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 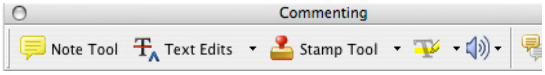

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 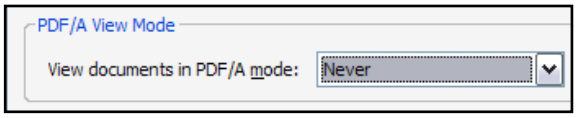

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 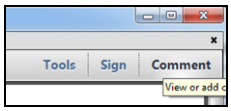

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 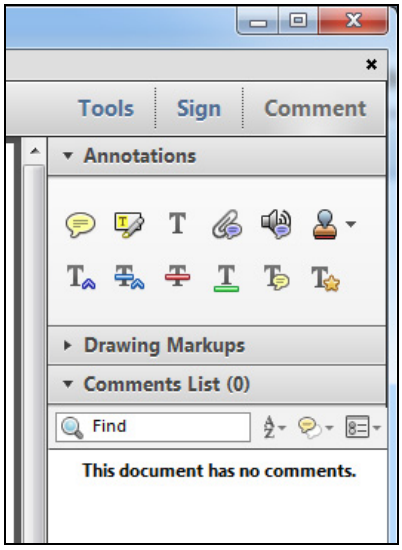
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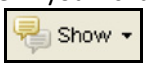
Review	To review your changes, click on the 'Show' button  on the Commenting tool bar. Choose 'Show Comments List'. Navigate by clicking on a correction in the list. Alternatively, double click on any mark-up to open the commenting box.	Your changes will appear automatically in a list below the Comment tool bar. Navigate by clicking on a correction in the list. Alternatively, double click on any mark-up to open the commenting box.
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Prophylactic mesh can be used safely in the prevention of incisional hernia after bilateral subcostal laparotomies

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Background. *The use of prophylactic mesh to prevent incisional hernia is becoming increasingly common in midline laparotomies and colostomies. The incidence of incisional hernia after subcostal laparotomies is lower than after midline incisions. Nevertheless, the treatment of incisional hernia is considered to be more complex. Currently, there are no published data about mesh augmentation procedures to close these laparotomies.*

Methods. *This was a longitudinal, prospective, cohort study of patients undergoing a bilateral subcostal laparotomy in elective operations. The mesh group was a group of patients operated consecutively between 2011 and 2013 with a prophylactic self-fixation mesh. The control group was selected from a retrospective analysis of patients operated between 2009 and 2010 and closed with a conventional protocol of 2-layer closure. The incidence of incisional hernia was recorded both clinically and radiologically for 2 years.*

Results. *A total of 57 patients were included in the control group and 58 in the mesh group. Most patients underwent gastric, hepatic, and pancreatic operations. Both groups were homogeneous in terms of their clinical and demographic characteristics. Operative time and hospital stay were similar in both groups. Both groups had a comparable rate of local and systemic complications. Ten patients (17.5%) in the control group developed an incisional hernia, and only 1 patient (1.7%) in the mesh group developed an incisional hernia (*P = *.0006).*

Conclusion. *The incidence of incisional hernia after a conventional closure of bilateral subcostal laparotomy is significant. The use of a mesh augmentation procedure for closing bilateral subcostal laparotomies is safe and may reduce the incidence of incisional hernia. (Surgery 2016;■:■-■.)*

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Bilateral subcostal laparotomy is still a frequent operative incision used in hepatobiliary and esophagogastric operations despite the increasing practice of the laparoscopic approach. The incidence of incisional hernia (IH) after a subcostal laparotomy has been defined between 4.8% and 31.3%, with few studies published regarding this subject.[1,2] Although the incidence of IH after subcostal incisions seems to be lower than after midline laparotomies,[3,4] its operative repair can be challenging due to the lack of aponeurosis in the lateral side of the abdomen and the proximity of bone limits. There are few reports about the outcomes after the repair of subcostal hernias, with recurrence rates as high as 25%.[5,6] As a matter of fact, a group of experts has recently included these lateral IH in the concept of complex abdominal wall hernia.[7]

Concerned about the occurrence of IH in patients who underwent bilateral subcostal incisions in our hospital and following the satisfactory

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results of a prophylactic mesh placement after midline laparotomies,[8-10] we planned to introduce a mesh augmentation procedure to reduce the incidence of IH after bilateral subcostal laparotomies.

