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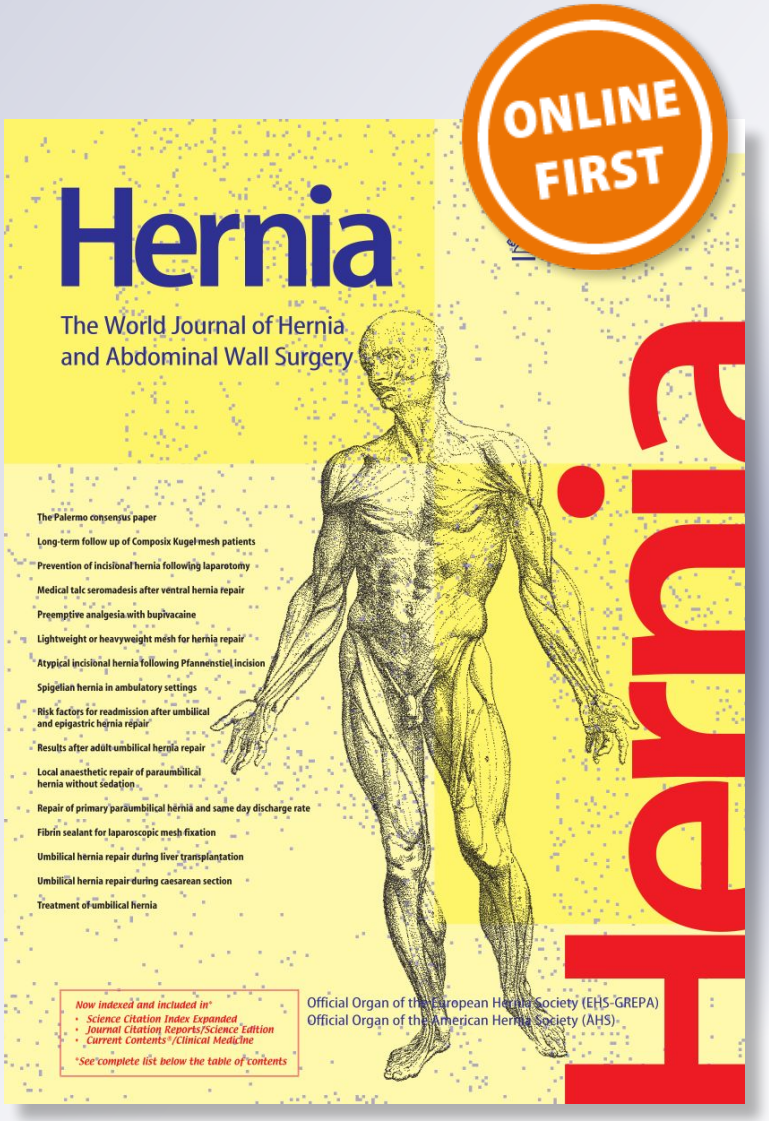

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ORIGINAL ARTICLE

Infection and recurrence rates of the C-QUR V-Patch™ in ventral hernia repairs

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Abstract

Purpose Ventral hernias are a common surgical issue and a myriad of surgical mesh designs has been developed for their treatment. Many of these new mesh designs have not been extensively tested and their complications rates are largely unknown. The C-QUR V-Patch Mesh™ combines a unique knit construction polypropylene mesh with an omega-3 fatty acid coating. There has only previously been one reported study investigating this mesh.

Methods A multicentre cohort study, with a single surgeon, of 168 consecutive patients with ventral hernias underwent repair using a standardized open pre-peritoneal approach with the novel C-QUR V-Patch Mesh™ between January 2013 and June 2015. A median follow-up of 37 months was completed to assess the patients for hernia infection and recurrence rates. Mesh infections were further classified into early and late infections for further subgroup analysis.

Results Infection and recurrence rates of the C-QUR V-Patch® were compared with similar published results of alternate mesh designs. Surgical site infection rates were 7.7% and recurrence rates were 2.4%. The infection rate rose dramatically to 19.0% when the mesh was placed intra-peritoneally. The rate of mesh explantation was 2.4% and usually occurred between 4 and 12 months post-operatively. Smoking was the only factor that appeared to be associated with recurrence.

