



Comparing the short-term cost-effectiveness of epidural steroid injections and medical management alone for discogenic lumbar radiculopathy

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ABSTRACT

Objective: Epidural steroid injections (ESIs) are a commonly used treatment strategy for low back pain and lumbar radiculopathy. However, their cost-effectiveness and ability to mediate long-term quality of life (QOL) improvements is debated. We sought to analyze the cost-effectiveness of lumbar epidural steroid injections (ESIs) compared to medical management alone for patients with lumbar radiculopathy and low back pain.

Patients and Methods: QOL outcomes were prospectively collected at 3- and 6-months following initial consultation. Metrics included the EuroQol-5 Dimensions (EQ-5D) questionnaire, the Pain Disability Questionnaire (PDQ), the Patient Health Questionnaire (PHQ-9) and the Visual Analogue Scale (VAS). Cost estimations were based on Medicare national payment amounts, median income, and missed workdays. A cost-utility analysis was performed based upon cost estimations and a cost-effectiveness threshold of \$100,000/Quality-adjusted life year (QALY).

Results: One hundred forty-one patients met our inclusion/exclusion criteria; 89 received ESI and 52 were treated with medical management alone. Both cohorts showed improved EQ-5D scores at 3 months but were similar to one another: ESI (Δ EQ-5D = 0.06; $p = 0.03$) and medical-alone (Δ EQ-5D = 0.07; $p = 0.03$). No significant difference was seen between groups for total costs (\$2,190 vs. \$1,772; $p = 0.18$) or cost-utility ratios (\$38,710/QALY vs. \$27,313/QALY; $p = 0.73$). At both the 3-month and 6-month endpoints, absolute differences in cost-utility was driven by overall costs as opposed to QALY gains. Medical management alone was more cost effective at both points owing to lower expenditures, however these differences were not significant. No benefits were seen in either group on the EQ-5D or any of the patient reported outcomes at the 6-month time point.

Conclusion: ESIs were not cost-effective at either the 3-month or 6-month follow-up period. At 3 months, ESIs provide similar improvements in QOL outcomes relative to medical management and at similar costs. At 6 months, neither ESIs nor conservative management provide significant improvements in QOL outcomes.

Abbreviations: AMA, American Medical Association; CMS, Centers for Medicare and Medicaid Services; CPT, Current procedural terminology; DRG, Diagnosis related group; EMR, Electronic medical record; EQ-5D, EuroQOL-5 Dimensions; ESI, Epidural steroid injection; KP, Knowledge Program; ICER, Incremental cost-effectiveness ratio; IL, Interlaminar; MCID, Minimum clinically important difference; MS-DRG, Medicare severity diagnosis related group; NSAID, Non-steroidal anti-inflammatory drug; PDQ, Pain Disability Questionnaire; PHQ-9, Patient Health Questionnaire-9; PRO, Patient-Reported Outcome; QALY, Quality-adjusted life year; QOL, Quality of Life; RCT, Randomized controlled trial; TF, Transforaminal; VAS, Visual analog score

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1. Introduction

Each year more than 80 million outpatient visits are performed for neck pain, back pain, or radiculopathy, totaling more than \$20 billion. [1–3] As the population continues to age, the prevalence and costs associated with caring for these conditions is only expected to rise [4]. With this has come an emphasis on value-based care, which requires a critical appraisal of current therapeutic options.

First line therapy for degenerative lumbar pathologies is medical management, which includes non-steroidal anti-inflammatory drugs (NSAIDs), membrane stabilizing agents (e.g. gabapentin), and physical therapy. [3] Another common intervention is the use of epidural steroid injections – fluoroscopically-guided injections of a steroid and an analgesic into the epidural space. The approaches for injection include the more common interlaminar (IL) technique – targeting the region between the spinous processes – and the transforaminal (TF) technique, which directly targets the neural foramen. Many studies have demonstrated ESIs to produce moderate short-term improvements in pain [5,6] and quality of life (QOL) [7–10], though there is a lack of evidence showing long-term improvements in pain, disability, surgery usage, or narcotic usage. [6,11] Additionally, of the few studies directly comparing the efficacy of ESIs to other forms of conservative management, the data suggests that ESIs provide no significant long-term improvement relative to these other interventions [12–17]. Nevertheless, there has been a steady increase in ESI usage [18], which may contribute to the rising costs of spine care [4,19,20]. This demonstrates a need for studies evaluating both the relative efficacy and cost-effectiveness of ESIs relative to other conservative interventions.

