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RESEARCH ARTICLE

ROLE OF PERCUTANEOUS VERTEBROPLASTY IN VERTEBRAL COMPRESSION FRACTURES: EFFICACY AND SAFETY

Dr. Akshit Kumar, Dr. Preeti Sharma, Dr. Tariq Ahmed Gojwari, Dr. Gul Mohammad, Dr. M. Maqbool Lone, Dr. Naseer Ah. Mir, Dr. Abdul Rashid Bhat and Dr. Sarabjit Singh Chibber

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Abstract

Background: Percutaneous Vertebroplasty (PVP) is a minimally invasive interventional procedure performed by injecting bone cement or other therapeutic material into a painful osteoporotic or neoplastic compression fracture for pain or disability improvement. There is conflicting evidence regarding the use of vertebroplasty in osteoporotic vertebral compression fractures (VCFs) in the available literature.

Objectives: To evaluate the efficacy and safety of Percutaneous Vertebroplasty in painful vertebral compression fractures in terms of pain alleviation and disability improvement, and thereby, study the profile of complications. Study design: Prospective observational study
Study Participants: Patients with clinically symptomatic VCFs, who received various forms of treatment (interventional/conservative) were enrolled for the study. Patients who met the inclusion/exclusion criteria were finally selected.

Methodology: Out of the selected patients, two groups were made, one who received the Intervention (PVP) and another group who received conservative management (Bed rest, medications, physiotherapy, etc.). Out of 31 patients selected, 11 were treated by PVP and 20 were treated by conservative management. These patients were followed up at 1-month, 3-month and 6-month intervals to record the Visual analog pain scores (VAS), Ronald Morris disability scores (RDQ) and any complication.

Results: VAS scores in the vertebroplasty group decreased from (8.09±0.539) to (3.64 ± 0.674) at 1-month to (3.27±1.009) at 3-month to (3.09±0.831) at 6-month. VAS scores also decreased in the conservative group from (7.6±0.598) to (5.95±0.999) at 1-month to (5.1±1.294) at 3-month to (5.15±1.424) at 6-month. Vertebroplasty group showed the steep fall (-4.45) in VAS values as compared to a gradual decrease in VAS (-1.65) in the conservative group at 1 month follow up, concluding that conservative treatment has a slower effect on pain relief compared with the early response after PVP. Disability scores (RDQ) follow a similar trend with early and better improvement in the vertebroplasty group. RDQ scores: Vertebroplasty group (18.45±1.572 at baseline to 12.27±1.421 at 1-month to 11.82±1.079 at 3-month to 11.82±1.471 at 6-month), Conservative group (17.95±1.146 at baseline to 14.3±1.418 at 1-month to 12.9±1.518 at 3-month to 12.85±2.207 at 6-month). Subgroup analysis showed more benefit in

malignant VCFs treated by PVP. The procedure was largely uneventful. An immediate complication was noted in one patient with cement extravasation into the venous channels, however, the patient showed pain and disability improvement without any adverse effects. Furthermore, no additional complication was noted during the follow-up period in any other patient.

Conclusion: Percutaneous Vertebroplasty provides early and significant pain and disability improvement in vertebral compression fractures to comparison to conservative management. Implication: Minimal invasive technique for pain relief in osteoporotic and malignant vertebral compression fractures.

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Introduction:-

Osteoporotic Compression Fractures have been traditionally treated with bed rest, analgesics, braces, and physical therapy. However, such treatments are only partially effective, and about one-third of patients have reported suffering from persistent pain and progressive functional limitation and loss of mobility. Vertebral compression fractures secondary of spinal metastasis are treated by Radiotherapy(RT) as first-line particularly in lymphoma, seminoma, myeloma, prostate and breast cancer. Focused beams of radiation are used in Stereotactic Radiosurgery (SRS) for curative as well as palliative treatment⁽¹⁾.

