The Spine Journal 19 (2019) 1170–1179

Clinical Study

Postoperative direct health care costs of lumbar discectomy are reduced with the use of a novel annular closure device in high-risk patients

Jared D. Ament, MD, MPH[a,b,c,*], Bart Thaci, MD[a], Zhuo Yang, PhD[a], Adisa Kursumovic, MD[d], Richard Bostelmann, MD[e], Todd Lanman, MD[b], J. Patrick Johnson, MD[b], Susanne Fröhlich, MD[f], Kee D. Kim, MD[a]

[a] *Department of Neurological Surgery, University of California, Davis, CA, USA*
[b] *Department of Neurosurgery, Cedars Sinai Medical Center, Los Angeles, CA, USA*
[c] *Department of Neurosurgery, Sierra Neuroscience Institute, Los Angeles, CA, USA*
[d] *Department of Neurosurgery, Donauisar Klinikum Deggendorf, Deggendorf, Germany*
[e] *Neurosurgical Clinic, University Hospital Duesseldorf, Duesseldorf, Germany*
[f] *Orthopedic and Poly Clinics, Universitätsmedizin Rostock, Rostock, Germany*

Received 21 September 2018; revised 13 February 2019; accepted 13 February 2019

ABSTRACT

BACKGROUND CONTEXT: Lumbar discectomy is largely successful surgical procedure; however, reherniation rates in patients with large annular defects are as high as 27%. The expense associated with a revision surgery places significant burden on the healthcare system.

PURPOSE: To compare the direct health care costs through 5 years follow-up of conventional discectomy (Control) with those of discectomy supplemented by an adjunctive annular closure device (ACD) in high-risk patients with large annular defects.

STUDY DESIGN: This was a cost-effectiveness study.

METHODS: All-cause index level reoperations were reviewed from a multicenter, randomized controlled superiority trial that allocated 554 high-risk discectomy patients with large annular defects to either control or ACD. Medicare and private insurer (Humana) direct costs were derived from a commercially available payer database to estimate costs in the US healthcare system, including those associated with facility, surgeon, imaging, follow-up visits, physical therapy, and injections. A 50:50 split between Medicare and commercial insurers was assumed for the base case analysis. The analysis was also performed on a 80:20 commercial:Medicare payer basis. For the base case scenario, a 2-year time horizon and outpatient cost setting was established for the index procedure. Repeat discectomy was assumed to be performed on a 60:40 outpatient-to-inpatient basis. Complications requiring surgery, revisions, and/or fusion were assumed to be managed in the inpatient setting. Total costs of reoperation and per-patient costs of reoperation were compared between groups for both forms of insurers. One author received consulting fees of <$50,000 for the completion of this study, and the other eight authors did not have any financial associations with the current work. Funding for this study was provided by Intrinsic Therapeutics, but all analyses, interpretation, and writing were performed independently by the authors.

FDA Device/Drug Note: Not applicable.

Author disclosures: ***JA:*** Consulting: Telos Partners (C), Neuromonics (amount not disclosed). Fees for participation in review activities: Telos Partners (B). Payment for writing/reviewing manuscript: Telos Partners (C). ***BT:*** Nothing to disclose. ***ZY:*** Nothing to disclose. ***AK:*** Consulting: Intrinsic Therapeutics (F). Travel support: Instrinsic Therapeutics (C). Other: Instrinsic Therapeutics (F, paid directly to institution). Research Support: Intrinsic Therapeutics (E, paid directly to institution). ***RB:*** Research Support: Intrinsic Therapeutics (E, paid directly to institution); ***TL:*** Consulting: Medtronic (B). Royalties: Medtronic, Stryker (B). Research Support: Intrinsic Therapeutics (E, paid directly to institution). ***JPJ:*** Nothing to disclose. ***SF:*** Nothing to disclose. ***KDK:*** Royalties: Zimmer Biomet, Precision Spine (F). Board of Directors: Molecular Matrix (none). Grants: Medtronic, Empirical Spine, Orthofix, Vertex, Mesoblast, Zimmer Biomet, InVivo, Fziomed, Seikagaku (H, paid directly to institution).

* Corresponding author. Sierra Neuroscience Institute. 1500 E. Chevy Chase Drive, Suite 204, Glendale CA 91206. Tel: 818-827-3898, Fax 818-827-3897.

E-mail address: jament@sierraneuro.org (J.D. Ament).

https://doi.org/10.1016/j.spinee.2019.02.010

RESULTS: At two years follow-up, use of the ACD reduced the rate of symptomatic reherniations in a large defect population to 13% compared with 25% in the control group (p<.001). This reduction in symptomatic reherniations in the ACD group translated to a savings of $2,802 per patient in direct health care costs compared with Control at 2 years and $5,315 per patient by 5 years based on 50% private and 50% public (Medicare) payer split. Under the scenario of 80:20 private:public insurance reimbursement, the estimated direct cost savings were $3,215 and $6,099 per patient at 2- and 5-years postoperatively, respectively, with the use of the ACD.
CONCLUSIONS: Symptomatic reherniation and reoperation rates were nearly double among control patients compared with ACD-treated patients, which translated to markedly greater per-patient healthcare costs in the control group, where the ACD was not used.

Keywords: Lumbar disc herniation; Cost; Reherniation; Annular closure device; Direct costs; Cost-benefit analysis

Introduction

Lumbar discectomy is the most common surgical treatment for radiculopathy secondary to low back pain. Its widespread adoption is, in part, due to its extremely high success rate [1−4]. Clinical trials examining early symptomatic relief and functional improvement have consistently demonstrated that lumbar discectomy is superior to medical therapy [5]. When compared with conservative therapy, surgery is also highly cost-effective [6].

The lumbar discectomy procedure has undergone several variations since it was first described in 1934 by Mixter and Barr [7]. Utilization of the microscope, tubular systems, and endoscopy have all added to the procedure complexity while decreasing complications, shortening hospital length of stay, and increasing patient satisfaction [8−11]. The most prevalent and costly complication, however, is recurrent herniation that requires reoperation. It is estimated that this occurs in 3%−18% of patients [12,13]. Yet, patients with large annular defects (≥6 mm width) are at a particularly high risk for reherniation, with rates reported as high as 27% and often accompanied by disabling symptoms that significantly affect function and quality of life (QoL) [14−17].

