Efficacy and Effectiveness Literature for Lumbar Transforaminal Injections of Steroid

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March 11th 2016



DISCLOSURE

I have nothing to disclose



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 Med 2013;14(1):14–28.



MISCELLANEOUS CONDITIONS

EPIDURAL LIPOMATOSIS
SCOLIOSIS
HETEROGENEOUS DIAGNOSES

SPINAL STENOSIS
DISC HERNIATION
FAILED BACK SURGERY



MISCELLANEOUS CONDITIONS

EPIDURAL LIPOMATOSIS
SCOLIOSIS
HETEROGENEOUS DIAGNOSES
FAILED BACK SURGERY

For miscellaneous conditions, the literature on TFIS is sorely limited. Although authors have described the use of TFIS for these conditions, the evidence is not compelling for lack of corroborating studies and for lack of any form of controlled study.

SPINAL STENOSIS

Some 50% of patients achieve 50% relief of pain for six months or more, but controlled studies have not corroborated this outcome.



DISC HERNIATION

Up to 70% of patients achieve at least 50% relief of pain. TFIS is not a placebo.

TFIS reduces the need for other health care and has been shown to be surgery-sparing.

TFIS has been shown to be cost-effective for contained disc herniations.

25% - 40% of patients have relief that lasts 12 months.

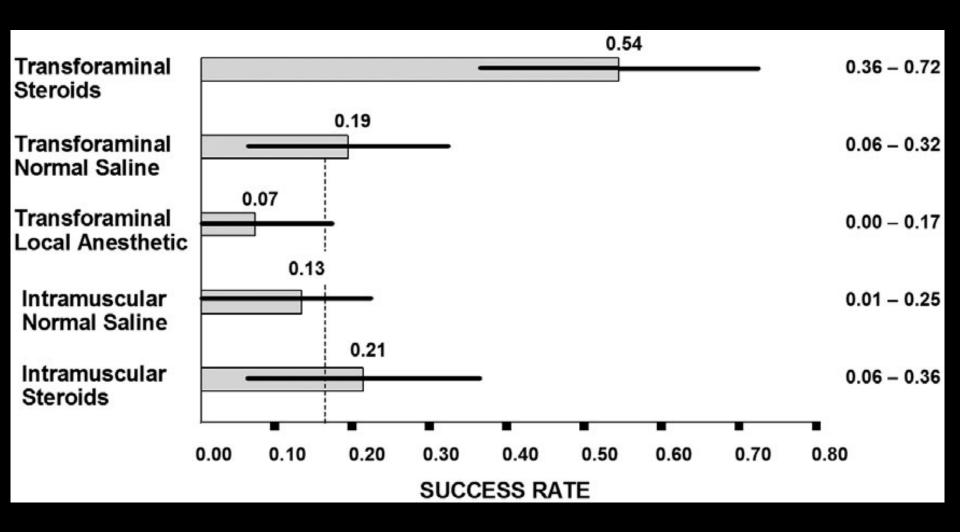


DISC HERNIATION

150 patients randomised to

transforaminal injection of steroid transforaminal injection of bupivacaine transforaminal injection of normal saline intramuscular injection of steroids intramuscular injection of normal saline





Ghahreman A, Ferch R, Bogduk N. The efficacy of transforaminal injection of steroids for the treatment of lumbar radicular pain. Pain Med 2010; 11:1149-1168.