The American College of Radiology (ACR) in collaboration with the American Society of Neuroradiology (ASNR), the American Society of Interventional and Therapeutic Neuroradiology, and the American Society of Spine Radiology (ASSR) defined the vertebral augmentation and laid down the guidelines for vertebral augmentation procedures. They defined Percutaneous Vertebroplasty (PVP) as “a minimally invasive surgical or image-guided intervention procedure, performed by percutaneously injecting radiopaque bone cement, osteoinductive substance, or other therapeutic material into a painful osteoporotic or neoplastic compression fracture or a painful vertebral body weakened by any other etiology”⁽²⁾.

There is conflicting evidence regarding the use of vertebroplasty in osteoporotic VCFs. Majority of the available literature favors the PVP as the good modality with a significant reduction in pain, reduction in analgesic requirement and disability improvement. However, the two RCTs^(3,4) published in 2009 and VERTOS IV study⁽⁵⁾ showed no additional benefit of PVP over sham procedures. Prior to 2009, evidence for the effectiveness of PV in osteoporotic VCF was based on multiple prospective and retrospective case series, and prospective comparative cohort studies⁽⁶⁾. Multiple observational studies had shown almost uniformly excellent results with PV, with moderate to marked pain relief experienced by 75–95% of patients. Similar results in the treatment of metastatic fractures have also been reported.

Aim:

To evaluate the efficacy and safety of percutaneous vertebroplasty in painful vertebral compression fractures.

Objectives:-

1. To study the outcome in terms of pain alleviation and disability status after vertebroplasty in painful vertebral fractures.
2. To evaluate the profile of complications that will occur during or after the procedure.

Study Design And Patient Selection

This prospective observational study was conducted in Sher-I-Kashmir Institute of Medical Sciences; for a period of 2 years from August 2019 to August 2021. Patients with clinically symptomatic vertebral compression fractures who received various forms of treatment (Interventional/Conservative) were enrolled for the study. Patients who met the Inclusion/Exclusion criteria were finally selected after proper consent.

Inclusion Criteria

1. Vertebral compression fractures causing pain and disability.

2. Vertebral compression fractures less than 1-year-old.
3. Metastatic vertebral compression fractures in which pain continues even after radiotherapy.
4. Pain measured on more than 5/10 on the numeric scale (Visual Analogue Scale).

Exclusion Criteria

1. Recent MRI or bone scan not showing any evidence of vertebral compression fracture.
2. Presence of neurological deficit or significant radicular pain.
3. Disruption of the posterior vertebral body wall.
4. Bleeding diathesis/coagulopathy.
5. Patients who refuse to give consent for the procedure.

Out of the selected patients, two groups were made, one who received the Intervention (Percutaneous Vertebroplasty) and another group who received the conservative management for pain relief, which includes: - Bed rest, Analgesics, Braces, Thermotherapy. Conservative management was given till the satisfactory subjective pain relief achieved or till their follow up to 6 months.

Out of 31 patients selected, 11 were treated by Percutaneous Vertebroplasty and 20 were treated by conservative management. There were 17 males and 14 females who were in the range of 58 -75 years.

These patients were followed up at 1 month, 3month and 6 months. Each time the patient was assessed clinically with the Pain score – Visual analog scale and disability score - Ronald Morris Disability score. Patients were instructed to call or report to the hospital, in case of any complication or worsening of symptoms in between the follow-up intervals.

Materials For Vertebroplasty

Equipment/Materials that were used during the study-

1. C arm Fluoroscopy unit (Siemens, Artis Zee)
2. Bone Cement (Polymethyl Methacrylate) (by STRYKER or MEDITRONICS) – bone cement by these manufacturers has the advantage of premixed radiopaque contrast material
3. 10-gauge trocar cannula, 11gauge bone access needle (by COOK or STRYKER), K- wire, hammer for advancement of needle within the vertebra, 5 cc Luer loc syringes
4. Local anesthetic (a mixture of short-acting Lignocaine with a long-acting agent, Bupivacaine).
5. Sedatives (midazolam and fentanyl), Prophylactic broad-spectrum i.v antibiotic (Cefotaxime 1 gm) was given to all patients one hour before the intervention.

