

Facet joint injections as a means of reducing the need for vertebroplasty in insufficiency fractures of the spine

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Abstract

Objectives Recent publications compared treatment of vertebral fractures reporting improvement in the majority but with no significant difference between the local anaesthetic and vertebroplasty groups. Potential explanations include placebo response or therapeutic response to the “control procedure”. We investigated whether preliminary facet joint injection can identify those patients whose pain arises from paravertebral structures rather than the vertebral insufficiency fracture itself.

Methods Patients referred for treatment by vertebroplasty were first offered local anaesthetic and steroid facet joint injection (FJI) at the most painful level. Those who failed to respond were offered a vertebroplasty.

Results Ninety one patients referred, 16 went straight to vertebroplasty. Sixty one of 75 were initially offered FJI. Twenty one were successful; two relapsed, had further FJIs with good results; three declined treatment; 5 had temporary benefit; 1 died from unrelated causes. Of 29 who failed to respond to FJIs, 24 underwent vertebroplasty and 23 had a successful outcome.

Conclusions A third of patients technically suitable for vertebroplasty responded beneficially to FJI. In this group

the pain mediator maybe one of instability and overload on the facet joints produced by adjacent wedge fracture. This protocol allows more selective and more successful vertebroplasty.

Keywords Vertebroplasty · Zygapophyseal Joint · Osteoporosis · Spinal Fractures · Fractures spontaneous

Introduction

Vertebral fractures resulting from minimal trauma are most commonly the result of osteoporosis, but maybe the consequence of osteoporosis induced by myeloma, myeloma deposits [1], metastatic malignant deposits in bone [2], haemangioma [3, 4] and other rare disorders of bone including osteogenesis imperfecta [5]. Patients referred with a history of osteoporotic vertebral fracture may be considered for percutaneous treatment after they have undergone a period of conservative management [6]. In the United Kingdom a period of 4 weeks conservative treatment before cement augmentation is required to comply with NICE (National Institute for Clinical Excellence) guidelines (<http://guidance.nice.org.uk/IPG12>). Conservative management normally consists of analgesia, including opiate medication and disability support. Whilst the majority of fractures heal within a few weeks, some do not respond to this management. Percutaneous vertebroplasty and variants including coblation vertebroplasty [7], kyphoplasty [8] and stent kyphoplasty [9] are methods of treating pain in patients who have failed to respond to conservative management of fractures. Vertebroplasty consists of percutaneous injection under image guidance of cement either Polymethyl methacrylate (PMMA) [10] or other compounds that provide structural support to the

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fracture. The treatment is intended to relieve pain. Numerous case series and some small un-blinded non-randomised controlled trials had shown this technique to be effective with success rates typically recorded between 75% and 85%. The United Kingdom NICE guidelines consequently determined that vertebroplasty was a technique that would be appropriate for treatment of patients with insufficiency fractures of the vertebra after a period of conservative management.

Two papers published in the *New England Journal of Medicine* in August 2009 compared randomised treatment in controlled trials [11, 12]. Our team was part of the INVEST study (INvestigational Vertebroplasty Efficacy and Safety Trial [11]). Both these studies compared the injection of local anaesthetic onto the posterior elements of the spine as a “control” procedure. The patients were either injected with local anaesthetic or underwent a vertebroplasty. If the clinician and the patient were not satisfied with the pain relief at the 1 month clinical follow up, they could cross-over to the other procedure. Neither the investigators performing the follow-up enquiries nor the patients were aware of which procedure was undertaken. Whilst both studies reported improvement in the majority of patients there was no significant difference in outcome between the local anaesthetic (“control”) group and the treatment group.

One possible reason for this result is that there is a significant placebo response to vertebroplasty and/or long lasting anaesthetic given that a substantial proportion of the patients were going to recover whatever the treatment. An alternative is that the “control” procedure provided a therapeutic benefit. The vertebroplasty procedure included local anaesthetic in the same region and if there was a response to this element of the treatment then both groups would benefit from this mechanism of pain relief. It was estimated that if approximately one third of patients treated by the “control” procedure were benefiting from the technique then the results might be explained assuming a modest placebo response.

