European Journal of Molecular & Clinical Medicine

ISSN 2515-8260 Volume 10, Issue 03, 2023

Original Research Article

Comparative study of treatment outcomes in osteoporotic compression fractures without neurologic injury with or without brace: A prospective randomized controlled trial

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Abstract
Vertebral compression fractures are the most common type of osteoporotic fracture. In the acute stage osteoporotic vertebral fractures cause severe back pain, disabilities in activities of daily living and deterioration in the quality of life. The efficacy of brace application for the treatment of osteoporotic compression fractures remains unclear. The purpose of this study was to compare the treatment outcome in patients with osteoporotic compression fracture with or without brace. We randomly assigned 42 patients with acute osteoporotic compression fractures within 2 wks of injury to the Brace and No Brace groups. Patients are followed up with clinical and radiological assessment till 6 months. The primary outcome was the Oswestry Disability Index score and secondary outcome measures were VAS for back pain, Body Compression Ratio and angle of kyphosis during the follow up interval. The Oswestry Disability Index score after compression fracture in the brace group was superior to that in the No brace group. During the follow-up assessment period, there was significant difference among the groups for the overall Oswestry Disability Index scores (p<0.001) and visual analog scale for pain scores for back pain. However, the Oswestry Disability Index scores and the visual analog scale scores for back pain significantly improved with time after the fractures (p< 0.001) in both groups. The body compression ratios significantly decreased (p=0.0414) and the cobbs angle significantly increased (p =0.0181) with time in No Brace group compared to traetment with Brace. The overall tolerability of the orthoses was good. Thereby, the use of an orthosis may represent an efficacious nonpharmacologic treatment option for spinal osteoporotic fractures.

Keywords: Osteoporosis, vertebral fractures, bracing, oswestry disability index

Introduction
Vertebral compression fracture is the most common problem in old age causing incapacitating pain which produces significant morbidity, disability and mortality. Osteoporosis is the most common disorder of bone in this old age group affecting approximately 120 million people worldwide. Owing to an increased aging population, the prevalence of the osteoporotic vertebral compression fractures has increased [1].

Over 61 Million Indians have osteoporosis, out of which 80% are women. On a global basis, Indians have the highest prevalence of osteopenia [2]. Compared to Western population, fractures related to osteoporosis in the Indians occur a decade earlier in age. On average, 45 Lakh Indian females above 60 yrs of age have a fractured spine compared to osteoporotic hip fractures every year which is 2.5 lakhs [3]. So vertebral compression fractures are the most common osteoporotic fracture, one vertebral compression fractures occurs every 45 seconds. 30-50% of all women develop vertebral compression fractures during their life time [4]. At the age of 75 yrs- 25% of all women have at least one vertebral compression fractures which

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increases to 50% at the age of 80yrs. One vertebral compression fracture increases the risk of 2nd vertebral compression fracture by 4 times, if Second fracture - 12 times higher chance of further compression fractures [5].

Vertebral compression fractures are the most common type of osteoporotic fracture. In the acute stage osteoporotic vertebral fractures cause severe back pain, disabilities in activities of daily living and deterioration in the quality of life but their long term outcome has been considered relatively good in terms of residual pain and deformity for a majority of patients(1). Benign osteoporotic compression fractures without neurologic injury are inherently stable fractures as they involve only the anterior column of the vertebral body. Therefore non operative treatment is considered the initial treatment of choice which usually comprise of short term bed rest, analgesic therapy and orthosis wearing [6].

Approximately 33% of the patients do not respond to conventional pain medication and conservative treatment. Ultimately vertebral compression fractures can lead to profound pain, morbidity, disability, and reduced life expectancy which has great impact on healthcare systems [7]. The fractured osteoporotic vertebrae may also progress to collapse and may lead to progressive burst fractures leading to kyphosis with variable degrees of cord compressions and further complications. This leads to reduced mobility which in turn leads to further bone loss and other problems like atelectasis, pneumonias, deep vein thrombosis, pulmonary embolism and so on [7]. In senior citizens, these morbidities cause loss of independence and reduced daily activities leading to social isolation and depression [8].