Conclusion This series finds that recurrence rates associated with the novel C-QUR V-Patch Mesh™ is acceptably low; however, infection rates appear to be higher when compared to comparable products for use in ventral hernia repairs.

Keywords Umbilical hernia · Ventral hernia · Mesh

Introduction

Small-to-medium-sized ventral hernias (umbilical, epigastric and incisional) are a very common general surgical problem. They are the second most common form of abdominal hernia representing about 26% of all abdominal hernias [1]. The significance of their burden to the health budget is large, costing an estimated US$3.2 billion per year in the United States alone [2].

In 1959, Usher and his colleagues described a new technique of hernia repair utilizing a Marlex mesh, which was a combination of a crystalline polypropylene and high-density polyethylene material [3].

This type of plastic was shown to resist infection and not fragment when deployed and is the same material of many mesh products available today. Mesh repair offers the advantage of significantly reducing recurrence rates over suture repairs [4].

It has been nearly six decades, since meshes were first deployed in hernia repair and a myriad of mesh products have come on the commercial market. The C-QUR V-Patch Mesh™ (Maquet Gentige Group, Germany) has not yet been sufficiently investigated and data on its complication rates are largely unknown. This study aims to investigate the infection and recurrence rates of this novel mesh product and compare this with published data of comparable mesh designs.

C-QUR V-Patch™ Mesh

The C-QUR V-Patch Mesh™ is designed for repair of small-to-medium-sized hernias such as epigastric, umbilical, or incisional defects from laparoscopic equipment. It is

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available in three sizes: small (4.3 cm), medium (6.4 cm), and large (8 cm). It is a combination of a polypropylene layer with a non-adherent layer consisting of Omega 3 fatty acid. This two-layer construction is sewn together around an omega 3 fatty acid coated stabilizing ring. It comes with two fixation straps for device positioning.

The advantages of this smaller patch design include its ease of handling and memory properties. The memory of the mesh allows it to be accurately seated through a small incision and it will retain its shape once appropriately positioned. Thus, the patch allows for smaller incisions and more accurate placement.

Materials and methods

Ethical approval

Ethical Approval for this research was obtained through The Avenue Hospital Ethics Committee and was conducted in accordance with the Australian National Statement on Ethical Conduct in Human Research (2007).

Study design

An observational cohort study involving 200 consecutive patients undergoing a ventral hernia repair with deployment of the C-QUR V-Patch™, between August 2011 and June 2015 was performed through a search of medical records. A single surgeon (CL), at one of either three institutions, operated on all the patients.

Patients were evaluated by the surgeon approximately 1 week post-operatively to assess the integrity of the wound. If any complications were identified, additional follow-up with the surgeon was arranged. However, in most cases, no further review was required.

Long-term follow-up was completed via telephone survey post-operatively assessing for any potential post-operative complications that may have arisen. Infections were followed up by clinical examination, with most having a wound swab. Recurrence was assessed via the telephone interview. The median follow-up was 37 months, with a range between 14 and 65 months.

Inclusion criteria

All patients who had undergone a ventral hernia repair utilizing the C-QUR V-Patch Mesh™ between August 2011 and June 2015.

Patient questionnaire

Long-term follow-up was via a telephone interview. Patients were assessed through a standardized questionnaire, screening for potential complications such as mesh infection, hernia recurrence and need for re-operation. If the patient had experienced a mesh infection, further questioning was undertaken to elicit if the infection was early (< 28 days) or late (> 28 days) in the post-operative period.

Statistical analysis

Statistical analysis was conducted using IBM SPSS Software™ and Pearson Chi-square analysis was used for categorical variables.

Operative technique

An open repair was performed in all patients. Nearly, all operations were performed under local anaesthesia with sedation, usually as a day case. The hernia defect usually ranged from 1 to 4 cm. Some patients who received a large mesh stayed in hospital overnight. Umbilical and paraumbilical hernias involved division of the umbilical stalk. This was repaired at the end of the procedure. Usually, the rectus envelop was not opened and the mesh was placed in a pre-peritoneal position deep to the posterior rectus sheath (Fig. 1).