When the pilot results were announced by the oversight committee of the INVEST study [11] before peer-review and publication, we were concerned that our vertebroplasty practice was possibly flawed and we could be exposing our patients to a potentially dangerous procedure, albeit with a low complication rate (approximately 1%). It was clear from our initial results in the INVEST study that we were successfully treating well over 80% of patients; however, it was not certain which part of the treatment was the more effective. We therefore reviewed our practice and elected whenever possible to offer patients who might be appropriately treated by vertebroplasty an initial local anaesthetic injection [1]. Only if they failed to respond would we proceed to

vertebroplasty. Our working hypothesis was that there was a significant group of patients who might respond to facet joint injection alone.

In this study we compare the pain scores before and after facet joint infiltration. For those who failed to respond we assess the effectiveness of subsequent vertebroplasty using the same criteria. Our hypothesis was that a proportion of patients with pain following vertebral insufficiency fracture do not have pain arising from the fracture itself.

Materials and methods We sought and received NHS Research Ethics written confirmation from the Chair of our local Research Ethics Committee that this study conformed to the principles of clinical audit giving approval to proceed. The data collection was identical for all patients in our practice within and outside the study group, therefore individual consent for the review was not considered necessary by the committee. However all patients attending our practice who received vertebroplasty were asked for written consent to the use of their anonymous data in research studies.

All patients treated in our practice are assessed before treatment decisions by a full clinical review and MR examination of the spine Table 1.

All patients underwent MR examination of the affected regions of the spine to include sagittal T1 weighted and Fast STIR (Short tau inversion recovery) plus axial T2 Fast Spin Echo images at the level of any fractures.

Those with vertebral fractures shown by MRI [4] at the site of the pain and technically suitable for treatment by vertebroplasty were included in our analysis. We then excluded patients when there was no oedema seen in the fracture using FSTIR MR sequences, where the complexity of the fracture or anaesthetic risks would prevent treatment by vertebroplasty and where the MR examination demonstrated fractures of the pedicles or articular processes of the facet joints.

Patients who have had previous successful vertebroplasty and present with a new fracture(s), those who have an unstable fracture(s) suitable for percutaneous treatment, those who have a fracture(s) caused by substantial trauma and patients with sacral fractures where there are no facet joints were offered vertebroplasty as a primary treatment and were not offered facet joint infiltration.

Patients offered facet joint infiltration included those with insufficiency fractures due to osteoporosis and osteoporotic pattern fractures associated with myeloma.

All other new patients to the practice who were considered clinically suitable for vertebroplasty were offered a facet joint injection in the first instance. After the injection they were asked to complete a pain diary,

recording pain levels at the following intervals: prior to the procedure, immediately after the procedure, one hour after the procedure, then at the end of days 1 to 3 and 2 weeks post procedure.

Facet injection

We reviewed the pain diaries at 2 weeks after facet joint injections. We used this data to determine the effectiveness

