Original Article

Surgical management of spinal multiple myeloma: insights from the National Inpatient Sample database

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Background: Management of multiple myeloma (MM) of the spine includes a multimodal approach consisting of chemotherapy, bisphosphonates, radiation, and surgical intervention. This study aims to explore the trends in surgical treatment of MM including hospital costs, odds of complications, and the impact of patient comorbidities on the risk of complications using the National Inpatient Sample (NIS) database.

Methods: The NIS was queried for patients with MM and plasmacytoma of the spine who underwent surgical intervention between 2005 and 2014. Rates of spinal decompression, spinal stabilization with or without decompression, and vertebral augmentation were analyzed. The effect of various patient characteristics on outcome was analyzed by multivariate analysis and stratified by surgical procedure.

Results: Vertebral augmentation (9,643, 65.7%) was the most commonly performed procedure, followed by spinal stabilization with or without decompression (4,176, 28.4%) and then decompression alone (868, 5.9%). The total population-adjusted rate of surgical management for MM remained stable during the study period, while the rate of spinal stabilization increased (P<0.001) and the rate of vertebral augmentation decreased (P=0.01). Vertebral augmentation was associated with shorter inpatient hospital stay, lower total cost, and higher likelihood of discharging to home. The complication rate increased over time for vertebral augmentation procedures (P<0.001) while spinal stabilization and decompression complication rates remained stable. The complication rate for all procedures was higher in male patients (P<0.001) and increased with the number of patient comorbidities (P<0.001).

Conclusions: Spinal surgery seems to be increasing for the management of spinal MM in the inpatient setting, while the rate of vertebral augmentation is decreasing. Vertebroplasty and similar palliative procedures may continue to decrease as advancements in surgical technology and technique allow for safer surgical intervention. The decision to employ aggressive surgical intervention, however, must always take into account the patient's comorbidities, overall systemic disease burden, and the potential for significant enhancement in meaningful clinical outcome.

Keywords: Multiple myeloma (MM); spinal cord tumor; surgery; hospital cost; National Inpatient Sample (NIS)

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Introduction

Multiple myeloma (MM) is a malignant proliferation of plasma cells and commonly involves the skull, ribs, vertebrae, and pelvis. Spine lesions are present in 60% of MM patients, leading to significant morbidity (1). Affected spinal levels may develop fractures and instability that may lead to significant pain and deterioration of neurological function due to spinal cord compression, which occurs in 11–24% of MM patients (2,3). Even in the absence of a fracture, MM can directly invade the spinal canal and cause spinal cord compression in 10% of patients (4). Plasmacytoma is a solitary lesion that is a precursor for MM but presents similarly if it causes vertebral body collapse and/or neurological compromise. MM mainly affects the vertebral bodies and less frequently the pedicles, transverse processes, and spinous processes (5). Over 90% of cases occur in adults over the age of 40 years, mainly occurring in the 7th decade of life (6).

Primary treatment for MM involves a combination of systemic chemotherapy, bisphosphonates, and radiotherapy for bone lesions (7). Spinal surgery is generally reserved for patients who demonstrate spinal instability and/or spinal cord compression resulting in debilitating pain or acute neurological deficits (8-10). Unlike other spine tumors, particularly metastatic tumors that result in neurologic deficit, MM patients with neurologic deficit secondary to spinal cord compression can often be treated without surgery using steroids and radiation with excellent neurologic results (7,11,12). Inpatient surgery for patients with MM traditionally occurs in the setting of spinal deformity or in patients with acute neurologic deficit with or without a known diagnosis of MM (12,13). Adjuvant therapy with chemotherapy and radiation is provided following surgery to treat local and systemic disease.

Various surgical options exist which include decompression of the neural elements in the setting of neurological compromise. Stabilization via anterior or posterior fixation with or without decompression is another option for patients with mechanical instability. Previous studies, mainly utilizing small cohorts of patients, have shown favorable outcomes following surgical intervention for MM and plasmacytoma (8,14,15). Cement augmentation via percutaneous vertebroplasty or balloon kyphoplasty are minimally invasive treatment options that strengthens the vertebrae and provides pain relief, mechanical stability, and improves quality of life (16,17). This study aims to investigate the trends in surgical treatment of MM, hospital costs, odds of complications, and the impact of patient comorbidities on the risk of complications utilizing a national database. We present this article in accordance with the STROBE reporting checklist (available at https://jss.amegroups.com/article/view/10.21037/jss-24-54/rc).

