ClinicoEconomics and Outcomes Research

Dovepress
open access to scientific and medical research

Open Access Full Text Article

ORIGINAL RESEARCH

Comparison of the costs of nonoperative care to minimally invasive surgery for sacroiliac joint disruption and degenerative sacroiliitis in a United States commercial payer population: potential economic implications of a new minimally invasive technology

This article was published in the following Dove Press journal:
ClinicoEconomics and Outcomes Research
24 May 2014

Stacey J Ackerman[1]
David W Polly Jr[2]
Tyler Knight[3]
Karen Schneider[4]
Tim Holt[5]
John Cummings Jr[6]

[1]Covance Market Access Services Inc., San Diego, CA, USA; [2]University of Minnesota, Orthopaedic Surgery, Minneapolis, MN, USA; [3]Covance Market Access Services Inc., Gaithersburg, MD, USA; [4]Covance Market Access Services Inc., Sydney, Australia; [5]Montgomery Spine Center, Orthopedic Surgery, Montgomery, AL, USA; [6]Community Health Network, Neurosurgery, Indianapolis, IN, USA

Correspondence: Stacey J Ackerman
Covance Market Access Services Inc.,
10300 Campus Point Drive, Suite 225,
San Diego, CA 92121-1511, USA
Tel +1 858 352 2498
Fax +1 858 200 1498
Email stacey.ackerman@covance.com

Introduction: Low back pain is common and treatment costly with substantial lost productivity and lost wages in the working-age population. Chronic low back pain originating in the sacroiliac (SI) joint (15%–30% of cases) is commonly treated with nonoperative care, but new minimally invasive surgery (MIS) options are also effective in treating SI joint disruption. We assessed whether the higher initial MIS SI joint fusion procedure costs were offset by decreased nonoperative care costs from a US commercial payer perspective.

Methods: An economic model compared the costs of treating SI joint disruption with either MIS SI joint fusion or continued nonoperative care. Nonoperative care costs (diagnostic testing, treatment, follow-up, and retail pharmacy pain medication) were from a retrospective study of Truven Health MarketScan® data. MIS fusion costs were based on the Premier's Perspective™ Comparative Database and professional fees on 2012 Medicare payment for Current Procedural Terminology code 27280.

Results: The cumulative 3-year (base-case analysis) and 5-year (sensitivity analysis) differentials in commercial insurance payments (cost of nonoperative care minus cost of MIS) were $14,545 and $6,137 per patient, respectively (2012 US dollars). Cost neutrality was achieved at 6 years; MIS costs accrued largely in year 1 whereas nonoperative care costs accrued over time with 92% of up front MIS procedure costs offset by year 5. For patients with lumbar spinal fusion, cost neutrality was achieved in year 1.

Conclusion: Cost offsets from new interventions for chronic conditions such as MIS SI joint fusion accrue over time. Higher initial procedure costs for MIS were largely offset by decreased nonoperative care costs over a 5-year time horizon. Optimizing effective resource use in both nonoperative and operative patients will facilitate cost-effective health care delivery. The impact of SI joint disruption on direct and indirect costs to commercial insurers, health plan beneficiaries, and employers warrants further consideration.

Keywords: epidural injection, iFuse, economic model, sacroiliac joint fusion, sacroiliac joint pain, insurance

Introduction

Low back pain (LBP) is a common condition, with 28.1% of adults in the US reporting to have experienced LBP within the previous 3 months.[1] The prevalence of chronic

submit your manuscript | www.dovepress.com
Dovepress
http://dx.doi.org/10.2147/CEOR.S63757

LBP has increased from 3.9% in 1992 to 10.2% in 2006.[2] National estimates of direct costs for chronic LBP in the US have been between $12.2 billion and $90.6 billion based on a systematic review.[3] Back pain treatment was the eighth most expensive medical condition in a national analysis of US private health insurance spending.[4] The total economic burden, including lost productivity and decreased wages, associated with LBP in the US ranges between an estimated $60 billion and $200 billion annually.[5,6] Of adults in the US labor force, 70.2% receive employer-based health insurance.[7] As such, both private health insurers and employers have a vested interest in maintaining a healthy and productive workforce.[8]

Chronic LPB is commonly caused by the sacroiliac (SI) joint.[9] The prevalence of SI joint pain among patients with chronic LBP is estimated to range from 15% to 30%, although not all of these patients with SI joint pain require surgery.[9,10] The prevalence of an *International Classification of Diseases*, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis of SI joint disruption and/or degenerative sacroiliitis has been reported as 0.9% among privately insured individuals in the US.[11] To diagnose the SI joint as the pain generator, three or more positive provocation tests are required, followed by an image-guided diagnostic injection confirming the SI joint as the source of pain; also, an immediate pain reduction of 50% or greater after a local anesthetic injection is required to confirm that the pain is generated from the SI joint.[12,13] SI joint pain has traditionally been treated with either nonoperative care or open SI joint arthrodesis surgery. Methods of nonoperative care include epidural injections, physical therapy, pain medications, radiofrequency ablation, and pain medications. Despite the fact that these nonoperative therapies are less invasive, they are of limited benefit because they do not address the fundamental cause of the pain but rather only relieve the symptoms of SI joint pain. Despite these limitations, nonoperative care such as epidural steroid injections, as well as facet joint and sacroiliac joint interventions, increased an average of 16.5% annually from 2000 to 2008.[14] When SI joint pain is unmanageable with nonoperative therapies, open SI joint arthrodesis has been the only alternative. Unfortunately, open SI joint surgery is invasive, requiring bone harvesting and large incisions, and necessitates hospital stays and lengthy periods of non-weight bearing.[15–17]

To address the need for additional treatment options for patients with SI joint pain, several minimally invasive surgery (MIS) arthrodesis systems have been developed. Minimally invasive surgical procedures achieve permanent linkage by inserting implants to stabilize the SI joint affected by SI joint disruption and/or degenerative sacroiliitis. MIS systems involve a smaller incision size and do not require bone grafting, which in turn curtails hospital length of stay and recovery time. Recent studies of MIS have demonstrated their clinical safety and effectiveness, including 4-year safety surveillance from a database of 5,319 MIS-treated patients and two retrospective studies of 12- and 40-month follow-up, respectively.[19–21] Despite the advent of new MIS technologies and techniques, the economic implications of new MIS SI joint treatments have not yet been explored from a US private health insurance perspective. This economic model evaluates the cost to the US commercial payer of MIS SI joint fusion compared to continued nonoperative care in patients with chronic LBP caused by SI joint disruption and degenerative sacroiliitis. We assessed whether and over what period of time the higher initial MIS SI joint fusion procedure costs were offset by decreased nonoperative care costs.

Methods

This research was performed according to guidelines (GPP2) established to minimize conflict of interest in pharmacoeconomic studies.[22,23] The coauthors of the present study (clinicians and methodologists) formed a multidisciplinary panel that provided the framework for the economic analysis and made all decisions about the model inputs, assumptions, analyses, and interpretation of the results.

The economic model was used previously to compare the costs of MIS SI joint fusion to nonoperative care for the treatment of SI joint disruption in the hospital inpatient setting among the US Medicare population (beneficiaries 65 years of age and older). The methods described below are similar to those in the previously published model.[24] The methods are repeated herein, with relevant adaptations for the US commercial payer population. The economic model estimated the cost differential (2012 US dollars [USD]) associated with treating commercially insured patients with MIS SI joint fusion in the hospital inpatient and hospital outpatient settings compared to the cost of nonoperative care in the same patients. The cost differential to the commercial insurer (that is, difference in total insurance payments) was estimated by subtracting the cost of treating patients with MIS SI joint fusion from the cost of nonoperative care among commercial insurance beneficiaries. Data from multiple sources were incorporated in the economic model. These sources include Truven Health MarketScan® (Truven

Health Analytics Inc., Ann Arbor, MI, USA) data, Premier's Perspective™ Comparative Database (Charlotte, NC, USA) data, the published literature, and clinical expert judgment. The costs included in the analysis were medical treatments, follow-up care, diagnostic tests, and retail pharmacy pain medication. The base-case analysis simulated the cost differential over a period of 3 years. This time period was selected based on the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Task Force recommendation of a 1- to 5-year time horizon for budget impact analyses for the United States.[25] Furthermore, a 3-year time horizon was selected to correspond with the available 3-year Truven Health commercial payer data to avoid extrapolation assumptions in the base-case analysis. Outcomes were discounted at 3.0% per annum and are reported in 2012 USD.