Table 1 Clinical pathway for patients referred for vertebroplasty

- 1) Referral for consideration of vertebroplasty.
- 2) Check that there is a recent MRI with STIR sequence?
- 3) If new fractures seen in clinic?
- 4) If no new fractures on MR refer back to referring clinician?
- 5) In clinic decide?
 - a. Are the fractures the cause of the pain?
 - b. Are there other medical conditions that may cause the pain?
 - c. Are there any medical conditions that might make procedures difficult?
 - d. Does the severity of the pain warrant the risks of treatment?
 - e. Can we safely treat the fractures?
 - f. Consider anaesthetic risks and if necessary obtain an opinion
 - g. Check that the underlying condition is being treated
 - h. If painful fractures warranting vertebroplasty pathway decide whether immediate cement augmentation is required
 - i. If so and patient consents book vertebroplasty procedure,
 - ii. If not and patient consents book facet injection.
 - iii. If patient does not consent write to referrer
 - i. If case does not warrant vertebroplasty pathway refer back to referring clinician
- 6) In clinic
 - a. Obtain consent for record keeping
 - b. Complete clinic pro forma
 - c. Record likely complexity of potential vertebroplasty and likely equipment requirements
- 7) Facet joint injections
 - a. Inject at level of pain—not the fracture
 - b. Periarticular injections are appropriate, use Bupivacaine and Triamcinolone, Record site of injection.
 - c. Issue pain diary
 - d. Check diary response—if not returned by 3 weeks telephone patient
 - e. If not helpful check with interventionalist and book cement augmentation
 - f. If recovered at 2 weeks discharge
- 8) Cement Augmentation
 - a. Book procedure and staff.
 - b. Ensure that equipment is ordered and onsite
 - c. Complete pain score and disability score before procedure
 - d. Undertake procedure
 - e. Telephone patient re progress at 2 weeks and record outcome, if potential complications contact interventionalist for decision
 - f. Arrange follow up appointment for 4 weeks
- 9) Follow up at 4 weeks
 - a. See all patient who have undergone cement augmentation in clinic
 - b. Complete pain score and disability scores
 - c. Decide with patient whether treatment has been effective
 - d. Exclude / treat complication of the procedure
 - e. Decide if MRI or CT is indicated
 - f. Decide if further procedures are necessary
 - i. Arrange these if necessary
 - g. Check again that treatment of underlying condition is underway—may need to write to GP
 - h. If further investigation or procedures not needed discharge to GP/Clinician or discharge recommending to GP to refer to another service.

and outcome of the treatment regime. However, the final decision as to whether the facet injection had worked was left to the patient who was contacted by one of the team and asked whether they were sufficiently improved to be discharged or whether they would prefer further treatment. Those who elected for further treatment were offered vertebroplasty.

Facet injection was performed using fluoroscopic control and aseptic technique with the patient in a prone position. The site of pain was identified with the patient's assistance when they were lying on the fluoroscopic table. The nearest pair of facet joints was identified. In cases of doubt the patient was asked to identify which level was most painful using manual palpation to demonstrate the potential injection sites. Using Lidocaine 1% local anaesthesia 21 gauge spinal needles were introduced by a direct posterior vertical approach to the posterior inferior recess of each joint until bone was reached. An injection of a non-ionic iodinated contrast agent (1 to 2 ml) was performed to exclude intravascular or intradural placement. Intra-articular or para-articular placement was accepted. Infiltration of 1 ml of Bupivacaine 0.5% and 20 mg of Triamcinolone Acetate was performed at each injection site. The patient was asked to return a 2 week pain diary using a 10 point visual analogue pain score.

The pain diary is usually an adequate measurement of whether a facet joint injection has worked but when the result was not clear to the patient or the member of our team contacting them patients were given the option of a further clinic appointment to discuss treatment options including whether they would like to have a vertebroplasty. At these appointments pain scores were obtained.

Vertebroplasty

Before the vertebroplasty patients were asked to complete a baseline questionnaire including a modified Roland Morris disability questionnaire (RDQ) [2, 3] and a pain score using a visual analogue scale between 0 and 10 indicating the patient's pain at its worst and best during the last week. Our clinic staff assisted elderly patients by oral questioning when there were difficulties with eyesight, language and understanding of the process. We measured pain and disability indices again at 1 month after the vertebroplasty procedure when patients returned for a further clinical appointment and used this data to judge overall outcome. We also recorded the patient's view as to whether they were sufficiently improved to be discharged or whether they would prefer further treatment.

Cement augmentation (in the main vertebroplasty but including stent vertebroplasty, kyphoplasty and coblation vertebroplasty) was undertaken at the level of active

fractures showing oedema on FSTIR MR images up to a maximum of three levels per procedure. Light general anaesthesia or heavy sedation was administered by an anaesthetist. The patient was treated in a prone position with powered C arm fluoroscopic control. The MR examination was used for planning on occasion supplemented by CT examination. Aseptic technique was employed. Lidocaine 1% local anaesthetic was infiltrated at the site of punctures. Twenty one gauge spinal needles were used to position further anaesthetic around the bone entry point and to ascertain a safe route of approach. Vertebroplasty needles were introduced normally by single parapedicular approach. Bipedicular or lateral oblique approaches were used when the parapedicular approach might be compromised by pedicle or vertebral morphology. Methylmethacrylate cement was injected under fluoroscopic control intending to achieve anterior central placement with end plate to end plate extension. The patients were treated as day cases and discharged within 4 hours of treatment. Follow up by telephone was undertaken at 2 weeks and then by full review in clinic at 1 month.

