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ORIGINAL ARTICLE

Early- Versus Late-Onset Prosthetic Mesh Infection: More than Time Alone

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Abstract Prosthetic mesh used for ventral incisional hernia makes hernia repair surgery simple, effective, and safe. The mesh infection is a formidable complication and bimodal distribution. The differences between early- and late-onset are unknown. This is a cohort study of patients undergoing ventral incisional hernia (VIH) repair from January 2003 to September 2013. Data of specific risk variables were collected from electronic medical record systems in Jinling Hospital. And, the quality of lives was evaluated by WHO Quality of Life-BREF. A total of 102 VIH repair patients were analyzed and followed including the noninfection group and early- and late-onset group. There were significant differences between the early- and late-onset group in clinical manifestation, descriptive analysis of the study population, and postoperative quality of lives. These differences might imply the different pathophysiologic process of early- and late-onset mesh infection. Permanent prosthetic mesh should be used with caution, and the study of intraperitoneal onlay mesh is still needed in long-term follow-up.

Keywords Ventral incisional hernia · Mesh infection · Late-onset · Quality of life

Introduction

Ventral incisional hernia (VIH) is a common complication of abdominal surgery with a reviewed overall incidence of 9.9 % after laparotomy [1]. Since Lichtenstein propose the concept of the tension free hernioplasty [2], it makes hernia repair surgery simple, effective, and safe to use prosthetic mesh. The mesh repair also has been widely used in ventral incisional hernia. And, numerous studies have identified that the mesh repair is superior to tissue repair because of its lower recurrence rate and less abdominal pain [3]. Nevertheless, the mesh is a permanent implant and foreign substance. Therefore, the recipient will take the risk of mesh infection which is a formidable complication of VIH during his entire postoperative life. The majority view is that using prosthetic mesh has higher incidence of infection than non-mesh-using [4]. Once the mesh was infected, hardly any effective treatment could eradicate the foci of infection. The bacterial biofilm or abscess can protect bacterium from being cleaned out by the immune system or antibiotic agents. Cobb and colleagues reported the incidence of mesh infection in VIH repair is up to 10 % [5]. In addition, since the definitions and classification criteria are inconsistent in studies, the true incidence of mesh infections may be underestimated [6].

In the prosthetic mesh infection, the enterocutaneous fistula (ECF) is a severe but rare complication. A cohort study showed that the incidence of ECF after mesh repairs was about 0.5, and 9 % of mesh removal was caused by ECF [7]. Occasionally, we can read cases on ECF following laparoscopic or laparotomy mesh repair [8–10]. But little researches studied the ECF or its classification after mesh repair systematically. Although the annual cases of VIH are approximately 400,000 in the USA [11], little study concerns these patients' postoperative quality of lives (QOL).

As data of mesh infection in VIH repairs were still scarce, we conducted this study. In our general surgery, we had some rare cases of ECF after mesh repair from other medical centers. Therefore, we might get a more comprehensive understanding of VIH mesh infections. The purpose of this article was to provide more clinical data of mesh infection and divide VIH mesh infections into two groups tentatively.

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Materials and Methods

With the approval of the Institutional Review Committee of Jinling Hospital, we retrospectively reviewed all VIH operations performed between January 1, 2003 and September 25, 2013 at the Research institute of General Surgery of Jinling Hospital, China. For this type of study, formal consent is not required. Patients of VIH were identified by searching the characters of "Ventral", "incision", and "Hernia" in the diagnosis of electronic medical record systems. Individual operative notes were physician-abstracted to obtain additional patients, and operation characteristics were obtained. To ensure the quality of data and confirm operation information, 10 % re-abstraction was performed. Patients were included if they underwent a mesh repair, were not urgent, or emergent. And these cases which suffered from mesh infection after VIH repair were selected by two independent researchers.

The primary independent variables were perioperative risk factors and mesh types. The mesh types were divided into polypropylene, polytetrafluoroethylene (PTFE), and composite (polypropylene/PTFE) mesh. The dependent variable was incident postoperative mesh infection. We obtained these data from the medical records and chose perioperative risk factors of postoperative mesh infections according to expert opinions and reviews of the literature [6]. We divided the mesh infections into two groups due to the bimodal distribution of onset: early onset, defined as mesh infections occurring within 6 months of operation; late onset, which exceed 6 months. We defined the boundary as 6 months by analyzing our data (Fig. 1) and previous literature [5, 7]. Also, we were interested in the difference of risk factors and the postoperative QOL between early- and late-onset mesh infections. We evaluated the QOL with WHO Quality of Life-BREF which had been identified as a reliable and effective scale to evaluate the QOL through phone calls and in-person visits [12].