Assumptions

As previously noted, the assumptions described below are similar to those in the previously published economic model among the US Medicare population.[24] The primary assumptions are repeated herein, with relevant adaptations for the US commercial payer population: 1) the base-case analysis applies only to commercially insured patients in the US who suffer from chronic LBP due to SI joint disruption and degenerative sacroiliitis and who are eligible for MIS; 2) this analysis applies to unilateral MIS procedures performed in the hospital inpatient or hospital outpatient settings; 3) MIS patients who were classified as clinical failures undergo additional treatment, as described in Table 1, where MIS treatment failure was defined as having one or more of the following: implant failure, loosening, and/or malpositioning; failure to relieve pain requiring repeat intervention; and/or infection requiring reoperation; 4) MIS patients who were classified as clinical successes incur minimal additional medical resources, such as a reduced class of pain medications or a reduced dose; 5) late complications of MIS such as infection or loosening requiring revision were reflected in the 1-year treatment failure rate for MIS; 6) the health-related quality-of-life (HRQoL) effects of MIS and nonoperative care have not been included in the present analysis; 7) the indirect costs associated with lost productivity and intangible costs of pain and suffering related to treatment morbidity have not been included in the present analysis; and 8) the analysis assumed that a single cohort of patients were followed over several years with no new patients entering or leaving the cohort in subsequent years.

Not all patients with SI joint pain and dysfunction necessarily have chronic pain and dysfunction despite medical intervention. However, it remains unknown how many patients truly seek care as little data exist on the effectiveness of nonoperative treatment. To estimate the population size, we assumed the percentage of SI joint disruption patients who experience chronic pain despite medical treatment strategies is 50%. Further, not all patients with SI joint pain and dysfunction are candidates for surgery. Because illness precludes some patients from general anesthesia, we have assumed that 95% of patients are eligible for MIS.

Medical resource utilization and costs: nonoperative care

The medical resource utilization and costs associated with nonoperative care was sourced from a previously published health insurance claims data analysis using the Truven Health MarketScan® database.[11,26] In this US commercial payer population (N=78,533), the mean age was 45.2 years (SD [standard deviation] 12.6) and approximately two-thirds (63.7%) were female. The most common diagnoses were sacroiliac subluxation (33.9%), followed by sacroiliitis (25.7%), and disorders of the sacrum (25.0%). These data represent commercial insurance payments (including retail pharmacy), which increased year-over-year. The cumulative commercial payer costs of beneficiaries with SI joint disruption and/or degenerative sacroiliitis at 1, 2, and 3 years were \$6,418, \$11,540, and \$16,789 per patient, respectively (inflated from 2011 to 2012 USD using the Medical Care component of the Consumer Price Index).[27] In the subgroup of patients who underwent lumbar spinal fusion (0.6%), the cumulative commercial payer costs at 1, 2, and 3 years were \$37,456, \$62,104, and \$95,081 per patient, respectively (2012 USD). In the subgroup of patients who did not undergo lumbar spinal fusion (99.4%), the cumulative commercial payer costs at 1, 2, and 3 years were \$6,246, \$11,259, and \$16,354 per patient, respectively (2012 USD).

Medical resource utilization and costs: minimally invasive surgery

The sources of parameter estimates are shown in Table 1 and include the Premier database and Medicare claims data. Previously, 50 patients treated with MIS (iFuse Implant System®; SI-BONE, Inc.)[28] experienced early and sustained clinically significant improvements in HRQoL (seven of nine domains) at 12-month follow-up.[29] At a mean follow-up of 40 months post-implant, the majority (82%) had a >2 point change in pain score,[20] which is the criteria for minimal

Table 1 Minimally invasive surgery values used in the economic model

Description	Value	Source
Percent of SI joint disruption patients with chronic pain despite medical treatment strategies	50%	CP (assumed 50% symptom resolution)
Percent of SI joint disruption patients who are eligible for MIS surgery	95%	CP (assumed 5% too ill for general anesthesia)
Percentage of MIS procedures performed in the hospital inpatient setting	84%	Morgan 2013[17]
MIS treatment success rate (treatment failure rate) in year 1	82% (18%)	Rudolf 2012,[20] Sachs 2013,[21] Miller 2013[19]
Percentage of MIS procedures with clinical, device-related, or procedure-related events	3.8%	Miller 2013[19]
Percentage of MIS failures that receive a repeat MIS procedure	10%	Miller 2013[19] (10% × 18% treatment failure rate =1.8% MIS SI joint fusion revisions)
Percentage of MIS failures that are managed with lumbar spinal fusion	35%	CP
Percentage of MIS failures managed with nonoperative care	55%	CP
Percentage of patients after MIS procedure with follow-up visits in the physician's office at 6 weeks, 3 months, and 6 months	100%	CP. Follow-up visits at 6 weeks and 3 months were assumed to fall under a 90-day global period for CPT 27280
Percentage of patients after MIS procedure with follow-up visits in the physician's office at 1 year	90%	CP
Percentage of patients after MIS procedure with follow-up visits in the physician's office at 2 years	80%	CP
Percentage of patients after MIS procedure receiving a four-view (AP, inlet, outlet, lateral) x-ray examination at each follow-up visit	100%	CP
Percentage of patients receiving a CT exam without contrast at the 6 month follow-up visit after MIS procedure	18%	CP (corresponds to MIS treatment failure rate)
Percentage of patients after MIS procedure that receive physical therapy twice a week for 12 weeks	100%	CP
Percentage of patients after MIS procedure that receive physical therapy twice a week for an additional 12 weeks following the first 12 weeks	18%	CP (corresponds to MIS treatment failure rate)
Percentage of patients in the 1st year after MIS procedure that have residual pain and receive a therapeutic injection of SI joint	18%	CP (corresponds to MIS treatment failure rate)
Percentage of patients in the 1st year after MIS procedure with an emergency room visit for uncontrolled pain	2%	CP
Percentage of patients after MIS procedure that received chiropractic manipulation, acupuncture, prolotherapy, pain stimulators, RF ablation, or any lumbar discography	0%	CP
Percentage of patients after MIS procedure that received a therapeutic injection (facet block, trigger point, or epidural steroid injection) in another joint	30%	CP. 10% each for facet block, trigger point, and epidural steroid injection
Percentage of patients after MIS procedure using oxycodone (5 mg q4h) for 2 months	50%	CP
Percentage of patients after MIS procedure using Vicodin (5 mg q4h) for 2 months	50%	CP
Percentage of patients after MIS procedure using gabapentin (300 mg q3h) for 6 months	5%	CP
Percentage of patients after MIS procedure with a hospital outpatient visit for pain treatment	40%	CP. Half coded as new patients and half coded as established patients
Percentage of patients who continue using oxycodone (5 mg q4h) for 2 months each year following year 1	0.748%	Miller 2013[19] (2.2% of patients with complaint of pain ×34% beyond 1 year =0.748%)
Percentage of patients who continue using Vicodin (5 mg q4h) for 2 months each year following year 1	0.748%	Miller 2013[19] (2.2% of patients with complaint of pain ×34% beyond 1 year =0.748%)
Percentage of patients who continue using gabapentin (300 mg q3h) for 6 months after MIS procedure each year following year 1	0.748%	Miller 2013[19] (2.2% of patients with complaint of pain ×34% beyond 1 year =0.748%)
Percentage of patients after MIS procedure with a therapeutic injection of SI joint in years 2 and 3	10%	CP

Note: Vicodin (manufactured for AbbVie Inc., North Chicago, IL, USA by Halo Pharmaceuticals Inc., Whippany, NJ, USA).
Abbreviations: AP, anterior-posterior; CP, clinical panel; CPT, Current Procedural Terminology; CT, computed tomography; DRG, diagnosis-related group; MIS, minimally invasive surgery; MPFS, Medicare physician fee schedule; OPPS, 2012 outpatient prospective payment system final rule; q3h, every 3 hours; q4h, every 4 hours; SI, sacroiliac.

clinically important difference.[29] Similarly, a clinically significant improvement was observed in all but one patient at 1-year follow-up in a retrospective analysis of 40 patients with MIS treatment using the same device.[21] Thus, an 82% 1-year treatment success rate for MIS was assumed for the economic model.

