Thoracic Interlaminar Epidural Injections in Managing Chronic Thoracic Pain: A Randomized, Double-Blind, Controlled Trial with a 2-Year Follow-Up

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Background: Reports of prevalence of spinal pain indicate the prevalence of thoracic pain in approximately 13% of the general population compared to 32% of the population with neck pain and 43% of the population with low back pain during the past year. Even though, thoracic pain is less common than neck or low back pain, the degree of disability resulting from thoracic pain disorders seems to be similar to other painful conditions. Interventions in managing chronic thoracic pain are also less frequent, leading to the paucity of literature about various interventions in managing chronic thoracic pain.

Thoracic intervertebral discs and thoracic facet joints have been shown to be pain generators, even though thoracic radicular pain is very infrequent.

Thoracic epidural injections are one of the commonly performed procedures in managing thoracic pain. The efficacy of thoracic epidural injections has not been well studied.

Study Design: A randomized, double-blind, active controlled trial.

Setting: Private interventional pain management practice and specialty referral center in the United States.

Objective: The primary objective was to assess the effectiveness of thoracic interlaminar epidural injections in providing effective pain relief and improving function in patients with chronic mid and/or upper back pain.

Methods: One hundred and ten patients were randomly assigned into 2 groups with 55 patients in each group receiving either local anesthetic alone (Group I) or local anesthetic with steroids (Group II). Randomization was performed by computer-generated random allocation sequence by simple randomization.

Outcomes Assessment: Outcomes were assessed utilizing Numeric Rating Scale (NRS), the Oswestry Disability Index (ODI) 2.0, employment status, and opioid intake.

The patients experiencing greater than 3 weeks of significant improvement with the first 2 procedures were considered as successful. Others were considered as failed participants.

Significant improvement was defined as a decrease of greater than 50% NRS scores and ODI scores with measurements performed at baseline, 3, 6, 12, 18, and 24 months post treatment.

Results: Significant improvement was seen in 71% in Group I and 80% in Group II at the end of 2 years with all participants; however, improvement was seen in 80% and 86% when only successful patients were considered. Therapeutic procedural characteristics showed 5 to 6 procedures per 2 years with total average relief of 80 weeks in Group I and 78 weeks in Group II in the successful patient category; whereas, it was 71 and 72 weeks when all patients were considered.

Limitations: Limitations of this assessment include lack of a placebo group.
Conclusions: Based on the results of this trial, it is concluded that chronic thoracic pain of non-facet joint origin may be managed conservatively with thoracic interlaminar epidural injections with or without steroids.

Key words: Chronic thoracic pain, chest wall pain, disc herniation, discogenic pain, radiculitis, thoracic interlaminar epidural injections, steroids, local anesthetic

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The reported prevalence of thoracic pain is approximately 13% of the general population compared to 43% of the low back pain population and 32% of the population with neck pain during the past year (1,2). In interventional pain management settings, thoracic pain has been reported at a highly variable proportion ranging from 3% to 33% of patients (3-7). Chronic pain in general and spinal pain in particular has been shown to be expensive and disabling (8-18). Similar to various other problems, a multitude of interventions are offered to manage chronic thoracic pain, including interventional techniques with facet joint interventions and epidural injections, which have been reported to be increasing at an uncontrollable pace (19-21). For all coding purposes, thoracic procedures are embedded with cervical procedures. Cervical and thoracic interlaminar epidural injections have shown an increase of 123% from 2000 to 2011 per 100,000 Medicare beneficiaries compared to 331% for sacroiliac joint interventions, 665% for lumbosacral transforaminal epidural injections, 359% for cervical/thoracic facet joint nerve blocks, and 836% for cervical/thoracic facet joint neurolysis (19). In addition, increases of surgical interventions are also smaller for the thoracic spine compared to the lumbar and cervical spine (22-28).

Epidural injections for managing chronic spinal pain, including thoracic spinal pain, are common interventions among multiple interventional techniques, surgery, physical therapy, and drug therapy (29-34). The effectiveness of thoracic interlaminar epidural injections has only been evaluated in a preliminary report of a randomized, double-blind, active-controlled trial (32) of 40 patients, which illustrated significant improvement defined as pain relief and reduction of disability by 50% from baseline. This improvement was reported in 80% of patients receiving local anesthetic only and 85% of those receiving local anesthetic with steroids.

