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**Percutaneous Vertebroplasty for pain relief in the management of
Compressive Vertebral Fractures.**

Vertebroplasty utilizing polymethyl methacrylate cement (PMMA, aka. bone cement) to enhance weakened vertebral bodies due to bony pathology has been in use since 1987. Deramond and Galibert (1987) were the first to report the injection of PMMA into the C-2 vertebra of a young female patient whose vertebra was infiltrated by an aggressive hemangioma. The patient's pain decreased significantly subsequent to the procedure. Vertebroplasty (PV) was later employed by others as an adjunct to internal fixation in the treatment of vertebral compression fractures due to metastases and primary bone tumors including hemangioma and giant cell tumors. The literature suggests that the primary purpose of this procedure is to reduce pain and to stabilize and strengthen the vertebral body. The procedure does not restore the height or the shape of the compressed vertebra.

Subsequent technical advances and improvements in instrumentation have increased its utilization. Vertebroplasty was introduced in the US in 1994. In May 2000, the Radiology department at Sunnybrook and Women's College Health Sciences Centre in Toronto offered vertebroplasty as a mean of treating intractable pain and pathological fractures due to osteolytic metastases, myeloma and osteoporotic vertebral collapse. In late 2002, the department of Radiology at the Vancouver Hospital began offering the same treatment. In its Issue no 31 (2002) on the Issues in Emerging Health Technologies, The Canadian Coordinating Office for Health Technology Assessment (CCOHTA) conducted a review on percutaneous vertebroplasty (PV) as a procedure for spinal pain relief.

Today's review from the WCB Evidence-Based Group is an attempt to summarize the majority of the published reports available. Within the literature itself, there is no 'summary' available, hence this communication to you.

Search strategy:

In order to identify and retrieve published studies on vertebroplasty, a search was done on the PubMed database by employing the keyword 'vertebroplasty' or 'percutaneous vertebroplasty'. Aside from limiting the search to human subjects and English only, there was no specific inclusion or exclusion criteria employed in this search. Only the latest up-date of repeated published studies by the same authors/group was included in this review.

Indications:

Ideally, PV should only be done among those patients:

- with severe non-radiating pain centered on or immediately adjacent to a diseased vertebral body
- where the pain is exacerbated by weight bearing or manual palpation
- with radiographic imaging that demonstrate an acute or subacute fracture of the vertebra body
- without significant wedging or kyphosis

Numerous experts indicate that careful patient selection is paramount to a successful outcome. Currently, other acceptable indications for the use of PV include:

- osteoporotic vertebral compression fractures ≥ 2 weeks (2 - 16 weeks) old in the cervical, thoracic and lumbar spine causing moderate to severe pain and unresponsive to conservative treatment
- painful metastasis and multiple myeloma with or without adjuvant radiation or surgical treatment
- painful vertebral hemangiomas or lymphomas
- previously irradiated eosinophilic granuloma
- painful vertebral fracture due to osteonecrosis
- reinforcement of a pathologically weak vertebral body before surgical stabilization procedure
- multiple compression deformities due to osteoporotic collapse on which further collapse would cause pulmonary compromise because of the deformity of the spine

It is hypothesized that PV reduces pain through:

- mechanical reinforcement at the fracture site. This may reduce pain by preventing further compression, deformity and micro-motion that may otherwise result in nociceptor stimulation
- the exothermic polymerization reaction of PMMA may damage pain-sensitive nerve endings within the vertebra and surrounding tissues
- leaching of non-reacted monomer may be neurotoxic, which contributes to the analgesic effect

Contra-indications

- absolute contra-indications:
 - osteoporotic fracture that is completely healed or is responding to conservative management (bed rest, oral/parenteral analgesics, muscle relaxants, external back-bracing or physical therapy)
 - spinal osteomyelitis
 - coagulopathy
 - sepsis
 - myelopathy
 - extensive vertebral destruction and collapse (vertebra plana)
 - presence of osteoblastic metastases
 - medical conditions that would make the patient ineligible for emergency decompressive surgery should it be necessary to treat a complication of the procedure

- relative contra-indications:
 - acute burst or high energy fracture
 - fracture > 1 year old
 - loss of vertebral body height > 80%
 - significant compromise of spinal canal by retro-pulsed bone fragment or tumor
 - multiple fractures with mild kyphosis
 - single fracture with significant kyphosis
 - involvement of posterior vertebral body wall

Outcomes (see Appendix 1):

Until March 2003, the results of PV have been reported in case series format only. There have been no published randomized/controlled trials comparing PV with conventional medical management of compressive vertebral fracture.