Highlight box

Key findings

- Rates of surgical stabilization for the management of spinal multiple myeloma (MM) are increasing, while rates of vertebral augmentation are decreasing.

What is known and what is new?

- There are multiple surgical options for the management of spinal MM, including vertebral augmentation, spinal decompression, and stabilization. Each of these treatment options is associated with unique risks and implications on healthcare costs.
- This study adds to the literature by analyzing data from a nationally representative database to investigate trends in surgical treatment of MM including hospital costs, odds of complications, and the impact of patient comorbidities on the risk of complications.

What is the implication, and what should change now?

- Vertebroplasty and similar palliative procedures may continue to decrease as advancements in surgical technology and technique allow for safer surgical intervention. The decision to employ aggressive surgical intervention, however, must always take into account the patient's comorbidities, overall systemic disease burden, and the potential for significant enhancement in meaningful clinical outcome.

Methods

Data

Data were obtained from the National Inpatient Sample (NIS) maintained by the Agency for Healthcare Research and Quality (AHRQ). Utilizing the International Classification of Diseases, 9th revision and Clinical Modification (ICD-9 CM) codes, rates of vertebral

augmentation, spinal decompression, and spinal stabilization with or without (+/–) decompression were calculated between 2005 and 2014. If more than one procedure was performed in the same patient, the procedure was coded by the most invasive procedure performed (spinal stabilization > decompression > vertebral augmentation). Medical comorbidities were calculated as described by Elixhauser *et al.* (18). Complications were identified using ICD-9 codes as previously defined in other work by this group, including Peterson *et al.* (19) and include "neurologic complications (997.00–997.09), pulmonary complications (518.81–518.85, 997.3), thromboembolic complications including deep venous thrombosis (DVT) and pulmonary embolism (387, 415, 415.11–415.19, 4510–4519, and 4530–4539), cardiac complications (410 and 997.1), urinary and renal complications (584 and 997.5), hemorrhage or hematoma complicating a procedure (998.1–998.13), and infectious complications (996.63, 998.02, 998.51, and 998.59)". The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the institutional review board of Wake Forest University (No. IRB000600095) and individual consent for this retrospective analysis was waived.

Inclusion criteria

Patients were identified by a primary diagnosis of MM (Clinical Classification Software code 40) or plasmacytoma (ICD-9 code 238.6: neoplasm of uncertain behavior of plasma cells) with a secondary diagnosis of secondary malignant neoplasm of the spinal cord. The ICD-9 codes utilized to capture all relevant patients and procedures have been previously defined in work by Zehri *et al.* (20).

Statistical analysis

All statistical procedures were performed as previously described in the methods of Peterson *et al.* (19), therefore only differences in methods will be reported here. Overall population estimates were obtained from the US Census Bureau and utilized when calculating yearly procedure rates (21). Weighting was used to account for the changes in sampling procedure during the study period as well as to produce national estimates for trends analysis. The weighting variable is included in the data and calculated by AHRQ for use in all analyses conducted on the NIS. Rates are calculated based on total number of cases; however, missing data counts differ by variable, therefore rates within each variable may not always total 100%. Rounding has been used as weighted frequencies are not always whole counts. Total charges were adjusted for inflation into 2023 US dollars (USD) using Consumer Price Index for All Urban Consumers (US Bureau of Labor Statistics).

Results

Surgical trends

The NIS query returned 14,687 cases of surgically managed MM and plasmacytoma from 2005 to 2014 and no cases were excluded from those identified. The vast majority of the population (95.9%) had a diagnosis of MM, while only 4.1% of the population had a diagnosis of plasmacytoma. Vertebral augmentation (9,643, 65.7%) was the most commonly performed procedure, followed by spinal stabilization (4,176, 28.4%) and decompression alone (868, 5.9%). A small percentage of the population underwent multiple procedures and were recategorized based on the most invasive procedure as described in the methods. This included 1.9% of the sample undergoing all three procedures, 1.7% undergoing decompression and vertebral augmentation, and 5.5% undergoing spinal stabilization and vertebral augmentation. Over the study period, the overall population-adjusted rate of surgical management for MM remained stable (P=0.13) along with the rate of decompression alone (P=0.20), while the rate of spinal stabilization increased (P=0.001) and the rate of vertebral augmentation decreased (P=0.01) (*Table 1*, *Figure 1*).

