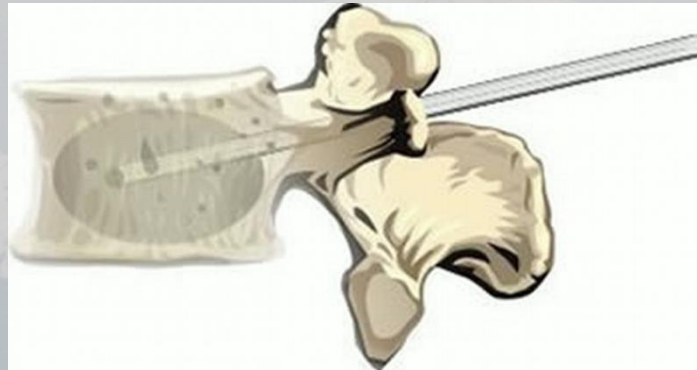


New Help For Back Pain

Percutaneous Vertebroplasty



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History of Percutaneous Vertebroplasty

- ✱ 1984 - First procedure performed¹
 - ✦ C2 vertebra with aggressive painful hemangioma
- ✱ 1989 - First procedure in osteoporotic VCF²
- ✱ 1990 - First Procedure performed in US
 - ✦ 2001 approx 38,000 procedures, by 2004 >100,000
- ✱ More than 450 articles on vertebroplasty published in the past 20 years

1. Galibert P, et al. Neurochirurgie 1987; 33:166—168 (Fre)

2. Lapras C et al. Ann Chir 1989; 43: 371—76

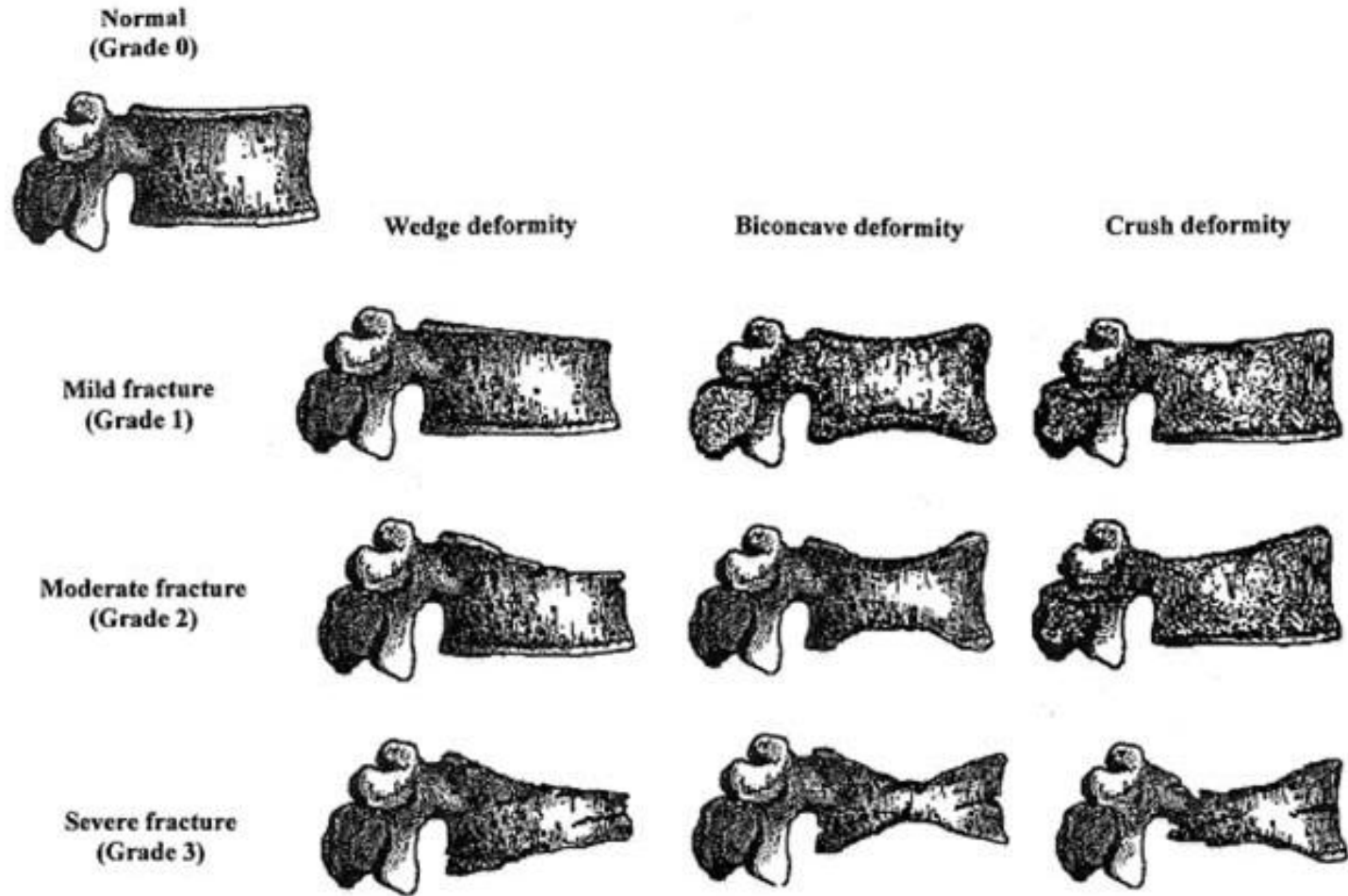
3. Voormolen MH et al. VERTOS study. Am J Neurorad 2007; 28: 555-60