This trial is designed to evaluate the role of thoracic interlaminar epidural injections of local anesthetics with or without steroids in patients with chronic, function-limiting, mid back and upper back pain with or without chest wall pain secondary to multiple abnormalities after excluding facet joint pain and intercostal neuritis. This report consists of the results of 110 patients at 2-year follow-up, which is a continuation of the preliminary report (32).

Methods

The study was approved by the Institutional Review Board (IRB) and was registered with the U.S. Clinical Trial Registry with an assigned number of NCT01071369. This randomized, double-blind, active-controlled trial of the effectiveness of thoracic interlaminar epidural injections has been conducted at a private interventional pain management practice and a specialty referral center in the United States. The trial is based on Consolidated Standards of Reporting Trials (CONSORT) guidelines (35,36).

There was no external funding used in conduct of this study.

Patients

The study patients were recruited from among new patients that presented to the interventional pain management practice. They were all provided with an IRB-approved protocol and informed consent.

Interventions

Of the 110 study patients, 55 were assigned into Group I receiving thoracic interlaminar epidural injections with local anesthetic only (lidocaine 0.5% preservative-free, 6 mL), and 55 were assigned into Group II receiving thoracic interlaminar epidural injections with 5 mL of 0.5% preservative-free lidocaine mixed with 1 mL or 6 mg of betamethasone for a total of 6 mL injected in both groups.

Pre-enrollment Evaluation

Pre-enrollment evaluation included patient demographic data, medical and surgical history with coexisting disease(s), radiologic investigations, physical
examination, pain rating scores using the Numeric Rating Scale (NRS), work status, opioid intake, and functional assessment by Oswestry Disability Index (ODI). Information on conservative management including other types of drug therapy and exercise programs was also collected.

**Inclusion Criteria**

Inclusion criteria were lack of diagnosis of thoracic facet joint pain with exclusion based on results of controlled, comparative local anesthetic blocks. In addition, patients must have been of at least 18 years of age with a history of chronic function-limiting mid back or upper back pain of at least 6 months duration, and having failed physician directed conservative management with drug therapy, physical therapy, structured exercise program, and other modalities. Furthermore, it was essential that patients understood the study protocol and could provide voluntary written informed consent with participation in outcome measures.

**Exclusion Criteria**

Exclusion criteria included facet joint pain, uncontrollable or unstable opioid use, uncontrolled psychiatric disorders, uncontrolled medical illness (acute or chronic), any condition that could interfere with the interpretation of the outcome assessments, pregnancy and lactation, and history of adverse reactions to local anesthetics or steroids. Patients with large disc herniations with symptoms of spinal cord compression or any signs of infection were also excluded.

**Description of Interventions**

All patients with disc herniation, radiculitis, or spinal stenosis were included in the study without any further evaluations. Other patients were assessed on 2 separate occasions with controlled comparative local anesthetic blocks (3,30,37).

Interlaminar epidural injections were performed under appropriate monitoring and sedation with sterile preparation. All patients had intravenous infusion fluids and were also sedated with midazolam and fentanyl when medically necessary. The injections were all performed in a prone position by a single physician (LM). The epidural space was accessed with an 18 gauge Tuohy needle using the loss of resistance technique with confirmation of the location of the epidural space with injection of nonionic contrast, generally 5 mL. The location of the entry of the needle into the epidural space was based on the patients’ pain complaints, as well as clinical and radiologic findings. The procedures were performed either between a space below or at the level indicated by the patients’ complaints and findings.

Repeat thoracic epidural injections were provided based on the response to prior epidural injections. The response was assessed by improvement in physical and functional status and repeat procedures were only provided when increased levels of pain were reported with deterioration of functional status and pain relief to below 50%.

**Co-interventions**

All patients continued drug therapy with either opioids or nonopioid analgesics, therapeutic exercise program, and normal activities, including work. No specific physical therapy, occupational therapy, or other interventions were offered other than the study interventions.

