to be certain of its extent because the published figures vary. Studies have been published that describe the occurrence of IH as between 9 and 20 % of the general population [4], although this can rise to between 26 and 39 % in higher-risk groups such as the morbidly obese or patients who have been operated on for abdominal aortic aneurysm [5]. IH may be asymptomatic or may cause pain, a decrease in the quality of life, or even incarcerations (6–15 %) or strangulations (2 %) that require urgent surgery [6]. Because of their high occurrence, financial cost, and effect on quality of life, there is general interest in their prevention [1].

Studies that have been published to date regarding the fitting of prophylactic meshes lack sufficient scientific evidence, which means that random prospective studies are required with sufficiently large samples and lengthy follow-up periods in order to obtain better conclusions.

For this reason, the principal objective of this study is to evaluate the prevention of IHs during the postoperative period of a midline laparotomy during elective surgery.

Material and methods

A controlled, prospective, randomized, simple blind study was carried out between May 2009 and November 2012. The study was registered on the international database of randomized studies (International Standard Randomized Controlled Trial) under the code ISRCTN98336745.

International Standard Randomized Controlled Trial number: ISRCTN98336745.

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The study was presented to and accepted by the Ethical Committee of the Joan XXIII University Hospital in Tarragona. Informed consent was obtained from all the patients before they were included in the study.

The study included patients with American Society of Anesthesiologists (ASA) score <4 who needed a midline laparotomy in elective surgery and who did not present any of the following exclusion criteria: ASA >4, life expectancy of less than 12 months, polypropylene allergy or intolerance, antecedents of incisional hernioplasty, ostomy wearers, and patients undergoing corticotherapy.

The randomization was carried out using a table created on computer software. Patients were randomly assigned a code group according to the order in which they were included in the study.

Study protocol

The patients in group A (mesh) were fitted with a prosthetic mesh with a low prophylactic polypropylene density (Biomesh Light P8 polypropylene mesh, Cousin Biotech, Wervicq-Sud, France) to reinforce the standard abdominal wall closure. The patients in group B (non-mesh) underwent a standard abdominal wall closure using continuous PDS loop 1 suture and were not fitted with the mesh.

All patients underwent a medium laparotomy consisting of a supra- and infra-umbilical midline incision of about 15–20 cm in length.

The mesh was polypropylene monofilament, which has the advantage of being thin, easy to handle, light (40 g/m^2), and macroporus (P8) so that it can be rapidly integrated into tissues.

The surgical technique of abdominal wall closure involves closing the abdominal wall with a continuous PDS loop no. 1 suture in stitches spaced 1 cm apart and at least 1 cm either side of the aponeurotic edges, following the rule of 4:1 in both groups [7]. In group A (mesh), the pre-aponeurotic plane was detached and the mesh was fitted to cover 3 cm either side of the middle and ends of the area of closure. The size of the mesh depended on the length of the laparotomy. The mesh was fixed to the aponeuroses with simple vicryl 2/0 sutures positioned peripherally and concentrically round the middle line of closure, leaving a 1–2 cm space between the stitches. The placement of the mesh was developed by members of the surgery service without requiring the assistance of a specialist in abdominal wall. A redon suction drainage system was fitted to the subcutaneous tissue. The redon is removed when the debit is <50 cc/day.

Independent follow-ups were carried out on all patients in the study at external healthcare centers both for the pathology that had led to the surgery and for the present study. All patients were followed-up until the end of the study or until the diagnosis of IH. If the patients were re-operated, the mesh was removed and the patients were excluded from the study. All patients remained blind until the end of the study. The independent follow-up for the study involved an independent observer (a member service without access to the randomization data) who carried out physical explorations to check for the appearance of IH at 1, 3, and 6 months, and 1 year, and then every 6 months until the end of the study. IH was considered to have occurred if a defect appeared in the abdominal wall or if there was a palpable hernial protrusion under the laparotomy scar when Valsalva manoeuvres were carried out in the supine decubitus position and/or in the bipedestation posture. When eventration was clinically diagnosed, a computed tomography (CT) scan was carried out to confirm the diagnosis. A CT scan was also carried out 1 year after the operation in patients who had not previously been clinically diagnosed with IH. These scans were evaluated independently by two radiologists to ensure the study remained blinded.