The Problem¹ (USA figures)

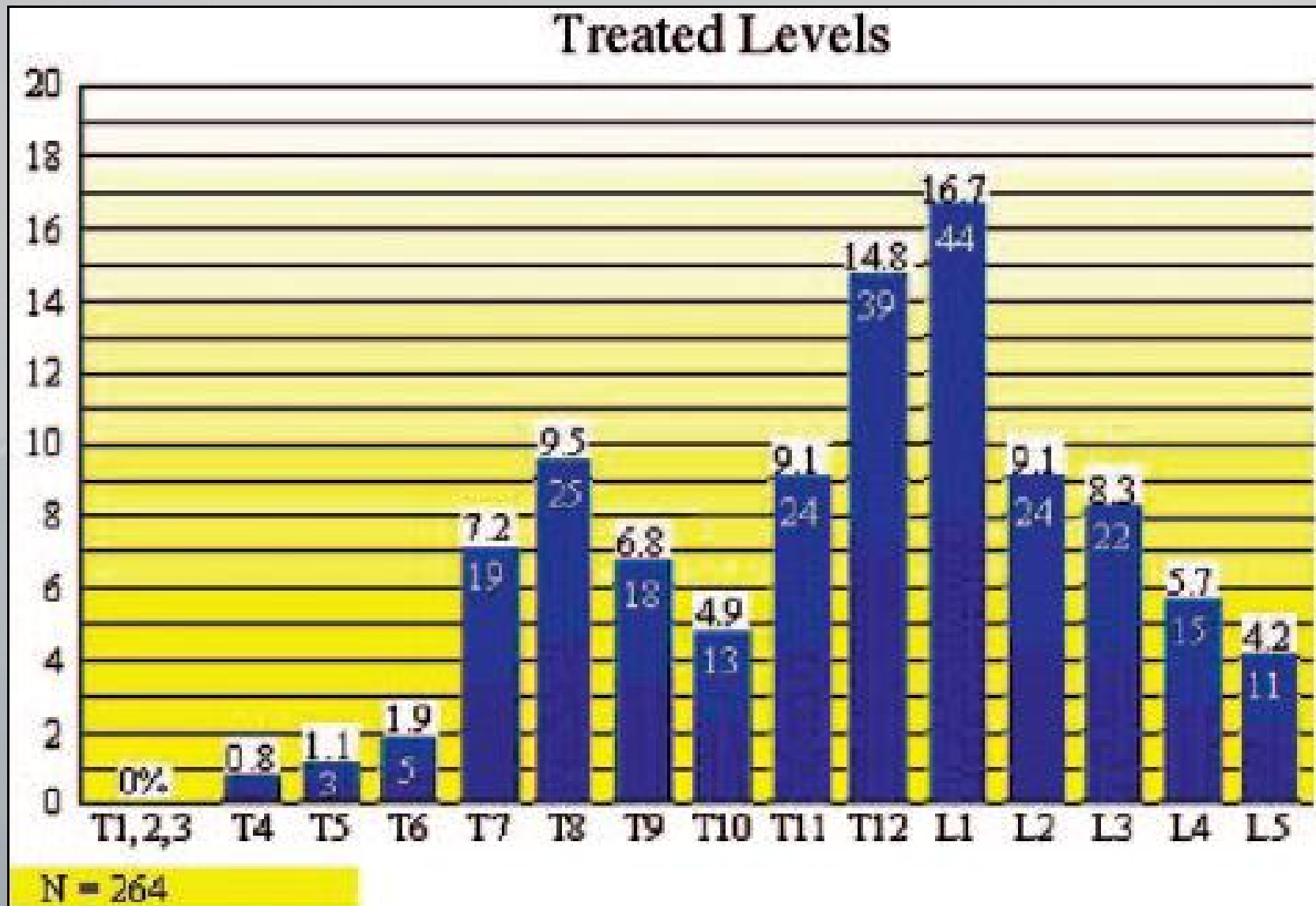
- * 1.5 million osteoporotic fractures
- * 700,000 Vertebral Compression Fracture's (VCF)
- * Between 8% and 50% of VCF's presenting for medical care require acute inpatient hospital care.
- * \$20 billion per year (2002)

1. Riggs BL, Melton LJ III: The worldwide problem of osteoporosis: insights afforded by epidemiology. *Bone* 17 (Suppl 5): 505S–511S. 1995

The Problem



✳ VCF's tend to cluster around T8, T12, L1 and L4



Vertebral Compression Fracture (VCF)

✦ Multi-disciplinary Team

- ✦ General Practice
- ✦ Geriatricians
- ✦ Rheumatology / Endocrinology
- ✦ Oncology
- ✦ Surgery (Orthopaedics, Neurosurgery)
- ✦ Radiology / Interventional Radiology
- ✦ General Practice