In various case-series reported on vertebroplasty (Appendix 1), pain relief was obtained in about 60% - 100% of patients. It was also reported that the mean pain reduction ranged from 50% - 100% of the pre-treatment pain score. The reason for this variability is probably due to the fact that patient selection and populations are different in various institutions. Pain relief was usually obtained within 7 days and often right after the procedure itself. Grados et al (2000) followed 25 post PV osteoporotic patients for 1460 days. At the end of that time period, they found that the intensity of pain was about half of that prior to PV being undertaken. Weill et al (1996) followed 37 post PV cancer patients for 180 days. After 6 months, 73% of patients had almost complete pain relief. In these series, the volume of cement injected varies between 1 and 20 ml.

Current advances show that it is technically feasible to do a 2 or 3 level PV from a single pedicular approach with the same cement mixture (Murphy KJ et al., 2002). Chung SK et al (2002) suggest that PV may be helpful in those patients with a radiculopathy as well. Gaughen JR et al. (2002) suggest that it is feasible to undertake numerous PV on the same vertebra.

Complications (see Appendix 2):

Toxicity of the PMMA has been reported in the literature in association with multiple different orthopaedic procedures. So far, no reports have been published in relation to PV, probably due to the small amount of cement injected and the small number of reported case-series.

Complications due to PV have ranged from transient fever to death due to cerebral or pulmonary embolism. The majority of complications are described as minor and transient in nature. Complication due to cement leak was the most frequently reported. The rate of reported complication varies from none to > 60%. There was a trend that older publications reported higher complication rates.

In a pooled series of 4087 procedures (among 2280 patients), the overall complication rate was about 10%. In general, complications occur in 23.9% among osteoporotic patients, 18% among cancer patients and about 4.6% among mix cases. There were 19 reported cases of pulmonary embolism and one case of cerebral artery embolism (out of 2285 patients).

It has been postulated that PV would increase pressure towards the adjacent vertebrae, thus resulting in the collapse of the adjacent vertebrae. In a series of 177 post PV patients, Uppin et al (2003) found that 22 (12.4%) of these patients developed a total of 36 new osteoporotic vertebral fractures following treatment. 24 (67%) of the 36 newly diagnosed fractures involved the adjacent of the previously treated vertebrae, while 12 (33%) were due to the collapse of the non-adjacent vertebrae. The event median time was 21 days post PV (mean \pm SD = 65 \pm 98 days). 24 (67%) of the 36 new fractures occurred within the first 30 days post-PV.

Cost:

Bone cement being used in PV has been available since the 1960s. A variety of PMMA bone cement is currently available from different manufacturers. In Canada, the supply cost includes cement (\pm \$66 per vertebra level) and a single use biopsy needle (\pm \$69) or a complete component to do 1-2 vertebra level for \pm \$450. Currently, various biodegradable PMMA substitutes are available or under development.

CCOHTA estimated that the physician and supply costs range from \$300 - \$600 per vertebra treated (in Canadian \$, excluding hospital and investigation costs). As of December 2002, BC-MSP did not have any specific fee item code for vertebroplasty. However, since April 2002, Ontario-MSP reimbursed \$148.10 for PV and \$174.05 for each additional PV (max. 3 per patient).

Kyphoplasty:

Kyphoplasty is a relatively newer procedure than vertebroplasty. It was developed in 1997 and has gained popularity since as the treatment option for osteoporotic compressive vertebral fractures. The technique involves the placement of inflatable bone tamps into the fracture vertebra. The balloon is then inflated to create a bone void and also to restore vertebral height. The premise behind this procedure is that more viscous bone cement can be injected under low pressure. Thus, a known volume of void can be filled. Watts NB et al (2001) and Lieberman IH et al (2001) note that variable height restoration can be achieved with this procedure. Even though both procedures share the same indications, kyphoplasty involves more complicated and expensive instrumentation than vertebroplasty. Kyphoplasty is not yet available in Canada that we are aware of.

One preliminary study (Lieberman IH et al., 2001) on the outcome of kyphoplasty showed complications in term of paralysis, epidural hematoma and transient fever and hypoxia occurred in about 1.2% of procedures. Cement leak occurred in about 8.6% of cases.

