

Factors affecting postoperative survival of patients with insufficient union following osteoporotic vertebral fractures and impact of preoperative serum albumin on mortality

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Abstract

Background: Numerous comparative studies of surgical procedures have focused on clinical and radiographical outcomes, as well as the effect of bone fragility on the outcome of spinal surgery; however, insights concerning a long-term risk of mortality or morbidity have been limited. Additionally, the effect of surgical therapy on survival after vertebral compression fractures remains controversial. Our aim was to evaluate the preoperative factors that affected the long-term survival of patients who underwent spinal surgery for an insufficient union following osteoporotic vertebral fractures (OVF) and to determine long-term mortality.

Methods: We retrospectively reviewed the cases of 105 consecutive patients who underwent spinal surgery for OVF. Mortality was estimated using the Kaplan-Meier method and a log-rank test. The preoperative backgrounds of patients were analyzed to determine which risk factors led to death among the OVF cases. Kaplan-Meier curves were used to estimate survival based on preoperative albumin levels of ≤ 3.5 g/dL (hypoalbuminemia) versus > 3.5 mg/dL.

Results: The mean follow-up time for survival was 4.1 ± 0.8 years. Two years after surgery, 15% of patients with OVF had died. The ratio of male-to-female was significantly higher for patients with OVF who died than for those who were still alive. No significant difference in mortality was observed among surgical procedures for OVF. Multivariate analysis revealed that only serum albumin ≤ 3.5 g/dL was a significant risk factor for long-term postoperative mortality of patients with OVF.

Conclusions: Preoperative hypoalbuminemia was associated with long-term postoperative mortality following surgery for OVF.

Level of Evidence: Level 3

Background

Osteoporotic vertebral fractures (OVF) are the most common type of fragility fractures, and they have become more prevalent as the proportion of the population that is older continues to increase.[1] Reports indicate that OVF increase overall mortality.[2, 3] Conventionally, OVF are viewed as benign and treated with conservative methods such as rest, immobilization, drugs, and bracing.[4] However, vertebral fractures sometimes fail to unite, resulting in progressive kyphosis due to vertebral collapse and/or pseudarthrosis. Affected patients often endure persistent back pain and/or neurological deficits. [5] Despite conservative treatment, the prevalence of an insufficient bone union among elderly patients with OVF reportedly ranges from 10.0% to 13.5%. The quality of life and activities of daily living of these patients are reduced severely.[6, 7] Despite the various surgical procedures proposed for the management of an insufficient bone union following OVF, optimal surgical procedures have not yet been clearly established. This is because of the poor general condition and frequent instrumentation failure resulting from low bone quality in elderly patients. Numerous comparative studies of surgical procedures have focused on clinical and radiographical outcomes, as well as the effect of bone fragility on the outcome of

spinal surgery.[8, 9] However, insights concerning the long-term risk of mortality or morbidity are limited. Additionally, the effect of surgical therapy on survival after vertebral compression fractures remains controversial.[10, 11] To establish an effective treatment strategy for patients with OVF, the long-term postoperative mortality of patients who have undergone surgery for OVF, and the preoperative risk factors predictive of mortality after surgery, should be elucidated.

In the present study, we sought to evaluate the preoperative factors affecting the long-term survival of patients who underwent spinal surgery for an insufficient bone union following OVF and determine long-term mortality.

Methods

Patient Cohort and Surgery

A total of 105 consecutive patients, with delayed osteoporotic thoracolumbar vertebral fractures, who underwent spinal surgery, were followed-up for a minimum of 6 months (Table 1). Surgeries were conducted by three board certified spinal surgeons at a single institution between 2010 and 2018. Initially, all patients with OVF were treated conservatively, and none of them had neurological deficits immediately after injury. Treatment options, including the use of a brace or drug therapy, or both, were selected by individual physicians based on their experience. Surgical treatment was indicated for all 105 patients because they had progressive neurological deficits or continuous severe lower back pain caused by vertebral collapse.

Three surgical procedures were applied in the treatment of the patients in this study (Table 1). Forty-nine patients underwent posterior decompression and short-segment fixation by vertebroplasty. This was accomplished with implanted hydroxyapatite blocks via the pedicle of the fractured vertebra and was combined with fixation of the two vertebrae above and one below with a pedicle screw. Another 18 patients received balloon kyphoplasty, and 38 patients underwent anterior spinal decompression and fusion, performed using a titanium cage and supplemented with posterior percutaneous pedicle screw fixation.