Presentation

- ✦ Sudden onset of back pain following routine activity or light strain
 - ✦ Lifting / Bending / Falling
 - ✦ Sneezing / Coughing / Turning over in bed
- ✦ Mid or Lower back pain
 - ✦ Localised with focal spinous process tenderness
 - ✦ Radiate anteriorly, mimicking chest or abdominal disease, or acute disc prolapse
- ✦ Severe(9/10) pain for 4-6 weeks

Treatment Options

- ✱ Medical Management

- ✱ Vertebroplasty

- ✱ Surgery

 - ✱ Kyphoplasty

- ✱ Radiotherapy

 - ✱ VCF secondary to malignant disease

Treatment

✦ Conservative treatment

- ✦ Bed rest
- ✦ Exercise and stretching programs
- ✦ Metabolic agents (calcitonin)¹
- ✦ Narcotic analgesia

✦ Most patients have a benign self limiting course of gradually resolving pain over 4 – 12 weeks

Conservative Treatment

- ✱ No consensus as to the best management and little published work on the subject
- ✱ No agreed guidelines on the minimum duration of conservative management
- ✱ Limitation of activity is unavoidable

Conservative Treatment¹

- * Immobilisation in elderly
 - ▲ ↓ Bone density
 - ▲ ↓ Muscle strength
 - ▲ ↓ Cardiac function
 - ▲ ↑ DVT and Pressure sores
- * Reduced mobility -independent predictor of;
 - ▲ Poor outcome at hospital discharge
 - ▲ ↓ activities of daily living
- * Elderly women with VCF have a higher mortality rate
 - ▲ 20 – 30% increase

Conservative Treatment

✦ The Study of Osteoporotic Fractures (SOF)¹

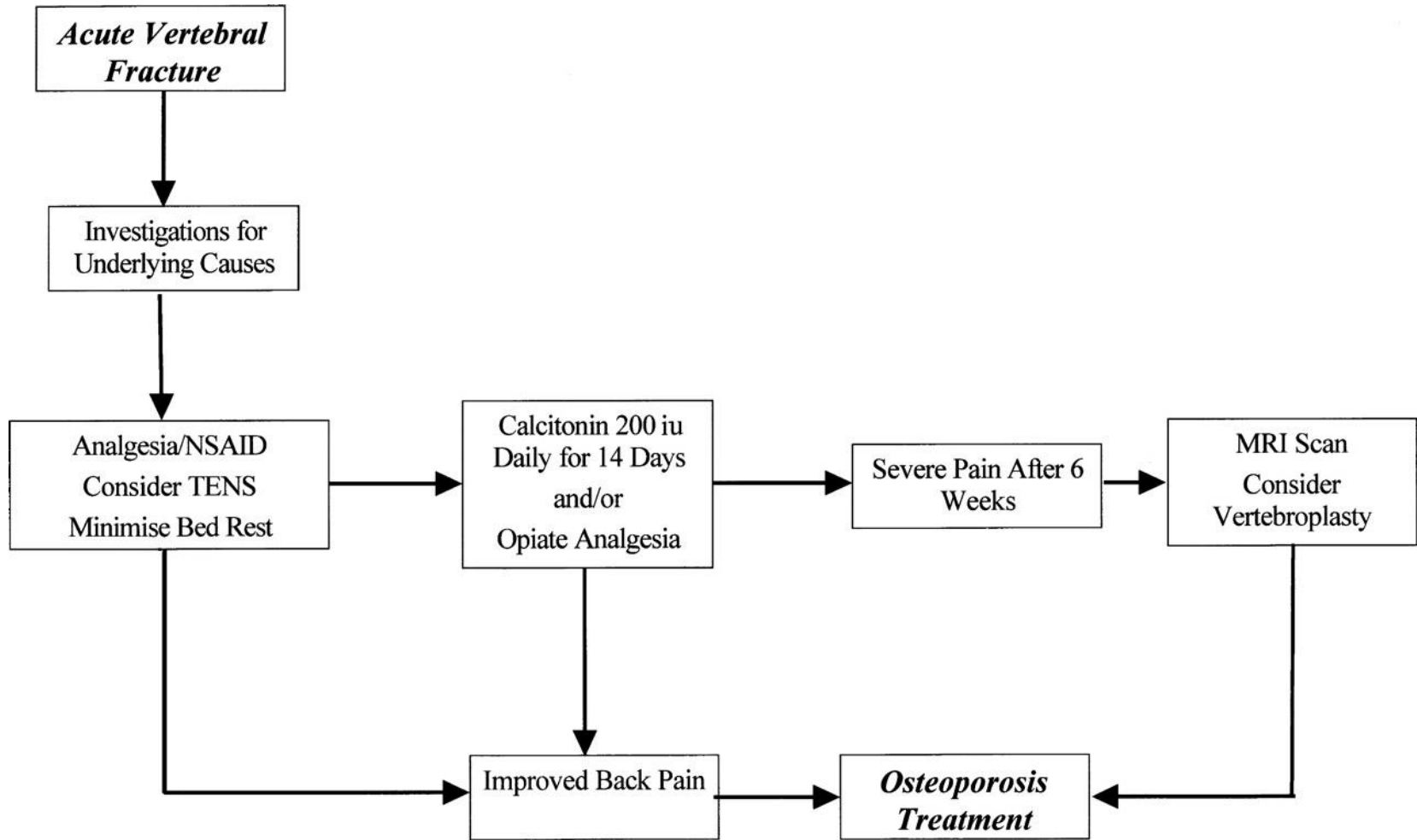
- ✦ increased disability
- ✦ pain
- ✦ fear for the future