In the present study, we perform a cost-utility analysis comparing combined ESIs and medical management to medical management alone for patients with low back pain and lumbar radiculopathy. We analyze three-month and six-month QOL outcomes, calculated cost-utility ratios for both cohorts, and calculate the incremental cost-effectiveness ratio (ICER) of ESIs versus conservative management.

2. Materials and methods

2.1. Demographic and health measurement data

After obtaining Institutional Review Board approval, we retrospectively queried the electronic medical records (EMR) of patients who presented to the outpatient clinic of a single tertiary care institution with complaints of low back pain and lumbar radiculopathy between 2009 and 2015. All patients had been prospectively enrolled in the Knowledge Program (KP), an integral component of the EMR which records patient outcomes on several standardized patient reported outcomes (PROs).

Queried records were reviewed for demographic information as well as postoperative health resource utilization (e.g., outpatient visits, medications). Included patients were older than 18 years of age and had complete medical charts including demographic information (race, age, sex), presenting symptoms, primary diagnosis, and completed PROs at the baseline and three-month timepoints. Patients were excluded if there was no documentation of current or prior ESI use in their chart, they had undergone prior lumbar spine surgery, they had non-spondyloitic causes of their radicular pain (e.g. tumor, infection), they had documented neuromuscular disease (e.g. multiple sclerosis), or they were involved in a workers' compensation claim. Patients were also excluded if they had received non-epidural steroid injections, including facet-joint injections, medial branch blocks, or caudal injections.

2.2. Patient-Reported Outcomes (PROs)

QOL scores including the Pain Disability Questionnaire (PDQ) [21], Patient Health Questionnaire-9 (PHQ-9) [22], and EuroQOL-5 Dimensions (EQ-5D) [23] were acquired via the institutional KP. For all

measures except the EQ-5D, a decrease in score represents improvement. The minimum clinically important difference (MCID) used for each questionnaire in a 1-year time frame was as follows: PDQ (26), PHQ-9 (5), and EQ-5D (0.1) [24,25]. In the present study, the pre-operative EQ-5D score and the postoperative EQ-5D score from the outpatient visit nearest the 3-month and 6-month mark was recorded and converted to the quality-adjusted life year (QALY) values using the United States valuation [26]. QALY is scored from 0 to 1, with 1 being a perfect year of health and 0 representing patient death [26]. The change in quality adjusted life years (Δ QALY) was obtained by subtracting the baseline utility scores from either 3 months or 6 months utility scores. The present results reflect net QALY changes at the follow-up point of interest (i.e. 3-month or 6-month); the establishment of having met the MCID was determined by comparing the QALY change at each time-point to the pro-rated MCID listed above.

2.3. Direct costs

Direct costs were defined as all hospital charges to the patient undergoing the procedure (i.e., the cost of resources used for treating a particular illness). [27] Medicare national payment amounts were used to estimate all direct cost data. The Medicare Severity Diagnosis Related Groups (MS-DRG) national Medicare payment amounts for hospitals were referenced in Optimum 360's DRG Expert book [28]. The American Medical Association (AMA) online database and Center for Medicare and Medicaid Services (CMS) were queried for current procedural terminology (CPT) code Medicare national payment amounts based on the physician fee schedule using the corresponding author's institutional geographic region and practice [29,30]. Diagnosis Related Group (DRG) and CPT code-associated costs were recorded in the year of surgery and then adjusted for inflation to 2015 dollars. Other direct costs included physical therapy days, outpatient visits, and diagnostic imaging. These costs were recorded from the EMR of patients. Pharmaceutical costs were estimated from the 2007 Red Book for Medications. [31]

2.4. Indirect costs

Indirect costs were defined as the value of resources lost due to the intervention and postoperative recovery (i.e., missed worked days). These costs are commonly estimated using a standard human capital approach, whereby the patient's reported gross pre-tax wage rate is multiplied by the total number of work-hours lost due to the intervention. [27] To estimate patient pre-tax wage rate, we converted the median annual household income based on the patients' zip code [32] into daily rates, which were then multiplied by the patient's self-reported days of missed work.