Sacroiliac joint fusion with MIS is performed in both the hospital inpatient (84%) and hospital outpatient (16%) settings.[30] The MIS index stay was defined as the hospital stay during which the patient underwent the MIS SI joint fusion. The cost of the MIS index stay was sourced from the Premier database, which contains a descriptor field that identifies a MIS SI joint fusion device (Table 2). The cost of the MIS index stay reflects hospital costs during the stay in which a unilateral MIS SI joint fusion procedure (with the iFuse Implant System in particular) was performed between January 2010 and February 2013 for patients with commercial insurance. The MIS index stay costs include costs associated with managing clinical, device-related, or procedure-related events that occurred during the index stay or within the assumed 90-day global period. Global periods are typically negotiated with commercial payers on a facility-by-facility basis. MIS procedures with clinical, device-related, or procedure-related events following the index stay and 90-day global period yet during year 1 are reflected in the costs associated with MIS revisions or other subsequent treatments such as lumbar spinal fusion or nonoperative care. Among commercially insured patients, the mean costs of hospital inpatient and hospital outpatient MIS SI joint fusion procedures (from a total of eleven sites) were estimated to be \$18,710 (N=24) and \$18,580 (N=9), respectively (2012 USD). These figures represent the actual costs for the hospital to provide the care to the patients from a hospital cost-accounting perspective and, therefore, do not reflect the cost to the commercial payer via insurance payments. To inflate hospital-based costs to commercial insurance payments, these figures were multiplied by 1.25 based on recent publications reporting the relationship between US Medicare fee-for-service payments and hospital costs for orthopedic procedures.[31,32]

The Medicare professional fee for the MIS procedure (\$1,033.38) was based on the 2012 payment for Current Procedural Terminology code 27280 (arthrodesis, sacroiliac joint – including obtaining graft);[33] it was then multiplied by 1.25 based on the 2011 Medicare Payment Advisory Commission report to Congress, which reports the relationship between Medicare and commercial payer professional fees.[34]

The medical resource use associated with follow-up care for MIS SI joint fusion (including pain medications) was sourced from Ackerman et al,[24] with relevant adaptations for the commercial payer population (Table 1). Given that Current Procedural Terminology global periods are negotiated with commercial payers on a facility-by-facility basis, two physician office visits in year 1 were assumed to be included under the postsurgical global period and would not incur additional cost, according to guidance and regulations issued by Centers for Medicare and Medicaid Services.[35,36] Follow-up costs were again multiplied by 1.25 to reflect commercial insurance payments.[31,32]

Sensitivity analysis

Similar to a previously described economic model that compares costs of nonoperative care to MIS among Medicare beneficiaries,[24] sensitivity analyses were performed in the present commercial payer analysis to determine the consequences of making alternative assumptions for model parameters, including: the inclusion of ICD-9-CM code 721.3 (lumbosacral spondylosis); the setting of care (hospital inpatient versus hospital outpatient); the durability of the MIS treatment success rate at year 1 (inclusive of the percentage of MIS procedures with clinical, device-related, or procedure-related events); the distribution of subsequent treatments for MIS failures; the MIS index stay costs; the multiplier to convert hospital costs for the MIS index stay to estimated commercial insurer payments; the percentage of patients with lumbar spinal fusions performed within 1 year before receiving a diagnosis of SI joint disruption and/or degenerative sacroiliitis;[37] the time horizon; and the discount rate for extrapolation. The robustness of the model results was assessed by varying the model inputs over plausible ranges to reflect realistic scenarios.

For the sensitivity analysis conducted on the time horizon of the model, assumptions for extrapolation were made. Specifically, the cumulative cost of nonoperative care was assumed to increase linearly from year 4 to year 10. The ongoing costs associated with MIS in year 4 to year 10 of the economic model were assumed to be the costs of pain medications and continued nonoperative care among MIS treatment failures; these ongoing costs were assumed to remain constant over time.

In addition, two threshold analyses were performed: 1) to estimate at what year cost neutrality was achieved following the MIS index stay; and 2) to estimate the MIS index stay commercial insurer payment that results in cost neutrality for the overall group by year following the MIS index stay. Cost neutrality is achieved when the cost of nonoperative care equals the cost of MIS.

Of note, for the base-case analysis, we adjusted the commercial payer population size to reflect patients who suffer from chronic LBP due to SI joint disruption and

Table 2 Minimally invasive surgery: estimated commercial insurance payment used in the economic model (2012 USD)

Description	Value	Source
Cost of the MIS index stay (hospital inpatient)	$23,388	Premier database. Multiplier from: Healy et al;[31] Rana et al.[32] Commercial hospital inpatient payment =1.25× hospital inpatient costs for commercially-insured patients ($18,710).
Cost of the MIS index stay (hospital outpatient)	$23,225	Premier database. Multiplier from: Healy et al;[31] Rana et al.[32] Commercial hospital outpatient payment =1.25× hospital outpatient costs for commercially-insured patients ($18,255).
Professional fee for the MIS procedure and for the lumbar spinal fusion procedure	$1,292	2012 CPT 27280. MPFS Relative Value Units File, July 2012. Multiplier from: MedPac 2011. Commercial payment =1.25× Medicare payment ($1,033.38).
Follow-up office visits unit cost	$90	Average of 2012 CPT codes 99212, 99213, 99214, MPFS Relative Value Units File, July 2012. Multiplier from: Healy et al;[31] Rana et al.[32] $72 multiplied by 1.25.
Pelvic X-ray unit cost	$70	Average of 2012 CPT codes 72170, 73500, 73510, 73520, MPFS. Relative Value Units File and OPPS Addendum B, July 2012. Multiplier from: Healy;[31] Rana et al.[32] $56 multiplied by 1.25.
CT without contrast unit cost	$457	Average of 2012 CPT codes 72131, 72132, 72133, 72192, 72193, 72194, 72195, 72196, 72197, 72198, OPPS Addendum B, July 2012. Multiplier from: Healy et al;[31] Rana et al.[32] $366 multiplied by 1.25.
Physical therapy unit cost	$39	Average of 2012 CPT codes 90901, 95831, 95851, 95852, 97001, 97002, 97010, 97032, 97110, 97112, 97116, 97124, 97140, 97150, 97530, 97535, OPPS Addendum B, July 2012. Multiplier from: Healy et al;[31] Rana et al.[32] $31 multiplied by 1.25.
Emergency room visit unit cost	$204	Average of 2012 CPT codes 99281, 99282, 99283, 99284, 99285, OPPS Addendum B, July 2012. Multiplier from: Healy et al;[31] Rana et al.[32] $163 multiplied by 1.25.
Lumbar spinal fusion unit cost	$35,648	Weighted average of 2012 estimated national average payments for DRGs 459 and 460. 2012 National Average DRG estimated payment based on actual CMS DRG payment data. Percentage of patients with DRG 459 (spinal fusion except cervical with major complication or comorbidity) and DRG 460 (spinal fusion except cervical without major complication or comorbidity): based on Miller[19] 2013 (3.8% of patients with clinical, device-related, or procedure-related events). Multiplier from: Healy et al;[31] Rana et al.[32] DRG 459 payment: $46,700, DRG 460 payment: $27,800, DRG 459 %: 3.8%. DRG 460 %: 96.2%=$28,518 multiplied by 1.25.
Therapeutic injection of SI joint unit cost	$214	2012 CPT code 27096, MPFS Relative Value Units File, July 2012. Multiplier from: Healy et al;[31] Rana et al.[32] $172 multiplied by 1.25.
Facet block unit cost	$159	Average of 2012 CPT codes 64490–64495, MPFS Relative Value Units File, July 2012. Multiplier from: Healy et al;[31] Rana et al.[32] $127 multiplied by 1.25.
Trigger point injection unit cost	$72	Average of 2012 CPT codes 20552, 20553, MPFS Relative Value Units File, July 2012. Multiplier from: Healy et al;[31] Rana et al.[32] $58 multiplied by 1.25.
Epidural steroid injection unit cost	$220	Average of 2012 CPT codes 62310, 62311, 64479, 64484, 77003, MPFS Relative Value Units File, July 2012. Multiplier from: Healy et al;[31] Rana et al.[32] $176 multiplied by 1.25.
Oxycodone 5 mg unit cost	$0.06	WAC price for generic, Thomson Reuters Redbook Online. Multiplier from: Healy et al;[31] Rana et al.[32] $0.05 multiplied by 1.25.
Vicodin 5 mg unit cost	$0.08	WAC price for generic, Thomson Reuters Redbook Online. Multiplier from: Healy et al;[31] Rana et al.[32] $0.06 multiplied by 1.25.