✦ Symptomatic vertebral fractures²

- ✦ poorer sleep
- ✦ emotional problems
- ✦ poorer mobility

1. Nevitt MC et al. Ann Intern Med 1998; 128: 793 — 800

2. Scane et al. Osteoporosis Int 1999; 9: 91 - 97



Vertebroplasty - Treatment Goals

✦ Minimise pain.

✦ Restore activities of daily living

✦ Lower analgesic requirements

✦ Reduce morbidity

Patient Selection for Vertebroplasty

- ✱ Back pain secondary to VCF
 - ✦ Clinical examination and plain X-ray
 - ✦ MRI
 - ✦ CT & Bone scintigraphy
- ✱ Failure of 6 weeks conservative treatment
 - ✦ Up to 30% of patients with VCF develop chronic pain unresponsive to conservative therapy
- ✱ Patients hospitalised for refractory back pain
 - ✦ Vertebroplasty as a first-line therapy

Patient Selection for Vertebroplasty

- ✦ Best outcomes from vertebroplasty;
 - ✦ Severe debilitating pain (9/10) from osteoporotic compression fractures
 - ✦ Fractures less than two months old
 - ✦ Acute changes on MRI
 - ✦ Pain on palpation of the posterior spinous process at the fracture level.

Patient Selection for Vertebroplasty

✦ Malignant Disease

✦ Multiple Myeloma

✦ Painful metastatic lesion

Chronic VCF

* Fractures >12 months

- ▲ 'Activity' not always demonstrated on imaging

* Response rate variable

- ▲ 15-20% pain "gone" (50% with 'acute' VCF Rx)
- ▲ 50-75% pain "improved"
- ▲ Overall up to 80% 'some improvement' (90% 'acute' VCF)

* Mobility

- ▲ 50% improved activity (70% 'acute' VCF).

* No increase in complications

Pre-procedure Imaging

* MRI

- ▶ Looking for marrow oedema
- ▶ T2W / STIR

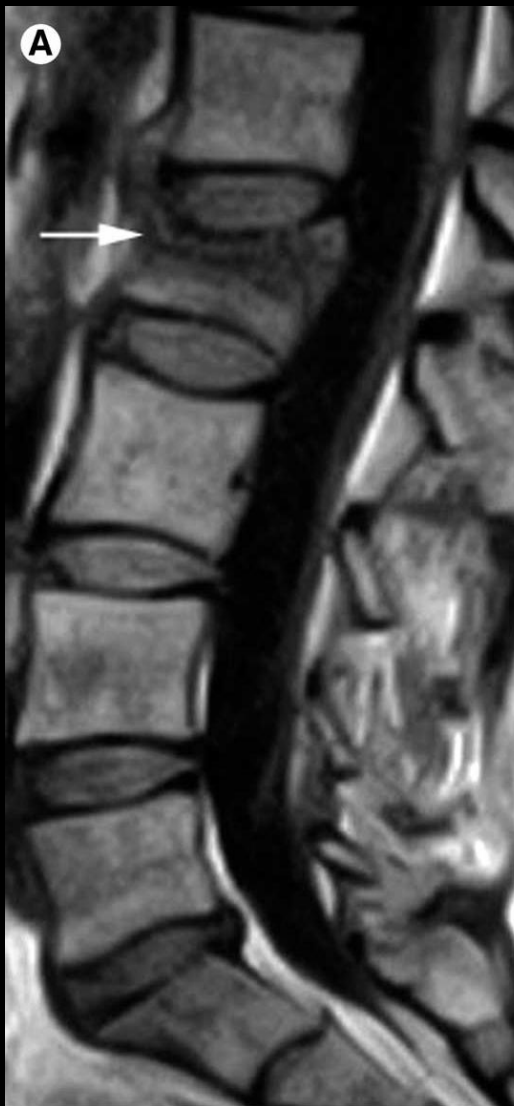
* CT

- ▶ If MR not available
- ▶ Better at assessing cortical disruption with mets

* Bone Scan

- ▶ Fracture 'activity'

TIW
MR
Spine



T2W
MR
Spine

L2 Vertebral compression fracture
with 'fracture activity'