There is no consensus in the literature about optimal treatment. The guidelines of the American Academy of Orthopaedic Surgeons for the treatment of symptomatic osteoporotic spinal compression fractures were unable to recommend or not recommend treatment with bed rest, opioids/analgesics, and braces [9]. Theoretically braces provide stability at the fracture site reducing pain, maintain alignment, reduce movements and prevent further kyphotic collapse at the fracture site [10]. However, early mobilization with back extensor exercises alone without orthosis produced similar outcomes. Braces also have potential disadvantages such as skin irritation, low compliance, impaired respiration and cumbersome nature of the brace.

Hence the need for study is to assess the usefulness of braces in the non-operative management of vertebral compression fractures.

Methodology

Study design

Randomized, comparative prospective study.

Groups to be studied

42 patients divided in to two groups.

Detailed Z description of Z the groups Z

Patients Z who are Z diagnosed with thoracolumbar spine fracture, who Z fulfil Z the inclusion Z criteria are Z included in the Z study. Patients were made to pick up the chits blindly, to decide which group the patient is included in: Bracing or Non Bracing group. Patients were allotted according to the chits they have picked up.

Sampling technique used

Randomized Sampling Technique

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Inclusion criteria

1. Patient willing to give informed consent
2. Age 50 yrs or older of either sex
3. Presentation with acute back pain caused by a thoracolumbar vertebral fracture defined as an axial compression of only the anterior column of vertebral body with intact posterior elements and no spinal canal narrowing confirmed by MRI within 1 week of trauma
4. No neurologic deficits
5. T- score of -2.5 or lower

Exclusion criteria

1. Vertebral compression fractures at more than two levels
2. Non ambulatory patients
3. With neurologic deficits
4. History of previous spinal surgery
5. Malignant compression fractures
6. Infections
7. Inability to complete questionnaire

On presentation in outpatient department detailed history from the patient were obtained, which includes name and age of the patient, date and time of injury, mode of injury, initial treatments and his/her present complaints were noted. True Anterior - posterior and true Lateral views X-rays of injured spine were taken & vertebral wedge compression fractures diagnosed. Baseline demographic and injury characteristics were noted. Any history suggestive of other illnesses to rule out causes for compression fractures and associated co morbid diseases were noted and taken care of.

Then patient was examined thoroughly and attention given to examination of spine like any local swelling, deformity, tenderness over the spine was noted. Neurological chart which included assessment of motor status, sensory status, bowel & bladder status were noted.

In all patients, Visual analog score for back ache, Oswestry disability score & Oswestry disability index at 1st visit were noted for the purpose of comparison of functional outcome.

Radiological evaluation was done in all patients. Fresh X-ray spine Antero posterior view & lateral view spine were taken, if needed dynamic x ray –flexion / extension lateral view were taken to rule out spinal instability. Specific findings were sought for integrity of anterior, middle, posterior column of spine. DEXA scan of spine is done to diagnose osteoporosis and t score of the patient is noted.

Magnetic resonance imaging (MRI) scan done to assess the age of the fracture, to rule out pathological fractures, Anterior and Posterior longitudinal ligament breach and any marrow and spinal cord changes.

Results

Table 1: Distribution of Patients according to vertebral level in two Groups

Vertebral level	Group A		Group B	
	Number	Percentage	Number	Percentage
D10	00	00	01	5.00
D12	02	9.09	01	5.00
D12,L1	01	4.55	01	5.00
L1	08	36.36	08	40.00
L1,L2	00	00	01	5.00
L2	04	18.17	02	10.00
L2,L3	01	4.55	01	5.00
L3	02	9.09	03	15.00

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L3,L4	01	4.55	00	00
L4	03	13.64	02	10.00
Total	22	100	20	100
p-value	0.8895(NS)			

The mean t score of the patients in the two groups are -3.63 and -3.75 respectively with p value of 0.49 showing statistically insignificant difference between the study groups.

Table 2: Mean and Standard deviation (SD) of DEXA (T SCORE) for two Groups and p value to compare

Group	Mean	SD
A	-3.63	0.58
B	-3.75	0.56
p value	0.4986(NS)	

The mean VAS was 7.92±0.82 for Group A (bracing) and 7.90±0.83 for Group B (No brace) at the time of enrollment.
The VAS for back pain in both group showed significant (p<0.001) decrease over the follow up assessment time. However the VAS of bracing group showed significant decrease when compared to the non-bracing group at each follow up assessment.

