

MANAGING VERTEBRAL COMPRESSION FRACTURES — A CLINICAL CARE PATHWAY

Summary of the technical report developed by a multispecialty panel using the RAND™/UCLA Appropriateness Method



INTRODUCTION

This paper summarizes a technical report presenting a clinical care pathway (CCP) for patients presenting to an emergency room or outpatient clinic with moderate to severe back pain (VAS ≥ 5) as the primary or secondary complaint.¹

The care pathway was developed by a multispecialty panel using the RAND™/UCLA Appropriateness Method (RAM) to provide patient-specific recommendations for the CCP. In the past, there has been a lack of consensus on the appropriate management of patients with or suspected of having a vertebral compression fracture (VCF), referred to in the study as vertebral fragility fracture.¹

Elements of the clinical care pathway

1. Key signs and symptoms of suspected VCF
2. Diagnostic evaluation of patients with suspected VCF
3. Appropriateness criteria for vertebral augmentation (VA) vs. nonsurgical management (NSM)
4. Contraindications for VA
5. Follow-up after treatment

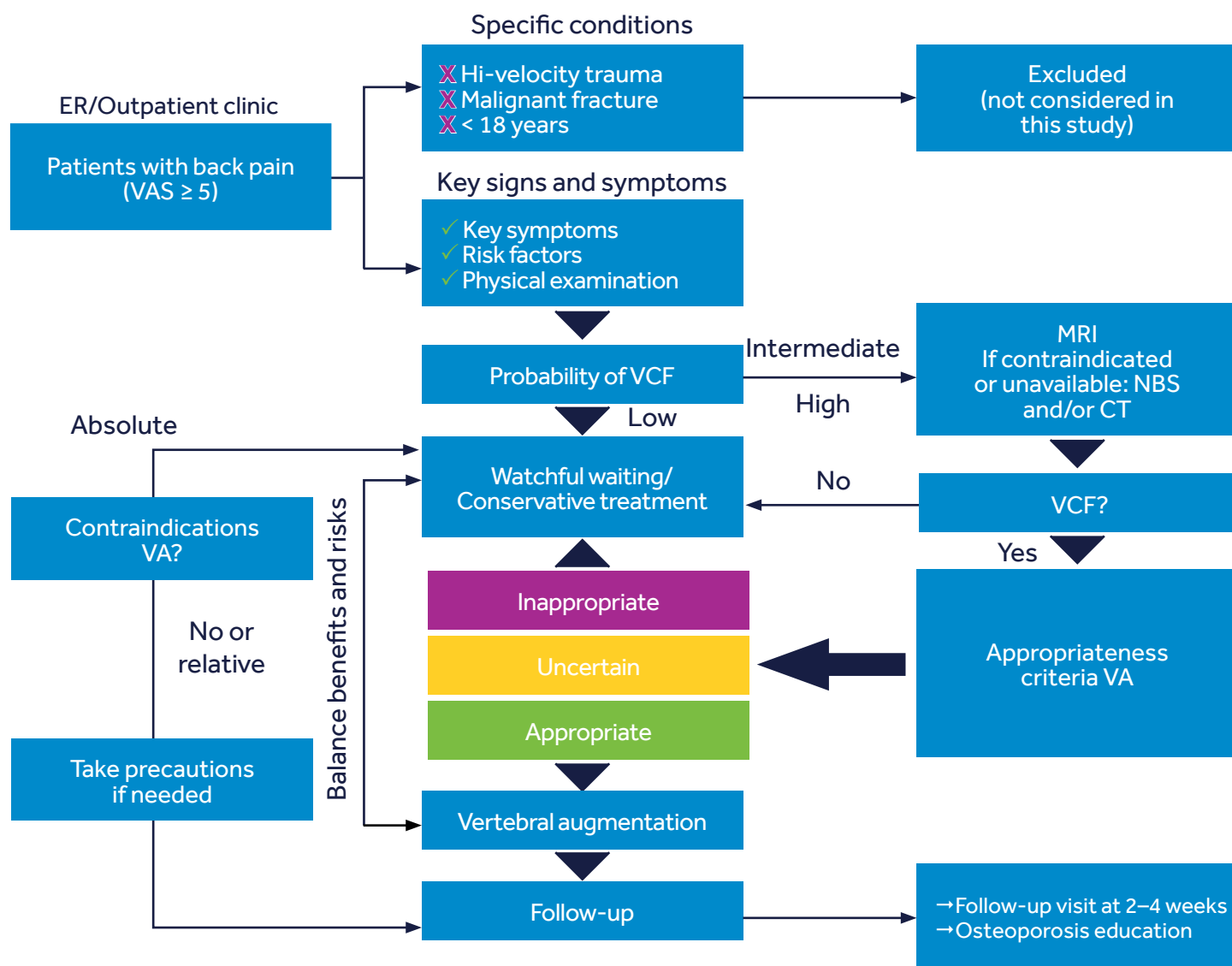
This project was supported by a grant from Medtronic. However, Medtronic was not involved in the design or execution of the project, nor the preparation and review of this manuscript. Names of panel members were not disclosed to the sponsor, and panel members were not informed about the identity of the sponsor before submission of the manuscript.

