

Efficacy of Conservative management in the treatment of osteoporotic vertebral compression fractures in post-menopausal female

Dharmendra Kumar¹, Deepak Kumar², Shailendra³, Amar Chandra Sharma⁴, Shah Waliullah^{5*}, Vineet Kumar⁶

¹Associate Professor, Dept. of Orthopaedic Surgery, King George Medical University, Lucknow, Uttar Pradesh, India

²Associate Professor, Dept. of Orthopaedic Surgery, King George Medical University, Lucknow, Uttar Pradesh, India

³Associate Professor, Dept. of Orthopaedic Surgery, King George Medical University, Lucknow, Uttar Pradesh, India

⁴Post-doc fellow, Dept. of Orthopaedic Surgery, King George Medical University, Lucknow, Uttar Pradesh, India

⁵Associate Professor, Dept. Of Orthopaedic Surgery, King George Medical University, Lucknow, Uttar Pradesh, India

⁶Associate Professor, Dept. of Orthopaedic Surgery, Ram Manohar Lohia Institute Of Medical Sciences, Lucknow, Uttar Pradesh, India

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Abstract

Introduction: Osteoporosis is a silent disorder, and usually, back pain due to the painful vertebral compression fracture(VCF) may be the initial manifestation. Symptomatic VCF, if left untreated or ill-managed, may result in significant morbidity and mortality. It may result in chronic back pain, spinal deformity and restrictive lung diseases. Post-menopausal females are vulnerable to developed osteoporotic VCF, which can be treated surgically or conservatively. With this study, we evaluated the efficacy of conservative treatment of acute VCF in post-menopausal females. **Methods & Material:** Total 47 post-menopausal females (age group 50- 75years) presented to our outdoor and emergency department, between Jan 2018 to Jan 2020, with diagnosed acute VCF were recruited in our study. All patients underwent bone mineral density assessment through dual-energy X-ray absorptiometry (DXA) scan. Patients were evaluated clinically, haematologically and radiologically. All patients were treated initially with bed rest, analgesics, hyper-extension bracing, supervised physical therapy programme and education. Patients were given Calcitonin nasal spray for two months, weekly alendronate(70mg) with daily calcium(1000mg) and weekly Vitamin D(60000 unit). All patients were followed up clinically, and functional outcome was evaluated by Oswestry Disability Index (ODI). Failure of treatment was defined as persistence of VAS score of 5 or more after two month of conservative treatment. **Results:** 47 post-menopausal females with mean age 62.9 ± 8.6 years and mean BMD spine 0.76 ± 0.09 gm/cm² were followed up for a minimum of one year. At the final follow up of one year, there was a significant improvement in VAS score($p < .001$) from 8.7 to 2.1 and ODI ($p < .001$) from 58.8 to 26 from baseline. All patients except nine showed a gradual reduction in VAS score and ODI score at successive follow-up. At final follow up the majority of patients had minimal or moderate disability(72.37%). Nine patients(21.42%) failed to respond to conservative treatment. **Conclusion:** We observed good results with conservative management in osteoporotic VCF that alleviate pain, reduce the risk of deformity and subsequently help in improving quality of life. We recommend conservative management should be tried first and for an adequate duration before stepping towards operative interventions.

Key-words: Conservative management, Osteoporotic vertebral compression fractures(VCF), Post-menopausal female

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Introduction

Osteoporosis is a systemic skeletal disorder characterized by decreased bone mass and micro-architectural deterioration of bone tissue, leading to increased bone fragility and fracture risk [1,2].

Osteoporosis can be categorized as primary or secondary. Primary osteoporosis is classified into Type I post menopausal and Type II Senile osteoporosis[3]. Type I post-menopausal osteoporosis in females is due to estrogen deficiency as a consequence of menopause. Estrogen governs bone health by regulating osteoclastic activity through estrogen receptors[4].

Osteoporotic fractures or fragility fractures occur due to trivial trauma. Osteoporosis is a silent disorder, and usually, back pain due to the painful vertebral fracture may be the initial manifestation[5]. However, only one-third of the patients with a vertebral fracture are symptomatic[5]. Vertebral compression fracture(VCF) are the commonest type[6]. Symptomatic VCF, if left untreated or ill-managed, may result in significant morbidity and mortality[7]. It may

*Correspondence

Dr. Shah Waliullah

Associate Professor, Department of Orthopaedic Surgery, King George Medical University, Lucknow, Uttar Pradesh, India.

