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ORIGINAL ARTICLE

A comparative study of sutured versus bovine pericardium mesh abdominal closure after open abdominal aortic aneurysm repair

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Abstract
Background Open abdominal aortic aneurysm (AAA) repair is followed by a high rate of incisional herniation. The purpose of this study was to evaluate whether this postoperative complication could be avoided by a prophylactic implantation of a biological mesh.
Methods In a prospective randomized clinical study, patients electively treated by open AAA repair were allocated equally to routine abdominal suture closure or to prophylactic placement of bovine pericardium mesh above the fascia. The study end points were postoperative complications and incidence of incisional hernia at a 3-year follow up.
Results Forty patients with a mean age of 74.3 (SD ± 5.8) years were studied. All patients had a successful operation and a quite uneventful postoperative course. The mean operative time in the mesh group was longer compared to the control group ($p < 0.001$). Two patients in the mesh group developed wound seroma postoperatively. Six patients (30 %) in the control group developed incisional hernia comparing to none in the mesh group. Cumulative proportion of freedom from incisional hernia was 100 % for mesh group at 3 years and 74.4 % (SE 9.9 %) for control group at 2 years ($p < 0.008$). In five patients (83 %), the incisional hernia was diagnosed by the second postoperative year. One patient underwent incisional hernia repair.
Conclusion The bovine pericardium mesh reinforcement of fascia closure in patients undergoing open AAA repair showed effectiveness and low complication rate in prophylaxis from incisional herniation. It should be considered as an alternative mesh material in selected patients.

Keywords Incisional hernias · Bovine pericardium · Aortic aneurysm surgery · Mesh prophylaxis

Introduction

Open abdominal surgery is followed by the risk of incisional hernia development with an incidence ranging between 11 and 23 % [1–4]. This is especially evident in patients undergoing open repair for AAA, possibly due to their underlying connective tissue disorders [5–9]. An approximately threefold increased risk for both inguinal and incisional hernias in AAA patients compared to aortoiliac occlusive disease (AOD) patients after an aortic operation has been estimated [8].

Abdominal closure with mesh implantation has been tested in several studies as a method for prevention of incisional hernia in AAA open repair with very good results [9–13]. Although the material used in all these studies was polypropylene mesh, biological meshes, such as bovine pericardium, may also have a role in preventing AAA incisional hernias. The reported advantages over synthetics include improved biocompatibility, better native tissue ingrowth, infection tolerance and lesser adhesion formation [15]. Bovine pericardium has been proven to be an

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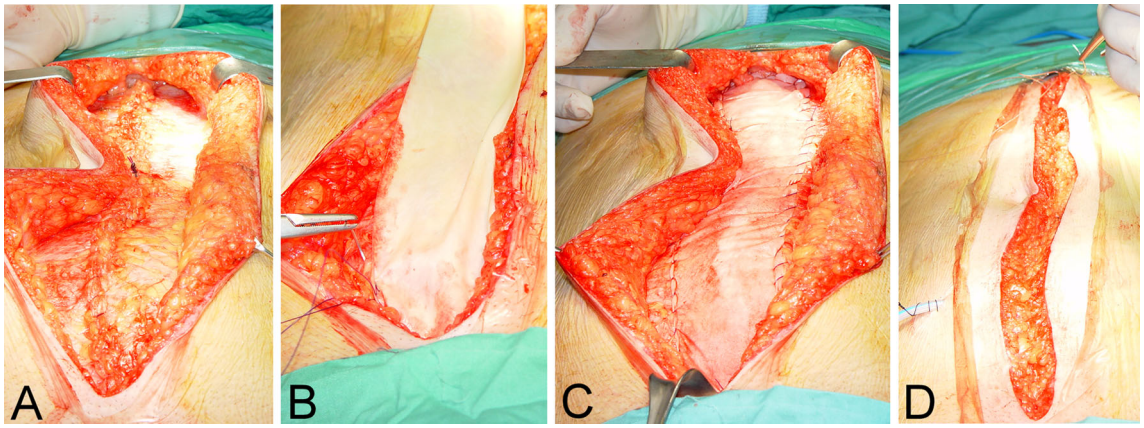

Fig. 1 Technique used in the mesh closure group. **a** Routine mass closure with a running, polydioxanone loop suture after the aneurysm sac and posterior peritoneum was closed. **b**, **c** Following the fascia closure a Peri-Guard biological mesh implantation using the onlay technique with a running non-absorbable suture. **d** Suction drain placement and subcutaneous closure followed

excellent patch closure material with wide application in cardiac and vascular surgery [16, 17]. It has been also tested in experimental hernia repair studies and in abdominal wall reconstruction in contaminated fields with encouraging results [16–18]. However, there are no studies examining its role in the prevention of incisional hernia, especially in the setting of AAA open repair.

