*I*ncisional *H*ernia *R*epair in *C*ontaminated *S*urgical fields (I.H.R.C.S.) study using biological prostheses in emergency surgery setting with contaminated hernias: a multicenter prospective observational study

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Abstract

There are still difficulties to find appropriate indication for prosthetic implant in hernia surgery in contaminated surgical fields. Biologic prosthetic materials have been developed and proposed for the clinical use in contaminated surgical fields with interesting outcomes. The aim of this study is to analyze data from nine Italian Emergency Surgery Units concerning patients consecutively admitted with diagnosis of strangulated incisional hernia (IH), submitted to surgery in emergency and treated with biological prostheses. This is a prospective observational study. Subjects submitted to single-staged IH repair in a contaminated surgical field, with the use of biologic mesh, were prospectively studied over a 1-year time period. All patients enrolled in this study were submitted to bowel/intestinal resection at the same operative time for perforation. Primary end points of our study were wound complication and hernia recurrence. Seventy-one patients were enrolled (F=21, M=50); the mean age was 69.2±11.1 standard deviation (SD) years and the mean American Society of Anesthesiologist (ASA) score was 3.1±0.8 SD. Twenty-one patients (29.57%) had a wound complication, associated with high ASA score, diabetes, smoking, chronic immunosuppression, number of previous hernia repairs, dirty surgical field, sublay extra peritoneal mesh placement and no anterior fascia closure. After a mean follow up time of 27.2 months, hernia recurrence occurred in 19 patients (26.76%). Predictors of hernia recurrence included wound complications, high ASA score, diabetes, chronic immunosuppression, dirty surgical field and sublay extra peritoneal mesh placement. Use of biological prostheses in contaminated fields is safe with favorable medium term recurrence rate (26.76% in our experience). Surgical technique performed is important to decrease hernia recurrence rate.

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Introduction

A significant number of patients affected by abdominal wall hernias requires a surgical treatment in an emergency setting for incarcerated or strangulated hernia with poor prognosis and high risk of postoperative complications (infections, recurrence). Prosthetic abdominal hernia repair, based on the *tension-free* techniques, which generally provide the use of non-absorbable prosthetic materials, such as polypropylene, polyester, and ePTFE (expanded polytetrafluoroethylene), is the common surgical procedure used with a significant reduction in incidence of recurrences, when confronted with the older non-prosthetic hernioplasties.[1,2]

Currently, there are still difficulties to find appropriate indication for prosthetic implant in hernia surgery in contaminated surgical fields. As a matter of fact, there is still a great debate if it is safe to use non-absorbable prostheses in contaminated operating fields.[3]

Any area in which surgery, with a possible risk of bacterial contamination, is performed (bowel resections, cholecystectomy, operations

on bile duct, parastomal hernias, *etc*.), is potentially at risk for a prosthetic repair (increased risk of postoperative complications).

The common consensus is not to position any kind of non absorbable prosthetic material in severely contaminated areas such as in peritonitis due to a very high risk of infection.[3-5]

On the other hand it is not demonstrated that there is an increased risk of contamination of the mesh in the case that simultaneous operations on the digestive tract are performed (contaminated surgical fields).[6-8]

All these problems could be avoided with the use of absorbable prosthetic materials such as those composed of lactic acid polymers or lactic and glycolic acid copolymers,[9] but the use of these absorbable prosthesis exposes the patient to a rapid and inevitable hernia recurrence as the complete and rapid dissolution of the prosthetic support.[9,10]

It is important to remember that prosthetic repair has been proven to have a significant less risk of recurrence than repair with direct sutures.[11]

In the meanwhile, new biologic prosthetic materials have been developed and proposed for the clinical use in infected surgical fields with good outcomes; however it is not still possible, to identify clear indications to the use of these bio-materials when considering its peculiarities and costs in the emergency hernia repair and in patients with high risk of infection of the non-absorbable prosthesis (*i.e*., immune-depressed subject).[12,13]

The aim of our study is to analyze data from nine Italian Departments of Emergency Surgery concerning patients consecutively admitted with diagnosis of strangulated incisional hernia (IH) and submitted to surgery in emergency to highlight the current clinical practice and outcomes of the surgical treatment of strangulated IH in a contaminated surgical field with bio-protheses.

