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Title

Surgical site infection in spinal metastasis: risk factors and countermeasures

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Mini Abstract.

Risk factors of surgical site infection and positive effect of prostaglandin E₁ in patients with spinal metastasis were evaluated. Diabetes and preoperative irradiation were the independent risk factors by multivariate analysis. Prostaglandin E₁ administration was found to decrease the rate of surgical site infection in patients with preoperative irradiation.

Key words:

Surgical site infection

spinal metastasis

irradiation

Abstract

Study Design. A retrospective review (Phase 1) and prospective clinical study (Phase 2)

Objectives. The objectives of this study were to identify independent risk factors for surgical site infection (SSI) and to evaluate the positive effect of prostaglandin E₁ (PGE₁) to decrease the risk of SSI in patients with spinal metastasis.

Summary of Background Data. Surgery for spinal metastasis is associated with an increased risk of SSI. Although previous reports have evaluated risk factors of SSI for spinal metastasis, most of the studies lack multivariate analysis. A recent study demonstrated the utility of PGE₁ in decreasing wound complications in patients with prior irradiation. The role of PGE₁ in surgery for spinal metastasis has not been previously evaluated.

Methods. 110 patients with spinal metastasis were retrospectively reviewed (phase 1). Risk factors for SSI were analyzed using logistic regression. Phase 2 was a prospective clinical trial investigating the utility of PGE₁ at reducing the rate of SSI. 94 patients for with spinal metastasis were treated at our institute. The infection rate and risk factors identified in phase 1 and 2 were compared.

Results. The rate of SSI during Phase 1 was 7.1%. Independent risk factors identified

by multivariate logistic regression were diabetes, and preoperative irradiation. The rate of SSI for patients who had irradiation before surgery was 32%, while the rate for patients without irradiation was 1.1%. This difference was statistically significant. The rate of SSI in Phase 2 was 3.1%. In Phase 2 patients who received preoperative irradiation, the rate of SSI was 4.5%. The difference between Phase 1 and Phase 2 was statistically significant.

Conclusions: This study identified diabetes and preoperative irradiation to be independent risk factors for SSI in patients with spinal metastasis. PGE₁ administration was found to significantly decrease the incidence of SSI in patients with spinal metastasis who underwent preoperative irradiation.

Introduction

The purposes of surgical treatment for spinal metastasis are to avoid recurrence of the tumor, and to control spinal paralysis to maintain the patient's quality of life until the last moment. On the other hand, patients with spinal metastasis might have poor nutritional status and be prone to immunosuppression from disease or treatments. Hence, the surgery for spinal metastasis is still controversial because it has potential risks of postoperative systemic complications. Recent literatures have reported excellent functional outcomes after the surgery for spinal metastasis with falling morbidity rates^{12, 13}, although, the rate of complication remains relatively high compared to other spinal surgeries. Wise et al¹¹ reported that the rate of complication was 25%. In all these reports, a major cause of morbidity was surgical site infection (SSI).

SSI is one of the serious complications and may compromise the quality of outcome. A variety of risk factors for SSI in spinal surgery have been reported. Patient characteristics reported to increase the risk of SSI following spinal surgery are advanced age, preoperative malnutrition, presence of diabetes, preoperative or perioperative steroid therapy, and preoperative adjunctive therapy including chemotherapy or irradiation at the surgical site. Surgery-related risk factors reported to be associated

with increase risk of SSI are increased duration of surgery, increased blood loss, repeat spinal surgery at the surgical site, posterior instrumentation surgery, and procedure of the tumor resection.¹⁻⁵ For the surgery in spinal metastases, the rate of SSI is reported from 12 to 20%⁵⁻⁷, higher than other spinal surgeries. Although previous reports have evaluated risk factors of SSI for spinal metastasis, most of the studies lack multivariate analysis. Furthermore, a recent study demonstrated the utility of prostaglandin E₁ (PGE₁) in decreasing SSI after laryngeal surgery in patients with prior irradiation. The role of PGE₁ in surgery for spinal metastasis has not been previously evaluated. So, there were two phases to this study, Phase 1 was to identify independent risk factors of SSI and Phase 2 was to evaluate the positive effect of PGE₁ to decrease the risk of SSI in patients with spinal metastasis.

Phase 1 Study

Material and Methods

110 patients (113 surgeries) with spinal metastasis, treated between 1993 January and 2003 March, were retrospectively reviewed. There were 45 women and 65 men, with a median age 56.0 years (range 32-72 years). The main lesion was located in the thoracic spine in 58 patients, in the lumbar spine in 40, and in the cervical spine in 12.

