



Original Article

Single Center Observational Study to Evaluate the Safety and Efficacy of Self-expanding Composite Mesh for Repair of Small Umbilical Hernias

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Abstract:

Background: There is evidence that mesh repair for umbilical hernias results in fewer recurrences. Early and late complication rates of mesh repair are variable with different techniques of mesh repair. In recent years, several mesh device for the repair of small ventral hernias have been developed, but some reports have been published reporting some adverse outcomes like high recurrences or wound related complications encountered with those mesh devices. The purpose of this study was to evaluate the safety and efficacy of small umbilical hernia (<3cm) repair using self expanding dual mesh.

Methods: In this study we used a composite self-expanding mesh with Polypropylene (PP) on one side and expanded polytetrafluoroethylene (ePTFE) on the other side. We introduced this technique in our department at BIRDEM General Hospital and IMC in March 2017 and collected patients data and outcome in an observational study of 25 consecutive patients matching our inclusion criteria until February 2019. In addition to the routine 1st week postoperative follow-up, We did a prospective follow-up at 1 month, 6 month and 1 year which included a questionnaire, clinical examination and ultra sonogram after 12 months.

Results: The study included 15 female and 10 male patients with age ranging from 25-62 years (Mean-47) having 16 primary umbilical hernia and 9 umbilical port hernias. The size of gap was <3cm and all except 2 hernias were reducible. In all patients a self expanding dual mesh was used with a diameter of 8cm (18 patients) or 6.4 (7 patients) cm. Early complications included superficial wound infection-1 (4%), seroma-1 (4%), serosanguinous discharge-1 (4%) and ecchymosis-1 (4%). No major wound problems were noted in 1 month or 6 month follow-up except 1 patient reporting hypertrophied scar. At 1st month follow up 21 patients were pain free, after 6 month only 1 patient reported mild pain, after 1 year 100% patients were pain free. 24 out of 25 patients ie 96% were very satisfied with the result of their repair. There was no recurrence after one year.

Conclusion: Umbilical and umbilical port hernia repair with Self expanding dual mesh is effective and is cosmetically very appreciated by patients as good as laparoscopic repair. Therefore, we recommend using these meshes only for umbilical and umbilical port hernias smaller than 3 cm. For larger or incisional hernias other techniques allowing the use of larger meshes is advocated.

Key Words: Umbilical hernia and umbilical port hernia, Dual mesh, Composite mesh.

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Received on: 24-05-2020

Accepted on: 03-06-2020

Introduction:

Umbilical hernia represents 6% of all abdominal wall hernias in adults¹. In most cases, the hernia consists of a rigid and fibrotic hernia gap that does not enlarge, but a hernia sac that enlarges substantially². When an umbilical hernia becomes symptomatic with a risk of incarceration, surgical repair is usually required. Increasing evidence

suggests that the use of prosthetic mesh is a preferable method for hernia repair, since traditional suture repair techniques have a high risk of recurrence of approximately 11% to 54%³⁻⁵. A prospective, randomized trial comparing suture and mesh repair of umbilical hernias in adults demonstrated a recurrence rate of 1% with mesh repair, compared with 11% with suture repair⁶.

Several type of mesh have been developed for repair of small and medium sized ventral/ umbilical hernia in recent years. The design of these meshes allows introduction of a mesh of appropriate size to cover the hernia defect, through a small incision. This technique is very attractive for the surgeons and the patients because the mesh usually can be introduced through a nearly invisible scar the umbilicus. The avoidance of fixation sutures omits the pain related to these sutures. In our present study we used self-expandable dual mesh for repair of Umbilical and umbilical port hernias less than 3 cm in size.

The Ventrallex™ hernia patch (Bard®, Davol, Warwick, RI), is a composite self-expanding and non-absorbable patch. It has a polypropylene (PP) side that remains in contact with the abdominal wall, encouraging tissue ingrowth and integration. The other side is made of expanded polytetrafluoroethylene (ePTFE) facing the intraperitoneal space, and providing a permanent barrier against adhesion formation. The main benefit of this technique is that fixation of the mesh is achieved principally by the intra-abdominal pressure that holds the prosthesis against the deep surface of the muscle, potentially improving tissue integration into the PP side of the mesh.

