

PERCUTANEOUS VERTEBROPLASTY AS A TREATMENT
FOR OSTEOPOROTIC VERTEBRAL FRACTURES
– a health technology assessment
Summary

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Percutaneous vertebroplasty as a treatment for osteoporotic vertebral fractures – a Health Technology Assessment; Summary

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What is HTA?

Health technology assessment contributes to decision making in the health care sector. A HTA collects and assess existing knowledge about a given health technology. A health technology is defined broadly as procedures and methods for prevention, diagnostics, treatment, care and rehabilitation including devices and medicine. An example could be a new method to treat patients. Focus is on healthcare, patient, organisational and economical aspects. New research can be conducted if the number of sufficient studies is limited to elucidate one or more of these aspects.

The HTA results in a report that can contribute to better planning, quality enhancement and prioritizing in the health care sector. The target group is decision-makers in the health political field. The primary users are therefore administrations and politicians and other decision-makers in the health political field. The HTA contributes to decisions within administration as well as political management as to which services should be offered in the health care sector and how they should be organized.

Health technology assessment is defined as:

- HTA is a comprehensive systematic assessment of the prerequisites and consequences of applying a health technology
- HTA is a research-based, application-oriented assessment of relevant existing knowledge about problem areas applying a technology within the field of health and illness.

The project is funded by a HTA-fund that was terminated in 2007. The purpose of the fund was to spread out knowledge and use of HTA locally. The funded HTA-reports are prepared in collaboration with an external interdisciplinary project group. The project group systematically reviews the existing literature, contributes with data collection and produces the chapters and conclusions of the report. The project management is placed at the National Board of Health who is also responsible for the editing of the final report. The report has been submitted to an external reference group and is also externally peer-reviewed.

Find more information about HTA at www.sst.dk/mtv under HTA toolbox:
“Handbook of Methods for Health Technology Assessment”
“Health Technology Assessment – Why? What? When? How?”

Summary

Introduction

Percutaneous Vertebroplasty (PVP) is a minimal invasive treatment for painful vertebral fractures resistant to conservative therapy. Technically bone cement, usually polymethylmetacrylat (PMMA) is injected in the vertebral body under fluoroscopic control. The procedure was invented in France in the eighties for the treatment of vertebral haemangiomas. Shortly after the procedure was used to treat osteoporotic vertebral compression fractures as well.

The purpose of this health technology assessment (HTA) is to provide sufficient evidence for decision-makers before introduction of PVP in Danish hospitals. The assessment seeks to clarify the clinical, economical, and organizational consequences of treating osteoporotic, vertebral compression fractures by PVP compared to conservative treatment. PVP as treatment of other pathological conditions such as metastasis, multiple myeloma, and haemangiomas is not the issue of this assessment.

Specific HTA-questions to be answered in the report:

Technology: What is the indication of the procedure? Should PVP be used instead of or as a supplement to conservative treatment? Is the procedure well documented and are the advantages of the procedure proportional to the risks?

Patient: To which group of patients can PVP be used and what is the effect of PVP compared with conservative treatment in terms of patients' pain experience and physical abilities?

Organization: Where and by whom should PVP be performed? Are staff and interior restructuring necessary?

Economy: What is the difference in average costs regarding PVP and conservative treatment of patients with osteoporotic fractures in the spine, and what treatment is most cost effective?

To answer these questions, a systematic review of the literature and clinical studies (randomised and nonrandomised) have been performed. Moreover the organizational and economical consequences are described.

Technology

Preoperative evaluation: A thorough anamnestic and physical examination together with a plain X-ray of the spine is mandatory. In case of more than one fracture or chronic fractures, MRI (STIR weighted) or bone scan (SPECT) is performed to detect the active fractures. Only patients with fractures showing bony oedema on MRI or increased bone turnover on SPECT are expected to benefit from PVP. Many experienced centres also recommend CT- or MRI-scan done preprocedural in order to detect further and often subtle fractures, bony fragments in the spinal canal and to exclude other pain sources like disc herniation, tumors etc.

The procedure: PVP is performed in almost the same way in most countries. The procedure is performed with the mildly sedated patient in a prone position and under local

anaesthesia. The patient is monitored by an anaesthetic educated nurse. One or two cannulas are placed in the affected vertebra. The PMMA is injected under continuous fluoroscopic control. After the procedure the patient is maintained recumbent for two hours while the PMMA hardens.

