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ORIGINAL ARTICLE

Effect of triclosan-coated sutures on surgical site infections in pilonidal disease: prospective randomized study

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Abstract

Purpose The aim of this study is to investigate the effect of triclosan-coated sutures on surgical site infections after wide excision and primary closure for pilonidal disease.

Methods One hundred seventy-seven patients were randomized into two groups: 91 in control and 86 in triclosan groups. In the control group, 1/0 monofilament polypropylene retention sutures, 3/0 polyglactin subcutaneous sutures, and 3/0 polypropylene skin sutures were used. In the triclosan group, 1/0 triclosan-coated monofilament polydioxanone, 3/0 triclosan-coated polyglactin, and 3/0 triclosan-coated monofilament polydioxanone were used. Postoperative care and follow-up was made by a surgeon according to Centers for Disease Control guideline. Surgical site infection rates between groups were compared. Secondary outcomes were seroma and wound dehiscence.

Results Seroma was seen in 30 (16.9%) patients: 20 (23.3%) in the triclosan group and 10 (10.9%) in the control group ($p = 0.030$). Thirteen (7.3%) patients had superficial wound dehiscence: 5 (5.5%) patients in the control group and 10 (11.6%) patients in the triclosan group ($p = 0.116$). Overall surgical site infection (SSI) rate was 15.8% ($n = 28$): 19 (20.8%) patients in the control group and 9 (10.5%) patients in the triclosan group ($p = 0.044$). Healing was observed on mean 17.8 ± 6.7 days. Primary and secondary healing rates and time to healing were similar between groups.

Conclusion Triclosan-coated sutures decreased surgical site infection rate but had no effect on time to healing in pilonidal disease. Seroma and wound dehiscence were more common in triclosan groups. Randomized trials are needed to clear the effect of triclosan-coated sutures on postoperative wound complications.

Keywords Surgical site infection · Pilonidal disease · Triclosan · Wound infection · Antibacterial sutures

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Introduction

Pilonidal disease (PD) is a common condition characterized with inflammation and epithelized sinuses caused by moving hair towards the gluteal sulcus. The presentation varies between asymptomatic hair pits and chronic fistulas with severe infection. Conservative and surgical treatments both have high wound complication and recurrence rates which causes considerable work day losses and increased healthcare costs [1, 2]. Surgical site infection (SSI) after PD surgery has been reported up to 38% and related with increased recurrence rate [3, 4].

During recent years, in addition to well-known precautions such as parenteral antimicrobial prophylaxis and preoperative bathing, new issues are focused to prevent SSI. These are glycemic control, maintaining normothermia, and oxygenation [5]. The effect of antimicrobial-coated biomaterials is still controversial. Many randomized trials on the effect of

triclosan-coated sutures in various surgical procedures have been published [6–8]; however, there are scarce data focusing on PD [9]. Recent meta-analyses showed moderate-quality evidence and robust effect that triclosan-coated sutures reduce SSI and costs [10–12]. The wound classifications and surgical procedures including abdominal, vascular, colorectal, head and neck, cardiac, and breast surgery are quite heterogeneous in these studies.

As PD is one of the most complicating procedures of surgical practice, we aimed to investigate the effect of triclosan-coated sutures on PD surgery.

Patients and methods

The study was approved by Dokuz Eylul University Ethics Committee (approval no. 20101193-17). The patients were detailly informed about the protocol and written consent was received. Patients older than 18 years old who underwent wide excision and primary closure for PD were included in the study. Exclusion criteria were immunosuppression, antibiotherapy and/or infection history within 1 week before surgery, acute abscess, recurrent PD, different procedures other than wide excision and primary closure, use of drain, and postoperative administration of antibiotics (Fig. 1).

