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Health outcomes in elderly individuals with acute severely painful osteoporotic vertebral compression fractures

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Abstract
There are minimal data describing outcomes after acute clinical osteoporotic vertebral compression fractures (OVCF). We report on pain scores, quality of life measures, complication and specific osteofragility risk factors in the placebo-treated individuals (n=59) in the VAPOUR study. By 6 months, three individuals (5%) withdrew, three (5%) had died, two (4%) had developed spinal cord compression and two (5%) had sustained new OVCF's. Mean baseline fracture compression of 46% of height loss had increased to 63%. Despite overall improvements, 27 (53%) had ongoing problematic back pain (numeric rating scale > 4) and 32 (63%) had significant disability (Roland Morris Questionnaire > 10) at 6-months. 44 (75%) were considered high risk for recurrent OVCF. These data confirm that elderly individuals with acute severely painful clinical OVCF treated with usual care, demonstrate adverse outcomes even at 6 months after fracture. Further research should focus on optimal treatments for this high-risk cohort. (Word count 150).

Keywords: vertebral fractures, osteoporosis, pain

1. Introduction
Vertebral compression fractures are a common complication of osteoporosis, affecting more than 700,000 Americans annually and accounting for more than 70,000 hospitalizations each year [1, 2]. Complications include chronic pain and impaired activities of daily living, respiratory complications (pneumonia and thromboembolism), muscle atrophy due to immobilisation, bone loss, recurrent OVCF, neural foramen and spinal cord compression, disfigurement (kyphosis/height loss) and psychological distress [3]. There is limited data on the natural history of acute clinical OVCF.

Age, pre-existing OVCF, severity of vertebral deformity, BMD and multiple comorbidities have been shown to be highly predictive of recurrent OVCF, post-fracture morbidity and mortality [4-9], while treatment with anti-osteoporotic agents have been shown to reduce the long term risk of these sequelae [10, 11]. This study reports on the natural history of acute clinical OVCF in the placebo-treated individuals who participated in the VAPOUR study [12]. We analysed specific risk factors to determine their effect on the clinical outcomes (pain scores, quality of life measures and complication) at 6-months after the fracture.

2. Materials and Methods
Study methodology and results of VAPOUR are published [12, 13]. VAPOUR is a multicentre randomised, blinded, parallel group, placebo-controlled trial of vertebroplasty for painful OVCF performed within 6-weeks post fracture. The entry criteria were patients' age > 60, back pain < 6 weeks duration, numeric rated scale (NRS) pain ≥ 7/10, and Magnetic Resonance Imaging (MRI) or single-photon emission computed tomography confirming one or two recent fractures. Exclusion criteria were inability to provide informed consent, chronic back pain requiring opiate use, significant fracture retropulsion, acute infection, spinal malignancy, neurologic complications, greater than two recent vertebral fractures.

Data were collected at baseline, 3-days, 14-days and 1, 3 and 6-months after procedure. Primary outcome measure was numeric rated scale (NRS) pain. Patients were asked to grade their pain with a number between 0 to 10, to estimate their pain intensity. Severe pain was defined as NRS ≥ 7/10 (disabling, unable to perform ADLs) and mild as NRS < 4/10 (nagging, annoying, Inter fering little with ADLs). Secondary outcome measure was Roland-Morris Disability Questionnaire (RMQ) comprising 24 questions about dysfunctions in daily activities experienced by patients with back pain, a total RMQ score ranging from 0-24, higher scores represent higher levels of pain-related disability. The RMQ has been shown to yield reliable measurements, which are valid for inferring the level of disability, and to be sensitive to change over time for groups of patients with low back pain. For the RMQ, a between-groups difference of 2 points is considered clinically important, whereas a within-patient change of 4 or 5 points is recognized as the threshold for a clinically important improvement. We calculated a RMQ score > 10 at follow-up as considered disabling. Sensitivity and specificity for

a threshold score of 4 were 94% (95% CI, 88–98) and 69% (95% CI, 52–83), respectively. Analgesic consumption recorded the use of analgesic medication within the previous 24 h. Duration of hospital stay was recorded for participants who were hospital inpatients at time of enrolment.

Calibrated standing spinal radiographs were obtained at baseline and 6-months to measure vertebral body height, incident vertebral fractures, height loss percentage and Genant score. Interval change of vertebral height loss from baseline to 6 months was calculated. Incident fracture was defined as a normal vertebral body at baseline that was deformed by at least 15% height loss on the 6-month image.

