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Patient-Reported Outcomes After Surgical Stabilization of Spinal Tumors: Symptom-Based Validation of the Spinal Instability Neoplastic Score (SINS) and Surgery

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Abstract

BACKGROUND CONTEXT: Neoplastic spinal instability is movement-related pain or neurologic compromise under physiologic loads with the Spinal Instability Neoplastic Score (SINS) developed to facilitate diagnosis. There is a paucity of evidence that mechanical instability correlates with patient-reported symptoms and that surgical stabilization significantly improves these patient-reported outcomes (PRO).

PURPOSE: The objective of this study was to determine if SINS correlates with patient-reported preoperative pain and disability and if surgical stabilization significantly improves PRO.

STUDY DESIGN: Single-institution prospective cohort study.

PATIENT SAMPLE: 131 patients who underwent stabilization for metastatic spinal tumor treatment between July 2014 and August 2016 were included.

OUTCOMES MEASURES: Pre-operative baseline and mean difference in perioperative patient reported outcomes (PRO) as assessed by the Brief Pain Inventory (BPI) and MD Anderson Symptom Inventory (MDASI).

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METHODS: SINS was analyzed as a continuous, ordinal, and categorical variable (Stable: 0–6, Indeterminate: 7–12, Unstable: 13–18). Statistical analysis was performed using Spearman Rank Coefficient (rho), the Kruskal-Wallis test, and an extension of the Cochran-Armitage trend test. SINS and association between the mean differences in post- and pre-operative PRO scores was analyzed using the Wilcoxon signed rank test.

RESULTS: There was a statistically significant positive correlation between increasing SINS and severity of preoperative pain with BPI average pain (rho=0.20; P=0.03) and MDASI pain (rho=0.19; P=0.03). Increasing SINS correlated with severity of preoperative disability with BPI walking (rho=0.19; P=0.04), MDASI activity (rho=0.24; P=0.006), and MDASI walking (rho=0.20; P=0.03). Similar associations were noted when SINS was analyzed as an ordinal categorical variable. Stabilization significantly improved nearly all PRO measures for patients with indeterminate and unstable SINS. Significant correlations persisted when controlling for neurologic status and were not affected based on the technique of surgical stabilization employed.

CONCLUSIONS: PRO-based validation of SINS confirms this scoring system for diagnosing neoplastic spinal instability and provides surgeons with a tool to determine which patients will benefit from stabilization. Surgical stabilization of cancer patients with SINS consistent with mechanical instability provides significant reduction in pain and improves patient mobility independent of neurologic status and stabilization technique.

Keywords

Spinal neoplastic instability score; Spinal tumor; Surgical stabilization; Patient reported outcomes

Introduction

Neoplastic spinal instability is defined as movement-related pain, deformity or neurologic compromise under physiologic loads [1]. While a significant source of morbidity in the 10% of cancer patients who develop metastatic spinal disease, initial reports on classifying spinal instability lacked consensus on diagnostic criteria and were not validated in prospective studies [2–6]. The Spinal Instability Neoplastic Score (SINS) was developed by the Spinal Oncology Study Group in order to facilitate diagnosis, improve communication between oncologic healthcare providers, and provide a standardized scoring system for future clinical studies. Since its inception, SINS has become the primary instrument for delineating instability in the vast majority of spine oncology studies [7].

SINS is comprised of six categories; five radiographic and one clinical. Radiographic criteria include tumor location within the spinal column, intrinsic nature of bony pathology (e.g., lytic vs. blastic), segmental alignment, percent vertebral body collapse (> or < 50%), and posterior element involvement. The sole clinical component is the presence of movement-related pain. Cumulative scores range from 0–18, with SINS 0–6 considered stable, 7–12 indeterminate (impending instability), and 13–18 unstable. For scores of 7 or above, evaluation by a spine surgeon is recommended.

While data supporting SINS validity and reliability exist, there is a paucity of evidence that mechanical instability correlates with patient-reported pain and disability and that surgical stabilization of mechanically unstable fractures significantly improves these patient-reported outcomes (PRO) [8–11]. The objective of this study was to establish an association between SINS and PRO in order to support the validity of SINS as a diagnostic instrument and to confirm the benefit of surgical stabilization in the setting of neoplastic mechanical instability.

