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PROCEDURAL RATES, ECONOMIC COSTS, AND GEOGRAPHIC VARIATION OF PRIMARY AND REVISION LUMBAR TOTAL DISC REPLACEMENT

by

Anthony J. Wheeler

A dissertation submitted in partial fulfillment
of the requirements for the degree

of

DOCTOR OF PHILOSOPHY

in

Psychology

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UTAH STATE UNIVERSITY
Logan, Utah

2013

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ABSTRACT

Procedural Rates, Economic Costs, and Geographic Variation of Primary and Revision Lumbar Total Disc Replacement

by

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Utah State University, 2013

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Department: Psychology

Lumbar degenerative disc disease is a remarkably common condition among patients presenting with chronic low back pain and physical disability. When a surgical treatment option is warranted, patients now have the option of undergoing lumbar total disc replacement (TDR), a relatively new procedure that is designed to replace lumbar fusion, the traditional surgical intervention for degenerative disc disease. The lumbar TDR procedure has demonstrated clinical efficacy equivalent to that of lumbar fusion, although concern remains about the longevity, safety, and costs related to the procedure. These issues were addressed in three separate observational studies using administrative claims data. The first study estimated the revision burden and economic revision burden of lumbar TDR. The second study examined the lumbar TDR *hybrid* procedure, where both a lumbar TDR and lumbar fusion are performed simultaneously. No observational data have been reported on the frequency, cost, and diagnostic indications related to the

TDR hybrid procedure. The third study mapped the geographic variation of procedural rates of lumbar TDR. Previous research has found substantial geographic variation in lumbar spine surgery rates and a similar analysis of lumbar TDR variation has yet to be reported.

The present series of studies found the revision burden and economic revision burden of lumbar TDR to be similar to data reported for this procedure from the mid-2000s, though the overall occurrence of the procedure appears to have declined. The economic revision burden made this a lower-cost procedure than lumbar fusion, with a tradeoff in terms of revision burden being higher for lumbar TDR. The lumbar TDR hybrid procedure was found to make up approximately 16% of the total number of TDR procedures, involving much higher costs than a single-level TDR procedure. Finally, geographic variation of the procedural rate of lumbar TDR varied dramatically across the U.S., surpassing the variation observed in lumbar fusion surgery. Limitations of the observational data used in these studies are described. Recommendations for future observational research are offered as well. Finally, implications for these studies on practice guidelines and reimbursement policies are provided.

(76 pages)

PUBLIC ABSTRACT

Procedural Rates, Economic Costs, and Geographic Variation of Primary and Revision Lumbar Total Disc Replacement

by

Anthony J. Wheeler, Doctor of Philosophy

Utah State University, 2013

Lumbar total disc replacement (TDR) surgery is a new procedure that treats degenerative disc disease, a remarkably common, disabling, and costly condition. Three distinct studies were conducted to address the longevity, costs, and geographic variation of the lumbar TDR procedure.

These three studies found lumbar TDR to have a revision burden and economic revision burden that has remained consistent since this procedure's introduction in the mid-2000s. The economic revision burden made this a lower-cost procedure than lumbar fusion, with a tradeoff in terms of revision burden being higher for lumbar TDR. The overall rate at which this procedure is performed has declined significantly, however. An uncommon and unstudied variant of TDR, the lumbar TDR *hybrid*, was found to make up about 16% of all lumbar TDR procedures performed. Lastly, substantial geographic variation was found in the procedural rates of lumbar TDR across the U.S.

The results of these studies are potentially useful to surgeons, policy makers, and patients. This project also speaks to the viability of observational data in addressing questions of medical device lifespan, costs, and geographic variation of surgical procedures.

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Anthony J. Wheeler

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CHAPTER I

LUMBAR TOTAL DISC REPLACEMENT SURGERY

Low back pain is a remarkably common problem in the U.S. (Deyo, Mirza, & Martin, 2006). In particular, the diagnosis of degenerative disc disease is increasing in prevalence, and in recent years lumbar fusion and lumbar total disc replacement (TDR) have become increasingly common surgical interventions for this condition (Deyo, Gray, Kreuter, Mirza, & Martin, 2005). Despite its popularity, lumbar fusion has been criticized in the literature for its inconsistent patient outcomes, controversial diagnostic indications, and exponentially increasing costs (Carragee et al., 2009; Deyo, Nachemson, & Mirza, 2004; Wheeler, Gundy, & DeBerard, 2012). Further, lumbar fusion surgery aims to eliminate motion at a vertebral segment, which has been implicated in initiating or hastening the degeneration of adjacent vertebral segments (Ekman, Moller, Shalabi, Yu, & Hedlund, 2009). When a fusion surgery needs to be revised due to adjacent segment disease, pseudoarthrosis, or the failure of an implant, functional improvement for patients is often diminished (Djurasovic, Glassman, Howard, Copay, & Carreon, 2011) and costs escalate with the additional procedure.

To address lumbar fusion surgery's resulting limited vertebral motion and risk for adjacent segment disease, the lumbar TDR procedure was developed. This procedure supplements a lumbar vertebral segment with a permanent, load-bearing disc that allows limited flexion and extension motion. The rationale for the TDR procedure is that it should ensure more natural movement of impacted spinal segments, less degeneration of adjacent segments, and less need for subsequent revision procedures versus lumbar fusion

(Frelinghuysen, Huang, Girardi, & Cammisa, 2005). Three separate devices (Charité;DePuy Orthopaedics, Warsaw, IN; ProDisc-L; Synthes Spine, Solothurn, Switzerland; Maverick-L; Medtronic Sofamor Danek, Memphis, TN) received Food and Drug Administration (FDA) approval for use in the U.S. in 2004 and 2006, respectively. Empirical support for lumbar TDR has come from randomized clinical trials conducted under the FDA's Investigational Device Exemption (IDE), which have found it to yield outcomes that are equivalent to lumbar fusion surgery (McAfee et al., 2005; Zigler et al., 2007).

Like lumbar fusion, lumbar TDR has received some criticism in its introductory years in the U.S. Degeneration at the zygapophysial (facet) joint is one of the greatest concerns associated with TDR, as this may create the need for additional surgical procedures (Pearcy, 2010). Lumbar TDR is also not immune to revision, which can involve removing a TDR prosthesis or fusing vertebral bodies together around a TDR construct (A.A. Patel et al., 2008).

A recently published article by Kurtz and colleagues (2010) examined the revision burden, or the proportion and economic cost of revisions of a given procedure in lumbar TDR as well as lumbar fusion. This study used nationally representative data from the Nationwide Inpatient Sample in the first year which lumbar TDRs were performed in the U.S. following FDA approval. The revision rate of 11.2% for TDR was found to be higher than for lumbar fusion, although the economic burden of revision was lower due to the reduced initial procedure cost of lumbar TDR. Many of the procedures included in this article are from FDA Investigational Device Exemption-status clinical

trials (Zigler, Guyer, Blumenthal, & Ohnmeiss, 2010), and may not be reflective of autonomous surgical practice outside the constraints of a clinical trial.

A unique variation of lumbar TDR is the hybrid procedure, where one vertebral level may be supplanted with an artificial disc and an adjacent level is fused, all in the same procedure (Erkan, Rivera, Wu, Mehbod, & Transfeldt, 2009). The hybrid procedure rose out of the debate over whether to use fusion or disc replacement when addressing more than one degenerative disc segment. At least one article suggested that a fusion at the inferior (lower) level may provide stability and the opportunity to preserve motion with disc replacement at the superior (upper) level (Erkan et al., 2009). Some authors have directed great criticism at the procedure (e.g., Bono, 2009), as little evidence supports the use of fusion or disc replacement for multi-level degenerative disc disease. In keeping with critiques of the procedure, only one small clinical study and no observational data have been reported on the hybrid procedure.

Geographic variation has also been expressed as a concern in lumbar spine surgery, particularly within the Centers for Medicare and Medicaid Services (Weinstein et al., 2006). It is thought that geographic variation may simply represent surgeon preferences for particular procedures, and in the absence of clinical practice guidelines or acceptable use criteria, these preferences may be for high-cost and/or less effective procedures (Weinstein et al., 2006). The Dartmouth Atlas of Health Care (2009) has found extremely high rates of lumbar fusion surgery relative to the rest of the U.S. in several hospital markets after adjusting for demographics, suggesting distorted and inconsistent surgical care. A distinct “surgical signature” has been observed in

demographically adjusted rates and costs of lumbar fusion surgery in particular geographic regions, suggesting distorted and inconsistent surgical care within the Medicare system. It is unknown how rates and costs of the lumbar TDR procedure vary by region.

A final impetus for the present studies is that spine surgery costs have escalated rapidly in recent years. A population-based investigation of the costs of lumbar fusion found Medicare spending for this procedure increased six-fold between 1992 and 2003 (Weinstein et al., 2006). Another study of lumbar fusion surgery showed average per-patient medical charges doubling after adjusting for inflation between 1998 and 2007 (Wheeler et al., 2012). This latter figure far exceeds the 66% increase in inflation-adjusted health care spending observed between 1995 and 2005, which by itself is already double the pace of gross domestic product inflation in the U.S. (Kaiser Family Foundation, 2012). In short, cost growth in spine surgery has been disproportionately greater than the rest of medicine in recent years.

In summary, lumbar TDR is a recently introduced procedure that may have clinical promise, though significant criticisms and concerns remain. Although considered the "gold standard," lumbar fusion has also seen great criticism in the literature. The economic burden and revision rates of lumbar TDR and contemporary lumbar fusion are unclear. Further, limited observational research exists that examines lumbar TDR, particularly since the completion of FDA IDE clinical trials. The prevalence of a controversial TDR/fusion hybrid procedure has also not been examined, as have geographic variations in the rates and costs of the TDR procedure.

The present study sought to fill these gaps in the literature through a three-pronged approach: (a) provide up-to-date estimates of the rates and economic costs of lumbar TDR, (b) examine the prevalence and costs of the TDR hybrid procedure, and (c) map the geographic variation of the rates and costs of lumbar TDR. It is hypothesized that revision rates for lumbar TDR will have increased since 2005, while costs would increase in step with the costs of lumbar fusion. It is also hypothesized that a distinct "surgical signature" of demographically adjusted rates and costs of the TDR procedure will emerge similar to that of lumbar fusion.

CHAPTER II

PROCEDURAL RATES AND ECONOMIC COSTS OF LUMBAR TOTAL DISC REPLACEMENT SURGERY

Abstract

TDR surgery is a relatively new procedure that involves implanting a disc prosthesis to treat degenerative disc disease. Researchers have expressed concerns that lumbar TDR may have a high surgical revision rate and this may result in an unacceptable total cost of care. The present study sought to estimate the national revision burden and economic revision burden for lumbar TDR in the U.S. using observational data as a gauge of the total cost of care. Nationally representative administrative claims data were used from the 2009 Nationwide Inpatient Sample to identify primary and revision lumbar TDR cases and estimated hospital costs associated with each procedure. The revision burden and economic revision burden of lumbar TDR for 2009 were estimated to be 12.95% and $24,654, respectively. These numbers represented a higher revision burden compared to lumbar fusion, though the economic revision was comparatively lower. Limitations of using observational claims data are discussed. Recommendations for policy makers are also provided.

Introduction

Low back pain (LBP) has been a highly prevalent and pervasive problem in the U.S. for generations. Nationally representative survey data from public and private

sources has estimated that 26% of the U.S. population reported at least one complete day of experiencing LBP in the past 90 days (Deyo et al., 2006). This same study also estimated that low back pain accounts for about 2% of all physician visits in the U.S., making it the fifth most common primary patient complaint when visiting a physician.

