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Clinical Study

Predicting surgical site infection after spine surgery: a validated model using a prospective surgical registry

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Abstract

BACKGROUND CONTEXT: The impact of surgical site infection (SSI) is substantial. Although previous study has determined relative risk and odds ratio (OR) values to quantify risk factors, these values may be difficult to translate to the patient during counseling of surgical options. Ideally, a model that predicts absolute risk of SSI, rather than relative risk or OR values, would greatly enhance the discussion of safety of spine surgery. To date, there is no risk stratification model that specifically predicts the risk of medical complication.

PURPOSE: The purpose of this study was to create and validate a predictive model for the risk of SSI after spine surgery.

STUDY DESIGN: This study performs a multivariate analysis of SSI after spine surgery using a large prospective surgical registry. Using the results of this analysis, this study will then create and validate a predictive model for SSI after spine surgery.

PATIENT SAMPLE: The patient sample is from a high-quality surgical registry from our two institutions with prospectively collected, detailed demographic, comorbidity, and complication data.

OUTCOME MEASURES: An SSI that required return to the operating room for surgical debridement.

MATERIALS AND METHODS: Using a prospectively collected surgical registry of more than 1,532 patients with extensive demographic, comorbidity, surgical, and complication details recorded for 2 years after the surgery, we identified several risk factors for SSI after multivariate analysis. Using the beta coefficients from those regression analyses, we created a model to predict the occurrence of SSI after spine surgery. We split our data into two subsets for internal and cross-validation of our model. We created a predictive model based on our beta coefficients from our multivariate analysis.

RESULTS: The final predictive model for SSI had a receiver-operator curve characteristic of 0.72, considered to be a fair measure. The final model has been uploaded for use on SpineSage.com.

CONCLUSIONS: We present a validated model for predicting SSI after spine surgery. The value in this model is that it gives the user an absolute percent likelihood of SSI after spine surgery based on the patient's comorbidity profile and invasiveness of surgery. Patients are far more likely to understand an absolute percentage, rather than relative risk and confidence interval values. A model such as this is of paramount importance in counseling patients and enhancing the safety of spine surgery. In addition, a tool such as this can be of great use particularly as health care trends toward pay for performance, quality metrics (such as SSI), and risk adjustment. To facilitate the use of this

FDA device/drug status: Not applicable.

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The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

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model, we have created a Web site (SpineSage.com) where users can enter patient data to determine likelihood for SSI. © 2014 Elsevier Inc. All rights reserved.

Keywords: Surgical site infection; Spine surgery; Complication; Predictive model; Registry; Spinesage.com

Introduction

As measures are taken to optimize safety and ensure quality in surgery, surgical site infection (SSI) is a topic that has become increasingly relevant [1–6]. In addition to the obvious deleterious effect it has on the patient, the occurrence SSI is now regarded as a reflection of ''quality.'' Numerous reports have described the incidence and risk factors for SSI. They have included diabetes, instrumentation, and lumbosacral surgery among many others depending on which study is cited. Frequently, the magnitudes of these risks are expressed in epidemiologic terms of probabilities, such as relative risk values or odds ratios (ORs). Although these values are statistically and academically valuable, they may be difficult for patients to interpret. When counseling patients regarding risks of surgical treatment, a probability estimate of risk in the form of a percentage likelihood of outcome is more likely to be of value to the patient compared with the more formal measurements of ORs or relative risks. We had previously identified, quantified, and reported statistically significant risk factors for SSI after a multivariate analysis of a prospective surgical spine registry. The Spine End Result Registry (SEER) is a prospectively collected registry for all surgical spine patients at University of Washington and Harborview Medical Center who underwent surgery from January 1, 2003 to December 31, 2004. Complications were defined explicitly a priori, and extensive demographic, comorbidity, and surgical details were prospectively recorded for each surgical patient for at least 2 years after their surgery [7–12]. The purpose of this study was to derive and validate a predictive model for SSI after spine surgery using the prospectively collected data from the SEER.

Methods

Patient population

This is a retrospective analysis of a prospective cohort of patients who participated in an SERR or a quality assurance/quality improvement database for the purpose of defining and assessing safety and outcomes for any patient undergoing spine surgery at one of two academic institutions. All patients were recruited to participate in the SERR to assess adverse events and provide outcome data. If patients declined to participate in the outcome portion of the registry (N=794/1,532, 51.8%), they were followed in the quality assurance/quality improvement study and only their adverse events were tracked. However, some information about their risk factors, such as smoking status and alcohol use, were missing, as the data for this group's adverse events were found either by notification from hospital staff or by medical record review. We performed our analysis assuming the missing data fields to be indicative of the absence of the risk factor. We also performed our analysis excluding these patients, and the results from both analyses did not differ substantially. This article presents the results of our analysis with the assumption of missing fields to be indicative of absence of the risk factor.

Exclusions

There were N=1,745 patients enrolled in the study from January 1, 2003 to December 31, 2004. Of those, 213 were excluded for the following reasons: missing exposure status (N=16/83, 19%) or exposure status equal to zero (N=67/83, 81%), less than 18 years of age (N=38/213, 18%), and those diagnosed with a previous infection (N=91/213, 43%). Exposure status equal to zero included those who did not have surgical intervention, including cast and halo placement and thoracolumbarsacral orthosis (Fig. 1).

Data collection

Classification of predictors, confounders, and outcomes

The primary outcome of interest was SSI that required return to the operating room for irrigation and debridement. Patients were followed for 2 years after the index procedure for the occurrence of complication. Throughout this registry, complications were recorded through seven mechanisms: daily dedicated medical record review by the research team; confidential forms in the operating rooms and inpatient and outpatient areas; telephone lines at each hospital; electronic mail with privacy protection; weekly spine clinical conferences; inpatient rounds; and outpatient clinics [12]. Risk factors examined included age, sex, smoking status, alcohol use, diabetes, body mass index, surgical approach (posterior, anterior, combined), revision surgery, surgery region (cervical, thoracic, lumbosacral), diagnosis (degenerative, trauma, neoplasm, infection, other), and surgical invasiveness (SI). In addition, the influence of preexisting medical comorbidity (cardiac disease, congestive heart failure [CHF], chronic obstructive pulmonary disease, hypertension, rheumatoid arthritis [RA], renal disease, liver disease, cancer, anemia, bleeding disorder) was also be considered as predictor variables. We used the surgical invasiveness index (SII) as described by Mirza et al. [12]. The surgical invasiveness index is a previously validated instrument that accounts for the number of levels decompressed, fused, or instrumented, posteriorly and anteriorly. It ranges from 0 to 48, with a higher score indicating

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