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Health Policy Review

Cost Utility Analysis of Caudal Epidural Injections in the Treatment of Lumbar Disc Herniation, Axial or Discogenic Low Back Pain, Central Spinal Stenosis, and Post Lumbar Surgery Syndrome

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Background: In this era of escalating health care costs and the questionable effectiveness of multiple interventions, cost effectiveness or cost utility analysis has become the cornerstone of evidence-based medicine, and has an influence coverage decisions. Even though multiple cost effectiveness analysis studies have been performed over the years, extensive literature is lacking for interventional techniques. Cost utility analysis studies of epidural injections for managing chronic low back pain demonstrated highly variable results including a lack of cost utility in randomized trials and contrasting results in observational studies. There has not been any cost utility analysis studies of epidural injections in large randomized trials performed in interventional pain management settings.

Objectives: To assess the cost utility of caudal epidural injections in managing chronic low back pain secondary to lumbar disc herniation, axial or discogenic low back pain, lumbar central spinal stenosis, and lumbar post surgery syndrome.

Study Design: This analysis is based on 4 previously published randomized trials.

Setting: A private, specialty referral interventional pain management center in the United States.

Methods: Four randomized trials were conducted assessing the clinical effectiveness of caudal epidural injections with or without steroids for lumbar disc herniation, lumbar discogenic or axial low back pain, lumbar central spinal stenosis, and post surgery syndrome. A cost utility analysis was performed with direct payment data for a total of 480 patients over a period of 2 years from these 4 trials.

Outcome included various measures with significant improvement defined as at least a 50% improvement in pain reduction and disability status.

Results: The results of 4 randomized controlled trials of low back pain with 480 patients with a 2 year follow-up with the actual reimbursement data showed cost utility for one year of quality-adjusted life year (QALY) of $2,206 for disc herniation, $2,136 for axial or discogenic pain without disc herniation, $2,155 for central spinal stenosis, and $2,191 for post surgery syndrome. All patients showed significant improvement clinically and showed positive results in the cost utility analysis with an average cost per one year QALY of $2,172.50 for all patients and $1,966.03 for patients judged to be successful.

The results of this assessment show a better cost utility or lower cost of managing chronic, intractable low back pain with caudal epidural injections at a QALY that is similar or lower in price than medical therapy only, physical therapy, manipulation, and surgery in most cases.

Limitations: The limitations of this cost utility analysis include that it is a single center evaluation, even though 480 patients were included in the analysis. Further, only the costs of interventional procedures and physician visits were included. The benefits of returning to work were not assessed.

Conclusion: This cost utility analysis of caudal epidural injections in the treatment of disc herniation, axial or discogenic low back pain, central spinal stenosis, and post surgery syndrome in the lumbar spine shows the clinical effectiveness and cost utility of these injections at less than $2,200 per one year of QALY.

Key words: Caudal epidural injections, chronic low back pain, lumbar disc herniation, lumbar discogenic pain, lumbar spinal stenosis, lumbar post surgery syndrome, cost utility analysis, cost effectiveness analysis, quality-adjusted life years

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The prevalence of chronic low back pain with or without lower extremity pain and health care costs in managing chronic pain continues to rise at an unsustaineable rate (1-13). With the increasing prevalence of chronic persistent low back pain, multiple diagnostic and therapeutic modalities are administered (13-23). The most invasive modality, surgery, is usually performed for the most common diagnoses for low back and leg pain: disc herniation, spinal stenosis, and degenerative spondylolisthesis (13-16,24-26). Prior to surgical intervention, after the failure of surgical intervention, and in patients with contraindications for surgical intervention, epidural injections are administered most commonly, for low back and lower extremity pain: disc herniation, spinal stenosis, post surgery syndrome and axial or discogenic low back pain (5,6,13,17-21).

Among the 3 approaches available to provide epidural injections, the caudal approach is commonly utilized for all causes of low back and lower extremity pain (5,6,13,17-19). In fact, studies of the Medicare population have shown dramatic increases in epidural injections along with other interventional procedures (5,6). Manchikanti et al (6) showed that all interventional techniques for chronic pain increased dramatically from 2000 to 2011 with a 228% overall increase and a 177% increase per 100,000 Medicare beneficiaries. Epidural injections increased 127% per 100,000 beneficiaries. Martin et al (1) evaluated health care expenditures for treating back and neck problems in the United States in 2005 and found that these expenditures totaled approximately $86 billion, with an increase of 65% between 1997 and 2005 and a 49% increase in the number of patients seeking spine-related care. Freburger et al (27), in an evaluation of a study from North Carolina, showed a significant increase in low back pain from 3.9% in 1992 to 10.2% in 2006.

The literature addressing the effectiveness of multiple interventional techniques in managing chronic low back pain continues to emerge (13,17-21,28-47). It has been debated in reference to effectiveness, appropriate medical necessity, and indications (13,17-21,48-53). Further, among multiple interventions, interventional techniques have been the focus of attention for payers, public policy health experts, and researchers. While the debate continues in reference to the effectiveness of interventional techniques, there is a strong desire to reduce or eliminate these techniques based on not only a lack of clinical effectiveness, but also a lack of cost effectiveness.

Due to escalating health care costs and the questionable effectiveness of multiple interventions, cost effectiveness or cost utility analysis has become a cornerstone of evidence-based medicine, clinical practice, and health policy (10-12,54-57). Multiple cost effectiveness analysis studies have been performed over the years about managing spinal pain, along with multiple systematic reviews (10-12,54-68). In health economics, the purpose of a cost utility analysis is to estimate the ratio between the cost of a health-related intervention and the benefit it produces in terms of the number of years lived in full health by the patient receiving the intervention, hence, it can be considered as a special type of cost effectiveness analysis; the 2 terms are often used interchangeably. In these scenarios, cost is measured in monetary units, unlike a cost-benefit analysis in which the benefits do not have to be expressed in monetary terms.

Kepler et al (10), conducted a systematic review and cost utility analysis in spine care that included 33 studies. The results showed that these 33 studies as well as 60 cost utility ratios published on various aspects of spinal care over 30 years varied widely in methodology. In these studies, 27 of 60, or 45%, of the cost utility assessments were less than $100,000 per quality-adjusted life year (QALY) gain, and 23.3% were greater than $100,000-QALY gain. However, only 12% of the studies contained the 4 key criteria of cost effectiveness research recommended by the U.S. panel on cost effectiveness in health and medicine. In another systematic review, Indrakanti et al (11) conducted a cost utility analysis of value-based care in the management of spinal disorders. They selected 27 studies meeting inclusion criteria. Studies of nonoperative treatments demonstrated greater value for graded activity over physical therapy and pain management; spinal manipulation over exercise; behavioral therapy and physiotherapy over advice; and acupuncture and exercise over usual general practitioner care. They concluded that the literature on cost utility for treating spinal disorders was limited and highly variable with diverse methodologies and results. However, none of these systematic reviews included epidural injections.

Furlan et al (12), in a systematic review and meta-analysis of the efficacy, cost effectiveness, and safety of selected complementary and alternative medicines for neck and low back pain, showed that complementary and alternative therapies did not significantly reduce disability compared to sham therapies. However, complementary and alternative medicine treatments were significantly more efficacious than no treatment, placebo, physical therapy, or usual care in reducing pain immediately or at short-term.

Dagenais et al (56) assessed cost of illness studies in the United States and internationally (57) as well as cost utility evaluations and their role in informed decision-making concerning interventions for low back pain. In their assessment of cost of illness studies (57), they provided a break down on direct costs. The largest proportion of direct medical costs for low back pain was spent on physical therapy (17%) and inpatient services (17%), followed by pharmacy (13%) and primary care (13%). In their assessment of the role of cost utility evaluations (56), their results showed most studies were from the United Kingdom and were published 3 years prior to their publication in 2009. Based on available data and converted to US dollars, they showed that the cost per QALY ranged from $304 to $579,527, with a median cost of $13,015.

Among recent assessments evaluating surgical interventions and conservative management, Tosteson et al (69) assessed the cost effectiveness of surgery versus nonoperative treatment for lumbar disc herniation over 2 years based on Spine Patient Outcomes Research Trial (SPORT) observational and randomized cohort participants. They showed that over a period of 2 years, surgery was more costly than nonoperative care. However, the cost for QALY gained for surgery relative to nonoperative care was $69,403 using general adult surgery costs and $34,355 using Medicare population surgery costs. Tosteson et al (70), based on SPORT data, assessed the cost effectiveness of surgical treatment for spinal stenosis with and without degenerative spondylolisthesis. The results show stenosis surgery improved health to a greater extent than nonoperative care at a cost of $77,600 for QALY gained. They also showed that degenerative spondylolisthesis surgery significantly improved health versus nonoperative care at a cost of $115,600 per QALY gained.