The medical and societal costs of LBP in the U.S. are staggering. A systematic review of the economic costs of LBP indicated annual expenditures for direct medical care (e.g., physician visits, surgery, prescription medications) to be between $50 billion and $100 billion annually in the U.S. (Dagenais, Caro, & Halderman, 2008). When accounting for additional indirect costs (e.g., lost wages and economic productivity), the same study estimated the total economic impact of LBP to be $200 billion annually.

One specific diagnosis with primary symptoms of LBP is degenerative disc disease (DDD). The degeneration process is thought to be a combination of normal aging and genetic predisposition, most commonly beginning between ages 50 and 60, although it may be hastened by a major impact or injury at any point in the life span (Zhang et al., 2008). It has also been suggested that degenerative disc disease is the single most frequent cause of discogenic (localized, nonreferred) lower back pain (Zhang et al., 2008).

When patients do not see relief from DDD through conservative and intermediate interventional treatments, spinal surgery may be the next option. Just as there are myriad nonsurgical treatment options for DDD, there are numerous surgical options, as well. One first-line surgical procedure is a discectomy or decompression. This procedure involves removing herniated or bulging disc tissue that is pressing on nerve roots in the spinal

canal. Removal of this disc material will, in effect, *decompress* the nerve and hopefully relieve pain. While lumbar discectomy is still commonly performed today, it is declining in popularity and becoming superseded by another common surgical intervention, lumbar fusion (Weinstein et al., 2006).

Lumbar fusion surgery takes a discectomy procedure one step further by completely removing all of the disc tissue in an affected segment and fusing the vertebrae together. This procedure was originally developed for the treatment of spinal deformities (e.g., scoliosis), vertebral fractures, and spinal tuberculosis. Research using census-based national health surveys estimate that these original indications now make up less than one-fourth of lumbar fusion procedures, with degenerative indications (i.e., degenerative disc disease) making up the other 75% of fusion cases (Deyo et al., 2006). Another population-based study using publicly available administrative claims data found rates of lumbar fusion surgery have increased by a multiple of approximately 2.5 in the U.S. between 1990 and 2001 (Deyo et al., 2005). Spending for lumbar fusion surgery has increased tremendously, as well, with a five-fold increase observed in a retrospective study of Medicare spending between 1992 and 2003 (Weinstein et al., 2006). The increases in spending and procedural rates have been presumed to be due to advances in technology including intervertebral body cage implants, pedicle screw and rod stabilization systems, osteoinductive products such as bone morphogenetic protein, and most recently the use of minimally invasive approaches that allow the procedure to be performed on an outpatient basis (Deyo et al., 2004; Lipson, 2004).

In light of the technological advances and rising rates of lumbar fusion surgery,

many authors have expressed concern regarding the complications and limitations of the procedure and perhaps its overuse (e.g., Carragee et al., 2009; Deyo et al., 2004). The paramount concern when utilizing lumbar fusion is that of pseudoarthrosis (or nonunion), which can occur when the targeted vertebral segments fails to fuse together after surgery. When non-union occurs, the most common resolution is to perform a revision surgery which attempts to refuse the affected segment. The occurrence of nonunion was recently found to drastically decrease the functional outcomes (measured using the Oswestry Disability Index) and increase costs for patients undergoing a revision surgery to correct non-union (Djurasovic et al., 2011).

It is also thought that lumbar fusion surgery places patients at increased risk for further disc degeneration in neighboring intervertebral spaces, a phenomenon known as adjacent segment disease (Helgeson, Bevevino, & Hillibrand, 2013). In a unique study with a 30-year follow-up period, Kumar, Jacquot, and Hall (2001) found the rate of adjacent segment disease to be 44% in a cohort of patients receiving fusion compared to 25% in a prospectively randomized cohort that received nonsurgical treatment. More evidence for adjacent segment disease comes from a systematic review of 22 lumbar fusion studies that obtained longitudinal follow-up data on adjacent segment disease (Park, Garton, Gala, Hoff, & McGillicuddy, 2004). Symptomatic adjacent segment degeneration ranged from 5% to 18% across the studies, and patients receiving pedicle screw and rod systems exhibited the greatest rate of adjacent segment disease. This finding suggests that complete elimination of motion through implanted hardware may hasten the degeneration process for neighboring segments, as pedicle screw fixation

creates an instantly rigid platform for fusion, while the absence of screws enables some flexibility for the platform to settle while bone grows together.

An additional concern expressed in the literature has been the limited quality of empirical evidence to support using lumbar fusion to treat DDD. The bulk of the literature on lumbar fusion for degenerative conditions is described in a critical review article by Bono and Lee (2004). Eighty-four articles published between 1979 and 2000 on this topic were reviewed and coded for their methodological design and the use of surgical implants, bone grafting technique, and rate of successful arthrodesis. Roughly half of the studies reviewed did not specify a research methodology (e.g., whether the study was prospective or retrospective, randomized or not) and were missing one or more of the aforementioned surgical variables. Using the available data, the authors found no improvement in the rate of successful arthrodesis over the study time interval, despite a corresponding increase in technology which is used to enhance arthrodesis. Specifically, the use of internal fixation devices rose from 23% in the 1980s to 41% in the 1990s, while the rate of successful arthrodesis was nearly unchanged at 88% in the 1980s and 87% in the 1990s.

Lumbar disc arthroplasty, or lumbar TDR, is a procedure where, like lumbar fusion, a degenerative intervertebral disc is first removed. Unlike fusion, however, lumbar TDR replaces the disc space with a load-bearing prosthesis. Inside the prosthesis sits an artificial polyethylene or ceramic disc which allows for a limited range of natural motion at the vertebral segment (Yue, Bertagnoli, & McAfee, 2009). This is different from fusion in that it: (a) retains some of the natural motion at the affected segment, (b)

allows for the affected segment to continue to support body weight in the lumbar spine, and (c) requires physical restructuring of the disc space to place a permanent prosthetic device.

Lumbar TDR was developed to addresses some of the shortcomings of lumbar fusion surgery (Yue et al., 2009). Most notable was the interest in preventing adjacent segment disease, or the degeneration of discs which neighbor the fused segment. It has been hypothesized that adjacent segment disease in lumbar fusion patients is the result of the elimination of motion inherent in fusing intervertebral segments (Gillet, 2003; Hilibrand & Robbins, 2004), and that the risk for adjacent segment disease is enhanced with pedicle screw fixation, a technique commonly used to better the chances for successful arthrodesis (Park et al., 2004). Lumbar TDR attempts to address this complication by retaining up to 10 degrees of motion (25 degrees of extension and up to 60 degrees of flexion motion is normal) at the affected intervertebral segment, as opposed to less than one degree of motion common in a fused segment (Link, 2002). The retention of motion prevents adjacent segments from bearing unnaturally heavy loads in the lumbar spine, a scenario that would theoretically hasten the degeneration of adjacent intervertebral discs (Chow, Luk, Evans, & Leong, 1996).

There are presently three devices which have received U.S. FDA approval to be marketed for lumbar TDR in degenerative disc disease. Each of these devices has been subjected to extensive premarket research under the FDA's Investigational Device Exemption (IDE) process. The first device is the Link SB Charité, manufactured by DePuy Orthopaedics, which received FDA approval for the indication of single-level

degenerative disc disease in 2004 (U.S. Department of Health and Human Services, 2004), after an expansive, multicenter clinical trial comparing it to anterior lumbar interbody fusion (Blumenthal et al., 2005; Guyer et al., 2009).The second lumbar TDR prosthesis to receive FDA approval was the ProDisc-L, manufactured by Synthes Spine. The ProDisc-L is differentiated from the Charité by its partially constrained core, which is fixed to the inferior endplate of the device, while the superior endplate is permitted to move dynamically across the surface of the core. This device received FDA approval for the treatment of single-level degenerative disc disease in 2006 (U.S. Department of Health and Human Services, 2006). A similar multisite clinical trial was conducted comparing the ProDisc-L device against circumferential anterior/posterior (also called 360-degree) lumbar fusion (Zigler et al., 2007).

A third lumbar TDR prosthesis, the Maverick artificial disc, manufactured by Medtronic, is unique in that it has no flexible core, instead consisting of two metal-on-metal endplates. While the Maverick device has been used on an investigational basis for several years, its for-sale distribution to hospitals has been temporarily halted by intellectual property litigation (U.S. Court of Appeals, Federal Circuit, 2010).

To complement the three different lumbar TDR prostheses, one European clinical trial randomized patients to receive posterior lumbar interbody fusion (PLIF) or one of the three fully developed lumbar TDR prostheses: Charité, ProDisc-L, or Maverick (Berg, Tullberg, Branth, Olerud, & Tropp, 2009). Lumbar TDR patients reported a statistically significant advantage in terms of patient satisfaction, pain, and global assessment of functioning at 2 years follow-up. A particularly important finding was that

only negligible differences were observed across all of the outcome measures between the three different lumbar TDR prostheses.

A capstone on the present clinical trial literature comparing lumbar TDR and fusion is provided in a meta-analysis by Yajun, Yue, Xiuxin, and Cui (2010). The authors reviewed nine articles, the data from which were based on five randomized clinical trials covering 837 patients. The authors' primary conclusions were an advantage for lumbar TDR in patient satisfaction after 2 years follow-up compared to lumbar fusion, while physical functioning and pain status were indistinguishable across groups. Rates of complications and reoperations were also considered clinically insignificant between the two interventions. Finally, this meta-analysis deemed the risk of bias in four studies (representing 770 patients) to be "extremely high," citing reasons such as a lack of blinding to outcome assessors, manufacturer-sponsorship of studies, and not providing information related to an overall intent-to-treat analysis.

While lumbar TDR has delivered outcomes which are at least equivalent, and sometimes superior to, lumbar fusion, it has also raised concerns regarding complications and revisions of the procedure. One question of great interest has been whether lumbar TDR does in fact reduce the incidence of adjacent segment disease, a hypothesized disadvantage of lumbar fusion surgery. This was specifically investigated by Harrop and colleagues (2008) in a systematic review of lumbar TDR and lumbar fusion clinical studies which reported adjacent segment degeneration or symptomatic adjacent segment disease. At an average 2.5 years follow-up, adjacent segment degeneration was observed in 34% of lumbar fusion patients and 9% of lumbar TDR patients, the difference being

statistically significant. Symptomatic adjacent segment disease, which is considered to be more clinically meaningful, was observed in 14% of fusion and 1% of lumbar TDR patients, respectively, the difference again being statistically significant.

Another potential long-term complication of lumbar TDR is disease of the zygapophysial joint, also called the facet joint, at the intervertebral level of a disc replacement. The hypothesized facet joint disease was investigated clinically by Siepe and colleagues (2010) in an x-ray and MRI evaluation study with an average 4.5 year follow-up. They observed facet joint degeneration in 20% of their 220 case sample, and this impacted patient-reported pain and disability to a statistically significant degree compared to patients who were not identified as having developed facet joint disease.

A more infrequent but complex set of complications of lumbar TDR are related to the placement of the prosthesis within the disc space. The concepts of migration, where the prosthesis moves or slides laterally in the disc space, and subsidence, where the prosthesis fractures and settles inside a vertebral body, were reported clinically by van Ooij, Oner, and Verbout (2003). In a cohort of 27 consecutive patients receiving lumbar TDR, one case of migration (anterior movement of the prosthesis) and one case of subsidence (settling of the prosthesis in the superior L5 vertebral body) were reported. Since that article, few FDA IDE studies have reported either of these complications, although the very large trial by Blumenthal and colleagues (2005) reported subsidence in 3% of cases and migration in 1% of cases. Occasionally, the aforementioned complications of lumbar TDR require that the procedure be revised. Revision entails a repeat surgical procedure at the original vertebral level of disc replacement to adjust,

replace, or remove the prosthetic implant. The incidence of a revision procedure adds not only to the recovery time and physiological burden for patients, but also adds to the cost burden for health payers.