Table 3: Mean and Standard deviation (SD) of VAS for two Groups and p value to compare

	Group A		Group B		p value by t test
	Mean	SD	Mean	SD	
1st Visit	7.95	0.82	7.90	0.83	0.8361(NS)
2nd Week	5.23	0.90	6.45	1.02	0.00025(S)
4th Week	2.82	1.03	5.60	0.80	8.768e-12(S)
8th Week	2.36	0.71	3.95	0.92	3.078e-07(S)
3 Month	2.27	0.62	3.50	0.74	1.211e-06(S)
6 Month	2.00	0.79	2.85	0.57	0.0004312(S)
P value by ANOVA	2.2e- 6(S)		2.2e- 6(S)		

The mean ODS and ODI of group A at the time of enrollment were 27.95±2.09 and 61.93 ± 4.65 respectively. Mean ODS and ODI of group B were 27.95±2.36 and 62.11±5.23 which was not statistically significant difference (p value by t test >0.05) between the two groups.
However the ODS and ODI for back pain has significantly improved (p<0.001) with time after the fracture in both groups. The ODI score for back pain showed better improvement in the bracing group compared to the non-bracing group as shown by the p value by t test at each visit.

Table 4: Mean and Standard deviation (SD) of ODS for two Groups and p value to compare

	Group A		Group B		p value by t test
	Mean	SD	Mean	SD	
1st Visit	27.9546	2.09	27.95	2.36	0.9949(NS)
2nd Week	25.36	2.01	27.25	2.05	0.0055(S)
4th Week	19.68	2.70	25.00	1.89	1.215e-08(S)
8th Week	14.55	2.06	21.55	0.06	2.4e-13(S)
3 Month	13.23	1.38	19.15	2.46	7.975e-12(S)
6 Month	10.68	1.26	15.15	1.82	2.836e-11(S)
p value by ANOVA	2.2e-16(S)		2.2e-16(S)		

Table 5: Mean and Standard deviation (SD) of ODI for two Groups and p value to compare

	Group A		Group B		p value by t test
	Mean	SD	Mean	SD	

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1st Visit	61.93	4.65	62.11	5.23	0.9080(NS)
2nd Week	56.36	4.47	60.56	4.55	0.0055(S)
4th Week	43.74	6.01	55.56	4.22	1.215e-08(S)
8th Week	32.32	4.58	47.89	4.58	2.4e-13(S)
3 Month	29.39	3.07	42.56	5.46	7.975e-12(S)
6 Month	23.74	2.79	33.67	4.05	2.836e-11(S)
p value by ANOVA	2.2e-16(S)		2.2e-16(S)		

The mean value of Cobbs angle at presentation were 11.18 ± 4.09 (Group A) and 11.40 ± 4.73 (Group B).

The Cobb's angle in non-bracing group showed significant (p =0.0181) increase with time but the difference in the angle between the two study groups was statistically significant (p value=0.0396) only at the 6th month of follow up.

Table 6: Mean and Standard deviation (SD) of Cobbs angle (θ) for two Groups and p value to compare

	Group A		**Group B**		**p value by t test**
	Mean	**SD**	**Mean**	**SD**	
Day one	11.18	4.09	11.40	4.73	0.8745(NS)
3 Month	11.18	4.09	12.00	4.59	0.5548(NS)
6 Month	12.64	3.83	15.55	4.81	0.0396(S)
p value by ANOVA	0.404(NS)		0.0181(S)		

The mean Body compression ratios of the two groups at enrollment were 0.74 ± 0.13 and 0.75 ± 0.14 respectively. The body compression ratio of non-bracing group showed significant reduction (p=0.0414) over time however when compared with the bracing group the decrease in body compression ratio was not statistically significant.

