ORIGINAL ARTICLE



Use of polyvinylidene fluoride (PVDF) meshes for ventral hernia repair in emergency surgery

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Received: 18 January 2020 / Accepted: 4 May 2020 © Springer-Verlag France SAS, part of Springer Nature 2020

Abstract

Purpose The implantation of non-absorbable meshes is the gold standard technique for ventral hernia (VH) repairs. However, emergency surgeries are often related to contaminated/infected fields, where the implantation of prosthetic materials may not be recommendable. Our aim was to evaluate the results of polyvinylidene fluoride (PVDF) meshes used for contaminated and/or complicated VH repairs in the acute setting.

Methods We conducted a retrospective analysis of patients with VH who underwent emergency surgery involving PVDF meshes, in a tertiary hospital (from November 2013 to September 2019). We analyzed postoperative complications and 1-year recurrence rates. We evaluated the relationships between contamination grade, mesh placement, infectious complications, and recurrences.

Results We gathered data on 123 patients; their mean age was 62.3 years, their mean BMI was 31.1 kg/m², and their mean CeDAR index was 51.6. 96.4% of patients had a grade 2–3 ventral hernia according to the Rosen index. The mean defect width was 8 cm (IQR 2–18). 93 cases (75.6%) were described as contaminated or dirty surgeries. A PVDF mesh was placed using an IPOM technique in 56.3% of cases, and via interposition location in 39.9%. The one-month recurrence rate was 5.7% and recurrence after one year was 19.1%. The overall mortality rate was 27.6%. Risk of recurrence was related to patients with a Rosen score over 2 (p < 0.001), as well as with postoperative SSI (p = 0.045). Higher recurrence rates were not related to PVDF mesh placement.

Conclusion The use of PVDF meshes for emergency VH repairs in contaminated surgeries seems safe and useful, with reasonable recurrence rates, and acceptable infectious complication rates, similar to those published in the literature.

Keywords Ventral hernia · Emergency surgery · Polyvinylidene fluoride · Non-absorbable meshes

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Introduction

Incisional hernias after abdominal surgical procedures remain a frequent long-term complication, with an incidence of 5–20%, but as high as 30% in high-risk patients [1]. Well-known risk factors for developing ventral hernias after abdominal surgery are a body mass index (BMI) > 30 kg/ m^2 , surgical site occurrence (SSO), being male, smoking, diabetes, hypoproteinemia, immunosuppression, malnutrition, and an advanced age [2].

Since primary suture repair is no longer recommended [4, 5], implantation of non-absorbable meshes is the gold standard technique for surgically treating ventral hernias (VH) [5]. Although permanent meshes have been demonstrated to reduce the risk of recurrence, even for small defects [3], there are several problems related to prosthetic material,

including chronic pain or discomfort, a higher risk of infection, and visceral adhesion [6].

In the emergency setting, acute care surgeons encounter numerous scenarios requiring abdominal wall reconstruction or even skin grafts/fasciocutaneous flaps in some cases. These common situations in emergency operations can be hindered by the fact that sometimes the surgeon is not comfortable with complex techniques, such as component separation in specific cases, and also due to the presence of contaminated, friable tissue that does not allow the abdominal wall components to be adequately manipulated, leading to scenarios in which "two-stage" procedures are preferable.

Furthermore, the higher risk of diffuse peritonitis or bowel resection in the case of incarcerated ventral hernia leads to a contaminated field where the implantation of prosthetic meshes may not be recommendable. In these complex situations, the information on the use of non-absorbable meshes remains highly controversial [7].

Different materials and mesh types have been developed to overcome these difficulties. From the range of currently available prosthesis types, the meshes used in the study cohort were made of polyvinylidene fluoride (PVDF). PVDF is a polymer with improved biostability [8] and high degradation resistance [9]. One of the most valuable features of PVDF is its optimal biocompatibility with a minimized foreign-body reaction; this enables reduced morphological tissue response [10]. Its textile structure provides the appropriate elasticity while retaining considerable porosity under load.

Due to these suggested advantages, our working hypothesis was that PVDF meshes might be both safe and effective in cases where other non-absorbable meshes cannot be used, i.e., large defects that require the use of bridging techniques in a contaminated or even dirty field.