Statistical analyses were undertaken by EB and VG at the NHMRC Clinical Trials Centre, University of Sydney. Individuals were stratified a priori according to their baseline osteofragility risk (using previously documented osteoporotic risk factors such as patients' age, pre-existing OVCF, severity of vertebral compression deformity and BMD T-scores). Opiate requirements, prior osteoporotic therapies and hospitalisation were considered a measure of their pain and fracture severity. Each variable was assigned a binary numerical value of 0-2 dependent on its weighted-risk. Age, calculated above or below the median for the group, <80 (=0) or >80 years (=1); previous OVCF, nil (=0), 1 fracture (=1) or >1 fracture (=2); Genant grading 1 (=0), 2 (=1) or 3 (=2); BMD T-score -2.5 to -3.0, classified as mild osteoporosis (=1) or <-3.0 as severe osteoporosis (=2); Opioids for pain, no (=0) or yes (=1); prior anti-osteoporotic therapies, no (=0) or yes (=1); and hospitalisation, no(=0) or yes (=1). The median score was calculated for all of the 59 patients (numerical value 5.9 per patient). Individuals were then stratified into either a low (score 0-5) or high risk (score >5) subgroup. Measures of effect are presented as either odds ratios or mean differences together with the respective 95% confidence intervals.

The trial was approved by the Human Research Ethics Committees of Bellberry Limited (2011-08-414) and North Sydney Local Health District (HREC/11/HAWKE/228). The Human Research Committee at each participating centre approved the study and all patients provided written informed consent. No funds were received in support of this work.

3. Results

Data were available on 59 of the 120 patients that were enrolled into the VAPOUR trial and randomized to 'placebo-treatment'. Their mean age was 81years, 68% were female and 86% were receiving anti-osteoporotic therapies. 39% of individuals were treated as outpatient and 61% were hospitalised. 48% had pre-existing OVCF. 66% had Genant grade 3 deformities in the newly diagnosed vertebral fracture. Their mean NRS pain (8.6) and RMQ scores (19.8) was indicative of severe pain and loss of function on presentation. 44 (75%) of individuals were considered to have a high osteofragility risk (Table 1). There were no baseline differences between individuals with either a low or high osteofragility risk (Table 2).

By 6 months, three individuals (5%) withdrew, three individuals (5%) had died and two (4%) had sustained spinal cord compression. One was managed with surgical decompression and spinal fusion whilst the other became paraplegic. Two (5%) had sustained new OVCF's. There were 35 (67%) individuals with persistent back pain (numeric rating scale > 4) at 3-months and 27 (53%) at 6-months after fracture. There were no significant differences in the number of individuals with NRS > 4 at 3 or 6-months in either the low or high osteofragility risk subgroups. There were 35 (70%) individuals with a persistent disability (RMQ scores > 10) at 3-months and 32 (63%) at 6-months after fracture. There were no significant differences in the number of individuals with RMQ scores > 10 at 3 or 6-months in either the low or high osteofragility risk subgroups. (Table 3). The mean NRS pain at 6-months was 4.5 (range 0 to 7) in the low and 3.1 (range 0 to 8) in the high osteofragility risk subgroup (P=0.082 for between-group comparisons). The mean change in RMQ scores over the 6-months was -4 (range -16 to 2) in the low and -9 (range -23 to 8) in the high osteofragility risk subgroup (P=0.032 for between-group comparisons).

Interval spinal radiographs over the 6-months demonstrated progressive vertebral height loss in both subgroups, -17% (range -45 to +1) in the low and -20% (range -50 to +1) in the high osteofragility risk subgroup (P=0.48 between-group comparisons).

4. Discussion

The presentation and outcomes of individuals with acute clinical OVCF differ significantly from those with chronic OVCF [14]. The pain severity and complications after an acute OVCF can be severely disabling and result in a rapid decline. Despite this, most individuals recover spontaneously albeit with varying residual disability. Those with recurrent or progressive fractures may progress to a chronic disability state. There is minimal data to predict which individuals do poorly after an acute clinical OVCF. In this report we compare the 6-month clinical outcomes and complications in individuals from placebo-treated arm of the VAPOUR study [12] to those who participated in other randomised trials of acute painful OVCF [15-17]. While the placebo-controlled vertebroplasty studies are often limited by smaller patient numbers, their study designs and comprehensive data collection make them more appealing for studying fracture outcomes compared to open longitudinal studies.

