Outcomes of Anterior Cervical Interbody Fusion in an Outpatient Clinic at Aarhus University Hospital

A Retrospective Study

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Outcomes of Anterior Cervical Interbody Fusion in an Outpatient Clinic at Aarhus University Hospital: A Retrospective Study

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**Introduction:** Anterior cervical interbody fusion (ACIF) is an established procedure for cervical radiculopathy that has not answered conservative treatments. Since December 2012, the neurosurgical department at the Aarhus University Hospital has been performing this procedure in an outpatient setting for selected patients. The main concern with the outpatient setting is the risk of retropharyngeal hematoma. The aim of this study is to evaluate the ACIF procedure in this novelty setup and compare to international literature.

**Methods and materials:** All patients from December 2012 to December 2013 were included. They had a structured telephone nurse-lead interview one week and eight weeks post-surgery. Patient files were reviewed for baseline and pre-surgical data and post-surgery complications. Statistical calculations were done in STATA. McNemar’s test with hypothesis of no difference was applied.

**Results:** 55 consecutive patients were included. There was a significant reduction in upper extremity pain at one week and eight weeks, risk ratio (RR) = 0.48 [95% CI=0.34-0.66], $p<0.01$ and RR=0.46 [0.31-0.67], $p<0.01$, respectively. There was also significant reduction in neck pain at eight weeks (RR=0.70 [0.53-0.91], $p=0.01$). Incidence of upper extremity paresthesia (RR=0.74 [0.40-1.13], $p=0.24$) and motor weakness (RR=0.8 [0.54-1.18], $p=0.45$) had a tendency to improve at eight weeks, although it was not statistically significant. Complications occurred in three patients (5%): One root lesion and two cases of hemorrhage (one with 1000 mL bleeding with the patient re-admitted within a month; one with 400 mL bleeding in which the decompression could not be finished and the patient was moved to a regular ward). Six other events occurred (11%): two large hemorrhages (350 mL and 250 mL, respectively); two cases of hoarseness requiring medical intervention; two patients with adjacent disc disease requiring new ACIF surgery within 8 months of the original surgery.

**Discussion:** The follow-up frequency is lower than expected and may call on re-evaluation of the follow-up method used. The number of total events seems higher than expected, further analyzes are needed to outline causes. A more rigorous and constant follow-up is recommended to insure patient safety.
List of abbreviations

ACIF – Anterior Cervical Interbody Fusion
ADD – Adjacent disc disease
AUH – Aarhus University Hospital
ECM – Extracellular matrix
IVD – Intervertebral disc
IVF – Intervertebral foramen
RLN – Recurrent laryngeal nerve
ROM – Range of motion
SCM - Sternocleidomastoid
TDR – Total disc replacement
Introduction

This paper describes a retrospective study done at the Aarhus University Hospital (AUH) in the spring of 2014. Since December 2012, the neurosurgical department at the AUH has been offering patients an Anterior Cervical Interbody Fusion (ACIF) in an outpatient setting. ACIF is a surgical treatment for cervical radiculopathy in which the intervertebral disc (IVD) is removed and an artificial cage inserted between the vertebrae to maintain the height of the spine. Only selected, uncomplicated cases are possible candidates for the outpatient procedure. A traditional procedure is still an offer for surgical candidates not selected as outpatients. In this introduction will be reviewed the relevant anatomy and pathology related to this ailment as well as the ACIF procedure itself.

Anatomy of the cervical spine

The neck has a complicated anatomy. A cylindrical structure, it carries the blood supply and drainage of the head, the spinal cord, myriad of muscles as well as being a passageway for food and air and the home of one of the body’s largest endocrine glands. At the same time, the neck has to withstand the weight of the head as well as allowing for a generous amount of flexibility. This flexibility is achieved through 76 separate joints, making the neck a very complicated articular system.\(^1\) This complexity comes at a cost, however, with over 50% of the population suffering from significant neck pain at some time in their lives.\(^2\) In this chapter I will describe the anatomy of the cervical spine and the neck region as a whole, focusing on the structures relevant for the discussion of cervical herniated disc and for the ACIF procedure.

The vertebrae

The seven cervical vertebrae are named after their sagittal position from C1, the most cranial one, to C7 that articulates with the first thoracic vertebra, T1. Of these, C1 (Atlas) and C2 (Axis) are considered atypical and C7 (vertebra prominens) is unique. The other four, C3-C6, have typical structures. Apart from giving structural integrity to the body and providing attachments for muscles, the main purpose of the vertebrae is to protect the spinal cord.

The typical cervical vertebrae consist anteriorly of the vertebral body. Between the bodies are the IVDs. Posterolaterally the vertebral body connects to the pedicles,
which subsequently connect posteromedially to the laminae. Together the vertebral body, the pedicles and the laminae form a circle that surrounds the vertebral canal, in which the spinal cord lies. Also lining the vertebral canal are the IVDs and the ligamenta flava, the latter stretch longitudinally between the laminae of different levels. Stretching posteriorly in the midline from where the laminae on both sides combine is the spinous process. This process is what we palpate when we roll a finger down a person’s back.¹

![Figure 1: The structure of a typical cervical vertebra and the surrounding structures.](source: Wikimedia Commons)

In addition, each vertebra has lateral processes on each side, called transverse processes. These processes divide into anterior and posterior roots. These roots then end as anterior and posterior tubercles. The tubercles are connected by the intertubercular lamellae on each side.³ Together the anterior and posterior roots, the intertubercular lamella and the pedicle mark the boundaries of the foramen of the transverse process, through which the vertebral artery passes.⁴ Adjacent and posterior to the transverse process are the superior and inferior articular processes, facing the vertebrae above and below, respectively. These processes form the zygapophysial joints (Z-joints).¹ Fracture of the transverse process can cause damage to the vertebral artery or the nerve root.³

The typical cervical vertebrae as well as C7 also have lateral lips (uncinate processes) arising from the superior aspect of their bodies. The uncinate process
articulates with the next vertebral body above. The uncinate processes also serve as barriers to the latero-posterior protrusion of the IVDs. The structure of a typical cervical vertebra is shown in Figure 1.

C7, or vertebra prominens, gets its name from usually being the most prominent of the cervical vertebrae, although T1 is sometimes more prominent. This is because of its large spinous process that serves as a landmark in the cervical region. Atlas and Axis will not be discussed further since they have little relevance with regards to cervical herniated disc.

The disc

The intervertebral discs (IVDs) are cartilaginous structures that lie between the cervical vertebral bodies, anteriorly to the spinal cord. The IVDs help in separating the vertebrae and distributing the pressure while allowing for motion of the neck. The importance of the IVDs in the motion of the neck is clearly seen after interbody fusion, when the range of motion of the neck as a whole is reduced compared to normal subjects. The discs are made of two parts, the outer annulus fibrosus and the inner nucleus pulposus. The nucleus pulposus is softer than the annulus, but it hardens with age and by the age of 45 it becomes hard to distinguish the nucleus from the annulus in a cervical IVD. It is important to note that there are no IVDs between the occipital bone and atlas or between atlas and axis. Therefore, the first cervical IVD is located between vertebrae C2 and C3, at the level of the exit of the second cervical spinal nerve.

