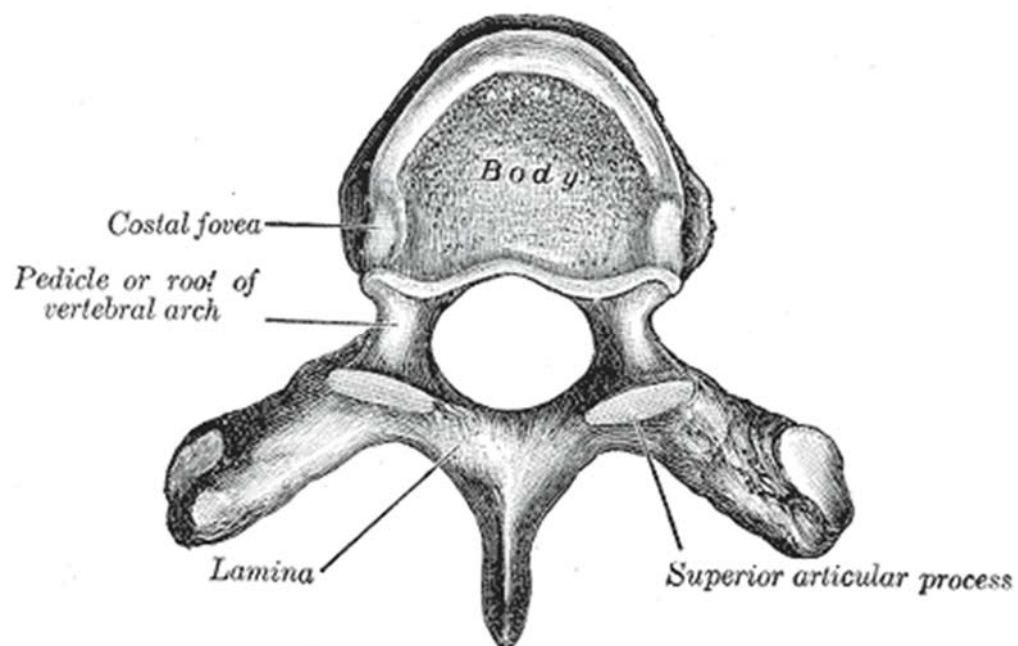


## SYNTHESIS

# PERCUTANEOUS VERTEBROPLASTY AND BALLOON KYPHOPLASTY





## SYNTHESIS

# PERCUTANEOUS VERTEBROPLASTY AND BALLOON KYPHOPLASTY

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## ■ FOREWORD

Back pain in general belongs to the most frequent health problems and is responsible for a substantial share of work disability. Is this the price that our species has to pay for having dared to stand upright barely seven millions years ago? Has our head, while *Homo erectus* was becoming *Homo sapiens*, started to weigh too much on this spine that did not have the time yet to get used to the upright position? Whatever the answer may be, with his hands henceforth freed to create tools and with his oversized brain, modern man relentlessly tries to invent new technological fixes to his physical ailments.

Medical industry indeed continuously brings innovative devices on the market, developed in collaboration with clinicians, in an attempt to enrich our therapeutic arsenal. In these two reports published simultaneously, we assessed two technological approaches likely to 'repair' failing backs: firstly the vertebroplasties by means of cement injection in a fractured and compressed (generally lumbar) vertebra, possibly preceded by a re-expansion by a balloon (or balloon kyphoplasty); and secondly the intervertebral disc replacement prostheses.

These new approaches are based on logical thinking and seem to promise new avenues in the notoriously delicate spine surgery. But in fact, do these innovations actually deliver what they promise? More precisely, do the statistically significant results observed in some studies also reflect clinically tangible improvements? In this field eminently subject to psychosomatic influences, do the studies succeed in neutralizing the powerful placebo effect a surgical procedure may engender? And, finally, are the observed results confirmed on the long term? Whoever decides to take a closer look should better be prepared for some surprising results.

