Motion preservation in cervical prosthesis surgery: Implications for adjacent segment degeneration

Yang, X.

Chapter 1

Introduction & Outline of the thesis

INTRODUCTION

Cervical radiculopathy is a frequently occurring neurologic disorder[1]. It was first described as a clinical diagnosis by Parkinson in 1817[2], although he ascribed it to 'rheumatic affection of the deltoid muscle'. Elliott then described how radicular symptoms might arise through narrowing of intervertebral foramina secondary to arthritic changes of the cervical spine in 1926[3]. In 1936, Turner and Oppenheimer described that intervertebral foraminal narrowing was caused by 'thinning' of the disc[4]. Nowadays, the clinical symptoms of cervical radiculopathy are considered to be characterized by radiating pain in the arm and/or fingers corresponding to the dermatome involved[5]. Generally, the symptoms are caused by spinal nerve root compression, which is usually attributable to disc herniation or spondylosis. The annual incidence rate of cervical radiculopathy indicated by a population-based study from Rochester, Minnesota, is 107.3 per 100,000 for men and 63.5 per 100,000 for women, with a peak of 202.9 per 100,000 persons for the age group of 50-54 years[2].

Although there are no universally accepted diagnosis criteria for cervical radiculopathy[6], the clinical diagnosis is based on the information collected from the medical history and physical examination. The cause of the radiculopathy can be compression of the spinal nerve root and this can be identified by diagnostic imaging (MRI) or supported by surgical findings[7]. In recent years, the understanding concerning the pathology, aetiology and implications regarding the treatment for cervical radiculopathy has increased[5,8-10]. The majority of patients has a favourable outcome with conservative treatment[2]. Usually, a wait and see policy in which the patients are treated with analgesics is successful[11]. In addition, physiotherapy is recommended to be effective for the treatment of neck pain[12]. Kuijper et al.[5] conducted a prospective, randomised controlled trial among patients with less than one month of symptoms of cervical radiculopathy, and demonstrated that the neck and arm pain reduced significantly for the patients with a semi-hard cervical collar and three to six weeks rest or physiotherapy with six-week home exercises compared with the wait and see policy.

The role of epidural injections is controversial. Some studies reported a favourable outcome with translaminar and transforaminal epidural injections of corticosteroids[13,14]. The complications, however, can be serious, including severe neurologic sequelae from brainstem and spinal cord infarction[15].

If patients are unresponsive to conservative treatment, surgical intervention may be considered. Surgical treatment of cervical radiculopathy has become more common and this led to an increase in the number of surgeries in treatment of cervical radiculopathy[8,10,16,17]. The surgical approach can be divided into posterior procedures, anterior procedures or a combination of these. In the first half of the last century, only posterior surgery was performed for cervical spinal pathologies. In the 1940s, posterior foraminotomy was introduced for managing cervical radiculopathy[18,19]. Subsequently, the popularity of the anterior approach for discectomy and fusion has increased because this approach avoids exposure of the spinal

canal and results in less soft tissue damage[20]. In the 1950s, anterior cervical discectomy was described with the use of autologous iliac crest interbody bone graft (ACDF) to result in reliable fusion rate and generally maintain spinal structural integrity[21-23]. However, in 1961, Hirsch debated the necessity of interbody fusion[24]. Anterior cervical discectomy (ACD) is the basic surgical treatment of patients with radicular pain caused by cervical disc herniation. The purpose of ACD is removal of the intervertebral disc in order to decompress the nerve root and alleviate radicular pain. However, cervical instability and segmental collapse with recurrent radicular pain has been documented after anterior discectomy. At present, ACDF is defined as the gold standard for cervical disc herniation since clinical researchers have demonstrated excellent clinical outcome with low complication rates in long term follow-up. The procedure remained largely unchanged until the 1990s. Cages and allograft bone were introduced to reduce the complications of harvesting autologous bone graft from the iliac crest. To decrease the prevalence of pseudarthrosis, plates were successfully introduced[25-27].

Frequently, surgeons perform ACDF to maintain disc height and cervical alignment, and to promote bony fusion to prevent instability. However, arthrodesis of a motion segment leads to increased mechanical load and stress at the levels adjacent to the fusion site. Therefore, the concept of accelerated adjacent segment degeneration (ASD) is proposed and widely discussed. Hilibrand et al.[28] reported a large retrospective study of patients who underwent ACDF. Symptomatic ASD occurred at a relative constant incidence of 2.9% annually. They predicted that 25.6% of the patients would have new disease at the adjacent level within 10 years after the operation[28]. This finding was generally considered with sepsis since it was not the experience that patients that had once had an ACDF regularly returned with radiculopathy at the adjacent level. Since Hillibrand et al. did not give insight in baseline degeneration data, it was thought that the changes diagnosed at 10-year follow-up were already present at baseline. Moreover, Hillibrand et al. reported that symptomatic ASD was less in patients who had ACDF at two levels. This finding supports the thought that baseline degeneration plays an important role.

