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Laparoscopic Ventral Hernia Repair with Poly-4-Hydroxybutyrate Absorbable Barrier Composite Mesh

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ABSTRACT

Background: Repair of ventral and incisional hernias (VIHR) is a common procedure, newly introduced resorbable mesh biomaterials provide an attractive option to reduce the use of permanent synthetic mesh in hernia surgery and reduce its complications. However, data on the use of slowly resorbable mesh materials remains scarce, this study aims to evaluate the use of poly-4-hydroxybutyrate/absorbable barrier composite mesh (P4HB/ABCM) in laparoscopic repair of VIHR.

Methods: This is a retrospective study of a sequential cohort of patients undergoing laparoscopic VIHR utilizing a P4HB/ABCM mesh. Perioperative characteristics and clinical outcomes were collected.

Results: In total, 26 patients including 10 females and 7 males underwent laparoscopic VIHR using P4HB/ABCM. All surgeries were performed in a single institution by the same surgeon. The average patient age was 52.6, and the mean BMI was 35.5. All patients had a clean wound classification. The average defect size was 136.4 cm^2. All patients were seen in clinic with a median follow-up of 28 months. We observed 4 wound seromas, and no wound infections or recurrences during the follow-up period.

Conclusion: Results of laparoscopic VIHR with P4HB/ABCM are favorable and encourages further studies on the role of absorbable biosynthetic mesh materials in hernia surgery.

Key Words: Ventral Hernia, Laparoscopy, Surgical Mesh.

INTRODUCTION

Repair of ventral hernias is a common procedure with more than 300,000 cases being performed annually in the United States.[1] With the increasing number of ventral hernia repairs,[1] both the surgical techniques and mesh materials continue to evolve.[2] Multiple studies have demonstrated that mesh repair is superior to suture repair in decreasing recurrences.[3,4] This reduction in hernia recurrence can be offset at least in part by mesh-related complications including infection, chronic pain, erosion, and need for reoperation and explanation.[5] Theodore Billroth[2] envisaged prostheses use in hernia repair, and in 1857 proposed "If we could artificially produce tissue of the density and toughness of fascia and tendon, the secret of the radical cure of the hernia repair would be discovered." The search for the optimal mesh material is paramount. Permanent synthetic mesh is widely used and is considered the standard of care in modern hernia repair techniques. Although effective in reducing recurrences, permanent synthetic mesh will always pose a risk of complications due to the inherent permanence. The introduction of absorbable biologic mesh materials offered many desirable characteristics including higher resistance to infection and rapid revascularization.[6–8] However, high cost and questionable long-term durability,[9,10] in addition to cultural and religious issues remain an obstacle to the wide use of allogenic and xenogeneic mesh materials.[11]

Resorbable biosynthetic materials have been introduced in an attempt to leverage the desirable characteristics of both permanent synthetic and biologic mesh materials. Phasix™ ST mesh (C.R. Bard, Inc. [Davol], Warwick, RI) is a biosynthetic resorbable monofilament mesh with an

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absorbable barrier. It is derived from poly-4-hydroxybutyrate (P4HB), which is fully absorbed in 12–18 months.[12,13] It has initial mechanical properties similar to polypropylene mesh and allows for remodeling to native host tissue over the period of its resorption.[12] Although promising in concept, few studies have reported clinical outcomes of its use in ventral and incisional hernias.[14–18]

The purpose of this study is to evaluate the clinical outcomes of the use of a fully absorbable poly-4-hydroxybutyrate/absorbable barrier composite mesh (P4HB/ABCM) mesh in laparoscopic ventral hernia repair.

METHODS

This is a retrospective study of a sequential cohort of patients undergoing midline ventral and incisional hernia repair in a single university hospital. All surgeries were performed by a single senior surgeon between April 2016 and November 2018. This study was reviewed and approved by the Institutional Review Board. All patients' demographic data and risk factors were collected including age, sex, and medical comorbidities. In addition, clinical outcome data including hernia type, defect size, mesh size, length of stay, complications, readmissions, reoperations, and the presence of hernia recurrence were obtained through chart review. Patients were followed in clinic at one week, one month, three months, six months, one year, and annually thereafter. Pain was assessed using the visual analog scale (VAS) and was recorded as present if patients reported any pain at rest or movement. GraphPad Prism statistical software was used to generate reported descriptive statistics and study figure.