Obviously, considering the current context of savings, only innovations with a real and observable added value should be reimbursed. It is a matter of separating the wheat from the chaff, not only to save the scarce health insurance resources for genuinely effective therapies but also to prevent patients from feeding false hopes.

We are thankful to the experts and practicing clinicians who have accompanied us in the development of these two reports, and, by doing so, have contributed, together with us, to an ever more *evidence-based* health insurance.

Christian LÉONARD  
Deputy general director

Raf MERTENS  
General director



## ■ ABSTRACT

### OBJECTIVES

To conduct a rapid review to evaluate the clinical effectiveness, safety and cost-effectiveness of percutaneous vertebroplasty or balloon kyphoplasty versus conservative treatment or against each other in the management of vertebral compression fractures (VCF).

### METHODS

Systematic literature review of randomised controlled trials (RCTs), systematic reviews of RCTs, and full economic evaluations in Medline, Embase, Cochrane and CRD (CDSR, DARE, HTA, NHS EED and CENTRAL). Analysis of national administrative databases and industry-launched survey results.

### RESULTS

Most evidence is available for VCF related to osteoporosis. However, most trials are non-blinded with only two small blinded RCTs, leading to low quality evidence overall. Some of the clinical outcomes (pain, quality of life, functionality, mobility and radiographic parameters) are in favour of vertebroplasty or kyphoplasty, with larger effects on the short term in the non-blinded studies. However, most of these outcomes are not statistically significantly different in the two blinded studies. On the long term most of these outcomes improve in both arms of the studies. In the two studies that directly compare both techniques no statistically significant difference is found for most outcomes.

For VCF unrelated to osteoporosis only very low quality evidence from one RCT is available.

Incidence of complications is rare, but when occurring consequences can be serious and even life-threatening. A lower long-term mortality rate associated with these techniques has been reported but is very uncertain.

The results of the economic evaluations are divergent.



## CONCLUSIONS

There is considerable uncertainty and no convincing evidence regarding the clinical effectiveness of either technique compared to conservative treatment. Due to this clinical uncertainty, cost-effectiveness evaluations are highly dependent upon uncertain assumptions.



## ■ SYNTHESIS

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## LIST OF ABBREVIATIONS

### ABBREVIATION

### DEFINITION

EQ-5D

EuroQol 5 dimensions

HRQoL

Health Related Quality of Life

HTA

Health Technology Assessment

NICE

National Institute for Health and Care Excellence (UK)

NRS

Numeric Rating Scale

OPM

Optimal Pain Management (or non-surgical optimal pain management)

QoL

Quality of Life

QUALEFFO

Quality of Life Questionnaire of the European Foundation for Osteoporosis

RCT

Randomised Controlled Trial

ScHARR

School of Health And Related Research

VAS

Visual Analogue Scale

VCF

Vertebral Compression Fractures



## 1. INTRODUCTION

In this rapid review we reconsider the evidence on clinical effectiveness, safety and cost-effectiveness of two minimally invasive procedures for the treatment of painful Vertebral Compression Fractures (VCF). These VCF are most frequently caused by osteoporosis and occur mainly in women. However VCF can also have other causes, including malignancies, for which the body of evidence is much poorer.

In both techniques cement is injected in the fractured vertebra. In vertebroplasty this is done through direct injection. In balloon kyphoplasty a balloon is first inflated in the vertebra to reduce the vertebral height loss caused by the fracture and restore the natural curvature of the spine, then removed prior to the injection of cement. Both techniques are commonly also described as *vertebral augmentation*.

More recently, other techniques to achieve similar effects have been introduced, such as stenting of the vertebra, but the body of evidence on those techniques is much more limited. Therefore, those techniques are not considered in this report.

### Vertebroplasty and balloon kyphoplasty in Belgium

In the past, percutaneous balloon kyphoplasty was reimbursed under strict conditions while vertebroplasty was not reimbursed at all. Since April 2015 this has changed triggered by budgetary constraints. Although reimbursement for the cement (€82) and the medical fees (€305) linked to kyphoplasty is maintained, the reimbursement for the balloon kit was reduced from €4258 to €0. Cement used during vertebroplasty is now reimbursed (€82), but the medical act and the vertebroplasty kit (around €500) are not.

