Retrospective Evaluation

Increased Dose of Betamethasone for Transforaminal Epidural Steroid Injections Is Not Associated with Superior Pain Outcomes at 4 Weeks

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Background: Fluoroscopically guided transforaminal epidural steroid injections (FG-TFESIs) have been shown to provide both immediate and long-term improvement in patients' self-reported pain. Administration of the lowest possible dose of epidural betamethasone is desired to minimize side effects while maintaining efficacy. We hypothesize that a 3 mg or a 6 mg dose of betamethasone will demonstrate equivalent analgesic properties.

Objectives: To compare the analgesic efficacy of 3 mg and a 6 mg dose of betamethasone for use in FG-TFESI.

Study Design: Retrospective evaluation.

Setting: Academic outpatient pain center.

Methods: One hundred fifty-eight patients underwent FG-TFESI for lumbar back pain between 2012 and 2013. Depending on the date of service, a dose of 3 mg or a dose of 6 mg betamethasone was used in the single level unilateral TFESI. Opioid consumption and NRS-11-11 pain score were analyzed pre-procedurally and at a clinic visit 4 weeks post-procedurally.

Results: Changes in numerical rating scale (NRS-11-11) pain score (-1.21 + 2.61 vs. -0.81 + 2.40 respectively, $P = 0.17$) and changes in opioid consumption as measured in oral morphine equivalents (-2.94 + 16.4 mg vs. -2.93 + 14.8 mg, $P = 0.17$) were statistically equivalent between both groups. Intergroup sub-analysis of those with > 50% reduction in baseline NRS-11-11 pain score was not different (15.2% vs. 34%, $P = 0.56$), and the proportion with a VRS pain score < 3 were similar (24.5% vs. 23.8%, $P = 0.92$).

Limitations: Potential selection bias inherent with study design.

Conclusions: Reduction in NRS-11-11 pain scores and narcotic usage at 4 weeks after FG-TFESI were statistically equivalent between patients who received 3 mg or 6 mg of betamethasone, suggesting that a lower steroid dose has similar analgesic efficacy.

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Lumbar back pain (LBP) remains a common complaint at presentation to pain management clinics. The lifetime incidence of back pain approaches 80% occurring most frequently between the third and fifth decade of life (1,2). The natural history of LBP suggests that 75% of patients will recover with conservative treatment after 2 months (3). The emphasis of treatment is controlling pain in order to facilitate rehabilitation and physical therapy.

Fluoroscopically guided transforaminal epidural steroid injection (FG-TFESI) has been demonstrated to be efficacious in the treatment of LBP with or without radiculopathy and for the facilitation of physical therapy (4). The American Society of Interventional Pain Physicians' guidelines for the treatment of LBP indicate that FG-TFESIs are recommended as treatment for patients with radicular back pain but not axial back pain without radicular features (5,6). The addition of corticosteroids to bupivacaine solutions offers prolonged and more complete pain relief (7,8). Epidural steroids decrease nerve root inflammation through inhibiting the conversion of phospholipase A2 (PLA2) by cyclooxygenase to pro-inflammatory prostaglandins and leukotrienes (9,10). Escalating doses of dexamethasone in lumbar TFESIs from 4 mg to 12 mg failed to demonstrate added benefit (11). Similarly, the use of 80 mg of methylprednisolone did not show benefit over 40 mg of methylprednisolone for TFESIs (12). Additionally, escalating doses of triamcinolone in lumbar TFESIs from 10 mg to 40 mg failed to demonstrate increased clinical benefit (13).

An established medical practice is to use the minimal effective dose of medications, including epidural betamethasone. In December 2012, a practice change at the institution's pain management center was to decrease the commonly used dose of betamethasone used for unilateral single level FG-TFESIs from 6 mg to a lower range of 3 mg. Opioid prescription, physical therapy, and post procedural mobilization practices remained unchanged. Anecdotal evidence from patients suggested retention of efficacy of FG-TFESIs when lower doses of betamethasone were used. The aim of this study is to quantify and compare the amount of pain relief, as measured by numerical rating scale (NRS-11) and opioid consumption, between those patients who received FG-TFESIs with 6 mg prior to the modification of practice with those who received lower doses of 3 mg after the practice modification. We hypothesize an equivalent change in patients' NRS-11 pain scores and opioid consumption 4 weeks following injection.

