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Expanded analysis of vertebral endplate disruption and its impact on vertebral compression fracture risk

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Abstract

Background and Objectives Vertebral compression fracture (VCF) is a potential serious complication of spinal stereotactic body radiotherapy (SBRT). Previously we noted a correlation between advanced Spinal Instability Neoplastic Score (SINS), tumor-related endplate (EP) disruption, and certain primary pathologies with increased VCF risk. Here, we report on an expanded patient cohort to further examine EP disruption's role in VCF.

Methods This retrospective cohort study was conducted at a single institution, gathering demographic and treatment data from patients who underwent spinal SBRT between 2013 and 2020. EP disruption was identified on pre-SBRT CT scans. Chronic steroid use was defined as steroids administered for 4 weeks or more. The 1-year cumulative incidence of VCF was evaluated by follow-up MRI and CT scans at 3-month intervals post-treatment. Based on multivariate analysis, a nomogram was created using four independent predictors: EP disruption, steroid use, SINS ≥ 7 , and adverse histology.

Results A total of 173 patients were included. The median follow-up was 19 months. Approximately 69 patients (40%) had EP disruption. Thirty patients (17%) experienced a VCF at a median of 4.8 months from SBRT. Patients with adverse histology (HR 2.98, 95% CI [1.42–6.30], p 0.004), steroid use (HR 3.60, 95% CI [1.36–9.51], p 0.01), EP disruption (HR 4.16, 95% CI [1.57–11.05], p 0.004) and a SINS of ≥ 7 (HR 3.63, 95% CI [1.39–9.46], p 0.001) were associated with increased risk of VCF. Based on these findings, a nomogram was created with these four variables stratifying groups at low, intermediate, and high risk of VCF correlating with rates of 2%, 21% and 58% risk ($P < .001$).

Conclusion In this expanded pooled analysis, consistent with previously published findings, EP disruption, adverse pathology, and higher SINS scores were associated with an increased risk of VCF. Additionally, we found that chronic steroid use for four weeks or greater also correlated with a higher risk of VCF.

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Keywords Endplate, Radiosurgery, Metastasis, Vertebroplasty

Introduction

The global increase in cancer cases, alongside rising life expectancy, has resulted in more patients living longer with spinal metastases [1]. As such, it is critical to optimize treatment approaches and carefully weigh the risks and benefits. Spinal stereotactic body radiotherapy (SBRT), a highly precise radiation technique, delivers high doses to a well-defined target, offering improved tumor and pain control compared to conventional fractionated radiotherapy [2–5]. Nevertheless, vertebral compression fracture (VCF) is a significant potential complication of SBRT. Sahgal et al. estimated the risk of VCF after SBRT to range from 11 to 39%, vs. 5% with conventional fractionation [6].

Several factors are linked to an increased risk of VCF, including gross tumor volume (GTV) over 10 cc, lumbar location, epidural extension, and a SINS score greater than 6 [7]. Five of the six spinal instability neoplastic score (SINS) components, as well as dosimetric thresholds like $D80\% > 25$ Gy, $D50\% > 30$ Gy, a prescription isodose line below 70%, and dose per fraction over 12 Gy, have been associated with a higher likelihood of VCF [8].

A recent study on endplate (EP) disruption identified three key factors that significantly increased the risk of VCF: adverse histology, SINS score ≥ 7 , and EP disruption [9]. VCF rates were particularly elevated in patients with non-small cell lung cancer (NSCLC), breast adenocarcinoma, and ano-colorectal cancer. Based on these findings, a nomogram was developed to stratify patients into low- and high-risk groups, with one-year VCF incidences of 2% and 38% for low-risk and, respectively high-risk patients ($p < .001$) [9]. *However, chronic steroid use was underrepresented in the previous cohort, limiting the ability to assess its contribution to VCF risk. In the current study, we analyzed an expanded patient cohort with more representative inclusion of steroid-exposed patients and systematically evaluated additional clinical variables, including chronic steroid use, to refine and enhance the predictive performance of the nomogram.*