What distinguishes the IVDs from most other tissues in the body is the fact that it is almost avascular. Apart from small capillaries that penetrate the surface of the annulus, the nutrient supply and waste extraction is entirely dependent upon the diffusion of nutrients from the capillary beds in the vertebral bodies and the soft tissues around the annulus. Even though the nucleus pulposus is not rich in cells, the ones present are nevertheless crucial for the normal function of the disc. The rate at which glucose, oxygen and other nutrients reach these cells is determined both by the blood flow in the vertebral capillaries as well as by the diffusion capacity of the ECM in the disc. The ECM is filled with proteoglycans and between them are pores that nutrients can flow through, and the size of these pores determines the diffusion capacity of the ECM. If the density of proteoglycans is increased, the movement of solutes through the disc is both decreased and delayed. Sustained mechanical load on
the disc also reduces solute diffusion into the disc and is therefore likely to accelerate degeneration. The blood flow is also important with regards to disc health. Studies have shown that chronic back pain is significantly more common in people whose lumbar arteries are occluded or narrowed.9

**The spinal cord, arteries and nerves**

Two adjacent vertebrae form between them an intervertebral foramen (IVF) on each side, posterolaterally to the vertebral bodies. Through this foramen the spinal nerve root passes from the spinal cord. This is also a site of potential compression of the root through stenosis of the IVF. The most common causes of stenosis of the IVF are prolapses of the IVD or osteophyte formation from the adjacent vertebral bodies or uncinate process.10 As the nerve root passes out of the IVF, it splits into the large ventral ramus and the smaller dorsal ramus.11

The vertebral artery arises from the subclavian artery and runs upward and to the posterior. It passes through the transverse foramen of the sixth cervical vertebrae and eventually passes through the foramen magnum.4 Cutting the artery could result in complicated neural morbidity and preventing injury to it is high on the surgeon’s mind. However, inadequate medial to lateral decompression of the spinal canal can occur when attempting to prevent injury to it.12 The cervical spinal cord is mainly supplied by the anterior spinal artery and the paired posterior spinal arteries, all of them arising from the vertebral arteries but also anastomosing with several branches from other cervical arteries.13

**Radiculopathy**

According to Carette et al., "cervical radiculopathy is a neurological condition characterized by dysfunction of a cervical spinal nerve, the roots of the nerve, or both.” It’s usually unilateral with pain in the neck and arm, as well as loss of sensory or motor function or changes in reflexes in the nerve-root distribution.14 It is often caused by compression of the nerve or the nerve root, usually as it exits the spinal cord or when it passes through the IVF.11 The compression of the nerve root can cause the motor deficit and motor weakness but the cause of the radicular pain is not fully understood. It is generally thought that some form of inflammatory response is necessary in addition to the compression. Adjacent blood vessels also show increased permeability under compression, resulting in secondary edema of the nerve root.15
There are various causes, some of them, such as Lyme disease and some autoimmune diseases, are non-compressive. Among the compressive radiculopathies, the great majority is caused by compression of the nerve root within the spinal column. Extrarespinal compression and the non-compressive radiculopathies will not be discussed here as a surgical removal of the IVD is not a treatment for those ailments. Among the compressive radiculopathies in the spine (henceforth called radiculopathy), two mechanisms are responsible for most cases. The most frequent one (70%) is spondylosis while herniation causes 20%. Other causes include tumors and various infectious processes. The frequency of causes of radiculopathy vary with the age of the patients. While spondylosis is more common among older people, trauma leading to disc herniation into the IVF is more common among younger people.

According to historical studies, radiculopathy is most common in the C7 nerve root which comes out between the C6 and C7 vertebrae. The reason for the increased involvement of the C7 root could be because of the narrower intervertebral foramina at that level. The foramina are largest between the C2 and C3 vertebrae and get progressively smaller until the C6/C7 level.

**Spondylosis**

Spondylosis is the formation of osteophytes that narrow the intervertebral foramen and compress the nerve root within the foramen, causing radiculopathy. Spondylosis usually develops more gradually than herniation. If spondylosis is the cause of the radiculopathy, it can often coexist with myelopathy. In addition to compressing the nerve root and spinal cord, the osteophytes can compress other neural structures, which might be the cause of neck pain in many cases. Spondylosis can reduce the range of motion of the neck, thereby limiting the ability of the patients to do certain activities of daily living.

**Herniation**

Herniation of the IVD accounts for 20% of cases of cervical radiculopathy. It is usually caused by degeneration of the disc but can also be caused by trauma. It is important to note that a degenerated disc does not always lead to symptoms, and sometimes even an abnormal MRI scan can be symptomless. Degeneration can, however, lead to a whole range of syndromes if the disc starts to compress the adjacent structures, including radiculopathy, myelopathy and spinal stenosis.
effects are mainly decided by the direction of the hernia. If it pushes centrally it is likely to compress the spinal cord and cause myelopathy, while a lateral hernia would more likely compress the nerve root and result in radiculopathy. A third possibility would be a paracentral hernia which would cause a hemicord compression (Brown-Sequard syndrome).

Degeneration of the IVDs is a multifactorial disorder with a strong hereditary background, with the importance of heredity being established by several large studies. It is a chronic process with a strong correlation with age, with degenerated discs occurring in over 90% of those above the age of 50. Many biological changes have been observed that are believed to play a part in the degeneration process. The most significant change seems to be the reduction in cell density in the disc which is accompanied by a reduction in the ECM components in the cartilage.

There is a strong intra-individual correlation in disc degeneration, meaning that a patient with degeneration in the cervical region is likely to also have a degenerated disc in the thoracic or lumbar spine. Several polymorphisms have been found to be associated with disc degeneration and they could possibly become good predictors of the disease. These include genes for structural proteins (especially collagen IX), matric metalloproteases (MMP3), inflammatory cytokines (IL-1 and IL-6) and the vitamin-D receptor.

Herniation can also be caused by whiplash injuries, often from car crashes or from playing contact sports such as American football.

**Epidemiology**

The 2010 Global Burden of Disease (GBD) study ranked all disorders and diseases based on how many years lived with disability (YLDs) it caused globally. The study found neck pain to be the fourth leading cause of YLDs, after low back pain, major depressive disorder and iron-deficiency anaemia. Neck pain was also ranked fourth in Western Europe alone. The study highlights the severe social cost of neck pain, both in the western world and worldwide. Neck pain is not always associated with radiculopathy, but a much quoted study from Rochester, Minnesota puts the annual incidence of cervical radiculopathy at 85 per 100,000. This is a lower incidence than for lumbar radiculopathy but a far from insignificant number.
**Possible remedies**

Conservative treatment is almost always the first option for patients presenting with radicular pain. If the symptoms do not improve with the conservative treatment, the neurosurgeon might consider a surgical intervention. Surgery can be performed from the posterior aspect but the anterior approach is preferred in most cases. There are several non-surgical methods available with limited evidence to determine which is the most effective. Therefore, the treatment is often chosen based on local availability and the preference of the patient, but the aim of treatment should always be to alleviate pain, improve function and prevent recurrences. NSAIDs and paracetamol are common recommendations early in the course of radiculopathy, with opioids sometimes used as well. Epidural injection of steroids has been proven to be effective although possible complications limit its use. Immobilization by the use of collars is sometimes recommended for a short time but lengthy use can be counterproductive, while complete bed rest is not recommended anymore. Other modalities include exercise therapy after pain has subsided and cervical traction, in which distracting force is applied to the neck with the aim of separating the cervical segments and reduce the compression of the nerve root.

