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The Effect of the Use of Synthetic Mesh Soaked in Antibiotic Solution on the Rate of Graft Infection in Ventral Hernias: A Prospective Randomized Study

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Wound infections and seroma formations are important problems in ventral hernia repair operations using synthetic mesh grafts. The aim of this study was to investigate the effect of the use of synthetic mesh soaked in vancomycin solution on the rate of graft infection. The total number of subjects was 52. The subjects were randomized into 2 groups using a software program. Group 1 (n = 26) was the control group. In group 2 (n = 26), synthetic mesh was soaked in a Vancomycin solution before it was implanted. The patients were compared with respect to demographic characteristics and preoperative, intraoperative, and postoperative variables. There were no significant differences between the groups with respect to the available variables. Seroma development was significantly more common in group 2 ($P < 0.041$). Three patients (5.7%) developed superficial wound infection, and 9 (17%) developed surgical site infection 2–type wound-site infection. No significant difference was found between the groups in terms of infection. The use of synthetic mesh soaked in vancomycin solution had no beneficial effects on the rate of wound-site infection. Future randomized, controlled, large-scale studies using the same mesh and suture types, and meshes soaked in larger spectrum antibiotics are needed.

Key words: Ventral hernia – Surgical mesh – Vancomycin – Surgical wound infection

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Ventral hernia repair (VHR) is a common surgical procedure in general surgical practice. More than 365,000 VHR are performed in the United States alone each year.[1] Use of synthetic mesh significantly reduces recurrence rates, and it is the recommended standard for VHR.[2] VHR operation using mesh is associated with reduced early and late recurrences compared with repairs using primary suture.[3–5] However, the use of mesh may cause small bowel stenosis, surgical field infection, mesh-to-skin sinus formation, and enterocutaneous fistula.[6,7] As with all other synthetic materials, mesh use in VHR also carries a risk of infection.[8] VHR with mesh use is associated with an infection rate of up to 16%.[2,8–10] This significant complication causes increased patient morbidity. Moreover, it leads to removal of synthetic material, prolonged antibiotic therapy, longer hospital stay, additional surgical interventions, and significantly higher costs.[9] Methicillin-resistant *Staphylococcus aureus* (MRSA) is the most common microorganism isolated from the mesh infections.[11,12] Reducing the rate of infection with strains of staphylococcus, the members of skin flora, which are the most common pathogens in mesh infections, may be accomplished by using meshes soaked in Vancomycin solution.[13] Ventral incisional hernia, one of the most important complications of abdominal surgical operations, and the umbilical hernia, commonly observed in obese patients, still cause trouble for surgeons despite technical advances. In particular, synthetic mesh infections after hernia repair lead to significant clinical (patient morbidity and mortality) and social (cost, loss of labor force, etc.) problems. An animal study aiming to reduce these high-morbidity complications found that the use of synthetic mesh materials soaked in Vancomycin (Vancomycin, Abbott, Chicago, Illinois) may reduce the infection rate.[13] One inexpensive method commonly employed by surgeons to potentially reduce mesh infections is to soak the mesh in antibiotic solutions prior to implantation. Despite this common clinical practice, there was no available study to investigate the effect of use of synthetic mesh soaked in antibiotic solution on graft infection. So far, only 2 studies have investigated the effect of mesh soaked in antibiotic solution on infection rates, and both of them were animal studies.[13,14] Furthermore, no prospective clinical study has as yet explored the effect of the use of propylene mesh soaked in antibiotic solution on the infection rate.

The aim of the present study was to investigate the impact of the use of synthetic mesh soaked in Vancomycin solution on the risk of graft infection in a homogenous patient population in which only polypropylene mesh was used.

Material and Methods

Study design

This study included patients who underwent synthetic mesh implantation via open technique for VHR at Adana Baskent University Application and Research Hospital, Department of General Surgery, between November 2013 and October 2014. This study was approved by Baskent University Institutional Review Board. The total number of study participants was 71. Patients who declined operation, underwent laparoscopic VHR, had repair with a technique other than synthetic mesh use, had a simultaneous operation, or had an urgent operation were excluded (17 patients). Synthetic mesh was removed in 2 patients who developed small intestinal perforation or stenosis, and they were excluded from the trial. As a result, 19 patients were excluded from the study. The patients were allocated into 2 groups by the order of randomization according to software (available at http://stattrek.com/site/about.aspx). In group 1 (n = 26), the synthetic mesh was soaked in 0.9% saline solution 15 minutes before implantation. In group 2 (n = 26), the synthetic mesh was soaked in Vancomycin solution (10 mg/mL) 15 minutes before implantation. All patients were evaluated in terms of age, sex, type and number of previous surgical interventions, body mass index (BMI), comorbidities, synthetic material used, previous incision site, surgical technique used for hernia repair, operation time, hernia size, mesh size, suture material used for abdominal closure, amount and dose of antibiotic used for prophylaxis, drain use, time of drain removal, the postoperative day of infection development, types of medical and surgical treatments applied after diagnosing the infection, type of pathogen proliferating in tissue culture, other postoperative complications, wound-site revision, number of revisions, follow-up duration, Valve Anti-Cheat (VAC) system use, early-term recurrence, mesh removal, and mortality. All patients were managed in a single center by the same University Hospital team.

