Cement Vertebroplasty In The Elderly With Osteoporotic Vertebral Fractures. A Preliminary Study On The Change In Activity Of Daily Living After Treatment

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Background: To assess the effect of cement vertebroplasty on the activity of daily living of elderly patients who have sustained a vertebral osteoporotic fracture.

Patients and Methods: Seven patients with clinically significant and radiologically proven osteoporotic vertebral compression fractures suitable to be treated with percutaneous cement vertebroplasty were recruited. Evaluation was based on pre- and post-procedure activity by clinical documentation (including interview) and by a self-developed questionnaire (including quality of life).

Results: Following the procedure, 54% of patients resumed their activities of daily living with minimal pain while 46% of patients were able to do so without any pain ($p<0.05$). Up to 85% of patients did not require any form of medication ($p<0.05$) and 77% of patients were found to have no pain. In addition to that, almost 62% of patients were able to ambulate normally.

Conclusion: Percutaneous cement vertebroplasty appears to significantly improve the activities of daily living of elderly patients who have sustained vertebral osteoporotic fractures. It is also found to be a safe procedure which contributes to reduced usage of medication, immediate pain reduction and improvement in functional status of the patient.

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Introduction

Osteoporosis is a skeletal disorder characterized by compromised bone strength which predisposes an individual to an increased risk of fracture. It is the most prevalent metabolic bone disease and very often the cause of vertebral compression fractures in the elderly[1,2] which is associated with a wedge deformity predisposing to kyphotic angulation of the spine. Vertebral compression fractures are usually associated with acute pain which is frequently severe and functionally debilitating.[3]

It is estimated that 200 million women worldwide are affected by it.[4] In Malaysia, osteoporotic fractures have been identified as a major health problem particularly in the elderly.[5] As a result of osteoporosis, the high annual cost of healthcare, loss of productivity and quality of life has become a major issue that has to be dealt with.[5] Therefore, this study was done on the basis of evaluating the effects of a minimally invasive procedure that could provide internal splinting and structural support for a partially compressed vertebral body, with the goal of decreasing impairment and subsequent morbidity.

Currently there are various methods of managing osteoporotic vertebral fractures. Conventional methods of managing these fractures include relief of pain with narcotics, analgesics, NSAIDs, and immobilization followed by rehabilitation which is commonly done through mobilization with or without braces and subsequent exercise. Via this approach, pain is said to decrease significantly by 4 weeks to 3 months.[6]

With advancement in technology in recent times, stabilization of vertebral bodies has been attempted with the injection of polymethylmethacrylate (PMMA) bone cement into fractured vertebrae via a needle which is introduced percutaneously.[7-10] This procedure which is also known as percutaneous cement vertebroplasty has been noted to provide substantial pain relief[9,10] probably due to its ability to provide mechanical stabilization of the spine.[11]

Currently, the amount of literature on the benefits and effects of percutaneous cement vertebroplasty in the Malaysian context is found to be limited. The aim of this study is to assess the effect of cement vertebroplasty on the activity of daily living in elderly patients who have sustained a vertebral osteoporotic fracture.

Methodology

Patient Population

The population consisted of three men and four women with a mean age of 78 years (range 72-84 years). These patients had clinically significant osteoporotic vertebral compression fractures as defined by back pain

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with or without leg pain, with a radiologically proven fracture (compression and osteoporosis) and were seen between January 2005 and March 2007 (27 months). They had recurrent vertebral compression fractures occurring at different vertebral levels. Thirteen procedures were performed for both lumbar and thoracic fractures in these seven patients.

Patient Selection

These patients had significant medical co-morbidities, and were severely restricted in activity subsequent to sustaining the fractures. Patients whom conservative management had failed to provide relief were considered for this procedure. Patients who responded to conservative therapy were not considered. Patients with other pain causing conditions such as herniated disc, spinal stenosis, facet joint disease, or other spinal abnormalities not associated with the fracture were disqualified.

Percutaneous Cement Vertebroplasty Procedure

The procedure was performed with standard protocols for each patient. It was performed under sterile conditions with the patient lying prone on an angiographic table. Surgical disinfection followed by draping was then done. The site for each vertebral body to be treated was localized under fluoroscopic control and local anesthesia was administered to the respective site. On each occasion, a 10-gauge or 15-gauge needle was introduced into the vertebral body under fluoroscopic control. These needles were advanced into the vertebral body by using one of four possible approaches. They were advanced either through the bilateral transpedicular approach, latero-vertebral approach, latero-transpedicular approach or the latero-anteropedicular approach. Before the polymethylmethacrylate (PMMA) cement is introduced into the vertebral body, venography is conducted to ensure that the needle is within the confines of the vertebral body and to exclude needle placement directly within the vertebral body vein. PMMA cement is then injected under fluoroscopic control until (a) a hemi-vertebral or holo-vertebral filling is observed, (b) injection of cement into the vertebral body had reached its limit or (c) extravasations of cement into the veins or disc space was noted. Following the procedure, each patient is to be rested in bed for approximately one hour before being warded for at least a day. They are subsequently allowed to return home once they are able to ambulate.