PATIENTS AND METHODS

A cohort study was designed to assess the efficacy and safety of the use of a prophylactic mesh for the prevention of IH in patients undergoing elective bilateral subcostal laparotomies. The study was performed at the Henares University Hospital's Department of Surgery. Our hospital is a 200-bed facility located in the periphery of Madrid. It belongs to the Spanish National Health Service and attends a population of 170,000 people. The operative team comprises 12 surgeons with specialization in general and digestive surgery. Two surgeons dedicated to hepatobiliary and gastrointestinal operations were present for all operative procedures in both groups.

We included in the mesh group all patients who consecutively underwent an elective bilateral subcostal laparotomy with the placement of a prophylactic mesh between 2012 and 2013. An informed consent was obtained. In the control group, we included retrospectively all the patients operated consecutively between 2009 and 2011. Inclusion criteria were patients >18 years who underwent bilateral subcostal laparotomies in elective operative procedures. Exclusion criteria were rejection of participation, prior subcostal laparotomy, previous supraumbilical incisions, life expectancy of <1 year (eg, peritoneal carcinomatosis), emergency operation, and hemodynamic instability during the procedure.

All patients received a single-dose of antibiotic prophylaxis, according to the kind of operation performed; the dose was repeated after the fourth hour of operative time in cases of long operations. In the control group, the abdominal wall closure was performed following a protocol previously established in our department: a 2-layer closure with a running, slowly absorbable, monofilament suture made of Poly-4 Hydroxybutyrate (Monomax USP 1 loop, HR40; B. Braun, Melsungen, Germany) in a 4:1 ratio, and the stitches spaced 1 cm apart and 1 cm from the cut edge.

In the first layer, the internal oblique muscle, the transversus abdominis muscle, and the posterior rectus sheath were sutured. The second layer involved the closure of the external oblique muscle, its aponeurosis, and the anterior rectus sheath. No subcutaneous stitches were used. The skin was closed with staples. Before the abdominal wall closure and following our protocol, gloves were changed and new instruments were used.

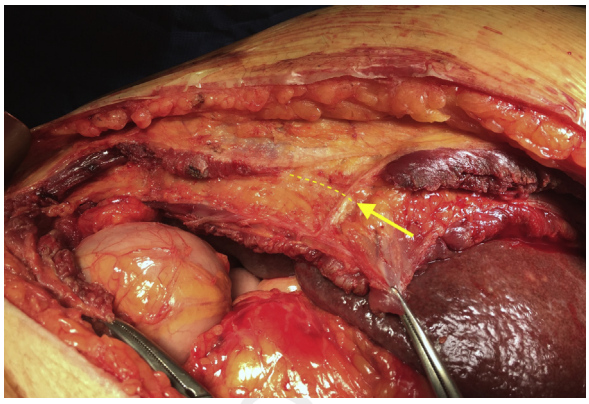

Fig 1. The picture shows the right side of a bilateral subcostal incision. The *arrow* and *line* indicate the place to start and the direction of the release of the anterior component of the internal oblique sheath to obtain a continuous retromuscular space, at the level of the semilunaris line. (Color version of this figure is available online.)

The abdominal wall closure in the mesh group was performed in the same way, except for the placement of a self-fixating mesh made of polypropylene and polyglycolic acid (Parietene ProGrip Self-Fixating Mesh; Medtronic, Minneapolis, MN) between the 2 layers (Video). The mesh was placed over the posterior rectus sheath and laterally in the plane between the external oblique muscle and the internal oblique. After the closure of the first layer, a blunt dissection of the retromuscular space over the posterior rectus sheath was performed medially, and the avascular plane between both internal and external oblique muscles lateral to the semilunaris line was also dissected. After this dissection, the anterior sheath of the internal oblique muscle, which forms the anterior rectus sheath, was transected 2 cm both cranial and caudal from the border of the laparotomy (Fig 1). [F1]

With this maneuver, a space wide enough for the placement of a mesh 4.5 cm wide was created, covering the suture of the first layer. A 15 × 9–cm mesh was cut longitudinally to obtain 2 strips of 15 × 4.5 cm that were placed and trimmed to adjust the dissected spaces on both sides. No method for mesh fixation was used. Both strips remained enveloped between the first and second layer and separated by the closure at the linea alba (Fig 2). Finally, the second layer and skin were closed as in the control group. No drains were used for the closure of the incision. [F2]

