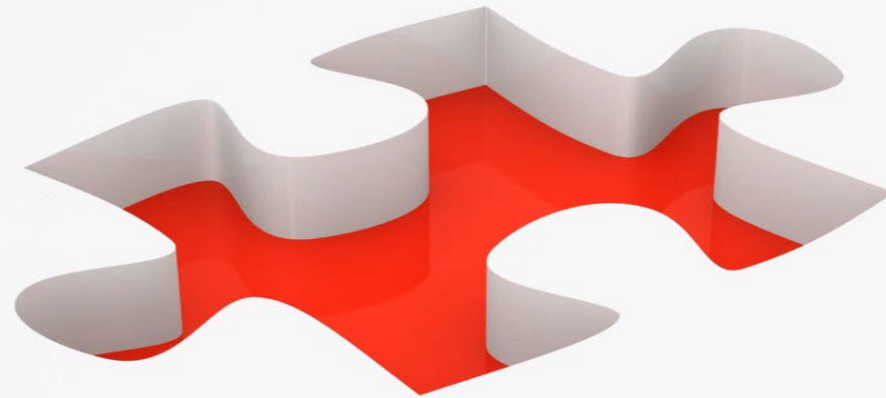


Epidural: Clinical Relevance and Cost Utility

Laxmaiah Manchikanti, MD



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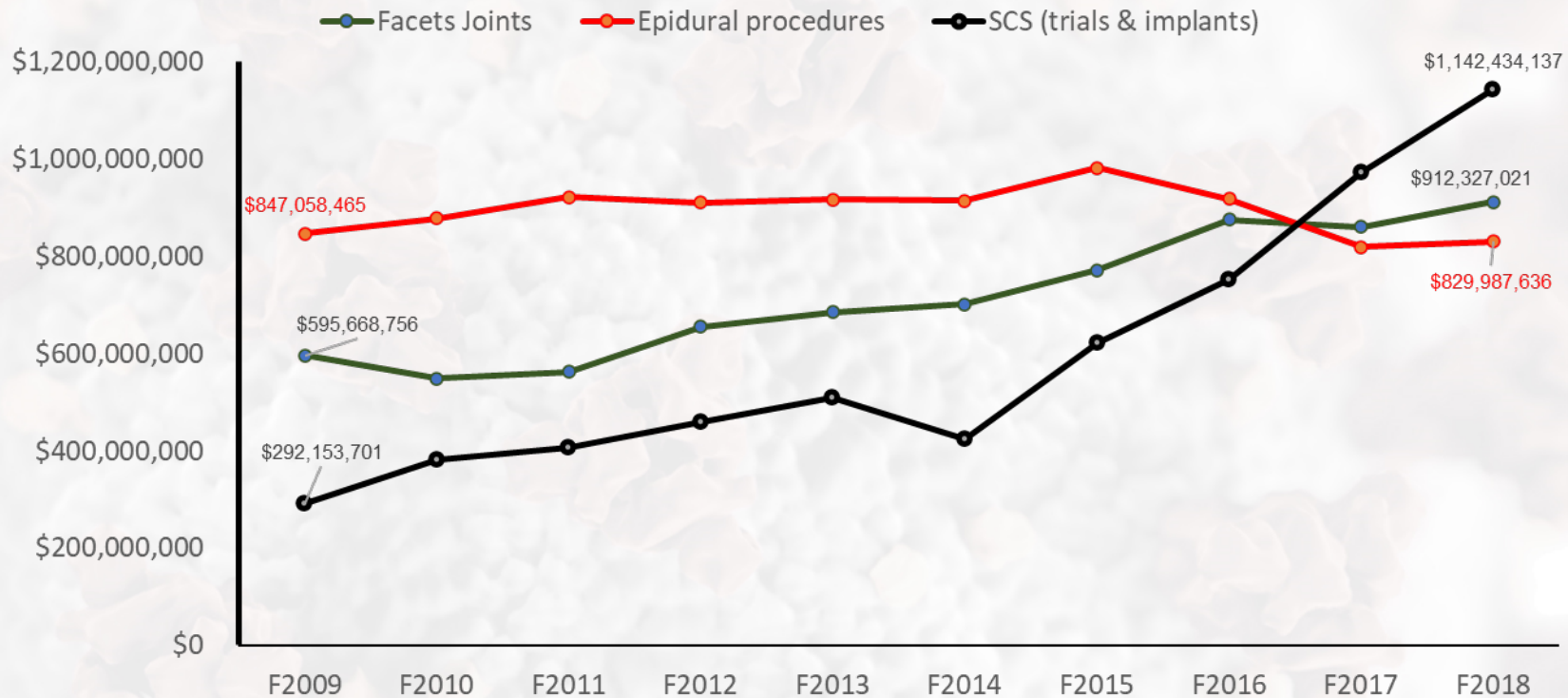
Publications: Over 600 articles and 12 books

2

Editorial Peer Review: 25 journals



Total cost for facet joints interventions, epidural services, spinal cord stimulators on Medicare Beneficiaries



What is real evidence-based medicine and how do we achieve it?