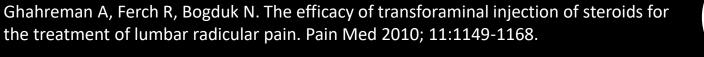
Ghahreman et al

Transforaminal injection of steroid

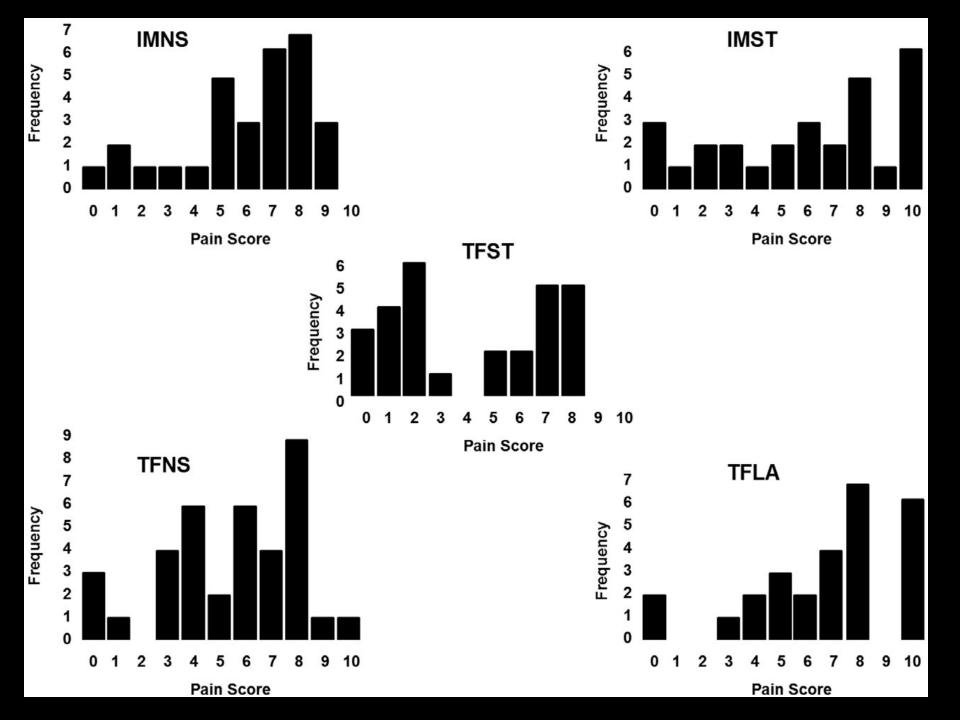
At 1 month 54% (36-72%) of patients obtained at least 50% relief

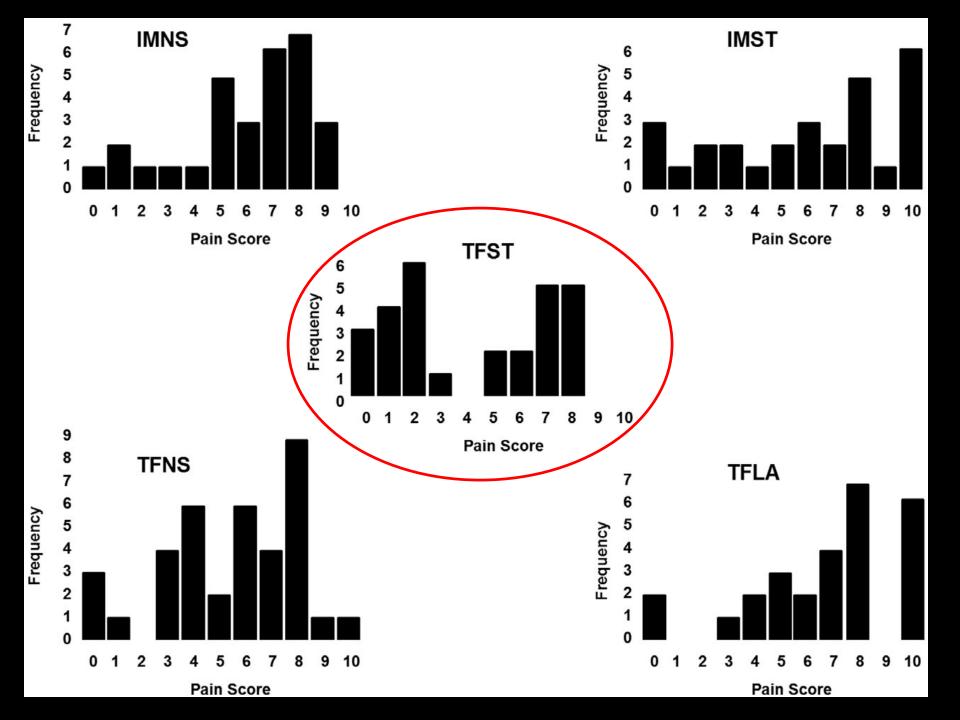
At 12 months

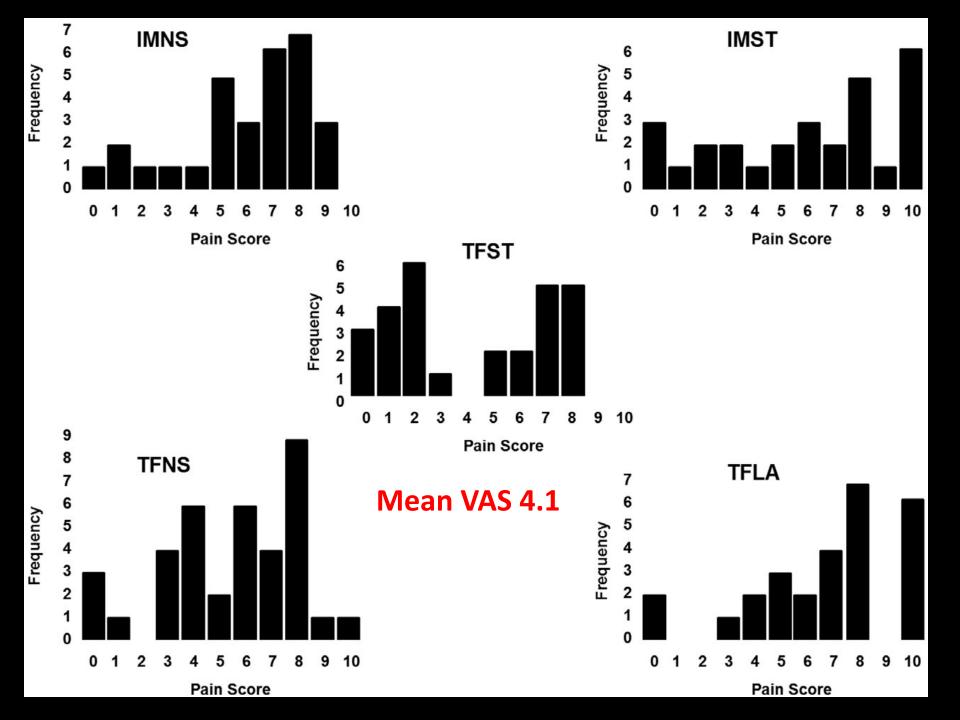
11% of patients still had at least 50% relief of pain, and a further 14% had complete relief