Occasionally, there was dense adherence between peritoneum and the posterior rectus sheath. In this instance, the posterior sheath was opened and the mesh was placed in a pocket created superficial to the posterior rectus sheath. This was done to prevent breaching the peritoneum. Rarely, however, the pre-peritoneal plane was unable to be defined and the mesh was placed intra-peritoneally, usually in the

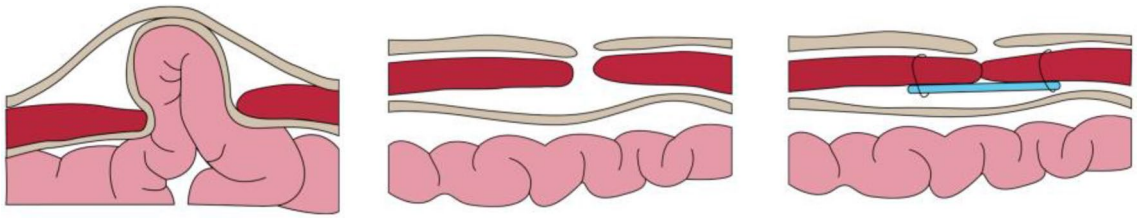

Fig. 1 Placement of C-QUR V-Patch Mesh™ in a pre-peritoneal position

setting of recurrent hernias. Prophylactic intravenous antibiotics were administered to all patients. Cephazolin was the antibiotic of choice and when an umbilical hernia was repaired, metronidazole was also given.

In all cases, the mesh was sutured to the overlying anterior rectus sheath with interrupted transmuscular 2/0 Ethibond™. The sutures picked up the mesh at its periphery. For a small mesh four sutures were used, for a medium mesh eight sutures were used and for a large mesh twelve sutures were placed. Following fixation, the two tags were cut flush with the mesh. The rectus sheath was then almost always able to be closed transversely using 2/0 Ethibond™. The transverse skin incision was closed with staples.

Results

Patient demographics

A total of two hundred patients were identified as being eligible for the study. All patients were reviewed by the surgeon in clinic usually 1-week post-surgery. 168 of the patients were followed up during the telephone questionnaire, with 31 patients unable to be contacted (16% loss to follow-up). One patient with a background of severe chronic obstructive pulmonary disease died of a respiratory illness unrelated to the hernia repair.

During the 4-year study period, 168 patients underwent a total of 182 of ventral hernia repairs utilizing the C-QUR V-Patch Mesh™. The study population consisted of 112 males (66.7%) and 56 females (33.3%) with a median age of 57 (IQR 46–66). The median body mass index (BMI) was 29 kg/m^2 (IQR 26–32). One hundred and forty-eight (88.1%) of the participants were either overweight or obese, with a BMI that exceeded 25. Eighteen (10.7%) individuals had diabetes and fifty-four (32.1%) of the participants were ex-smokers at the time of their operation, whilst ten (6.0%) patients were current smokers.

The type of ventral hernias operated on consisted of 118 (64.8%) umbilical hernias, 48 (26.4%) incisional hernias, 15 (8.2%) epigastric hernias, and 1 (0.5%) spigelian hernia. Six of the hernias were recurrences referred following a previous operation elsewhere. The number of each size of mesh deployed were 108 (59.3%) small, 50 (27.5%) medium, and 24 (13.2%) large (Table 1).

Table 1 Demographic characteristics of the study population

Population size $n=168$ Number of mesh implants $n=182$	
Gender (male/female) ($n=$)	112/56
Age (median, interquartile range)	57 years (46–66)
BMI (median, interquartile range)	29 kg/m^2 (26–32)
Normal weight < 25	20
Overweight 25-29.9	75
Obese > 30	73
Diabetes ($n=$)	18
Smoking status ($n=$)	
Ex-smoker	54
Smoker	10
Never smoked	104
Type of hernia ($n=$)	
Umbilical	118 (64.8%)
Incisional	48 (26.4%)
Epigastric	15 (8.2%)
Spigelian	1 (0.5%)
Recurrent hernia ($n=$)	6
Size of V-Patch™ Mesh ($n=$)	
Small (4.3 cm)	108 (59.3%)
Medium (6.4 cm)	50 (27.5%)
Large (8.0 cm)	24 (13.2%)
Median operation time per patch size (min)	
Small (4.3 cm)	60
Medium (6.4 cm)	70
Large (8.0 cm)	90

Recurrence

Four patients (2.4%) reported having a clinically significant recurrence of their hernia during telephone interviews. Of these, one patient had an umbilical hernia repair, two patients had incisional hernia repairs and one patient had an epigastric hernia repair. 1 patient who had an intra-peritoneal mesh reported a recurrence. The sizes of mesh involved in the recurrences were one small, two medium and one large sized mesh.

