

#### **Duke** Anesthesiology

# Update on Epidural Safe Use Guidelines

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#### **Disclosures**

#### None





#### Epidural Injections and the New Subspecialty of Pain Medicine





Anesthesiology. Vol 121, No. 5, November 2014, pg A23

#### **Steroid Effects**

Glucocort

 Upregula
 Downreg
 Binds GF
 Inhibits ii
 Produced





#### **Steroid Names**

 Kenalog -Triamcinolone Depomedrol - Methylprednisolone Celestone Betamethasone Decadron - Dexamethasone



# **Steroid Comparison**

#### **Table 1.** Profile of commonly used epidural steroids

Drug	Fauivalent	Equivalent Epidural		Sodium	<b>Duration of Adrenal Suppression</b>		
	Dose	Dose	inflammatory Potency	Retention Capacity	IM	Single Epidural	Three Epidurals
Hydrocortisone	20 mg	N/A	1	1	N/A	N/A	N/A
Depo-Methyl Prednisolone (Depo-Medrol)	4 mg	40-80 mg	5	0.5	1-6 weeks	1-3 weeks	N/A
Triamcinolone diacetate (Aristocort)	4 mg	25-50 mg	5	0	1-2 weeks	1-5 weeks	N/A
Triamcinolone acetonide (Kenalog)	4 mg	40-80 mg	5	0	2-6 weeks	N/A	2-3 months
Betamethasone (Celestone Soluspan)	0.6 mg	6-12 mg	25	0	1-2 weeks	N/A	N/A
N/A = Not applicable Data a	adapted and mo	dified from N	McEvoy et al (70)	, Jacobs et al	(71), Kay et al	(72), Hsu et al	(74), Mikhail et

al (75, 76), and Schimmer and Parker (77).

or pharmacology of the steroids (9). Numerous formulation of injectable preparations are available in the United States

# **Steroid Side Effects**

- Adrenal suppression
- Weight gain
- Osteoporosis
- Hyperglycemia (glucocorticoid)
- CHF/fluid retention
- Nerve toxicity (intrathecal)
  - -Very controversial related to vehicle
  - Possibly due to concomitant LA dosing



# **Adrenal Suppression**

Type	Etiologies	Features
Tertiary Most common form	Usually from iatrogenic corticosteroid therapy and suppression of the hypothalamic-pituitary- adrenal axis	Hypothalamic/pituitary suppression or absence
Secondary Uncommon	Decreased or absent ACTH (may be panhypopituitary or anterior pituitary dysfunction)	ACTH dependent
	Pituitary depression, dysfunction/damage	Signs and symptoms usually due to loss of glucocorticoid function
	Tumor, postpartum	Usually have intact mineralocorticoid function
-		Renal hypovolemic, more commonly hypoglycemic
Primary Autoimmune (709 Rare States), frequently ass deficiency syn Prevalence: 40-110 cases/r	Autoimmune (70% -90% of cases in United States), frequently associated with a polyglandular deficiency syndrome Prevalence: 40-110 cases/million	ACTH independent Adrenal gland dysfunction, destruction, or replacement; requires >90% loss of adrenal tissue Loss of mineralocorticoid and glucocorticois production
	Infection HIV is the most common infectious cause in the United States. AI develops in 30% of patients with advanced AIDS. Tuberculosis is the most common infectious cause worldwide	Increased ACTIf production
	Inflammation	May be hyperpigmented
	Cancer (breast, lung, melanoma most common)	Requires lifetime therapy
	Acute addisonian crisis Incidence: 6 cases/million per year	



#### **ESI Effectiveness**

Tune of Pain	Method of Injection	Level of Evidence for			Level of Evidence for	
Type of Falli	wethou of mjection	Sho	rt-Term Pain R	elief	Long-Term Pain Relief	
Cervical radiculopathy	Interlaminar		Moderate		Moderate	
Cervical nerve root	Transforaminal		Moderate		Moderate	
Lumbar nerve root	Transforaminal		Strong		Strong	
Lumbar radicular	Lumbar interlaminar		Strong		Limited	
Lumbar radicular	Lumbar transforaminal		Strong		Moderate	
Lumbar radicular pain						
post lumbar			Moderate		Moderate	
laminectomy		L				
Lumbar spinal stenosis	Transforaminal		Limited		Limited	
Lumbar radiculopathy	Caudal epidural		Strong		Moderate	
Post-lumbar						
laminectomy	Caudal epidural		Strong		Moderate	
syndrome						

Abdi S, Datta S, Trescot AM *et al.* Epidural steroids in the management of chronic spinal pain: a systematic review. *Pain.Physician.* 2007; **10:** 185-212.