Complications: A rate of 1-2 % symptomatic, often transient complications is reported in the literature, most frequently PMMA leakage causing nerve compression. Leakage is seen reported up to 65 %, but is without symptoms in the majority of cases. Other infrequent, but serious complications have been reported such as pulmonary PMMA embolies, infections, damage to the spinal cord and nerve roots.

Conservative treatment: Traditionally patients with osteoporotic compression fractures are treated with bed rest, analgetics, perhaps brace treatment and physiotherapy. Hospitalization may be necessary because of intense pain. In most cases the patients will recover in two to three months. Bed rest and immobilisation for longer periods increases the risk of potentially serious complications such as deep venous thrombosis, pneumonia and progression of osteoporosis.

Patient

Literature review

International and Danish studies indicate that PVP generally is a safe procedure with a significant pain relieving effect in patients with painful, osteoporotic vertebral fractures. In the review of the literature we only found three randomised studies showing immediate pain reduction in patients treated with PVP compared to conservatively treated patients. Patients randomised to conservative treatment were allowed to change therapy from optimal pain medication to PVP in case of persistent pain after two weeks. Since almost all patients eventually received PVP, the Dutch study cannot estimate long term effects and for that reason the study was terminated.

Three comparative, nonrandomised studies have been found. They cannot be compared directly, since two of the articles, describing one and two years follow up from the same study, are testing the effect of PVP on acute fractures, and the latter study is testing the effect on fractures more than six weeks old. On the other hand the studies are complementary and the conclusion might be that PVP and conservative treatments are comparable for osteoporotic vertebral fractures less than six weeks old. For patients with back pain for more than six weeks it seems that PVP is superior to conservative treatment until six months after treatment. The patients in these comparative studies were not randomly distributed to either PVP or conservative treatment though and therefore the groups are not directly comparable.

Twenty-four prospective and ten retrospective studies chosen from the literature review all indicate a pain relieving effect of PVP on both acute and chronic, osteoporotic vertebral fractures. However, the effect is not compared to conservative treatment and therefore, the pain relieving effect of PVP over conservative treatment cannot be documented.

The Danish randomised study indicate, like the international studies, an efficient and immediate pain relieving effect of PVP, but also a similar level of pain after three and 12 months as well as physical and mental function. This might be explained by the fact that osteoporotic vertebral fractures usually will heal after three months causing reduction in the pain level. The study in Odense has estimated the risk of new frac-

tures after PVP, but the study is too small to detect a significant difference in the frequency of new fractures between the two treatments. The number of new fractures adjacent to a cemented level is very small though, and it is known that women with preexisting vertebral fractures have a four time increased risk of subsequent fractures. Therefore the risk of new fractures should not be taken into account when planning PVP.

For osteoporotic, vertebral fractures more than eight weeks old (chronic fractures), the nonrandomised study in Odense indicates an efficient and immediate pain relieving effect of PVP. The pain relieving effect and the improvement of physical and mental parameters was stable after three and 12 months. The mean fracture age in this study was more than nine months, indicating that even old fractures may benefit from PVP. The most important factor in patient selection is the clinical investigation. The frequency of new fractures in this study, similar to the randomised study, is very low and the risk should not be taken into account when planning a PVP.

In conclusion, it is recommended that PVP is offered to patients with persistent pain after a period of conservative treatment. Patients with acute pain will recover spontaneously in most cases, perhaps supported by analgetics and brace treatment. Patients with persistent pain after two to three months of conservative treatment may be offered PVP preceded by MRI-scanning or SPECT. Though some acute patients may benefit from early PVP, for instance patients with intense pain, who still need hospitalization after a few days of conservative treatment, patients with chronic obstructive lung disease, who cannot be treated with opioids, and other weak patients who might not recover after several weeks of immobilisation.

Organisation

Departments of spinal surgery and radiology already performing percutaneous diagnostic or therapeutic procedures in the spine will not experience any major organisational challenges taking up PVP.