All adverse developments and postoperative complications related to the surgical wound were recorded during the first 30 days after the operation. Seroma was defined as a serous collection in the subcutaneous tissue. Infection of the surgical area was defined according to the Centers for Disease Control (CDC) definitions [8].

The sample size was calculated to obtain a power of 80 % and an alpha risk of 5 %. Literature reports suggest that IH occurs after midline laparotomy in around 20 % of cases; however, we predicted that the mesh could reduce this to below 10 %. Consequently, the number of patients we included was 70 per group. Assuming a withdrawal rate during follow-up of 10 %, the number of patients included was 160.

Continuous variables are described with mean ± standard deviation (SD), and absolute and relative frequencies (%) are used to describe categorical variables.

The Chi-squared (χ^2) test was used to compare the groups and Fisher's exact test was used for the categorical variables. The Student's *t* test was used for the continuous variables.

A Kaplan–Meier survival analysis with Breslow's hypothesis contrast test was used to compare the principal variable between the groups. The dependent variable was the presence of IH and the follow-up period from the date of surgery to the date of diagnosis of IH, the date of the last control or the date of the end of the study. The likelihood of IH and the Kaplan–Meier curves are presented at 12 months for both groups.

A multivariate Cox proportional hazards analysis fixed model, the most reliable method, was used to evaluate the relation between the mesh and non-mesh groups and the appearance of IH, adjusting for other variables that can act as confounding factors (location in the colon and neoplasia as a base disease).