Baseline patient characteristics

The mean age of all patients was 66.4 years old, and patients undergoing vertebral augmentation were significantly older than those receiving other surgical procedures (*Table 2*). The majority of patients in the cohort were White (Caucasian) (64.4%), and male patients compromised a majority (56.2%) of the patient population who received a surgical procedure. Of the three surgical categories, surgical decompression had the highest proportion of males (66.2%). The most common payer for surgical procedures was Medicare (56.0%). Overall, 20.2% of the population had 0 or 1 comorbidity, 44.4% had 2 to 3 comorbidities, and 35.4% had 4 or more.

Discharge characteristics

Overall in-hospital mortality was 1.3%. Mortality differed

Table 1 Trends in surgical management of MM, 2005–2014

Procedure type	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	Total
Decompression	80	90	79	58	75	57	109	130	110	80	868
Spinal stabilization	286	254	383	420	433	444	526	435	465	530	4,176
Vertebral augmentation	1,373	972	1,045	1,334	936	1,046	662	840	695	740	9,643
Total	1,739	1,317	1,507	1,811	1,444	1,547	1,297	1,405	1,270	1,350	14,687

Yearly case counts of spinal stabilization increased over time (P=0.001) while yearly rates of vertebral augmentation decreased (P=0.01) over this time period. Yearly spinal decompression rates did not change during this period (P=0.20). The total number of all surgical procedures remained steady over this time period (P=0.13). MM, multiple myeloma.

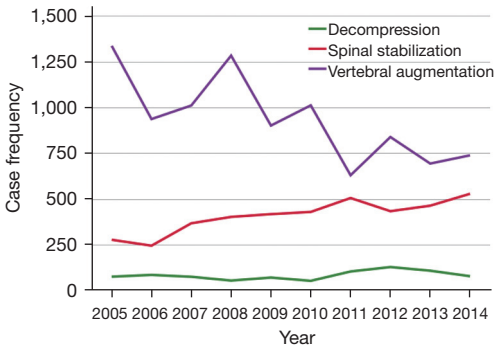

Figure 1 Trends in surgical management of MM, 2005–2014. MM, multiple myeloma.

by procedure (P=0.01) with patients undergoing vertebral augmentation (0.9%) and spinal stabilization (1.6%) having lower mortality compared to decompression alone (3.3%). Vertebral augmentation was associated with shorter length of stay (8.8 days), lower total cost ($107,819), and significantly higher likelihood of a favorable discharge to home (75.3%) (*Table 3*). Of the three surgical procedures, spinal stabilization had the highest total cost ($247,990) and was associated with a more favorable discharge to home and decreased length of stay *vs.* decompression only.

Complications

The total rate of complications was 22.4% across all procedures (*Table 4*). The probability of complication increased over time for vertebral augmentation procedures (P<0.001) while the probability of complication for spinal stabilization and decompression remained stable (P=0.98 and P=0.69, respectively) (*Figure 2*). The overall rate of complications for the entire time period did not differ by procedure [decompression (27.1%), spinal stabilization (22.8%), and vertebral augmentation (21.8%)]. On subgroup comparison between decompression and vertebral augmentation groups, there were significantly more pulmonary complications (6.5% *vs.* 2.9%, P=0.03), postoperative hemorrhages (6.8% *vs.* 0.7%, P<0.001), neurologic complications (1.2% *vs.* 0.0%, P<0.001) and infectious complications (1.1% *vs.* 0.1%, P<0.001). Several differences were also identified between the spinal stabilization and vertebral augmentation groups, with the spinal stabilization group having higher rates of postoperative hemorrhage (4.1% *vs.* 0.7%, P<0.001) and infectious complications (1.4% *vs.* 0.1%, P<0.001). There were more urinary or renal complications in the vertebral augmentation group than the spinal stabilization group (16.8% *vs.* 9.7%, P<0.001). Regardless of the type of surgical procedure, the presence of any complication was associated with increases in length of stay, in-hospital mortality, and total costs (*Table 5*).

The odds of any complication occurring did not differ by the type of procedure (P=0.71), but sex and number of comorbidities did affect the risk of occurrence of a complication (*Table 6*). For each additional comorbidity, the likelihood of complication increased by 1.44 [95% confidence interval (CI): 1.36–1.52; P<0.001]. Males were 1.50 times as likely to have a complication as females (95% CI: 1.25–1.80; P<0.001). Lastly, subgroup analysis showed there was no difference in rate of complication between procedure types for patients with the same number of comorbidities (groups: 0–1, 2–3, or 4+ comorbidities) (*Table 7*).