**Objectives**

The study was designed to evaluate the effectiveness of thoracic interlaminar epidural injections with or without steroids under fluoroscopy in managing chronic mid back and/or upper back pain with or without chest wall pain secondary to various causes except for the pain originating from facet joints.

**Outcomes**

This trial included a number of outcome measures to be recorded at baseline, 3, 6, 12, 18, and 24 months post treatment. The primary outcome measure was combined improvement in pain scores and functional status improvement. Significant improvement was defined as at least 50% pain relief and improvement in functional status measured by NRS and ODI, a robust measure compared to traditional 20% decrease in pain services (38-40). NRS has been validated in assessing chronic pain of various origins (41). Similarly, ODI has been validated for low back pain; however, it has not been validated for thoracic pain (42-44). The patients experiencing greater than 3 weeks of significant improvement with the first 2 procedures were considered as successful. Others were considered as failed patients.

Opioid intake measurements were carried out with conversion of opioid intake to morphine equivalence (45).

For consideration of the employment, enrollees were divided into multiple groups based on their employment or unemployment status.
Sample Size
The sample size calculations were based on significant pain relief. There have not been any studies in the thoracic spine to consider for sample size calculation. Thus, considering a 0.05 two-sided significance level, a power of 80%, and an allocation ratio of 1:1, 55 patients in each group were required (46).

Randomization
Of the 110 patients assigned to participate, 55 patients were randomly assigned into either Group I or II.

Sequence Generation
Randomization was a simple randomization from a computer-generated random allocation sequence.

Allocation Concealment
Patients were randomized into 2 groups and the drugs were prepared by the same individual from one of the 3 coordinators, but not assisting with the procedure.

Blinding and Masking
The group assignment was blinded to all involved in the care including the physician and the patients. Both solutions were clear with nonparticulate Celestone so the group assignment was unidentifiable. In addition, all the study patients were mixed with other patients receiving routine treatments in all spinal regions, and the physician performing the procedure was not informed of the nature of the patients participating in this study.

Statistical Methods
Data analyses were carried out using the Statistical Package for Social Sciences version 9.01 (SPSS Inc., Chicago, IL). For categorical and continuous data comparison, Chi-square (Fisher test where necessary) and t-test were used respectively. Because the outcome measures of the patients were measured at 6 points in time, the repeated measures analysis of variance were performed with the post hoc analysis. Univariate analyses with gender, BMI as covariates were performed on reduction in average pain scores and Functional improvements between groups. A P value was less than 0.05 was considered as statistically significant.

An intent-to-treat analysis was performed utilizing either the last follow-up data or initial data in all patients who dropped out of the study and for whom no other data were available.

Results

Patient Flow
Patient flow is illustrated in Fig. 1. The recruitment period spanned from January 2008 to September 2010.

Baseline Data
Baseline demographic and clinical characteristics are shown in Table 1. There were significant differences noted in relation to gender, body height, and body mass index among both groups. There were more women in Group I, they were shorter than patients in Group II, and had a higher body mass index.

Pain Relief and Functional Assessment
Table 2 shows NRS pain scores and ODI disability scores.

Fig. 2 illustrates the proportion of patients with a significant reduction in the NRS and ODI with greater than 50% reduction from baseline.

Therapeutic Procedural Characteristics
Therapeutic procedural characteristics are shown in Table 3. Epidural entry was at T9-10 and T10-11 in 30% and 31% of the patients respectively. Epidural entry was at T8-9 in 17% of the patients and T7-8 in 12% of the patients. All other levels were 6% or less.

Patients experiencing at least 3 weeks of significant improvement with the first 2 procedures were considered as successful.

Average relief per year showed significant improvement with the first 2 procedures were considered as successful.

The average number of procedures for 2 years was 5 to 6; whereas they were 3 to 4 for one year. The total relief for 2 years was approximately 80 weeks in the successful patient group and 72 weeks in all patients out of 104 weeks.

Covariates of Gender and BMI
Univariate analyses with gender and BMI as a covariate revealed no significant differences in Average pain scores and ODI scores between Group I and Group II.

Employment Characteristics
The employment characteristics, showed nonsignificant improvement in both groups with number of employed increasing from 22 at baseline to 33 at 24 months among 35 eligible for employment.
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Fig. 1. Schematic presentation of patient flow at 2-year follow-up.
Table 1. Baseline demographic characteristics.