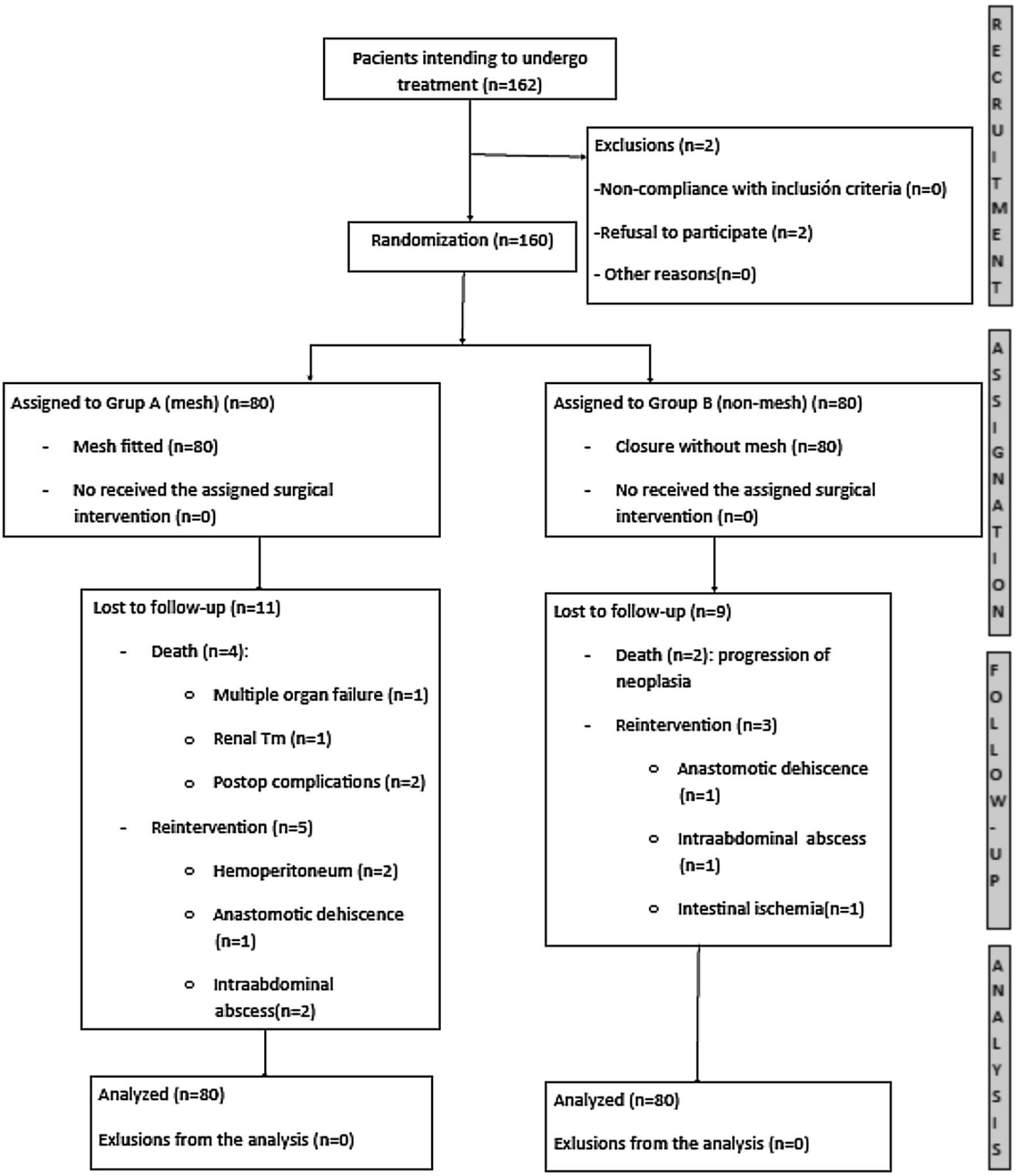

Fig. 1 CONSORT (consolidated standards of reporting trials) flow diagram showing the withdrawal and exclusion of patients

The accepted level of statistical significance is $p \leq 0.05$.

Data were analyzed using the SPSS statistical program, version 15.0 (IBM, Armonk, NY, USA).

Results

The analysis included 160 patients who underwent a programmed midline laparotomy between May 2009 and November 2012. All laparotomies carried out were supra-infraumbilical.

After randomization, both group A (mesh) and group B (non-mesh) contained 80 patients. All patients were subject to a protocol analysis. Figure 1 shows the number of patients who withdrew or were excluded. Re-interventions were carried out because of complications with the principal surgical technique and in no case due to the fitting of the mesh.

Table 1 Demographic characteristics of the patients

	Group A (mesh)	Group B (non-mesh)	*p* value
Sex			
Women	36 (45)	34 (42.5)	
Men	44 (55)	46 (57.5)	0.87
Mean age	64.32 ± 14.27	67.32 ± 11.11	0.12
ASA anesthetic risk			
ASA 1	7 (8.8)	4 (5.1)	
ASA 2	39 (48.8)	44 (55.7)	0.53
ASA 3	34 (42.5)	31 (39.2)	
BMI			
<30	56 (73.7)	51 (69.9)	0.71
>30	20 (26.3)	22 (30.1)	
Diabetes mellitus			
Yes	13 (16.3)	14 (17.5)	1
No	67 (83.8)	66 (82.5)	
Cardiomyopathy			
Yes	18 (22.5)	24 (30)	0.36
No	62 (77.5)	56 (70)	
COPD			
Yes	19 (23.8)	16 (20)	0.70
No	61 (76.3)	64 (80)	

Data are presented as *N* (%) or mean ± SD unless otherwise indicated

ASA American Society of Anesthesiologists, *BMI* body mass index, *COPD* chronic obstructive pulmonary disease, *SD* standard deviation

Table 2 Surgical data of the patients

	Group A (mesh)	Group B (non-mesh)	*p* value
Degree of surgical contamination			
Clean	11 (13.8)	3 (3.8)	
Clean contaminated	8 (10)	4 (5)	0.06
Contaminated	59 (73.8)	72 (90)	
Dirty	2 (2.5)	1 (1.3)	
Neoplastic pathology			
Yes	58 (72.5)	72 (90)	<0.01
No	22 (27.5)	8 (10)	
Type of surgery			
Colon surgery	43 (53.8)	63 (78.8)	<0.01
Others	37 (46.3)	17 (21.3)	
Mean surgery time (min)	133.58 ± 50.4	117.83 ± 72.2	0.11

