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Evaluating the use of antibiotic prophylaxis during open reduction and internal fixation surgery in patients at low risk of surgical site infection

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ABSTRACT

Background: Widespread overuse and inappropriate use of antibiotics contribute to increasingly antibiotic-resistant pathogens and higher health care costs. It is not clear whether routine antibiotic prophylaxis can reduce the rate of surgical site infection (SSI) in low-risk patients undergoing orthopaedic surgery. We designed a simple scorecard to grade SSI risk factors and determined whether routine antibiotic prophylaxis affects SSI occurrence during open reduction and internal fixation (ORIF) orthopaedic surgeries in trauma patients at low risk of developing SSI.
Methods: The SSI risk scorecard (possible total points ranged from 5 to 25) was designed to take into account a patient's general health status, the primary cause of fractures, surgical site tissue condition or wound class, types of devices implanted, and surgical duration. Patients with a low SSI risk score ($\leq$8 points) who were undergoing clean ORIF surgery were divided into control (routine antibiotic treatment, cefuroxime) and evaluation (no antibiotic treatment) groups and followed up for 13–17 months after surgery.
Results: The infection rate was much higher in patients with high SSI risk scores ($\geq$9 points) than in patients with low risk scores assigned to the control group (10.7% vs. 2.2%, $P < 0.0001$). SSI occurred in 11 of 499 patients in the control group and in 13 of 534 patients in the evaluation group during the follow-up period of 13–17 months. The SSI occurrence rate did not differ significantly (2.2% vs. 2.4%, $P = 0.97$) between the control and evaluation groups.
Conclusions: Routine antibiotic prophylaxis does not significantly decrease the rate of SSI in ORIF surgical patients with a low risk score. Implementation of this scoring system could guide the rational use of perioperative antibiotics and ultimately reduce antibiotic resistance, health care costs, and adverse reactions to antibiotics.

Introduction

Open reduction and internal fixation (ORIF) is a commonly used orthopaedic procedure to treat fractures with excellent outcomes. However, surgical site infection (SSI), a devastating complication associated with orthopaedic implants, can prolong the length of hospital stay and dramatically increase the medical costs [16,20]. To minimise SSI occurrences, perioperative prophylactic antibiotics have been routinely used for all patients undergoing ORIF procedures. Although it is generally accepted that prophylactic antibiotics are effective in reducing the incidence of SSI in contaminated and dirty wounds [3,5], it remains uncertain whether antibiotics should be used routinely with patients undergoing clean ORIF surgeries who are at low risk of developing SSI [13,17].

The evolution of resistant pathogens has developed into a worldwide health crisis. Rampant and unnecessary administration of antibiotics is one of the major contributors to the development of drug-resistant pathogens [28]. To prevent and reduce the spread of microorganisms resistant to treatment, we need to better understand what, when, and how antibiotics should be used [16]. In modern orthopaedic practice, a large number of patients with closed fractures undergo ORIF procedures in ultra-clean ventilated operating rooms. Nevertheless, most physicians routinely use prophylactic antibiotics for patients receiving clean ORIF procedures because of undue fear of SSI. There are some clinical

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guidelines for the use of prophylactic antibiotics in general surgeries that are designed to reduce the rapid growth of drug-resistant organisms [9]. However, there are no evidence-based clinical studies that can provide clear guidelines for the rational use of antibiotics specifically for patients undergoing ORIF surgeries. Also, there is no strong evidence regarding whether prophylactic antibiotics can reduce the occurrence of SSI in orthopaedic patients at low risk of developing infection.

Although our understanding of SSI remains incomplete, various types of risk factors, such as the patient's general health status and the degree of trauma and fractures, can contribute to the development of SSI in orthopaedic patients [18,22,24,32,34]. We reasoned that the major risk factors that predispose a person to SSI could be assessed and graded for patients receiving ORIF surgeries. A simple and easy-to-use scoring method could be applied clinically to guide the rational use of antibiotics in orthopaedic patients at low risk of SSI. Therefore, the objective of our prospective study was to design a simple SSI risk scoring system specifically for ORIF surgeries and determine whether the routine use of prophylactic antibiotics during the perioperative period reduces postoperative SSI in ORIF surgical patients at low risk of infection. We hypothesised that routine perioperative antibiotic treatment does not influence the rate of SSI occurrence in this population of patients.

Patients and methods

Design of SSI risk factor scorecard

We designed a SSI risk factor scorecard (Table 1) by considering five major SSI risk factors associated with ORIF surgeries according to related literature about SSI in surgical patients [15,22,24,25,31,33,34]. Each risk factor was assessed as low (1 point), medium (2 points), or high (5 points). The five risk factors are general health status, primary cause of fracture, surgical site tissue condition/wound class, type of implant, and duration of surgery.