Method

Study design

This Institutional Review Board (IRB)-approved retrospective analysis was conducted for patients with spine metastases treated with SBRT between 2013 and 2020 at a single, high-volume institution. Patient consent was not sought nor required by our IRB for this retrospective chart review study. Patients with a history of surgical intervention at any spinal site or previous radiation to the site treated with SBRT were excluded from this study. Demographic and treatment data were collected,

including age, gender, performance status, body mass index, osteoporosis (defined by DEXA scan), steroid use exceeding one-month within ± 4 weeks of SBRT, systemic therapies received within ± 4 weeks of SBRT, and the use of bone antiresorptive medications (such as bisphosphonates or denosumab) within four weeks of radiation. SBRT details such as dose, fractionation, PTV coverage, and conformity index were also documented. Additionally, disease characteristics were collected, including histopathology, SINS criteria, bone lesion quality (osteoblastic, osteolytic, or mixed), Bilsky spinal cord compression grade, and EP disruption. EP disruption is defined as cortical disruption of the superior and/or inferior EP by tumor. *All pre-treatment CT scans for EP evaluation were independently reviewed by two board-certified neuroradiologists who were blinded to clinical outcome.* Based on these variables and the previously established nomogram, a new predictive nomogram was developed for VCF.

Treatment volumes for spine SBRT were contoured according to established guidelines, based on extent of disease and bone anatomy. No additional margin from clinical target volume (CTV) to planning target volume (PTV) was added, following the same methodology as described in our previous manuscript [9]. All patients received image-guided single fraction or fractionated SBRT. Immobilization was achieved using an Aquaplast frameless mask for cervical spine cases and a stereotactic body frame with Vac-Lok bag for thoracic, lumbar, and sacral spine cases. The radiation dose was prescribed to ensure that at least 95% of the PTV received 95% of the prescribed dose. However, in cases where critical structures precluded full coverage, priority was given to organs at risk tolerance (e.g., spinal cord) tolerance per AAPM TG-101 guidelines, and target coverage was adjusted accordingly [10].

Study endpoints

The primary endpoint of this study was the 1-year cumulative incidence of VCF in patients with spinal metastases treated with SBRT. *Cumulative incidence of VCF included both de novo fractures and progression of pre-existing compression at the treated level, confirmed by imaging follow-up.* Secondary endpoints included the evaluation of various prognostic factors for VCF, such as demographic characteristics, clinical factors (e.g., use of steroids or antiresorptive medications), radiation dose parameters, and tumor-specific factors (e.g., Bilsky spinal cord compression grade, SINS score, and EP disruption). This study also assessed the impact of these factors on clinical outcomes, with the goal of defining a high-risk patient

Table 1 Patients' demographics

Variable	Number (%) *	Number (%) **
Number of Patients	111	62
Median Age (yr.) (Range)	60 (24–87)	65 (29–82)
Sex		
Male	59 (53)	43 (69)
Female	52 (47)	19 (31)
Karnofsky Performance Status		
≥70%	96 (86)	57 (92)
<70%	15 (14)	4 (8)
Median BMI (range)	27 (16–47)	28 (15–46)
Osteoporosis		
Yes	9 (8)	1 (2)
No	102 (92)	61 (98)
Steroid Use =/≥4weeks		
Yes	12 (11)	6 (10)
No	99 (89)	56 (90)
Bisphosphonate Use		
Yes	20 (18)	23 (37)
No	91 (82)	39 (63)
Denosumab Use		
Yes	8 (7)	12 (19)
No	103 (93)	50 (81)
Concurrent systemic therapy		
None	58 (52)	34 (55)
Chemotherapy	19 (17)	11 (17)
Immune therapy	15 (14)	11 (17)
Targeted therapy	19 (17)	6 (11)
Median Prescription Dose (Gy) (Range)	27 (10–35)	27 (25–35)
Median Prescribed BED10 (Gy) (Range)	51.3 (20–60)	51.3 (37.5–60)
Median D80% (Gy)	27 (10.2–36)	28 (22.2–35.9)
Median D50% (Gy)	28 (10.3–38)	29 (24.1–37.8)
Isodose line		
>=95%	74 (67)	40 (65)
<95%	37 (33)	22 (35)
Median PTV (cc) (Range)	50 (8–465)	50 (6.3–348)
Median Conformity index (Range)	1.05 (0.42–1.4)	1 (0.7–1.16)
PTV coverage		
Partial vertebra	83 (75)	58 (94)
Circumferential	28 (25)	4 (6)
Fractionation		
Single Fraction	22 (20)	0 (0)
Multi Fraction	89 (80)	62 (100)
Number of Treated Spinal Levels		
1 level	64 (58%)	39 (63)
2 levels	32 (29%)	13 (21)
>2 levels	15 (13%)	10 (16)
Histopathology		
NSCLC/Breast/ano-colorectal	36 (32)	15 (34)
Others	75 (68)	47 (66)
Spinal Instability Neoplastic Score Criteria		
< 7	73 (66)	32 (52)
7	13 (11)	9 (14)
>7	25 (23)	21 (34)
Bone lesion quality		