## **FDA Safe Use Initiative**

- Launched November 4, 2009
- Preliminary recommendations for epidural steroid injections presented at ANESTHESIOLOGY™ annual meeting October 12, 2013
- Collaboration with multi-society pain working group
- Final recommendations February 9 2015

# **FDA Safe Use Initiative**

- Increased chance of neurologic injury when particulate steroids are used for transforaminal injections.
- Increased chance of neurologic injury with transforaminal epidural approach compared to the interlaminar approach.
- Use of image-guidance is mandatory when performing transforaminal injections.

http://www.asahq.org/For-the-Public-and-Media/Press-Room/ASA-News/Safe-Use-Initiative-Epidural-Injections.aspx





U.S. Food and Drug Administration Protecting and Promoting Your Health

#### **Drug Safety Communications**

FDA Drug Safety Communication: FDA requires label changes to warn of rare but serious neurologic problems after epidural corticosteroid injections for pain A class of drugs commonly used to reduce swelling or inflammation Injectable corticosteroids include methylprednisolone, hydrocortisone, triamcinolone, betamethasone, and dexamethasone

into the epidural space of the spine may result in rare but serious adverse events, including loss of vision, stroke, paralysis, and death. The injections are given to treat neck and back pain, and radiating

pain in the arms and legs. We are requiring the addition of a *Warning* to the drug labels of injectable corticosteroids to describe these risks. Patients should discuss the benefits and risks of epidural corticosteroid injections with their health care professionals, along with the benefits and risks associated with other possible treatments.



## **Particulation**

- Can result in spinal cord infarct
- Dexamethasone non-particulate
- Betamethasone, methylprednisolone, and triamcinolone all particulate
- Variations in clumping



#### **Particulation**

					Particle	e Distribution	_	
Preparation	Dilution	Diluent	No. of particles	0–20 μm	21–50 µm	51–1,000 μm	>1000 µm	P Value
Methylprednisolone acetate 80 mg/ml	Undiluted		66	63	14	17	6	•
(MPA 80)	1:1	Saline	164	73	11	12	4	0.03
	1:2	Saline	142	58	8	26	8	
	1:3	Saline	174	52	9	32	7	
	1:1	Lidocaine 1%	214	52	17	24	7	0.17
	1:2	Lidocaine 1%	226	63	11	22	4	
	1:3	Lidocaine 1%	224	55	15	28	2	
Methylprednisolone acetate 40 mg/ml	Undiluted		298	64	8	27		•
(MPA 40)	1:1	Saline	492	63	9	25	3	0.37
	1:2	Saline	415	67	15	16	2	
	1:3	Saline	281	67	15	17	1	
	1:1	Lidocaine 1%	311	51	20	28	1	0.28
	1:2	Lidocaine 1%	278	62	18	18	2	
	1:3	Lidocaine 1%	281	55	20	24	1	
Triamcinolone acetonide 40 mg/ml	Undiluted		476	79	9	11	1	
(TBA 40)	1:1	Saline	324	66	10	23	1	0.15
The second secon	1:2	Saline	340	72	10	17	1	
	1:3	Saline	241	58	18	23	1	
	1:1	Lidocaine 1%	585	64	14	21	1	0.29
	1:2	Lidocaine 1%	580	63	14	23	0	0.000
	1:3	Lidocaine 1%	376	68	15	17		
CLTN Betamethasone sodium	Undiluted		1968	92	6	2	0	
phosphate/betamethasone acetate	1:1	Saline	519	93	5	2	0	0.29
6 mg/ml (Celestone Soluspan®)	1:2	Saline	560	95	4	1	0	
o mg/mi (ociostorio obidopani )	1.3	Saline	257	85	12	3	0	
	1.1	Lidocaine 1%	405	93	6	1	õ	0.27
	1:2	Lidocaine 1%	588	91	8	1	ő	0.21
	1.3	Lidocaine 1%	270	83	15	2	n i	
Retamethasone sodium phosphate/	Undiluted	Eldocarric 170	844	68	10	21	Y	
betamethasone acetate 6 mg/ml	1.1	Salino	517	82	8	10	0	0.12
(PTM Pan)	1.2	Saline	699	86	6	8	0	0.12
(Brivinep)	1-3	Salino	325	70	0	12	ő	
	1.1	Lidocaine 1%	185	51	16	32	1	0.005
	1.2	Lidocaine 1%	108	51	20	20	0	0.000
	1.2	Liuocame 170	100	01	20	20	0	