In an evaluation of the cost effectiveness of current treatment strategies for lumbar spinal stenosis including nonsurgical care, laminectomy, and X-STOP, Burnett et al (71) showed that laminectomy was found to be the most effective treatment strategy, followed by X-STOP and then conservative treatment at a 2-year time horizon. They showed an incremental cost effectiveness of $102,234 for laminectomy and $51,719 for X-STOP. Parker et al (72), in an assessment of the cost effectiveness for lumbar stenosis associated with radiculopathy, showed multilevel hemilaminectomy was associated with a mean 2-year cost per quality gained of $33,700 QALY.

Taylor et al (58) demonstrated that the incremental cost effectiveness of spinal cord stimulation compared with conventional medical management was £5,624 per QALY, with an 89% probability that spinal cord stimulation is cost effective at a willingness to pay threshold of £20,000. They also showed that compared with reoperation, the incremental cost effectiveness of spinal cord stimulation was £6,392 per QALY, with an 82% probability of cost effectiveness at £20,000 threshold. However, Hollingworth et al (60) in an analysis of the cost effectiveness of spinal cord stimulation for failed back surgery syndrome in a workers' compensation population, showed that the mean medical cost per spinal cord stimulation patient over 24 months was $52,091, which was $17,291 higher than the pain clinic group and $28,128 higher than in the usual care group.

Consequently, there is a wide variability that exists in cost effectiveness and cost utility analysis and interpretation of the data, not only with surgery and other interventions, but also with pharmacotherapy (10-12,56,58-72). Even though it has been done very ineffectively, the cost effectiveness of epidural steroid injections to manage chronic low back pain has been performed (61-66,68).

In early evaluations, Price et al (62) showed interlaminar epidural injections to lack cost effectiveness. They showed that the charge to purchaser for realizing an improvement at 3 weeks in one patient based on the trial protocol was £16,816 to £23,963 depending on the number of epidural steroid injections needed to treat assumed as 8 to 11.4. If only one epidural was provided, the total charge to purchasers to improve one patient at 3 weeks was £7,936 to £11,306. In contrast, Manchikanti et al (68), comparing the 3 routes of epidural steroid injections for low back pain utilizing fluoroscopically directed caudal epidural injections and blind lumbar interlaminar epidural injections, along with transforaminal epidural injections, showed the cost per one year of improvement in quality of life was $3,635 and $2,927 for caudal and transforaminal epidural injections compared to $6,024 for blind interlaminar epidural injections per one year of improvement of quality of life. In another study, Manchikanti et al (66) reported the cost for one year improvement of quality of life was $2,550 in 2001.

Whynes et al (61) evaluated 39 patients over a period of 13 weeks showed QALY gain. Based on modelled resource use and data from other studies, the mean cost of an injection was estimated at £219 (SD 83). The cost utility ratio of 2 injections amounted to £8,975 per QALY gained. They concluded that when provided in an outpatient setting, epidural steroid injections are a short-term, but nevertheless cost effective, means of managing chronic low back pain.

However, in multiple studies these procedures were not performed in contemporary interventional pain management settings, or were performed without fluoroscopy and included only short-term evaluations or an inappropriate provision of the procedures.

Thus, the current evaluation is being undertaken to produce valid, and reliable, cost utility information for caudal epidural injections in managing disc herniation and radiculitis, spinal stenosis, post surgery syndrome, and axial or discogenic pain without facet joint pain or disc herniation and radiculitis based on 4 randomized trials that had a 2 year follow-up (40-43).

Methods

Study Design:

The cost utility analysis was performed from 4 double-blind, randomized controlled trials evaluating caudal epidural injections (40-43). The study design and methodology is described in the manuscripts (40-43). In short, patients underwent caudal epidural injections after the failure of conservative management based on a diagnosis of lumbar disc herniation or radiculitis, lumbar central stenosis, lumbar post surgery syndrome, and axial or discogenic pain. Patients were also assessed using controlled diagnostic blocks for potential facet joint or sacroiliac joint pathology for diagnosing axial or discogenic etiology. All the randomized trials were performed with Institutional Review Board approval in a contemporary interventional pain management setting in the United States. The clinical data was prospectively acquired as part of these RCTs.

All patients were provided with drug therapy and a structured exercise program as indicated. Caudal epidural injections were performed in an ambulatory surgery center. The protocols were registered on the US Clinical Trial Registry with an assigned number of NCT00370799.

Analysis:

There were 120 patients in the studies assessing disc herniation and radiculitis (40) and axial low back pain without disc herniation or discogenic pain (43). There were 100 patients in the central spinal stenosis assessment (41), whereas there were 140 patients with 70 patients in each group in the post lumbar surgery syndrome study (42). All the patients were divided equally in each study into 2 groups who either received local anesthetic alone or received local anesthetic with steroids.

All costs assessed are based on actual reimbursement for the facility and physician services during the study period, which lasted from August 2006 through December 2011.

Outcome Measures:

Pain was assessed with the numeric rating scale (NRS) (0 to 10) whereas function was assessed by the Oswestry Disability Index (ODI) (0 to 50) scale. Other assessments included employment status and opioid intake in terms of morphine equivalence. All outcomes were assessed at 3, 6, 12, 18, and 24 months posttreatment. The reliability of the NRS and ODI have been established (73,74). In all the evaluations, robust measures of improvement with significant pain relief and reduced disability status of 50% or more was utilized (40-43,47,75-84). Consequently, any other response that was less than 50% combined was considered as a failure.

Statistical Analysis

Sample sizes were determined appropriately for all 4 studies. The same statistical methodology was utilized for all the studies. An intent-to-treat analysis was also applied for all studies.

Cost Utility Analysis:

Using reimbursement data, we examined medical costs for 24 months postenrollment. The reimbursement data included payments for physician assessment for each visit, and facility expenses for all procedures. We used actual reimbursement amounts during the study periods. We have not considered the cost of oral drugs utilized outside the interventions since the majority of the patients were on higher doses of these drugs prior to. If pretreatment versus posttreatment costs of oral medications are calculated, we posit that there will be substantial gains.

We used quality of life improvement per year (52 weeks) for 2 years (104 weeks) based on the costs of caudal epidural injections and primary outcomes of significant pain relief and improvement in function of 50%. There was no discounting of costs as has been used by other investigators (60).

We compared the unadjusted mean costs per patient for 4 condition groups. Both groups in each study (local anesthetic alone or with steroids) were combined for each condition since there were no significant differences at the end of 2 years in reference to the primary outcome measures. Thus, an incremental cost effectiveness analysis was not performed since there was only one group for each condition.

Employment was not utilized in this analysis.

Results

Patient Flow

Figure 1 illustrates the patient flow characteristics of all 4 studies.

Outcomes

Table 1 shows the baseline demographic and clinical data for each condition. Table 2 shows comparison summaries of NRS for pain and ODI score for function at 6 time points. Figure 2 shows the combined improvement with significant reduction in NRS and ODI. Table 3 shows employment characteristics. In all 4 groups there was significant improvement in overall employment compared to baseline with an increase of 82 to 117 among the patients who were employable.

Adverse Events

There were no major adverse events reported over the 2-year study period in any of the 480 participants.