In our study of elderly women and men who presented with acute severely painful OVCF (NRS pain ≥ 7/10), duration < 6 weeks and treated by standard care, three individuals (5%) died and two (5%) sustained recurrent OVCF's by 6-months. Improvements were noted in all measures of pain and disability, but their residual mean NRS pain and RMQ scores remained significantly elevated throughout the trial, even at 6-months after fracture. In an open label randomised trial in a similar patient cohort with early fractures less than three weeks duration, Yang and colleagues [15], found that four patients (7.8%) developed new OVCF and 18 (35.3%) experienced complications such as pneumonia, urinary tract infections, venous thrombosis, pulmonary emboli, depression and sleep disturbances at 12-months after fracture. They also noted improvements in outcomes in their placebo-treated group (n=51), but with significant residual pain (VAS) and disability scores (Oswestry Disability Index and QUALEFFO) at 6- and 12-months after fracture. Klazen and colleagues [18] in an open labelled study showed that a third of their patients (11/36) who presented with acute OVCF had persistent severe pain (VAS > 50%) requiring pain medications and physical therapy even at 24-months after

fracture. Ong and colleagues [19], in a 6-month longitudinal study (Nottingham Spinal Health Study) of 90 hospitalised patients reported that 18% died, 12% required a new care home admission and 37% reported pain to be severe and physical functioning worse than their preadmission state. These negative 6 to 12-month outcomes have been noted in most trials of acute painful OVCF irrespective of their study designs (longer post fracture interval of enrolment, no MRI verification of fracture activity and trauma-related) [19-22].

A number of clinical risk factors may potentially affect the recovery of an individual after an acute OVCF. The Fracture Risk Assessment Tool (FRAX) has been shown to predict fracture risk on the basis of clinical risk factors, with or without the use of femoral neck bone mineral density, but there are no reports assessing the use of this calculator in patients after an acute clinical OVCF [23]. Ong and colleagues [19] looked at the effects of multiple co-morbidities, a clinical frailty scale and the Montreal Cognitive Assessment score on the outcomes of their hospitalised patients with acute OVCF. None of these variables predicted the post fracture recovery. Klazen and colleagues [18] showed that none of their baseline variables such as patient age, mean number of OVCF, fracture grading or cause were able to predict significant pain relief at 6- or 24-months after an acute OVCF. In our study we were unable to show a difference in pain scores, quality of life measures and complication at 6-months after fracture in individuals with either a low or high osteofragility risk. The pathophysiology of persistent back pain after an acute OVCF is unclear. It remains uncertain whether progressive vertebral height loss due to ongoing fractures, alterations in facet joint mechanics, kyphotic deformities inducing para-spinal muscular spasm or thecal sac compression from vertebral fracture fragments contribute to post fracture pain and disability [24-27]. In the VERTOS IV study [17], 45% of individuals (39/86) in the sham procedure group demonstrated progressive vertebral height loss at 6-months after fracture and had significantly higher VAS scores. In our study, we found interval vertebral height loss of 17-20% in the fractured vertebral body on spinal radiographs performed at 6-months after fracture compared to baseline. These data confirming that the vertebral deformity after an acute clinical OVCF may be progressive with time leading to severe spinal deformity and persistent backpain.

Managing patients with acute painful OVCF remains a clinical challenge. Analgesia, lumbar bracing and physical therapies are simple and can easily be offered to all individuals presenting with acute painful OVCF [1, 14, 28]. Importantly, all individuals with OVCF, whether acute or chronic, require long term anti-osteoporotic therapies to prevent a recurrent episode [11]. The choice of therapy may influence outcome; in one 24-week prospective randomised trial of acute painful OVCF, subcutaneous teriparatide was shown to be superior to oral/parenteral bisphosphonate therapies in promoting fracture healing [29]. While anti-resorptive/anabolic bone therapies are an important long-term prevention strategy, the challenge for clinicians is how to best achieve positive short and long-term outcomes for patients in the early weeks post fracture. Percutaneous vertebroplasty has been reported to significantly reduce pain and prevent progressive vertebral height loss in well-designed randomised studies [12, 15,16] in individuals with acute severely painful OVCF and fracture duration < 3-weeks. It remains uncertain; however, which individuals require these more aggressive therapies.

The limitations of of our study is its short duration and small cohort. The study design and meticulous detail to pain, disability and radiological changes in vertebral dimensions has given us the ability to carefully track the natural history after an acute painful clinical OVCF.