Table 1 (continued)

Variable	Number (%) *	Number (%) **
Blastic	38 (34)	13 (21)
Mixed	24 (22)	21 (34)
Lytic	49 (44)	28 (45)
Bilsky grade		
0	88 (79)	38 (61)
1a	7 (6)	7 (11)
1b	13 (12)	11 (18)
1c	3 (3)	6 (9)
VCF		
Yes	20 (18)	10 (16)
No	91 (82)	52 (84)
Median time to VCF (mo) (range)	5.2 (1.1–57.4)	3.6 (0.7–37.4)
EP-disrupted		
Yes	48 (43)	21 (34)
No	63 (57)	41 (66)

abbreviations: BMI: body mass index; BED10: biologically effective dose alpha/beta 10; PTV: planning target volume; EP: endplate; NSCLC: Non-Small Cell Lung Cancer; SINS: spine instability neoplastic score

*The previously published cohort

**The new cohort

subgroup who may benefit from additional prophylactic interventions or treatment modifications.

Statistical analysis

Statistical analyses were conducted using SPSS Statistics version 29.0.1.0 (Armonk, NY). Continuous demographic variables were summarized using medians and ranges, while frequency counts and proportions were used to describe categorical variables. The primary endpoint of the 1-year cumulative incidence of VCF was evaluated using inverse Kaplan-Meier curves. Univariate analysis, utilizing a proportional hazards model, was conducted to assess the association between clinically relevant variables and an increased risk of VCF. These variables included age, gender, histology, body mass index (BMI), steroid use, bone remodeling therapies, radiotherapy dose, fractionation, SINS score (location, pain characteristics, bone lesion type, spinal alignment, vertebral body collapse, and posterior spinal element involvement), bone lesion quality, and EP disruption. A p -value of <0.05 was considered statistically significant, and continuous variables were dichotomized at the median value. Subsequently, multivariate Cox proportional hazards analyses were performed, incorporating statistically significant variables from the univariate analysis, to determine their impact on VCF risk. The results guided the creation of a VCF risk stratification nomogram. Each statistically significant variable identified in the multivariate analysis contributed one point to the scoring system, with total scores ranging from 0 to 4. Patients were categorized into risk groups based on their scores: low-risk (0–1 points), intermediate-risk (2 points), and high-risk (3–4 points). To account for mortality, we estimated vertebral

compression fracture-free survival based on the nomogram scores.