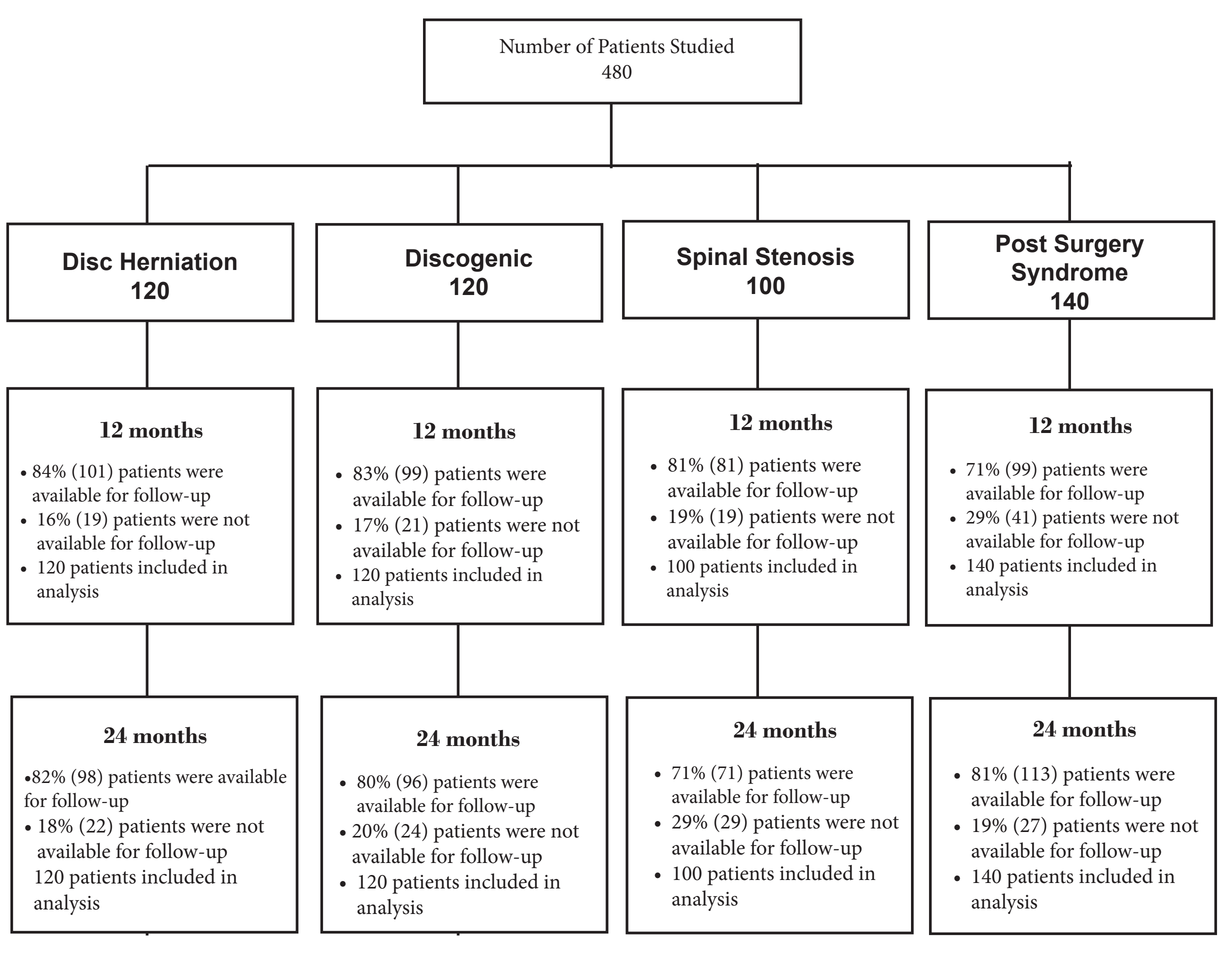

Fig. 1. *Patient flow diagram of 4 trials.*

Table 1. *Analysis of cost effectiveness of caudal epidural injections in managing pain and disability of disc herniation, axial or discogenic pain, spinal stenosis, and post surgery syndrome.*

	Disc Herniation	Axial or Discogenic Pain	Spinal Stenosis	Post Surgery Syndrome	Pooled
Number of patients	120	120	100	140	480
Age	49 ± 14.3	46 ± 14.5	56 ± 15.1	50 ± 13.3	49 ± 14.8
Gender (M/F)	29.2% / 70.8%	35.0% / 65.0%	41.0% / 59.0%	45.0% / 55.0%	37.7% / 62.3%
Duration of Pain (Months)	96 ± 86.0	87 ± 84.2	100 ± 75.0	157 ± 109.2	112 ± 95.3
Onset of the Pain (gradual)	65%	62%	75%	60%	62%
Low Back Pain Distribution (bilateral)	83%	71%	75%	79%	74%

Table 2. *Pain relief and functional assessment evaluated by Oswestry Disability Index characteristics.*

Numeric Rating Score	Disc Herniation	Axial or Discogenic Pain	Spinal Stenosis	Post Surgery Syndrome	Pooled
Baseline	8.0 ± .93	7.9* ± .96	7.8 ± .89	7.8 ± .94	7.9 ± .93
6 months	3.9* ± 1.66 (73%)	3.7* ± 1.75 (79%)	4.2* ± 1.79 (57%)	4.2* ± 1.82 (63%)	4.0 ± 1.76 (68%)
12 months	4.1* ± 1.70 (68%)	3.8* ± 1.76 (73%)	4.4* ± 1.90 (47%)	4.3* ± 1.81 (59%)	4.1 ± 1.80 (62%)
24 months	4.2* ± 1.82 (61%)	3.9* ± 1.81 (66%)	4.5* ± 1.88 (43%)	4.4* ± 1.87 (52%)	4.2 ± 1.85 (56%)
Oswestry Disability Index					
Baseline	28.3 ± 4.86	28.6 ± 4.72	29.0* ± 4.45	29.4 ± 5.26	28.8 ± 4.87
6 months	15.3* ± 7.04 (68%)	14.6* ± 7.06 (73%)	17.0* ± 7.67 (52%)	17.0* ± 6.91 (59%)	16.0* ± 7.20 (63%)
12 months	15.4* ± 6.91 (64%)	14.2* ± 7.09 (71%)	17.2* ± 7.69 (47%)	17.0* ± 6.98 (58%)	16.0* ± 7.22 (60%)
24 months	15.7* ± 7.09 (59%)	14.6* ± 7.30 (65%)	17.3* ± 7.43 (44%)	17.2* ± 7.08 (52%)	16.2* ± 7.28 (55%)

* significant difference with baseline values (P < 0.001)
(____) illustrates proportion with significant pain relief (≥ 50%) from baseline

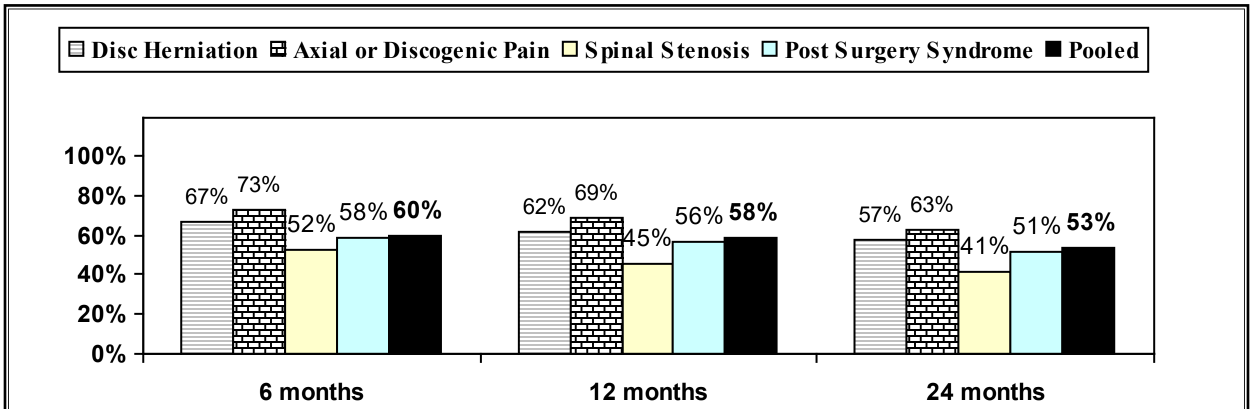

Fig. 2. *Proportion of patients with significant reduction in Numeric Rating Score and Oswestry Disability Index (≥ 50% reduction from baseline).*

Table 3. *Employment characteristics.*

Employment Status	Disc Herniation		Axial or Discogenic Pain		Spinal Stenosis		Post Surgery Syndrome		Pooled	
	Baseline	24 mos.	Baseline	24 mos.	Baseline	24 mos.	Baseline	24 mos.	Baseline	24 mos.
Employed part-time	6	7	8	8	2	2	3	3	19	20
Employed full-time	16	29	17	32	11	13	19	23	63	97
Unemployed	13	5	15	2	3	1	4	3	35	11
Off work due to pain	1	1	1	1	2	1	3	1	7	4
Total Employed	22	36	25	40	13	15	22	26	82	117*
Eligible for employment	36	36	41	41	18	18	29	29	124	124
Housewife	12	6	10	7	6	6	3	3	31	22
Disabled	62	62	55	56	48	48	85	84	250	250
Over 65 year of age	10	10	14	14	28	29	23	23	75	76
Total Number of Patients	120	120	120	120	100	100	140	140	480	480

* significant difference with baseline values (P < 0.001)

Table 4. *Analysis of cost effectiveness of caudal epidural injections in managing pain and disability of disc herniation, discogenic pain, spinal stenosis, and post surgery syndrome in 480 patients.*

	Disc Herniation	Axial or Discogenic Pain	Spinal Stenosis	Post Surgery Syndrome	Total
Number of patients	120	120	100	140	480
Total number of procedures for 2 years	601	647	400	696	2344
Number of treatments for 2 years per patient (mean) ± SD	5.0 ± 2.55	5.4 ± 2.63	4.0 ± 2.57	5.0 ± 2.76	4.9 ± 2.67
Number of weeks with significant improvement for all patients in the study in weeks for 2 years	6294	7254	4305	7096	24949
Significant improvement in weeks per procedure (mean) ± SEM	9.4 ± 7.23	10.7 ± 8.25	9.7 ± 13.54	8.4 ± 6.14	9.5 ± 8.92
Number of weeks with significant improvement per patient for 2 years	52.5 ± 38.46	60.4 ± 37.71	43.1 ± 41.52	50.7 ± 38.71	52.0 ± 39.33
Total Cost ($)					
Physician	$74,761.00	$81,729.00	$45,944.00	$88,776.00	$291,210.00
Facility	$192,225.00	$216,268.00	$132,468.00	$210,168.00	$751,129.00
Total	$266,986.00	$297,997.00	$178,412.00	$298,944.00	$1,042,339.00
Cost per procedure ($)					
Physician	$124.40	$126.30	$115.10	$127.60	$124.30
Facility	$319.80	$334.30	$332.00	$302.00	$320.60
Total	$444.20	$460.60	$447.10	$429.50	$444.90
Cost per 1-week QALY ($)	$42.42	$41.08	$41.44	$42.13	$41.78
Cost per 1-year QALY ($)	$2,205.79	$2,136.18	$2,155.03	$2,190.68	$2,172.50
Cost per 2-year QALY ($)	$4,411.59	$4,272.36	$4,310.07	$4,381.37	$4,344.99
Average Total cost per patient for 2 years	$2,225.00	$2,483.00	$1,784.00	$2,135.00	$2,172.00

Cost Utility Analysis

Cost utility analysis was based on the quality of life improvement and cost for procedure per QALY based on the primary outcomes of pain relief and improvement in functional status (Table 4).