Methods

After obtaining approval from the Institutional Review Board, a retrospective analysis was performed of 200 consecutive patients with LBP associated with radicular lower extremity pain without radiculopathy who underwent their initial unilateral single level FG-TFESIs at a single outpatient pain management clinic performed by board certified pain management specialists between August 2012 and July 2013. Procedures during this time were performed both prior to and after the modification of the commonly used dose of betamethasone. Patients were included in the analysis if they were between the ages of 18 to 80 years old, had clinical evidence of nerve root impingement originating from an intervertebral disk herniation into the lateral recess of the spinal canal at a single lumbar level with confirmatory magnetic resonance imaging (MRI) studies, and had failed prior conservative treatments. Lumbar MRIs were formally evaluated by both a board certified radiologist and a pain management specialist confirming the presence of single level unilateral lumbar intervertebral disk herniation into the lateral recess that correlated with both the level and the side corresponding to pain symptoms elicited in a physical exam. Other causes of lumbar foraminal stenosis such as spondylolithesis, spondylosis, traumatic fractures, or compression from neoplasms were not observed with radiographic studies. Exclusion criteria included having clinical evidence of radiculopathy including weakness and/or decreased reflexes on physical exam, prior FG-TFESIs, and having a second or non-nerve root impingement pain generator such as central canal stenosis, discogenic pain, facet arthropathy, sacroilitis, or other neuropathic pain syndromes including those which may require bilateral or multiple level therapeutic FG-TFESIs. No other epidural steroid injection or other injection for low back pain was performed prior to the 4 week follow-up. Data was collected from hospital and pain clinic charts. The main outcome variable was a change in the patient's self-reported post-procedural pain.

Patients' pain was evaluated a NRS-11 pain scale, with 0= no pain and 10= most severe pain imaginable. Demographic data including age, gender, weight, BMI, and comorbidities; pre-procedural data including opioid and co-analgesic consumption, and NRS-11 pain scores; procedural information including injected steroid dose, number of levels, and laterality; and post-procedural information including NRS-11 pain scores at 4 weeks, opioid and co-analgesic consumption were recorded. Post-procedure NRS-11 scores and opioid

consumption were obtained at a clinic visit 4 weeks following the FG-TFESI. The total amount of opioid was converted to the equianalgesic dose of oral morphine using a standardized conversion (Table 1) (14). No patient was taking IV, transdermal, intrathecal, or other non-oral formulations of opioid pain medications. One of the primary purposes of performing FG-TFESIs is to facilitate participation in physical therapy. Although all patients did participate in physical therapy, such activity was conducted at outside clinics to whose records the investigators did not have access.

FG-TFESIs were carried out by board certified pain management specialists (HR and BS). Written consent for the procedure was obtained from each patient or legal representative. The patient was positioned prone on a fluoroscopy table. All patients were given supplemental oxygen and monitored by an attending anesthesiologist. The patient's back was prepped and draped with chlorhexidine and sterile drapes. A blunt 18g "skin finder" needle was placed flat against the patient's back and both frontal (anterior- posterior) and lateral images were obtained to identify the bony anatomy and the segmental level of interest. A 25g needle was used to anesthetize the skin and subcutaneous tissue with 1 mL of 1% lidocaine. A 22g 3½ inch quinke point spinal needle was then advanced through the skin towards the superior and anterior aspect of the intended foramen under fluoroscopic guidance. Once the needle was in the correct tissue plane, negative aspiration for blood and cerebrospinal fluid was confirmed and 1 mL of radiopaque contrast dye was injected under fluoroscopy to confirm appropriate spread along the nerve root. No radiographic evidence of vascular or intrathecal uptake was observed. Once spread along the nerve root was confirmed, patients would receive 0.5 mL of 0.25% Bupivicaine mixed with a dose of betamethasone. The exact dose of betamethasone used was determined by the date on which the patient received the FG-TFESIs with 6 mg used prior to December 2012 and 3 mg used after December 2012. No national database for reporting complications and/or side effects of epidural steroids has been established. At the end of the procedure, patients were taken to the recovery area. Prior to discharge, they were monitored for at least 30 minutes for any adverse neurologic changes e.g., dizziness, loss of consciousness, visual changes, dense paralysis, worsening pain.

Patients were classified into those who received a lower dose (3 mg), and a higher dose (6 mg) of betamethasone depending on if their procedure was performed prior to or after the institution of the change in the commonly used betamethasone dose. All data was coded in an Excel file (Microsoft, Redmond, WA) and imported into SPSS statistical software package (IBM Corp., Armonk, NY). Normally distributed data was presented as mean and standard deviation and non-parametric data as median and interquartile range. A Kolmogorov-Smirnov test was used to determine normalcy of data distribution. Differences in normally distributed categorical variables were analyzed using Chi-squared test and parametric t-tests were used for continuous variables. All associations with a $P < 0.05$ were considered statistically significant.