The present study compared abdominal wound closure after open AAA repair by either fascia suturing or onlay bovine pericardium mesh implantation, regarding the development of incisional hernia.

Methods

This was a prospective randomized study that recruited patients who had been listed for an elective open AAA repair between September 2007 and March 2009. The patients were allocated in two groups: (a) suture fascia closure (control group) and (b) suture fascia closure reinforced by an onlay mesh implantation. Treatment allocation was performed by the method of minimization to ensure adequate balance between the two groups according to age, sex, chronic obstructive pulmonary disease (COPD), body mass index (BMI) and diabetes mellitus. All patients, in order to participate, were fully informed and provide a written consent. Any patient with a previous abdominal surgery or receiving medications such as steroids and other immunosuppression drugs was excluded from the study.

All procedures were performed by the same surgical and anesthesiology team. After induction to general anaesthesia the peritoneal cavity was entered via a long midline incision. The aortic replacement was undertaken with a synthetic polyester graft (InterGard Silver, InterVascular, La Ciotat, France) by the standard inlay technique. After the aneurysm sac and posterior peritoneum was closed, the patients who had been randomized to suture fascia closure underwent routine mass closure in a running 4:1 ratio polydioxanone loop suture No. 1 (PDS^{TM} II, ©Ethicon INC, Norderstedt, Germany). In the mesh closure group, following the fascia closure, a biological mesh derived from processed bovine pericardium (Peri-Guard, Synovis Surgical Innovations, Minnesota, USA) was implanted using the onlay technique. The mesh had to completely cover the sutured fascia line for at least 4 cm wide and secured in place by a running non-absorbable suture (Fig. 1). Small incisions were made in the mesh surface to prevent serum accumulations. Suction drains were placed in the subcutaneous space and removed when the drainage fluid was $<$30 ml/24 h.

Patient follow-up was undertaken after 1 and 12 months and then annually for 3 years. Follow-up appointments included clinical examination by an experienced vascular surgeon and a computed tomography (CT) of the abdomen at the annual appointment. Every patient had a second consultation by a general surgeon in order to confirm the development of an incisional hernia.

The primary outcome was the development of an incisional hernia at the end of the 3-year follow up. Other parameters that have been estimated were the duration of surgery, postoperative complications and reoperation rate for incisional hernia. Assuming the frequency of postoperative hernia after elective AAA open repair is 18–20 %, the study required 40 patients in both groups to have the minimum 50 % power to detect a decrease in frequency below 10 %. Statistical analysis was undertaken using SPSS Statistics 20 software (IBM Corporation, NY, USA) and Stata 12 (StataCorp LP, College Station, Texas, USA) using crosstabs, non-parametric statistics and Kaplan–

Meier analysis. Continuous variables are expressed as mean ± standard deviation, and categorical variables as median values, number *n* or % percentage. Estimates of Kaplan–Meier analysis were considered statistically significant for standard error values <10 %, while the results of the rest statistically analysed data were considered significant for *p* values <0.05.

Results

During the study period, 40 patients were admitted for elective open AAA repair and met the inclusion criteria. Twenty patients were randomized to each group (mesh closure and suture closure group). The two groups did not differ with regard to BMI, COPD, age, sex and diabetes mellitus (Table 1). The mean operative time in the mesh group was longer compared to the control group (181 ± 38 vs 131 ± 27 respectively, $p < 0.001$, Table 2). The groups did not differ with regard to the implanted type of grafts ($p = 0.52$, Table 2), straight or bifurcated.

The rates of postoperative morbidity and mortality were similar between the two groups (Table 2). One patient in the control group suffered from mild pulmonary insufficiency and one patient in the mesh group had a myocardial ischemia. Both patients recovered uneventfully. Wound complications (seroma) occurred in two patients of mesh group and in one of no mesh group (Table 2). In the mesh group, seroma had developed following the early removal of the indwelling drain, which in most cases was removed at postoperative day 4. All patients were treated successfully by percutaneous drainage. One patient in each group died from myocardial ischemia and completed only the 2-year follow up, but none of them had developed hernia at the time of last examination.