A.A. Patel and colleagues (2008) conducted a literature review of the surgical strategies and reasons for revision of a lumbar TDR procedure. They reported that revision was commonly the result of poor patient selection or malpositioning of the prosthetic device during surgery. The actual failure of a prosthetic device (a rupture of the core or endplate fracture) was quite rare. The authors also added that complications including revision and device failure are likely underreported, since rates of complications may be higher outside of the highly controlled FDA IDE studies.

A societal-level concern related to lumbar TDR is apprehension from health payers in the U.S. towards reimbursement for the procedure. One industry report from 2008 that summarized the reimbursement environment at that time described significant barriers towards reimbursement, adding that reimbursement outside of FDA IDE trials often required substantial advocacy from surgeons on a patient-by-patient basis (Life Science Intelligence, 2009). Another account of interaction with private health payers came from a paper presented at the North American Spine Society Annual Meeting that compared costs for lumbar TDR versus fusion in patients for whom the TDR procedure was denied for reimbursement (Blumenthal, Guyer, Hume, Ohnmeiss, & Zigler, 2010). The presenters described insurance denial as frequent for lumbar TDR, although they reported hospital charges for lumbar TDR as being approximately one third less than for fusion. It is worth noting that these data came from just one hospital, and that there is

great variation in the reimbursement amounts negotiated for a given procedure at different hospitals.

While payers are reluctant to reimburse the lumbar TDR procedure, the current but limited literature suggests its costs are lower. V.V. Patel, Estes, Lindley, and Burger (2008) conducted a retrospective cost identification analysis of 10 patients receiving lumbar TDR and 30 receiving three different modalities of lumbar fusion. Lumbar TDR was the least expensive in terms of hospital charges at an average of approximately $28,000 per patient, with mean fusion charges ranging from $32,000-$44,000. Curiously, this study only included supply charges from the hospital where the procedures were performed, with professional fees and operating room lease time being estimated based upon the operating times described in the FDA IDE study on the ProDisc-L device. This method is not preferred because it does not examine costs from the payer perspective (which are the actual dollar amounts disbursed to hospitals and providers).

An additional article reporting costs of lumbar TDR compared to lumbar fusion used nationally representative claims data from 2005 and 2006 (Kurtz et al., 2010). Average hospital charges for lumbar TDR were roughly $61,000, while anterior and posterior lumbar fusion averaged $100,000 and $80,000 per patient, respectively. This article also calculated the costs of revision TDR and fusion procedures, which averaged $81,000 for lumbar TDR and $85,000-$110,000 for lumbar fusion. These data represent a variety of health payers, whereas the article by V.V. Patel and colleagues (2008) utilized data from just one private payer, and the investigation by Guyer and colleagues (2009) used data from a proprietary database with no public documentation.

Revision Burden and Economic Revision Burden

Because the revision of lumbar TDR represents an initial failure of the procedure, increased risk of further complications, and greater economic costs, the revision burden of this procedure is a useful metric of overall effectiveness of the procedure. The revision burden is the proportion of original procedures which are repeated, or revised, in order to address a post-surgical complication or failure of a surgical device. The revision burden of a procedure was first described for total hip arthroplasty, another common orthopedic surgical procedure which has been systematically tracked nationwide in Sweden using an outcomes registry (Malchau, Herberts, Eisler, Garellick, & Soderman, 2002).

While there are presently no nationwide registries of orthopedic procedures in the U.S., a similar study of the national revision burden for lumbar TDR has been conducted (Kurtz et al., 2010). This study used the Nationwide Inpatient Sample, a federally maintained dataset of approximately 20% of all inpatient hospital stays in the U.S. The incidence of primary and revision procedures for lumbar TDR utilize separate coding, allowing for the estimation of revision rates. This article found a revision rate of 11.2%, while the revision burden of anterior lumbar fusion was found to be 5.8%. Although lumbar TDR demonstrated a greater revision burden than fusion it was associated with shorter hospital stays and lower hospital charges.

It is important to recognize that the study by Kurtz and colleagues (2010) utilized data from the first year of the Charité and the ProDisc-L receiving FDA approval for the U.S. market (2005 and 2006, respectively). In the only long-term observational study of an orthopedic prosthesis (total hip arthroplasty; Malchau et al., 2002), the revision burden

was found to grow consistently over a 20-year observation period, as complications often took several years to develop. While lumbar TDR prostheses have been implanted in the U.S. for at least 10 years, the rates of lumbar TDR have been estimated to have grown substantially after FDA approval (Gilbride, 2010). Moreover, the ability to observationally study lumbar TDR using administrative claims data has been limited in prior years, as administrative procedural codes have only been in existence since October, 2004. Finally, the study by Kurtz and colleagues (2010) did not directly quantify the revision burden in terms of expenditures. That is, the probability and cost of a revision procedure, an *economic* revision burden, was not priced into the cost of a primary TDR or fusion procedure. Estimating the revision burden while accounting for the costs of each procedure may be useful for payers and policy makers making a value judgment about the procedure.

Due to the recent FDA approval of lumbar TDR prostheses, the increased use of the procedure, and the burden of revision, there is a need for continued observational research on lumbar TDR in the U.S. The existing observational study of lumbar TDR (Kurtz et al., 2010) is limited by its probable inclusion of many carefully selected FDA IDE trial patients and also by it not having calculated an *economic* revision burden of lumbar TDR. Nationally representative administrative claims data are now available for 2009, a point at which the majority of FDA IDE trials had completed.

The proposed study had four purposes: (a) provide current estimates of the revision burden of lumbar TDR in the U.S., (b) estimate an economic revision burden of both lumbar TDR and lumbar fusion, (c) identify changes in both the rates, revision

burden, and inflation-adjusted costs of lumbar TDR compared to those observed in 2005, and (d) compare these observed figures of revision burden and costs to those of anterior and posterior lumbar fusion surgery.

Methods

This study utilized data from the Nationwide Inpatient Sample (NIS), a nationally representative data set which is part of the U.S. Agency for Healthcare Research and Quality's ongoing Healthcare Cost and Utilization Project (HCUP). The data are a representative sample of approximately 20% of all inpatient hospital stays in the U.S., are aggregated on an annual basis, and are provided regardless of a patient's source of payment for their stay (e.g., Medicare, private health insurance, workers' compensation, etc.). Approximately 1,000 hospital institutions participate in the NIS, and 100% of their inpatient hospital stays are abstracted for aggregation in the NIS. NIS data are used by both public and private sector researchers and have been used to conduct previous population-based investigations of spine surgery in the peer-reviewed literature (e.g., Deyo et al., 2005; Gray et al., 2006; Kurtz et al., 2010).

Surgical procedures in the NIS are coded using the ninth revision of the International Classification of Diseases, clinical modification (ICD-9-CM). The specific codes which were used to identify the relevant procedures are as follows: 84.65 (primary lumbar disc arthroplasty), 84.68 (revision lumbar disc arthroplasty), 81.06 (primary anterior lumbar fusion), 81.36 (revision anterior lumbar fusion), 81.51 (primary posterior lumbar fusion), and 81.53 (revision posterior lumbar fusion).

Procedural costs were measured from the hospital perspective using the NIS variable "total hospital charges," which is a total of the direct expenses as billed. This variable was transformed to estimated hospital costs, or the actual amount that would be reimbursed by a payer, using the HCUP's cost-to-charge ratio files. The cost-to-charge ratio files provide an estimated multiplier for each hospital charge based on geographic location, payer type, and procedure code.

The revision burden was calculated as the proportion of revision procedures relative to the total number of procedures during 2009. The economic revision burden was calculated as the mean cost of a lumbar TDR procedure during 2009 plus the product of the cost and revision burden of a revision procedure. In other words, the average cost of a revision procedure is multiplied by the revision burden to adjust for the cost and probability of a revision procedure occurring. This figure is then added to the average cost of a primary procedure.

Patient health status was controlled for using the All Patient Refined-Diagnostic Related Group (APR-DRG) Severity of Illness scoring system (3M Corporation, 2003). This system estimates the severity of comorbidities experienced by patients who present with the respective diagnoses listed in their medical records. Diagnoses are aggregated by disease family into a Diagnostic Related Group (DRG), and comorbidity severity is assigned using a four point scale to each DRG. The 4-point scale was iteratively tested using clinical hypotheses from a panel of specialty-specific physicians, which were then tested against administrative claims data reporting patient outcomes over several years. The APR-DRG scoring systems are used by state and federal health payers, private health

insurers, and hospital operators.

National estimates of procedure totals were calculated using discharge weights provided in the NIS dataset which are relative to the sampling procedure used in collecting NIS data. Because hospitals are sampled for this dataset based on local demographics, economic factors, and physician market factors, each patient case in the dataset is given a multiplying factor (discharge weight) to estimate its occurrence if the data were expressed for the whole U.S.

Analyses

A multinomial logistic regression model was used to compare the estimated mean hospital costs and revision burden of lumbar TDR, anterior lumbar fusion, and posterior lumbar fusion. In this model the type of primary procedure performed (TDR, ALF, PLF) was the dependent variable, while hospital costs and revision status were used as predictors. Patient health status measured by the APR-DRG Severity score was also used as a predictor in this model to control for the severity of any comorbidities present.

Results

Results of the revision burden estimates are displayed in Table 1. Lumbar TDR had the highest revision burden in 2009 (12.95%) compared to anterior lumbar fusion (4.72%) and posterior lumbar fusion (8.46%). Patients undergoing lumbar TDR tended to be younger (mean age: 41.6 years) and in a lower severity of illness category (APR-DRG = 1: 76.1%) than their fusion counterparts. The gap in severity of illness between primary

Table 1

Revision Burden and Patient Demographic Characteristics of Lumbar TDR, Anterior Lumbar Fusion, and Posterior Lumbar Fusion Procedures

	Lumbar TDR		Anterior fusion		Posterior fusion	
Variables	Primary	Revision	Primary	Revision	Primary	Revision
Total number of procedures (95% CI)[a]	2293 (1364-3222)	297 (179-415)	41419 (34120 - 48718)	1954 (1489 - 2419)	193158 (170977 - 215339)	16335 (13626 - 3222)
Revision burden	12.95%		4.72%		8.46%	
Mean age in years (*SD*)	41.6 (9.5)	55.2 (14.2)	51.4 (14.0)	52.9 (13.2)	57.3 (14.8)	57.0 (13.6)
% male	52.4%	43.9%	45.3%	51.6%	44.6%	44.3%
APR-DRG score[b] (% = 1)	76.1%	45.6%	27.1%	36.8%	43.8%	39.8%

[a] Total is a national estimate created using NIS discharge weights
[b] APR-DRG score of 1 = minor or no loss of function

and revision procedure patients was largest with lumbar TDR, where 76.1% of primary TDR patients had an APR-DRG score of 1 while 45.6% of revision TDR patients had the same score.