Results

Two hundred patients were included in the initial medical record review. Forty-two patients were excluded for having a prior FG-TFESIs or undergoing bilateral or multiple level FG-TFESIs. Of remaining 158 patients who underwent single-level lumbar FG-TFESIs, 105 patients received 6 mg epidural betamethasone and 53 patients received 3 mg betamethasone . Pre-procedural

Table 1. *Opioid Equianalgesic Conversion Table.*

Opioid Name	Administration Route	Dose Equivalent to 10 mg Oral Morphine (mg)
Morphine	Oral	10 mg
Hydromorphone	Oral	7.5 mg
Hydrocodone	Oral	10 mg
Oxycodone	Oral	7 mg
Codeine	Oral	80 mg
Tramadol	Oral	40 mg
Propoxyphene	Oral	44 mg
Methadone	Oral	10 mg

All equianalgesic doses are given relative the equivalent dose of 10 mg of oral morphine. mg = milligram.

demographic data including gender, weight, BMI, or diabetes type II prevalence were not statistically different (Table 2). However, patients receiving 3 mg of betamethasone had a statistically higher mean age but only by fewer than 5 years with overlap between the groups (56.5 + 9 for 3 mg vs. 52 + 12.7 for 6 mg, P = 0.03). Pre-procedural NRS-11 scores and narcotic usage were not statistically different between the 2 groups. Transforaminal levels at which the injection was performed (L1-L2, L2-L3, L3-L4, L4-L5, or L5-S1) were not significantly different amongst these groups (Table 2). Four weeks following the FG-TFESI, the change in NRS-11 pain score and opioid consumption had decreased in both groups to a statistically equivalent degree (Table 2). The 3 mg betamethasone group had a higher proportion of patients achieving at least a 50% reduction in NRS-11 pain score at 4 weeks than those in the 6 mg group (34% vs 15.2% respectively), but it was not statistically significant (Table 3). Similarly, the percentage of patients reporting an NRS-11 at 4 weeks pain score < 3 post-procedure were statistically equivalent between the 2 dosing regimens. The use of co-analgesics was not significantly different between the 2 groups prior to or after receiving the FG-TFESIs (Table 4). None of the 158 patients were lost to follow-up. Central neurologic changes were not observed during the procedure. Nevertheless, there were no adverse central neurologic outcomes and/or cardiopulmonary compromise in the recovery area.

Table 2. *Demographic, pre- and post-procedural results of 158 patients.*

	3 mg Betamethasone	6 mg Betamethasone	*P* value
N	53	105	
Age (years)	56.5 + 9	52 + 12.7	0.03*
Gender (male/female)	(28/25)	(61/44)	0.53+
Weight (Kg)	76.9 ± 17.7	81.9 ± 20.3	0.15
BMI (Kg/m2)	26.6 + 5.3	28.5 + 6.1	0.07
Diabetes Mellitus	3 (5.7%)	7 (6.7%)	0.81
NRS-11 pain score prior to injection (0 – 10)	6.48 + 2.11	6.43 ± 2.44	0.90
NRS-11 pain score after injection	5.22 ± 2.18	5.86 ± 2.62	0.20
NRS-11 pain score change	-1.21 + 2.61	-0.81 + 2.40	0.17
Opioid use prior to injection (mg)	42.9 ± 37.5	47.0 ± 52.4	0.75
Opioid use 4 weeks after injection (mg)	40.7 ± 40.2	43.8 ± 46.9	0.80
Opioid use change (mg)	-2.94 + 16.4	-2.93 + 14.8	0.99
Injection level (count & %)			
L1-L2	1 (1.9%)	0	0.16
L2-L3	4 (7.5%)	2 (1.9%)	0.08
L3-L4	5 (9.4%)	18 (17.1%)	0.19
L4-L5	18 (34%)	39 (37.2%)	0.70
L5-S1	25 (47.2%)	46 (43.8%)	0.69

Data reported as average (standard deviation) for continuous data and count (percent of total), gender data reported as (number of males / number of females). Chi-squared test used+. Kg = kilogram, m = meters, mg = milligrams, NRS-11 = numerical rating scale. P < 0.05 is considered significant*.

Table 3. *Patients experiencing at least a post-procedural 50% reduction in pain or NRS-11 pain score of < 3.*

Group	50% reduction in pain	95% Confidence Interval	*P*-value	NRS-11 pain score 3 or less post-procedure	95% Confidence Interval	*P*-value
3 mg	10/53 (0.340)	(0.203 – 0.457)	0.561	13/53 (0.245)	(0.129 – 0.361)	0.920
6 mg	16/105 (0.152)	(0.083 – 0.221)		34/105 (0.238)	(0.157 – 0.320)	

* *P* < 0.05 considered significant on Chi-square analysis.