Methylprednisolone 80 mg/mL







Triamcinolone 40 mg/mL



Betamethasone sodium phosphate/betamethasone acetate (Celestone Soluspan®)







MPA





TA

BSP





#### **Embolization Anatomy**







FDA Briefing Information for the November 24-25, 2014 Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee













Figure 4 Distribution of the intraforaminal locations of the remaining 113 radiculomedullary arteries, as determined at the mid-pedicular plane, is graphically depicted using the foraminal ratio, in 0.10 increments. The artery of Adamkiewicz was located in the upper one-half of the foramen 97% of the time (110/113) and was never seen in the most inferior one-fifth of the foramen.

Murthy NS<sup>1</sup>, Maus TP, <u>Behrns CL</u>. Intraforaminal location of the great anterior radiculomedullary artery (artery of Adamkiewicz): a retrospective review.<u>Pain Med.</u> 2010 Dec;11(12):1756-64. doi: 10.1111/j.1526-4637.2010.00948.x. Epub 2010 Sep 7.







Figure 5. Number of Epidural Injections per Month in Medicare January 2009-March 2014





#### Particulate vs Non-particulate

- Retrospective study of cervical TFESI for radiculopathy
- 220 patients received triamcinolone 40 mg and 221 patients dexamethasone 15 mg

 No statistically significant difference in the mean reduction in pain score between the two groups

Shakir A, Ma V, Mehta B. Comparison of pain score reduction using triamcinolone vs. dexamethasone in cervical transforaminal epidural steroid injections. *Am J Phys.Med Rehabil.* 2013; 92: 768-75.



## **Particulate vs Non-particulate**

Reference Year	Design	Subjects	Interventions	Results
Dreyfuss et al.[34] 2006	Randomized	30 Patients with unilateral cervicalTF ESI with 0.75Y1 mL 4 lidocaine + either: A: Dexamethasone 12.radiculopathyB: Triamcinolone 60 m		Nonsignificant trend favoring particulate steroid
Lee et al.[ <b>35</b> ] 2009	Retrospective	159 Patients with cervical radiculopathy who failed IL ESI or had previous surgery	TF ESI with either: A: Dexamethasone 10 mg B: Triamcinolone 40 mg	Nonsignificant trend favoring particulate steroid
Kim and Brown[ <b>36]</b> 2011	Randomized Single-blind	60 Patients with lumbar radiculopathy ≥ 6 mo	IL ESI with 10 mL consisting of 2 mL 0.25% bupivacaine + NS + either: A: Dexamethasone 15 mg B: Methylprednisolone 80 mg	Nonsignificant trend favoring particulate steroid
Park et al.[37] 2010	Randomized	106 Patients with lumbar radiculopathy	TF ESI with 1 mL 1% lidocaine + either: A: Dexamethasone 7.5 mg B: Triamcinolone 40 mg	Particulate > nonparticulate steroid for pain reduction
Noe and	Retrospective	52 Patients with LBP referred for	IL ESI with either: A: Betamethasone 15 mg	Particulate > nonparticulate
Haynsworth [38] 2003		ESI	B: Methylprednisolone 80 mg	steroid for pain reduction, improvement in disability
Shakir et al. <b>[39]</b> 2013	Retrospective	441 Patients with cervical radiculopathy	TF ESI with 1 mL of 1% lidocaine + either: A: Dexamethasone 15 mg B: Triamcinolone 40 mg	No difference in pain score reduction between groups