Objective:

The aim of this study was to evaluate the safety and efficacy of self expanding composite mesh repair and to address recurrence at 12 months follow up after repair of small(<3cm) umbilical umbilical and umbilical port hernias .

Materials & Methods:

It is an observational study.All patients operated between March 2017 and February 2019 at a single center by two surgeons using same technique was

evaluated and described. All patients presenting with umbilical hernia(primary or port) during study period with gap size <3cm were included in this group. Clinical examination, questioning and ultrasound when indicated were used to evaluate the patients both preoperatively and post operatively. Post-operatively, investigator's main focus was on the incidence of complications related to the use of this mesh, during the first year. Also the investigators looked at recurrence rate at 12 months, occurrence of pain at 12 months and foreign body feeling. The trial was seen as a quality control of a cohort of patients treated with an innovative mesh device. Informed written consent was taken from all patients taking part in this study. Total number of patients was 25. Data was collected regarding early mesh related complication like pain, infection, late complications like recurrence at 12 months, Quality of life, and overall satisfaction. No sponsoring from the company producing the mesh (Bard^R) was solicited.

Surgical Technique: All repairs were performed under the care of same surgical team, two surgeons using similar technique. Patients were given 1g of intravenous ceftriaxone immediate preoperatively. Under general anaesthesia using mechanical ventilation by laryngeal mask airway, a small infraumbilical curvilinear skin incision was made. The hernia sac was dissected out, opened and excised if necessary after reduction of its contents. The mesh device is folded in half to allow entry through the small gap , inserted through the defect and positioned intraperitoneally such that the ePTFE side faces the peritoneal cavity and PP side faces the parietal wall. A medium (6.4cm) or large(8cm)-sized mesh was deployed and the straps were secured onto the edges of the defect with 2/0 Polypropylene, ensuring they were not too tight to avoid a cupping effect of the mesh. The aponeurotic defect was then approximated anteriorly using interrupted 1- round Polypropylene. Skin was closed by interrupted intradermal absorbable suture, and a waterproof dressing was applied and kept undisturbed intact for 5 days. Patients were discharged home on 1st post-operative day, on oral antibiotic for 5 days and simple analgesia as required.



Fig.-1: Curvilinear skin incision below umbilicus.



Fig.-2: Dissection of the hernia sac.

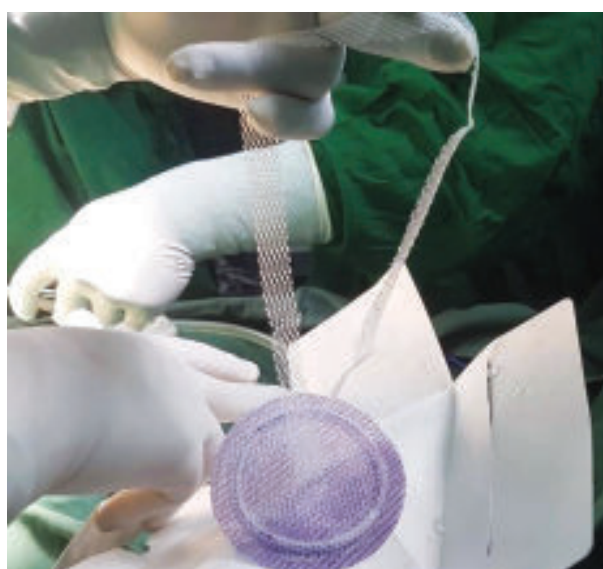


Fig.-3: The self-expandable dual mesh with tails.



Fig.-4: Mesh is folded and inserted.



Fig.-5: Fixation of the tails of the mesh with aponeurotic margin.

