



Two-Year Results of the Prospective Spine Treatment Outcomes Study: An Analysis of Complication Rates, Predictors of Their Development, and Effect on Patient Derived Outcomes at 2 Years for Surgical Management of Cervical Spondylotic Myelopathy

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■ **OBJECTIVES:** To investigate the baseline patient characteristics, nonoperative modalities, surgical procedures, and complications rates of surgical cervical spondylotic myelopathy (CSM) patients. To evaluate risk factors for developing complications and compare the changes in health-related quality of life (HRQOL) from baseline to 2 years postoperatively.

■ **METHODS:** A retrospective review was performed on a prospectively collected database of CSM patients. Baseline patient demographic data, comorbidities, clinical information, nonoperative treatment modalities, surgical procedures, and complication rates were collected. HRQOL outcomes were assessed using the Short Form 36 (SF-36) Physical Score Component (PCS) and Mental Score Component (MCS) and the Neck Disability Index (NDI) at baseline and 2 years postoperatively. Statistical analyses included paired-sample *t* tests and multivariate logistic regression controlling for age, sex, and body mass index (BMI).

■ **RESULTS:** A total of 203 surgical CSM patients were identified (43% female). Average age was 57.7 years and average BMI was 29.6 kg/m². Before surgical intervention, patients underwent various nonoperative treatment modalities, most commonly nonsteroidal anti-inflammatory drugs (34%), analgesics (32%), and physical therapy (26%). The

overall rate of complications was 7.4%. Complications included cerebrospinal fluid leak (2.5%), postoperative radiculopathy (1.0%), and excessive bleeding (1.0%). A previous history of cervical spine surgery was the sole significant risk factor for developing a complication (odds ratio, 9.22; *P* = 0.034). Average HRQOL scores improved significantly from baseline to 2 years postsurgery.

■ **CONCLUSIONS:** The overall complication rate was 7.4% for the cohort. Baseline clinical information, comorbidities, use of nonoperative treatment modalities, and procedure type were not significantly associated with an increased risk of complications. Previous cervical spine surgery increased the risk of complications by 9-fold. The patients showed significantly improved SF-36 PCS, SF-36 MCS, and NDI scores at 2 years after surgery.

INTRODUCTION

Cervical myelopathy retains an ambiguous clinical presentation with the potential to cause serious musculoskeletal and neurologic symptoms. Myelopathy, referring to disease within the spinal column, has various etiologies, including trauma, tumor, abscess, and metabolic disorders, among others.¹ Although the exact prevalence of myelopathy is unclear, it most

Key words

- Cervical
- Cervical spondylotic myelopathy
- Complications
- Health-related quality of life
- Nonoperative
- Outcomes
- Spine surgery

Abbreviations and Acronyms

- CSF:** Cerebrospinal fluid
CSM: Cervical spondylotic myelopathy
HRQOL: Health-related quality of life
JOA: Japanese Orthopedic Association
MCS: Mental Component Score
NDI: Neck Disability Index
NSAID: Nonsteroidal anti-inflammatory drug

PCS: Physical Score Component
SF-36: Short Form 36

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commonly manifests as a result of degenerative changes in the cervical spine in patients over age 55, a condition known as cervical spondylotic myelopathy (CSM).² CSM is a process marked by cervical spinal canal dysfunction secondary to compression and narrowing of the spinal column, with signs and symptoms dependent on the affected cervical spine level(s). Debate over the natural history of CSM has continued since the disorder was originally described by Brain et al in 1952³; however, it is currently accepted that a combination of static and dynamic factors results in repetitive injury to the spinal cord.

The wide variety of clinical presentations that encompass the clinical diagnosis of CSM, along with the varying anatomic features seen in the cervical spine on presentation, have fueled the ongoing debate about the factors influencing the progression and outcomes of CSM following surgical treatment. As a result, there has been an abundance of literature published in the past decade examining the influence of these factors on postoperative functional and neurologic recovery. Evidence for anatomic features, such as a small transverse area of the spinal column, as influential factors in surgical outcomes, has been widely reported.⁴⁻⁶ Despite these comprehensive investigations, less is known regarding the risk associated with surgical treatment of CSM and factors influencing the development of surgical complications. Reported postoperative complication rates for the surgical treatment of CSM range from 5% to 11.3%.⁷⁻¹² This wide range demonstrates the need for more research into potential complications of surgery. Recent reports have shown a rising prevalence of CSM nationwide, owing to the aging population and popularization of new surgical methods.^{13,14} This calls for more extensive investigation into the factors surrounding surgical management of the disease.