Postoperative Mortality

The mean follow-up time for survival was 4.1 ± 0.8 years. The primary endpoint was death by the close of the study period, which ended in March 2019. Data were censored if the patient survived until the end of the study period. If a recent follow-up was not available from clinical records, patients were contacted by telephone to confirm their survival.

Data Collection

For each patient who underwent spinal surgery for OVF, we searched clinical records and a laboratory database. Only measurements recorded 1–14 days before the date of surgery were used for preoperative measurements of body mass index (BMI), left ventricular ejection fraction (LVEF) measured using an

echocardiogram, serum albumin, B-type natriuretic peptide (BNP), creatinine clearance (CCr), and preoperative neurological impairment (according to a modified Frankel classification). Standardized bone mineral density (BMD, % young adult men [YAM]) measurements at the lumbar spine (L2–L4) and the femoral neck were performed using a Lunar Prodigy dual-energy X-ray absorptiometry system (General Electric) at baseline. The American Society of Anesthesiologists (ASA) classification is a readily available and widely-accepted method for stratification of surgical patients according to their perioperative risk.^[12] The visual analog scale (VAS) score for the lumbar spine and leg were evaluated at the time of hospital admission and 1 year after surgery. Radiographic classification of burst fractures was based on the Denis classification using preoperative computed tomography^[13].

Statistical Analyses

Continuous variables were compared using unpaired *t* tests and categorical variables were assessed using Fisher's exact test for baseline characteristics between deceased patients versus those who had survived 2 years after surgery. Crude and adjusted hazard ratios (HRs) of mortality, using Cox proportional univariate and multivariate models, were calculated, respectively. We also illustrated Kaplan-Meier estimates of all-cause mortality according to serum albumin levels as a possible risk factor of death in the Cox multivariate model. A log-rank test was used to assess the significance of differences between Kaplan–Meier estimates. All statistical calculations were conducted using Prism software, version 8.0 (Graph Pad Software, La Jolla, CA) and SAS statistical software, version 9.4 (SAS Institute, Cary, NC, USA). R statistical software (version 3.6.1, R Project for Statistical Computing, Vienna, Austria) was used to generate Kaplan-Meier estimates. All reported *p* values were two-sided and *p*<0.05 indicated statistical significance.

Results

Patient characteristics between those who died versus those who survived 2 years after surgery.

Table 1 summarizes the characteristics of patients with OVF who underwent surgical procedures. Surgical invasions among procedures were compared in Figure 2. Estimated blood loss in patients treated with BKP was significantly lower than that in patients treated with VP (HA) + PF or ADF + PF. There was no significant difference in estimated blood loss between patients treated with VP (HA) + PF and ADF + PF (Figure 2A). Surgical time in patients treated with BKP was significantly shorter than that in patients treated with VP (HA) + PF or ADF + PF. Surgical time in patients treated with VP (HA) + PF was significantly shorter than that in patients treated with ADF + PF (Figure 2B). The VAS scores for both the lumbar spine and leg were significantly improved 1 year after surgery compared to scores at the time of hospital admission (Table 2).

Two years after surgery, 19/75 patients (15%) with OVF had died. Table 3 summarizes the preoperative baseline characteristics of the patients with OVF who died compared with those who were still alive 2 years after surgery. There were no significant differences in the age, BMI, LVEF (%), BNP level, CCr, or

BMD, follow-up period, time from original injury to surgery, distribution of preoperative fracture type based on Denis's classification, or estimated blood loss and operative time between groups. A significant difference in mortality among the three surgical procedures was not found (Table 3). In contrast, the ratio of male-to-females was significantly higher among the patients with OVF who died than for those who were still alive. Additionally, preoperative serum albumin levels and CCr were significantly lower in patients who died than in those who were still alive (Table 3).

Preoperative factors affecting the long-term survival of the patients who underwent spinal surgery for an insufficient bone union following OVF.

The presurgical hazard ratios (95% confidence interval) for mortality associated with patient characteristics are summarized in Table 4. According to a past report, hypoalbuminemia was defined as serum albumin ≤ 3.5 g/dL [14]. The univariate analysis showed male gender, serum albumin < 3.5 g/dL, CCr < 60 mg/dL, and an ASA classification ≥ 3 were significant risk factors for postoperative mortality (Table 4). The multivariate analysis revealed hypoalbuminemia was the only significant risk factor for long-term postoperative mortality of OVF (adjusted hazard ratio was 3.37; $p=0.014$; Table 4).

Effect of preoperative serum albumin level on postoperative mortality.