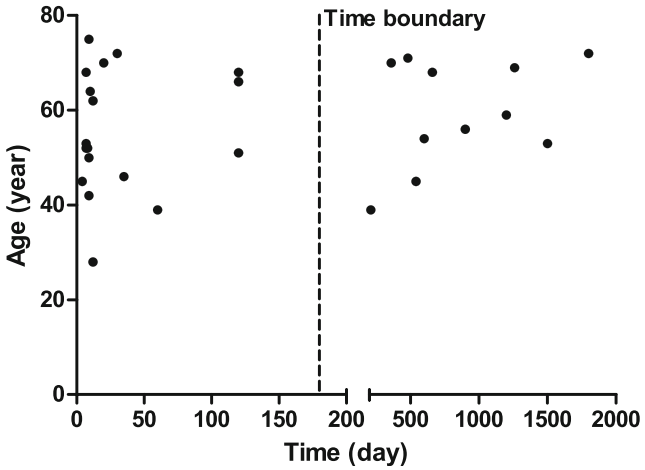

Fig. 1 The bimodal distribution of prosthetic mesh infection and time boundary of 6 months

Scanning the literature, no definitions of mesh infection are available. But we diagnosed all cases in this research as mesh infection based on the signs, symptoms, and imaging examination. And, all cases' operative notes confirmed the diagnosis.

Univariate analyses of demographic and operation-associated factors were performed to describe the study population. Missing data ranged from 0 to 5 % for all independent variables. Shapiro-Wilk W test for testing normality were conducted on all continuous variables. Fisher's exact test and Cochran-Mantel-Haenszel statistics were used to examine differences in groups. $P \leq 0.05$ was considered significant. All statistical tests were performed using SAS Version 9.2 (SAS Institute Inc., Cary, NC).

Results

During the study period, 412 patients with an abdominal wall hernia were identified between 1996 and 2012. Exclusion criteria for this analysis included did not undergo hernia repair (n=154), did not undergo a mesh repair (n=82), umbilical hernia repair (n=49), urgent or emergent operation (n=21), and absence of electronic operative notes (n=4). The study population included 102 patients. Twenty-nine patients suffered from mesh infection after VIH repair. They all underwent open permanent mesh repair. Seven of them underwent VIH repair in our hospital, the other were operated in other medical centers. Two of early-onset patients were cured by antimicrobial treatment and abscess drainage. And, all the rest underwent surgical management to remove mesh.

The signs and symptoms of prosthetic mesh infection had some difference between early and late onset (Table 1). In the early-onset group, more patients presented the sign of pus at the initial incision than the late-onset group. While, late-onset patients tended to present erythema overlying incision. Most late-onset patients' chief complaints were the pain of initial incision rather than the infected fluid.

Descriptive analysis of the study population was summarized in Table 2. Most of the patients were men with a median age of 58 years. The body mass index was significantly reduced in the noninfection group as compared with that of the early-onset group. In preoperative risk factors, the site of prior operative incision had no difference in groups. The incidences of wound infection, sepsis, and malnutrition were low. And almost half of patients smoked. Fourteen percent of noninfection group patients had COPD which was lower than the early-onset group. There were about 10 % diabetic in all groups. The use of steroid was rare. The composition of mesh type was different among groups. In the early-onset group, there were more PTFE mesh (50 %) and less polypropylene (17 %) than in the other two groups. In the late-onset group, the type of onlay repair accounted 27 % lower than in the

Table 1 Signs and symptoms of prosthetic mesh infection

	Early-onset (n=18) (%)	Late-onset (n=11) (%)	P value
Infection[a]			
Pus from incision	78	36	0.03
Erythema overlying incision	11	45	0.05
Sepsis[b]	78	91	0.28
ECF	33	63	0.17
Sinus	6	18	0.27
Other problems			
Pain	39	82	0.03
Small bowel obstruction	6	27	0.13

[a] Some are overlapping

[b] Sepsis diagnosed according to the guideline (12)

noninfection group. While, intraperitoneal onlay mesh (IPOM) repair (36 %) was higher. In the early-onset group, the incidences of drain, enterotomy, bowel resection, concomitant procedure, and operative time were all significantly higher than in the noninfection group. However, the late-onset group did not show these features.

