

Original Research Article

Outcome of primary ventral hernia repair with monofilament polyester composite ventral patch in a community-based hospital

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Received: 05 February 2024

Revised: 05 March 2024

Accepted: 08 March 2024

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ABSTRACT

Background: Ventral hernia repair (VHR) is one of the common surgical procedures carried out in general surgery. This study assessed the post operative outcomes in patients with primary ventral hernia undergoing repair using monofilament polyester composite ventral patch Parietex™ Covidien (PCO-VP).

Methods: A prospective single proportion observational study of 54 patients undergoing open VHR for primary ventral hernia with the PCO-VP in a community-based hospital was carried out. The patients were followed up for a period of one year from day of surgery. Primary outcome was recurrence, and secondary outcomes were reoperations and complications including seroma, hematomas, abdominal wall abscess, wound infections, and mesh infections.

Results: Our sample size of (n=54) included 35 (65%) females and 19 (35%) males with a mean hernia defect diameter of 3.5±0.4 cm. 83% (45) underwent elective surgery (EL) and 17% (9) underwent emergency surgery with a mean operative time of 98.5 minutes, 11% (n=6) patients needed alteration of the technique and 20% (n=11) patients needed mesh repositioning, 12 adverse events were noted during the hospital stay. No mesh infections, early recurrences, readmissions or revision surgeries were noted. Patients had a average Carolina comfort scale score of 4/115 noted at the end of study.

Conclusions: The use of PCO-VP to repair primary ventral hernia yielded nearly nil early recurrence rate, low postoperative complications and high satisfaction ratings, PCO-VP repair is a highly effective method for small and moderate size ventral hernias in both elective and emergency setting.

Keywords: Hernia, Ventral hernia, Composite patch, Parietex

INTRODUCTION

Surgical repair of ventral hernia has come up a long way starting with primary suture closure of defect (Mayo repair) which was associated with recurrence rates of upto 40%.¹ Usage of prosthesis in the form of meshes even for small ventral hernias have been shown to reduce the incidence of recurrence in open hernia repairs.²

Use of meshes have been associated with adhesions, bowel injury, mesh failure and inflammatory reactions. To

overcome these drawbacks, composite meshes were devised to get better results and significant reduction in the incidence of adverse effects. But the ideal composite mesh and the position of the mesh is yet to be agreed upon in VHRs. Even with use of composite meshes, there have been problems encountered like improper deployment, fixation, mesh integration, conformability with the abdominal wall and formation of enteric fistulas.

The ideal prosthesis should integrate functionally with the abdominal wall with minimal inflammation to overcome

these shortcomings. Self-expanding mesh devices which are currently being used are introduced through the defect into the peritoneal cavity through an incision at the level of the hernia.³ However, clinical studies have revealed cases of improper deployment, inadequate fixation, bowel related complications and higher recurrence rates compared to traditional retromuscular mesh placement.⁴ To overcome the above problems, a monofilament polyester composite ventral patch PCO-VP is being used.

PCO-VP-Parietex™ is a 2nd generation composite mesh specifically designed for repair of small to moderate size ventral hernia defects of upto 4 cm. It contains a dual-facing mesh composed of a nonabsorbable 3D monofilament polyester textile as mesh filament with large pores (1.5×1.8 mm) which ensures adequate tissue ingrowth between the pores and hence helps in proper tissue incorporation and abdominal wall reinforcement. It has a resorbable collagen barrier on one side to limit visceral adhesions. Mesh conforms to the abdominal cavity due to the expanders; the mesh handles help in stretching the mesh adequately and the flaps help to hold the patch in place when the trans fascial sutures are placed. This peripheral fixation to the abdominal wall helps in the process of the tissue integration and ingrowth.¹

Recent studies in animal models have showed better outcomes compared to other composite devices. Studies in humans have also shown better outcomes with patient acceptability and reduction in the rates of postoperative adhesions. This study assessed the post-operative outcomes of patients with primary ventral hernia, undergoing surgical management with PCO-VP and using the global Carolinas comfort scale (CCS) as a tool to assess the physical quality of life of the patients in the post-operative period.⁵

METHODS

The study was a prospective observational study undertaken after approval of the scientific advisory committee and the internal review board and ethical committee at Dr. Rangarajan Memorial Hospital, Sundaram Medical Foundation, Chennai during the period from October 2020 to September 2022.