The department should however be aware of the following preconditions:

- A minimum of 50-60 PVP or percutaneous transpedicular approaches per year with a minimum of two clinicians performing the procedure regularly
- the aseptics during the PVP procedure must be at the level of an operating theatre
- some patients needs hospitalization following PVP
- a few patients will need acute surgical decompression of the neural structures following PVP
- some fragile patient need general anaesthesia and postoperative intensive care.

Economy

Based on data from the randomised clinical trials at Odense University Hospital an estimation of the cost per patient with use of either PVP or conservative treatment was made. The studies show that the average cost of conservative treatment was 64.000 DKK (€ 8,600) per patient versus 50.000 DKK (€ 6,700) of PVP.

The estimated difference in the cost per patient is statistically significant and shows that the costs of the surgical procedure are outweighed by the reduction in the cost caused by a shorter hospitalisation of patients treated with PVP.

The perspective in the calculation of the costs is societal and twenty cost elements are included in the calculations. For nine of these cost elements, information of the amount of resources used was collected for each individual patient. Based on this the method used for data collected is expected to give a solid foundation for the assessment of the costs of PVP on patients with osteoporotic, vertebral fractures at hospitals in Denmark.

Overall evaluation

The indication for PVP is painful osteoporotic vertebral fractures in patients, who still need hospitalization after two to three days of conservative treatment with strong analgetics and perhaps brace treatment. In addition weak patients who cannot take several months of immobilisation and patients with chronic obstructive lung disease, who cannot be treated with opioids, will benefit from PVP. In addition the procedure is indicated for patients with chronic, osteoporotic vertebral fractures, who still have disabling pain after two to three months of conservative treatment.

The effect of PVP is documented in the clinical, randomised study at the University Hospital of Odense on acute and subacute, osteoporotic vertebral fractures. The documentation is supported by international clinical, nonrandomised and non comparative studies. The effect on chronic pain is documented in several international studies and in the clinical nonrandomised study at the University Hospital of Odense.

The procedure is in general correlated with few and harmless complications, but rare and severe complications as nerve compression and cement embolies in the lungs have been reported. Though, with the right indication the benefits clearly outweigh the risk of complications, as the pain relieving effect in general is immediate and permanent.

The procedure is in most cases performed under conscious sedation and local anaesthesia. Cement is injected through cannulas placed transpedicularly in the anterior part of the vertebral body. The patients may feel discomfort during the injection of PMMA, but in general the procedure is well tolerated. The patients may be operated in general anaesthesia but the possibility of early detection of PMMA leakage causing irradiating pain is then reduced.

It is recommended that the PVP is performed by clinicians who already handle fluoroscopic guided transpedicular procedures, that is spine surgeons and interventional radiologists. A minimum of 50-60 transpedicular procedures need to be performed yearly by minimum two clinicians to ensure continuity and sufficient qualifications. The procedure must be performed aseptic in an operating theatre with the possibility of general anaesthesia. Access to surgical decompression must be present in case of severe PMMA leakage. There is no need for staff and interior restructuring if PVP is performed by a spine surgeon. Radiologists need to cooperate with a clinical department, because of the possible need for hospitalization, acute decompression, and follow up. Education of surgeons and assisting staff takes a few days.

In the randomised study in Odense including patients with acute and subacute osteoporotic, vertebral fractures the average costs were calculated to 64.000 DKK (€ 8,600) for conservatively treated patients and 50.000 DKK (€ 6,700) for patients treated with PVP. The difference was statistically significant. Thus, from an economic point of view, PVP is superior to conservative treatment. The economic advantage is predominantly due to shorter hospitalization for operated patients compared to conservatively treated patients.

The overall conclusion is that PVP is a pain relieving procedure with prompt effect and few complications in patients with acute as well as chronic, osteoporotic vertebral fractures. Though, patients with acute fractures can be treated conservatively, as the majority of patients will recover spontaneously within two to three months. PVP should be considered in acute fractures with intense pain for more than 2-3 days requiring hospitalization or in case of physical weak patients. No or few organizational changes are necessary and the surgeons and assisting staff can be trained in a few days. Economical the procedure is profitable compared to conservative treatment for patients with acute and subacute, osteoporotic fractures.

Perspectives

Sufficient evidence needs more documentation than the few papers cited in this HTA. The results need further consolidation in national and international, randomized trials focused on the pain relieving effects in acute as well as chronic pain. We recommend an update of this HTA when further documentation is available.

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