## Why are we worried?





## Why are we worried?





Table 5. Descriptive characteristics of FAI excluding arachnoiditis, reported with ESI – April 23, 2014	ERS cases of serious neurolo, use, received by FDA from 1	gic adverse events, November 1, 1997
(1	N=90)	
Age (years) (n=/9)	Mean	50.4
	Median	24
	Kange	23-89
Gender (n=75)	Female	49
	Male	20
FDA Receipt Date	1997-2002	16
	2003-2008	32
	2009-2014	42
Report type	Expedited	59
	Direct	25
	Periodic	6
Reporter	Health Care Provider	43
	Consumer	47
Reported Primary Outcome	Death	3
A State of the sta	Hospitalization	35
	Life Threatening	1
	Disability	17
	Other serious	34
Steroid reported (n=88)	Methylprednisolone	45
	Triamcinolone	37
	Betamethasone	3
	Dexamethasone	3
Epidural route (n=22)	Transforaminal	15
	Interlaminar	5
	Caudal	2
Time to onset from start of therapy $(n=62)$	Within 1 day	47
	1  dav - 1  month	13
	1 month - 6 months	1
	6 months - 1 year	1
Anesthetic administered (n=35)	Bupivacaine	21
a series and a series of the s	Lidocaine	19
	Ropivacaine	1
Anesthetic route of administration (n=22)	Epidural	20
and start to be a structure of the second	Local	1
	Epidermal and local	1
Imaging (n=33)*	Contrast Agent	23
	Fluoroscopy	21
	Computed tomography	2
	Angiography	2



#### **Embolic outcome case reports**

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- G. Chang Chien. Spinal epidural hematoma resulting in tetraplegia after cervical interlaminar epidural steroid injection and intramuscular ketorolac: A case report. Phys Med Rehabil. 2012;4/10, Suppl. 1:S320
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- Lee J, Hausman E. Catastrophic Neurologic Outcome after Transforaminal Epidural Steroid Injection, 14 May 2010.



Table 1. Au	Table 1. Anaylsis of Cases of Spinal Cord and Posterior Circulation Ischemia						
Case/	/ Injection Presentation/Clinical						
Reference	Site	Medications	Method	Course	Investigations	Outcome	
1	C5-C6	Methylprednisolone	Typical	Flaccid quadriplegia, dissociative sensory loss with C5 level	MRI: cord infarct at C4-C6	3 weeks: quadriplegic	
212	(R)C5-C6	Triamcinolone Bupivacaine	Typical	Flaccid paralysis, transient coma then quadriplegic	MRI: extensive cord infarction	Death	
313	(L)C5-C6	Triamcin olone Bupivacaine	Typical	Quadriplegia, dissociative sensory loss	MRI: extensive cord infarction C2-T1	Unknown	
4 <sup>6</sup>	C6-C7	Methylprednisolone	Atypical	Quadriplegic, respiratory arrest	MRI: no infarction	6 months: regained some strength requiring daily assistance	
515	(L)C5-6 (L)C6-7	Methylprednisolone Bupivacaine	Atypical	Arms paretic with paraplegia, T4 sensory level	MRI: cervical cord edema and medullary infarction	8 weeks: ambulating with walker	
614	(R)C6-C7	Lidocaine	Atypical	Transient quadriparesis, dissociative sensory loss	None	20 minutes: resolution	
718	(L)C6-C7 (L)C7-C8	Steriod not named	Atypical	Numbness and weakness of (L) arm	MRI: petechial hemorrhages in lateral cord	(L) C7 radiculopathy with weakness and numbness	
87	(L)C5-C6	Unknown	Atypical	Confusion, (L) ann weakness	CT: dissection of left vertebral artery at (L) C3-C6	24 hours: resolution	
919	(L)C6-C7	Triamcinolone Mepivacaine	Atypical	Flaccid quadriplegia, respiratory arrest, C4 sensory level	MRI: high cervical to upper thoracic cord edema	3 months: breathing unassisted	
10 <sup>8</sup>	(L)C6-C7	None (contrast only)	Atypical	Quadriparesis, (L)C6 sensory level	CT: intracord air bubble MRI: cervical cord edema	(L) arm paresis otherwise restored strength	
115	(R)C5-C6	Triamcinolone Bupivacaine	Typical	Transient unresponsiveness, quadriplegia	MRI: cerebellar infarct.	Death	
1216	(R)C7-T1	Methylprednisolone Lidocaine	Typical	Neck pain, beadache, nausea then intermittent apnea, posturing	MRI: cerebellar infarct with edema and subsequent hemiation	Posterior fossa craniectomy and meningitis. Recovered with diplopia and memory deficits	
13 <sup>17</sup>	(L)C5-C6	Methylprednisolone	Typical	Nausea, vomiting and headache followed by decreased consciousness and dysarthria	MRI: midbrain, pons, L thalamic infarction.	Death	
14 <sup>18</sup>	(L)C5-C6	Betamethasone Lidocaine	Atypical	Transient unresponsiveness. Dysarthria, ataxia, numb arms, (L) arm plegic, (R) arm paretic	MRI: cerebellar infarct and C1-C4 cord infarct	Unknown.	
15 <sup>9</sup>	(L)C5-C6	Anesthetics, unspecificed	Atypical	Nystagmus. Subsequent blindness, seizures, obtundation, aphasia, dysphagia	MRI: L occipital cortex cerebral edema	Day 30: memory deficits and (R) homonymous hemianopia	
16 <sup>11</sup>	(L)C6-C7	Methylprednisolone Bupivacaine	Atypical	Immediately noncommunicative	CT: brainstem hemorrhage, intraventricular hemorrhage	Death	