Results

Patient characteristics

As shown in Table 1, this study analyzed a combined total of 173 patients, with a median age of 62 years (range 24–87). Males comprised 59% of the cohort. Most patients (88%) had a Karnofsky Performance Status of 70% and greater. Osteoporosis was present in 6% of the patients. Steroid use for four weeks or greater was reported in 11%, while bisphosphonate and denosumab use occurred in 25% and 12%, respectively. Adverse pathology (NSCLC/breast adenocarcinoma/ano-colorectal) was reported in 29% of patients. The median prescription dose was 27 Gy, and partial vertebral coverage was the most common treatment (82%). Most patients (88%) received multi-fraction treatments targeting one or two vertebral levels. Lytic bone lesions were the most common (45%). The median SINS score was 6 (range 1–13). There were no spinal cord bilsky grade 2 or above in this cohort. VCF occurred in 17% of patients, with a median time to event of 4.8 months (range 0.7–57.4). EP disruption was observed in 40% of cases at the time of radiation evaluation.

Vertebral compression fracture

Table 2 summarizes the 1-year cumulative incidence of VCF in 173 patients, with several key variables. Patients older than 60 had a 16% incidence of VCFs, compared to 17% in those younger than 60 ($p=.65$). Males had a lower incidence (14%) than females (18%), though this was not statistically significant ($p=.12$). Primary cancers

Table 2 Cumulative incidence of vertebral compression fracture

Variable	Number (173)	1-year cumulative incidence of VCF	P value
Age			
≥60	101	16%	0.65
<60	72	17%	
Sex			
Male	102	14%	0.12
Female	71	18%	
Primary cancer			
NSCLC/Breast/ano-colorectal	51	25%	<0.001
Others	122	10%	
BMI			
<25	59	18%	0.33
25-29.9	53	10%	
≥30	61	10%	
Steroid use			
Yes	18	38%	0.01
No	155	13%	
Antiresorptive medicine			
Yes	59	16%	0.77
No	114	15%	
Osteoporosis			
Yes	10	0%	0.83
No	163	17%	
Fractionation			
Single	22	20%	0.90
Multiple	151	14%	
Radiotherapy dose			
BED10 < 51.3 Gy	63	20%	0.35
BED10 ≥ 51.3 Gy	110	10%	
D80% < 27 Gy	56	14%	0.45
D80 ≥ 27 Gy	117	15%	
D50% < 28 Gy	77	10%	0.14
D50% ≥ 28 Gy	96	20%	
Bilsky			
0	126	10%	<0.001
1	47	28%	
SINS score			
≥7	75	32%	<0.001
<7	98	4%	
EP disruption			
Yes	69	30%	<0.001
No	104	5%	

abbreviations: BMI: body mass index; BED10: biologically effective dose alpha/beta 10; PTV: planning target volume; EP: endplate; NSCLC: Non-Small Cell Lung Cancer; SINS: spine instability neoplastic score; VCF: vertebral compression fracture

like NSCLC, breast, and ano-colorectal (adverse histology) were associated with a higher VCF incidence (25%) compared to other cancers (10%, $p < .001$). Steroid use was linked to a significantly higher incidence of VCFs (38% vs. 13%, $p = .01$), while antiresorptive medicine had no significant impact ($p = .77$). Osteoporosis did not

influence VCF incidence ($p = .83$). Patients treated with single-fraction SBRT had a 20% VCF incidence, while those receiving multi-fraction SBRT had 14% ($p = .90$). Those receiving BED10 > 51.3 Gy had a lower VCF rate (10%) compared to BED10 < 51.3 Gy (20%), though this was not statistically significant ($p = .35$). SINS ≥ 7 and EP disruption were both strongly associated with higher VCF incidences (32% vs. 4%, $p < .001$, and 30% vs. 5%, $p < .001$, respectively). Additionally, patients with Bilsky grade 1 had a higher VCF incidence (28%) compared to grade 0 (10%, $p < .001$).

