Cervical Interlaminar Epidural Injections In The Treatment Of Cervical Disc Herniation, Post Surgery Syndrome, Or Discogenic Pain: Cost Utility Analysis From Randomized Trials

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Background: Neck pain is one of the major conditions attributing to overall disability in the United States. There have been multiple publications assessing clinical and cost effectiveness of multiple modalities of interventions in managing chronic neck pain. Even then, the literature has been considered sparse in relation to cervical interlaminar epidural injections in managing chronic neck pain. In contrast, cost utility studies of lumbar interlaminar injections, caudal epidural injections, cervical and lumbar facet joint nerve blocks, percutaneous adhesiolysis demonstrated costs of less than $3,500 for quality-adjusted life year (QALY).

Objectives: To assess the cost utility of cervical interlaminar epidural injections in managing chronic neck and/or upper extremity pain secondary to cervical disc herniation, post-surgery syndrome in neck, and axial or discogenic neck pain.

Study Design: Analysis based on 3 previously published randomized trials of the effectiveness of cervical interlaminar epidural injections assessing their role in disc herniation, cervical post-surgery syndrome, and axial or discogenic pain.

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

Methods: Cost utility of cervical interlaminar epidural injections with or without steroids in managing cervical disc herniation, cervical post-surgery syndrome, and cervical discogenic or axial neck back pain was conducted with data derived from 3 randomized controlled trials (RCTs) that included a 2-year follow-up, with inclusion of 356 patients. The primary outcome was significant improvement defined as at least 50% in pain reduction and disability status. Direct payment data from all carriers from 2018 was utilized for the assessment of procedural costs. Overall costs, including drug costs, were determined by multiplication of direct procedural payment data by a factor of 1.67 to accommodate for indirect payments respectively for disc herniation, discogenic pain, and cervical post-surgery syndrome.

Results: The results of the 3 RCTs showed direct cost utility for one year of QALY of $2,412.31 for axial or discogenic pain without disc herniation, $2,081.07 for disc herniation, and $2,309.20 for post surgery syndrome, with an average cost per one year QALY of $2,267.57, with total estimated overall costs with addition of indirect costs of $3,475.38, $4,028.55, $3,856.36, and $3,785.89 respectively.

Limitations: The limitation of this cost utility analysis includes that it is a single center evaluation. Indirect costs were extrapolated.

Conclusion: This cost utility analysis of cervical interlaminar epidural injections in patients nonresponsive to conservative management in the treatment of disc herniation, post surgery syndrome and axial or discogenic neck pain shows $2,267.57 for direct costs with a total cost of $3,785.89 per QALY.

Key words: Cervical interlaminar epidural injections, chronic neck pain, cervical disc herniation, cervical discogenic pain, post surgery syndrome, cost utility analysis, cost effectiveness analysis, quality-adjusted life years

Chronic neck pain is one of the leading sources of global disability with a substantial burden on the health care system and society, with loss of productivity and consumption of a large proportion of health care resources (1). In assessing U.S. spending on personal health care and public health and factors associated with the increase in U.S. health care spending from 1996 to 2003, Dielman et al (2,3) reported yearly spending of $87.6 billion for low back and neck pain. In this regard, expenses for low back and neck pain accounted for the third highest amount. Other studies from 1990 to 2016 have demonstrated that morbidity and chronic disability now account for nearly half of the United States health burden, despite substantial progress and improvements in health (4,5). Further, it also has been shown that neck pain ranked number 3 in the United States among the 30 leading diseases and injuries contributing to years lived with disability in 2010, whereas low back pain ranked number one (4). Even though neck pain has been estimated to be low in prevalence, the estimates of regional pain have shown neck pain as number 2 in its ranking with 32% prevalence (6). Global burden of the neck pain and disability also have shown a point prevalence of neck pain of 4.9%, with a significant proportion of patients suffering from chronic neck and arm pain with a high disability index (7).

