

Vertebral compression fractures – best practice treatment



Case study and expert review by:

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demonstrating the balloon
kyphoplasty procedure.



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Introduction

Vertebral compression fractures (VCFs) can lead to chronic pain, disfigurement, height loss, impaired activities of daily living, pneumonia and psychological distress.¹ While many patients are asymptomatic, the presence of a VCF may be identified incidentally on radiography or on investigation when a patient reports abrupt pain onset with sudden position changes, e.g. coughing, sneezing or lifting heavier objects.

A population-based study of women² aged 75-80 years was undertaken in Sweden. Subjects were randomly recruited and completed a questionnaire related to back pain and physical disability, after which they were examined using dual-energy x-ray absorptiometry (DXA) to identify VCF. The prevalence of vertebral fracture was found to be 27% in this symptomatic population of older women, of whom one in five had severe fractures. Even mild fractures were associated with reduced physical function (30 seconds chair stand test, one-leg standing test, time to get up and go from seated to walking).

Usual care by primary care practitioners in Australia revealed that most VCFs were treated with opioid analgesics and only one in 10 was referred to specialist- or hospital-level intervention.³ Most fractures occur in the thoracic and thoracolumbar region and many can be addressed by conservative measures, including short bed rest, analgesics, bracing and exercises. However, up to 30% of fractures can develop painful, non-union progressive kyphosis and neurological deficit.⁴



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KEY MESSAGES

- Even mild VCFs are associated with inferior physical health and inferior physical function, including acute and chronic back pain
- Individuals with vertebral fracture due to osteoporosis have a fivefold increased risk of subsequent vertebral fracture
- Osteoporotic vertebral fractures constitute 50% of osteoporotic fractures worldwide
- Up to 30% of these fractures can develop non-union progressive kyphosis and neurological deficit
- In primary care practice, VCF is most commonly treated with opioid analgesics and only 12% are referred to specialist level, despite innovations in VCF resolution
- Balloon kyphoplasty (BKP) is an effective percutaneous option for healing painful cancer- and osteoporosis-related VCFs
- BKP has been shown to be safe and effective in randomised trials, systematic reviews, registry studies (retrospective and prospective) and South African clinical practice
- Comorbidities are common in patients with VCF and primary care clinicians need to be alert to the higher risk of VCF in patients with cancer, osteoporosis and Parkinson's disease. BKP can be performed safely in these patients, providing they are not immunocompromised or have underlying infection.

International experience with BKP

Interventions to reduce physical disability and pain from VCF

Conventional open surgery for vertebral fractures is associated with risk and is normally reserved for fractures with associated neurological impairment. BKP, introduced in the early 2000s, is a minimally invasive procedure that reduces pain, disability and vertebral deformity.

BKP involves using a catheter with inflatable bone tamps, which can be placed within the affected vertebral body. The balloon inflation compacts the cancellous bone and pushes the endplates apart. Once the balloons have been removed, the resulting space is filled with viscous cement to stabilise the vertebral body.⁵ (Click here to see the two-minute video) The procedure can be done under general anaesthesia or conscious sedation, as a day case or with an overnight stay.

When it was first introduced as an innovation almost 20 years ago, reports

of pain reduction and improved function were anecdotal. The most comprehensive randomised controlled trial comparing BKP to non-surgical care was the FREE trial among osteoporotic patients with 1-3 vertebral fractures from T5 to L5. At least one of the fractures had to show oedema when assessed by MRI or there had to be at least a 15% loss of height. Single fractures were to meet both these criteria. All 300 patients were included in the intention-to-treat analysis. Importantly, fractures were present only for a mean of 5.6 weeks prior to BKP (Table 1).

The grading of the fractures showed that the majority at baseline were Grade 2 or more (Genant assessment). Assessment of the procedure or non-surgical intervention was done at one, three, six and 12 months.

