Surgical Treatment of Osteoporotic Vertebral Fracture with Neurological Deficit
– A Nationwide Multicenter Study in Japan –

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- Naobumi Hosogane analyzed and wrote the manuscript, and all other authors participated in acquisition or analysis of data, drafting the work. All authors have read, reviewed and approved the article.
This study protocol was approved by the Institutional Review Board of Keio University (approval number 20110142).
Abstract

Introduction

The prevalence of patients with osteoporosis continues to increase in aging societies, including Japan. The first choice for managing osteoporotic vertebral compression fracture (OVF) is conservative treatment. Failure in conservative treatment for OVF may lead to non-union or vertebral collapse, resulting in neurological deficit and subsequently requiring surgical intervention. This multicenter nationwide study in Japan was conducted to comprehensively understand the outcomes of surgical treatments for OVF non-union.

Methods

This multicenter, retrospective study included 403 patients (89 males, 314 females, mean age 73.8 ± 7.8 years, mean follow-up 3.9 ± 1.7 years) with neurological deficit due to vertebral collapse or non-union after OVF at T10-L5 who underwent fusion surgery with a minimum 1-year follow-up. Radiological and clinical outcomes at baseline and at the final follow-up (FU) were evaluated.

Results

OVF was present at a thoracolumbar junction such as T12 (124 patients) and L1 (117 patients). A majority of OVF occurred after a minor trauma, such as falling down (55.3%) or lifting objects (8.4%). Short segment fusion, including affected vertebra, was conducted (mean 4.0 ± 2.0 vertebrae) with 256.8 minutes of surgery and 676.1 g of blood loss. A posterior approach was employed in 86.6% of the patients, followed by a combined anterior and posterior (8.7%), and an anterior (4.7%) approach. Perioperative complications and implant failures were observed in 18.1% and 41.2%, respectively. VAS scores of low back pain (74.7 to 30.8 mm) and leg pain (56.8 to 20.7 mm) improved significantly at FU. Preoperatively, 52.6% of the patients were unable to walk and the rate of non-ambulatory patients decreased to 7.5% at FU.
Conclusions

This study demonstrated that substantial improvement in ADL was achieved by fusion surgery. Although there was a considerable rate of complications, fusion surgery is beneficial for elderly OVF patients with non-union.

Keywords

Vertebral compression fracture, Osteoporosis, Multicenter study
Introduction

The prevalence of patients with osteoporosis continues to increase as societies skew towards an older demographic, which is particularly acute in aging societies including Japan. Osteoporosis prevalence has been estimated to be as high as 38% in women and 4% in men aged 50 years and above\(^1\). According to the 2015 Guidelines for Prevention and Treatment of Osteoporosis published by the Japan Osteoporosis Society, 12.8 million patients are estimated to have osteoporosis in Japan which accounts for more than 10% of the population.

These patients are at risk of developing vertebral compression fracture after a minor trauma. An estimated 1.4 million new osteoporotic fractures at the vertebrae occurred in the year 2000\(^2\). Most patients can be managed conservatively, such as through bed rest, medication, or a spinal brace. Lee et al. reported a 95% success rate with conservative treatment in patients who showed favorable results after the initial three weeks of treatment\(^3\). However, failure during appropriate conservative treatment of osteoporotic compression fracture may result in a severe deterioration of ADL, with neurological deficits or progression of kyphosis, requiring surgical intervention. Since the first surgical case for paraplegia due to OVF was reported by Kempinsky et al.\(^4\), many studies have reported various surgical techniques and outcomes for this condition, such as anterior decompression and fusion, posterolateral fusion, posterior spinal shortening, posterior fixation with vertebroplasty, and combined anterior and posterior fixation\(^5-8\). Many of these studies are case series at a single institution, or cohort studies from a few institutions; studies with a large sample size are limited. There is one systematic review that included 596 patients from 29 publications comparing three different surgical methods: anterior decompression and reconstruction, posterior surgery, and posteroanterior surgery\(^9\).
However, inclusion criteria may vary among the studies, so it is difficult to perform statistical analysis comparing each surgical procedure, or on various radiological parameters, as the data from each individual patient was not available in this systematic review.