Table 3 summarizes the univariate and multivariate analyses. In the univariate analysis, several factors showed significant correlations with VCF. Steroid use (HR 2.98, 95% CI [1.21–7.36], $p = 0.023$), Bilsky spinal compression grade (HR 3.22, 95% CI [1.55–6.69], $p = 0.002$), SINS score (HR 1.63, 95% CI [1.37–1.94], $p < .001$), EP disruption (HR 6.02, 95% CI [2.46–14.76], $p < .001$), adverse pathology (HR 3.26, 95% CI [1.58–6.71], $p = 0.001$), and circumferential PTV coverage (HR 2.35, 95% CI [1.11–4.97], $p = 0.022$), were all associated with increased risk of VCF. In the multivariate analysis, steroid use (HR 3.60, 95% CI [1.36–9.51], $p = 0.011$), SINS score (HR 3.63, 95% CI [1.39–9.46], $p = 0.001$), EP disruption (HR 4.16, 95% CI [1.57–11.05], $p = 0.004$), and adverse histology (HR 2.98, 95% CI [1.42–6.30], $p = 0.004$), remained significant independent predictors of VCF. Bilsky grade and circumferential PTV lost significance in the multivariate model.

Vertebral compression fracture nomogram

The previously published nomogram was re-evaluated in predicting VCF development [9]. Variables included those previously noted from the prior nomogram including adverse histology, SINS score, and EP disruption, with the addition of chronic steroid use as noted on this analysis. Similar to the previously published nomogram, each factor was given one point. We classified patients into three groups: high-risk (HR) (3–4 points), intermediate-risk (IR) (2 points), and low-risk (LR) (0–1 point). As shown in Fig. 1, the 1-year cumulative incidence of VCF was 58% vs. 21% vs. 2%, $p < .001$ for HR, IR, LR groups, respectively. As shown in Fig. 2, the 1-year VCF free survival was 63% vs. 48% vs. 29%, $p = 0.004$ for LR, IR and HR groups, respectively.

Vertebral compression fracture consequences

Among the 21 h pts, 13 (62%) developed VCF. Two (10%) underwent vertebroplasty due to uncontrolled pain, two (10%) underwent decompression with instrumented fusion due to spinal cord compression from bony retro-pulsion, and four (20%) required at least one emergency department visit due to uncontrolled pain. Among the 47 IR patients, 14 (30%) developed VCF. One (2%) patient underwent vertebroplasty due uncontrolled pain, and

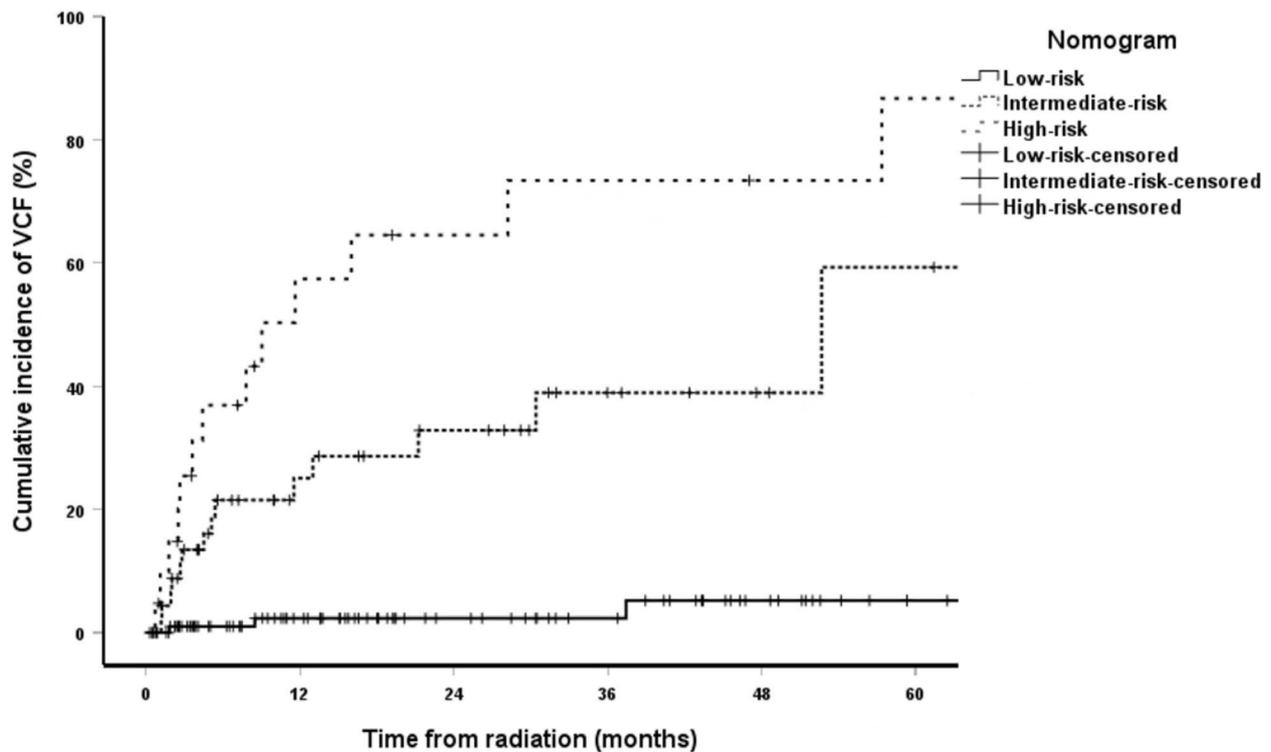
Table 3 Univariate and multivariate analysis correlation with vertebral compression fracture