Reherniations requiring additional medical therapies or reoperations dramatically increase the costs to an already strained healthcare system. Although initially costlier than conservative management alone, primary lumbar discectomy remains an established and highly cost-effective treatment strategy [18−20]. For example, in an outpatient setting, approximate Medicare ambulatory direct costs for a lumbar microdiscectomy surgery have been reported to be $10,300 [18]. This surgical cost is quite reasonable given the gain in quality-adjusted life years (QALYs) that far outweighs the gains from conservative treatment alone [18]. However, when accounting for other diagnostic and ancillary services along with reoperation costs, symptomatic lumbar disc reherniation is estimated to cost closer to $26,000−$40,000 [21−23]. This is exacerbated by high rates of dissatisfaction, morbidity, and complications in these patients, challenging the perceived cost-effectiveness defined by the initial surgery [24]. As a result, there has been extensive research into developing novel techniques to decrease the rates of recurrent lumbar disc herniation and, in turn, the associated morbidity and healthcare costs [22,25−28].

An example of one such method is a novel annular closure device (ACD), recently tested in a large multicenter, randomized controlled trial (RCT) (Clinicaltrials.gov Identifier: NCT01283438) [29], and the 2-year results (primary endpoint) were recently published in the spine literature [30]. This device has been evaluated in several clinical studies, repeatedly demonstrating improved clinical outcomes [20,30−33]. The ACD was shown to reduce symptomatic reherniation and reduce reoperation rates when compared with conventional discectomy controls [30,32]. The hypothesis of this study was that direct healthcare costs would be markedly lower among ACD-treated patients compared with control discectomy patients due to the lower incidence of symptomatic reherniations. Therefore, the purpose of this study was to utilize clinical outcomes data from the RCT to estimate the differences in direct healthcare costs between ACD-treated patients and controls based on recent data representing the US healthcare system.

Methods

Study design

The data was obtained from a multicenter, RCT involving patients with chronic radicular leg pain unresponsive to conservative care. The trial was approved by all local ethics committee review boards and was registered with ClinicalTrials.gov (NCT01283438) [29]. All patients signed ethics committee-approved informed consent forms before participation in the trial. This post-hoc direct cost-analysis models patient scenarios from the time of their index lumbar discectomy procedure through 5-years postoperatively, with a focus on the 2-year outcomes to align with the main endpoint of the RCT. Both the ACD and control arms were compared. Primary outcomes included direct costs associated with the index procedure and all reherniations, device- and procedure-related complications, and revision procedures. Numerous examples of the methodology used for this type of analysis are available in the literature [34−36].

Participants

Patients were eligible for inclusion and randomization if they presented with image-confirmed, single-level disc herniation between L1 and S1, with a posterior disc height ≥5 mm and a history of unresponsiveness to conservative care of ≥6 weeks duration. A principal inclusion criterion was the presence of a large annular defect after discectomy, defined as ≥6 mm wide. Patients were excluded if they had: previous back surgery at the index level, foraminal or extraforaminal disc herniation, extraspinal cause of sciatica, pre-existing spinal pathology, bone mineral density with a t-score less than −2.0 (for subjects requiring DEXA), scoliosis of more than 10°, or other abnormalities such as spondylolysis or spondylolisthesis that would potentially interfere with the surgical procedure.

Randomization

Eligible patients were randomized intraoperatively following discectomy (if an annular defect ≥6 mm wide was present) using a web-based platform that allowed for real-time computer-generated random treatment assignment. Patients were randomized 1:1 to receive either discectomy with the ACD or discectomy alone.

Annular closure device

The Barricaid annular closure device (Intrinsic Therapeutics, Inc., Woburn, MA, USA) is an implantable device used as an adjunct to lumbar discectomy. The device serves to occlude the annular defect, retaining the nucleus pulposus within the normal anatomical disc space. The use of this device has been described previously [30]. In brief, the device consists of a rigid titanium bone anchor to ensure proper fixation of the device to the selected adjacent vertebral body, and a flexible polymer mesh that occludes the annular defect and prevents subsequent migration of the nuclear material (Fig. 1). A radiopaque platinum-iridium marker is embedded in the occlusion component and is visible on radiographs, allowing for visualization and proper placement during implantation.

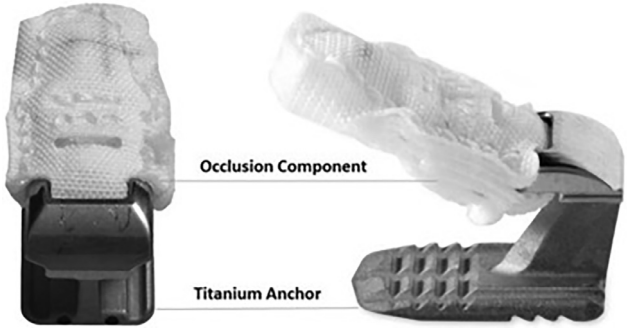

Fig. 1. Barricaid® annular closure device.

Surgical interventions

An operative microscope or surgical loupes were used to perform discectomy via the interlaminar transflaval approach [37]. The randomization process was finalized following removal of the herniated disc material and defect measurement. Annular defect height and width was measured with graduated defect measurement instruments, and if the defect was between 4 and 6 mm in height and 6–10 mm in width, the patient was eligible for randomization and no further disc material was removed. For patients randomized to the control group, the discectomy procedure was concluded using standard closure techniques. For those randomized to the ACD group, the bone-anchored ACD was inserted under fluoroscopic control.

Costs

For the purposes of this study, only direct healthcare costs were evaluated. A societal perspective (including indirect costs related to return-to-work) was considered only in the sensitivity analysis. Direct medical costs included, but were not limited to, operating room time, facility and/or hospital stay, postoperative medications, physical therapy, epidural steroid or facet injections, reoperations for symptomatic reherniations, diagnostic imaging, follow-up visits (scheduled and unscheduled), and surgery-related complications. Data on these clinical events and utilization of resources were gathered from the RCT and costs were estimated for the US healthcare system based on private and public claims data.

Humana and Medicare 2014 claims data were collected from a commercially available payer database (PearlDiver). Humana claims included payments covered by the national insurer Humana Inc. Medicare claims included payments covered by The Centers for Medicare and Medicaid services. Humana and Medicare were considered to represent nationwide commercial and public payer data, respectively. Payer reimbursements were abstracted for pertinent diagnosis-related group for inpatient scenarios, Ambulatory Payment Classifications for outpatient scenarios, and Current Procedural Terminology codes for relevant procedures and services (Table 3).