Based on the threshold values defined, there were two preoperative serum albumin levels, ≤ 3.5 g/dL and > 3.5 g/dL.¹⁴ Thirty-eight patients (36.2%) had hypoalbuminemia. The estimated risk of mortality at the final follow-up, using the Kaplan-Meier method, was significantly greater in patients with preoperative serum albumin ≤ 3.5 g/dL than in those with a serum albumin > 3.5 g/dL ($p < 0.0001$ for log-rank test; Fig. 1).

Discussion

Numerous studies have found an association between OVF and increased mortality, with pulmonary and cardiovascular-related deaths suggested as being explanatory factors for the excess mortality.¹⁴⁻¹⁶ A past study showed a 2- to 8-times increased risk of age-matched mortality following OVF.^[15] Surgical intervention is highly recommended for patients who have an insufficient bony union of OVF, persistent back pain, and/or neurological deficits.^[16] Recently, interest has increased in the mortality and morbidity of patients who undergo spinal surgery.^[17, 18] Additionally, numerous reports have surfaced for comparative studies of surgical procedures for OVF; these have focused on surgical invasiveness and complications^[19] By contrast, the long-term survival of patients with an insufficient bony union of OVF after surgery remains largely unknown. A recent study indicated that instrumented fusion surgery for lumbar trauma in the elderly is associated not only with increased morbidity, but also with reduced mortality.^[20] Therefore, we sought to elucidate the preoperative risk factors which may predict postoperative mortality. Interestingly, our study indicated no significant differences in postoperative mortality among the 3 different surgical procedures assessed for OVF. In contrast, preoperative serum albumin levels were significantly lower in the patients with OVF who died, than in those who remained

alive. The present study shows a significant association between a low preoperative serum albumin level of ≤ 3.5 g/dL, and a reduction in overall survival for patients undergoing surgery for an insufficient union of OVF.

The association between lower malnutrition and mortality risk has been shown in patients with hip fractures [21, 22]. Serum albumin is well known as an important marker of preoperative nutritional status. Low levels of serum albumin can be prognostic by way of influencing organ vascularization. Moreover, low levels of serum albumin may hinder antibiotic therapy, prolong inflammation, and prompt intravascular coagulation.

This study has some limitations. First, this study was retrospective and had a small sample size and duration of follow-up; a prospective study and a longer follow-up time would have been preferable. Second, the cause of death in many cases could not be determined accurately. If a recent follow-up was not available from clinical records, patients were contacted by telephone to confirm their survival. Third, we do not know whether surgical therapy or a difference in surgical techniques had an impact on the patient's prognosis in the present study. Further study is needed to clarify the strategy for selecting surgical procedures and to include OVF patients treated with conservative therapy. However, to our knowledge, this is the first report to indicate that preoperative hypoalbuminemia can predict poor postoperative survival in patients with an insufficient bony union following OVF. This result suggests that designing a treatment strategy that takes into consideration indications and optimal timing for OVF surgery may have clinical significance. Based on the present study, we propose that if OVF patients are found to have poor nutrition by preoperative examination, attention to nutrition should be paid postoperatively, and/or less surgical intervention should be considered

Additionally, efforts should be made to improve nutrition status in the time before surgery is performed as much as possible. Further studies are needed to investigate the effects on postoperative mortality of improving nutritional status before surgery.

Conclusion

Hypoalbuminemia was associated with increased postoperative mortality over the long-term following OVF surgery.

List Of Abbreviations

Osteoporotic vertebral fractures (OVF) , Lumbar spinal canal stenosis (LSS), Body mass index (BMI), Left ventricular ejection fraction (LVEF), B-type natriuretic peptide (BNP) level, Creatinine clearance (CCr), Bone mass density (BMD), The American Society of Anesthesiologists (ASA)

Declarations

Ethics approval and consent to participate

This study was approved by the institutional review board Ethics Committee of the University of Yamanashi School of Medicine, Chairperson Zentarou Yamagata (Application number 1183).

Consent for publication

Not applicable

Availability of data and material

Not applicable

Competing interests

The first author Tetsuro Ohba is an Editorial Board member for the journal.

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There was no funding to support this research.

Authors' contributions

"TO analyzed and interpreted the patient data and was a major contributor to writing the manuscript. HY developed the study design. KK performed the statistical analyses. TN and OK collected patient data. HH was an editorial supervisor for this study. All authors read and approved the final manuscript."