Statistical analysis of perioperative and demographic data found that only smoking proved statistically significant when comparing patients that developed recurrences and those that did not. ($\chi^2=11.47$, $df=4$, $p=0.022$).

Infection

A total of thirteen (7.7%) patients had wound infections post-operatively. Of the patients with wound infections, nine patients were complicated by a wound infection early in the post-operative period (< 28-day post-operation), whilst the remaining four patients established a late infection post-operatively (> 28-day post-operation). The late infections occurred between 4 and 12 months post-operatively, and no late infections were reported after 12 months of follow-up.

Nine of these patients had wound cultures taken. Four patients cultured *Staphylococcus Aureus*, with one of these being Methicillin-Resistant *Staphylococcus Aureus*, two patients cultured *Staphylococcus Lugdunensis*, one patient cultured *Pseudomonas aeruginosa*, one patient cultured

Serratia marcescens, and two patients cultured normal skin flora.

Six of the patients required another procedure to treat the infection. Of these six, four patients required explantation of their mesh, one patient had an exploration and debridement of the infected tissue and one patient had an abscess aspirated. The other infections were treated conservatively with oral antibiotics. Of the patients with early infections, the majority were able to be treated conservatively with oral antibiotics, whilst all the late infections required more invasive treatment. 3 out of the four mesh explantations were due to late infections (Table 2).

Analysis of perioperative and demographic data found smoking to be the only patient demographic to have a statistically significant difference between patients who developed a wound infection and those that did not. ($\chi^2 = 13.097$, $df = 4$, $p = 0.011$).

21 patients had intra-peritoneal mesh placement. Of these, four patients had mesh infection (19.0%), one of which was explanted.

Discussion

Ventral hernias are a common general surgical condition, the treatment of which has undergone considerable change over the last few decades.

Numerous new patch designs have arisen to treat small-to-medium-sized ventral hernias. These include the Ethicon Prolene Hernia System™, Ethicon Proceed Ventral Patch™, and Bard Ventralex Patch™. The infection and recurrence rates regarding these patch designs has previously been published in the literature. However, the C-QUR V-Patch™ has yet to be substantially studied. This is the largest study of the C-QUR V-Patch™ in repairs of hernias of the ventral abdominal wall.

152 patients (90.5%) were operated on using local anaesthesia and sedation, the vast majority as day cases. Many of the patients are obese and have comorbidities which make general anaesthesia a higher risk. 16 patients (9.5%) were operated on using general anaesthesia. We deliberately do not use muscle relaxation when we close the rectus sheath to avoid tension, which may occur after muscle relaxant is reversed. Our criteria for using general anaesthesia is if the defect is so large that the amount of local anaesthesia required would be in excess of what would be considered safe (Table 3).

Our reported surgical site infection rate was 7.7%. The majority of the infections were able to be managed conservatively with oral antibiotics alone and no further complications arose. Four patients had deep infections that required mesh explantation which appears to be a similar rate to other products such as the Ethicon Prolene Hernia System™, Ethicon Proceed Ventral Patch™ and the Bard Ventralex Patch™. It should be noted that studies found in our literature search of other meshes varied widely in their sample size as well as follow-up period. With 168 study participants and a median follow-up period of 37 months, we believe our study was able to adequately assess the long-term complication rates of the C-QUR V-Patch Mesh™.

A similar study performed by Keating et al. on the C-QUR V-Patch Mesh™ found a lower rate of surgical site infections compared to our study (1.9 versus 7.7%). However, the rate of serious infections requiring mesh explantation appears to be similar (2.5 versus 2.4%).

