Title: An assessment of key risk factors for surgical site infection in patients undergoing surgery for spinal metastases

Running Title: Risk factors for SSI following spinal metastatic tumour surgery

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Abstract

Objectives

This study aimed to determine the rate of surgical site infection (SSI) in patients undergoing surgery for spinal metastases, and identify key risk factors for SSI among this patient group.

Methods

A retrospective case note review was undertaken in 152 adult patients being treated at a single specialist centre for spinal surgery.

Results

Overall SSI rate was 11.2% per patients (9.7% per procedure). An increase in the risk of SSI was observed when surgery involved a greater number of vertebral levels (odds ratio 1.26, P=0.019) when controlling for primary spinal region. Controlling for the number of spinal levels, the odds of SSI increased by a factor of 5.6 (P=0.103) when the primary surgical region was thoracic, as opposed to cervical or lumbar.

Conclusions

In conclusion, surgery associated with multiple vertebral levels for treatment of spinal metastases, particularly of the thoracic spine, is associated with increased risk of SSI.

Highlights

- Multi-level metastatic spinal tumour surgery is associated with greater risk of SSI.
- The odds of SSI are increased with surgery at the thoracic level.

Key words

Metastases; Spine; Surgical site infection; Vertebrae; Wound.

Introduction

Spinal metastases are common in cancer patients and surgical treatment is the most effective way to relieve symptoms [1]. Symptoms include spinal and radicular pain, weakness, difficulty in walking, sensory loss and bladder or bowel dysfunction associated with spinal metastatic spinal cord compression (MSCC). MSCC occurs in 10-20% of those with bony spinal disease [2], equating to approximately 4000 cases per year in England and Wales according to the National Institute for Health and Care Excellence (NICE) [3]. It is important that patients with symptomatic MSCC are treated appropriately in a timely manner to optimise the chance of preventing decline in physical functioning. The number of patients requiring surgery is likely to rise in coming years [4], due to the success of many primary cancer therapies which are improving patient survival.

Surgical site infection (SSI) is a serious potential complication of any type of surgical procedure. SSIs are estimated to account for approximately 16% of all healthcare-acquired infections [5], with reported rates varying, according to the type of surgery. Interventions aimed at reducing the rate of SSIs in general have included: administration of antibiotic prophylaxis; rigorous pre-operative hand washing by the surgical team; use of specific methods of skin preparation; strict procedures in theatre, such as the use of sterile gowns and double gloving; use of laminar flow theatres (among other interventions). Despite this multifaceted approach, SSI rates in certain areas remain stubbornly high.

Surgery for metastases of the spine has been shown to be a risk factor for the failure of primary wound healing in comparison to other types of spinal surgery [6]. However, there are several other factors within this group which may also contribute significantly to SSI; not least immunosuppression resulting from the malignant process and pre-operative radio- and chemotherapeutic treatments, as well as the use of opiate analgesia [7, 8]. Spinal tumour surgery is extensive, and patients are often malnourished and catabolic [9]. These factors, coupled with the high metabolic demands of wound healing, and the fact that spinal surgery is often lengthy and involves large surgical incisions, means that patients undergoing surgery for spinal metastases are affected by a host of factors potentially contributing to wound breakdown and SSI. This predisposition to wound complications can, in turn, impact significantly on quality of life for the patient, family and carers. The clear identification of such factors will lead to advances in clinical practice, in terms of care management and patient education regarding the ways SSIs occur and how they can be prevented.

This study was therefore undertaken to identify key risk factors contributing to SSIs in this patient group.

Methods

This study was approved by the Greater Manchester North Research Ethics Committee (reference 12/NW/0269).