The aim of this study was to evaluate the results of PVDF meshes used for contaminated and/or complex ventral hernias in the acute setting, particularly focusing on surgical site occurrence (SSO) and long-term recurrence.

Methods

We conducted a retrospective cohort study including all consecutive patients with VH who underwent emergency surgery, from November 2013 to September 2019, involving the insertion of a PVDF mesh. The study population was recruited from the acute care surgery unit registry of a tertiary hospital that carries out a mean of 4700 emergency surgeries each year.

Emergency procedures were defined as non-elective operations, including reoperations after elective surgery. The operations were performed by consultant general surgeons who were non-specialists in abdominal wall repair. The main criteria for using PVDF meshes was the inability to place an onlay polypropylene mesh, which was the gold standard for emergency ventral hernia repair in our center at the time of the study.

All the prosthetic meshes had a double-component structure, and comprised 88% high-purity PVDF and 12% polypropylene (PPL).

The inclusion criteria were: patients over 18 years of age undergoing an emergency laparotomy and in which a PVDF mesh was implanted. All the patients signed an informed consent form for surgery, the implantation of the mesh, and participation in a research study, prior to undergoing the surgical procedure.

The exclusion criteria were: patients who died during the first 48 postoperative hours, since the most frequent causes of death (pulmonary embolism, ongoing septic shock, or respiratory failure) were excluded from the analysis, due to the lack of follow-up data on complications relating to the type of repair and mesh-related complications.

The primary outcome parameter was the 1-year recurrence rate.

The data gathered included the following variables: demographic data; comorbidities (BMI, chronic obstructive pulmonary disease, cardiovascular risk factors, chronic kidney disease, immunosuppression, liver disease, heart failure); CeDAR score for the risk of infectious complications [11]; the ROSEN index for defining hernia size and contamination grade (grade 1 for a VH smaller than 10 cm and a clean wound; grade 2 for a VH greater than 10 cm and a clean wound, or smaller than 10 cm for a contaminated/infected wound; and grade 3 for a VH greater than 10 cm and a contaminated or infected wound) [12]; previous laparotomies; contamination grade according to the CDC Wound Classification [13]; the need for bowel resection or previous mesh explantation during the procedure; and mesh position. Variables relating to postoperative complications were registered according to the Clavien–Dindo classification [14], the occurrence of enteroatmospheric fistula, chronic infection, or the need for mesh explantation, as well as recurrence.

The clinical follow-up data recorded included information on early postoperative complications, and records of clinical or radiological recurrence at 1 and 12 months.

The qualitative variables were summarized as frequencies and proportions. The quantitative variables were summarized as their mean and standard deviation (SD), and variables that did not follow a normal distribution were expressed as the median and interquartile range (IQR). The Chi-square test or Fisher's exact test were used to determine the differences between the categorical variables; the Student *t* test or ANOVA test were used to evaluate the differences between the quantitative variables. A significant statistical difference was assumed if p < 0.05 or if the 95% confidence interval for the OR excluded value 1.

The data was processed and analyzed using the SPSS statistical software package (IBM Corp. Released 2016. IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp®).

Results

One hundred and twenty-three patients underwent emergency surgery and PVDF mesh implantation during the study period; they had a mean age of 62.3 years. Their mean BMI was 31.1 kg/m² (SD 6.4 kg/m²) and the mean CeDAR index was 51.6 (SD 22.7). 96.4% of patients had grade 2–3 ventral hernias according to the Rosen index.

Previous abdominal surgical procedures were described in 85.4% of cases, of which 45 patients reported previous ventral hernia repair (36.6%). Concomitant procedures included at least one organ resection in 48.7% of surgeries and previous contaminated mesh explantation in 11.5%. Table 1 presents the demographic and surgical data of the patients.

Information on the hernia measurements and mesh sizes, the classification according to the European Hernia Society (EHS), the contamination grade and the type of hernia repair is presented in Table 2 and Fig. 1. According to the Rosen score, 3.3% of patients were grade 1, 70.6% were grade 2, and 26.1% were grade 3. In 14 patients (11.5%) a previous mesh was removed due to lack of mesh integration.