Popescu A et al. Stroke following Epidural Injections-Case Report and Review of Literature. Journal of Neuroimaging. 2013;23(1):118-121



# **FDA Safe Use Guidelines**

#### Safeguards to Prevent Neurologic Complications after Epidural Steroid Injections

#### Consensus Opinions from a Multidisciplinary Working Group and National Organizations

James P. Rathmell, M.D., Honorio T. Benzon, M.D., Paul Dreyfuss, M.D., Marc Huntoon, M.D., Mark Wallace, M.D., Ray Baker, M.D., K. Daniel Riew, M.D., Richard W. Rosenquist, M.D., Charles Aprill, M.D., Natalia S. Rost, M.D., M.P.H., Asokumar Buvanendran, M.D., D. Scott Kreiner, M.D., Nikolai Bogduk, M.D., Ph.D., D.Sc., Daryl R. Fourney, M.D., Eduardo Fraifeld, M.D., Scott Horn, D.O., Jeffrey Stone, M.D., Kevin Vorenkamp, M.D., Gregory Lawler, M.D., Jeffrey Summers, M.D., David Kloth, M.D., David O'Brien, Jr., M.D., Sean Tutton, M.D.



Statement/Clinical Consideration	Number of Organizations Agreeing	Number of Organizations Disagreeing	Number of Organizations Unable to Reach Consensus
<ol> <li>Cervical IL ESIs are associated with a rare risk of cata- strophic neurologic injury (fig. 1).</li> </ol>	13	0	0
<ol> <li>TF ESI using particulate steroid is associated with a rare risk of catastrophic neurovascular complications (fig. 3).</li> </ol>	13	0	0
3. All cervical IL ESIs should be performed using image guid- ance, with appropriate AP, lateral, or contralateral oblique views and a test dose of contrast medium (fig. 5).	13	0	0
<ol> <li>Cervical TF ESIs should be performed by injecting contrast medium under real-time fluoroscopy and/or digital subtrac- tion imaging, using an AP view, before injecting any sub- stance that may be hazardous to the patient (fig. 6).</li> </ol>	11	4*	1
5. Cervical IL ESIs are recommended to be performed at C7-T1, but preferably not higher than the C6-C7 level.	13	0	0
6. No cervical IL ESI should be undertaken, at any segmental level, without reviewing, before the procedure, prior imag- ing studies that show there is adequate epidural space for needle placement at the target level.	13	0	0
7. Particulate steroids should not be used in therapeutic cervi- cal TF injections.	13	0	0
<ol> <li>All lumbar IL ESIs should be performed using image guid- ance, with appropriate AP, lateral, or contralateral oblique views and a test dose of contrast medium.</li> </ol>	13	0	0
<ol> <li>Lumbar TF ESIs should be performed by injecting contrast medium under real-time fluoroscopy and/or digital subtrac- tion imaging, using an AP view, before injecting any sub- stance that may be hazardous to the patient (fig. 7).</li> </ol>	12	1*	0
<ol> <li>A nonparticulate steroid (e.g., dexamethasone) should be used for the initial injection in lumbar transforaminal epidural injections.</li> </ol>	11	0	2
11. There are situations where particulate steroids could be used in the performance of lumbar TF ESIs.	13	0	0
12. Extension tubing is recommended for all TF ESIs.	12	1	0
<ol> <li>A face mask and sterile gloves must be worn during the procedure.</li> </ol>	13	0	0
14. The ultimate choice of what approach or technique (IL vs. TF ESI) to use should be made by the treating physician by balancing potential risks vs. benefits with each technique for each given patient	13	0	0
<ol> <li>Cervical and lumbar IL ESIs can be performed without contrast in patients with documented contraindication to use of contrast (e.g., significant history of contrast allergy or anaphylactic reaction)</li> </ol>	11	0	2
16. TF ESIs can be performed without contrast in patients with documented contraindication to use, but in these circum- stances, particulate steroids are contraindicated and only preservative-free, particulate-free steroids should be used.	13	0	0
<ol> <li>Moderate-to-heavy sedation is not recommended for ESIs, but if light sedation is used, the patient should remain able to communicate pain or other adverse sensations or events</li> </ol>	13	0	0