With respect to medication costs, the type and number of medications taken immediately postoperatively were assumed to differ from later follow-up periods. For medications missing a start date, the middle of the month (ie, the 15th) was imputed. Data were cross-referenced with the 2011 Redbook MarketScan to calculate medication costs [38]. The Redbook file contains the average wholesale price for all drugs assigned a national drug code. Cost was estimated at 85% of average wholesale price. This multiplier was based on Medicare's 2010 reimbursement rate for medications. After 2010, Medicare changed to an average sales price reimbursement method that is not publicly available. Ancillary costs associated with recurrence and/or complications and/or revisions, including follow-up office visits, epidural steroid injections, spine imaging

(computed tomography and/or magnetic resonance imaging) and physical therapy were classified together as *conservative therapy total* (Table 3). Scheduled office visits were those occurring at 6 weeks, and at 3, 6, 12, 24, 36, 48, and 60 months postoperatively.

To understand the cost-benefit over time for patients receiving the ACD compared with conventional discectomy within the US healthcare system, a scenario-based model was utilized, which included the following cost-related assumptions: (1) all index operations occurred in the outpatient setting; (2) patient population was split 50:50 based on their insurance status (Commercial vs. Medicare); and (3) repeat discectomies were performed on a 60% inpatient-basis and 40% outpatient-basis [39]. The index procedure costs were assumed to be identical in the ACD and control groups (ACD device cost was not included) in order to focus on direct comparisons of postoperative care. All cost inputs were adjusted for inflation to 2017 US dollars by using the U. medical care Consumer Price Index [40].

Statistical analysis

Descriptive statistics were calculated and recorded as means and standard deviations. Comparisons between groups were made using the independent t-test, assuming unequal variances, for continuous data and Fisher's exact test for categorical data. The expected complication and reoperation rates beyond 2 years were estimated based on the number of events divided by the person-months beyond 2 years. Univariate scenario and multivariate probabilistic sensitivity analyses were also conducted to examine the uncertainty and generalizability of the model. In the univariate analysis, all parameters were varied by ±20% from their baseline. In the multivariate probabilistic sensitivity analysis, 1,000 simulations of cost differences were examined at 90 days, 1 year, 2 years, and 5 years postoperatively. An alternate payer mix scenario of 80% Commercial and 20% Medicare was also considered (Table 5). Statistical significance was set, *a priori*, at p<.05.

Results

A total of 554 patients who underwent surgery for lumbar discectomy between 2010 and 2014 were included in the initial RCT and in this cost analysis. Patients were randomized into the ACD (N=276) or control (N=278) groups. The 2-year postoperative milestone was completed for all patients and follow-up compliance through 2 years was 91% in the ACD group and 93% in the control group. Considering that the trial is ongoing and not all patients have reached 5 years of follow-up at the time of this analysis, 5-year data was only available for 40% of ACD patients and 39% of control patients. There were no significant differences amongst the groups. Mean age was 43 years old, with 59% male population and body mass index of 26 (Table 1). All patients had a single level intervention and most patients required surgery at L4–L5 and L5–S1 interspaces (96%–98%).

Table 1
Patient characteristics

Characteristic	ACD (N=276)	Control (N=278)
Age, (mean±standard deviation)	43 ± 11	44 ± 10
Male sex, no (%)	156 (57)	171 (62)
Body mass index, (kg/m^2)	26 ± 4	26 ± 4
Smoking history, no (%)	173 (64)	175 (63)
Index level — no (%)		
L2–L3	2 (1)	1 (<1)
L3–L4	8 (3)	5 (2)
L4–L5	123 (45)	101 (36)
L5–S1	139 (51)	171 (62)
Disk height, mm (mean±standard deviation)	8.9 ± 2.1	8.9 ± 2.2

At 6 months follow-up, 13% of the control group had experienced a symptomatic recurrent disc herniation compared with 6% in the ACD group (p=.005). By 2 years, 25% of patients in the control group experienced a symptomatic reherniation at the index level compared with only 13% in the ACD group (p<.001). There were 61 reoperations in 45 patients in the control group and 29 reoperations in 24 patients in the ACD group through 2 years. Both groups had a similar proportion of patients (4%; p=.99) requiring fusion procedures after recurrent disc herniation. Other complications also differed between groups. In the control group, three patients required surgical intervention for epidural hematomas, three required surgery for wound infections, and two required pain stimulator placement for intractable pain. In contrast, the ACD group reported only one wound debridement and no epidural hematomas or stimulators (Table 2).

The estimated 2-year direct costs associated with the ACD and control groups were $11,488 and $14,290 per patient, respectively (Table 4; Fig. 2B). Considering the index procedure costs were assumed to be identical in the ACD and control groups, the $2,802 difference in per-patient costs was attributable to the additional complications and reoperations required in the control group. By 5 years, the estimated cost savings increased to $5,315 per patient with ACD treatment.

Sensitivity analysis

A greater cost benefit of the ACD is realized when the payer distribution is shifted from 50% Commercial and 50% Medicare to 80% Commercial and 20% Medicare (Table 5). At 2- and 5-years, for example, the cost savings

Table 2
Surgical complications

Surgical interventions	ACD, N (%)	Control, N (%)	p Value
Recurrent herniation	10 (3.6)	36 (12.9)	<.0001
Recurrence with fusion	10 (3.6)	11 (4.0)	.99
Epidural hematoma	0 (0)	3 (1.1)	.25
Wound infection	1 (0.4)	3 (1.1)	.62
Implantation of stimulator	0 (0)	2 (0.7)	.50

Table 3
Estimated costs for interventions, by Payer Type

	Medicare, $	Humana, $
Index operation outpatient		
Medicare - PT × 2 sessions	122.85	93.04
Medicare - MRI	203.84	791.94
Medicare - CT	146.26	140.33
Medicare - Injection × 2	132.34	290.66
APC 5114 (Medicare)	5,219.36	7,150.52
Medicare - Surgeon	578.63	1,938.61
Total	6,403.28	10,405.10
Recurrence discectomy outpatient		
Medicare - Conservative therapy	892.49	1,621.35
APC 5114 (Medicare)	5,219.36	7,150.52
Medicare - Surgeon	578.63	1,938.61
Total	6,596.24	10,710.48
Recurrence discectomy inpatient		
Medicare - Conservative therapy	892.49	1,621.35
Medicare - DRG 519	10,290.00	15,526.14
Medicare - Surgeon	578.63	1,938.61
Total	11,666.88	19,086.10
Recurrence with fusion		
Medicare - Conservative therapy	892.49	1,621.35
Medicare DRG 459/460	30,945.65	49,760.12
Medicare - Surgeon	619.60	2,034.79
Total	32,363.50	53,416.26
Epidural hematoma		
Medicare - Conservative therapy	892.49	1,621.35
Medicare - DRG 920	6,327.00	7,402.00
Medicare - Surgeon	424.06	1,279.62
Total	7,549.31	10,302.97
Wound infection		
Medicare - Conservative therapy	892.49	1,621.35
Medicare - DRG 856	16,948.88	24,177.83
Medicare - Surgeon	424.06	1,279.62
Total	18,171.18	27,078.81
Implantation of stimulator		
Medicare - Conservative therapy	892.49	1,621.35
Medicare - DRG 029	20,946.67	34,262.00
Medicare - Surgeon	142.00	492.00
Total	21,886.91	36,375.35
Ancillary costs		
MRI CPT-73221	203.84	791.94
CT Scan CPT-77217	146.26	140.33
Epidural steroid injection CPT-62311	132.34	290.66
Physical therapy CPT-97530	122.85	93.04
Unscheduled office visit CPT-99215	192.96	305.38
Conservative therapy total	892.49	1,621.35