The PVDF meshes were placed intraperitoneally using the IPOM technique in 58.5% of cases, and extraperitoneally

 Table 1
 Overview of patient

 demographic and surgical data

 Table 2
 Characteristics of Ventral hernia defects and types of surgical wounds

8 (IQR 2–18)
11.5 (IQR 3-20)
19 (15.4%)
14 (11.4%)
16 (13%)
39 (31.7%)
54 (43.9%)

in the other 41.5%. A laparoscopic repair was performed in eight patients (6.5%).

The mean hospital stay was 15 days (IQR 8–40). SSO was observed in 68 patients (54.8%), of which 16 patients (13.1%) developed a chronic PVDF mesh infection requiring the partial or total removal of the mesh. Postoperative seroma and hematoma rates were 21.1% and 10.6%, respectively.

Complications of grades 3–5 according to the Clavien Dindo classification were recorded in 56.1% of the patients. Nine patients with wound infection developed an intestinal fistula (7.3%). The overall mortality was 27.6% (34 patients), while 11 patients died during the follow-up (immediate postoperative mortality 18.7%). None of the lethal cases seemed to be mesh related. The readmission rate was 15.7%, onemonth recurrence was 5.7%, and recurrence after one year was 24.7% (23 patients).

Tables 3 and 4 present the postoperative outcomes and complications.

When comparing the short-term outcomes between clean/ clean-contaminated, and contaminated/infected wounds,

	Primary ventral hernia $(n=78)$	Incisional hernia $(n=45)$	<i>p</i> value
Age (years)	61.5 (SD 12.9)	61.2 (SD 13.8)	0.889
Female sex (n)	23 (29.49%)	25 (55.56%)	0.085
BMI (kg/m ²)	34 (SD 7.22)	29.61 (SD 6.5)	0.002
Malignant disease (n)	32 (41.03%)	16 (25.56%)	0.258
Diabetes mellitus (n)	15 (19.23%)	13 (28.89%)	0.302
Anticoagulant therapy (n)	15 (19.23%)	4 (8.89%)	0.121
Active smoking (n)	40 (51.28%)	16 (35.56%)	0.086
Hypertension (n)	44 (56.41%)	32 (71.11%)	0.439
Heart failure (n)	12 (15.28%)	6 (13.33%)	0.562
$\operatorname{COPD}^*(n)$	25 (32.05%)	8 (17.78%)	0.058
ASA score $> 3(n)$	46 (58.97%)	21 (46.67%)	0.108
Laparoscopic approach (n)	4 (5.13%)	4 (8.89%)	0.085
Previous surgery (<i>n</i>)	72 (100%)	45 (100%)	0.121

Statistical differences are marked in bold

"*" symbol means Chronic Obstructive Pulmonary Disease

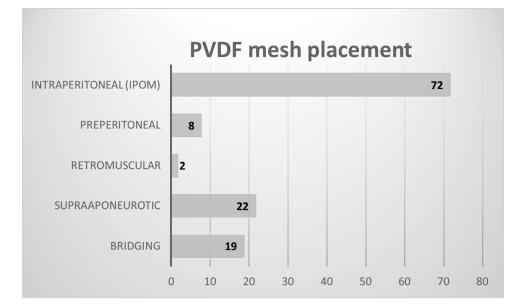


Fig. 1 PVDF mesh placement location

 Table 3
 Postoperative outcomes and complications

	n (%)
Seroma	26 (21.13%)
Hematoma	13 (10.6%)
Surgical site occurrence	68 (55.3%)
Ileus	35 (28.5%)
Intestinal fistulae	9 (7.3%)
Evisceration	11 (8.9%)
Pneumoniae	14 (11.4%)
Heart failure	14 (11.4%)
Reoperation	30 (24.4%)
Readmission	16 (13%)
Chronic seroma	3 (2.4%)
1-month clinical recurrence	5 (4.1%)
1-month radiological recurrence	7(5.7%)
1-year clinical recurrence	23 (18.7%)
1-year radiological recurrence	23 (18.7%)
Chronic pain	1 (0.8%)
Grade III–V Clavien–Dindo	73 (59.3%)
Exitus	34 (27.6%)

several differences were observed (Table 5). Overall, the number of SSO was significantly higher for the contaminated wound group. Patients in the contaminated wound group also had a higher reoperation rate (p=0.017), longer hospital stays (p < 0.001), higher grade III–V complication rates according to the Clavien–Dindo classification (p < 0.001), and a higher recurrence rate after 1 year of

follow-up (p < 0.001). Finally, SSO was significantly related to mortality (3.9% vs 1.2%, p = 0.008).

