Evidence-Based Medicine

骨科 R1 蔡沅欣 2013.3.18

Clinical Scenario

- 82 y/o male
- Fell down about 3 months ago, no significant discomfort, except mild back pain
- In recent 2 months, back pain progressed, bilateral lower leg weakness and numbness noted
- urine and stool incontinence (+)
- MRI showed L₁ burst fracture with spinal cord compression
- OP:
 - L1 laminectomy and decompression
 - T11-12, L2-3 posterior instrumented fusion
 - L1 vertebroplasty

Image study





MRI







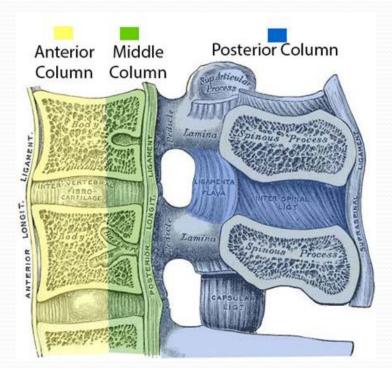
Post operation





Background knowledge

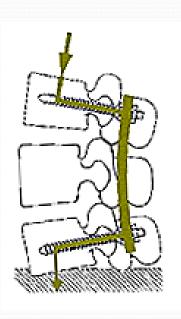
- Denis three column system
 - anterior column
 - middle column
 - posterior column



- Burst Fractures
 - vertebral fracture with compromise of the anterior and middle column

- Management of burst fracture
 - Nonoperative
 - bracing with a thoracolumbosacral orthosis
 - neurologically intact, mechanically stable
 - retropulsed fragments resorb and usually do not cause neurologic deterioration
 - Operative
 - Indication of surgical treatment
 - neurologic deficits with radiographic evidence of cord/thecal sac compression
 - unstable fracture

- Treatment of spine burst fracture
 - Operation
 - Neural decompression
 - direct: remove retropulsed bone
 - indirect: restore spine alignment by posterior instrumentation
 - spinal stabilization
 - instrumentation



Foreground question

 Whether vertebroplasty or kyphoplasty needed for burst fracture?

提出可回答的臨床問題(Asking)

PICO

Focus question for therapy

PICO

- P: patient with burst fracture
- I: vertebroplasty with surgical decompression and spinal stabilization
- C: surgical decompression & spinal stabilization
- O: spinal stability

搜尋最有用的資料(Acquire)

搜尋資料庫	Uptodate→ ACP journal → Cochrane → Pubmed
最初使用關鍵字	burst fracture, vertebroplasty
初步搜尋後修正 關鍵字(Key word)	由PubMed MeSH database的MeSH search找出同義 字或關鍵字上游較廣義的字彙
	Burst fracture, Spinal Fractures [etiology;*surgery], Vertebroplasty [contraindications;*methods],
搜尋設限(Limits)	Clinical Trial, randomized control trial, review

搜尋歷程

Summaries: Uptodate→ 1篇

Clinical manifestations and treatment of osteoporotic thoracolumbar vertebral compression fractures

Synopses: ACP journal→0 篇

Syntheses: Cochrane→ 2篇

Studies: Pubmed→ 67篇

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burst fracture vertebroplasty

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Clinical manifestations and treatment of osteoporotic thoracolumbar vertebral compression fractures