Methods

Patient Selection and Evaluation

PRO, including Brief Pain Inventory (BPI) and MD Anderson Symptom Inventory – Spine Tumor (MDASI-SP) [12, 13], were prospectively collected. Patients who underwent instrumented surgical stabilization for metastatic spine tumor treatment between July 2014 and August 2016 were included. Age, gender, primary tumor, surgical stabilization technique, epidural spinal cord compression (ESCC) grade [14], pre- and post-operative ASIA scores, pre-operative SINS, and time to follow-up were collected. Patients completed pre-operative paper or tablet-based questionnaires and post-operative questionnaires were completed by e-mail. In situations where e-mails were not returned, paper or tablet-based questionnaires were completed in the clinic setting during follow-up. Patients with primary spine tumors, those without pre-operative PRO data, and those with post-operative PRO collected <14 days or >180 days after surgery were excluded from analysis. Patients undergoing revision surgeries, which are predominantly due to progressive spinal metastatic disease requiring extension of an existing construct, infections, or hardware failure, were also excluded from analysis due to concerns that these factors may confound preoperative symptomatology and quality of life metrics. The NOMS paradigm, which stands for Neurologic, Oncologic, Mechanical and Systemic considerations, was used to determine surgical indications. [15]. Surgeries were performed via an open or percutaneous posterolateral approach with lateral mass/pedicle screw and bilateral rod fixation. The approach was individually determined for each patient by the operating surgeon based on anatomic, radiographic, and clinical factors. All surgeries were performed by two surgeons (M.B. and I.L.). The percentage of patients receiving radiotherapy or chemotherapy at any point within 6 months following surgery was also collected.

Statistical Analysis

SINS was analyzed as a continuous, ordinal, and categorical variable (Stable 0–6, Indeterminate 7–12, Unstable 13–18). Association between SINS and pre-operative symptom burden was analyzed using Spearman Rank Coefficient (rho), Kruskal-Wallis test, and an extension of the Cochran-Armitage trend test. The Wilcoxon signed rank test was used to evaluate the change in PRO scores from pre-operatively to post-operatively overall and within SINS categories (Indeterminate and unstable). Ordinal pre-operative SINS categories were associated with the mean differences in post- and pre-operative PRO scores using an extension of the Cochran-Armitage trend test. The association between pre-operative PRO scores and surgical stabilization technique was analyzed using the Wilcoxon two-sample test. Any patient who had missing PRO data was excluded from each respective analysis. *P*-values less than 0.05 were considered statistically significant. Analyses were performed in SAS (version 9.4) and Stata (version 13.0).

Results

A total of 131 patients with preoperative SINS and PRO were included for analysis (mean 61.4 years old; 57% male). Post-operative PRO data collected between 14 and 180 days after surgery was available for 98 patients (mean 34.4 days, range 16–125 days). The most common primary tumors were non-small cell lung (N=29), renal cell (N=18), breast (N=12), prostate (N=12), and sarcoma (N=12). A validated epidural spinal cord compression scoring system (ESCC) [14] demonstrated 41 patients with an ESCC 0–1c (i.e. bone only or epidural impingement) and 89 patients with an ESCC 2–3 (spinal cord compression with or without spinal fluid visualized). Patients had preoperative SINS of 0–6 (N=7), 7–9 (N=28), 10–12 (N=65), and 13–18 (N=31). The majority of patients (102, 78%) underwent open instrumented stabilization and 29 patients underwent percutaneous instrumented stabilization. About 72% and 62% of all patients received radiotherapy and chemotherapy, respectively. The percentage of patients receiving radiotherapy was overall similar regardless of SINS grouping (71–74%). About 63–67% of patients with indeterminate and unstable SINS received chemotherapy, compared to only 14% of stable SINS patients (Table 1).

