Cost Savings Associated with Prevention of Recurrent Lumbar Disc Herniation with a Novel Annular Closure Device: A Multicenter Prospective Cohort Study

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Abstract

Objective Same-level recurrent disc herniation is a well-defined complication following lumbar discectomy. Reherniation results in increased morbidity and health care costs. Techniques to reduce these consequences may improve outcomes and reduce cost after lumbar discectomy. In a prospective cohort study, we set out to evaluate the cost associated with surgical management of recurrent, same-level lumbar disc herniation following primary discectomy.

Methods Forty-six consecutive European patients undergoing lumbar discectomy for a single-level herniated disc at two institutions were prospectively followed with clinical and radiographic evaluations. A second consecutive cohort of 30 patients undergoing 31 lumbar discectomies with implantation of an annular closure device was followed at the same hospitals and same follow-up intervals. Cost estimates for reherniation were modeled on Medicare national allowable payment amounts (direct cost) and patient work-day losses (indirect cost).

Results Annular closure and control cohorts were matched at baseline. By 2 years follow-up, symptomatic recurrent same-level disc herniation occurred in three (6.5%) patients in the control cohort versus zero (0%) patients in the annular closure cohort. For patients experiencing recurrent disc herniation, mean estimated direct and indirect cost of management of recurrent disc herniation was $34,242 and $3,778, respectively. Use of an annular closure device potentially results in a cost savings of $222,573 per 100 primary discectomy procedures performed (or $2,226 per discectomy), based solely on the reduction of reoperated reherniations when modeled on U.S. Medicare costs.

Conclusions Recurrent disc herniation did not occur in any patients after annular closure within the 12-month follow-up. The reduction in the incidence of reherniation was associated with potentially significant cost savings. Development of novel techniques to prevent recurrent lumbar disc herniation is warranted to decrease the associated morbidity and health care costs associated with this complication.

Keywords
- cost
- disc herniation
- annular repair

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Introduction

Lumbar discectomy is the most common surgical procedure performed in the United States for patients experiencing back and leg pain from herniated lumbar discs.[1,2] Although lumbar discectomy results in improvement in bodily pain, physical function, and disability in the vast majority of patients,[2–6] ~10% of patients incur same-level recurrent lumbar disc herniation.[7,8] Additionally, some patients develop progressive degeneration and loss of height of the operative disc space.[9–11] Recurrent disc herniation and/or progressive disc space loss often leads to increased pain and disability, which may necessitate repeat surgery.[11–13]

The reported incidence of same-level recurrent disc herniation following lumbar discectomy varies between 3% and 18% in retrospective studies.[3,7,8,14–16] This wide range is secondary to variations in follow-up time, management paradigms, annular disruption, and surgical technique.[3,7,8,14–16] We recently reported the results of a prospective, controlled, multi-institutional cohort study with standardized sequential imaging for 2 years after lumbar discectomy.[17] This study demonstrated a 10% incidence of symptomatic same-level recurrent disc herniation requiring reoperation.[17] More importantly, this study demonstrated that patients requiring revision discectomy reported worsened disability and quality of life at 2 years, suggesting that recurrent herniation may be associated with both immediate and long-term consequences. These results support the need to develop techniques to prevent recurrent herniation and disc height loss after discectomy.

In addition to its negative impact on disability and quality of life, recurrent disc herniation can also be associated with significant resource utilization and health care cost. Ambrossi et al reported that diagnosis and management of recurrent lumbar disc herniation was associated with a mean cost of $26,593 per patient.[18] Development of novel techniques to prevent recurrent lumbar disc herniation is warranted to decrease the associated morbidity and health care costs associated with this complication. A potential technique to decrease reherniation is annular closure (►**Fig. 1**). Annular closure devices allow for closure of the postdiscectomy annular defect through which recurrent nucleus pulposus herniation can occur. We set out to evaluate the cost associated with surgical management of symptomatic and radiographically confirmed recurrent, same-level lumbar disc herniation following primary discectomy using data from a prospective, nonrandomized, comparison cohort study.

Methods

Patient Selection

A prospective, controlled, nonrandomized comparative cohort study was conducted at two European medical institutions with the primary aim of comparing the 12-month incidence of same-level recurrent disc herniation, disc height loss, and outcome after primary lumbar discectomy between patients receiving implantation of an annular closure device versus those who were not. Secondary end points included perioperative morbidity and postoperative improvement in pain and disability. Following completion of the prospective cohort study, a post-hoc analysis was initiated to evaluate the estimated cost associated with surgical treatment of same-level, recurrent lumbar disc herniation.