Materials and Methods

This is a prospective observational clinical study involving 9 Italian Departments of Emergency Surgery (Parma, Bari, Roma, Bergamo, Brescia, Catania, Viterbo, Macerata, Bologna).

All adult patients admitted with diagnosis of strangulated incisional hernia and consecutively submitted to open surgery in emergency, in presence of contaminated surgical field from January 2012 to October 2014 and treated with biological prostheses were included in the study.

IH was defined as abdominal hernia developed at the site of a prior surgery (with the exclusion of inguinal and femoral hernias). Hernia is defined as strangulated when the blood supply to the contents of the hernia is compromised; hernia becomes irreducible and intestinal obstruction can occur with risk of necrosis, perforation and peritonitis.

The contamination of the surgical field was classified as: i) clean-contaminated when a viscus was entered under controlled conditions and without unusual contamination; ii) contaminated, in case of open wounds, operations with major breaks in sterile technique, gross spillage from viscus, purulent inflammation; iii) dirty, in presence of old wounds with retained devitalized tissue, foreign bodies, fecal contamination, existing clinical infection, perforated viscus.

All data (demographics, diagnosis of admission, type of abdominal hernia, co-morbidities, American Society of Anesthesiologist (ASA) score, body mass index, surgical procedure, duration of intervention, surgical technique, early postoperative complications, outcomes) were collected using a common case report form and stored in a single database by a clinical monitor.

Antibiotic therapy was given according World Society of Emergency Surgery (WSES) guidelines.[14]

Statistical analysis

Statistical analysis was performed by IBM SPSS 22.0 program (IBM Corp., Armonk, NY, USA). Data are expressed as percentages (%) and means ± standard deviation (SD). P<0.05 was considered statistically significant.

Results

Between January 2012 and October 2014, 71 patients were enrolled in our study. Mean age was 69.2±11.1 SD years; 50 were males and 21 patients were females with a ratio of 2.3. Twenty five patients were affected by chronic obstructive pulmonary disease (35.2%), 22 patients by diabetes mellitus (30.9%); 15 (21.12%) patients presented with chronic immunosuppression. The mean body mass index was 28±5.2 kg/m^2. Smoking was present in 20 patients (28.1%). All the patients had an history of abdominal surgery: mean number of previous abdominal surgeries was 2.1±1.4 SD and of previous hernia repairs was 1.2±1.5 SD. Mean ASA score was 3.1±0.8 SD. The surgical field resulted contaminated in 27 patients (38%), potentially contaminated in 19 patients (26.7%) and dirty in 25 patients (35.2%) (Table 1).

Sublay extra peritoneal mesh repair (biologic mesh is placed underneath the fascial edge) was the surgical technique used to treat 45 patients (63.3%); inlay repair (that is an interposition repair in which the bio-prosthesis is sutured directly to the fascial edge) was performed in 19 patients (26.7%); underlay (intraperitoneal) mesh repair was the technique used to treat 6 patients (8.4%); onlay mesh repair was performed in one patients only (1.4%). Anterior fascia closure was performed in 52 patients (73.23%); 19 patients (26.76%) were treated by no anterior fascia closure. Component separations technique was performed in 12 patients (16.9%) (Table 1).

Biological meshes used were: porcine small intestine submucosa in 45 patients (63.38%), porcine dermal collagen in 7 patients (9.85%), bovine pericardium in 19 patients (26.76%). (Table 2).