2.5. Cost-utility ratio and ICER

Here we defined cost-utility ratios as the total cost (direct + indirect costs) associated with the intervention divided by the QALYs gained from the intervention. To compare the cost effectiveness of the interventions employed in the ESI and conservative groups, we employed the incremental cost-effectiveness ratio (ICER), which we defined as the difference in cost-utility ratios of the ESI and conservative groups. [33]

Cost-utility ratios were calculated by dividing the total costs by the incremental increase in QALYs from baseline to the timepoint of interest, as defined by the EQ-5D. Direct costs were added to indirect costs to obtain the total cost for each patient in each cohort. The pre-operative utility score was used as a baseline for pre-treatment health status (i.e. initial EQ-5D score) for each cohort. The mean total cost was calculated and divided by the mean gain in QALY to obtain the cost-utility ratio for each cohort at the 1-year mark. The ICER was then calculated as the difference in the total cost for each intervention divided by the difference in QALY gains between the interventions. The

resultant cost-utility ratios and ICER were then compared to the cost effectiveness threshold of 1 year (\$100,000/QALY gained) converted to 3 months (\$25,000/QALY gained) and 6 months (\$50,000/QALY gained) to assess for cost effectiveness. [34]

2.6. Statistical analysis

Descriptive statistics were performed using mean and standard deviation for continuous variables and proportions for categorical or dichotomous variables. For inferential statistics, we employed student's t-tests for continuous variables; unpaired tests were used to compare between groups and paired t-tests were used to compare outcomes at the baseline, 3-month, and 6-month within groups. Fisher's exact tests were used to evaluate dichotomous outcomes, whereas χ^2 analyses were used for categorical outcomes. All analyses were performed using the Analysis Toolpak in Microsoft Office Excel (Redmond, WA) using an α of 0.05 as the threshold for significance.

3. Results

3.1. Demographics

Of the 810 patients screened, we identified a total of 141 patients meeting inclusion criteria, all of whom were treated with conservative management including epidural steroid injections (n = 89) or with conservative management alone (n = 52) (Table 1A and Table 1B). Within both groups, patients were predominately white (92.9%) and male (61.0%). Across both cohorts the average age was 68.5 years and mean body mass index (BMI) was 29.7 kg/m². The most common reasons for presentation were spinal stenosis (41.8%), spondylosis (24.1%), and degenerative disc disease (21.3%). No significant differences were noted between groups with regard to diagnosis, medication usage, or any of the demographic variables. Patients in the conservative group were noted to have tried physical therapy at a significantly higher rate than patients in the ESI group though (44.2% vs. 19.1%; p = 0.002).

Of the 141 patients, 56 within the ESI cohort and 31 within the conservative cohort had 6-month PROs available for analysis. No significant difference was noted between the two cohorts with regards to age, race, sex, BMI, tobacco use, or presenting diagnosis. It was noted

Table 1A Demographics – 3-Month Cohort.