Medtronic
Further, Together



CLINICAL CARE PATHWAY FOR PATIENTS PRESENTING WITH MODERATE TO SEVERE BACK PAIN

Figure 1: Clinical care pathway for managing vertebral compression fractures



Watchful waiting: While it is not depicted in the graphic, a number of patients who are not treated, but who continue to have untreated symptoms, may end up being "looped" back into the algorithm at some point.

Reprinted from *The Spine Journal* 2018, Hirsch JA, Beall DP, Chambers MR et al. [Management of vertebral fragility fractures: a clinical care pathway developed by a multispecialty panel using the RAND/UCLA Appropriateness Method](#). Nov;18(11):2152-2161, Copyright 2018, with permission from Elsevier.

CT = computed tomography; MRI = magnetic resonance imaging; NBS = nuclear bone scan; VA = vertebral augmentation; VAS = Visual Analogue Scale; VCF = vertebral compression fracture

METHODS

The RAM provides a highly structured approach to produce patient-specific recommendations, by combining the collective judgment of an expert panel with the best available scientific evidence.

EXPERT MULTIDISCIPLINARY PANEL	PUBLISHED EVIDENCE
<p>Chosen by the Steering Committee based on scientific and clinical expertise in diagnosing and treating patients with VCF.</p> <p>The panel consisted of:</p> <ul style="list-style-type: none">▪ Neurosurgeons▪ Interventional (neuro) radiologists▪ Pain specialists▪ Orthopedic surgeons	<p>Presented as a literature overview rather than a review, to avoid interpretation bias.</p> <p>The final document included the results of:</p> <ul style="list-style-type: none">▪ 83 randomized controlled trials (RCTs), systematic reviews (SRs), and observational studies▪ Studies included at least 200 patients

Relevant to VCF, the expert panel assessed:

- Importance of 10 signs and symptoms
- Relevance of 3 diagnostic procedures
- Appropriateness criteria of VA vs. NSM for 576 clinical scenarios
- Adequacy of six aspects of follow-up care

Limitations — The principal limitations of this study are related to selecting a panel and the subjectivity of panel member recommendations. The project mandated the multidisciplinary experts strictly adhere to RAND™ methodology, based on published clinical evidence and their clinical expertise.

All panel members were proceduralists, chosen because practical experience was considered important to assess the appropriateness of VA vs. NSM for a variety of patient scenarios. The involvement of referring physicians is a prerequisite for further research to validate the CPP in clinical practice.

RESULTS

Figure 1 illustrates how the five elements of the clinical care pathway connect — starting with a patient presenting with back pain, through the appropriate evaluation and treatment, and ending with a follow-up visit and osteoporosis education.

RAM PANEL RECOMMENDATIONS

1. Key signs and symptoms of VCF

The panel assessed key signs and symptoms found in the literature. Ten were considered to be most specific for VCF:

HISTORY OF PRESENT ILLNESS

- Severe limitation in mobility/activities of daily living (ADL) due to pain
- Pain diminishes or is resolved with rest
- Recent history of minimal/low-velocity trauma
- Pain is related to activity or movement

PAST MEDICAL HISTORY, INCLUDING RELATIVE RISK FACTORS

- Osteoporosis or osteopenia
- Previous VCF
- Chronic use of corticosteroids

PHYSICAL EXAM

- Tenderness to palpation/percussion over posterior spinous process(es)
- Pain exacerbates by change of position, with reluctance to move
- Midline back pain

The probability of a VCF was categorized based on the number of signs and symptoms present:

PROBABILITY OF VCF	NUMBER OF SIGNS AND SYMPTOMS
Low	1–3
Intermediate	4–6
High	≥ 7

2. Diagnostic evaluation of patients with suspected VCF

After weighing the appropriateness of all advanced imaging modalities (MRI, CT, nuclear bone scan) for patients suspected of having VCF, the panel considered advanced imaging:

- **Unnecessary** for patients with **moderate symptoms** and a **low probability of VCF**
- **Indicated** for all patients with **severe symptoms** and/or **intermediate to high probability of VCF**
- With **MRI** being **most appropriate**
- With **nuclear bone scan** and **CT** good alternatives when **MRI cannot be performed**

Table 1: Panelists were asked to determine if imaging was appropriate once a VCF is suspected. Scenarios that had at least 75% agreement were deemed appropriate for imaging (highlighted in table).