(*Continued*)

Table 2 (*Continued*)

Description	Value	Source
Gabapentin 300 mg unit cost	$0.18	WAC price for generic, Thomson Reuters Redbook Online. Multiplier from: Healy et al;[31] Rana et al.[32] $0.14 multiplied by 1.25.
Hospital pain clinic unit cost	$207	Average of 2012 CPT codes 99201, 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215, OPPS Addendum B July 2012. Multiplier from: Healy et al;[31] Rana et al.[32] $166 multiplied by 1.25.

Note: Vicodin (manufactured for AbbVie Inc., North Chicago, IL, USA by Halo Pharmaceuticals Inc., Whippany, NJ, USA).
Abbreviations: CPT, Current Procedural Terminology; DRG, diagnosis-related group; MIS, Minimally invasive surgery; MPFS, Medicare physician fee schedule; OPPS, outpatient prospective payment system; USD, United States dollars; CMS, Centers for Medicare and Medicaid Services; WAC, wholesale acquisition cost.

degenerative sacroiliitis who are eligible for MIS. Sensitivity analyses were performed for the percentage of patients with chronic pain and the percentage of patients who are eligible for MIS surgery.

Results

In the overall group, the estimated cumulative 3-year commercial insurance payments for patients treated with nonoperative care were $16,339 per patient compared to $30,884 per patient for MIS, resulting in a per-patient differential of $14,545 as shown in Table 3. For patients with lumbar spinal fusion (N=553), the per-patient differential was $54,817, due to higher cumulative 3-year costs for nonoperative care of $92,470 per patient compared to cumulative 3-year costs for MIS at $37,653 per patient. For patients without lumbar spinal fusion (99.4% of the sample population), the per-patient differential of $14,931 was similar to that of the overall group.

Sensitivity analyses

Sensitivity analyses were performed to address uncertainty in the economic model and to determine which variables substantially affected the results. When key model parameters were varied, such as the durability of MIS treatment success at year 1 and the percentage of MIS procedures with clinical, device-related, or procedure-related events, the costs fell within a relatively narrow range, suggesting that the economic model is robust to plausible parameter values based on realistic clinical scenarios. As expected, the results were sensitive to extending the time horizon, modifying the MIS index stay costs, and changing the multiplier to convert hospital costs for the MIS index stay to estimated commercial insurance payments (Table 4 and Figure 1). The results were less sensitive to changes in the distribution of subsequent treatments for MIS failures, setting of care, and discount rate.

In the base-case analysis that evaluated cumulative 3-year costs, the differential in commercial insurance payments

Table 3 Commercial payer population results from the economic model, cumulative 3-year and 5-year costs, excluding ICD-9-CM diagnosis code 721.3 (2012 USD)

Parameter	Overall	Patients with lumbar spinal fusion	Patients without lumbar spinal fusion
Cumulative 3-year costs			
Per-patient cost of nonoperative care	$16,339	$92,470	$15,916
Per-patient cost of MIS	$30,884	$37,653	$30,846
Per-patient differential (cost of nonoperative care – cost of MIS)	($14,545)	$54,817	($14,931)
Differential per 100,000 beneficiaries[a]	($6,218,073)		
Cumulative 5-year costs			
Per-patient cost of nonoperative care	$25,673	$143,166	$25,019
Per-patient cost of MIS	$31,810	$42,674	$31,749
Per-patient differential (cost of nonoperative care – cost of MIS)	($6,137)	$100,493	($6,730)
Differential per 100,000 beneficiaries[a]	($2,623,464)		

Notes: Parentheses indicate negative values (where MIS is more costly than nonoperative care). [a]Prevalence of SI joint disruption and degenerative sacroiliitis (0.9%) based on Truven Health MarketScan (Truven Health Analytics Inc., Ann Arbor, MI, USA) data from privately-insured individuals in the US.[11] Prevalence adjusted to reflect patients with chronic pain despite medical treatment strategies (50%) who are eligible for MIS because they are not too ill to undergo general anesthesia (95%). This equates to an estimated 428 patients per 100,000 health plan beneficiaries (100,000 beneficiaries ×0.9% prevalence ×50% chronic ×95% eligible for MIS).
Abbreviations: ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification; MIS, minimally invasive surgery; SI, sacroiliac; USD, United States dollars.

Table 4 Sensitivity analysis for minimally invasive surgery compared with nonoperative care (2012 USD), cumulative 3-year costs, excluding ICD-9-CM diagnosis code 721.3

	Overall	Patients with lumbar spinal fusion	Patients without lumbar spinal fusion
	Per-patient differential (cost of nonoperative care – cost of MIS)		
Base-case analysis	($14,545)	$54,817	($14,931)
Including ICD-9-CM code 721.3 (lumbosacral spondylosis)	($8,763)	$60,661	($9,611)
Setting of care			
100% hospital inpatient	($14,572)	$54,790	($14,957)
100% hospital outpatient	($14,406)	$54,956	($14,792)
Durability of MIS treatment success at 1 year			
Decrease MIS treatment success from 82% to 72%	($16,882)	$48,302	($17,245)
Increase MIS treatment success from 82% to 92%	($12,208)	$61,332	($12,617)
Percentage of MIS procedures with clinical, device-related, or procedure-related events			
Increase from 3.8% to 5%	($14,563)	$54,799	($14,949)
Increase from 3.8% to 10%	($14,637)	$54,725	($15,023)
Increase from 3.8% to 15%	($14,712)	$54,650	($15,098)
Retreatment of MIS failures[a]			
More patients retreated nonoperatively[b]	($14,345)	$54,401	($14,728)
More patients retreated invasively[c]	($14,745)	$55,232	($15,134)
More patients retreated with MIS[d]	($14,724)	$55,869	($15,116)
Percentage of patients after MIS procedure that receive physical therapy twice a week for 12 weeks			
Decrease from 100% to 50%	($14,081)	$55,282	($14,466)
Percentage of patients who continue using pain medications following year 1			
Increase from 0.748% to 18%	($14,588)	$54,775	($14,973)
MIS index stay costs based on hospital inpatient costs of $17,344 for Medicare FFS beneficiaries (N=16) from the Premier database (rather than $18,710 and $18,580 for commercially-insured hospital inpatients and outpatients, respectively)	($12,833)	$56,529	($13,219)
MIS costs during the index stay $\pm$ SD =$5,509 for hospital inpatient and $\pm$ SD =$6,003 for hospital outpatient			
Plus SD	($21,656)	$47,706	($22,042)
Minus SD	($7,434)	$61,928	($7,820)
Multiplier to convert hospital inpatient and hospital outpatient costs for MIS index stay to estimated commercial insurer payments			
Decrease from 1.25 to 1.1	($11,691)	$57,671	($12,077)
Decrease from 1.25 to 1.0	($9,789)	$59,573	($10,174)
Increase from 1.25 to 1.5	($19,302)	$50,061	($19,687)
Patients who underwent lumbar spinal fusion within 1 year before receiving a diagnosis of SI joint disruption and/or degenerative sacroiliitis			
Include lumbar spinal fusion costs (applies to 17% of patients in the lumbar spinal fusion subgroup)	($14,512)	$60,877	N/A
Percentage of patients increased from <1% to 18%	($2,376)	N/A	N/A
Percentage of patients increased from <1% to 48%	$18,548	N/A	N/A
Time horizon			
Extension of time horizon from 3 to 5 years	($6,137)	$100,493	($6,730)
Extension of time horizon from 3 to 10 years	$12,873	$206,120	$11,797
Reduction in time horizon from 3 to 1 year	($23,303)	$5,430	($23,463)
Increase discount rate from 3% to 5%	($14,795)	$53,353	($15,174)
Savings to the commercial payer per 100,000 beneficiaries[e]			
Base-case analysis	($6,218,073)		
Patients with chronic pain			
Decrease from 50% to 25%	($3,109,036)		
Increase from 50% to 75%	($9,327,109)		