Conclusions:

- Low level (IV - V, i.e. case series and expert opinion) evidence shows that, with careful patient selection, PV can reduce pain due to compressive vertebral fractures. The best candidate for PV appears to be those patients with severe non-radiating pain centered on or immediately adjacent to a compressed vertebral body accompanied by imaging evidence of a new or progressive vertebral compression fracture.
- At present, there are no randomized controlled trials (RCT) that demonstrate any benefit of PV over conventional medical management in reducing pain due to compressive vertebral fractures. Given the relatively low cost of the procedure and the relative effectiveness in reducing pain, there may not be many RCT against conventional medical management being conducted. There is one randomized controlled trial listed in the National Research Register, UK, entitled 'A randomized controlled trial of vertebroplasty for the treatment of osteoporotic vertebral crush fracture'. The study is being conducted from May 2002 - May 2004. No further information is provided about this trial at present.
- Given the above evidence on the relief of pain, either immediate or during follow-up, it is important to take into account the fact that:
 - patients in these series were more likely to get the treatment at the height of their pain. It is well known that, across time, this pain may subside due to the natural course of the disease process itself. Thus, a 'regression toward the mean' phenomenon may be involved in the observed pain reduction during follow-up
 - placebo effect is well known in the area of pain study. The placebo effect cannot be measured at all in a case series due to the lack of controls

At present, there is no long-term study available nor is one planned (that we are aware of) that has or will look at the potential long term adverse effects of this procedure.

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Appendix 1: Summary on Outcomes.

<u>Osteoporotic patients</u>										
First author	Kallmes DF	Cortet B	Jensen ME	Barr JD	Peters KR	Grados F	Cyteval C	Maynard AS	Ng PP	Lin DDM
- No of patients	63	16	29	47	42	25	20	27	40	75
- Outcome: Pain – VAS										
* mean pain reduction	82.5%	88%			84%	57%				
- % patient with complete pain relief			90%	85%			75%	93%	75%	94%
- Outcome: reduce in analgesic use	50%				84%		70%			
- Outcome: no had mobility increase	73.3%		90%		84%			> 35%		
- Mean follow-up period (days)	90	180	1	540	180	1460	1	180	1	unknown
- QoL		Nottingham			SF-36					
Special case										

<u>Cancer patients</u>					
First author	Cotten A	Weill A	Wetzel SG	Kaemmerlen	Fourney DR
- No of patients	37	37	1	20	34
- Outcome: Pain - VAS					
* mean pain reduction			100%	80%	
- % patient with complete pain relief	98%	73%			84%
- Outcome: reduce in analgesic use					
- Outcome: no had mobility increase					
- Mean follow-up period (days)	1	180	270	unknown	1
- QoL					
Special case			atlas		

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Mixed patients									
First author	McGraw KJ	Evans AJ	O'Brien JP	Munk PL	Gangi A	Heini PF	Amar AP	Zoarski GH	Martin JB
- No of patients	100	245	6	11	868	17	97	30	40
- Outcome: Pain - VAS									
* mean pain reduction						51%			
- % patient with complete pain relief	93%	62%	60%	73%			98%	73%	80%
- Outcome: reduce in analgesic use		reduce			73%-83%		63%		
- Outcome: no had mobility increase	93%	75%					51%		
- Mean follow-up period (days)	645	210	90	unknown	210-1368	365	441	+ - 495	495
- QoL								MODEMS	
Special case			>70% collapse	from VGH					

Special cases					
First author	Mathis JM	Gaughen JR	Chung SK	Dunn J	Wenger M
- No of patients	1	6	3	1	13
- Outcome: Pain - VAS					
* mean pain reduction					
- % patient with complete pain relief	100%	83%	100%	100%	100%
- Outcome: reduce in analgesic use					
- Outcome: no had mobility increase					
- Mean follow-up period (days)	270	1	270	210	90
- QoL					
Special case	steroid induce	re-treated at same vertebrae	radiculopathy	L1-L5	Transpedicular approach

Appendix 2. Summary on complications.