Patients undergoing surgical discectomy for a single-level, herniated lumbar disc resulting in radiculopathy between January 2003 and May 2006 were eligible for inclusion in the control cohort. These control cohort patients were a subset of a previously published five-institution study evaluating the effect of annular defect size and disc volume removed on recurrent herniation.[17] These consecutive patients underwent discectomy without any form of annular closure. Patients undergoing surgical discectomy between May 2008 and May 2009 at the same two institutions were eligible for inclusion in the annular closure cohort. These consecutive patients received implantation of the annular closure device (Barricaid, Intrinsic Therapeutics, Woburn, Massachusetts, USA; CE approved) at the completion of the discectomy. Surgeons, institutions, follow-up and all patient care were standardized across both cohorts. The implant study was prospectively approved by the local site Ethics Committees. Changes were made to the implant design and protocol which were submitted for Ethics review following implementation. All patients provided informed consent. The Barricaid cohort was monitored by an independent data safety monitoring board (DSMB).

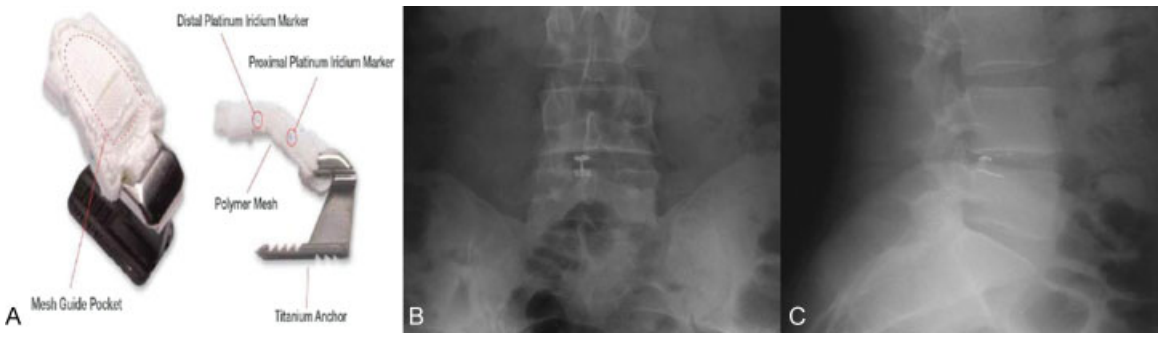

Fig. 1 (A) Illustration depicting the annular closure device. (B) Anterior-posterior and (C) lateral radiographs demonstrating placement of the annular closure device.

To be included in either cohort, a patient had to have (1) failed at least 6 weeks of conservative therapy (or had a neurological deficit for controls), (2) a preoperative magnetic resonance imaging (MRI) study confirming a disc herniation localizing to radicular symptoms, (3) leg pain graded on the visual analog scale (VAS) of at least 40/100, (4) dysfunction graded on the Oswestry Disability Index (ODI) of at least 40/100, and (5) an age of 18 to 70 years.

The only surgery offered to the surgical candidates was a unilateral posterior lumbar discectomy. All patients were evaluated and operated on by the same three surgeons, regardless of cohort.

Patients were excluded if they had (1) a history of a previous back operation, (2) foraminal or extraforaminal disc herniation, (3) an extraspinal cause of sciatica, (4) an active medical or workman's compensation lawsuit, (5) any pre-existing spinal pathology, or (6) were unwilling or unable to participate with follow-up procedures. Patients with notable nonintervertebral disc abnormalities (such as spondylolysis, spondylolisthesis, inflammatory arthritis, or metabolic bone disease) were also excluded.

Surgical Technique

Posterior lumbar discectomy was performed in all cases. All patients received prophylactic antibiotics at incision. In some patients, the discectomy could be performed through the interlaminar space alone. A small unilateral laminotomy was performed in the remaining patients. Medial facetectomy was performed rarely and only if the medial facet was clearly impinging on the nerve root after discectomy. Surgical technique was similar for the annular closure and control cohorts and was performed by the same three surgeons. Disc removal was achieved via sequestrectomy, with disc material deep to the annulus not uniformly removed.