E-mail: shahwali2008@gmail.com

result in chronic back pain, spinal deformity and restrictive lung diseases[5,8]. It is a major cause of significant socio-economic burden to an individual as well as to society. The occurrence of one vertebral fracture increases the likelihood of a second fracture by four times, and a further second fracture raises the risk of another fracture by 12 times[9].

The optimal treatment for acute VCF remains controversial; it can be treated with percutaneous augmentation, conservatively or operatively. Vertebroplasty[10] and Kyphoplasty[11] are standard treatment care desired to restore vertebral height and alleviate pain; however, they are associated with significant complications. Operative management is indicated in patients with chronic back pain due to spinal instability, spinal deformity and neurological deficit[12]. We believe structured conservative treatment can provide effective pain relief and rehabilitation in acute painful VCF. In this study, we evaluated the efficacy of conservative treatment of osteoporotic Vertebral Fractures in post-menopausal females. We took post-menopausal females as study subjects as this population is vulnerable to developing fractures and further associated complications; this study can provide evidence in favor of conservative treatment of acute VCF in post-menopausal females.

Methods & Material

Total 47 post-menopausal females (age group 50- 75years) presented to our outdoor and emergency department, between Jan 2018 to Jan 2020, with diagnosed acute VCF were recruited in our study. Informed consent was taken from all the patients. All patients underwent bone mineral density assessment through dual-energy X-ray absorptiometry (DXA) scan (Lunar Prodigy Advance DXA System, GE Healthcare, analysis version 12.30). DXA scan was interpreted in terms of T score as per World Health Organisation (WHO) guidelines[13]. Patients suffering from the chronic hepato-renal disorder, endocrinal disorders, thyroidism, hyperparathyroidism and malignancy were excluded from our study. Any patient with a history of previous surgical intervention, pathological fractures secondary to primary or metastatic tumors, infections and patients with arthritic hip or knee joint causing secondary spinal deformity were excluded. Patients were evaluated clinically, haematologically and radiologically. Neurological examination was done at the time of admission. Any patient with a neurological deficit was excluded.

Back pain was assessed using the visual analog scale (VAS)[14] and disability assessment using Oswestry Disability Index (ODI)[15]. Routine haematological investigation including complete blood haemogram, liver function test, kidney function test, serum calcium, serum PTH, serum alkaline phosphatase, serum 25(OH) Vit D level, thyroid profile was done at the time of admission. The radiological investigation includes x-rays of the dorsal and lumbar spine in all cases. Computed tomography(CT) and magnetic resonance imaging(MRI) was done in selective cases as required. Fracture location, the morphology of fracture, the coronal and sagittal plane deformity was assessed on x-ray. The patient's fracture was classified as per Sugita et al. classification[16].

All patients were treated initially with bed rest, analgesics followed by hyper-extension bracing, then underwent a supervised physical therapy programme and education regarding their fracture management and prevention. Bed rest was given for two to five days as per pain bearing threshold of the individual patient; patients were encouraged for early mobilization. Patients were given NSAIDs initially, and if not responding, opioids were given for a short duration. Hyper-extension Anterior Spinal Extension (ASHE) brace was advised to avoid hyperflexion at fracture. Brace was given for four to six weeks. All patients underwent supervised rehabilitation for strengthening of core back muscles. Calcitonin nasal spray with metered-dose 200 IU everyday alternate nostrils was started at the initiation of pharmacotherapy for two month. All patients were given weekly alendronate(70mg) with daily calcium(1000mg) and weekly Vitamin D(60000 unit). All patients were followed up clinically, and functional outcome was evaluated by Oswestry Disability Index (ODI). Failure of treatment was defined as persistence of VAS score

of 5 or more after two month of conservative treatment. Patients were followed up initially at four-weekly intervals for three months than at three monthly intervals to evaluate long term complications.

Statistical Analysis

Statistical analysis was carried using SPSS software (SPSS Inc., Chicago, IL, USA) for Windows program (16.0 version). The dichotomous variables were presented in number/frequency and were analyzed using the Chi-square test or Fisher's exact test as required. The continuous variables were evaluated by mean (standard deviation) or range value. For comparison of the means between the two groups, analysis by Student's t-test was used. The p-value of < 0.05 or 0.001 was regarded as significant.