The Charlson Comorbidity Index and the Charlson Age Comorbidity Index were calculated in each

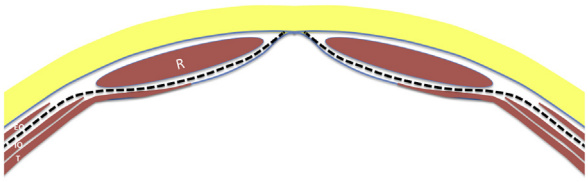

Fig 2. Schematic, cross-sectional view of the location of the mesh between the muscle layers. *R*, Rectus muscle; *EO*, external oblique muscle; *IO*, internal oblique muscle; *T*, transversus abdominis. (Color version of this figure is available online.)

group to evaluate homogeneity of comorbidities.[11] Operative risk homogeneity was also assessed by calculating the American Society of Anesthesiologists (ASA) and the Portsmouth Physiological and Operative Severity Score for the Enumeration of Mortality and Morbidity (P-POSSUM) scores.[12]

To assess the efficacy and safety in the prevention of IH after performing a bilateral subcostal laparotomy, all patients were followed up during the first 24 months after the operation, as is our current practice after hepatobiliary and gastrointestinal operations. In both groups, follow-up visits at 3, 6, 12, 18, and 24 months after the operation were performed by 2 of the authors. All oncologic patients had a computed tomography (CT) scan at 6, 12, and 24 months after the operation; in nononcologic patients in both groups, a CT scan was performed 24 months after the operation. A blinded radiologist interpreted the CT scans.

The primary outcome of the study was the development of an IH, as defined by the European Hernia Society (EHS) ~~Guidelines: any defect in the abdominal wall with or without gap surrounding the operative scar, both perceptible or palpable by physical exam or imaging~~.[13]

To assess the safety of the mesh implantation, the incidences of surgical site infection (SSI), seroma, evisceration, mesh rejection, and any systemic complications were compared between study groups. SSI was defined as the presence of signs, such as redness, pain, heat, or swelling at the site of the incision, or by the drainage of pus.[14] Seroma was defined as swelling or inflammation in the operative wound due to the accumulation of serum liquid, without signs or symptoms of SSI.[15] Evisceration was defined as an abdominal wall disruption in the immediate postoperative period. Mesh rejection was defined as chronic infection of the operative wound that required mesh removal for resolution.

An approximation to the sample size was calculated considering IH as the primary outcome. A prevalence of 18% was expected in the control group, and 2% was expected in the mesh group. Assuming an alpha error of .05%, 108 patients (54 in each group) were needed to detect a 16% difference between both groups.[16]

Variable description and statistical analysis were performed with the Statistical Package for the Social Sciences software (SPSS version 22; IBM Corp, Armonk, NY). The intention to treat analysis included all the patients. Quantitative variables were expressed as mean and standard deviation. Statistical analysis of the quantitative variable for independent groups was performed with the Student *t* test. Qualitative variables were described with absolute values and percentages and were analyzed by the χ^2 test and Fisher exact test. The occurrence of IH during follow-up was analyzed by the Kaplan-Meier method and the log-rank test (Mantel-Cox).

RESULTS

Between May 2011 and November 2013, 58 bilateral subcostal laparotomies that met the inclusion and exclusion criteria were performed in our hospital (Fig 3). In all cases, a prophylactic mesh was placed following the aforementioned technique. In the retrospective control group, between January 2009 and May 2011, we found 57 bilateral subcostal laparotomies that met the same criteria and were closed with the conventional protocol.

The 24-month follow-up was not completed in 15.22% of patients in the mesh group (10 out of 58 patients) and in 18.1% of patients in the control group (14 out of 57 patients). Causes for incomplete follow-up were death due to disease progression (7 patients in the mesh group and 8 in the control group), liver resection for metastasis (4 patients in the control group), loss to follow-up (2 patients in each group), and a reoperation for the resection of neuroendocrine tumor (1 patient in the mesh group). None of the reoperated patients had an IH. During the reintervention, we had the opportunity to check the abdominal wall strength and the complete integration of the mesh into the scar tissue (Fig 4).