Discussion

This study is the first to analyze the trends in the surgical management for MM using a national database. Total yearly surgical procedures for MM remained stable from 2005 to

Table 2 Baseline characteristics

Characteristics	Overall	Decompression	Spinal stabilization	Vertebral augmentation	P value
Number of discharges	14,687	868	4,176	9,643	–
Age (years)	66.4 [0.3]	64.2 [0.8]	62.1 [0.4]	68.4 [0.4]	<0.001
Race					<0.001
White	9,454 (64.4)	475 (54.7)	2,542 (60.9)	6,437 (66.8)	
Black	1,488 (10.1)	188 (21.7)	527 (12.6)	774 (8.0)	
Hispanic	983 (6.7)	68 (7.8)	310 (7.4)	605 (6.3)	
Other	552 (3.8)	34 (3.9)	213 (5.1)	305 (3.2)	
Female	6,440 (43.8)	293 (33.8)	1,505 (36.0)	4,642 (48.1)	<0.001
Payer					<0.001
Medicare	8,228 (56.0)	445 (51.3)	1,818 (43.5)	5,966 (61.9)	
Medicaid	757 (5.2)	70 (8.1)	283 (6.8)	405 (4.2)	
Private insurance	5,008 (34.1)	313 (36.1)	1,797 (43.0)	2,898 (30.1)	
Self-pay/other	657 (4.5)	35 (4.0)	258 (6.2)	365 (3.8)	
Number of comorbidities					0.06
0–1	2,969 (20.2)	124 (14.3)	878 (21.0)	1,966 (20.4)	
2–3	6,518 (44.4)	357 (41.1)	1,901 (45.5)	4,259 (44.2)	
4+	5,200 (35.4)	386 (44.5)	1,396 (33.3)	3,417 (35.4)	

Data are presented as number, mean [SEM], or n (%). Rates are calculated based on total number of cases; however, missing data counts differ by variable, therefore rates within each variable may not total 100%. SEM, standard error of the mean.

Table 3 Discharge characteristics

Characteristics	Overall	Decompression	Spinal stabilization	Vertebral augmentation	P value
Number of discharges	14,687	868	4,176	9,643	–
Length of stay (days)	9.8 [0.3]	12.5 [0.9]	11.4 [0.4]	8.8 [0.3]	<0.001
Total charges (in 2023 USD, $)	150,606 [4,355]	163,036 [8,848]	247,990 [6,775]	107,819 [4,072]	<0.001
Disposition					<0.001
Routine	7,278 (49.6)	259 (29.8)	1,472 (35.2)	5,548 (57.5)	
Short-term hospital	222 (1.5)	34 (3.9)	113 (2.7)	74 (0.8)	
Another facility	4,412 (30.1)	391 (45.0)	1,808 (43.3)	2,213 (22.9)	
Home health care	2,572 (17.5)	154 (17.7)	705 (16.9)	1,712 (17.8)	
Against medical advice	10 (0.1)	0 (0.0)	10 (0.2)	0 (0.0)	
Died	187 (1.3)	29 (3.3)	67 (1.6)	91 (0.9)	
Discharge to home[†]	9,860 (67.1)	413 (47.6)	2,187 (52.4)	7,260 (75.3)	<0.001

Data are presented as number, mean [SEM], or n (%). [†], includes routine, home health care, and against medical advice percentage based on total discharges within procedure. USD, US dollars; SEM, standard error of the mean.

Table 4 Rate of complications

Complication type	Overall (n=14,329)[†]	Decompression[‡] (n=850)	Spinal stabilization[‡] (n=4,085)	Vertebral augmentation[‡] (n=9,394)	Overall P value	Subgroup comparison
Any complication	3,210 (22.4)	230 (27.1)	932 (22.8)	2,048 (21.8)	0.28	–
Pulmonary	472 (3.3)	55 (6.5)	146 (3.6)	270 (2.9)	0.03	[§]
Thromboembolic (DVT + PE)	592 (4.1)	29 (3.4)	227 (5.6)	337 (3.6)	0.07	–
Urinary or renal	2,104 (14.7)	129 (15.2)	396 (9.7)	1,580 (16.8)	<0.001	[¶]
Postoperative hemorrhage or hematoma	294 (2.1)	58 (6.8)	166 (4.1)	70 (0.7)	<0.001	[§,¶]
Neurologic	50 (0.3)	10 (1.2)	40 (1.0)	0 (0.0)	<0.001	[§]
Cardiac	220 (1.5)	25 (2.9)	90 (2.2)	104 (1.1)	0.08	–
Infectious	76 (0.5)	9 (1.1)	57 (1.4)	10 (0.1)	<0.001	[§,¶]

Data are presented as n (%). [†], number of cases where complication data were available; [‡], percentages calculated within each procedure; [§], indicates a significant difference between decompression and vertebral augmentation, using a Bonferonni adjustment; [¶], indicates a significant difference between spinal stabilization and vertebral augmentation, using a Bonferonni adjustment. DVT, deep vein thrombosis; PE, pulmonary embolism.