**The ACIF procedure**

The anterolateral approach for cervical interbody fusion was first used by Smith and Robinson and described in a paper from 1958. The same year, Cloward published his own paper about the same approach. Prior to this, the posterior approach had already been established but the anterior approach has taken over as the preferred surgical route for the removal of a pathological IVD. The removal of the disc is believed to relieve the pressure on the nerve roots through decompression. Ever since those papers were published, there have been concerns about accelerated degeneration at adjacent cervical levels. This has led to the development of arthroplasty as an alternative to traditional interbody fusion.

**The workup and indications for a surgery**

The main components of the work-up for a neck surgery are the physical examination and the diagnostic imaging. A match between the findings on the images and the neurological signs is required for a patient to be considered a candidate for an ACIF. However, the physical examination has its limitations with regards to diagnosing radiculopathy. Lauder and colleagues found that among patients with
electrodiagnostically verified radiculopathy, 31% had no motor weakness on physical examination and 45% had no sensory abnormalities that physical examination could detect.\textsuperscript{28} Several reasons can be behind this. Among those is the overlapping between myotomes or dermatomes so that each muscle or area of skin is usually innervated by more than one nerve root. Another is the fact that a compression of a nerve root might only damage a portion of the axons in that nerve while a damage to a relatively large portion of axons of a particular skin area or muscle would be required to produce symptoms of lack of sensation or muscle weakness.\textsuperscript{29}

Several tests are commonly used in a physical exam for cervical radiculopathy although they have a varying amount of clinical evidence for their usefulness. The golden standard is the Spurling test, also known as a foraminal compression test. The basis of it is to compress the affected nerve root within its spinal foramen in order to detect radicular pain on the ipsilateral side to the head rotation. This is achieved by neck extension and rotation while pressing downwards on the head. One study found this test to be 92% sensitive and 95% specific.\textsuperscript{30} Other tests include the shoulder abduction test, Lhermitte sign and the upper limb tension test.\textsuperscript{29}

However, a positive physical examination for radiculopathy is not enough to indicate surgery. Neuroimaging has to explain the symptoms found on the physical exam, otherwise the symptoms might as well be of a different origin and the surgery do more harm than good. Generally a surgery is not indicated unless the patient has failed to respond to at least 6 weeks of conservative treatment, unless the neurological deficits are progressive in which case an early intervention is indicated.\textsuperscript{31} Laboratory studies are of little value and not recommended. CPR and erythrocyte sedimentation rate can be evaluated in case of spinal infection or cancer, but even in those cases it is unspecific.\textsuperscript{14}

**The different types of anterior cervical discectomies**

The ACIF procedure takes advantage of normal anatomic fascial planes and can be performed from either the left or the right side. A horizontal cut is usually made from the midline to the anterior side of the sternocleidomastoid (SCM). Then the deep cervical fascia is divided while keeping the SCM and carotid sheath laterally and the staph muscles medially. After identifying the midline, the prevertebral fascia is dissected which exposes the IVD. The disc is then removed all the way to the anterior edge of the posterior longitudinal ligament.\textsuperscript{31}
There are several types of anterior cervical discectomies. First of all, the surgery can include the removal of a single IVD or the removal of more than one IVD. After removing the disc or discs, the surgeon has a choice of using a bone graft or a cage. The bone graft can either be harvested from the iliac crest during the surgery or be an allograft, with the iliac graft being associated with additional short- and long-term morbidity. In addition, newer methods aimed at preserving the motion of the joint are available, called either arthroplasty or total disc replacement (TDR). After inserting the selected item, the surgeon can then choose to insert a plate that is screwed to the vertebral bodies above the most superior discectomy and below the most inferior one. Using a plate is associated with additional problems, including risk of dysphagia, and is often avoided in single level surgeries. These several different varieties of the procedure make comparison of outcomes more difficult.

Range of motion (ROM) in the neck is often reduced in people with spondylosis or other cervical spinal problems and fusion is often equated with restricting motion, which would be detrimental for those already with decreased ROM. However, despite post-operative ACIF patients having decreased ROM compared to those without neck problems, a prospective study by Landers et al. found that ROM is increased after ACIF compared to the pre-operative state. These concerns with decreased ROM due to fusion and the belief that fusion causes progressive degeneration in adjacent cervical levels has led to the development of alternative methods, namely arthroplasty. A recently updated Cochrane review analyzed studies comparing arthroplasty with fusion. Their evidence was in favor of arthroplasty, although they stated that the difference was not clinically relevant because of low quality of evidence. They also warn that new-technology bias might play a role, especially since most of the studies were based on patient-reported outcomes. Jacobs et al. did not find significant difference for pain relief between fusion with a bone graft and with a cage.

**The outpatient clinic**

The ACIF procedure has been performed in an outpatient setting since at least the mid-nineties and is now increasingly being done that way, mostly as a mean of lowering costs. A US study from 2007 reported savings from $4000-8000 for an outpatient ACIF compared with the inpatient procedure. In a national health care system, that should also lead to reduced waiting time for the patient if he decides to
undergo the procedure as an outpatient instead of an inpatient, and therefore to faster return to work. However, there are other potential benefits apart from monetary gain, for example decreased exposure to nosocomial infections. Nosocomial infections might not be very relevant for the current protocol at AUH since the patients do stay overnight within the hospital, but they should spend less time there than if they had undergone the procedure as inpatients.

The main reasons for reluctance among surgeons to perform this procedure in an outpatient clinic are the potential devastating complications associated with it, mainly the lethal retropharyngeal hematoma as well as epidural hematomas, which could lead to neurologic injury without medical intervention. These worries have been somewhat calmed with various studies reporting very low complication rates. For example, Garringer et al. reported on a series of 645 consecutive daycare patients of which only 2 developed epidural hematoma and none retropharyngeal hematoma. In addition, both cases of hematoma started within an hour from the end of the surgery and were therefore spotted in the clinic with both cases resolving without further complications. Other studies have also reported low complication rates and very high patient satisfaction for outpatient ACIF.

**Aim of the study**

The aim of this study is to evaluate the success of the outpatient surgeries and the rate of complications associated with them. Since this is an established procedure in an unorthodox setting, the author feels that there is an urgent need to look at the procedures as a whole and to evaluate if the outcome is acceptable. The goals of the study are twofold:

- Primary question: Is it safe to perform the ACIF procedure under the current protocol in the outpatient clinic?
- Secondary question: What are the improvement and relief outcomes for the patients with regards to different symptoms?
Methods and materials

Selection of patients

The patients enrolled in this study were consecutive surgical patients that had undergone ACIF in the outpatient clinic at AUH between 14. December 2012 and the end of the year 2013, with the last patient being operated on 13. December 2013. The starting point corresponds to the first ACIF procedure in the outpatient clinic. The cut-off point was chosen in order to make sure that all patients had been called up for the 8-week follow-up.

Every patient underwent ACIF with the surgical technique established by Smith and Robinson. A cage was used instead of an iliac crest graft to facilitate fusion and to prevent kyphosis; with the Cornerstone cages from Medtronic used for all patients. The operations could be either on a single level or on two levels but any operation on more than two levels would not be done in the outpatient clinic. Revision surgeries are never done in the outpatient clinic. Plating was never used but a drain was put in all the patients to prevent retropharyngeal hematoma. A nurse removed the drain the morning after and the patient was allowed to leave 2 hours after the removal of the drain.