The results show an average cost per procedure of $444.90. The cost for one week improvement in quality of life was $41.78 with improvement for one year at $2,172.50, whereas it was $4,344.99 for a 2-year QALY. The total cost of the procedures at 2 years was on average $2,171.54. There was no significant difference noted among the groups with reference to cost or cost utility.

Further, an assessment of the cost utility of only successful patients, those who responded to the initial 2 injections with at least 3 weeks of relief, was $37.81 per week, $1,966.03 for one year, and $3,932.06 for 2 years for QALY (Table 5).

Discussion

This cost utility analysis of caudal epidural injections involved 4 randomized controlled trials with 480 patients with 2 years of follow-up. We used the actual reimbursement data and studied patients in chronic pain after failure of conservative management, either secondary to disc herniation, axial or discogenic pain without facet joint pain or disc herniation, central spinal stenosis, or post lumbar surgery syndrome,. Our analysis demonstrated a cost utility for one year of quality adjusted life at $2,206 for disc herniation, $2,136 for axial or discogenic pain without disc herniation, $2,155 for central spinal stenosis, and $2,191 for post surgery syndrome. There was no difference in cost effectiveness in disc herniation and discogenic pain compared to spinal stenosis and post lumbar surgery syndrome. Thus, all patients showed significant improvement, clinically and in cost utility. However, the number of procedures performed per patient was somewhat less for the spinal stenosis group compared to the other 3 conditions. However, an analysis of only the successful group of patients shows a higher average significant improvement per week, as well as total improvement for a 2-year period in all groups. This also increases the average number of procedures over 2 years, with spinal stenosis patients receiving overall significantly

Table 5. *Analysis of the cost effectiveness of caudal epidural injections in managing pain and disability of disc herniation, discogenic pain, spinal stenosis, and post surgery syndrome in successful group with 357 of 480 patients.*

	Disc Herniation	Axial or Discogenic Pain	Spinal Stenosis	Post Surgery Syndrome	Total
Number of patients	78	97	74	108	357
Total number of procedures for 2 years	472	593	357	648	2070
Average number of treatments for 2 years per patient (mean ± SD)	6.1 ± 2.2	6.1 ± 2.3	4.8 ± 2.4	6.0 ± 2.3	5.8 ± 2.3
Number of weeks with significant improvement for all patients in the study in weeks for 2 years	5697	7120	4213	7022	24052
Significant improvement in weeks per procedure (mean) ± SEM	12.8 ± 6.5	12.8 ± 7.7	12.8 ± 14.6	10.5 ± 5.3	12.1 ± 8.9
Number of weeks with significant improvement per patient for 2 years	73.0 ± 28.06	73.4 ± 29.31	56.9 ± 39.30	65.0 ± 32.17	67.4 ± 32.73
Total Cost ($)					
Physician	$57,470.00	$73,058.00	$41,307.00	$82,624.00	$254,459.00
Facility	$150,361.00	$190,814.00	$120,072.00	$193,658.00	$654,905.00
Total	$207,831.00	$263,872.00	$161,379.00	$276,282.00	$909,364.00
Cost per procedure ($)					
Physician	$121.80	$125.10	$116.00	$127.50	$123.50
Facility	$318.60	$326.70	$337.30	$298.90	$317.90
Total	$440.30	$451.80	$453.30	$426.40	$441.40
Cost per 1-week QALY ($)	$36.48	$37.06	$38.31	$39.35	$37.81
Cost per 1-year QALY ($)	$1,897.00	$1,927.16	$1,991.86	$2,045.95	$1,966.03
Cost per QALY ($)	$3,794.00	$3,854.31	$3,983.72	$4,091.90	$3,932.06
Average total cost per patient for 2 years	$2,665.00	$2,720.00	$2,181.00	$2,558.00	$2,547.00

fewer procedures compared to all other groups. Overall, significant improvement per procedure was 12.1 ± 8.9 weeks in the successful group, whereas it was 9.5 ± 8.92 weeks when all patients were combined. Overall average relief was 67.4 ± 32.7 weeks in the successful group whereas it was 52.0 ± 39.33 weeks when all patients were combined. Cost for one week improvement in QALY was $37.81 versus $41.78; for one year it was $1,966.03 versus $2,172.50; and for 2 years it was $2,547 in the successful group versus $2,172 in the combined group.

The cost effectiveness and utility of all spinal interventions has been questioned. In assessing the costs and cost effectiveness of spinal cord stimulation for failed back surgery syndrome, Hollingworth et al (60) showed that the high procedure cost of spinal cord stimulation was not counterbalanced by lower costs of subsequent care, and therefore spinal cord stimulation was not cost-effective. They showed a mean medical cost per spinal cord stimulation patient over 24 months was $52,091 which was $17,291 higher than a pain clinic group and $28,128 higher than a usual care group. However, in contrast, Taylor et al (58), utilizing a United Kingdom National Institute for Health and Care Excellence (NICE) cost effectiveness analysis, and analyzing the impact on cost effectiveness, showed the incremental cost effectiveness of spinal cord stimulation compared with conventional medical management was £55,624 per QALY year. They considered that utilizing a £20,000 threshold for spinal cord stimulation was cost effective.

Price et al (62) showed epidural injections to be extremely cost ineffective. In contrast, Manchikanti et al (66,68) showed significant cost utility with less than $3,000 per QALY improvement with caudal epidural injections. Whynes et al (57) also showed cost effectiveness of £8,975 per QALY. In patients with more than 3 months of nonspecific low back pain severe enough to lead to disability, physical therapy had an incremental cost effectiveness of $4,594/QALY relative to brief pain management with a greater than 83% probability of being cost effective at a willingness to pay threshold of £10,000 or $15,930/QALY in patients with less than 12 weeks of nonspecific low back pain (85). In other studies, adding a community-based active exercise component to education had a cost effectiveness of $8,650/QALY over education alone (86) in managing persistent low back pain lasting over 3 months. In another study, individual physiotherapy had a favorable cost utility of $2,216/QALY over spinal stabilization physiotherapy (87). In another study, physiotherapy was more cost effective than advice alone at a cost utility of $6,379/QALY for patients with greater than 6 weeks of low back pain (88). Based on these assessments, spinal manipulation appears to be the most cost effective intervention, followed by manipulation and community exercise being the best care for patients with longer than 4 weeks of low back pain (89).

Multiple studies have compared the cost utility of operative lumbar discectomy compared with nonoperative care. Among the studies comparing the relative cost utility of operative versus nonoperative studies was one for lumbar disc herniation, in which operative care demonstrated a significant incremental benefit and outcome advantage over nonoperative care in all 4 studies and clear cost effectiveness compared with nonoperative care in 3 of 4 studies. In inflation-adjusted 2010 US dollars, surgery relative to nonoperative care was estimated at an incremental cost-utility ratio (ICUR) of $80,160/QALY (69), ICUR of $4,891/QALY (69,90), and ICUR of $44,089/QALY (91). One study evaluated the cost savings to society, demonstrating a cost saving of more than $4,000 for early operative care compared with nonoperative care (92). In an assessment of the SPORT data, Tosteson et al (70) showed that spinal stenosis surgeries improved health to a greater extent than nonoperative care at a cost of $77,600 per QALY gained. They also showed that degenerative spondylolisthesis surgery significantly improved health versus nonoperative care at a cost of $115,600 per QALY gained.

In a cost effectiveness study of multilevel laminectomy, Parker et al (72) showed that multilevel hemilaminectomy was associated with a mean 2-year cost per QALY gained of $33,700. In comparing the cost effectiveness of multiple strategies for lumbar spinal stenosis with either nonsurgical care, laminectomy, or X-STOP, Burnett et al (71) showed laminectomy to be the most effective treatment strategy, followed by X-STOP and then conservative treatment at a 2-year time horizon. While it was difficult to assess the overall costs, they showed that cost per QALY added by both laminectomy and X-STOP was within accepted modern norms, with incremental cost per QALY of about $50,000 more for single-level laminectomy than for X-STOP under the study parameters.