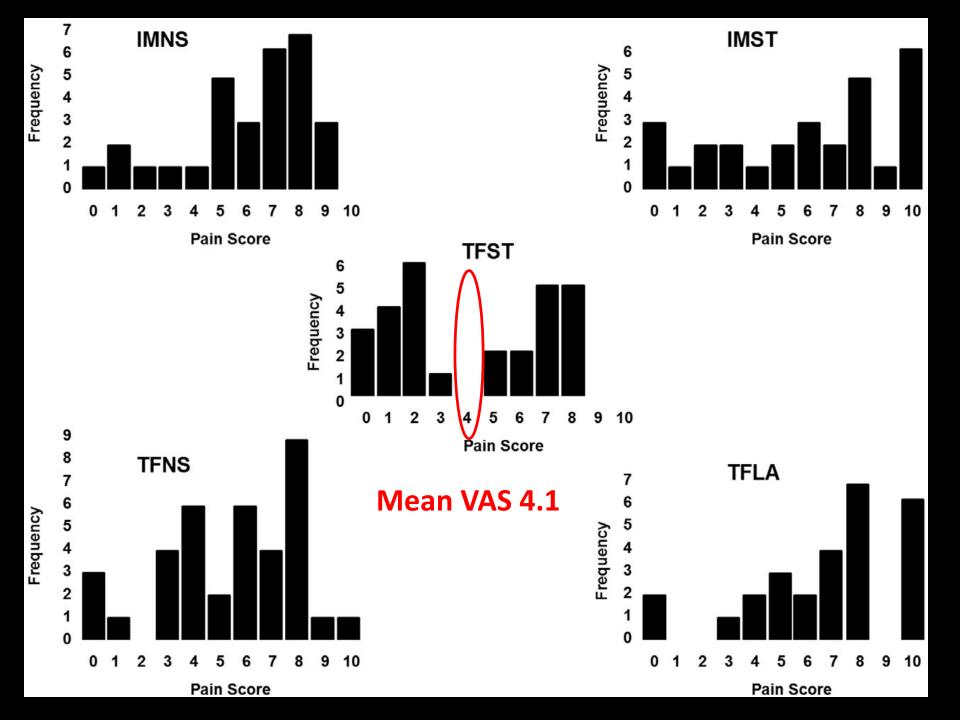


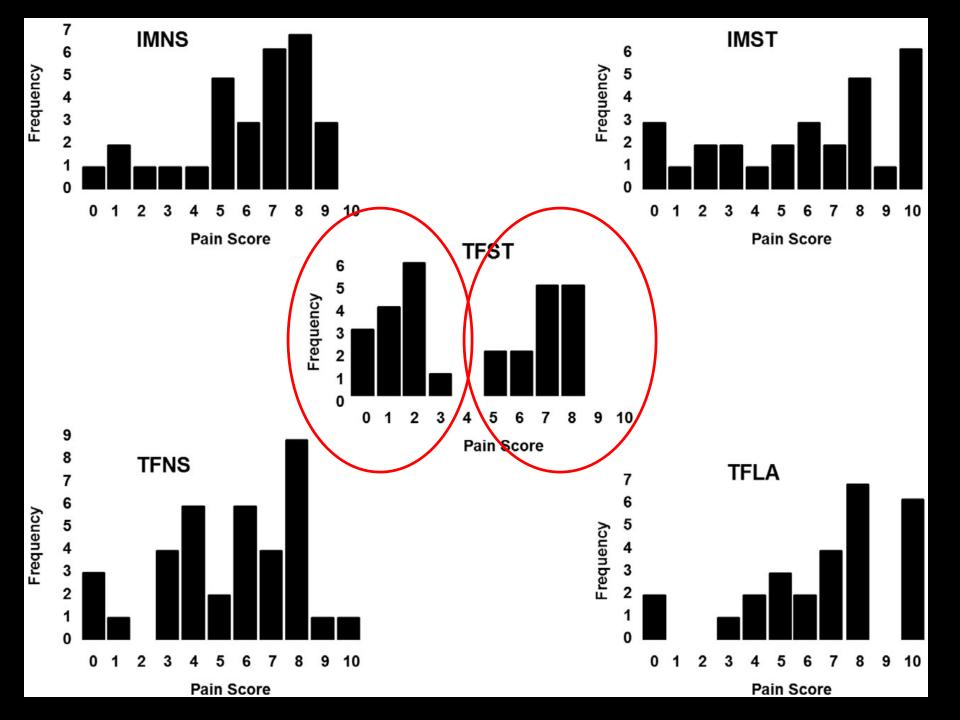


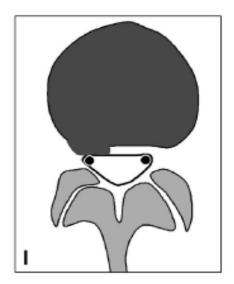












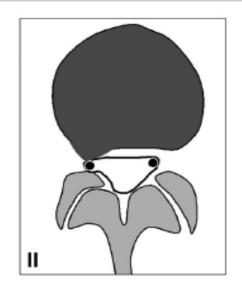
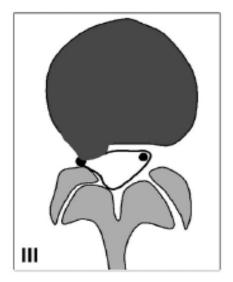
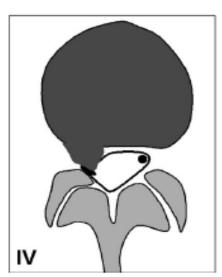


Figure 1 Sketches of axial scans of the lumbar spine showing the grading system used for compression of nerve roots by paracentral disc herniations. Grade I: the disc simply contacts the nerve root. Grade II: the nerve root is displaced but periradicular CSF or fat is preserved. Grade III: periradicular CSF or fat is obliterated. Grade IV: the nerve root is morphologically distorted. CSF = cerebrospinal fluid.



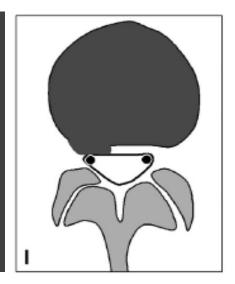


Ghahreman A, Bogduk N. Predictors of a favorable response to transforaminal injection of steroids in patients with lumbar radicular pain due to disc herniation. Pain Med 2011; 12:87 879.

FAVOURABLE RESPONSE TO TFIS:

Low grade compression - 75%

High grade compression – 26%



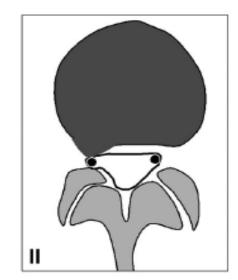
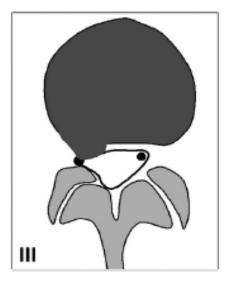
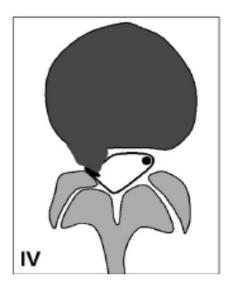


Figure 1 Sketches of axial scans of the lumbar spine showing the grading system used for compression of nerve roots by paracentral disc herniations. Grade I: the disc simply contacts the nerve root. Grade II: the nerve root is displaced but periradicular CSF or fat is preserved. Grade III: periradicular CSF or fat is obliterated. Grade IV: the nerve root is morphologically distorted. CSF = cerebrospinal fluid.





Ghahreman A, Bogduk N. Predictors of a favorable response to transforaminal injection of steroids in patients with lumbar radicular pain due to disc herniation. Pain Med 2011; 12:87 879.

PERCEPTION OF SAFETY

The effectiveness and safety of injection of corticosteroids into the epidural space of the spine have not been established, and FDA has not approved corticosteroids for this use.

FDA safety alert 23.04.2014



PERCEPTION OF SAFETY

Interlaminar epidural steroid injection should always be the first line injection treatment in [upper lumbar, thoracic, and cervical regions]

Cohen Reg Anes Pain Med 2013

The multitude of risks associated with these injections [epidural steroids] outweighs the benefits

Epstein Surg Neurol Int 2013



Spinal cord infarction

Houten JK, Errico TJ. Paraplegia after lumbosacral nerve root block: Report of three cases. Spine J 2002;2:70–5.

