ELSEVIER

CrossMark

The Spine Journal 17 (2017) 922–932

THE SPINE JOURNAL

Clinical Study

Is the use of minimally invasive fusion technologies associated with improved outcomes after elective interbody lumbar fusion? Analysis of a nationwide prospective patient-reported outcomes registry

Matthew J. McGirt, MD[a,*], Scott L. Parker, MD[b], Praveen Mummaneni, MD[c], John Knightly, MD[d], Deborah Pfortmiller, PhD[a], Kevin Foley, MD[e], Anthony L. Asher, MD[a]

[a]*Carolina Neurosurgery and Spine Associates, 225 Baldwin Ave, Charlotte, NC 28204, USA*

[b]*Department of Neurosurgery, Vanderbilt University Medical Center, 1161 21st Ave So, Nashville, TN 37232, USA*

[c]*Department of Neurosurgery, University of California San Francisco Medical Center, 505 Parnassus Ave, San Francisco, CA 94143, USA*

[d]*Atlantic Neurosurgical Specialists, 310 Madison Ave, Suite 300, Morristown, NJ 07960, USA*

[e]*Semmes-Murphey Neurologic & Spine Institute & Department of Neurosurgery, University of Tennessee Health Science Center, 6325 Humphreys Blvd, Memphis, TN 38120, USA*

Received 27 January 2016; revised 23 January 2017; accepted 6 February 2017

Abstract

BACKGROUND CONTEXT: Over the last decade, clinical investigators and biomedical industry groups have used significant resources to develop advanced technologies that enable less invasive spine fusions. These minimally invasive surgery (MIS) technologies often require increased expenditures by hospitals and payers. Although several small single center studies have suggested MIS technologies decrease surgical morbidity and reduce hospital stay, evidence documenting benefit from a patient perspective remains limited. Furthermore, MIS outcomes have yet to be evaluated from the perspective of multiple practice types representing the broad spectrum of US spine surgery.

PURPOSE: This study aimed to examine a population of patients who underwent one- or two-level interbody lumbar fusion diagnosed with lumbar stenosis or Grade 1 spondylolisthesis in an observational, prospective national registry for the purposes of determining how MIS and traditional open technologies affect postsurgical and patient-reported outcomes (PROs).

STUDY DESIGN/SETTING: This study used observational analysis of prospectively collected data.

PATIENT SAMPLE: The sample consisted of cases from the National Neurosurgery Quality and Outcomes Database (N^2QOD).

OUTCOME MEASURES: Numeric rating scale for back and leg pain, Oswestry Disability Index, EuroQol-5D, return to work, and perioperative morbidity were the outcome measures.

METHODS: The N^2QOD is a prospective PROs registry enrolling patients undergoing elective spine surgery from 60 hospitals in 27 US states via representative sampling. We analyzed the N^2QOD aggregate dataset (2010–2014) to identify one- and two-level lumbar interbody fusion procedures performed for lumbar stenosis or Grade 1 spondylolisthesis with 12 months' follow-up where surgical instrumentation and implant types were clearly identified. Perioperative and 1-year outcomes were compared between cases performed with MIS enabling technologies versus traditional open technologies before and after propensity matching.

FDA device/drug status: Not applicable.

Author disclosures: ***MJM:*** Consulting: Depuy, Stryker (amount not disclosed), outside the submitted work. ***SLP:*** Nothing to disclose. ***PM:*** Royalties: Depuy, QMP, Thieme (amount not disclosed); Stock Ownership: Spinicity (amount not disclosed); Speaking and/or Teaching Arrangements: Depuy, Globus (amount not disclosed); Grants: NREF, AANS/CNS Spine section (amount not disclosed), outside the submitted work. In addition, PM renders services for free as Director at Large at Congress of Neurological Surgeons; Chair Elect at AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves; and Etext Cmte Chair at Scoliosis Research Society. ***JK:*** Nothing to disclose. JK serves as Board of Directors at NeuroPoint Alliance. ***DP:*** Nothing to disclose. ***KF:*** Royalties: Medtronic (amount not disclosed); Stock Ownership: BioD, DiscGenics, and TrueVision (amount not disclosed); Consulting: ArthroCare, Medtronic, NuVasive (amount not disclosed), outside the submitted work. ***ALA:*** Stock Ownership: Hyperbranch Corporation (Nonfinancial); Consulting: Medtronic (amount not disclosed), outside the submitted work. In addition, ALA is Director at National Neurosurgery Quality and Outcomes Database, and Director at Large at the American Association of Neurological Surgeons.

The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

Funding: None.