Interestingly, all the patients with late infections in our study were not able to be treated conservatively with oral antibiotics but required interventional treatment such as abscess drainage or mesh explantation. From our study, the chance of salvage of the mesh from a late infection appears low. This could be an area for further research to

Table 2 C-QUR V-Patch Mesh™ early versus late infections requiring invasive treatment

	Early infection	Late infection
Patient 1		Mesh explantation
Patient 2	Wound debridement and vacuum dressings	
Patient 3	Mesh explantation	
Patient 4		Mesh explantation
Patient 5		Mesh explantation
Patient 6		Abscess drained

Table 3 Comparison of the C-QUR V-Patch Mesh™ with other mesh materials

Prosthetic employed	Current study	Keating et al.	Other studies		
	C-QUR V-Patch™	C-QUR V-Patch™ [5]	Ethicon Prolene Hernia System™ [6]	Ethicon Proceed Ventral Patch™ [7–10]	Bard Ventralex Patch™ [11–15]
Study size	168	157	17	24–101	51–152
Infection	7.7%	1.9%	5.8%	4.1–12.8%	2.2–6.0%
Recurrence	2.4%	3.8%	0%	1.7–12%	1.9–8.9%
Explantation	2.4%	2.5%	0%	1.7–5.0%	2.2–3.3%

elucidate the reason behind the relationship between more serious infections and late presentations. The late infections occurred between 4 and 12 months post-operatively and we did not find any late infections that occurred after 12 months of follow-up. Thus, from our study, we suggest that the likelihood of a patient developing a surgical site infection past 12 months is low.

A recent randomised control trial has validated the use of mesh repair in reducing recurrence in small-to-medium-sized ventral hernias measuring 1–4 cm in diameter compared to suture repair [17]. Our reported recurrences from the patient questionnaire remains low. The rate of recurrences reported by Keating et al. appears higher than compared with our study (3.8 versus 2.4%) [5]. It should be noted that formal radiographic evidence or clinical examination was not obtained in all of these patients, a potential limitation of our study. However, patients presented initially with a self-assessed hernia, and therefore, it was reasonable for evaluation to be again through self-assessment.

Exact measurements for the size of the hernia was not routinely obtained. However, our study did not find a correlation between the size of the mesh used and the rate of recurrence.

The C-QUR V-Patch Mesh™ is designed to be placed either in the intra-peritoneal or pre-peritoneal space. However, pre-peritoneal placement of the mesh is favoured. Previous studies have suggested that an intra-peritoneal placement of the mesh may lead to increased risk of adhesions and infections which can require further more complex surgical interventions [17–19]. Our reported surgical site infection rate of intra-peritoneal mesh is high at 19.0%. However, only two of these required further surgical intervention. In one patient, an abscess was aspirated and the other patient had to have their mesh explanted. Our sample size of intra-peritoneal mesh placement was small but the high infection rate warrants further investigation.

As a result of this study, a higher than desirable infection rate was identified, particularly in patients with intra-peritoneal placement of their mesh. Although operative technique is always a factor, nevertheless there may be reason for concern regarding the C-QUR V-Patch Mesh™ itself. There is anecdotal evidence from other surgeons that this may be the case, and it is thought that the fish oil backing could be implicated.

Conclusion

This is the largest reported study on the C-QUR V-Patch Mesh™. Our findings show that the rates of explantation are similar to those found in studies on comparable products. Although our rate of recurrence is comparable or even better than other studies, our rate of surgical site infection is higher than what we would consider to be acceptable. Moreover, when the C-QUR V-Patch Mesh™ was placed intra-peritoneally the rate of surgical site infection rose dramatically. Therefore, we are hesitant to fully endorse the use of this mesh until further studies demonstrate an infection rate within a more acceptable range.

Compliance with ethical standards

Conflict of interest DC, LB and CL declare no conflict of interest. This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Ethical approval Ethical Approval for this research was obtained through The Avenue Hospital Ethics Committee and was conducted in accordance with the Australian National Statement on Ethical Conduct in Human Research (2007).

Statement of human and animal rights This article does not contain any studies with animals performed by any of the authors.

Informed consent Informed consent was obtained from each of the study participants.

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