Huntoon M, Martin D. Paralysis after transforaminal epidural injection and previous spinal surgery. Reg Anesth Pain Med 2004;29:494–5.

Somyaji HS, Saifuddin A, Casey ATH, Briggs TWR. Spinal cord infarction following therapeutic computed tomography-guided left L2 nerve root injection. Spine 2005;30:E106–8.

Glaser SE, Falco FM. Paraplegia following a thoracolumbar transforaminal epidural steroid injection: A case report. Pain Physician 2005;8: 309–14.

Kennedy DJ, Dreyfuss P, Aprill CN, Bogduk N. Paraplegia following image-guided transforaminal lumbar spine epidural steroid injection: Two case reports. Pain Med 2009;19:1389–94.



Spinal cord infarction

Chang Chien G, Candido K, Knezevic, Digital Subtraction Angiography Does Not Reliably Prevent Paraplegia Associated with Lumbar Transforaminal Epidural Steroid Injection. Pain Physician: 2012; 15:515-523

Kalia H. An unusual case of ASIA C T-10 Paraplegia after Lumbar Transforaminal Epidural Steroid Injection. Journal of Pain; 15(4):S99

Takla RD et al. Conus medullaris syndrome after epidural steroid injection: Case report. International Journal of Spine Surgery 6 (2012) 29–33



Multi-institutional study 16,638 consecutive procedures: 14,956 TFESI and 1,682 interlaminar epidural injections

Minor complications

- Vasovagal reactions 1.2%
- Dural punctures 0.04%

El-Yahchouchi CA, Plastaras CT, Maus TP, Carr CM, McCormick Z, Geske JR, Smuck M, Pingree MJ, Kennedy DJ. Complication rates of transforaminal and interlaminar epidural steroid injections: a multi-institutional study.



Multi-institutional study 16,638 consecutive procedures: 14,956 TFESI and 1,682 interlaminar epidural injections

Minor complications

- Vasovagal reactions 1.2%
- Dural punctures 0.04%

No neurologic, hemorrhagic or infectious complications

El-Yahchouchi CA, Plastaras CT, Maus TP, Carr CM, McCormick Z, Geske JR, Smuck M, Pingree MJ, Kennedy DJ. Complication rates of transforaminal and interlaminar epidural steroid injections: a multi-institutional study.



Spinal cord infarction

PREVENTION

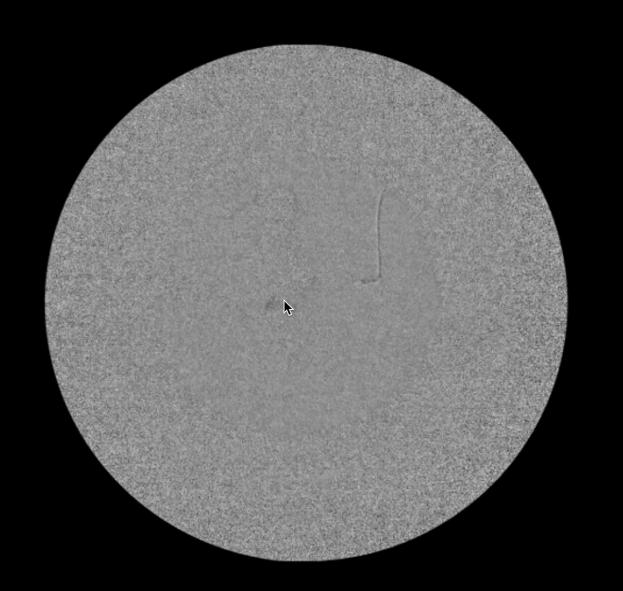
Real-time injection of contrast medium



Spinal cord infarction

PREVENTION
Real-time injection of contrast medium
Digital subtraction angiography

McLean JP, Sigler JD, Plastaras CT, Garvan CW, Rittenberg JD. The rate of detection of intravascular injection in cervical transforaminal epidural steroid injections with and without digital subtraction angiography. PMR 2009;1:636-642.