	Univariate analysis		Multivariable analysis	
	HR (95% CI)	p-value	HR (95% CI)	p-value
Age	1.02 (0.98–1.05)	0.211		
Sex	1.75 (0.85–3.61)	0.132		
Osteoporosis	0.85 (0.20–3.59)	0.833		
Steroid use ≥ 4 weeks	2.98 (1.21–7.36)	0.023	3.60 (1.36–9.51)	0.011
Antiresorptive medicine	1.12 (0.52–2.40)	0.772		
Bilsky spinal compression grade	3.22 (1.55–6.69)	0.002	1.90 (0.88–4.10)	0.091
SINS score	1.63 (1.37–1.94)	< 0.001	3.63 (1.39–9.46)	0.001
EPD	6.02 (2.46–14.76)	< 0.001	4.16 (1.57–11.05)	0.004
Adverse pathology	3.26 (1.58–6.71)	0.001	2.98 (1.42–6.30)	0.004
Prescribed dose (BED10)	0.95 (0.91–1.01)	0.073		
PTV- volume	1.01 (0.99–1.01)	0.94		
Circumferential radiotherapy	2.35 (1.11–4.97)	0.022	1.81 (0.081-4.03)	0.150

abbreviations: BED10: biologically effective dose alpha/beta 10; PTV: planning target volume; EPD: endplate disruption; SINS: spine instability neoplastic score