<table>
<thead>
<tr>
<th></th>
<th>Group I (55)</th>
<th>Group II (55)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>14% (8)</td>
<td>44% (24)</td>
<td>0.001</td>
</tr>
<tr>
<td>Women</td>
<td>86% (47)</td>
<td>56% (31)</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>Mean ± SD</td>
<td>42.8 ± 13.7</td>
<td>40.8 ± 13.1</td>
</tr>
<tr>
<td>Weight</td>
<td>Mean ± SD</td>
<td>174.9 ± 42.8</td>
<td>168.0 ± 39.1</td>
</tr>
<tr>
<td>Height</td>
<td>Mean ± SD</td>
<td>64.9 ± 3.1</td>
<td>66.9 ± 4.3</td>
</tr>
<tr>
<td>Body Mass Index</td>
<td>Mean ± SD</td>
<td>29.1 ± 6.3</td>
<td>26.1 ± 4.3</td>
</tr>
<tr>
<td>Duration of Pain (months)</td>
<td>Mean ± SD</td>
<td>103 ± 90.7</td>
<td>91 ± 85.7</td>
</tr>
<tr>
<td>Onset of the Pain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gradual</td>
<td>62% (34)</td>
<td>67% (37)</td>
<td>0.690</td>
</tr>
<tr>
<td>Injury</td>
<td>48% (21)</td>
<td>33% (18)</td>
<td></td>
</tr>
<tr>
<td>Mid Back Pain Distribution</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bilateral</td>
<td>71% (39)</td>
<td>82% (45)</td>
<td>0.178</td>
</tr>
<tr>
<td>Left or Right</td>
<td>29% (16)</td>
<td>18% (10)</td>
<td></td>
</tr>
<tr>
<td>Numeric Rating Score (NRS)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>7.9 ± 0.8</td>
<td>7.7 ± 0.6</td>
<td></td>
</tr>
<tr>
<td>Oswestry Disability Index (ODI)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>29.5 ± 5.1</td>
<td>29.5 ± 8.0</td>
<td></td>
</tr>
</tbody>
</table>

Table 2. Comparison of Numeric Pain Rating Scale and Oswestry Disability Index score for 2 years.

<table>
<thead>
<tr>
<th>Time Points</th>
<th>Group I (55)</th>
<th>Group II (55)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Numeric Pain Rating scale</td>
<td>Oswestry Disability Index</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td>Baseline</td>
<td>7.9 ± 0.8</td>
<td>7.7 ± 0.6</td>
<td>29.5 ± 5.1</td>
</tr>
<tr>
<td>3 months</td>
<td>3.4* ± 1.4</td>
<td>3.4* ± 1.3</td>
<td>14.0* ± 5.6</td>
</tr>
<tr>
<td></td>
<td>(78%)</td>
<td>(87%)</td>
<td>(80%)</td>
</tr>
<tr>
<td>6 months</td>
<td>3.5* ± 1.4</td>
<td>3.4* ± 1.1</td>
<td>14.3* ± 6.2</td>
</tr>
<tr>
<td></td>
<td>(76%)</td>
<td>(86%)</td>
<td>(75%)</td>
</tr>
<tr>
<td>12 months</td>
<td>3.5* ± 1.3</td>
<td>3.3* ± 1.1</td>
<td>14.0* ± 5.9</td>
</tr>
<tr>
<td></td>
<td>(73%)</td>
<td>(84%)</td>
<td>(73%)</td>
</tr>
<tr>
<td>18 months</td>
<td>3.3* ± 1.1</td>
<td>3.2* ± 1.1</td>
<td>13.5* ± 5.9</td>
</tr>
<tr>
<td></td>
<td>(80%)</td>
<td>(87%)</td>
<td>(82%)</td>
</tr>
<tr>
<td>24 months</td>
<td>3.6* ± 1.3</td>
<td>3.3* ± 1.3</td>
<td>13.8* ± 5.7</td>
</tr>
<tr>
<td></td>
<td>(73%)</td>
<td>(80%)</td>
<td>(76%)</td>
</tr>
<tr>
<td>Group Difference</td>
<td>0.804</td>
<td>0.203</td>
<td></td>
</tr>
<tr>
<td>Time Difference</td>
<td>0.001</td>
<td>0.001</td>
<td></td>
</tr>
<tr>
<td>Group by Time Interaction</td>
<td>0.440</td>
<td>0.716</td>
<td></td>
</tr>
</tbody>
</table>