The risk of recurrence was related to a Rosen score greater than 2 (p < 0.001), as well as with postoperative SSI (p=0.045). The mesh placement did not significantly impact the recurrence rates. A bivariate analysis of outcomes relating to PVDF mesh placement (Table 5), reported a lower risk of major postoperative complications (54.9% vs 71.1%, p=0.018) when the PVDF mesh was placed in an intraab-dominal position (54.9% vs 71.1%, p=0.018). No other significant differences were found with regard to PVDF mesh placement.

Of the 93 remaining patients with a complete year of follow up, hernia recurrence was reported in 23 cases (24.7%). Table 6 shows the correlation factors in the regression analysis for hernia recurrence. Those factors that correlated to the recurrence of hernia were a Rosen index score over 2, diabetes mellitus (DM), a history of heart failure, the need for reoperation, SSO, and postoperative pneumonia.

Discussion

Historically, the use of synthetic meshes in a contaminated field is generally not recommended, and even contraindicated, because of the risk of mesh infection and problems arising from its placement [15–20]. Hence, according to the Center for Disease Control and Prevention, the key in terms of mesh placement is not so much the degree of emergency surgery but rather the degree of contamination following surgical wound contamination [21].
 Table 4
 Differences between

 clean, clean-contaminated
 and contaminated

 and contaminated or infected
 wounds

	Clean, clean-contaminated wounds $(n=30)$	Contaminated, dirty wounds $(n=93)$	р
Rosen > 2(n)	19	70	0.004
BMI (kg/cm ²)	34.514	30.334	0.023
CeDAR	38.667	56.039	< 0.001
Deffect size (H) (cm)	14.75	30.565	0.258
Deffect size (L) (cm)	29.56	37.41	0.714
Malignant disease (n)	9	39	0.399
Diabetes mellitus (n)	8	20	0.115
Active smoking (n)	6	50	0.003
Heart failure (<i>n</i>)	5	13	0.576
COPD (n)	6	27	0.467
Mesh explantation (n)	2	12	0.412
Preperitoneal repair (n)	4 (13.3%)	4 (4.3%)	0.146
Retromuscular repair (n)	0 (0%)	2 (2.2%)	0.437
Onlay repair (n)	5 (16.7%)	17 (18.3%)	0.422
Bridge repair (n)	5 (16.7%)	14 (15.1%)	0.828
IPOM repair (n)	16 (53.3%)	56 (60.2%)	0.781
Evisceration (n)	1	10	0.260
Reoperation (n)	2	28	0.017
Pneumoniae (n)	2	12	0.427
Seroma (n)	8	18	0.305
Hematoma (n)	1	12	0.158
Surgical site ocurrence (n)	5	63	< 0.001
Ileous (n)	7	28	0.583
Fistulae (n)	0	17	0.013
Length of stay (days)	7.69	32.89	< 0.001
ICU (n)	3	56	< 0.001
Clavien Dindo > 3 (n)	5	68	< 0.001
1-year recurrence (n)	2	22	0.006
Exitus (<i>n</i>)	4	30	0.062

Statistical differences are marked in bold

Table 5 PVDF placement related complications

	Extraperito- neal (%)	Intraperito- neal (%)	р
Seroma	14.8	17.2	0.088
Hematoma	9.8	5.7	0.071
Surgical site occurrence	70.5	50.6	0.945
Fistulae	19.7	10.6	0.212
Clavien Dindo > III	71.1	54.9	0.018
1-year recurrence	12.2	8.1	0.081

Statistical differences are marked in bold

In a clean situation, the principles are well defined, but in contaminated and dirty fields there is no consensus about the use of meshes, their types, situation, and management. For example, Choi et al. [22] reported on a large group of patients from the National Surgical Quality Improvement Program (NSQIP) in the United States, comparing ventral hernia repairs in clean and clean-contaminated or contaminated fields, and evidencing higher risks of surgical site infection, wound disruption, pneumonia, and sepsis in the group with clean-contaminated or contaminated wounds.