Among the multiple causes of chronic neck and upper extremity pain, cervical disc herniation, axial or cervical discogenic pain without disc herniation, central spinal stenosis, and finally cervical post surgery syndrome have been described as common conditions leading to multiple modalities of treatments (8-31). Multiple modalities including surgical interventions have been increasing rapidly (18-22), non-steroidal anti-inflammatory agents (8,24), antiepileptic drugs (23), opioids (24-29,31), and finally interventional techniques including epidural injections and facet joint interventions (10,11). The most expensive categories are the surgical interventions with a certain rate of failure and also with the need for treatments following surgery including repeat surgery, epidural injections, physical therapy, and drug therapy (21,32). In fact, failure rates have been shown to range from 13.4% to 32% resulting in cervical post surgery syndrome (21,32). However, Rihn et al (33) in an analysis of economic outcomes of recalcitrant cervical radiculopathy concluded that anterior cervical fusion remained the dominant strategy compared with cervical epidural injections if the surgical avoidance rate of such injections was less than 50% in cervical radiculopathy. Further, they commented that if there is a greater than 50% surgery avoidance rate with injections, the cervical epidural injections would be considered a cost-effective strategy with a role in the management of cervical radiculopathy before surgery. This assessment was not based on randomized controlled trials (RCTs), it was limited to an economic analysis based on surgical practices. In fact, a systematic review and meta-analysis of the role of epidural injections to prevent surgical intervention in patients with chronic sciatica (34) showed a significant improvement with avoidance of surgery in 80% of the patients. In addition, epidural injections are also a treatment in post surgery syndrome with clinical effectiveness and cost utility (8,9,35-37). Overall, interventional techniques have been shown to be clinically effective, with appropriate cost utility with multiple interventions (8,9,33-53). Challenges with evidence assessment for cost utility analysis are that they have been reported to be redundant, inappropriate, and biased (34,54-67).

Cervical interlaminar epidural injections are the preferred methodology for cost utility analysis due to complications related to cervical transforaminal epidural injections (68,69). Thus, the use of cervical interlaminar epidural injections has been increasing steadily (10,11), despite the decline in the utilization of other interventions including lumbar interlaminar epidural injections, but less than a multitude of other interventions including facet joint interventions and sacroiliac joint interventions (36,70). The use of cervical/thoracic interlaminar epidural injections have increased 108% per 100,000 Medicare beneficiaries from 2000 to 2016, with a smaller increase of 4% noted from 2009 to 2016 compared to 101% from 2000 to 2009.

Escalating health care costs and continuous debates on the effectiveness of multiple interventions, cost effectiveness or cost utility analysis has become a cornerstone in health policy including for epidural injections (35,36,51-53,71-77). Further, multiple assessments have shown significant improvements with non-operative treatment including epidural injections with avoidance of surgery in at least 50% of the patients in cervical radiculopathy and 80% in sciatica (31,32). Despite these encouraging results, inappropriately performed cost utility analyses (78,79) have yielded either poor (78) or mixed results (79).

Based on the Spine Patient Outcomes Research Trial (SPORT) literature with 2 well publicized cost effectiveness studies of surgical versus non-operative treatment for lumbar disc herniation (75) and spinal stenosis
with and without degenerative spondylolisthesis (76), gold standards of cost utility analysis were published. These studies showed cost per quality-adjusted life year (QALY) in managing lumbar disc herniation of $69,403 and $77,600 in managing spinal stenosis without degenerative spondylolisthesis and $115,600 in managing spinal stenosis with degenerative spondylolisthesis. Based on these landmark studies by Tosteson et al (75,76), direct costs were attributed to 60% of the total in spinal stenosis and 68% in disc herniation, and 71% in spinal stenosis with degenerative spondylolisthesis, with highest indirect costs for spinal stenosis of 40%. Manchikanti et al (51-53) utilized direct medical costs at 60% and multiplied the direct cost data by 1.67%, deriving overall cost utility.

In this assessment, therefore, the present investigation sought to derive a reliable and valid overall assessment of cost utility data with assessment of direct costs and addition of indirect costs utilizing 3 cervical interlaminar epidural injection RCTs in disc herniation, discogenic pain without disc herniation or facet joint pain, and post cervical surgery syndrome with chronic neck pain and upper extremity pain with a 2-year-follow-up (80-82).

**METHODS**

**Study Design**

The cost utility analysis for this assessment was performed based on 3 double-blind RCTs, which assessed effectiveness of cervical interlaminar epidural injections in managing chronic neck pain secondary to disc herniation (80), discogenic or axial pain without disc herniation or facet joint pain (81), and cervical post surgery syndrome (82). The methodology utilized in performing these studies has been described in their respective manuscripts (80-82). Appropriate diagnosis was established in all patients with disc herniation, axial or discogenic pain, and cervical post surgery syndrome based on a multitude of investigations including diagnostic facet nerve blocks in patients with discogenic pain. Further, all the patients had failed conservative management with a structured exercise program, physical or occupational therapy, and drug therapy.