Procedure:-

The patient was prepared in the ward in the morning on the day of surgery and baseline (preop) Visual analog scores and Ronald Morris Disability questionnaire scores were recorded just before the procedure. The patient was positioned prone under C arm with cushions placed under the abdomen to make the region of interest in spine prominent. The intravenous antibiotic cover was given (1 gm of cefotaxime) one hour prior to the procedure and small amount antibiotic was also routinely mixed in with the cement.

Area to be operated was painted using povidone Iodine and 20ml of lignocaine with adrenaline was infiltrated over the proposed site of operation. Under image intensifier, we locate the pedicle percutaneously, a small incision was made lateral and superior to the cutaneous pedicle location which allowed proper convergence through the tissues to the proposed pedicle entry point.

Using K-wire, entry point was made at 10'o clock or 2 o'clock position on the lateral border of the pedicle and 10-gauge trocar cannula with 11-gauge access needle used for engagement of bone, the lateral projection was checked for needle trajectory in the cephalo-caudal plane. Through a transpedicular approach, the needle was placed into the body at the junction of posterior two-third & anterior one-third of vertebral body which was confirmed in the lateral view.

Vertebroplasty PMMA Cement slowly injected into the vertebral body under C-Arm. With the adequate pressurization, cement-filled in the anterior body crossing the midline to the other side and then the posterior side of

the body. Sterile dressing at the puncture site was done. The patient was maintained in prone for a few minutes and shifted to recovery.

Postoperative Protocol

The patients were advised to remain in bed supine preferably, for next 3-4 hours with dressing at puncture sites. Patients were discharged after 24 hrs and were advised to take oral antibiotics. Tablet Cefuroxime for three more days and Tablet Tramadol / Tablet Diclofenac for residual pain for 7 days.

Discussion:-

Percutaneous Vertebroplasty, in the last three decades, has emerged as a minimally invasive technique that offers an alternative to conventional therapy for the management of these fractures. Vertebroplasty has been extensively studied with conflicting results. Various retrospective and prospective studies, RCTs and their meta-analyses have demonstrated the benefits of PVP^(6,18,19,20) whereas there are few randomized control trials that have not shown any significant benefit⁽³⁻⁴⁾. These conflicting outcomes had a negative influence on the frequency with which vertebroplasty is performed and have stirred up the debate among referring clinicians, practicing interventional radiologists and patients regarding the use of vertebroplasty and the ideal candidates that may benefit from the procedure.

A total of 31 patients were part of this study, out of which, 20 patients were managed conservatively by- Bed rest, analgesics, braces, thermotherapy, isometric contraction exercises to strengthen the spinal musculature. Conservative management continued till the satisfactory subjective pain relief or till their follow up to 6 months. 11 patients with 7 metastatic (primary lung carcinoma in 3, prostate cancer in 3 and breast carcinoma in 1 patient) and 4 osteoporotic vertebral compression fractures were treated by Percutaneous Vertebroplasty.

Recent studies stress to perform vertebroplasty in acute fractures less than 6 weeks⁽¹⁸⁾ for the better outcome especially in osteoporotic VCFs, however, it's still the common practice in most centres, including ours, to offer pain medications and bed rest as first-line management and thus the interventional procedures are often delayed. MR imaging was used for selection of patients because bone marrow edema and associated height loss on STIR images are very sensitive for the compression fracture. Eleven vertebral levels (number of D11=1, L1=1, L2=3, L3=4, L4=1, L5=1) were treated using the unipedicular approach and mean 3.28 cc of cement injected.

Our results show a clear improvement in pain and disability status of the patients. There is a decrease in VAS scores in vertebroplasty group from (8.09±0.539) to (3.64 ± 0.674) at 1 month to (3.27±1.009) at 3 months to (3.09±0.831) at 6 months. VAS scores also decrease in the conservative group from 7.6±0.598 to 5.95±0.999 at 1 month to 5.1±1.294 at 3 months to 5.15±1.424 at 6 months (**Table 1**). However, the p-values obtained at 1 month, 3 months and 6 months also indicate a statistically significant difference between the two groups on the measure of pain. This suggests more pain relief in the vertebroplasty group.