In this study, we performed a nationwide, multicenter, retrospective study of patients that underwent fusion surgery for osteoporotic vertebral collapse to comprehensively understand and gain an overview of patient demographics, surgical methods, and outcomes.

Materials and Methods

Study design

This study was a retrospective, multicenter study conducted through the Japan Association of Spine Surgeons with Ambition (JASA), which consists of 52 university hospitals all over Japan. Inclusion criteria were patients who had neurological deficits due to vertebral collapse or non-union after OVF at T10-L5 and underwent fusion surgery with a minimum 1-year follow-up. Patients with back pain due to kyphotic deformity without any neurological deficit or patients who underwent BKP alone were excluded from this study. A datasheet was sent to each site, and spine surgeons were asked to fill in the datasheet to include the information noted below. A total 403 patients (89 males, 314 females, mean age 73.8 ± 7.8 years, mean follow-up 3.9 ± 1.7 years) from 28 university hospitals and affiliated hospitals were included in this study. Most of the patients (394 patients) were followed longer than two years.

Information included in the datasheet

The datasheet included information about patient background such as age, gender, comorbidities, type of traumatic event, medication for osteoporosis, existence and cause of
secondary osteoporosis, and amount of steroid intake. Information about surgery, such as
method of fixation, upper (UIV) and lower instrumented vertebra (LIV), estimated blood
loss, and surgical time were collected. Information about perioperative complications
within six weeks after the surgery and need for revision surgery were also collected.
Radiological findings, such as mechanical failure, newly developed fracture after the
surgery, and pseudoarthrosis were evaluated. Mechanical failures were defined as a failure
related to the implant within the fused vertebra, such as loosening or back out of a pedicle
screw, hook dislodgement, rod fracture, dislodgement or subsidence cage, and fracture at
UIV or LIV. The local kyphosis angle (LKA) was defined as the angle between the upper
endplate of a proximal adjacent vertebra and lower endplate of a distal adjacent vertebra of
an affected vertebra and was measured preoperatively, early after the surgery, and at the
final follow-up. Pseudoarthrosis was defined as one of following at the final follow-up:
instability with flexion/extension radiographs, presence of clear zone around the bone graft,
or rod fracture.
Clinical outcomes were evaluated preoperatively and at the final follow-up with VAS
scores of low back pain and leg pain, and JOA score. For JOA score, only scores for
subjective symptoms (9 points), clinical signs (6 points), and urinary bladder function (−6
points) were included; a full score was 15 points. For activities of daily living, patients
were classified into the original six categories focused on gait ability, such as: (1)
bedridden, (2) wheelchair, (3) walking while holding on to wall or creep, (4) walking with
walker, bilateral canes, or 1 cane with support from others, (5) walking with unilateral cane
without any support, and (6) walking freely.

Statistical analysis
Paired Student’s t-test was used to compare the LKA, JOA score, and VAS scores
between preoperative and at the final follow-up. All data were presented as mean ±
standard deviation. Statistical analyses were performed using SPSS ver. 21 (IBM Inc.). For
all statistical analyses, a p value < 0.05 was considered statistically significant.

Results

Patient demographics

Table 1 shows the demographic data for all patients. In a majority of the patients,
vertebral fractures were associated with minor trauma such as falling down, lifting objects,
or sneezing, and 23.6% of the patients recognized no traumatic event indicating that bone
fragility may underlie this injury. Nearly one-third of patients (30.8%) had primary causes
that induce osteoporosis, such as steroid intake. A majority of the patients (67.5%) had at
least one comorbidity and 6.9% had more than three comorbidities.

Table 2 shows the rate of osteoporosis treatment and type of medication used. Although a
majority of the patients in this study were elderly females, the rate of osteoporosis
treatment was limited to 40.1% at the time of vertebral fracture (Table 2). This rate
significantly increased to 75.3% after surgery. Bisphosphonates were the most frequently
used medication before the fracture; however, a marked increase of teriparatide use was
observed after surgery.