There was a statistically significant positive correlation between increasing pre-operative SINS and the severity of pre-operative pain as measured by BPI average pain (rho=0.20, *P*=0.03) and MDASI pain (rho=0.19, *P*=0.03) items. Increasing pre-operative SINS also correlated with increasing severity of pre-operative functional impairment measured by BPI walking (rho=0.19, *P*=0.04), MDASI activity (rho=0.24, *P*=0.006), and MDASI walking (rho=0.20, *P*=0.03) items (Table 2). Analysis of SINS stability groups (“stable”, “indeterminate”, “unstable”) as a categorical variable showed significant differences across groups in BPI worst pain (P=0.0009), BPI average pain (P=0.01), BPI activity (P=0.04), MDASI pain (P=0.001), MDASI spine pain (0.009) and MDASI activity (P=0.03). Analysis for trend resulted in a significant association between progressive SINS groups and MDASI pain (P=0.04) and MDASI spine pain (P=0.03) (Table 3).

The magnitude of post-operative symptom relief correlated with increasing SINS, with patients with higher SINS scores experiencing greater decrease in BPI worst pain (P=0.04) and MDASI spine pain (P=0.04) (Table 4) after surgical stabilization.

In order to analyze the effect of spinal stabilization on PRO separately from the effect of neurological change in patients with indeterminate or unstable SINS, separate analysis of PRO change among patients without neurologic change (ASIA) was performed. The statistically significant changes in PRO were preserved across nearly all BPI and MDASI scores when patients with and ASIA change were excluded (Table 5).

Open and percutaneous instrumented stabilization provided comparable PRO change after surgery, without any statistically significant difference between the results of the two techniques (P-values ranging from 0.11–0.81)..

Discussion

Indications for surgical referral in patients with metastatic spinal column disease include evaluation for decompression in the setting of epidural tumor mass effect and for spinal column stabilization of mechanically unstable spines. SINS was developed to facilitate the diagnosis of mechanical instability of the spinal column in patients with cancer. SINS development employed a modified Delphi process synthesizing expert opinion based on systematic literature review and clinical experience [16]. Since its publication, numerous studies have confirmed the reliability of SINS among several oncologic specialties [17, 18]. The validity was tested using several clinical scenarios and the ability of SINS to correlate with expert opinion about case-based mechanical stability. Furthermore, systematic implementation of SINS results in improved data reporting and earlier recognition of neoplastic spinal instability [7]. The current study represents the first effort to establish the relationship between SINS-diagnosed mechanical instability and patient-reported symptoms. Establishment of association between SINS and symptoms associated with mechanical instability provides clinical validation of SINS.

Secondly, the current study analyzed the effect of instrumented surgical stabilization on patient-reported symptoms. The requirement for restoration of spinal stability in order to provide symptom relief represents the central assumption guiding therapy for mechanical instability of the spine. The strength of this assumption results in a paucity of data directly comparing outcomes of surgical and non-surgical management for spinal instability. To date, one prospective randomized trial comparing the outcomes after balloon kyphoplasty to outcomes after non-surgical management of painful vertebral compression fractures (VCF) in patients with cancer showed that stabilization resulted in significantly quicker and greater symptom relief [19]. These data support the assumption that patients with mechanical instability require restoration of stability in order to experience symptom relief; however the effect of instrumented surgical stabilization in the setting of a wider range of mechanical instability requires further study.

Previous prospective studies examining the benefits of surgery on patient-reported pain and overall function in the setting of spinal metastases used validated, patient-driven, quality of life (QOL) scoring measures. Choi et al. reported data amassed from a multi-institutional study of 922 patients and demonstrated significant improvements in the EuroQol 5 dimensions (EQ-5D) score within three months of surgery, and these trends were sustained for up to 2 years [20, 21]. De Ruiter et al. similarly followed 113 patients with spinal metastases and showed significant improvements in EQ-5D postoperatively following stabilization with or without decompression [22]. Quan et al. used the European Organization for Research and Treatment of Cancer QLQ-C30 to show incremental improvement in pain and function scores following surgery for intractable pain, instability, and neurologic deficits for up to one year.[23] Other studies have leveraged the Oswestry Disability Index, Short Form 36 Health Survey (SF-36), and pain-related Visual Analog Score (VAS) as alternative surrogates for evaluating QOL following surgery [21, 24, 25]. While providing important insight into the benefits of surgery in this subpopulation of cancer patients, these studies did not differentiate individuals with mechanical instability as defined by SINS.