Data are presented as *N* (%) or mean ± standard deviation unless otherwise indicated

Table 1 shows the demographic characteristics of the patients in both groups. No statistical differences were obtained between the groups for the variables of sex, age, ASA anesthetic risk, body mass index (BMI), and pathological antecedents (which were grouped as diabetes mellitus, respiratory pathology, and cardiopathy). The principal variables were analyzed in relation to the surgical procedure and no statistically significant differences were found between the groups in terms of blood loss during surgery and the degree of surgical contamination (Table 2). In contrast, statistically significant differences were found between the groups in terms of the location of the surgery and neoplastic pathology. More patients in group B (non-mesh) had neoplastic pathology and surgery located in the colon. Therefore, the groups are homogenous except in terms of the location of the surgery and the neoplastic pathology. Table 3 shows the location of the surgery.

Table 3 Description of pathology location

Location	Group A (mesh)	Group B (no mesh)	Total (%)
Stomach	32	14	47 (29.4)
Spleen	3	2	5 (3.1)
Small bowel	1	1	2 (1.3)
Right colon	23	49	72 (45)
Left colon/sigma	17	17	34 (21.3)

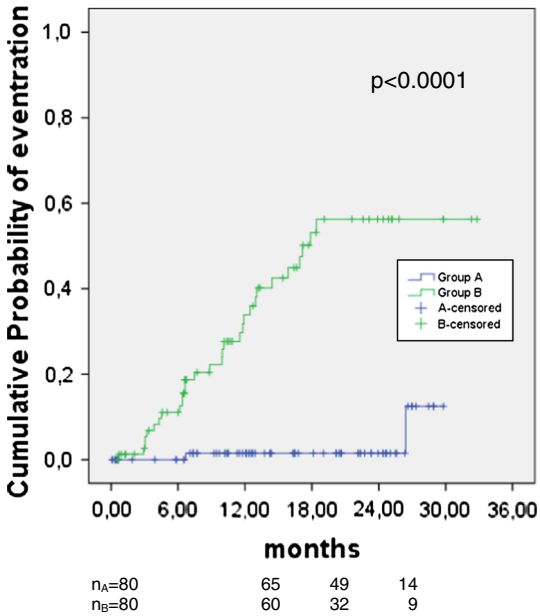

Fig. 2 Comparison of the study groups' likelihood of developing incisional hernia: Kaplan–Meier survival analysis. *Group A* mesh; *group b* non-mesh

The principal variable evaluated in the study was the efficacy of fitting a prophylactic mesh to the closure of a midline laparotomy during programmed surgery to reduce the risk of developing postoperative IHs.

The mean monitoring period for group A (mesh) was 14.8 ± 8.3 months and for group B it was 12.5 ± 8.5

Table 4 Multivariable Cox regression analysis of appearance of postoperative incisional hernia adjusted for location in colon, neoplastic pathology, and fitting of mesh

Variables	RR	95 % CI	
Pathology: neoplastic	0.85	0.27	2.50
Location: colon	0.82	0.33	2.17
Group B/group A: group B	21.4	5.1	71.2

CI confidence interval, *RR* rate ratio

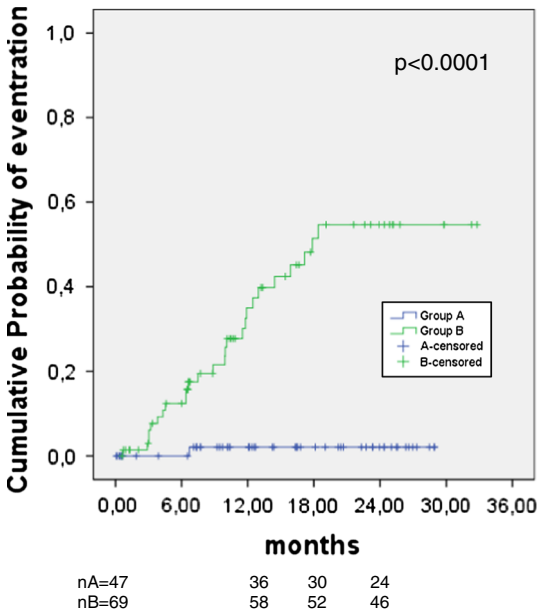

Fig. 3 Accumulated likelihood of incisional hernia in group with neoplastic pathology: Kaplan–Meier survival analysis. *Group A* mesh; *group b* non-mesh