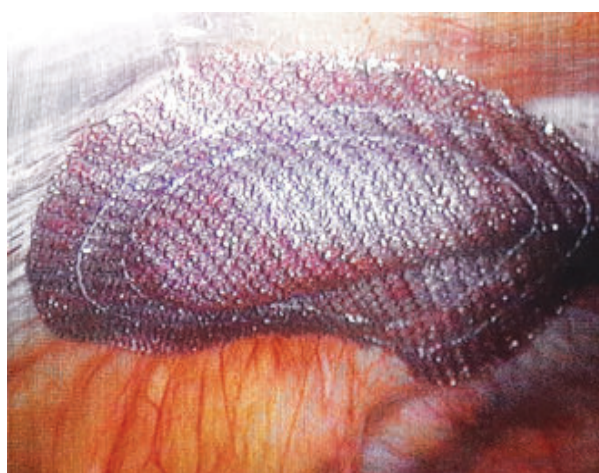


Fig.-6: A laparoscopic view of how the self-expandable mesh is deployed inside the abdomen.



Fig.-7: *Cosmetic outcome after placement of umbilicus and removal of skin stitches.*

Patient follow-up and evaluation of patient satisfaction

Following routine post-operative visits at 1st week and 1 month, patients had subsequent follow-up organized if deemed necessary. All patients were contacted via telephone and an interview was made at 6 months and 12 months post operatively. Inquiries comprised any adverse event related to the procedure, including hernia recurrence and return of symptoms such as pain, discomfort or swelling. Chronic pain was assessed using the visual analogue score⁷ (VAS) and QoL using a comprehensive scoring system (Carolinas comfort scale [CCS]) (Table 4) specially designed for hernia repairs⁸. Overall satisfaction of patients regarding the surgery

and outcome was also assessed. Patients dissatisfied with their long-term clinical outcome or concerned with potential hernia recurrence were offered a follow-up consultation with the operating surgeon at any point of their follow up. Any suspicion of recurrence was evaluated by ultra sonogram.

Result

Total number of patients were 25, out of which 10 were male and 15 were female. Age ranged from 25-62 year (mean 47). Most of them were (16) had Primary umbilical hernia with no h/o previous abdominal surgery. The rest(9) of them had history of laparoscopic procedure previously and developed an umbilical port hernia. Size of the gap ranged from 0.8-3cm as seen on ultra sonogram. Content of hernia was omentum in all cases ,2 of which were irreducible . In case of hernia gaps <1.5 cm, a medium size mesh (6.4cm) was used, in larger gaps a large 8cm mesh was used.

Total 4 patient developed minor early complications like superficial wound infection, serosanguinous discharge, bruise/Ecchymosis, and seroma one of each (table-II). None of them required readmission or surgical intervention, and were managed in surgical OPD by dressing, change of antibiotic according to culture sensitivity, control of diabetes and counseling. One patient developed wound infection on which was limited to subcutaneous fat and did not extend deeper into the mesh.

Post operative followup at 1 month , 6 month and 12 month were done to asses pain at operating site which was measured by Visual analog scale in centimeters (Fig:1), is shown in table 3. Assesment of foreign body sensation from the mesh, movement restriction when performing day to day activity, or exercise is assesed by Carolina's comfort scale which is specially designed questionnaire to asses quality of life and expressed in terms of overall satisfaction of the patient (Table-IV). Most Patients(21) were pain free in 1st month follow up and were very satisfied by the CCS score(<0.05). 3 patients had mild pain and 1 patient who had wound infection , had moderate pain. At 6 month 24 out of 25 patients were pain free; only one patient complained of mild pain, and 23 patients were very satisfied by CCS score. After 1 year follow up 100% patient were pain free and were very satisfied with the result of their surgery.

