



The appropriate management of osteoporotic vertebral compression fractures : a single institute evaluation using the VCF Monitor

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Osteoporosis-related vertebral compression fractures (OVCF) are commonly seen in clinical practice. Treatment choice is often challenging due to heterogeneity of the patient population. A European multidisciplinary expert panel developed patient-specific recommendations for treatment choice that were embedded in an online evaluation tool (VCF Monitor).

This study aimed to evaluate the appropriateness of treatment choice in patients with OVCF in a German hospital.

The prospective observational study in 190 patients with OVCF (2013-2015). Using the VCF Monitor, treatment choices were compared with the recommendations of the European expert panel.

Treatment choices included balloon kyphoplasty (61%), non-surgical management (36%) and other surgical procedures (3%). Compared to the panel recommendations, 70% of treatment choices were appropriate, 24% uncertain, and 3% inappropriate. Less appropriate choices were partly due to patient preferences.

The VCF Monitor proved to be a helpful tool for quality assurance in the management of OVCF.

Keywords : Vertebral compression fractures ; appropriateness of care ; utilisation review ; balloon kyphoplasty ; non-surgical management.

INTRODUCTION

Osteoporosis-related vertebral compression fractures (OVCF) are commonly seen in clinical practice.

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The worldwide number of clinical OVCFs has been estimated at 1.4 million for the year 2000 with the highest incidence in Europe (7). The most pronounced initial complaint is pain, but significant morbidity and disability may develop due to spinal deformity (12,13). Clinical guidelines recommend non-surgical management (NSM : bed rest, analgesics and occasionally bracing) as the initial strategy (3,10). In patients with insufficient response to conservative treatment, minimally invasive surgery such as balloon kyphoplasty (BKP) and vertebroplasty (VP) may be indicated (2,3,10). In well-selected patients, these treatments have been shown to produce more favourable outcomes in terms of greater pain relief, fewer subsequent fractures, and shorter hospital stay when compared to (prolonged) NSM (8,11). In clinical practice, however, it is often difficult to determine which patients may benefit most from such procedures. To support appropriate treatment choice, a European expert panel used the RAND/UCLA method to formulate recommendations in relation to specific patient characteristics (1).

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The panel recommendations were embedded in an online program (VCF Monitor) that allows the user to compare his own treatment choice with the opinion of the expert panel. A recent prospective observational study confirmed the feasibility of this program in daily clinical practice (14). Within the framework of quality assurance and improvement, we tested the use of the VCF Monitor in our hospital. The principal aim of this study was to determine the appropriateness of treatment choice for patients with an OVCF in comparison to the recommendations of the European expert panel.

METHODS

A detailed description of the development of appropriateness criteria for treatment choice in

patients with OVCF has been published elsewhere (1). Using the RAND/UCLA Appropriateness Method (RUAM) (5,6), an international multi-disciplinary expert panel assessed the appropriateness of three commonly used treatment options (non-surgical management, vertebroplasty and balloon kyphoplasty) for 128 clinical scenarios, using a 9-point scale. The scenarios were mutually exclusive combinations of the values of 7 clinical variables considered most relevant to treatment choice : time since fracture, MRI findings, evolution of symptoms, impact of symptoms on quality of life, spinal deformity, ongoing fracture process, and pulmonary dysfunction. Appropriateness of treatment was based on the median panel score and the extent of agreement, resulting in three potential outcomes : appropriate, inappropriate, or uncertain.