months, this difference not being statistically significant. In group A, 2/80 IHs were diagnosed, whereas in group B the number was 30/80. Figure 2 compares the Kaplan–Meier survival curves. As can be seen, the likelihood of IH at 12 months is 1.5 % in group A compared with 35.9 % in group B ($p < 0.0001$), which means that the differences are statistically significant. IH diagnosis was made clinically in 22 patients and by CT in ten patients.

Given that the sample is not homogenous in terms of neoplastic pathology and location of the surgery in the colon, a multivariate Cox regression was carried out in order to evaluate the association between the two groups and the appearance of IH. The results were adjusted for these two variables to avoid possible confounding factors. The results (Table 4) show that the association found between group B and IH during the univariate analysis is maintained and that it is independent of the location of the surgery or the neoplastic pathology.

To address the lack of homogeneity in the groups, independent specific univariate analyses were carried out

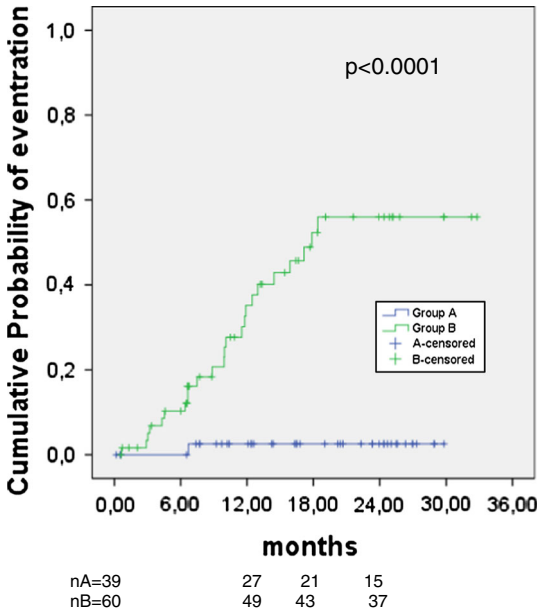

Fig. 4 Accumulated likelihood of incisional hernia in colon group: Kaplan–Meier survival analysis. *Group A* mesh; *group b* non-mesh

Table 5 Postoperative complications

Postoperative complications	Group A (mesh)	Group B (non-mesh)	*p* value
Superficial infection	5 (6.3)	6 (7.5)	0.88
Deep infection	3 (3.8)	2 (2.5)	
Organ-cavity infection	2 (2.5)	1 (1.3)	
Seromas	23 (28.8)	9 (11.3)	<0.01
Hematomas	1 (1.3)	3 (3.8)	0.62

Data are presented as *N* (%) unless otherwise indicated

for surgical location in the colon and for neoplastic pathology to determine whether the same results occur as for the general sample. Both studies analyzed the effect of fitting a mesh or not on the appearance of IH and show, as in the general group, that the mesh has a preventive effect on the development of postoperative IH in both the group with pathology of the colon (group A 1/46 IHs vs. group B 24/63) and the group with neoplasia (group A 1/58 vs. group B 26/72). Figures 3 and 4 show the Kaplan–Meier survival curves for these two groups.

Table 5 shows the postoperative complications recorded. Statistically significant differences were only found between the groups in terms of the seromas, which were more frequent in group A (23 in group A vs. 9 in group B). It should be noted that none of the seromas needed to be drained and were therefore considered to be grade one in the Clavien classification [9].

