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· 论 著 ·

Surgical site infection and related risk factors among patients following spinal surgery

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[Abstract] **Objective** Surgical site infection (SSI) is associated with morbidity, increased healthcare costs and in some cases poor outcomes in patients. The purpose of this study was to identify the burden of SSI and the risk factors among hospitalized patients undergoing spinal surgery in a Chinese hospital. **Methods** A prospective cohort study was performed in patients who underwent spinal surgery in a hospital of traditional Chinese medicine (TCM) in China from June 26 to November 30 in 2014. SSI was diagnosed according to the Centers for Disease Control and Prevention (CDC) criteria of the U. S. , and was identified by bedside surveillance and post-discharge follow up. The detailed characteristics of pre-, intra- and post-operative patients were recorded with a standardized data collection form. **Results** A total of 192 patients with spinal surgery were included in the study, 7(3.6%) of these patients developed SSI. Contaminated and dirty/infected wound, surgical drainage, and blood transfusion were associated with increased Odds of SSI by bivariate analysis. Intravenous antimicrobial prophylaxis (AMP) was given in 120 of 192 (62.5%) spinal surgery. The average duration of AMP administered was 2.2 days (range, 1-9), 139 (72.4%) of 192 patients were prescribed TCM after spinal surgery. **Conclusion** The incidence of SSI among patients after spinal surgery in a hospital of TCM in China was identified. This study is served as a reference for studying SSI in spinal surgery in future, and also provides the valuable information to formulate SSI prevention programs.

[Key words] surgical site infection; spinal surgery; healthcare-associated infection; risk factor; traditional Chinese medicine

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脊柱手术后患者外科手术部位感染及相关危险因素

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[摘要] **目的** 外科手术部位感染(SSI)是脊柱手术后常见的并发症之一,与感染发病率增高,治疗时间延长,医疗费用增加,患者预后效果不良有着密不可分的关系。本研究的目的是探索某教学医院患者进行脊柱手术后发生 SSI 的现状与其相关危险因素。**方法** 采用前瞻性队列研究方法,对 2014 年 6 月 26 日-11 月 30 日该院所有脊柱手术患者进行目标性监测,以美国疾病控制与预防中心(CDC)颁布的指南作为 SSI 的诊断依据,通过床旁调查与出院后的检查发现 SSI 病例,使用标准化的数据收集脊柱手术患者术前,术中及术后资料。**结果** 2014 年 6

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月 26 日—11 月 30 日共监测 192 例脊柱手术患者,其中 7 例(3.6%)发生了 SSI。通过双变量分析的方法发现切口类型(污染/感染切口)、外科引流、输血与增加 SSI 风险的密切相关。在 192 例脊柱手术患者中,120 例(62.5%)给予静脉使用预防性抗菌药物,使用周期为 2.2 (1~9)d,139 例(72.4%)使用中成药。**结论** 该研究有助于了解该教学医院脊柱手术后患者 SSI 发病率,亦为今后进行脊柱手术后患者发生 SSI 的研究提供有价值的信息。

[关键词] 外科手术部位感染; 脊柱手术; 医院感染; 危险因素; 中成药

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Introduction

Surgical site infection (SSI) is associated with morbidity, increased healthcare costs and in some cases patients' poor outcome^[1]. SSI is reported to be the third most common healthcare-associated infection(HAI) in Europe, U. S. , and China^[2-5].

The incidence of SSI among patients who underwent spinal surgery in different studies and different areas of the world ranged from 1.3% to 13.7%^[6-9], in China ranged from 1.8% to 7.7%^[10-12]. According to the *Guideline of Hospital Management and Assessment* published by National Health and Family Planning Commission of the People's Republic of China (NHFPC)^[13], the goal is that the overall incidence of SSI in clean surgery should be $\leq 1.5\%$.

The following factors are shown to increase the risk of developing SSI after spinal surgery: American Society of Anesthesiologists (ASA) score ≥ 3 , inappropriate timing of AMP, duration of surgical procedure ≥ 3 hours, wound classified as contaminated or dirty \ infected, and longer length of stay in hospital^[2,14-16]. However, a systematic review indicated that there is a paucity of solid evidence of robust risk factors associated with spinal surgery^[14].

In China, public reports of SSI, obtained via ongoing national surveillance activities, few have been reported over the past decades^[17]. Therefore, the main purpose of this study was to identify the burden of SSI and its associated risk factors among patients undergoing spinal surgery in a Chinese hospital between June 26 and November 30, 2014. The use of AMP and TCM were also analyzed.

Materials and methods

This was a prospective cohort study conducted by the Dongguan Hospital of Traditional Chinese Medicine. The hospital was established in 1965, with the integrated function of medical treatment, teaching and research, it has 955 hospital-beds.

The study included all hospitalized patients who underwent spinal surgery between June 26 and November 30, 2014. Surgical sites were observed within 30 days after surgery for surveying the development of SSI. Other HAIs were not recorded.

