Appendix E3. Epidural Steroid Injections for Nonradicular Pain

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental and control groups, dose, duration of treatment)
Lee, 2009	RCT	South Korea Single center Physical medicine clinic	Axial back pain without radiation for >3 months, due to herniated intervertebral disc or spinal stenosis	Unilateral or bilateral leg pain, arterial vascular disease, lumbar epidural steroid injection in last 2 months, prior lumbar spine surgery, presence of neurological deficits	Approached: Not reported Eligible: Not reported Randomized: 202 Analyzed: 192 (116 vs. 76) at 2 weeks to 4 months	A: Transforaminal epidural injection with 20 mg triamcinolone acetonide (0.5 ml) with lidocaine 0.5% (4 ml) with fluoroscopic guidance (n=116) B: Interlaminar epidural injection with 40 mg triamcinolone acetonide (1 ml) with lidocaine 0.5% (8 ml) with fluoroscopic guidance (n=76)
Manchikanti, 2012 Also Manchikanti 2011 Manchikanti 2008	RCT	USA Single center Pain clinic	No evidence of disc herniation and negative controlled local anesthetic blocks for facet or sacroiliac joint pain; ≥18 years of age; history of chronic function-limiting low back pain for >6 months; failure to improve with conservative management; imaging findings not specified	Facet joint pain; previous lumbar surgery; uncontrolled or unstable opioid use; uncontrolled psychiatric disorders; uncontrolled medical illness, either acute or chronic; pregnant or lactating; history or potential for an adverse reaction or reactions to study medications	Approached: 147 Eligible: 133 Randomized: 120 (60 vs. 60) Analyzed: 120 (60 vs. 60) at 24 months, including 22 (10 vs. 12) lost to followup	A: Caudal epidural with 6 mg betamethasone or 40 mg methylprednisolone (1 ml) with lidocaine 0.5% (9 ml) with fluoroscopic guidance (n=60) B: Caudal epidural with lidocaine 0.5% (10 ml) with fluoroscopic guidance (n=60)

Appendix E3. Epidural Steroid Injections for Nonradicular Pain

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance
Lee, 2009	A vs. B: Age (mean): 42 vs. 42 in herniated disc group, 62 vs. 62 years in spinal stenosis group Male: 61% vs. 50% in herniated disc group, 35% vs. 26% in spinal stenosis group Duration of pain: 4.5 vs. 3.7 m in herniated disc group, 14 vs. 16 months in spinal stenosis group Baseline pain (0-10 NRS): 6.5 vs. 6.8 in herniated disc group, 6.6 vs. 6.6 in spinal stenosis group Baseline function: Not reported	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Not specified Other patient characteristics: 52% herniated disc, 58% spinal stenosis (analyzed separately)	Number of injections: Mean not reported, maximum of three interlaminar injections at minimum 2 week intervals, maximum number of transforaminal injections not reported (injection performed bilaterally) Number of levels: Appears to be single Provider experience: Not reported	Fluoroscopy with contrast verification in epidural space
Manchikanti, 2012 Also Manchikanti 2011 Manchikanti 2008	A vs. B: Age (mean): 44 vs. 48 years Male: 37% vs. 22% Duration of pain (months): 92 vs. 100 Baseline pain (0 to 10 NRS): 7.9 vs. 8.0 Baseline ODI (0 to 50): 28 vs. 28	A vs. B: Treatments prior to intervention: Not specified Treatments following intervention: Not specified Other patient characteristics: Not reported	Number of injections: Mean 5.5 vs. 4.5 over 2 years, frequency not specified Number of levels: Caudal Provider experience: Not reported	Fluoroscopy with contrast verification in epidural space