- Makes the ethical care of the patient its top priority
- Demands individualized evidence in a format that clinicians and patients can understand
- Is characterized by expert judgment rather than mechanical rule following
- Shares decisions with patients through meaningful conversations
- Builds on a strong clinician-patient relationship and the human aspects of care
- Applies these principles at community level for evidence-based public health



Guidelines Preparation

- **Four aspects of lack of integrity**
 - **Pre-possession**
 - The mental phenomenon whereby, when we seek the evidence of our preconceptions, we find it.
 - **Vagary**
 - The obsessive pursuit of a particular conclusion, decided upon early, whatever the contrary evidence.
 - **Rationalization**
 - The intellectual art of piecing together valid evidence in such a way as to produce an invalid conclusion.
 - **Congeniality of conclusion**
 - Whereby we reach the conclusion we *like* rather than the one dictated by evidence and logic.



An Algorithmic Approach to Epidural Steroid Injections

Indications

1. Radiculopathy or Radicular pain and/or neurogenic claudication (Except WPS?)
2. Pain duration of 4 weeks and failed 4 weeks of conservative management
3. Effectiveness: Three months of pain relief \geq 50% relief, in conjunction with conservative management
4. Pain scale **OR** functional assessment

Limitations

1. Steroids Dosage limits (Triamcinolone 80 mg – Betamethasone 12 mg , dexamethasone 15 mg) – **No Methyl Prednisone**. Steroids almost mandatory unless allergy or contraindication.
2. CT or Fluoro – except contrast allergy or pregnancy where ultrasound guidance without contrast may be considered
3. Imaging – Minimum of 2 views (Final needle position and contrast flow should be retained)
4. Only mild sedation

Utilization

1. No multiple procedures
2. Two unilateral or bilateral for transforaminal. Maximum 4 per year per region.
3. Document medical necessity
4. Limited ICD-10 codes



Covered Indications

1. **EPIDURAL** steroid injection (ESI) will be considered medically reasonable and necessary when the following three (3) requirements are met:

- History, physical examination, and concordant radiological image-based diagnostic testing supporting one of the following⁵:
 - Lumbar, cervical or thoracic radiculopathy, radicular pain and/or neurogenic claudication due to disc herniation, osteophyte or osteophyte complexes, severe degenerative disc disease, producing foraminal or central spinal stenosis⁵; **OR**
 - Post-laminectomy syndrome⁶⁻⁸; **OR**
 - Acute herpes zoster associated pain⁶

AND

- Radiculopathy, radicular pain and/or neurogenic claudication is severe enough to greatly impact quality of life or function. An objective pain scale or functional assessment must be performed at baseline (prior to interventions). The same scale* must be repeated at each follow-up for assessment of response.

AND

- Pain duration of at least four (4) weeks, and the inability to tolerate noninvasive conservative care or medical documentation of failure to respond to four (4) weeks of noninvasive conservative care **or** acute herpes zoster refractory to conservative management where a four (4) week wait is not required.⁹

Covered Indications

6. Repeat ESI when the first injection directly and significantly provided improvement of the condition being treated may be considered medically reasonable and necessary when the medical record documents at least 50% of sustained improvement in pain relief and/or improvement in function measured from baseline using SAME scale* for at least three months,^{7,8}

If a patient fails to respond well to the initial ESI, a repeat ESI after 14 days can be performed, using a different approach, level and/or medication if appropriate, with the rationale and medical necessity for the second ESI documented in the medical record.

7. MacVicar J, King W, Landers MH, Bogduk N. The effectiveness of lumbar transforaminal injection of steroids: a comprehensive review with systematic analysis of the published data. *Pain Medicine*. 2013;14(1):14-28.