Early postoperative (between the 3rd and the 7th postoperative day) wound infection occurred in 21 patients (29.57%). High ASA score (>=3) [odds ratio (OR)=2.82; confidence interval (CI) 1.85-6.43; P=0.03), smoking (OR=4.1; CI 1.73-6.35; P=0.02), diabetes (OR=3.23; CI 1.92-4.38; P=0.04), chronic immunosuppression (OR=2.41; CI 0.33-5.25; P=0.003), previous hernia repair (OR= 1.99; CI 1.5-2.9; P=0.002), dirty surgical field (OR=1.87; CI 0.35-4.4; P=0.04), sublay extra peritoneal bio-prosthesis placement (OR= 0.45; CI 0.27-1.13; P=0.009), and no anterior fascia closure (OR=0.33; CI 0.2-2.3; P=0.04) were associated with wound complications (Table 3).

After a mean follow up time of 27.2 months, hernia recurrence occurred in 19 patients (26.76%). Wound infection (OR=3.4; CI 2.2-5.9; P=0.002), high ASA score (>=3) (OR=3.2; CI 2.2-6.4; P=0.02), diabetes (OR=3.21; CI 1.83-4.33; P=0.02), chronic immunosuppression (OR=2.2; CI 0.44-5.23; P=0.001), dirty surgical field (OR=2.39; CI 1.25-4.8; P=0.002), sublay mesh repair (OR=1.45; CI 1.1-4.55; P=0.001) were risk factors for recurrence (Table 4; Figure 1).

Discussion

In clinical practice there are still difficulties to find appropriate indication for prosthetic implant (non-absorbable, absorbable, bio-remodelable materials) in emergency hernia repair because of contaminated and potentially contaminated surgical fields.[15,16]

Three main type of prosthetic mesh are available: i) synthetic mesh (such as polypropylene or polyester), characterized by high tensile

strength and vigorous tissue ingrowth, unsuitable for intra-abdominal placement because of its tendency to induce bowel adhesions; ii) composite or barrier coated mesh, which is a dual sided prosthetic having a synthetic parietal side to promote a strong repair and a visceral surface that repels tissue ingrowth and decreases adhesions; iii) biologic mesh, which is a collagen-based human, porcine or bovine scaffold that may be implanted in the extra- or intra-peritoneal position.[1-4]

Their physico-chemical properties influence the process involved in the hernia repair, and consequently the indications, early and long-term outcomes of surgery.

Synthetic meshes when implanted, although extremely biocompatible, stimulate a foreign-bodies reaction within the host. After the initial inflammatory phase, the reaction is followed by an intense deposition of nonspecific fibrotic tissue and concluded by a permanent encapsulation of the alloplastic material in the host's tissues. If these are the physiopathological bases that explain the success of alloplastic non-absorbable prosthetic materials in hernia surgery, they are also the reasons for not uncommon complications such as infections.[5-9]

Absorbable materials are attacked by an inflammatory reaction that removes and digests the implanted prosthetic material completely; this exposes the patient to a rapid and inevitable hernia recurrence.[17,18]

The *remodeling* process, stimulated by biological materials, is made possible as these new prosthetic materials are all essentially composed by an extracellular matrix deprived of its cellular components and substantially different only in relation to the source from which the extracellular matrix is obtained (porcine small intestine submucosa, cadaveric human derma, porcine dermal collagen, bovine pericardium and something else),[11,12,19,20] through a process of incorporation, where a reproduction of a site-specific tissue similar to the original host tissue is created. The reconstructed tissue tends to resemble the original specific tissue that replaces, not only from the histological point of view, but also functionally. In fact the patient can incorporate the prosthetic material by reconstructing *from himself* the specific damaged tissue and, in particular, recreate a mature *neo-fascia* that has a normal supportive and contenitive function.

Biological meshes can be further subdivided in two categories: those totally remodeling that are completely substituted by a new created tissue and those partially remodeling that due to a cross-linking process do not disappear completely.[21-23]

Complicated IH repair is still a surgery with poor prognosis and high morbidity. The introduction of such materials in clinical practice has provided a new perspective for abdominal wall defect repair in contaminated surgical fields.