Appendix E3. Epidural Steroid Injections for Nonradicular Pain

Author, Year Title	Type of Comparison	Results (acute and subacute, or chronic, or mixed)
Lee, 2009	Transforaminal versus interlaminar epidural injection with corticosteroid plus local anesthetic	Herniated disc group Roland pain score (0 to 5): 3.34 vs. 3.25 at baseline, 1.55 vs. 1.53 at 2 w, 1.57 vs. 1.59 at 2 m, 1.66 vs. 1.72 at 4 m Patient Satisfaction Index score 1 or 2 (1 to 4 scale): 78% (46/59) vs. 85% (29/34) at 2 w, RR 0.91 (95% CI 0.75 to 1.11); 83% (49/59) vs. 85% (29/34) at 2 m, RR 0.97 (95% CI 0.81 to 1.17); 76% (45/59) vs. 85% (29/34) at 4 m, RR 0.89 (95% CI 0.73 to 1.09) Pain score improved ≥2 points (0-10 pain NRS): 68% (40/59) vs. 65% (22/34) at 2 w, RR 1.05 (95% 0.77 to 1.42); 75% (44/59) vs. 65% (22/34) at 2 m, RR 1.15 (95% CI 0.86 to 1.54); 66% (39/59) vs. 50% (17/34) at 4 m, RR 1.32 (95% CI 0.90 to 1.94) Spinal stenosis group Roland pain score (0 to 5): 3.39 vs. 3.31 at baseline, 1.6 vs. 2.19 at 2 w, 1.67 vs. 2.12 at 2 m, 1.79 vs. 2.19 at 4 m ($p<0.05$ at 2 w, 2 m, and 4 m) Patient Satisfaction Index score 1 or 2 (1 to 4 scale): 75% (43/57) vs. 64% (27/42) at 2 w, RR 1.17 (95% CI 0.90 to 1.54); 70% (40/57) vs. 57% (25/42) at 2 m, RR 1.18 (95% CI 0.87 to 1.59); 67% (38/57) vs. 52% (22/42) at 4 m, RR 1.27 (95% CI 0.90 to 1.79) Pain score improved ≥2 points (0-10 pain NRS): 54% (31/57) vs. 36% (15/42) at 2 w, RR 1.52 (95% CI 0.95 to 2.44); 61% (35/57) vs. 36% (15/42) at 2 m, RR 1.72 (95% CI 1.09 to 2.71); 51% (29/57) vs. 31% (13/42) at 4 m, RR 1.64 (95% CI 0.98 to 2.76)
Manchikanti, 2012 Also Manchikanti 2011 Manchikanti 2008	Caudal epidural injection with local anesthetic	A vs. B <u>Pain</u> Pain (mean NRS, 0 to 10): 7.9 vs. 8.0 at baseline, 3.6 vs. 4.2 at 3 months, 3.7 vs. 4.1 at 6 months, 3.8 vs. 4.3 at 12 months, 4.0 vs. 4.4 at 24 months (p=0.52 for group difference) Pain relief >=50% from baseline: 80% (48/60) vs. 68% (41/60) at 3 months, 80% (48/60) vs. 68% (41/60) at 6 months, 72% (43/60) vs. 63% (38/60) at 12 months, 65% (39/60) vs. 57% (34/60) at 24 months <u>Function</u> ODI (0 to 50): 28 vs. 28 at baseline, 14 vs. 16 at 3 months, 14 vs. 16 at 6 months, 14 vs. 16 at 12 months, 15 vs. 16 at 24 months (p=0.21 for group difference) ODI improved >=50% from baseline: 75% (45/60) vs. 60% (36/60) at 3 months, 75% (45/60) vs. 62% (37/60) at 6 months, 72% (43/60) vs. 56% (34/60) at 12 months, 63% (38/60) vs. 56% (34/60) at 24 months <u>Other Outcomes</u> Opioid use (mg MED/day): 36 vs. 34 at baseline, 30 vs. 29 at 3 months, 31 vs. 32 at 6 months, 30 vs. 32 at 12 months, 30 vs. 31 at 24 months (p=0.45 for group difference)

Appendix E3. Epidural Steroid Injections for Nonradicular Pain

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating	Comments
Lee, 2009	4 months	10/192 at 2 weeks to 4 months	Not reported	Not reported	Wooridul Spine Foundation	Fair	
Manchikanti, 2012 Also Manchikanti 2011 Manchikanti 2008	24 months	A vs. B: 17% (10/60) vs. 20% (12/60) at 24 months	Appears complete	"None of the patients reported significant adverse events"	None reported	Fair	Primary ITT analysis based on baseline data or last followup for patients lost to followup