The outpatient clinic consists of two identical operation theaters and each procedure could be performed in either one. The nursing staff was all surgical nurses but not specialized in neurological surgery, opposed to the nurses in the traditional surgical theatres. The outpatient operating theatre does not have a surgical microscope as the operating theatres in the neurological department do, but the surgeons have surgical magnifying glasses to assist them.

The group of patients was selected based on strict inclusion criteria. These criteria include having an ASA score of three or lower; understanding and speaking Danish, or otherwise having a translator with them; having someone to take care of them after the surgery; not having type 2 diabetes or being obese; having low risk of bleeding (appendix II).

Data collection

The data on each patient came from two sources: patient files and a questionnaire filled in by trained nurses through telephone interviews post-surgery.
Choosing which data points to look at was somewhat limited by the data available, as is the nature of a retrospective study. We chose the parameters in a sectioned manner:

- Going through the literature for inspiration.
- A meeting of the author and instructors to get a consensus about the ideal parameters.
- A short pilot study of five cases was done to see which of the parameters could be reliably determined from the files.
- After that a final list of parameters was composed.

**The patient files**

After being referred to the neurosurgical department, each patient is seen by a neurosurgeon and evaluated for a surgery. If a surgery is scheduled for the patient, he will also see an anesthesiologist. We looked through the files from these interviews as well as files written by the doctors and nurses pre- and post-surgery. To assess whether the patient was re-admitted to the hospital in the month following the surgery, or if any complications that required medical assistance had arisen, we looked for the presence of notes from medical staff in the files.

Most of the files are stored digitally in the AUH computer system but few of them, including the anesthesia monitoring sheets as well as the questionnaire, were only available on paper in the hospital file storage. The secretaries of the department collected the paper files for the purpose of this study.

The parameters we looked for in the patient files were:

- The basic information about the patient, including age, height, weight, the American Society of Anesthesiologists’ physical status classification system (ASA score)\(^{43}\), when the patient came in for consultation, and if the patient smokes or drinks alcohol.
- The pathology of the patient, including the level and laterality of the protrusion, if the operation was on one or multiple (two) vertebral levels, and previous cervical spinal surgery. This was determined from the original work-up by the neurosurgeon and checked against the surgical notes.
- The patient’s baseline symptoms and the duration of the patient’s symptoms. This was also determined from the original work-up by the neurosurgeon and was only noted as presence or absence of each symptom. This information about symptoms was then used to establish a baseline status of
the patient, which could then be compared to the information given by the patients in the questionnaire.

- The surgery, including: who was the principal surgeon, whether there were any complications (dural, root or spinal lesions); if the patient received antibiotics; if the patient was moved to a regular surgical ward post-surgery; if the patient was re-admitted within a month after the surgery; the date of the surgery; blood loss, time under anesthesia and actual operating time.

**The questionnaire**

At two points, one week and eight weeks after the surgery, a nurse called the patients for a structured telephone interview. The answers were written in a preformed paper questionnaire and stored in the hospital file storage. The original purpose of the questionnaire was to make sure that the patients were not experiencing any dangerous complications and to determine if a consultation with a neurosurgeon was needed.

The patients were asked about the presence of:

- Pain in the neck or shoulder
- Pain in upper extremity
- Paresthesia in upper extremity
- Decreased strength in upper extremity
- Pain in lower extremity
- Signs of dysphagia or hoarsenedness.
- Signs of inflammation in the surgical wound

In addition, the patients presenting with any symptoms were asked to grade them and/or asked if the symptoms were better or worse than after the surgery (appendix I). For those patients whose questionnaires were not completely filled out, the patient files were searched for any notes from doctors in the post-operative period. If the date was similar to the 1-week and 8-weeks timeframes and the note described the current symptoms of the patient, that information was also used to determine the patient’s status.

**Input into Epidata**

To collect the data we used the program Epidata, a program specially created for collecting epidemiological data. It allow the user to create a sheet in the form of a questionnaire. It also allows for the creation of input criteria, with the program not
allowing any values that go against the criteria. This feature of the program helps with avoiding input errors.

Using the program, we created an Epidata database with all the parameters to be used for the study. After making sure that all the data could be reliably extracted from the patient files or the questionnaire, we went through the files of all the patients and put them into the sheet. All the data was put into the program anonymously to make sure the information was non-identifiable. The data was then stored in the computer system of the AUH.

**Analyzing the data**

Statistical analyzes was done in STATA. McNemar’s test was used to calculate risk ratios, confidence intervals and p-values for the relief of symptoms and the improvement of symptoms. All other statistical workup was done in Excel.

**Interpreting the results**

Since this is not a randomized trial, it is important to establish a standard to compare the outcome to. This can either be done by a case-control study where we would look at inpatients from before the outpatient operations started and match them with the outpatients, or by searching the literature for comparable studies on both in- and outpatients. Even though the first method is more direct, the latter one was chosen for this study. This is for several reasons. First of all is the time constraint of this project, especially since the lack of computer-stored patient files for older cases would require a greater amount of time for data collection. Second of all, no follow-up questionnaire has been filled out for any inpatients. Therefore we would not have any real follow-up on those patients and could only register complications during or soon after the surgery.
Results

Baseline patient data

In total there were 55 patients with no exclusions from the study. Eight surgeons performed the procedures, with one of the surgeons performing 31 of the 55 operations (56%). Six of the surgeons, performing 48 (87%) of the procedures, were consultants while the other two, performing the remaining seven (13%) operations, were surgical residents. The age of the patients followed a normal distribution with the center in the 46-50 year old group (see Table 1). The mean age was 48.9 years, ranging from 34-66 years. In total there were 32 women and 23 men. The average BMI was 26.1 (range 20.0–36.1) with the mean and range being almost identical for both genders. According to the definition of BMI, 31 patients were overweight and six of them obese (two being “severely overweight”). The weight of the male patients ranged from 60-127 kg and for the females from 47-108 kg. Two of the patients had a previous cervical spinal surgery. The physical measures of the patient group are summarized in Table 2.

![Age distribution in 5-year intervals](image)

Table 1: Age distribution in 5-year intervals

<table>
<thead>
<tr>
<th>Age</th>
<th>n</th>
<th>Mean</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>55</td>
<td>48.9</td>
<td>34-66</td>
</tr>
<tr>
<td>Weight (men)</td>
<td>23</td>
<td>86.7</td>
<td>60-127</td>
</tr>
<tr>
<td>Weight (women)</td>
<td>32</td>
<td>71.8</td>
<td>47-108</td>
</tr>
<tr>
<td>BMI</td>
<td>55</td>
<td>26.1</td>
<td>20.0-36.1</td>
</tr>
</tbody>
</table>

Table 2: Physical measures of the patient group

The waiting time from consultation with a neurosurgeon at the department until the surgery was on average 31.7 days (range 2-93 days). This excludes the waiting
time for a consultation after a referral. For the 49 patients for whom we could estimate the starting point of symptoms, they had been ongoing for 419 days on average at the date of surgery. 41% had had symptoms for over a year, including the 18% that had them for over two years.

**Data availability**

Pre-surgical data was available for all 55 of the patients. The paper questionnaire, however, was missing in total of twelve cases (22%) either because they could not be reached or the files could not be found in the hospital. After extracting data from patient files written by the doctors in the weeks following surgery, there were seven (13%) patients with no data on their post-operative symptoms. Therefore, 48 patients (87%) had some data on their post-operative symptoms but this varied between symptoms and it was lower in week eight than in week one.