The study followed 54 patients for a period of one year from the day of surgery after obtaining the informed written consent.

Study population

Inclusion criteria

All patients aged ≥18 years with primary ventral hernia (umbilical, epigastric, paraumbilical) with defect of size less than 4 cm who consented for being included in the current study.

Exclusion criteria

Patients who were not willing to participate, or who could not be followed up during subsequent hospital visits, patients with ventral hernia abdominal defect more than 4 cm in the greatest diameter, patients who were pregnant, patients with a history of surgery for hernia at the same location of repair, patients with a body mass index (BMI) >35 kg/m² and patients with an American Society of Anesthesiologist (ASA) score ≥4 were excluded from the study.

Study procedure

Demographic details, clinical examination and history were collected during the time of admission and during preoperative evaluation. Type of surgery (elective/emergency), chief complaints were all recorded preoperatively. Duration of surgery, intraoperative events like type of hernia, defect size, size of the mesh used were recorded during surgery. Intra operative complications like bleeding, injury to bowel, change of technique and need for additional fixation were noted.

Clinical assessment was performed in the immediate postoperative period during the hospital stay, where the wound was inspected on the 1st post-operative day, and at regular intervals till discharge. Comorbid illnesses were addressed and vitals serially monitored. Specific treatment given for specific problems like need for potassium supplementation in hypokalemia, ileus, need for additional doses of antibiotics in cases of strangulated hernia, need for oxygen supplementation and any other special medications if needed were recorded.

The number of analgesics given through IM/IV and oral routes were recorded and incidence of early recurrence, bleeding, infection, seroma and re-explorations if any during the hospital stay and in the follow up period was recorded.

Serial follow ups were done at 2 weeks, 1 month and 12-month periods after surgery. At each regular follow up, patient was assessed for potential complications by direct interviews and clinical examinations, radiological examinations if warranted, and the quality of life through CCS questionnaires and the details were charted.

Data analysis was done both manually and by computer. Calculated data was arranged in a systemic manner and presented in various tables and figures. P values were calculated. P<0.05 were considered statistically significant.

Statistical methods

All the collected data was entered in MS excel and SPSS-19.0 (statistical packages for social sciences) version and used for statistical analysis. Data was analysed for the incidence of complications and Chi-square tests was done to compare the incidence of complications with age, gender, type of hernia and also the follow up details at 2

weeks, 1 month and 1 year. P value was considered significant if $p \leq 0.05$. Mean was calculated for age, BMI, duration of surgery and hospital stay and other variable parameters.

RESULTS

The study included 54 patients of which 65% were female (35) and 35% were males (19). The mean age was 51 years (range, 22 to 82 years). The mean BMI of the patients was found to be 27 (range, 17 to 35). It was noted that majority of the patients 41% (n=22) were overweight with BMI between 25-29.9, 28% (n=15) were obese, 28% (n=15) were within ideal body weight and 3% (n=2) were under weight. Obesity has been already established as an independent risk factor for ventral hernia.⁶

Nearly 98% of the patients (53/54) were symptomatic. Only 1 patient (2%) was asymptomatic who had been diagnosed to have ventral hernia on routine check-up and opted for elective surgery (EL). Among the study sample 63% (n=34) presented with chief complaint of swelling over the umbilicus, 17% (n=9) presented with a swelling above the umbilicus (supra umbilical), 18% (n=10) presented with swelling below the umbilicus (infra umbilical/ para umbilical) and 1 (2%) patient presented with gross abdominal distension with umbilical swelling. 42 (78%) patients had significant past medical or surgical history. The hernia was reducible in 59% of the patients (n=32), partially reducible in 9% (n=5), irreducible in 32% of the patients (n=17). It was noted that in 2 patients with large irreducible hernia, the skin had thinned out over the hernia.

