Cost-Effectiveness of Different Surgeries for CSM

July 10, 2023

Primary Investigator

Zoher Ghogawala, MD – Department of Neurosurgery, Lahey Hospital and Medical Center, Burlington, Massachusetts

Co-Investigators

Robert Whitmore, MD – Department of Neurosurgery, Lahey Hospital and Medical Center, Burlington, Massachusetts

Art Eleanore, MPH – Department of Neurosurgery, Lahey Hospital and Medical Center, Burlington, Massachusetts

Mohamad Bydon, MD – Department of Neurological Surgery, Mayo Clinic Rochester, Minnesota

Giorgos D. Michalopoulos, MD – Department of Neurological Surgery, Mayo Clinic Rochester, Minnesota

Konstantinos Katsos, MBBS – Department of Neurological Surgery, Mayo Clinic Rochester, Minnesota

Bijan J. Borah, PhD – Department of Health Services Research, Mayo Clinic, Rochester Minnesota

James P. Moriarty, MS - Department of Health Services Research, Mayo Clinic, Rochester Minnesota

Ruchita Dholakia, MS, MBA - Department of Health Services Research, Mayo Clinic, Rochester Minnesota

DESCRIPTION OF STUDY

A. Purpose

1. To determine if ventral surgery is more cost-effective compared to dorsal (fusion or laminoplasty) surgery.

2. To determine the relative cost-effectiveness between anterior cervical discectomy and fusion (ACDF), posterior cervical fusion (PCF), and cervical laminoplasty.

A. Background

This study aims to compare the cost of care of anterior versus posterior surgical approaches for the management of Cervical Spondolytic Myelopathy (CSM). Due to the significant gap in today's literature, we aim to conduct a post hoc analysis of data from the randomized trial "Cervical Spondylotic Myelopathy Surgical Trial" (www.ClinicalTrials.gov; identifier: NCT02076113; LCID# 2013-085) to determine the cost effectiveness of various procedures as related to the management of CSM. Specifically, we aim to compare 1) the cost effectiveness of ventral surgery versus dorsal (fusion or laminoplasty) surgery; and 2) to determine the relative cost-effectiveness between anterior cervical discectomy with fusion (ACDF), posterior cervical fusion (PCF), and cervical laminoplasty.

The aforementioned study that the proposed analysis is based on was conducted in collaboration between multiple academic institutions in North America. The resulting clinical and patient-reported outcomes from the CSM-S RCT suggested similar effectiveness in both anterior and posterior surgical approaches. Of note, the study showed that cervical laminoplasty, a relatively low instrumentation-related cost procedure, was effective in managing CSM. The findings of the proposed analysis will offer further consideration on patient financial burdens as related to CSM management to better improve related clinical decision-making for both patients and their providers.

B. Specific Location of Study

This is a post hoc analysis of data from a multicenter randomized clinical trial entitled "Cervical Spondylotic Myelopathy Surgical Trial" (www.ClinicalTrials.gov; identifier: NCT02076113), which took place in eleven institutions across North America. Data will be analyzed by Mayo Clinic statisticians specializing in cost analyses.

C. Duration of Project

Statistical analysis and manuscript writing is expected to be completed within a 12-month period.

D. Research Plan[1]

1. Post hoc analysis will be conducted on the following data that were collected during the trial (LCID#2013-085) The study flow schema is outlined in Figure 1[1]

    1. Our post hoc study will utilize the health resource information, well-known quantitative scales to measure functional outcomes (SF-36, Oswestry Neck, mJOA, and EuroQol-5D taken at pre-op, 3 months, 6 months, 1 year, 2 years, 3 years, 4 years, and 5 years), costs related and incidence of re-operations and complications at 30 days and 1 year after surgery to compare the costs related to each procedure: comparing the cost effectiveness of ventral surgery versus dorsal (fusion or laminoplasty) surgery and comparing the relative cost-effectiveness between anterior cervical discectomy with fusion (ACDF), posterior cervical fusion (PCF), and cervical laminoplasty. Quality of life measures (I.e. SF-36 as one overall score per timepoint) will be utilized to determine patient satisfaction with the procedure of choice and subsequently create a comprehensive snapshot for clinical decision making. Utilization of quality-of-life scales will help relate success of the procedure as deemed by the patient in relation to the related costs.
    2. Health resource utilization information was collected using patient diaries along with copies of all medical bills and receipts at 1 month, 3 months, 6 months, and 12 months post-operatively for all patients. Participants were asked to monitor days missed from work and days unable to perform usual activities, in addition to days missed from work for medical treatments or evaluations.