**Outcome Measures**

Outcome measures included pain rating and disability status. Pain rating was determined on an 11-point Numeric Rating Scale (NRS) and disability and functional status was assessed based on a 50-point Neck Disability Index (NDI). Intermittent post treatment outcomes were assessed for 2 years. Primary outcome was determined as significant improvement of 50% reduction in pain and increase in function.

**Analysis**

A total of 356 patients were studied among the 3 studies. Two of the studies with disc herniation (80) and discogenic pain (81), utilized 120 patients total in each study, whereas in post surgery syndrome (82) there were 116 patients. In each trial these patients were assigned to either a control group receiving 5 mL of 0.5% local anesthetic only or an intervention group receiving 4 mL of 0.5% local anesthetic mixed with 6 mg of 1 mL of Celestone.

For analysis of the direct procedural cost utility, actual reimbursement rates by various carriers (not Medicare allowed rates) were utilized from 2018 for calculating costs for physician services and the facility costs based on each patient’s payer status. Overall costs were estimated by multiplying direct procedural costs by a factor of 1.67 based on previous studies (75,76).

**RESULTS**

**Patient Flow**

Figure 1 shows the patient flow diagram for all 3 RCTs (80-82).

**Outcomes**

Table 1 shows characteristics of pain relief and functional status improvement as evaluated by Numeric Rating Scale (NRS) and Neck Disability Index (NDI). There was no significant difference between patients undergoing cervical interlaminar epidural injections for either discogenic pain, disc herniation, or pain of post surgery syndrome. Figure 2 shows the proportion of patients with significant reduction in pain scores and improvement in NDI scores.

**Adverse Events**

No additional costs were incurred due to adverse events occurring in any of the 356 patients during the study period.

**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. As shown in Table 2, direct
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Cost utility for one-year improvement in QALY was $2,412.31 for axial or discogenic pain without disc herniation, $2,081.07 for disc herniation, and $2,309.20 for post surgery syndrome. Overall direct procedural cost utility for one year of improvement in quality of life was $2,847.57. Average total direct cost per patient in 2 years was $22,847.57. Total costs for one-year improvement of quality of life with multiplication of direct cost by a factor of 1.67 showed cost utility of $4,028.55 for discogenic pain per QALY, $3,475.38 for disc herniation per QALY, $3,856.36 for post surgery syndrome per QALY, and $3,785.89 on average for all cervical epidural injections per QALY.

**Discussion**

The cost utility analysis was derived from 3 RCTs with a 2-year follow-up with data from 356 patients, nonresponsive to conservative management, undergoing cervical interlaminar epidural injections with appropriate outcomes data utilizing significant improvements defined as 50% improvement in pain and functional scores. The outcomes results showed significant improvement in 71% of the patients at the end of 2 years. The overall costs with direct costs added to extrapolated indirect costs resulting in overall cost of $4,028.55 for one year of quality of life improvement for discogenic pain. In patients with discogenic pain without disc herniation or facet joint pain, $3,475.38 for patients with disc herniation and $3,856.36 for post surgery syndrome with an overall cost utility rate of $3,785.89 for cervical interlaminar epidural injections in 356 patients. Further, there was no significant difference in patients either receiving local anesthetic alone or local anesthetic with steroids. The costs were higher,
though statistically insignificant, in patients with axial or discogenic pain due to larger than average treatments compared to disc herniation and postsurgery syndrome [5.7 ± 2.4 versus 5.4 ± 2.6 or 2.7] with slightly lesser significant improvement per procedure compared to disc herniation, but similar to post surgery syndrome. In contrast, a lumbar discogenic pain with lumbar interlaminar epidural injections, costs were lower. The significant improvement was higher in discogenic pain group compared to central spinal stenosis.

The results of the present assessment reflect similar cost utility analysis rates with caudal epidural injections and lumbar epidural injections with or without steroids (35,51-53). For lumbar interlaminar epidural injections (51), overall cost was shown to be $3,301 and for caudal epidural injections (35) it was $3,628. These total costs were also similar to therapeutic lumbar facet joint nerve blocks with a cost of $4,432 for QALY (52), and also cervical facet joint nerve blocks with a cost of $4,261, and percutaneous adhesiolysis with a cost of £

Table 1. Pain relief and functional status improvement evaluated by and Neck Disability Index (NDI).