Perioperative period

The patients were admitted the day before the operation. All patients completed a surgical in-

formed-consent form. Skin cleansing was performed the night before the operation if necessary. All patients received antibiotic prophylaxis prior to the operation, before entering the operating room (2 g first-generation cephalosporin (Sefazol, Mustafa Nevzat, Istanbul, Turkey).

Meshes, sutures, and operative procedures

Heavyweight macroporous polypropylene meshes were used for all patients. All meshes used in hernias were fixed by nonabsorbable monofilament polypropylene sutures (Prolene Mesh, Ethicon, Sommerville, New Jersey). Hernia repair with graft was performed under general anesthesia. The hernia and mesh size were determined by the operating surgeon at the operating table. All operations (100%) were considered clean according to the criteria of the National Academy of Sciences/National Research Council.[15] The wounds were routinely reevaluated at the second postoperative day during the first dressing change. The skin sutures were removed at 10th or 14th day after the operation.

Postoperative care

All patients received systemic antibiotic therapy during the first 2 postoperative days, and low molecular heparin was routinely administered. Early mobilization was the rule, usually on the evening of surgery. Patients' abdominal incisions were routinely examined every week after surgery. An abdominal binder was required for 12 weeks after surgery until the date of the first follow-up consultation.

Treatment and documentation of mesh graft infection

All patients were evaluated by the same surgeon after the operation. The diagnosis of superficial surgical field infection was made on the basis of the existence of cardinal signs and symptoms of infection including redness, edema, locally increased temperature, and purulent discharge. A more advanced classification of infections was made according to the current Centers for Disease Control and Prevention (CDC) criteria[16] and included surgical site infection 1 (SSI 1; superficial), SSI 2 (deep surgical field), and SSI 3 (organ/space surgical field) types. In the case of infection, the sutures were removed, and a smear culture from the wound was sent for culture proliferation that dictated the antibiotic therapy. The wound size was measured at the start of infection and during treatment. All patients were managed with periodic dressing changes, wound irrigation, and fluid absorbers on the basis of the European Wound Management Association (EWMA) guideline.[17] A large-sized open wound accompanied by graft infection or a clearly infected graft was treated with the use of VAC. As a general rule, secondary wound closure was avoided because an open wound may have caused activation of infection. Wounds with a large opening, no proliferation in control smear cultures, and adequate granulation tissue were primarily sutured. Antibiotic therapy was regularly continued and adjusted according to the culture results.

Statistical analysis

Statistical analysis was performed using the statistical package SPSS software (Version 17.0, SPSS Inc, Chicago, Illinois). If continuous variables were normal, they were described as the mean ± SD [$P > 0.05$ in Kolmogorov-Smirnov test or Shapiro-Wilk ($n < 30$)], and if the continuous variables were not normal, they were described as the median. Comparisons between sex and BMI were applied using Student t test for normally distributed data. The categoric variables between the groups were analyzed using the χ^2 test or Fisher exact test. Values of $P < 0.05$ were considered statistically significant.

Results

A total of 52 patients underwent open VHR with a synthetic mesh. The demographic variables were not significantly different between groups. Six patients had more than 1 comorbidity, and 3 patients had diabetes mellitus. The study data are summarized in Table 1. The complication rates were higher in group 2. As for the type of complication, seroma development was significantly more common in group 2 ($P < 0.041$). Yet, the overall complication rates were not significantly different between groups. The distributions of the complications are shown in Table 2. There were no significant differences between groups with respect to intraoperative and postoperative variables. These results are presented in Table 3. A total of 12 (23%) patients developed wound infection. Of these, 3 (5.7%) had superficial infection, while 9 (17%) had SSI 2–type wound-site infection. A sample was sent for culture from the wound-site aspiration fluid in 9 patients who developed SSI 2–type wound-site infection; 8 of

