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A Pragmatic Study Of Porcine Acellular Dermal Matrix Mesh In Ventral And Parastomal Hernia Repairs. Evaluation Of Outcomes From A Tertiary Centre

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ORIGINAL

Abstract

Aims and Objectives: The incidence of complex ventral hernias and those contaminated is increasing. Synthetic meshes are not favoured due to the increased risk of wound complications. Biologic meshes are used as an alternative given their biocompatible safety, but there is a lack of strong evidence to recommend its routine use. Hence, it is up to institutions to evaluate the safety and efficacy to support its continuing usage, which is the basis of this study.

Methods: A retrospective review of a prospectively maintained PADM mesh database was performed, focusing on midline and parastomal hernias. Demographic data, surgical techniques, and short- and long-term complications were reviewed.

Results: 71cases (acute/elective 10/61) were included. The median age group, sex ratio in the acute and elective groups were 67 years (36-83yrs) and 62years (25-93yrs), 2:1 and 4:3 respectively. Mean ASA score was 3.4 in the acute and 2.4 in the elective group. Midline hernias constituted 37/ 61 (60%), and Parastomal hernias, 40% (24/61). Component separation was performed in 29 cases, which include bilateral anterior component separation in 16, unilateral anterior component in 11, and posterior component separation in 2. Median length of stay was 11days (1-180d) and 15 days (1-159d) in the elective and acute groups, respectively. Median length of follow-up was 18 months (12 -72 months). There were 5 deaths within 90 days. Recurrences were noted in 6/37 (16%) midline repairs and 8/24 (33%) parastomal hernias.

Conclusion: Our limited PADM series showed acceptable results in comparison with available studies. As such, we find it a useful adjunct in the repair of complex ventral hernias.

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Introduction

Complex ventral hernia repair is challenging, with the jury still out as to the type of mesh to be used in contaminated settings. At the same time, the prevalence of clean-contaminated and contaminated ventral hernias is increasing, with a risk of recurrences and need for further repairs (1). Previous studies have shown that in complex ventral hernias biological meshes which may be used in conjunction with component separation are superior to fascial closure with sutures alone (2). The Ventral Hernia Working Group (VHWG) suggested the use of Biological meshes in contaminated settings, and the modified classification of Ventral Hernias based on risk factors for complications, seem to reliably predict short-term outcomes following repair, especially the need for further hernia surgery, which is about 10% (1). Although about 200 times costlier than synthetic meshes, the safety profile in terms of surgical site occurrences (SSO) of biological meshes was similar to synthetic meshes in contaminated hernias (3). Recurrence rates of up to

32% have been reported following ventral hernia repair with Biologic mesh (4). In the repair of Parastomal Hernias, Biological mesh was associated with recurrence rates of up to 20.5%(5).

It appears thus, that institutions using Biological Meshes should be able to justify its continuing use even in special circumstances considering the equivocal data and weak evidence available in literature to recommend its use. We feel that it would be possible by doing a pragmatic study of the use of biological mesh and its outcomes as and how it happens in routine care, rather than in an experimental or controlled setting.

Aims

Against the above background, we proposed to evaluate the short- and long-term outcomes of Porcine Acellular Dermal Matrix (PADM) mesh in complex ventral hernia and parastomal hernia repairs at our tertiary referral center.

Methods

A retrospective review of a prospectively maintained PADM mesh database was performed between 01/05/2016 and 30/09/2022. Focus was aimed towards midline and parastomal hernias. Electronic charts were reviewed to obtain demographic data and surgical logs were interrogated to obtain indication and surgical techniques. The primary outcome measured was radiological recurrence. Secondary outcomes were Surgical site occurrences including seromas, wound infections, and return to theatre. Those that required further hernia surgery for recurrences were noted. All cases of Ventral and Parastomal hernias repaired using PADM was included. Perineal, Diaphragmatic and Groin Hernias were excluded.

