Osteoporotic Spine Fractures: Incidence and Management Outcomes

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ABSTRACT

Introduction

Multiple medical treatments available for Osteoporotic vertebral compression fractures including hormone replacement therapy, calcitonin, and bisphosphonates--are effective in maintaining or increasing bone mass and reducing the risk of compression fracture.

Materials and methods

60 patients attending Civil Hospital Ahmedabad during July 2012 to April 2014 were included in study.

Observations and results

The study consists of 60 cases of osteoporotic vertebral fractures. The data analyzed to the following findings. Fracture rate is high in the age group of 61-70 and female to male ratio of 2. Rate of osteoporosis and osteomalacia increased drastically in age groups above 60 years which is associated with increased BMI. PCS score improvement was more in Vertebroplasty (avg 12.0 -18.0) compared with calcitonin and teriparatide (avg 6.0-12.0). MCS score improvement was more in Vertebroplasty (avg 12.0 – 18.0) compared calcitonin and teriparatide (avg 6.0 -12.0). Mean recovery period for calcitonin is observed to be 140 days teriparatide to be 60 days and for vertebroplasty to be 15 days.

Conclusion

All patients of osteoporotic vertebral fractures should be given initial conservative treatment for 6 weeks in the form of calcium, vitamin D3, bracing and analgesics. At the end of 6 wks, patients who have intolerable pain, vacuum sign on MRI and who are willing and fit for surgery should be operated for vertebroplasty under general or local anaesthesia, whereas patients who have relief in pain were continued conservative treatment alongwith anti-osteoporotic medications like calcitonin or teriparatide. However there is no significant difference in the treatment due to either calcitonin or teriparatide as calcitonin is associated with lower efficacy but higher compliance due to easy mode of delivery and immediate pain relief, while teriparatide has higher efficacy but lower compliance due to high treatment cost and no immediate pain relieving effect. Teriparatide therapy is preferred for those who have repeated and multiple new-onset vertebral compression fractures (VCF).

Index Terms- Calcitonin, comparison, Osteoporotic Vertebral Fractures, Teriparatide, Vertebroplasty
1 INTRODUCTION

Osteoporotic vertebral compression fractures are a commonly encountered clinical problem. Although the majority of patients with this injury experience a benign and self-limited course of gradually resolving pain, a significant number continue to experience chronic pain and disability. In evaluating a patient with a vertebral compression fracture, the differential diagnosis must consider not only osteoporosis, but also various causes of osteomalacia, endocrinopathy, and malignancy. Multiple compression fractures and increased thoracolumbar kyphosis are associated with a poor prognosis. Multiple medical treatments—including hormone replacement therapy, calcitonin, and bisphosphonates—are effective in maintaining or increasing bone mass and reducing the risk of compression fracture. Conventional treatment in the form of pain medication, activity limitation, and occasionally bracing is effective in returning most patients to their previous level of functioning. When therapies fail, patients may be considered for minimally invasive treatments such as vertebroplasty or kyphoplasty.

2 AIMS AND OBJECTIVES

To study incidence and various treatment modalities in osteoporotic spine fracture.

3 MATERIALS AND METHODS

60 patients attending Civil Hospital Ahmedabad during July 2012 to April 2014 were included in study.

STUDY DESIGN

Randomized, prospective study was done.

All patients were divided in four groups.

1. Calcium and vit D3 group.
2. Calcitonin group
3. Teriparatide group
4. Vertebroplasty group

INCLUSION CRITERIA

BMD< -2.5 SD (OSTEOPOROTIC) on DEXA scan
AGE> 50 Years
Compression fracture at one or more level
Fracture occurred due to trivial trauma only
EXCLUSION CRITERIA

Patients with severe comorbid conditions

History of significant trauma

METHODS

All patients were given conservative treatment in form of calcium and vit D3, bracing, analgescics, Medications as per their groups for 6 weeks. At the end of 6 wks, Who had intolerable pain, vacuum sign on MRI, failed conservative treatment. And willing and fit for surgery were operated for vertebroplasty under general as well as local anaesthesia. Patients who had relief in pain were continued conservative treatment for 1 year. Assessment of patient were done on basis of SF36 version 2 scores at every 3 months for 1 year.

FOLLOW UP

Patients were followed up at every 3 months for 1 yr and on every visit SF36v2 scores were noted and also complications occurred were noted.
4 OBSERVATIONS AND RESULTS

Fig 1-Age Distribution of subjects:

Thus, in our study of 60 patients it was observed that 40% patients fell in the age group of 61-70 years than in other age groups. Fracture rate is high in the age group of 61-70 because of many associated medical illness and associated osteoporosis in that age group.