Contra-indications

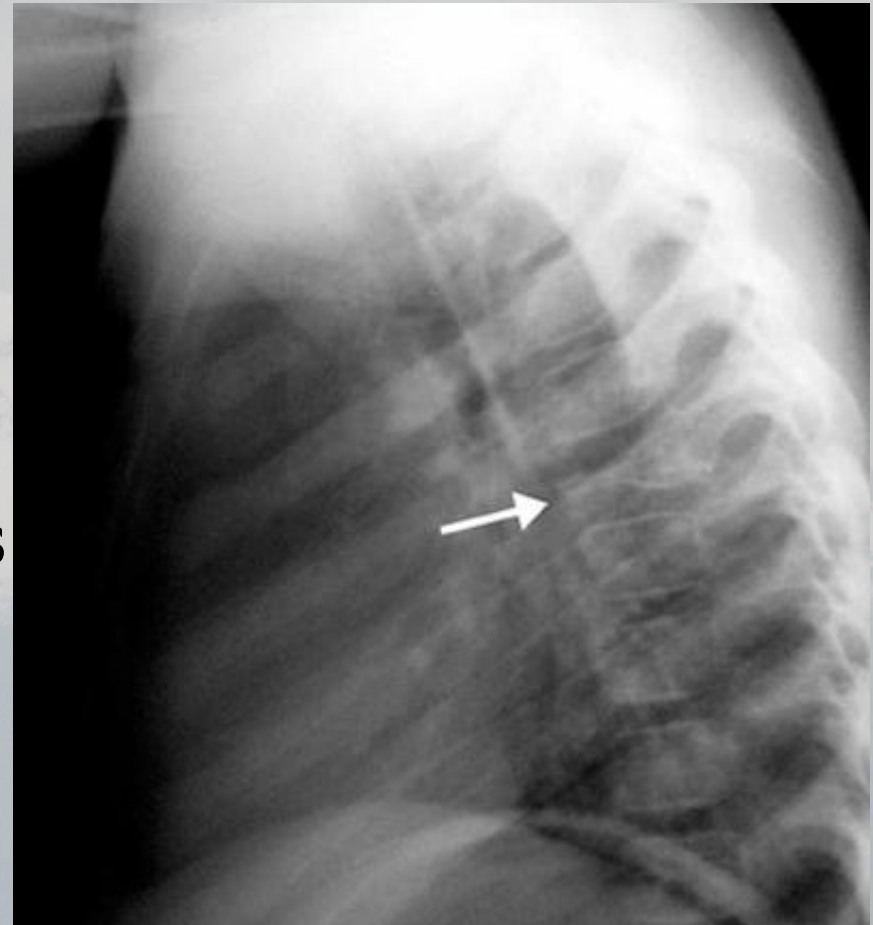
* Anti-coagulant therapy

* Infection

* Neurological symptoms

* Vertebrae plana

* Breach of posterior cortex / unstable fracture



Technique

- ✱ Local anaesthetic and Sedo-analgesia

 - ✧ Only occasionally General Anaesthetic

- ✱ Prone or slightly on their side

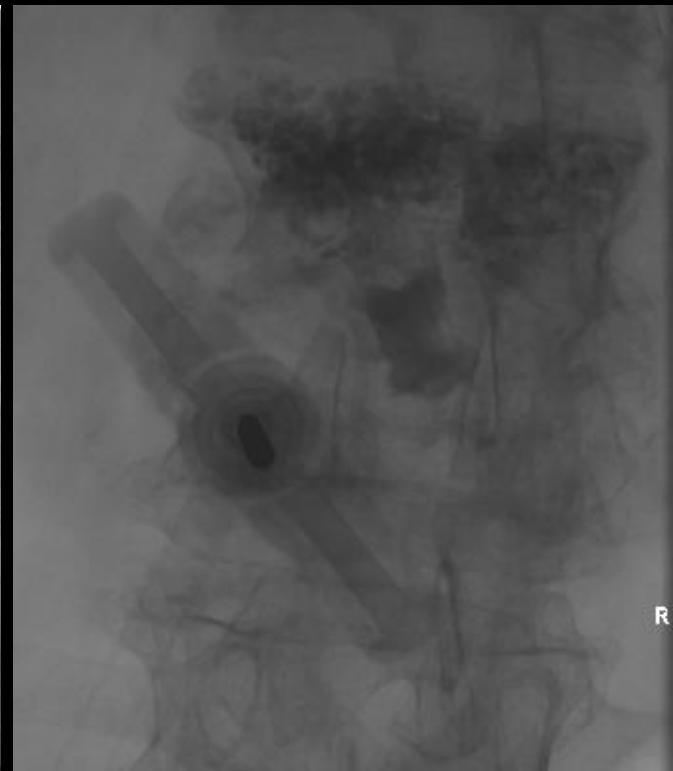
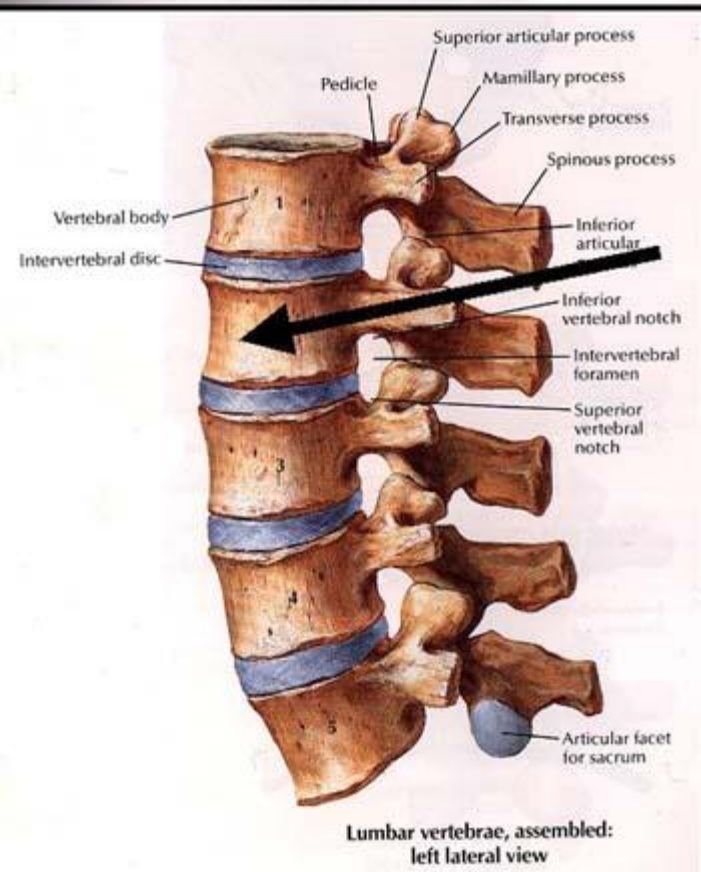
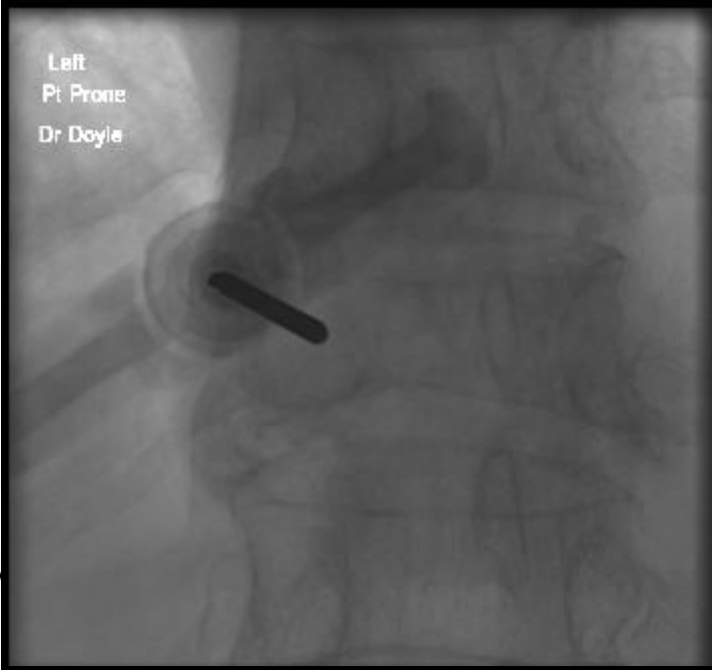
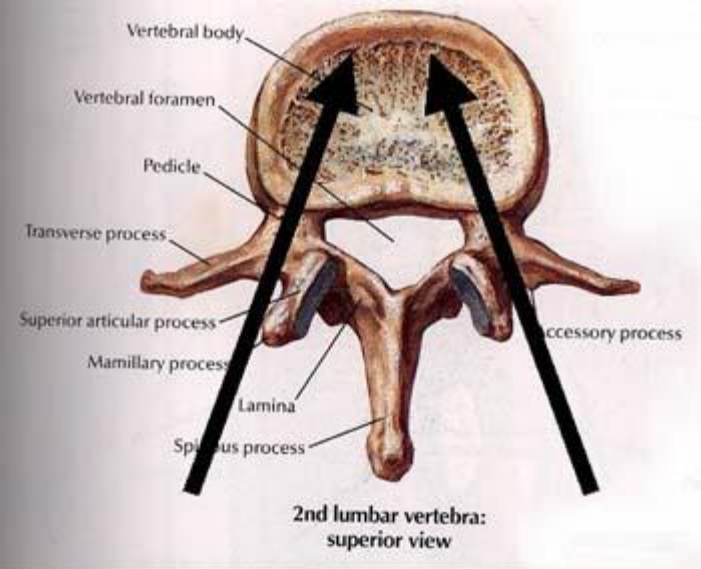
 - ✧ 60min procedure