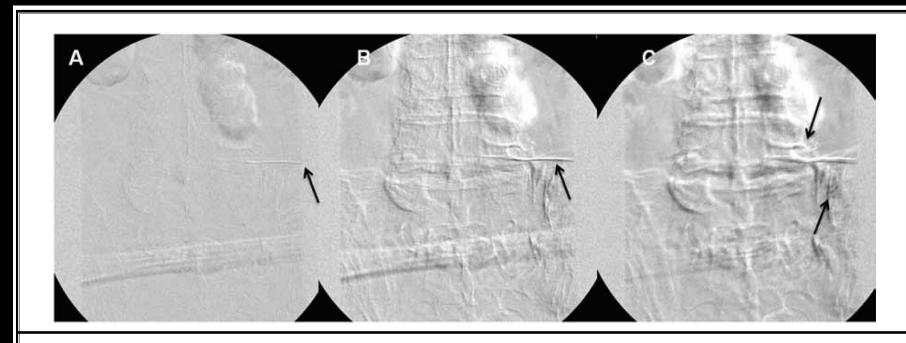


Fig. 1. Digital Subtraction Angiography. A. Needle (arrow) entering right L5-S1 transforaminal space; anteroposterior view. B. Injection phase: arrow represents needle; C. Injection phase: Arrows point to spread of contrast medium. No definitive arterial injection observed.

Chang Chien G, Candido K, Knezevic N. Digital Subtraction Angiography Does Not Reliably Prevent Paraplegia Associated with Lumbar Transforaminal Epidural Steroid Injection. Pain Physician: 2012; 15:515-523



Spinal cord infarction

PREVENTION
Real-time injection of contrast medium
Digital subtraction angiography
Test dose of lignocaine

Karasek M, Bogduk N. Temporary neurologic deficit after cervical transforaminal injection of local anesthetic. Pain Med. 2004 Jun;5(2):202-5.

Smuck M, Maxwell MD, Kennedy D, Rittenberg JD, Lansberg MG, Plastaras CT. Utility of the anesthetic test dose to avoid catastrophic injury during cervical transforaminal epidural injections. Spine J 2010; 10:857-864.



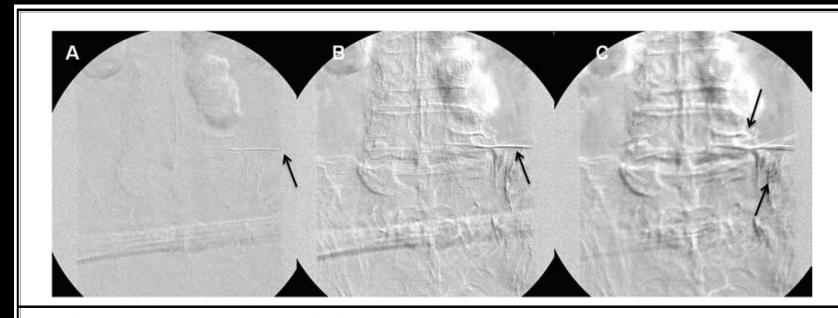


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Test dose: 0.5ml 1% lignocaine

Chang Chien G, Candido K, Knezevic N. Digital Subtraction Angiography Does Not Reliably Prevent Paraplegia Associated with Lumbar Transforaminal Epidural Steroid Injection. Pain Physician: 2012; 15:515-523



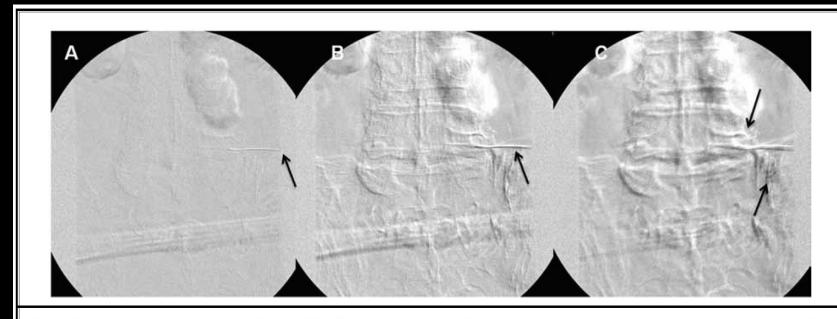


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Therapeutic injection: 1.0ml 1% lignocaine + 80mg triamcinolone

Chang Chien G, Candido K, Knezevic N. Digital Subtraction Angiography Does Not Reliably Prevent Paraplegia Associated with Lumbar Transforaminal Epidural Steroid Injection. Pain Physician: 2012; 15:515-523

Spinal cord infarction

PREVENTION
Real-time injection of contrast medium
Digital subtraction angiography
Test dose of lignocaine
Non-particulate steroids



DISC HERNIATION

Triamcinolone 40 mg or dexamethasone 7.5 mg

Triamcinolone - 100% of 53 patients treated had at least 50% relief at one month

Dexamethasone - 45% had at least 50% relief at one month

Park CH, Lee SH, Kim BI. Comparison of the effectiveness of lumbar transforaminal epidural injection with particulate and nonparticulate corticosteroids in lumbar radiating pain. Pain Med 2010; 11:1654-1658.