Sex wise distribution of subjects

In our study it was observed that out of total of 60 subjects 40 were females compared with 20 males. Thus it was seen that there was female to male ratio of 2 because we found that osteoporosis is quite common in females compared to males after menopause.

Fig 2-BMD class in age wise distributed subjects

It was observed that only 25% had BMD below 0.8 in age groups <60 years while in age group >60 years 66% patients had BMD below 0.8. Rate of osteoporosis and osteomalacia increased drastically in age groups above 60 years.

Impact of Smoking on new vertebral fractures

In our study we observed that out of 60 patients only 13 were smokers and rest 47 were nonsmokers. Thus 21.11% new vertebral fractures were associated with smoking. Thus smoking seemed to be protective in preventing new vertebral fractures.

Impact of Drinking on new vertebral fractures

In our study we observed that out of 60 patients only 14 were alcohol drinkers and rest 47 were non alcoholics. Thus 23.33% new vertebral fractures were associated with alcohol. Thus alcohol seemed to be protective in preventing new vertebral fractures.
Sex based distribution of fractures.

It is observed that 45% of fractures in females and 60% fractures in males affected L1 vertebrae. L1 being in a vulnerable anatomical position having angle such that it bears maximum pressure during routine work leading to compressive fractures.

### Table 1 - Comparison of various treatment modalities

<table>
<thead>
<tr>
<th></th>
<th>Calcitonin</th>
<th>Teriparatide</th>
<th>Vertebroplasty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good compliance</td>
<td>100%</td>
<td>60%</td>
<td>62.50%</td>
</tr>
<tr>
<td>Mortality</td>
<td>0%</td>
<td>0%</td>
<td>8.33%</td>
</tr>
<tr>
<td>Complication rate</td>
<td>4.70%</td>
<td>0</td>
<td>8.30%</td>
</tr>
<tr>
<td>Duration of hospital stay (in days)</td>
<td>&lt;1</td>
<td>1.5</td>
<td>9</td>
</tr>
<tr>
<td>Recovery period (in months)</td>
<td>4</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Subsequent fractures</td>
<td>4.76%</td>
<td>0%</td>
<td>8.30%</td>
</tr>
</tbody>
</table>

**Patient compliance**

Compliance was best seen with calcitonin nasal spray and worst with teriparatide because of drastic immediate pain relief and easy mode of delivery given by calcitonin. Longer duration of treatment without much immediate pain relief led to lesser compliance in teriparatide group.

**Mortality**

It was observed in our study that patients treated with calcitonin and teriparatide had no mortality compared to patients treated with vertebroplasty who had 8.33% mortality. Apart from the risks of operative procedure, compliance and patient selection led to above results.

**Complication rate**

Teriparatide had least (0%) complications than Calcitonin (4.76%) and Vertebroplasty (8.33%). Calcitonin was associated with allergic reactions while vertebroplasty was associated with cement leakage and wound infection.

**Duration of hospital stay**

Both calcitonin and teriparatide gave good immediate pain relief leading to less hospital stay. Vertebroplasty gave good immediate pain relief but hospital stay increased due to strict post operative care to avoid post operative complications.
PCS score improvement

In our study, 9 out of 21 patients from calcitonin group, 3 out of 15 from teriparatide group and 3 out of 24 from vertebroplasty group fell in PCS score improvement range of 0-5.9, 6 out of 21 patients from calcitonin group, 9 out of 15 from teriparatide group and 11 out of 24 from vertebroplasty group fell in PCS score improvement range of 6.0-11.9, 6 out of 21 patients from calcitonin group, 13 out of 15 from teriparatide group and 9 out of 24 from vertebroplasty group fell in PCS score improvement range of 12-17.9 and no patients from calcitonin and teriparatide group and 1 out of 24 from vertebroplasty group fell in PCS score improvement range of >18. Thus it is observed that PCS score improvement was more in Vertebroplasty (avg 12.0 -18.0) compared with calcitonin and teriparatide (avg 6.0-12.0).

Table 2- Comparison of PCS score improvement

<table>
<thead>
<tr>
<th>PCS Score Improvement</th>
<th>Calcitonin</th>
<th>Teriparatide</th>
<th>Vertebroplasty</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-5.9</td>
<td>9</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>6.0 – 11.9</td>
<td>6</td>
<td>9</td>
<td>11</td>
</tr>
<tr>
<td>12-17.9</td>
<td>6</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>&gt;18</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>21</td>
<td>15</td>
<td>24</td>
</tr>
</tbody>
</table>

Chi-square value -5.232 p.value-0.514

MCS score improvement.