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Tables

TABLE 1. Preoperative characteristics and demographics of patients with OVF*

Patients with OVF	(N = 105)
Age at the time of admission, y	76.3 ± 7.5
Gender, female/male, n	65/40
BMI (kg/m ²)	22.4 ± 3.3
BMD (%YAM)	69.7 ± 13.5
Follow-up duration, months	28.3 ± 31.8
Type of Denis's classification (A/B/C)	56/46/3
Intraoperative technique, n	
VP (HA) + PF	49
BKP	18
ADF + PF	38

*Mean ± standard deviation, unless otherwise indicated.

ADF, anterior spinal decompression and fusion; BKP, balloon kyphoplasty;

BMI, body mass index; BMD, bone mineral density; HA, hydroxyapatite; OVF, osteoporotic vertebral fractures; PF, posterior fixation; VP, vertebroplasty.

TABLE 2. Pre- and postoperative patient VAS scores (lumbar and leg)

	Preoperative	1 year after surgery	p value
VAS score (lumbar)	7.4 ± 3.4	5.8 ± 3.8	<0.05*
VAS score (leg)	6.7 ± 2.8	3.4 ± 2.1	<0.05*

*Mean ± standard deviation, unless otherwise indicated.

*P < 0.05 in the comparison between groups.

VSA = visual analog scale

TABLE 3. Characteristics of patients who died versus those who survived 2 years after surgery

Characteristic	Died (n = 19)	Survived (n = 56)	p value [†]
Male gender, n (%)	11 (57.9)	16 (28.6)	0.029*
Age, years	79.1 (7.6)	75.6 (8.0)	0.10
BMI, kg/m ²	21.3 (3.1)	22.5 (3.0)	0.15
LVEF, %	70.3 (9.6)	71.9 (14.1)	0.65
Serum albumin, g/dL	3.4 (0.5)	3.9 (0.5)	0.0016*
BNP, pg/mL	45.3 (36.4)	44.9 (47.2)	0.98
CCr, mL/min	49.9 (20.1)	63.1 (21.6)	0.021*
BMD, %YAM	63.4 (14.0)	66.8 (13.4)	0.47
Follow-up, months	57.1 (21.2)	66.4 (25.3)	0.13
Time from original injury to surgery, months	4.4 (2.1)	4.6 (0.49)	0.21
Type of Denis's classification (A/B/C)	12/7	34/21	0.72
Surgical procedures			0.087
VP (HA) + PF	8 (42.1)	23 (41.1)	
BKP	1 (5.3)	13 (23.2)	
ADF + PF	4 (21.1)	12 (21.4)	
ASA classification ≥3	7 (36.8)	6 (10.7)	0.016*
Modified Frankel classification			
C versus D or E	8 (47.1)	21 (38.2)	0.58
Estimated blood loss, ml	168 (155)	335 (499)	0.11
Operative time, min	162 (98.9)	201 (114.3)	0.13

[†]p value for Fisher's exact test or Student's t test.

*P < 0.05 in the comparison between groups.

Variables are presented as mean (standard deviation) unless noted otherwise.

ADF, anterior spinal decompression and fusion; ASA, American Society of

Anesthesiologists; BMD, bone mass density; BKP, balloon kyphoplasty; n, number in

group; BMI, body mass index; BNP, B-type natriuretic peptide; CCr, creatinine

clearance; HA, hydroxyapatite; LVEF, left ventricular ejection fraction; PF, posterior

fixation; VP, vertebroplasty; YAM, young adult male.

TABLE 4. Pre-surgery hazard ratios (95% CI) of mortality based on patient characteristics (N = 105)

Explanatory variable	Crude	p value	Adjusted HR [†]	p value
Male vs female gender	2.74 (1.17, 6.41)	0.021	1.82 (0.76, 4.40)	0.18
BMI ≥25 vs 18.5-24.9 kg/m ² BMI ≥25 vs. 18.5-24.9 kg/m ²	1.45 (0.41, 5.09)	0.56	1.67 (0.44, 6.32)	0.45
BMI <18.5 vs 18.5-24.9 kg/m ² BMI <18.5 vs. 18.5-24.9 kg/m ²	2.78 (0.99, 7.81)	0.052	2.81 (0.96, 8.25)	0.061
Serum albumin <3.5 g/dL	4.99 (2.00, 12.43)	0.0006	3.37 (1.28, 8.89)	0.014
CCr <60 mg/dL	3.40 (1.15, 10.06)	0.027	1.96 (0.63, 6.05)	0.25
ASA physical status classification ≥3	3.93 (1.68, 9.21)	0.0017	2.36 (0.93, 6.01)	0.072

[†]Explanatory variables were selected using p<0.2 in the univariate analysis for crude hazard ratios. All of the variance inflation factors in the multivariate model for the calculation of adjusted hazard ratios were <1.22, indicating there was no multicollinearity.