Lower the value indicates better condition
* significant difference with baseline values within the group (P < 0.001)
(____) illustrates proportion with significant pain relief (≥ 50%) from baseline
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![Graph showing pain reduction and Oswestry Disability Index over time for Successful Patients and All Patients]

Fig. 2. Illustration of reduction (at least 50%) in pain and Oswestry Disability Index from baseline.

Table 3. Therapeutic epidural procedural characteristics with average relief per procedure, and average total relief in weeks over a period of 2 years for thoracic pain.

<table>
<thead>
<tr>
<th></th>
<th>Successful Patients</th>
<th>Failed Patients</th>
<th>All Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group I (49)</td>
<td>Group II (51)</td>
<td>Group I (6)</td>
</tr>
<tr>
<td>At one year</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average number of procedures per one year</td>
<td>3.5 ± 1.0</td>
<td>3.7 ± 1.1</td>
<td>1.8 ± 0.4</td>
</tr>
<tr>
<td>Total number of procedures in one year</td>
<td>171</td>
<td>189</td>
<td>11</td>
</tr>
<tr>
<td>Total relief per one year (weeks)</td>
<td>41.2 ± 11.6</td>
<td>43.6 ± 12.3</td>
<td>1.5 ± 1.8</td>
</tr>
<tr>
<td>At 2 years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average number of procedures per 2 years</td>
<td>6.0 ± 2.2</td>
<td>5.8 ± 2.4</td>
<td>1.8 ± 0.4</td>
</tr>
<tr>
<td>Total number of injections in 2 years</td>
<td>292</td>
<td>294</td>
<td>11</td>
</tr>
<tr>
<td>Total relief per 2 years (weeks)</td>
<td>79.9 ± 25.0</td>
<td>77.8 ± 26.4</td>
<td>1.5 ± 1.8</td>
</tr>
<tr>
<td>Average relief per procedure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>For initial 2 procedures in weeks</td>
<td>10.9 ± 10.7</td>
<td>12.0 ± 15.5</td>
<td>0.8 ± 1.2</td>
</tr>
<tr>
<td>After initial 2 procedures</td>
<td>15.0 ± 9.2</td>
<td>14.4 ± 6.3</td>
<td>-</td>
</tr>
<tr>
<td>All procedures</td>
<td>13.6 ± 9.9</td>
<td>13.6 ± 10.5</td>
<td>0.8 ± 1.2</td>
</tr>
</tbody>
</table>

Successful patients: At least 3 weeks of significant improvement with first 2 injections

Opioid Intake
Opioid intake is shown in Table 4. There was a significant decrease from baseline to all follow-up periods and at 2 years. There were also significant differences between Group I and II at 18 month follow-up.

Changes in Weight
There was no significant weight gain at one year or 2 years with 42% in Group I and 33% in Group II gaining weight at the end of 2 years.

Adverse Events
Of the 606 thoracic interlaminar epidural procedures performed, there were 2 subarachnoid punctures. No postoperative headache was reported. One patient developed immediate postoperative pain and spasms, lasting for 3 hours, with no technical difficulties. Another patient experienced transient pain in the lower extremity, returning after 6 hours, lasting for 3 months.
This trial of thoracic interlaminar epidural injections with 110 patients with 55 patients in each group with local anesthetic with or without steroids is the first of its nature in the literature with a randomized, double-blind, active control design. The procedures were performed under fluoroscopy. The results showed significant improvement in 71% of the patients in the local anesthetic group and 80% of the patients in the local anesthetic with steroids group. Significant improvement was defined with robust outcome measures utilizing at least 50% pain relief and 50% improvement in functional status as measured by NRS and ODI, in contrast to previous measures of 30% improvement. Furthermore, in patients who were defined as successful, based on the response to the first 2 initial procedures with at least 3 weeks of improvement, significant improvement was seen in 80% in Group I and 86% in Group II at 2-year follow-up. This trial is the first performed appropriately in a contemporary interventional pain management setting utilizing fluoroscopy and repeating the procedures when the improvement deteriorated below 50%. Thus, this study embodies the practical nature of interventional pain management with an active-control group instead of placebo group measuring the effectiveness and clinical importance which provides meaningful clinical and practical outcomes.