Some questionnaires were partially filled out, meaning that the availability of data was not the same for every symptom asked about in the questionnaires. At one week, the response rate for each symptom ranged from 69-76% (with neck/shoulder pain being the best reported and motor weakness the worst). At eight weeks, the response rate ranged from 55-65%, again with motor weakness at the bottom and neck/shoulder pain at the top. The exact number of patients with available data is shown in Table 6 in connection to the relief from symptoms.

**Surgical level and laterality**

Of the 55 operations, 47 were single vertebral level surgeries, the other eight were on two levels. Of the single level operations, most were on the disc between C5 and C6, where the C6 nerve root exits. Most of the other ones were at the C6/C7 disc, where the C7 nerve root exits. All the double levels were done on the C5/C6 and the C6/C7 discs. Seven of the eight doubles were done on males. This means that 30% of the male surgical patients had an operation on two vertebral levels but 3% of the female patients. The number of surgeries at each level and each side are shown in Table 3.
Baseline symptoms

The most common symptoms mentioned in the original surgical work-up are neck- or shoulder pain (89%) and arm pain (96%). Around half had reduced strength in the upper extremity and 71% had upper extremity paresthesia. Symptoms from lower extremities were present in three cases (5%). The baseline symptoms are listed in Table 4.

We also recorded the ASA score of the patients. No patient had an ASA score higher than two (mild systemic disease). 38% of the patients had an ASA score of two, with the other 62% scoring one (healthy person). 47% of women and 26% of men had an ASA score of two.

<table>
<thead>
<tr>
<th>Type of hernia</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single level</td>
<td>47</td>
<td>85%</td>
</tr>
<tr>
<td>C3/C4</td>
<td>1</td>
<td>2%</td>
</tr>
<tr>
<td>C4/C5</td>
<td>2</td>
<td>4%</td>
</tr>
<tr>
<td>C5/C6</td>
<td>31</td>
<td>56%</td>
</tr>
<tr>
<td>C6/C7</td>
<td>13</td>
<td>24%</td>
</tr>
<tr>
<td>Two levels</td>
<td>8</td>
<td>15%</td>
</tr>
<tr>
<td>C5/C6+C6/C7</td>
<td>8</td>
<td>15%</td>
</tr>
</tbody>
</table>

Table 3: Type and side of the hernias

Perioperative events

The reporting of hemorrhage in the anesthesiology files was inconsistent, most cases simply being marked as zero. Therefore, calculating the average blood loss would be meaningless. However, there were four cases of large hemorrhages (the fifth largest reported was 80 mL). Those four cases were 1000 mL, 400 mL, 350 mL and 250 mL, respectively. The two smaller bleedings had no consequences. For the patient with 400 mL of blood loss, the operation was stopped and decompression could not be finished. The patient was moved to the general surgical ward following surgery. This was the only case of unexpected admission. The patient with 1000 mL of blood...
loss was re-admitted to the hospital within a month, this was also the only case of re-admission in the follow-up period.

There were no cases of spinal cord injuries but one case of a nerve root lesion. The patient came in with a left radiculopathy with improvement following surgery. However, new symptoms arose contralateral, including motor weakness in the upper extremity. He still had troubles on the right side at the end of the follow-up period.

There were four other events: Two patients had a new ACIF procedure on a different cervical level, both around seven months after the initial operation. The other two patients had trouble with hoarseness, one being diagnosed with an immobile vocal chord and the other with recurrent laryngeal nerve paralysis. In total there were nine events. Of those nine events, eight were associated with surgeries performed by one surgeon. There were no cases of damage to the vertebral artery, esophagus, sympathetic trunk or the thoracic duct.

The mean operation time was 80 minutes (range 44-185) while the patients were under anesthesia for 117 minutes (range 54-226). For the cases with full data (n=52), the patient had to wait under anesthesia before and after surgery for a mean of 36.9 minutes. The double level operation lasted longer with a mean operation time of 106 minutes versus 75 minutes for the single levels. The operation time and other surgical and clinical data is shown in Table 5.

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Mean</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waiting time (days)</td>
<td>55</td>
<td>31.7</td>
<td>2 - 93</td>
</tr>
<tr>
<td>From initiation of symptoms to surgery (days)</td>
<td>49</td>
<td>419</td>
<td>18 - 1828</td>
</tr>
<tr>
<td>Operation time (min.)</td>
<td>55</td>
<td>80</td>
<td>44 - 185</td>
</tr>
<tr>
<td>Time under anesthesia (min.)</td>
<td>52</td>
<td>117</td>
<td>54 - 226</td>
</tr>
<tr>
<td>Difference between anesthetic and operation time (min.)</td>
<td>52</td>
<td>36.9</td>
<td>2 - 77</td>
</tr>
</tbody>
</table>

Table 5: Surgical and clinical data

**Post-operative outcomes**

The risk ratios (RR) for complete relief from symptoms at one week and eight weeks are shown in Table 6. All symptoms show a tendency for reduction at eight weeks and this is statistically significant for neck/shoulder pain and for upper extremity pain, with relief of upper extremity pain also statistically significant after one week. The RR for pain in upper extremity at one week is 0.48 [CI=0.34-0.66] and at eight weeks 0.46 [0.31-0.67]. The RR for neck/shoulder pain is 0.92 [0.77-1.10] at one week and 0.70 [0.53-0.91] at eight weeks. The relief of paresthesia is on the edge of statistical significance after one week (RR= 0.67 [0.46-0.97]) but becomes non-
significant after eight weeks (RR=0.74 [0.49-1.13]) as the reporting of symptoms dropped. The incidence of motor weakness stays the same after one week but has dropped after eight weeks (RR=0.80 [0.54-1.18]) without reaching statistical significance. There were only three cases of pre-operative symptoms from lower extremities and statistical conclusions could not be drawn about them. However, two of the patients had improved by eight weeks. The last patient’s condition was unknown.

<table>
<thead>
<tr>
<th>One week</th>
<th>Risk ratio</th>
<th>95% confidence interval</th>
<th>p</th>
<th>Number evaluated (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neck and shoulder pain</td>
<td>0.92</td>
<td>(0.77; 1.10)</td>
<td>0.54</td>
<td>42</td>
</tr>
<tr>
<td>Paresthesia in upper extremity</td>
<td>0.67</td>
<td>(0.46; 0.97)</td>
<td>0.05</td>
<td>40</td>
</tr>
<tr>
<td>Pain in upper extremity</td>
<td>0.48</td>
<td>(0.34; 0.66)</td>
<td>&lt; 0.01</td>
<td>40</td>
</tr>
<tr>
<td>Motor weakness in upper extremity</td>
<td>1.00</td>
<td>(0.69; 1.44)</td>
<td>1.00</td>
<td>38</td>
</tr>
<tr>
<td>Discomfort in lower extremities</td>
<td>0.50</td>
<td>(0.05; 5.51)</td>
<td>1.00</td>
<td>39</td>
</tr>
</tbody>
</table>

| Eight weeks                      |
|----------------------------------|------------|------------------------|------|---------------------|
| RR                               | 95% CI     | p                      | n    |
| Neck and shoulder pain           | 0.70       | (0.53; 0.91)           | 0.01 | 36                  |
| Paresthesia in upper extremity   | 0.74       | (0.49; 1.13)           | 0.24 | 32                  |
| Pain in upper extremity          | 0.46       | (0.31; 0.67)           | < 0.01| 36                  |
| Motor weakness in upper extremity| 0.80       | (0.54; 1.18)           | 0.45 | 30                  |
| Discomfort in lower extremities  | x *        | x *                    | 0.50 | 31                  |

Table 6: The risk ratios for complete relief from symptoms following surgery.

