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ORIGINAL ARTICLE

Long-term outcomes after prophylactic use of onlay mesh in midline laparotomy

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Abstract

Background The prevalence of incisional hernias (IHs) is still high after midline laparotomy (ML). There is an increasing body of evidence that prophylactic mesh placement (PMP) can be safe and efficient in the short-term outcomes, but there still are some concerns about the potential long-term complications of these meshes. This study describes our long-term PMP experience.

Methods Observational and prospective study including all patients undergoing the use of prophylactic onlay large-pore polypropylene meshes for the closure of ML since 2008 to 2014. Outcome measures included demographics, perioperative details, wound complications, recurrences, reoperations and chronic complications.

Results A cohort of 172 patients was analysed: 75% elective surgery, 25% emergency cases. Mean age was 68 years with mean body mass index (BMI) of 28.6 kg/m^2. Wound classification: 6.4% clean; 85% clean-contaminated; 1.2% contaminated and 8.1% dirty. Follow-up of patients was up to 8 years (mean: 5 ± 1.6). Two meshes were removed due to chronic infection in first six postoperative months. Of the 13 patients (9.02%) who developed IH, 5 of them have been reoperated for IH repair without any difficulty related to previous mesh. During follow-up, 8 patients have been reoperated for other reasons and the integrity of abdominal wall was also checked. After the comparative study, higher BMI and emergency surgery were still risk factors for IH despite PMP.

Conclusions In our setting, the use of polypropylene prophylactic meshes in MLs is safe, efficient and durable.

Keywords Incisional hernia · Prophylactic mesh · Midline laparotomy · Polypropylene mesh

Abbreviations

ASA	American Society of Anesthesiologists
BMI	Body mass index
COPD	Chronic obstructive pulmonary disease
CT	Computed tomographic scan
IH	Incisional hernia
ML	Midline laparotomy
PMP	Prophylactic mesh placement
QoL	Quality of life
RCT	Randomized controlled trial
RR	Risk ratio
SPSS	Statistical package for the social sciences
SSI	Surgical site infection

This study has not been previously published or submitted elsewhere for publication and it will not be sent to another journal until a decision will be made concerning publication by HERNIA.

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Introduction

Incisional hernias (IH) are a frequent complication of abdominal wall incisions. They occur in 5–20% of the general patient population [1–3]. In high-risk patients, the incidence of IH can increase to more than 60% [4, 5]. In the emergency setting, the reported incidence of IH is greater than 50% [6, 7]. IH can cause morbidity and have a negative

effect on patients' quality of life (QoL). Despite advances in IH repair, recurrence rates remain high (12–54%) [8], and those who experience recurrence are susceptible to a vicious cycle of complications, as each subsequent repair presents a greater technical challenge with an increased risk of further recurrence and morbidity [9]. In terms of healthcare economics, in 2011, a study from France has shown that if the rate of IH after abdominal surgery could be reduced to 5%, a total of 4 million Euros would have been saved [10]. Therefore, prevention of IH is important for both patients and health care providers [3].

Risk factors for IH development are both patient related and secondary to technical considerations for abdominal wall closure [11]. Some patient-related risk factors can be modified to reduce the rate of IH, including smoking cessation, optimizing diabetic control, weight loss and implementing bundles to reduce SSI. The technical considerations that can be employed to reduce the incidence of IH include the choice of suture material and the use of either small bites to close the linea alba and prophylactic mesh placement (PMP) [12].

Previous systematic reviews and meta-analyses have shown that PMP is safe and effective at preventing IH [3, 13]. However, in the specific setting of PMP, there is minimal data on which is the optimal mesh composition, the best anatomical position to place the mesh within the abdominal wall or the best method of mesh fixation [9]. There is also fear regarding the potential long-term sequelae of PMP, such as chronic seroma, chronic pain, infection or mesh explantation. Additionally, there are no data on how to manage those patients that develop an IH after PMP.

Concerned about this problem, and following our satisfactory short- to mid-term results in PMP after midline laparotomies (ML) in colorectal surgery [14], we wanted to investigate what happened to patients undergoing PMP after several years. So, the aim of this study was to evaluate the long-term outcomes after prophylactic use of onlay mesh in ML.

Methods

This observational study was conducted in the Department of General and Digestive Surgery of Henares University Hospital in Madrid, Spain, between 2008 and 2014. Our center is a 250-bed facility that belongs to the Spanish National Health Service and attends to over 160,000 patients in the periphery of Madrid, with 20% of immigrants from Eastern Europe. Surgical team comprises 12 surgeons with specialization in general and digestive surgery who were responsible for both elective and emergency operations.

The primary outcome of the study was to assess the long-term incidence of IH after PMP. Secondary outcome measures were the need for reoperation, chronic infection, chronic seromas, mesh explantation and chronic pain.

From a prospective maintained database, we have identified those patients over 18 years old, operated by ML with PMP, in either an emergency or elective setting with a minimum follow-up of 2 years. The STROBE Statement recommendations were followed [15]. The decision to perform PMP was made by the surgeon responsible for the patient. All patients were informed and consented prior to surgery.