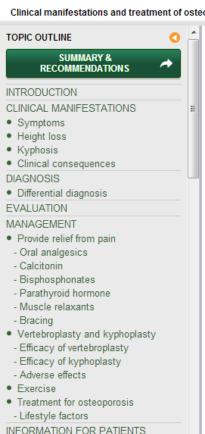








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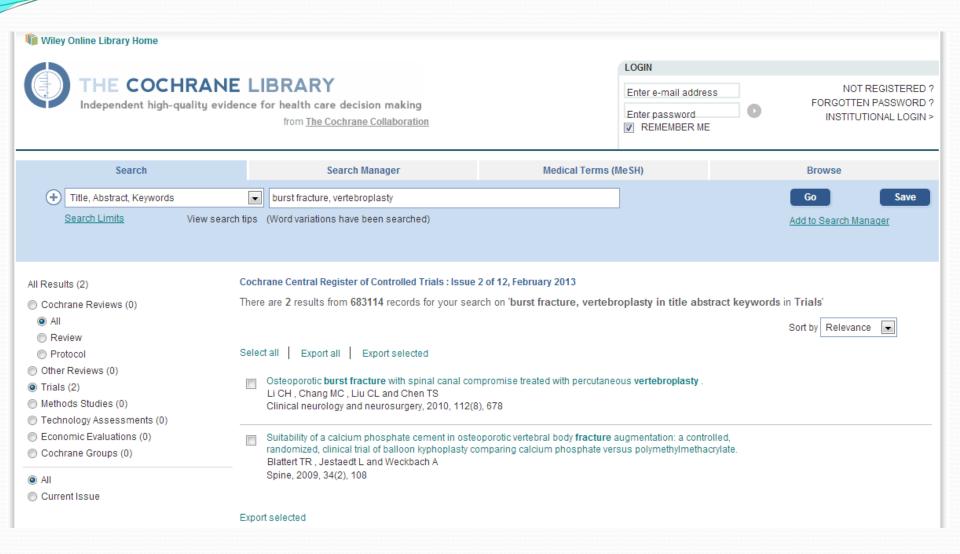
SUMMARY AND RECOMMENDATIONS Vertebroplasty and kyphoplasty — Vertebroplasty and kyphoplasty involve the percutaneous injection of bone cement under fluoroscopic guidance into a collapsed vertebra. Kyphoplasty also involves the introduction of inflatable bone tamps into the fractured vertebral body for elevation of the endplates prior to fixation of the fracture with bone cement [29]. These procedures are performed in an outpatient setting, although the optimal timing related to fracture acuity is unclear [30,31].

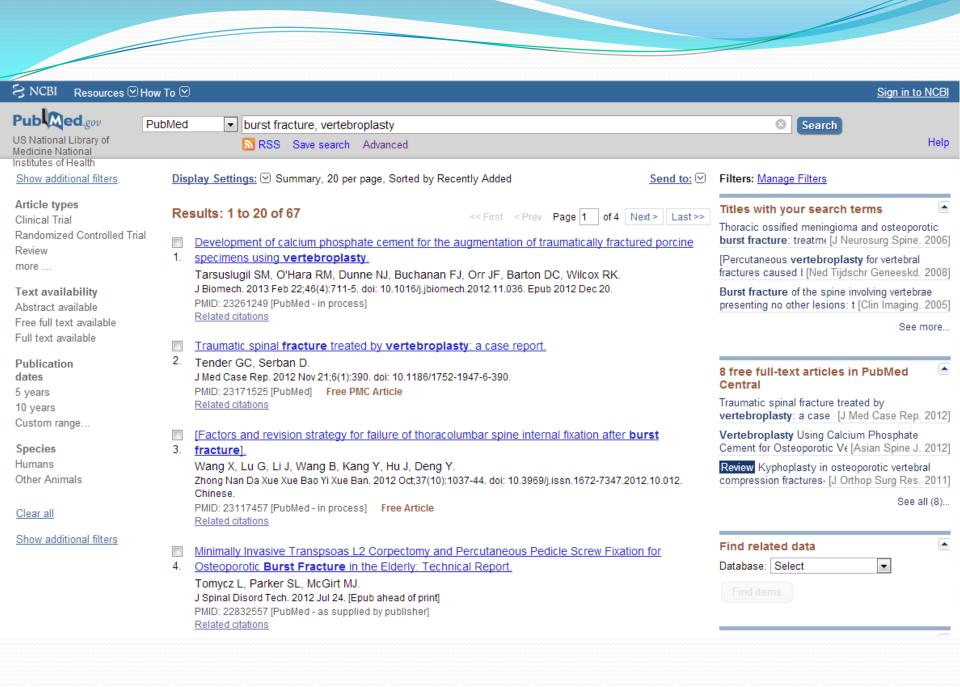
The potential short-term benefit for both procedures is improvement in pain, whereas potential long-term benefits include prevention of recurrent pain at the treated level(s), limitation or reversal of height loss and spinal deformity, and improved functional capability. Indirect comparisons based upon outcomes from case series indicate that both procedures provide equivalent pain relief, with more improvement in functionality and a suggestion of fewer adverse events (pulmonary emboli and neurologic sequelae) with balloon kyphoplasty [32,33]. In the only randomized trial comparing the two procedures, 100 patients with osteoporotic compression fracture were randomly assigned to vertebroplasty or kyphoplasty [34]. There was no difference in pain scores between the treatment groups at three days and six months [34]. The postoperative increase in vertebral body height (0.91 versus 0.31 cm) and the reduction in kyphotic wedge angle (8 versus 3 degrees) were significantly greater in the kyphoplasty group.

