Viscosity of PMMA Bone Cement in Percutaneous Vertebroplasty for Osteoporotic Vertebral Compression Fractures: A Randomized Controlled Trial

Published: 12-05-2010
Last updated: 10-08-2024

Establishment whether usage of high viscosity PMMA bone cement in PVP for OVCFs leads to a reduction in leakage incidence compared to usage of conventional (low-medium) viscosity PMMA bone cement in PVP for OVCFs.Since evidence is scarce or…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Endocrine and glandular disorders NEC
Study type	Interventional

Summary

ID

NL-OMON34964

Source
ToetsingOnline

Brief title
Viscosity of PMMA Bone Cement in Percutaneous Vertebroplasty

Condition

- Endocrine and glandular disorders NEC
- Fractures
- Nervous system, skull and spine therapeutic procedures

Synonym
"broken back", vertebral fractures

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Onafhankelijke bijdrage aan de leverancier van het vertebroplastiekinstrumentarium is gevraagd. Deze zal geen inmenging in de trial hebben op welke wijze dan ook en zal geen gegevens van de trial krijgen/inzien behalve degene die uiteindelijk ter publicatie worden aangeboden.,Stryker medical

Intervention

Keyword: Osteoporosis, Vertebral Fractures, Vertebroplasty, Viscosity

Outcome measures

Primary outcome

Incidence of cement leakage per treated vertebra.

Secondary outcome

* Incidence and clinical relevance of pulmonary and cardiac

cement emboli. The association between emboli and (type of)detected

(local) cement leakage will be assessed.

* Incidence of new (adjacent) OVCFs during the first year after

PVP. The association between new OVCFs and (type of) detected

cement leakage will be assessed.

* Sensitivity and specificity of conventional radiography of

the thoracic region in detection of cement leakage compared to CT-

scanning of this region (gold standard).

Study description

Background summary

With over 15000 to 20000 new symptomatic cases each year in the Netherlands, Osteoporotic Vertebral Compression Fractures (OVCFs)comprehend a substantial

social problem with corresponding burden on the health care system. Percutaneous augmentation, with Percutaneous VertebroPlasty (PVP) as its main proponent and by far the most executed procedure, is currently the only available interventional treatment modality for this problem. After PVP , 80 - 90% of patients experience an immediate, substantial and durable pain relief which enables them to return to a more active lifestyle and prevents them from complications due to a bed-bound lifestyle, as well as reducing the continuing burden on health care systems.

PVP as a treatment modality for OVCFs shows a rather high incidence of cement leakage, especially when assessed using postoperative CT-scanning (gold standard). Cement leakage, however, was considered mostly asymptomatic and harmless to the patient.
Recently, however, several studies have been published indicating clincally revelevant sequelae of cement leakage may be more common than previously thought. The first, and thus far only high quality, prospective study on the occurrence of Pulmonary Cement Emboli (PCE) after PVP in OVCFs reported an unexpectedly high incidence: in 18 of 78 (23%) patients one or more PCE were detected. More high-quality studies are required to confirm or discard this finding. Also, several studies found an association between cement leakage to the intervertebral space and induction of new, adjacent OVCFs - the very problem the procedure is treating!

Based on the available literature, the current perception is that increasing viscosity of PMMA bone cement in PVP for OVCFs reduces the incidence of cement leakage, but concomittantly might limit the penetration and interdigitation of bone cement into the cancellous bone, leading to a more clump-like filling pattern with the potential to meaningfully alter the biomechanics of the vertebral column and induce new OVCFs. Only the former fact, i.e. reduction of cement leakage, has been shown by us and several international studies. The other claims could are not confirmed and also could not be established by our own study (accepted to Spine) and therefore appear unlikely.

Considering the substantial incidence of cement leakage, the increasing evidence indicating a higher frequency of clinically revelant sequelae of cement leakage than previously assumed and the gain expected to be obtained from usage of high viscosity bone cements, a compelling need for the definitive establishment of the effects of bone cement viscosity exists. Currently, this is absent and the very reason this study is proposed.