As previously described [14], abdominal wall closure was performed by a standardized protocol of PMP. Briefly, the linea alba was closed with running sutures of long-term resorbable monofilament USP number 0 or 1, spaced 1 cm apart and 1 cm from the cut edge. A large-pore, medium-density polypropylene mesh (Optilene Mesh Elastic; B. Braun, Melsungen, Germany) was placed in the fascial onlay position. The mesh was 5 cm wide and the length of the mesh was adapted to the incision with an overlap of 2 cm at both ends. The meshes were fixed to the anterior rectus sheath with interrupted resorbable sutures 3–4 cm apart. When an ostomy was placed, the mesh did not reach or cover the stoma site. The subcutaneous tissue was closed by interrupted polyglactin 2/0 stitches fixed to the mesh and a suction drain was left over the mesh. Staples were used for skin closure.

Registered preoperative clinical data included age, sex, body mass index (BMI), American Society of Anesthesiologists (ASA) grade, comorbidities [hypertension, diabetes, chronic obstructive pulmonary disease (COPD), cardiopathy, collagen disease, etc.], previous history of cancer and smoking. Intraoperative variables included operative status (elective or emergency), diagnosis, operative procedure, stoma formation and operation time. Patients who developed full thickness abdominal wall dehiscence (evisceration) or required further surgery within the first 30 days post-operatively undergoing removal of the mesh without any new mesh implantation were excluded from data analysis. All post-operative surgical site occurrences were included in the analysis. Centers for Disease Control and Prevention definitions of SSI were used [16]. Seroma was defined as a mass or swelling in the wound caused by the localized accumulation of clear serum liquid without SSI signs. Chronic pain was defined as any pain lasting more than 12 weeks [17]. VAS score > 2 and the need for analgesia were considered as pain. Mesh explantation was defined as a chronic wound infection that required mesh removal. Complications were diagnosed and registered by the surgeons of the department.

Patient follow-up was carried out in the outpatient clinic by clinical examination. Incisional herniation was diagnosed according to EHS definition [18]. Computed tomographic (CT) scan was performed as part of routine surveillance for oncological patients, when there was any

clinical uncertainty regarding the presence of an IH, and for investigation of other complaints not related to the previous surgery.

The description of variables and the statistical analysis were performed using the Statistical Package for the Social Sciences (SPSS) program (version 19.0 for Windows). Quantitative variables were expressed as mean and standard deviation, and categorical variables as absolute numbers and percentages. The statistical analysis of the quantitative variables for independent groups was performed with the nonparametric Mann–Whitney *U* test. In the statistical analysis of categorical variables, the Pearson $\chi 2$ (Fisher's) test was used. The appearance of IH during follow-up was analysed with the Kaplan–Meier estimation method and comparative analysis of time-to-event data was performed using the log rank test. Statistical significance was accepted as $p < 0.05$.

Results

Between 2008 and 2014, a cohort of 172 patients underwent PMP following ML (Fig. 1). These include 96 men (56%) and 76 women (44%), with a mean age of 68 years (62–77) and mean BMI of 28.6 kg/m^2 (25.2–30.8).

Comorbidities (summarized in Table 1) were: smoking, 71 (41.3%) patients; heart disease, 53 (30.8%) patients; hypertension 94 (54.7%) patients; COPD, 24 (14%) patients; diabetes, 38 (22.1%) patients; obesity, 44 (25.6%) patients; and previous history of cancer, 34 (19.8%) patients. The most common indication for surgery was uncomplicated colorectal cancer (70% of cases). Other diagnoses included ischemia, acute diverticulitis and bowel obstruction.

The procedures performed included left hemicolectomy/sigmoidectomy, 45(26.2%) patients; right