The primary tumors were cancer of the kidney (22), breast (17), lung (14), colon (11), thyroid (10), prostate (5), liver (4), unknown (5), and others (22). According to the surgical strategy for spinal metastases by Tomita et al⁸, an appropriate oncologic surgical procedure was selected for each patient based on the prognostic score, which is obtained by summing points of the three prognostic factors. Wide or marginal excision such as total *en bloc* spondylectomy was performed in 38 patients (two-staged surgeries were performed in 3 patients). Debulking surgery such as piecemeal excision or eggshell curettage was performed in 43 patients. Palliative surgery such as spinal cord decompression with spinal stabilization was performed in 29 patients. (Table 1) The mean prognostic score was 3.7 points in patients treated by wide or marginal excision, 5.1 points in patients treated by debulking surgery, and 6.4 points in patients treated by palliative surgery.

Perioperative patient characteristics and surgery-related characteristics reported to be risk factors for SSI in previous studies^{4,5,9} were evaluated in this study. All of the patients in this study received prophylactic antibiotics (Cephem antibiotic agent was given in 94 patients, Penicillin antibiotic agent in 8 patients, and other prophylactic antibiotics in 11 patients). To detect a difference between the incidence of SSI and risk factors, univariate methods were used. Contingency tables were used to assess

association by Fisher's exact test. A P value less than 0.05 was considered statistically significant. For multivariate analysis, multivariate stepwise logistic regression was used to identify independent risk factors for SSI. The variables with univariate P values less than 0.2 were considered as candidates for multiple logistic regression. Statistical analyses was performed using SPSS 11.0 software (SPSS Inc., Chicago, IL).

Results

In the period of this study, the incidence of SSI was 7.1% (8/113 surgeries). Microorganisms isolated from these wounds were coagulase-negative *Staphylococcus* in 3 cases, *Staphylococcus aureus* in 2 cases, *Escherichia coli* in 1 case, *Candida albicans* in 1 case, and *Pseudomonas aeruginosa* in 1 case. (Table 2) All cases were classified as deep SSI, and five of the 8 patients underwent repeated surgery because of their SSI. The results of the univariate analyses of risk factors are shown in Table 3 and 4. The median age of the patients was 56.0 years. Age >56 was not a statistically significant risk factor by univariate analysis (odds ratio [OR] 0.58, 95% confidence interval [CI] 0.13-2.54, P = 0.71). Gender was not a significant risk factor (male OR 1.16, 95% CI 0.26-5.15, P = 0.84). All the diabetic patients were type I and were treated with oral

therapy. The presence of diabetes was a significant risk factor (OR 17.7, 95% CI 3.64-43.6, $P < 0.01$). In this study, a serum albumin less than 3.5 g/dL was defined to be malnutrition.¹⁰ Malnutrition was not a significant risk factor (OR 2.21, 95% CI 0.39-12.5, $P = 0.37$). American Society of Anesthesiologists class (ASA) indicates the extent of illness. ASA of 3 or 4 was not a statistically significant risk factor (OR 1.72, 95% CI 0.87-3.40, $P = 0.11$). In this study, 37 of 110 patients received chemotherapy as treatment of the primary tumor. The history of chemotherapy was not a statistically significant risk factor (OR 3.80, 95% CI 0.85-16.9, $P = 0.08$). Prior irradiation at surgical site was performed in 22 patients. The rate of SSI with irradiation was 31.8% (7 of 22 cases), much higher than those without irradiation (1.1%, 1 of 91 cases). This difference was statistically significant (OR 41.0, 95% CI 4.82-63.6, $P < 0.01$). Administration of perioperative steroids was performed in 67 patients who had paraparesis due to spinal cord compression. The use of steroids was not a significant risk factor (OR 2.06, 95% CI 0.40-10.7, $P = 0.39$). 74 patients had neurologic deficit due to spinal cord compression. The presence of neurologic deficit did not affect SSI (OR 3.96, 95% CI 0.47-33.5, $P = 0.21$). In phase 1 study, total *en bloc* spondylectomy was performed in 38 patients (41 surgeries), debulking surgery in 43 patients, and palliative surgery in 29 patients. Two (4.8%) of 41 surgeries