8. Mattie R, Schneider BJ, Smith C. Frequency of Epidural Steroid Injections. *Pain Medicine*. 2020;21(5):1078-1079.

Limitations

- ESIs are limited to a maximum of four (4) sessions per spinal region in a rolling twelve (12) month period.
- **Steroid dosing should be the lowest effective amount, it is recommended not to exceed 80 mg of triamcinolone, 12 mg of betamethasone, 15 mg of dexamethasone per session.**
- It generally would not be considered medically reasonable and necessary for treatment with ESI to extend beyond 12 months. Frequent continuation of epidural steroid injections over 12 months may trigger a focused medical review. Use beyond twelve months requires the following:
 - Pain is severe enough to cause a significant degree of functional disability or vocational disability.
 - ESI provides at least 50% sustained improvement of pain and/or 50% objective improvement in function (using same scale as baseline).
 - Rationale for the continuation of ESIs including but not limited to patient is high-risk surgical candidates, the patient does not desire surgery, recurrence of pain in the same location relieved with ESIs for at least three months
 - The primary care provider **must be notified** regarding continuation of procedures and prolonged repeat steroid use.

Limitations- Continued ...

Evidence synthesis

Disc herniation:

Evidence: Level I: Caudal epidural injections, lumbar interlaminar epidural injections, lumbar transforaminal epidural injections, and cervical interlaminar epidural injections **with strong recommendation** for long-term effectiveness.

Evidence: Level II with moderate to strong recommendation for thoracic epidural with fluoroscopic guidance, with or without steroids, the evidence is for long-term effectiveness.

Evidence: Level II with moderate to strong recommendation for Percutaneous adhesiolysis long-term improvement in patients nonresponsive to conservative management and fluoroscopically guided epidural injections.



Evidence synthesis

Spinal stenosis:

Evidence: Level III to II for fluoroscopically guided caudal epidural injections **with moderate to strong recommendation**

Evidence: Level II for fluoroscopically guided lumbar and cervical interlaminar epidural injections **with moderate to strong recommendation** for long-term effectiveness.

Evidence: Level IV to III: Lumbar transforaminal epidural injections with fluoroscopically guided **with moderate recommendation.**

Evidence: Level II for Percutaneous adhesiolysis **with moderate to strong recommendation** for long-term improvement after failure of conservative management and fluoroscopically guided epidural injections.



Evidence synthesis

Axial discogenic pain:

Evidence: Level II for axial discogenic pain without facet joint pain or sacroiliac joint pain in the lumbar and cervical spine with fluoroscopically guided caudal, lumbar and cervical interlaminar epidural injections **with moderate to strong recommendation** for long-term improvement, with or without steroids.

Post-surgery syndrome:

Evidence: Level II for caudal and cervical interlaminar epidural injections with fluoroscopically guided, with or without steroids, is **with moderate to strong recommendation** for long-term improvement.

Evidence: Level I For percutaneous adhesiolysis **with strong recommendation** for long-term improvement after failure of conservative management and fluoroscopically guided epidural injections.