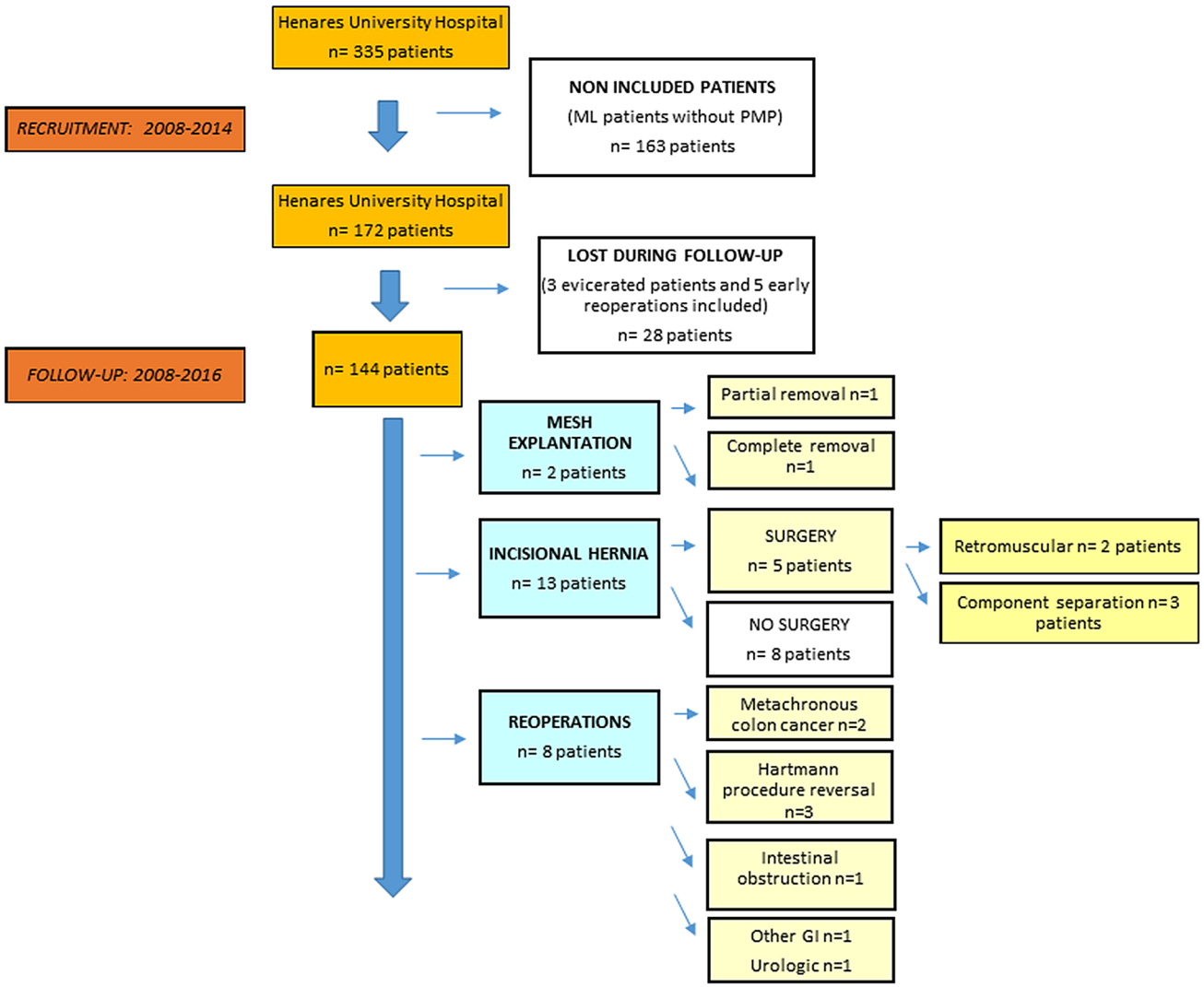

Fig. 1 Flow diagram of patients

Table 1 Descriptive characteristics of patients

Demographics	
Age (years), median (Q25–Q75)	68 (62–77)
Sex (M:F)	96:76
BMI (kg/m^2), median (Q25–Q75)	28.6 (25.2–30.8)
Comorbidities (*n*, %)	
Smoking	71 (41.3%)
Heart disease	53 (30.8%)
Hypertension	94 (54.7%)
Chronic obstructive pulmonary disease	24 (14%)
Diabetes	38 (22.1%)
Obesity	44 (25.6%)
Previous history of cancer	34 (19.8%)
Diagnosis (*n*, %)	
Acute diverticulitis	6 (3.5%)
Colorrectal cancer (complicated)	7 (4.1%)
Colorrectal cancer (no complicated)	121 (70.3%)
Recurrence of colorrectal cancer	3 (1.7%)
Intestinal obstruction	17 (9.9%)
Complications of previous surgeries	3 (1.7%)
Ischemia	1 (0.6%)
Abdominal sepsis	4 (2.3%)
Others	10 (5.8%)
Treatment (*n*, %)	
Left hemicolectomy/sigmoidectomy	45 (26.2%)
Right hemicolectomy	39 (22.7%)
Anterior resection of rectum	30 (17.4%)
Total/subtotal colectomy	16 (9.3%)
Small bowel resection	9 (5.2%)
Abdominoperineal resection	8 (4.7%)
Exploratory laparotomy	12 (7%)
Adhesiolysis	11 (6.4%)
Operative status (*n*, %)	
Elective	129 (75%)
Urgent	43 (25%)
Wound classification (*n*, %)	
Clean	11 (6.4%)
Clean-contaminated	145 (85%)
Contaminated	2 (1.2%)
Dirty	14 (8.1%)
Stomas (*n*, %)	
Colostomies	29 (16.9%)
Ileostomies	19 (11%)
Surgical site occurrences (*n*, %)	
Surgical site infections (superficial)	17 (9.9%)
Surgical site infections (deep)	2 (1.1%)
Seromas	23 (13.4%)
Organ/space infections	9 (5.2%)

hemicolectomy, 39 (22.7%) patients; anterior resection of rectum, 30 (17.4%) patients; total/subtotal colectomy, 16 (9.3%) patients; small bowel resection, 9 (5.2%) patients; abdominoperineal resection, 8 (4.7%) patients; exploratory laparotomy, 12 (7%) patients; and adhesiolysis, 11 (6.4%) patients. Emergency surgery was performed in 43 (25%) patients.

