Laminectomy without or with dorsal fusion for cervical myeloradiculopathy: a (multi center randomized trial)

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Cervical myelopathy is caused by static components like stenosis, and probably worsened by movement. From this point of view, decompression with fusion will have better clinical results when compared to decompression solely. In literature,...

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

Summary

ID

NL-OMON30923

Source
ToetsingOnline

Brief title
LamiFuse

Condition

- Spinal cord and nerve root disorders
- Therapeutic procedures and supportive care NEC

Synonym
cervical myelopathy, cervical spinal stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: de aanvragen voor subsidiering lopen nog.

Overigens valt het grootste deel binnen reguliere zorg. Extra gelden voor verzekering en datamanagemnt zullen van belang zijn,Indien we onvoldoende subsidie vanuit de Cervical Spine Research Society ontvangen is de bedoeling verschillende industriën te benaderen, die het implantaat leveren. Om enigszins neutraal te blijven willen we 3 of 4 industriën tegelijk benaderen

Intervention

Keyword: Cervical stenosis, fusion, Laminectomy, Myelopathy

Outcome measures

Primary outcome

Primary endpoints

Several score systems exist for grading the severity of cervical myelopathy.

The modified Japanese Orthopedic functional score (Appendix A) evaluates four

groups: the function of the arms, of the legs, the micturation, and the

sensibility. It has the major advantage that it assesses motor function of the

arms and of the legs separately, sensation, and evaluates urinary symptoms[6].

Although it has been established that outcome after decompressive surgery

reaches a plateau at six months postoperatively[7], the primary endpoint will

be evaluated at one year postoperatively just to be sure.

Secondary outcome

Secondary endpoints

Since instrumentation is added in the fusion group, the costs will be higher.

Otherwise it is assumed that a mean better recovery will take place in the

fusion group. Therefore, the additional costs (nursing costs, auxillary

supports, etc.) may be lower. A careful evaluation of the costs of the

treatment related to the outcome is performed. To obtain a reliable insight in

the costs the following will be noted in a kind of diary: hospitalisation, out

- patient contacts, additional medication, house keeping support, instruments to support daily activities, e.g. walking, eating etcetera. Of each item the sort and amount will be recorded.

Apart from the cost - effectiveness, the difference in the general quality of life will be evaluated. It is assumed that the quality of life of a laminectomy will improve after adding a fusion. This will be reflected in a difference of the SF - 36 score (Appendix B). SF - 36 Health Status Questionnaire is a widely-used generic health status. This instrument consists of eight subscales and two summary scales. On each scale higher scores indicate better outcomes. Scores can be compared with published age - and sex - matched general population or disease-specific norms[8].

Complications are separately registered. Complications related to the cervical myelopathy are postoperative hemorrhage, postoperative infection, temporary or permanent impairment of neurologic function, and kyphotic deformation of the cervical spine[4]. Complications related to adding lateral mass screws or/and pedicle screws are vertebral artery injury and temporary or permanent nerve root damage[4]. In order to prevent damage to the spinal cord , the instrumentation should be completed before the laminectomy.

Study description

Background summary

Cervical spondylosis is a progressive degenerative disease of the spine. As people grow older, the prevalence of cervical spondylosis increases. It is a natural process of aging. Cervical spondylosis is seen in 10% of individuals in the age of 25 years, whereas in 95% of the persons of 65 years[1].