developed SSI following *en bloc* spondylectomy, compared with two (4.7%) of 43 surgeries following debulking surgery, and four (13%) of 29 surgeries following palliative surgery. There was no association between type of the surgery and SSI (Table 4). The history of multiple operation at surgical site affected SSI by univariate analysis (OR 1.85, 95% CI 1.11-3.05, P = 0.02). Emergency surgery was performed in 17 patients due to acute paraparesis. The emergency surgery was not a statistically significant (OR 0.92, 95% CI 0.45-1.90, P = 0.83). Prolonged operation time and high blood loss were reported to be risk factors for SSI in spinal surgery². However, most of the surgery for spinal metastasis was long duration (median 315min), and high blood loss (median 1560ml). Neither the operation time (OR 0.83, 95% CI 0.60-1.16, P = 0.29) nor blood loss (OR 0.52, 95% CI 0.56-1.51, P = 0.39) were statistically significant in surgery for spinal metastasis. In this study, both univariate and multivariate analyses were used to evaluate potencial risk factors. Stepwise regression analysis included the three significant factors (P < 0.05) and two factors which were relatively large, with P values of less than 0.2 by univariate analysis. These five factors were diabetes, prior irradiation, multiple operations at the surgical site, preoperative chemotherapy, and ASA class. Only diabetes and irradiation at surgical site were the independent risk factors significantly by multivariate logistic

regression. Multiple operations at the surgical site with statistical significance by univariate but not by multivariate analyses did not have a direct relation, but might serve as markers of increased risk (Table 5).

Diabetes was an independent risk factor for SSI in spinal metastasis (OR 17.1, P = 0.011). The infection rate of the patients with diabetes was 35.7% (5 of 14 cases). The rate of the patient without diabetes was 3.0% (3 of 99 cases), which was significantly different (P<0.01). A prior irradiation at surgical site was also independent risk factor for SSI in spinal metastasis (OR 19.5, p = 0.016). The rate of SSI with irradiation was 31.8% (7 of 22 cases), much higher than those without irradiation (1.1%, 1 of 91 cases).

Phase 2 Study

Material and Methods

The second portion of the study (Phase 2) was a prospective clinical trial investigating the utility of PGE₁ at reducing the rate of SSI in patients treated with preoperative irradiation. Phase 2 occurred between April 2003 and December 2007, during which time 94 patients (97 surgeries) with spinal metastasis were treated at our institute. There were 41 women and 53 men, with a mean age 57.7 years (range 29-82

years). The main lesion was in the thoracic spine in 68 patients, in the lumbar spine in 20, and in the cervical spine in 6. Wide or marginal excision such as total *en bloc* spondylectomy was performed in 50 patients (two-staged surgeries were performed in 3 patients). Debulking surgery such as piecemeal excision or eggshell curettage was performed in 27 patients. Palliative surgery such as spinal cord decompression with spinal stabilization was performed in 17 patients. All the patients with prior irradiation at surgical site received intravenous PGE₁ administration at 60 µg twice daily after the surgery, for mean duration 7 days. The infection rate and risk factors identified in Phase 1 and Phase 2 were compared.

Results

The incidence of SSI was 3.1% (3/97 surgeries). Microorganisms isolated from these wounds were *Staphylococcus aureus* (methicillin resistant) in 2 cases, *Enterococcus faecalis* in 1 case. All cases were classified as deep SSI, and they all underwent repeated surgery. The rate of SSI between Phase 1 and Phase 2 were not significantly different ($p = 0.23$, Fisher's exact test). When the patients who had prior irradiation were compared, there were no significant difference between Phase 1 and Phase 2 in age, gender, operation time, blood loss amount, total dose of irradiation

before surgery, and interval between irradiation and operation. (Table 6) On the other hand, the rate of SSI for patients who had prior irradiation in phase 2 was 4.5% (1/22 cases), the difference between phase 1 and 2 was statistically significant. ($p = 0.046$, Fisher's exact test) (Table 7).

Discussion

Several risk factors for infection after the surgery for spinal metastasis have been identified. Bridwell et al⁶ reported that wound dehiscence in 3 (12%) of 25 patients who had undergone posterior instrumentation with posterolateral decompression and debulking for spinal metastasis. McPhee et al⁵ found that SSI occurred 15 (20%) of 75 cases after the surgery. Preoperative protein depletion and perioperative steroid administration were risk factors for SSI by univariate analysis. Sundaresan et al⁷ identified that wound breakdown and infection occurred in 11 (14%) of 80 cases who underwent surgery for spinal metastasis. Major risk factors for the surgery of spinal metastases was age over 65 years, paraparesis, and the prior use of radiation, chemotherapy, or both. In this study, diabetes, prior irradiation, multiple operation at surgical site were associated with a higher incidence of surgical site infection by univariate analysis. However, risk factors by univariate but not multivariate analysis

might not have a direct relation to SSI. In this study, independent risk factors identified by multivariate logistic regression were diabetes, and preoperative irradiation.