Osteoporosis patients														Subtotal osteo (n, %)	Total series (osteo+ca+mix) (n, %)
First author	Jensen	Wenger	Cyteval C	Cortet B	Grados F	Barr JD	Lee BJ	Kallmes	Yeom JS	Peters	Maynard	Lin DD	Ryu KS		
- No of patients	29	13	20	16	25	47	8	41	118	42	27	75	159	620	2280
- No of procedures	47	21	23	20	34	84	24	63	118	56	35	112	347	984	4087
- Type of patient	osteo	osteo	osteo	osteo	osteo	osteo	osteo	osteo	osteo	osteo	osteo	osteo	osteo		
- Transitory fever	0	0	0	0	2	0	0	0	0	0	0	0	0	2 (0.2)	2 (0.0)
- Transient worse pain	0	0	0	0	1	0	0	0	0	0	0	0	0	1 (0.1)	3 (0.1)
- Transient radiculopathy	0	1	0	0	2	1	1	0	0	0	0	0	0	5 (0.5)	16 (0.4)
- Prolonged radiculopathy	0	0	1	0	0	0	0	0	0	0	0	0	0	1 (0.1)	17 (0.4)
- Transient hypotension	0	0	0	0	0	0	0	0	0	1	0	0	0	1 (0.1)	3 (0.1)
- Transient hypoesthesia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1 (0.0)
- Spinal cord compression	0	0	0	0	0	0	1	0	0	0	0	0	0	1 (0.1)	3 (0.1)
- Pedicle fracture	0	0	0	0	0	0	0	1	0	0	0	0	0	1 (0.1)	1 (0.0)
- Rib fracture	2	0	0	0	0	0	0	0	0	2	0	0	0	4 (0.4)	11 (0.3)
- Adjacent fracture	0	0	0	0	0	0	0	0	0	4	0	0	0	4 (0.4)	4 (0.1)
- Infection	0	0	0	0	0	0	0	1	0	0	0	0	0	1 (0.1)	1 (0.0)
- Cement leakage. n (%)	10 (21)	10 (48)	8 (35)	13 (65)	7 (21)	0 (0)	10 (42)	0 (0)	49 (42)	11 (20)	0 (0)	0 (0)	92 (27)	210 (21.3)	334 (8.2)
*epidural	1	5	0	3	7	0	1	0	0	0	0	0	0		
*foraminal	9	0	2	0	0	0	0	0	0	0	0	0	0		
*intradiscal	0	1	5	3	0	0	0	0	0	0	0	0	0		
*paravertebral tissues	0	3	0	6	0	0	9	0	0	0	0	0	0		
*perivertebral vein	0	1	1	1	0	0	0	0	0	0	0	0	0		
- Cerebral artery embolization	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0
- Pulmonary embolism	2	0	0	0	2	0	0	0	0	0	0	0	0	4 (0.4)	13 (0.3)
- Leg – deep thrombosis	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1 (0.0)
- Dural tear	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1 (0.0)
Total complication (%)	14 (29.8)	11 (52.4)	9 (39.1)	13 (65.0)	14 (41.2)	1 (1.2)	12 (50.0)	2 (3.2)	49 (41.5)	18 (32.1)	0	0	92 (26.5)	235 (23.9)	411 (10.1)

Cancer related patients						
First author	Jang JS	Cotten A	Weill A	Kaemmerle n P	Fourney DR	Subtotal ca (n) (n,%)
- No of patients	27	37	37	20	34	155
- No of procedures	72	40	40	27	65	244
- Type of patient	ca	ca	ca	ca	ca	
- Transitory fever	0	0	0	0	0	0
- Transient worse pain	0	0	0	1	0	1 (0.4)
- Transient radiculopathy	0	0	3	0	0	3 (1.2)
- Prolonged radiculopathy	0	0	0	0	0	0
- Transient hypotension	0	0	0	0	0	0
- Transient hypoaesthesia	0	0	0	0	0	0
- Spinal cord compression	0	0	0	1	0	1 (0.4)
- Pedicle fracture	0	0	0	0	0	0
- Rib fracture	0	0	0	0	0	0
- Adjacent fracture	0	0	0	0	0	0
- Infection	0	0	0	0	0	0
- Cement leakage. n (%)	0 (0)	25 (63)	5 (13)	0 (0)	6 (9)	36 (14.8)
*epidural	0	15		0	0	
*foraminal	0	8		0	0	
*intradiscal	0	8		0	0	
*paravertebral tissues	0	21		0	0	
*perivertebral vein	0	2		0	0	
- Cerebral artery embolization	0	0	0	0	0	0
- Pulmonary embolism	3	0	0	0	0	3 (1.2)
- Leg – deep thrombosis	0	0	0	0	0	0
- Dural tear	0	0	0	0	0	0
Total complication (%)	3 (4.2)	25 (62.5)	8 (20.0)	2 (7.4)	6 (9.2)	44 (18.0)

Percutaneous Vertebroplasty for pain relief in the management of Compressive Vertebral Fractures.