In literature synthetic prostheses have been shown to be superior in efficacy to simple suture. However, they cannot be used in any area in which surgery is performed with a possible risk of bacterial contamination.

Table 1. Patients' characteristics.

Characteristics	Mean±standard deviation Frequency (%)
Age	69.2±11.1
Sex male/female	50/21
ASA score	3.1±0.8
Body mass index (kg/m^2)	28±5.2
Smoking	20/71 (28.16%)
Diabetes mellitus	22/71 (30.98%)
Chronic obstructive pulmonary disease	25/71 (35.21%)
Immunosuppressed	15/71 (21.12%)
No. previous abdominal surgeries	2.1±1.4
No. previous hernia repairs	1.2±1.5
Potententially contaminated	19/71 (26.76%)
Contaminated	27/71 (38%)
Dirty	25/71 (35.21%)
Onlay	1/71 (1.40%)
Inlay (interposition repair, in which the BP is sutured directly to the fascial edge)	19/71 (26.76%)
Sublay extraperit. (BP is placed underneath the fascial edge)	45/71 (63.38%)
Sublay intraperitoneal (=underlay)	6/71 (8.45%)
Anterior fascia closure	52/71 (73.23%)
No anterior fascia closure	19/71 (26.76%)
Component separation	12/71 (16.90%)

ASA, American Society of Anesthesiologist; BP, biological prosthesis.

Table 2. Type of bio-prostheses used in our study.

Type of biological mesh	No. of patients (%)
Porcine small intestine submucosa	45/71(63.38%)
Porcine dermal collagen	7/71 (9.85%)
Bovine percardium	19/71 (26.76%)

The common consensus is to not use non-absorbable materials in severely contaminated areas, such as in peritonitis, due to a very high risk of infection.[24-28]

There have been several recent studies that have demonstrated good clinical outcomes in the use of biological materials. However, no long-term results are currently available and there have not been randomized controlled trials published comparing recurrence rate of the non-absorbable materials and biological prostheses in complicated IH hernia repair.[29-31]

Meanwhile, other studies are underway to develop the indications for bioprostheses, in particular in contaminated fields.[32-37]

Nedelcu *et al.*[38] carried out a multicenter prospective randomized single-blind study to compare the surgical treatment of inguinal hernia and abdominal incisional hernia by simple parietal herniorrhaphy without prosthetic reinforcement (Group A), and with biological prosthesis reinforcement parietal herniorrhaphy (Group B), in a potentially contaminated setting. One hundred thirty-four patients were enrolled. At one month after surgery, the rate of infectious complications was not significantly different between the two groups (18% group A *vs* 19% group B). After one year, survival without recurrence was significantly greater in Group B (group A recurrence: 10; group B recurrence: 3; P=0.0475). The authors concluded that the use of bioprosthesis for hernia repair or IH in a potentially contaminated workplace reduces the risk of short-term recurrence without increasing overall comorbidity.[38]

These encouraging short-term outcomes show the great benefit from the use of biomaterial in IH repair in potentially contaminated field. Our study is not randomized or comparative, but data prospectively collected confirmed that bio-prostheses have an acceptable recurrence rate also in contaminated and dirty fields for patients operated in emergency (after a mean follow up time of 27.2 months, our recurrence rate was 26.76%), but we noted a high early postoperative wound infection rate (29.57%-21 patients), even if no patients needed for surgical treatment.

Lupinacci *et al.*[39] retrospectively analyzed and prospectively observed 43 patients consecutively submitted to complex abdominal hernias repair with biological prostheses, to evaluate early and mid-term outcomes in the largest French series. He reported that 58% of the population study had an incisional hernia. Nineteen hernias were *clean-contaminated*, 12 *contaminated*, 7 *dirty*. In this study, wound-related morbidity occurred in 17 patients; 4 patients needed re-operation for cutaneous necrosis or abscess. Smoking was the only risk factor associated with wound complication (P=0.022) and no postoperative wound events required removal of the prosthesis. The recurrence rate was 9%. A previous attempt at repair (P=0.018) and no complete fascia closure (P=0.033) were associated with hernia recurrence. Lupinacci showed that the use of bioprostheses in complex hernia repair allowed successful single-stage reconstruction but wound-related complications were frequent.[39]

In our experience, we can explain the high rate of wound infections with the emergency setting and with the high incidence of dirty surgical field (25 patients *vs* 7 in Lupinacci's study).