Goffin et al. showed 92% additional radiological degeneration at the adjacent disc levels at late follow-up after ACDF[29], but they failed to demonstrate the clinical implication of radiological degenerative findings. Gore evaluated 200 asymptomatic persons radiographically. At 10 years follow-up, he showed new or progressive degenerative changes in 100 of the 159 participants (63%), but only 15% of patients reported pain in neck or arm, and only one patients actually underwent surgery for cervical radiculopathy[30].

These results suggest that the occurrence of degeneration at the adjacent levels is a physiological process, which is only natural to occur in patients upon aging. In absence of clinical complaints that can be attributed to the degeneration at the adjacent level, they should not be considered a complication of interbody fusion. To confirm this suggestion, investigating the relationship between radiological findings and clinical outcome is needed.

Instead of further investigating the relation between radiological findings and clinical symptoms, a new device was introduced to prevent accelerated ASD. And in the process of finding a market for this new device, the cervical disc prosthesis (ACDA), radiological findings were stressed to convince the surgeons to switch the ACDF procedure to the ACDA procedure. To prevent accelerated ASD, the cervical prosthesis was developed to maintain segmental range of motion (ROM) as well as to restore disc height, and thereby avoid neck pain and disability in post-surgical follow-up[31].

In this thesis we will use the results that are delivered by trials with the prosthesis to do what should have been done initially, namely, to investigate the correlation between radiological and clinical data in the follow up of anterior discectomy surgery.

The Netherlands Cervical Kinematics (NECK) trial is a multicentre prospective randomized controlled trial among patients with single level cervical radiculopathy due to a herniated disc, which was performed in Leiden University Medical Centre, Haaglanden Medical Centre and Alkmaar Medical Centre in the Netherlands. In the NECK trial, the effectiveness of ACDA was compared to ACD as well as to ACDF with a two-year follow-up[32]. It was shown that ACDA did not demonstrate a superior clinical outcome[33]. In the Radboud University Medical Centre, Nijmegen, the PROCON trial was performed with similar design and objectives, and a comparable clinical outcome was demonstrated between ACDA and ACD with or without fusion[34]. The radiological and clinical findings of these NECK trial and PROCON trial will be used to elaborate on the correlation between the two.

OBJECTIVES AND OUTLINE OF THIS THESIS

The main objective of this thesis is to unravel the relationship between radiological findings and clinical outcome in patients who were subjected to surgery for cervical radiculopathy via an anterior approach.

The first objective of this study is to summarize the radiological evaluation methods and outcome data that are described in literature (**chapter 2**). In spite of being scientifically debated, MRI is frequently prescribed in patients with cervical radiculopathy who are unresponsive to conservative treatment. **Chapter 3** reports on the correlation between the size of cervical disc herniation and clinical condition.

In **chapter 4**, data are presented on the occurrence of ASD in patients from the NECK and PROCON trial. The incidence of radiological ASD is compared between patients who underwent cervical arthroplasty and those who underwent arthrodesis. Subsequently, these ASD data were correlated to the ROM of the cervical spine before and after the three different forms of surgery. Not only was the influence of the surgical intervention regarding the ROM studied on the index level, but also with regard to the ROM of the total cervical spine (**chapter 5**).

Sagittal alignment of the cervical spine may be influenced by anterior cervical spine surgery. Altered sagittal alignment due to anterior discectomy may influence ASD. Therefore, cervical spine balance parameters, will be correlated to observed ASD in patients from the NECK and PROCON trial (**chapter 6**).

In the search for causes of (accelerated) degenerative changes in patients with radiculopathy, Modic vertebral end-plate signal changes visualized by MRI have been proposed as a possible cause. In **chapter 7**, a literature overview is presented of the association between clinical symptoms and Modic changes and cervical disc degeneration. In **chapter 8**, the results of NECK and PROCON trial are reported on the incidence of Modic changes and the observed correlation between the presence of Modic changes and radiological degeneration in cervical radiculopathy.

Heterotopic ossification has been reported as the adverse outcome after cervical arthroplasty, which counteracts motion preservation. In **chapter 9**, the occurrence and progression of heterotopic ossification is reported in the patients from the NECK and PROCON trial. The correlations between high grade heterotopic ossification, ROM and clinical outcome is studied.

Finally, the clinical and radiological outcome data of the two different cervical disc prostheses used in the NECK and PROCON trial are compared (**chapter 10**).

Discussions and conclusions with regard to the results are presented in **chapter 11**. The dissertation is concluded with a summary in **chapter 12**.

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