Short-term placebo-controlled (sham procedure) trials of vertebroplasty in patients with osteoporotic compression fractures have not shown a significant benefit in reducing pain [35,36]. In addition, a systematic review of eight trials comparing vertebral augmentation (seven trials vertebroplasty, one trial kyphoplasty) with placebo or standard medical care showed significant improvement in pain from baseline in both the treatment and control groups at 1, 3, and 12 months [37]. In the six trials that did not use a sham procedure (four of the six were funded by the device manufacturers), the reduction in pain at one month was better with vertebral augmentation than controls. However, the two sham-controlled trials, which provide the highest quality of evidence, did not show benefit of vertebroplasty, one kyphoplasty) reported similar findings [38]. Although the mean difference in the pain visual analog scale was statistically significant favoring vertebral augmentation (mean difference 0.73, 95% CI 0.35-1.10, and 0.58, 95% CI 0.19-0.97 for early [<12 weeks] and late [6 to 12 months] time points, respectively), the sham-controlled trials did not show a significant benefit of vertebral augmentation over control [38]. These trials are discussed in more detail below. (See 'Efficacy of vertebroplasty' below and 'Efficacy of kyphoplasty' below.) Additional trials evaluating kyphoplasty, particularly compared with a sham procedure, are required.

There are no trials that address long-term (beyond two years) benefits. In an industry-sponsored review of a Medicare database with 858,978 patients who had vertebral fracture, operative management with vertebroplasty or kyphoplasty was associated with a 37 percent lower mortality than non-operative management [39]. However, this was not a randomized study, and there are likely unmeasured patient characteristics that account for the observed difference. In addition, patients who received operative management might have been cared for more aggressively than the non-operative group.

We do not recommend vertebroplasty or kyphoplasty for the acute management of pain due to osteoporotic compression fractures. In most patients with osteoporotic vertebral compression fracture, the acute pain resolves gradually over four to six weeks and completely resolves within three months [40]. In some patients, the pain may persist beyond three months (sometimes due to paraspinal spasm). These modalities have not been adequately evaluated for the treatment of chronic pain.





Article acquired

Spine (Phila Pa 1976). 2008 Feb 15;33(4)

Direct reduction of thoracolumbar burst fractures by means of balloon kyphoplasty with calcium phosphate and stabilization with pedicle-screw instrumentation and fusion.

Korovessis P, Repantis T, Petsinis G, Iliopoulos P, Hadjipavlou A.

• OBJECTIVE:

To evaluate the outcomes of the treatment of acute thoracolumbar burst fractures by transpedicular balloon kyphoplasty with calcium phosphate cement and posterior instrumented fusion.

• SUMMARY OF BACKGROUND DATA:

In the surgical treatment of thoracolumbar fractures, the major problem after posterior correction and transpedicular instrumentation is failure to support the anterior spinal column, leading to the loss of correction and instrumentation failure.