In the present study we used two patient-reported symptom inventories that have been validated specifically in patients with cancer: the BPI and MDASI-SP [12, 13]. The BPI and MDASI-SP are 9- and 19- question surveys, respectively, that assess the severity of pain and interference with daily activity. The MDASI-SP survey also includes a spine-specific module. From these modules, we focused our analysis on quantitative pain-specific questions and functional impairment items as pertaining to walking and overall activity.

Our data demonstrate that patients with increasing SINS report higher pre-operative pain severity and functional impairment, clinically validating SINS as an instrument for diagnosis of spinal mechanical instability. The association between increasing SINS and post-operative symptom relief supports the role of surgical stabilization for pain relief and improved functional status in the setting of mechanically unstable spines. Additionally, patients with metastatic spinal disease often undergo stabilization in conjunction with epidural tumor decompression for separation surgery or focal neurologic deficits unrelated to movement-associated instability [26, 27]. By controlling for pre- and post-operative ASIA scores, we were also able to demonstrate that PRO improvement was based on stabilizing mechanically unstable spines rather than improvements related to purely neurological-based function. Lastly, the improvements in post-operative PRO were independent of stabilization technique, consistent with prior studies comparing minimally invasive percutaneous instrumentation to traditional open procedures [28–30].

It should be noted that several patients with SINS 0–6, considered mechanically stable, were included in this analysis since they also underwent instrumented stabilization. The primary indication for surgery in patients with SINS 0–6 was high-grade spinal cord compression requiring decompressive surgery for preservation or restoration of neurologic function. Such decompressive surgery includes a laminectomy, facetectomy and transpedicular approach to the ventral epidural space in order to achieve circumferential decompression of the spinal cord. The extensive removal of bone for the purpose of spinal cord decompression results in iatrogenic instability requiring instrumented spinal stabilization. Furthermore, these patients are at risk for development or progression of deformity or post-radiation therapy vertebral body compression fractures [31–33] further supporting the role of instrumented stabilization at the time of decompression. Our data indicate that this small group of patients demonstrated little improvement in PRO following stabilization, however this is expected since they did not exhibit symptomatic or radiographic evidence of spinal instability preoperatively and did not undergo surgery for the primary purpose of spinal column stabilization.

There are a number of limitations with the present study that may impact its applicability in certain clinical scenarios. First, patients with metastatic cancer experience a wide range of symptoms unrelated to the spine, and differentiation of functional impairment due to spinal disease and other sites may be challenging. Second, patients with multi-level spinal metastatic disease present a unique challenge in that each tumor dictates their own SINS by virtue of their location and radiographic characteristics. In our study cohort, the tumor that was causing the highest degree of neural compression or that was most symptomatic from an instability standpoint was used as the primary data generator. However, in cases where more than one tumor contributed to preoperative symptoms or surgical decision making is unable to be parsed. Third, the majority of patients undergoing spinal stabilization surgery for metastatic disease will go on to receive radiation, chemotherapy/biologics, and/or bone modifying agents. However, these therapies generally take effect in a delayed fashion, therefore the early clinical difference observed after surgery is likely attributable to the surgical intervention rather than adjunct therapies. There have been no high-quality studies assessing SINS and pain/functional impairment relief in conjunction with the use of systemic therapies (chemotherapy or biologics) or bone-modifying agents. However, a previous retrospective study utilizing SINS to define spinal instability found that patients with higher SINS responded poorly to radiation therapy [34], supporting the assumption that patients with mechanical instability require restoration of stability in order to experience symptom relief, as opposed to biological pain which may respond to radiation therapy or steroids. Fourth, as recently emphasized by Versteeg et al., how individual components of SINS affect surgical decision-making is controversial, especially in settings where an individual component score suggests severe instability while the overall score does not [7]. The extent to which each individual component score contributes to overall instability and should dictate intervention will be the focus of future studies.

