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A randomized trial of antibiotic prophylaxis for the prevention of surgical site infection after open mesh-plug hernia repair

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Abstract

BACKGROUND: The efficacy of antibiotic prophylaxis for the prevention of surgical-site infection (SSI) after open tension-free inguinal hernia repair remains controversial.

METHODS: A double-blind, randomized, placebo-controlled trial was conducted. Patients who underwent elective open mesh-plug hernia repair were eligible for randomization. In the antibiotic prophylaxis group, 1.0 g cefazolin was intravenously administrated 30 minutes before the incision. In the placebo group, an equal volume of sterile saline was administered. The primary end point was the incidence of SSI.

RESULTS: A total of 200 patients were enrolled. SSI developed in 2 of 100 patients (2%) in the antibiotic prophylaxis group and 13 of 100 patients (13%) in the placebo group, indicating a significant difference between the 2 groups (relative risk ratio, 0.25; 95% confidence interval, 0.070 to 0.92; $P = .003$). Other complications occurred in 23 patients: 7 (7%) in the antibiotic prophylaxis group and 16 (16%) in the placebo group ($P = .046$).

CONCLUSIONS: This study indicates that antibiotic prophylaxis is effective for the prevention of SSI after open mesh-plug hernia repair.

Surgeons routinely administer antibiotic prophylaxis when a prosthetic device is involved, for example, in cardiothoracic surgery and in hip arthroplasty, because infection can result in critical conditions such as removal of the prosthesis, prolongation of the hospital stay, and an increase in cost. On the other hand, it is questionable whether the routine use of antibiotic prophylaxis is necessary for the prevention of surgical-site infection (SSI) in a simple, clean surgical procedure such as inguinal hernia repair or breast surgery.[1]

In patients undergoing inguinal hernia repair, 10 randomized controlled trials have been conducted during the past decade[2–12] to evaluate the effectiveness of the routine use of antibiotic prophylaxis. Two of these studies[2,4] showed that prophylactic antibiotics were effective in reducing infection rates, but 8 of the studies[3,5–11] recommended against their use. However, most of the studies had a relatively small number of patients and therefore did not have the statistical power necessary to detect a significant difference. Likewise, 6 meta-analyses failed to show statistically conclusive evidence that prophylactic antibiotics were effective.[12–17] This is therefore still a controversial

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issue. The randomized controlled trials enrolled low-risk patients rather than high-risk patients. On the basis of these results, the European Hernia Society guidelines[18] state that there is no indication for the routine use of antibiotic prophylaxis for low-risk adult patients in clinical settings with low infection rates (<5%) but that their use is recommended in the presence of risk factors for SSI, such as recurrence of hernia, advanced age, and immunosuppression.

Approximately 160,000 inguinal hernia repairs are performed annually in Japan, and >1 million repairs are performed annually in both the United States and Europe.[3] If antibiotic prophylaxis can be avoided in inguinal hernia repairs, we can not only minimize cost but also reduce the risk for allergic side effects and the possible development of bacterial resistance.[19] Furthermore, the risk for a clinically significant infection is not large enough to justify the routine use of antibiotic prophylaxis, because SSI develops in only 1% to 4% of patients undergoing inguinal hernia repair.[20] In addition, a review of inguinal hernia repairs at our institution, performed with mesh and without mesh, indicated that SSI occurred in approximately 1% of patients (unpublished data). We subsequently found that our surgeons were administering prophylactic antibiotics despite the absence of any evidence of their effectiveness. The above concerns are the main arguments against the routine use of prophylactic antibiotics.

We therefore conducted a single-center, randomized, double-blind, placebo-controlled trial to clarify whether antibiotic prophylaxis for primary inguinal hernia surgery reduces morbidity.

Methods

Study design

The trial was conducted in the Department of General Surgery at the Nihon University School of Medicine from July 2007 to December 2011. The ethics committees at the hospital approved the trial, and all patients provided written informed consent. The trial was registered at ClinicalTrials.gov (NCT00636831).

Inclusion and exclusion criteria

Inpatients who were scheduled for elective primary unilateral or bilateral open mesh-plug hernia repair were eligible for the study. Because open inguinal hernia repairs for outpatients were uncommon in Japan (the Japanese Ministry of Health, Labor, and Welfare reported approximately 1.6% of the rate of the surgery in 2011; http://www.e-stat.go.jp/SG1/estat/List.do?lid=000001097372), we excluded outpatients from this study. The exclusion criteria were outpatient status; day surgery; age <18 years; recurrent hernia; incarcerated or strangulated hernia requiring emergency hernia repair; pregnancy or lactation; earlier history of allergy, sensitivity, or anaphylaxis to β-lactam or cephalosporin antibiotics; antibiotic therapy <48 hours before surgery; presence of an infection at the time of surgery; cardiac valvular problem; increased risk for infection secondary to a coexisting medical condition; immunosuppression (eg, human immunodeficiency virus infection, malignancy, or chemotherapy); American Society of Anesthesiologists (ASA) grade > IV; and refusal to participate in the study. If patients had diabetes mellitus, we controlled the value of glycosylated hemoglobin at <6.5%.

Randomization

Patients were randomly assigned on admission in a double-blinded manner to either the antibiotic prophylaxis group or the placebo group. All surgeons and other staff members were blinded to randomization and to patients' details. According to a computer-generated list in blocks of 50 patients, a pharmacist carried out randomization.

Surgical technique

A certified surgeon or surgical resident who was blinded to study group assignment performed surgery under general and local anesthesia, and this was standardized among surgeons. The skin was shaved just before surgery and prepared using 10% povidone iodine. All patients underwent elective open mesh-plug hernia repair using a monofilament polypropylene mesh (PerFix Plug; CR Bard, Cranston, RI). The mesh-plug was sutured in place using 2-0 monofilament polypropylene sutures (Polysorb; Covidien, MI). Any subcutaneous suture was not used. The skin was closed with interrupted 2-0 nylon sutures (Alfresa Pharma, Ltd, Tokyo, Japan). No drain was placed. This was standardized among surgeons.

Intervention

The antibiotic prophylaxis group received 100 mL sterile saline with 1.0 g cefazolin (Astellas Pharma, Ltd, Tokyo, Japan) by continuous intravenous infusion. An equal volume of sterile saline (Otsuka Pharmaceutical Factory Ltd, Tokushima, Japan) was administrated to the placebo group 30 minutes before the incision.

Follow-up

Although a type of wound dressing was not standardized in the hospital, surgeons uniformly removed the dressing and suture 7 to 8 days after surgery (the first follow-up visit) in the outpatient clinic. The second and third follow-up visits were at 1 and 3 months after surgery. All wounds were carefully examined by 2 certified surgeons, who did not perform the operations. According to the most recent criteria from the Centers for Disease Control and Prevention, wound infection was categorized as superficial SSI or deep SSI (DSSI).[21] These criteria define superficial SSI as occurring