 - ✧ 15 - 30min per level

- ✱ Flatten spine as much as possible

Technique

- ✦ 11 or 13 gauge vertebroplasty needle
- ✦ Needle to junction of middle and anterior third and to the midline.
- ✦ Uni-pedicular in preference to Bi-pedicular approach
- ✦ PMMA (polymethylmethacrylate)



✱ Total of 1 – 6ml cement per level

✧ Under constant fluoroscopic imaging

✧ Exothermic reaction (peak temp of up to 113°C)

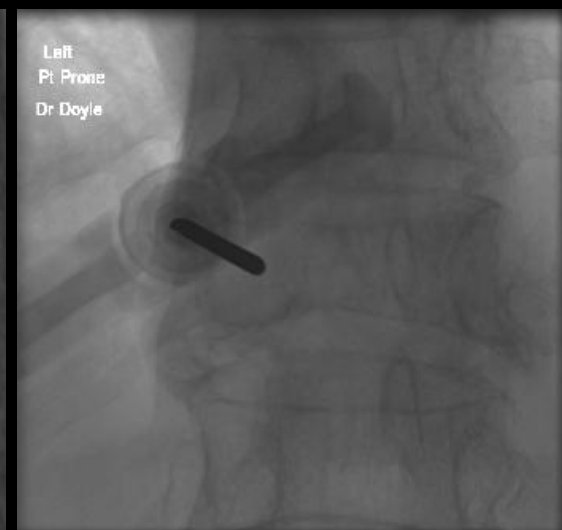
✧ No correlation between pain reduction and volume injected.