Results

47 post-menopausal females with mean age 62.9 ± 8.6 years and mean BMD spine 0.76 ± 0.09 gm/cm² were followed up for a minimum of one year. Meantime since menopause was 14.2 ± 3.5 years, radiologically majority of patients had a fracture of the lumbar spine(67%), with L1 the commonest(33%) fractured vertebrae followed by T12 vertebrae(22%) in the thoracic spine. As per Sugita et al. classification, in our series, maximum patients(44%) had concave type fracture pattern followed by bow-shaped(23%). There was a significant increase in height collapse at final follow up(<.001) and positively correlated with increasing age.

At the final follow up of one year, there was a significant improvement in VAS score(p<.001) from 8.7 to 2.1 and ODI (p<.001) from 58.8 to 26 from baseline. All patients except nine showed a gradual reduction in VAS score and ODI score at successive follow-up. At final follow up the majority of patients had minimal or moderate disability(72.37%).

Nine patients(21.42%) failed to respond to conservative treatment. We observed old age, obesity, non-compliance to pharmacotherapy and physiotherapy to be associated with treatment failure. Two patients were lost to follow up while three patients died due to other associated comorbidities.

Discussion

Due to the lack of standardized protocol and treatment modalities, optimal treatment of osteoporotic VCF remains controversial, whether conservative or operative[10,11,17]. Adequate conservative treatment implementation is necessary to avoid surgical complications and costs. Studies in the past have questioned the efficacy of percutaneous vertebroplasty and found that augmentation procedures are not superior to conservative management[18,19,20]. However, recent studies have proven the pain-relieving efficacy of augmentation procedures and found it superior to conservative treatment[10,11,21]. There is still a treatment dilemma to conserve or augment VCF and if augment when to do it.

This prospective cohort study with post-menopausal females having acute VCF shows a 78% success rate with conservative management. Due to estrogen deficiency, post-menopausal females are at increased risk of developing osteoporotic VCF. Prevalence of osteoporotic VCF is more in women than men[22]; however, few studies showed equal distribution of osteoporotic vertebral fracture in both males and females or even higher in males[23,24].

Conservative management for VCF includes pain management, rehabilitation and education to prevent further fractures. For pain relief, analgesic drugs can be given for 6 to 12 weeks[17]. Non-steroidal anti-inflammatory (NSAID) and Opioids can be used depending upon patient response. In our study, the majority of patients responded to NSAIDs, Calcitonin and VAS scores came down below four after eight weeks of treatment in the majority of patients(63.5%). On subsequent follow-up, the patient showed improvement in VAS score; at four months of follow up, 68% of patients had VAS score below 3. Shah et al. [25], in their study on 30 patients, observed gradual improvement in VAS score at successive follow-up and reported 49% improvement in VAS score from baseline at final follow up. Venmans et al. [26], in their study with

conservative management on 95 patients with VCF, observed 60% of patients had VAS \leq 3 at the end of one year of follow up. Diamond HT et al.[27] had observed, at six weeks with conservative management of VCF, the VAS score came down to 61%, which further improved to 71% at six to 12 months of treatment. Disability as a consequence of vertebral fracture was measured with ODI. In our study, at the final follow-up, most of our patients had minimal or moderate disability(72.37%) with a significant improvement in ODI score. Improvement in ODI was due to effective rehabilitation, including supervised physiotherapy and patient education. All patients underwent a standardized muscle strengthening programme involving back extensors muscle strengthening by a trained physiotherapist. At first, follow up, patients were educated about the natural history of osteoporotic VCF, prevention of falls and subsequent fractures and the importance of exercises to prevent deformity. Shah et al[25], observed 47.23% improvement in ODI score at final follow up; 56.67% of patients had minimal disability while 36.67% had a moderate disability. Our study has few limitations. Due to the single centric, prospective observational analysis, results cannot be generalized. We do not have a control group to prove the superiority of conservative management. We have taken only the female population, though osteoporosis is more common in females but is widely prevalent in males as well. Future multicentric studies involving both male and female subjects with standardized conservative treatment protocol can provide further robust evidence to prove the efficacy of conservative management.

Conclusion

We observed good results with conservative management in osteoporotic VCF that alleviate pain, reduce the risk of deformity and subsequently help in improving quality of life. Our conservative treatment protocol involves pain relief, anti-osteoporotic medications, hyperextension brace, rehabilitation and patient education. This protocol is simple and effective for the treatment of post-menopausal VCF. We recommend conservative management should be tried first and for an adequate duration before stepping towards operative interventions.

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