Table 7: Mean and Standard deviation (SD) of Beck's index for two Groups and p value to compare

	Group A		**Group B**		**p value by t test**
	Mean	**SD**	**Mean**	**SD**	
Day one	0.74	0.13	0.75	0.14	0.8366(NS)
3 Month	0.74	0.13	0.73	0.14	0.8011(NS)
6 Month	0.68	0.13	0.64	0.16	0.3519(NS)
p value by ANOVA	0.203(NS)		0.0414(S)		

Table 8: p value by Tukey POST HOC test to compare two periods

Between	**Group A**		**Group B**	
	Cobbs angle(θ)	**Beck's index**	**Cobbs angle(θ)**	**Beck's index**
D and 3 Months	1.0000(NS)	1.0000(NS)	0.9187(NS)	0.9065(NS)
D and 6 Month	0.4722(NS)	0.2680(NS)	0.0234(S)	0.0474(S)
3 Month and 6 Month	0.4722(NS)	0.2680(NS)	0.0607(S)	0.1198(NS)

Table 9: Complications in the study groups

Complications	**Group A**	**Group B**
Skin Irritation/ulcer	2	0
Neurological deficit	0	1
New osteoporotic fracture	1	1
Radicular pain	1	1
Spondylolisthesis	0	1
Kyphosis	0	2

Discussion

The mean VAS was 7.92±0.82 for Group A (bracing) and 7.90±0.83 for Group B (No brace) at the time of enrollment. The VAS for back pain in both group showed significant (p<0.001)

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improvement over the follow up assessment time. However the VAS of bracing group showed significant decrease when compared to the non-bracing group at each follow up assessment showing that the use of brace markedly improved the pain management in these patients.

The mean baseline ODI score of the two groups were 61.93±4.65 and 62.11±5.23 respectively. The primary outcome measure for our study, ODI for back pain has significantly improved ($p<0.001$) with time after the fracture in both groups. The ODI score for back pain showed better improvement ($p<0.05$) in the bracing group compared to the non-bracing group as shown by the p value by t test at each visit indicating a better functional outcome in the brace group.

The radologic outcome measures i.e body compression ratio (p=0.0414) and angle of kyphosis (p =0.0181) of the patints in the non-bracing group showed significant worsening during the follow up assessment period compared to that in patients treated with brace indicating an inferior radiologic outcome.

Kim and colleagues [6] published a non-inferiority randomized controlled trial (RCT) in 2014, comparing bracing with a rigid orthosis, soft orthosis, and no orthosis. A total of 60 patients were randomized, with 20 allocated to each group. The primary outcome measure was Oswestry Disability Index (ODI) at 12 weeks.

All groups had equivalent outcomes, that is, no group gained a 10 point advantage over any other group. Secondary measures included ODI, visual analogue scale (VAS) for back pain, general health status, and progression of the body compression ratio over all visits; and treatment satisfaction at 12 weeks after fracture. There was no difference between groups. All groups experienced significant improvement in VAS and ODI over the course of the study. The authors did not report any complications. Compliance with bracing was over 90%.

Pfeifer *et al*. [11] in two separate studies demonstrated using a thoracolumbar orthosis in the 6-month period following an OVCF resulted in increased core strength, decreased kyphosis, decreased pain, and improved function and quality of life.

Wearing the orthosis Spinomed during a 6-mo period was associated with a 72% (64%) increase in back extensor strength ($p<0.01$), a 44% (56%) increase in abdominal flexor strength ($p<0.01$), an 11% (11%) decrease in the angle of kyphosis ($p<0.01$), a 23% (20%) decrease in body sway (P = 0.03 and P = 0.02), a 19% (18%) increase in vital capacity (p < 0.01 and P = 0.03), a 41% (47%) decrease in average pain ($p<0.01$), an 18% (18%) increase in well-being ($p<0.01$), and a 49% (54%) decrease in limitations of daily living ($p< 0.01$), respectively.

In 2013, Hoshino and colleagues reported a multicenter prospective cohort trial of 362 patients with acute compression fracture. Participants were treated with bracing (custom-made hard, custom-made elastic, or ready-made elastic), or no brace, at the discretion of the treating physician. Significantly more patients with middle-column involvement were allocated to bracing. There was no significant difference in outcomes between groups, including SF-36, VAS, MMSE, VB collapse, or ADLs. The authors did not report complications related to treatment [12].

Conclusion

In conclusion, we demonstrated that the disability outcomes of treatment of the osteoporotic fractures with a brace was superior compared to treatment without a brace and allowed for better pain control and quality of life in these patients. The overall tolerability of the orthosis was good. Thereby, the use of an orthosis may represent an efficacious non-pharmacologic treatment option for spinal osteoporotic fractures.

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