Table 1 Demographics and clinical data of the patients

Parameters	Group 1	Group 2	Total
Number of patients, n	26	26	52
Sex, male/female	8/18	11/15	19/33
Age, n (median)	53 (31–74)	54 (31–78)	53 (31–78)
BMI, kg/m^2			
<30	9 (34.6)	9 (34.6)	18 (34.6)
>30	17 (65.4)	17 (65.4)	34 (65.4)
Comorbidities, n (%)	8 (30.8)	17 (65.4)	25 (48.1)
Smoking, n (%)	4 (15.3)	5 (9.6)	13 (25)
Steroids/immunosuppression, n (%)	–	–	–

them had culture proliferation. One patient did not have culture proliferation. Of the 9 patients, 7 were in group 2, and 2 in group 1. No significant difference was found between groups. The 9 patients were compared between the groups and in overall patient population with respect to mean operation time, mesh size, hernia size, and BMI, and no significant difference was observed. The pathogens that proliferated in culture are summarized in Table 4. The incision type of the previous operation was compared between the groups and in the overall patient population, and no significant difference was detected. The most common incision types in both groups were midline, xiphoid to pubis. The incision types are shown in Table 5. Among 9 patients who developed SSI 2–type infection, 5 had seroma and 1 had bleeding prior to infection. All 5 patients having seroma were in group 2. Of 9 patients developing SSI 2, 7 underwent wound-site revision. Three patients received VAC. The synthetic mesh was totally removed in 2 patients and partially in 1 patient. All 3 patients with mesh removal were in group 2. Mesh was preserved via conservative follow-up in 6 patients. Three patients developed SSI 1–wound-site infection, and they received wound care and oral antibiotics. A total of 9 patients underwent wound-site revision. Six (66%) of them had more than 1 revision operation; the mean number of revisions was 2.1 (range, 1–4). Of them, 7 were the patients having SSI 2–type proliferation. None of the patients died.

Discussion

SSI 2 developing after VHR with synthetic mesh continues to be a significant problem for both patients and surgeons. The rate of synthetic mesh infection after VHR ranges from 5% to 16%.[2,10,18,19] However, reporting a standard rate for all complications after VHR mostly yields different results. This is because the patient groups are composed of heterogeneous groups in the published series. For patients in this group, the risk factors for surgical field infections (*i.e.*, infection, seroma, wound dehiscence, or the formation of an enterocutaneous fistula) were not properly differentiated from each other.[18,20,21]

Synthetic mesh infection arising after VHR causes serious complications, including increased patient morbidity, re-operation rates, hospital cost, and hernia recurrence.[8,22] It also leads to wound revision, mesh removal, and abdominal re-operations.[23] Determining methods that are cost-effective, readily available, and easy to use in routine practice to reduce synthetic mesh infections may provide better results for patients undergoing VHR. The majority of synthetic mesh infections are caused by pathogens found in normal skin flora. *Staphylococcus aureus* and *Staphylococcus epidermidis* are the most common bacteria in skin flora.[24] *S aureus* is responsible for more than 75% of all mesh infections.[9] However, a member of Staphylococci family was the causative agent in 3 of 8 patients (37%) with culture proliferation (Table 4). Bacteria of normal

Table 2 Complications after VHR

Complications	Group 1	Group 2	Total	*P*
Seroma formation, n (%)	1 (3.8)	7 (26.9)	8 (15.4)	0.041
Bleeding, n (%)	–	1 (3.8)	1 (1.9)	0.05
Wound infections				
SSI 2, n (%)	2 (7.7)	7 (26.9)	9 (17.3)	0.05
SSI 1, n (%)	2 (7.7)	1 (3.8)	3 (5.8)	0.05

Table 3 Intraoperative and postoperative variables

Parameters	Group 1	Group 2	Total
Surgical technique, n (%)			
Onlay repair (on the fascia)	1 (3.8)	4 (15.3)	5 (9.6)
Sublay repair (behind the muscle)	25 (96.1)	22 (84.6)	47 (90)
Operation time, min (median)	105 (60–240)	110 (60–180)	110 (60–240)
Use of drains, n (%)	24 (92.3)	26 (100)	50 (96)
Size of hernia defect, n (range)	88 (20–300)	81 (12–250)	85 (12–300)
Size of mesh graft used, n (range)	313 (112–450)	303 (50–450)	307 (50–450)
Use of nonabsorbable sutures, n (%)	26 (100)	26 (100)	52 (100)
Type of the mesh graft, n (%)			
Polypropylene mesh	26 (100)	26 (100)	52 (100)
Wound revision, n (%)	3 (11.5)	6 (23)	9 (17.3)
Use of VAC, n (%)	–	3 (11.5)	3 (5.7)
Removal of the prosthetic mesh, n (%)	–	3 (11.5)	3 (5.7)
Use of postoperative antibiotics, n (%)	25 (96.1)	24 (92.3)	49 (94.2)