Study objective

Establishment whether usage of high viscosity PMMA bone cement in PVP for OVCFs leads to a reduction in leakage incidence compared to usage of conventional (low-medium) viscosity PMMA bone cement in PVP for OVCFs.

Since evidence is scarce or conflicting, incidence of cement leakage related

sequelae will assessed, reported and subsequently related to viscosity of bone cement used. Specifically mentioned regarding this matter are Pulmonary Cement Emboli (PCE) after PVP and new OVCFs (whether in the presence of cement leakage etc).

In addition, sensitivity and specificity of radiography of the thorax compared to CT-scanning of the thorax (gold standard) in detection of PCE are unknown and will be determined, assessing feasability of chest radiography for routine screening of PCE .

Study design

This study is designed as a randomized, controlled trial comprising two arms: one group will receive PVP for OVCFs using low-medium viscosity PMMA bone cement (the control group) and the other group will receive PVP for OVCFs using high viscosity PMMA bone cement (the treatment group). Analysis will be performed on both an intention-to-treat basis and on per-protocol basis.

o Primary outcome: Incidence of cement leakage per treated vertebra.

o Secondary outcomes:
* Incidence and clinical relevance of pulmonary and cardiac cement emboli. The association between emboli and (type of)detected (local) cement leakage will be assessed.
* Incidence of new (adjacent) OVCFs during the first year after PVP. The association between new OVCFs and (type of) detected cement leakage will be assessed.
* Sensitivity and specificity of conventional radiography of the thoracic region in detection of cement leakage compared to CT-scanning of this region (gold standard).

After the inclusion of forty patients, an interim analysis will be performed. When a statistically significant and clinically relevant difference regarding the aforementioned major adverse outcomes in one arm is detected, it may be considered unethical to continue the study and termination of the study will be considered.

Intervention

PVP with usage of either conventional (low-medium) viscosity PMMA bone cement or high viscosity PMMA bone cement.

The PVP-procedure is performed on a biplane angiography unit using conscious sedation. A 10G vertebroplasty needle is gently hammered into the (anterior third of the) VB and a bone biopsy will be obtained, followed by injection of PMMA bone cement until a satisfactionary distribution of the cement, i.e.

symmetrical filling of the central and anterior parts of the VB, was obtained or when cement leakage was noted. When necessary, a second needle was advanced into the VB through the contralateral pedicle, followed by injection of cement.

Patients are encouraged to start mobilizing after 2 hours and will leave the hospital at the end of the day. The procedure itself takes less than 30 minutes.

Study burden and risks

The only additional burden for patients participating in the trial (compared to patients who do not participate) is additional radiography and CT-scanning of the chest. Practically, this translates to:
- A slightly longer postoperative work-up, although CT-scanning of the chest will be performed in the same session as the routine postoperative Ct-scanning of the treated levels.
- A somewhat higher radiation exposure, although not excessively since it concerns routine imaging procedures.
- Possible psychological and physical consequences due to accidental findings of (possibly) pathological nature. Policy of LUMC is to always inform the patient regarding such findings, possibly leading to distress or difficult (treatment) desicions. On the other hand, however, early detection might be beneficial due to generally better chances of curative treatment, which otherwise might not have been detected (yet).

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
2333 ZA Leiden
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
2333 ZA Leiden
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

(I) Presence of an Osteoporotic VCF, (II) focal back pain in the midline refractive to at least eight weeks of appropriate conservative treatment, (III) back pain related to the location of the VCF on radiography, (IV) the presence of bone marrow edema on MRI T2-weighted short tau inversion recovery (STIR) sequences in the corresponding collapsed VB, (V) age over 40 years and (VI) written informed consent.

Exclusion criteria

(I) VCFs due to other causes than osteoporosis, (II) spinal cord compression or stenosis of the vertebral canal > 30% of the local canal diameter, (III) neurological deficits, (IV) incorrectable bleeding disorders, (V) infections related to the vertebral column, (VI) inability to lie prone for two hours, (VI) an American Society of Anesthesiologists (ASA)-score >= 4

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2010
Enrollment:	86
Type:	Actual

Ethics review

Approved WMO

Date:	12-05-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL31933.058.10