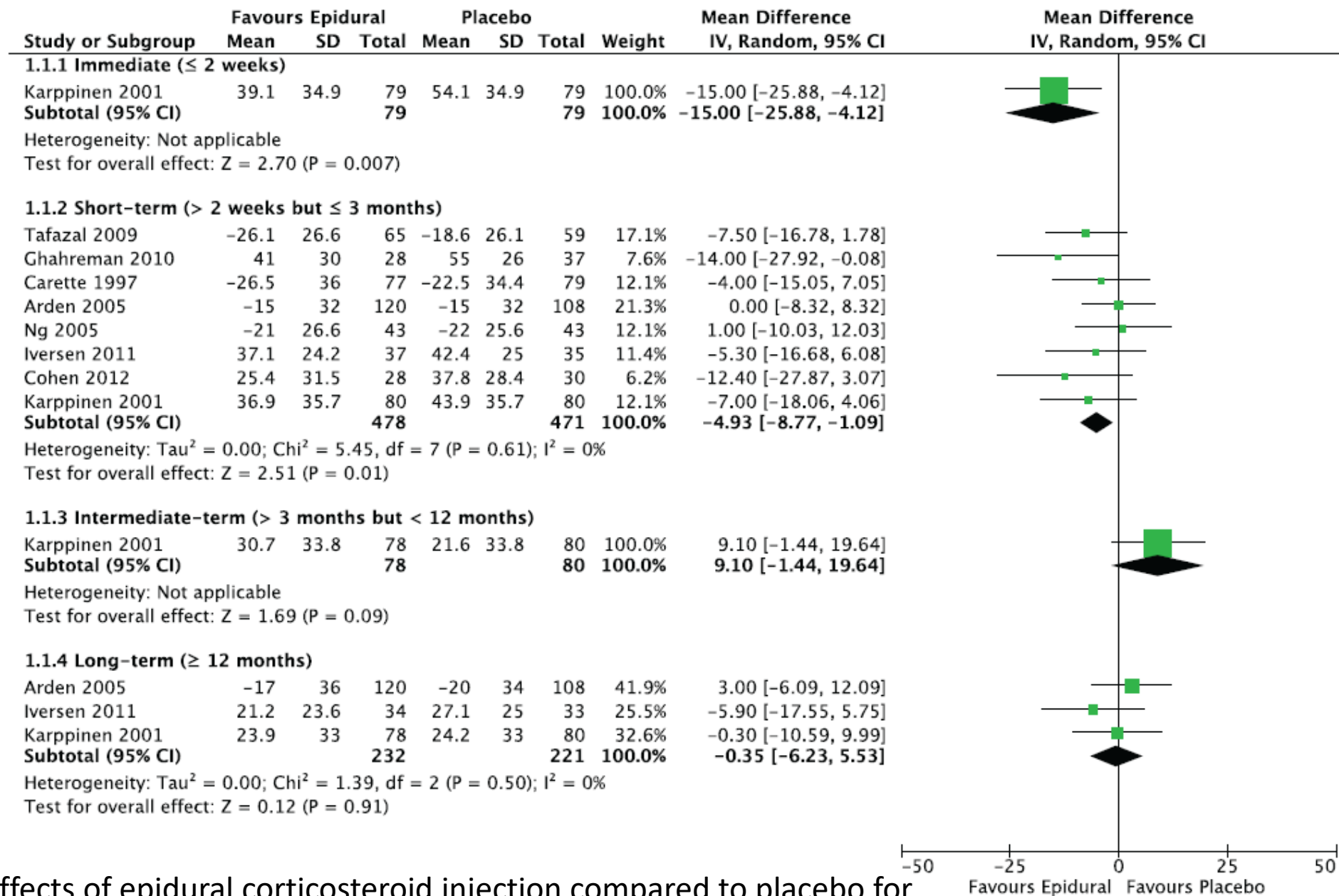
Epidural Corticosteroid Injections for Sciatica

An Abridged Cochrane Systematic Review and Meta-Analysis

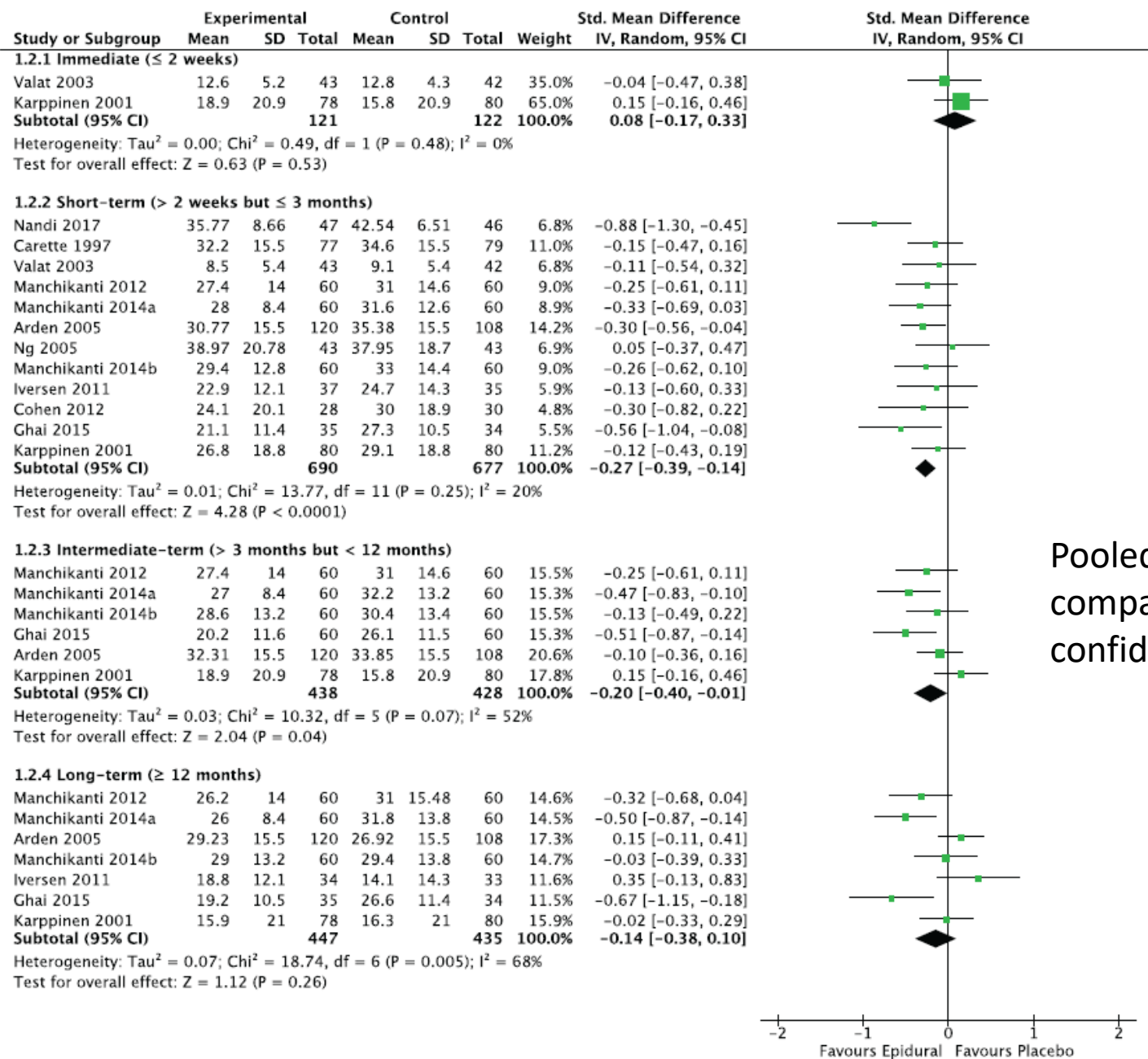
Crystian B. Oliveira, PhD,^a Christopher G. Maher, PhD,^b Manuela L. Ferreira, PhD,^c
Mark J. Hancock, PhD,^d Vinicius Cunha Oliveira, PhD,^e Andrew J. McLachlan, PhD,^f
Bart W. Koes, PhD,^{g,h} Paulo H. Ferreira, PhD,ⁱ Steven P. Cohen, MD,^j
and Rafael Z. Pinto, PhD^k