Table 2 shows estimates of hospital charges, costs, and economic revision burdens of the three procedures of interest. Lumbar TDR was less expensive in each measure of costs with average hospital costs for a primary procedure of $21,617 (*SD* = $12,809) and $23,454 (*SD* = $17,147) for a revision procedure. The economic revision burden (or the revision-adjusted cost of a primary procedure) of lumbar TDR was estimated to be $24,654, as compared to $39,392 for anterior fusion and $32,952 for posterior fusion

Table 2

Economic Costs and Economic Revision Burden of Lumbar TDR, Anterior Lumbar Fusion, and Posterior Lumbar Fusion Procedures

	Lumbar TDR		Anterior fusion		Posterior fusion	
Variables	Primary	Revision	Primary	Primary	Revision	Primary
Mean hospital charges (SD)	$68,135 ($52,139)	$91,231 ($86,810)	$126,534 ($92,963)	$147,483 ($103,892)	$100,393 ($69,863)	$108,251 ($88,640)
Mean hospital costs[1]	$21,617 ($12,809)	$23,454 ($17,147)	$37,406 ($25,618)	$42,080 ($23,273)	$30,190 ($17,979)	$32,644 ($23,927)
Revision burden	12.95%		4.72%		8.46%	
Economic revision burden[2]	$24,654		$39,392		$32,952	

[1] Hospital costs were calculated using the NIS All-Payer Inpatient Cost-to-Charge Ratios (APICC)
[2] Economic revision burden is calculated as (mean hospital cost of primary procedure) + (mean hospital cost of revision procedure*revision burden)

Results of the multinomial regression analysis are presented in Table 3. When comparing anterior lumbar fusion to lumbar TDR, hospital costs were on average 8.6% higher for anterior lumbar fusion when controlling for revision status and patient comorbidity severity (OR = 1.086, 95% CI = 1.072-1.099). Lumbar TDR patients were more than three times as likely to be having a revision surgery when compared to anterior fusion patients, however, when controlling for hospital costs and patient comorbidity severity (OR = 3.025, 95% CI = 2.179-4.199). Posterior lumbar fusion patients averaged 7.9% higher hospital costs than TDR patients (OR = 1.079, 95% CI = 1.065-1.092). Lumbar TDR patients were approximately 85.6% more likely to be having a revision surgery when compared to posterior fusion patients, when controlling for hospital costs and patient comorbidity severity (OR = 1.856, 95% CI = 1.376-2.505). Patient

Table 3

Multinomial Logistic Regression Results Comparing Hospital Costs and Revision Burden of Lumbar Total Disc Replacement, Anterior Fusion, and Posterior Fusion Controlling for All-Patient Refined Disease-Related Severity Score

Dependent category	Predictor variables	B	SE	*p* value	Exp(B)	95% CI
Anterior lumbar Fusion	Mean hospital costs	0.082	0.006	<0.001	1.086	1.072-1.099
	Revision = 0	1.107	0.167	<0.001	3.025	2.179-4.199
	APRDRG severity score = 1	-0.368	1.015	0.717	0.692	0.095-5.057
	APRDRG severity score = 2	0.234	1.018	0.818	1.264	0.172-9.295
	APRDRG severity score = 3	1.494	1.128	0.185	4.455	0.488-40.638
	APRDRG severity score = 4					
Posterior lumbar fusion	Mean hospital costs	0.076	0.006	<0.001	1.079	1.065-1.092
	Revision = 0	0.619	0.153	<0.001	1.856	1.376-2.505
	APRDRG severity score = 1	-0.568	1.008	0.573	0.567	0.079-4.089
	APRDRG severity score = 2	0.400	1.012	0.692	1.492	0.205-10.834
	APRDRG severity score = 3	1.788	1.122	0.111	5.975	0.663-53.856
	APRDRG severity score = 4					

Note. Reference category: Lumbar total disc replacement.

comorbidity severity did not vary significantly when comparing either of the fusion procedures to lumbar TDR.

Discussion

The present study estimated national procedure rates, revision burdens, and estimated hospital costs for lumbar TDR, anterior lumbar fusion, and posterior lumbar fusion surgery. Mean hospital costs for the lumbar TDR procedure were lower than those

calculated for anterior or posterior lumbar fusion surgery. Despite a higher revision burden, the economic revision burden was in fact lower than for either of the fusion procedures, offset by the procedure's lower overall hospital costs for both primary and revision procedures. These differences remained despite controlling for patient comorbidity severity in the multinomial regression models (Table 3).

When compared to the results of a similar TDR study using nationally representative data from 2005-2006, lumbar TDR had a very similar revision burden (12.95% vs. 12.5% in the previous study) and mean hospital costs were likewise very similar. What has changed since 2005-2006, however, was the prevalence of the procedure, with an estimated 3,650 procedures in 2005, 2,465 in 2006, and 2,293 in 2009 (present study). Early estimates from 2010 NIS data suggest another decline in total TDR procedures to 1863 (U.S. Agency for Healthcare Research and Quality, 2012). Anterior lumbar fusion, meanwhile, increased substantially in prevalence from 28,408 primary procedures in 2005 to 41,429 procedures in 2009, an increase of nearly 46%. The prevalence of posterior lumbar fusion also increased by 40% over the same 4-year period.

This study built on a previous administrative claims study of lumbar TDR (Kurtz et al., 2010) in two ways. First, the specific types of prostheses and context they were delivered in have likely changed. Some clinical trials of lumbar TDR were occurring during 2005 and 2006, and outside of clinical trials the only prosthesis that was FDA approved at that time was the Charité, and it was likely that a large proportion of cases in the previous study used this particular device. The ProDisc-L was subsequently approved in 2006 and the Maverick disc began clinical trial testing began in 2008, suggesting that

both of these devices were more completely represented in the present study. Second, the present study used data from a time point where more lumbar TDR procedures had been performed and the respective devices had the opportunity to fail, perhaps allowing for a percentage of revision procedures that was more reflective of future years. However, this percentage grew only slightly since 2005-2006.

The potential reasons for why lumbar TDR surgery has not gained traction in the U.S. are many, and this comes despite lower overall hospital costs, a lower economic revision burden, and clinical trial research indicating statistically equivalent patient outcomes compared to lumbar fusion. Perhaps chief among the concerns with lumbar TDR is the higher revision rate compared to fusion, posing as a barrier to patients and their surgeons who are weary of the possibility of replacing or revising the prosthetic device at some point in the patient's future. Additionally, both public and private payers have been reluctant to cover the TDR procedure, the most powerful decision coming from the Centers for Medicare and Medicaid Services issuing a negative National Coverage Determination position (Centers for Medicare and Medicaid Services, 2007). This position was eventually revised to only deny coverage for patients age 60 and older, though the initial position was influential in setting a precedent for private payers, many of whom only reimburse for the procedure on a case-by-case basis.

Another interesting finding was that patient health status was relatively good in lumbar TDR patients, while only 27% of anterior fusion patients had an APR-DRG Severity score of "1" (minimal or no risk of comorbidity severity) and 44% of posterior fusion patients having the same score. It is unclear whether lumbar TDR patients are

perhaps being offered this procedure because of their better health status, fusion patients are undergoing a longer or different pathway of care to their procedure allowing for the development of more severe comorbidities, or some combination of both. That the lumbar TDR procedure was performed in a group of patients with relatively low comorbidity severity suggests that this should be at least considered, if not statistically controlled for, in research comparing these procedures. Lastly, TDR patients were on average 10-15 years younger than fusion patients. This is likely due to younger patients having a more active lifestyle and thus benefitting from a motion preserving surgery.

It is important to consider that the true cost of the lumbar TDR and fusion procedures would best be accounted for over a 5-10 year period, rather than a 1-year cross sectional view as was observed in the present study. Capturing the true cost and probability of revision, as well as rehabilitation and after care costs, return to work status, and other patient-reported outcomes requires several years of follow-up data that are not systematically collected and published in the U.S. Such data would best be captured with a surgical registry, a direction which has been taken in Switzerland (Schluessmann et al., 2009) and is also under development in the U.S (North American Spine Society, 2011).

The results of this investigation of claims data still prod the question of whether lumbar TDR should be covered by Medicare and private health payers in the U.S. It is tempting to consider broader reimbursement for lumbar TDR because of the reduced economic revision burden estimate generated here. Though it is unclear how pricing of the procedure may change in years to come, in the interim lumbar TDR presents as a less expensive alternative to lumbar fusion, the latter posing as a large cost burden to health

payers. However, because of the relatively high revision burden compared to lumbar fusion and the unknown clinical consequences for patients of undergoing a revision surgery, the present findings hint at further scrutiny and reluctance to reimburse from health payers. Until the revision rate or the clinical consequences of revision procedures can be reduced, lumbar TDR does appear to have a clear-cut economic or clinically meaningful advantage to lumbar fusion.

One limitation of the present study is the scope of outcomes being analyzed and presented. While these data address the prevalence and cost of revision surgeries, they do not address other relevant questions of the effectiveness of lumbar TDR, such as the reduction of adjacent segment disease compared to fusion or the lifespan of the respective prosthetic devices. The former question was recently addressed in a systematic review which concluded that there is a lower risk of developing adjacent segment disease after lumbar TDR compared to fusion, though it was simultaneously concluded that insufficient evidence existed to support the notion that fusion increased the risk of adjacent segment disease relative to lumbar TDR. In short, the evidence on adjacent segment disease is still quite mixed. Estimating the lifespan of lumbar TDR prostheses is even more uncertain, as individual patients may stress and tolerate the devices to very different degrees of years of use. Patient outcomes registries will again be helpful in answering these questions in the coming years and will provide a more complete picture of lumbar TDR's long-term performance relative to lumbar fusion.

CHAPTER III

PREVALENCE AND ECONOMIC COSTS OF THE LUMBAR TOTAL DISC REPLACEMENT HYBRID PROCEDURE

Abstract

The lumbar TDR procedure has been used as a treatment option for degenerative disc disease since at least the mid-2000s in the U.S. For patients with multi-level degenerative conditions, the TDR *hybrid* procedure, where a lumbar TDR and fusion are performed concurrently on adjacent segments, has been proposed (Erkan et al., 2009). Little research exists that describes this procedure and no observational data about the prevalence and costs of the procedure have been presented in peer-reviewed literature. The present study sought to estimate the prevalence, hospital costs, and diagnostic indicators of the TDR hybrid procedure. Nationally representative data were used from the 2009 Nationwide Inpatient Sample. Results indicated that an estimated 439 TDR hybrid procedures were performed in the U.S. during 2009. This number reflects approximately 16% of all lumbar TDR procedures performed in the U.S. in 2009. Approximately one-third of patients were diagnosed with a herniated lumbar disc in addition to having been diagnosed with degenerative disc disease. Discussion of policy implications for these findings and data limitations are provided.

Introduction

Lumbar TDR surgery has become a surgical alternative to lumbar fusion surgery

in recent years, particularly for patients with degenerative disc disease (Kurtz et al., 2010). Several FDA Investigational Device Exemption clinical trials have been conducted and suggest TDR's clinical efficacy may be equivalent to lumbar fusion surgery for single-level degenerative disc disease in the lumbar spine (e.g., McAfee et al., 2005; Zigler et al., 2007). A recent meta-analysis of lumbar TDR for patients with degenerative disc disease affirmed that short-term outcomes of TDR may be equivalent to fusion; however, the review raised concern regarding the lifespan of the prosthetic devices being used in TDR surgery (Jacobs et al., 2013).

Lumbar TDR is often seen as attractive for its ability to retain motion at the affected intervertebral segment, as opposed to fusion where motion is nearly eliminated (Yue et al., 2009). This is thought to reduce the incidence of adjacent segment disease, or the development of pathology at a level adjacent to the originally affected level (Harrop et al., 2008). The procedure has been met with criticism, however, primarily regarding the lifespan of the TDR prosthesis, which has been estimated by manufacturers to be 15-20 years (Schluessmann et al., 2009). This lifespan figure has yet to be truly tested because the procedure has not seen widespread use for enough time.