Figure 1 shows the distribution of the primary affected vertebra. A thoracolumbar
junction, such as T12 and L1, was the most frequent level of the fracture; however, 18.9%
had a fracture at the mid to lower lumbar spine (L3 to L5).

The degree of osteoporosis was evaluated with dual-energy X-ray absorptiometry (DEXA)
in 220 patients (69 patients in lumbar spine and 151 patients in femoral neck). The mean
bone mineral density was 0.724 ± 0.14 g/cm² in the lumbar spine, 0.604 ± 0.17 g/cm² in the
femoral neck, and the mean YAM (young adult mean) value was 71.6 ± 5.9%.
Surgical information and radiological results

Table 3 reveals that a posterior approach is the current mainstream method for the treatment of this pathology followed by a combined anterior and posterior approach and anterior-only approach. Among patients who had a posterior approach, 44.5% had vertebroplasty combined with posterior fusion and 33.5% had 3-column osteotomy. A mean 4.0 ± 2.0 vertebrae were fused with moderate surgical invasion such as 256.8 ± 115.0 minutes of surgery and 676.3 ± 1166.9 g of blood loss. Perioperative complication was observed in 18.1% of the patients, including delirium (23 patients), dural tear (5 patients), deep wound infection (4 patients), superficial infection (4 patients), hematoma (4 patients), pneumonia (3 patients), and deep vein thrombosis (3 patients).

Mechanical failure was observed in 41.2% of the patients. Loosening of pedicle screws was the most common mechanical failure (99 patients), followed by back out of pedicle screws (38 patients) and fracture of UIV (23 patients). A majority of the patients accomplished bone union at the final follow-up with a pseudoarthrosis rate of 6.2%.

Figure 2 shows the change of LKA. Preoperative LKA was 22.0 ± 16.9° and corrected to 5.2 ± 13.1°. LKA at the final follow-up was 12.0 ± 15.2° with a mean correction loss of 6.7 ± 8.8°.

Clinical outcomes

Figure 3 shows that both VAS scores of LBP and leg pain significantly improved after surgery. Also, JOA score was significantly improved (by approximately 5 points) at the final follow-up. Evaluation of ADL revealed that 52.6% of patients were unable to walk before surgery (bedridden or wheelchair), which decreased to 7.5% at the final follow-up (Table 4). More than 65% of patients were able to walk without any support (walking with
1 cane without support or freely) at the final follow-up.

Discussion

The thoracolumbar/lumbar spine is one of the most common sites for fracture due to osteoporosis. An osteoporotic vertebral compression fracture (OVF) may affect activities of daily living. Olenski et al. reported that, among low BMD postmenopausal women, vertebral fracture was shown to be associated with decreased HRQOL score. Additionally, OVF has been shown to be related to a higher mortality rate at a 10-year follow-up. Therefore, appropriate management of OVF is important in aging societies where the number of osteoporosis patients will likely continue to increase.

There are many previous studies evaluating various surgical methods for OVF non-union. Kanayama et al. evaluated surgical outcomes after anterior spinal reconstruction with instrumentation in 31 OVF patients with neurological compromise and reported the advantages of this method, such as safety and reliability of decompression, with a success rate of 80%. Akata et al. investigated the results of posterior spinal fusion without decompression for thoracolumbar OVF with neurological deficits and reported that substantial improvements of back pain and neurological symptoms were obtained. Matsuyama et al. demonstrated the efficacy of posterior spinal fusion, combined with vertebroplasty using calcium phosphate cement, in five OVF patients. Saita et al. were the first to report the surgical technique of posterior spinal shortening osteotomy, which was intended to reduce the force that may dislodge implants by correcting the kyphosis. The efficacy of this method was confirmed in 13 OVF patients with paraparesis in a subsequent study.

In addition to these case-series of certain surgical methods, there are several comparison...
studies of several surgical methods. Kashii et al. reviewed 88 OVF patients with neurological deficits who underwent surgery at four facilities with three different methods: anterior decompression and reconstruction, posterior shortening osteotomy, and posterior fusion combined with vertebroplasty\(^{13}\). An equivalent improvement of neurological deficits and ADL function were achieved with every surgical method and posterior fusion combined with vertebroplasty was shown to have the least surgical invasion. Another comparative study was reported by Nakashima et al. who included 93 patients from six hospitals\(^{14}\). They compared patients who underwent combined anterior and posterior surgery and posterior fusion with vertebroplasty and revealed that stability of the fixation was superior in combined anterior and posterior surgery.