HETEROGENEOUS GROUP

3645 injections, 2634 patients

Various steroids following lidocaine 1% test-dose

Dexamethasone since Oct 2010

Phone follow-up 2 weeks and 2 months



El-Yahchouchi et al

At least 50% reduction in NRS:

Particulate steroid Dexamethasone

2 months 44.2% 52.3%



El-Yahchouchi et al

Complete relief:

Triamcinolone Betamethasone Dexamethasone

2 months 16.4% 16.9% 17.0%



El-Yahchouchi et al

Repeat injections required:

Triamcinolone Betamethasone Dexamethasone 2 months 9.9% 6.0% 4.2%



El-Yahchouchi et al

Conclusion:

Dexamethasone non-inferior to particulate steroids

El-Yahchouchi CA, Geske JR, Carter RE, et al. The noninferiority of the nonparticulate steroid dexamethasone vs the particulate steroids betamethasone and triamcinolone in lumbar transforaminal epidural steroid injections. Pain Med 2013;14(11):1650–7.



DISC HERNIATION

Double-blind RCT Radicular pain, single level HNP, consistent MRI findings Dexamethasone 15mg (41) or triamcinolone 80mg (37) Up to 3 injections

Primary outcomes

Need for surgery

Number of injections

Proportions with >50% relief at 2/52, 3/12, 6/12

Kennedy DJ, Plastaras C, Casey E et al. Comparative Effectiveness of Lumbar Transforaminal Epidural Steroid Injections with Particulate Versus Nonparticulate Corticosteroids for Lumbar Radicular Pain due to Intervertebral Disc Herniation: A Prospective, Randomized, Double-Blind Trial. Pain Medicine 2014; 15: 548–555



Kennedy et al

Need for surgery

Dexamethasone 15mg 14.6%

Triamcinolone 80mg 18.9%

Kennedy DJ, Plastaras C, Casey E et al. Comparative Effectiveness of Lumbar Transforaminal Epidural Steroid Injections with Particulate Versus Nonparticulate Corticosteroids for Lumbar Radicular Pain due to Intervertebral Disc Herniation: A Prospective, Randomized, Double-Blind Trial. Pain Medicine 2014; 15: 548–555



Kennedy et al

> 50% relief

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$$2/52 - 31.7\%$$

$$3/12 - 73.2\%$$

$$6/12 - 73.2\%$$

Triamcinolone 80mg

$$2/52 - 43.2\%$$

$$3/12 - 73.0\%$$

$$6/12 - 75.7\%$$



Kennedy et al

Number of injections

)exam	etha	sone	15mg
			-

$$1 - 22 (54\%)$$

$$2 - 12 (29\%)$$

$$3-7(17\%)$$

Triamcinolone 80mg

$$1 - 24 (65\%)$$

$$2 - 12 (32\%)$$

$$3 - 1 (3\%)$$



COMPLICATIONS

SUMMARY

Serious complications extremely rare
No evidence that dexamethasone is inferior to
particulate steroids
Spinal cord infarction is probably avoidable



EFFECTIVENESS



HETEROGENEOUS GROUP

Single injection in 2024/3110 patients

At least 50% reduction in NRS:

2 weeks 40.9%

2 months 45.6%



HETEROGENEOUS GROUP

3645 injections, 2634 patients

NRS ≤ 2.0 after procedure in 73% of patients

Association with successful response at 2 months:

OR = 1.67



HETEROGENEOUS GROUP

3645 injections, 2634 patients

NRS ≤ 2.0 after procedure in 73% of patients

Association with successful response at 2 months:

OR = 1.67

"Don't bother waking up for odds ratio < 3" - N Bogduk (EBM 1)

El-Yahchouchi CA, Wald J, Brault J, et al. Lumbar Transforaminal Epidural Steroid Injections: Does Immediate Post-Procedure Pain Response Predict Longer Term Effectiveness? Pain Medicine 2014; 15: 921–928



El-Yahchouchi et al

Strong association between relief at 2 weeks and relief at 2 months: OR = 6.49



EFFECTIVENESS OF MULTIPLE INJECTIONS

2087 TFESI in 933 subjects

In the entire cohort, there was slight loss of benefit for repeat TFESI within 1 year

In sub-acute pain patients (< 3 months), there was complete recovery of benefit from prior injection

In patients receiving early repeat TFESI due to incomplete response, there was cumulative benefit, magnified in acute pain patients

The Efficacy of Multiple Lumbar Transforaminal Epidural Steroid Injections. N Murthy, J Geske, J Wald, F Diehn, K Thielen, T Kaufmann, J Morris, V Lehman, K Amrami, R Carter, T Maus *Pain Med* 2014; 15 (10): 1686-94.