The lumbar TDR hybrid procedure has been developed to address cases of multi-level degenerative disc disease. Degenerative disc disease is a relatively common pathology associated with low back pain in adults (Deyo et al., 2006) and is thought to involve multiple intervertebral levels in approximately 30% of diagnoses at the lumbar level (Pearcy, 2010). Surgical treatment for multilevel degenerative disc disease with lumbar TDR has been controversial, with one study finding highly satisfied patients

(Bertagnoli et al., 2005) and another reporting decreased patient satisfaction and higher complication rates (Siepe, Mayer, Wiechert, & Korge, 2006).

The hybrid construct is unique in that it combines a lumbar TDR procedure at one intervertebral level and an anterior lumbar interbody fusion (ALIF) at another, both occurring in the same procedure. This technique may be advantageous for multi-level cases because a fusion at the inferior level may provide a more stable foundation on which to perform an adjacent TDR procedure. Erkan and colleagues (2009) investigated the feasibility of this model in an in-vitro comparison study using cadavers to examine the biomechanical properties of the hybrid construct. They found almost no difference in terms of flexion and extension motion between a 2-level Maverick disc construct and a hybrid Maverick disc/ALIF construct.

One clinical study exists that examined outcomes of hybrid procedures (Pimenta, Oliveira, Schaffa, Coutinho, & Marchi, 2011). This study compared 2-year follow-up data from 36 cases of minimally invasive lumbar TDR, 18 of which were hybrid procedures where an anterior lumbar fusion was performed at the L5-S1 vertebral level combined with a lumbar TDR at the adjacent L4-L5 vertebral level. The only observed outcome difference was in facet joint pain, with 4 of 18 (22%) hybrid patients reporting pain diagnosed at the facet joint via diagnostic injections, while no patients in the single-level lumbar TDR reported facet joint pain. This study did not compare the hybrid procedure to a two-level fusion or lumbar TDR. Moreover, the extreme lateral approach is very uncommon in the lumbar TDR procedure, and does not represent a plausible approach technique to compare to other studies of lumbar TDR (Yue et al., 2009).

Bono (2009) provided a critique of the hybrid construct, noting that not only is there no clinical evidence to substantiate the purported advantages of the hybrid procedure, but also that the spine field is still conflicted in endorsing any kind of surgery for multi-level degenerative disc disease. Discussion at professional conferences and in online patient message boards suggests that the hybrid procedure is clearly being used, although there is no evidence to suggest how often, what the costs are, and what diagnostic indications may encourage a surgeon to implement this option. The lack of any observational data on the hybrid procedure and only one small clinical study using a very novel approach technique represents a distinct gap in the literature regarding hybrid procedures.

The incidence and costs of the lumbar TDR-fusion hybrid procedure have yet to be examined in the literature. This procedure has been described from the perspectives of biomechanics research and clinical anecdotes, but it is unknown how often and under what diagnostic indications this procedure is performed. Thus, the present study aims to assess the incidence, costs, and diagnostic precursors of the lumbar TDR-fusion hybrid procedure using a large, nationally representative claims database.

Methods

This study utilized data from the Nationwide Inpatient Sample (NIS), a nationally representative data set which is part of the U.S. Agency for Healthcare Research and Quality's ongoing Healthcare Cost and Utilization Project (HCUP). The data were a representative sample of approximately 20% of all inpatient hospital stays in the U.S., are

aggregated on an annual basis, and are provided regardless of a patient's source of payment for their stay (e.g., Medicare, private health insurance, workers' compensation, etc.). Approximately 1,000 hospital institutions participate in the NIS, and 100% of their inpatient hospital stays are abstracted for aggregation in the NIS. NIS data are used by both public and private sector researchers and have been used to conduct previous population-based investigations of spine surgery in the peer-reviewed literature (e.g., Deyo et al., 2005; Gray et al., 2006, Kurtz et al., 2010). Frequency counts and costs in the dataset can be extrapolated to national estimates using NIS discharge weights which are calculated using the NIS hospital sampling procedure. The dataset contains approximately 530 inpatient stay records of lumbar TDR cases in 2009.

Surgical procedures in NIS are coded using the ninth revision of the International Classification of Diseases, clinical modification (ICD-9-CM). The specific codes which were used to identify the relevant procedures are as follows: 84.65 (primary lumbar disc arthroplasty), 84.68 (revision lumbar disc arthroplasty), 81.06 (primary anterior lumbar fusion), 81.36 (revision anterior lumbar fusion), 81.51 (primary posterior lumbar fusion), and 81.53 (revision posterior lumbar fusion). Hybrid procedures were identified by the presence of both a primary lumbar disc arthroplasty code (84.65) in addition to a primary anterior lumbar fusion code (81.06) in the same inpatient instance of stay abstract.

Procedural costs were measured from the hospital perspective using the NIS variable "total hospital charges," which is a total of the direct expenses as billed. This variable was transformed to estimated hospital costs, or the actual amount that would be reimbursed by a payer, using the HCUP's cost-to-charge ratio files (U.S. Agency for

Healthcare Research and Quality, 2011). The cost-to-charge ratio files estimate costs based on the admitting hospital's geographic location, state-aggregated chargemaster data, and the Medicare Part B fee schedule.

Diagnostic indicators for the lumbar TDR hybrid procedure were deduced using diagnostic (ICD-9-CM) codes related to lumbar spinal pathology in each inpatient abstract. Each of the spine-related diagnoses was reported in order prevalence. The severity of diagnostic comorbidities was measured using the All Patient-Refined Diagnostic Related Group (APR-DRG) Severity of Illness scoring system (3M Corporation, 2003). This system assigned a 0- to 4-point rating of the severity of any medical comorbidities present in a patient's medical records and is widely used in administrative claims research (e.g., Kurtz et al., 2010).

Analyses

National estimates of the hybrid procedure and lumbar TDR without co-occurring fusion were generated using the NIS discharge weighting system. This allowed for the NIS dataset's nationally representative sample to be expanded to the nationwide level and includes 95% confidence intervals of the estimates. Costs are the mean hospital costs estimated for each procedure category.

Results

Results related to prevalence and costs of the TDR hybrid procedure are displayed in Table 4. A national estimate of 439 hybrid procedures occurred in 2009 in the U.S.

Table 4

Prevalence and Economic Costs of Lumbar Total Disc Replacement Hybrid Procedure Compared To Lumbar Total Disc Replacement Without A Co-Occurring Fusion

Variables	Lumbar TDR hybrid	Lumbar TDR without co-occurring fusion	Effect size difference (Cohen's *d*)
Total number of procedures (95% CI)[a]	439 (386 - 815)	2151 (1205 - 3179)	--
Mean hospital charges (*SD*)	$111,141 ($63,028)	$57,642 ($43,724)	0.99
Mean reimbursement costs (*SD*)[b]	$35,252 ($16,302)	$18,345 ($9,329)	1.28

[a] Total is a national estimate created using NIS discharge weights
[b] Hospital costs were calculated using the NIS All-Payer Inpatient Cost-to-Charge Ratios (APICC)

(95% CI = 386-415) out of 2590 total primary or revision lumbar TDR procedures (95% CI = 1543-3637). A large effect size difference was found in terms of both mean hospital charges (d = 0.99) and mean reimbursement costs (d = 1.28) when comparing TDR hybrid procedures with TDR procedures without co-occurring fusion.

Table 5 shows diagnoses that were present in patients receiving the hybrid and non-hybrid procedures. These results were very similar, with slightly fewer hybrid patients indicating the most common diagnoses of lumbar disc herniation (34.3%) or a degenerative lumbar disc (37.4%). Patients did differ in terms of comorbidity severity, however, with 53.7% of hybrid patients indicating an APR-DRG Severity score of 1 (indicating minimal or no comorbidity severity) and 81.7% of nonhybrid TDR patients with a severity score of 1.

Discussion

The present study estimated the national incidence of the lumbar TDR hybrid

Table 5

Lumbar Spine-Related Pathology Present In Patients Receiving Lumbar TDR Hybrid and Lumbar TDR Without Co-Occurring Fusion Procedures

Diagnosis	Lumbar TDR Hybrid	Lumbar TDR without co-occurring fusion
% with displacement of lumbar disc (722.10)	34.3%	39.4%
% with degeneration of lumbar disc (722.52)	37.4%	41.1%
APR-DRG severity score (% = 1)[a]	53.7%	81.7%

[a] APR-DRG score of 1 = minor or no loss of function.

procedure in the U.S. in 2009 to be 439 procedures, a small number among the relatively uncommon lumbar TDR procedure as a whole, with an estimated 2,590 procedures in 2009. With this number in mind, virtually no peer-reviewed evidence examining the *in vivo* use of the TDR hybrid procedure exists, a point which has not been lost on some authors criticizing the procedure (e.g., Bono, 2009). Observational research using nationally representative data has afforded a real-world look at the use of this procedure for the first time.

The lumbar TDR hybrid procedure was most prominently presented in the literature in an *in vitro* study of the biomechanical properties of such a construct as compared to the properties of a two-level TDR construct (Erkan et al., 2009). This study was promising in terms of preservation of motion in the superior intervertebral segment (L4-L5 in this case) while creating a constrained and limited motion segment at L5-S1. If multi-level surgical treatment was appropriate, this study suggested perhaps motion could be retained at one level with a strong foundation of fusion beneath it, and without the

uncertain mechanics of a two-level TDR. No clinical research was conducted beyond this study, however, and the hybrid procedure was ultimately used in a limited number of patients in 2009.

This study found a substantial difference in terms of severity of comorbidities for patients undergoing TDR hybrid procedures compared to patients undergoing TDR without co-occurring fusion. While 81% of TDR patients had an APR-DRG Severity score of 1 (indicating little or no comorbidity severity), 57% of TDR hybrid patients had the same score. This may simply be reflective of a greater presence of comorbidities in multi-level degenerative disc disease or could suggest more severely comorbid patients are being seen as more suitable for the TDR hybrid procedure. Nonetheless, this distinction could raise concerns for highly comorbid patients undergoing a more complex multi-level procedure.

Costs of the TDR hybrid procedure were also substantially higher than TDR without co-occurring fusion by approximately $17,000, an unsurprising figure given the multi-level nature of the procedure. What was not clear was how these costs compare to a two-level lumbar fusion or lumbar TDR procedure. Previous research on the costs of these procedures in single-level form (Kurtz et al., 2010) suggested that the TDR hybrid would likely be a compromise in terms of costs between two-level TDR and the more expensive two-level fusion.

A particular contention surrounding the hybrid procedure has been the discussion or consideration of the procedure in light of limited evidence to support either TDR *or* fusion for multi-level degenerative disc disease (Bono, 2009). Moreover, health payers

and the spine care community continue to debate the merits of fusion for single-level degenerative disc disease (North American Spine Society, 2010), making the TDR hybrid procedure appear to be a stretch for many professionals in terms of evidence and necessity.

Interestingly, the lumbar TDR procedure-hybrid or not-has been decreasing in prevalence since its U.S. introduction in 2005. The reasons behind this failure to gain popularity are many, though patient-plaintiff litigation (Brown v. DePuy Spine, Inc., 2007) and the debated superiority of TDR outcomes compared to lumbar fusion (Resnick & Watters, 2007) were chief among them. The decreasing occurrence of the lumbar TDR procedure has likely dampened much of the debate on whether or not the TDR hybrid procedure is useful and effective for patients.

The greatest limitation to the current study is in the identification of the hybrid procedure in administrative claims data using only ICD-9-CM coding. The hybrid procedure has been described in the literature as a lumbar total disc replacement procedure combined with an anterior lumbar fusion procedure (Erkan et al., 2009), and thus it was most pragmatic to identify hybrid cases where both a lumbar TDR and posterior lumbar fusion procedure were performed in the same inpatient stay. It is quite possible, however, that a limited number of cases identified in the data as hybrids in fact are cases of multiple, independent procedures being performed in the same inpatient stay.