✧ Correlation to volume injected and complications – ‘overfilling’

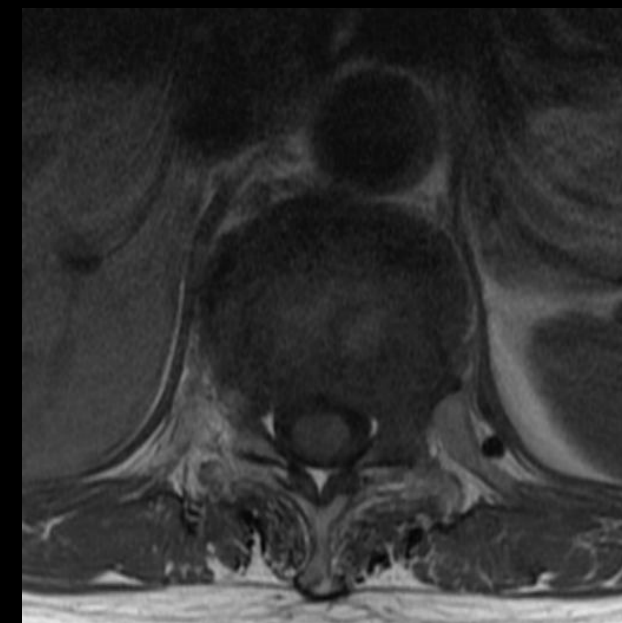
✱ 2 - 4 hr post procedure observation

✧ Can be performed as a day case.





**Malignant
VCF with
pain**



Mechanism of Action

✱ Mechanical stabilisation.

✧ Fixation of fracture

✱ Local thermal & chemical toxicity.

✧ ? To intra-osseous nerves & surrounding tissue.

Outcomes

- ✦ Consistent in > 100 studies over the past 20 years
- ✦ Significant improvement in 80- 90%
 - ✦ Pain score 8-9 /10 pre-procedure Vs 2 – 3/10 post^{1,2}
- ✦ Up to 25% can stop all analgesia at 24hrs
- ✦ Average in-patient stay (for acute #) 40% less when treated with PVP.

1. McGraw et al. J Vasc Interv Radiol 2002; 13: 883 - 886

2. Do et al. Am J Neuroradiol 2005; 26:1623 - 1628

Vertebroplasty VS Medical Therapy¹

- ✱ Palliative procedure
- ✱ Clinical outcomes similar at 6 - 12months
 - ✳ Benefit is in early control of pain
 - ✳ Early mobilisation
 - ✳ Reduced analgesic requirement
- ✱ Metastases / Myeloma
 - ✳ 70% pain relief
 - ✳ Case reports of tumour ablation

Outcome Data

- * Visual Analog Scoring (VAS)
 - ▲ Well validated assessment of pain control
 - ▲ No measurement of other symptoms and disabilities
- * Roland-Morris Disability Questionnaire (RDQ)
 - ▲ Well-validated and back pain-specific
- * Rest pain, activity pain, and RDQ score showed a significant decrease¹
 - ▲ 1 week, 1 month, 6 months, and 1 year post-vertebroplasty

Further Evidence

- ✱ Multicentre, randomised, double-blind, placebo-controlled trial of vertebroplasty for painful osteoporotic spinal
- ✱ Australia – expected publication date 2010
- ✱ US – expected publication date 2009
- ✱ Significant difficulty recruiting patients

Complications

✱ Very low (<1-10%)