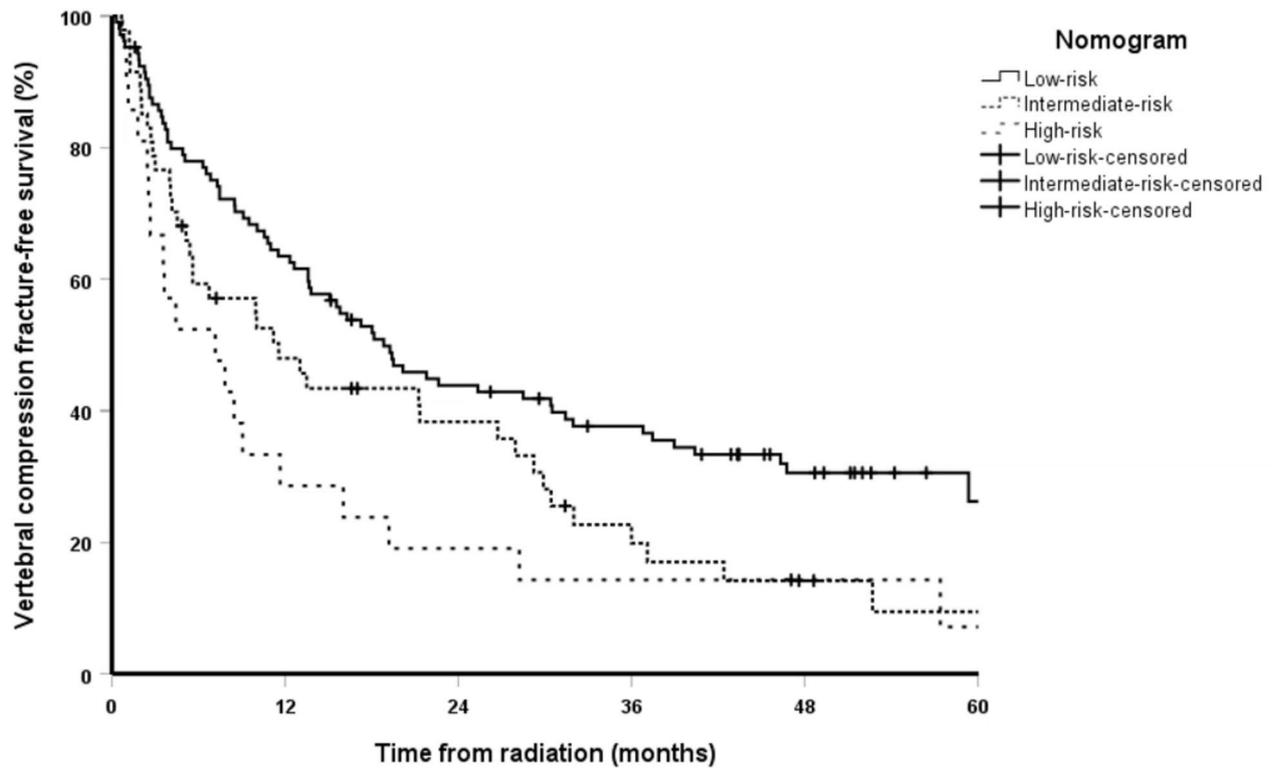
other (2%) underwent decompression with instrumented fusion due to spinal cord compression from bony retropulsion. Five (10%) required at least one emergency department visit due to uncontrolled pain, and four (9%)

were admitted for uncontrolled pain or surgical intervention. Among the 105 LR patients, 3 (3%) developed VCF. One patient underwent posterior fixation, and the other underwent decompression with instrumented fusion due



LR	105	66	44	35	22	12
IR	47	21	15	7	4	2
HR	21	6	4	3	2	1

Fig. 1 The 1-year cumulative incidence of VCF for low- vs. intermediate vs. high-risk groups (the 1-year cumulative incidence of VCF for LR (low-risk) vs. IR (intermediate risk) vs. high-risk (HR) was 2% vs. 21% vs. 58%, respectively, $P < .001$). VCF, vertebral compression fracture



LR	105	66	44	35	22	12
IR	47	21	15	7	4	2
HR	21	6	4	3	2	1

Fig. 2 The 1-year VCF-free survival for low- vs. intermediate vs. high-risk groups (the 1-year VCFFS for LR (low-risk) vs. IR (intermediate risk) vs. high-risk (HR) was 63% vs. 48% vs. 29%, p 0.004). VCF, vertebral compression fracture

to spinal cord compression from bony retropulsion. All patients that developed VCF required opioids at some point regardless of risk category.

Discussion

This expanded study confirms EP disruption remains significantly associated with an increased risk of VCF after Spine SBRT. In addition to the previously identified factors—a higher SINS score, adverse histology, and EP disruption—steroid use for four weeks or greater was found to significantly increase the risk of VCF. We also revised our previously published nomogram [9], categorizing patients into HR, IR and LR groups based on this cohort. Most HR patients (62%) developed VCF with some VCF-related consequences; this group of patients may benefit from prophylactic intervention such as vertebral augmentation.

In a meta-analysis for patients treated with vertebroplasty due to osteoporotic fracture, data from 17 combined studies revealed three factors linked to the incidence of new VCFs following vertebroplasty [11]. These included low bone mineral density (BMD) (SMD

−0.375; 95% CI −0.579 to −0.171), multiple treated vertebrae (Odds Ratio (OR) 2.027; 95% CI 1.442 to 2.851), and a history of steroid use (OR 2.632; 95% CI 1.399 to 4.950). The pathophysiology of steroid induced bony fracture is multifactorial, but primarily related to osteoblastic dysfunction [12]. In our study, steroid use for 4 weeks and greater were associated with increased VCF risk in univariate and multivariate analyses.