In spite of its limitations, the present study used nationally representative observational data to examine the prevalence and economic costs of a very uncommon and perhaps controversial procedure. With the uncertain future of the lumbar TDR

procedure the controversy surrounding the TDR hybrid procedure may likely diminish. What might be most useful from this particular study, then, is the power of observational and administrative claims data for investigating even the most uncommon of spine procedures. As the demand for real-world examinations of spine procedures grows, administrative claims data can be used to meet this need, and the present study shows this possible for gathering basic data on even unique and rarely used procedures.

CHAPTER IV

GEOGRAPHIC VARIATION OF LUMBAR TOTAL DISC REPLACEMENT SURGERY

Abstract

Substantial geographic variation has been reported in the procedural rates and costs of lumbar spine surgery since the 2000s, particularly for lumbar fusion surgery. This variation has been found irrespective of demographics and surgeon supply, and has been implicated in inconsistent patient care and unnecessarily high costs of care in some regions. Lumbar TDR surgery is a relatively new procedure designed to take the place of lumbar fusion for certain patients, and no previous research has examined geographic variation of its prevalence. The present study used nationally representative claims data from the 2009 Nationwide Inpatient Sample to assess the U.S. State-level procedural rates of lumbar TDR. Substantial geographic variation was found, from zero procedures performed in several states to a rate 11 times the U.S. average in one state. Implications for practice guidelines and reimbursement policy are discussed, in addition to the limitations and highlights of using administrative claims data for this inquiry.

Introduction

The variation of procedural rates by geographic region is a critical topic in U.S. health care as a whole and spine surgery specifically (Dartmouth Atlas of Health Care, 2009). Such variation is of great interest to public policy makers, researchers, and

physicians as it represents inconsistencies in an increasingly public share of health care spending (U.S. Congress, 2009). Using Medicare claims data, Weinstein and colleagues (2006) found age- and sex-adjusted rates of lumbar fusion surgery to vary by a multiple of 23 (0.2 to 4.6 per 1,000 Medicare enrollees) across Medicare's U.S. hospital referral regions. This variation was found while controlling for the supply of orthopaedic surgeons and neurosurgeons, as well as controlling for geographic adjustments in Medicare reimbursement rates. Finally, while growth in the rates of lumbar fusion surgery has occurred nationwide, the same "surgical signature" of extremely high and low rates of fusion surgery remained between the mid-1990s and mid-2000s.

The most consistently voiced explanation for the extreme geographic variation in spine surgery rates is scientific uncertainty (Weinstein, Bronner, Morgan, & Wennberg, 2004; Weinstein et al., 2006). Only limited—and sometimes vague or conflicting—guidelines have been developed for the practice of spine surgery. Other authors have suggested that the aforementioned growth in technology in lumbar fusion surgery has outpaced the development of scientific evidence to support it (Deyo et al., 2005; Irwin et al., 2005). This may lead physicians to rely more on regional practice trends and peer recommendation than nationally issued practice guidelines when making clinical decisions. Under this explanation, geographic variation may run high in lumbar TDR, as reimbursement opinions and peer-reviewed literature have been inconsistent and conflicting in their viewpoints on the procedure.

Finally, extreme geographic variation may be representative of inconsistent quality of care. Weinstein and colleagues (2004) longitudinally examined age-, sex-, and

race-adjusted geographic variation in surgical procedure rates for degenerative major joint and spine conditions in the Medicare patient population. By aggregating their study's data with the Centers for Medicare and Medicaid Services' Institutional Quality Benchmark data, no relationship could be found between procedure rates and quality of care, even after adjusting for demographics and Charlson-scored medical comorbidities. The authors conclude by suggesting clinical decision making guidelines in orthopedics should be offered in a centralized, consistent, and evidence-based manner in order to reduce the geographic variation in procedural rates. No previous research has examined the geographic variation in the rates and costs of lumbar TDR, a task which the research suggests is important in the reimbursement decision process.

Lumbar TDR has been described as an alternative to lumbar fusion surgery for patients with degenerative disc disease in the U.S. since at least the mid-2000s (e.g., McAfee et al., 2005; Zigler et al., 2007) and in Europe since the 1980s (Cinotti, David, & Postacchini, 1996). The assumed advantage of the TDR procedure is that it retains some of the natural motion at the affected spinal disc segment, as opposed to its lumbar fusion surgery counterpart which eliminates motion (Link, 2002). Further, it is thought that the retained motion may reduce the occurrence of adjacent segment disease (Zigler, Glenn, & Delamater, 2012), a burdensome problem for patients and health payers (Adogwa et al., 2012). A series of U.S.-based clinical trials have demonstrated effectiveness of lumbar TDR to be at least equivalent to lumbar fusion for single-level degenerative disc disease (McAfee et al., 2005; Zigler et al., 2007), and nationally representative observational research has suggested lumbar TDR to have lower economic costs associated with it

(Kurtz et al., 2010).

Because of the tendency for wide geographic variation in spine surgery paired with the consequences of inconsistent public spending and uncertain standards of patient care, there is an interest in examining the rates of lumbar TDR surgery by geographic area. This procedure is newly introduced, high in cost, and under consideration for reimbursement by both public and private health payers. Thus, it is a likely candidate for high geographic variation. Finding such variation and addressing it in a meaningful way —with the introduction of definitive practice guidelines for surgeons and payers to agree to, for example—may allow this procedure to be more well-received by payers and provide more appropriate and affordable access to patients who could benefit from this technology.

This study sought to identify geographic variation in demographically adjusted procedure rates of lumbar TDR surgery. We also sought to examine how this geographic variation compares to that spine surgery overall, and to identify whether or not the use of lumbar TDR exhibited the same "surgical signature" as other lumbar spine procedures.

Methods

This analysis used data from the 2009 Nationwide Inpatient Sample (NIS), a nationally representative sample of 20% of all inpatient hospital stays in the U.S (U.S. Agency for Healthcare Research and Quality, 2011). These data were aggregated on an annual basis since 1988 and as of 2009 included 44 participating states. The NIS is unique in that it contains data from all types of health payers (i.e., Medicare, HMOs,

workers' compensation, etc.). NIS data are used by both public and private sector researchers and have been used to conduct previous population-based investigations of spine surgery in the peer-reviewed literature (e.g., Deyo et al., 2005; Gray et al., 2006; Kurtz et al., 2010).

Procedures were identified in the NIS using ICD-9-CM procedure codes. In identifying lumbar TDR procedures, ICD codes 84.65 (primary lumbar total disc replacement) and 84.68 (revision lumbar total disc replacement) were used. The incidence of lumbar fusion surgery was identified by either codes 81.06 or 81.36 (primary and revision anterior lumbar fusion, respectively) or 81.08 or 81.38 (primary and revision posterior lumbar fusion, respectively).

Procedural rates of lumbar TDR were calculated at the state-level due to insufficient reporting of data at the level of zip codes or physical addresses, which would have allowed for a more detailed analysis. Procedure rates were adjusted to the economic status of each state using the state mean of Medicare's Geographic Practice Cost Index (GPCI), with each GPCI factor being assigned one of four values: less than 90% of the national average, 90% to 100% of the national average, 101% to 110% of the national average, and greater than 110% of the national average. Last, procedure rates were adjusted to the supply of surgeons using data from the Dartmouth Atlas of Healthcare (2006) describing the number of orthopedic and neurosurgeons per 100,000 people at the state level. Each state's surgeon supply number was put into one of four categories: 0-10.0, 10.1-15.0, 15.1-20.0, or greater than 20.0 surgeons per 100,000. Standardization was computed using the indirect method in each GPCI-surgeon supply category. For

simplicity of interpretation, each state's final standardized rate was converted to a ratio of the state-specific rate to the average U.S. rate.

To compare the geographic variation in lumbar TDR to lumbar fusion, a linear regression model was used with the unadjusted ratio of the procedure rate of lumbar fusion surgery as the dependent variable and the unadjusted ratio of the procedure rate of lumbar TDR as the independent variable. Each state's respective spine surgeon supply figure (expressed as surgeons per 100,000 population) and Medicare GPCI factor were included in the model as control variables.

Results

Figure 1 shows substantial geographic variation was found in the adjusted procedure rates of lumbar TDR surgery. The state-level rate varied from zero procedures performed (found in nine U.S. States) to a rate that was 11 times the U.S. average rate in the state of Arkansas. The unadjusted U.S. average rate for lumbar TDR was 0.05 procedures per 10,000 people, making it a relatively uncommon procedure.

Compared to lumbar TDR, the adjusted procedure rates of lumbar fusion showed far less geographic variation (Figure 2), with a minimum adjusted procedure rate that was just 5% of the U.S. average (Maine) to a maximum of 2.54 times the U.S. average (Colorado). Table 6 shows the results of the regression model comparing the rates of lumbar fusion and TDR. Significant variation between the two procedures was found at the state-level ($r^2 = 0.24$, $p = 0.013$) while controlling for the supply of spine surgeons and the cost of medical practice and reimbursement.

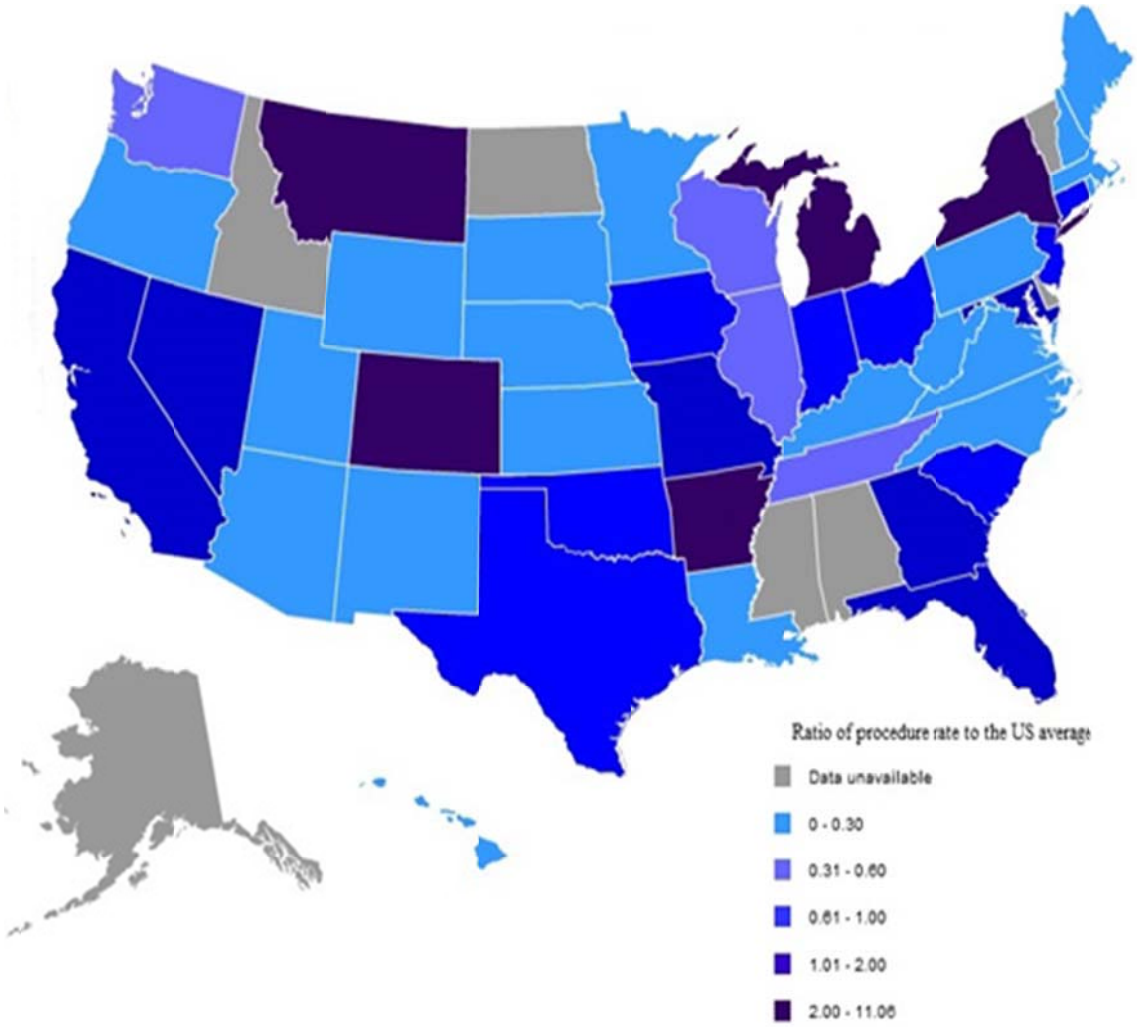

Figure 1. State-level ratio of procedure rates per 100,000 population to the U.S. average of lumbar total disc replacement surgery: Year 2009.

