

Vertebroplasty Update: A miracle for painful vertebral osteoporotic fractures or a clinical illusion.....

Sushant Ghate^{1,3}, Ashok K Shyam^{2,3}

PREVIEW:

Vertebral insufficiency fractures are most common type of fractures occurring in patients with osteoporosis [1]. Nearly two third are asymptomatic and rest one third presents with acute back pain [2]. Usually such patient present with acute back pain and radiographs showing evidence of osteoporotic fracture and are generally considered for vertebral augmentation procedure either vertebroplasty or kyphoplasty on failure of conservative management. But two recent randomized controlled trials performed by Kallmes Et al and Buchbinder Et al has introduced doubts in mind of treating physicians regarding these procedures for relief of pain in vertebral insufficiency fractures [3, 4]. These papers subsequently sparked a lot of controversy and many authors have pointed out limitations and deficiency in designs of these studies. This is a very important factor to analyse, which should be considered before these studies alter our treatment strategy.

REVIEW OF LITERATURE:

Buchbinder et al (2009) performed a multicenter double blind randomized trial in participants having osteoporotic vertebral fractures less than 12 months duration and unhealed as confirmed by MRI, randomly allotting them to undergo vertebroplasty or sham procedure. 35 underwent vertebroplasty and 36 were in placebo group [4]. At 3 months mean reductions in score for pain in vertebroplasty and control group were 2.6+/-2.9 and 1.9+/-3.3 respectively. They concluded that there was no beneficial effect of vertebroplasty in patients having painful osteoporotic vertebral fractures as compared to sham group at 1 week, 1 month, 3 month or 6 month after treatment [4].

Kallmes et al (2009) conducted a multicenter trial randomly assigning 131 patients who had one to three painful osteoporotic fractures to undergo vertebroplasty or a simulated procedure without cement (control group) [3]. Patients were allowed to cross over to other study group after

one month. They reported improvement in pain and pain related disability in patients having osteoporotic compression fractures was same in both vertebroplasty and control group with no statistical difference. At 3 months there was higher cross over in control group as compared to vertebroplasty group [3].

Contribution of these two studies is really appreciated. But many authors had found flaws in these two trials. We will try to look into literature about these drawbacks.

These two trials have included different subgroup of patients than we treat with vertebroplasty. They have included patients who had back pain less than 12 months which is far too long as far as pain is considered because this will be like performing a vertebroplasty in healed osteoporotic fractures as per Afshin et al (2010) and Bono et al (2010) [1, 5]. Natural history of vertebral fractures is that most will resolve in 4-8 weeks [6]. So according to Smith (2010) it is possible that many patients included in this study may be having old vertebral fracture or other chronic spinal pathology that is unlikely to respond to vertebroplasty [7]. In both studies candidates who refused to participate outnumber those who participated [1, 7, 8]. So it is possible that patients with more severe pain, who actually need vertebroplasty were excluded from study. It would have been better if we can know which candidates refused to participate in the study [1, 2, 7]. An intention to treat analysis should have performed for better assessment of the situation. According to smith (2010) patients having pain scale of 3 will improve 2 due to this selection bias likely to minimize the improvement in vertebroplasty group. As per Max Aebi (2010) in the study by Buchbinder et al 78 patients studied over 54 months in 4 unequal centers make the study questionable in terms of methodology and unreliable [8].

Next sham procedure in these studies involved injecting bupivacaine into the periosteum next to facet joint. It is known that medial branch facet block can cause relief of pain for about 15 weeks [9]. So as per Smith (2010) this could account for relief of pain in poorly selected elderly patients as most of the elderly are expected to have facet joint arthritis.

Kallmes et al did not perform MRI on all the patients and did bone scan without CT scan. As per Smith et al Kallmes might be targeting patients with arthritis or some other spine pathologies in few cases [7]. As per Afshin et al 2010 patients

¹Dept of Ortho. R N Cooper Municipal General hospital, Juhu, Mumbai

²Department of Orthopaedics, Sancheti Institute for Orthopaedics and rehabilitation, Pune Maharashtra, India.