All variables which were already in the hospital surveillance system were included in this study, such as age, gender, ASA score, wound classification, duration of surgical procedures, categories of AMP (such as first and second generation cephalosporins), duration of AMP administration, as well as risk factors referred by the CDC and identified by studied articles, such as diabetes mellitus, orthopedic instrumentation, intra-operative blood loss, surgical drainage, and blood transfusion^[10,18-22]. The use of TCM (such as *Panax notoginseng saponins*, *Salvia miltiorrhiza*, and *Lumbricus rubellus*) as an alternative variable was also involved in the study.

All SSIs were defined according to the CDC criteria, and were classified as superficial incision, deep incision or organ/space SSIs^[23]. The investigators performed bed-side observation and inspected patients' wound three days a week (Monday, Wednesday and Friday), and determined if the patient was prescribed antimicrobial agents, had positive microbiological result, with a temperature over 37°C, and with one of the following comorbidities: diabetes mellitus or malnutrition.

SSIs among patients were monitored for 30 days after surgery, post-discharged patients were followed up by phone-interview using a pre-defined questionnaire. Incisional wounds of all patients attending the outpatient clinic were examined.

Ethical clearance was obtained both from Regional Committees for Medical and Health Research Ethics in Norway and Ethics Committee from the Dongguan Hospital of Traditional Chinese Medicine in China. Before the phone-interview, oral informed consent was obtained.

The descriptive statistical analysis was conducted, and the data was analyzed with IBM SPSS 22.0 (SPSS, Inc, Chicago, IL, USA), patient's characteristics related to SSI were compared with *Chi-square* test or *Fisher's exact* test for categorical variables. Associations between potential risk factors and SSI were analyzed by calculating crude Odds ratio (OR) with bivariate logistic regression.

Results

All 192 patients who underwent spinal surgery between June 26 and November 30, 2014 were included in the study. There were 130 (67.7%) females and 62(32.3%) males, the mean age was 61.7 years (range, 20 – 89), and the females were older than males (65.3 years vs 54.3 years). More characteristics of patients are shown in Table 1.

According to *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* codes, the top three spinal surgery procedures were vertebroplasty (51.0%), spinal decompression (14.6%), and spinal fusion (7.3%).

Among 192 patients, 7 (3.6%) developed SSI, all SSIs were detected among inpatients. 3 (1.6%) were diagnosed with superficial incisional

SSI, 4 (2.1%) were deep incisional SSI, and none of patients were diagnosed with organ/space SSI. 71.9% of 192 patients were conducted a post-discharge follow-up by phone-interview.

Table 1 Characteristics of 192 patients undergoing spinal surgery at Dongguan Hospital of Traditional Chinese Medicine between June 26 and November 30, 2014

Characteristic	Spinal surgery(n[%])/ (n[range])
Male	62 (32.3)
Female	130 (67.7)
Mean age in years	61.7 (20 – 89)
Mean days of pre-operative stay	7.2 (1 – 33)
Mean total days of hospital stay	18.3 (5 – 77)
Mean duration of surgery in minutes	124 (20 – 575)
No. of SSI ^a	7 (3.6)
No. of superficial SSI	3 (1.6)
No. of deep SSI	4 (2.1)
No. of SSI diagnosed in hospital	7 (3.6)

a SSI: Surgical site infection

Table 2 summarized the analysis of factors linked to SSI of spinal surgery, a higher wound contamination class (OR, 45.5 [95%CI, 6.9 – 298.8]), surgical drainage (OR, 8.8 [95%CI, 1.0 – 74.6]), and blood transfusion (OR, 5.6 [95%CI, 1.2 – 26.5]) were associated with increased Odds of SSI. 120 of 192 (62.5%) patients received intravenous AMP, and all of them received AMP within 2 hours before spinal surgery. The average duration of AMP administered was 2.2 days (range, 1 – 9). The top four prescribed AMP were cefotiam (40.0%), cefathiamidine (24.2%), cefuroxime (15.8%), and cefamandole (10.0%), these four prescriptions accounted for 90.0% of the total AMP given. However, 7 of 120 patients who received AMP also developed SSI.

Table 2 Factors associated with surgical site infection among 192 patients undergoing spinal surgery at Dongguan Hospital of Traditional Chinese Medicine between June 26 and November 30 , 2014