Discussion

The present study found marked geographic variation in the adjusted procedure rates of lumbar TDR surgery, and this variation was inconsistent with that found for the much more common lumbar fusion surgery. These procedure rates were found after adjusting for the supply of spine surgeons in each state as well as economic incentives in the form of geographic Medicare payment adjustments.

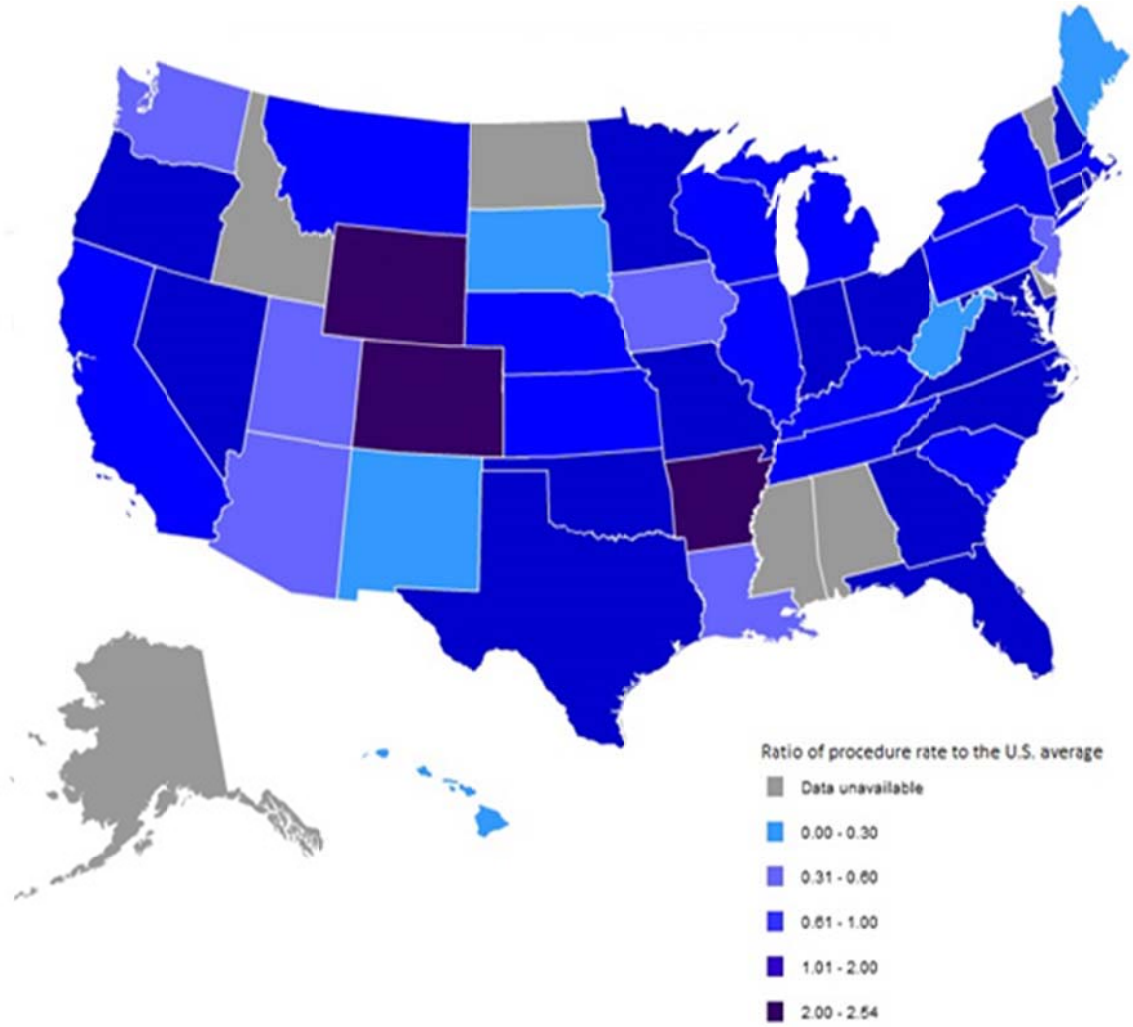

Figure 2. State-level ratio of procedure rates per 100,000 population to the U.S. average of lumbar fusion surgery: Year 2009.

The most obvious explanation for the geographic variation observed in lumbar TDR is scientific uncertainty about the effectiveness, safety, and longevity of the procedure. In spite of there being ample clinical trial evidence to support the equivalent efficacy of lumbar TDR to fusion for patients with degenerative disc disease, the most recent synthesis of the literature suggests that lumbar TDR may in fact produce limited clinical benefit (Jacobs et al., 2013). Although a vast amount of evidence on the practice

Table 6

Simultaneous Entry Multiple Regression: Comparing the Geographic Variation of Procedure Rates of Lumbar TDR and Lumbar Fusion

	Unstandardized coefficients[a]		Standardized coefficients	
Variable	β	*SE*	β	*p* value
Ratio of rate of lumbar TDR	0.11	0.04	0.40	0.007
State supply of spine surgeons	0.09	0.04	0.29	0.050
Medicare geographic adjustment factor	-0.05	1.23	-0.01	0.965
(constant)	0.218	1.315		0.869

[a] $R^2 = 0.24$; $p = 0.01$.

of lumbar TDR exists, much of it is conflicting and/or draws limited conclusions. This results in few practice guidelines and surgical judgment is left to contribute to some amount of geographic variation. Surgeons may decline to offer the procedure in the wake of the limited evidence, while others may find it an appropriate option for their patients.

What is less clear is how surgeons make practice decisions in the wake of this scientific uncertainty. It may be that local or regional trends gather, where one surgeon's positive or negative outcomes with lumbar TDR influence the decisions of their local colleague. Alternatively, positive or negative patient experiences with lumbar TDR may influence the interest of patients who are in the treatment process of degenerative disc disease. Lastly, participating in a clinical trial or having a locally large presence of lumbar TDR distribution and marketing may influence surgeons' comfort level and decision to adopt this technology.

The scientific uncertainty behind lumbar TDR underscores the conflicting opinions over how degenerative disc disease should be treated surgically, or whether

surgery is even appropriate at all. In a commentary on the lumbar TDR hybrid procedure (which combines an arthroplasty at one level and a fusion at an adjacent level), Bono (2009) describes this point quite well, noting that the suitability of TDR and fusion for degenerative disc disease are very much open for debate. While the commentary by Bono referred to a multi-level procedure, the use of fusion to treat single-level degenerative disc disease has been criticized as well. Deyo and colleagues (2004), for example, point out the limited supportive evidence, rapidly increasing use, and high costs of lumbar fusion for degenerative conditions. In short, it seems that the spine community is still considering the value of any surgical treatment for degenerative lumbar conditions, never mind whether lumbar TDR should be considered as a viable alternative to lumbar fusion.

Another explanation for such dramatic geographic variation in the rates of lumbar TDR may lie in reimbursement for the procedure from health payers. Because Medicare and most private health plans only cover lumbar TDR on a case-by-case basis (i.e., not often), a particularly high or low procedure rate may be influenced by the inability to be reimbursed for the procedure or, conversely, by a surgeon's ability to successfully obtain reimbursement. By contrast, lumbar fusion surgery has a much narrower range of geographic variation and also far more uniform reimbursement policy from both public and private health payers.

The geographic variation observed here and in other studies of spine care should be inspirational for the creation of more robust clinical practice guidelines or appropriate use criteria for lumbar TDR and other surgical spine procedures. It is clear that substantial geographic variation exists in the relative commonality of these procedures

from one city or state to the next. What is less clear is evidence suggesting when these procedures are most appropriately used. The present analysis of geographic variation is in keeping with previous analyses of the geographic variation of other spinal procedures (e.g., Weinstein et al., 2004). Further, it supports the proposition that scientific uncertainty and a lack of clinical agreement on when to offer these procedures is contributing to great disparities in care for patients. Development of more specific and evidence-based practice guidelines or use criteria are the most logical next step to delivering more consistent, high-quality surgical spine care.

The limitations of this analysis are focused on the geographic information available. Because data were examined at the state-level, small local and regional variations were not able to be accounted for. Having a more detailed level of analysis-at the level of Medicare Hospital Referral Regions, for example-would also have allowed for a more useful comparison with previous studies of geographic variation in spine surgery rates (e.g., Weinstein et al., 2006).

Another limitation is the relatively small number of TDR procedures observed in this limited time span. While this is an uncommon procedure being studied for this very reason, the geographic distribution of its use may be different if it were adopted on a widespread basis by surgeons, patients, and payers. Thus, judgments about geographic variation are being made with only a limited sample of the potential volume of use of the procedure.

In spite of its limitations, the present investigation provides support to the notion that substantive geographic variation exists in the use of lumbar spine surgery, and that

lumbar TDR is no exception. The variation in procedure rates coupled with scientific uncertainty and an unclear reimbursement environment suggest the need for clear and evidence-based practice guidelines for lumbar TDR. Having more definitive standards for when to perform the procedure would likely provide some resolve to scientific uncertainty, create a higher comfort level for health payers considering if and when to reimburse surgeons for the procedure, and minimize the great geographic disparities seen in where the procedure is performed. Though the present body of research on lumbar TDR suggests general inconclusiveness, continued observational and retrospective research such as the present study may provide informative evidence for the development of practice guidelines and reimbursement policy.

CHAPTER V

SUMMARY AND CONCLUSIONS

The revision rate and economic revision burden of the lumbar total disc replacement procedure appear to be holding steady since the introduction of the procedure in the mid-2000s. The prevalence of the procedure, however, has decreased substantially in the wake of inconclusive reviews of the literature and negative or unclear reimbursement policy from health payers. Although lumbar TDR has demonstrated clinical efficacy that is at least equivalent to lumbar fusion for single-level degenerative disc disease, there is uncertainty surrounding the long-term viability of the prosthesis used in TDR and also the risk for complications such as facet joint degeneration or symptomatic adjacent segment disease.

In an inquiry of a very uncommon and rarely investigated procedure, the lumbar TDR hybrid procedure was found to be occurring on a limited basis, with relatively high costs, and for patients diagnosed with multi-level degenerative disease and one or more displaced lumbar discs. Though a very infrequently performed procedure, lumbar TDR hybrids did still make up approximately 16% of the total number of lumbar TDR procedures. This was a surprisingly high proportion considering almost no evidence exists to support its use and that no published practice guidelines in the U.S. could be found that describe the procedure. The hybrid procedure truly represents the investigational nature of lumbar TDR itself, as a large amount of scientific uncertainty, differing surgeon opinions, and interested patients all interact to generate procedural rates and variations that are far greater than those for other surgeries of the lumbar spine.