Among the study population 83% (n=45) were admitted for elective surgery. The remaining 17% (n=9) patients were admitted through the emergency room and required emergency (EM) surgery on the day of admission.

During surgery, the defect size was measured and patch size was used accordingly. The mean size of the defect was 3.5 ± 0.4 cm with greatest being 4 cm and least being 2.8 cm. Accordingly 8.6 cm patch was used in 94% (n=51) patients and 6.6cm patch was used in 6% (n=3) patients. The average duration of surgery was 98 minutes (average of 98.5 ± 26 minutes) the longest duration being 180 minutes and shortest being 70 minutes.

Nearly 89% (n=48) of the patient underwent routine procedure with no alteration of technique, whereas 11% (n=6) patients needed slight alteration of technique in terms of adhesiolysis (n=2), need for additional laparoscopic port (n=2) and abdominal lavage (n=2). During surgery there were no iatrogenic bowel injuries (n=0), but bowel adhesions were noted in 5.5% of cases (n=3), 2 patients had congested bowel, and 2 patients had constriction ring causing obstruction with proximal bowel dilation and oedema. The bowel was examined and replaced when it was deemed viable. The other 92.5% (n=50) patients had healthy bowel. 20% patients (n=11)

needed repositioning of mesh after laparoscopic visualisation for adequate cover and proper integration before the fixation stitches were placed.

The 96% (n=52) of the patients went through surgery without any adverse effects whereas the remaining 4% (n=2) required intensive care post procedure. Both these patients were taken up for emergency surgery, one of them had presented with obstruction and had persistent metabolic acidosis with respiratory alkalosis and shock for which the patient required post op ventilation and the other patient presented with irreducible hernia and bronchial asthma which needed continuous cardiac monitoring in view of perioperative bradycardia. There were no events of excessive bleeding, or need for additional fixation or any other significant complications during surgery.

The average duration of hospital stay for the patients was about 2.62 ± 1.5 days noted with the longest stay about 10 days and the shortest being 1.5 days. In the postoperative period, there were 3 patients who had complications related to the mesh repair and 7 patients who had complications not directly related to the mesh repair but attributable to the surgery. Complications that were associated with mesh repair: 5.5% patients (n=3) had seroma noted during the hospital stay, there were no hematoma, surgical site infections, early recurrence or need for re-exploration during the post operative period.

The 17.5% (n=7) of patients encountered 9 events of other complications among which 7 events related to ileus, 1 event of respiratory depression and 1 event of shock. Of the 7 events of ileus, 4 were related to hypokalemia who recovered with correction and 3 events of generalised ileus which recovered after bowel rest. Each patient on an average needed 4 doses of IM analgesics in the form of opioid analgesia, greatest being 12 doses and least being 2 doses and 4 doses of oral analgesics in form of paracetamol, greatest being 6 doses and least being 2 doses during their hospital stay.

The follow up evaluations were done at the end of 2 weeks, 1 month and 1 year where clinical examinations and questionnaire was administered and data collected. Around 61% (n=33) of the patients needed analgesics in form of oral paracetamol at the end of 2 weeks, 19% (n=10) patients needed analgesics at the end of 1 month and no patients needed any form of analgesia at the end of 1 year. It showed that none of the patients experienced chronic pain with PCO-VP repair.

Skin infection was noted in 5% of the patients (n=2) at the end of 2 weeks. They were treated accordingly and no wound infection was noted at the end of 1 month and no late infections were noted at the end of 1 year. No recurrences were noted throughout the study upto a period of 1 year (n=0). Seroma was noted in 27.5% of patients (n=15) noted at the end of 2 weeks which was persistent upto 1 month in 9% (n=5) of the patients. No seroma was noted at the end of 1 year.