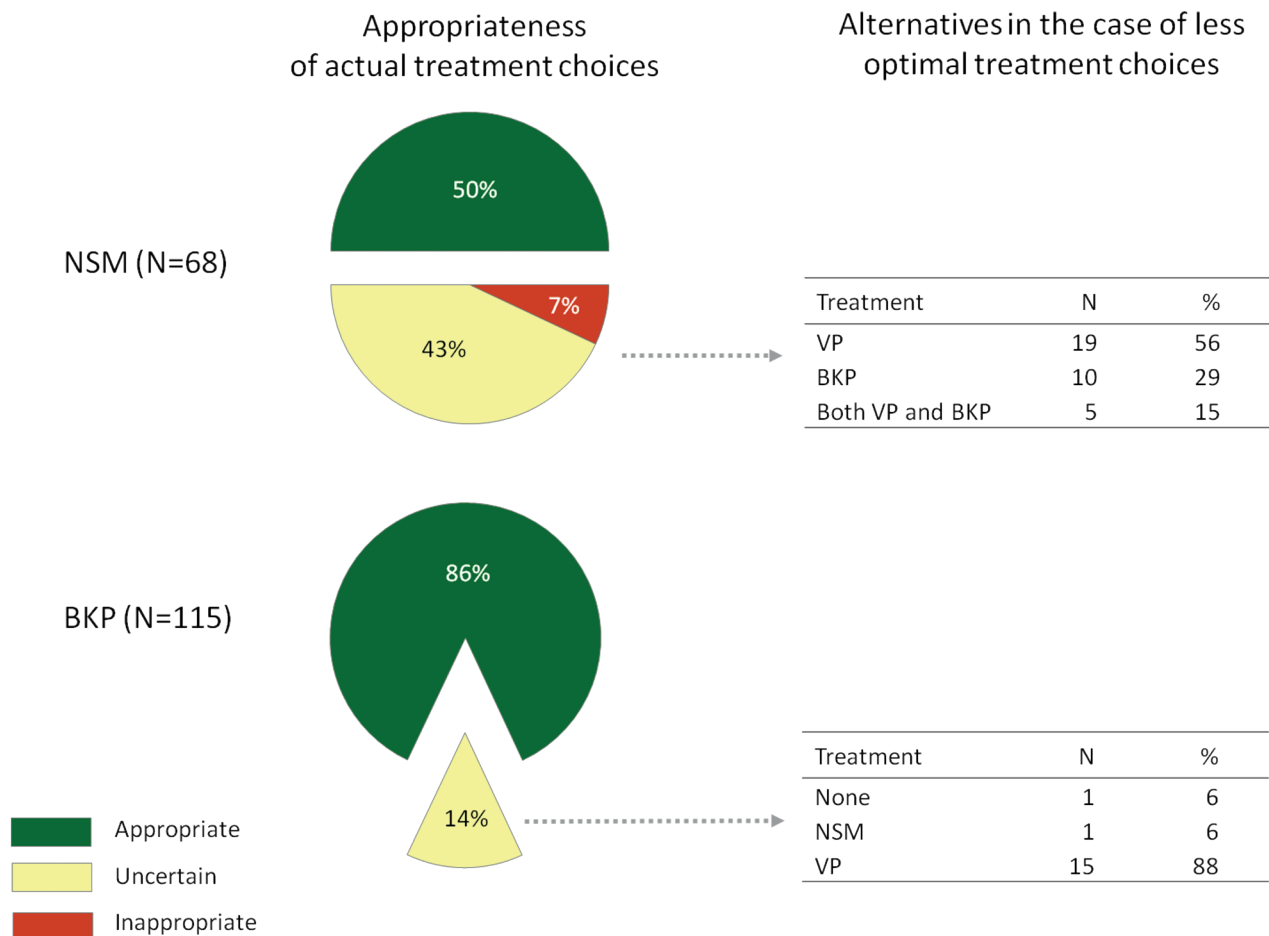


Fig. 1. — Appropriateness of treatment choices and alternative treatments in the case of suboptimal choices; comparison with the recommendations of the European expert panel (1).

This prospective observational study took place at the Department of Orthopaedics and Trauma Surgery of the Bayreuth Medical Center, a large hospital in northern Bavaria, Germany. The study population consisted of consecutive patients with an osteoporotic VCF, admitted via the emergency room or newly referred by their local family physician. Patient inclusion started in March 2013 and ended in April 2015.

Inclusion criteria were similar to those applied in the RUAM panel study (1): a) OVCF type A, documented with an appropriate imaging technique, b) having at least moderate symptoms (visual analogue score (VAS) ≥ 5) correlating with the fracture, c) absence of neurological symptoms, d) age ≥ 18 years, and e) absence of absolute contraindications for active treatment (not fit enough to undergo surgery, spine infection, coagulation disorder).

Trauma patients were excluded. Minimal impact trauma (e.g. stumbling) was accepted, but only if osteoporosis was most likely to be the principal cause of the fracture. Part of the patients had also been included in the above-mentioned international feasibility study (14).

Data collection was performed using the VCF Monitor, an online program with a fixed routine, not allowing any changes after completion of a previous step:

1. Check on inclusion criteria
2. Completion of the patient profile, including the clinical variables that were used for the RUAM panel study
3. Documentation of treatment choice and principal reason(s) behind this choice
4. Display of the panel recommendations (appropriate, inappropriate, uncertain) for each of the treatment options
5. Further explanation of treatment choice if this differed from the panel recommendations (i.e. if another option was considered more appropriate)

Separately, data on length of hospital stay and pain medication upon discharge from hospital were documented.