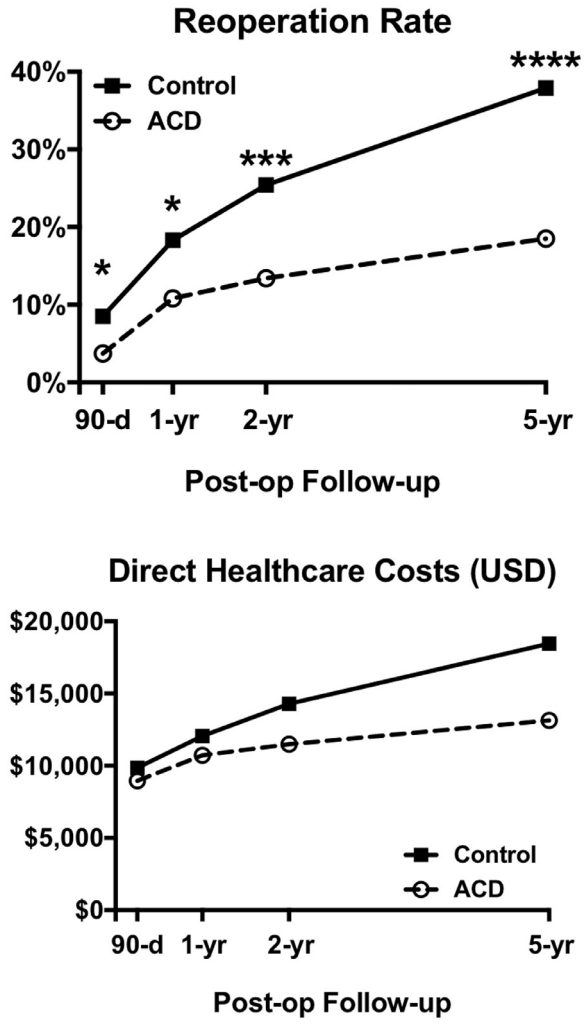

Fig. 2. Reoperation rates and direct healthcare costs were significantly lower among ACD-treated patients compared to Control. * p<.05, *** p<.001, **** p<.0001 by Fisher's exact test.

increase $3,215 and $6,099 per patient, respectively. When return-to-work (societal perspective) is considered, the cost benefit occurs earlier in the postoperative course and is of greater magnitude in all scenarios (Tables 4 and 5).

In the one-way sensitivity analysis, reherniation rates and fusion costs in the control group had the greatest impact on cost (Fig. 3). In 89.3% of the multivariate probabilistic simulations, the ACD group costs less than the control at 90 days (Fig. 4A). This increases to 93.8%, 99.8%, and 100% at 1, 2, and 5 years, respectively (Fig. 4B–D).

Some of the reoperations observed in the RCT may have been disproportionate between the ACD and control groups by chance (ie unrelated to the difference in treatment). These may include hematomas, infections, and spinal cord stimulator placement. In the base case analysis, the costs were increased in the control group by an average of $96 per patient for hematomas (3%), $162 per patient for infections (6%), and $210 per patient for stimulators (7%). The base case analysis observed a cost difference of +$2,802 for the control group at 2 years. If the ACD group and control group were matched for reoperations on hematomas, infections, and stimulators, the control group costs would exceed those of the ACD group by $2,334 at 2 years.

Discussion

The prevalence of back pain is increasing with the aging population and, as a result, inflation-adjusted expenditures increased 129% in less than a decade since 2000, with small subsets of patients carrying the majority of costs [41]. For lumbar disc herniation, conservative therapy remains the

Table 4
Base case cost comparison (50/50 Medicare/Humana) for different postsurgical lengths and from health system (direct medical cost only) and societal (direct medical cost + productivity loss) perspectives

	With ACD		Control		Difference
	Reoperations (%)	Costs ($)	Reoperations (%)	Costs ($)	Costs ($)
Health system perspective					
90 day	3.7	8,955.60	8.5	9,864.60	909.00
1 year	10.8	10,722.40	18.3	12,057.50	1,335.10
2 years	13.4	11,488.20	25.4	14,290.10	2,801.90
5 years	18.5	13,140.80	37.9	18,455.30	5,314.50
Societal perspective					
90 day	3.7	15,929.30	8.5	16,869.90	940.60
1 year	10.8	29,035.60	18.3	30,890.00	1,854.40
2 years	13.4	43,027.10	25.4	48,102.80	5,075.70
5 years	18.5	83,639.30	37.9	95,895.00	12,255.70

Table 5
Alternate payer scenario: 80% commercial and 20% medicare

	With ACD		Control		Difference
	Reoperations (%)	Costs ($)	Reoperations (%)	Costs ($)	Costs ($)
Health system perspective					
90 days	3.7	10,257.70	8.5	11,299.20	1,041.50
1 year	10.8	12,297.30	18.3	13,803.00	1,505.70
2 years	13.4	13,138.90	25.4	16,353.70	3,214.80
5 years	18.5	15,001.40	37.9	21,100.10	6,098.70
Societal perspective					
90 days	3.7	17,231.40	8.5	18,304.50	1,073.10
1 year	10.8	30,610.50	18.3	32,635.50	2,025.00
2 years	13.4	44,677.80	25.4	50,166.40	5,488.60
5 years	18.5	85,499.90	37.9	98,539.80	13,039.90