2. The overall cost will be estimated for each patient from a societal perspective and will include the following components:

    I. *Index Hospitalization Cost – performed on all patients*:

    - Hospital Costs: Total hospital charges (Total HC) will be used to estimate costs using hospital-specific and year-specific Medicare cost-to-charge ratios (CCR). The costs will be adjusted for inflation to the latest year of the study (2018) without a 3% discount. – *Assumptions*: cost-to-charge ratios for all hospitals and all relevant years will be provided. Data will be complete for all patients from all sites.
    - Hospital charges for specific revenue centers (i.e., radiology, pharmacy, physiotherapy, and occupational therapy) will be converted to costs using hospital-specific and year-specific CCRs. This will allow the identification of the major drivers of the difference in cost between the surgical strategies. A crosswalk between the revenue center and the cost center will have to be created. – *Assumptions*: Total hospital charges will be segmented out into the relevant revenue centers. All patients will have charges segmented in this manner. No major differences in how total hospital charges will be segmented by each site will exist.
    - For professional services (identified with either HCPCS code or CPT-4 codes) provided to patients during the index hospitalization, costs will be calculated using national reimbursement amounts from the appropriate Medicare fee schedules for the respective year. – *Assumptions*: Detailed line-item services of all HCPCS codes and CPT-4 codes (including any necessary billing modifiers) will be provided for all professional services. Data will be complete for all patients from all sites.

II. *One-year All-Cause Cost – performed on patients from sites capturing 1 year utilization*:
- One-year all-cause costs will be calculated for hospital and professional services in the manner described above. – *Assumptions*: The same underlying assumptions described above.

III. *Time to Return to Work – performed on all patients reporting employment*:
- We will assume that the work halted for patients on the procedure date).
- For patients to whom this outcome applies, we will compare different cohorts using return to work as a time-to-event outcome.
    - Lost wages will be estimated using the median weekly earnings in the US as reported by the Bureau of Labor Statistics.
        - Patients providing no employment information will be assumed to have zero lost wages.
        - Job-specific wages will not be estimated.

IV. Index hospitalization costs and one-year all-cause costs will be combined with costs due to loss of productivity (indirect costs) to estimate total costs for each patient from a societal perspective.

E. Data and Safety Monitoring Plan

1. Deidentified data from the published primary study will be utilized for the post hoc analysis.

F. Timepoints of Data Collection

1. Data variables included in the analysis:

I. Procedure costs and related costs; related CPT codes
II. SF-36 (pre-op, 3 months, 6 months, and 1 years)
III. EQ5D (pre-op, 3 months, 6 months, and 1 years)
IV. Neck pain disability index (pre-op, 3 months, 6 months, and 1 years)
V. Baseline Demographics
VI. MJOA (pre-op, 3 months, 6 months, and 1 years)
VII. Return to Work Status 1 Month, 3 Months, 6 Months, 1 Year
VIII. Health Resource Utilization Diary (1 month, 3 months, 6 months, 1 year)
IX. Inpatient Hospital and Rehabilitation Utilization Data
X. Hospital-specific and year-specific Medicare cost-to-charge ratios

2. Study Endpoints

I. The primary endpoint will be the cost-effectiveness comparison between ventral and dorsal surgery in CSM.

II. The secondary endpoint will be the cost-effectiveness comparison between dorsal cervical fusion and laminoplasty

3. Data Timepoints
   I. Preop: SF36, EQ5D, neck pain disability index
   II. Procedure: related hospital costs, hospital-specific and year-specific Medicare cost-to-charge ratio
   III. 1 month: Complications and related costs (if applicable), health resource utilization diary, Return to Work Status
   IV. 3 months: SF36, EQ5D, neck pain disability index, health resource utilization diary, Return to Work Status
   V. 6 months: SF36, EQ5D, neck pain disability index, health resource utilization diary, Return to Work Status
   VI. 1 year: SF36, EQ5D, neck pain disability index, health resource utilization diary, Return to Work Status