Variable	Total No. of patients (SSI case)	Crude Odds ratio(95%CI) ^a
Age(yrs)	≤62	Reference Cat.
	>62	0.5 (0.1 – 2.5)
Gender	Female	Reference Cat.
	Male	0.8 (0.2 – 4.4)
Body mass index	≤25	Reference Cat.
	>25	1.3 (0.2 – 12.0)
	Missing	–
Hypertension	Yes	–
	No	Reference Cat.
Diabetes mellitus	Yes	–
	No	Reference Cat.
Rheumatoid arthritis	Yes	5.0 (0.5 – 48.0)
	No	Reference Cat.
Bone oncology	Yes	–
	No	Reference Cat.
Pre-operative stay(d)	≤7	Reference Cat.
	>7	1.1 (0.2 – 5.7)
Orthopedic implant	Yes	3.1 (0.7 – 14.2)
	No	Reference Cat.
ASA score	1 + 2	Reference Cat.
	3	2.6 (0.5 – 13.9)
Wound classification	Class 1 + 2	Reference Cat.
	Class 3 + 4	45.5 (6.9 – 298.8)
Skin preparation	Yes	Reference Cat.
	No	1.1 (0.1 – 9.7)
Duration of operation(h)	<3	Reference Cat.
	≥3	1.3 (0.2 – 6.8)
No. of surgeons participating the orthopedic surgery	3~5	Reference Cat.
	6~9	4.6 (0.9 – 24.5)
Intraoperative blood loss(mL)	≤500	Reference Cat.
	>500	4.4 (0.9 – 20.7)
Surgical drainage	Yes	8.8 (1.0 – 74.6)
	No	Reference Cat.
Blood transfusion	Yes	5.6 (1.2 – 26.5)
	No	Reference Cat.
WBC ^b before surgery(×10 ⁹ /L)	4~11	Reference Cat.
	>11	1.9 (0.4 – 10.3)
WBC after surgery(×10 ⁹ /L)	4~11	Reference Cat.
	>11	2.2 (0.4 – 11.5)
	Missing	–
AMP ^c administration	Yes	Reference Cat.
	No	–
Duration of AMP administration(d)	No-AMP	–
	≤1	Reference Cat.
	>1	0.9 (0.2 – 4.1)
TCM ^d administration	Yes	Reference Cat.
	No	2.0 (0.4 – 9.4)

a CI: Confidence interval

b WBC: White blood cell

c AMP: Antimicrobial prophylaxis

d TCM: Traditional Chinese Medicine

139 (72.4%) of 192 patients were prescribed TCM after spinal surgery, the top three constituents of TCM in this study were *Panax notoginseng saponins* (59.7%), *Salvia miltiorrhiza* (21.6%), and *Lumbricus rubellus* (6.5%), and 4 of 7 patients who developed SSI received TCM.

Discussion

The incidence of SSI among patients after spinal surgery in this study was 3.6%. Bivariate analysis showed that contaminated and dirty/infected wound, surgical drainage, and intra-operative blood transfusion were associated with increased Odds of SSI following spinal surgery. We estimate that the incidence of SSI identified by this study might be underestimated due to no SSI cases being detected after patients were discharged from hospital. Other study showed that the proportion of SSI cases detected varies between 21% and 94% [24].

A possible explanation for no SSI cases being detected after patients were discharged from hospital was that some patients lived far away from the Dongguan Hospital of Traditional Chinese Medicine, they might have attended to other hospitals for check-up or readmission, there was no system that enabled us to identify SSI among patients in other hospitals.

In our surveillance, 71.9% of cases conducted the post-discharge phone-interview. The mean age of patients non-responding was older than those being interviewed by phone (67.2 years vs 59.6 years). It is known that older people have a higher risk of SSI [14]. It might be that there were SSIs among those not being interviewed.

The risk factors identified in this study were also reported by previous studies [2,14-16,25,26]. These factors have been identified to be associated with SSI after spinal surgery, such as higher ASA scores, duration of surgical procedure ≥ 3 hours, and longer duration of AMP administered. However, we could not find out the relationship between these factors and SSI of spinal surgery in this study, a possible explanation is that the pres-

ent study was underpowered and therefore unable to identify association between SSI and some variables. Multiple regression analysis in this study was not recommended due to small samples [27].

In the present study, we identified that only 62.5% of the patients included in this study were given AMP. AMP is recommended for spinal surgery with and without surgical implantation instruments [28]. However, according to Chinese national guidelines for clinical use of antimicrobial agents before 2016 [29,30], AMP is not commonly recommended in general spinal surgery, so there is no specific recommendation on AMP in relation to spinal surgery in China until 2016 [30].

We identified that first or second generation cephalosporins were administered for routine surgical prophylaxis. This finding was consistent with recommendations [29,31] referred by NHFPC and identified by studied articles [32]. The mean duration of AMP administration was 2.2 days, however Chinese and international guidelines recommend the duration of AMP administration should be less than 24 hours after the surgery [28-29,32]. We described the use of TCM, however we can't confirm its effect on preventing SSI, despite supports in the literatures have showed that TCM such as "*Panax notoginseng saponins*" prescribed in this study could induce the biological effect on inhibiting pathogens [33,34,35]. Nevertheless, no research evidence have indicated that patients being treated with TCM were less likely to develop SSI.

Short-term surveillance and insufficient numbers of cases were the limitation of this study. This might be an explanation for this study not being able to identify association between SSI and some variables. Significantly, it provided some information about the burden of SSI and its risk factors in a Chinese hospital by using standardized surveillance method. More studies with appropriate sample size are needed to identify risk factors associated with SSI among patients undergoing spinal surgery in China.

This study has identified the incidence of SSI (3.6%) after spinal surgery in an orthopedic ward

of Dongguan Hospital of Traditional Chinese Medicine. Contaminated and dirty/infected wound, surgical drainage, and blood transfusion were identified as the risk factors. This research is served as a reference for SSI study in future and also provides valuable information to formulate SSI prevention programs.

Conflict of interest

The authors declare no potential conflict of interest with respect to the research, authorship, and/or publication of this article.

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