	ESI	Conservative	p-value*
3-Month Cohort			
n	89	52	–
Age	68.3 ± 10.0	68.8 ± 11.4	0.77
Male	51 (57.3%)	35 (67.3%)	0.28
Smoker (previous or current)	55 (61.8%)	24 (46.2%)	0.08
Diabetic	25 (28.1%)	11 (21.1%)	0.43
BMI (kg/m ²)	29.5 ± 5.9	30.1 ± 5.0	0.52
Caucasian	82 (92.1%)	49 (94.2%)	0.75
<i>Diagnoses</i>			
Spinal Stenosis	38 (42.7%)	21 (40.4%)	
Spondylosis	25 (28.1%)	9 (17.3%)	
Degenerative Disc Disease	15 (16.9%)	15 (28.8%)	0.29
Spondylolisthesis	7 (7.9%)	6 (11.5%)	
Disc Herniation	4 (4.5%)	1 (1.9%)	
<i>Medications</i>			
Muscle Relaxant	45 (50.5%)	30 (57.7%)	0.49
Analgesic	36 (40.4%)	20 (38.5%)	0.86
Opioid Use	32 (36.0%)	13 (25.0%)	0.20
Oral Steroids	5 (5.6%)	4 (7.7%)	0.73
Physical Therapy	17 (19.1%)	23 (44.2%)	0.002*
Income	\$63,679 ± 19,152	\$60,948 ± 17,694	0.39

Key: BMI – body mass index; ESI – epidural steroid injection. * p ≤ 0.05.

Table 1B Demographics – 6-Month Cohort.

	ESI	Conservative	p-value*
6-Month Cohort			
n	56	31	–
Age	67.8 ± 10.4	68.9 ± 10.0	0.62
Male	34 (60.7%)	22 (71.0%)	0.36
Smoker (previous or current)	28 (50.0%)	22 (71.0%)	0.07
Diabetic	17 (30.4%)	9 (29.0%)	1.00
BMI (kg/m ²)	30.3 ± 6.6	29.4 ± 5.3	0.50
Caucasian	49 (87.5%)	27 (87.1%)	1.00
<i>Diagnosis</i>			
Spinal Stenosis	24 (42.9%)	15 (48.4%)	
Spondylosis	19 (33.9%)	5 (16.1%)	
Degenerative Disc Disease	6 (10.7%)	8 (25.8%)	0.24
Spondylolisthesis	4 (7.1%)	2 (6.5%)	
Disc Herniation	3 (5.4%)	1 (3.2%)	
<i>Medications</i>			
Muscle Relaxant	35 (62.5%)	26 (83.9%)	0.02*
Analgesic	19 (33.9%)	11 (35.4%)	1.00
Opioid Use	24 (42.9%)	12 (38.7%)	0.82
Muscle Relaxant	8 (14.3%)	3 (9.7%)	0.74
Physical Therapy	7 (12.5%)	11 (35.5%)	0.03*
Income	\$67,700 ± 18,337	\$57,210 ± 19,923	0.02*

Key: BMI – body mass index; ESI – epidural steroid injection. * p ≤ 0.05.

that patients within the conservative group had significantly higher odds of having used muscle relaxants (83.9% vs. 62.5%; p = 0.02) or physical therapy (35.5% vs. 12.5%; p = 0.03). Patients within the conservative cohort also resided in location with lower median incomes (p = 0.02).

Within the 3-month and 6-month ESI cohorts, TF approaches were 2–3 times more commonly employed than IL approach (Table 2). No significant differences were noted between the 3- and 6-month cohorts in terms of the mean number of injections received (p = 0.87) or approach used (p = 0.35). Patients in the 3-month cohort were more likely to have received an injection at the L5/S1 level, however this difference was not statistically significant.

3.2. Health-related outcomes and costs

At 3 months, both the ESI (Δ EQ-5D = 0.06, p = 0.03) and conservative cohorts (Δ EQ-5D = 0.07, p = 0.03) showed significant improvements relative to baseline on the EQ-5D (Table 3). No significant differences were noted relative to baseline on any of the other PROs. Similarly, no differences were noted between cohorts with regard to any of the PROs. At 6-month follow-up, no significant differences were detected between groups or within groups on any of the collected PROs. Sub-analysis of the ESI group failed to demonstrate any significant

Table 2 Treated levels and approach for 3-month and 6-month epidural steroid injection cohorts.