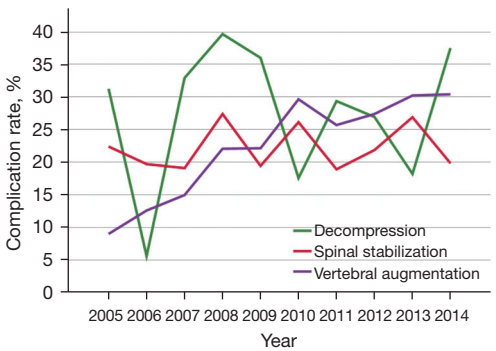

Figure 2 Trends in complication rate by procedure over time, 2005–2014.

2014 with an increase in yearly cases of surgical stabilization and a decrease in yearly vertebral augmentation cases, especially in the latter half of the study period. This trend towards more aggressive surgical management over this time period is likely influenced by a randomized control trial indicating that decompressive surgery with radiotherapy is superior to radiotherapy alone (22). Thus, the increase in more aggressive surgical treatment of MM will likely continue, especially in those with mechanical instability and neurological compromise. A prior study examined outcomes of various cancer types, including MM, causing spinal cord compression using the NIS database from 1998 to 2006. They found similar results with increasing rates of surgical intervention along with decreasing rates of treatment with inpatient radiation alone for all cancer types (3). The decreasing rates of inpatient vertebral augmentation may be related to earlier detection of MM and treatment with vertebral augmentation for pain relief in the outpatient setting.

In terms of patient demographics, the majority of patients had three or more comorbidities. More invasive surgical procedures were performed irrespective of the number of patient comorbidities, as well as in younger patients. However, more invasive procedures were associated with greater length of stay, greater total cost, and lower likelihood of discharge home when compared to vertebral augmentation, likely related to the complexity of the surgical procedure. The overall complication rate was 22.4%, which is consistent with reported complication rates of 14–34% after spinal surgery for spinal metastases in the literature (23,24). There was no significant difference in the probability of complications across all three procedure types, which differs from the lower rate of complications with vertebral augmentation found in other cancer types such as breast and lung spinal metastases (19,20). In this population, there was a much higher rate of urinary or renal complications than with more invasive procedures. This may be secondary to cement emboli into the renal vasculature that can occur with vertebral augmentation but not with surgical decompression or stabilization, although the available data does not allow further elaboration on this issue.

When predicting complication occurrence for all surgical

Table 5 Length of stay, mortality and total charges by number of complications (weighted)

Number of complications	Number of discharges (n=14,329), n (%)	Length of stay (days), mean (SEM)	Mortality†, n (%)	Total charges (in 2023 USD, $), mean [SEM]
0	11,119 (77.6)	8.0 (0.2)	67 (0.6)	128,319 [4,010]
1	2,711 (19.0)	14.6 (0.6)	44 (1.6)	210,585 [8,385]
2	411 (2.9)	22.0 (2.1)	42 (10.2)	300,626 [26,236]
3 or 4	88 (0.6)	28.9 (5.7)	29 (33.0)	417,243 [63,503]

†, percentage is calculated with denominator of total discharges within each number of complications category. SEM, standard error of the mean; USD, US dollars.

Table 6 Logistic model predicting odds of a complication

Dependent: odds of a complication	OR	95% CI	P value
Age	0.99	0.98–0.99	0.001
Sex (ref = female)	1.50	1.25–1.80	<0.001
Number of comorbidities	1.44	1.36–1.52	<0.001

Males are 1.5 times likely to have a complication compared to females (P<0.001). As number of comorbidities increase by 1, the likelihood of complication increases by 1.4 (P<0.001). OR, odds ratio; CI, confidence interval.