SURGICAL TECHNIQUE

Preoperative laxatives and antibiotics were given to all patients. The hernia site and location is marked prior to establishing general anesthesia. Patients are placed in a supine position, and both arms are tucked with feet and shoulder support. The operative field is cleaned and draped and a veress needle was used to establish pneumoperitoneum. Trocars (5 mm) are then introduced followed by preperitoneal injection of the hernia defect with 0.5% of bupivacaine and saline.[19] Following lysis of adhesions and reduction of hernia content, the defect is measured and a 12-mm trocar is introduced through the center of the hernia sac. An appropriate size mesh (Phasix™ ST mesh from C.R. Bard, Inc. [Davol], Warwick, RI) is then tailored allowing at least 4 cm overlap in all direction, the mesh was then mounted with sutures at all corners and introduced into the abdomen as previously described.[20] The central trocar is then removed, and its incision extended minimally as needed to allow for hernia sac excision in addition to the excision of any extra fat or old mesh material. This is followed by fascial closure utilizing a P4HB suture adhering to the small bite technique, this is done in an open fashion or utilizing a suture passer depending on the size of the defect.[21] Resuming the pneumoperitoneum, the mesh is wetted intraperitoneally with 0.5% bupivacaine. The corner sutures are then retrieved transfascially and the mesh fixed using laparoscopic tackers (permanent tack) in a central to peripheral fashion to prevent wrinkling. The transfascial sutures are then tied before concluding the procedure with pneumoperitoneum evacuation and closure of all skin incisions with metallic clips.

RESULTS

There were 26 patients, 19 females and 7 males. The average age was 52.6 years. The average BMI was 35.5 kg/m^2. Most patients were in grade 2 according to the ventral hernia working group grading (**Table 1**). There were 20 ventral and 6 incisional hernia. The average size of the defect is 136.4 cm^2 (36 to 576 cm^2) (**Table 2**). All patients had their mesh placed in an intraperitoneal fashion. The mesh was then tacked and sutured to the peritoneal surface.

The postoperative hospital stay was 0.6 day (0 to 9 days). Patients were followed up in the clinic. Four patients

Table 1.
Baseline Characteristics of the Study Cohort

Patient Characteristics[a]	Study Cohort (n = 26)
Age (year) (mean (SD))	52.6 (12.5)
Sex (female) (n (%))	19 (73)
BMI (kg/m^2) (mean (SD))	35.5 (7.2)
Smoking (n (%))	0
Comorbidities	
T2DM (n (%))	2 (7.7)
HTN (n (%))	3 (11.5)
Obesity (n (%))	19 (73.1)
Diagnosis	
Primary ventral hernia (n (%))	20 (76.9)
Primary incisional hernia (n (%))	6 (23.1)

[a]BMI, body mass index; T2DM, type-2 diabetes mellitus; HTN, hypertension.

Table 2.
Operative Characteristics and Postoperative Outcomes

	Study Cohort (n = 26)			
Variable	**Mean (SD)**	**Median (range)**	**Male**	**Female**
Wound classification				
Clean (n (%))	26 (100)		7	19
Wound characteristics				
VHWG grade I (n (%))	3 (11.5)		3	0
VHWG grade II (n (%))	23 (88.5)		4	19
Hernia Type				
Umbilical (n (%))	19 (73.1)		4	15
Epigastric (n (%))	1 (3.8)		1	0
Incisional (n (%))	6 (23.1)		2	4
Hernia defect characteristics				
Defect size (cm^2)	136.4 (104.9)	126 (36 to 576)	-	-
Mesh dimension (cm^2)	309.3 (144.8)	300 (150–900)	-	-
Surgical procedure time (minutes)	94.2 (31.8)	95 (22–151)	-	-
Length of stay (days)	0.6 (2)	0 (0-9)	-	-
Repair outcomes				-
Seroma (N (%))	4 (15.4)			
Wound Infection (N (%))	0		0	0
Hernia recurrence (N (%))	0		0	0
Follow-up (months)	28 (6.5)	26 (20–36)		

VHWG, ventral hernia working group classification; SD, standard deviation.

were found to have seromas in postoperative imaging ordered as indicated. All seromas were managed conservatively. No wound infection or signs of recurrence were encountered during follow-up (**Table 2**).

At each follow-up patients were questioned about their pain using the visual analog scale. No patient reported score higher than 3 in our cohort, and frequency of patients reporting pain continued decreasing during the follow-up period (**Figure 1**).

DISCUSSION

This work outlines the results of a pilot study of laparoscopic repair of ventral and incisional hernias with P4HB/ABCM mesh. To our knowledge this is the first study looking at outcomes of P4HB/ABCM mesh use in laparoscopic ventral hernia repair. In our small series of 26 patients with an average follow-up of 28 months, no hernia recurrences were observed. We believe this is due to many factors including following modern concepts of hernia repair, such as defect closure, sac removal, and adequate mesh overlap. In addition, most of our patients had primary hernias with relatively small defect size, as none of our patients required component separation. However, we will continue to follow our patients' outcomes beyond the limited follow-up period of this study understanding that half of recurrences occur beyond 5 years. In this cohort we also observed no wound infections, and 4 seromas, which were managed conservatively.