Other rare events reported were 5 (9%) patients had skin edge necrosis at end of 2 weeks and required topical ointments, 1 patient reported constipation at 2 weeks and 1 patient had skin ecchymosis over wound site at end of 2 weeks. Constipation, skin necrosis and skin ecchymosis were not reported at 1 month and 1 year follow up.

The 35% (n=18) of the patients required additional medications other than the regular medications for comorbidities at the end of 2 weeks in form of topical ointments for the surgical wounds (n=12), laxatives to treat constipation (n=7) and 9% of the patients (n=5) needed additional medications at the end of 1 month as laxatives (n=3), and topical ointments (n=2). No patients required additional medications at the end of 1 year. No recurrences or mesh infections were noted during the entire period of study. Need for additional imaging, readmission and repeat surgery was not necessary.

The 42.5% of the patients (n=23) returned to their routine work by the end of 2 weeks, 89% of them (n=48) by the end of 1 month. All the patients (n=54) were able to do their routine work at the end of 1 year. Patient satisfaction

and physical quality of life index was assessed through the CCS, through questionnaires provided at follow up visits.

The p values of outcomes measured between 2 weeks and 1 month were about 0.0001 which were statistically significant with decrease in overall incidence of complications and improvement of quality of life when compared with between 1 month and 1 year data.

The average score of CCS recorded was 40 at end of 2 weeks maximum value of 77 and a minimum value of 10, average of 18 at end of 1 month with a maximum value of 41 and a minimum value of 3, average of 3.33 the end of 1 year with maximum value of 9 and minimum value of 0. The average score was between 0 to 5 showed scoring of 2 (1.73) at the end of 2 weeks, 1 (0.78) at the end of 1 month and 0 (0.15) at the end of 1 year showing a decreased trend. Among the study population, 3 patients (6%) were not satisfied with the procedure at the end of 2 weeks, but the patients were satisfied with the procedure at the end of 1 month and 1 year. The entire study population was satisfied with the surgery and outcome at the end of the study.

Table 1: Demography and operative statistics.

Demography statistics		Operative statistics	
Characteristics	Total=54	Characteristics	Total=54
Male	19	Elective	45
Female	35	Emergency	9
Age median (in years)	51	Defect size	3.5±0.4 cm
BMI median (kg/m ²)	27 (17-35)	Mesh size (cm)	
Asymptomatic	1	8.6	51
		6.6	3
Supraumbilical swelling	9	Mean duration of the surgery	98.5±26 minutes
Umbilical swelling	34	Alteration of technique	6
Infra/ paraumbilical swelling	10	Need for fixation	0
Past medical history	42	Repositioning of mesh	11
Reducible hernia	32	Average hospital stays	2.62±1.5 days
Partially reducible hernia	5	Surgery related complications	3 (seroma)
Irreducible hernia	17	Non-surgical complications	9 (7 patients)

Table 2: Follow up statistics.

Parameters	2 weeks	1 month	1 year
Need for analgesics	33	10	0
Need for other medications	18	5	0
Wound infection	2	0	0
Recurrence	0	0	0
Return to work	23	48	54
Complications	15 (seroma), 5 (skin necrosis)	5 (seroma)	0 (seroma)
CCS	40	18	3
Patient satisfaction	51	54	54



Figure 1: Parietex-composite ventral patch.

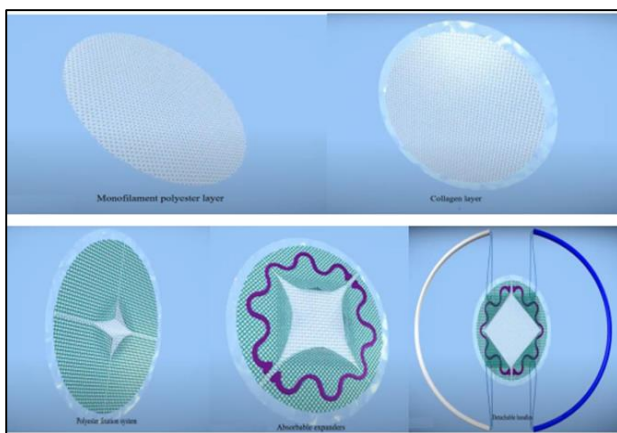


Figure 2: Parts of Parietex.