Ethics approval for this study was provided by the Ethics Committee of the Friedrich-Alexander University of Erlangen-Nuernberg.

Frequency tables and cross-tabulations were used to describe and analyse the following topics:

- Patient characteristics in relation to the criteria from the RAND/UCLA panel study
- Appropriateness of treatment choices made
- Length of hospital stay and pain medication at discharge in relation to appropriateness of treatment

Table I. — Clinical characteristics of patients admitted for OVCF (N=190)

Characteristic	Categories	N	%
Age (years)	< 65	20	10
	65-74	51	27
	≥ 75	119	63
Sex	Male	63	33
	Female	127	67
Previous VCF(s)	No	96	51
	Yes	94	49
Location of fracture*	Cervical	1	1
	Thoracic	61	33
	Thoracic + lumbar	10	5
	Lumbar	111	60
	Sacral	1	1
Number of fractures*	1	141	77
	2	35	19
	≥ 3	8	4

*Missing data for 6 patients

Where applicable, the Pearson's Chi-square test for categorical data was used.

Student's t test was used for comparison between means. All analyses were performed using SPSS for Windows Release 22.0.

RESULTS

The profiles of 195 patients were entered in the VCF Monitor, of whom 190 (97%) met all inclusion criteria. The median age of these patients was 79 years (range 48-100 years), and 90% were 65 years

Table II. — Distribution of key clinical factors* by treatment choice

Variables/categories	Treatment choice		
	NSM (N=68) %	BKP (N=115) %	Other surgery (N=7) %
Time since fracture			
< 6 weeks	41	42	72
6 weeks – 3 months	21	43	14
> 3 months	38	15	14
MRI findings			
Negative	24	1	14
Positive	76	99	86
Impact on daily functioning			
Moderate	49	8	0
Severe	51	92	100
Evolution of symptoms			
Stable	85	40	29
Has worsened	15	60	71
Spinal deformity			
No	96	76	14
Yes	4	24	86
Proof of ongoing fracture process			
No	97	77	14
Yes	3	23	86
Pulmonary dysfunction			
No	94	94	100
Yes	6	6	0

* Clinical factors identified as determinants of treatment appropriateness in the RUAM panel study (1).

or older (Table I). The number of women was twice as high as that of men. Around half of the patients had had a previous VCF. Two-thirds of the fractures were located in the lumbar spine. Multiple fractures were seen in 23% of patients (Table I), the maximum number of fractures was 5.

Treatment choice and related clinical factors

Principal treatment choices were BKP (61%) and NSM (36%). Other procedures were used for 7 patients (3%) and included cement-augmented

dorsal instrumentation, internal fixation or combination techniques. VP was never used.

The distribution of clinical factors used in the RUAM panel study showed marked differences between the treatments chosen (Table II). Apart from pulmonary dysfunction, the frequency of unfavourable conditions was much higher for the interventional treatments, and most pronounced for the small group of other surgical techniques.

Appropriateness of treatment choices

Using the criteria of the European expert panel (1), 70% of the treatment choices in the Bayreuth population were appropriate, 24% uncertain, and 3% inappropriate. For the remaining 3% (7 patients with other surgical procedures) no panel recommendations were available. BKP was considered appropriate for the vast majority of patients for whom this procedure was chosen, while the outcomes for NSM were mixed (Fig. 1).

If the outcome was uncertain or inappropriate, more appropriate options had been available for almost all situations (Fig. 1). The dominant reasons for choosing a 'suboptimal' treatment option (open question) were 'poor performance status' and 'afraid of anaesthetics' for NSM and 'higher safety' for BKP.

Hospital stay and pain medication

Table III summarises the figures on length of hospital stay and pain medication at discharge for the principal treatment choices. For all parameters, BKP showed significantly better results than NSM.

An analysis of these parameters for appropriate versus inappropriate/uncertain treatment choices did not reveal statistically significant differences.

DISCUSSION

The VCF Monitor appeared to be a good 'professional mirror' to compare own treatment decisions for OVCF patients with the opinions of an expert panel. Differences in treatment choice were primarily induced by case mix (differences in patient profiles), and were completely in line with the panel recommendations for 70% of cases. Inappropriate choices were seen for only few cases (3%). Part

Table III. — Hospital stay and pain medication by principal treatment choice

	Treatment choice		P
	NSM (N=68)	BKP (N=115)	
Hospital stay			
Mean number of days	13.8	10.3	0.001
Pain medication at discharge			
Mean number	2.1	1.5	0.000
Use of opioids (%)	32	17	0.013

of the less appropriate choices may be justified by specific patient conditions and preferences, such as the patient's fear of anaesthetics as an argument for not performing BKP (if considered more appropriate than NSM by the expert panel).