Due to the degenerative process reduction of height of the intervertebral discs, formation of spondylophytes and sometimes instability occurs. This may lead to a stenosis of the cervical spinal canal. In most instances it will remain asymptomatic. However, in some persons the stenosis of the spinal canal leads to a compression of the spinal cord. It is important to realize that not only static compression leads to neurological symptoms, but also dynamic factors do. In a normal situation the spinal cord will move during flexion and extension. Ventral osteophytes in the spinal canal prevent up - and downward movement[1]. Furthermore, the spinal cord is more stretched over the anterior bars increasing axial tension within the spinal cord. These forces are multidirectional creating secondary shearing forces resulting in strech and shear injury to myelin and neural elements[2-4].
Patients may present with a diversity of well known signs and symptoms with variable intensities. Disturbance of the sensibility in the arms, clumsiness of the hands and problems with micturation may occur. However, the hallmark symptoms are gait abnormalities, weakness of the legs or stiffness of the legs[1,5].
The natural course of the cervical myelopathy is variable. But patients developing mild or moderate symptoms are less likely to improve spontaneously. Non operative treatment will mainly affect neck pain or accompanying radiculopathy. Improvement has been noted but is variable[6,7]. Patients with myelopathic signs and symptoms will, however, likely benefit from surgery[5,7,8].
Surgical approaches for cervical myelopathy due to cervical spondylosis can be anterior, posterior or combined. The last option is reserved for deformity correction. In most instances a lordotic or slight kyphotic cervical spine is present. The choice for an anterior or posterior approach is dependent on the main site of compression, the shape of the cervical sagittal curvature and to a lesser account on the preference of the surgeon.
Dorsal approaches are laminectomy or laminoplasty. A difference in clinical outcome has never been established. Prevention of post - laminectomy kyphosis is a reason for laminoplasty. If an additional, instrumented dorsal fusion is performed, the change of developing a post-surgical kyphosis is nearly zero[9]. It should be memorized that spondylotic processes also generate reduced motion of the spinal segments, a natural course[1]. Frequently used dorsal fusion techniques today use lateral mass screws and cervical pedicle screws. This is relatively safe with a minimal persistent complication rate. Furthermore, in experienced hands these techniques do not add substantial time to the duration of the surgery [7,9].
Despite a long-lasting interest in the various techniques, the clinical superiority of one method over the other has never been established. To our knowledge, a randomized controlled trial comparing laminectomy with or without fusion has never been performed.

References

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Study objective

Cervical myelopathy is caused by static components like stenosis, and probably worsened by movement. From this point of view, decompression with fusion will have better clinical results when compared to decompression solely. In literature, indications in this direction are found. This randomised controlled trial has been developed to compare laminectomy without dorsal fusion versus laminectomy with dorsal instrumented fusion.

Hypothesis
Patients that are surgically treated for signs and symptoms due to a stenosis of the cervical spinal canal have a better clinical outcome when a dorsal fusion is performed in addition to a laminectomy compared to those that have solely a laminectomy.
At the end of the study, the quality of life, complications, and the costs will be evaluated comparing these two treatment groups.

Study design

multi center, randomised controlled trial

Intervention

Surgical technique
Cervical laminectomy of the compressed levels is performed. Previous to the laminectomy a dorsal fusion is done. Dorsal fusion includes lateral mass screws from C2 to C6. In C2, C7 and the upper thoracic spine levels, pedicle screws will be placed. The screws are connected by rods or plates. Transverse connectors are used when indicated. In order to keep the posterior tension band intact, the fusion will extend from one level above the planned most cranial laminectomy level to at least one level below the most caudal planned laminectomy site. If the lowest level of fusion would include C7 or lower extension of the fusion to the upper thoracic spine (Th2 or Th3) is recommended. This extension of the fusion is thought to prevent junction disease at the cervicothoracic junction. For example, if the laminectomy includes the levels C4 to C6, the fusion would be from C3 to C7. Because C7 is the lowest fusion level , incorporation of Th1 is recommended.

Study burden and risks

We do not expect any extra burden or risks for the patient, since it are standard procedures. An exception is filling in the SF 36 questionnaires.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In - and exclusion criteria
Patients with a minimal age of 60 years are included (Table 1). At neurologic examination myelopathic changes must be apparent. At magnetic resonance imaging, concordant stenotic alterations at the cervical level(s) must be present. At the plain sitting lateral radiograph a lordotic spine must be shown. The shape of the cervical spine is lordotic when the vertebral bodies of C3 to C6 are in front of a line drawn from a point of the posterior inferior part of C2 to a point at the posterior superior part of C7 (Figure 1).
Only patients that sign the informed consent after some time of reflection (1 week) are included.

Exclusion criteria

Exclusion
Previous cervical surgery for myelopathic signs and symptoms
Solely radiculopathy, or most important complaint

Unable to undergo MRI
Life expectancy less than 1 year
Other diseases interfering with neurologic symptoms and signs, for example spinal cord glioma, thoracic herniated disc with spinal cord compression, multiple sclerosis etc.
Rheumatoid arthritis
Trauma to the neck in history
Diseases interfering with rehabilitation, for example severe cardiac congestive disease.
Participation in another study

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2007
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL16633.091.07