A majority of these studies focusing on surgical outcomes for OVF with neurological deficits were reported from Japan, a country with the most advanced aging society in the world. There are several studies from other countries such as China, France or Korea; however, the number of patients in their samples were small and studies with a large number of patients is limited\(^{15-17}\). There is one previous, large-scale, systematic review that included 596 OVF patients with delayed neurological deficit from 29 publications\(^9\). In this review, posterior surgery was conducted in 60.6% of patients followed by anterior decompression and reconstruction in 36.6%. Although 21 out of 29 publications were from Japan, the proportion for anterior surgery in this review (36.6%) was largely different from our study (4.7%). One of the reasons for this discrepancy might be due to the difference in period of publication. Many studies used in this review were published in the 1990s to 2000s, whereas our patients had surgery recently. The other discrepancies between this review and our study were the rates of complication and implant failure. These rates were reported to be 12.2% for complication and 15.8% for implant failure, which were lower compared to our study (complication 18.1% and mechanical failure 41.2%). A possible
explanation for these differences might be due to definitions for complication and implant failure varies among the studies included in this review which may underestimate these rates.

In this study, we intended to comprehensively understand current trends and outcomes for the surgical treatment of OVF with neurological deficit, and did not aim to compare certain surgical methods or to reveal the risk factors for complications or mechanical failures. Toward this purpose, we designed a multicenter study that included 41 facilities throughout Japan, where the number of OVF patients who require surgical treatment is rapidly expanding. Our study revealed that subjects of the surgical treatment were elderly patients who had OVF with minor or no trauma, which suggests underlying bone fragility in these patients. Short segment posterior fusion at the affected level is the current mainstream approach in surgical treatment with an acceptable surgical invasion of 256.8 minutes of surgery, 676.3 g of blood loss and 18.1% for perioperative complications. Clinical outcomes assessed with JOA score and VAS score significantly improved after surgery, and a majority of the patients were able to walk postoperatively, suggesting that spinal fusion surgery is effective for quality of life improvement even for the elderly patients.

There are several limitations in this study. This was a multicenter retrospective study, and the indication for fusion surgery or choices of surgical procedures were not standardized and were dependent on the surgeons in charge of the treatment at each facility. Secondary, as clinical outcomes or complications were obtained from chart review, the accuracy of the information might be inferior compared to a prospective study.

In conclusion, we comprehensively conducted an overview of the current surgical treatment for OVF with neurological deficit and found the relevance of the spinal fusion surgery. We also elucidated the high rate of mechanical failure. Future studies are required to assess how to prevent such failures related to implants and to improve overall outcomes.
References


9. Sheng X, Ren S. Surgical techniques for osteoporotic vertebral collapse with


Figure legends

Figure 1. Distribution of primary affected vertebra.
T12 and L1 are the most frequently affected vertebrae.

Figure 2. Change of local kyphosis angle.
The local kyphosis angle was defined as the angle between the upper endplate of a proximal adjacent vertebra and the lower endplate of a distal adjacent vertebra of affected vertebra.

