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Major Article

Incidence and risk factors for infection in spine surgery: A prospective multicenter study of 1764 instrumented spinal procedures

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Background: Surgical site infection (SSI) is a common complication in spinal surgery, imposing a high burden on patients and society. However, information about its characteristics and related risk factors is limited. We designed this prospective, multicenter study to address this issue.

Methods: **:** From January 2015 through February 2016, a total of 1764 patients who had spinal trauma or degenerative spinal diseases were treated with instrumented surgeries and followed up for 1 year with complete data. Data on all patients were abstracted from electronic medical records, and SSIs were prospectively inspected and diagnosed by surgeons in our department. Any disagreement among them was settled by the leader of this study. SPSS 19.0 was used to perform the analyses.

Results: A total of 58 patients (3.3%, 58 of 1764) developed SSI; 1.1% had deep SSI, and 2.2% had superficial SSI. Of these, 60.6% (21 of 33) had a polymicrobial cause. Most of them (51 of 58) occurred during hospitalization. The median occurrence time was 3 days after operation (range: 1–123 days). SSI significantly prolonged hospital stays, by 9.3 days on average. The univariate analysis revealed reason for surgery as the only significant risk factor. The multivariate analysis, however, revealed 8 significant risk factors, including higher BMI, surgical site (cervical), surgical approach (posterior), surgery performed in summer, reasons for surgery (degenerative disease), autograft for fusion and fixation, and higher preoperative platelet level.

Conclusion: Identification of these risk factors aids in stratifying preoperative risk to reduce SSI incidence. In addition, the results could be used in counseling patients and their families during the consent process.

INTRODUCTION

With the rapid development of transportation and the aging of the population, the incidence of spinal trauma and degenerative spinal diseases is on the rise. Spinal surgery with instrument fixation is currently the predominant treatment choice for such diseases. However, postoperative complications are inevitable, and surgical site infection (SSI) is the most common type, with a reported incidence[1-4] of 1%–15%. The occurrence of SSI has a substantial impact on patients. Aside from its substantive effect on patient survival and quality of life, SSI markedly increases health care costs for patients undergoing spinal surgery, with prolonged hospital stay being a major contributor. In addition, readmission to the hospital for wound treatment and management is another costly intervention, required for approximately 25% of these patients.[5] Therefore, comprehensive preoperative evaluation of patients' medical conditions, identification of related risk factors for SSI, and introduction of cost-effective interventions for preventing SSI are certainly warranted.

Several risk factors have been found to be significantly associated with the occurrence of SSI in spine surgery: male gender, advanced age, higher body mass index (BMI; >30), smoking, diabetes, poor nutritional status (preoperative albumin level <3.5 mg/dL), history of infection in the surgical site, preoperative steroid therapy, spinal trauma, posterior spinal fusion, number of levels

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fused, and prolonged surgical time (>3 hours).[6–13] However, most of these results come from single-center, retrospective studies that generally were limited by inaccuracy of collected data owing to patients'recall bias and incomplete medical records. Consequently, underestimation of the incidence of this complication, and imprecise estimation of risk for some variables, are inevitable. In addition, a tertiary referral center is generally the type of institution at which research of a certain sample of participants can be conducted; thus, participants' medical conditions are typically more severe and do not represent the overall incidence of spinal surgery. Given these issues, we designed the current research as a prospective, multicenter study with 2 aims: to describe the incidence and characteristics of SSI in instrumented spine surgeries during at least 1-year of follow up; and to investigate related risk factors for SSI.

METHODS

This prospective, multicenter study involved 3 hospitals (1 level I and 2 level II hospitals) in the Xinjiang Province of China and was performed during a 14-month period from January 2015 through February 2016. All patients aged 18 years or older who had spinal diseases (traumatic fractures; degenerative spinal diseases such as spinal canal stenosis, spondylolisthesis, and lumbar disk herniation) treated by instrumented surgery (decompression or fusion) were included. The exclusion criteria were: age less than 18 years; history of spinal surgery; pathological fractures (metastasis, tuberculosis); old fractures (>21 days from initial injury); and reoperation for other specific reasons (deformity, revision, infection, malignancy).

