Surgery 000 (2018) 1–5

Contents lists available at ScienceDirect

Surgery

journal homepage: www.elsevier.com/locate/surg

Effect of triclosan-coated sutures on the incidence of surgical site infection after abdominal wall closure in gastroenterological surgery: a double-blind, randomized controlled trial in a single center

Kosuke Ichida, Hiroshi Noda*, Rina Kikugawa, Fumi Hasegawa, Tamotsu Obitsu, Daisuke Ishioka, Rintaro Fukuda, Ayuha Yoshizawa, Shingo Tsujinaka, Toshiki Rikiyama

Department of Surgery, Saitama Medical Center, Jichi Medical University, Saitama, Japan

ARTICLE INFO

Article history:
Received 11 October 2017
Revised 6 December 2017
Accepted 13 December 2017
Available online xxx

ABSTRACT

Background: Surgical site infection is one of the most common postoperative complications after gastroenterologic surgery. This study investigated the effect of triclosan-coated sutures in decreasing the incidence of surgical site infections after abdominal wall closure in gastroenterologic surgery.

Methods: A prospective, double-blind, randomized, controlled parallel adaptive group-sequential superiority trial was conducted from March 2014 to March 2017 in a single center. Eligible patients were those who underwent gastroenterologic surgery. Patients were allocated randomly to receive either abdominal wall closure with triclosan-coated sutures (the study group) or sutures without triclosan (the control group). The primary end point was the incidence of superficial or deep surgical site infections within 30 days after operation. This study was registered with the University Hospital Medical Information Network-Clinical Trials Registry (http://www.umin.ac.jp/ctr/), identification number UMIN000013054.

Results: A total of 1,013 patients (study group, 508 patients; control group, 505 patients) were analyzed by a modified intention-to-treat approach. The wounds in 990 (97.7%) of the 1,013 patients were classified as clean-contaminated. The primary end point (incidence of superficial or deep surgical site infections) was 35 (6.9%) of 508 patients in the study group and 30 (5.9%) of 505 in the control group. The incidence of surgical site infections did not differ markedly between the 2 groups (95% confidence interval: 0.686–2.010, $P = .609$). Of the 65 infections, 42 (64.6%) were superficial surgical site infections, with similar frequencies in the 2 groups, and 23 (35.4%) were deep surgical site infections, again with similar frequencies in the 2 groups.

Conclusion: Triclosan-coated sutures did not decrease the incidence of surgical site infections after abdominal wall closure in gastroenterologic surgery.

Surgical site infection (SSI) is one of the most common postoperative complications after gastroenterologic surgery.[1,2] Although the current risk of SSIs after any procedures is <2%,[3] the incidence of SSIs after gastroenterologic surgery have been reported as ≥15%.[1,2] SSIs cause increased morbidity and mortality, prolonged hospital stay, and greater health-care costs.[4-7] The suture material has been considered to be one of the factors that affect SSI development.[8,9] To prevent microbial colonization of suture materials in operative incisions, triclosan [5-chlolo-2-(2, 4-dichlorophenoxy) phenol]-coated sutures have been developed and used in a novel attempt to decrease the incidence of SSIs.[10-14] Several studies have shown that the use of triclosan-coated sutures leads to a decrease in the number of bacteria in vitro and also decreases the incidence of wound infections in animals,[10-14] encouraging the introduction of triclosan-coated sutures to the medical market. The efficacy of these sutures, however, is controversial,[15-23] possibly due to the different backgrounds of patients and heterogeneity in the methodologic designs of clinical trials. Therefore, while many meta-analyses have investigated the effect of triclosan-coated sutures to decrease SSI, the results have been controversial,[24-29] as the available evidence is of moderate to low quality. The guideline of the Centers for Diseases Control and Prevention (CDC) revised in 2017 gave only a weak recommendation for the use of triclosan-coated sutures for the prevention of SSI.[30]

To investigate the effect of triclosan-coated sutures in decreasing SSIs in patients who undergo gastroenterologic surgery, we designed a double-blind, randomized, controlled trial (RCT). The

* Corresponding author. Department of Surgery, Saitama Medical Center, Jichi Medical University, 1-847 Amanuma-cho, Omiya-ku, Saitama, 330-8503, Japan. (H. Noda).
E-mail address: noda164@omiya.jichi.ac.jp (H. Noda).

https://doi.org/10.1016/j.surg.2017.12.020
0039-6060/

aim of study was to yield reliable data regarding whether or not triclosan-coated sutures are effective for decreasing SSIs in abdominal wall closure after gastroenterologic surgery. At present, this is a largest double-blind RCT of its kind from a single center.

Methods

This prospective, double-blind, randomized, controlled, parallel adaptive group-sequential superiority trial was conducted from March 2014 to March 2017. The study protocol was approved by the Ethics Committee of Jichi Medical University on August 17, 2013 (reference number 13-05) and was registered with the University Hospital Medical Information Network-Clinical Trials Registry (http://www.umin.ac.jp/ctr/), identification number UMIN000013054.

Patients who underwent gastroenterologic surgery in the Department of Surgery, Saitama Medical Center, Jichi Medical University, Japan, between March 2014 and February 2017 were included. The exclusion criteria were the identification of bacterial infection or use of antibiotic therapy prior to operation, presence of a contaminated abdominal cavity due to intestinal fistula or drainage tube, known allergy to triclosan, and pregnancy. Written informed consent was obtained from all included patients before randomization. After the patients signed their informed consent, the preoperative demographic characteristics and perioperative data were registered prospectively in an electric database.