All surgeons aspire to identify the optimal technique for hernia repair and continue to search for the ideal mesh. Karl Leblanc[22] described the technique for laparoscopic ventral hernia repair with intraperitoneal onlay mesh placement (IPOM) in 1992. Since then, few modifications have been shown to improve outcomes including primary closure of the hernia defect.[23] Sac removal was also advocated to reduce seroma formation. Beyond technique, focus has been on improving mesh material in an attempt to reduce recurrence rate, complications, and adhesion

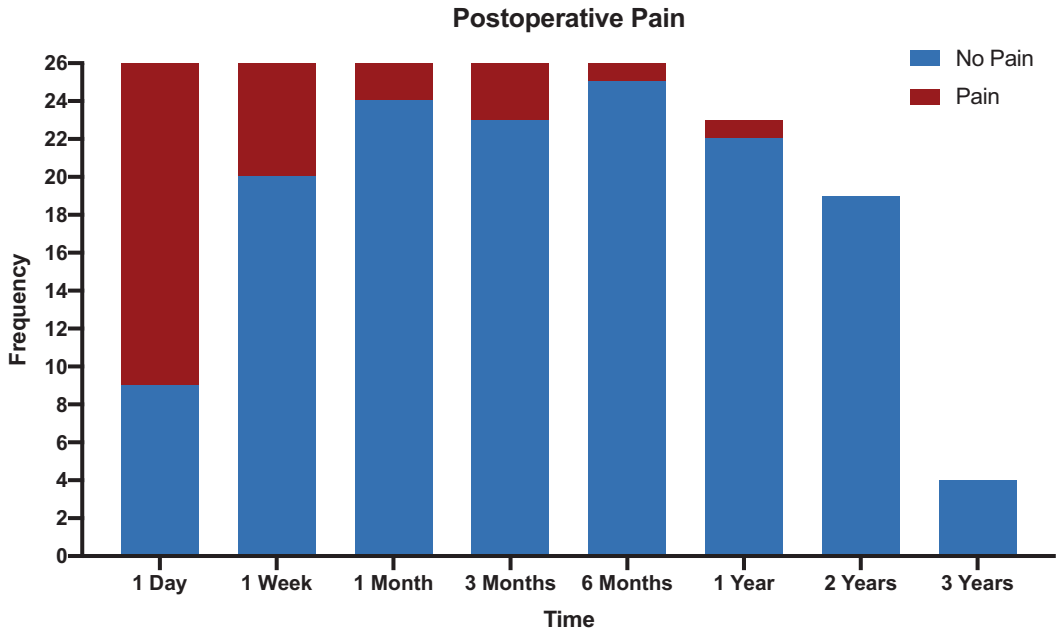

Figure 1. Frequency of postoperative pain.

formation. The current standard of care for tissue reinforcement is the use of a macroporous, monofilament, synthetic permanent mesh. Although effective in reducing recurrences, reports of erosion, migration, and infection supports the need for an alternative material.[5] Biosynthetic mesh made from poly-4-hydroxybutyrate has the advantages of being slowly absorbable (over 12–18 months) to allow for host tissue remodeling and neotissue deposition and having a mechanical strength comparable to traditional polypropylene mesh.[12] Although theoretically some strength is lost during the absorption period, mechanical testing of burst strength at the hernia repair site with P4HB mesh remained comparable at 6 and 52 weeks in a porcine model.[24]

Our previous experience in using P4HB mesh in laparoscopic repair of inguinal hernias encouraged us to use P4HB/ABCM mesh in laparoscopic repair of ventral hernias.[20] However, the data on the utilization of the P4HB mesh in ventral hernia repair remains limited, Buell et al[16] reported outcomes of 31 patients undergoing complex abdominal wall reconstruction using P4HB mesh. They reported a recurrence rate of 6.5%, and an infection rate of 12.9%, with 41.9% of their reported cohort requiring component separation. These promising results were also reported in another study of 31 patients undergoing open Rives-Stoppa repair.[17] The authors of the second study reported 0 recurrence at median follow up of 414 days, with adverse events in 6 patients including 4 seromas, one patient with wound dehiscence, and one patient who experienced soft tissue wound necrosis requiring debridement and wound vacuum-assisted closure therapy.[17]

In early 2020, an analysis of the Italian Hernia Club registry identified 75 patients who underwent hernia repair with P4HB mesh.[15] Most of the 75 patients had incisional hernia repair (n = 54), two cases were done laparoscopic and endoscopic, with 45.3% requiring component separation. The reported recurrence rate was 8%, and wound complications included 3 superficial infections requiring intervention and 5 seromas requiring drainage. The Italian data also reported significant improvement in patients' quality of life.[15]

More recently, a single arm, prospective, multicenter study of P4HB mesh in potentially contaminated incisional hernias reported short-term outcomes of 82 patients. Authors reported 11 surgical site infections, 9 wound dehiscences, 7 seromas, 2 hematomas, 2 skin necroses, and 1 fistula. No recurrences were observed in this short-term report of 3 months follow up period.[14]

In this study the use of P4HB mesh in laparoscopic ventral hernia repair was found to be associated with favorable outcomes. No hernia recurrences were noted during the study follow-up period, and postoperative complications were low. However, the study remains to be limited by its retrospective nature, and small number of patients. We

encourage reporting early outcomes of absorbable mesh utilization in hernia repair and we will use our results as the basis for future research.

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