Participant Selection

Adult patients (aged ≥18 years) who had undergone surgical treatment for spinal metastatic tumours at Salford Royal NHS Foundation Trust (SRFT) between 1st January 2009 and 31st December 2012 were included in this study. Data collection occurred as part of the local SSI surveillance programme and so participants~~Patients~~ were not approached to give consent, as per the ethical approval~~, due to the retrospective nature of the study~~. The Clinical Audit department generated a list of potentially eligible patients. This list was filtered using the primary IDC10 code C79.5 (secondary malignant neoplasm of bone and bone marrow) and OPCS4 codes beginning with V (i.e. those which correspond to bones and joints of the skull and spine). In order that only appropriate patients were included, patient notes were initially screened prior to data collection to confirm that patients had in fact undergone surgery for metastatic tumours (i.e. not patients who had undergone conservative treatment or those undergoing treatment for primary tumours). In cases where incorrect coding had been documented [10], patients were removed from the screening list and no data were collected. Clinical nursing staff from the Spinal Unit were asked to review the patient list generated by the Clinical Audit department and cross check against their own documented records, where possible, to ensure a complete list of patients was identified. Of primary interest in confirming metastatic spinal tumour diagnosis were histopathology reports, where available. The opinion of a Consultant Neuropathologist was sought where ambiguity regarding diagnosis arose (i.e. primary versus metastatic tumour). In the event that histopathological diagnosis was not available, evidence of metastatic spinal tumour diagnosis was sought from clinical correspondence or other clinical notes held in patients' records.

Definition of SSI

The presence or absence of an SSI (superficial or deep) was the primary outcome measure for the study, as defined by the criteria set out by Public Health England [5], which is largely based on the work of Horan et al. [11]. Regular observation of the wound was carried out by ward staff according to standard practice whilst patients were resident in the hospital. Patients were discharged with information about signs and symptoms suggestive of SSI (e.g. pain or tenderness, localised swelling, redness, heat and discharge) and asked to contact the ward directly should they experience any of these or have additional concerns about their wound. Such patients were then reviewed promptly in

clinic. For purposes of this study, patient documentation was reviewed ~~SSIs were classified~~ by the SSI surveillance nurse for the neurosurgery department, who confirmed diagnosis of infection as per the standard routine for the reporting of SSIs through the SSI Surveillance Service.

Data Collection

Data were collected from existing patient case notes and were anonymised prior to analysis; no patient or relative contact was required for additional data collection.

Data were collected on the following demographic, lifestyle, health and procedural characteristics: patient age; sex; height; weight; body mass index (BMI); primary spinal region (cervical, lumbar or thoracic; categorised according to the location of the majority of the vertebrae operated on); direction of surgical approach (anterior, posterior or combined anterior-posterior); whether or not the patient was on the emergency operation list; type of admission ward (specialised spinal unit or other ward); survival data (date of death or status as of 11th March 2013); site of primary tumour; Malnutrition Universal Screening Tool (MUST) score; Waterlow score; whether or not the patient self-reported as consuming excessive alcohol; whether or not the patient was a current smoker; whether or not patients had undergone pre-operative radiotherapy to the spine (within 24 months); whether or not the patient had received pre-operative chemotherapy (within 6 months); whether or not the patient had received pre-operative treatment with dexamethasone (in addition to those administered at the time of surgery); American Society of Anaesthesiologists (ASA) grade; whether or not the patient had low levels of pre-operative serum albumin (< 35 g/L), serum protein (< 62 g/L) or lymphocytes (< 1.5^{9}/L) pre-operatively, or increased levels of serum C-reactive protein (CRP) (< 10 mg/L); control of intra-operative blood glucose (≤ 11 nmol/L in recovery); maintenance of normothermia (core temperature of ≥ 36°C in recovery); administration of appropriate antibiotics (according to local guidelines within 60 minutes prior to surgical start); whether or not the incision closure method included the use of a braided suture (Vicryl or any other type); type of immediate post-operative wound dressing (recommended Opsite PostOp Visible or any other type); the location to which the patient was discharged (home or other care setting); length of surgical incision; number of spinal levels operated on; duration between interval and operation; duration of operation; type of theatre (laminar flow or non-laminar flow); number of staff members listed as being present in theatre.