- Included 25 clinical trials (from 29 publications) providing data for a total of 2470 participants with sciatica,
 - Epidural corticosteroid injections were probably more effective than placebo in reducing short-term leg pain (MD -4.93, 95%CI - 8.77 to -1.09 on a 0–100 scale), short-term disability (MD -4.18, 95% CI: -6.04 to -2.17 on a 0–100 scale)
 - **May be slightly more effective** in reducing short-term overall pain (MD -9.35, 95% CI -14.05 to -4.65 on a 0–100 scale).
 - There were mostly minor adverse events (i.e., without hospitalization) after epidural corticosteroid injections and placebo injections without difference between groups (RR 1.14, 95% CI: 0.91–1.42). The quality of evidence was at best moderate mostly due to problems with trial design and inconsistency.
- **Conclusion: moderate-quality evidence that epidural corticosteroid injections are effective**, although the effects are small and short-term. There is uncertainty on safety due to very low-quality evidence.

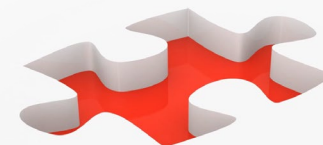




Pooled effects of epidural corticosteroid injection compared to placebo for leg pain. 95% CI indicates 95% confidence interval; SD, standard deviation.



Pooled effects of epidural corticosteroid injection compared to placebo for disability. 95% CI indicates 95% confidence interval; SD, standard deviation.