Conclusion

PRO-based validation of SINS clinically confirms this scoring system for the diagnosis of neoplastic spinal instability and provides a tool for surgeons to determine which patients will benefit most from surgical stabilization. Surgical stabilization of cancer patients with SINS scores consistent with mechanical instability provides significant reduction in pain and improves patient mobility independent of neurologic status and stabilization technique.

Abbreviations:

ASIA	American Spinal Injury Association impairment score
BPI	Brief Pain Inventory
ESCC	Epidural Spinal Cord Compression scale
MDASI	MD Anderson Symptom Inventory
NSCLC	Non-small cell lung cancer
PRO	Patient reported outcomes
SINS	Spinal instability neoplastic score
SD	standard deviation

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Table 1.

Patient Characteristics

Characteristic	Total Cohort
Age at surgery, mean (SD), years	61.4 (12.5)
Sex, No. (%)	
Male	75 (57.3)
Female	56 (42.7)
Metastatic tumor diagnosis, No. (%)	
Lung (NSCLC)	29 (22.1)
Renal	18 (13.7)
Breast	12 (9.2)
Prostate	12 (9.2)
Sarcoma	12 (9.2)
Myeloma	7 (5.3)
Colorectal	7 (5.3)
Other	34 (26.0)
Preoperative SINS, No. (%)	
Stable (0–6)	7 (5.3)
Indeterminate (7–12)	93 (71.0)
Unstable (13–18)	31 (23.7)
Preoperative ASIA, No. (%)	
C	4 (3.1
D	18 (13.7)
E	108 (82.4)
N/A	1 (0.8)
Preoperative ESCC, No. (%)	
0	9 (6.8)
1a	6 (4.6)
1b	12 (9.2)
1c	14 (10.7)
2	33 (25.2)
3	56 (42.7)
N/A	1 (0.8)
Treatment level, No. (%)	
Cervical	3 (2.3)
Thoracic	48 (36.6)
Lumbar	24 (18.3)
Occipito-cervical	3 (2.3)
Cervico-thoracic	15 (11.5)
Thoraco-lumbar	28 (21.4)
Lumbo-sacral	10 (7.6)
Stabilization technique, No. (%)	

Characteristic	Total Cohort
Open	102 (77.9)
Percutaneous	29 (22.1)
Postoperative Radiation Therapy *	
All Patients (N=131)	94 (71.8)
SINS 0–6 (N=7)	5 (71.4)
SINS 7–12 (N=93)	66 (71.0)
SINS 13–18 (N=31)	23 (74.2)
Postoperative Chemotherapy *	
All Patients (N=131)	81 (61.8)
SINS 0–6 (N=7)	1 (14.3)
SINS 7–12 (N=93)	59 (63.4)
SINS 13–18 (N=31)	21 (67.7)

Abbreviations: ASIA, American Spinal Injury Association impairment score; ESCC, Epidural Spinal Cord Compression scale; No., Number; NSCLC, non-small cell lung cancer; SD, standard deviation; SINS, Spinal Instability Neoplastic Score.

*Postoperative therapies received within 6 months following surgery.

Table 2.

Correlation Between SINS and Preoperative PRO Scores

PRO item	Spearman Rank Coefficient	*P*
BPI: Worst Pain	0.13	0.13
BPI: Least Pain	0.03	0.75
BPI: Average Pain	0.20	0.03
BPI: Pain Now	0.10	0.26
BPI: Activity	0.15	0.08
BPI: Walking	0.19	0.04
MDASI: Pain	0.19	0.03
MDASI: Spine Pain	0.13	0.15
MDASI: Activity	0.24	0.006
MDASI: Walking	0.20	0.03

Abbreviations: BPI, Brief Pain Inventory; MDASI, MD Anderson Symptom Inventory; PRO, patient reported outcomes; SINS, Spinal Instability Neoplastic Score.

Table 3.