During the median 41 months (rang from 6 months to 84) follow-up, 83 patients responded to the questionnaires. Four patients died and 15 cases were lost to follow-up. The recurrence rate of VIH and result of QOL were given in Table 3. Most of the mesh infection patients' VIH recurred after mesh removal. All of these patients received the second mesh implantation. The recurrence of VIH in the noninfection group (16 %) was lower than in the early-onset group (40 %). In the questionnaires of the WHO Quality of Life-BREF, the noninfection group patients had higher score in quality of life, satisfaction of health, physical health, and psychological health. Besides, early-onset group patients had a worse comment of physical health domain than the late-onset ones.

Discussion

This study was the first one to try to divide VIH into early-onset and late-onset groups and analyze their differences. As early as 40 years ago, Bothra reported the first case of late-onset mesh infection which presented ECF caused by tantalum mesh [13]. And, subsequently, sporadic cases were reported. Recently, we also could read these unusual cases occasionally [14, 15]. But no study systematically investigated this kind of mesh infection. Previous study showed that bimodal distribution of mesh infection and the majority of mesh complications occurred within the first 6 months after operation [5, 6]. Therefore, this study defined the time boundary as 6 months.

We found some slight difference between the early-onset and late-onset group in the signs and symptoms of prosthetic mesh infection. These findings seemed to keep identical with the cases [14, 15]. The late-onset group patients' chief complaints were the local pain rather than the foul discharge which occurred in most early-onset patients. The early-onset mesh infection was significantly associated with BMI, COPD, drain, enterotomy, bowel resection, concomitant procedure, and operative time. However, late-onset mesh infection did not have this association. The result of early-onset mesh infection was in accordance with previous studies [16, 17]. In addition, there were also differences between the two groups in the type of mesh and operation. In the early stage, the PTFE repair had higher infection rate. Although the result did not indicate significant difference, it seemed that more late-onset cases were caused by polypropylene repair. And, the complication of IPOM repair was more likely to present in the late stage. The PTFE mesh has smaller pore diameter, and less tissue grow into the mesh. At the same time, the PTFE has worse resistance to infection. Hawn and colleagues also found that PTFE meshes were explanted earlier than polypropylene meshes by 331 days [7]. Polypropylene mesh is well incorporated but easy to be crumpled in scar tissue. In this study, most late-onset patients' operative notes described that the polypropylene mesh crumpled and adhered toughly to the surrounding tissue with rough surface. More than half of the notes showed that a loop of intestine was densely adhesive to the mesh which had eroded into the bowel wall and caused ECF. It seemed to be necessary to find a balance between infection and corrosion. So, the study which indicated reducing the density or "weight" of biomaterials for hernia repair improved abdominal wall physiology and left behind less foreign body was reasonable [18, 19]. Nowadays, the laparoscopic treatment of VIH is becoming increasingly widespread in the hernia repair field. And, the evidence-based guidelines also recommend the laparoscopic approach is safe and effective [20]. Our result indicated IPOM was a risk factor for late-onset mesh infection. Therefore, the long-term effect of the laparoscopic treatment was still required to be studied.

Almost all of the mesh infection patients had to receive two additional operations, but four late-onset cases' VIH did not recur in surprise. According to our investigation, the early-onset patients had a higher recurrence rate and worse QOL, especially in the physical health domain. But the late-onset ones' QOL of postoperative lives were similar to that of the noninfection ones. The scores of all mesh repair patients were much lower than the norm scores. And, another long-term follow-up studied manifested about 10 % patients complained of clinically relevant pain after incisional hernia repair [21, 22]. Hence, the long-term QOL of these patients remained to be followed up and investigated.

In conclusion, there were several significant differences between early- and late-onset mesh infections. These

Table 2 Comparison of demographics, perioperative risk factors, and operative characteristics among patients with noninfection, early-onset, and late-onset mesh infection