<table>
<thead>
<tr>
<th></th>
<th>Group I Discogenic Pain</th>
<th>Group II Disc Herniation</th>
<th>Group III Post surgery Syndrome</th>
<th>Pooled</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Numeric Rating Score</strong></td>
<td></td>
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</tr>
<tr>
<td>Baseline</td>
<td>7.7 ± 0.9</td>
<td>7.9 ± 0.9</td>
<td>8.0 ± 0.9</td>
<td>7.9 ± 0.9</td>
</tr>
<tr>
<td>6 months</td>
<td>3.6* ± 1.3 (78%)</td>
<td>3.7* ± 1.4 (78%)</td>
<td>3.7 ± 1.4 (76%)</td>
<td>3.7 ± 1.4</td>
</tr>
<tr>
<td>12 months</td>
<td>3.6* ± 1.3 (78%)</td>
<td>3.8* ± 1.5 (72%)</td>
<td>3.8 ± 1.4 (74%)</td>
<td>3.7 ± 1.4</td>
</tr>
<tr>
<td>24 months</td>
<td>3.6* ± 1.5 (75%)</td>
<td>3.7* ± 1.6 (70%)</td>
<td>3.7 ± 1.6 (71%)</td>
<td>3.7 ± 1.5</td>
</tr>
</tbody>
</table>

| **Oswestry Disability Index** |                         |                          |                                 |            |
| Baseline               | 29.1 ± 5.6              | 29.4 ± 5.7               | 30.2 ± 4.9                      | 29.6 ± 5.4 |
| 6 months               | 14.3* ± 5.8 (71%)       | 14.5* ± 6.2 (78%)       | 15.5* ± 6.4 (73%)               | 14.8* ± 6.1 |
| 12 months              | 14.3* ± 5.9 (72%)       | 14.5* ± 6.4 (72%)       | 15.1* ± 6.3 (73%)               | 14.6* ± 6.2 |
| 24 months              | 14.0* ± 6.1 (73%)       | 14.0* ± 6.3 (72%)       | 14.8* ± 6.4 (71%)               | 14.2* ± 6.3 |

(____) illustrates proportion with significant pain relief (≥ 50%) from baseline

* significant difference with baseline values (P < 0.001)

Fig. 2. Proportion of patients with significant reduction in numeric rating score and neck disability index (≥ 50% reduction from baseline).
$4,426 (53). However, these costs are lesser than spinal cord stimulation of £5,624 (about $8,400 in 2010) for QALY (77). The costs are very similar as all other studies performed by Manchikanti et al (35,51-53) provided similar methodology and were performed in the same clinical setting with a pragmatic approach in an ambulatory surgery setting. However, these results were superior to other lumbar epidural injection studies. Whynes et al (83) with lumbar interlaminar epidural injections with £8,975 (about $13,500 in 2012) per QALY, which was more expensive than spinal cord stimulation, and short-term evaluation of cost utility by appropriate analysis by Carreon et al (78) only in failed patients with $62,175 per QALY and short-term assessment of cervical epidural injections in a 3 month pilot study in a small number of patients by Alvin et al (79) with a cost utility of $21,884 per QALY gained.

Looking at a global picture analysis of various modalities of interventions utilized in spine treatment, only 45% of the cost utility studies showed costs less than $100,000 per QALY, compared to 23% of the costs showing greater than $100,000 per QALY (72). Similar results were also reported by others even though the majority of the reviews showed greater value with non-operative treatments (73). With specific analysis in cost utility analysis in the neck pain, Furlan et al (74) showed that alternative medicine treatments such as acupuncture for neck pain was associated with significantly higher total cost compared to usual care (£1,565 versus £1,496) with $12,469 per QALY gained in patients with chronic neck pain in a systematic review and meta-analysis of efficacy, cost effectiveness, and safety. Additionally, in another systematic review of conservative treatments for neck pain and cost-effectiveness by Driessen et al (84) manual therapy plus advice and exercise compared to advice and exercise (85), showed $34,000 per QALY threshold. Further, in another study looking at evaluating cost-effectiveness of spinal manipulative therapy,
supervised exercise, and home exercises for old adults with chronic neck pain (86), inflation-adjusted cost in 2004 was $65,731 per QALY.