Statistical Analysis

Following exploratory analyses to verify that the effect of clustering of procedures within patients was negligible, a series of binary logistic regression analyses was conducted on the data under the assumption of a single level (*procedure*-level) data structure. Initially uncontrolled models, each including a single factor or covariate, were derived as a screening process to identify potentially important predictors of infection. Not all variables analysed descriptively were included in this analysis: those which did not discriminate adequately between cases with and without an SSI, or those for which little clinical evidence of a link with the outcome measure existed, were excluded. Survival data were also excluded from the analysis due to the lack of a temporal criterion for causality. Any factors and covariates exhibiting significant or substantive association with the outcome measure in uncontrolled models were then carried forward for inclusion in a multiple logistic regression model. Key numerical variables showing substantive association with the outcome measure were subject to further analysis by calculation of the area under the receiver operating characteristic (ROC) curve in order to determine the ability of these variables to discriminate between cases of infection and non-infection. All descriptive and inferential statistical analyses were undertaken using IBM SPSS for Windows, Version 20.0 (Chicago, IL).

Results

A total of 152 patients (77 females and 75 males; mean age 60.3 years (SD 12.6 years) were included. Three patients underwent multiple procedures. Breast (28.3%), lung (20.4%) and prostate (12.5%) were the most common primary tumours, with other types of primary (as well as those unknown primaries) making up the remainder (38.8%). Metastases occurred predominantly at the thoracic spine in most cases (70.4%), with the lumbar and cervical regions also being predominant in 16.5% and 13.1% of cases, respectively. A full descriptive summary of sample characteristics is given in Table 1 (categorical factors) and Table 2 (covariates). Frequencies and percentages, and means and standard deviations are based on total number of procedures (*n*=176) except where starred, which are based on total number of patients (*n*=152).

[INSERT TABLES 1 AND 2 HERE]

SSI Rate

A total of 17 procedures (in 17 individual patients) resulted in a SSI (11.2% of patients; 9.7% of procedures). Of two patients affected by SSI who underwent more than one surgical procedure, both infections occurred as a result of the first operation. There were 14 superficial and 3 deep SSIs.

Risk Factor Analysis

Uncontrolled binary logistic regression analysis found occurrence of an SSI to be significantly associated with number of spinal levels involved in surgical procedure. Some additional factors, notably whether or not the patient was undergoing a procedure associated with thoracic vertebrae and whether or not the patient was on the emergency list, were also shown to exhibit some substantive significance with the outcome measure (Table 3).

[INSERT TABLE 3 HERE]

Variables corresponding to number of spinal levels, primary spinal region and emergency list status were carried forward for inclusion in a multiple logistic regression analysis. Using a backward elimination modelling strategy, an analysis conducted on the full data set retained the variables corresponding to number of spinal levels and primary spinal region (thoracic or non-thoracic) in the model. Number of spinal levels was found to be significantly associated with SSI occurrence in a multiple model; whereas primary spinal region (thoracic or non-thoracic) was found to be substantively but not significantly associated with SSI occurrence in a multiple model. The variable corresponding to whether or not a patient was placed on the emergency list was not retained in the model (Table 4).

[INSERT TABLE 4 HERE]

Discussion

The rate of SSI following surgery for spinal metastatic tumours in the present study is within the 10 to 20% range reported in the existing literature [12-14]. This is considerably higher than the overall 2.8% previously reported by Olsen et al. when considering laminectomy and fusion procedures.