We confirmed that anterior fascia closure, when it is possible, *preserves* patients from wound infection and smoking is an important risk factor for wound infection.

Nevertheless, clinical evidence is that the systemic use of the bioprostheses is still limited for high costs and limited availability.

Mariette *et al.* carried out a survey to determine French surgical practice patterns among academic surgeons in complex ventral hernia repair (CVHR) and he reported that biologic meshes are being used by 90% of surveyed surgeons for CVHR above all in contaminated or infected fields. Primary closure without reinforcement was the surgical technique preferred in 31.6% of cases, primary closure using the component separation technique without mesh use was performed in 43.7% of cases, mesh positioned as a bridge in 16.5% of cases, size reduction of the defect by using aponeurotomy incisions without mesh use in 8.2% of cases. There was a strong consensus among surveyed

Table 3. Univariate analysis between covariates and wound infection.

Preoperative variables	Odds ratio (confidence interval) - P-value
Age	1.11 (1.09-1.25) 0.32
Gender (M)	0.93 (0.52-1.37) 0.45
ASA score (per unit increase)	2.82 (1.85-6.43) 0.03*
Body mass index (per kg/m^2)	0,93 (0.84-1.19) 0.22
Smoking	4.1 (1.73-6.35) 0.02*
Diabetes mellitus	3.23 (1.92-4.38) 0.04*
COPD	1.92 (1.01-7.72) 0.85
Immunosuppressed	2.41 (0.33-5.25) 0.003*
No. previous abdominal surgeries	1.86 (0.95-2.1) 0.33
No. previous hernia repairs	1.99 (1.5-2.9) 0.002*
Potententially contaminated	1.82 (0.77-4.82) 0.3
Contaminated	2.69 (0.25-8.2) 0.42
Dirty	1.87 (0.35-4.4) 0.04*
Mesh location: sublay intraperitoneal (=underlay)	1.22 (0.65-2.2) 0.8
Mesh location: sublay extraperit. (BP is placed underneath the fascial edge)	0.45 (0.27-1.13) 0.009*
Mesh location: inlay (interposition repair, in which the BP is sutured directly to the fascial edge)	0.93 (0.1-9.3) 0.88
Mesh location: onlay	0.88 (0.2-4.5) 0.08
Component separation	0.47 (0.1-2.7) 0.09
Anterior fascia closure	0.89 (0.3-2.5) 0.07
No anterior fascia closure	0.33 (0.2-2.3) 0.04*

ASA, American Society of Anesthesiologist; COPD, chronic obstructive pulmonary disease; BP, biological prosthesis. *Statistical significance P<0.05.

surgeons for not using synthetic mesh in contaminated or dirty fields (100%), but for using it in clean settings (100%). There was also a strong consensus between respondents for using biologic mesh in contaminated (82.5%) or infected (77.5%) fields and for not using it in clean setting (95%). In clean-contaminated surgery, there was no consensus for defining the optimal therapeutic strategy in CVHR. Infection was the most common complication reported after biologic mesh used (58%). The most commonly reported influences for the use of biologic grafts included literature, conferences and discussion with colleagues (85%), personal experience (45%) and cost (40%).[40]

Long term outcomes confirming the efficacy of bio-materials in complicated IH repair in emergency setting and cost-effectiveness analysis data justifying their use in contaminated surgical field in comparison with other less expensive meshes are still unavailable. Randomized controlled trials comparing the use of biomaterials and traditional meshes in infected IH repair are necessary. The Simbiose study is an ongoing multicenter, phase III, randomized, controlled trial comparing the use of a biological mesh *versus* traditional wound care without biological mesh in infected incisional ventral hernias. This study was planned to last for 5 years and 100 patients need to be included.[41] No data are currently available.