STATEMENT REGARDING DIAGNOSTIC IMAGING	% (STRONGLY) AGREE
All patients suspected of VCF (based on key signs and symptoms, medical history, and physical exam) should firstly undergo conventional radiography.	17
If conventional radiography is used in patients suspected of VCF, standing AP and lateral radiographs are highly recommended.	75
In patients with moderate symptoms (VAS 5–6) and a low probability of VCF , a conservative treatment regimen without further imaging is usually the most appropriate strategy.	92
In patients with severe symptoms (VAS \geq 7) and low probability of VCF , advanced imaging (MRI, CT, bone scan) is indicated.	92
All patients with intermediate to high probability of VCF , with or without supportive evidence from conventional radiography, should be referred.	100
For patients with an intermediate to high probability of VCF, with or without supportive evidence from conventional radiography, MRI is the preferred advanced imaging technique.	100
If MRI is unavailable or if the patient has a contraindication for MRI, CT scan and nuclear bone scan are the best alternatives.	100
If a treatment decision on vertebral augmentation is necessary, advanced imaging must be repeated if the previous image was performed more than 30 days ago.	67

AP = anterior-posterior; CT = computed tomography; MRI = magnetic resonance imaging; VAS = Visual Analogue Scale; VCF = vertebral compression fracture

3. Appropriateness criteria of vertebral augmentation vs. nonsurgical management

- The panel agreed on seven key clinical findings used to prescribe VA or NSM (Table 2).
- Panelists were asked to individually assess the appropriateness of VA versus NSM for 576 clinical scenarios, based on a 9-point scale (1 = NSM appropriate; 9 = VA appropriate; 5 = equivocal or uncertain).
- A threshold of 75% agreement among panelists was used to define consensus on statements.
- Appropriateness of diagnostic procedures and treatment for VA vs. NSM was calculated based on median panel score and extent of agreement between the panelists.
 - ✓ VA appropriate: median score of 7–9
 - ✓ VA not appropriate: median score of 1–3
 - ✓ Uncertain: all other outcomes

CLINICAL FINDINGS USED TO PRESCRIBE VA OR NSM

Table 2: Seven key clinical findings were used to prescribe vertebral augmentation or nonsurgical management to treat patients with VCF. The appropriateness of VA increases with the number and relative weight of unfavorable conditions.

CLINICAL FINDING	CATEGORIES CONSIDERED
1. Duration of pain	<ul style="list-style-type: none"> ▪ < 1 day ▪ 1–3 days ▪ 3–6 days ▪ > 6 weeks
2. Advanced imaging findings (MRI, CT, nuclear bone scan)	<ul style="list-style-type: none"> ▪ Negative ▪ Positive (concordant with or supportive of acuity of fracture)
3. Degree of vertebral height reduction	<ul style="list-style-type: none"> ▪ Mild (< 25%) ▪ Moderate (25–40%) ▪ Severe (> 40%)
4. Kyphotic deformity	<ul style="list-style-type: none"> ▪ No ▪ Yes
5. Progression of vertebral height loss (additional height reduction on radiologic images at follow-up)	<ul style="list-style-type: none"> ▪ No ▪ Yes
6. Evolution of symptoms	<ul style="list-style-type: none"> ▪ Improved since onset but VAS still ≥ 5 ▪ Stable on medication but VAS still ≥ 5 ▪ Worsened despite optimal medication
7. Impact of VCF on daily functioning	<ul style="list-style-type: none"> ▪ Moderate (cf. Roland Morris Disability Questionnaire 12–17) ▪ Severe (cf. Roland Morris Disability Questionnaire > 17)