Results

Over a period of 6 years, PADM was used in the repair of 45 Ventral Hernias and 26 Parastomal Hernias (N=71) in both elective and acute settings. Of these, there were 61 elective repairs and 10 acute repairs. Surgeons varied in their experience, techniques used, choice of suture materials, and post-operative care, however, they all used the same type of PDAM mesh (Cellis R). The Largest size of mesh used was 30cmX 30cm. Mesh was cut to size and shape to suit the defect and a variety of sutures like polydiaoxanone (PDS) or prolene were used to fix the mesh in an interrupted or continuous fashion. Meshes were also placed in different positions as per surgeon preference. All patients however had pre-operative antibiotic prophylaxis and postoperative DVT prophylaxis as per hospital protocol.

For the sake of analysis, we grouped the cases into elective and acute repairs for both ventral and parastomal hernias. All acute cases were admitted as an emergency from Accident and Emergency with CT-proven small bowel obstruction or ischaemia. We used the modified VHWG classification to group the ventral hernias into groups 1 or 2 and 3 or 4 Figure 1.

Table 1 shows the analysis of the cases in two groups, acute and elective. Although of similar age and sex profile, acute cases were considerably sicker. It is noteworthy that the majority of the ventral hernias (67%) belonged to modified classes 3 and 4 portraying the complexity of most cases. Loss of Domain being a major issue in such cases, some form of component separation technique was commonly employed (78%). The median BMI of Ventral Hernias was 32.25 kg/m2 (IQR 19.4-42.2), and that of Para Stomal Hernias was 32.4 kg/m2 (IQR 19-50.2). Risk factors like smoking, Diabetes Mellitus, and COPD, were not very common accounting for less than 20% of cases in both Ventral and Parastomal Hernias. All cases were seen in the clinic after discharge at least twice in the first twelve months. Long-term follow-up varied, with a median of 18 months, and IQR of 12-72 months. Three patients were lost to follow-up. There were five

Grade 1 Low risk	Grade 2 Co-morbid	Grade 3 Potentially contaminated	Grade 4 Infected
- Low risk of complications - No history of wound infection	- Diabetes - COPD - Immunosuppression - Active smoker - Obese	- Previous wound infection - Stoma present - Violation of gastrointestinal tract	- Infected mesh - Septic dehiscence

Grade 1 Low risk	Grade 2 Co-morbid	Grade 3 Contaminated
- Low risk of complications - No history of wound infection	- Diabetes - COPD - Immunosuppression - Active smoker - Obese	- Stoma present - Violation of gastrointestinal tract - Infected mesh - Septic dehiscence

Figure 1. VHWG classification of Ventral Hernias and Kanter's modified VHWG classification. Adapted from 1 and 4.

deaths, three in the acute and two in elective groups. These were due to significant co-morbidities and post-operative cardiorespiratory complications.

Table 1. Demographics And Analysis

N =71	Acute =10	Elective = 61
Age (median IQR)	67 yrs. (36-83)	62 yrs. (25-93)
Sex F:M	2:1	4:3
Mean ASA score	3.4	2.4
Parastomal Hernias (PH)	2	24
Ventral Hernias (VH)	8 (80%)	37 (60%)
VHWG classes 1 and 2	2/8 (25%)	12/37 (33%)
VHWG classes 3 and 4	6/8 (75%)	25/37 (67%)
Cases of component separation (VH)	2	29/37 (78%)
Length of Stay (median IQR)	15 days (1-150)	11 days (1-180)
Recurrences after VH repair	1/8 (12%)	6/37 (16%)
Recurrences after PH repair	½ (50%)	8/24 (33%)

Figure 2, shows few high risk characteristics and their relative prevalence in the cohort of the ventral hernias that were repaired