(*Continued*)

Table 4 (*Continued*)

	Overall	Patients with lumbar spinal fusion	Patients without lumbar spinal fusion
	Per-patient differential (cost of nonoperative care – cost of MIS)		
Patients who are MIS SI joint fusion candidates			
Decrease from 95% to 75%	($4,909,005)		
Increase from 95% to 100%	($6,545,340)		

Notes: Parentheses indicate negative values (where MIS is more costly than nonoperative care). [a]Base-case distribution of MIS failure retreatment: MIS (10%), fusion (35%), and nonoperative care (55%); [b]MIS failures retreated with MIS (10%), fusion (30%), and nonoperative care (60%); [c]MIS failures retreated with MIS (10%), fusion (40%), and nonoperative care (50%); [d]MIS failures retreated with MIS (20%), fusion (35%), and nonoperative care (45%); [e]reflects health plan beneficiaries with chronic pain despite medical treatment strategies who are eligible for MIS because they are not too ill to undergo general anesthesia.

Abbreviations: FFS, fee for service; ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification; MIS, minimally invasive surgery; N/A, not applicable; SD, standard deviation; SI, sacroiliac; USD, United States dollars.

(calculated as cost of nonoperative care – cost of MIS) was $14,545 per patient whereas, in the sensitivity analysis that estimated cumulative 5-year costs, the differential was $6,137 per patient (Table 3). A threshold analysis was performed to estimate at what year cost neutrality was achieved following the MIS index stay. By extending the time horizon, MIS treatment achieved cost neutrality in the overall group at approximately 6 years (Figure 2), whereby much of the costs for MIS accrued in year 1, whereas the costs of nonoperative care accrued over time with 92% of up-front MIS procedure costs being offset by year 5 (Figure 3). For patients with lumbar spinal fusion, cost neutrality was achieved in year 1.

A threshold analysis also was performed to estimate the MIS index stay commercial insurer payment that results in cost neutrality for the overall group by year following the MIS index stay. The MIS index stay was defined as the hospital stay in which the MIS SI joint fusion procedure was performed. The MIS index stay commercial insurance payment that achieved cost neutrality at year 3 (the base-case time horizon) was $9,073, whereas the amount that achieved cost neutrality at year 5 (the ISPOR Task Force recommended time horizon for chronic conditions) was $17,333 (Figure 4).

Discussion

US commercial payers have traditionally focused on 1- to 3-year timeframes for economic models, which correspond to their budget and contracting cycles. However, the information gleaned from economic models extends beyond forecasting the fiscal impact of a new medical technology on health plan budgets.[38] Rather, economic models facilitate: 1) exploring the extent to which costs of a new intervention may be offset by reductions in other medical costs; and 2) identifying subpopulations that benefit most.[38]

This study demonstrates that cumulative 3-year costs associated with MIS SI joint fusion are higher than with

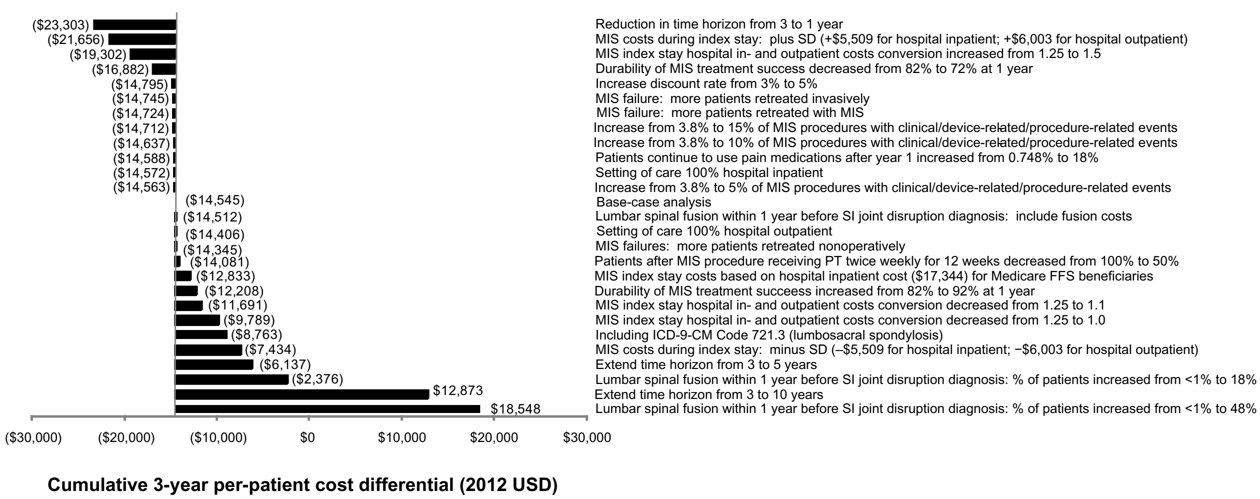

Figure 1 Sensitivity analysis of 3-year cost differentials between nonoperative care and minimally invasive surgery (2012 USD).

Notes: A tornado diagram of the sensitivity analysis shows the impact of individual parameters on the 3-year per-patient cost differential between nonoperative care and MIS. The tornado diagram illustrates the difference from the base-case analysis performed from the commercial payer perspective. Three-year cost differentials were calculated as per-patient differential equals cost of nonoperative care minus cost of MIS. Parentheses indicate negative values (where MIS is more costly than nonoperative care).

Abbreviations: clin, clinical; FFS, fee-for-service; ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification; MIS, minimally invasive surgery; pts, patients; PT, physical therapy; SD, standard deviation; SI, sacroiliac; USD, United States dollars.

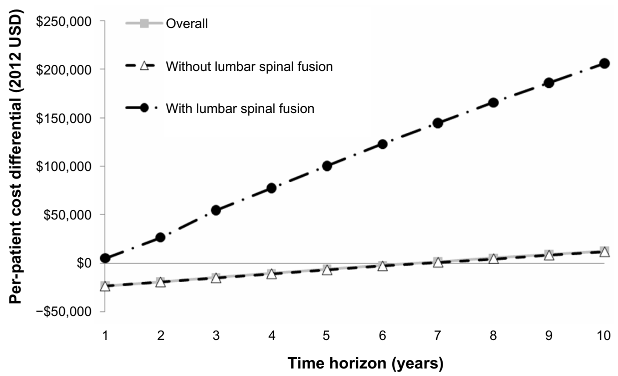

Figure 2 Per-patient cost differential over time (2012 USD).
Notes: Per-patient cost differential was calculated as cost of nonoperative care minus cost of MIS. Cost neutrality is achieved when the per-patient cost differential =0. Cost neutrality was achieved at approximately 6 years for both the overall group and the subgroup without lumbar spinal fusion. For the subgroup with lumbar spinal fusion, cost neutrality was achieved in year 1.
Abbreviations: MIS, minimally invasive surgery; USD, United States dollars.