Table-I. Patient demography and baseline characteristics. (n=25)

Demographic Data	No. of patient (n=25)
• Male/Female Ratio	10/15
• Age in Year (Range)	47(25-62)
Clinical characteristics of hernia	
• Primary umbilical hernia	16
• Umbilical Port hernia	9
• Reducible hernia	23
• Irreducible hernia	2
Mesh Characteristics	
• 6.4 cm mesh	7
• 8 cm mesh	18

Table II. Complications (n=05)

Type of Complication	Number (%)	Action Taken
i) Early Complications 4(16%)		
Superficial Wound	1(4%)	Dressing+
Infection		Antibiotic
Seroma Formation	1(4%)	Conservative
Serosanguinous discharge	1(4%)	Regular
Complicationdressing		
Bruise/Echymosis	1(4%)	Conservative.
ii) Late Complications 1(4%)		
Hypertrophied Scar	1(4%)	Topical steroid

Table-III. Analysis of Postoperative pain and Overall satisfaction by quality of life assessment (n=25)

VAS*	1 month	6 month	12 month
No pain(<0.5cm)	21	24	25
Mild pain(>0.5to<4.5cm)	3	1	0
Moderate pain(>4.5to<7.5cm)	1	0	0
Severe pain(>7.5cm)	0	0	0
CCS**			
Very Satisfied(<0.05)	21	23	24
Satisfied(>0.5to <0.3)	2	1	0
Neutral(>0.3to<0.6)	2	1	1
Not Satisfied(>0.6)	0	0	0

*Visual Analog score in cm.

**Carolin's comfort score- Calculated by;

X obtained by patient through questionnaire and dividing it with maximum score 115 or 100 if patient is unable to exercise.



Fig.1: Visual Analog Scale in cm.

Table 4. *Carolina's Comfort scale questionnaire.*

Number	Question	Scores
1	While lying down, do you have?	
	Sensation of mesh	0 1 2 3 4 5 N/A
	Pain	0 1 2 3 4 5 N/A
2	While bending over do you have?	
	Sensation of mesh	0 1 2 3 4 5 N/A
	Pain	0 1 2 3 4 5 N/A
	Movement limitation	0 1 2 3 4 5 N/A
3	While sitting up do you have?	
	Sensation of mesh	0 1 2 3 4 5 N/A
	Pain	0 1 2 3 4 5 N/A
	Movement limitation	0 1 2 3 4 5 N/A
4	While performing daily activities, do you have?	
	Sensation of mesh	0 1 2 3 4 5 N/A
	Pain	0 1 2 3 4 5 N/A
	Movement limitation	0 1 2 3 4 5 N/A
5	When coughing or deep breathing do you have?	
	Sensation of mesh	0 1 2 3 4 5 N/A
	Pain	0 1 2 3 4 5 N/A
	Movement limitation	0 1 2 3 4 5 N/A
6	When walking or standing do you have?	
	Sensation of mesh	0 1 2 3 4 5 N/A
	Pain	0 1 2 3 4 5 N/A
	Movement limitation	0 1 2 3 4 5 N/A
7	When walking up or down stairs do you have?	
	Sensation of mesh	0 1 2 3 4 5 N/A
	Pain	0 1 2 3 4 5 N/A
	Movement limitation	0 1 2 3 4 5 N/A
8	While Exercising do you have?	
	Sensation of mesh	0 1 2 3 4 5 N/A
	Pain	0 1 2 3 4 5 N/A
	Movement limitation	0 1 2 3 4 5 N/A

Discussion

A variety of methods are used to repair umbilical hernias, ranging from simple suture repair, Mayo repair to mesh repair (Onlay, Retromuscular, preperitoneal, intraperitoneal); Open or complex laparoscopic hernioplasty. While repair techniques without mesh are associated with high recurrence rate, mesh repair by onlay, retromuscular or

preperitoneal, technique requires a wide dissection for placement of the mesh in both open and laparoscopic approach, which seems to be an overkill for a small umbilical hernia with <3cm gap. Tension-free hernioplasty with mesh in anterior rectus compartment, posterior rectus compartment or preperitoneal technique have been popular, especially for larger defects (>3 cm in diameter)