	Noninfection group (n=73)	Early-onset group (n=18)	Late-onset group (n=11)
Patient demographics			
Age, median (range) in years	58 (24–82)	56 (28–75)	60 (39–72)
Male gender	77 %	78 %	67 %
BMI, kg/m^2	24.9*	28.8	25.1
Preoperative risk factors			
Site of prior operative incision			
Midline	49 (67 %)	10 (56 %)	7 (64 %)
Paramedian	11 (15 %)	5 (28 %)	3 (27 %)
Transverse	7 (10 %)	2 (11 %)	1 (9 %)
Kocher	4 (5 %)	1 (6 %)	0 (0 %)
Mcburny	2 (3 %)	0 (0 %)	0 (0 %)
Preoperative wound infection	5 %	11 %	0 %
Preoperative sepsis	4 %	11 %	0 %
Preoperative malnutrition[a]	1 %	6 %	9 %
Preoperative albumin, median (range) in grams per liter	3.8 (2.5–5.0)	3.5 (2.6–4.9)	3.9 (2.8–5.1)
Smoking	42 %	50 %	45 %
COPD	14 %*	33 %	27 %
Diabetes	10 %	11 %	18 %
Steroid use	3 %	0 %	0 %
Operative characteristics			
Mesh type (n, %)	*	**	
Polypropylene	43 (59 %)	3 (17 %)	9 (82 %)
PTFE	9 (12 %)	9 (50 %)	1 (9 %)
Composite mesh	21 (29 %)	6 (33 %)	1 (9 %)
Operative type (n, %)			***
Onlay	44 (60 %)	7 (39 %)	3 (27 %)
Sublay	18 (25 %)	7 (39 %)	4 (36 %)
Inlay	5 (7 %)	1 (6 %)	0 (0 %)
IPOM[b]	6 (8 %)	3 (17 %)	4 (36 %)
Primary hernia repair	92 %	94 %	100 %
Drain	32 %*	61 %	36 %
Enterotomy	5 %*	28 %	18 %
Bowel resection	5 %*	28 %	9 %
Strangulated hernia	3 %	0 %	0 %
Concomitant procedure	14 %*	39 %	27 %
Operative time, median (range) in hours	1.0 (0.3–5.5)*	2.4 (1.0–6.5)	1.1 (0.3–3.5)
ASA 1	3 %	0 %	0 %
ASA 2	49 %	44 %	55 %
ASA 3	45 %	50 %	45 %
ASA 4	3 %	6 %	0 %

* P<0.05 noninfection group vs. early-onset group; ** P<0.05 early-onset group vs. late-onset group; *** P<0.05 late-onset group vs. noninfection group

[a] Malnutrition defined as weight loss >10 % in 6 months prior to surgery

[b] Intraperitoneal onlay mesh

differences mentioned above might imply the different pathophysiologic process. In our opinion, the bacteria infection and technical factors played a major role in the early-onset mesh infection. However, it was the focus of infection and tissue reaction to the mesh which were responsible for the late-onset mesh infection. So, permanent prosthetic mesh should be used

Table 3 Statistics of the follow-up questionnaires

	Noninfection group (n=57)	Early-onset group (n=16)	Late-onset group (n=10)
Recurrence of VIH (n, %)[a]	9 (16 %)*	15 (94 %)**	6 (60 %)***
Recurrence of VIH (n, %)[b]	9 (16 %)*	6 (40 %)	1 (17 %)
Quality of life, mean (SD)	3.2 (0.91)*	2.6 (0.88)	3.1 (0.99)
Satisfaction of health, mean (SD)	3.5 (1.24)*	2.4 (0.81)	3.5 (1.08)
Physical health, mean (SD)	60.8 (19.10)*	41.75 (14.74)**	56.40 (18.86)
Psychological, mean (SD)	54.8 (17.62)*	43.1 (12.57)	52.4 (14.17)
Social relationships, mean (SD)	63.7 (21.14)	66.0 (19.85)	62.4 (14.17)
Environment, mean (SD)	47.05 (15.61)	45.5 (16.76)	46.4 (15.66)

* $P<0.05$ noninfection group vs. early-onset group; ** $P<0.05$ early-onset group vs. late-onset group; *** $P<0.05$ late-onset group vs. noninfection group

[a] Recurrence of VIH after mesh infection

[b] Recurrence of VIH after the second mesh implantation in infection groups

with caution and the study of IPOM was still required in long-term follow-up.

There were several limitations of this article. This was a retrospective cohort study with no standardization protocol for the type of mesh used and no standardized program for deciding if and when to explant the mesh. Thus, potential bias might be introduced from unmeasured confounders. Twenty-two mesh infection patients were from other medical centers, and more than half of them presented ECF which was a severe but rare complication. Therefore, it might have selection bias. Further research was required to verify the differences and discuss the rationality of dividing VIH mesh infections into two groups.

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Conflict of Interest The authors of this research declare that they have no conflict of interest.

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