Figure 3. Clinical outcomes.
a. VAS scores of low back pain (LBP) and leg pain.
b. JOA score with a full score being 15 points.
*p < 0.05 with Student’s t-test.
<table>
<thead>
<tr>
<th>Variables</th>
<th></th>
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<tbody>
<tr>
<td>Type of traumatic event</td>
<td></td>
</tr>
<tr>
<td>Fall down</td>
<td>55.3%</td>
</tr>
<tr>
<td>Lifting of object</td>
<td>8.4%</td>
</tr>
<tr>
<td>Other (sneeze, farm work, etc.)</td>
<td>1.0%</td>
</tr>
<tr>
<td>No trauma</td>
<td>23.6%</td>
</tr>
<tr>
<td>Undetermined</td>
<td>11.7%</td>
</tr>
<tr>
<td>Secondary osteoporosis</td>
<td>30.8%</td>
</tr>
<tr>
<td>Steroid intake</td>
<td></td>
</tr>
<tr>
<td>0 mg</td>
<td>87.3%</td>
</tr>
<tr>
<td>&lt;5 mg</td>
<td>4.7%</td>
</tr>
<tr>
<td>5–10 mg</td>
<td>6.7%</td>
</tr>
<tr>
<td>10–20 mg</td>
<td>0.7%</td>
</tr>
<tr>
<td>&gt;20 mg</td>
<td>0.5%</td>
</tr>
<tr>
<td>History of smoking</td>
<td>13.4%</td>
</tr>
<tr>
<td>Number of comorbidities</td>
<td></td>
</tr>
<tr>
<td>none</td>
<td>32.5%</td>
</tr>
<tr>
<td>1</td>
<td>38.0%</td>
</tr>
<tr>
<td>2</td>
<td>22.6%</td>
</tr>
<tr>
<td>&gt;3</td>
<td>6.9%</td>
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Table 2. Medication for Osteoporosis

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<tr>
<th>Types of medication used (including duplicates)</th>
<th>Preoperatively</th>
<th>Postoperatively</th>
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<tr>
<td>Bisphosphonates</td>
<td>100</td>
<td>147</td>
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<tr>
<td>Vitamin D analogs</td>
<td>27</td>
<td>30</td>
</tr>
<tr>
<td>Teriparatide</td>
<td>23</td>
<td>118</td>
</tr>
<tr>
<td>SERM</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>Vitamin K2</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Calcium compounds</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Calcitonin</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Denosumab</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>164</strong></td>
<td><strong>311</strong></td>
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### Table 3. Information Related to Surgery

<table>
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</thead>
<tbody>
<tr>
<td>Surgical approach</td>
<td></td>
</tr>
<tr>
<td>Posterior only</td>
<td>349 (86.6%)</td>
</tr>
<tr>
<td>Anterior only</td>
<td>19 (4.7%)</td>
</tr>
<tr>
<td>Combined anterior and posterior</td>
<td>35 (8.7%)</td>
</tr>
<tr>
<td>Surgical time (minutes)</td>
<td>256.8 ± 115.0</td>
</tr>
<tr>
<td>Blood loss (g)</td>
<td>676.1 ± 1166.9</td>
</tr>
<tr>
<td>Number of fused segments</td>
<td>4.0 ± 2.0</td>
</tr>
<tr>
<td>Complication within 6 weeks</td>
<td>18.1%</td>
</tr>
<tr>
<td>Mechanical failure</td>
<td>41.2%</td>
</tr>
<tr>
<td>Pseudoarthrosis</td>
<td>6.2%*</td>
</tr>
</tbody>
</table>

*Among 385 patients who were able to judge the bone union.
Table 4. ADL Classification

<table>
<thead>
<tr>
<th>Activity Description</th>
<th>Baseline (%)</th>
<th>Follow-up (%)</th>
</tr>
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<tbody>
<tr>
<td>1. Bedridden</td>
<td>12.9</td>
<td>0.5</td>
</tr>
<tr>
<td>2. Wheelchair</td>
<td>39.5</td>
<td>7.0</td>
</tr>
<tr>
<td>3. Walking while holding on to wall, creeping</td>
<td>15.1</td>
<td>6.3</td>
</tr>
<tr>
<td>4. Walking with walker, 2 canes, 1 cane with support</td>
<td>14.1</td>
<td>19.8</td>
</tr>
<tr>
<td>5. Walking with 1 cane without support</td>
<td>13.4</td>
<td>31.8</td>
</tr>
<tr>
<td>6. Walking freely</td>
<td>5.0</td>
<td>34.6</td>
</tr>
</tbody>
</table>
Figure 1

254x190mm (96 x 96 DPI)
Figure 2. Change of local kyphosis angle
Figure 3. Clinical outcomes

Figure 3
254x190mm (96 x 96 DPI)