* Number of affected patients too low: three patients report having symptoms at baseline, two improved, one unknown at eight week post-surgery

For upper extremity pain and upper extremity motor weakness, those patients that still had either symptom were asked if it had gotten worse, improved or was unchanged since discharge. Using this data, we calculated the risk ratios for improvement of symptoms, i.e. the likelihood of a patient either being completely relieved of the symptom or having improved (see Table 7). After one week, there is significant improvement in upper extremity pain (RR=0.27 [0.16-0.44]). At eight weeks, there is marked improvement in both pain (RR=0.28 [0.16-0.47]) and motor weakness (RR=0.47 [0.25-0.85]).
Table 7: Risk ratios for improvement of symptoms

<table>
<thead>
<tr>
<th></th>
<th>RR</th>
<th>95% CI</th>
<th>p</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>One week</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain in upper extremity</td>
<td>0.27</td>
<td>(0.16; 0.44)</td>
<td>&lt; 0.01</td>
<td>41</td>
</tr>
<tr>
<td>Motor weakness in upper extremity</td>
<td>0.72</td>
<td>(0.43; 1.22)</td>
<td>0.33</td>
<td>40</td>
</tr>
<tr>
<td><strong>Eight weeks</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain in upper extremity</td>
<td>0.28</td>
<td>(0.16; 0.47)</td>
<td>&lt; 0.01</td>
<td>37</td>
</tr>
<tr>
<td>Motor weakness in upper extremity</td>
<td>0.47</td>
<td>(0.25; 0.85)</td>
<td>0.02</td>
<td>30</td>
</tr>
</tbody>
</table>

After one week, 25 of the 44 (57%) patients with available data said they had either difficulty swallowing or hoarseness. Of these 25 patients, 18 said that it was better than at discharge, one that it was unchanged and none said it was worse. After eight weeks there was only data for 31 patients, with eleven patients (35%) reporting difficulty swallowing or hoarseness.

One patient reported mild inflammation in his wound after one week and another one did so after eight weeks. Neither patient had any records of having seen a doctor or having further problems.
Discussion

Summary of main results

The main results are that there were nine adverse events, giving a rate of 16%. For secondary outcomes, there was a tendency for improvement on all symptoms by eight weeks from surgery. This is statistically significant for neck/shoulder pain (RR=0.70) and upper extremity pain (RR=0.46). There was also reduction, although not statistically significant, of upper extremity paresthesia (RR=0.74) and upper extremity motor weakness (RR=0.80). Discomfort from lower extremity also seemingly improved, although the rarity of this symptom did not allow for calculation of risk ratio. When improvement is considered instead of complete relief of symptom, both upper extremity pain (RR=0.28) and upper extremity motor weakness (0.47) were statistically significant at eight weeks.

Gender differences

Females were 58% of the patients, which is in contrast to the distribution of radiculopathy in the population, with the disease being over 60% more common in males than females. It is noticeable that all but one of the original symptoms were more common in females (leg discomfort, with only three total cases, being the exception). In total, the females had on average 3.34 symptoms present while the males had 2.78. However, the females were more likely to have a higher ASA score, with 47% of females and 26% of males scoring two on ASA. The males were much more likely to have a surgery on two levels than the females, with seven of the eight double level surgeries being performed on males. This means that 30% of the males had a double while only 3% of the females. This difference could be a reflection of the selection of the patients.

The surgical outcomes

Hemorrhages and lesions

One study on 103 cases undergoing ACIF as outpatients found the average blood loss to be 103.8 mL, ranging from 25-200 mL. A meta-analysis from 2013 by Gao et al. analyzed blood loss in ACIFs across three studies of 265 patients in total, and found the average blood loss to be 58 mL. As previously stated, the blood loss registration in our study was not adequate to determine average blood loss. However,
the four cases (7%) of large hemorrhages in our study in 55 patients are all larger than the largest one in the aforementioned series of 103 cases. Cause-analysis for this finding is beyond the scope of this report.

There was one case (2%) of root lesion but no cases of damage to the spinal cord or other neurological problems, apart from the recurrent laryngeal nerve palsy discussed in connection with dysphonia. A large study from 1982 based on answers from surgeons about 36,657 cases reported a neurological complication rate of 0.7%, not counting recurrent laryngeal nerve palsies, with radiculopathy being the most common.\textsuperscript{47} Newer studies also report very low rates of neurological complications. Garringer et al. report zero cases in a series of 645 patients in an outpatient setting\textsuperscript{41}, with Silvers et al. reporting the same in a series of 103 patients\textsuperscript{37}. The nature of this study makes conclusions on individual complications difficult, however the combined number of complications seems higher than one would expect.

\textbf{The role of surgeons in complications}

Of the nine events we found in this study, eight were from surgeries performed by a single surgeon. Even though this surgeon performed 56\% of the surgeries, the numbers of surgical events are unevenly distributed. Looking into surgical education and surgeon selection for this procedure in this new environment could be one factor for the department to evaluate.

\textbf{Dysphagia and dysphonia}

According to Edwards et al, the prevalence of dysphagia and dysphonia after ACIF varies greatly between studies, either in the 1-15\% range or in the 40-60\% range.\textsuperscript{48} They argue that the reason for this bimodal distribution of results is the source of the information. If the information derives from reports written by the surgeons, then the prevalence is in the 1-15\% range but in the 40-60\% range if the information is derived from questionnaires filled out by the patients. Since our questionnaire data is coming from the latter, we could expect the prevalence to be somewhere between 40\% and 60\%. It is, however, important to note that different studies may measure prevalence at different time points, which would hinder comparison. In our study we did not differentiate between dysphagia and hoarseness, the patients were only asked if they had either symptom.

Dysphagia is in general quite common immediately after surgery but the incidence reduces for at least the first twelve months afterwards.\textsuperscript{49} For example, Rihn
et al. found that 71% of patients had symptoms of dysphagia after two weeks but this was reduced to only 8% by twelve weeks.\textsuperscript{50} Therefore, a patient that has symptoms of dysphagia during our follow-up will not necessarily have prolonged problems with swallowing.

In this study, we have two ways of estimating the rate of dysphonia/dysphagia. The first one is from the questionnaire, a patient reported measure, which shows that 57% of the patients had either symptom after one week, which drops to 35% at eight weeks. The other way is by looking at the patients that went to see an ENT specialist for their problem; these are likely to be more severe cases and could constitute permanent problems. We found two cases of that, which gives us a rate of 3.6%. However, it is worth noting that the time from surgery to the collection of data varied from four to sixteen months and, therefore, some of the last patients might have a problem that they had not sought consultation for when their patient files were searched.

The study by Edwards et al. also brings up important questions with regards to case studies like this one in general. How well can we trust the data that we obtain if the methods of obtaining them have such a large impact on the results? There should be little doubt that this case of accurately reporting dysphagia is not unique to reporting on symptoms of dysphagia. Whether the difference between methods is as large with regards to other symptoms, for example for arm pain, would be nothing but guesswork but there probably is a difference. Another angle on the issue is who is correct, the patients or the doctors? Are all cases of patient-reported dysphagia really cases of what would be diagnosed as a dysphagia? In the study by Edwards et al., large portion of the patient-reported cases were defined as mild. However, underreporting among those who reported severe dysphagia or dysphonia was still 57%.\textsuperscript{48} At least we can conclude that comparison between different studies will be misleading unless the sources of the data are comparable.