The increased risk of SSI in patients with diabetes after spinal surgery is well reported^{2, 17, 18}. Multi-factorial reasons, such as ischemia due to impaired granulocyte adherence²⁰ and microangiopathy¹⁹, have been documented. Olsen et al reported that diabetes, and a preoperative serum glucose level of > 125 mg/dL or a postoperative glucose level of > 200 mg/dL were the independent risk factors by multivariate analysis²¹. Therefore, more aggressive intravenous control of serum glucose level might reduce the incidence of SSI in spinal surgery. In cardiac surgery, it is recently reported that insulin-delivery pumps have been shown to be effective in reducing the risk of SSI²². Additional study will be needed to confirm the efficacy of continuous intravenous insulin infusion in patients with diabetes for spinal surgery. On the other hand, the positive effect of PGE₁ in reducing the incidence of infection has not been shown. PGE₁ is one of a potent vasodilator that will increase peripheral blood flow. Therefore, there is a possibility that PGE₁ administration might decrease the incidence of SSI in patients with diabetes. Further investigation will be needed whether PGE₁ administration might decrease the incidence of SSI in patients with diabetes.

The relationship between poor nutritional status and SSI has been reported. Klein et

al. found that preoperative nutritional status defined by serum albumin level was a significant risk factor for infectious complications in patients with elective lumbar surgery¹. Contrary, Blam et al reported that depressed preoperative serum albumin was not statistically associated with wound infections in patients with spinal injury²⁷. In this study, malnutrition defined by serum albumin was not statistically significant. However, we could not determine whether the patients with low albumin were associated with increased risk of SSI for spinal metastases because of the small number in this study population. A higher statistical power might be needed to disprove that other negative factors in this study are not at work.

Irradiation has multiple negative influences on wound repair, including decreased vascularity with fibrosis, hypoxia, and impairment of proliferative capacities of local tissues, which are responsible for the remodeling of collagen in surgical wounds¹⁴. Experimental study demonstrated that irradiated tissue cannot tolerate bacterial contamination resulting in an incidence of SSI¹⁶. Ghogawalla et al¹⁵ reported that the rate of wound complication was 32% in patients who received prior irradiation, which was three times higher than in patients without irradiation. Sunderesan et al also reported that the rate of wound breakdown was 25% (10 out of 40 patients) in patients who received prior irradiation. In this study, the rate of SSI with irradiation was

31.8% (7 of 22 cases), much higher than those without irradiation (1.1%, 1 of 91 cases).

Our result that preoperative irradiation increased the rate of SSI has been substantiated by the results in other studies. Wise et al¹¹ indicated that a decision should be made before radiation therapy about whether conservative or operative treatment will be pursued because the preoperative irradiation raised the rate of SSI.

On the other hands, a recent study demonstrated the positive effect of PGE₁ in decreasing wound complications after laryngeal surgery in patients with preoperative irradiation²³. PGE₁ is a potent vasodilator that will increase peripheral blood flow. Clinically, PGE₁ has been found useful for ischemia in patients with peripheral arterial occlusive disease²⁴, performing free flap salvage²⁵, and so on. The positive effects of PGE₁ on increasing skin and muscle blood flow have been shown in a dog model²⁶. The role of PGE₁ in spine surgery has not been previously evaluated. So, we performed a prospective clinical trial to investigate the utility of PGE₁ in patients with prior irradiation. In this study, PGE₁ administration was found to significantly decrease the incidence of SSI in patients with spinal metastasis who underwent preoperative irradiation. By PGE1 usage, possible side effects are generally pain at the injection site, headache, mild decrease of blood pressure, and hemorrhagic tendency. However, side effects by PGE1 administration should be reduced in doses below 0.01

micrograms/kg/min. Furthermore, monitoring is not generally required. In this series, PGE₁ was administered below 0.01 micrograms/kg/min in all cases, and 3 cases of pain at the injection site were seen. Although small patient numbers limits the significance of the current study, the positive effect of PGE₁ in patients with spinal metastasis is encouraging and merits further evaluation.

Key points

We investigated risk factors of surgical site infection and evaluated the positive effect of prostaglandin E₁ administration in patients with spinal metastasis.

Independent risk factors by multivariate logistic regression were diabetes and preoperative irradiation.

Prostaglandin E₁ administration was found to decrease the incidence of surgical site infection in patients with spinal metastasis who underwent preoperative irradiation.