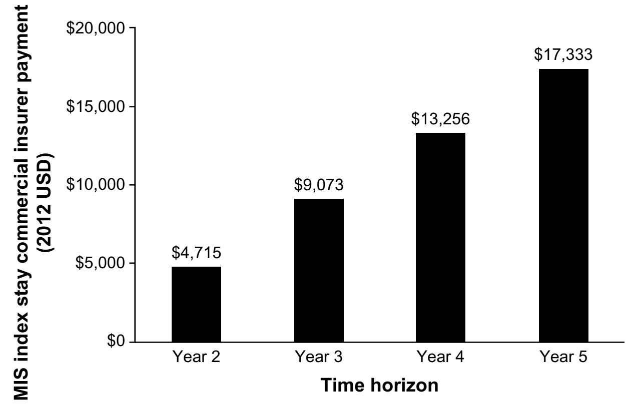

Figure 4 MIS index stay insurer payment that results in cost neutrality for the overall group by year following the MIS index stay (2012 USD).
Notes: The MIS index stay was defined as the hospital stay in which the MIS SI joint fusion procedure was performed. Cost neutrality is achieved when cost of nonoperative care equaled cost of MIS over the specified time horizon. The MIS index stay commercial insurance payment that achieved cost neutrality at year 3 was $9,073, whereas the amount that achieved cost neutrality at year 5 was $17,333.
Abbreviations: MIS, minimally invasive surgery; SI, sacroiliac; USD, United States dollars.

nonoperative care where cost neutrality is achieved at approximately 6 years in the overall group and during year 1 for patients with lumbar spinal fusion. The base-case time horizon of 3 years was chosen based on available Truven Health commercial payer data in addition to the ISPOR Task Force guidelines on conducting budget impact analyses, which recommend a 1- to 5-year time horizon, with longer and shorter time horizons included to provide more complete information of budgetary consequences.[25] For chronic conditions with longer-term consequences, it has been argued that employers and private health insurers should be interested in time horizons longer than 3 years,[38] particularly when one considers conditions that affect working age individuals, such as SI joint disruption, because productivity gains may offset increased health care expenditures.[8,25,39] Several recent

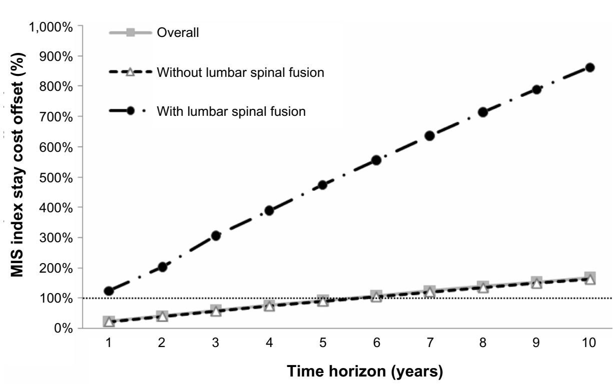

Figure 3 MIS index stay cost offset (%).
Notes: Cost offset was calculated as the percentage of up-front MIS procedure costs offset by reductions in nonoperative care costs; overall, 92% of initial MIS procedure costs were offset by year 5.
Abbreviation: MIS, minimally invasive surgery.

economic models evaluating treatments for chronic conditions, including chronic low back pain, from the US private payer perspective have included longer timeframes, such as a lifetime.[40,41]

MIS costs accrue largely in year 1, whereas the costs of nonoperative care accrue over time so that, as noted by the ISPOR Task Force, a longer time horizon is oftentimes required to capture the cost offsets from new interventions for chronic health conditions such as MIS SI joint fusion. Importantly, sensitivity analyses were conducted by varying the time horizon from 1 to 10 years and are shown annually to provide the most complete and useful set of results. As shown in Figures 2 and 3, longer time horizons may be required to capture the costs and benefits that accrue over time due to ongoing costs associated with chronic conditions. In addition, a threshold analysis was conducted to estimate the commercial insurance payment for the MIS index stay that results in cost-neutrality over a 5-year time horizon, and the values were reported by year (Figure 4). The MIS index stay commercial insurance payment that achieved cost neutrality at year 5 (the ISPOR Task Force recommended time horizon for chronic conditions) was $17,333, which is similar to the hospital inpatient MIS index stay costs among Medicare fee-for-service beneficiaries of $17,344 from the Premier database.

The mean age in the Truven Health commercial payer data used here was 45.2 years (SD =12.6) and approximately two-thirds of the population (63.7%) were female.[11] While some SI joint disruption patients are of child bearing age, the effect of MIS SI joint fusion on vaginal delivery and whether caesarean would be needed is not known. More broadly, SI joint disruption affects a working-age population. Approximately 61% of covered workers in the US are in a self-insured health plan.[42,43] In response to the Patient Protection and Affordable Care Act, health insurers are predicting an increase in self-insured health insurance plans by US employers. In addition to direct medical costs, patients are subject to lost wages, and employers are subject to the indirect costs of lost productivity and lost time from work (for example, due to recurring nonoperative interventions), which have not been included in the present analysis. The substantial absenteeism, lost productivity, and lost wages in this working-age population[5,6] are particularly relevant to employers given that productivity gains may offset increased health care expenditures.[8,39] Further, the average duration of employment at a given company in the US is 4.6 years,[44] which makes a longer (eg, 5-year) time horizon particularly relevant when considering treatment of chronic conditions such as SI joint disruption.

In the economic analysis, MIS costs accrued largely in year 1, whereas the costs of nonoperative care accrued over time with 59% and 92% of initial MIS procedure costs being offset by year 3 and year 5, respectively (Figure 3). As noted earlier, the HRQoL effects of MIS treatment and nonoperative care were not included in this analysis. Yet, early and sustained clinical improvement through 1-year follow-up were reported among MIS patients in the following HRQoL domains: pain; pain effect on social interest; sleep; activities (light, moderate, and vigorous); and overall happiness.[20] In addition, Duhon et al reported improvements in HRQoL (6.7 point improvement in short form 36, P=0.003) at 6-months' follow-up with MIS.[45] Compared to nonoperative care, long-term costs of MIS may be lower and HRQoL improvements of MIS may be greater due to the need for continued nonoperative therapy over time.[24]

Because of the difficulty in diagnosing SI pathology, lumbar spinal fusion is known to be performed on patients who actually have SI pathology. In the present analysis, less than 1% of commercial payer patients underwent lumbar spinal fusion in the year before or 3 years after receipt of a SI joint disruption diagnosis. In contrast, 3.7% of Medicare patients diagnosed with SI joint disruption and/or degenerative sacroiliitis underwent lumbar spinal fusion within 1 year before or 5 years after diagnosis.[26] Previous lumbar spinal fusion has been reported in 18% and 48% of patients treated with MIS SI joint fusion (mean ages 54 years and 58 years, respectively),[20,21] suggesting that the 4-year window based on the Truven Health data that informed the present analysis may have been too short to completely capture the patients who underwent lumbar spinal fusion before or after MIS SI joint fusion.