Nonoperative care for the management of nonspecific lumbar degenerative disorders such as failed back surgery syndrome and nonspecific chronic low back pain lasting over 12 months is favored over nonspecific operative strategies (11). The ICUR for operative care was $77,930/QALY (93) with less than 20% probability of being cost effective at £30,000 ($47,835/QALY). At a willingness to pay threshold of $45,000 QALY (55) established by NICE, 2 of the studies (69,93) indicated favorable cost utility of surgery over nonoperative care, whereas the other 2 studies (90,91) supported nonoperative care over operative interventions. Other studies assessing the cost utility of operative care showed circumferential fusion was cost effective compared with posterolateral fusion with an ICUR of $49,306/QALY; it costs less and provides greater utility more than 80% of the time in patients with ischemic spondylolisthesis or primary/secondary disc herniation (94).

In a value-based health care economy, the preferred goal for health care delivery is superior patient value (11,95). Consequently, using the interventions that provide the most value to patients is essential for achieving this high standard of patient care. The cost utility of an intervention may be used to identify interventions that provide the most benefit to patients as measured by patient-centered outcome measures while incurring the least expense. The outcome measures used in cost effectiveness analysis studies in chronic pain research mainly include outcomes, such as disability days saved, pain-free days, or improved quality of life (96). Evaluation of the quality of life, which is also known as functional status, includes health status, or health-related quality of life; well being of the patient; satisfaction with care; health service utilization/economic analysis; and medical findings (97). The quality of life assessment is designed to evaluate the patient's ability to function in his or her own world. Physical function measures the ability to perform physical activities such as walking, climbing stairs, or carrying things.

This evaluation reaffirms the cost utility of caudal epidural injections in patients with chronic pain at less than $2,200 per QALY for any of the low back conditions studied. This cost utility is less than some medical therapies, surgical interventions, physical therapy, and manipulation (55,69-72,85-94).

Maas et al (98) designed a cost effectiveness study of minimal interventional procedures for chronic mechanical low back pain which included 4 randomized controlled trials with an economic evaluation. However, the results of this study are not available yet.

Limitations of this analysis include the fact that only the actual cost of the medical care was utilized. Other medical costs or benefits derived, including a return to work, have not been utilized. This evaluation shows that there were 82 patients were employed from 124 patients at baseline, whereas, at the end 117 of 124 employable were employed increasing the employment from 66.1% to 94.3%. Thus, calculating the number of individual employed with an average salary of $34,000 in McCracken County or $40,000 in Kentucky, the salary benefits alone in these patient will exceed $1 million equivalent or higher than the total expenditures for all the procedures in these patients. Thus, cost utility is achieved even without considering improvement in all other patients who have not returned to work. Further, we were unable to carry out an incremental cost utility ratio analysis due to insignificant differences in both groups since these trials were active-control trials.

However, incorporating additional costs as illustrated in multiple studies does not exceed $2,000 in both surgical groups and the nonoperative care groups (69,70). We estimated our cost of drug therapy is less than what has been shown in the past (69,70). The average costs of drug therapy, including insurance payments, in these patients ranges from $500 to a maximum of $2,400 over a period of 2 years, thus adding $1,200 at the most to each patient and most likely a QALY of one year.

Some investigators have used difficult to understand methodologies to calculate the economic impact of spinal disorders (99). Dagenais et al (100) described a case of an executive with high income and disproportionately excessive charges for treatments received show a nonoperative cost of $53,595 for one attack of acute radiculitis with each transforaminal epidural injection costing $2,500. The hypothetical patient in this article received 2 transforaminal epidural injections, along with 4 weeks of physical therapy and $200 worth of opioids. Even though the authors state this to be a realistic example, based on the results of our evaluation, they are excessive. However, challenging interpretation of data is not new in medicine, particularly in interventional pain management (13,48-53,99,100).

Cost utility analysis or cost effectiveness analysis are forms of financial analysis used to guide procurement decisions. In health economics, the purpose of cost utility analysis is to estimate the ratio between the cost of a health-related intervention and the benefit it produces in terms of the number of years lived in full health by the beneficiaries. Consequently, it is considered a special case of cost effectiveness analysis, and the 2 terms are often used interchangeably. The incremental cost effectiveness ratio is the ratio between the difference in costs and the difference in benefits of 2 interventions. As with any system financing health care, countries have a limited budget and a vast number of potential spending options. Consequently, choices must be made as how this limited budget is spent and control the escalating costs. By comparing cost effectiveness in terms of health quality gained for the money that is spent, decisions can be made about treatment options that provide the most efficient results.

NICE, the National Institute for Health and Clinical Excellence (55) in the United Kingdom, recently was changed from a special authority to a nondepartmental public body. NICE attempts to assess the cost effectiveness of potential expenditures within the National Health Services to assess whether or not they represent "better value" for money than treatments that would be neglected if the expenditures took place. It also assesses the cost effectiveness of new treatments by analyzing the cost and benefit of the proposed treatment relative to the next best treatment that is currently in use. NICE utilizes the QALY to measure the health benefits delivered by a given treatment regimen. When combined with the relative cost of treatments, this information can be used to form an incremental cost effectiveness ratio to allow comparing a suggested expenditure against current resource use at the margin or cost effectiveness threshold. As a guideline rule, NICE accepts as cost effective those interventions with an incremental cost effectiveness ratio of less than £20,000 per QALY and that there should be increasingly strong reasons for accepting as cost-effective interventions with an incremental cost effectiveness ratio or threshold of £30,000 per QALY. The work that NICE is involved with has attracted the attention of many groups, including doctors, the pharmaceutical industry, and patients. Consequently, NICE is often associated with controversy because the need to make decisions at a national level can conflict with what is or what is not believed to be in the best interest of an individual patient. Interventional pain management has taken center stage under NICE.

In the United States, there is no organization such as NICE to calculate the cost effectiveness. In fact, many of the regulations state that cost effectiveness is not to be taken into consideration, but common sense dictates that these are being used based on budgetary constraints.

These cost utility analyses are based on reimbursements for physician and facility charges in an ambulatory surgery center setting in a contemporary interventional pain management facility. Thus, this may not be generalizable to all settings and all populations. It is estimated that costs of this analysis may be approximately 30% to 40% higher in a hospital setting and approximately 20% lower in an office setting. Overall this cost utility analysis shows lower costs with caudal epidural injections than various other therapies including medical therapy in most cases.

Conclusion

This cost utility analysis of caudal epidural injections in the treatment of disc herniation, axial or discogenic low back pain, central spinal stenosis, and post lumbar surgery syndrome shows clinical effectiveness and cost utility at less than $2,200 per one year of QALY.