* Corresponding author. Carolina Neurosurgery and Spine Associates, 225 Baldwin Ave, Charlotte, NC 28204. Tel.: +1 704 376 1605.

E-mail address: matt.mcgirt@cnsa.com (M.J. McGirt)

http://dx.doi.org/10.1016/j.spinee.2017.02.003

RESULTS: There were 467 (24%) patients who underwent elective interbody lumbar fusion using MIS enabling technologies whereas 1,480 (76%) underwent the procedure using traditional open technologies. The MIS patients were slightly healthier (American Society of Anesthesiologists grade), had private insurance more frequently, and underwent two-level fusion less frequently. Unmatched, the MIS cohort was associated with reduced blood loss, a 0.7-day reduction in mean length of hospital stay, and 5% reduced need for post-discharge inpatient rehabilitation, but equivalent 90-day safety measures. After propensity matching, the MIS cohort remained associated with reduced blood loss and a shorter length of stay for one-level fusion ($p<.05$) but had equivalent length of stay for two-level fusion. Outcomes in all other 90-day safety measures were similar. In both unadjusted and propensity-matched comparison, MIS versus open technologies were associated with equivalent return to work, patient-reported pain, physical disability, and quality of life at 3 and 12 months' follow-up.
CONCLUSIONS: In a representative sampling registry of elective interbody lumbar spine fusion procedures spanning 27 US states, nearly a quarter of procedures performed from 2010 to 2014 used minimally invasive enabling technologies. Regardless of approach, interbody lumbar fusion was associated with significant and sustained improvements in all measured health domains. When used in everyday care by a wide spectrum of spine surgeons in non-research settings, the use of MIS technologies was associated with reduced intraoperative blood loss but only a half-day reduction in mean length of hospital stay for one-level fusions. Minimally invasive surgery was not associated with any improved perioperative safety measures or 12-month outcomes. Although MIS enabling technologies may increase some in-hospital care efficiencies, MIS clinical outcomes are similar to open surgery for patients undergoing one- and two-level interbody lumbar fusions.

Keywords: Lumbar fusion; Minimally invasive; National quality outcomes registry; Outcomes; Perioperative measures; Return to work

Introduction

Growing evidence suggests that the greatest variability in surgical costs lies within the post-acute care episode, specifically in the immediate days to weeks following hospital discharge after surgery [1–6]. Length of hospital stay, surgical complications, hospital readmission, acute need for reoperation (infection, hematoma, etc.), and need for inpatient rehab or skilled nursing care, are all significant drivers of costs in the post-acute care episode. In the context of spinal surgery, it has also become apparent that a significant portion of total expenditures relates to indirect costs associated with missed work following surgery [7–9]. Therefore, any technology or surgical approach that can reduce the prevalence of adverse perioperative events or quicken return to work has the potential to improve the quality and reduce the cost of spinal surgery.

Over the last decade, clinical investigators and biomedical industry groups have used significant resources to develop advanced technologies that enable less invasive spine fusions. Although it is intuitively appealing to assume that less invasive surgical techniques will result in reduced morbidity and increased efficiencies in care, this deduction has not been generally validated. What is suggested is that these minimally invasive surgery (MIS) technologies often require increased expenditures by hospitals and payers [10].

The true MIS value question is whether the greater upfront operating room costs of MIS technologies are offset by downstream cost reduction benefits. Although several small, mostly single center studies have suggested MIS technologies decrease surgical morbidity and reduce hospital stays, little evidence exists to support benefit from a patient perspective [11–15]. A national emphasis on the development of a patient-centered health-care system has increased the demand for patient-reported outcomes (PROs). There is a documented discrepancy between patient and clinical estimates of symptoms and functional impairment [16,17]. Additionally, PROs may be more reflective of underlying health status than physician reporting. For these reasons, PROs are increasingly recognized as valid and important outcomes for facilitating quality improvement, and demonstrating the value of care.

In addition to the lack of data related to PROs in MIS versus open approaches, MIS outcomes have yet to be evaluated from the perspective of multiple practice types representing the broad spectrum of US spine surgery. For these reasons, we set out to examine a population of patients who underwent one- or two-level interbody lumbar fusion diagnosed with lumbar stenosis or Grade 1 spondylolisthesis in an observational, prospective national registry for the purposes of determining how MIS and traditional open technologies affect postsurgical and patient-reported outcomes.

Methods

For purposes of this study, we accessed the aggregate National Neurosurgery Quality and Outcomes Database (N^2QOD) dataset for cases performed in 2010–2014 to analyze case entries that had passed their 12-month follow-up period. Inclusion criteria for this analysis included patients having a one- or two-level elective interbody lumbar fusion for a