To analyze the relationship between risk factors and SSI, as much information as possible was collected about the patient, the surgical procedure, and laboratory test results. Patient-related characteristics included the following: age; gender; BMI; place of residence (city or village); current smoking status; current alcohol use level; and comorbidities (diabetes mellitus, hypertension, coronary heart disease, pulmonary disease, chronic nephrosis, anemia, long-term steroid therapy, and any previous operation). Surgery-related variables included the following: reason for surgery (trauma, degenerative diseases); length of preoperative hospital stay; length of total hospital stay; surgical location (cervical, thoracic, lumbosacral); season in which surgery was performed; hospital level (I or II); surgeon level (visiting staff, vice archiater, and archiater); American Society of Anesthesiologists, anesthesia type (general, regional); intraoperative antibiotic use; postoperative antibiotic use; duration of surgery; incision cleanness grades; level of intraoperative blood loss; number of instrumented levels; and postoperative drainage use. Variables from laboratory tests were as follows: white blood cell count; red blood cell count; platelet (PLT) level; hemoglobin level; neutrophil count; lymphocyte count; monocyte count, eosinophil count; basophil count; total protein level; albumin level; globulin level; and albumin/globulin ratio.

Definition and identification of SSI and quality control

An SSI was diagnosed on the basis of the SSI definition criteria put forth by Mangram et al.[14] at the Centers for Disease Control and Prevention. We considered an SSI to be deep if it met any of the following criteria: infection beyond the deep fascia, persistent wound discharge or dehiscence, visible abscess or gangrene requiring surgical debridement and instrument exchange or removal. Wound swabs were collected and sent for causative agent culture and sensitivity analysis, if available. Any patient who commenced antibiotic treatment for wound problems (redness, swelling, heat, pain) and did not meet the criteria for diagnosis of deep SSI was deemed to have a superficial SSI, irrespective of any microbiology results. Based on the timing of SSIs, we created a line chart, with the x-axis indicating timing (day of occurrence), and the y-axis indicating the overall number of SSIs over the elapsed time.

Data on infection were collected by the 6 surgeons in the department of spinal surgery, who were trained by the infection control team of our hospital before the start of this study. These 6 surgeons visited the patients' wards every day and inspected suture sites for signs of infection, starting from the second postoperative day and continuing until patients were discharged from the hospital. Any disagreements on the identification of a specific SSI were settled by the leader of this study (Jiang Zhao, corresponding author). After patients were discharged, surgeons followed up with them via telephone to determine if SSI was present, at 2 weeks, and 1, 3, 6, and 12 months postoperatively. For patients suspected of having SSI were asked to provide detailed information on timing of occurrence, treatment course, and results. If any doubts arose regarding accuracy of patient reporting, the patient was excluded from the study, to ensure precision of the data.

Definition of variables of interest

Patients' BMI was calculated, as weight divided by the square of height, and was divided into 5 groups on the basis of Chinese reference criteria (underweight, <18.5; normal, 18.5–23.9; overweight, 24–27.9; obese, 28–31.9; morbidly obese, ≥32). Preoperative hospital stay, defined as the interval between admission to the hospital and day of surgery, was divided into 3 groups, by duration in days: <3, 3–6, and ≥7.

Patients' lifestyles and comorbidities were obtained directly from patients and their relatives or from electronic medical records, and were represented as being present or not. Specifically, smoking status is indicated as "present" only if a patient was a then-current smoker; those who had smoked previously or who smoked only very occasionally (<1 cigarette every 3 days) are defined as "not present." Corticosteroid use in a regular regime for at least 1 month before the hospitalization is indicated as "present"; any other use was classified as "not present." Cleanness of the operating room was classified into 1 of 4 levels, according to the bacterial quantity per square centimeter. Intraoperative blood loss level was divided into 5 groups (in ml): <200, 200–399, 400–599, 600–799, and ≥800.

For results of laboratory tests, we documented their values and divided them into 3 groups: normal (range), above upper limit, and below lower limit.

This study was approved by the institutional review board of each of the 3 centers; all participants provided written consent.

STATISTICAL ANALYSIS

The mean and standard deviation were calculated for continuous variables; number and percentage were calculated for categorical variables. First, a univariate logistic regression analysis was performed to evaluate the relationship between each categorical variable and SSI. The *t*-test or Mann-Whitney U test was used for continuous variables, depending on the data distribution (equal variance and normality or not). A P value <.05 was considered to be significant. Further, all the related variables were entered into the multivariate logistic regression model to determine the independent risk factors for SSI. The Hosmer-Lemeshow C test was used to evaluate the goodness of fit of the final model.

RESULTS

During the 14-month study interval, all 1764 patients with a diagnosis of spinal disease (spinal trauma and degenerative diseases) who were treated with surgical instrumentation in the selected institutions were included. Of these, 933 were men and 831 were