**Unplanned admissions**

For the purpose of this study we defined an unplanned admission as an admission into the regular surgical ward following a surgery due to a complication. Possible complications include, but are not limited to, epidural hematoma, severe pain or nausea. Garringer et al. reported in 2010 that 24 of 392 (6.1%) outpatients had an unplanned admission after the surgery. Of those, nine cases (2.3%) were attributable
to the iliac crest graft that was harvested during the surgery. It is worth noting that his patients only stayed in the hospital for a minimum of 4 hours and therefore his results might not be comparable to this study where the patients usually stayed overnight in the hospital, as well as not undergoing iliac crest harvest.\textsuperscript{41}

There was one patient admitted to the ward (due to venous bleeding) in this study, giving an overall rate of 1.8%. This study is too small to determine an accurate rate of unplanned admissions but it seems to be a rare event.

\textit{Adjacent disc disease}

A long term complication of fusion is the higher rate of degeneration at other cervical levels, which is referred to as adjacent disc disease (ADD).\textsuperscript{36} The reasons for the higher rate is a common topic in spine surgery circles. One view is that it’s due to natural progression of the disease while the opposite view is ADD being a consequence of the surgery. It is, however, most likely multifactorial as no study has proven that a single factor directly correlates with this pathology.\textsuperscript{51} Biomechanical studies on cadavers have shown that fusion increases the intradiscal pressure at adjacent cervical levels, especially during flexion.\textsuperscript{52} This probably explains at least partly the increased degeneration of other IVDs after cervical fusion procedures.

Studies suggest that over 25\% of patients will develop adjacent disc disease within ten years of surgery.\textsuperscript{7} Hilibrand et al. reported an annual incidence of 2.9\%.\textsuperscript{53} Since our study is based only on short-term follow-up, ADD is not something that we should be able to measure. However, there were two cases (4\%) of re-operations at adjacent level within eight months of the initial surgery. It is possible that these are not true cases of ADD, rather these patients might have needed surgery on two levels to begin with and the re-operation reflected this. Longer follow-up of the patient group would be required to determine a more exact incidence.

\textit{Improvement of symptoms}

The main aim of ACIF is to relief pain in the upper extremity.\textsuperscript{23} Neck pain does often improve as well, but it is customary for the surgeon to warn the patient that it might not. Considering this, the improvement of upper extremity pain (RR=0.27 at one week, RR=0.28 at eight weeks) is very encouraging. For both cure and improvement, there is very little difference in the risk ratios from one week to eight weeks (RR=0.48 at one week, RR=0.46 at eight weeks for cure). This suggests that either there is adequate decompression of the nerve and the pain is relieved quickly or
it is not relieved at all. For neck/shoulder pain, paresthesia and motor weakness, however, the risk ratios are lower after eight weeks compared to at one week, suggesting that the recovery from these symptoms might be more gradual than the recovery from upper extremity pain.

The surgical protocol

Performance of the system

Villavicencio et al. reported an average operation time of 90 minutes (range 40-240 minutes) in a study of 103 patients undergoing single, double or triple ACIFs in an outpatient setting. The mean operation time of 80 minutes that we found is therefore comparable to the findings of Villavicencio.

Although not documented in this study, it was a common theme that the patients were initially seen by one surgeon and then operated on by another. The operator would then only be basing the operation on the report written by a different surgeon and the MRI scans. As previously mentioned, there is often a discrepancy between the images and the actual symptoms and the surgeon bases his surgical choice largely on his feeling for where the patient’s problems originate. This could therefore lead to worse surgical outcomes. It is also a concern from the point of patient satisfaction, since it might feel uncomfortable for the patient to be operated by somebody he/she has never seen before. The author recommends that this will be reviewed in the protocol.

The use of drains

Included in the protocol is to insert a drain at the end of the surgery, which is then removed the morning after before discharge. The purpose of the drain is to prevent the possibly life-threatening retropharyngeal hematoma from developing. The use of a drain is somewhat debated. Garringer et al. reported of 645 consecutive patients with none developing retropharyngeal hematomas despite a drain not being put in. He calls into question the use of drains based on those results. In this study, there was not a single case of retropharyngeal hematoma.

The follow-up

Calling every patient twice after surgery is mandatory in our protocol, replacing the time consuming referral to an outpatient surgical follow-up. However, the percentage of patients lost to follow-up is high, with information being available for
as little as 55% of patients. Several reasons can be behind this. First of all, the patient folder could not be located for seven patients. Some of these patients might have had a filled out questionnaire, but either way we could not locate them. Some of the others were never called, not called again if they didn’t answer first time or the questionnaire was not properly filled out.

In order to survey outpatient clinic patients, proper, rigorous, and complete follow-up is necessary. One way to do this would be to make it easier for the nurses to fill in the questionnaires, for example by making them digital and through education in thorough completion of each questionnaire. That would also make it easier to extract the information for follow-up studies. There also needs to be a system to remind the nurses of calling the patients at the correct dates, for example by putting reminders into the calendar after each surgery.

**Strengths and weaknesses of this study**

The strengths of this study is the complete coverage of all patients in the computerized storage of patient files, meaning that any event that required medical attention was most likely recorded in this study. This allows for an accurate assessment of the rate of complications.

The weaknesses of this study are mainly the lack of longer follow-up and especially the low number of patients with available data. Better filled in questionnaires would be needed in order to be confidently conclude about the outcomes of the surgeries. A larger patient group would also have increased the power of the study as well as allowing for further analysis, for example by seeing if certain pre-surgical measures were associated with better or worse outcomes. The retrospective nature of this study is also a weakness by itself and limits the gathering of data. Here are further discussed two issues that can influence the accuracy of the results.

**Different sources of data**

When evaluating the outcome in this study it is important to note the different baseline conditions of our patients compared to that of the normal group of ACIF candidates. Since it’s a procedure with very grave, albeit rare, potential complications, patients are selected into the daycare based on specific inclusion criteria. Therefore it is not possible to measure the outcome against an unmatched sample of general ACIF candidates. Likewise, when reviewing the literature it is important to note what the
inclusion and exclusion criteria were for the particular studies in order to steer away from selection bias.

Another thing to consider when evaluating the rate of complications is the age of the patients, which is likely to be lower in the outpatients than with the general ACIF candidates. Older patients have drastically higher rate of complications after an ACIF, according to one study the rate was 35% for those 70 years old and over, and 9.7% for those under 70.54

**Response shifts and its possible implications**

When assessing results from clinical research that measures health at different time points, it is worth being aware of the concept of response shift. Response shift refers to changes in the self-evaluation of a concept by a patient, for example pain score or quality-of-life score. This can be because of changes in internal standards, changes in values or changes in conceptualization.55

Lets take an example of a middle-aged man who undergoes ACIF after having had arm pain with reduced strength in his arm for quite some time. Before the surgery, he has become acclimatized to his condition and does not compare himself to healthy men anymore when evaluating his condition. Then after having the surgery, he expects to be better and starts playing basketball again. Now, however, he feels very inadequate as he starts comparing his ability to his healthy colleagues and might rate his quality of life differently because he has had a shift in his internal standards.