The severity of PD was determined according to Chavoin classification [13]: grade I: asymptomatic hair pits at midline, grade II: drainage from midline sinuses, grade III: acute abscess, and grade IV: chronic drainage and painful swelling with midline and lateral sinuses. Chavoin grade III patients were initially treated with abscess drainage and oral antibiotics; elective surgery was planned at least 1 week after antibiotherapy was stopped. When collecting data, Chavoin classifications were recorded based on the symptoms on presentation; thus, those patients were recorded as Chavoin grade III, but they did not have acute abscess at the time of surgery.

Study groups and randomization

Between January 2011 and January 2013, 222 patients were assessed for PD. Patients were tiered into two groups using block randomization at 1:1 ratio. The surgeon (NCA, TA, CT) was not blinded to the randomization as he/she used and recognized the sutures. Another surgeon (GA) performed the postoperative care and assessment of the surgical site. In the control group, conventional suture materials were used. In the study (triclosan) group, triclosan-coated sutures were used. The primary end-point of the study was to compare SSI rates between study and triclosan groups. Secondary end-points were comparing wound dehiscence without infection and seroma rates.

Surgery

Rectal enema was applied to all the patients 2 h before operation. Under general or locoregional anesthesia, patients were positioned in prone. Intravenous 1.5 g cefuroxime axetil and 500 mg metronidazole were administered 30 min before incision. The buttocks were retracted with bandages. Hair was shaved with razor on the operation table (Fig. 2a). An elliptical incision as small as possible but covering all the pits and sinuses was made (Fig. 2b). Pilonidal cyst was excised with clean surgical borders (Fig. 2c). The bandages were removed (Fig. 2d). Retention sutures were prepared, and subcutaneous tissue was closed with interrupted sutures. Skin was closed, and retention sutures were tied over a compression gauze (Fig. 3). Skin sutures were seated paramedian and retention sutures were median on the gauze.

Except suture materials, all the steps of surgery were similar in all patients. In the control group, the retention sutures were 1/0 monofilament polypropylene (Prolene®, Ethicon, USA), subcutaneous sutures were 3/0 polyglactin (Vicryl®, Ethicon, USA), and skin sutures were 3/0 polypropylene (Prolene®, Ethicon, USA). In the triclosan group, 1/0 triclosan-coated monofilament polydioxanone (PDS Plus®, Ethicon, USA) was used for retention, 3/0 triclosan-coated polyglactin (Vicryl Plus®, Ethicon, USA) was used for subcutaneous tissue, and 3/0 triclosan-coated monofilament polydioxanone (PDS Plus®, Ethicon, USA) was used for skin closure.

Follow-up and definition of complications

All the patients were discharged on the same day after surgery. Antibiotics were not continued. Outpatient visits were performed by a surgeon (GA) on postoperative days 1, 3, 7, 15, and 30. At the first visit, dressings were changed. On postoperative day 3, dressings were removed, and the wound was left open. Hair removal during at least 2 years with razor or depilation gel was recommended to all patients. The retention sutures were removed on postoperative day 7 and skin sutures were removed on day 14 in uneventful patients.

Surgical site infection

Centers for Disease Control guideline was used to define SSI [5].

Superficial SSI Infection is associated with skin and subcutaneous tissue within 30 days after surgery and at least one of the following:

1. Purulent drainage with or without culture confirmation
2. Positive tissue or fluid culture

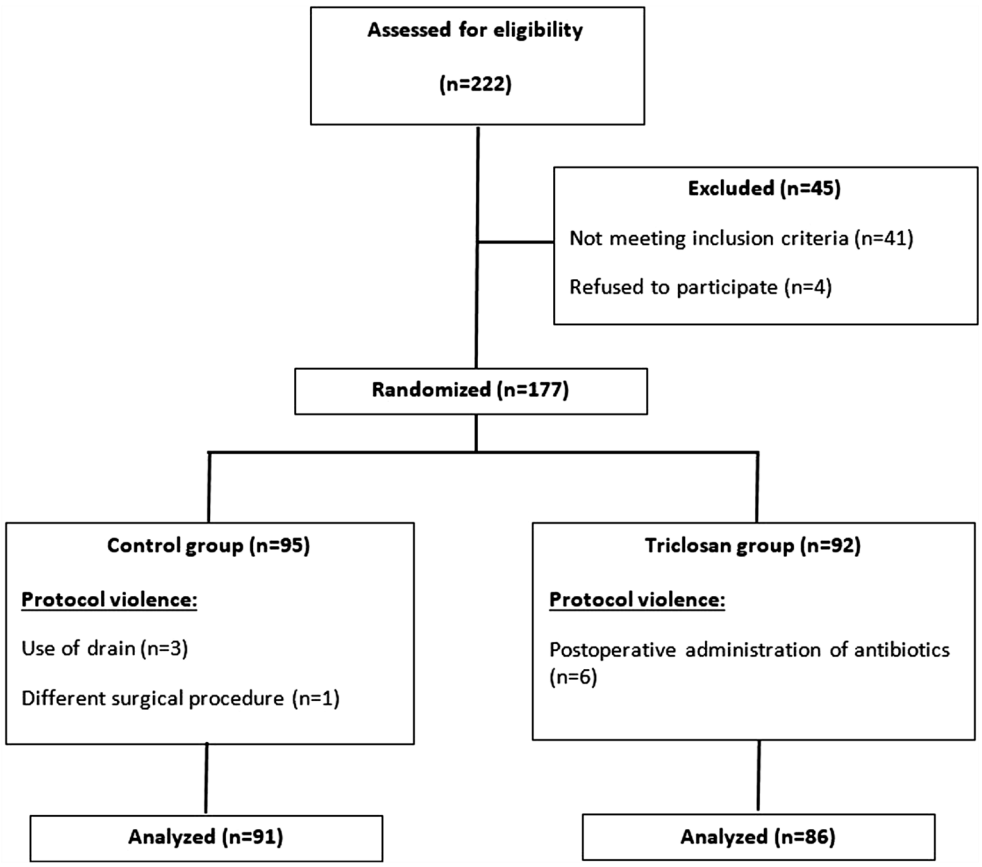

Fig. 1 Flow diagram of the study

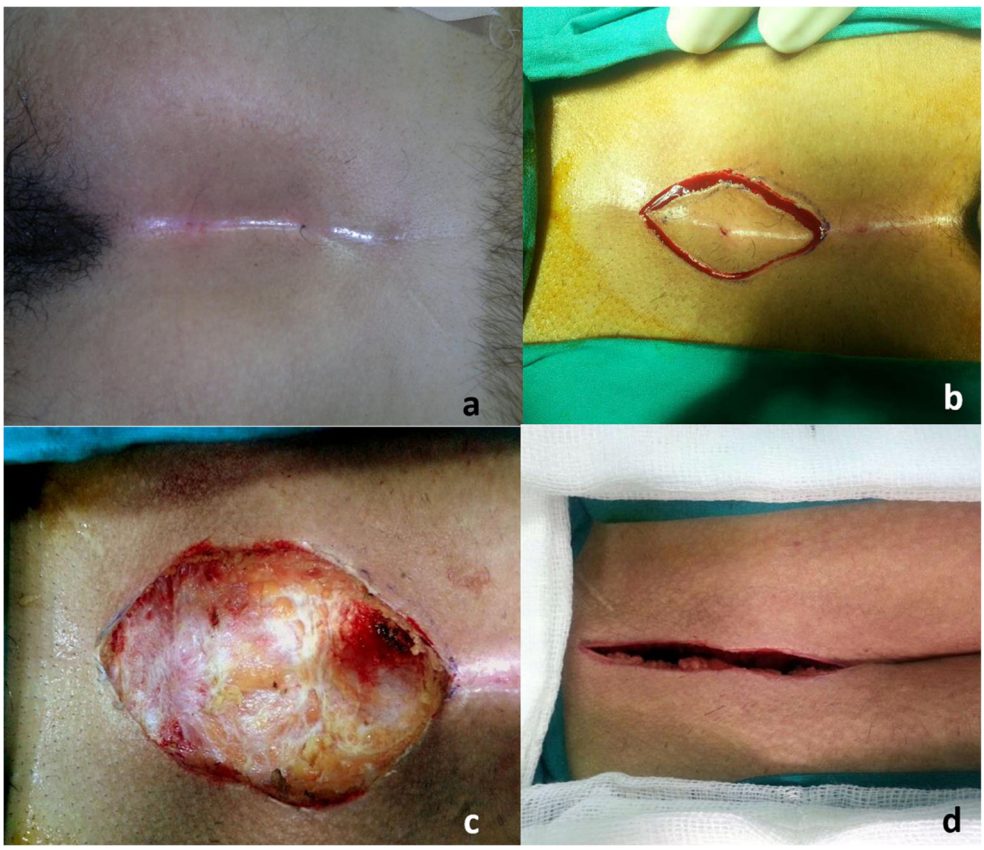

Fig. 2 Preparation of the surgical site and excision of the sinus

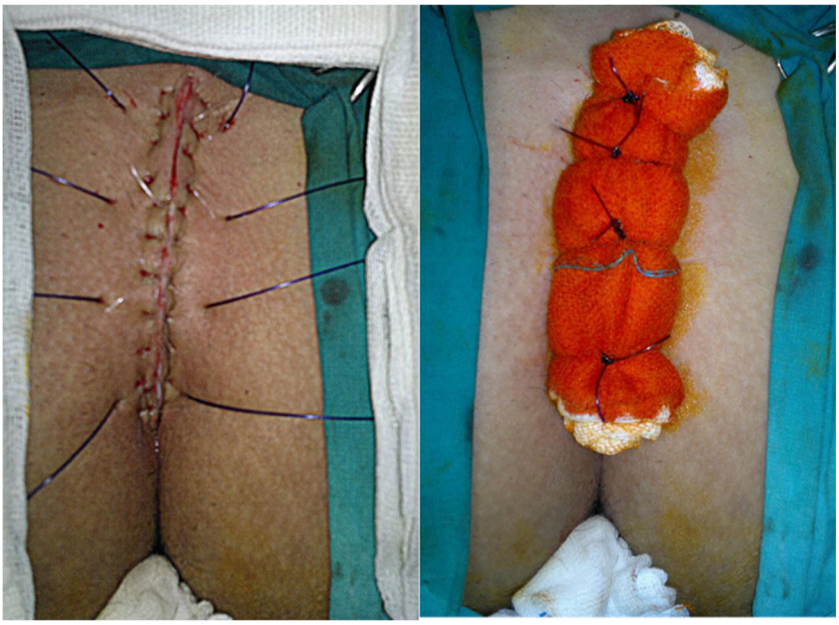

Fig. 3 Closure of the wound and compression dressing tied with retention sutures

3. Incision opened by the surgeon with at least one of pain, tenderness, swelling, redness and heat—unless culture is negative
4. Diagnosis of superficial incisional infection made by a surgeon or attending physician

Deep SSI Infection associated with deep tissues (e.g., fascia, muscle) within 30 days after surgery and at least one of the following:

1. Purulent drainage from the deep incision
2. A deep incision spontaneously dehisces or opened by the surgeon with at least one of fever, pain, tenderness—unless culture is negative
3. Radiologically or histologically detected abscess or deep infection
4. Diagnosis of deep incisional infection made by a surgeon or attending physician

Superficial wound dehiscence

Superficial wound dehiscence includes superficial or partial separation of the wound edges without any signs of infection. Spontaneous separation of the entire incision is described as complete dehiscence and included in deep SSI (abovementioned).