The consequences of VCF varies, including acute/chronic pain, biomechanical changes, and kyphotic deformity [13]. Previously published data on osteoporotic VCF indicates that direct hospitalization costs per VCF range from \$8,000 to \$16,000; while indirect costs, including lost productivity and caregiving needs add significantly to the economic burden, contributing to an estimated \$4.5 to \$6.4 billion in indirect costs of osteoporotic fractures in the United States [13]. In our cohort, among the 30 patients who developed VCF, 7 (23%) underwent surgical intervention, 9 (30%) presented to ED for uncontrolled pain, and 6 (20%) were admitted to the hospital for uncontrolled pain. Based on our risk stratification nomogram, VCF and VCF-related consequences

were more common in the HR group. We propose using our nomogram to identify HR patients who may benefit from upfront vertebral augmentation to mitigate post-SBRT VCF related consequences.

While the results are promising, limitations exist, and further prospective clinical trials are essential to validate these findings. Our analysis is based on a retrospective dataset, which constrains the generalizability of our conclusions. A larger, multicenter sample size, extended follow-up, and additional VCF cases are needed to clarify subgroup effects within our study. Additionally, examining the economic impact of VCF-related consequences is warranted.

Conclusion

This expanded analysis confirms that EP disruption, adverse pathology, high SINS scores, and chronic steroid use are associated with increased VCF risk. Stratified into low, intermediate, and high-risk groups, patients demonstrated VCF rates of 2%, 21%, and 58%, respectively ($P < .001$). The 1-year VCF rates for LR, IR, HR was 63% vs. 48% vs. 29%, $p = 0.004$. These findings highlight the nomogram's utility in identifying high-risk patients for preventive interventions, such as prophylactic vertebral augmentation, to minimize post-SBRT VCF-related consequences.

Abbreviations

VCF	Vertebral compression fracture
EP	Endplate
SBRT	Stereotactic body radiotherapy
PTV	Planning target volume
CTV	Clinical target volume
GTV	Gross tumor volume
SINS	Spine instability neoplastic score
BMI	Body mass index
NSCLC	Non-small cell lung cancer
BED10	Biologically effective dose alpha/beta 10

Author contributions

• Khaled Dibs: Conception and design of the study, data collection, manuscript drafting, and revision. • Prasath Mageswaran: Contributed to study conception, data interpretation, and manuscript revision. • Raju Raval, Evan Thomas, Natalie Peters, and Emile Gogineni: Provided data interpretation and revised the manuscript. • Jeff Pan and Brett Klamar: Led data analysis and drafted the statistical analysis section. • Ahmet Ayan and Eric Cochran: Focused on data analysis from a physics perspective and revised the physics section. • Eric Bourekas and Daniel Boulter: Reviewed MRIs/CT scans and contributed to the radiology section. • Nicholas Fitko: Further refined the radiological analysis. • Vikram Chakravarthy, James Elder, John McGregor, and Russel Lonsler: Reviewed and revised the surgical aspects. • Esmerina Tili: Contributed to the conceptualization of metastatic spinal disease biology and revised that section. • Ahmed Elguindy and Eugene Yap: Assisted with data collection and manuscript revision. • William Marras and Soheil Soghratti: Contributed to the engineering concepts and manuscript revision. • John Grecula and Arnab Chakravarti: Provided data interpretation and manuscript revisions. • Joshua Palmer: Assisted with manuscript revision. • Dukagjin Blakaj (Corresponding Author): Led the study's conception and design, provided critical revisions, and supervised the research.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

This study was conducted in accordance with the ethical standards of Institutional Review Board (IRB) of The Ohio State University. The need for informed consent was waived by the due to the retrospective nature of the study (Approval Number: 2022C0198).

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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