No statistically significant differences were found between the 2 groups regarding age, sex, risk factors for IH, Charlson Comorbidity Index, Charlson Age Comorbidity Index, diagnosis, operative technique, operation time, or need for transfusion (Table I). Regarding the operative wound classification, 40 patients in the mesh group (68.97%) presented either clean-contaminated field or contaminated field versus 36 in the control

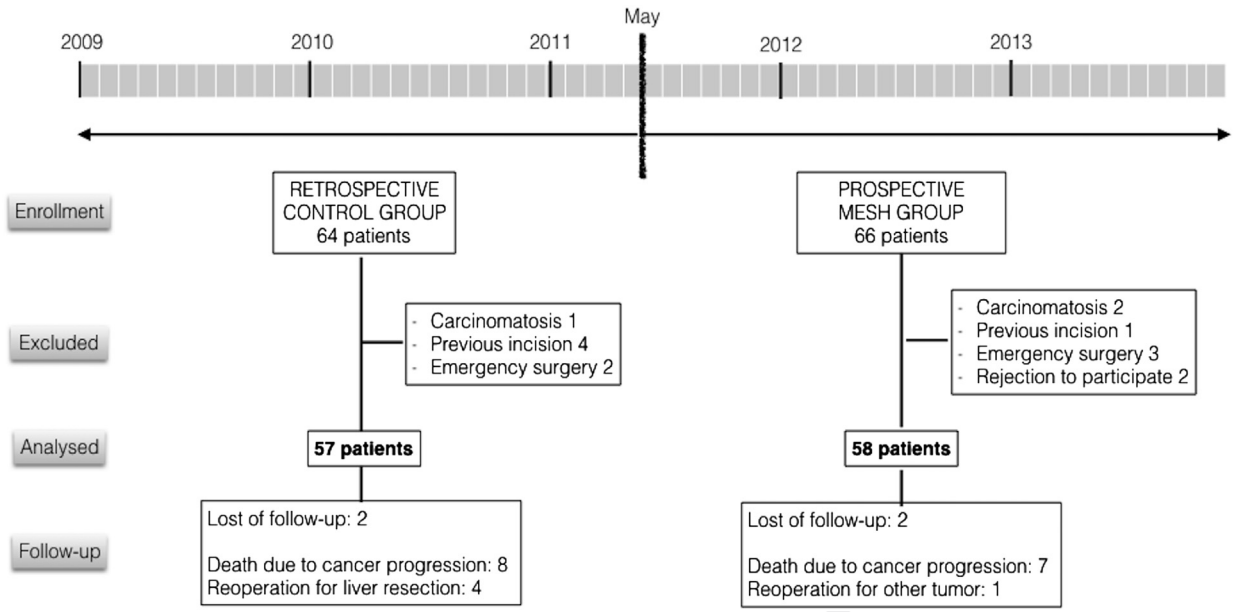

Fig 3. Flow diagram.

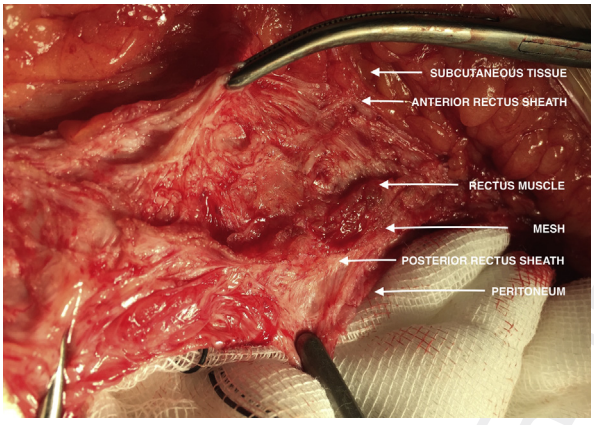

Fig 4. The picture shows the different planes of the incision in the case of reoperation on the patient who had a previous prophylactic mesh. (Color version of this figure is available online.)

group (63.16%), without statistically significant difference.