No statistically significant differences were observed between groups in rate of infection and hematoma.

The surgery time was analyzed to determine whether it was increased by the fitting of the mesh, and no statistically significant differences were observed between the groups (Table 2).

Discussion

The main aim of the study was to evaluate the prevention of IH in elective midline laparotomies by fitting a supra-aponeurotic mesh to the abdominal wall closure.

The study has confirmed its main hypothesis in that only two cases of IH (2/80) were detected in group A (mesh) compared with 30/80 in group B during the year of post-operative follow-up; results that clearly show that fitting a prophylactic mesh on the abdominal wall closure reduces the occurrence of IH.

Regarding the surgical technique of closing the abdominal wall and the material used in this study, as other authors have stated, the suture material must contribute to strengthening the wound during a sufficiently long period and, as the aponeurosis heals rather slowly, it needs the support of the suture for at least 6 weeks. Non-absorbable monofilament suture materials and slowly absorbable materials, supporting the wound for at least 6 weeks, produce similar rates of IH. The PDS suture is a slowly absorbable material that is totally absorbed in 180–210 days (6–7 months) [10, 11].

These results reinforce the findings of other authors who have carried out similar studies on smaller groups of selected patients [12–15]. Other authors, such as Bevis et al. [12], Strzelczyk et al. [13], El-Khadrawy et al. [14], and Gutierrez de la Peña et al. [15], have published similar studies but only include patients with factors that increase the risk of IH (obesity, abdominal aortic aneurysm, etc.). They found similar results to those of the present study regarding the protective effect of the mesh and regard it as a safe and effective procedure [12–15]. The present study expands on the observations described in the bibliography by including patients both with and without risk factors. We excluded the patients receiving steroid therapy because they are a very small group of patients and we thought that their inclusion might affect the results of the study. We included all other patients, with and without risk factors, to determine the effect of the mesh in the general population. Furthermore, the demographic characteristics of the patients in the two groups did not present statistically significant differences, and so the patients with risk factors were distributed equally into the two groups.

The study also provides statistically significant evidence that fitting a supra-aponeurotic mesh prevents postoperative IH in any patient who undergoes a programmed midline laparotomy.

Patient losses were due to patients not completing the follow-up, and were losses that had been calculated for when designing the study (ten per group). In any case, we believe that the differences are so great that these losses do not affect the results.

Of the two cases of IH diagnosed in group A (mesh), one was an obese patient who presented with a hematoma from the surgical wound in the immediate postoperative period that could have influenced the development of IH despite there being no evidence in the literature that surgical hematomas increase the risk of postoperative IH. In group B (non-mesh) IH occurred in 37.5 % of cases at 1 year after the operation, which is a much higher figure than that found in the literature (20 %), [5, 16, 17] and which is attributed to the exhaustive controls carried out on the patients. The meticulous search for IH gives us information about the real incidence of this problem (35–40 %). The patients in both groups were closed with the same technique and the same surgeons, and had the same follow-up, including CT and physical examination; therefore, the prophylactic effect of the mesh is real.

The surgical technique of abdominal wall closure involves closing the abdominal wall with a continuous PDS loop no. 1 suture in stitches spaced 1 cm apart and at least 1 cm either side of the aponeurotic edges, following the rule of 4:1 in both groups. This is the standard closure technique. It has been demonstrated that, with large stitches, more soft tissue is compressed or cut through than with small stitches [18, 19]. In a randomized clinical trial, midline incisions were closed continuously with a suture length-to-wound length ratio of more than four and were allocated to suture either large stitches placed more than 10 mm from the wound edge or smaller stitches. The rate of surgical site infection (SSI) was 10.2 % with large stitches and 5.2 % with small stitches. Furthermore, Millbourn et al. [20, 21] published a randomized controlled trial in which short stitch length was associated with a lower rate of IH than were large stitches.

The postoperative complications of both groups have been compared and classified as seromas, and hematomas, and superficial, deep, and organ-cavity infections. The only differences observed between the two groups were in the appearance of seromas that, as in the literature, are related to fitting the mesh in a supra-aponeurotic position.