Figure 1: Cervical Spondylotic Myelopathy Trial Study Flow Schema from CSM Trial[1]

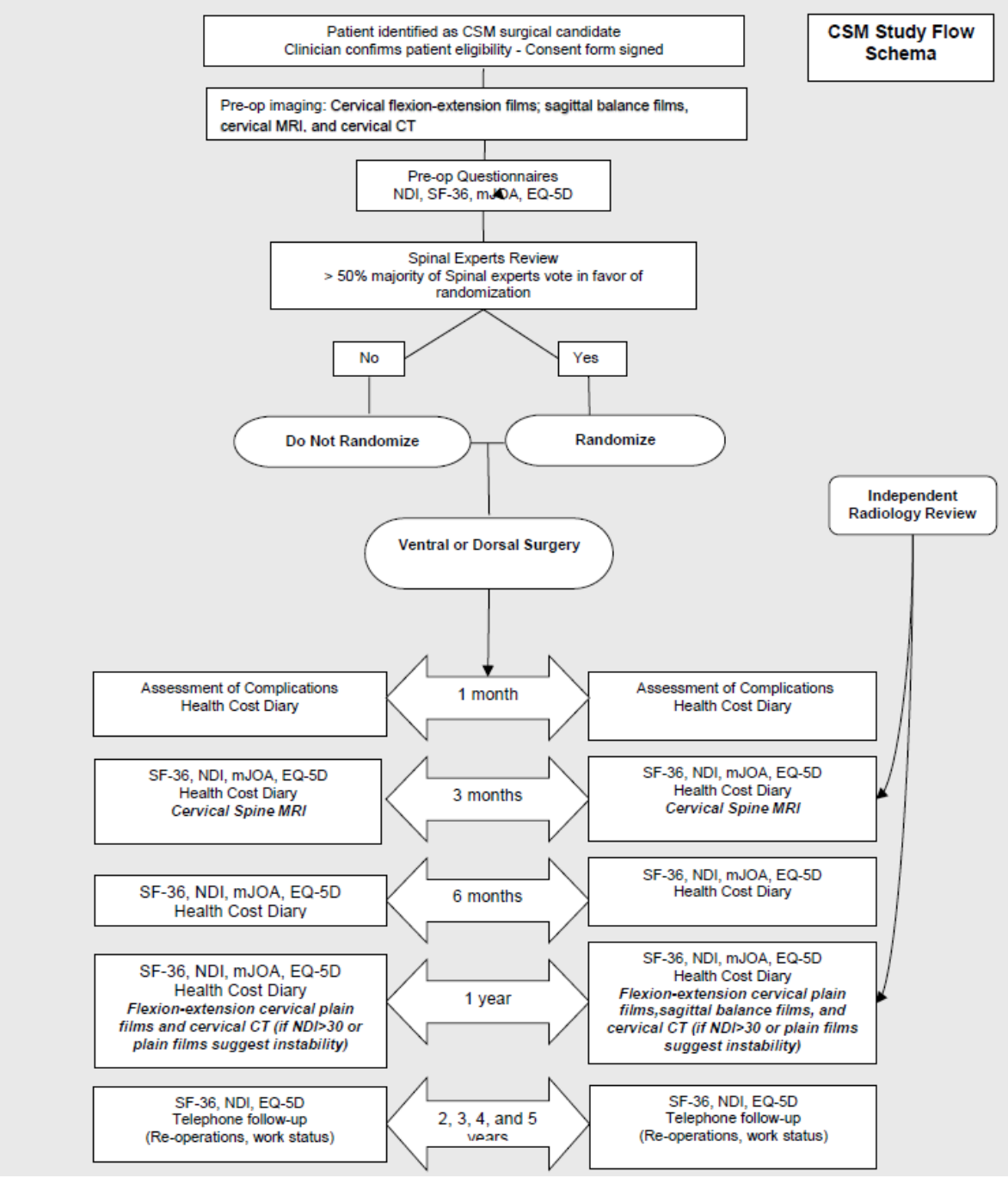
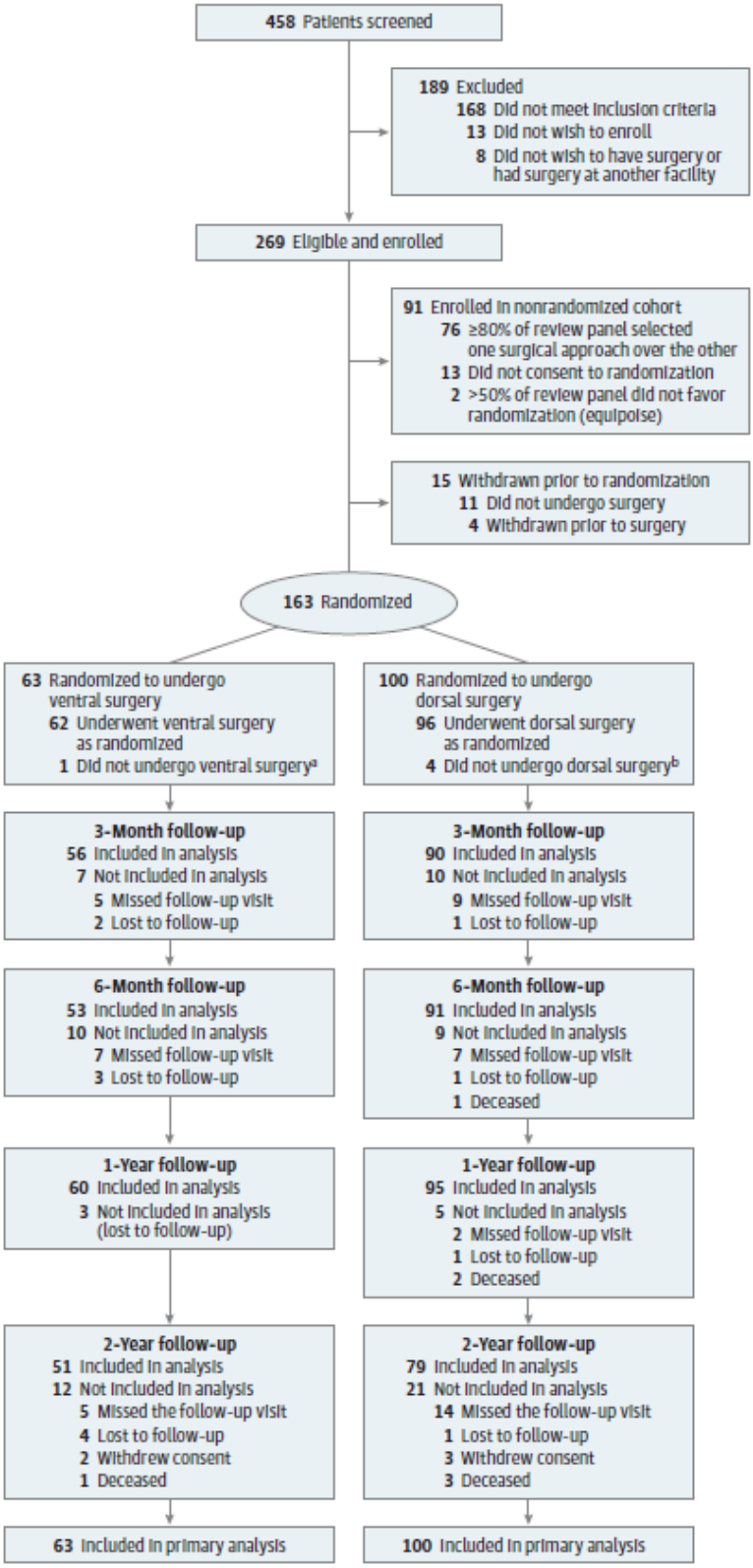


Figure 2: Flow of Participants in the Cervical Spondylotic Myelopathy Surgical Trial[1]



References

1. Ghogawala Z, Benzel EC, Heary RF, et al. Cervical spondylotic myelopathy surgical trial: randomized, controlled trial design and rationale. *Neurosurgery*. Oct 2014;75(4):334-46. doi:10.1227/NEU.0000000000000479