We found no statistically significant difference between study groups concerning postoperative mortality, with no deaths in the conventional group versus 1 death in the mesh group. The P-POSSUM score was homogeneous between study groups with no significant differences (Table II). [T2]

The incidence of complications was similar in both groups, with no statistically significant differences regarding local or systemic complications. One patient in the mesh group required a reoperation on the 10th postoperative day after a Whipple procedure due to intestinal obstruction. The initial mesh was removed, but a new mesh was used to close the abdomen following the mesh protocol. No patient in the control group needed a reoperation before 30 postoperative days. The rest of the intra-abdominal complications in both groups were managed with percutaneous catheter or treated conservatively.

A surgical wound infection index of 10.34% was found in the mesh group versus 15.79% in the control group ($P = .4200$). All cases were superficial infections managed with antibiotic therapy and drained when necessary. None of them required deep wound debridement. There was no need to remove any mesh due to infection or mesh rejection. In-hospital stay was similar in both groups.

After 24 months of follow-up, using both clinical and radiologic criteria, IHs were found in 10 out of 57 patients in the control group and in 1 patient in the mesh group ($P = .0041$; Table III). Among patients who developed IH, 5 patients in the control group have been reoperated by an open retromuscular approach; 3 with tumor progression and 2 with minor symptoms have not undergone IH repair. The patient in the mesh group also has minor symptoms, and repair has not been offered yet. The Kaplan-Meier curve regarding development of IH is shown in Fig 5. The log-rank test (Mantel-Cox) showed that the estimated freedom of IH curves was significantly different across study groups (χ^2 8.02, $P = .005$). [T3] [F5]

Table I. Descriptive characteristics of both groups

	Mesh group	*Control group*	P *value*
Age, y (SD)	62.59 (11)	61.96 (12)	.7696
Sex (male:female)	35:23	35:22	1.0000
Charlson score, mean (SD)	3.12 (3)	3.10 (2.47)	.9690
Charlson age score, mean (SD)	4.86 (3)	4.67 (3)	.8585
Diabetes mellitus	11 (18.97)	12 (21.05)	.8191
BMI, mean (SD)	27.33 (5.68)	28.35 (5.40)	.4192
Smokers	18 (31.03)	15 (26.32)	.6810
COPD	9 (15.92)	6 (10.53)	.7834
Immunosuppression	14 (24.14)	16 (28.07)	.6752
Cancer	44 (75.86)	39 (68.42)	.4107
Diagnosis			.0509
Gastric cancer	20 (34.48)	11 (19.30)	
Hepatocarcinoma	3 (5.17)	3 (5.26)	
Liver metastasis	8 (13.79)	12 (21.05)	
Benign liver tumors	6 (10.34)	12 (21.05)	
Pancreatic cancer	8 (13.79)	6 (10.53)	
Other pancreatic tumors	4 (6.90)	3 (5.26)	
Others	9 (15.52)	10 (17.54)	
Operative technique			.2238
Liver lobectomy	3 (5.17)	4 (7.02)	
Other liver resections	12 (20.68)	16 (28.07)	
Whipple	7 (12.07)	8 (14.04)	
Distal pancreatectomy	4 (6.90)	3 (5.26)	
Total gastrectomy	12 (20.69)	6 (10.53)	
Subtotal gastrectomy	11 (18.97)	9 (15.79)	
Biliodigestive diversion	3 (5.17)	2 (3.51)	
Others	6 (10.34)	9 (15.76)	
Operative time, mean (SD)	214 (68)	207 (72)	.5930
Blood transfusion	17 (29.31)	21 (36.84)	.4320
Hospital stay, mean (SD)	14 (12)	13.71 (23.19)	.9329

Values are expressed as absolute number (percentage) unless otherwise indicated.
SD, Standard deviation of the mean; *BMI*, body mass index; *COPD*, chronic obstructive pulmonary disease.

DISCUSSION

The recently published EHS guidelines indicate that there are not enough data available about closing nonmidline incisions and that no recommendations can be given on suture material or suturing technique for the closure of these incisions.[17] Our investigation aims to start a study on the incidence and prevention of IH after subcostal laparotomies. To our knowledge, this is the first study to evaluate the incidence of IH in a cohort of patients after 2 years with both a conventional running sutures technique and a mesh augmentation procedure.

In our cohort, we decided to use a slowly absorbable monofilament material, per our hospital's former protocol for closing lateral incisions, and therefore, we could already have a control group for comparison. To evaluate the protective effect of the mesh, we maintained the same method of closure with the single modification of introducing a mesh in the plane between the 2 layers of closure.