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Table 1. Patient characteristics of the FREE study

	Kyphoplasty (n=149)	Control (n=151)
Age (years)	72.2 (9.3)	74.1 (9.4)
Female	115 (77%)	117 (77%)
Underlying cause		
Primary osteoporosis	145 (97%)	143 (95%)
Secondary osteoporosis	2 (1%)	6 (4%)
Multiple myeloma/metastatic	2 (1%)	2 (1%)
Bisphosphonate use for stratification	49 (33%)	49 (32%)
Glucocorticoid use	26 (17%)	26 (17%)
Baseline fractures		
One	100 (67%)	115 (76%)
Two	34 (23%)	28 (19%)
Three	15 (10%)*	8 (5%)
Baseline fracture location†		
Thoracic (T5–T9)	49 (23%)	41 (21%)
Thoracolumbar junction (T10–L2)	127 (59%)	130 (67%)
Lumbar (L3–L5)	38 (18%)	24 (12%)
Treated fractures per patient		
None‡	10 (7%)	N/A
One	100 (67%)	N/A
Two	29 (19%)	N/A
Three	10 (7%)	N/A

Data are n (%) or mean (SD). N/A=not applicable. Groups were similar at baseline with the exception of multiple fractures.
 * One patient had a fourth index fracture identified between screening and planned surgery.
 † Kyphoplasty n=214, control n=195 (i.e., number of index fractures identified at baseline).
 ‡ Ten kyphoplasty patients did not receive surgery.

During the study, more patients in the control group received walking aids, back braces, physical therapy and analgesics during follow-up than did patients in the

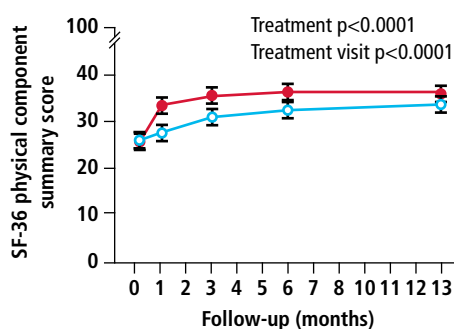
kyphoplasty group. Similar proportions of patients in each group received treatment for osteoporosis.

Advantages of BKP

This comparative trial showed that BKP patients treated with inflatable bone tamps and polymethylmethacrylate bone cement (the BKP delivery system) showed

significantly better improvement in the parameters of quality of life, disability and back pain (Figure 1).

A. Physical component (SF-36)

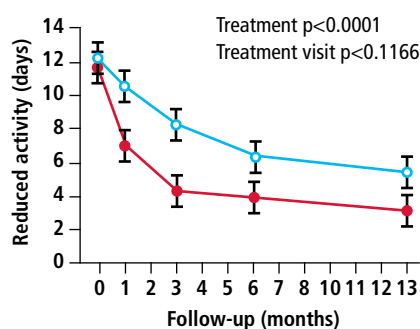


Number of patients with data available*

Kyphoplasty	143	136	131	127	110
Control	149	125	110	110	106

—●— Kyphoplasty —○— Control

B. Number of days spent in bed due to pain

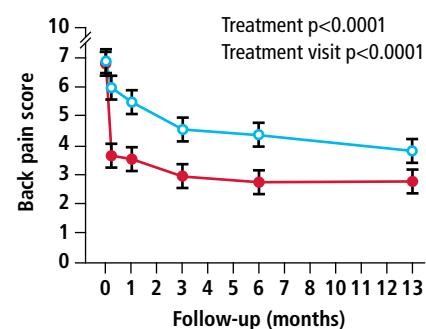


Number of patients with data available*

Kyphoplasty	146	128	126	125	117
Control	142	118	107	100	105

—●— Kyphoplasty —○— Control

C. Back pain scale



Number of patients with data available*

Kyphoplasty	148	137	156	132	128	121
Control	150	137	128	114	115	108

—●— Kyphoplasty —○— Control

Figure 1. Physical component, disability, and back pain at baseline and after kyphoplasty treatment or non-surgical care