Data Collection

The clinical profile of each patient and the details of the procedure performed were obtained from patient medical records. Data of each patient was obtained by a single researcher via a questionnaire that was specifically developed for the study. Pre procedural data was obtained on the day the patient first consulted the surgeon. Post procedural data was obtained a week to a month after the procedure during the patient's scheduled follow up appointment. The questionnaire included questions on the date and cause of the fracture, assessment of pain, usage of medication, ability to ambulate, quality of life and activities of daily living. Evaluation of pain was done via an evaluation scale: 1 = no pain, 5 = unbearable pain. Usage of medication was evaluated with a three point scale: 1 = narcotics, 2 = NSAIDs/analgesics, 3 = none. Ability to ambulate was evaluated with a 5 point scale: 1 = normal, 2 = ambulating but with minimal pain, 3 = limited movement with pain, 4 = wheelchair required, 5 = bedridden/unable to move. Quality of life was evaluated with a three point scale: 1 = normal, 2 = subnormal, 3 = bad. Activity of daily living was evaluated with a three point scale: 1 = able to perform, 2 = able to perform but with minimal pain, 3 = able to perform but with significant pain/unable to perform.

Radiographic Definitions

Regions of the vertebral column were categorized to simplify analysis. The categories were: thoraco-lumbar junction = T11-L2, lumbar spine = L3-L5.

Data Analysis

Descriptive statistics was applied to the data obtained from the questionnaire. Crude differences between means obtained pre and post procedurally of the different parameters assessed were obtained.

These differences were analyzed by the author for significant change using dependent t-tests.

Results

Each patient involved in this study met the pre-requisites set for the suitability to undergo the percutaneous cement vertebroplasty procedure.

The age range of the patient population was 72-84 years (mean age 78 years). 57% of the patients were women. The mean number of vertebral fractures per patient was 1.9 with 29% of patients presenting with multiple fractures. 43% of patients had recurrent vertebral fractures after treatment at different vertebral levels. 69% of patients suffered from at least one fracture in the thoraco-lumbar region while 31% presented with fractures in the lumbar region. 46% of patients suffered from fractures which were caused by falls while 54% had no known precipitating event.

Post procedurally, none of the patients were found to suffer from complications due to the procedure. There were no cases of death, permanent neurological deficit or symptomatic pulmonary embolism reported post procedurally.

Pain, Usage of Medication, Ambulation, Quality of Life and Ability to Perform Activities of Daily Living

Pre procedurally, the mean score for pain was 3.85 ± 0.55 while the mean score for the ability to ambulate was 3.54 ± 1.13. Both these parameters were measured using a five point scale. NSAIDs/analgesics were the most commonly used form of medication pre-procedurally. The mean score for quality of life was at 2.15 ± 0.38 based on a three point scale. Activities of daily was found to be disrupted significantly due to pain as the mean score was at 2.69 ± 0.48 based on a three point scale.

Following the procedure, there were improvements in the activities of daily living and usage of medication was found to have been significantly reduced ($p<0.05$). Up to 85% of patients did not require any form of medication after the procedure. 77% of patients had no pain on follow up visits while only 33% complained of mild pain. Pain in this context included pain in the legs which was experienced by some patients. Nearly 62% of patients were able to ambulate normally after the procedure.

As this study was done with the main purpose of assessing change in the activity of daily living following the procedure, it is encouraging to see almost 54% of patients resuming their activities of daily living with minimal pain and 46% without pain following the procedure. This result confirms the research hypotheses that cement vertebroplasty improves the activity of daily living of elderly patients who have sustained a vertebral osteoporotic fracture.

Discussion

Due to pain caused by osteoporotic vertebral compression fractures and the associated physical, functional and psychosocial impairment, quality of life is diminished significantly compared with age-matched controls.[12] This has led to the search for an ideal form of treatment which may alleviate these problems.