Table 4. *Use of co-analgesics among studied patients.*

	3 mg Betamethasone	6 mg Betamethasone	*P* value
N	53	105	
Pre-procedure gabapentin (mg)	1116.67 + 926	1009.1 + 647	0.75
Post-procedure gabapentin (mg)	1116.67 + 926	870 + 478.53	0.46
Pre-procedure pregabalin (mg)	150 + 108	150 + 101.7	1.00
Post-procedure pregabalin (mg)	87.5 + 62.9	172.7 + 95.2	0.12
Pre-procedure ibuprofen (mg)	1675 + 965	1260 + 866	0.17
Post-procedure ibuprofen (mg)	1612.5 + 989	1365 + 843	0.43
Pre-procedure naproxen (mg)	797.5 + 387.14	641.3 + 279	0.28
Post-procedure naproxen (mg)	797.5 + 387.14	728 + 448	0.71
Pre-procedure acetaminophen (mg)	1354 + 712	1460 + 1073	0.67
Post-procedure acetaminophen (mg)	1395 + 843	1427 + 1035	0.9
Pre-procedure celecoxib (mg)	266.7 + 115	200 + 0	0.29
Post-procedure celecoxib (mg)	300 + 200	115 + 0	0.13
Pre-procedure duloxetine (mg)	58 + 39.7	47.5 + 36.5	0.61
Post-procedure duloxetine (mg)	64 + 41.6	55.6 + 29.2	0.66

Data reported as average (standard deviation). mg = milligrams $P < 0.05$ is considered significant*.

Discussion

As epidural corticosteroids have dose dependent side effects beyond pain control, avoidance of unnecessarily high doses should be practiced and a minimally effective dose would be useful in guiding interventional therapeutics (12). Epidural steroid side effects may include dizziness, anxiety, headache, transient hypotension or hypertension, low-grade fevers, gastritis, insomnia, post-injection flare, hyperglycemia, and cutaneous flushing (15). Although added pain relief is not seen with escalating doses, the incidence of side effects such as hyperglycemia and flushing is higher for several days following the epidural steroid injection in a dose dependent manner (12,16,17). Increased doses of methylprednisolone injected epidurally will cause hypothalamic-pituitary mediated hyperglycemia for up to 3 weeks post-procedurally (18).

Particulate steroids, such as betamethasone or methylprednisolone, and non-particulate steroids, such as dexamethasone, have been demonstrated to have similar efficacy and safety profiles for lumbar steroid injections (19-21). However, some have advocated the routine use of non-particulate steroids for FG-TFESIs due to a potentially lower risk of arterial embolization (22).

In this single-center retrospective study, a recent change in clinical practice prompted the comparison of 3 mg of betamethasone to 6 mg betamethasone for use in FG-TFESIs with the primary endpoint being changes in NRS-11 pain scores and opioid consumption post-procedurally. NRS-11 pain score changes and the reduction in opioid use 4 weeks post-injection were equivalent between the 2 dosing groups. Likewise, there was no statistically significant difference in the number of patients attaining a > 50% NRS-11 pain score at 4 weeks and no difference in the percentage of those achieving a post-injection NRS-11 pain score < 3 at 4 weeks.

This study is meant to be a reference for the future design of randomized controlled trials to conclusively elucidate the relationship between epidural betamethasone dose and quantification of pain relief. As a retrospective study, only an association but not causation can be determined. Moreover, the fact that there were more patients in the 6 mg betamethasone group compared to the 3 mg betamethasone group is due to the timing of when the practice changed to use a 3 mg dose of betamethasone. Selection bias may have resulted by only examining initial FG-TFESIs performed at a single center. However, this may also have created a more homogenous cohort. The study is potentially further limited by a relatively small study population.

Although no association was observed between elevated doses of betamethasone and improved NRS-11 pain scores at 4 weeks, this study did not examine relationships between elevated doses and the incidence

of steroid dose-dependent side effects or effects on physical therapy and rehabilitation. This study did not account for differences in the physical therapy routines that patients underwent following their injections. The addition of a functional metric, such as the Oswestry low back pain questionnaire, could potentially clarify the results (23). Determination of the degree of experienced pain relief is complicated by the different degrees of opioid usage in the study's population. This study also did not characterize the duration of lumbar pain prior to interventions, which can influence patient responses to FG-TFESIs (24,25).

Conclusion

In conclusion, the treatment of lumbar back pain associated with radicular lower extremity pain with FG-TFESIs using either 6 mg or 3 mg of betamethasone is associated with equivalent decreases in NRS-11 pain scores and post-procedure opioid use at 4 weeks. It is possible that the use of lower dose betamethasone may provide similar analgesia with fewer dose-dependent steroid side effects. Large prospective studies are indicated to confirm the optimal dose of betamethasone for FG-TFESIs.

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