Limitations

The study has a number of limitations. First, the MIS treatment success rate at 1 year (82%) is based on two retrospective studies with 50 and 40 consecutive patients, respectively.[20,21] In the first retrospective study by Rudolf, 82% of patients reached minimal clinically important difference in pain score at a mean follow-up of 40 months post-implant. These patients also experienced improvements in seven of nine HRQoL domains at 1-year follow-up; the improvements were both statistically significant and clinically relevant despite the small sample size (N=50).[20] The same MIS system was evaluated in a retrospective study of 40 patients; 39 out of 40 patients achieved clinically significant improvements at 1-year follow-up.[21] In the Rudolf study, half of perioperative complications were minor (mild hematoma at the incision site and superficial cellulitis) and required little to no intervention.[20] The other perioperative complications (N=5) were major, with three patients requiring retraction of a misplaced implant in the operating room, one patient experiencing a nondisplaced fracture that healed without intervention, and one patient experiencing a deep soft tissue wound infection that resolved with a course of intravenous antibiotics. The 20% rate of perioperative complications resembles previously published rates.[20] The 50-patient cohort experienced a revision rate of 8% after 3 years,[20] which was also comparable to revision rates for other MIS treatments (8%–15%).[16,18,46–49] A recent post-market complaints database analysis for a new MIS system reported a complication rate of 3.8% (204 of 5,319 patients) over a 4-year period.[19] In that study, 96 revision surgeries (94 patients [1.8%]) were performed at a median follow-up time of 4 months. A total of 56 revisions were performed in the early postoperative period due to either a symptomatic malpositioned implant (N=46) or an improperly sized implant in an asymptomatic patient (N=10).[19] Late revisions were primarily to treat symptom recurrence (N=34).[19] Preliminary results of a prospective, single-arm, multicenter study (N=26) further support the effectiveness data described above.[45] At 6-months post-implant, significant improvements were noted in pain (49-point improvement in visual analog pain scale score, $P<0.0001$) and disability (15.8 point improvement in Oswestry Disability Index, $P<0.0001$).[45]

Similar to the previously published economic model among Medicare beneficiaries,[24] we have defined MIS treatment failure as having one or more of the following: implant failure, loosening, and/or malposition; failure to relieve pain requiring repeat intervention; and infection requiring reoperations. The findings discussed above[19–21] suggest that the 82% 1-year MIS treatment success rate is reasonable as a base-case value for the economic model. With that being said, the lasting effects of MIS treatment on symptoms of SI joint disruption can only be estimated because durability data for MIS are only available for up to 4 years.[19] Therefore, a MIS failure rate of 18% within the first 12 months has been incorporated in the economic model based on the reported clinical experience to date. Recognizing the small sample sizes in the Rudolf[20] and Sachs[21] studies (50 and 40 patients, respectively) and limited longer-term durability data, we varied the 1-year MIS treatment success rate from 72% to 92% in a sensitivity analysis (Figure 1). Of note, modifying the MIS treatment success rate at 1 year did not affect the results as much as other factors such as the time horizon.

In the economic model, the multiplier to convert the MIS index stay costs to commercial insurer payments was set at 1.25,[31,32] acknowledging that there was substantial variability in the Premier data for estimating the MIS index stay costs and that the sample size was limited. The uncertainty in the relationship between MIS index stay costs and commercial insurance payments was addressed by performing a sensitivity analysis in which the multiplier was varied from 1.0 to 1.5. Furthermore, given that commercial insurer payment changes dynamically with adjustments in Medicare payments, a sensitivity analysis was performed by using Premier data MIS index stay costs based on hospital inpatient costs of $17,344 for Medicare fee-for-service beneficiaries, which is similar to the commercially-insured hospital inpatient and outpatient MIS index stay costs of $18,710 and $18,580, respectively; as such, the results remained similar.

Conclusion

Cost offsets from new interventions for chronic health conditions such as MIS SI joint fusion accrue over time. Despite the higher up-front MIS SI joint fusion procedure costs, the costs of MIS were largely offset by decreased nonoperative care costs over a 5-year time horizon from a US commercial payer perspective. This is particularly relevant to self-insured employers in light of the substantial absenteeism, lost productivity, and lost wages in this working-age population, whereby productivity gains may offset increased health care expenditures.[8,39] Optimizing effective resource use in both nonoperative and operative patients will facilitate cost-effective health care delivery and improved HRQoL. The impact of SI joint disruption and degenerative sacroiliitis on direct and indirect costs to commercial insurers, health plan beneficiaries, and employers warrants further consideration.

Acknowledgment

We thank Karen Spach, PhD, of Covance Market Access Services, for her editorial contribution to this manuscript.

Disclosure

This research was performed according to guidelines (GPP2) established to minimize conflict of interest in pharmacoeconomic studies.[22,23] A multispecialty panel comprising clinicians and methodologists (the coauthors) provided the framework for the economic analysis and completed the data analysis and interpretation of the results. The sponsor, SI-BONE, Inc., did not participate in the data analysis, interpretation of the results, or writing of the manuscript. SI-BONE was provided a final version of the manuscript for informational purposes only. It did not provide comments or influence the content or writing of the manuscript. SJA, KS, and TK are consultants to SI-BONE through their employment at Covance. DWP has not received any financial support from SI-BONE. DWP receives research support from the Department of Defense, Orthopaedic Research and Education Foundation, Minnesota Medical Foundation, and Chest Wall and Spine Deformity Foundation. TH and JC are paid teaching and clinical research consultants for SI-BONE. The authors report no other conflicts of interest.

References

1. Committee on Advancing Pain Research Care and Education [webpage on the Internet]. Board on Health Science Policy. Pain as a Public Health Challenge. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*. Washington, DC: The National Academies Press; 2011. Available from: http://www.painsproject.org/documents/iom_report.pdf. Accessed April 28, 2014.
2. Freburger JK, Holmes GM, Agans RP, et al. The rising prevalence of chronic low back pain. *Arch Intern Med*. 2009;169(3):251–258.
3. Dagenais S, Caro J, Haldeman S. A systematic review of low back pain cost of illness studies in the United States and internationally. *Spine J*. 2008;8(1):8–20.
4. Thorpe KE, Florence CS, Howard DH, Joski P. The rising prevalence of treated disease: effects on private health insurance spending. *Health Aff (Millwood)*. 2005;Suppl Web Exclusives:W5-317–W5-325.
5. Katz J. Lumbar disc disorders and low-back pain: socioeconomic factors and consequences. *J Bone Joint Surg Am*. 2006;88 Suppl 2:21–24.
6. Murray W. Sacroiliac joint dysfunction: a case study. *Orthop Nurs*. 2011;30(2):126–131; quiz 132–123.
7. Janicki H. *Employment-Based Health Insurance: 2010*. Suitland, MD: United States Census Bureau; 2013.
8. Worker Productivity [webpage on the Internet]. Atlanta, GA: Centers for Disease Control and Prevention; 2013. Available from: http://www.cdc.gov/workplacehealthpromotion/businesscase/reasons/productivity.html. Accessed March 6, 2014.
9. Sembrano JN, Polly DW Jr. How often is low back pain not coming from the back? *Spine (Phila Pa 1976)*. 2009;34(1):E27–E32.