Systematic Review

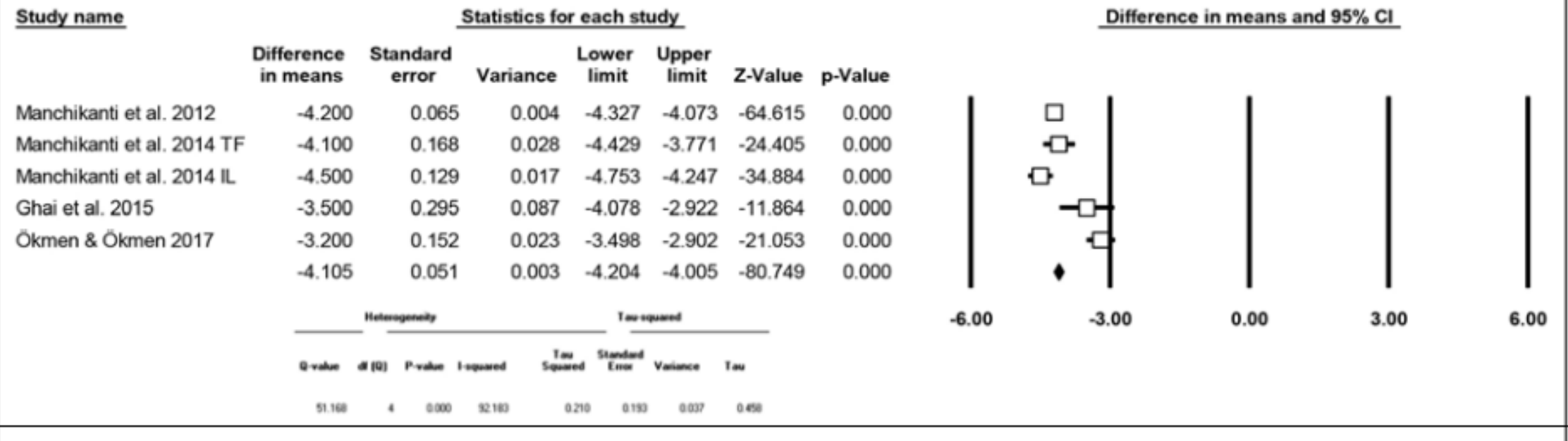
e Epidural Injections for Lumbar Radiculopathy or Sciatica: A Comparative Systematic Review and Meta-Analysis of Cochrane Review

Laxmaiah Manchikanti, MD¹, Emilija Knezevic², Nebojsa Nick Knezevic, MD, PhD³, Mahendra R. Sanapati, MD¹, Srinivasa Thota, MD¹, Alaa Abd-Elseyed, MD⁴, and Joshua A. Hirsch, MD⁵

- In this analysis, a total of 21 RCTs were utilized with at least 6 months of follow-up and performed under fluoroscopic guidance.
 - However, only 6 of 25 trials from Cochrane review met inclusion criteria for this review. Based on qualitative analysis,
 - of the 21 trials included in the present analysis, there was only one placebo-controlled trial found to be negative.
- With conventional meta-analysis, there was no significant difference among the studies because all of the studies were active control with local anesthetic or local anesthetic and steroids.
- Single-arm analysis, of the 5 trials included in that portion of the study, significant improvement was seen with local anesthetic alone compared to local anesthetic and steroids.
 - There was a tendency for better improvement with steroids in terms of both pain relief and functional status.
- Epidural injections with or without steroids for radiculopathy showed significant effectiveness with Level I or strong evidence for local anesthetic with steroids and Level II to I or moderate to strong evidence with local anesthetic alone.