	3 Months	6 Months	p-values
Mean ESIs	1.40 ± 0.72	1.43 ± 0.93	0.87
Total ESIs	125	80	–
<i>ESI Level</i>			
L 2-3	3 (2.4%)	2 (2.5%)	1.00
L3-4	18 (14.4%)	18 (22.5%)	0.19
L4-5	41 (32.8%)	16 (31.3%)	0.06
L5-S1	63 (50.4%)	27 (43.8%)	0.02*
<i>ESI Approach</i>			
Interlaminar	40 (32.0%)	20 (25.0%)	0.35
Transforaminal	85 (68.0%)	60 (75.0%)	0.35

Key: ESI – epidural steroid injection. *p ≤ 0.05.



Table 3
Quality of Life Outcomes – 3 Months and 6 Months.

	ESI		Conservative		p-value (intercohort)
	Mean ± SD	p-value	Mean ± SD	p-value	
3-Month Cohorts					
VAS					
Baseline	5.1 ± 2.5	0.84	4.0 ± 2.9	0.68	0.02*
3 months	5.0 ± 2.6		3.8 ± 2.5		0.01*
Change	0.0 ± 2.6	—	0.1 ± 2.1	—	0.77
PDQ					
Baseline	66.9 ± 27.9	0.98	58.8 ± 26.0	0.76	0.15
3 months	66.8 ± 30.6		56.6 ± 28.4		0.19
Change	2.4 ± 20.2	—	3.1 ± 7.3	—	0.36
PHQ-9					
Baseline	5.9 ± 5.3	0.86	5.4 ± 5.0	0.76	0.59
3 months	5.8 ± 5.6		5.8 ± 4.4		0.99
Change	0.7 ± 4.3	—	1.1 ± 4.3	—	0.16
EQ-5D/QALY					
Baseline	0.595 ± 0.211	0.03	0.593 ± 0.197	0.03	0.96
3 months	0.651 ± 0.200		0.658 ± 0.186		0.85
Change	0.057 ± 0.245	—	0.065 ± 0.209	—	0.84
6-Month Cohorts					
VAS					
Baseline	5.0 ± 2.4	0.89	4.0 ± 2.8	0.68	0.08
6 months	5.4 ± 2.4		4.6 ± 3.1		0.23
Change	0.3 ± 3.1	—	0.5 ± 2.6	—	0.84
PDQ					
Baseline	65.4 ± 30.7	0.82	60.0 ± 29.9	0.79	0.45
6 months	64.5 ± 31.2		70.2 ± 27.0		0.54
Change	4.8 ± 32.4	—	11.9 ± 30.8	—	0.10
PHQ-9					
Baseline	6.2 ± 4.9	0.70	5.4 ± 5.2	0.52	0.86
6 months	5.7 ± 5.3		5.6 ± 6.1		0.79
Change	0.6 ± 3.4	—	0.3 ± 4.2	—	0.32
EQ-5D/QALY					
Baseline	0.606 ± 0.213	0.84	0.668 ± 0.180	0.29	0.15
6 months	0.599 ± 0.210		0.624 ± 0.201		0.59
Change	-0.007 ± 0.249	—	-0.044 ± 0.225	—	0.48

Key: ESI = Epidural Steroid Injection; PDQ = Pain Disability Questionnaire; PHQ = Pain Health Questionnaire; EQ-5D = EuroQol 5-Dimensions; QALY = Quality Adjusted Life Year; VAS = Visual Analogue Score.
*p ≤ 0.05.

differences in the 3- or 6-month outcomes between patients receiving TF ESI and those receiving IL ESI.

Review of the billing data identified costs of \$118.64 and \$166.04 for IL and TF ESI, respectively (Table 4). At 3 months, the total costs

Table 4
Medical Costs – 3 Months and 6 Months.

	ESI	Conservative
3-Month Cohorts		
Interlaminar ESI	\$ 118.64	—
Transforaminal ESI	\$ 166.04	—
Total Direct Costs	\$ 1088.24 ± 619.07	\$ 1070.24 ± 674.80
Indirect Costs	\$ 1102.15 ± 1826.83	\$ 701.98 ± 1421.44
Total Costs	\$ 2190.39 ± 1966.95	\$ 1772.22 ± 1653.34
6-Month Cohorts		
Interlaminar ESI	\$ 118.64	—
Transforaminal ESI	\$ 166.04	—
Total Direct Costs	\$ 1470.51 ± 889.56	\$ 1642.42 ± 974.30
Indirect Costs	\$ 1100.46 ± 2011.25	\$ 834.07 ± 1536.98
Total Costs	\$ 2570.96 ± 2088.95	\$ 2476.49 ± 2111.96

Key: ESI – epidural steroid injection.
*p ≤ 0.05.