10. Schwarzer AC, Aprill CN, Bogduk N. The sacroiliac joint in chronic low back pain. *Spine (Phila Pa 1976)*. 1995;20(1):31–37.
11. Ackerman SJ, Polly DW Jr, Knight T, Holt T, Cummings J. Management of sacroiliac joint disruption and degenerative sacroiliitis with nonoperative care is medical resource-intensive and costly in a United States commercial payer population. *Clinicoecon Outcomes Res*. 2014;6:63–74.
12. Laslett M, Young SB, Aprill CN, McDonald B. Diagnosing painful sacroiliac joints: A validity study of a McKenzie evaluation and sacroiliac provocation tests. *Aust J Physiother*. 2003;49(2):89–97.
13. Szadek KM, van der Wurff P, van Tulder MW, Zuurmond WW, Perez RS. Diagnostic validity of criteria for sacroiliac joint pain: a systematic review. *J Pain*. 2009;10(4):354–368.
14. Manchikanti L, Pampati V, Falco FJ, Hirsch JA. Growth of spinal interventional pain management techniques: analysis of utilization trends and Medicare expenditures 2000 to 2008. *Spine (Phila Pa 1976)*. 2013;38(2):157–168.
15. Giannikas KA, Khan AM, Karski MT, Maxwell HA. Sacroiliac joint fusion for chronic pain: a simple technique avoiding the use of metalwork. *Eur Spine J*. 2004;13(3):253–256.
16. Moore JD Jr. Under new authority. KU Hospital joins movement toward independence. *Mod Healthc*. 1997;27(7):44, 48.
17. Morgan PM, Anderson AW, Swiontkowski MF. Symptomatic sacroiliac joint disease and radiographic evidence of femoroacetabular impingement. *Hip international: the journal of clinical and experimental research on hip pathology and therapy*. March–April 2013;23(2):212–217.
18. Buchowski JM, Kebaish KM, Sinkov V, Cohen DB, Sieber AN, Kostuik JP. Functional and radiographic outcome of sacroiliac arthrodesis for the disorders of the sacroiliac joint. *Spine J*. 2005;5(5):520–528; discussion 529.
19. Miller LE, Reckling WC, Block JE. Analysis of postmarket complaints database for the iFuse SI Joint Fusion System®: a minimally invasive treatment for degenerative sacroiliitis and sacroiliac joint disruption. *Med Devices (Auckl)*. 2013;6:77–84.
20. Rudolf L. Sacroiliac joint arthrodesis-MIS Technique with titanium implants: report of the first 50 patients and outcomes. *Open Orthop J*. 2012;6:495–502.
21. Sachs D, Capobianco R. Minimally invasive sacroiliac joint fusion: one-year outcomes in 40 patients. *Adv Orthop*. 2013;2013:536128.
22. Graf C, Battisti WP, Bridges D, et al. Research Methods and Reporting. Good publication practice for communicating company sponsored medical research: the GPP2 guidelines. *BMJ*. 2009;339: b4330.
23. Schulman KA, Rubenstein LE, Glick HA, Eisenberg JM. Relationships between sponsors and investigators in pharmacoeconomic and clinical research. *Pharmacoeconomics*. 1995;7(3):206–220.
24. Ackerman SJ, Polly DW, Knight T, Schneider K, Holt T, Cummings J. Comparison of cost of non-operative care to minimally invasive surgery for sacroiliac joint disruption and degenerative sacroiliitis in a United States Medicare population: potential economic implications of a new minimally-invasive technology. *Clinicoecon Outcomes Res.* 2013;5:575–587.
25. Sullivan SD, Mauskopf JA, Augustovski F, et al. Budget impact analysis-principles of good practice: report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force. *Value Health.* 2014;17:5–14.
26. Ackerman SJ, Polly DW Jr, Knight T, Holt T, Cummings J Jr. Nonoperative care to manage sacroiliac joint disruption and degenerative sacroiliitis: high costs and medical resource utilization in the United States Medicare population. *J Neurosurg Spine.* April 2014;20(4):354–363.
27. Consumer Price Index – All Urban Consumers [webpage on the Internet]. Washington, DC: Bureau of Labor and Statistics; 2013. Available from: http://data.bls.gov/timeseries/CUUR0000SAM?include_graphs=false&output_type=column&years_option=all_years. Accessed November 4, 2013.
28. US Food and Drug Administration. *SI-Bone's iFuse SI Fusion System 501(k) Summary Letter*. Silver Spring, MD: US Food and Drug Administration; 2011. Available from: http://www.accessdata.fda.gov/cdrh_docs/pdf11/K110838.pdf. Accessed September 13, 2012.
29. Copay AG, Glassman SD, Subach BR, Berven S, Schuler TC, Carreon LY. Minimum clinically important difference in lumbar spine surgery patients: a choice of methods using the Oswestry Disability Index, Medical Outcomes Study questionnaire Short Form 36, and pain scales. *Spine J*. 2008;8(6):968–974.
30. Lorio MP, Polly DW, Andresson G. Prevalence of Minimally Invasive Sacroiliac Joint Fusions and Site of Service. *8th Interdisciplinary World Congress Lower Back and Pelvic Pain*. Dubai, United Arab Emirates. October 27–31, 2013.
31. Healy WL, Rana AJ, Iorio R. Hospital economics of primary total knee arthroplasty at a teaching hospital. *Clin Orthop Relat Res*. 2011;469(1):87–94.
32. Rana AJ, Iorio R, Healy WL. Hospital economics of primary THA decreasing reimbursement and increasing cost, 1990 to 2008. *Clin Orthop Relat Res*. 2011;469(2):355–361.
33. National Physician Fee Schedule Relative Value File July Release [webpage on the Internet]. Baltimore, MD: Centers for Medicare and Medicaid Services; 2012. Available from: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files-Items/RVU12C.html. Accessed September 11, 2012.
34. Medicare Payment Advisory Commission. *Report to the Congress: Medicare Payment Policy*. Washington, DC: MedPAC; 2011.
35. Department of Health and Human Services. *Global Surgery Fact Sheet*. Baltimore, MD: Centers for Medicare and Medicaid Services; 2012. Available from: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/GloballSurgery-ICN907166.pdf. Accessed February 17, 2012.
36. *Medicare Claims Processing Manual*. Baltimore, MD: Centers for Medicare and Medicaid Services; 2012. Available from: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf. Accessed February 12, 2013.
37. Ackerman SJ, Holt TA, Polly DW, Knight T. How Often Is Lumbar Spinal Fusion Performed Prior to Diagnosis of Sacroiliac Joint Disruption? Paper presented at: International Society for the Advancement of Spine Surgery 2014 Annual Meeting; May 2, 2014; Miami Beach, FL.
38. Watkins JB, Minshall ME, Sullivan SD. Application of economic analyses in US managed care formulary decisions: a private payer's experience. *J Manag Care Pharm*. 2006;12(9):726–735.
39. Partnership for Prevention [webpage on Internet]. Leading by Example: CEOs on the business case for worksite health promotion. Washington, DC2005. Available from: http://www.prevent.org/data/files/initiatives/lbe_smse_2011_final.pdf. Accessed April 28, 2014.
40. Wielage RC, Bansal M, Andrews JS, Klein RW, Happich M. Cost-utility analysis of duloxetine in osteoarthritis: a US private payer perspective. *Appl Health Econ Health Policy*. 2013;11(3):219–236.
41. Wielage RC, Bansal M, Andrews JS, Wohlreich MM, Klein RW, Happich M. The cost-effectiveness of duloxetine in chronic low back pain: a US private payer perspective. *Value Health*. 2013;16(2): 334–344.
42. Kaiser Family Foundation 2012. Employer Health Benefits Survey. Available from: http://kff.org/private-insurance/report/employer-health-benefits-2012-annual-survey/. Accessed November 6, 2013.
43. ebri.org. *Self-insured Health Place: State Variation and Recent Trends by Firm Size*. Washington, DC: ebri.org: 2012. Available from: http://www.ebri.org/pdf/notespdf/EBRI_Notes_11_Nov-12.Slf-Insrd1.pdf. Accessed November 6, 2013.
44. Employment Tenure Summary [webpage on the Internet]. Washington, DC: Bureau of Labor Statistics; 2012. Available from: http://www.bls.gov/news.release/tenure.nr0.htm. Accessed February 18, 2014.
45. Duhon BS, Cher DJ, Wine KD, Lockstadt H, Kovalsky D, Soo CL. Safety and 6-month effectiveness of minimally invasive sacroiliac joint fusion: a prospective study. *Med Devices (Auckl)*. 2013;6: 219–229.
46. Kibsgård TJ, Røise O, Sudmann E, Stuge B. Pelvic joint fusions in patients with chronic pelvic girdle pain: a 23-year follow-up. *Eur Spine J.* 2013;22(4):871–877.
47. Al-Khayer A, Hegarty J, Hahn D, Grevitt MP. Percutaneous sacroiliac joint arthrodesis: a novel technique. *J Spinal Disord Tech*. 2008;21(5):359–363.

48. Wise CL, Dall BE. Minimally invasive sacroiliac arthrodesis: outcomes of a new technique. *J Spinal Disord Tech*. 2008;21(8): 579–584.

49. Waisbrod H, Krainick JU, Gerbershagen HU. Sacroiliac joint arthrodesis for chronic lower back pain. *Arch Orthop Trauma Surg*. 1987;106(4): 238–240.