because of their lower recurrence rate, decreased postoperative pain, and faster recovery⁹⁻¹¹. The question remains as to whether defects smaller than 3 cm should be treated similarly with prosthetic repair. However, as primary closure often fails and as these hernias are prone to complications, mesh repair should be considered even in these smaller hernias¹¹⁻¹⁴. In a cohort study, the number of patients with a small umbilical or epigastric hernia recurrence was reduced by more than 50%, even for very small defects <1cm using mesh reinforcement (10%) compared with simple suture repair (21%), without increasing the risk of chronic pain (6% and 5%)¹⁵. A randomised, double-blind, controlled, multicentre trial published in the Lancet showed there were fewer recurrences in the mesh group than in the suture group with small umbilical hernias of diameter 1 to 4 cm (4% vs 12%)¹⁶. Laparoscopic Intraperitoneal Onlay Mesh Repair (IPOM) or IPOM Plus (with fascial closure) require a sophisticated setup and long learning curve. Moreover fixation sutures are required at 4 corners in IPOM/IPOM Plus, or open onlay that causes post operative pain¹⁷. So the technique we have chosen a self expanding dual mesh device placed intraperitoneally, that will avoid fixation sutures and/or extensive dissection. The mesh can be deployed through a very small, almost invisible scar at umbilicus, which makes it minimally invasive, cosmetically very attractive for patient and technically very simple for surgeon. In our study, we used Ventralex mesh intraperitoneally and a fascial closure for umbilical and umbilical port hernias with defects smaller than 3 cm.

Even though all of our patients were routinely discharged from hospital on prophylactic oral antibiotics, one of them (4%) developed superficial wound infection that was successfully treated with oral antibiotics (Table 2). Abdominal wall and mesh infection are known risk factors for early hernia recurrence and sometimes require prosthesis removal, especially when containing ePTFE¹⁸. Ventral and in particular umbilical hernia repairs are associated with a higher rate of infection of up to 20%¹⁹. Beside older age and comorbidities like diabetes, wound infection may relate to skin devascularisation when creating the umbilical skin flap or as a consequence of normal umbilical bacterial colonization. Therefore, we think that gentle cleansing of umbilicus with antiseptic solution and closing the fascia at the end of the procedure will minimize the

risk of developing deep wound and mesh infection, as well as the aforementioned risk of recurrence. Studies utilising other type of mesh have also found that fascia closure was associated with lower infection²⁰ and hernia recurrence²¹ rates. Other early complications like seroma-1(4%), Haemoserous discharge-1(4%), and Ecchymosis-1(4%) occurred in relatively larger sacs and irreducible hernias. It is important to dissect out the complete hernia sac from underneath the umbilical skin, however thin that might be, as peritoneum is a secretory surface and may exacerbate seroma formation if kept intact. It is best not to use power source for this dissection as that may result in de vascularization and subsequent loss of skin.

Long term complications were assessed by Questionnaire, examination and USG if needed. We did not have any recurrence in our series, and only one patient developed a hypertrophied scar. As the incision involves midline patient was counseled, reassured about the condition and advised to apply topical steroid.

Following 1 month of surgery 21(84%) of our interviewed patients did not experience any residual pain, defined as a VAS score of 0/10. Furthermore, 96% of them reported being very satisfied with their hernia repair as assessed by the CCS (Table 4) after 1 year. In comparison, Tollens et al¹¹ mentioned a significant number of patients who experienced a painful sensation when wearing tight clothing (12%) and/or complaint of a foreign-body type sensation (5%). Iversen and colleagues²¹ only reported 'chronic pain' in 1.3%. Many clinicians define chronic pain as a pain lasting for more than 3 months despite the fact that the injury has healed. This definition is too broad, unclear and makes it therefore difficult to objectively compare results arising from different studies. Thus, assessing QoL rather than a VAS pain score after hernia surgery is ultimately more accurate and should be preferentially employed when comparing results⁸.

Conclusion:

In summary, we believe that the merits of our short and long term results directly relate to a meticulous repetition of easily reproducible surgical steps for the placement of the self expandable dual mesh. In order for surgeons unfamiliar with this technique to achieve similar outcomes, there are several key points that should always be abided by: we recommend using

this approach for small defects 1-3cm in diameter, avoiding using a large-sized patch, fixing the positioning straps with minimum tension, always closing the fascia defect .

Financial Interest: The authors have no financial interest with Bard^R .

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