In our study, 0 out 21 patients from calcitonin group, 3 out of 15 from teriparatide group and 0 out of 24 from vertebroplasty group fell in MCS score improvement range of 0 – 5.9, 11 out of 21, 10 out of 15 from teriparatide group and 16 out of 24 from vertebroplasty group fell in MCS score improvement range from 6.0-11.9, 10 out of 21 patients from calcitonin group, 2 out of 15 from teriparatide group and 4 out of 24 vertebroplasty group fell in MCS score improvement range of 12 – 17.9 and no patients from calcitonin and teriparatide group and 4 out of 24 from vertebroplasty group fell in MCS score improvement range of >18. Thus it is observed in our study MCS score improvement was more in Vertebroplasty (avg 12.0 -18.0) compared calcitonin and teriparatide (avg 6.0 -12.0)
Table 3-Comparison of MCS Score Improvement

<table>
<thead>
<tr>
<th>MCS Score Improvement</th>
<th>Calcitonin</th>
<th>Teriparatide</th>
<th>Vertebroplasty</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-5.9</td>
<td>2</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>6.0-11.9</td>
<td>12</td>
<td>11</td>
<td>14</td>
</tr>
<tr>
<td>12-17.9</td>
<td>8</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>&gt;18</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>24</td>
<td>21</td>
<td>15</td>
</tr>
</tbody>
</table>

Chi square value-11.909, p-value-0.064

Recovery period

In our study we observed that most of the patients treated with calcitonin recovered within 4 months, most of the patients treated with teriparatide recovered within 2 months and most of the patients treated with vertebroplasty recovered within 1 month. Mean recovery period for calcitonin is observed to be 140 days teriparatide to be 60 days and for vertebroplasty to be 15 days.

Subsequent fractures

In our study 8.3% of patients treated with vertebroplasty and 4.76% patients treated with calcitonin encountered subsequent vertebral fractures. Vertebroplasty did local repair thus giving no significant benefit to preventing fractures in other vertebrae while teriparatide and calcitonin gave protective effect to all vertebrae thus preventing subsequent fractures.
5 DISCUSSION

Vertebral fractures result in a deterioration of the health-related quality of life mainly through back pain, reduced physical capability, perceived poor general health and emotional status (e.g. fear of falling, lack of independence, purposeful limitation of activity and of social interactions)

In contrast to previous study of Pawel Szulc1, Mary L Bouxsein et al, international osteoporosis foundation, our study showed 66% new vertebral fractures were females and majority fell in the post menopausal age group suggesting post menopausal osteoporosis as a significant contributor to the condition.

As per Pawel Szulc1, Mary L Bouxsein et al, international osteoporosis foundation, the incidence of vertebral fractures increases dramatically with age (5,11). For instance, the risk of sustaining a new vertebral fracture is about two times higher at 75 years of age than at 65 years of age.

In contrast to previous study of Pawel Szulc1, Mary L Bouxsein et al, international osteoporosis foundation, our study showed Fracture rate is high in the age group of 61 – 70 because of many associated medical illness and associated osteoporosis in that age group. This discrepancy in comparison to other studies might be because of low life expectancy and less trauma exposure in that age group, low compliance and low tendency to seek hospital care due to varied financial and social reasons.

Both the studies showed more improvement in PCS and MCS scores of SF-36v2 inveribroplasty group in comparision to conservative treatment group.

In accordance with many previous studies, In our study It was observed that only 25% had BMD below 0.8 in age groups <60years while in age group >60 years 66% patients had BMD below 0.8. Rate of osteoporosis and osteomalacia increased drastically in age groups above 60 years. The risk of vertebral fractures increases significantly with decreasing BMD.

Diamond et al demonstrated a 53% improvement in pain scores and a 29% improvement in physical functioning 24 hours after vertebroplasty. At 2 weeks, vertebroplasty patients used fewer analgesics and had significantly better quality of life and disability scores. The differences in the functional outcomes between the groups (surgical vs conservative therapy) may be dramatic over the first days after therapy, but they progressively decrease to become non-significant after several weeks or months. In our study we observed that most of the patients treated with calcitonin recovered within 4 months, most of the patients treated with teriparatide recovered within 2 months and most of the patients treated with vertebroplasty recovered within 1 month. Mean recovery period for calcitonin is observed to be 140 days, teriparatide to be 60 days and for vertebroplasty to be 15 days. Thus our study reconfirmed the findings of Diamond et al.