While patients undergoing spinal surgery for cancer are understood to be at increased risk of SSI [6], few previous studies have been undertaken to determine whether any additional key risk factors exist within this specific population [12]. Results of the present study suggest that patients undergoing surgery on multiple vertebral levels are at greater risk of developing SSI. Controlling for primary spinal region, the odds of an SSI increase by approximately 26% for each additional spinal level involved in the surgical procedure. This is perhaps due to multiple level surgery requiring larger incisions, and generally being longer in duration, both of which provide greater opportunity for the entry of pathogens. While incision length itself was included as a variable, it is likely that no association between this and risk of SSI was found because wound length is generally documented after being estimated by treating staff observing the wound, rather than being objectively measured. Previous studies have suggested that surgery performed at more than three vertebral levels is associated with greater infection risk [6, 15], though these analyses were not confined only to patients undergoing tumour and surgery. Although primary spinal region (thoracic or non-thoracic) was not found to be significantly associated with SSI, when controlling for number of spinal levels involved in the surgical procedure, the odds of an SSI increase by a factor of approximately 5.6 (at best estimate) when the primary surgical region is the thoracic, as opposed to the cervical or lumbar regions.

These results indicate that patients whose operation may involve surgery on several tumours along the length of the spine are at greater risk of SSI. It is difficult to infer whether this can be alleviated by adaptations in surgical intervention. In cases where there are multiple operable tumours, it is perhaps conceivable that a move towards more minimally invasive techniques could limit incision length and blood loss, and may even expedite discharge.

Protein depletion and the peri-operative administration of corticosteroids have previously been shown to be risk factors for the development of SSI after spinal tumour surgery [12]. Despite no such association being observed in the present cohort, these factors contribute to immunosuppression and so are likely to have some effect on the ability of the host to defend against pathogens responsible for SSI.

Avoidance or reduction of SSI is essential in patients undergoing surgery for spinal tumours, and as such clinical teams must initiate preventative strategies in the pre-operative period. Given that SSI rates are considerably higher in this patient group, psychological support for this highly undesirable complication would be beneficial pre-operatively, with tissue viability teams offering advice of precautionary steps patients could take, as well as facilitating the use of devices such as negative pressure wound therapy (NPWT) [16] that may reduce the risk of SSI. Furthermore, appropriate use and management of prophylactic antibiotics requires consideration and discussion with the patient; NICE (2013) maintain that antibiotic prophylaxis should be given to patients before clean surgery involving the placement of a prosthesis or implant [17]. The importance of working as an inter-professional team cannot be over-emphasized in the pre-operative period; these teams should include: surgeons, anaesthetists, dieticians, ward nurses, theatre staff, tissue viability specialists, pain teams, infection control, social workers, care in the community teams and palliative care if necessary. Effective and clear discharge planning would be required to guarantee timely discharge with all community services *in situ* where necessary.

Limitations

It is acknowledged that this study is limited in its design. Data collected as part of routine care over a number of years will inevitably vary in its quality and completeness. Accurate documentation in patient case notes should be a priority, especially with respect to the administration of drugs, to facilitate the delivery of best care, and to ensure errors can be addressed and rectified where possible in a timely manner. Inaccurate recording and reporting of data, especially with respect to treatment compliance, may have legal and financial implications [18]. In addition, a more complete, accurate data base provides greater opportunity for carrying out high quality audit and research. Nevertheless, this study is based on the largest case series of spinal metastatic tumour patients with regards to SSI and despite these limitations, the retrospective analysis of existing data in this way provides a snapshot of real-life treatment and documentation in a modern health service, and as such is useful in the development of future proposals for research.

Conclusions

Surgery on multiple vertebral levels for metastatic spinal tumours significantly increases the chance of SSI, with patients undergoing operations on the thoracic region of the spine being more at risk. Clinical teams should focus on identifying such high risk patients and ensure that patients are

afforded the best levels of care. Optimisation of patient fitness prior to surgery should also remain a priority wherever possible.

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Tables

TABLE 1: Descriptive characteristics of sample: categorical factors.