Although some authors argue against fitting prosthetic material in surgery that has been contaminated by the opening of the gastrointestinal tract [22], our study coincides with that published by Geisler et al. [23] in 2003 and Birolini et al. [24] in 2000 in finding no complications related to the fitting of a prophylactic supra-aponeurotic mesh during surgery in which the gastrointestinal tract has

been opened [23, 24]. Even in patients who have undergone colon surgery, which is considered to be contaminated, the number of surgical wound infections does not increase.

In contrast, discussion is still ongoing as to the best place to fit the mesh, regardless of whether the aim is to repair IHs or to act as a prophylactic [25–27]. Following Gutierrez de la Peña et al. [15], we preferred to fit the mesh supra-aponeurotically because it is a simple, quick, and feasible technique for all members of the surgery department that also avoids contact with the peritoneal content. Other authors have fitted the mesh in a preperitoneal position, with the aim of reducing the appearance of seromas and infections [8]. It should be emphasized that despite having observed more seromas in the group in whom the mesh was fitted, all cases were resolved with conservative treatment and without requiring drainage. De la Portilla et al. [28] carried out a study in which they fitted a supra-aponeurotic mesh to prevent eviscerations, and they coincide with the present study in that they detected more seromas in the group that underwent closure with mesh than in the group that underwent closure with suture, although the patients with mesh needed percutaneous drainage to resolve the seromas.

For this reason, we preferred to leave the drainage in the patients fitted with meshes, despite losing the blind of the observer. In any case, the fitting of subcutaneous drainage and elastic compression devices is recommended to reduce postoperative seromas. It has also been observed that the appearance of seromas is related to the dissection of the subcutaneous plane caused by fitting the mesh; and so for this reason in the present study we carried out the minimum necessary dissection that would allow us to fit the mesh.

Experimental studies have been published advocating the fitting of an inverted T-shaped mesh to bring the prosthetic material into line with the sutures [29]. López-Cano et al. [30] recently published an experimental pilot study in which they used a biological absorbable mesh to reinforce the abdominal wall by taking advantage of the benefits that fitting this kind of material confers; that is, the prosthetic material reinforced the suture line and stimulated tissue growth whilst also preventing complications resulting from fitting an unreabsorbable mesh (seromas, infections, rejection of the prosthetic material, etc.). Llaguna et al. [31] also used a biological prophylactic prosthesis to close the abdominal wall of patients at high risk of IH (diabetics, smokers, and the obese). A disadvantage of this technique is that biological prostheses are still very expensive [32].

One limitation to the study may be that the groups at the start were not homogenous given that group B (non-mesh) included more patients with neoplastic and colon pathology, although this was resolved by carrying out a Cox regression analysis adjusted for these variables that showed that the results do not vary and that the group B (non mesh)-IH relationship is maintained. Furthermore, the specific univariant analyses per group regarding colon and neoplastic pathology confirmed the protective effect of the mesh in both groups. We attribute these differences to the fact that inclusion correlates to time and that the pathologies that were treated are not homogenously distributed throughout the year. These differences may also be related to the high number of contaminated procedures in group B (non-mesh). The differences are not statistically significant but may be considered clinically significant. In any case, these differences do not seem to be related to the increase in infections in the group with greater colonic pathology and so we do not believe that the cleanliness or contamination of the procedure affects the protective effect of the mesh. Neither do we believe that the type of laparotomy has a significant effect given that all of those carried out were supra-infraumbilical midline laparotomies.

The drain placement in the mesh group can be considered a study limitation; for this reason we designed the study to be single-blind (only the patient is blind), so we believe that this does not affect the results.

Conclusion

Fitting a prophylactic supra-aponeurotic mesh in patients who have undergone elective midline laparotomy surgery prevents IH independently of other factors. We recommend the technique with the mesh to close the abdominal wall in all patients, with and without risk factors, in view of the high incidence of IH observed after midline laparotomy in the general population. Furthermore, the study has shown that fitting these meshes is safe because it does not increase postoperative complications.

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