VP is not or seldom performed in our department of orthopaedics and trauma surgery. This may partly be ascribed to the fact that we typically see patients with recent fractures (< 6 weeks), for whom BKP may be more indicated than VP (1). Furthermore, we consider the risk of cement leakage to be an important drawback of VP (4). Finally, we prefer BKP for its potential to restore vertebral body height (9). However, as this study revealed some cases for which VP may have been a better choice when compared to the recommendations of the European panel (1), an interdisciplinary discussion will be initiated with surgeons and interventional radiologists to explore its position in the therapeutic arsenal for OVCF in our hospital.

Our study confirms the favourable outcomes of BKP versus NSM in well-selected patients (8,11): both the length of hospital stay and medication use at discharge were significantly lower for BKP.

The results of applying the VCF Monitor in this study are, of course, limited to our hospital. A broader application in hospitals in Italy, Germany, United Kingdom, Belgium and Switzerland showed similar results (14). As the tool offers a quick and efficient instrument for direct feedback and self-reflection, we would strongly advise its use to colleagues in other hospitals. A demonstration version of the tool can be found on <http://www.vcf-monitor.org/> (username : demo; password : demo).

REFERENCES

1. Anselmetti GC, Bernard J, Blatter T et al. Criteria for the appropriate treatment of osteoporotic vertebral compression fractures. *Pain Physician* 2013 ; 16 : E519-30.
2. Baerlocher MO, Saad WE, Dariushnia S et al. Quality improvement guidelines for percutaneous vertebroplasty. *J Vasc Interv Radiol* 2014 ; 25 : 165-170.
3. Barr JD, Jensen ME, Hirsch JA et al. Position statement on percutaneous vertebral augmentation: a consensus statement developed by the Society of Interventional Radiology (SIR), American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), American College of Radiology (ACR), American Society of Neuroradiology (ASNR), American Society of Spine Radiology (ASSR), Canadian Interventional Radiology Association (CIRA), and the Society of NeuroInterventional Surgery (SNIS). *J Vasc Interv Radiol* 2014 ; 25 : 171-181.
4. Boonen S, Wahl DA, Nauroy L et al. Balloon kyphoplasty and vertebroplasty in the management of vertebral compression fractures. *Osteoporos Int* 2011; 22 : 2915-2934.
5. Brook RH, Chassin MR, Fink A et al. A method for the detailed assessment of the appropriateness of medical technologies. *Int J Technol Assess Health Care* 1986 ; 2 : 53-63.
6. Fitch K, Bernstein SJ, Aguilar MS et al. The RAND/UCLA appropriateness method user's manual. http://www.rand.org/pubs/monograph_reports/MR1269. Accessed 5 June 2016.
7. Johnell O, Kanis JA. An estimate of the worldwide prevalence and disability associated with osteoporotic fractures. *Osteoporos Int* 2006 ; 17 : 1726-1733.
8. Lange A, Kasperk C, Alvares L et al. Survival and cost comparison of kyphoplasty and percutaneous vertebroplasty using German claims data. *Spine* 2014 ; 39 : 318-326.
9. Liu JT, Liao WJ, Tan WC et al. Balloon kyphoplasty versus vertebroplasty for treatment of osteoporotic vertebral compression fracture: A prospective, comparative, and randomized clinical study. *Osteoporos Int* 2010; 21 : 359-364.
10. National Institute for Health and Clinical Excellence. Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures, 2013. <http://www.nice.org.uk/guidance/ta279>. Accessed 5 June 2016.
11. Papanastassiou ID, Phillips FM, Van Meirhaeghe J et al. Comparing effects of kyphoplasty, vertebroplasty, and non-surgical management in a systematic review of randomized and non-randomized controlled studies. *Eur Spine J* 2012 ; 21 : 1826-1843.
12. Pluijm SM, Tromp AM, Smit JH et al. Consequences of vertebral deformities in older men and women. *J Bone Miner Res* 2000; 15 : 1564-1572.

13. **Salaffi F, Cimmino MA, Malavolta N et al.** The burden of prevalent fractures on health-related quality of life in postmenopausal women with osteoporosis: the IMOF study. *J Rheumatol* 2007 ; 34 : 1551-1560.
14. **Schupfner R, Stoevelaar HJ, Blattert TR et al.** Treatment of osteoporotic vertebral compression fractures: applicability of appropriateness criteria in clinical practice. *Pain Physician* 2016 ; 19:E113-120.