For obvious reasons, cost of surgical interventions is the highest in managing spinal pain (87-89). However, cost-effectiveness of surgical interventions was shown to be comparable with other modalities of treatments even though much higher than cervical interlaminar injections or cervical facet joint nerve blocks at $3,785.89 and $4,261 per QALY. Cost utility analysis showed a rate of $20,547 per QALY for posterior cervical fusion (89), whereas it was shown to be $52,816 for QALY for anterior cervical disectomy and fusion (88), with wide variation.

In modern medicine, looking at reducing the cost, improving the quality and access, as envisioned by Obamacare (90-94) there have been challenges achieving these goals. Cost utility analysis is an important aspect even though it is not part of the Affordable Care Act (ACA) or Medicare coverage policies. Thus, cervical interlaminar epidural injections are superior to other modalities of treatments, but similar to cervical facet joint nerve blocks of a different etiology with chronic neck pain. In addition, the cost utility analysis was also less if only the patients who responded to initial 2 treatments considered as responsive group compared to overall population with overall cost of $3,680.21.

Even though cost utility analysis is not utilized in making coverage determinations based on the ACA (90), in other countries, including the United Kingdom, cost-effectiveness of potential expenditures is crucial. In fact, the National Institute for Heath and Clinical Excellence (NICE) (95) in the United Kingdom is well known for assessment of cost-effectiveness and their utility in making coverage decisions. NICE accepts as cost-effective of those interventions with an incremental cost-effectiveness ratio of less than £20,000 (about $40,000 in 2008) per QALY and an incremental cost-effectiveness ratio or threshold of £30,000 (about $60,000 in 2008) per QALY in extenuating circumstances.

As with many other studies, this cost utility analysis also suffers from limitations. These include extrapolation of indirect costs at 40% or multiplied by a factor of 1.67 of direct procedural costs, however this is appropriate based on highly regarded SPORT studies (24, 75, 76) that are used as a gold standard in spine literature in the United States and abroad. However, in this analysis we have not included extensive benefits derived by returning to work. The second disadvantage is related to a single center assessment of 356 patients recalcitrant to conservative management incorporating 3 RCTs and assessing long-term improvement, with an active control design with local anesthetic with or without steroids. The second limitation also is considered as an advantage because of pragmatic nature of the assessment with utilization of real-world evidence as promoted in recent years (96-99). The third limitation is that the present investigation used direct costs instead of Medicare allowable, which in essence uses a picture at the current time, but may be subject to variations in reimbursement rates.

The estimated costs are only applicable in a pragmatic setting such as described here. The procedures were performed in an ambulatory surgery setting with reasonable charges, and also following the appropriate guidance by not exceeding 2 procedures in the diagnostic phase, and not exceeding 4 procedures in the therapeutic phase per year. It is also estimated that the costs may be higher in a hospital outpatient setting ranging from 30% to 70% and 20% to 30% lower in an office setting (100).

Multiple limitations of this analysis include consideration of current procedural costs and extrapolation of indirect costs at 40% or multiplication by a factor of 1.67 of direct procedural costs. However, there was no benefit analyzed for return to work even though there was a significant proportion of patients returning to work. Further, the study is derived from a single center assessment of 360 patients, even though this included a large population of chronic pain patients recalcitrant to conservative management incorporating 3 RCTs and assessing long-term improvement. However, these limitations may be considered as advantages. In addition, the cost of provision of epidural injections have decreased in 2017 compared to 2016, which in fact may lower the cost utility with use of 2017 data (100).

The costs estimated here are only applicable in a practical pragmatic setting such as described here in private practice with performance of these procedures in an ambulatory surgery setting with reasonable charges (100). Consequently, the results of this analysis may not be generalizable to all settings and all populations. Further, it is estimated that cost utility may be 30% to 70% higher in a hospital setting and approximately 20% to 30% lower in an office setting (100).

**Conclusion**

The present analysis of 3 RCTs of cervical interlaminar epidural injections in a private practice setting in patients after failure of conservative management...
shows cost utility of epidural injections at $3,785.89 per QALY. The results also showed cost effectiveness at $3,475.38 for managing disc herniation, $4,028.55 for managing discogenic pain, and $3,856.36 for managing central spinal stenosis with or without steroids with no significant differences observed among the groups for those receiving steroids or those receiving local anesthetic only.

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