³Indian Orthopaedic Research Group, Maharashtra, India

Address for correspondence: Dr Sushant Ghate
Dept of Ortho. R N Cooper Municipal General hospital, Juhu,
Mumbai, India. Email- ssushantghate@gmail.com

must undergo MRI or bone scan if MRI is contraindicated. MRI is necessary to detect marrow edema when no fracture line is seen on X ray^(1, 10).

According to Afshin et al (2010) lumbar vertebroplasty requires 11G needle with high pressure systems for injecting cement. But in these 2 studies 13 G needle and 1cc syringe was used for injection injecting about 2.8 cc cement. As per Afshin et al 2010 and smith et al 2010 this is less as compared to 4.1 cc cement injected in Vertos 2 trial and will not feel the cracks well^(1, 7, 11).

Several prospective studies and randomized and non randomized trials from 2000 to 2009 have shown vertebroplasty to be more effective as compared to standard medical care⁽¹²⁻¹⁹⁾.

Supporters of vertebroplasty like Afshin et al (2010) advice the procedure for patients with acute osteoporotic fractures less than 8 weeks who have uncontrollable pain and patients progressing to osteonecrosis and Intravertebral vacuum phenomenon (kummels disease) and they mention that MRI seems to be critical for patient selection demonstrating edema⁽¹⁾.

Vertos trial 2 which still awaits publication have included 202 patients randomized in 2 groups vertebroplasty and routine care demonstrated excellent pain relief in vertebroplasty group which remained significant at 1 year follow up⁽²⁰⁾.

According to Alvarez et al (2006) who assessed functional improvement in patients having osteoporotic vertebral fractures treated with vertebroplasty compared with non operative treatment there was significant improvement at 3 months follow up but there was no difference at 6 month and 1 year follow up⁽²¹⁾.

Vertebroplasty is not without risk. Nerve root compression and irritation, soft tissue damage has been described as complications of cement leak. Rarely pulmonary embolism, Respiratory, cardiac arrest and deaths have been reported^(22, 23, 24).

CONCLUSION:

We need to identify the subgroup of patients who may really get benefit from these vertebral augmentation procedures and is it really cost effective, using proper controlled studies. Given the limitations of the studies by Kallmes et al and Buchbinder et al it is difficult to determine that vertebral augmentation procedures should be no longer done. Our aim is to present all the recent literature regarding vertebroplasty to readers for their own judgement with different opinions presented side by side. But in the end do not forget that osteoporosis is the utmost important aspect to treat after an insufficiency fracture.

REFERENCES:

1. Gangi A, Clark WA. Have recent vertebroplasty trials changed the indications for vertebroplasty? *Cardiovasc Intervent Radiol* 2010;33:677-80.

