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Clinical Study

# Accurately measuring the quality and effectiveness of cervical spine surgery in registry efforts: determining the most valid and responsive instruments

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**Abstract**

**BACKGROUND CONTEXT:** There is a growing demand to measure the real-world effectiveness and value of care across all specialties and disease states. Prospective registries have emerged as a feasible way to capture real-world care across large patient populations. However, the proven validity of more robust and cumbersome patient-reported outcome instruments (PROi) must be balanced with what is feasible to apply in large-scale registry efforts. Hence, commercial registry efforts that measure quality and effectiveness of care in an attempt to guide quality improvement, pay for performance, or value-based purchasing should incorporate measures that most accurately represent patient-centered improvement.

**PURPOSE:** We set out to establish the relative validity and responsiveness of common PROi in accurately determining effectiveness of cervical surgery for neck and arm pain in registry efforts.

**STUDY DESIGN:** Prospective cohort study.

**PATIENT SAMPLE:** Eighty-eight patients undergoing primary anterior cervical discectomy and fusion (ACDF) for neck and arm pain.

**OUTCOME MEASURES:** Patient-reported outcome measures for pain (numeric rating scale for neck pain [NRS-NP] and arm pain [NRS-AP]), disability (neck disability index [NDI]), general health (short-form 12-item survey physical component summary [SF-12 PCS] and mental component summary [SF-12 MCS]), and quality of life (Euro-Qol-5D [EQ-5D]) were assessed.

**METHODS:** Eighty-eight patients undergoing primary ACDF for neck and arm pain were entered into a Web-based prospective registry. Baseline and 12-month patient-reported outcomes (NRS-NP, NRS-AP, NDI, SF-12 PCS, SF-12 MCS, and EQ-5D) were assessed. Patients were also asked whether they experienced a level of improvement after ACDF that met their expectation (meaningful improvement). To assess the validity of NRS-NP, NRS-AP, and NDI (measures of pain and disability) to discriminate between meaningful and nonmeaningful improvement and the validity of SF-12 PCS, SF-12 MCS, and EQ-5D (measures of general health and quality of life) to discriminate between meaningful and nonmeaningful improvement, receiver-operating characteristic curves were generated for each outcome instrument. The greater the area under the curve (AUC), the more valid the discriminator. The difference between standardized response means (SRMs) in patients reporting meaningful improvement versus not was calculated to determine the relative responsiveness of each outcome instrument to changes in pain and QOL after surgery.

**RESULTS:** For pain and disability, both NDI (AUC=0.75) and NRS-AP (AUC=0.74) were valid discriminators of meaningful improvement. Numeric rating scale for neck pain (AUC=0.69) was a poor discriminator. Neck disability index was also most responsive to postoperative improvement

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(SRM difference 0.78), followed by NRS-AP (SRM difference 0.59) and NRS-NP (SRM difference 0.46). For general health and quality of life, SF-12 PCS (AUC=0.79) was the only valid discriminator of meaningful improvement. Euro-Qol-5D (AUC=0.68) and SF-12 MCS (AUC=0.44) were poor discriminators. Short-form 12 physical component summary (SRM difference 1.08) was also most responsive compared with EQ-5D (SRM difference 0.89) and SF-12 MCS (SRM difference 0.01).

**CONCLUSIONS:** For pain and disability, NDI is the most valid and responsive measure of improvement after surgery for neck and arm pain. Numeric rating scale for neck pain and NRS-AP are poor substitutes for NDI when measuring effectiveness of care in registry efforts. For health-related quality of life, only SF-12 PCS could accurately discriminate meaningful improvement after cervical surgery and was found to be most valid and responsive. Large-scale registry efforts aimed at measuring effectiveness of cervical spine surgery should use NDI and SF-12 to accurately assess improvements in pain, disability, and quality of life. 

*Keywords:* Cervical surgery; Validity; Responsiveness; Patient-reported outcome instruments

## Introduction

Degenerative changes in the cervical spine are commonly diagnosed in a large contingent of the elderly population, with marked geographic variation throughout the United States [1,2]. The annual incidence of cervical radiculopathy has been reported to be 83/100,000, and it increases significantly in the fifth decade of life [3]. From 1990 to 2000, the total number of cervical spine procedures performed annually more than doubled, from 53,810 to 112,400 [2]. More recently, cervical spine fusions for degenerative cervical disease increased 206% among Medicare beneficiaries from 1992 to 2005 [4]. In an environment of increasingly scarce health-care resources, efforts must be made to valuate costly interventions, maximize patient quality of life, and assess effectiveness of cervical spine surgery.

To control cost and target, the value of spine surgery, effectiveness of surgery as it pertains to patient outcomes, and quality-of-life measures must be closely defined. Prospective registries have emerged as a feasible way to capture real-world care across large patient populations [5–8]. Registries have the potential to create reliable and expeditious access to outcome data such as patient satisfaction, quality of life, and cost-effectiveness [9]. National [9–13] and international [14,15] spine registries have been created to assess both outcomes and economic impacts of novel therapies. Although not an alternative to a randomized controlled trial, prospectively organized registries are more feasible and closer to day-by-day clinical situations [8]. Furthermore, prospective registries measure quality and effectiveness on patient populations in real-world health-care delivery settings that are not biased by artificial trial criteria.

Within prospective registry data collection systems, patient-reported outcome instruments (PROi) are increasingly being employed to assess effectiveness of care. The proven validity of more robust and cumbersome PROi must be balanced with what is feasible to apply in large-scale registry efforts. Therefore, the use of outcome instruments that are most simple and feasible while not compromising accuracy and validity is preferred. We set out to determine the relative validity and responsiveness of common PROi in accurately determining effectiveness of cervical surgery for neck and arm pain in a single-center prospective registry.

## Methods

### *Patient selection*

Eighty-eight patients undergoing anterior cervical discectomy and fusion (ACDF) for neck and radicular arm pain at a single medical center were enrolled into a Web-based prospective longitudinal registry and followed for 12 months. The primary inclusion criteria were neck and radicular arm pain, radiological evidence of cervical nerve root impingement from herniated disc or osteophyte, and age of 18 to 70 years. Patients were excluded if they had only myelopathic symptoms, history of previous cervical spine surgery, or were unwilling or unable to participate in follow-up outcome interviews.

### *Clinical outcome measures*

Patient demographics, clinical presentation, indications for surgery, radiological studies, and operative variables were assessed for each case. Baseline and 1-year postoperative pain, disability, and quality of life were assessed by phone interview by an independent investigator not involved with clinical care. Patient-reported outcome instruments included numeric rating scale for neck pain (NRS-NP) and arm pain (NRS-AP) [16,17], neck disability index (NDI) [18,19], Euro-Qol-5D (EQ-5D) [20], and short-form 12-item survey physical component summary (SF-12 PCS) and mental component summary (SF-12 MCS) [21]. Patients were also asked the North American Spine Society satisfaction questionnaire. This four-item questionnaire allows for the determination of a patient's satisfaction with their surgery. The choices provided include ‘‘the treatment met my expectations; I did not