Table 1
SSI risk factor scorecard for patients undergoing ORIF surgeries.

Risk factor	Classification	Score
General health status[a]	Healthy, no known disease	1
	Mild systemic disease	2
	Severe systemic disease (ASA score >3)	5
Primary cause of fracture[b]	Indirect low-energy fracture	1
	Direct low-energy fracture	2
	Direct high-energy fracture	5
Surgical site tissue condition/wound class	Intact skin with minor soft tissue damage	1
	Minor, superficial skin abrasion	2
	Extensive, deep skin and tissue damage	5
Types of implant	Pins and screws only	1
	1 metal plate	2
	>2 metal plates	5
Surgical duration[c]	<2 h	1
	2–4 h	2
	>4 h	5

[a] Severe systemic disease includes diabetes, cancer, liver or kidney failure, autoimmune disease, acquired immune deficiency syndrome, sepsis, neutrophilic granulocytopenia, peripheral vascular disease, chronic obstructive airway disease, and chronic use of nicotine, alcohol or steroids.

[b] Indirect low-energy fractures refer to fractures distal to the primary site of trauma. Direct high-energy fractures are those caused by, for example, a motor vehicle accident or a fall from high height.

[c] Surgical duration refers to the period from skin incision to skin closure. ASA, American Society of Anesthesiologists.

With this scoring system, the lowest total score possible is 5 points, and the highest total score possible is 25 points. If a patient's SSI risk score reached 9 points, at least one risk factor had been assigned the highest grade or four risk factors had been given a medium grade. Thus, we considered patients with a score of ≥9 points as having a high risk of developing SSI and patients with a score of ≤8 points having a low risk.

Patient selection and data collection

The study was approved by the Institutional Human Subject Ethics Committee (approval #: JY2010-2; approval date: February 1, 2010). This prospective study was conducted in the orthopaedic surgery department from March 2010 through October 2013. Patients aged >8 years of either sex who were scheduled for ORIF procedures and were able to give informed consent were included in the study. Preliminary scoring using the SSI risk factor scorecard was done by an attending surgeon; these scores were subsequently verified by the antibiotic use assessment group in the orthopaedic surgery department.

A total of 3415 patients was initially assigned to group A or group B using alternating blocks of 6, and 3256 patients completed the one-year follow-up. For the purpose of this study, only a subgroup of patients at low risk of developing SSI (≤8 points) from group A and group B was selected for further study. Specifically, those patients with a risk score ≤8 in group A were then allocated to the evaluation group (no antibiotic treatment, $n = 551$). Group B patients at low risk were subsequently assigned to the control group (antibiotic treatment, $n = 529$). For all low-risk patients, the surgical incisions were classified as clean (Class I) according to the wound classification system by American College of Surgeons. All patients in the control group were given an intravenous injection of cefuroxime (0.75 g in normal saline, 3 doses; Esseti Farmaceutici) 30 min before skin incision, 12 h postoperatively, and 24 h postoperatively [6,7]. Patients in the evaluation group were not given any antibiotics during the perioperative period.

All patients with a high risk score (≥9 points) in group A and group B received routine prophylactic cefuroxime treatment, and therefore, were not part of the study. For each patient, surgical duration was initially estimated before surgery on the basis of past clinical experience. If the surgical duration was unexpectedly prolonged, a higher score was then assigned to the patient. Whenever the score reached ≥9 points, the patient was excluded from the control or evaluation group, and cefuroxime was administered accordingly.

SSI surveillance and management

All patients were treated with standard ORIF surgical procedures. We used a two-step combination of 2% tincture of iodine and 70% isopropyl alcohol for skin preparations in the operating room. Until time of discharge, each day patients were closely monitored for signs of SSI after surgery (until the sutures were removed), asked whether they had any local pain or discomfort, and had their temperature taken. After discharge, the patients were followed up for at least 13 months for any signs of SSI. The follow-up assessment of SSI was made blind with respect to knowledge of whether antibiotics were received by patients.

All cases of SSI were initially diagnosed clinically, which included the classic signs and symptoms of inflammation (progressive swelling, increasing pain, and erythema in the region) and the presence of pus at the surgical site [20]. When SSI was clinically diagnosed, microbiological assessment was performed immediately using samples collected from pus and wound aspirate according to standard protocols (culture, identification and antimicrobial susceptibility). Because SSI associated with ORIF