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References

1. Martin BI, Turner JA, Mirza SK, Lee MJ, Comstock BA, Deyo RA. Trends in health care expenditures, utilization, and health status among US adults with spine problems, 1997-2006. *Spine (Phila Pa 1976)* 2009; 34:2077-2084.
2. Manchikanti L, Caraway DL, Parr AT, Fellows B, Hirsch JA. Patient Protection and Affordable Care Act of 2010: Reforming health care reform for the new decade. *Pain Physician* 2011; 14:E35-E67.
3. Manchikanti L, Falco FJ, Benyamin RM, Helm S 2nd, Parr AT, Hirsch JA. The impact of comparative effectiveness research on interventional pain management: Evolution from Medicare Modernization Act to Patient Protection and Affordable Care Act and the Patient-Centered Outcomes Research Institute. *Pain Physician* 2011; 14:E249-E282.
4. Manchikanti L, Falco FJE, Singh V, Benyamin RM, Hirsch JA. The Independent Payment Advisory Board. *Pain Physician* 2011; 14:E313-E342.
5. Manchikanti L, Pampati V, Falco FJE, Hirsch JA. Growth of spinal interventional pain management techniques: Analysis of utilization trends and Medicare expenditures 2000 to 2008. *Spine (Phila Pa 1976)* 2013; 38:157-168.
6. Manchikanti L, Falco FJE, Singh V, Pampati V, Parr AT, Benyamin RM, Fellows B, Hirsch JA. Utilization of interventional techniques in managing chronic pain in the Medicare population: Analysis of growth patterns from 2000 to 2011. *Pain Physician* 2012; 15:E969-E982.
7. Manchikanti L, Parr AT, Singh V, Fellows B. Ambulatory surgery centers and interventional techniques: A look at long-term survival. *Pain Physician* 2011; 14:E177-E215.
8. Manchikanti L, Singh V, Hirsch JA. Saga of payment systems of ambulatory surgery centers for interventional techniques: An update. *Pain Physician* 2012; 15:109-130.
9. Manchikanti L, Caraway DL, Falco FJE, Benyamin RM, Hansen H, Hirsch JA. CMS proposal for interventional pain management by nurse anesthetists: Evidence by proclamation with poor prognosis. *Pain Physician* 2012; 15:E641-E664.
10. Kepler CK, Wilkinson SM, Radcliff KE, Vaccaro AR, Anderson DG, Hilibrand AS, Albert TJ, Rihn JA. Cost-utility analysis in spine care: A systematic review. *Spine J* 2012; 12:676-690.
11. Indrakanti SS, Weber MH, Takemoto SK, Hu SS, Polly D, Berven SH. Value-based care in the management of spinal disorders: A systematic review of cost-utility analysis. *Clin Orthop Relat Res* 2012; 470:1106-1023.
12. Furlan AD, Yazdi F, Tsertsvadze A, Gross A, van Tulder M, Santaguida L, Gagnier J, Ammendolia C, Dryden T, Doucette S, Skidmore B, Daniel R, Ostermann T, Tsouros S. A systematic review and meta-analysis of efficacy, cost-effectiveness, and safety of selected complementary and alternative medicine for neck and low-back pain. *Evid Based Complement Alternat Med* 2012; 2012:953139.
13. Manchikanti L, Abdi S, Atluri S, Benyamin RM, Boswell MV, Buenaventura RM, Bryce DA, Burks PA, Caraway DL, Calodney AK, Cash KA, Christo PJ, Cohen SP, Colson J, Conn A, Cordner HJ, Coubarous S, Datta S, Deer TR, Diwan SA, Falco FJE, Fellows B, Geffert SC, Grider JS, Gupta S, Hameed H, Hameed M, Hansen H, Helm II S, Janata JW, Justiz R, Kaye AD, Lee M, Manchikanti KN, McManus CD, Onyewu O, Parr AT, Patel V, Racz GB, Sehgal N, Sharma M, Simopoulos TT, Singh V, Smith HS, Snook LT, Swicegood J, Vallejo R, Ward SP, Wargo BW, Zhu J, Hirsch JA. An update of comprehensive evidence-based guidelines for interventional techniques of chronic spinal pain: Part II: Guidance and recommendations. *Pain Physician* 2013; 16:S49-S253.
14. Kovacs FM, Urrútia G, Alarcón JD. Surgery versus conservative treatment for symptomatic lumbar spinal stenosis: A systematic review of randomized controlled trials. *Spine (Phila Pa 1976)* 2011; 36:E1335-E1351.
15. Jacobs WC, van Tulder M, Arts M, Rubinstein SM, van Middelkoop M, Ostelo R, Verhagen A, Koes B, Peul WC. Surgery versus conservative management of sciatica due to a lumbar herniated disc: A systematic review. *Eur Spine J* 2011; 20:513-522.
16. Rajaee SS, Bae HW, Kanim LE, Delamarter RB. Spinal fusion in the United States: Analysis of trends from 1998 to 2008. *Spine (Phila Pa 1976)* 2012; 37:67-76.
17. Manchikanti L, Buenaventura RM, Manchikanti KN, Ruan X, Gupta S, Smith HS, Christo PJ, Ward SP. Effectiveness of therapeutic lumbar transforaminal epidural steroid injections in managing lumbar spinal pain. *Pain Physician* 2012; 15:E199-E245.
18. Parr AT, Manchikanti L, Hameed H, Conn A, Manchikanti KN, Benyamin RM, Diwan S, Singh V, Abdi S. Caudal epidural injections in the management of chronic low back pain: A systematic appraisal of the literature. *Pain Physician* 2012; 15:E159-E198.
19. Benyamin RM, Manchikanti L, Parr AT, Diwan SA, Singh V, Falco FJE, Datta S, Abdi S, Hirsch JA. The effectiveness of lumbar interlaminar epidural injections in managing chronic low back and lower extremity pain. *Pain Physician* 2012; 15:E363-E404.
20. Diwan SA, Manchikanti L, Benyamin RM, Bryce DA, Geffert S, Hameed H, Sharma ML, Abdi S, Falco FJE. Effectiveness of cervical epidural injections in the management of chronic neck and upper extremity pain. *Pain Physician* 2012; 15:E405-E434.
21. Benyamin RM, Wang VC, Vallejo R, Singh V, Helm II S. A systematic evaluation of thoracic interlaminar epidural injections. *Pain Physician* 2012; 15:E497-E514.
22. Manchikanti L, Abdi S, Atluri S, Balog CC, Benyamin RM, Boswell MV, Brown KR, Bruel BM, Bryce DA, Burks PA, Burton AW, Calodney AK, Caraway DL, Cash KA, Christo PJ, Damron KS, Datta S, Deer TR, Diwan S, Eriator I, Falco FJE, Fellows F, Geffert S, Gharibo CG, Gla-

ser SE, Grider JS, Hameed H, Hameed M, Hansen H, Harned ME, Hayek SM, Helm II S, Hirsch JA, Janata JW, Kaye AD, Kaye AM, Kloth DS, Koyyalagunta D, Lee M, Malla Y, Manchikanti KN, McManus CD, Pampati V, Parr AT, Pasupuleti R, Patel VB, Sehgal N, Silverman SM, Singh V, Smith HS, Snook LT, Solanki DR, Tracy DH, Vallejo R, Wargo BW. American Society of Interventional Pain Physicians (ASIPP) guidelines for responsible opioid prescribing in chronic non-cancer pain: Part I – Evidence assessment. *Pain Physician* 2012; 15:S1-S66.