Table 5
Cost-Utility Ratio and ICER (1-Year) – 3 Months and 6 Months.

	ESI	Conservative
3-Month Cohorts		
ΔQALY 1-Year	0.057 ± 0.245	0.065 ± 0.209
Cost/QALY gained 1-Year	\$ 38,710.24 / QALY gained	\$ 27,313.42 / QALY gained
ICER 1-year	Dominated ¹	
6-Month Cohorts		
ΔQALY 1-Year	-0.007 ± 0.249	-0.044 ± 0.225
Cost/QALY gained 1-Year	\$ (375,910.77) / QALY gained	\$ (56,574.10) / QALY gained
ICER 1-year	\$ 2557.89 / QALY lost ²	

Key: ESI = Epidural Steroid Injection; QALY = Quality Adjusted Life Year. ICER = Incremental Cost Effectiveness Ratio = ((Total Cost ESI cohort - Total Cost Conservative cohort))/((ΔQALY ESI cohort - ΔQALY Conservative cohort)).
*Significant value p ≤ 0.05; the Student's t-test was used for data analysis.

¹At 3 months, ESIs seem to be an economically dominated strategy in terms of cost-effectiveness when compared to medications and physical therapy alone. ESIs result in less gain in QALY when compared to conservative management.
²At 6 months, neither ESIs nor conservative management provide a gain in QALYs, resulting in a similar amount spent for QALYs lost.

incurred by the ESI cohort patients were \$2,190.39, whereas total costs for the conservative cohort summed to \$1,772.22. No significant differences were noted between groups in terms of direct (p = 0.88), indirect (p = 0.15), or total costs (p = 0.18), though indirect and total costs trended towards being lower in the conservative group. Similarly, no differences were noted between groups at 6-months in terms of direct, indirect, or total costs. The number of missed days was similar in both cohorts: the ESI cohort averaged 8 missed days in the ESI cohort at three- and six-months, and the conservative management group averaged 5 days at three-month follow-up and 6 days at six-month follow-up.

3.3. Cost effectiveness

Significant increases in quality-adjusted life years for both the ESI (ΔQALY = 0.06) and conservative groups (ΔQALY = 0.07) were identified (Table 5). No differences were noted between the two groups, however. All QALY improvement were lost by 6-month follow-up however, as neither group demonstrated a significant improvement in ΔQALY relative to baseline.

Cost analysis at the 3-month follow-up identified an average cost-utility ratio of \$38,710 per QALY for ESI and \$27,313 per QALY for conservative management. Using our pre-defined thresholds for cost-effective treatment (\$25,000/QALY per 3-month period), neither therapy proved to be cost-effective. At 6 months, the cost-utility ratios for both cohorts were negative, however they did not differ significantly from zero, suggesting that in both groups, money was spent without any increase in the number of QALYs. There was no significant difference in cost-utility ratios between the ESI and conservative cohorts.

As there was no significant difference in QALY gain at 3 months between patients in the ESI and conservative cohorts, the incremental cost-effectiveness ratio was expenditure-driven (economically-dominated) and therefore favored conservative management. Similarly, at 6-months, as neither intervention produced a significant increase in QALYs, the ICER was economically dominated and favored conservative management due to lower overall expenditures within this group. Neither of these differences was statistically significant though.