Nevertheless, in the World Society of Emergency Surgery (WSES) guidelines for complicated abdominal wall hernias, "primary repair is recommended in contaminated dirty surgical fields when the defect is small (<3 cm) but, when hernia repair is not feasible, a biological mesh may be used", even stating, "if a biological mesh is not available, either polyglactin mesh repair or open wound management with delayed repair may be a viable alternative" (grade 2c recommendation). These are two examples of the current discrepancy in the published literature and guidelines [23].

In Spain, synthetic meshes are still the most commonly used prostheses in emergency situations, even in contaminated—contaminated and dirty fields, with the use of

Table 6 Risk Factors for 1-year hernia recurr

	1-year recurrence		
	$\overline{\text{Yes}(n\!=\!23)}$	No (<i>n</i> =66)	р
$\operatorname{Rosen} > 2(n)$	23 (100%)	0 (0%)	< 0.001
BMI (kg/cm ²)	31.306	31.144	0.931
CeDAR	52.522	41.306	0.045
Defect size (H) (n)	36.266	34.800	0.961
Defect size (L) (n)	44.800	42.33	0.947
Malignant disease (n)	9 (39.1%)	14 (21.2%)	0.842
Diabetes mellitus (n)	10 (43.5%)	18 (27.3%)	0.015
Active smoking (<i>n</i>)	13 (56.5%)	43 (65.2%)	0.181
Heart failure (<i>n</i>)	1 (4.3%)	7 (10.6%)	0.030
COPD (n)	4 (17.4%)	9 (13.6%)	0.763
Previous surgery (n)	22 (95.6%)	34 (51.6%)	0.885
Previous mesh explantation (<i>n</i>)	5 (21.7%)	4 (6.1%)	0.614
Evisceration (<i>n</i>)	4 (17.4%)	1 (1.5%)	0.073
Reoperation (n)	10 (43.5%)	5 (7.6%)	0.013
ASA > 3(n)	13 (56.5%)	19 (28.8%)	0.830
Pneumoniae (<i>n</i>)	5 (21.7%)	0 (0%)	0.007
Seroma (<i>n</i>)	7 (30.4%)	6 (9.1%)	0.228
Hematoma (<i>n</i>)	4 (17.4%)	2 (3.0%)	0.149
Surgical site occurrence (<i>n</i>)	22 (95.6%)	46 (69.7%)	0.016
Ileus (n)	11 (47.8%)	8 (12.1%)	0.087
Fistulae (n)	2 (8.7%)	4 (6.1%)	0.751
ICU (n)	11 (47.8%)	13 (19.7%)	0.403

Statistical differences are marked in bold

biological meshes being merely anecdotal. In addition, these procedures tend to be carried out by surgeons who are not skilled in abdominal wall repair [24].

Polyvinylidene fluoride (PVDF) is a non-absorbable polymer with improved textile and biological properties that has been used for many years as a suture material, with better long-term biostability than PPL [25, 26]. It induces less cellular inflammatory processes and generates less fibrotic tissue than other materials, such as polytetrafluoroethylene (PTFE) or PPL27. PVDF meshes have anti-adhesive properties, tend to shrink and resist infections, and may have superior biostability than PPL, especially in the long term [27]. Nonetheless, there are still very few in vivo studies of PVDF mesh effectiveness compared to other materials. In this respect, our study contributes to showing clinical outcomes in a large population who underwent a ventral hernia repair involving a PVDF mesh in the emergency setting.

In the analysis of our 123-patient sample, 75.6% were described as having contaminated or infected wounds. Our results showed a high rate of infectious complications (SSI=55.3%) and a 1-year recurrence rate of 24.7%; these are expectable outcomes in the presence of contamination. SSO was found to be related to the CeDAR scale, evisceration, previous mesh explantation, seroma and hematoma,

and also related to poor prognostic outcomes, such as grade III–V Clavien–Dindo complications, a high reoperation rate, the need for ICU units, and mortality.