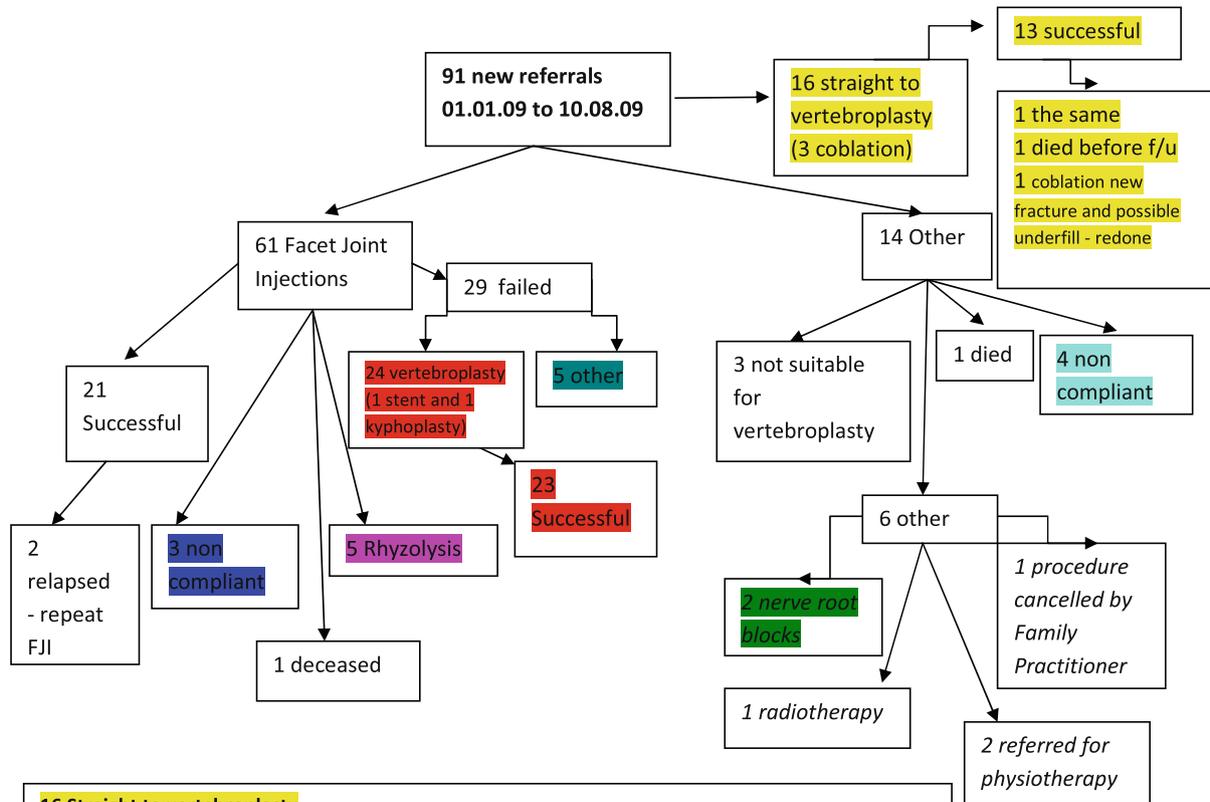
Results

Between the 01/01/2009 and 10/08/2009 91 patients were referred for consideration for treatment of osteoporotic fractures by vertebroplasty Table 2.