23. Manchikanti L, Abdi S, Atluri S, Balog CC, Benyamin RM, Boswell MV, Brown KR, Bruel BM, Bryce DA, Burks PA, Burton AW, Calodney AK, Caraway DL, Cash KA, Christo PJ, Damron KS, Datta S, Deer TR, Diwan S, Eriator I, Falco FJE, Fellows F, Geffert S, Gharibo CG, Glaser SE, Grider JS, Hameed H, Hameed M, Hansen H, Harned ME, Hayek SM, Helm II S, Hirsch JA, Janata JW, Kaye AD, Kaye AM, Kloth DS, Koyyalagunta D, Lee M, Malla Y, Manchikanti KN, McManus CD, Pampati V, Parr AT, Pasupuleti R, Patel VB, Sehgal N, Silverman SM, Singh V, Smith HS, Snook LT, Solanki DR, Tracy DH, Vallejo R, Wargo BW. American Society of Interventional Pain Physicians (ASIPP) guidelines for responsible opioid prescribing in chronic non-cancer pain: Part 2 – Guidance. *Pain Physician* 2012; 15:S67-S116.
24. Weinstein JN, Lurie JD, Tosteson TD, Tosteson AN, Blood EA, Abdu WA, Herkowitz H, Hilibrand A, Albert T, Fischgrund J. Surgical versus nonoperative treatment for lumbar disc herniation: Four-year results for the Spine Patient Outcomes Research Trial (SPORT). *Spine (Phila Pa 1976)* 2008; 33:2789-2800.
25. Weinstein JN, Tosteson TD, Lurie JD, Tosteson AN, Blood E, Hanscom B, Herkowitz H, Cammisa F, Albert T, Boden SD, Hilibrand A, Goldberg H, Berven S, An H; SPORT Investigators. Surgical versus nonsurgical therapy for lumbar spinal stenosis. *N Engl J Med* 2008; 358:794-810.
26. Weinstein JN, Lurie JD, Tosteson TD, Zhao W, Blood EA, Tosteson AN, Birkmeyer N, Herkowitz H, Longley M, Lenke L, Emery S, Hu SS. Surgical compared with nonoperative treatment for lumbar degenerative spondylolisthesis. Four-year results in the Spine Patient Outcomes Research Trial (SPORT) randomized and observational cohorts. *J Bone Joint Surg Am* 2009; 91:1295-1304.
27. Freburger JK, Holmes GM, Agans RP, Jackman AM, Darter JD, Wallace AS, Castel LD, Kalsbeek WD, Carey TS. The rising prevalence of chronic low back pain. *Arch Intern Med* 2009; 169:251-258.
28. Falco FJE, Manchikanti L, Datta S, Sehgal N, Geffert S, Onyewu O, Singh V, Bryce DA, Benyamin RM, Simopoulos TT, Vallejo R, Gupta S, Ward SP, Hirsch JA. An update of the systematic assessment of the diagnostic accuracy of lumbar facet joint nerve blocks. *Pain Physician* 2012; 15:E869-E907.
29. Falco FJE, Manchikanti L, Datta S, Sehgal N, Geffert S, Onyewu O, Zhu J, Coubarous S, Hameed M, Ward SP, Sharma M, Hameed H, Singh V, Boswell MV. An update of the effectiveness of therapeutic lumbar facet joint interventions. *Pain Physician* 2012; 15:E909-E953.
30. Falco FJE, Datta S, Manchikanti L, Sehgal N, Geffert S, Singh V, Smith HS, Boswell MV. An updated review of diagnostic utility of cervical facet joint injections. *Pain Physician* 2012; 15:E807-E838.
31. Falco FJE, Manchikanti L, Datta S, Wargo BW, Geffert S, Bryce DA, Atluri S, Singh V, Benyamin RM, Sehgal N, Ward S, Helm II S, Gupta S, Boswell MV. Systematic review of therapeutic effectiveness of cervical facet joint interventions: An update. *Pain Physician* 2012; 15:E839-E868.
32. Atluri S, Singh V, Datta S, Geffert S, Sehgal N, Falco FJE. Diagnostic accuracy of thoracic facet joint nerve blocks: An update of the assessment of evidence. *Pain Physician* 2012; 15:E483-E496.
33. Manchikanti KN, Atluri S, Singh V, Geffert S, Sehgal N, Falco FJE. An update of evaluation of therapeutic thoracic facet joint interventions. *Pain Physician* 2012; 15:E463-E481.
34. Helm II S, Benyamin RM, Chopra P, Deer TR, Justiz R. Percutaneous adhesiolysis in the management of chronic low back pain in post lumbar surgery syndrome and spinal stenosis: A systematic review. *Pain Physician* 2012; 15:E435-E462.
35. Simopoulos TT, Manchikanti L, Singh V, Gupta S, Hameed H, Diwan S, Cohen SP. A systematic evaluation of prevalence and diagnostic accuracy of sacroiliac joint interventions. *Pain Physician* 2012; 15:E305-E344.
36. Hansen H, Manchikanti L, Simopoulous TT, Christo PJ, Gupta S, Smith HS, Hameed H, Cohen SP. A systematic evaluation of the therapeutic effectiveness of sacroiliac joint interventions. *Pain Physician* 2012; 15:E247-E278.
37. Manchikanti L, Cash RA, McManus CD, Pampati V, Fellows B. Fluoroscopic caudal epidural injections with or without steroids in managing pain of lumbar spinal stenosis: One year results of randomized, double-blind, active-controlled trial. *J Spinal Disord* 2012; 25:226-234.
38. Manchikanti L, Singh V, Cash KA, Pampati V, Damron KS, Boswell MV. A randomized, controlled, double-blind trial of fluoroscopic caudal epidural injections in the treatment of lumbar disc herniation and radiculitis. *Spine (Phila Pa 1976)* 2011; 36:1897-1905.
39. Manchikanti L, Cash KA, McManus CD, Pampati V, Smith HS. One year results of a randomized, double-blind, active controlled trial of fluoroscopic caudal epidural injections with or without steroids in managing chronic discogenic low back pain without disc herniation or radiculitis. *Pain Physician* 2011; 14:25-36.
40. Manchikanti L, Singh V, Cash KA, Pampati V, Damron KS, Boswell MV. Effect of fluoroscopically guided caudal epidural steroid or local anesthetic injections in the treatment of lumbar disc herniation and radiculitis: A randomized, controlled, double blind trial with a two-year follow-up. *Pain Physician* 2012; 15:273-286.
41. Manchikanti L, Cash KA, McManus CD, Pampati V, Fellows B. Results of 2-year follow-up of a randomized, double-blind, controlled trial of fluoroscopic caudal epidural injections in central spinal stenosis. *Pain Physician* 2012; 15:371-384.
42. Manchikanti L, Singh V, Cash KA, Pampati V, Datta S. Fluoroscopic caudal epidural injections in managing post lumbar surgery syndrome: Two-year results of a randomized, double-blind, active-control trial. *Int J Med Sci* 2012; 9:582-591.
43. Manchikanti L, Cash KA, McManus CD, Pampati V. Fluoroscopic caudal epidural injections in managing chronic axial low back pain without disc herniation, radiculitis or facet joint pain. *J Pain Res* 2012; 5:381-390.
44. Iversen T, Solberg TK, Romner B, Wilsgaard T, Twisk J, Anke A, Nygaard O, Hasvold T, Ingebrigtsen T. Effect of caudal epidural steroid or saline injection in chronic lumbar radiculopathy: Multicentre, blinded, randomised controlled trial. *BMJ* 2011; 343:d5278.

45. Dashfield AK, Taylor MB, Cleaver JS, Farrow D. Comparison of caudal steroid epidural with targeted steroid placement during spinal endoscopy for chronic sciatica: A prospective, randomized, double-blind trial. *Br J Anaesth* 2005; 94:514-559.
46. Gharibo C, Varlotta G, Rhame E, Liu ECJ, Bendo J, Perloff M. Interlaminar versus transforaminal epidural steroids for the treatment of sub-acute lumbar radicular pain: A randomized, blinded, prospective outcome study. *Pain Physician* 2011; 14:499-511.
47. Manchikanti L, Singh V, Cash KA, Pampati V, Datta S. Assessment of effectiveness of percutaneous adhesiolysis and caudal epidural injections in managing lumbar post surgery syndrome: A 2-year follow-up of randomized, controlled trial. *J Pain Res* 2012; 5:597-608.
48. Chou R, Huffman L. *Guideline for the Evaluation and Management of Low Back Pain: Evidence Review*. American Pain Society, Glenview, IL, 2009. www.ampainsoc.org/pub/pdf/LBPEvidRev.pdf
49. Manchikanti L, Datta S, Gupta S, Munglani R, Bryce DA, Ward SP, Benyamin RM, Sharma ML, Helm II S, Fellows B, Hirsch JA. A critical review of the American Pain Society clinical practice guidelines for interventional techniques: Part 2. Therapeutic interventions. *Pain Physician* 2010; 13:E215-E264.
50. Chou R, Atlas SJ, Loeser JD, Rosenquist RW, Stanos SP. Guideline warfare over interventional therapies for low back pain: Can we raise the level of discourse? *J Pain* 2011; 12:833-839.
51. Manchikanti L, Benyamin RM, Falco FJE, Caraway DL, Datta S, Hirsch JA. Guidelines warfare over interventional techniques: Is there a lack of discourse or straw man? *Pain Physician* 2012; 15:E1-E26.
52. Manchikanti L, Giordano J, Fellows B, Hirsch JA. Placebo and nocebo in interventional pain management: A friend or a foe – or simply foes? *Pain Physician* 2011; 14:E157-E175.
53. Pinto RZ, Maher CG, Ferreira ML, Hancock M, Oliveira VC, McLachlan AJ, Koes B, Ferreira PH. Epidural corticosteroid injections in the management of sciatica: A systematic review and meta-analysis. *Ann Intern Med* 2012; 157:865-877.
54. Dagenais S, Haldeman S, Polatin PB. It is time for physicians to embrace cost-effectiveness and cost utility analysis research in the treatment of spinal pain. *Spine J* 2005; 5:357-360.
55. National Institute for Health and Clinical Excellence. *Guide to the Methods of Technology Appraisal*. NICE, London, 2008.
56. Dagenais S, Roffey DM, Wai EK, Haldeman S, Caro J. Can cost utility evaluations inform decision making about interventions for low back pain? *Spine J* 2009; 9:944-957.
57. 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; 8:8-20.
58. Taylor RS, Ryan J, O'Donnelll R, Eldabe S, Kumar K, North RB. The cost-effectiveness of spinal cord stimulation in the treatment of failed back surgery syndrome. *Clin J Pain* 2010; 26:463-469.
59. Guillemette S, Witzke S, Leier J, Hinnenthal J, Prager JP. Medical cost impact of intrathecal drug delivery for noncancer pain. *Pain Med* 2013; 14:504-515.
60. Hollingworth W, Turner JA, Welton NJ, Comstock BA, Deyo RA. Costs and cost-effectiveness of spinal cord stimulation (SCS) for failed back surgery syndrome: An observational study in a workers' compensation population. *Spine (Phila Pa 1976)* 2011; 36:2076-2083.
61. Whynes DK, McCahon RA, Ravenscroft A, Hardman J. Cost effectiveness of epidural steroid injections to manage chronic lower back pain. *BMC Anesthesiol* 2012; 12:26.
62. Price C, Arden N, Coglan L, Rogers P. Cost-effectiveness and safety of epidural steroids in the management of sciatica. *Health Technol Assess* 2005; 9:1-58, iii.
63. Jackson C, Broadhurst N, Bogduk N. An audit of the use of epidural injections for back pain and sciatica. *Aust Health Rev* 2003; 26:34-42.
64. McGregor AH, Anjarwalla NK, Stambach T. Does the method of injection alter the outcome of epidural injections? *J Spinal Disord* 2001; 14:507-510.
65. Opstelten W, van Wijck AJ, van Essen GA, Moons KG, Verheij TJ, Kalkman CJ, van Hout BA. Cost effectiveness of epidural injection of steroids and local anesthetics for relief of zoster-associated pain. *Anesthesiology* 2007; 107:678-679.
66. Manchikanti L, Pampati V, Rivera JJ, Beyer CD, Damron KS, Barnhill RC. Caudal epidural injections with Sarapin or steroids in chronic low back pain. *Pain Physician* 2001; 4:322-335.
67. Wielage R, Bansal M, Wilson K, Klein R, Happich M. The cost-effectiveness of duloxetine in chronic low back pain: A Quebec societal perspective. *Spine (Phila Pa 1976)* 2012 Dec 17. [Epub ahead of print]
68. Manchikanti L, Pakanati RR, Pampati V. Comparison of three routes of epidural steroid injections in low back pain. *Pain Digest* 1999; 9:277-285.
69. Tosteson AN, Skinner JS, Tosteson TD, Lurie JD, Andersson GB, Berven S, Grove MR, Hanscom B, Blood EA, Weinstein JN. 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; 33:2108-2115.
70. Tosteson AN, Lurie JD, Tosteson TD, Skinner JS, Herkowitz H, Albert T, Boden SD, Bridwell K, Longley M, Andersson GB, Blood EA, Grove MR, Weinstein JN; SPORT Investigators. Surgical treatment of spinal stenosis with and without degenerative spondylolisthesis: Cost-effectiveness after 2 years. *Ann Intern Med* 2008; 149:845-853.
71. Burnett MG, Stein SC, Bartels RH. Cost-effectiveness of current treatment strategies for lumbar spinal stenosis: Nonsurgical care, laminectomy, and X-STOP. *J Neurosurg Spine* 2010; 13:39-46.
72. Parker SL, Fulchiero EC, Davis BJ, Adogwa O, Aaronson OS, Cheng JS, Devin CJ, McGirt MJ. Cost-effectiveness of multilevel hemilaminectomy for lumbar stenosis-associated radiculopathy. *Spine J* 2011; 11:705-711.
73. Fairbank JC, Pynsent PB. The Oswestry Disability Index. *Spine (Phila Pa 1976)* 2000; 25:2940- 2952.
74. Manchikanti L, Benyamin RM, Helm S, Hirsch JA. Evidence-based medicine, systematic reviews, and guidelines in interventional pain management: Part 3: Systematic reviews and meta-analysis of randomized trials. *Pain Physician* 2009; 12:35-72.
75. Manchikanti L, Singh V, Falco FJE, Cash KA, Pampati V. Evaluation of lumbar facet joint nerve blocks in managing chronic low back pain: A randomized, double-blind, controlled trial with a 2-year follow-up. *Int J Med Sci* 2010; 7:124-135.
76. Manchikanti L, Singh V, Falco FJE, Cash KA, Fellows B. Comparative outcomes of a 2-year follow-up of cervical medial branch blocks in management of chronic neck pain: A randomized, double-blind controlled trial. *Pain Physician*