According to our analysis of administrative databases and a survey launched by the industry, the number of vertebroplasties performed in our country was estimated at around five hundred per year and the number of kyphoplasties at approximately eight hundred per year. The procedures are predominantly performed in women (around 65%) with an average age around 70 years.

## 2. CLINICAL EFFECTIVENESS

### 2.1. Included studies

The evidence for this rapid review is largely based on a systematic review of randomised controlled trials (RCTs) on VCF related to osteoporosis published in 2014.<sup>1</sup> This review will further be called the SchARR review. It includes nine RCTs: two blinded RCTs comparing vertebroplasty with non-surgical optimal pain management (OPM) and placebo intervention, five non-blinded RCTs comparing vertebroplasty to OPM, one non-blinded RCT comparing kyphoplasty with OPM and one non-blinded RCT comparing both vertebral augmentation techniques.

After searching the literature for additional RCTs published after that review we identified one supplementary non-blinded RCT (KAVIAR) published by the end of 2014, comparing kyphoplasty with vertebroplasty.<sup>2</sup>

For non-osteoporotic VCF we identified only one non-blinded RCT (CAFÉ) published in 2011, comparing kyphoplasty with OPM.<sup>3</sup>

In the discussion we also briefly describe the evidence from observational studies.

### 2.2. Results

We judged the quality of the evidence on the clinical effectiveness for both vertebral augmentation techniques for VCF related to osteoporosis as low, because of the small size of the RCTs and the non-blinded nature of most of them. Only two small RCTs are blinded. Moreover, results are conflicting. However, results from a new blinded RCT on vertebroplasty (VERTOS IV) are expected towards the end of 2015 or early 2016. Those results might remove some of the uncertainty.

Evidence on VCF unrelated to osteoporosis is scarce and limited to observational evidence, except for one small RCT on malignant VCF. The quality of the evidence for these indications is judged to be very low.



### 2.2.1. Osteoporotic VCF

#### 2.2.1.1. Quality of Life and Pain

Quality of life is most often assessed with the generic EuroQol 5-dimensions (EQ-5D) and/or the disease specific QUALEFFO scale. Pain is most often measured on either a visual analogue scale (VAS) or on a numeric rating scale (NRS).

Broadly speaking, the RCTs show that patients in the vertebroplasty, kyphoplasty and control groups all experience improvement of health-related quality of life (HRQoL) and pain reduction over time.

The non-blinded trials and the observational studies suggest that both vertebroplasty and kyphoplasty provide greater improvement of quality of life and pain reduction than non-surgical management, especially on the short term. After more than 6 months the effect difference appears to become smaller. Although agreeing that in general the positive treatment effect difference on pain relief and quality of life reduces over time, some experts argue that only considering long-term results is not fair since both vertebral augmentation techniques have an immediate and significant treatment effect.

However, the two double-blinded trials comparing the vertebroplasty with the sham (placebo) intervention also indicate this immediate treatment effect whatever the intervention and show no statistically significant difference between the vertebroplasty and the sham intervention for those two outcomes (quality of life and pain). No blinded trials of kyphoplasty compared with sham treatment have been performed so far. Results from an ongoing blinded trial (VERTOS IV) comparing vertebroplasty to sham intervention are anticipated by the end of 2015 at the earliest. These should allow for a better understanding of this apparent discrepancy between evidence from blinded and non-blinded trials.

#### 2.2.1.2. Other outcomes

Other outcomes include back-specific functionality and mobility, but also radiographic parameters such as vertebral body height, angular deformity and fracture progression.

Results for these outcomes are mixed, with in general an improvement in back-specific functionality and mobility in both the intervention and the

control groups. However, some of the non-blinded studies report more improvement in the intervention groups.

Results on vertebral body height, angular deformity and fracture progression are conflicting and difficult to compare between studies because of different methodologies.