There were 145 (85%) patients with clean-contaminated wounds; 11 (6.4%) patients with clean wounds; 2 (1.2%) patients with contaminated wounds and 14 (8.1%) patients with dirty wounds. 29 (17%) patients were given a colostomy, of which 7 (24%) were temporary; and 19 (11%) patients had an ileostomy, of which 13 (68.4%) were temporary. The mean postoperative hospital stay was 11 (range 7–18) days.

Related with surgical site occurrences, we registered: 17 (9.9%) patients with a superficial SSI (Clavien-Dindo grade I); 23 (13.4%) patients with wound seromas (Clavien-Dindo grade I); 9 (5.2%) patients with organ/space infection (2 Clavien-Dindo grade IIIa, 2 grade IIIb, 3 grade IVa and 2 grade IVb); and 2 (1.1%) patients with deep SSI (Clavien-Dindo type IIIb). In these last two cases the mesh needed to be removed within the first 6 months after surgery due to chronic infection (Fig. 2). The bacterial wound culture isolated *Pseudomonas aeruginosa* and *Escherichia coli*, respectively.

Patients were followed up for up to 8 years in the outpatient clinic, with a mean follow-up of 5 ± 1.6 years (Fig. 3). Those patients that were not currently followed-up by the surgeon that performed the original surgery were invited to attend the outpatient clinic for an up-to-date clinical examination by the main author (CSM). Most of them have been reviewed during the past 2 years before the analysis (Fig. 3). The estimated freedom from IH is shown in Fig. 4. During follow-up, a global mortality of 29 (20%) patients was registered. None of these were thought to be directly related to PMP. A total of 28 (16.2%) patients were lost to follow-up, due to migration of foreign patients or other unknown reasons. Patients undergoing reoperation within 30 postoperative days with removal of the mesh without any new mesh implantation were excluded from data analysis. This included 3 (1.74%) patients with full thickness abdominal wall dehiscence; and 5 (2.9%) patients requiring early reoperations (2 anastomotic leaks after colorectal surgery, 1 intra-abdominal abscess, 1 early haemoperitoneum and 1 case of peritoneal carcinomatosis). Data from 144 patients were used for final IH analysis.

During follow-up, 8 patients (4.65%) underwent further surgery. These included a Hartmann's procedure reversal (3 patients), metachronous colon cancer (2 patients), adhesions causing intestinal obstruction (1 patient), gastric cancer procedure (1 patient) and urologic surgery (1 patient). No hernia was found during these relaparotomies. A dense fibrosis was

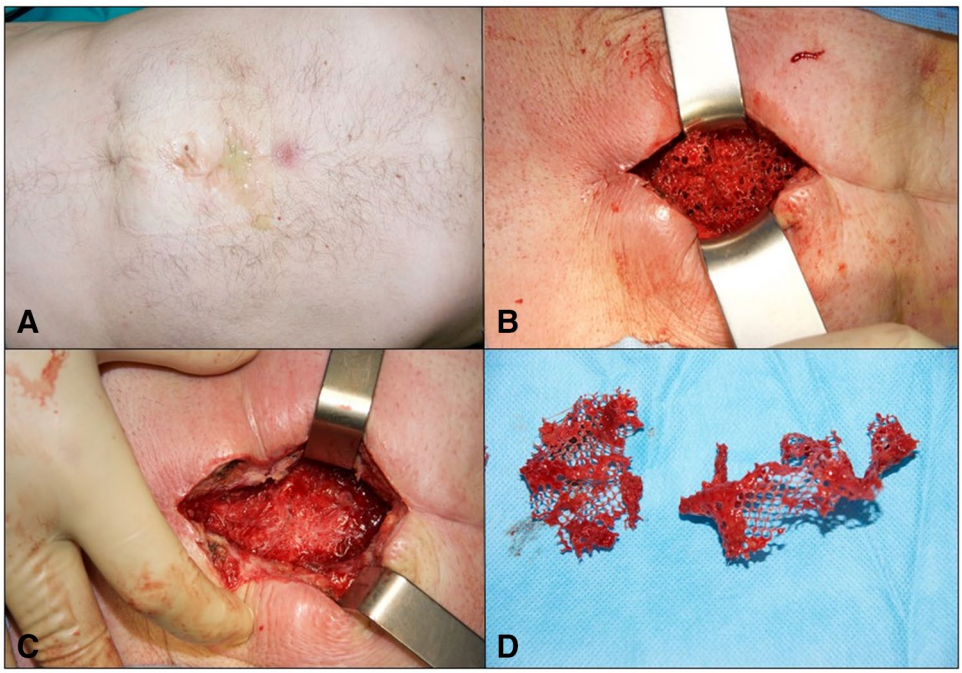

Fig. 2 Case of mesh explantation **a** chronic infection, **b** Mesh exposure, **c** Mesh removal, **d** Mesh explanted