(Amended from Ref 5)

Group calculated means and 95% CIs are shown for balloon kyphoplasty (n=149) and non-surgical control (n=151) groups for (A) the short-form (SF)-36 physical component summary scores (scale 0–100); where higher scores indicate improvement, while in B and C lower scores indicate improvement. (B) the number of days (within past 2 weeks) patients reported spending greater than half the day in bed because of back pain; and (C) back pain (0–10 scale; 0=no pain). The treatment by visit p value relates to a time-related change of this difference. A significant treatment by visit interaction indicates that the treatment effect difference is not constant throughout the year. *Numbers of patients with data available are shown to provide information about the amount of missing data that exists for each measure.

Table 2 summarises the benefits of treating painful, inflamed VCF with BKP.

Table 2. Benefits of BKP from randomised controlled trials

- Quality of life improved to age-matched normative values of women without VCF
- Physical function improved with 60 fewer days of restricted activity
- Back pain was significantly reduced
- Kyphoplasty patients used significantly less pain medication (opioid analgesics mainly) than the non-surgical group.

“Our BKP results are similar to the international experience and reflect the burden of our ageing population.”

Case Study

South African experience

Practical insights and a case study from a South African practice

In the past four years, Dr Jacobsohn’s practice has performed close on 200 BKP procedures.

“Our BKP results are very similar to those of the international published studies and reflect the burden of our ageing

population,” Dr Jacobsohn said.

VCF is underdiagnosed in South Africa and clinicians need to have a higher index of suspicion. Symptoms in clinical practice that should raise concern are summarised in Table 3.

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Table 3. Red flags that raise suspicion of VCF

- Back pain as a result of minor movement (coughing, bronchitis, turning in bed)
- Back pain in a post-menopausal woman who has never experienced back pain before
- Back pain on standing that is not experienced while lying in bed
- In patients with tumours and new back pain, the presence of pathological fractures should be investigated.

A guide to the inclusion and exclusion criteria for patients being considered for BKP is provided in Table 4.

Table 4. Guide to inclusion and exclusion criteria for referral of BKP**Inclusion**

- As soon as possible after diagnosis/high risk assessment by primary care practitioner (see case study too)
- In any age-group, except after an acute high-velocity fracture in a young person
- Osteoporotic fractures should be referred early to avoid kyphosis
- Patients who need to avoid analgesics such as opioids

Exclusion

- Immunocompromised patients
- Underlying infections
- Coagulation issues (warfarin, rivaroxaban or dabigatran)

“BKP performed by trained hands is safe, effective and minimally invasive.”

Conclusion

Dr Jacobsohn stressed that BKP performed by trained hands is safe, effective and minimally invasive. Leakage seldom occurs. This is particularly reassuring to primary healthcare practitioners

considering referral of a patient. The procedure does not require overnight hospitalisation and the patient returns home on the same day.

Clinical questions

1. In a Swedish cohort of older women (75-80 years), who experienced back pain and physical disability, VCFs were found in:

- A. 15% B. 27% C. 35%

2. In primary care practice, most patients with a VCF are treated with:

- A. Opioid analgesics B. Back braces
C. Physical therapy D. All of the above

3. In the FREE study, BKP using polymethylmethacrylate bone cement and the accompanying delivery device showed:

- A. Improvement in physical comfort scores
- B. Less back pain
- C. Less inactivity due to back pain
- D. A and B
- E. A, B and C

4. In the FREE study, the average age of the patients was:

- A. 60-70 years
- B. 70-75 years
- C. 75-80 years

5. Randomised clinical trials of patients following BKP have shown improved physical function:

- A. With 30 fewer days of restricted activity
- B. With 60 fewer days of restricted activity

6. Which of the following symptoms should raise an index of suspicion that your patient has a VCF?

- A. Back pain on minor movement
- B. Back pain in a post-menopausal woman previously pain-free
- C. Back pain on standing
- D. In patients with a tumour experiencing back pain
- E. All of the above