Both groups show the significant change (p-value <0.001) (**Table 3**) compared to baseline, but the maximum pain alleviation noted in first 1 month in both groups which were maintained at 3 and 6 months. Vertebroplasty group showed the steep fall (-4.45) in VAS values as compared to a gradual decrease in VAS (-1.65) in the conservative group at 1 month follow up, concluding that conservative treatment has a slower effect on pain relief compared with the early response after PV. Baseline values in vertebroplasty and the conservative group is significantly different (p=0.031) with less VAS value in the conservative group, this can be attributed to the fact that patients who suffered from more pain opted for PVP.

RDQ scores follow the similar decreasing trend in both the groups: vertebroplasty group (18.45±1.572 at baseline to 12.27±1.421 at 1 month to 11.82±1.079 at 3 months to 11.82±1.471 at 6 months) Conservative group (17.95±1.146 at baseline to 14.3±1.418 at 1 month to 12.9±1.518 at 3 months to 12.85±2.207 at 6 months). The p-values obtained at 1 month and 6 months also indicate a statistically significant difference between the two groups on the measure of pain with no statistically significant difference noted at 3 months (p=0.046) (**Table 2**). Both groups show the significant change (p-value <0.001) (**Table 3**) compared to baseline, but the maximum improvement noted in the first 1 month in both groups. And no significant change in RMD values noted between 3 months and 6 months value.

In our vertebroplasty experience, complications were seen in one case with cement extravasation into the venous channels, however, the patient showed clinical pain and disability improvement without any adverse effects. In our study, no new adjacent fracture noted in 6 months follow up period.

Although all precautions were taken to make the study methodologically strong, however, still some of the limitations could not be avoided. There are a few limitations to our study: 1. The sample size was small in the vertebroplasty group, 2. Randomization was not done, as it could raise ethical issues, 3. All the patients were given the choice for either treatment and no motivation was given to any patient to opt for any particular treatment, still, observational studies are known for selection bias and this could exaggerate the results in favour of any particular treatment arm.

Pain Status

Table 1:- Comparison of Pain scores between both the groups at different timelines.

Timeline	Vertebroplasty (mean±sd)	Conservative (mean±sd)	p-values
Baseline VAS	8.09±0.539	7.6±0.598	0.031
1 month VAS	3.64±0.674	5.95±0.999	<0.05
3 month VAS	3.27±1.009	5.1±1.294	0.001
6 month VAS	3.09±0.831	5.15±1.424	<0.05

p<0.05 are significant at 0.05 level of significance

Table 1 shows a comparison of pain scores between both the groups. At baseline, a value of p=0.031 is obtained which shows that there is a statistically significant difference among the two groups on the measure of pain with the severity of pain is more in the Vertebroplasty group.

The p-values obtained at 1 month, 3 months and 6 months also indicate a statistically significant difference between the two groups on the measure of pain.

This shows better pain alleviation by vertebroplasty than conservative management and the maximum pain alleviation is in the first 1 month.

Disability Status

Table 2:- Comparison of Disability scores between both the groups at different timelines.

Timeline	Vertebroplasty (mean±sd)	Conservative (mean±sd)	P
Baseline RDQ	18.45±1.572	17.95±1.146	0.313
1 month RDQ	12.27±1.421	14.3±1.418	0.001
3 month RDQ	11.82±1.079	12.9±1.518	0.046
6 month RDQ	11.82±1.471	12.85±2.207	0.177

p<0.05 are significant at 0.05 level of significance

Table 2 shows a comparison of disability scores between both groups. At baseline, a value of p=0.313, which shows that there is statistically no significant difference among the two groups on the measure of disability.

The p-values obtained at 1 month and 3 months indicate a statistically significant difference between the two groups on the measure of disability. At 6 months period, there is statistically no significant difference between the two groups.

Vertebroplasty group performed better compared to the conservative group in disability improvement at 1 month and 3-month interval.

Table 3:- Comparison of pain and disability assessment in the two groups from baseline to 1 month,3 months and 6 months.