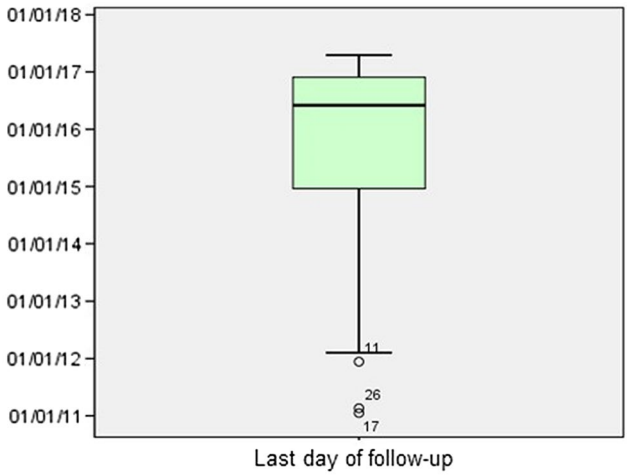

Fig. 3 Follow-up of patients. Box-plot

found to be covering the linea alba and no adhesions were found directly related to the fibrosis or mesh itself (Fig. 5 and Video).

After clinical and radiological examination, 13 patients were diagnosed with IH. One patient was diagnosed with an IH on CT after a negative clinical exam. The overall incidence of IH was 9.02% (13/144) (Table 2). The incidence of IH in those patients requiring emergency surgery was 19.4% (7/36) and 5.5% (6/108) for elective surgery. In those patients that developed an IH, 8 were in patients with colorectal cancer. The remaining cases included 3 patients with non-cancer related bowel obstruction, 1 exploratory laparotomy due to sepsis secondary to duodenal ulcer and 1 acute diverticulitis, requiring a Hartmann's procedure. The incidence of IH in non-cancer patients was 16.1% (5/31 patients) and 7% (8/113 patients) in the oncological group.

In those patients that developed an IH, 5 of them (3.47%) underwent a repair by either retrorectus (2 patients) or component separation techniques (3 patients). There were no complications related to the previous mesh insertion. Even in 2 cases, the prophylactic mesh was not even discerned during surgical repair. The other 8 patients remain asymptomatic and do not want further surgery. No chronic seromas or foreign body reaction have been observed. None of the patients have developed chronic pain.

In the comparative analysis, obesity was a risk factor for IH ($p=0.05$) (Fig. 6). The incidence of IH was also statistically different in the operative status: 19.4% (7/36) in emergency surgeries and 5.55% (6/108) in elective procedures ($p=0.01$; RR 4.99: 1.15–21.5). Survival plot after log-rank test affirmed these differences ($p=0.031$) in operative status but not in obesity (BMI ≥ 30) ($p=0.081$) (Fig. 7). There were no statistical differences regarding any other preoperative, intraoperative or postoperative variables (Table 3).

Discussion

To date the most widely accepted, albeit still controversial, surgical techniques to reduce the incidence of IH are the use of small bites technique to close the linea alba [19, 20] and mesh augmentation procedure [2]. In the latest European Hernia Society (EHS) guidelines both methods were given only a weak recommendation [12]. Three recent systematic