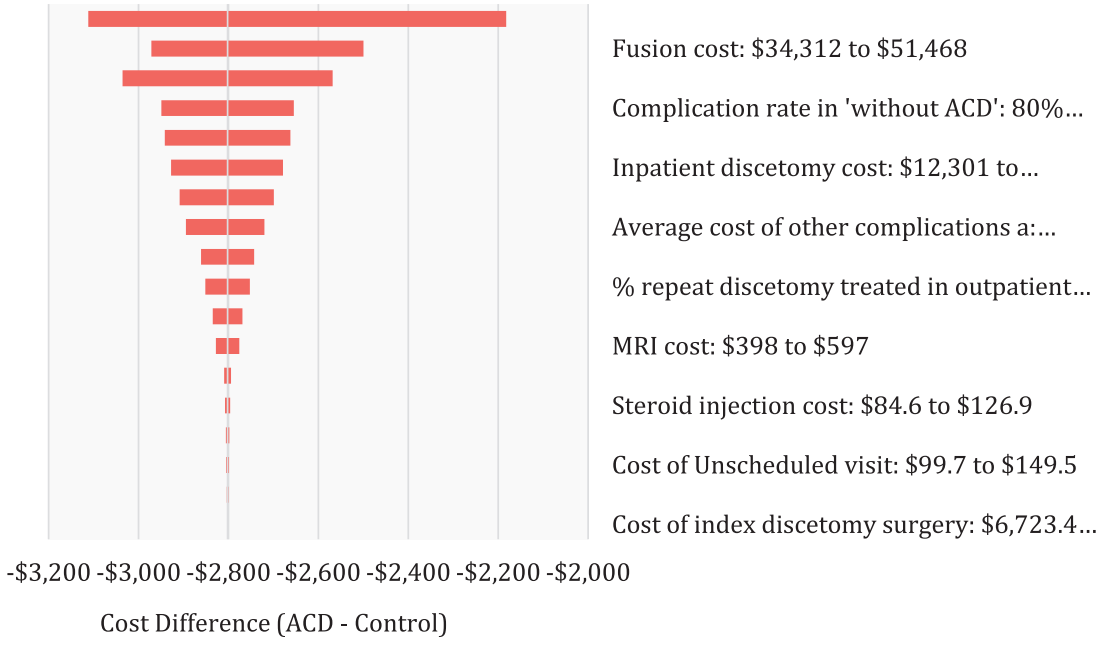

Fig. 3. Tornado diagram of 2-year cost difference between ACD and control groups.

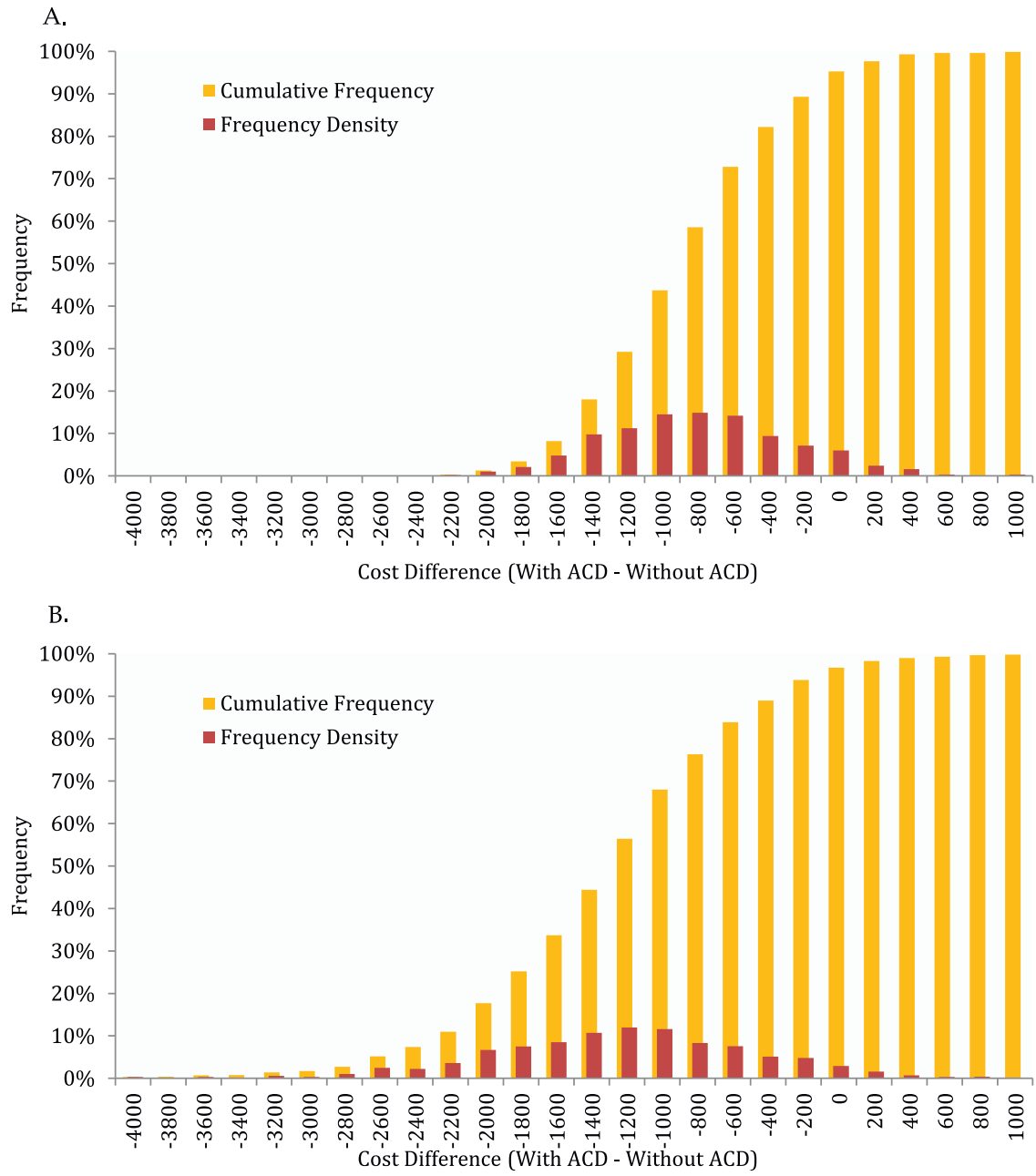

Fig. 4. Probabilistic sensitivity analysis on cost difference for base case patient population (50/50 Commercial/Medicare) from a health system perspective, based on 1,000 simulations. 90-day cost-difference (A), 1-year cost difference (B), 2-year cost difference (C), 5-year cost difference (D).

first-line strategy for patients without neurological deficits. For patients that remain symptomatic, two primary management options exist: prolonged conservative therapy or lumbar discectomy. Continued conservative therapy circumvents surgery in 50%–60% of instances [5]. Patients who fail, however, often progress to needing delayed surgery.

