Long-Term Outcome of Split Laminectomy for Cervical Spondylotic Myelopathy

Published: 12-05-2016 Last updated: 17-04-2024

To determine long-term radiological and clinical outcome of a muscle-sparing surgical technique for posterior decompression of the cervical spinal cord (cervical split laminectomy).

Ethical review	Approved WMO
Status	Pending
Health condition type	Spinal cord and nerve root disorders
Study type	Observational invasive

Summary

ID

NL-OMON44400

Source ToetsingOnline

Brief title Cervical split laminectomy

Condition

- Spinal cord and nerve root disorders
- Nervous system, skull and spine therapeutic procedures

Synonym

cervical spondylotic myelopathy

Research involving Human

Sponsors and support

Primary sponsor: Sint Lucas Andreas Ziekenhuis

Source(s) of monetary or material Support: Stichting Ruggensteun and internal funding by OLVG

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Intervention

Keyword: Cervical myelopathy, Complications, Outcome, Surgery

Outcome measures

Primary outcome

Primary study parameters are the occurence of cervical kyphosis and segmental

instability on a cervical radiograph performed at least 2 years after surgery.

Secondary outcome

Secondary study parameters include the Neck Disability Index, the Nurick score

the Japanes Orthopaedic Association score and perceived recovery on a 5-point

Likert scale.

Study description

Background summary

Cervical spondylotic myelopathy (CSM) is a frequent cause of gait disturbance and impairment in the elderly, which often requires surgical treatment. The common surgical therapy for multisegmental CSM is posterior decompression of the spinal canal by removing the involved cervical lamina and the ligamentum flavum. Unfortunately, this procedure is associated with significant postoperative problems such as axial neck pain, restriction of cervical motion, cervical instability and kyphotic deformity occurring in up to 20% of cases after multilevel cervical spine laminectomy. These problems are putatively due to surgical damage to the posterior extensor mechanism of the cervical spine. To avoid kyphosis while maintaining cervical mobility, muscle-sparing techniques aiming to preserve the posterior muscle-ligament complex have been proposed. We have developed a modified *split-laminectomy* technique that aims at selective decompression of the spinal canal with only minimal interruption of the muscular and ligamentous attachments to the lamina and spinous processes. This surgical technique included preservation of the multifidus and semispinalis muscle attachments to spinous processes using an interlaminar approach. Earlier, we have demonstrated that this surgical technique is safe and produces short-term clinical results that compare well to conventional laminectomy. Importantly, the duration of surgery appeared to be shorter, the surgical wounds were smaller and there was little blood loss associated with

the new technique. Whether the long-term results of in terms of neurological outcome and kyphotic deformities also compare favorably to standard laminectomy, however, is still unknown.

Study objective

To determine long-term radiological and clinical outcome of a muscle-sparing surgical technique for posterior decompression of the cervical spinal cord (cervical split laminectomy).

Study design

Retrospective observational cohort study

Study burden and risks

There are no specific benefits for the study participants. The burdens of participating in this study include filling out questionnaires, one visit to the hospital, undergoing a brief neurological examination and a cervical radiograph. This burden is considered minor and risk is very low. The radiation dose of a cervical radiograph is approximately 0,2 mSv, which equals one-tenth of the normal annual background radiation in the Netherlands. We believe that this risk is acceptable in relation to the possible benefits that may be gained from this study, i.e. improved outcome of surgery for CSM.

Contacts

Public Sint Lucas Andreas Ziekenhuis

Jan Tooropstraat 164 1006 AE Amsterdam 1006 AE NL Scientific Sint Lucas Andreas Ziekenhuis

Jan Tooropstraat 164 1006 AE Amsterdam 1006 AE NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

All patients who underwent a cervical split laminectomy because of cervical myelopathy between 1 01-01-2005 and 31-12-2014 in OLVG-west (formerly Sint Lucas Andreas Ziekenhuis) are considered for inclusion in this study. To be eligible to participate, a subject must meet all of the following criteria: 1. Male and female subjects aged 18 - 80 years at the time of surgery 2. Subject was diagnosed with cervical myelopathy from degenerative spinal disease requiring posterior surgical decompression 3. Cervical Split Laminectomy was performed between 2004 and 2013 4. Radiological diagnosis was in accordance with clinical signs and symptoms 5. Medical records and radiological images are available for review. 6. Subject is able and willing to comply with the study protocol 7. Subject is able to provide written informed consent

Exclusion criteria

1. No split but conventional laminectomy was performed 2. Medical records or radiological images are not available 3. Subject underwent previous neck operations 4. Subject underwent surgery for other indications than spondylotic (degenerative) myelopathy, e.g. trauma, tumor, infection 5. Additional posterior fusion and fixation was performed in the same session 6. Subject had a congenital deformity of the cervical spine, e.g. Klippel-Feil or achondroplasia 7. Subject had significant concomitant neurological disease, e.g. severe polyneuropathy or neurodegenerative disease 8. Subject has died 9. Subject cannot be contacted

Study design

Design

Study type: Observational invasive

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-04-2016
Enrollment:	100
Туре:	Anticipated

Ethics review

Approved WMO	
Date:	12-05-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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 CCMO **ID** NL56669.100.16