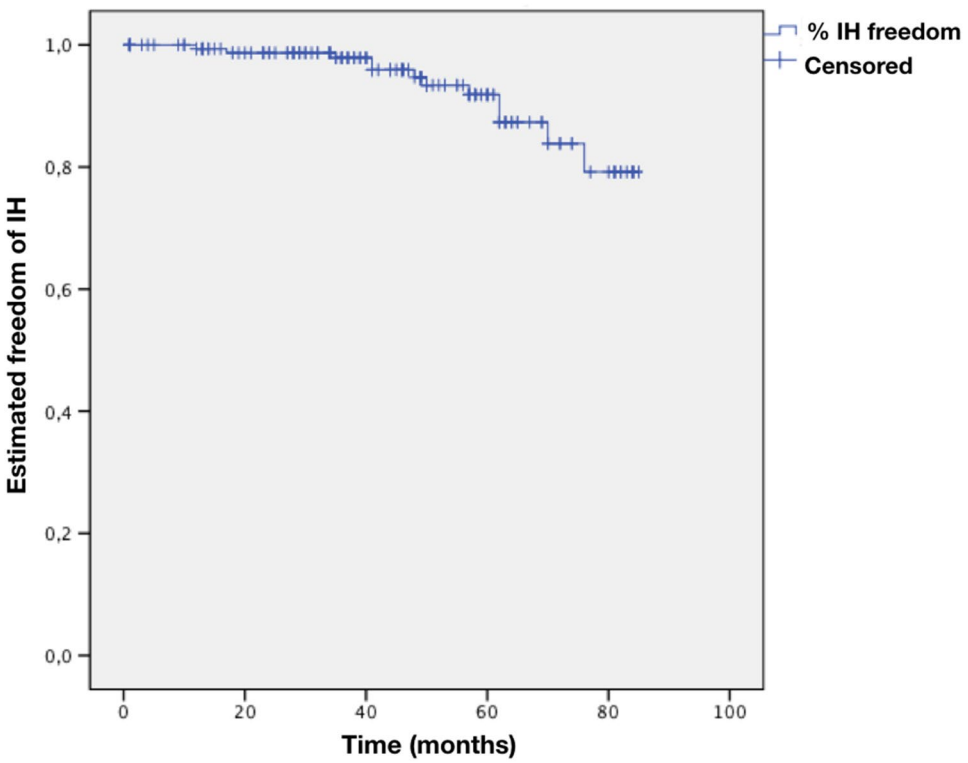

Fig. 4 Estimated freedom of incisional hernia curves

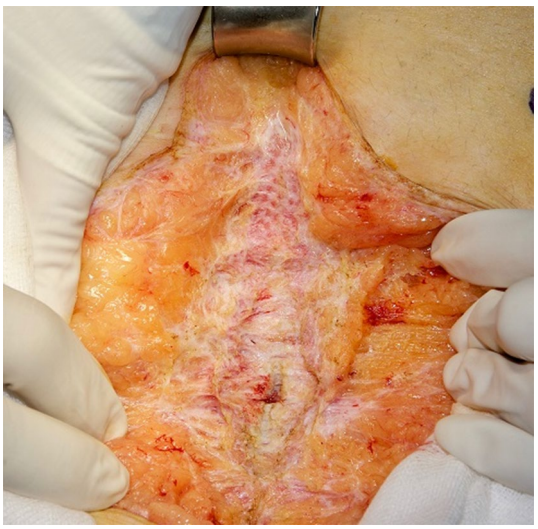

Fig. 5 Intraoperative findings during reoperation of a PMP patient

Table 2 Incidence of IH in different groups of patients

Incidence	Total	Priority of surgery		Type of surgery	
		Emergency	Elective	Oncological	Non-oncological
Number	13/144	7/36	6/108	8/113	5/31
%	9.02	19.4	5.55	7	16.1

reviews have shown that mesh prophylaxis reduces the risk of developing an IH by 85% [9, 21, 22]. Subgroup analyses confirmed this benefit whether the mesh was placed in an onlay, retrorectus, or preperitoneal location. However, there are no data available on more than 2 years follow-up.

This study shows that the use of PMP in ML, in elective and emergency surgery, to prevent incisional hernias is effective and safe in the long term. At mean follow-up of 5 years the incisional hernia rate was 5% for elective and 19% for emergency surgery, with an overall incidence of 9%.

Which mesh type to use and the best anatomical layer to place the mesh within the abdominal wall has not been determined. We chose a very large-pore mesh because these low-density polypropylene meshes tolerated contaminated fields in our previous experimental model of contamination [23], and was satisfactorily applied in our randomized controlled trial (RCT), that included patients in emergency situation and contaminated settings [14].

Polypropylene meshes have been commonly used to prevent IH following abdominal aortic aneurysm surgery, obesity surgery or colorectal surgery [24–27]. A few studies have been published on the use of biological, composite and biosynthetic meshes to prevent IH but currently there are little data to support their use [28–30]. The use of other synthetic meshes made from either polyester or polyvinylidene fluoride has not been described.

Related to surgical site occurrences, seroma formation is the only one that has been related to the layer of the