Reherniation-related reoperation costs are significant and place substantial stress on the healthcare system. It is estimated that $17 billion is spent annually on the readmission of medical and surgical patients in the US. Reducing these costs has become a critical and necessary societal goal [42]. In this analysis, the cost of treating recurrent lumbar disc herniations made up 32% of the total cost of treating these patients. As such, strategy to minimize the rate of reoperations is paramount for improving patient outcomes as well as healthcare resource utilization. In this analysis of direct costs, the ACD reduced reherniations and reoperations, resulting in a net savings compared with control. The cost benefit was realized early (90 days postoperatively) and increased over time.

The direct costs associated with uncomplicated traditional lumbar discectomy correlate well with other observations.

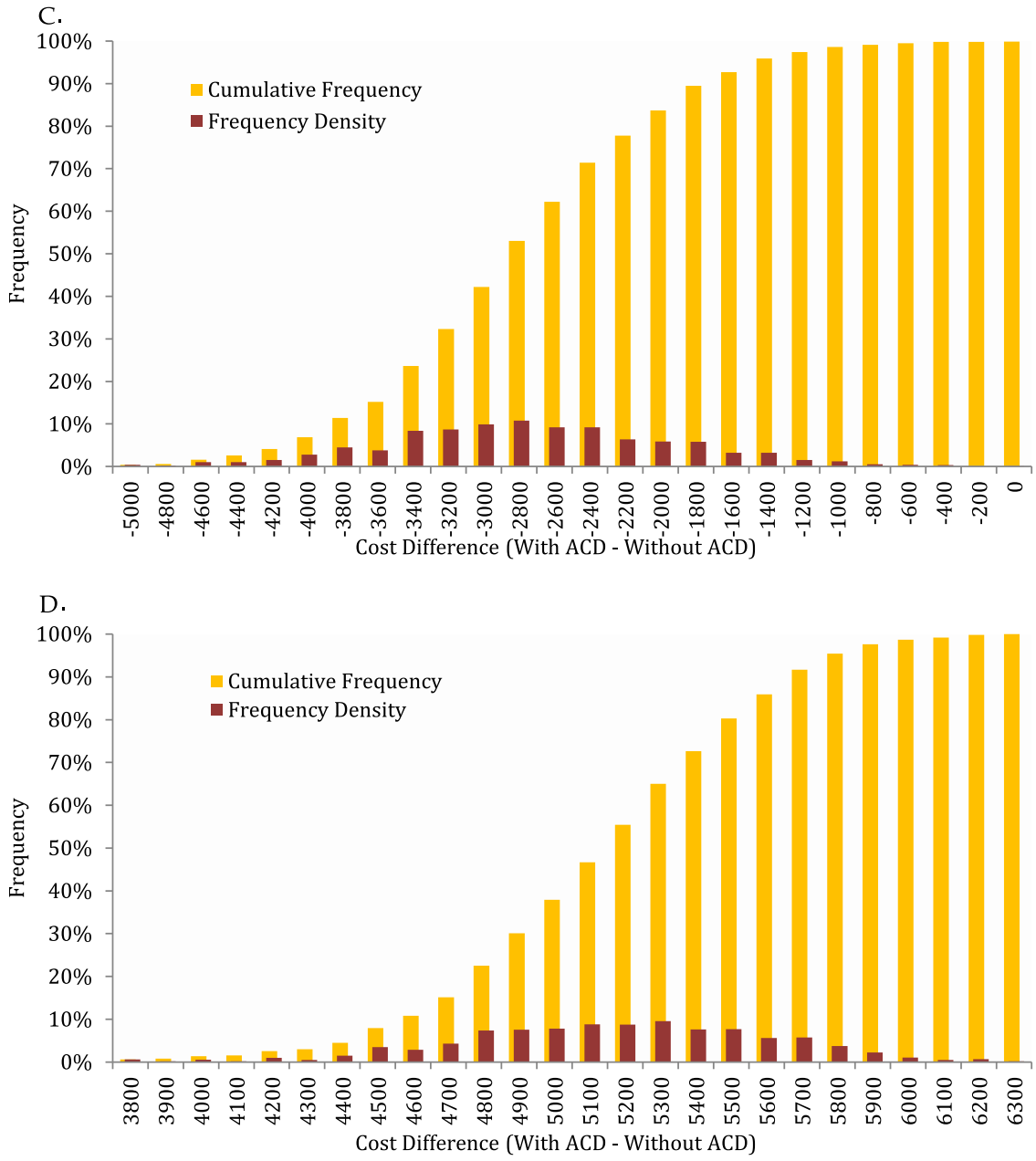

Fig. 4 Continued.

We found conventional discectomy surgery to cost $5,200–$7,100 according to 2017 adjusted Medicare and Humana reimbursement rates, falling within the range of other published reports [6,43]. Hansson et al. examined the cost-utility of lumbar discectomy by QALYs in patients who had surgery versus conservative therapy [18]. Despite surgery initially carrying substantially greater costs than conservative management, it resulted in a 10-fold improvement in quality of life. This therefore yielded an incremental cost-effectiveness ration of $4,648/QALY, which is well within the accepted US-threshold for cost-effectiveness of $100,000/QALY [43–45]. Despite this, the high recurrence rates associated with lumbar discectomy surgery, particularly in the high-risk patient populations, continues to challenge this "cost-effectiveness" argument.

Reherniation incidence rates vary in the literature. Risk factors have been reported to include age >50, body mass index >25, Modic end-plate changes, quantity of disc removed, and annular integrity after discectomy (eg, annular defect size) [12,14,15,46,47]. Aggressive discectomy mitigated recurrent herniation rates at 2 years but was associated with worse back pain; the opposite was true for limited discectomy [12,47]. Large annular defects (≥6 mm wide) are also associated with higher rates of reherniation [14,16,17]. These high-risk patients with larger annular defects were the focus of this RCT, which observed a

dramatic reduction in symptomatic reherniation rates when the ACD was utilized. Similarly, Parker et al. reported zero reherniations in a smaller cohort of ACD patients over 2-years and Bouma et al. found that only 1.4% of their 75-patient series with the ACD had symptomatic reherniations [48,49]. In an early report from this RCT, Klassen et al. observed a 40% reduction in reherniation rates with the ACD within the first 90 days, postoperatively [16].