Carolinas Comfort Scale questionnaire (maximum: 115 points).		
No	Question	Scores
1	While laying down, do you have Sensation of mesh Pain	0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A
2	While bending over, do you have Sensation of mesh Pain Movement limitations	0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A
3	While sitting up, do you have Sensation of mesh Pain Movement limitations	0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A
4	While performing activities of daily living (getting out of bed, bathing, getting dressed), do you have Sensation of mesh Pain Movement limitations	0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A
5	When coughing or deep breathing, do you have Sensation of mesh Pain Movement limitations	0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A
6	When walking or standing, do you have Sensation of mesh Pain Movement limitations	0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A
7	When walking up or down stairs, do you have Sensation of mesh Pain Movement limitations	0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A
8	When exercising (other than work-related), do you have Sensation of mesh Pain Movement limitations	0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A

Patients were asked to answer each question scoring 0 for no sensation of mesh, no pain, or no movement limitations and up to 5 for the worst symptoms. N/A: Not applicable.

Figure 3: Carolina comfort scale.⁷

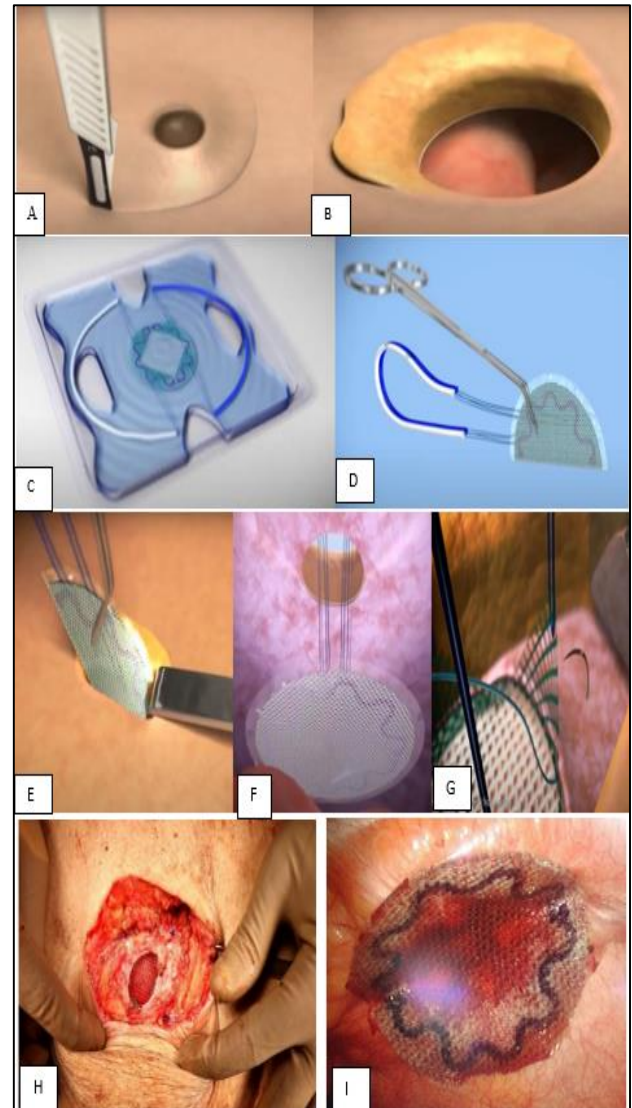


Figure 4 (A-I): Steps in deployment of Parietex patch-skin incision, excision of sac after reducing of contents, immersion of device in sterile distilled water, folding of device, introduction of device into the abdomen defect, spreading of device and pull of flaps, fixation of wings, intra op appearance post fixation and mesh lie intraperitoneal post fixation.