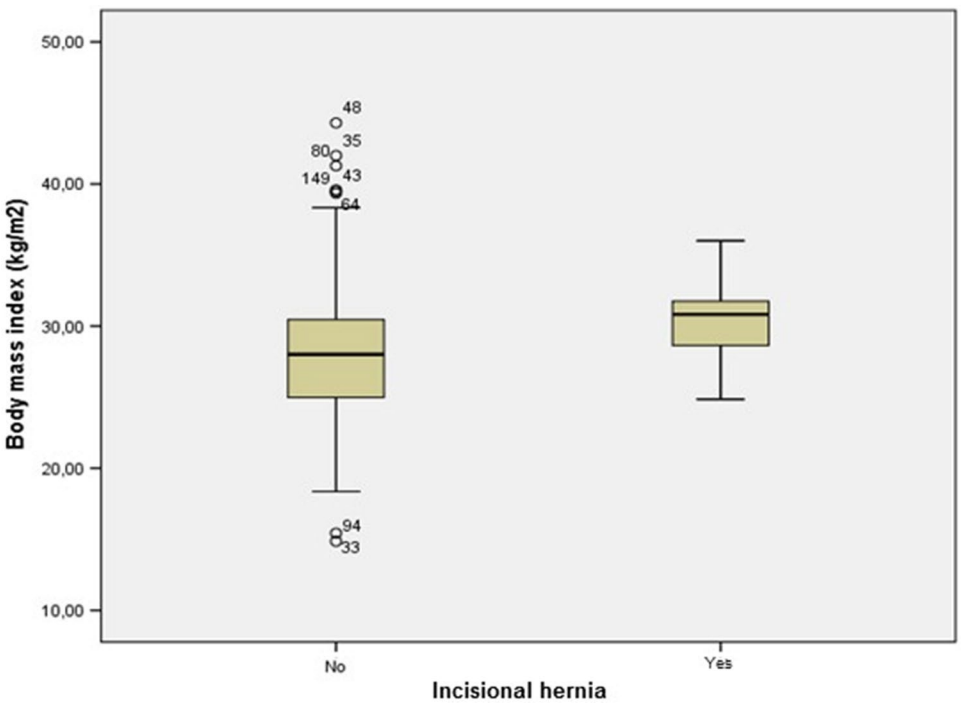

Fig. 6 Development of incisional hernia by body mass index

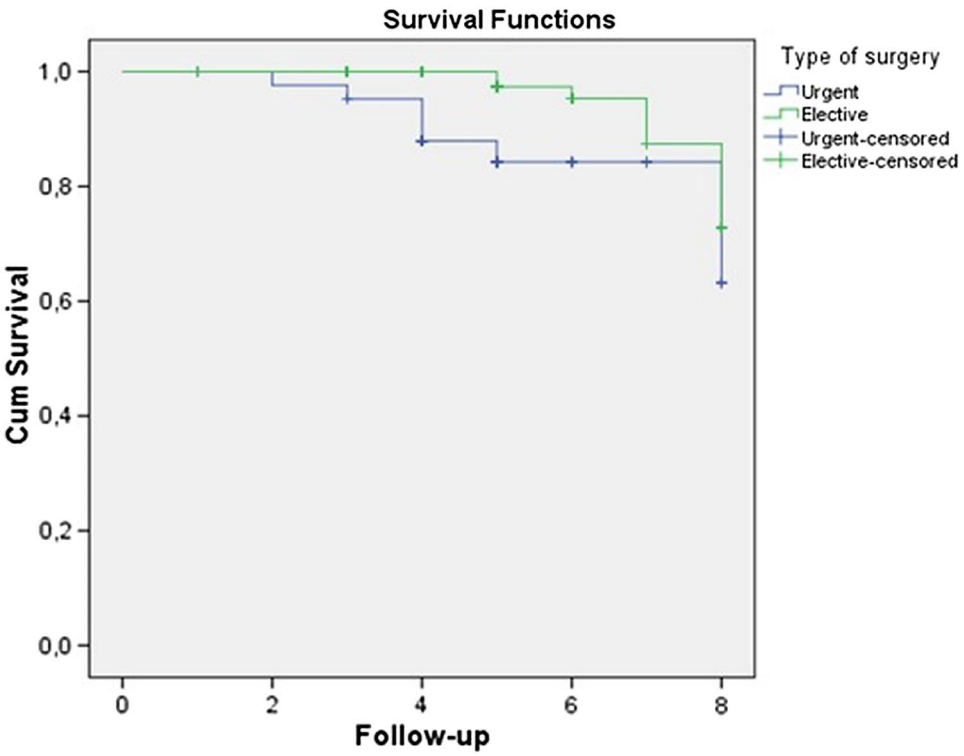

Fig. 7 Estimated freedom of incisional hernia curves by operative status

abdominal wall the mesh is placed. This is observed more frequently in patients that have an onlay compared with sublay mesh reinforcement [3]. We present 13% cases of seromas, which are consistent with other reported results with rates of up to 18% [31]. There were no reported clinically relevant outcomes in relation to the seromas in our series. Our preference is to use a subcutaneous drain to reduce the incidence of seroma formation but we accept there is no clear evidence to support its use [32]. One study has shown that fibrin sealant may reduce seroma formation following

Table 3 Statistical analysis of variables in the study

Variable	IH		*p* (Mann-Withney *U*)	
	Yes	No		
BMI (kg/m^2)	30.7 (28.6–32.4)	28 (24.9–30.5)	**0.050**	
Age (years)	68 (60–73)	69 (62–77)	0.620	
Variable			*p* (χ^2)	*p* (log-rank)*
Sex (e. g. men)	7 (8.6%)	79 (91.4%)	1.000	0.921
Obesity	6 (15.4%)	33 (84.6%)	0.080	0.049
Smoking	6 (9.5%)	57 (90.5%)	0.763	0.280
Cardiopathy	4 (10%)	36 (90%)	0.756	0.780
Hypertension	7 (9.3%)	68 (90.7%)	1.000	0.859
COPD[a]	2 (9.5%)	19 (90.5%)	1.000	0.661
Diabetes	1 (3.4%)	28 (96.6%)	0.467	0.433
Wound classification			0.094	0.715
Clean	2 (22.2%)	7 (77.8%)		
Clean contaminated	9 (7.4%)	113 (92.6%)		
Contaminated	1 (50%)	1 (50%)		
Dirty	1 (9.1%)	10 (90.9%)		
Type of surgery			0.626	0.278
Left hemicolectomy/sigmoidectomy	4 (9.3%)	30 (90.7%)		
Right hemicolectomy	3 (9.1%)	30 (90.9%)		
Anterior resection of rectum	1 (4.2%)	23 (95.8%)		
Total/subtotal colectomy	0 (0%)	13 (100%)		
Small bowel resection	1 (16.7%)	5 (83.3%)		
Abdominoperineal resection	0 (0%)	6 (100%)		
Exploratory laparotomy	1 (12.5%)	7 (87.5%)		
Adhesiolysis	2 (22.2%)	7 (77.8%)		
Urgent surgery	7 (19.4%)	29 (80.6%)	**0.010**	**0.031**
Stoma formation			0.491	0.249
Ileostomy	0 (0%)	18 (100%)		
Colostomy	3 (13%)	20 (87%)		

*Applicable in cathegorical variables/[a] Chronic obstructive pulmonary desease

Bold values indicate variables which have found statistical differences in the analysis

onlay mesh reinforcement [33], but this was not confirmed in the PRIMA trial [3].