We have not used the small bites technique that seems to reduce the incidence of IH in midline laparotomies,[18,19] which is the current suggestion from the EHS guidelines of midline incisions closure with "weak" recommendation.[13] However, although the small bites technique could be applied to the closure of the rectus sheaths in subcostal incisions, it is more difficult to apply laterally to linea semilunaris, since there is no aponeurosis, and the 3 lateral muscles are covered by only weak fasciae. Nevertheless, we think that future studies should include the small bites technique to evaluate its protective effect on IH prevention in lateral incisions.

Due to the lack of information about the incidence of IH after subcostal incisions, our sample size calculation was based mostly on our clinical experience. The studies published

Table II. Morbidity, mortality, and risk indexes

	Mesh group	*Control group*	P *value*
Wound classification			.2078
Clean	18 (31.04)	21 (36.84)	
Clean-contaminated	34 (58.62)	25 (43.86)	
Contaminated	6 (10.34)	11 (19.30)	
ASA >2	27 (46.55)	23 (40.35)	.5740
P-POSSUM morbidity, mean (SD)	61.60 (25.52)	55.44 (25.75)	.2002
Overall morbidity	28 (48.28)	27 (47.37)	1.0000
Wound complications	9 (15.52)	12 (21.05)	.4780
Operative site infection	6 (10.34)	9 (15.79)	.4200
Seroma	3 (5.17)	3 (5.26)	1.0000
Reoperation before 30th d	1 (1.72)	0 (0)	1.0000
Evisceration	0 (0)	1 (1.75)	.4957
Systemic complications	23 (39.66)	21 (36.84)	.8484
Fistula/anastomotic dehiscence	10 (17.24)	6 (10.53)	.4200
Intra-abdominal abscess	6 (10.34)	5 (8.77)	1.0000
Respiratory complications	8 (13.79)	9 (15.79)	.7983
P-POSSUM mortality, mean (SD)	9.75 (12.73)	8.09 (12.20)	.4769
Postoperative mortality	1 (1.72)	0 (0)	1.0000

Values are expressed as absolute number (percentage).
SD, Standard deviation of the mean.

Table III. Analysis of the incidence of incisional hernia

	Mesh group (n = *58*)	*Control group* (n = *57*)	P *value*
Incidence of IH, *n* (%)	1 (1.72)	10 (17.54)	.0006
IH classification[13]			
L1W1		1	
L1W2		3	
M2W1	1	3	
M2W2		3	
	Risk indicator	*95% Confidence interval*	
Relative risk	0.1	0.01–0.74	
Relative risk reduction	0.90	0.26–0.99	
Absolute risk reduction	0.16	0.05–0.26	
Number needed to treat	6.32	3.81–18.54	

L1W1, L1W2, M2W1, M2W2.

previously are scarce and very heterogeneous, because they include unilateral subcostal, bilateral subcostal, extended right subcostal, or Mercedes-type incisions.[1,20-22] The number of patients included is small, and the follow-up is <1 year. In a study comparing transverse versus midline incisions, the incidence of IH was 8% at 1-year follow-up.[4] Something similar occurs in the evaluation of IH after different operative incisions in liver transplantation, with a published incidence up to 43%.[2,23-26] Nevertheless, liver transplantation series cannot be compared because immunosuppression impairs wound healing.

To avoid heterogeneity in our series, we have not included unilateral subcostal incisions. This approach is scarcely used in our hospital to treat biliary tree diseases that cannot be solved by laparoscopic approach. Mercedes-type or extended right subcostal incisions are made only occasionally, but in our opinion, they deserve to be investigated. In our series, the incidence of IH after conventional running closure is high

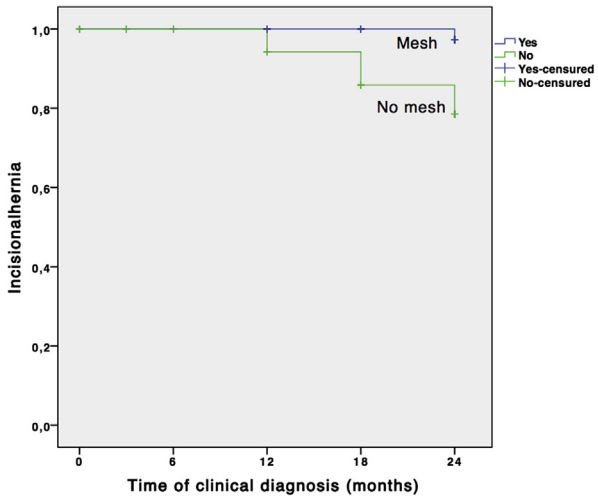

Fig 5. Kaplan-Meier curve for the incidence of IH. (Color version of this figure is available online.)