#### 2.2.1.3. Vertebroplasty versus kyphoplasty

The two studies that directly compare both vertebral augmentation techniques show no statistically significant differences at any point of time in the follow-up for most of the outcomes. Only for vertebral body height the two studies report a better restoration in the kyphoplasty groups either immediately postoperative (Liu et al.)<sup>4</sup> or after 24 months (KAVIAR).<sup>2</sup>

No trial reports data on vertebral fracture progression.

#### 2.2.1.4. Observational evidence and expert opinion

A recent non-systematic review on vertebral augmentation techniques includes RCTs and observational evidence.<sup>5</sup> This review concludes that vertebroplasty and kyphoplasty are both superior to non-surgical management in clinical and radiological parameters, but this conclusion is mainly based on non-randomised observational evidence. Moreover, it omits two of the RCTs included in the SchARR review.<sup>1</sup>

The NICE recommendation from 2013 was largely based on this SchARR review. However, for the appraisal NICE also includes evidence from observational studies and the input from several stakeholders. Therefore, the NICE appraisal recommends that:<sup>6</sup>

*“Percutaneous vertebroplasty and percutaneous balloon kyphoplasty without stenting, are recommended as options for treating osteoporotic vertebral compression fractures only in people:*

- who have severe ongoing pain after a recent, unhealed vertebral fracture despite optimal pain management,*
- and*
- in whom the pain has been confirmed to be at the level of the fracture by physical examination and imaging.”*



'Recent' in this appraisal is defined as around 6 weeks. The rationale behind this timing is that in many patients the severity of the pain will decline after 2 to 3 weeks and many will be free of pain at 6 weeks.<sup>6</sup> This observation is also confirmed in the RCTs where both groups have improved quality of life and pain control regardless of whether or not they had the intervention.

#### 2.2.1.5. Subgroups

There is an ongoing debate on whether vertebral augmentation is more effective in the treatment of acute versus chronic VCF. However, the included studies are too small to permit the identification of subgroups of patients who might benefit more from vertebroplasty or kyphoplasty. Analysis of individual patient data from the two blinded RCTs on vertebroplasty suggests that effectiveness is unrelated to fracture acuity.<sup>1, 7</sup> Recently published long-term follow-up results at 12 and 24 months from one of these studies also showed no difference between patient groups.<sup>8</sup>

More research is needed to explore the selection of patients that might benefit most from vertebral augmentation interventions. Several attempts to improve this selection using MRI, radiographic techniques, reported pain and time since fracture have been made. However, those are mainly based on experts consensus. Gathering more evidence on these selection criteria should be high on the research agenda.

#### 2.2.2. VCF unrelated to osteoporosis

Evidence for VCF unrelated to osteoporosis is mainly observational, apart from one small RCT in cancer patients. This very low-quality evidence shows mixed results for the reduction of pain, improvement of quality of life and improvement of back-specific function after both vertebroplasty and kyphoplasty.

### 2.3. Overall conclusion

There is considerable uncertainty and no convincing evidence regarding the clinical effectiveness of either technique in comparison to conservative management, especially in the long term. Consequently, extrapolations on cost-effectiveness as described further are highly hypothetical. In the long term, symptoms improve in all patient groups whether or not they had the intervention.

In the non-blinded RCTs and in observational studies, vertebroplasty and kyphoplasty often perform better in the short term than non-surgical management for improving quality of life and reducing disability and pain.

In the two blinded studies on vertebroplasty, however, the between group differences are not statistically significant and symptoms improve in both groups in the short term. It was suggested that the main reason might be an important placebo effect.<sup>1, 7</sup> Another reason, however, might be that those are chance findings in small studies or that patient selection in those studies was not optimal.

The evidence on the effectiveness of the techniques is thus of low quality and conflicting. More evidence can be anticipated from ongoing studies, especially the sham-controlled VERTOS IV study where results are expected by the end of 2015 or early 2016.

There is no convincing evidence on different clinical outcomes for kyphoplasty compared to vertebroplasty.