Mixed cancer & osteoporosis											
First author	McGraw JK	Evans AJ	Vasconcelos C	Cotton A	Munk PL (BC)	Gangi A	Martin JB	Zoarski GH	Amar AP	Heini PF	Subtotal mix (n, %)
- No of patients	100	245	137	258	11	570	40	30	97	17	1505
- No of procedures	156	937	205	258	11	868	67	54	258	45	2859
- Type of patient	mix	mix	mix	mix	mix	mix	mix	mix	mix	mix	
- Transitory fever	0	0	0	0	0	0	0	0	0	0	0
- Transient worse pain	0	1	0	0	0	0	0	0	0	0	1 (0.0)
- Transient radiculopathy	1	1	0	0	0	3	0	0	3	0	8 (0.3)
- Prolonged radiculopathy	0	1	1	13	0	0	0	0	1	0	16 (0.6)
- Transient hypotension	0	0	1	0	0	0	0	0	1	0	2 (0.1)
- Transient hypoaesthesia	0	0	1	0	0	0	0	0	0	0	1 (0.0)
- Spinal cord compression	0	0	0	1	0	0	0	0	0	0	1 (0.0)
- Pedicle fracture	0		0	0	0	0	0	0	0	0	0
- Rib fracture	0	7	0	0	0	0	0	0	0	0	7 (0.2)
- Adjacent fracture	0	0	0	0	0	0	0	0	0	0	0
- Infection	0	0	0	0	0	0	0	0	0	0	0
- Cement leakage. n (%)	0 (0)	0 (0)	53 (26)	0 (0)	0 (0)	15 (6)	4 (6)	1 (2)	7 (3)	8 (18)	88 (3.1)
*epidural	0	0	0	0	0	15	0	1	4	0	
*foraminal	0	0	0	0	0	0	0	0	3	2	
*intradiscal	0	0	18	0	0	0	0	0	0	0	
*paravertebral tissues	0	0	34	0	0	0	0	0	0	5	
*perivertebral vein	0	0	1	0	0	0	0	0	0	1	
- Cerebral artery embolization	0	0	0	0	0	0	0	0	0	0	0
- Pulmonary embolism	0	0	0	0	0	2	0	1	3	0	6 (0.2)
- Leg - deep thrombosis	0	0	0	0	0	0	1	0	0	0	1 (0.0)
- Dural tear	0	0	0	0	0	0	0	0	1	0	1 (0.0)
Total complication (%)	1 (0.6)	10 (1.1)	56 (27.3)	14 (5.4)	0	20 (2.3)	5 (7.5)	2 (3.7)	16 (6.2)	8 (17.8)	132 (4.6)

Reports on complication only (n)					
First author	Scroop R	Padovani B	Piergiorgio T	Chen HL	Bernhard J
- No of patients	1	1	1	1	1
- No of procedures					2
- Type of patient	osteo	ca	osteo	osteo	osteo
- Transitory fever	0	0	0	0	0
- Transient worse pain	0	0	0	0	0
- Transient radiculopathy	0	0	0	0	0
- Prolonged radiculopathy	0	0	0	0	0
- Transient hypotension	0	0	0	0	0
- Transient hypoesthesia	0	0	0	0	0
- Spinal cord compression	0	0	0	0	0
- Pedicle fracture	0	0	0	0	0
- Rib fracture	0	0	0	0	0
- Adjacent fracture	0	0	0	0	0
- Infection	0	0	0	0	0
- Cement leakage. n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
*epidural	0	0	0	0	0
*foraminal	0	0	0	0	0
*intradiscal	0	0	0	0	0
*paravertebral tissues	0	0	0	0	0
*perivertebral vein	0	0	0	0	0
- Cerebral artery embolization	1	0	0	0	0
- Pulmonary embolism	1	1	1	1	2
- Leg - deep thrombosis	0	0	0	0	0
- Dural tear	0	0	0	0	0