DISC HERNIATION

STUDY	DESIGN	n	OUTCOME	% relief	FOLLOW- UP	SUCCESS RATE
Ghai	Pragmatic RCT	32	Pain relief	>50%	3 months	76%
Manson	Retrospective	91	Avoidance of surgery		103 – 747 days	56%
van Helvoirt	Prospective	69	Avoidance of surgery		1 year	78%
van Helvoirt	Prospective	69	Pain relief	90 – 100%	1 year	62%

DISC HERNIATION

Ghai B, Vadaje KS, Wig J, Dhillon MS. Lateral parasagittal versus midline interlaminar lumbar epidural steroid injection for management of low back pain with lumbosacral radicular pain: a double-blind, randomized study. Anesth Analg. 2013;117:219–27

Manson NA, Abraham EP, McKeon MD. Transforaminal epidural steroid injections prevent the need for surgery in patients with sciatica secondary to lumbar disc herniations: a retrospective case series. Canadian Journal of Surgery. 2013; 56(2): 89-96.

Van Helvoirt, H., Apeldoorn, A.T., Ostelo, R.W., Knol, D.L., Arts, M.P., Kamper, S.J. et al, Transforaminal epidural steroid injections followed by mechanical diagnosis and therapy to prevent surgery for <u>lumbar disc herniation</u>. *Pain Med*. 2014;15:1100–1108



SPINAL STENOSIS

Multicentre RCT (16 sites)

Central lumbar canal stenosis
Pain in the lower back, buttock, leg, or a combination of these sites. Buttock and/or leg worse than back pain

Either interlaminar or transforaminal injection

Steroid + lidocaine or lidocaine only

Could repeat at 3 weeks

Could cross-over at 6 weeks



Primary outcomes:

RMDQ at 6 weeks

Average pain over the previous week



Primary outcomes:

RMDQ at 6 weeks

Average pain over the previous week

Secondary outcomes:

Proportion with ≥ 30% relief at 6 weeks

Proportion with ≥ 50% relief at 6 weeks



Steroid + lidocaine (200)

 \geq 30% relief at 6 w – 49.2%

 \geq 50% relief at 6 w - 38.3%

transforaminal injection (57)

RMDQ – 14.4 to 12.0

1 week avg pain - 7.0 to 4.9



Steroid + lidocaine (200)

 \geq 30% relief at 6 w – 49.2%

≥ 50% relief at 6 w – 38.3%

transforaminal injection (57)

RMDQ – 14.4 to 12.0

1 week avg pain – 7.0 to 4.9

Lidocaine only (200)

≥ 30% relief at 6 w – 49.7%

 \geq 50% relief at 6 w – 38.3%

transforaminal injection (61)

RMDQ – 14.8 to 12.1

1 week avg pain – 7.0 to 4.9



SPINAL STENOSIS

31 patients, surgery proposed

Central and subarticular stenosis – all

Foraminal stenosis - 11

Success = 50% relief from leg pain at 6 months



Ploumis et al

31 patients, surgery proposed

Central and subarticular stenosis – all

Foraminal stenosis - 11

Success = 50%

Caudal epidural

6/11 (55% [95% CI:29-85%])

Second injection – 2

Surgery - 2

Transforaminal

18/20 (90% [95% CI: 77-100%)]

Second injection – 0

Surgery - 0

Ploumis A, Christodoulou P, Wood K. Caudal vs Transforaminal Epidural Steroid Injections as Short-Term (6 Months) Pain Relief in Lumbar Spinal Stenosis Patients with Sciatica. Pain Medicine 2014; 15: 379–385



FAILED BACK SURGERY



RADICULAR PAIN AFTER FAILED BACK SURGERY

n

56/489 (11.5%)

124/1009 (12.3%)

Success: least 50% reduction of pain for longer than 3/12

Associations between a successful response and features on MRI were explored.

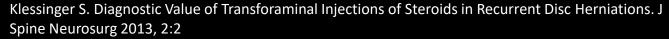
Klessinger S. Radicular pain in Post Lumbar Surgery Syndrome: The Significance of Transforaminal Injection of Steroids. Pain Med 2013; 14: 243-246.



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Success 27% (95% CI: 15-40%) 31% (95% CI: 23-39%)

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Revision surgery Successful TFIS 0%

Unsuccessful TFIS 36/86 (42%)

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Strong correlation between unsuccessful TFIS and recurrent or new disc protrusion

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Klessinger S. Diagnostic Value of Transforaminal Injections of Steroids in Recurrent Disc Herniations. J Spine Neurosurg 2013, 2:2



Triamcinolone 10 mg Bupivacaine 0.25%

n 56/489 (11.5%) 124/1009 (12.3%)

Success 27% (95% CI: 15-40%) 31% (95% CI: 23-39%)

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CONCLUSIONS

Lumbar transforaminal injections of steroid are safe, provided: adequate precautions are taken

Disc herniation – strong evidence of efficacy and effectiveness Spinal stenosis – jury still out



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THANK YOU