Seroma

Seroma includes fluid collection in subcutaneous tissue without any signs of infection. When SSI, wound dehiscence, or seroma was observed, cultures were taken. If there were severe signs of infection (high fever, leukocytosis, wide cellulitis around the incision), empirical antibiotics were administered. Otherwise, local wound care was performed and antibiotherapy was decided after culture results. Surgical site infections were treated with daily dressings or negative pressure wound therapy and debridement in operative room when needed. The wound was primarily closed or left for secondary healing. When complete wound dehiscence occurred, primary closure was performed. If the dehiscence was partial/small, the patient was followed up with daily changed dressings. Seroma was aspirated and followed up in outpatient visits. Complete healing was recorded as the postoperative day on which the sutures were removed for uneventful patients. For complicated patients, removal of the sutures or healing without any need of dressing/care was accepted as complete healing.

Statistical analysis

Continuous variables were expressed as means and standard deviation, and categorical variables as frequencies and percentages. Differences between groups were tested by chi-square, Fisher exact, and independent sample t tests. $p < 0.05$ was accepted as significant.

Results

Among 222 patients, 177 met the inclusion criteria. Ten patients were excluded after randomization due to protocol violence. Finally, 91 patients in the control group and 86 patients in the study group were included in the analysis. Flow diagram of the study is given in Fig. 1.

The mean age was 25.6 ± 5.9 years, 155 (87.6%) patients were male, and 22 (12.4%) were female. The mean BMI was 25.9 ± 2.7 kg/m^2. The mean duration of the symptoms was 17.1 ± 20.2 months. Twenty-eight (15.8%) patients had family history of PD and 6 (3.4%) had comorbidities. Smoking history was positive in 79 (44.6%) patients. Ten (5.6%) of the procedures were under general anesthesia. The mean operative time was 40.1 ± 12.4 min. The mean distance between the anus and distal edge of the incision was 3.7 ± 1.3 cm. The mean number of sinuses was 2.1 ± 0.9. Groups were similar in terms of demographic, clinical, and surgical characteristics (Tables 1 and 2).

Seroma was seen in 30 (16.9%) patients: 20 (23.3%) in the triclosan group and 10 (10.9%) in the control group (p = 0.030). These patients were followed up with aspiration once in 3 days and primary healing was achieved at usual time in all. Thirteen (7.3%) patients had superficial wound dehiscence. There were 5 (5.5%) patients in the control and 10 (11.6%) patients in the triclosan group with wound dehiscence, but the difference was not statistically significant (p = 0.116). Complete spontaneous dehiscence of the entire incision was seen in one patient each in both groups; these were accepted as deep SSI. There was no correlation between length of incision and wound dehiscence incidence; the mean length of wound was 48.5 ± 17.9 in patients without dehiscence and 47.6 ± 13.9 in patients with dehiscence (p = 0.863). Patients with complete dehiscence underwent primary closure after negative culture was seen; others were followed up with dressings.

The overall SSI rate was 15.8% (n = 28). In the control group, 19 (20.8%) patients had SSI, and this was significantly higher when compared with 9 (10.5%) patients with SSI in the triclosan group (p = 0.044). Healing was observed on mean 17.8 ± 6.7 days. Primary and secondary healing rates and time to healing were similar between groups (Table 3). The most common microorganism isolated from the cultures was *Escherichia coli*. In contrast with the control group, there was no *Staphylococcus aureus* and *Pseudomonas aeruginosa* infection in the triclosan group (Table 4). The patients with SSI were treated with debridement and daily dressings (n = 22) and negative pressure wound therapy (n = 6). Four patients (2 in the control and 2 in the triclosan groups) with leukocytosis and high fever were administered oral antibiotherapy.