2. Bolster MB. Consternations and questions about two vertebroplasty trials. *Cleveland Clinic Journal of Medicine* 2010 Jan;77(1):12-6.
3. Kallmes DF, Comstock BA, Heagarty PJ, Turner JA, Wilson DJ, Diamond TH et al. A randomised trial of vertebroplasty for osteoporotic spinal fractures. *N Engl J Med* 2009;361:569-79.
4. Buchbinder R, Osborne RH, Ebeling PR, Wark JD, Mitchell P, Wreidt C. A randomised trial of vertebroplasty for painful osteoporotic vertebral fractures. *N Engl J Med* 2009 Aug ;361(6):557-68.
5. Bono CM, Heggeness M, Mick C, Resnick D, Watters WC. Commentary: Newly released vertebroplasty randomised controlled trials: A tale of two trial. *The Spine Journal* 10 (2010);238-40.
6. Lyritis GP, Masasis B, Tsakalakos N. The natural history of osteoporotic vertebral fracture. *Clin Rheumatol* 1989;8(Suppl 2):66-9.
7. Smith SJ, Vlahos A, Sewell LE. An Objection to New England Journal of medicine Vertebroplasty articles. *Canadian Association of Radiologist Journal*. 2010 Apr;61(2):121-2.
8. Aebi M. Vertebroplasty: About sense and non sense of uncontrolled "controlled randomized prospective trials" *Eur Spine J* 2009;18:1247-8.
9. Manchikanti L, Singh V, Falco FJ. Lumbar facet joint block in the managing chronic facet joint pain: one year follow up of randomized double blind controlled trial: *Clinical Trial NCT. 00355914 Pain Physician* 2008;11:121-33.
10. Pham T, Azulay-Parrado J, Champsuar P, Chagnaud C, Legre V, Lafforgue P (2005) "Occult osteoporotic vertebral fractures: vertebral body fractures without radiological collapse. *Spine (Phila Pa 1976);30(21):2430-5*.
11. Klazen CA, Verhaar HJ, Lampmann LE. VERTOS 2: Percutaneous vertebroplasty Vs conservative therapy in painful osteoporotic vertebral fractures: A randomized controlled trial *BMC. Musculoskelet Disord* 9:156.
12. Macgraw JK, Lippert JA, Minkus KD, Rami PM, Davis TM, Budzik RF. Prospective evaluation of pain relief in 100 patients undergoing percutaneous vertebroplasty: results and follow up. *J Vasc Interv Radiol* 2002;13:883-6.
13. Zoarski GH, Snow P, Olan WJ. Percutaneous vertebroplasty for osteoporotic compression fracture: quantitative prospective evaluation of long term outcome. *J Vasc Interv Radiol* 2002;13:139-48.
14. Evans AJ, Jensen ME, Kip KE. Vertebral compression fracture. Pain reduction and improvement in functional mobility after percutaneous polymethylmethacrylate vertebroplasty retrospective report of 245 cases. *Radiology* 2003;226:366-72.
15. Groh JG, Matzner M, Trieb K, Krepler P. Minimally invasive stabilization of osteoporotic vertebral fractures: a prospective non randomized comparison of vertebroplasty and balloon kyphoplasty. *J Spine Disorder Tech* 2005;18:238-42.
16. Kallmes DF, SchweickMar PA, Marx WF, Jensen ME. Vertebroplasty in Mid and upper thoracic spine. *Am J Neuroradiol* 2002;23:1117-20.
17. Grados F, Depriester C, Cayrolle G, Hardy N, Deramond H, Fardellone P. Long term observations of vertebral osteoporotic fractures treated by percutaneous vertebroplasty. *Rheumatology (Oxford)* 2000;39:1410-14.
18. Legroux-Gerot I, Lormeau C, Boutry N, Cotten A, Duquesnoy B, Courtet B. Long term follow up of vertebral osteoporotic fractures treated by percutaneous vertebroplasty. *Clin Rheumatol* 2004;23:310-17.
19. Voormolen MH, Mali WP, Lohle PN. Percutaneous vertebroplasty compared with optimal pain medication treatment: short term outcomes of patients with sub acute or chronic painful vertebral osteoporotic fractures. The VERTOS study. *Am J Neuroradiol* 2007;28:555-60.
20. Klazen CA, Verhaar HJ, Lampmann LE. (2007) VERTOS 2: Percutaneous vertebroplasty VS conservative treatment in patients with painful vertebral osteoporotic compression fractures: rationale, objectives and design of multicenter randomized control trial. *Trials* 8:33.
21. Alvarez L, Alcaraz M, Perez-Higueras. Percutaneous vertebroplasty: Functional improvement in patients with osteoporotic compression fractures. *Spine* 2006;31:1113-8.
22. Weinstein JN. Balancing science and informed choice in decision about vertebroplasty. *Editorial N Engl J Med* 2009;361(6):619-21.
23. Childers JC Jr. Cardiovascular collapse and death during vertebroplasty. *Radiology* 2003;228:902-3.
24. Mathis JM, Wong W. Percutaneous vertebroplasty: Technical considerations. *J Vasc Interv Radiol*.2003;14:953-60.

Source of Support: Nil, Conflict of Interest: none