As per the conclusions of many previous studies, In our study also it was observed that patients treated with calcitonin had 100% compliance, that with teriparatide had 55% and that with vertebroplasty had 66%. Compliance was best seen with calcitonin nasal spray and worst with teriparatide mostly because of treatment cost and no immediate pain relieving effect as compared to calcitonin and vertebroplasty.

In a retrospective study by Lin et al., fractures in 10 out of 14 patients during a one year follow-up period were associated with cement leakage into the disk. A separate study by Lazary et al suggests that vertebral filler materials such as PMMA can accelerate degeneration of nucleus pulposus cells, resulting in a less flexible disk and possibly an increased risk of new vertebral fractures. In our study teriparatide had least (0%) complications than Calcitonin (12%) and Vertebroplasty (24%) Calcitonin was associated with allergic reaction while vertebroplasty was associated with cement leakage and wound infection. These findings were supported by many previous studies like Diamond et al.

In one other study, by Kimi L. Londo, in dec, 2008 There is substantial morbidity with osteoporotic VCFs. Patients experience reduced quality of life, difficulties with activities of daily living, loss of independence, depression or low self-esteem, impaired gait, poor balance, and higher mortality.
rates1,2,3,4,5. Vertebral body height loss and progressive kyphosis, especially in patients with multiple osteoporotic VCFs, result in reduction in volume of the thoracic and abdominal cavities leading to reduced pulmonary function and early satiety, respectively.1,2. Even patients with asymptomatic osteoporotic VCF or those who are nonsmokers may have a decline in pulmonary function tests due to the increased kyphotic deformity.6,7,8 Patients with asymptomatic osteoporotic VCF also experience decreased quality of life, increased hospitalization, and mortality.

In a study of 115 patients, the incidence of new fractures in patients with secondary osteoporosis and primary osteoporosis was 48.6% and 11.3%, respectively.9-10 The high incidence of new fractures within the first 2 to 3 months following vertebral augmentation may be the result of increased mobility or activity secondary to the relief of pain.

Of interest, salmon calcitonin appears to reduce the pain associated with acute vertebral fractures.11 Salmon calcitonin is safe apart from very rare allergic reactions leading it high compliance for this medicine. The combined results from 13 trials (n = 589) determined that calcitonin significantly reduced the severity of acute pain in recent OVCFs. Pain at rest was reduced by week 1 (mean difference (MD) = -3.39, 95% confidence interval (CI) = -4.02 to -2.76), with continued improvement through 4 weeks.

A frequent complication of vertebroplasty (50% of cases) is PMMA leakage. The leakage into the epidural space or the central canal may induce neurological deficits. The leakage of PMMA through a neuroforamen may induce a nerve root compression and radiculopathy, which, in very rare cases (<1%), may necessitate surgical decompression.

A separate study by Lazary et al suggests that vertebral filler materials such as PMMA can accelerate degeneration of nucleus pulposus cells, resulting in a less flexible disk and possibly an increased risk of new vertebral fractures.

In our study teriparatide had least (0%) complications than Calcitonin (12%) and Vertebroplasty (24%). Calcitonin was associated with allergic reaction while vertebroplasty was associated with cement leakage and wound infection. These findings were supported by many previous studies like Diamond et al.

In our study patients treated with calcitonin and teriparatide had no mortality compared to patients treated with vertebroplasty who had 8.33% mortality. Apart from the risks of operative procedure, compliance and patient selection led to above result. But we can conclude that overall mortality was significantly reduced in patients who were given treatment with calcitonin, teriparatide and vertebroplasty.

### 6 CONCLUSION

All patients of osteoporotic vertebral fractures should be given initial conservative treatment for 6 weeks in the form of calcium, vitamin D3, bracing and analgescics. At the end of 6 wks, patients who have intolerable pain, vacuum sign on MRI and who are willing and fit for surgery should be operated for vertebroplasty under general or local anaesthesia, whereas patients who have relief in pain were continued conservative treatment alongwith anti-osteoporotic medications like calcitonin or teriparatide. However there is no significant difference in the treatment due to either calcitonin or teriparatide as calcitonin is associated with lower efficacy but higher compliance due to easy mode of delivery and immediate pain relief, while teriparatide has higher efficacy but lower compliance due to high treatment cost and no immediate pain relieving effect. Teriparatide therapy is preferred for those who have repeated and multiple new-onset vertebral compression fractures (VCF).
REFERENCES