Sixteen patients went straight to vertebroplasty treatment—of these 13 were conventional vertebroplasty and three were coblation vertebroplasty procedures. Of these five were found to have metastases or discrete myeloma deposits, two were cancer patients who had already had a previous vertebroplasty, three had new fractures in previously treated patients who had had a successful vertebroplasty and who asked for vertebroplasty as the first line treatment. Two were young patients with traumatic injuries. Three patients had fractures of the sacrum and one had an old fracture with new oedema. Thirteen patients in this group of 16 had a successful outcome in terms of needing no further treatment after the vertebroplasty and a positive response on the Roland Morris disability questionnaire. Of the three patients who did not fulfill our criteria of a successful result, one patient had the same score on the Roland scale but chose not to have further treatment, one died from unrelated causes before follow up and one who had received a coblation vertebroplasty, sustained a new fracture at the same level and was treated by a second vertebroplasty procedure successfully.

Fourteen patients were not offered facet joint injection as the first procedure—Table 2. three were not suitable for vertebroplasty, one died before the facet

Table 2 Results



16 Straight to vertebroplasty
 3 vertebroplasty of sacrum – 2 successful, 1 under fill with cement (redone)
 2 former vertebroplasty and cancer patients – 2 success (1 had 2 vertebroplasty) both now deceased
 1 car accident – requested vertebroplasty not FJI - success
 1 fell off ladder, previously offered spinal stabilisation surgery – requested vertebroplasty - coblation - success
 3 new fracture previous vertebroplasty patients – 1 the same, 1 success, 1 refractured before f/u and 2nd vertebroplasty a success
 5 cancer patients – 2 successful (1 coblation), 1 died before f/u (coblation), 2 now in hospital but successful x 2 vertebroplasty
 1 old fracture, new oedema and kyphosis - successful

5 Rhyzylisis
 3 Failed
 1 died before procedure
 1 refused treatment

3 Non Compliance FJI
 1 relapsed and refused vertebroplasty
 2 did not return pain diaries

5 Other FJI
 1 referred to pain team
 1 no further treatment – new MR no active #'s
 1 agreed to no further treatment offered
 1 walking frame prescribed for kyphosis
 1 referred to physiotherapy

4 non compliant
 1 decided not to go ahead
 2 offered vert. but declined
 1 did not attend on day of vertebroplasty

2 Successful Nerve root blocks
 1 oedema in spinous process of L2 & L3 secondary to kyphosis
 1 lumbar sacral spinous processes

24 Vertebroplasty after FJI
 23 successful including 1 kyphoplasty (1 myeloma patient had 2 vertebroplasties, 2 patients refractured within 2 weeks and had successful second vertebroplasty)
 1 stent patient fractured either side of stent – had successful adjacent vertebroplasties.

joint injection procedure, four were non-compliant, two underwent nerve root blocks, one was treated with radiotherapy, two were referred for physiotherapy and one facet joint procedure was cancelled by the patient's family doctor—Table 2.

The remaining 61 patients were offered a facet joint injection as the first treatment. Sixty were patients with fractures due to idiopathic osteoporosis and one was a patient with osteoporotic pattern fractures associated with myeloma. The injections were performed bilaterally at the site of the patient's pain. In 37 this was adjacent to the level of the oedematous fractures identified using MRI, 12 of these were successful. In 24 where the injection site was more than two segments below the site of oedematous fractures nine had a successful outcome, one died before follow up, three were referred for physiotherapy, one was offered rhizolysis, nine went on to have a successful vertebroplasty and one died before vertebroplasty. In no cases was the injection site above the level of the fracture.

Twenty one of the 61 patients who underwent facet joint infiltration had a successful outcome as measured by pain scores and they declined further treatment. Two relapsed and were treated by a repeat facet joint injection with good results. Three elected not to have further treatment despite a poor pain response. Five recovered temporarily and were offered rhizolysis. One further patient died from unrelated causes before follow-up. Of the 29 patients who failed to respond to facet joint injections, 24 underwent vertebroplasty (including one kyphoplasty and one stent procedure) and of these 23 had a successful result. The one unsuccessful patient was the one who underwent a stent procedure and suffered adjacent fractures which were treated by additional vertebroplasties leading to a successful outcome. Within this group there was one myeloma patient with multiple osteoporotic pattern fractures who had two successful vertebroplasties, and two patients who re-fractured due to falls within 2 weeks and had successful second vertebroplasties. Five patients who failed to respond to facet joint injection were not offered vertebroplasty as there was clinical doubt that it would be successful. One was referred to the pain team; one was offered physical therapy, one was recommended a walking frame, one agreed to no further treatment and in one case a follow-up MR showed no active fractures.