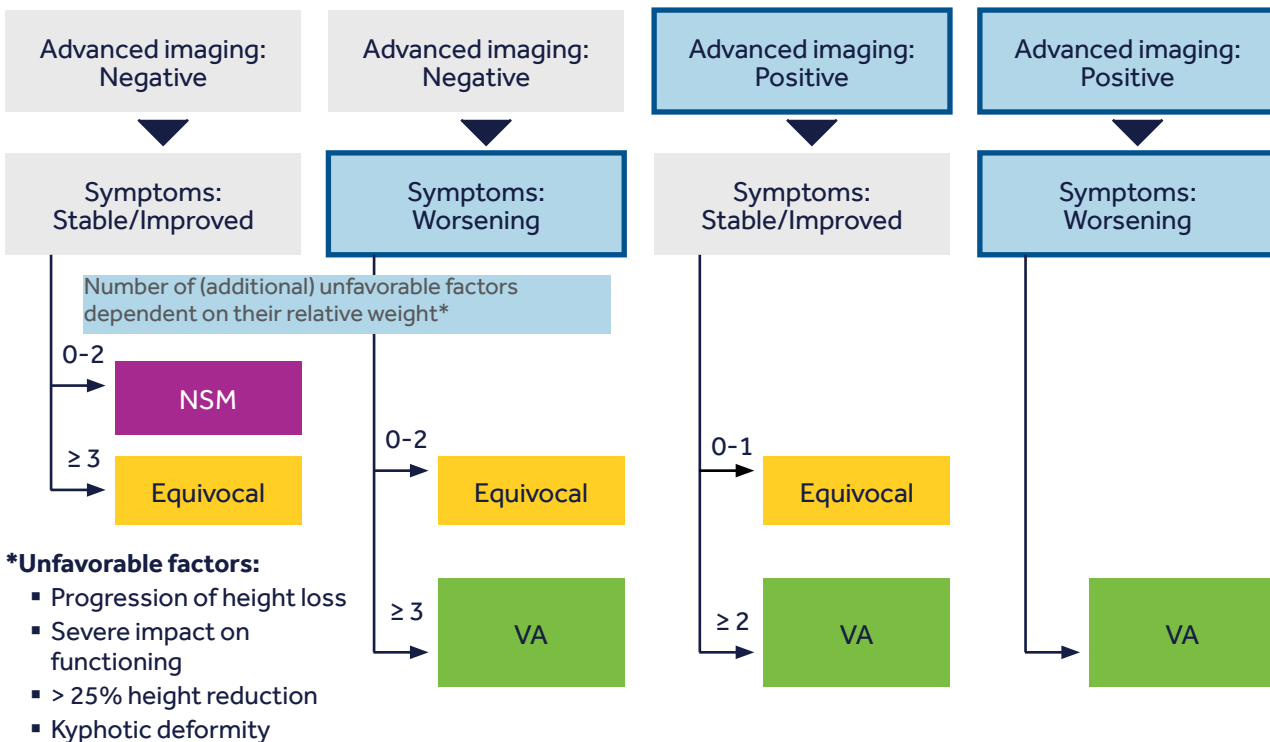
Of the 576 clinical scenarios:

- 46% were deemed appropriate for VA
- 16% were deemed appropriate for NSM
- 38% uncertain

To see which treatments are appropriate for specific scenarios, access the study at:
doi.org/10.1016/j.spinee.2018.07.025

SUMMARY OF PANEL RECOMMENDATIONS FOR TREATMENT

Figure 2: Panel recommendations on the appropriateness of treatment for VCF. Blue outlined boxes indicate a present condition.



Reprinted from *The Spine Journal* 2018, Hirsch JA, Beall DP, Chambers MR et al. [Management of vertebral fragility fractures: a clinical care pathway developed by a multispecialty panel using the RAND/UCLA Appropriateness Method](#). Nov;18(11):2152-2161, Copyright 2018, with permission from Elsevier.

4. Contraindications for vertebral augmentation

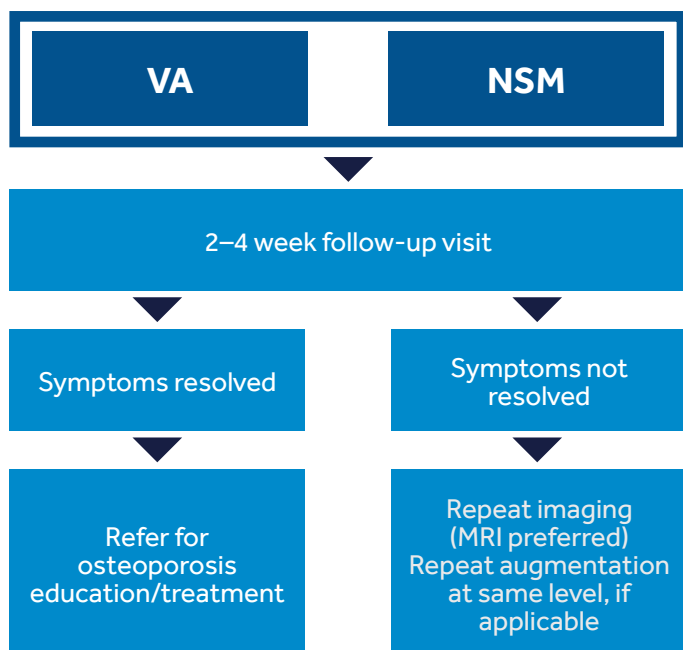
The panel considered 11 conditions to assess appropriateness for VA. Full agreement was reached on recommendations for absolute and relative contraindications for vertebral augmentation:

Absolute contraindication	<ul style="list-style-type: none">▪ Active infection at surgical site▪ Untreated blood-borne infection
Strong contraindication	<ul style="list-style-type: none">▪ Osteomyelitis
Usually contraindicated	<ul style="list-style-type: none">▪ Pregnancy
Relative contraindication	<ul style="list-style-type: none">▪ Allergy to fill material▪ Coagulopathy▪ Spinal instability▪ Myelopathy from the fracture▪ Neurologic deficit▪ Neural impingement
Generally not a contraindication	<ul style="list-style-type: none">▪ Fracture repulsion▪ Canal compromise

RECOMMENDED FOLLOW-UP FOR PATIENTS TREATED FOR VCF

5. Follow-up after treatment

Figure 3: The panel agreed that follow-up of patients treated for VCF is a key step in the clinical care plan.



Panel consensus was reached on the following statements related to follow-up of patients:

- After either VA or NSM, a follow-up visit should be planned at 2 to 4 weeks.
- In patients with a satisfactory result of VA at first follow-up (2 to 4 weeks after the procedure), there is generally no need for further post-operative monitoring. Follow-up for management of the underlying pathology does not need to be managed by the proceduralist.
- All patients presenting with VCF should be referred for evaluation of bone mineral density and osteoporosis education for subsequent treatment as indicated.
- All patients with VCF should be instructed to take part in an osteoporosis prevention/treatment program.
- If symptoms are not resolved at follow-up, repeat imaging (preferably MRI) is mandatory.
- If the pain is not resolved after VA, a repeat augmentation (at the same level) may be considered, but does require a careful diagnostic evaluation to identify any other sources of pain (additional fractures, facet arthropathy, etc.)

CONCLUSION

Using the RAND/UCLA Appropriateness Method, a multispecialty expert panel established a comprehensive clinical care pathway (CCP) for the management of vertebral compression fractures (VCF).

The CCP may guide clinicians in making informed and reasoned decisions on the detection, diagnostic evaluation, treatment choice, and follow-up of patients after treatment. The pathway may be used in many healthcare settings and may be helpful to reduce undesirable practice variations and improve quality of care.¹

The appropriateness outcomes allow a simple two-step algorithm as a first step when considering patients for either nonsurgical management or vertebral augmentation. An extensive supplementary appendix of hundreds of VCF-related clinical scenarios may be used for a more tailored approach. Access the study at: doi.org/10.1016/j.spinee.2018.07.025

Further research is recommended to test the validity of recommendations and usefulness in daily practice needs.

About Balloon Kyphoplasty (BKP)

BKP is a minimally invasive procedure for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesion. The complication rate with BKP has been demonstrated to be low. There are risks associated with the procedure (e.g., cement extravasation), including serious complications, and though rare, some of which may be fatal.

Risks of acrylic bone cements include cement leakage, which may cause tissue damage, nerve or circulatory problems, and other serious adverse events, such as: cardiac arrest, cerebrovascular accident, myocardial infarction, pulmonary embolism, or cardiac embolism.

For complete information regarding indications for use, contraindications, warnings, precautions, adverse events, and methods of use, please reference the devices' Instructions for Use included with the product.

Reprinted from *The Spine Journal* 2018. Hirsch J., Beall D., Chambers M., et al. Management of vertebral fragility fractures (VCF): a clinical care pathway developed by a multispecialty panel using the RAND/UCLA Appropriateness Method. Copyright 2018, with permission from Elsevier.

REFERENCE

1. Hirsch JA, Beall DP, Chambers MR et al. [Management of vertebral fragility fractures: a clinical care pathway developed by a multispecialty panel using the RAND/UCLA Appropriateness Method.](#) *Spine J.* 2018 Nov;18(11):2152-2161. doi: 10.1016/j.spinee.2018.07.025.

Medtronic

Medtronic
Spinal and Biologics Business
Worldwide Headquarters

2600 Sofamor Danek Drive
Memphis, TN 38132



Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132

(901) 396-3133
(800) 876-3133
Customer Service: (800) 933-2635

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.



Consult instructions for use at this website www.medtronic.com/manuals.

Note: Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat™ Reader with the browser.