Treatment Group		Baseline	1 month	P	3 months	p	6 months	P
Vertebroplasty	VAS	8.09±0.539	3.64±0.674	<0.001	3.27±1.009	<0.001	3.09±0.251	<0.001
	RDQ	18.45±0.474	12.27±0.428	<0.001	11.82±1.07	<0.001	11.82±1.471	<0.001
Conservative	VAS	7.6±0.598	5.95±0.999	<0.001	5.1±1.294	<0.001	5.15±1.424	<0.001
	RDQ	17.95±1.146	14.3±1.418	<0.001	12.9±1.518	<0.001	12.85±2.207	<0.001

p<0.05 are significant at 0.05 level of significance

Table 3 Compares preop VAS score versus VAS score at one month, three months, six months from which it is evident that p-value < 0.001 in all postoperative period. Statistically, significant pain relief in the postoperative period which was maintained at the end of 6 months also has been obtained in both the groups.

The Mean±S.D values suggest that pain relief is higher in the vertebroplasty group and the maximum decrease in VAS scores occurred at 1 month after treatment initiation.

RDQ score at one month, three months, six months show statically significant reduction as compared to baseline, with p-value < 0.001 in all postoperative period show a significant decrease in disability scores in the post-operative period and it was maintained at the end of 6 months also.

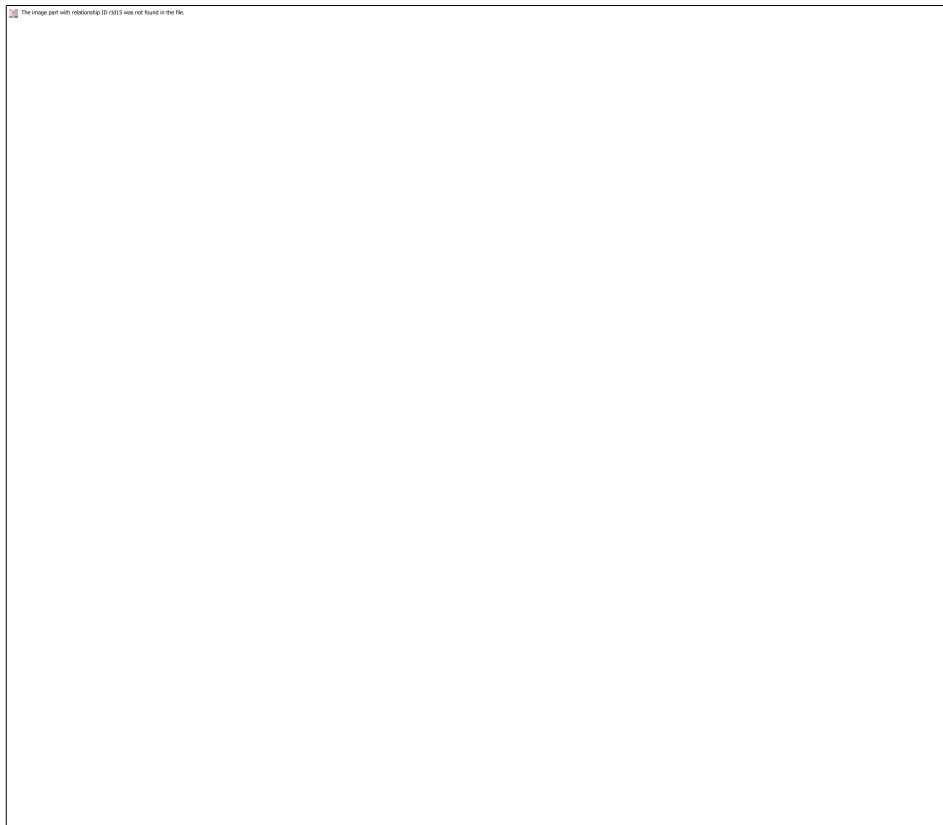


Figure 1:- Pre-procedure flouroscopy image showing the compression of L3 and L5 vertebral body.



Figure 2:- Confirmation of needle position before cement injection.



Figure 3:- Flouroscopy image showing cement in the veretbra.

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