The PRIMA study, a multicentre, double-blind, randomised controlled trial, showed there was no difference in IH rate whether mesh was placed in the onlay or sublay position [3]. We recommend the onlay placement of mesh as it is less technically complex and requires less operative time than the sublay or preperitoneal approach. Sublay mesh placement in the retrorectus plane (the Rives-Stoppa technique) can pose a significant technical challenge and add operative time that may lead to poor uptake among surgeons in the prophylactic setting [9]. Prophylactic onlay mesh placement offers a relatively easy, generalizable technique for all patients undergoing midline laparotomy, for surgeons of all specialties, including vascular surgery, urology and gynaecology [3].

Currently we use long-term resorbable sutures to fix the mesh, but accept other techniques for mesh fixation, such as the use of glues or staples, may have a role, particularly in reducing operative time. However, we do not believe their use would obtain better results in terms of morbidity or IH formation.

There are concerns about the long-term problems associated with mesh implantation [34]. In our series, there were only two cases of chronic infection requiring mesh removal. Although using general anaesthesia, the surgical removal of the mesh was simple and did not produce IH. This seems a reasonable price to pay for overall IH rates under 10%. Interestingly, the use of PMP did not cause any problems in patients requiring surgery at a later date for other causes. The surgical repair of IH that developed

despite PMP was not modified by the presence of the onlay mesh that was not even noticed in two cases.

One other study has reported the use of PMP in emergency surgery to prevent IH [7]. The authors retrospectively assessed 51 emergency operations with 1-year follow-up. They reported a 6% IH rate. Although our IH rate after emergency surgery was 19%, we believe this may, at least in part, be due to our longer follow-up. On log rank testing we have shown that emergency surgery is a risk factor for the development of IH: 5 times higher.

Additionally patients with BMI equal to or higher than 27 kg/m^2 have a more than 30% chance of developing IH after ML [35]. We have also observed that a higher level of BMI is a risk factor for the development of IH, even when a prophylactic mesh is used. Nonetheless, this fact was not confirmed on log-rank testing.

Nonetheless, our study has some important limitations. Due to our inclusion criteria we assessed a heterogeneous population in terms of baseline characteristics and operations performed. The indication to perform PMP was not standardized but based on the judgement of the surgeon responsible for the patient, but our data may be considered a truly representative every-day scenario. Another interesting point would have been to also consider the incidence of parastomal hernias even in case of temporary ones. We believe that future studies must take this into account. Assessment of IH by CT was only made in oncological patients or in case of clinical doubts in non-oncological. If all patients had undergone a CT scan, a slightly higher number of IH might have potentially been identified. Although we did not include evaluation of QoL in our study, we have not found that abdominal wall pain was an impairment symptom in our patients. We have not considered the cost-effectiveness in our study, which would be an interesting point, since a recent cost–utility analysis revealed that PMP is less costly and overall more effective than primary suture closure [36].

Finally, it has been affirmed that a higher incidence of IH is typically seen with a longer duration of follow-up [37, 38]. However, we present the largest long-term follow-up of patients with PMP published, reporting an incidence of IH smaller than 10%, which demonstrates its long-term efficacy.

Conclusions

The published data to date have shown that PMP at the time of closing midline laparotomies is safe and effective at reducing the rate of incisional hernias up to 2 years follow-up. This study shows that its use, in elective and emergency surgery, is safe and effective in the long-term as well.

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Author contributions MAGU, LAB and JLM conceived of the presented idea. MAGU, CS and DM designed the study. CS, EJ, CJ and PL collected data from the registry and AR verified the analytical methods. MAGU and EG encouraged CS, DM and EJ to investigate and supervised the findings of this work. All authors discussed the results and contributed to the final manuscript.

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Compliance with ethical standards

Conflict of interest Dr. San Miguel reports no biomedical financial interests or potential conflicts of interest. Dr. Melero reports no biomedical financial interests or potential conflicts of interest. Dra. Jiménez E reports no biomedical financial interests or potential conflicts of interest. Dra. López reports no biomedical financial interests or potential conflicts of interest. Dr. Robin reports no biomedical financial interests or potential conflicts of interest. Dr. Blázquez reports having received lecture fees from WL Gore & Associates. Dr. López-Monclús reports having received grants from Gore. Dr. González reports no biomedical financial interests or potential conflicts of interest. Dra. Jiménez C reports no biomedical financial interests or potential conflicts of interest. Dr. García-Ureña reports having received lecture fees from Covidien and B Braun, grants from Gore and fees for development of educational presentations from Gore and Medtronic.

Ethical approval Approval from the institutional review board was not required for this study.

Human and animal rights The study including human participants has been performed in accordance with the ethical standards of the Declaration of Helsinki and its later amendments.

Informed consent Informed consent was obtained from all patients prior to all surgical procedures.

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