skin flora are frequently isolated from postoperative wound-site and synthetic-mesh infections. Thus, skin sterilization, reducing mesh–skin contact, and preoperative antibiotic use are important measures to lower the bacterial load of the wound site. Hence, in our study, all patients received prophylactic antibiotic therapy, a proper surgical field cleansing was carried out, and the wound edges were covered by a sterile drape as soon as the mesh was brought into the surgical field. When bacteria breach into surgical incision, the development of mesh infection depends on the bacterial adhesion to the synthetic material. Mesh infection usually contains skin flora, and therefore it probably occurs during mesh placement. The adhesion rate varies by the synthetic mesh used.[13] In our study, all patients received a synthetic polypropylene mesh. This ensured a homogenous group in terms of bacterial adhesion. Likewise, all patients were preoperatively prepared and operated on by the same surgical team. Preoperative care, positioning, and sterilization of the patients were performed by the same ancillary health care team.

Some mesh structures may alter the adherence and biofilm properties of bacteria found in normal skin flora after their contact with synthetic mesh.[9,25] Compared with hydrophilic multifilament polyester mesh, hydrophobic monofilament mesh (polypropylene mesh) has been shown to reduce MRSA growth.[11,22,26] We used a polypropylene mesh in all patients.

Augmentation of the antibiotic level within the surgical wound to reduce mesh infections may be accomplished by various methods. This idea has been based on prophylactic intravenous antibiotic use. However, this application has come into question owing to the systemic side effects of drugs and the lack of a consistent benefit.[27] At this point, novel treatment algorithms and applications have come forth in an attempt to reduce surgical-field infections. Efforts have been made to avoid the systemic side effects of antibiotics and to provide the surgical field with increased antibiotic concentrations.[28] Some mesh manufacturers, therefore, loaded antibacterial agents onto synthetic meshes.[13] All the research and advances aim at reducing the rate of mesh infections that occur after VHR and lead to serious social and medical issues. Despite all advances, however, mesh infections continue to be a serious complication, with a rate of 16%.[2,10] Extremely diverse risk factors may play a role in mesh infections. A study defined coronary artery disease, chronic obstructive pulmonary disease, low preoperative serum albumin, chronic steroid use, and prolonged operative time as the risk factors for surgical-field infections.[21] Of 9 patients who developed SSI 2–type infection in our study, 2 had more than one comorbidity, 1 had chronic obstructive pulmonary disease, 1 had coronary artery disease, and 1 had hypertension. The albumin level was normal in all patients. None of our patients were

Table 4 Bacterial spectrum

Bacterial species	Group 1 (n)	Group 2 (n)	Total (n)
Pseudomonas aeruginosa	–	2	2
Coagulase-negative *Staphylococcus*	–	1	1
Staphylococcus aureus	1	–	1
Enterococcus faecalis	–	1	1
Proteus mirabilis	–	1	1
Escherichia coli	–	1	1
S aureus + E coli	1	–	1

Table 5 Original incision leading to the ventral hernia

Incision type	Group 1, n (%)	Group 2, n (%)	Total, n (%)
Midline: xiphoid to pubis	10 (38.4)	13 (50)	23 (44.2)
Midline: upper abdominal	3 (11.5)	4 (15.2)	7 (13.4)
Pfannenstiel	3 (11.5)	4 (15.2)	7 (13.4)
Right paramedian transrectus	4 (15.2)	1 (3.8)	5 (9.6)
Midline: infraumbilical	2 (7.6)	1 (3.8)	3 (5.7)
Midline: umbilical	1 (3.8)	2 (7.6)	3 (5.7)
Transverse umbilical	1 (3.8)	1 (3.8)	2 (3.8)
McBurney	–	1 (3.8)	1 (1.9)
Flank	1 (3.8)	–	1 (1.9)

using steroids or immunosuppressant drugs. However, operative variables were not considered among the risk factors. Considering preoperative risk factors alone is not sufficient when evaluating surgical-field infections. We evaluated preoperative, operative, and postoperative variables. The effect of the variables on the infection rate was analyzed statistically. A retrospective study encompassing 13 centers demonstrated that the rate of wound-site infection was related to repair technique, preoperative wound infection, smoking, chronic steroid use, congestive heart failure, chronic obstructive pulmonary disease, enterotomy, bowel resection, emergency procedure, prolonged operative time, inpatient procedure, and total hospital stay.[7,18,19] Since our study did not include emergency cases and cases with other concomitant surgeries, the variables such as preoperative wound infection, enterotomy, bowel resection, or emergency procedure had no impact on the surgical-field infection of our patients.

