Assessment of intraoperative embolism during spinal surgery with transesophageal echocardiography.

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To assess the incidence and severity of embolic events during spinal instrumentation surgery with intraoperative transesophageal echocardiography monitoring.

Ethical review	Not approved
Status	Will not start
Health condition type	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
Study type	Observational invasive

Summary

ID

NL-OMON33863

Source
ToetsingOnline

Brief title
Embolism during spinal surgery.

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
- Bone and joint therapeutic procedures

Synonym
Embolism

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Embolism, Spinal surgery, Trans Esophageal Echocardiography

Outcome measures

Primary outcome

a) The incidence and extent of echogenic material visualized with intraoperative transesophageal echocardiography

b) Intraoperative cardiopulmonary function

Secondary outcome

Age, gender, Body mass index (BMI), history of deep venous thrombosis or pulmonary embolism, preoperative physical status (ASA- class), history of smoking, co-morbidity of osteoporosis, diabetes, paralysis of lower extremities, bleeding disorder, (antithrombotic) medication, previous estrogen therapy

Type of surgical procedure, level and number of fusion of vertebral bodies, number of instrumentations placed, operative time, blood loss, units of red blood cells transfused, clinical embolic events after surgery, other surgical complications, and mortality.

Study description

Background summary

Sudden intraoperative or perioperative cardiopulmonary dysfunction as a result of embolism is a well-known complication of bone and joint surgery. Fat and bone-marrow emboli are frequently produced during the pressurization and manipulation of the intramedullary canals of long bones during *xation of

fractures or joint replacement surgery. They are a serious concern among orthopaedic surgeons and anesthesiologists as they can lead to severe clinical as well as subclinical perioperative complications and are potentially fatal.

Before introducing the screw, the pedicle, that anatomically resembles a tubular bone with an intramedullary canal, is prepared with a blunt probe, similar to the introduction of a joint prosthesis or intramedullary nail. Also, in the treatment of traumatic or pathologic fractures, bone cement is introduced into the cancellous bone of the vertebral body which may also lead to thrombo-embolic events.

Spinal instrumentation surgery is advancing and the use of pedicle screws is increasing worldwide but occurrence and incidence of (subclinical) embolic events during spinal procedures remain a matter of debate.

Study objective

To assess the incidence and severity of embolic events during spinal instrumentation surgery with intraoperative transesophageal echocardiography monitoring.

Study design

Observational study performed at the University Medical Center Utrecht.

Study burden and risks

The use of transoesophageal echocardiography is considered to be non-invasive, especially when patients are under general anesthesia. TEE-associated complications are a rarity; a 0%-0.5% complication rate has been reported in a study of 7200 patients undergoing TEE (Kallmeyer, 2000) Most of these complications are related to the insertion of the echo probe in the esophagus; odynophagia occurred in 0.1% of patients, swallowing abnormality in 0.01%, esophageal abrasion in 0.06%, upper gastrointestinal hemorrhage in 0.03%, esophageal perforation in 0.01% and dental injury in 0.03%. The benefits are: gaining more knowledge about incidence and direct consequences of intraoperative embolism on cardiopulmonary function.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Patients where spinal instrumentation surgery is indicated.

Exclusion criteria

Multi-trauma patients and contra-indications for the use of transesophageal echocardiography: oropharyngeal carcinoma, oesophageal varices, oesophageal stricture, oesophageal diverticulum, oesophagitis, Mallory-Weiss tear, recent upper gastro-intestinal hemorrhage, gastric ulcer, symptomatic hiatal hernia.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	72
Type:	Anticipated

Ethics review

Not approved

Date:	20-04-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL24729.041.08