Categorical Factor	Frequency (valid %)		
	SSI cases	Non-SSI cases	Full sample
Gender			
Male	10 (62.5%)	65 (47.4%)	75 (49.0%)*
Female	6 (37.5%)	72 (53.6%)	78 (51.0%)*
Primary spinal region			
Cervical	0 (0.0%)	23 (14.5%)	23 (13.1%)
Thoracic	16 (94.1%)	108 (67.9%)	124 (70.5%)
Lumbar	1 (5.9%)	28 (17.6%)	29 (16.5%)
Direction of approach			
Anterior	1 (7.7%)	15 (9.2%)	16 (9.1%)
Posterior	12 (92.3%)	148 (90.8%)	160 (90.9%)
Emergency list			
Yes	14 (82.4%)	93 (58.5%)	107 (60.8%)
No	3 (17.6%)	66 (41.5%)	69 (39.2%)
Ward type			
Specialist spinal ward	14 (82.4%)	99 (62.3%)	113 (64.2%)
Other	3 (17.6%)	60 (37.7%)	63 (35.8%)
Patient survival			
Yes	3 (17.6%)	52 (38.5%)	55 (36.2%)*
No	14 (82.4%)	83 (61.5%)	97 (63.8%)*
Primary cancerous organ			
Breast	4 (23.5%)	39 (29.1%)	43 (28.4%)*
Lung	5 (29.4%)	26 (19.4%)	31 (20.5%)*
Prostate	3 (17.6%)	16 (11.9%)	19 (12.6%)*
Other/unknown	5 (29.4%)	53 (39.6%)	58 (38.4%)*
MUST score			
0	14 (100.0%)	142 (95.3%)	156 (95.7%)
1	0 (0.0%)	6 (4.0%)	6 (3.7%)
2	0 (0.0%)	1 (0.7%)	1 (0.6%)
Pre-operative radiotherapy received			
Yes	1 (5.9%)	15 (9.3%)	16 (9.1%)
No/unknown	16 (94.1%)	147 (90.7%)	160 (90.9%)
Pre-operative chemotherapy received			
Yes	1 (5.9%)	1 (0.6%)	2 (1.1%)
No/unknown	16 (94.1%)	158 (99.4%)	174 (98.9%)
Prescription of dexamethasone			
Yes	12 (70.6%)	96 (60.4%)	108 (61.3%)
No/unknown	5 (29.4%)	63 (39.6%)	68 (39.4%)
Excess self-reported alcohol consumption	1 (5.9%)	8 (5.9%)	9 (5.9%)*
Yes	16 (94.1%)	127 (94.1%)	143 (94.1%)*
No			
Smoker	1 (6.3%)	21 (15.4%)	22 (14.5%)*
Yes	15 (93.7%)	115 (84.6%)	130 (85.5%)*
No			
Dexamethasone administered	11 (68.8%)	97 (60.6%)	108 (61.4%)
Yes	5 (31.2%)	63 (39.4%)	68 (38.6%)
No			
Antibiotic according to local guideline	13 (76.5%)	107 (79.3%)	120 (78.9%)*
Yes	4 (23.5%)	28 (20.7%)	32 (21.1%)*
No			
Glucose controlled within 11 nmol/L	17 (100.0%)	135 (100.0%)	152 (100.0%)*
Yes	0 (0.0%)	0 (0.0%)	0 (0.0%)*

No			
Normothermia maintained	16 (94.1%)	122 (90.4%)	138 (90.7%)*
Yes	1 (5.9%)	13 (9.6%)	14 (9.3%)*
No			
ASA score	12 (75.0%)	117 (73.1%)	129 (73.3%)
High	4 (25.0%)	43 (26.9%)	47 (26.7%)
Low			
Diabetic	0 (0.0%)	8 (5.9%)	8 (5.3%)*
Yes	17 (100.0%)	128 (94.1%)	145 (94.7%)*
No			
Dressing used	2 (12.5%)	41 (25.6%)	43 (24.4%)
Opsite	14 (87.5%)	119 (74.4%)	133 (75.6%)
Other			
Discharge	8 (47.1%)	101 (63.5%)	109 (61.9%)
Home	9 (52.9%)	58 (36.5%)	67 (38.1%)
Care setting/other			