Additionally, the Rosen index score, CeDAR scale, previous mesh explantation, reoperation, and other postoperative complications such as ileus and pneumonia were identified as risk factors for 1-year hernia recurrence.

Despite the fact that most reports in the literature do not support the use of synthetic non-absorbable meshes in contaminated surgeries, due to infection-related concerns, a few studies have considered the use of synthetic meshes, presenting different rates of success in a contaminated setting [28, 29]. This generally non-advisable treatment may, then, be considered as a last resource for well-selected patients.

All the patients enrolled in this study presented a challenging situation due to the emergency nature, the size of the ventral hernia defect, the contamination grade, and the impossibility of performing a gold standard abdominal wall repair using polypropylene mesh in a preperitoneal, retromuscular or supra-aponeurotic position. Furthermore, the patient population had significant comorbidities, increasing the postoperative complications.

When comparing our results to those of prospective longitudinal studies evaluating outcomes for ventral hernias utilizing absorbable meshes in contaminated or infected wounds, we found similar SSO and 1-year recurrence rates [12, 17].

In the past, the use of biological mesh for contaminated wounds seemed to be an acceptable treatment strategy for ventral hernias in contaminated surgeries, but the discouraging results in terms of SSO rates and the long-term recurrence rates of these expensive treatments [30], led to a decrease in popularity in recent years, in favor of new materials like PVDF and PTFE [12, 31].

A particularly interesting area is the use of biosynthetic meshes in contaminated or infected fields. In recent years, these emerging materials have been considered to be a costeffective alternative to biological meshes, particularly for complex or complicated hernias. However, the current evidence does not support the use of these meshes when bridging is required during a ventral hernia repair, and there is a lack of studies comparing the use of biosynthetic versus synthetic meshes in contaminated/infected fields in complicated hernias [32].

We found that the mesh position did not affect the final outcome in terms of infectious complications, reoperation rate, length of stay, or the 1-year hernia recurrence rate.

At the present time, the literature on ventral hernia repair in the elective setting and clean environments, suggests that sublaying the mesh, especially in the retromuscular space, may result in fewer recurrences and SSO than onlay or inlay placement [33]. Other studies [12] have reported higher recurrence rates when the mesh was placed in the intraperitoneal position, although different prosthetic materials were used depending on the type of repair and implantation location of the mesh, and this may have impacted the ultimate outcomes. Nevertheless, for contaminated ventral hernias and complex emergency situations, these results should be interpreted with caution.

The large number of procedures recorded, involving the use of a PVDF mesh during an emergency ventral hernia repair in a contaminated field, is a considerable strength of our study.

However, considering that this work involves a retrospective analysis using records from an emergency surgery unit, it is not exempt from bias and there is possible imprecision with regard to certain results. The follow-up period of 1 year does not seem to be sufficient to clarify long-term recurrence, even though this is a frequently selected time point. Although primary ventral hernias and incisional hernias are considered to be different with regard to conditions and outcomes, and pooling data analysis is no longer recommended for interventional studies [34], some of the statistical analyses included both ventral and incisional hernias to obtain more events, since both groups were comparable in our sample, with the exception of the BMI. However, this must be highlighted as another limitation of our study.

Furthermore, the absence of an appropriate control group does affect the generalizability of the results. Indeed, another limitation of our study is the lack of a propensity-matched comparison with similar patients who underwent a ventral hernia repair involving other prosthetic materials, especially with recent promising biosynthetic meshes which might be another proper alternative for complex or complicated hernias, although at high economic costs.

Conclusion

In our experience, the use of PVDF meshes in an emergency VH repair in a contaminated field presents reasonable recurrence rates, and acceptable infectious complication rates, similar to those associated with other prostheses published in the literature. Since our results do not encourage us to take a stance on either PVDF or other prosthetic meshes, further research into optimal materials for VH repair in the emergency setting is needed.

Compliance with ethical standards

Conflict of interest The authors do not declare any conflict of interest or sources of funding for the present work. The authors also declare that the present work is not based on a previous communication to a society or meeting.

Ethical approval Ethical approval for this retrospective study was not required.

Human and animal rights All procedures performed in the study involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments.

Informed consent For this type of study, formal consent was not required.

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