Table 1 Demographic and clinical characteristics of the patients

	Control group (n = 91)	Triclosan group (n = 86)	p
Age (years, mean ± SD)	25.5 ± 5.5	25.8 ± 6.5	0.733
Sex			0.113
Male	76	79	
Female	15	7	
BMI (kg/m^2, mean ± SD)	26.2 ± 2.8	25.6 ± 2.6	0.128
Duration of the symptoms (months, mean ± SD)	19.8 ± 21	14.2 ± 18.9	0.063
Family history (+)	14	14	1.000
Smoking (+)	38	41	0.453
Chavoin classification			0.198
I	10	7	
II	65	56	
III	11	10	
IV	8	10	

SD standard deviation, *BMI* body mass index

Table 2 Surgical characteristics of the patients

	Control group (n = 91)	Triclosan group (n = 86)	p
Length of the specimen (cm, mean ± SD)	5.1 ± 1.8	5.6 ± 2.1	0.324
Width of the specimen (cm, mean ± SD)	3.2 ± 1	3.4 ± 0.8	0.512
Depth of the specimen (cm, mean ± SD)	2.4 ± 0.6	2.6 ± 0.7	0.438
Distance between anus and distal edge of the incision (cm, mean ± SD)	3.6 ± 1.2	3.7 ± 1.3	0.445
Number of sinuses (mean ± SD)	2.1 ± 1.1	2.02 ± 0.8	0.852
Anesthesia			0.527
General	5	5	
Locoregional	86	81	
Operative time (min, mean ± SD)	40.1 ± 12.5	40.8 ± 12.6	0.778

SD standard deviation

Table 3 Comparison of complications between control and study groups

	Control group (n = 91)	Triclosan group (n = 86)	p
Seroma	10 (10.9%)	20 (23.2%)	0.030
Wound dehiscence	5 (5.5%)	10 (11.6%)	0.116
Superficial	4	9	
Deep	1	1	
Surgical site infection	19 (20.8%)	9 (10.4%)	0.044
Superficial	18	8	
Deep	1	1	
Primary healing	70	69	0.715
Secondary healing	21	17	0.469
Time to healing (days, mean ± SD)	17.9 ± 6.4	17.6 ± 7.1	0.689

SD standard deviation

Table 4 Details of the patients with surgical site infection

Patient	SSI diagnose (postoperative day)	Sex	Age	Wound culture
Control group				
1	7	F	28	*Escherichia Coli (E. coli)*
2	7	M	19	*Staphylococcus epidermidis (S. epidermidis)*
3	7	M	20	*E. coli*, Bacteroides fragilis (*B. fragilis)*
4	7	M	32	*E. coli*
5	9	M	19	*Staphylococcus aureus (S. aureus)*
6	5	M	30	*E. coli*
7	7	M	29	*Pseudomonas aeruginosa (P. aeruginosa)*
8	7	M	26	*E. coli*
9	7	M	24	*E. coli*
10	5	M	25	*S. epidermidis*
11	7	M	42	*E. coli*, *B. fragilis*
12	5	M	22	*S. epidermidis*
13	4	M	24	*E. coli*, *B. fragilis*
14	6	M	26	*E. coli*
15	5	M	28	*S. aureus*
16	8	F	21	*E. coli*
17	7	M	19	*P. aeruginosa*
18	7	M	33	*E. coli*
19	15	F	20	*E. coli*
Triclosan group				
1	3	M	29	*E. coli*
2	7	F	27	*E. coli*
3	7	M	18	*S. epidermidis*
4	9	M	22	*E. coli*, *B. fragilis*
5	7	M	24	*E. coli*
6	7	M	32	*S. epidermidis*
7	6	M	21	*S. epidermidis*
8	7	M	29	*E. coli*, *B. fragilis*
9	6	M	26	*E. coli*

F female, *M* male

Discussion

Pilonidal disease is a chronic inflammatory condition. Both the natural history of the disease and wound complications after treatment eventuate in a substantial morbidity [14]. Several conservative options including simple drainage of the sinus, crystallized phenol, laser ablation, and endoscopic video-assisted debridement have been suggested; however, surgery remains the main definitive treatment [1, 15–18]. Unfortunately, major complication rates and healthcare costs are still high after surgery [2]. Older age, male gender, obesity, presence of chronic gastrointestinal conditions, midline closure techniques, smoking, and lack of antibiotic prophylaxis have been considered responsible for SSI and recurrence after PD surgery [4, 19].