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Table 1.
Characteristics of 110 patients
with spinal metastases

Median age (range)	56 (32-72)
Gender (male : female)	65:45
Type of Primary Tumor	
Kidney	22
Breast	17
Lung	14
Colon	11
Thyroid	10
Prostate	5
Liver	4
Unknown	5
Other	22
Spine level	
Cervical	12
Thoracic	58
Lumbar	40
Type of Surgery	
En bloc	38
Debulking	43
Palliative	29

Table 2.

Types of Organisms Cultured from the Postoperative Infections

Organism	No. of cases
coagulase-negative Staphylococcus	3
Staphylococcus aureus	2
Escherichia coli	1
Candida albicans	1
Pseudomonas aeruginosa	1

Table 3.

Univariate Analysis of Patient Characteristics Following Surgery for Spinal Metastases

Factor	No. (%) W/o infection	No. (%) W/ infection	Odds Ratio (95% CI)	P Value
Age (56 >)	52 (49.5)	3 (37.5)	0.58 (0.13, 2.54)	0.71
Gender (male)	60 (57.1)	5 (62.5)	1.16 (0.26, 5.15)	0.84
Diabetes	9 (8.5)	5 (62.5)	17.7 (3.64, 43.6)	<0.01
Nutrition (albumin <3.5)	15 (14.2)	2 (25.0)	2.21 (0.39, 12.5)	0.37
ASA*(3, 4)	33 (31.4)	5 (62.5)	1.72 (0.87, 3.40)	0.11
Chemotherapy	32 (30.4)	5 (62.5)	3.80 (0.85, 16.9)	0.08
Irradiation	15 (14.3)	7 (87.5)	41.0 (4.82, 63.6)	<0.01
Steroid therapy	61 (58.1)	6 (75.0)	2.06 (0.40, 10.7)	0.39
Neurologic deficit	67 (63.8)	7 (87.5)	3.96 (0.47, 33.5)	0.21

The P values were calculated with Fisher exact test, and significant values (<0.05) Are listed in bold type.

* American Society of Anesthesiologists class

Table 4.

Univariate Analysis of Surgery-related Risk Factors Following Surgery for Spinal Metastases

Factor	No. (%) W/o infection	No. (%) W/ infection	Odds Ratio (95% CI)	P Value
Procedure				
En bloc	39 (37.1)	2 (25.0)	reference	
Debulking	41 (39.0)	2 (25.0)	0.95 (0.13, 7.08)	0.96
Palliative	25 (23.8)	4 (50.0)	3.12 (0.53, 18.3)	0.21
Multiple op.	22 (21.0)	5 (62.5)	1.85 (1.11-3.05)	0.02
Emergency	16 (15.2)	1 (12.5)	0.92 (0.45-1.90)	0.83
Operation time (>5hr)	83 (79.0)	5 (62.5)	0.83 (0.60-1.16)	0.29
Blood loss (>1550ml)	56 (53.3)	3 (37.5)	0.52 (0.12-2.31)	0.39

Table 5.

Multivariate Analysis Results

Factor	Adjusted Odds Ratio (95% CI)		P Value
Irradiation	19.5	(1.72, 110)	0.016
Diabetes	17.1	(1.93, 76.5)	0.011
Multiple op.	1.89	(0.92, 3.89)	0.08

Stepwise logistic regression selected two risk factors with significantly independent association with surgical site infection. Significant P values (< 0.05) are listed in bold type.

Table 6.**Patient characteristics with Prior Irradiation**

	W/o PGE1 (n = 22)	W/ PGE1 (n = 22)	P value
•Age (yr)	58.4 ± 8.3	54.1 ± 11.1	NS
•Gender (male/female)	11 / 11	9 / 13	NS
•Operation time (min)	295 ± 171	400 ± 183	NS
•Blood loss (mL)	1310 ± 945	1104 ± 585	NS
•Total dose of radiation (Gy)	44.1 ± 10.5	39.9 ± 12.3	NS
•Interval between radiation and operation (months)	12.1 ± 9.1	15.1 ± 14.5	NS

Values are given as mean ± standard deviation. NS = not significant. The P values were calculated with Student's t test and χ^2 test.

Table 7.

The Effect of PGE₁ Administration in Patients with Prior Irradiation

	No. (%) W/o infection	No. (%) W/ infection
W/ PGE1	21 (95.5)	1 (4.5)
W/o PGE1	15 (68.2)	7 (31.8)

P = 0.04, with Fisher exact test