ASA, American Society of Anesthesiologists; BMI, body mass index; CCr, creatinine clearance; CI, confidence interval; HR, hazard ratio.

Figures

Figure 1

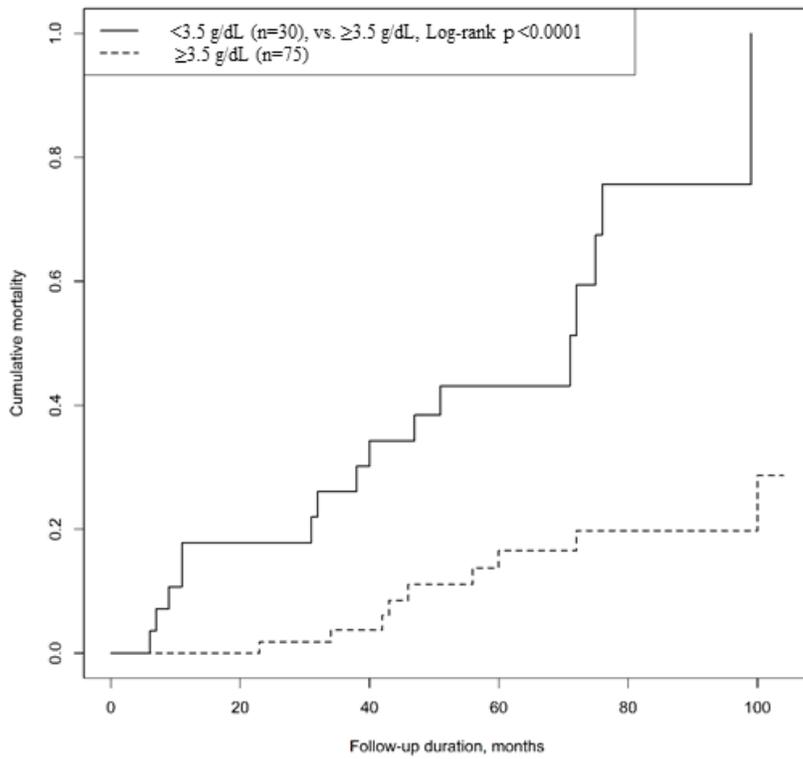


Figure 1

Overall survival comparison based on preoperative serum albumin levels (dashed line, ≤ 3.5 g/dL; solid line, > 3.5 g/dL) using the Kaplan-Meier method.

Figure 2

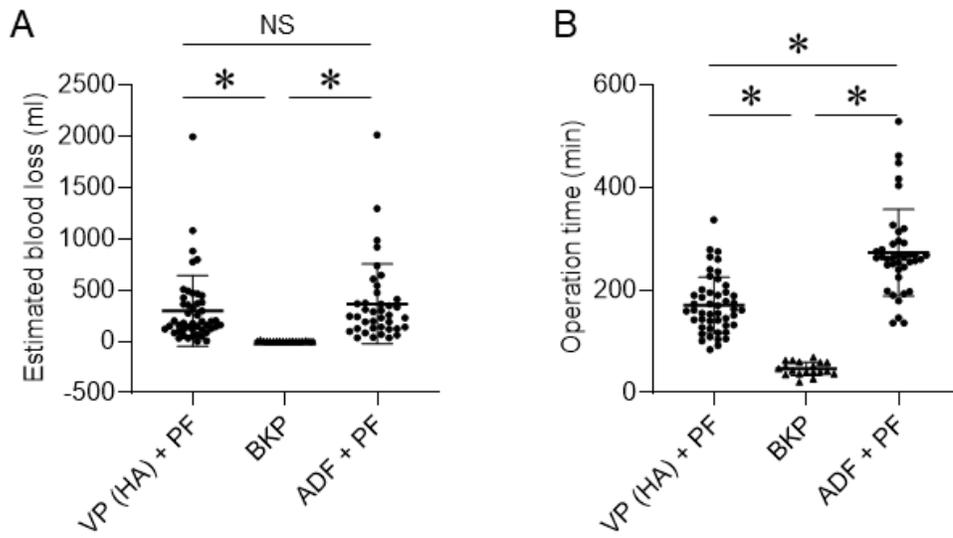


Figure 2

Comparisons of blood loss (A) and surgical time (B) among surgical procedures. ADF, anterior spinal decompression and fusion; BKP, balloon kyphoplasty; HA, hydroxyapatite; PF, posterior fixation; VP, vertebroplasty. * $P < 0.05$ NS = not significant. Data were analyzed using the unpaired T test.