Randomization and masking

The patients were allocated randomly to receive either abdominal wound closure with triclosan-coated sutures or sutures without triclosan. Permuted-block randomization with an allocation ratio of 1:1 and a block size of 2 was used.

A research doctor who was not involved in the operation placed pieces of paper containing the randomized allocations into sealed envelopes according to a randomized allocations list. A research nurse who was not involved in the patients' follow-up opened the randomization envelope and delivered the allocated sutures to the operating room. Only the nurses in the operating theater knew to which group each patient had been randomized. Both the coated and noncoated sutures which looked identical were taken from their packages and put on the surgical assistant table without any identification marks before the abdominal wall closure. The surgeons could not determine which sutures had been allocated, because the coated and noncoated sutures were indistinguishable from each other in terms of physical properties, such as color, texture, and tying properties. Neither the surgeons, the nurses in the surgical ward, nor the patients knew to which group a patient had been randomized. Surgeons assessing the wound status were also blinded, because the used suture material could not be identified postoperatively. The randomization code was kept separately from the trial data until the end of the study.

Procedures

Perioperative care protocols and wound management were as recommended in the guideline developed by the CDC.[31] In both groups, all patients received intravenous antibacterial prophylaxis of cephalosporin 30 minutes before skin incision and repeated every 3 hours during the operation. When antibiotic therapy was necessary to treat postoperative infectious conditions, it was given appropriately. Patients undergoing elective colorectal resection underwent preoperative bowel preparation both chemically using antibiotics and mechanically using oral laxatives.

The trial intervention was abdominal wound closure after gastroenterologic surgery with triclosan-coated sutures or noncoated sutures. Wound contamination often involves both deep and superficial incision sites. Therefore, to maximize the benefit from triclosan-coated sutures, we used these sutures for both superficial and deep layers of abdominal wounds.[18,22,29] In the study group, the abdominal fascia and peritoneum were closed with interrupted sutures using polyglactin 910 antimicrobial sutures coated with triclosan (Vicryl Plus; Ethicon, Johnson & Johnson, Somerville, NJ). After the fascia was closed, the wound was irrigated with normal saline to secure hemostasis and evacuate cell debris. Interrupted subcutaneous sutures were then used for skin closure using polydioxanone antimicrobial sutures coated with triclosan (PDS Plus; Ethicon, Johnson & Johnson). In the control group, identical procedures were carried out using uncoated polyglactin 910 sutures (Vicryl; Ethicon, Johnson & Johnson) and polydioxanone sutures (PDS II; Ethicon, Johnson & Johnson). Finally, the wound was covered with sterile dressing, which was left in place for at least 48 hours unless macroscopic bleeding soiled the dressing. Suture material and suture techniques apart from those described previously and subcutaneous drains were not allowed.

Before participating in this trial, the staff surgeons and residents were educated and trained in the procedure, and monthly meetings were held to confirm the progress of the trial and the appropriate performance of procedure throughout the study. In the majority of cases, abdominal wound closure usually was performed by residents who were well trained at our institution with staff surgeons. Therefore, the technical variance was controlled to a minimum.

Outcomes

The primary end point was the incidence of superficial or deep SSIs according to the CDC criteria.[31] In patients with clinical signs of SSIs with drainage, bacterial cultures were collected. Cases in which an incision was opened deliberately by surgeons were designated as SSI unless the cultures were negative.

After the operation, patients were followed-up daily during their hospital stay by research surgeons and nurses in the surgery wards, and after discharge, patients were monitored at the outpatient clinic for up to 30 days.

Statistical analyses

Due to a lack of published data, the sample size calculation was derived from a retrospective cohort of patients who underwent gastroenterologic surgery and had their abdominal wounds closed by the same procedure using uncoated polyglactin 910 sutures and uncoated polydioxanone sutures at our institution in 2012. An overall SSI rate of 9.0% was found, with expected SSI rates of 4.5% for the study group and 9.0% for the control group. With a 2-sided α level of 0.05, a total of 974 patients were estimated to be needed for the trial to have 80% power to detect superiority in the reduction of the frequency of SSIs.

The primary analysis was performed under the modified intention-to treat (mITT) principle, which excluded from the analysis the patients who did not receive any of the allocated interventions to represent clinical practice. Dichotomous data and counts are presented as the number and percentage. Continuous data are presented as the mean $\pm$ standard deviation.

The groups were compared by Student t test (continuous normally distributed data), the Mann-Whitney U test (continuous data not normally distributed), or Fisher exact test (categorical variables). We used the StatView software program, version 5.0 (SAS Institute Inc., Cary, NC) for the statistical analyses.

Results

A total of 1,023 patients were allocated randomly to receive either triclosan-coated sutures (512 patients) or noncoated sutures

Please cite this article as: K. Ichida et al., Effect of triclosan-coated sutures on the incidence of surgical site infection after abdominal wall closure in gastroenterological surgery: a double-blind, randomized controlled trial in a single center, Surgery (2018), https://doi.org/10.1016/j.surg.2017.12.020