1 Table 2: Descriptive characteristics of sample: covariates

Covariate	Mean (SD)		
	SSI cases	Non-SSI cases	Full sample
Age	63.1 (11.1)*	60.3 (13.1)*	60.6 (12.9)*
Length of stay	31.3 (15.0)*	19.2 (20.1)*	20.3 (18.9)*
Height (m)	1.75 (0.07)*	1.68 (0.11)*	1.68 (0.11)*
Weight (kg)	85.1 (10.3)*	74.4 (15.0)*	74.9 (14.9)*
BMI (kgm^{-2})	28.1 (5.1)*	26.2 (4.7)*	26.4 (4.7)*
Waterlow score	8.8 (4.3)	8.4 (4.4)	8.42 (4.3)
Albumin level (g/litre)	32.4 (16.9)	28.8 (17.6)	29.2 (17.4)
Protein level (g/litre)	65.7 (7.3)	64.3 (8.5)	64.5 (8.4)
Lymphocyte level ($x10^9$)	1.3 (1.0)	1.5 (1.5)	1.4 (1.4)
Pre-operative CRP level (mg/L)	19.1 (24.6)	42.1 (65.2)	38.8 (61.5)
Survival time after operation (days)[1]	198.7 (213.9)*	195.1 (200.0)*	195.6 (200.7)*
Age at death (years)[1]	64.4 (11.7)*	62.4 (14.0)*	62.7 (13.7)*
Wound length (cm)	15.3 (10.7)	13.9 (13.6)	14.1 (13.3)
Number of spinal levels	7.2 (2.0)	5.6 (2.7)	5.7 (2.7)
Interval between admission and operation (days)	3.2 (3.4)	4.6 (5.3)	4.4 (5.1)
Duration of operation (hours)	4.2 (1.3)	4.0 (1.5)	4.0 (1.5)
Number of staff listed as present in operating theatre	8.1 (0.9)	8.0 (1.4)	8.0 (1.4)

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Table 3: Statistical significance, odds ratios and associated confidence intervals: uncontrolled logistic regression models

Factor/covariate	*p*-value	Odds ratio	95% CI for odds ratio
Gender	0.364	0.63	(0.23, 1.72)
Age	0.263	1.03	(0.98, 1.07)
Primary spinal region = thoracic	0.053	7.56	(0.98, 58.5)
Emergency list	0.068	3.31	(0.92, 12.0)
Waterlow score	0.390	1.05	(0.94, 1.19)
BMI	0.715	1.04	(0.86, 1.24)
Excessive alcohol intake	0.867	0.84	(0.10, 6.90)
Smoker	0.813	0.83	(0.18, 3.88)
Dexamethasone administration	0.431	1.55	(0.52, 4.62)
Antibiotic prescription regime	0.981	0.99	(0.30, 3.20)
ASA score	0.756	1.21	(0.37, 3.90)
Albumin level	0.429	1.01	(0.98, 1.05)
Protein level	0.650	1.02	(0.95, 1.08)
Lymphocyte level	0.632	0.89	(0.54, 1.45)
Pre-operative CRP	0.377	0.99	(0.96, 1.01)
Use of Opsite wound dressing	0.216	0.38	(0.08, 1.85)
Wound length	0.723	1.01	(0.97, 1.05)
Number of spinal levels in surgery	0.006	1.30	(1.08, 1.57)
Interval between admission and operation	0.250	0.93	(0.81, 1.06)
Duration of operation	0.816	1.04	(0.76, 1.42)
Number of staff present in theatre	0.755	1.06	(0.74, 1.53)

Table 4: Statistical significance, odds ratios and associated confidence intervals: multiple logistic regression model

Factor/covariate	p-value	Odds ratio	95% CI for odds ratio
Number of spinal levels	0.019	1.26	(1.04, 1.54)
Primary spinal region			
Non-thoracic (reference)			
Thoracic	0.103	5.59	(0.71, 44.3)

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