In this study, we analyzed data from a prospectively collected multicenter database consisting of patients with a diagnosis of cervical myelopathy who underwent surgical management. We sought to identify baseline patient characteristics, nonoperative treatment modalities, surgical procedures, complication rates, and risk factors for complications in these patients. In addition, we aimed to evaluate the changes in health-related quality of life (HRQOL) from baseline to 2 years postsurgery, in an effort to guide physicians in surgical treatment decisions and to educate patients about their own health management.

METHODS

Data Source

This study was a retrospective review performed of a prospectively collected multicenter nationwide database, with a total capture of 2221 patients with cervical spine pathology. Of this total patient population, 1818 underwent spinal surgery, and 203 had a diagnosis of cervical myelopathy. Cervical spine diagnoses represented in the database for operative and nonoperative cases included degenerative disorders, pseudoarthrosis, revision, infection, tumor, and kyphosis. Institutional Review Board approval was obtained by the Ethics Review Board at each participating site.

Inclusion and Exclusion Criteria

Inclusion criteria for this study were age 18 to 89 years at the time of surgery, presenting with CSM requiring level 1 to 2 surgical intervention, and grade ≤ 1 spondylolisthesis in Meyerding's

classification scheme. Exclusion criteria included grade ≥ 2 spondylolisthesis at the involved level, imprisonment, mental incompetence, pregnancy, inability to complete follow-up/data collection schedule, and institutionalization in a nonvoluntary and/or dependent residence.

For each patient, collected data included baseline demographics, comorbidities, baseline clinical information, nonoperative treatment modalities, surgical procedures (e.g., decompression, discectomy, fusion, anterior/posterior, instrumentation, bone grafts), and complication rates. Complications included cervical cord injury, cerebrospinal fluid (CSF) leak, excessive bleeding (≥ 4 L), ineffective fixation, infection, intraoperative monitoring change, nerve root injury, postoperative radiculopathy, soft tissue injury, vascular injury, and "other," a category used in the database for all additional complications experienced. HRQOL outcomes were assessed with the Short Form 36 (SF-36) Physical Component Score (PCS), SF-36 Mental Component Score (MCS), and Neck Disability Index (NDI) at baseline and 2 years postoperatively.

Statistical Analysis

Statistical analyses included multivariate logistic regression, controlling for age, sex, and body mass index (BMI), to investigate total complication rates. Changes in HRQOL from baseline to 2 years postsurgery were analyzed using the paired-sample *t* test. Statistical significance was defined as $P < 0.05$.

RESULTS

Patient Demographics

The study population comprised 203 patients (43% females) who underwent surgical management for CSM. The average patient age was 57.7 years, and the average BMI was 29.6 kg/m².

Presenting Clinical Characteristics

The most prominent presenting baseline comorbidities in the study population were diabetes (8%) and metabolic disorders (4%). In addition, 10% of the patients reported having undergone a previous cervical spine surgery, and 8% of the reported surgeries in this database and currently analyzed represented revisions.

At baseline, 51% of patients presented with neck pain, 45% with arm pain, 22% with motor deficit, 25% with sensory deficit, 17% with reflex deficit, and 28% with fine motor movement difficulties. On average, patients experienced symptoms for 22.27 months before seeking treatment, whether conservative or surgical. In the patients with a history of previous cervical spine surgery, the most common level operated on was C5-C6 (4%).

Previous Nonoperative Treatments

Before surgical intervention, the patients received various forms of nonoperative treatment (Table 1). The most common conservative treatments implemented were nonsteroidal anti-inflammatory drugs (NSAIDs; 34%), analgesics (32%), and physical therapy (26%), with forms of pain management not including epidurals the least used modalities (5%).

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