Discussion

We have found the visual analogue measures of pain are more difficult to interpret as they are strongly affected by the analgesia and the patient's level of activity. They are

also influenced by the patient's pain threshold and personal perception of pain. One patient's score of six out of 10 could be another's 10 out of 10. There are issues with semantics, for example how does a patient define pain. Some regard a dull ache as pain whilst others do not. For pain scoring we would categorise both as pain but have to explain this to patients.

As a consequence we place weight on the patient's own view as to whether they feel further treatment is needed as a practical and probably more reliable end point. However, this measure can be influenced by the patients concerns that the proposed treatment may carry risk or discomfort and other psychological factors.

The modified Roland-Morris disability questionnaire (RDQ) is widely used to assess physical disability associated with back pain. Through experience we have found the patients who show an improvement in excess of 5 points are usually very satisfied with the treatment and we have found that this is a relatively reliable measure of success.

It seems to us that there are many patients in whom the biomechanical impact of deformity secondary to a vertebral fracture leads to sagittal imbalance and overload of facet joints, paraspinal muscles and occasionally impingement of spinous processes. We suspect that these factors are why patients may present with pain several vertebral segments away from the fractures identified on imaging.

It is possible that in a significant proportion of cases the pain mediator is one of instability and overload on the facet joints produced by adjacent anterior wedge fracture as biomechanical studies show increased pressure in the posterior elements as opposed to joint distraction.

Most studies describing the outcome of vertebroplasty and other forms of cement augmentation for painful vertebral fractures include all patients with a fracture in the region of the pain and do not consider that there may be more than one mechanism for pain generation. Criticism of the randomised trials published in the NEJM in 2009 [11, 12] has included comments on the patient selection, the longevity of symptoms and the study size. However the studies both showed very high levels of patient benefit well in excess of the rate that might be expected by placebo response or even selection bias. Some factor within the management of the control group was more effective than conservative management at a rate well above that which might result from placebo alone. Both vertebroplasty and control groups had local anaesthetic agents infiltrated around the posterior elements of the spine. If this is an effective pain management method in a proportion of patients then an overlap between the two groups might exist. Our study attempts to remove this group from consideration. The surprisingly high success rate from

vertebroplasty in the subsequently treated patients supports the hypothesis that vertebroplasty is a very effective technique when offered to patients who have the majority of their pain arising from the fracture itself.

In all cases the pain was at the level of the fracture or below. This supports the hypothesis that there is a biomechanical element to the pain arising from the posterior structures.

A potential weakness of the study is that we included patients with fractures due to osteoporosis and those with osteoporotic pattern fractures associated with myeloma. This was in part due to the difficulty of distinguishing the mechanism of fractures in undiagnosed fractures but also because we feel that the pain generating mechanisms are the same in these two groups.

This is a study of practice without randomisation or control procedures. As such we cannot exclude substantial placebo response. Similarly we cannot determine whether there are factors in the presentation, nature of pain or history that might predict response to local anaesthetic.

Summary and conclusion

Around a third of patients with pain associated with fractures will respond to facet joint injections. Whilst we can speculate that is the result of different mechanisms of pain and a placebo response we do not currently have a practical means of pre-selecting these patients.

If we offer facet joint infiltration at the level of pain to all patients we may reduce the need for more complex, expensive and potentially hazardous cement augmentation techniques. This approach offers the likelihood of higher than average success rates in those who are subsequently offered vertebroplasty.

There is need for further research to identify clinical and imaging factors that may define indication parameters more precisely.

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