4. Discussion

ESIs are commonly used among patients with lumbar radiculopathy [7,12,35–37], but there is little evidence regarding their cost-

effectiveness. Here we directly compared the cost-effectiveness of epidural steroid injections (ESI) and medical management-alone in patients presenting with primary complaints of lower back pain and lower extremity radiculopathy. We found that ESI and conservative management produced similar improvements in QOL at 3-months; neither intervention was identified as producing a significant improvement on any of the examined PROs at 6-month follow-up. Cost analysis failed to identify a statistically significant difference in cost-effectiveness between groups at either the 3-months or 6-month timepoints, however in both cases the incremental cost effectiveness ratio favored the conservative management group due to lower overall economic costs.

Numerous prior studies have looked at short-term outcomes following epidural steroid injection and several systematic reviews have been formulated from these studies, including contemporary publications by Manchikanti [38], Lee [6], and Chou [39]. These studies have predominately shown steroid injections to provide moderate improvements in short-term pain, however they have failed to show either superiority relative to injection with anesthetics alone or long-term improvement relative to conservative management without injections [40]. Our results parallel these findings, noting a significant improvement in patient quality-of-life at the 3-month, but not 6-month follow-up. Importantly, similar improvements were demonstrated in the conservative-only group, suggesting that epidural injections confer no additional benefit in the non-surgical management of degenerative lumbar pathologies.

The earliest cost-analysis of ESIs was performed by Lafuma et al., who found the addition of epidural steroid injections increased care costs in the inpatient setting for patients being treated for sciatica. [41] A subsequent publication by Price et al. using a multicenter outpatient cohort also found ESI to be a cost-inefficient means of treating sciatica, though they failed to include a comparison group treated without ESI [14]. By contrast, Whynes et al. reported epidural injections to be a cost-effective means of managing chronic lower back pain (LBP) as determined by procedural cost relative to utility gained [42]. Like Price et al., they did not compare results directly to patients receiving only conservative management. Subsequently, Manchikanti and colleagues reported that epidural steroid injection are a cost-effective means of treating pain caused by multiple degenerative spine pathologies [16]. None of the aforementioned studies, however demonstrated that the addition of steroids to confer improved clinical benefit or decreased care costs relative to the anesthetic-only control group.

More recent studies have looked at the costs of ESI to all payors in an attempt to evaluate the societal costs of ESI. A contemporary randomized trial by Spijker-Huiges et al. [43] directly comparing ESI to usual care found the use of an additional ESI decreased overall societal costs associated with the treatment of lumbar radiculopathy. Their analysis was intended to consider direct and indirect costs to all stakeholders though and may not reflect the true cost-effectiveness of the intervention for the patient. Carreon et al. examined the cost-effectiveness of ESI in a prospective cohort of 323 patients treated for degenerative lumbar spine disease. [44] The authors concluded that ESI was not cost effective with estimated total costs of \$250,000–270,000 per QALY when considering all treated patients. Even limiting the analysis to patients who experienced a QALY increase from ESI demonstrated that the treatment was only marginally cost effective, with a price of \$62,000–\$114,000 depending upon the metric used to estimate QALY gain.

Two possible explanations for the heterogeneity of the existing literature are: 1) the definition of cost effectiveness used by these studies, and 2) the time frame over which cost effectiveness is determined. One of the more common thresholds employed for cost effectiveness is \$50,000 per QALY. This value is based on a 1970s estimate of the threshold above which the costs of providing dialysis to patients with end-stage renal disease was deemed financially infeasible for the Medicare program. [34] Based upon this benchmark, studies examining direct costs alone have tended to find the intervention to be cost-

effective, whereas those examining total cost have not, perhaps due to increases in average wage, which have substantially raised indirect costs associated with disability over the four decades since this benchmark was set. Second, many reviews suggest that the clinical benefit of ESI is largely in the short-term relief of symptoms (6weeks-3months). This is where QALY gain is greatest and hence where injections are most cost-effective. Consequently, studies looking a shorter-term follow-up are more likely to find ESI to be a cost-effective intervention. Consistent with this, we have found that ESI may be a cost-effective option for 3-month, but not 6-month QALY gain.