The use of polyfilament mesh, the mesh size, and the onlay mesh position are additional factors affecting mesh infection.[29] The effect of drain use on infection risk is still controversial.[29] In our study, no polyfilament mesh was used in any of the patients, a drain was used in only 2 patients in group 1, and an onlay mesh was placed in only 5 patients. No significant differences were observed in the intragroup and intergroup comparisons of these parameters. Similarly, hernia size leading to the width of dissection and, consequently, the mesh size were not significantly different between groups.

Synthetic meshes used for VHR may be placed in 3 separate anatomic fields: the onlay, sublay (preperitoneal), and intraperitoneal fields. Higher complication rates have been reported in hernia repairs done with synthetic mesh placed in onlay and intraperitoneal fields.[30] We, therefore, prefer sublay repair in our routine clinical applications. An onlay (prefascial) repair was performed in 5 of 52 patients (9.6%), and a sublay repair (retromuscular) in 47 patients (90%). Eight of 9 patients (88%) who developed SSI 2–type mesh infection underwent sublay repair and 1 patient (12%) underwent onlay repair. An increased dissection rate during sublay repair may have contributed to a greater seroma occurrence.

We did not find any statistically significant differences between patient groups and in overall patient group with respect to risk factors for SSI 2–type mesh infection, including smoking, steroid/immunosuppressant medication use, BMI, comorbidity (*e.g.*, diabetes mellitus), hernia size, mesh type, and prophylactic antibiotic use. However, 1 patient in group 1 and 7 patients in group 2 had seroma, a factor that is considered to be a precursor for mesh infection. Seroma developed in 5 out of 7 patients who developed SSI 2 in group 2. There were no significant differences between the groups with regard to overall complication rates. However, the rate of seroma occurrence was significantly higher in group 2 ($P < 0.041$). Five patients who developed seroma and then SSI 2–type infection had a longer operation time and greater hernia and mesh size. It was thus suggested that operational dissection and the resulting seroma may have been larger. We believe that in patients with inadequate fluid drainage, the fluid collection becomes infected and facilitates mesh infection over time. One of 7 patients in group 2 who developed SSI 2–type infection also had a bleeding complication. That patient was operated on early, and hemostasis was achieved. We think that reoperation increased the risk of infection in this patient.

Although there are some studies suggesting a conservative approach would be more effective in treating mesh infections,[31] the overall tendency of surgeons is to remove the infected synthetic mesh. Some studies have argued the beneficial effects of using VAC during conservative approach.[31] In our study, we removed the synthetic mesh in 3 patients with SSI-2 infection, all of whom were in group 2.

Two patients in that group first received VAC therapy and conservative therapy, but no adequate response could be elicited.

Mesh use in VHR has been associated with increased complication rates (such as infection, bowel obstruction, and fistula) in previous studies.[8] A study compared open mesh hernia repair and open suture and found 2 times more complications in mesh repair. Despite these results, however, high recurrence rates with open suture have made mesh repair preferable. The rate of wound-site infection is increased 4-fold after the use of absorbable mesh. It was reported that permanent mesh use was not predictive of incident wound infections.[18] We used nonabsorbable monofilament mesh in all patients to reduce both the recurrence rates and the infection risk.

Among many risk factors for wound infection after VHR, smoking appears to be the only preventable risk factor.[18] Unfortunately, most patient-related risk factors could not be eliminated, despite all efforts. At this point, intraoperative variables have begun to come to the forefront. Operation room sterilization conditions, personnel training, surgical expertise, surgical-field cleansing, a reduced contact of mesh with surgical field, and prophylactic antibiotic use are the preventable factors. Furthermore, animal studies have recently suggested that synthetic meshes soaked in antibiotic solution to attain higher antibiotic levels reduced infection rates. Our results are not in agreement with those obtained in animal trials,[13,14] since our control group developed less surgical-field infection.

Conclusion

Use of synthetic mesh soaked in Vancomycin solution had no beneficial effect on wound-site infection. This may have been because the majority of proliferated bacteria were different from the members of normal skin flora, and thus Vancomycin had limited effect. Future randomized, controlled, large-scale studies using the same mesh and suture types for VHR, and meshes soaked in larger spectrum antibiotics are needed.

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