### 3. SAFETY

Incidence of serious complications is rare, but when they occur consequences can be serious. Most of these complications are associated with the leakage of bone cement outside the treated vertebra. Although intradiscal leakage is unlikely to lead to complications, epidural and intravascular leakage can have serious consequences. A number of procedure-related deaths are reported in case reports. Reported adverse events include pulmonary embolism, periprocedural hypotension, radiculopathy, damage to surrounding tissue, paraparesis, paraplegia, rib fracture and postoperative infection.

A meta-analysis of mortality rates from RCTs suggests that vertebroplasty might be associated with a reduction in mortality at 12 months.<sup>1</sup> However, this effect did not reach statistical significance and the included trials were not designed to detect this outcome. A reduction in mortality is also reported from registry data, but since these are not randomised the causal relation is uncertain.

### 4. ECONOMIC EVALUATION

#### 4.1. Included studies

The systematic review of the published economic literature allowed the identification of 11 relevant studies: five recent literature reviews,<sup>9-13</sup> five full economic evaluations,<sup>14-18</sup> and the SchARR HTA also including both a review of the literature and a primary economic evaluation.<sup>1</sup>

After qualitative appraisal of the six reviews we decided to retain the most recent systematic review from 2015 by Borgström et al.<sup>9</sup> This literature review covers five of the six economic evaluations identified, but excludes the US cost-effectiveness study by Edidin et al.<sup>14</sup> as it did not comply with Borgström's inclusion criteria of being a cost-utility analysis (i.e. with outcomes expressed as quality-adjusted life-years instead of life-years only). Our description and conclusions about the cost-effectiveness of vertebroplasty and kyphoplasty are thus based on the review by Borgström et al.<sup>9</sup> updated with the results of Edidin et al.<sup>14</sup>

The economic evaluations are all related to vertebral compression fractures of osteoporotic origin; economic evidence for non-osteoporotic fractures alone (e.g. malignant VCF) was not found.

#### 4.2. Results

There is a large diversity in the results of studies.

Three studies compare vertebroplasty to non-surgical optimal pain management (OPM).<sup>14, 16, 18</sup> They all report that vertebroplasty is a cost-effective option and one study<sup>18</sup> even reports dominance of vertebroplasty over OPM, meaning that vertebroplasty is both more clinically effective and less costly than OPM. However, in two of those studies sensitivity analyses are not performed,<sup>14, 18</sup> while the third study does not provide details about the methods and assumptions used in the model.<sup>16</sup> Therefore, it is not possible to assess the robustness of those results.

Four studies compare kyphoplasty to OPM. In three studies kyphoplasty is found to be a cost-effective intervention<sup>14, 17, 18</sup> whereas the opposite is reported in another study.<sup>15</sup> Three studies also report that uncertainty analyses show that their cost-effectiveness results are highly sensitive to the uncertain assumptions in the models.<sup>15, 17, 18</sup> In Edidin et al.,<sup>14</sup> no sensitivity analysis is performed.



A comparison of kyphoplasty versus vertebroplasty is reported in two studies. One study reports that kyphoplasty is cost-effective compared to vertebroplasty<sup>14</sup> while the other study more prudently concludes that it may be cost-effective.<sup>18</sup> In the first study,<sup>14</sup> no sensitivity analysis of the results is performed. In the second study, the sensitivity analysis shows that the results are very sensitive to the uncertain underlying assumptions.

The SchARR study compares vertebroplasty, kyphoplasty, OPM and sham (placebo) treatment.<sup>1</sup> The results of this modelling show that no firm conclusions on the cost-effectiveness of vertebroplasty or kyphoplasty can be made due to the uncertainty of the input parameters, especially the assumptions on mortality, quality of life, hospitalisation costs and sham costs.