The Barricaid annular prosthesis is a device designed to close defects in the annulus following discectomy and is implanted immediately following the discectomy prior to closure. This device has a titanium anchor that is placed into one of the adjacent vertebral bodies via tamp and mallet. A mesh polymer preassembled to the anchor covers the posterior intervertebral space in the region of the annular defect, overlying the residual physiologic nucleus pulposus. Two platinum-iridium markers within the polymer mesh allow visualization on plain films.

Radiographic Measures

Patients underwent computerized tomography (CT) of the lumbar spine preoperatively and 12 and 24 months after surgery. Patients also underwent MRI of the lumbar spine without contrast preoperatively and 12 and 24 months after surgery. Patients experiencing symptoms indicative of recurrent disc herniation during standardized clinical follow-up between discharge and 24 months after surgery underwent MRI and CT of the lumbar spine at the time of symptom onset to assess for same-level reherniation. X-rays, taken at each follow-up visit, were assessed for device migration, dislodgement and integrity.

Health Care Costs

Direct health care costs associated with surgical management of same-level recurrent lumbar disc herniation were estimated using the macrocosting method. Using 2012 Medicare national allowable payment amounts, hospital costs were modeled against and estimated from the diagnosis related group (DRG) and medical provider professional fees from Current Procedural Terminology (CPT) codes. Per standard cost conversion, private payer costs were estimated at 170% of Medicare fees.[19]

Indirect health care costs were estimated by the standard human capital approach[20] by multiplying the change in hours worked by the gross-of-tax wage rate. For the purposes of this analysis, mean duration of missed work after lumbar discectomy surgery was estimated using the reported value from the SPORT trial (27.7 days),[19] and the 2009 median annual U.S. household income ($49,777) was used as the gross-of-tax wage rate.[21]

Statistical Analysis

Parametric data was expressed as mean $\pm$ standard deviation and compared via the student's *t*-test. Percentages were compared using the two-tailed chi-square tests.

Results

Patient Population

Forty-six patients were enrolled in the control cohort, and 30 patients were enrolled in the annular closure cohort. One patient in the annular closure cohort underwent a two-level discectomy for concurrent herniated discs and received annular closure at both levels. Annular closure versus control cohorts were similar with respect to mean $\pm$ SD age (38 ± 9 versus 41 ± 9 years), weight (83 ± 9 versus 81 ± 12 kg), preoperative disc height (8.6 ± 1.7 versus 8.3 ± 1.3 mm), and preoperative low-back disability (ODI: 63 ± 14 versus 57 ± 13). Preoperative VAS-BP (back pain) (66 ± 17 versus 50 ± 23) and VAS-LP (leg pain) (80 ± 13 versus 69 ± 17) were greater in the annular closure cohort ($p < 0.01$). Levels of disc herniation were similar between the annular closure and control cohorts: L3–4 [0 (0%) versus 2 (4%)], L4–5 [19 (64%) versus 24 (48%)], and L5–S1 [12 (36%) versus 20 (40%)] (►**Table 1**).

Recurrent Disc Herniation

All patients in both cohorts were followed for 24 months for recurrent disc herniation. Recurrent same-level disc herniation occurred in three (6.5%) patients in the control cohort. No patients in the annular closure cohort experienced symptomatic recurrent disc herniation. This difference (0% versus 6.5%) in symptomatic recurrent disc herniation in the annular closure cohort did not reach statistical significance for this sample size ($p = 0.27$).

Cost Associated with Surgical Treatment of Recurrent Disc Herniation

Mean total Medicare direct health care cost associated with recurrent disc herniation was $17,920 (hospital fee: $15,582,

Table 1 Baseline characteristics of annular closure versus control cohorts

Variable	Annular closure ($n = 30$)	Control ($n = 46$)	p Value
Age (years)	38 ± 9	41 ± 9	0.19
Weight (Kg)	83 ± 9	81 ± 12	0.53
L3–4	0 (0%)	2 (4%)	0.52
L4–5	19 (64%)	24 (48%)	0.36
L5-S1	12 (36%)	20 (40%)	0.82
Pre-op disc height (mm)	8.6 ± 1.7	8.3 ± 1.3	0.39

radiology/surgeon fees: $1,800, radiology: $538). Mean total private payer cost was $30,464 (hospital: $26,489, radiology/surgeon fees: $3,060, radiology: $915). Based on the 2011 median annual U.S. household income ($49,777) and established average duration of missed work after lumbar discectomy (27.7 days),[19] the indirect cost associated with surgical management of recurrent disc herniation was estimated as $3,778 per recurrence.