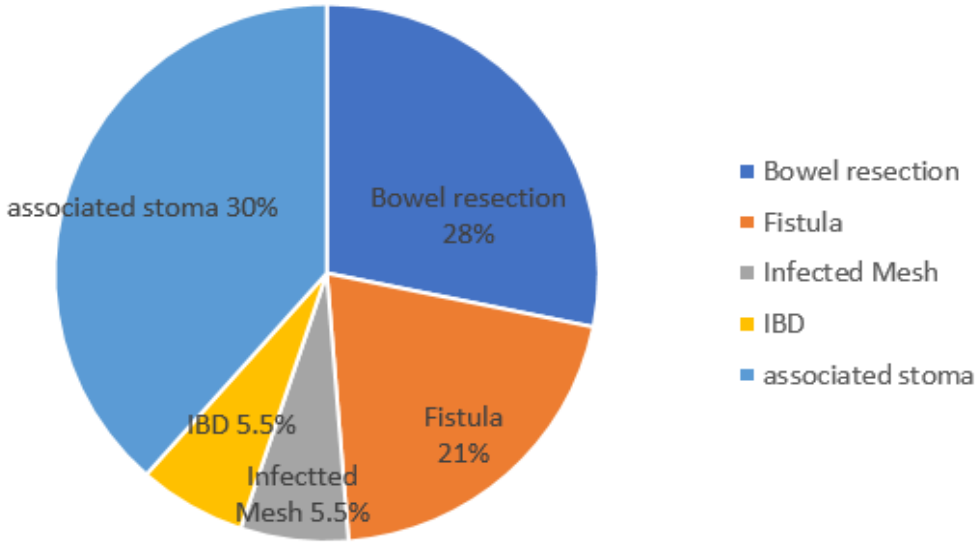

Figure 2. Risk Factors In Complex Ventral Hernia Repairs.

Component Separation: Twenty-nine (29/37, 78%) elective ventral hernia repairs and two of the eight (2/8, 25%) acute ventral hernias had component separation. Of the elective group, 16/29 (55%) had bilateral anterior component separation, 11/29 (38%) had unilateral anterior component separation, and 2/29 (7%) had posterior component separation. Of the acute group, 2/8 ventral hernias had unilateral component separation.

Recurrences following Ventral Hernia Repair: There were 16% (6/37) CT-proven recurrences after elective repairs. The median BMI in this group was 31 Kg/m2 (IQR 20.2 – 34.6). Four recurrences (84%) happened with onlay mesh repair, and one each with IPOM and sub-lay mesh repairs. 80% (5/6) recurrences occurred in VHWG classes 3 or 4. Only one out of eight (12%) acute ventral hernia repairs had a recurrence. This again was a VHWG class 4 hernia with anterior component separation and onlay mesh. Two-component separations in the elective group and one in the acute group had a recurrence. Thus, the total recurrence rate after component separation in either group was 8% (3/39). Four patients (4/45, 9%) who had recurrence went on to have further hernia repair in the follow-up period.

Recurrences following parastomal hernia repairs: There were 33% (8/24) recurrences after elective PH repair and one out of two acute repairs recurred. The median BMI of this group was 34.7 Kg/m2 (IQR 22.1- 41.5). Of the PH recurrences in the elective group, 3 each had IPOM and sub-lay repairs and 2 had onlay repairs. In the acute group, the only recurrence was in IPOM repair. Two patients (2/26, 8%) went on to have further hernia repairs. Secondary Outcomes. Seromas were the commonest surgical site occurrence, 30% (22/71), followed by wound infection in 33% (24/71) in VH and PH repairs. 15% (11/71) of the patients returned to theatre for wound-related complications or perioperative complications.

Discussion

For the sake of planning operative repair, it is important to define what a complex abdominal wall hernia is. A consensus published in Netherlands by Slater and colleagues classified it into four major categories based on location and size of defect, presence of contamination and condition of soft tissue, co-morbidities, and clinical picture. These were further divided into grades, minor,

moderate, and severe (6). However, this classification is itself complex. The VHWG classification, later modified by Kanters etal; is simpler (4; 7). This too, falls short of accounting for the size of defect or risk of recurrence. A recent French survey aimed to define “giant” ventral hernias as those with loss of domain volume of hernia over 30% of abdominal volume (8). The European Hernia Society has developed a platform to record ventral hernia repairs and postoperative complications. They suggest using the European Hernia Society classification of ventral hernias based on size and location, which do not accommodate for co-morbidities or the nature of the hernia defect. They however suggested that institutions using prosthetic meshes should attest to the safety of the products they use as a recommendation cannot be made in this regard based on any studies so far considering the various products available in the market. Quality control is necessary, and it is down to the institutions and surgeons to ensure that (9).