#### 4.3. Main drivers of the results

Due to the limited evidence on clinical effectiveness and procedure safety, the results of the economic evaluations are very dependent on uncertain assumptions regarding those parameters. The three parameters that most strongly drive the results of the studies are:

- **The mortality benefit attributed to vertebral augmentation techniques.** Assuming such a reduced mortality with kyphoplasty and vertebroplasty has a significant impact on the results of the cost-effectiveness studies. If the mortality benefit observed in non-randomised studies is accounted for, kyphoplasty and vertebroplasty could be considered cost-effective compared to OPM. So far, however, this potential difference in mortality between patients undergoing kyphoplasty and vertebroplasty compared to OPM remains unproven. Studies of the mortality effect should be high up on the coming research agenda.
- **The assumed difference in length of stay associated with patients receiving kyphoplasty and vertebroplasty versus OPM.** Assuming such a difference leads to more favourable results for vertebral augmentation procedures. However, the length of stay associated with patients receiving kyphoplasty, vertebroplasty and OPM is not known with certainty.

- **The treatment effect.** There remains considerable uncertainty about the efficacy and the effectiveness of either technique. There is some evidence from short-term non-blinded RCTs and observational studies that vertebroplasty and kyphoplasty result in better QoL outcome than OPM. Results from blinded RCTs, however, report no statistically significant difference. There is also no convincing evidence of a different clinically meaningful outcome between kyphoplasty and vertebroplasty. Ongoing studies should provide further evidence.

#### 4.4. Overall conclusion

These economic evaluations are mostly related to vertebral compression fractures related to osteoporosis. This review highlights that the baseline assumptions across the economic evaluations are extremely varied, and that their results are diverse and highly sensitive to changes in those assumptions. Obtaining further evidence on those uncertainties should be high on the research agenda.

The main uncertainties for the cost-effectiveness results are:

- the mortality benefit accorded to vertebral augmentation techniques;
- the assumed difference in length of stay associated with patients receiving kyphoplasty, vertebroplasty or OPM;
- the treatment effect.

Furthermore, none of the economic evaluations was performed in Belgium with costs and outcome data reflecting the Belgian health care system and organization. Therefore, given the lack of current knowledge and awaiting confirmation of those crucial assumptions, it is difficult to currently draw final conclusions regarding the cost-effectiveness of kyphoplasty and vertebroplasty.



## ■ RECOMMENDATIONS<sup>a</sup>

THE FOLLOWING RECOMMENDATIONS CONCERN EXCLUSIVELY THE PERCUTANEOUS VERTEBROPLASTY AND THE CLASSIC PERCUTANEOUS BALLOON KYPHOPLASTY, EXCLUDING ALL OTHER AND NEWER VERTEBRAL AUGMENTATION TECHNIQUES

*To the Technical Medical Council and the Commission for the Reimbursement of Implants and Invasive Medical Devices*

- Given the limited evidence and the existing uncertainties on the clinical effectiveness and cost-effectiveness of percutaneous vertebroplasty and balloon kyphoplasty, we recommend to apply the same reimbursement tariff for both procedures, but under different nomenclature codes.
- We recommend to assess and revise, where necessary, both the limitative list of clinical indications and the required diagnostic modalities in collaboration with the clinical experts in the domain.

*To the hospital responsables and physicians*

- In accordance with the law of 2002 relative to the patients' rights, the patient should be clearly informed of the respective advantages and disadvantages as well as the cost of each alternatives.

*Recommendations for further clinical research*

- Future RCTs studying these interventions should include an arm with optimal pain management combined with a sham intervention and a blinded assessment of outcomes.
- More research is needed to explore the optimal selection of patients that might benefit most from vertebral augmentation interventions.

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<sup>a</sup> The KCE has sole responsibility for the recommendations.





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## COLOPHON

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- **The external experts were consulted about a (preliminary) version of the scientific report. Their comments were discussed during meetings. They did not co-author the scientific report and did not necessarily agree with its content.**
- **Subsequently, a (final) version was submitted to the validators. The validation of the report results from a consensus or a voting process between the validators. The validators did not co-author the scientific report and did not necessarily all three agree with its content.**
- **Finally, this report has been approved by common assent by the Executive Board (see <http://kce.fgov.be/content/the-board>).**
- **Only the KCE is responsible for errors or omissions that could persist. The policy recommendations are also under the full responsibility of the KCE.**

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