Using U.S. private payer cost estimates, mean total cost of symptomatic same-level recurrent disc herniation was $34,242. Based on the recurrent disc herniation incidence of 6.5% in the control cohort, the estimated cost of recurrent disc herniation per 100 primary discectomy procedures is $222,573. The 6.5% to 0% reduction in recurrent disc herniation with the annular closure device was associated with a cost savings of $222,573 per 100 primary discectomy procedures performed (or $2,226 per discectomy).

Discussion

In this prospective comparison cohort study, there was no device-related morbidity associated with implantation of a novel annular closure device, including durotomy, nerve root injury, and/or post-operative device migration. Although this study was underpowered to observe statistical significance, annular closure was associated with a decrease in the incidence of recurrent disc herniation from 6.5% to 0%. The observed reduction in recurrent herniation was associated with a potentially significant cost savings. Modeled on U.S. private payer costs and missed work, the total (direct + indirect) cost associated with surgical management of symptomatic recurrent disc herniation was found to be $34,242. The reduction in recurrent disc herniation from 6.5% to 0% observed with the annular closure device was associated with an estimated total potential cost savings of $222,573 per 100 primary discectomy procedures performed (or $2,226 per discectomy).

Lumbar discectomy is the most common surgical procedure performed for herniated disc causing back and/or leg pain.[1,2] Many studies have found that this procedure is more effective at improving patient symptoms, disability, and quality of life than other common spine procedures such as lumbar fusion.[22–24] Although the majority of patients experience significant clinical improvement following lumbar decompression, up to 20% of patients may not experience sustained clinical improvement with long-term follow-up.[2–6] This lack of clinical improvement has been attributed to a variety of factors, including disc reherniation, disc height loss, and degeneration.[3,7,8,14–16]

In addition to its negative impact on disability and quality of life, recurrent disc herniation can also be associated with significant resource utilization and health care cost. Using direct billing costs at a single institution, Ambrossi et al reported that the direct cost for treatment of recurrent lumbar disc herniation was $26,593 per patient.[18] Their cost calculations included diagnostic testing ($1,594), conservative therapies ($1,084), and revision discectomy ($23,915). In their study, cost was calculated from actual private payer claims. Their findings of $26,593 were similar to the macrocosting estimates used in this study. In the current study, though European patients were treated, we modeled against Medicare national allowable payments for facility and professional fees based on DRG and CPT coding to establish estimated costs, as private payers negotiate per medical center and practice group, making private payer cost estimations less accurate for a medical center or practice group interpreting this study. Although hospitals routinely negotiate payments anywhere from 120% to 200% of Medicare, 170% has emerged as an accepted macrocosting estimate.[19] Development of novel techniques to prevent recurrent lumbar disc herniation is warranted to decrease the associated morbidity and health care costs associated with this complication.

The limitations inherent in this study have implications for its interpretation. First, though this study represents a multi-institutional prospective European cohort study, the current study analysis was performed in a post-hoc manner. Because we did not capture individual patient resource utilization or missed work, the cost values reported in the current study represent cost estimates. Costs will certainly vary for each health care system analyzed, and this may be influenced by societal/cultural biases. However, in the current study, only direct health care costs were assessed, which are likely less influenced by cultural differences compared with indirect costs. U.S. health care metrics were used, as this is known to be one of the most expensive health care environments with ongoing reform. Although recurrent herniation is considered the most typical complication following discectomy, other sequelae such as disc height loss, disc degeneration, and severe back pain can be expensive as well. Further studies, particularly those from prospective clinical studies and/or

real-world registry databases, are needed to fully characterize the absolute incidence of recurrent disc herniation as well as the associated morbidity and cost of this and other complications. Future analyses should also take into account the effect of treatment on patient quality of life.

Conclusions

Recurrent disc herniation did not occur in any patients after annular closure within the 12-month follow-up period. The reduction in the incidence of reherniation was associated with a potential significant cost savings. Development of novel techniques to prevent recurrent lumbar disc herniation is warranted to decrease the associated morbidity and health care costs associated with this complication.

Conflict of Interest
Dr. Matthew McGirt is a paid consultant of Intrinsic Therapeutics.

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