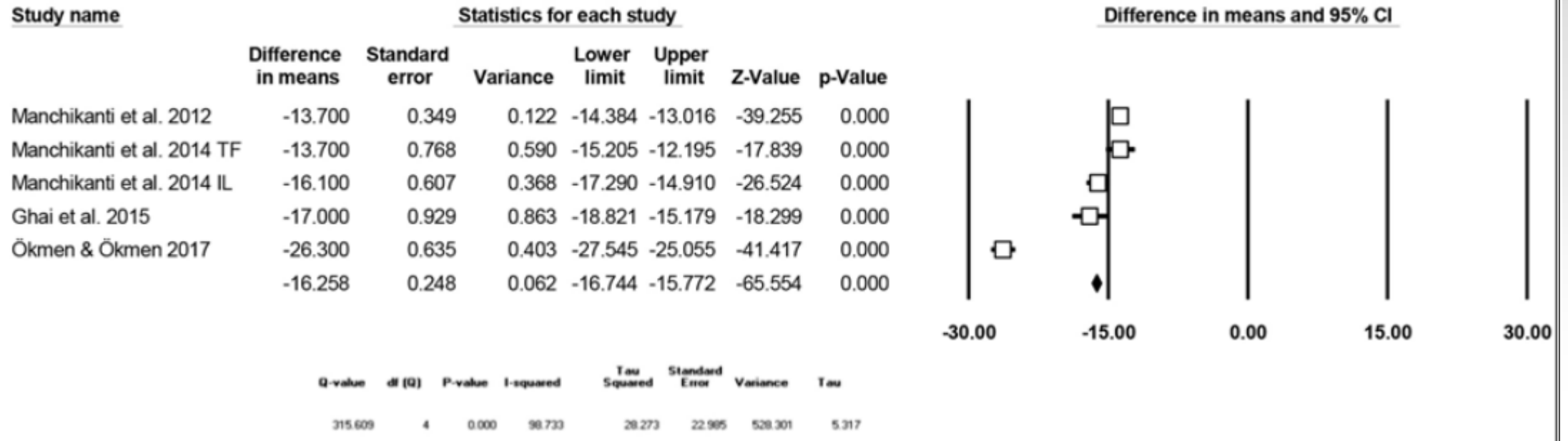
2C



Change in pain level using the numeric rating scale (NRS) from baseline at 6 months. A) Change in pain level at 6 months (local anesthetic vs. local anesthetic with steroid). B) Change in pain level at 6 months (LA). C) Change in pain level at 6 months (local anesthetic with steroid).



3C



Change in functionality level using Oswestry Disability Index (ODI) from baseline at 6 months. A) Change in functionality level at 6 months (local anesthetic vs. local anesthetic with steroids). B) Change in functionality level at 6 months (local anesthetic). C) Change in functionality level at 6 months (local anesthetic with steroid).



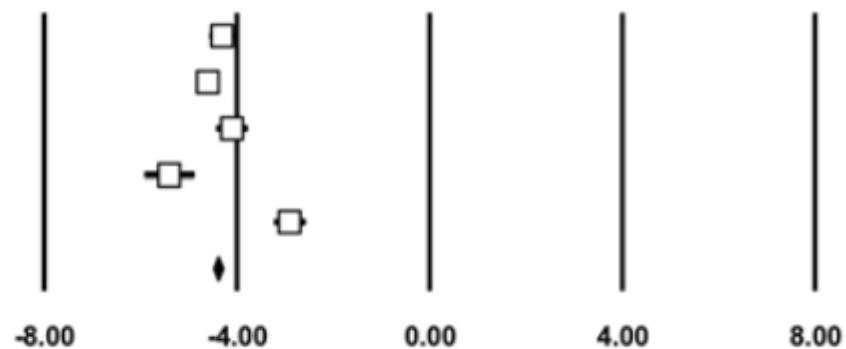
4C

Study name

Statistics for each study

Difference in means and 95% CI

	Difference in means	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
Manchikanti et al. 2012	-4.300	0.129	0.017	-4.553	-4.047	-33.333	0.000
Manchikanti et al. 2014 IL	-4.600	0.060	0.004	-4.718	-4.482	-76.667	0.000
Manchikanti et al. 2014 TF	-4.100	0.161	0.026	-4.416	-3.784	-25.466	0.000
Ghai et al. 2015	-5.400	0.259	0.067	-5.908	-4.892	-20.849	0.000
Ökmen & Ökmen 2017	-2.900	0.161	0.026	-3.216	-2.584	-18.012	0.000
	-4.388	0.048	0.002	-4.483	-4.294	-90.993	0.000



<u>Heterogeneity</u>				<u>Tau-squared</u>			
Q-value	df (Q)	P-value	I-squared	Tau Squared	Standard Error	Variance	Tau
116.836	4	0.000	96.576	0.481	0.428	0.184	0.693

Change in pain level using NRS from baseline at 12 months. A) Change in pain level at 12 months (local anesthetic vs. local anesthetic with steroid). B) Change in pain level at 12 months (local anesthetic). C) Change in pain level at 12 months (local anesthetic with steroid).