With costs between $26,593 and $39,836 for the diagnostics, ancillary services, and overall management of lumbar disc reherniations that require reoperation, the importance of preventive technologies is clear [48]. Parker et al found that using the ACD resulted in a net savings of $2,226 per discectomy, over 2 years [48]. Similarly, in this analysis, the direct cost savings at 2 years was estimated to be $2,802; at 5 years, the estimated direct cost savings increased to $5,314. Although costs associated with disability and quality of life were beyond the scope of this manuscript, it is likely that the reduction in reherniations (and its associated symptoms) as well as secondary surgical interventions (instrumented fusion in some cases) would further amplify the cost-benefit of the ACD.

This study should be interpreted in the context of several limitations. The device cost was not considered in this analysis because, in part, this device is currently investigational and prices have yet to be determined. Based on the data provided from this analysis, it is easy to assess the effect of adding in the device cost for break-even analyses or other interpretations. For example, if the device cost is assumed to be $3,000, the net average cost would be +$198 ($3,000−$2,802 in postoperative savings) in the ACD group over 2 years and a net average savings of $2,315 over 5 years ($3,0000−$5,315 in postoperative savings). However, it is also important to consider that any net costs could be well justified to prevent further patient morbidity and socioeconomic costs by avoiding recurrent symptomatic herniation and associated reoperations.

In addition, one author's economic corporation received consulting fees of <$50,000 for the completion of this study, and the other eight authors did not have any financial associations with the current work. Although funding from Intrinsic Therapeutics was provided to support the completion of this study, the analysis, interpretation, and conclusions were reviewed by all authors to ensure integrity. Also, though the 2-year patient data is complete, the study is still ongoing and the long-term results (eg, 5 years) are based on current follow-up data that represent approximately 40% of the study population. The patient cohorts were limited to RCT data that had strict inclusion criteria with respect to disc height and annular defect size. Therefore, these findings may not be generalizable to patients with smaller defects or disc heights. Additionally, although randomized, this study was not blinded, leading to potential expectation bias. Finally, the model assumptions and imprecision associated with predicted savings, along with the reliance on Medicare and Humana reimbursement rates, clearly limits the external validity. Yet, the robust sensitivity analysis provides some estimates of the inherent uncertainty and, overall, corroborates the robustness of the conclusions.

Conclusions

Use of the ACD reduced estimated costs over time by decreasing index-level reherniations and complications. As early as 90 days postoperatively, a cost benefit was appreciated. This realization continued to improve over time, resulting in substantial cost savings through 5 years. When novel technologies, such as this ACD, reduce complications, morbidity and costs over time, they are worthy of careful consideration for utilization.

Acknowledgement

The authors would like to thank Dr. Wimar van den Brink for his support and efforts in data collection.

Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.spinee.2019.02.010.

References

[1] Gray DT, Devo RA, Kreuter W, et al. Population-based trends in volumes and rates of ambulatory lumbar spine surgery. Spine 2006;31:1957–63.
[2] Deyo RA, Weinstein JN. Low back pain. N Engl J Med 2001;344:363–70.
[3] Li XC, Zhong CF, Deng GB, et al. Full-endoscopic procedures versus traditional discectomy surgery for discectomy: a systematic review and meta-analysis of current global clinical trials. Pain Physician 2016;19:103–18.
[4] Wang XS, Sun RF, Ji Q, et al. A meta-analysis of interlaminar minimally invasive discectomy compared to conventional microdiscectomy for lumbar disk herniation. Clin Neurol Neurosurg 2014;127:149–57.
[5] Peul WC, van Houwelingen HC, van den Hout WB, et al. Surgery versus prolonged conservative treatment for sciatica. N Engl J Med 2007;356:2245–56.
[6] Tosteson AN, Skinner JS, Tosteson TD, et al. The cost effectiveness of surgical versus nonoperative treatment for lumbar disc herniation over two years: evidence from the Spine Patient Outcomes Research Trial (SPORT). Spine (Phila Pa 1976) 2008;33:2108–15.
[7] Mixter W, Barr J. Rupture of the intervertebral disc with involvement of the spinal canal. N Eng J Med 1934;211:210–5.
[8] Williams RW. Microlumbar discectomy: a conservative surgical approach to the virgin herniated lumbar disc. Spine (Phila Pa 1976) 1978;3:175–82.
[9] Koebbe CJ, Maroon JC, Abla A, et al. Lumbar microdiscectomy: a historical perspective and current technical considerations. Neurosurg Focus 2002;13:E3.
[10] Choi KC, Kim JS, Lee DC, et al. Percutaneous endoscopic lumbar discectomy: minimally invasive technique for multiple episodes of lumbar disc herniation. BMC Musculoskelet Disord 2017;18:329.
[11] Overdevest GM, Peul WC, Brand R, et al. Tubular discectomy versus conventional microdiscectomy for the treatment of lumbar disc herniation: long-term results of a randomised controlled trial. J Neurol