Tables

Table 1: Scoring of individual osteofragility risk factors and treatments

Risk factor	Level	n (%)
Age	<80 (0 points)	25 (42%)
	>80 (1 point)	34 (58%)
Prior OVCF, excludes current fracture (s)	Unknown (0 points)	1
	None (0 points)	30 (52%)
	1 (1 point)	19 (33%)
	2 or more (2 points)	9 (16%)
Genant grading	Genant 1 (0 points)	8 (14%)
	Genant 2 (1 point)	12 (20%)
	Genant 3 (2 points)	39 (66%)
BMD T-score (femoral neck/lumbar spine)	Unknown (0 points)	4
	> -2.5 (0 points)	2 (4%)
	-3.0 to -2.5 (1 point)	4 (7%)
	<-3.0 (2 points)	49 (89%)
Opioids for pain	Unknown (0 points)	1
	No (0 points)	10 (17%)
	Yes (1 point)	48 (83%)
Baseline anti-osteoporotic therapies	No (0 points)	8 (14%)
	Yes (1 point)	51 (86%)
Hospitalisation	No (0 points)	23 (39%)
	Yes (1 point)	36 (61%)
Total score	3	3 (5%)
	4	3 (5%)
	5	9 (15%)

	6	7 (12%)
	7	13 (22%)
	8	17 (29%)
	9	7 (12%)
Osteofragility Subgroup[a]	Low (0-5)	15 (25%)
	High (>5)	44 (75%)

Abbreviations: BMD = Bone Mineral Density a = Subdivided according to the median value for all 59 patient

Table 2: Baseline characteristics according to low/high osteofragility risk

			Osteofragility Risk	
Characteristic	Value	Low	High	All patients
Sex - Female	n (%)	10 (67)	30 (68)	40 (68)
Male	n (%)	5 (33)	14 (32)	19 (32)
Multiple acute fractures	n (%)	2 (13)	4 (9)	6 (10)
Thoracic fracture	n (%)	2 (13)	14 (32)	16 (27)
Thoraco-lumbar fracture	n (%)	11 (73)	25 (57)	36 (61)
Lumbar fracture	n (%)	2 (13)	8 (18)	10 (17)
Fracture duration (weeks)	Mean (range)	2.6 (1.0 to 6.0; n=14)	2.4 (1.0 to 6.0; n=44)	2.5 (1.0 to 6.0; n=58)
% Vertebral compression	Mean (range)	37.3 (20.0 to 70.0; n=15)	49.1 (19.0 to 74.0; n=44)	46.1 (19.0 to 74.0; n=59)
NRS	Mean (range)	8.5 (7.0 to 10.0; n=15)	8.6 (6.0 to 10.0; n=43)	8.6 (6.0 to 10.0; n=58)
RMQ	Mean (range)	20.1 (14.0 to 24.0; n=15)	19.8 (0.0 to 24.0; n=44)	19.8 (0.0 to 24.0; n=59)

Abbreviations: NRS = Numeric Rated Scale of Pain, on a scale 0-10 RMQ = Roland-Morris Disability Questionnaire, total RMQ score ranging from 0-24

Table 3: Categorical outcomes over time according to low/high osteofragility risk

		n	**(%)**	
		Osteofragilty	Risk	
Outcome	Study visit	Low	High	All
NRS > 4	Baseline	15 (100)	43 (100)	58 (100)
	Day 3	13 (93)	37 (90)	50 (90)
	Day 14	13 (87)	32 (76)	46 (79)
	Month 1	12 (80)	35 (83)	47 (82)
	Month 3	10 (71)	25 (66)	35 (67)
	Month 6[a]	10 (77)	17 (45)	27 (53)
RDQ > 10	Baseline	15 (100)	44 (98)	58 (98)
	Day 3	14 (93)	37 (93)	51 (93)
	Day 14	10 (71)	35 (83)	45 (80)
	Month 1	12 (86)	33 (85)	45 (83)
	Month 3	10 (77)	25 (68)	35 (70)
	Month 6[b]	11 (85)	21 (55)	32 (63)
Any new vertebral fracture – number (%)	Month 6	2 (17)	0 (0)	2 (5)
%Change in vertebral height (mean + SD)	Month 6	17 (14)	20 (14)	19 (14)
Length of hospital stay – days (mean + SD)	Month 6	16 (7)	17 (14)	17 (13)
Death – number (%)	Month 6	1 (7)	2 (5)	3 (5)

Abbreviations: NRS = Numeric Rated Scale of Pain, on a scale 0-10 NRS > 4 is considered 'painful' RMQ = Roland-Morris Disability Questionnaire, total RMQ score ranging from 0-24 RMQ > 10 is considered 'disabling' P Value: a: P=0.054 (between group comparisons at 6-months) b: P=0.074 (between group comparisons at 6-months)

5. Conclusion

The data presented in this paper, together with data from other randomised trials, demonstrate that there is a group of individuals treated with usual conservative care who have poor outcomes post-acute OVCF. Ongoing back pain may often be related to progressive vertebral height loss post fracture as shown in our cohort. These individuals usually have significant osteofragility risk factors. Further studies are needed to identify better therapies for this high-risk patient group to improve their clinical outcomes.

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