In 2013, WSES, to help surgeons in clinical practice, after a consensus conference, stated that for patients with intestinal strangulation and/or concurrent bowel resection (potentially contaminated surgical field), direct suture is recommended when the hernia defect in question is small; synthetic mesh repair may be performed, but with caution. Biological meshes may be a valid option but merit detailed cost-benefit analysis.[41] The choice between a cross-linked or a non cross-linked biological mesh should be evaluated depending on the defect size and degree of contamination. Cross-linked biological meshes may be considered an option in abdominal wall reconstruction.[42]

Conclusions

Our experience showed that the use of biological prostheses in contaminated or dirty surgical field in emergency setting is safe with good mid term outcomes in patients at high risk to present wound infection and hernia recurrence. The choice of the surgical technique in repairing the incisional hernia is important to avoid wound complication, that remains high in emergency setting and dirty surgical field, and to decrease the recurrence rate.

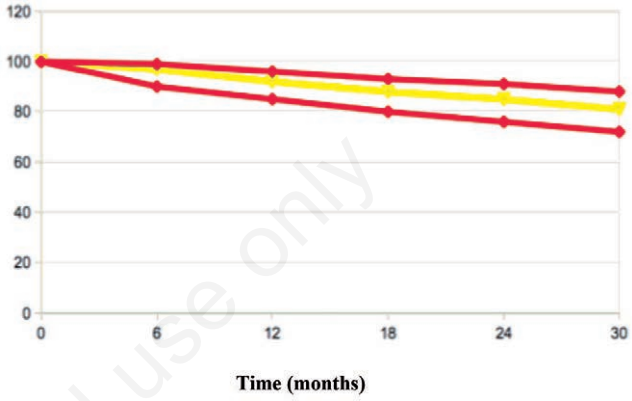

Figure 1. Kaplan-Meier curves for recurrence [95% confidence interval (CI)].

Table 4. Univariate associations between covariates and recurrence.

Preoperative variables	Hazard ratio effects estimated (95% confidence interval) - P-value
Age	1.22 (0.83-1.33) 0.30
Gender (M)	0.77 (0.25-1.56) 0.23
ASA score (per unit increase)	3.2 (2.2-6.4) 0.02*
Body mass index (per kg/m^2)	0.83 (0.55-1.92) 0.10
Smoking	1.5 (0.95-2.41) 0.33
Diabetes mellitus	3.21 (1.83-4.33) 0.02*
COPD	1.9 (0.33-4.36) 0.07
Immunosuppressed	2.2 (0.44-5.23) 0.001*
No. previous abdominal surgeries	1.92 (0.93-2.52) 0.09
No. previous hernia repairs	1.93 (2.231-3.44) 0.4
Potententially contaminated	1.99 (0.73-4.20) 0.9
Contaminated	2.89 (0.51-5.2) 0.7
Dirty	2.39 (1.25-4.8) 0.002*
Mesh location: sublay intraperitoneal (=underlay)	1.22 (2.67-3.89) 0.08
Mesh location: sublay extraperit. (BP is placed underneath the fascial edge)	1.45 (1.1-4.55) 0.001*
Mesh location: inlay (interposition repair, in which the BP is sutured directly to the fascial edge)	0.98 (1.1-7.2) 0.85
Mesh location: onlay	0.42 (1.4-6.6) 0.5
Component separation	0.9 (1.2-3.5) 0.7
Anterior fascia closure	2.3 (1.9-2.3) 0.08
No anterior fascia closure	3.1 (1.8-4.2) 0.2
Wound infection	3.4 (2.2-5.9) 0.002*

ASA, American Society of Anesthesiologist; COPD, chronic obstructive pulmonary disease; BP, biological prosthesis. *Statistical significance P<0.05.

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