Table 7 ORs for complication occurrence stratified by number of comorbidities

Stratified by	Surgical procedures	OR	95% CI	P value
4+ comorbidities	Decompression *vs*. vertebral augmentation	1.31	0.83–2.06	0.25
	Decompression *vs*. spinal stabilization	1.15	0.71–1.86	0.57
	Spinal Stabilization *vs*. vertebral augmentation	1.13	0.86–1.50	0.38
2–3 comorbidities	Decompression *vs*. vertebral augmentation	0.90	0.44–1.84	0.78
	Decompression *vs*. spinal stabilization	0.99	0.50–1.95	0.97
	Spinal stabilization *vs*. vertebral augmentation	0.92	0.67–1.25	0.58
0–1 comorbidity	Decompression *vs*. vertebral augmentation	2.00	0.67–6.37	0.20
	Decompression *vs*. spinal stabilization	1.24	0.41–3.78	0.71
	Spinal stabilization *vs*. vertebral augmentation	0.89	0.89–3.14	0.12

OR, odds ratio; CI, confidence interval.

procedures, men were 50% more likely to incur one or more complications. Furthermore, increasing the number of comorbidities by a factor of one also increased the likelihood of complication by 1.4 times for all procedure types which is similar to data shown in previous large database studies examining surgery for metastatic spinal disease (24). After controlling for gender and number of comorbidities, the probability of a complication decreased approximately 1% for every 1-year increase in age [odds ratio (OR): 0.99]. Our complication model also assessed the occurrence of post-operative complications based on numbers of morbidities and procedure types. There was no difference in complication occurrence between the three procedure types for patients with similar number of comorbidities (*Table* 7). These findings deviate from our previously published breast and lung cancer spinal metastasis data that shows greater complication occurrence for more invasive procedure types (19,20). This study

provides insight into various factors for the clinician in choosing the most appropriate patient treatment for this complex hematological cancer.

There are a number of patient-related factors that may contribute to overall outcome that are unavailable in this large national database analysis, including: baseline functional status, details of the operative approach or technique, recent or current use of radiation or chemotherapy, location and number of spinal tumors, location and number of tumors outside the spine, and reoperation/readmission rates after the index surgery. There are a very limited number of studies examining outcomes of MM patients receiving surgical interventions and are limited to single institution retrospective studies (25,26). These studies suggest that favorable prognostic factors may include preoperative adjuvant therapy, favorable functional status, and limited MM disease burden. While those factors could not be examined in this study based on available data, male sex and increased number of comorbidities were found to be associated with increased likelihood of a complication and are therefore potential unfavorable prognostic factors. Larger prospective, multi-institutional studies are needed that examine various prognostic factors and long-term outcomes of the various surgical procedures performed for MM spinal disease.

There are several limitations of this study that warrant further discussion. The inclusion of patients with plasmacytoma and MM was done to capture all patients with a spine lesion requiring intervention, regardless of stage of disease. Plasmacytoma patients do not carry the systemic disease burden of MM and therefore may have less or different comorbidities which have not been accounted for. However, only 4.1% of the study population had a diagnosis of plasmacytoma, and it is felt that the overall results are representative of the wide-ranging disease population as a whole. Additionally, a small percentage of the population (9.1%) underwent a combination of procedures, and this cohort was ultimately categorized by the most invasive procedure for the purpose of this analysis. It was not possible to attribute a specific complication to a particular procedure in patients who underwent multiple procedures during a given hospitalization. Therefore, it is possible, if unlikely, that what we identified as the "less invasive procedure" was actually the primary driver of complications in the multi-intervention cohort. Lastly, our analysis does not include outpatient surgical procedures and therefore likely underrepresents the overall incidence of procedures including vertebroplasty/kyphoplasty, which are commonly performed in the outpatient setting. While acknowledging the above limitations, we consider our study to offer a valuable glimpse of the trends regarding in-hospital outcomes in the surgical management of MM patients from 2005 to 2014.

Conclusions

Spinal surgery seems to be increasing for the management of spinal MM in the inpatient setting. Vertebroplasty and similar palliative procedures may continue to decrease as advancements in surgical technology and technique allow for safer surgical intervention. The decision to employ aggressive surgical intervention, however, must always take into account the patient's comorbidities, overall systemic disease burden, and the potential for significant enhancement in meaningful clinical outcome.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://jss.amegroups.com/article/view/10.21037/jss-24-54/rc

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jss.amegroups.com/article/view/10.21037/jss-24-54/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the institutional review board of Wake Forest University (No. IRB000600095) and individual consent for this retrospective analysis was waived.

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