The strengths of this trial include its comparative evaluation which has become pivotal in modern evidence-based medicine (78-81). The study provided insight into not only the effectiveness of local anesthetic with or without steroids, but also into successful and failed groups based on the first 2 procedures. Overall the study has shown no significant difference whether steroids were used or not. The trial was conducted in a contemporary interventional pain management setting utilizing fluoroscopy and repeating the procedures when the improvement deteriorated below 50%. Thus, this study embodies the practical nature of interventional pain management with an active-control group instead of placebo group measuring the effectiveness and clinical importance which provides meaningful clinical and practical outcomes.

**Limitations**

The limitations include the lack of a placebo group. However, the design of the study with an appropriate placebo has been discussed widely with enormous placebo effects, specifically when impure placebos are utilized, or inactive solutions are injected into active structures (30,82-89). Consequently, even local anesthetic injection has been interpreted as placebo in the past (61,62). The effects of placebo, nocebo, Hawthorne effect, natural course of the disease, (even though not applicable to these chronic pain patients), and regression to mean have been extensively discussed in reference to placebo, nocebo, and pure, impure, and fake placebos (82-84). While appropriate placebo design is difficult in interventional pain management settings, 2 such studies have been performed with proper placebo

Table 4. Opioid intake (morphine equivalents in mg).

<table>
<thead>
<tr>
<th>Time</th>
<th>Group I (55)</th>
<th>Group II (55)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td>Baseline</td>
<td>105.7 ± 145.9</td>
<td>103.4 ± 153.3</td>
</tr>
<tr>
<td>3 months</td>
<td>63.4* ± 66.7</td>
<td>57.0* ± 101.5</td>
</tr>
<tr>
<td>6 months</td>
<td>59.6* ± 64.6</td>
<td>45.8* ± 36.7</td>
</tr>
<tr>
<td>12 months</td>
<td>59.1* ± 64.7</td>
<td>40.4* ± 29.9</td>
</tr>
<tr>
<td>18 months</td>
<td>59.3* ± 65.2</td>
<td>38.9*± 29.0</td>
</tr>
<tr>
<td>24 months</td>
<td>55.7* ± 62.7</td>
<td>38.2* ± 29.5</td>
</tr>
</tbody>
</table>

* indicates significant difference from their baseline values \(P < 0.05\).
# indicates significant difference with Group I at 18 months \(P < 0.05\).
design by Ghahreman et al (90) and Gerdesmeyer et al (91). These trials essentially showed when proper placebo design is achieved with injection of an inactive solution into inactive structure, it is not only considered as true placebo, but the results are strikingly effective in the treatment groups.

Another limitation of this assessment is the time invested in recruiting the patients due to thoracic pain and combination of a multitude of thoracic conditions except for facet joint pain into one group, rather than studying only disc herniation, discogenic pain, spinal stenosis, or post surgery syndrome. Finally, the differences in baseline characteristics with height and body mass index may not be significant in outcomes assessment. Despite appropriate randomization, the significant differences were noted. Thus, randomization may not be a foolproof process to have similar baseline characteristics in both groups (6). Further analysis showed lack of influence of BMI, age and gender on outcomes.

Based on previous cost utility analysis, thoracic epidural injections may be cost effective at less than $3,000 per quality-adjusted life year (92).

In conclusion, this large randomized, active-control trial of the effectiveness of thoracic epidural injections with local anesthetic with or without steroids for chronic thoracic pain secondary to various ailments, except for facet joint pain, showed effectiveness in 80% of patients in the local anesthetic group and 86% in the steroid group, with improvement in pain and functional status in the successful groups, requiring an average of 5 to 6 procedures providing approximately 80 weeks of relief over a 2 year period.

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