Neurosurg Psychiatry 2017 (online first: https://doi.org/10.1136/jnnp-2016-315306.
[12] McGirt MJ, Ambrossi GLG, Datoo G, et al. Recurrent disc herniation and long-term back pain after primary lumbar discectomy: review of outcomes reported for limited versus aggressive disc removal. Neurosurgery 2009;64:338–44.
[13] Yorimitsu E, Chiba K, Toyama Y, et al. Long-term outcomes of standard discectomy for lumbar disc herniation. Spine J 2001;26:652–7.
[14] Carragee EJ, Han MY, Suen PW, et al. Clinical outcomes after lumbar discectomy for sciatica: the effects of fragment type and anular competence. J Bone Joint Surg Am 2003;85-A:102–8.
[15] Carragee EJ, Spinnickie AO, Alamin TF, et al. A prospective controlled study of limited versus subtotal posterior discectomy: short-term outcomes in patients with herniated lumbar intervertebral discs and large posterior anular defect. Spine J 2006;31:653–7.
[16] Kim KT, Lee DH, Cho DC, Sung JK, Kim YB. Preoperative risk factors for recurrent lumbar disk herniation in L5-S1. J Spinal Disord Tech 2015;28:E571–7.
[17] Miller LE, McGirt MJ, Garfin SR, Bono CM. Association of annular defect width after lumbar discectomy with risk of symptom recurrence and reoperation: systematic review and meta-analysis of comparative studies. Spine 2018;43:E308–15.
[18] Hansson E, Hansson T. The cost-utility of lumbar disc herniation surgery. Eur Spine J 2007;16:329–37.
[19] Mummaneni PV, Whitmore RG, Curran JN, et al. Cost-effectiveness of lumbar discectomy and single-level fusion for spondylolisthesis: experience with the NeuroPoint-SD registry. Neurosurg Focus 2014;36:E3.
[20] Tatar M, Senturk A, Dalgali Y. Cost-effectiveness of use of barricaid (r) in lumbar discectomy surgery in Turkey. Value Health 2014;17:A380.
[21] Ambrossi GLG, McGirt MJ, Sciubba DM, et al. Recurrent lumbar disc herniation after single-level lumbar discectomy: incidence and health cost analysis. Neurosurgery 2009;65:574–8.
[22] Guan J, Ravindra VM, Schmidt MH, et al. Comparing clinical outcomes of repeat discectomy versus fusion for recurrent disc herniation utilizing the N(2)QOD. J Neurosurg Spine 2017;26:39–44.
[23] O'Donnell JA, Anderson JT, Haas AR, et al. Treatment of recurrent lumbar disc herniation with or without fusion in workers' compensation subjects. Spine (Phila Pa 1976) 2017;42:E864–70.
[24] Fritzell P, Knutsson B, Sanden B, et al. Recurrent versus primary lumbar disc herniation surgery: patient-reported outcomes in the Swedish spine register swespine. Clin Orthop Relat Res 2015;473:1978–84.
[25] Buchmann N, Preu A, Gempt J, et al. Outcome after surgical treatment for late recurrent lumbar disc herniations in standard open microsurgery. World Neurosurg 2016;89:382–6.
[26] Mamuti M, Fan S, Liu J, et al. Mini-open anterior lumbar interbody fusion for recurrent lumbar disc herniation following posterior instrumentation. Spine (Phila Pa 1976) 2016;41:E1104–14.
[27] Qi L, Li M, Si H, et al. The clinical application of "jetting suture" technique in annular repair under microendoscopic discectomy: a prospective single-cohort observational study. Medicine (Baltimore) 2016;95:e4503.
[28] Suh BG, Uh JH, Park SH, et al. Repair using conventional implant for ruptured annulus fibrosus after lumbar discectomy: surgical technique and case series. Asian Spine J 2015;9:14–21.
[29] Klassen PD, Hes R, Bouma GJ, et al. A multicenter, prospective, randomized study protocol to demonstrate the superiority of a bone-anchored prosthesis for anular closure used in conjunction with limited discectomy to limited discectomy alone for primary lumbar disc herniation. Int J Clin Trials 2016;3:120.
[30] Thomé C, Klassen PD, Bouma GJ, et al. Annular closure in lumbar microdiscectomy for prevention of reherniation: a randomized clinical trial. Spine J 2018;18:2278–87.
[31] Hahn BS, Ji GY, Moon B, et al. Use of annular closure device (Barricaid(R)) for preventing lumbar disc reherniation: one-year results of three cases. Kor J Neurotr 2014;10:119–22.
[32] Parker SL, Grahovac G, Vukas D, et al. Effect of an annular closure device (Barricaid) on same-level recurrent disk herniation and disk height loss after primary lumbar discectomy: two-year results of a multicenter prospective cohort study. Clin Spine Surg 2016;29:454–60.
[33] Trummer M, Eustacchio S, Barth M, et al. Protecting facet joints post-lumbar discectomy: barricaid annular closure device reduces risk of facet degeneration. Clin Neurol Neurosurg 2013;115:1440–5.
[34] Kevin J, et al. Health care technology assessment. Basic Principles and clinical applications. JBJS 2004;86:1305–14.
[35] Callaghan J, et al. Symposium: introducing new technology into orthopedic practice. How should it be done. JBJS 2005;87:1146–58.
[36] Congressional Budget Office Publication. Research on the comparative effectiveness of medical treatments: issues and options for an expanded federal role. Congress of the United States, Congressional Budget Office Publication Number 2975.Washington, DC. 2007. Available at: http://www.cbo.gov/ftpdocs/88xx/doc8891/12-18-ComparativeEffectiveness.pdf.
[37] Spengler DM. Lumbar discectomy. Results with limited disc excision and selective foraminotomy. Spine (Phila Pa 1976) 1982;7:604–7.
[38] Marketscan. Commercial Claims and Encounters and Medicare Supplemental Databases 2015. Available at: http://redbook.com/redbook/awp//. Accessed September 6, 2017.
[39] Pugely AJ, Martin CT, Gao Y, Mendoza-Lattes S. Causes and risk factors for 30-day unplanned readmissions after lumbar spine surgery. Spine (Phila Pa 1976) 2014;39:761–8.
[40] Bureau of Labor Statistics. Medical Consumer Price Index. Washington, DC: Bureau of Labor Statistics; 2016. Available at http://www.bls.gov/cpi/cpifact4.htm. Accessed September 1, 2017.
[41] Smith M, Davis MA, Stano M, Whedon JM. Aging baby boomers and the rising cost of chronic back pain: secular trend analysis of longitudinal medical expenditures panel survey data for years 2000 to 2007. J Manipul Physiol Therapeu 2013;36:2–11.
[42] Bernatz JT, Anderson PA. Thirty-day readmission rates in spine surgery: systematic review and meta-analysis. Neurosurg Focus 2015;39:E7. https://doi.org/10.3171/2015.7.FOCUS1534.
[43] Hansson E, Hansson T. The cost-utility of lumbar disc herniation surgery. Eur Spine J 2007;16:329–37.
[44] Neumann PJ, Cohen JT, Weinstein MC. Updating cost-effectiveness—the curious resilience of the $50,000-per-QALY threshold. N Engl J Med 2014;371:796–7.
[45] Final Value Assessmetn Framework for 2017-2019 – ICER. Available at: https://icer-review.org/.
[46] Yao Y, Liu H, Zhang H, et al. Risk Factors for the recurrent herniation after microendoscopic discectomy. World Neurosurg 2016;95:451–5.
[47] Ambrossi GL, McGirt MJ, Sciubba DM, et al. Recurrent lumbar disc herniation after single-level lumbar discectomy: incidence and health care cost analysis. Neurosurgery 2009;65:574–8. discussion 8.
[48] Parker SL, Grahovac G, Vukas D, et al. Cost savings associated with prevention of recurrent lumbar disc herniation with a novel annular closure device: a multicenter prospective cohort study. J Neurol Surg A Cent Eur Neurosurg 2013;74:285–9.
[49] Bouma GJ, Barth M, Ledic D, et al. The high-risk discectomy patient: prevention of reherniation in patients with large anular defects using an anular closure device. Eur Spine J 2013;22:1030–6.