Table 1. Statements and Clinical Considerations of the Working Group Endorsed by the MultiSpecialty Work Group

\* The organization voting against questions 4 and 9 commented, "Digital Subtraction Imaging should be mandatory before injecting a potentially hazardous substance transforaminally."

AP = anteroposterior; C6-C7 = the interspace between the sixth and seventh cervical vertebrae; C7-T1 = the interspace between the seventh cervical and first thoracic vertebrae; ESI = epidural steroid injection; IL = Interlaminar; TF = trasforaminal.



#### Cervical IL ESIs are associated with a rare risk of catastrophic neurologic injury (fig. 1).

TF ESI using particulate steroid is associated with a rare risk of catastrophic neurovascular complications (fig. 3).

All cervical IL ESIs should be performed using image guidance, with appropriate AP, lateral, or contralateral oblique views and a test dose of contrast medium (fig. 5).

Cervical IL ESIs are recommended to be performed at C7-T1, but preferably not higher than the C6-C7 level.

No cervical IL ESI should be undertaken, at any segmental level, without reviewing, before the procedure, prior imaging studies that show there is adequate epidural space for needle placement at the target level.



- All lumbar IL ESIs should be performed using image guidance, with appropriate AP, lateral, or contralateral oblique views and a test dose of contrast medium.
- Lumbar TF ESIs should be performed by injecting contrast medium under real-time fluoroscopy and/or digital subtraction imaging, using an AP view, before injecting any substance that may be hazardous to the patient (fig. 7).
- 10. A nonparticulate steroid (e.g., dexamethasone) should be used for the initial injection in lumbar transforaminal epidural injections.
- 11. There are situations where particulate steroids could be used in the performance of lumbar TF ESIs.



12. Extension tubing is recommended for all TF ESIs.
 13. A face mask and sterile gloves must be worn during the procedure.

#### Anesthesiology 2015; 122:974-84



- 14. The ultimate choice of what approach or technique (IL vs. TF ESI) to use should be made by the treating physician by balancing potential risks vs. benefits with each technique for each given patient
- 15. Cervical and lumbar IL ESIs can be performed without contrast in patients with documented contraindication to use of contrast (*e.g.*, significant history of contrast allergy or anaphylactic reaction)
- 16. TF ESIs can be performed without contrast in patients with documented contraindication to use, but in these circumstances, particulate steroids are contraindicated and only preservative-free, particulate-free steroids should be used.
- 17. Moderate-to-heavy sedation is not recommended for ESIs, but if light sedation is used, the patient should remain able to communicate pain or other adverse sensations or events



#### Conclusions

- Accepted to use particulate steroids for interlaminar injections
- Use image guidance with multiple views for epidural placement
- Strongly consider use of DSA for detection of vascular uptake
- Strongly consider use of nonparticulate steroids for lumbar TFESI