A large population-based study in the US showed that following incisional hernia repair, about 12% had to undergo further repair in five years, and this figure doubles if no mesh was used (10). This finding was attested by a Dutch multicentre trial comparing suture vs mesh repair of incisional hernias which found double the number of recurrences in the suture repair group; (43% vs 24%) (11). Anterior component separation (ACS) is commonly used in bigger defects, with the repair augmented using various types of meshes. Recurrence rates ranged between 10% to 30% within five years and surgical site infections ranged between 26 to 42%. Biological mesh compared to soft polypropylene mesh did not add any additional advantage to the strength and durability of these repairs (12). Transversus Abdominis Release (TAR) on the other hand was found to be useful in repairing bigger defects with even less complications. A recent systematic review quoted a two-year recurrence rate of 4%, and surgical site occurrence around 15%. The recurrence is about a third and SSO is nearly half compared to ACS (13).

Thus, it would be fair to say that a standardised approach to complex ventral hernia repair is far from practical. From, the optimisation of co-morbidities to the type of repair and selection of meshes, several permutations and combinations are available, each of which could be applied to a given case depending on the circumstances. Biological meshes, and PADM as discussed in this paper, are therefore essential tools that should be available in the surgeon’s stockpile. Therefore, any study about the outcomes of PADM meshes in complex ventral hernias should ideally be a pragmatic one, and not in a controlled or experimental setting. This is what we have tried to emulate in this paper.

The recurrence rates following complex ventral hernia repairs using biological meshes have been reported to be between 12% to 33% and that of wound complications to be between 15% to 40% (14; 15). The present study has shown a recurrence rate of 16% for ventral hernias and 33% for parastomal hernias. Surgical site occurrences were around 30%. These observations are in keeping with the available literature. In addition, component separation with PADM (CS/PADM) was found to be superior to conventional bridged repair, quoting a recurrence rate of 17% for CS/PADM (16). Our cohort showed much less recurrence after CS/PADM, 8%. When considering biological meshes, there is little to choose between porcine and bovine dermal matrix meshes as the surgical site occurrences and recurrence rates of hernias were similar (17).

Multicentre blinded trials comparing synthetic mesh with biological mesh showed a three-fold reduction in hernia recurrence with synthetic mesh in clean contaminated and contaminated fields. The safety profile and need to return to the theatre were similar, although biological meshes were significantly costlier (3). A recent meta-analysis from Spain has showed no meaningful differences between mesh types in high-risk ventral hernias, but biosynthetic meshes had favourable outcomes in terms of reduced recurrence rate of 9% and 14% incidence of SSI (18).

Our study has some obvious drawbacks. Being a retrospective study, the data collection was not exhaustive, yet we were able to obtain meaningful data regarding BMI and risk factors, ASA status, and VHWG classification. The lack of standardisation of operating technique and mesh placement makes comparisons with other similar studies impossible. However, we feel that our study is more pragmatic and hence likely to reflect the performance of similar institutions in the United Kingdom. The study represents what came through our doors over the six years and the outcomes of PADM repair performed in this cohort. This could be taken as a quality control

exercise in complex ventral hernias, to justify its continuing use. Such a practice is encouraged by the EHS. This in our view is essential as we do not yet have any strong evidence base to recommend any technique or mesh in the management of such cases. It thus comes down to the institutions and the surgical teams to choose the type of mesh they would want to use in high-risk ventral hernias.

Conclusion

PADM mesh was shown to be safe with recurrence rates and wound complications well within reported figures in literature. As such, our study and available literature provide no support to deny its use in the repair of complex high-risk ventral hernias. More such data from similar centres would help to consolidate and generate a wider consensus on the use of PADM in complex ventral hernias.

Conflict Of Interest

All authors declare no conflict of interest of any kind.

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