Another example might be if the same man had severe arm pain along with a mild neck pain before surgery, rating his neck pain as three on VAS. After the surgery, however, he does not have the arm pain anymore to mask over the neck pain. Now he might rate the neck pain as five on VAS even though it might not have changed at all or even improved. Both of these are examples of response shift, which can have great impact on the results of clinical studies and should be kept in mind when interpreting the results.

**Conclusion**

The total number of complications is higher than expected when compared to international literature. The surgical setup should be evaluated to adjust the approach. In addition, the follow-up needs to be improved in order to accurately survey the performance of the patients following surgery.
Acknowledgements

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The Surgical staff at AUH
References


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Appendix I – The Questionnaire

Spørgeskema til telefonkonsultation med patient efter CTTI/CAGE operation
Patienten kontaktes postoperativ efter 1 uge samt efter 8 uger.

1. Har du nakke- og skuldersmerter?
   - 1 uge: Ja___ Nej___
   - 8 uger: Ja___ Nej___

Hvis ”Ja”:
   Scor smerten på en skala fra 0-10 (NRS-skala), hvor 0 er ingen smerte og 10 er den værst tænkelige smerte:
   1 uge: Smertescore i hvile = ___
           Smertescore i aktivitet = ___

   8 uger: Smertescore i hvile = ___
            Smertescore i aktivitet = ___

Hvis smertescoren er over 3 i hvile eller over 5 i aktivitet:

2. Har du parastesier i arme/fingre?
   - 1 uge: Ja___ Nej___
   - 8 uger: Ja___ Nej___

2.b Har du smerter i armen(e)?
   - 1 uge: Ja___ Nej___
   - 8 uger: Ja___ Nej___

Hvis ”Ja” til 2b:
   1 uge: Smertescore i hvile = ___
           Smertescore i aktivitet = ___

   8 uger: Smertescore i hvile = ___
            Smertescore i aktivitet = ___

Ved smertescore over 3 i hvile eller over 5 i aktivitet:
Informér om at en læge fra afdelingen vil kontakte pt. indenfor få dage.

2c. I forhold til før operationen er smerterne så:
   1 uge: Mindre___ Uændrede___ Forværrede___
   8 uger: Mindre___ Uændrede___ Forværrede___

Hvis smerterne er mindre end før operationen:
Opfordrer patienten at aftrappe smertebehandling med hjælp fra egen læge.

Hvis smerterne er uændrede:
Informér om at en læge fra afdelingen vil kontakte pt. indenfor få dage.
Hvis smerterne er forværrede:
Informere om at en læge fra afdelingen vil kontakte pt. indenfor få dage.

3. Har du nedsat kraft i armen(e)?
- 1 uge: Ja___ Nej___
- 8 uger: Ja___ Nej___

Hvis ”Ja”: Når du tænker tilbage på tiden lige efter udskrivelsen, er kraftnedsettelserne så:
1 uge: Mindre___ Uændrede___ Forværrede___
8 uger: Mindre___ Uændrede___ Forværrede___

Hvis kraftnedsettelserne er uændret eller forværret efter udskrivelsen:
Informere om at en læge fra afdelingen vil kontakte pt. indenfor få dage.

4. Har du gener i benene?
- 1 uge: Ja___ Nej___
- 8 uger: Ja___ Nej___

Hvis ”Ja”: Når du tænker tilbage på tiden lige efter udskrivelsen, er kraftnedsettelserne så:
1 uge: Mindre___ Uændrede___ Forværrede___
8 uger: Mindre___ Uændrede___ Forværrede___

5. Har du synkebesvær og/eller hæshed?
- 1 uge: Ja___ Nej___
- 8 uger: Ja___ Nej___

Hvis ”Ja” er synkebesvær/hæshed forværret efter udskrivelsen?
- 1 uge: Ja___ Nej___
- 8 uger: Ja___ Nej___

Hvis ”Ja”, informere om at en læge fra afdelingen vil kontakte pt. indenfor få dage.
Hvis ”Nej” informere pt. om at se an 3-4 uger endnu, og herefter tage kontakt til Neurokirurgisk Afdeling NK, hvis ikke synkebesvær/hæshed er forsvundet.

6. Er der tegn til betændelse i såret?
- 1 uge: Ja___ Nej___
  Rødme___ Udtalt ømhed___ Varme___ Feber___ Pus___ Udtalt hævelse___ ej symptomer___
- 8 uger: Ja___ Nej___
  Rødme___ Udtalt ømhed___ Varme___ Feber___ Pus___ Udtalt hævelse___ ej symptomer___

Ved rødme, ømhed og varme: Opfordrer pt. til at kontakte egen læge.
Ved feber, pus og udtalt hævelse: Kontakt akutvagten på Afdeling NK, der skal ringe tilbage til pt.
Appendix II – The surgical protocol

Ambulant rygkirurgi Dagkirurgisk Center

Selektion:

Der selekteres efter normalt gældende kriterier for Dagkirurgi,
- Pt er instillet efter ambulant behandling
- ASA I-III
- Ingen svær overlægt
- Ringe risiko for blødning
- Kontrol af postoperative smerter
- Pårørende I hjemmet til næste morgen
- Talere og forstå dansk, ellers tolk med.
- Ikke NIDDM

Specielt for rygkirurgiske patienter er selection vigtig, idet erfaringer fra USA viser at dette er nøglen til succes. Det er vigtigt at undgå patienter med langvarig anamnese og stort fast forbrug af analgetica. Patienter på morfica behandling gennem længere tid klarer sig dårligere end ikke morfica forbrugende patienter.

Patienter med kongruerende myofascielle smerter som fibromyalgia og eller whiplash klarer sig ligeledes dårligtambulant. Deres smerteproblematikker er ofte meget komplekse og kræver indlæggelse.

Information

Ligeledes er det helt essentielt med god information. Denne skal gives således at patienten ikke efter operationen sidder tilbage med spørgsmål angående kirurgi og smertebehandling. Efterforløbet skal være velbelyst, hvad kan forventes og hvad skal føre til kontakt med sygehusvæsenet.

Derudover er det meget vigtigt at indgyde patienten en fornemmelse af at være nyopereret og ikke ”rygpatient”. Det er vigtigt at fortælle patienten at hans ryg er stærk, der resterer kun smerter fra de berørte muskler. Patienten må belaste til smertegrænsen. Der er ingen restriktioner ud over hvad smerten medfører.

Informationen skal gives af kirurgen og Dagkirurgisk Centers personale.
Anæstesi:

Patienterne anæsteres efter normalt gældende principper på Dagkirurgisk Center, dvs

- Trombose profylakse med TED og Fragmin 2500 ie sc
- Propofol
- Remifentanil
- Mivacurium til intubation
- Atropin antisialogt
- Lokalanalgesi ved afslutning af kirurgi
- Toradol ved afslutning af kirurgi
- Ponv profylakse efter gældende kriterier.

Smertebehandling:

- Paracetamol 1g x 4 startende præoperativt
- Naproxen 500 mg x 2 startende præoperativt
- Fentanyl efter gældende kriterier
- Kodein/ketogan efter behov

Mobilisation:

Patienterne må mobiliseres fuldstændig efter evne postoperativt.

Udskrivelse:

Patienterne udskrives til hotellet efter gældende regler. Det er dog vigtigt at have focus på vandladningen postoperativt. Pt skal informeres om at dette kan være et problem og at de skal have ladt vandet senest 8 timer efter operationen. Ellers kontaktes vagthavende neurokirurgisk afdeling. Patienten skal ses næste dag inden udskrivelsen af neurokirurg.