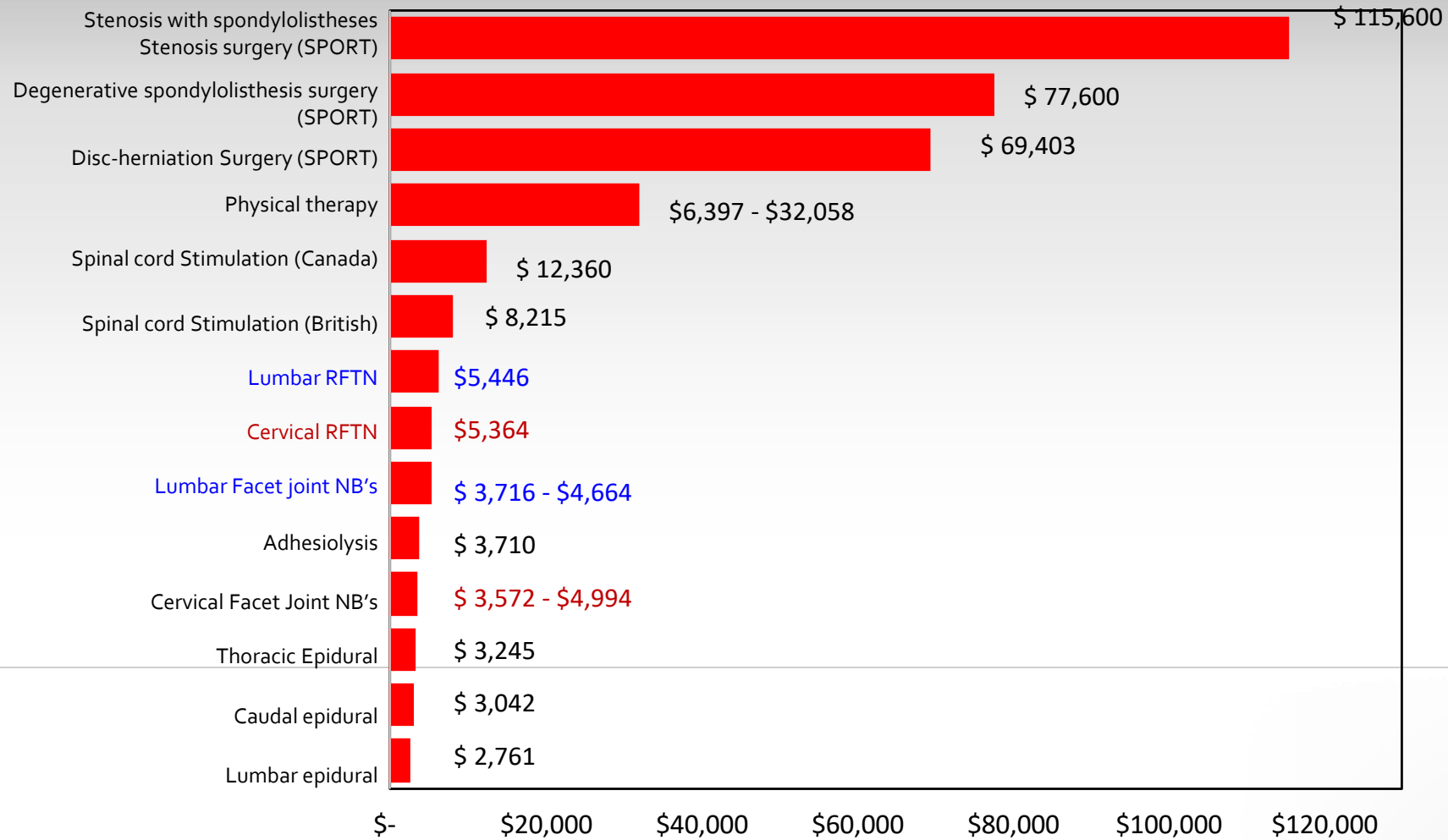
Critical analysis of Cochrane review of epidural injections for lumbar radiculopathy or sciatica and systematic bias: a comparative systematic review and meta-analysis.

Manchikanti et al, in Press

- ◆ Based on the analysis of 14 placebo-controlled studies with 6 studies with 463 patients meeting the inclusion criteria comparing a placebo group with epidural steroid group.
 - Results showed a statistically significant difference in pain levels between these 2 groups at one-month, a borderline significant difference between the placebo and the treatment group at 3 months, but no significant difference noted in function between these 2 groups at one-month or 3 months. At one month 463 patients and at 3 months there were 683.
- ◆ Utilizing active controlled trials with 7 of 11 utilizing fluoroscopic guidance with 7 studies and 793 patients at 3-month follow-up showed a significant difference between the local anesthetic group and steroid group favoring the steroids. Similarly, single-arm meta-analysis also showed effectiveness of local anesthetic alone or with local anesthetic and steroids.
 - Overall, the evidence is Level I for epidural injections at one-month based on placebo-controlled trials with pain relief without significant difference with functional status and Level I at 3-month follow-up with borderline significant difference with pain relief with dual-arm analysis and significant improvement compared to baseline with single-arm analysis.
 - At 6 months and 12 months there was no data available for placebo controlled trials; however, based on active control trials there was Level II evidence of epidural injections with local anesthetic alone or with steroids.



Cost Effectiveness per Quality-Adjusted Life-Year (QALY)



Multiple Other Issues

- Transforaminal
 - Cervical/Thoracic
 - Intraneural/supraneural
 - Particulate vs non-particulate
- Indications
 - Stenosis
 - Degenerative Disc Disorder
 - Discogenic pain



Thank you

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