7. How early after a fracture and treatment with BKP has the evidence shown benefit of this intervention?

- A. 3 weeks
- B. 5-6 weeks
- C. 3 months

8. If a patient is on enoxaparin, should he/she undergo BKP?

- A. Yes
- B. No

9. If an elderly patient has diabetes and is on insulin, can he/she undergo BKP?

- A. Yes
- B. No

10. In which of the following situations should BKP not be done?

- A. Immunocompromised patients
- B. Severe anticoagulation issues
- C. Underlying infection
- D. All of the above

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Test your knowledge and approach in this case study

Patient: 55-year-old male

History:

- Patient picked up a water tank from the back of his pickup truck

- Experiences severe back pain
- No weakness in his legs
- Normal bladder control
- No medical history.

11. What would your initial management be?

- A. Treat only symptomatically with analgesia and anti-inflammatories
- B. Request plain X-rays

Expert comment

I have a high index of suspicion for osteoporotic or pathological fractures in this age group even with minimal trauma. Therefore suggest plain X-ray.



X-ray shows possible fracture of L5 vertebral body with a superior endplate

depression. This is deemed a stable fracture and there is no neurological risk.

12. What would your further management be?

- A. Continue with analgesia
- B. Check ESR and CRP
- C. Refer for MRI
- D. Check bone density

Expert comment

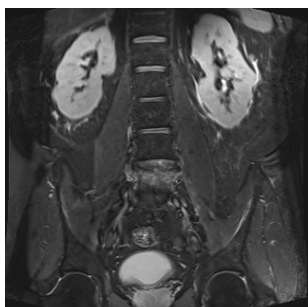
As there are abnormalities on the plain X-ray, further investigation is warranted. An ESR and CRP will exclude a pathological fracture and a spondylodiscitis. The latter is a contraindication for BKP. If the patient responds to oral analgesia and the septic markers are normal then referral for MRI is not necessarily a priority. It would be worthwhile, however, to check the bone mineral density as osteopaenia is underdiagnosed. If there is osteopaenia, it will raise the suspicion of an insufficiency fracture.

13. When would it be appropriate to refer for an MRI?

- A. Never, as the fracture will heal in his age group
- B. Failure on oral analgesia after a short period (1-2 weeks)
- C. Failure on oral analgesia after six weeks

Expert comment

Referral for an MRI would be advised within the first two weeks if his pain cannot be controlled. Because the literature shows the superior results from intervention through BKP, early referral will benefit the patient. Conservative management is acceptable, if the pain is controlled on oral analgesia and on assessment of bone density there is no osteopaenia.



14. When does an MRI change management?

- A. Shows surrounding soft tissue swelling
- B. Excludes neurological injury
- C. Determines the age of the fracture

Expert comment

A limited MRI (sagittal STIR and T1) will be able to determine the age of the fracture. Most of these patients have no neurological deficits and hence a full MRI scan will not add value. These fractures are normally stable and do not result in neurological injury. An MRI scan will show increased signal in an acute fracture on the STIR sequences, and lower signal on T1 sequences. This represents oedema within the vertebral body. If this is present, the patient is a candidate for a BKP. If these signal changes are absent, it means the fracture is either an old fracture or has reunited. BKP in such situations will not add any value.

15. How soon following a BKP procedure can the patient return to usual activities?

- A. The following day
- B. After two weeks
- C. After six weeks once the wounds have healed

Expert comment

The cement sets within four hours. Usual practice is that the patient gets discharged on the same day. There are no limitations on their activities. Most patients can return to work within 48 hours. As this is a minimally invasive approach done by a percutaneous needle, there are no wounds requiring a recovery period.

16. Do you wish to learn more about BKP and its use in South Africa?

- A. Yes
- B. No

If yes, a company representative with BKP training will contact your offices.

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