Correlation Between Categorical SINS and Mean Preoperative PRO Scores

PRO item	SINS 0–6	SINS 7–12	SINS 13–18	*P* (association)[a]	*P* (trend)[b]
BPI: Worst Pain	2.6	7.8	7.6	0.0009	0.20
BPI: Least Pain	1.4	3.1	2.8	0.18	0.49
BPI: Average Pain	2.1	5.7	5.7	0.01	0.08
BPI: Pain Now	1.7	4.4	4.6	0.055	0.08
BPI: Activity	2.7	7.2	6.6	0.04	0.44
BPI: Walking	2.6	6.3	5.7	0.08	0.56
MDASI: Pain	2.6	8.0	8.2	0.001	0.04
MDASI: Spine Pain	1.0	5.7	6.2	0.009	0.03
MDASI: Activity	2.6	7.5	7.2	0.03	0.24
MDASI: Walking	2.6	6.7	6.3	0.054	0.52

[a]Kruskal Wallis p-value for differences in PRO items across unordered SINS categories

[b]P-value for trend in PRO items as SINS categories increase

Abbreviations: BPI, Brief Pain Inventory; MDASI, MD Anderson Symptom Inventory; PRO, patient reported outcomes; SINS, Spinal Instability Neoplastic Score.

Table 4.

Correlation Between Categorical SINS and Mean Difference in Preoperative and Postoperative PRO Scores

PRO item	Delta (postop-preop): SINS 0–6	Delta (postop-preop): SINS 7–12	Delta (postop-preop): SINS 13–18	*P**
BPI: Worst Pain	1.5	−2.3	−3.0	0.04
BPI: Least Pain	0.2	−0.9	−0.9	0.52
BPI: Average Pain	−0.2	−1.8	−2.2	0.21
BPI: Pain Now	0.0	−1.4	−1.4	0.46
BPI: Activity	1.2	−1.9	−2.0	0.46
BPI: Walking	1.5	−1.2	−0.8	0.61
MDASI: Pain	2.5	−2.2	−2.8	0.04
MDASI: Spine Pain	0.3	−2.0	−3.6	0.07
MDASI: Activity	1.7	−1.3	−1.1	0.66
MDASI: Walking	1.7	−0.6	−1.0	0.30

*P-value for trend in PRO items as SINS categories increase

Abbreviations: BPI, Brief Pain Inventory; MDASI, MD Anderson Symptom Inventory; PRO, patient reported outcomes; SINS, Spinal Instability Neoplastic Score.

Table 5.

Mean Difference in Preoperative and Postoperative PRO Scores For Indeterminate and High SINS, All Patients and Patients With No Change in Perioperative ASIA Grade

PRO item	Delta (postop-preop): SINS 7–12	*P**	Delta (postop-preop): SINS 7–12 (No ASIA change)	*P**	Delta (postop-preop): SINS 13–18	*P**	Delta (postop-preop): SINS 13–18 (No ASIA change)	*P**
BPI: Worst Pain	−2.3	<0.0001	−2.5	<0.0001	−3.0	<0.0001	−3.0	<0.0001
BPI: Least Pain	−0.9	0.02	−1.1	0.009	−0.9	0.12	−0.9	0.14
BPI: Average Pain	−1.8	<0.0001	−1.8	<0.0001	−2.2	<0.0001	−2.1	0.0002
BPI: Pain Now	−1.4	0.003	−1.3	0.007	−1.4	0.06	−1.2	0.11
BPI: Activity	−1.9	0.0001	−1.8	0.001	−2.0	0.04	−2.0	0.04
BPI: Walking	−1.2	0.03	−0.7	0.27	−0.8	0.45	−0.8	0.45
MDASI: Pain	−2.2	<0.0001	−2.3	<0.0001	−2.8	0.001	−2.8	0.002
MDASI: Spine Pain	−2.0	0.0006	−1.9	0.005	−3.6	0.004	−3.4	0.009
MDASI: Activity	−1.3	0.006	−1.1	0.02	−1.1	0.15	−1.2	0.13
MDASI: Walking	−0.6	0.24	−0.5	0.42	−1.0	0.10	−0.9	0.15

* Wilcoxon Signed Rank Test

Abbreviations: ASIA, American Spinal Injury Association impairment score; BPI, Brief Pain Inventory; MDASI, MD Anderson Symptom Inventory; PRO, patient reported outcomes; SINS, Spinal Instability Neoplastic Score.