✦ 1 % for osteoporosis

✦ 2.5% for haemangiomas

✦ 10% for neoplastic disease

✱ Worsening pain acutely

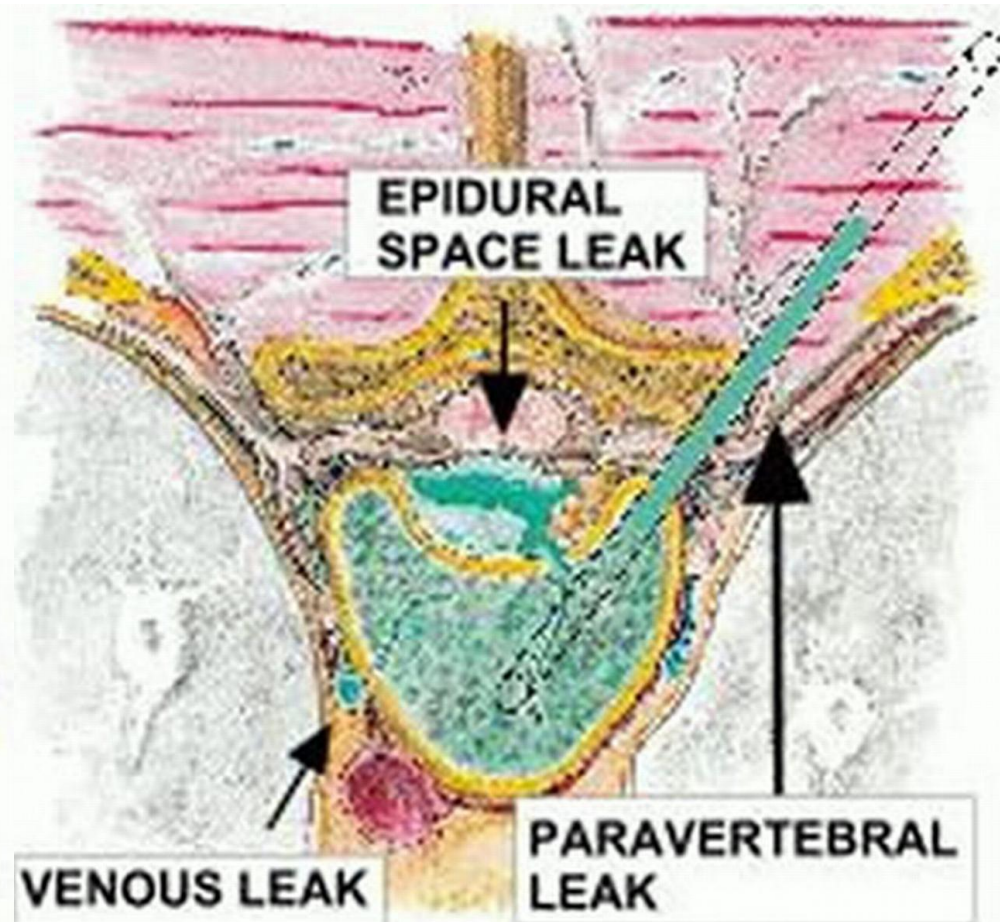
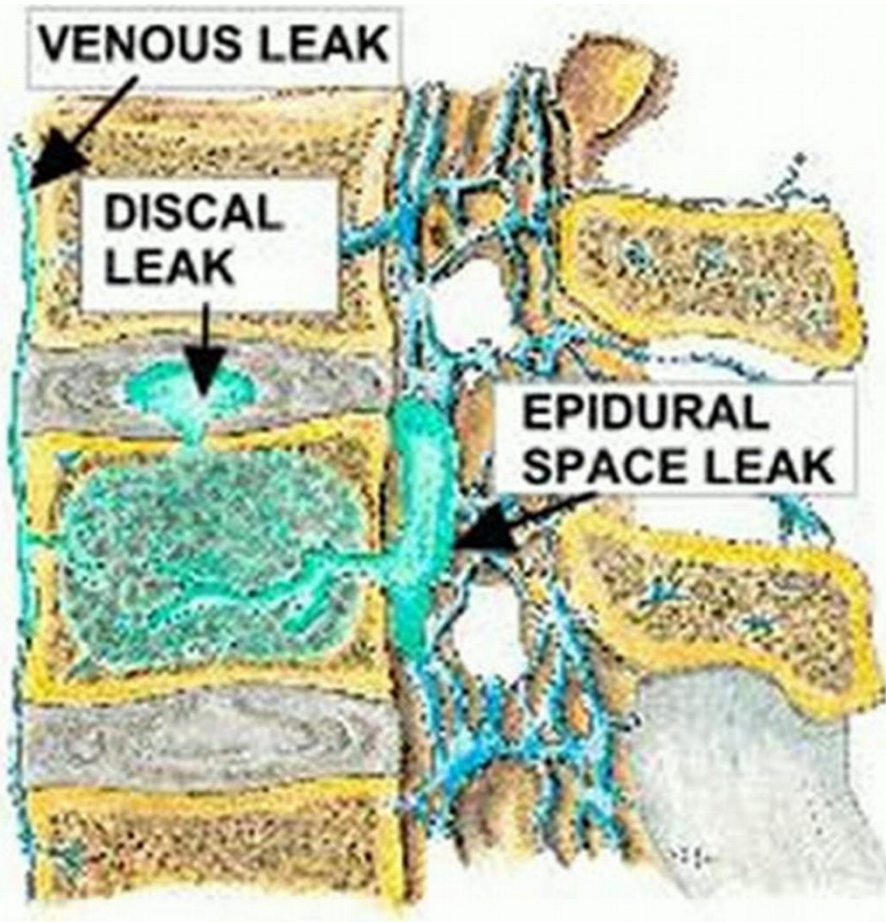
✦ Rare and transient, treated symptomatically

✱ Leakage of PMMA (polymethylmethacrylate)

✦ Epidural

✦ Para-vertebral

Complications - Cement Leak



Future Developments

✦ Biodegradable bone cements

- ✦ Calcium phosphate cement

- ✦ Remodels to bone

- ✦ 1 week to max strength

- ✦ Similar to PMMA

Conclusion

✦ In well selected patients vertebroplasty:

✦ Provides excellent pain relief and rapid re-mobilisation

✦ Good efficacy in up to 90% of patients

✦ Safe

✦ Reduces analgesic requirements

✦ Further long term follow-up required