In recent times, approach to treatment of osteoporotic vertebral compression fractures has been through various methods. Despite the wide range of treatment modalities available, it has been found that current medical and surgical methods remain inadequate in treating pain and disability faced by patients who have suffering from osteoporotic vertebral compression fractures.[13]

Results

FUNCTIONAL STATUS	NO. OF VERTEBRAL LEVELS	PRE-PROCEDURE	POST-PROCEDURE
Mean pain score ± SD	13	3.85 ± 0.55	1.23 ± 0.44
Ability to ambulate	13		
Normal = 1		0(0)	8(8)
Ambulating but with pain = 2		3(6)	3(6)
Limited movement with pain = 3		3(9)	0(0)
Wheelchair required = 4		4(16)	2(8)
Unable to move/bedridden = 5		3(15)	0(0)
Mean score ± SD		3.54 ± 1.13	1.69 ± 1.11
Usage of Medication	13		
None = 1		1(1)	11(11)
NSAIDs/Analgesics = 2		10(20)	2(4)
Narcotics = 3		2(6)	0(0)
Mean score ± SD		2.08 ± 0.49	1.15 ± 0.38*
Quality of life	13		
Normal = 1		0(0)	10(10)
Subnormal = 2		11(22)	3(6)
Bad = 3		2(6)	0(0)
Mean score ± SD		2.15 ± 0.38	1.23 ± 0.44
ADL	13		
Able to perform = 1		0(0)	6(6)
Able to perform but with minimal pain = 2		4(8)	7(14)
Unable to perform = 3		9(27)	0(0)
Mean score ± SD		2.69 ± 0.48	1.54 ± 0.52*

**(p<0.05) compared to before percutaneous cement vertebroplasty*

Conservative management of osteoporotic vertebral compression fractures typically aims to relieve pain using NSAIDs and narcotics. In recent times, the use of pharmacologic agents to improve bone marrow density has also been receiving widespread acceptance.[14] In addition to medication, the use of functional braces to provide support has also been noted.[13] Despite these measures, they are not seen as a long term solution to the problems faced by the patient.

Surgical procedures to treat osteoporotic compression fractures are usually discouraged as there is difficulty in achieving adequate fixation of instruments within the structurally weakened bone. Besides the risks involved in surgery, post-procedure bed rest also poses added risks to the patient. With bed rest, the patient lacks physical activity which may predispose them deep vein thrombosis, pulmonary embolism and pneumonia. More importantly, the patient also rapidly loses bone and muscle mass as a result of inactivity.[15-18]

In view of the disadvantages of using the previously mentioned methods, percutaneous cement vertebroplasty offers another option in treating osteoporotic vertebral compression fractures. Based on this study, the ablility to ambulate and quality of life was improved, pain was reduced and there was resumption in the ability to perform activities of daily living without pain. Most significantly was the reduced need for medications after the procedure. Improvements in the ability to ambulate and reduction in the need for medication were also seen in other studies done.[10] These improvements were all attributable to the percuteneous cement vertebroplasty procedure.

Despite the positive outcomes of this study, there are limitations to it. Firstly, data was obtained from patient records which were based on the surgeon's interpretation of each parameter assessed in this study. There is a possibility that patients could have exaggerated or under-described the degree of benefit obtained from the procedure. Secondly, as each patient was assessed at different periods of time following the procedure, this could alter the outcome of the post-procedural assessment to a certain degree. The post procedural assessment depended on the scheduled follow up appointment which was determined by the surgeon. This duration varied from a week to a month post procedurally. Thirdly, the reliability of the questionnaire is not proven although it was based on a few different studies which also showed improvements after the procedure.[10] Lastly, as the patient population was small, the significance of the results is questionable.

As for the procedure itself, it is a well-known fact that the usage of polymethylmethacrylate for this procedure is safe as it is non-pyrogenic and non-mutagenic.[22] Despite the benefits, considerations for adverse effects must also be taken into account. Few studies on patients with similar fractures who underwent the procedure state that the complication rate is roughly between 5%-7% despite the no reports of complications during this present study.[19-21] Complications from this procedure are mostly medical and anesthesia related. It could also occur due to instrument misplacement, cement extravasation, adjacent level fracture and infection. Despite the possibility of complications, it is encouraging to know that no long term side effects of vertebroplasty have been reported since the procedure was first introduced in France in 1984.

In the hands of an experienced surgeon with appropriately selected patients, this procedure is known to be a safe and effective method of treating osteoporotic vertebral compression fractures. Patient satisfaction is also found to be high following the procedure.[22]

As osteoporotic vertebral compression fractures remains a public health issue especially among elderly patients in Malaysia and current evidence of the benefits of percutaneous cement vertebroplasty is lacking, further studies should be done to reaffirm the benefits of this procedure in comparison to other modalities available for the treatment of osteoporotic compression fractures.

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