Appendix E3. Epidural Steroid Injections for Nonradicular Pain

Author, Year Title	Study Design	Country Setting	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Type of Intervention (experimental and control groups, dose, duration of treatment)
Manchikanti, 2013 Also Manchikanti 2012 Manchikanti 2010	RCT	USA Single center Pain clinic	Lumbar axial or discogenic pain; age ≥18 years; function-limiting low back pain for >6 months; failure to improve with conservative management; imaging findings not specified	Lumbar facet joint or sacroiliac joint pain based on controlled, comparative local anesthetic blocks; previous lumbar surgery; uncontrollable or unstable opioid use; uncontrolled psychiatric disorders; uncontrolled medical illness; pregnant or lactating; history or potential for adverse reactions to study medications	Approached: 164 Eligible: 134 Randomized: 120 (60 vs. 60) Analyzed: 120 (60 vs. 60) at 24 months, including 13 (9 vs. 4) with missing data	A: Interlaminar epidural injection with 6 mg betamethasone (1 ml) and lidocaine 0.5% (5 ml) with fluoroscopic guidance (n=60) B: Interlaminar epidural injection with lidocaine 0.5% (6 ml) with fluoroscopic guidance (n=60)

Appendix E3. Epidural Steroid Injections for Nonradicular Pain

Author, Year Title	Subject Characteristics	Other Patient Characteristics (expectations of treatment benefit, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, other treatments received)	Number and Frequency of Injections Number of Levels Provider Experience	Imaging Guidance
Manchikanti, 2013 Also Manchikanti 2012 Manchikanti 2010	A vs. B: Age (mean): 43 vs. 41 years Male: 40% vs. 23% Race: Not reported Duration of pain (months): 129 vs. 104 Baseline pain (NRS 0 to 10): 7.7 vs. 8.0 Baseline ODI (0 to 50): 29 vs. 31	A vs. B: Treatments prior to intervention: Not specified Treatment following intervention: Not specified Other patient characteristics: Not reported	Number of injections: Mean 3.8 vs. 3.7 per year, frequency not specified Number of levels: Caudal Provider experience: Not reported	Fluoroscopy with contrast verification in epidural space

Appendix E3. Epidural Steroid Injections for Nonradicular Pain

Author, Year Title	Type of Comparison	Results (acute and subacute, or chronic, or mixed)
Manchikanti, 2013 Also Manchikanti 2012 Manchikanti 2010	Interlaminar epidural steroid injection with local anesthetic	A vs. B <u>Pain</u> Pain (mean NRS, 0 to 10): 7.7 vs. 8.0 at baseline, 3.5 vs. 3.6 at 3 months, 3.6 vs. 3.9 at 6 months, 3.7 vs. 3.7 at 12 months, 3.6 vs. 3.9 at 24 months (p=0.38 for group difference) Pain relief >=50% from baseline: 80% (48/60) vs. 68% (41/60) at 3 months, 80% (48/60) vs. 68% (41/60) at 6 months, 72% (43/60) vs. 63% (38/60) at 12 months, 65% (39/60) vs. 57% (34/60) at 24 months <u>Function</u> ODI (0 to 50): 29 vs. 31 at baseline, 15 vs. 15 at 3 months, 14 vs. 15 at 6 months, 15 vs. 15 at 12 months, 15 vs. 15 at 24 months (p=0.29 for group difference) ODI improved >=50% from baseline: 75% (45/60) vs. 60% (36/60) at 3 months, 75% (45/60) vs. 62% (37/60) at 6 months, 72% (43/60) vs. 56% (34/60) at 12 months, 63% (38/60) vs. 56% (34/60) at 24 months <u>Other Outcomes</u> Opioid use (mg MED/day): 53 vs. 57 at baseline, 40 vs. 36 at 3 months, 42 vs. 36 at 6 months, 42 vs. 36 at 12 months, 42 vs. 36 at 24 months (p=0.45 for group difference)

Appendix E3. Epidural Steroid Injections for Nonradicular Pain

Author, Year Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawal due to Adverse Events	Sponsor	Quality Rating	Comments
Manchikanti, 2013 Also Manchikanti 2012 Manchikanti 2010	24 months	A vs. B: 27% (16/60) vs. 17% (10/60) at 24 months	Appears complete	4 subarachnoid punctures without headache and one case of nerve root irritation, not reported by group	None reported	Fair	Primary ITT analysis based on baseline data or last followup for patients lost to followup

E=electronic; ITT=intention-to-treat; m=month; MED=minimal effective dose; n=number; NCS=Nerve Conduction Study; NRS=Numerical Rating Scale; ODI=Oswestry Disability Index; p=p value; RCT=randomized controlled trial; SI=sacroiliac

Please see Appendix C. Included Studies for full study references.