2010; 13:437-450.

77. Manchikanti L, Singh V, Falco FJE, Cash KA, Pampati V, Fellows B. The role of thoracic medial branch blocks in managing chronic mid and upper back pain: A randomized, double-blind, active-control trial with a 2-year follow-up. *Anesthesiol Res Pract* 2012; 2012:585806.
78. Manchikanti L, Singh V, Cash KA, Pampati V, Falco FJE. The role of fluoroscopic interlaminar epidural injections in managing chronic pain of lumbar disc herniation or radiculitis: A randomized, double-blind trial. *Pain Pract* 2012 Dec. 27. [Epub ahead of print]
79. Manchikanti L, Cash KA, McManus CD, Pampati V, Benyamin R. Fluoroscopic lumbar interlaminar epidural injections in managing chronic lumbar axial or discogenic pain. *J Pain Res* 2012; 5:301-311.
80. Manchikanti L, Cash KA, McManus CD, Damron KS, Pampati V, Falco FJE. Lumbar interlaminar epidural injections in central spinal stenosis: Preliminary results of a randomized, double-blind, active control trial. *Pain Physician* 2012; 15:51-63.
81. Manchikanti L, Cash KA, Pampati V, Malla Y. Fluoroscopic cervical epidural injections in chronic axial or disc-related neck pain without disc herniation, facet joint pain, or radiculitis. *J Pain Res* 2012; 5:227-236.
82. Manchikanti L, Cash KA, Pampati V, Wargo BW, Malla Y. Management of chronic pain of cervical disc herniation and radiculitis with fluoroscopic cervical interlaminar epidural injections. *Int J Med Sci* 2012; 9:424-434.
83. Manchikanti L, Malla Y, Cash KA, McManus CD, Pampati V. Fluoroscopic epidural injections in cervical spinal stenosis: Preliminary results of a randomized, double-blind, active control trial. *Pain Physician* 2012; 15:E59-E70.
84. Manchikanti L, Malla Y, Cash KA, McManus CD, Pampati V. Fluoroscopic cervical interlaminar epidural injections in managing chronic pain of cervical post-surgery syndrome: Preliminary results of a randomized, double-blind active control trial. *Pain Physician* 2012; 15:13-26.
85. Whitehurst DG, Lewis M, Yao GL, Bryan S, Raftery JP, Mullis R, Hay EM. A brief pain management program compared with physical therapy for low back pain: Results from an economic analysis alongside a randomized clinical trial. *Arthritis Rheum* 2007; 57:466-473.
86. Johnson RE, Jones GT, Wiles NJ, Chaddock C, Potter RG, Roberts C, Symmons DP, Watson PJ, Torgerson DJ, Macfarlane GJ. Active exercise, education, and cognitive behavioral therapy for persistent disabling low back pain: A randomized controlled trial. *Spine (Phila Pa 1976)* 2007; 32:1578-1585.
87. Critchley DJ, Ratcliffe J, Noonan S, Jones RH, Hurley MV. Effectiveness and cost-effectiveness of three types of physiotherapy used to reduce chronic low back pain disability: A pragmatic randomized trial with economic evaluation. *Spine (Phila Pa 1976)* 2007; 32:1474-1481.
88. Rivero-Arias O, Gray A, Frost H, Lamb SE, Stewart-Brown S. Cost-utility analysis of physiotherapy treatment compared with physiotherapy advice in low back pain. *Spine (Phila Pa 1976)* 2006; 31:1381-1387.
89. UK BEAM trial group. UK Back pain Exercise and Manipulation (UK BEAM) trial—national randomised trial of physical treatments for back pain in primary care: Objectives, design and interventions. *BMC Health Serv Res* 2003; 3:1-13.
90. Hansson E, Hansson T. The cost-utility of lumbar disc herniation surgery. *Eur Spine J* 2007; 16:329-337.
91. Malter AD, Larson EB, Urban N, Deyo RA. Cost-effectiveness of lumbar discectomy for the treatment of herniated intervertebral disc. *Spine (Phila Pa 1976)* 1996; 21:1048-1054; discussion 1055.
92. van den Hout WB, Peul WC, Koes BW, Brand R, Kievit J, Thomeer RT; Leiden-The Hague Spine Intervention Prognostic Study Group. Prolonged conservative care versus early surgery in patients with sciatica from lumbar disc herniation: Cost utility analysis alongside a randomised controlled trial. *BMJ* 2008; 336:1351-1354.
93. Rivero-Arias O, Campbell H, Gray A, Fairbank J, Frost H, Wilson-MacDonald J. Surgical stabilization of the spine compared with a programme of intensive rehabilitation for the management of patients with chronic low back pain: Cost utility analysis based on a randomised controlled trial. *BMJ* 2005; 330:1239.
94. Soegaard R, Bünger CE, Christiansen T, Høy K, Eiskjaer SP, Christensen FB. Circumferential fusion is dominant over posterolateral fusion in a long-term perspective: Cost-utility evaluation of a randomized controlled trial in severe, chronic low back pain. *Spine (Phila Pa 1976)* 2007; 32:2405-2414.
95. Porter ME, Teisberg EO. *Redefining Health Care. Creating Value-based Competition on Results*. Harvard Business School Press, Boston, 2006.
96. Goossens ME, Evers SM, Vlaeyen JW, Rutten-van Mölken MP, van der Linden SM. Principles of economic evaluation for interventions of chronic musculoskeletal pain. *Eur J Pain* 1999; 3:343-353.
97. Hopwood M. Outcomes assessment in pain management. In Abram SE (ed). *Pain Management*. Churchill–Livingstone, Philadelphia, 1998, pp 14.1-14.11.
98. Maas ET, Juch JN, Groeneweg JG, Ostelo RW, Koes BW, Verhagen AP, van Raamt M, Wille F, Huygen FJ, van Tulder MW. Cost-effectiveness of minimal interventional procedures for chronic mechanical low back pain: Design of four randomised controlled trials with an economic evaluation. *BMC Musculoskelet Disord* 2012; 13:260.
99. Dagenais S, Haldeman S. Commentary: Laboring to understand the economic impact of spinal disorders. *Spine J* 2012; 12:1119-1121
100. Dagenais S, Moher D. Re: Hurwitz EL, Morgenstern H, Vassilaki M, Chiang LM. Frequency and clinical predictors of adverse reactions to chiropractic care in the UCLA neck pain study. Spine 2005; 30: 1477-84. *Spine (Phila Pa 1976)* 2006; 31:253.