DISCUSSION

This study looks at the post-operative outcomes of VHR with a monofilament polyester composite ventral patch Parietex PCO-VP.

In this study, a diverse population was represented with wide demographic characteristics and variable medical history. Data yielded suggested that PCO-VP could be done without wide restrictions and demographic characteristics had no influence over the outcome.^{8,9}

In our study population, a higher incidence of primary ventral hernia among females was noted which can be attributed to increased intra-abdominal pressure during

pregnancy, obesity, prior history of abdominal surgery, stretching of the abdominal musculature and the presence of adipose tissue which acts to separate muscle bundles and layers and weakens the aponeurosis and musculature.¹⁰

In this study, incidence of ventral hernia was seen more in patients between 40-50 years of age indicating more prevalence among the middle-aged population. Prevalence was about 5% in patients below 30 years of age. In contrast to Jaykar et al study of ventral hernias in 2017 where prevalence of ventral hernia was noted to be higher in the age group between 61-70 years. Influence of age on ventral hernia is varied and non-contributory.¹¹

The average BMI of our study population was 27 indicating an overall increased prevalence of ventral hernia in the overweight and obese population. Maia et al study on ventral hernia and obesity suggested that ventral hernia among obese population was mostly due to the lax abdominal wall and adipose infiltration in between the tissue planes thus causing hernias.¹²

In our study, 98% were symptomatic with at least one complaint. The predominant complaint being abdominal wall swelling warranting repair to relieve patients' discomfort and prevent subsequent complications of incarceration, pain and strangulation. Repair of ventral hernia is recommended as early as possible before the complications arise.¹³

In this study, nearly 78% of the population had a significant past history of comorbidities such as systemic hypertension and diabetes mellitus which were adequately managed. Comorbidities once properly optimised and controlled do not hinder VHR and lead to reduced postoperative complications. Krpata et al study on ventral hernia suggested that increased postoperative complications were observed among the patients with comorbidities which were left uncontrolled.¹⁴

The 83% of patients underwent elective surgery and 17% underwent emergency surgery. It was demonstrated that this repair with PCO-VP could be done in both emergency and elective setting irrespective of the state of hernia with no added burden for the surgeon and the patient with respect to the duration of surgery and adverse effects. It was noted that patients who underwent emergency surgery stayed longer and had more wound related complications. Use of PCO-VP in emergency surgery can be done safely when there is no evidence of peritonitis and spillage.¹⁵

The average duration of the surgery was 98.5 minutes. This was comparable to Beervolt et al study on PCO-VP where the average duration of the surgery was about 84 minutes indicating that repair with PCO-VP can be done in a time efficient manner and can be easily reproduced indicating ease of deployment and fixation by surgeon.¹ Alteration of technique was needed only in 11% during surgery and need for laparoscopic repositioning 20% during surgery

suggests that handling and deployment of mesh in place was easy and not highly demanding. There was no need for additional fixation of mesh, establishing that mesh deployment was adequate and fixation of 4 flaps provided sufficient traction. Re-positioning of mesh prior to fixing with laparoscopic visualisation helped to ensure adequate deployment, prevented folding and avoided cupping effects. Thus, emphasising the need for laparoscopic visualisation for confirmation.¹

There were less adverse events noted in the immediate postoperative hospital stay amounting to a total of 12. Three events which were attributable directly to the surgery were related to hernia site seroma formation. The rest of the adverse events amounted to ileus (hypokalemia/general) and shock which were attributed to the degree of state of contents encountered during surgery and general status of the patient. This is in comparison to Berrevoet et al study, where they experienced 121 adverse events among 31% of the study population. PCO-VP repair can therefore be done with minimal adverse events.¹

During the follow up period, nearly 61% of the patients' needed analgesics at the end of 2 weeks, and the need for analgesics showed a falling trend with only 19% of patients requiring analgesia at the end of 1 month and almost no patients requiring analgesia at the end of 1 year. From this study, it is observed that there is no incidence of chronic pain whereas Berrevoet study showed the incidence of chronic pain to be 3% of study.²

The 35% of patients required medications other than analgesics and regular medications for comorbidities in form of topical ointments for incision site, laxatives for supplementing bowel habits and antacids for gastric discomfort. Such requirement also showed a decreasing tendency with only 9% requiring medications at end of 1 month and no patients requiring additional medications.