In light of this, there remains the question of how best to evaluate the cost-effectiveness of ESIs. An important issue in this discussion is whether ESIs produce incrementally greater QALY gain per dollar spent as compared to conservative management alone. Our results suggest that this is not the case as the incremental QALY gain for ESI was not inferior or superior to conservative management alone at 3-months. Moreover, ESI and conservative management alone both failed to produce QALY gain at 6-months and were consequently cost-ineffective.

It is important to recognize, however, that the evidence presented herein and the associated discussion relates to the effectiveness of ESI in providing short and long-term improvement in QALY. ESI is also used to assist in diagnosis and identifying anatomic correlates to patients' symptoms to enable more targeted surgical approaches. While our data suggest that ESI may not provide long term QALY gain and/or cost effectiveness, there may be value in its role in diagnosis and providing short-term relief. It is in this context that we have found ESIs useful in our own practice. Based in part upon the findings presented herein, we have seen our utilization of ESIs shift towards diagnostic adjuvants in patients with clinical signs of lumbar radiculopathy. Using a combination of clinical, imaging, and electrophysiology results (e.g. nerve conduction study) we identify the possible roots underlying the patient's symptoms, which are then targeted using either the transforaminal or interlaminar techniques, as preferred by the treating interventionalist. Where diagnosis alone is required, as in the case of radicular pain secondary to bony foraminal stenosis, we employ a selective nerve root block with local anesthetic-alone to demonstrate whether decompression of the targeted root may yield symptomatic relief. Yet for patients with foraminal stenosis secondary to disk impingement, we prefer a combined steroid-local anesthetic combination. Such an injection can both confirm the symptomatic root and serve as a temporizing measure by relieving the local inflammation that is thought to contribute to the pathogenesis of discogenic radiculopathy. [45]

4.1. Limitations

There are several limitations to the present study. The biggest issue is the relatively small sample size and moderate follow-up of the study population. The small sample size predisposes our results to skewing by statistical outliers as well as sampling bias. This in turn limits the degree to which the present results may be generalizable to the broader population of patients with discogenic radiculopathy. The relatively high dropout rate by 6-months poses another potential limitation; though the demographics of the 3-month and 6-month cohorts are similar, it is possible that they differ in some crucial but unidentified metric that accounts for the apparent difference in Δ QALY seen at these two time points. This could similarly limit the generalizability of the six-month results. Furthermore, although our ESI and control cohorts were statistically similar on collected demographic data, it is possible that clinically significant differences remained between them, which were not identifiable because of the small sample size.

Our study is additionally limited by the cost data available to us. Though we were able to effectively estimate the direct costs of procedures performed at and medications prescribed through our center, we were unable to incorporate costs incurred from procedures and medications acquired at outside facilities. The proportion of all expenditures

that these represent is unknown and consequently there exists the possibility that non-trivial outside costs were differentially incurred in one or both groups, which would alter the absolute and relative cost effectiveness of the interventions. Additionally, the direct costs reported in this study are based on Medicare reimbursement amounts, which are conventionally lower than those incurred by private insurance payors. It may therefore be the case that direct costs across all patients undergoing ESI are higher than reported here, limiting the generalizability of our result. Lastly, due to our sample size, we were unable to perform meaningful subanalyses for each of the primary treatment indications. It is possible that ESI might prove more cost effective for certain patient populations within our cohort, such as those presenting with relatively pure lumbar radiculopathy. In spite of these limitations though, we find the results to be largely in line with other studies in the literature in terms of cost-effectiveness and the timeframe over which ESI is beneficial.

4.2. Conclusion

Here we present one of the first studies to perform a direct comparison of total care costs incurred in patients undergoing epidural steroid injection (ESI) or conservative management-alone for degenerative lumbar spine pathologies. We find that ESI and conservative management provide similar improvements in QALY and are similarly cost effective at 3-month follow-up. Neither intervention is cost-effective for 6-month improvement however, suggesting that patients with persistent symptoms may require operative management for cost-effective symptomatic improvement. ESI may also have a role in diagnosis, but our study was not designed to specifically assess that. Additional studies are required to determine the cost-effectiveness of these two treatment strategies in the various etiologies of lumbar radiculopathy.

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