Last, the procedural rates of lumbar TDR were found to vary substantially by geography. Though only viewed at the State-level, these rates were adjusted for the market supply of orthopaedic and neurosurgical spine surgeons, as well as for the economic variation in Medicare patients. Rates varied from as a high as 11 times the U.S. average to as little as 0 procedures performed in several U.S. states. While this may have been somewhat expected due to the very inconclusive nature of the evidence for lumbar TDR, that was partly the exercise of the study. Wide geographic variation has been seen in other spine surgeries, particularly lumbar fusion. In light of lumbar TDR's greater degree of scientific uncertainty relative to fusion, the geographic variation of the procedure also increased. Such dramatic variation of appropriately adjusted procedure rates suggests great inconsistency in care for patients, and these findings emphasize the need for a more clear and uniform message of practice guidelines and reimbursement policy for lumbar TDR.

A process that could address the issues of scientific uncertainty in lumbar TDR is an outcomes registry covering all procedures performed under all types of payers in the U.S. This has been demonstrated successfully in European markets where it has been done on a voluntary basis (such as for total hip replacement in Sweden [e.g., Malchau et al., 2002]) or as part of a regulatory requirement (for the lumbar TDR procedure in Switzerland; Schluessmann et al., 2009). Registries such as these track not only the procedure and devices involved, but diagnostic indicators, patient outcomes, and economic costs. A procedure as specific and relatively low volume as lumbar TDR could easily be tracked using a nationwide outcomes registry.

As described here and in chapter one, outcomes registry data would be useful in resolving much of the scientific uncertainty about lumbar TDR and also in facilitating more consistent reimbursement policy from public and private health payers. Surgeons, too, could benefit by showing increased accountability to payers and enjoying more confidence in their decision to offer or recommend against particular procedures. Perhaps most importantly, patients could benefit by being directed to procedures that are most appropriate and clinically effective for their particular spine pathology. Considering the cost, volume, and potentially great benefits and harm to patients, gathering complete observational data on the lumbar TDR procedure appears essential to establishing sound practice guidelines and reimbursement decisions.

The present series of studies addresses some of the issues of lumbar TDR as a young surgical intervention with a declining prevalence and an uncertain future. What may be taken away from these studies regardless of the future of lumbar TDR is that these issues-revision burden, economic costs, and real-world effectiveness-are faced by most surgeries of the lumbar spine and there is little observational data to address them. Tools such as complete outcomes registries and studies using existing administrative claims data can help resolve inconclusive data from clinical trials, provide guidance as to the longevity and safety of relevant medical devices, and help direct patients to the best available treatment options for their condition.

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Wheeler, A.J., Gundy, J.G., & DeBerard, M.S. (2012). Predicting compensation and medical costs of lumbar fusion patients receiving workers' compensation in Utah. *Spine, 37*, 605-611.

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Zigler, J., Guyer, R.D., Blumenthal, S., & Ohnmeiss, D.D. (2010, October). *Analysis of re-operations after lumbar disc replacement: Experience in 1,000 consecutive cases beginning with first case experience of 11 surgeons.* Paper presented at the 2010 annual meeting of the North American Spine Society, Orlando, FL.

CURRICULUM VITAE

ANTHONY WHEELER

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PROFESSIONAL SUMMARY

I am a health services researcher with experience developing, conducting, and managing the entire research process. I have particular expertise working with administrative claims and clinical registry data in health care. I have been engaged in economic and patient-reported outcomes studies, as well as meta-analyses and randomized clinical trials. I enjoy collaborating with all stakeholders in health care, including payers, providers, policy makers, and academicians, and I love my work.

EDUCATION

PhD Utah State University, Logan, UT 2013
Dissertation: Procedural Rates, Economic Costs, and Geographic Variation of Primary and Revision Lumbar Total Disc Replacement

MS Utah State University, Logan, UT 2012
Thesis: Pre-surgical Biopsychosocial Variables as Predictors of Medical Costs in Lumbar Fusion Patients Receiving Workers' Compensation

BA Metropolitan State University, St. Paul, MN 2008
Graduated with honors

PROFESSIONAL AND RESEARCH EXPERIENCE

Manager of Payment Policy and Reimbursement, American Academy of Orthopedic Surgeons, Washington, DC 2013 - Present

- Lead the organization's position on reimbursement for orthopedic procedures and related lobbying efforts to government and private health payers
- Act as staff leader of the Academy's health systems, coding, and research committees as liaison to the American Medical Association's Relative Value Update Committee

- Conduct micro- and macroeconomic research to assess trends and shifts in reimbursement policy

Research Consultant, Utah State University, Logan, UT 2010 - Present

- Acted as an independent consultant to top-level academic faculty, building relationships with researchers, graduate students, and staff.

- Led project teams to design new research studies, conduct expert-level analyses, build and manage databases, write research proposals, and present complex findings in a simplified way.

- Simultaneously met stringent reporting, analysis, and data management requirements for externally funded multi-million dollar studies.

- My research has influenced C-level business executives, academicians, physicians, health and education policy makers, higher education administrators, and the judicial system.

Research Consultant, International Survey Associates 2011 - Present

- Conducted data analysis, report writing, and presentations for large-scale census surveys of statewide education systems

- Reported findings to survey company management, public sector policy makers, and peer-reviewed journals

- Performed this high-level work on a completely remote basis working under my own initiative and direction

Graduate Researcher, Utah Spine Research Project, Logan, UT 2009 - 2013

- Independently developed a productive line of research in spine care, chronic pain, and workers' compensation medical management

- Designed, managed, and presented top quality comparative effectiveness and economic evaluation studies using large administrative claims datasets, including nationally representative inpatient data covering 7 million+ patients per year.

- Trained and mentored two new researchers conducting similar research in health services and health economics.

- Built lasting relationships with physicians, administrators, and researchers in academia, medicine, and nursing.

Research Assistant, Metropolitan State University, St. Paul, MN 2007 – 2009

- Assisted in three large-scale meta-analysis research projects. Involved in literature reviews, treatment coding, data analysis, and scholarly writing.

- Trained two research assistants to double research activity.

TECHNICAL SKILLS

Expert: SPSS, MS Office (Excel, Access, Power Point, Word)
Intermediate: SAS, R, Stata, IBM Text Analytics
Basic: Comprehensive Meta-Analysis, EpiInfo, GeoCommons

Statistical Expertise: Regression (linear, logistic, Poisson), longitudinal analyses (hierarchical linear/non-linear modeling, generalized estimating equations), categorical data analyses (ordinal regression, zero-inflated binomial and Poisson regression, multinomial logit models)

PEER-REVIEWED PUBLICATIONS UNDER REVIEW

Gundy, J.G., **Wheeler A.J.**, & DeBerard, M.S. (In submission). Lumbar fusion in Utah workers' compensation patients: Changing outcomes across a decade. *Spine*.

Christensen, T.J., **Wheeler, A.J.**, & DeBerard, M.S. (In re-submission). Functional outcomes of radiofrequency facet neurotomy patients receiving workers' compensation. *The Spine Journal*.

Wheeler, A.J., Bates, S.C. (In submission). Use of Alcohol, tobacco, and marijuana in rural versus urban schools. *Journal of Adolescent Health*.

PEER-REVIEWED PUBLICATIONS

Wheeler, A.J., Smith, A.S., Gundy, J.G., Sautter, T., & DeBerard, M.S. (2012). Back pain in workers' compensation: An introduction for neuropsychologists. *The Clinical Neuropsychologist, 27*, 49-59.

Pratt, K.M., DeBerard, M.S., Davis, J.W., **Wheeler, A.J.**, & Gundy, J.M. (2012). Primary care providers' perception and satisfaction with an integrated healthcare model in a university setting. *Professional Psychology: Research and Practice*. Electronically published ahead of print.

Wheeler, A.J., Gundy, J.M., & DeBerard, M.S. (2012). Using presurgical biopsychosocial variables to predict cost outcomes of patients receiving lumbar fusion via workers' compensation. *Spine, 37,* 605-611.

DeBerard, M.S, **Wheeler, A.J.**, Gundy, J.M., Stein, D.M., & Colledge, A.L. (2011). Presurgical biopsychosocial variables predict medical, compensation, and aggregate costs of lumbar discectomy in Utah workers' compensation patients. *The Spine Journal. 11*, 395-401.

SCHOLARLY PRESENTATIONS

Snyder, M.S., **Wheeler, A.J.**, Grewe, J., Dance, C., & DeBerard, M.S. (2013). *Biopsychosocial Variables Predict Compensation and Medical Costs of Rotator Cuff Surgery in Workers' Compensation Patients*. Poster presented at the 2013 conference of the Society of Behavioral Medicine.

Gundy-Cuneo, J.G., **Wheeler, A.J.**, Potts, S.A., & DeBerard, M.S. (2013). *The Relationship between Pain Acceptance and Functional Outcomes Among Lumbar Fusion Patients*. Poster presented at the 2013 conference of the Society of Behavioral Medicine.

Wheeler, A.J., Christensen, T.J., Smith, A.M., & DeBerard, M.S. (2012). *Using Presurgical Psychological Variables to Predict Compensation and Medical Costs of Radiofrequency Neurotomy Patients Receiving Workers' Compensation*. Poster presented at the 2012 conference of the Society of Behavioral Medicine.

Wheeler, A.J., Gundy, J.M., & DeBerard, M.S. (2010). *Predicting medical and compensation costs in compensated lumbar fusion patients: A look at recent changes.* Paper presented at the 25th annual meeting of the North American Spine Society.

Gundy, J.M., **Wheeler, A.J.**, & DeBerard, M.S. (2010). *Functional outcomes of lumbar fusion patients receiving workers' compensation in Utah.* Paper presented at the 25th annual meeting of the North American Spine Society.

Wheeler, A.J., Gundy, J.M., & DeBerard, M.S. (2010). *Using presurgical psychological variables to predict compensation and medical costs of lumbar fusion patients receiving workers' compensation in Utah.* Poster presented at the 2010 conference of the Society of Behavioral Medicine.

Gundy, J.M., **Wheeler, A.J.**, & DeBerard, M.S. (2010). *Cost effectiveness of nurse case managers and vocational rehabilitation in lumbar fusion workers' compensation patients.* Poster presented at the Society of Behavioral Medicine Conference.

Spielmans, G.I., Benish, S., Marin, C., Bowman, W., Menster, M., & **Wheeler, A.J.** (2009). *Psychological treatment specificity for eating disorders? A meta-analysis of comparative trials.* Poster presented at the 117th conference of the American Psychological Association.

Spielmans, G.I., **Wheeler, A.J.**, and Kennedy-Suttle, A. (2008). *Specificity of psychological treatments for headache? A meta-analysis.* Poster presented at the 116th conference of the American Psychological Association.

INVITED PRESENTATIONS

Update in Medical and Compensation Costs of Utah Lumbar Fusion Patients Receiving Workers' Compensation. Continuing education course for executives and medical staff at the Workers' Compensation Fund of Utah. Sandy, UT. January, 2011.

Reimbursement and Policy Issues in Orthopaedic Clinical Data Registries. Symposium presentation given to physicians and policymakers at the American Joint Replacement Registry Policy Forum. Chicago, IL. March, 2013.

PROFESSIONAL ENGAGEMENT

Member: Workers Compensation Research Group
Society of Behavioral Medicine
Cochrane Review Spine Group

Contributor: Spine Journal: *The Spine Blog*
American Academy of Orthopaedic Surgeons: *Advocacy Now*