Nineteen patients in each group were alive at the end of the third postoperative year. Six patients (five males), all from the control group (31.6 %), were diagnosed to have an incisional hernia by clinical examination and/or abdominal CT scan during their follow up (Fig. 2). Kaplan–Meier cumulative proportion of freedom from incisional hernia was calculated to be 100 % at 3 years for the mesh group and 74.4 % [Standard error (SE) 9.9 %, 95 % confidence interval (CI) 48.9–88.5 %] at 2 years for the control group (Fig. 3). The estimate at 3 years for the control group was 69 % but did not reach significance (SE 10.5 %, 95 % CI 43.6–84.7). Log rank comparison between the two groups revealed statistical significant difference ($p = 0.008$) in incisional hernia occurrence in favor of the mesh group. There were no differences in comorbidities and operative data between the patients who developed an incisional hernia and the rest of the control

Table 1 Group matching according to patient characteristics

	Group		*p*
	Mesh	No mesh	
Age (median)[a]	75	75	0.9
Sex (male), *n* (%)[b]	18 (90)	18 (90)	1
BMI (median)[a]	25.4	24.4	0.35
COPD, *n* (%)[b]	10 (50)	7 (35)	0.52
Diabetes, *n* (%)[b]	4 (20)	6 (30)	0.72

[a] Mann–Whitney *U* test

[b] Fisher's exact test

Table 2 Perioperative data and complications

	Group		*p*
	Mesh	No mesh	
Operative time (mean ± SD)[a]	181 ± 38	131 ± 27	<0.0001
Graft implanted			
Straight/bifurcated *n* (%)[b]	12 (60)/8 (40)	9 (45)/11 (55)	0.52
Complications			
Cardiovascular, *n* (%)[b]	1 (5)	0 (0)	1
Pulmonary, *n* (%)[b]	0 (0)	1 (5)	1
Renal, *n* (%)[b]	0 (0)	0 (0)	1
Wound, *n* (%)[b]	2 (10)	1 (5)	1
Mortality, *n* (%)[b]	0 (0)	0 (0)	1

SD standard deviation

[a] Mann–Whitney *U* test

[b] Fisher's exact test

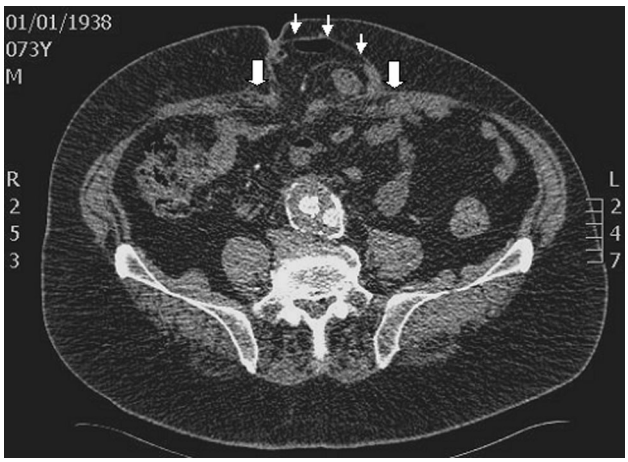

Fig. 2 Abdominal CT scan showing the development of a midline incisional hernia, 1 year after the open AAA repair. The *thick arrows* show the fascia defect and the *thin arrows* the hernia sac

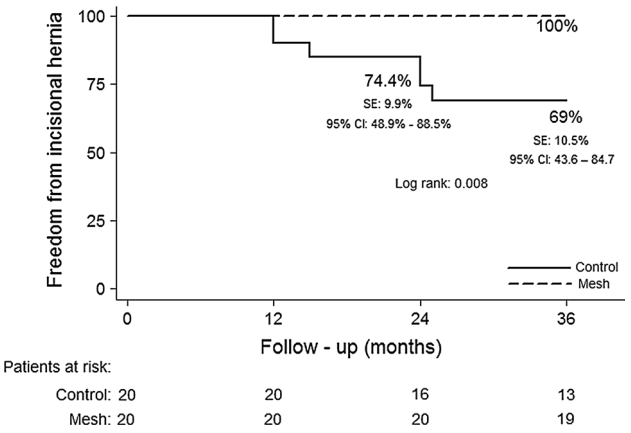

Fig. 3 Kaplan–Meier cumulative proportions of freedom from incisional hernia for both groups of patients

group. One patient had to be operated for incisional hernia repair 2 years after the AAA repair due to recurrent episodes of incarceration. No mesh complications were recorded during the 3-year follow-up.