(17%), although an even greater rate has been reported (20%).[21]

The use of a prophylactic mesh to close the abdominal wall is a matter of debate. There have been several randomized studies with encouraging results for the use of mesh augmentation in high-risk patients of bariatric operations,[27] aortic aneurysm operations,[28] and colorectal operations.[9,10] Moreover, there is also evidence to support the use of mesh to prevent parastomal hernias from both colorectal[29,30] and urologic operations.[31]

The mesh seems to be safe even when it is placed in contaminated fields.[8,10] However, the recent EHS Guidelines on the closure of abdominal wall incisions stated that "although the data are favorable and consistent for prophylactic mesh augmentation, … larger trials are needed to make strong recommendation."[17] In a more recent analysis, mesh augmentation strategies in high-risk patients seem to be more effective, less costly, and overall more cost effective.[32] Nevertheless, ongoing trials are now being performed to reinforce or weaken the recommendation of using a mesh.[33]

In our mesh group, the simple addition of a mesh without any fixation between the 2 layers of closure also seemed to prevent IH without adding wound morbidity: only 1 case of IH was registered in the 2-year follow-up. Although the number of different procedures and etiologies in both groups is high and may influence outcomes, there was no difference regarding operative risk and morbidity between groups. The mesh also seems to be safe, as there was no difference in wound complications between the 2 groups. In our study, the hypothesis that a polypropylene mesh can be used in clean-contaminated or contaminated wounds is also reinforced.[8,10,34]

Regarding the best plane for mesh placement, we think that the avascular plane between internal and external oblique muscles (laterally) and the retrorectus space (medially) are easy anatomic spaces to dissect and very suitable places to lay a flat piece of mesh. We decided to cut the anterior division of the internal oblique muscle sheath that helps form the anterior rectus sheath to avoid cutting the mesh at this position. Another option could have been to put 2 different strips on 1 or both sides without releasing this anterior division of the internal oblique muscle sheath.

We chose this type of mesh instead of a simple macroporous polypropylene due to the characteristic of self-fixation. We wanted to take advantage of the mesh's absorbable microgrips that allow placement without the need of a fixation method. The microgrips stick easily to the muscles in a similar way as it is used in the inguinal area. The microgrips are absorbed completely in a few months, and only the lightweight polypropylene fabric remains to provide long-term wall reinforcement.[35] In fact, the operative time was only 5 minutes longer in the mesh group, demonstrating that using this mesh does not prolong the time of an already lengthy operation. We thought that a macroporous, lightweight mesh would require several sutures or glues to avoid folding and wrinkling in this position.

We should not forget some important limitations of the study. Some of them have already been suggested. It was a longitudinal study, in which no randomization had been done, and the control group was selected retrospectively; therefore, there is an inherent bias, because the incisions of the mesh group could have been better closed unintentionally, although the incisions of the control group were also closed following a protocol. We have already referred to the possible heterogeneity involving multiple diagnoses and operative techniques that our patients presented, but they reproduce realistically the current indications of bilateral subcostal laparotomy. Finally, we have not used a small bites technique that seems to be a better method of closure in midline incisions.

From our study, we can conclude a significant 2-year incidence of IH after a conventional closure with a running absorbable suture of bilateral subcostal laparotomy. A mesh can be added safely to the closure without increasing wound complications. The simple addition of a mesh between 2 layers of closure seems to reinforce healing of the abdominal wall and reduce IH development.

Randomized trials are needed to add more evidence to these initial findings.

SUPPLEMENTARY DATA

Supplementary data related to this article can be found online at http://dx.doi.org/10.1016/j.surg.2016.05.010.

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Prophylactic mesh can be used safely in the prevention of incisional hernia after bilateral subcostal laparotomies

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The incidence of incisional hernia after a conventional closure of bilateral subcostal laparotomy is significant. The importance of this finding is that the use of a mesh is safe and can reduce the incidence of these incisional hernias.