• METHODS:

Twenty-three consecutive patients with an average age of 48 years, who sustained thoracolumbar A3-type burst fracture with or without neurologic deficit were included in this prospective study. Twenty-one of 23 patients had single fractures and 2 had each one additional A1 compression contiguous fracture. On admission 5 (26%) of 23 patients had neurologic lesion (5 incomplete, 1 complete). Bilateral transpedicular balloon kyphoplasty was performed with quick hardening calcium phosphate cement to reduce segmental kyphosis and restore vertebral body height and supplementary pedicle-screw instrumentation [long including 4 vertebrae for T9-L1 fractures and short (3 vertebrae) for L2-L4 fractures]. Gardner kyphosis angle, anterior and posterior vertebral body height ratio, and spinal canal encroachment were calculated before to after surgery.

謹慎的文獻評讀 (Appraisal)

效度Validity		
Randomization	NO	
Blind	NO	
Withdraw, incomplete or	NO	
loss to follow up >20%		
Intention-to-treat analysis	NO	
Enough participants	No, 23 patients were included	
(power calculation)		
證據等級Level of	Case series, Level 4	
evidence		

效益Impact		
Main result	All 23 patients were operated within 2 days after admission and were	
	followed for at least 24 months after index surgery. Operating time and	
	blood loss averaged 70 minutes and 250 cc, respectively. The 5 patients with	
	incomplete neurologic lesions improved by at least 1 American Spine Injury	
	Association grade, whereas no neurologic deterioration was observed in any	
case. Overall sagittal alignment was improved from an average pred		
	16 degrees to 1 degrees kyphosis at final follow-up observation. The ant	
	vertebral body height ratio improved from 0.6 before surgery to 0.9 (P <	
	0.001) after surgery, whereas posterior vertebral body height was improved	
	from 0.95 to 1 (P < 0.01). Spinal canal encroachment was reduced from an	
	average 32% before surgery to 20% after surgery. No differences in	
	preoperative values and postoperative changes in radiographic parameters	
	between short and long group were shown. Cement leakage was observed in	
	4 cases: 3 anterior to vertebral body and 1 into the disc without sequela. In	
	the last computed tomography evaluation, there was shown a continuity	
	between calcium phosphate and cancellous vertebral body bone.	
	Posterolateral radiological fusion was achieved within 6 to 8 months after	
	index operation. There was no instrumentation failure or measurable loss of	
	sagittal curve and vertebral height correction in any group of patients.	
Precise or	D value /050/ confidence intervalues above	
results	P value /95% confidence interval: as above	

Clinical bottom-line

Balloon kyphoplasty with calcium phosphate cement secured with posterior long and short fixation in the thoracolumbar and lumbar spine, respectively, provided excellent immediate reduction of post-traumatic segmental kyphosis and significant spinal canal clearance and restored vertebral body height in the fracture level in an equal amount both in the short and the long instrumentation.

J Bone Joint Surg Am. 2009 Jan;91(1)

Thoracolumbar burst fractures treated with posterior decompression and pedicle screw instrumentation supplemented with balloon-assisted vertebroplasty and calcium phosphate reconstruction.

→ The present study demonstrates that excellent reduction of unstable thoracolumbar burst fractures with and without associated neurologic deficits can be maintained with use of short-segment instrumentation and a transpedicular balloon-assisted reduction combined with anterior column reconstruction with calcium phosphate bone cement performed through a single posterior incision. The resultant circumferential stabilization combined with a decompressive laminectomy led to maintained or improved neurologic function in all patients with neurologic deficits, with a low rate of instrumentation failure and loss of correction.

是否可應用到此臨床個案上 (Apply)

臨床應用	我們的病患其主要疾病中是屬重症患者,接受本案討論的處置可獲得的療效屬 <u>高療效</u> ;有副作用的可能為 <u>低風險</u> 族群:。這項處置治療在本院做的可行性(feasibility):可行;部分健保給付是否有其他的選擇與相對成本利弊差異:有好處是否多於壞處:是 是否符合病人的期望(value):是		
醫療建議	綜合上面討論,我們的 臨床建議	我們建議給予病人脊椎固定與脊髓減壓 手術外,合併vertebroplasty以提升脊椎 穩定度與改善變型程度。	
	這樣建議的建議強度	Medium	

The End... Thanks