Wound infection was noted in 1 patient with infection restricted to the level of skin at the end of 2 weeks, which was treated and not observed in the subsequent visits at 1 month and 1 year follow up. No new infections were identified in between. Surgical site seroma was noted in 28% at the end of 2 weeks in mild to moderate quantities, among which 9% patients had persistent seroma at end of 1 month, no patient exhibited seroma at the end of 1 year of the study.

No evidence of mesh infection was noted throughout the study. These were comparable to the Beerevoet et al study where similar results were observed. However, this is in contrast to Nguyen et al in their study on VHR who concluded that repair with synthetic meshes was associated with a higher incidence of seroma and surgical site infections.¹⁶

Almost 42.5% of the patients (n=17) returned to their normal lives and routine work within 2 weeks after procedure and on further follow up it was observed that

89% patients resumed normal work by the end of 1 month suggesting that PCO-VP had little to no restriction on the daily activities and comfort of the patient. No early recurrences early or at the end of 1 year were observed. CCS scale assessment on the physical quality of life index in patients showed a favourable declining graph results with the highest average score of 40 at the end of 2 weeks which had favourably declined to 18 at the end of 1 month and to 3 at the end 1 year. This decline states that there was progressive increase in the physical quality index and patients were comfortable with the device. 94% of the patients were satisfied with the procedure at the end of 2 weeks. The dissatisfaction at 2 weeks were attributed to patients who had a prolonged and difficult hospital stay, though all the patients were satisfied with the procedure at the end of 2 months and 1-year post procedure.

Limitations

PCO-VP repair was done only when the defect size was less than 4 cm, larger defects require conventional composite meshes where PCO-VP cannot be deployed to ensure proper cover. This study excluded patients who were morbidly obese BMI>35, hence results of the outcomes of PCO-VP in these patients are lacking.

CONCLUSION

Repair with PCO-VP can be done in patients irrespective of age above 18 years, gender, prior medical comorbidities and type of primary ventral hernia. It was shown that similar comparable outcomes were observed among the study population irrespective of the study variables. It can be done routinely in both elective and emergency settings with minimal adverse effects. With use of laparoscopic assisted positioning and deployment of the device, adequate positioning and mesh overlap was ensured thereby reducing recurrences. Repair can be done with reduced operative time, reduced postoperative period of stay in hospital and reduced requirement of analgesics. There were no difficulties in deployment and fixation during usage of PCO-VP during surgery suggesting easier technique that could be easily acquired and practiced. It showed minimal postoperative adverse effects and early return to routine work. Immediate follow up results are also favourable with low to nil early recurrence, reduced postoperative or chronic pain and no evidence of infections or requirement of readmission or redo surgery during the study period. Patients followed up reported lower values in CCS indicating patients had high physical quality of life and all the patients were satisfied at end of one year. PCO-VP Parietex prosthesis can be recommended to be used as the first line of choice in repair of small to medium sized primary ventral hernia.

Recommendations

Study excludes patients under 18 years of age and patients with BMI >35 and patients were followed upto a period of 1 year. Outcome analysis study is needed for repair of

primary ventral hernia in the pediatric population. Further follow up for an extended period with an extended spectrum of patient factors is required to find out late complications and to determine the efficacy of the device in the long term.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Kumar HR, Solomon AA, Veeraraghavan R. Outcome of primary ventral hernia repair with monofilament polyester composite ventral patch in a community-based hospital. *Int Surg J* 2024;11:598-605.