Discussion

In a recent review, Takagi et al. [8] concluded that the risk of developing an incisional hernia is approximately three times higher in patients operated for AAA repair compared to those operated for AOD. The reported incidence of incisional hernia in AAA patients ranges 10–47 % [5–9]. The explanation of this higher incidence comparing to laparotomies in general (10–23 %) has been attributed to the elastase and collagen disorders, which could be also responsible for the AAA development [1, 5–8]. During the last decade, the evolution of endovascular aortic repair (EVAR) seemed to compensate the incisional hernia complication, since the laparotomy is being avoided. However, there are still patients that require an open AAA repair because they are not anatomically suitable for EVAR [19]. It is also possible that the AAA patient might need a laparotomy due to another concomitant pathology or as a secondary procedure after the initial EVAR.

Several methods have been applied in order to reduce the incidence of incisional hernia following laparotomy. Those include different fascia suturing techniques, transverse instead of midline incisions and prophylactic use of a mesh in fascia closure [9–13, 20–24]. The latter has been used for almost a decade and it seems to be an effective method in reducing the incidence of an incisional hernia in high-risk patients, including patients with open AAA repair [10, 12, 13]. Based on the data published from comparative studies, there is a reduction in the incidence of incisional hernia ranging 10–21 %, when prophylactic mesh is used [12, 20–22]. The most commonly evaluated mesh material in hernia prevention following laparotomy is polypropylene [10, 12, 13, 20, 21, 23]. Although synthetic meshes have proven their efficacy in hernia surgery, there is also evidence that their use is more frequently associated with wound infection compared to suture repair [10, 14]. In such conditions, removal of the mesh is required in 50–90 % of the cases [18]. This poses an additional problem in AAA surgery, where the aortic graft might be compromised by a systematic spread of the infection. On the other hand, bovine pericardium is a biologic material widely used in cardiovascular surgery [16, 17]. It comprises most of the advantages of the biological materials including favorable characteristics, strength, biocompatibility, native tissue ingrowth and lesser adhesion formation. Additionally, if a collagen cross-linking manipulation has been preceded, the bovine pericardium is considered to be relatively resistant to bacterial degradation, and therefore, safe to use in contaminated or infected hernia repair [15]. In hernia surgery, biological prostheses experience has been limited [15, 18, 25, 26]. Only one study utilized a biological mesh (human dermis) in clinical practice to prevent an incisional hernia [22].

In this study we compared the bovine pericardium mesh with fascia suture closure in the prevention of incisional hernia following open AAA repair. We chose this biological mesh because of its characteristics (appreciated in the carotid surgery), [17] and the reported resistance in potential infection. The mesh was positioned in an onlay fashion. Based on the current literature, this technique was easily performed and with comparable results to others (sublay) [14, 27]. Our study results are in agreement with other reports showing that a mesh abdominal closure is effective and prevents an incisional hernia compared to suture closure following open AAA repair [12, 20, 21]. Although the operation time was longer in the mesh group, this did not affect the postoperative morbidity. The only complications observed were two wound seromas, which were treated by a single session of percutaneous aspiration. We did not experience any wound infection in any of the study groups. Although previous studies have outlined wound infection as a frequent problem in mesh repair, probably the clean nature of AAA repair and the specific type of mesh used might had played a role. Of course a definite conclusion cannot be reached due to the small number of patients in this study.

To our knowledge, this is the first study evaluating the prophylactic bovine pericardium mesh reinforcement of laparotomy closure in patients undergoing open AAA repair. Bovine pericardium mesh showed good handling characteristics, low complication rate and effectiveness in prophylaxis from hernia formation. Based on our results, although it is premature to recommend the routine use of

bovine pericardium mesh in every open AAA repair, it seems that it should be considered at least as an alternative choice.

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