During recent years, efforts to prevent SSI have been focused on antibacterial-coated biomaterials. Several randomized trials and meta-analyses showed the favorable effect of triclosan-coated sutures on SSI [6, 7, 11, 12, 20] and healthcare costs [10]. A substantial part of these studies reported a decrease SSI rate, but the available evidence is moderate/low quality and many studies had conflict of interests, thus further studies are needed. The most recent meta-analysis by Jonge et al. [12] analyzed 21 randomized trials including 6462 patients and concluded that triclosan-coated sutures are effective in reducing SSI and the effect is robust with moderate-quality evidence. This meta-analysis included a wide range of surgical procedures such as colorectal, head and neck, cardiac, vascular, and breast surgery. The only study on PD surgery included in this meta-analysis is the present study (it was cited from a poster presentation).

In 2016, Karip et al. [9] published the results of 106 Karydakis flap repair. Poliglecaprone and triclosan-coated poliglecaprone sutures were compared. They reported 10 (19.2%) cases with SSI in the conventional suture group and 12 (22.2%) cases in the triclosan group ($p > 0.05$). Wound dehiscence rates were 15.5% and 18.5% in the conventional and triclosan groups ($p > 0.05$). They observed two recurrences both in the triclosan group. The overall SSI rate in this study is 20.7% and can be considered relatively high for Karydakis procedure [21, 22]. Our overall SSI rate was compatible with that of the literature and our historic series of wide excision and primary closure [23]. We observed a significant decrease—more than 2-fold—on SSI rate with triclosan-coated sutures. Seroma was significantly more common in the triclosan group. Moreover, higher wound dehiscence rate in the triclosan group was remarkable, and even this difference was not statistically significant. Time to healing was not different between groups. The reason for not achieving the expected decrease in time to healing in the triclosan group may be associated with high wound dehiscence rates. In the triclosan group, the SSI rate was decreased but in other respects, wound complications without infection caused a delay in healing. These findings may depend on the use of non-spouse sutures for retention and skin. In the control group, interrupted polypropylene was used for retention and skin sutures. Unfortunately, we used triclosan-coated polydioxanone as coated polypropylene was not commercially available. In a recent meta-analysis, subgroup analysis showed that conventional and coated polydioxanone sutures had no difference in reducing SSI in abdominal surgery; the favorable effect of coated sutures was observed in polyglactin sutures [24]. Secondary outcomes of the same meta-analysis reported no significant difference in length of hospital stay;

however, healthcare costs were decreased with triclosan-coated sutures. We did not perform a cost analysis. Apart from this, limited sample size and lack of long-term follow-up for recurrence were the limitations of our study.

Triclosan has an effective antimicrobial activity which has been shown to be safe in several in vivo and in vitro studies, with no adverse effect wound healing [25, 26]. Clinical studies with triclosan-coated sutures are very heterogeneous including various procedures. In a newly published review, the decrease in the SSI rate observed in abdominal surgery was not seen in cardiac and breast procedures [6]. In our series, we observed a reduction in SSI, but wound dehiscence rate was unsatisfactory. The good results for triclosan-coated sutures were mostly reported from abdominal surgery trials and valid for coated polyglactin sutures. Most of the wounds tested were linear wounds which are expected to heal well. In our patients, the tension of the wound edges was relatively high which could explain high dehiscence rate conformably with a previous double-blind randomized study of breast augmentation [27].

Conclusion

Triclosan-coated sutures reduce SSI rate but has no effect on time to healing after wide excision and primary closure for PD. Increased seroma and wound dehiscence rates should be taken into consideration. Further randomized studies focused on specific procedures are needed to clear the effect of triclosan-coated sutures.

Compliance with ethical standards

The study was approved by Dokuz Eylul University Ethics Committee (approval no. 20101193-17). The patients were detailly informed about the protocol and written consent was received.

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