Original Article

A Randomized Clinical Trial of Three Different Steroid Agents for Treatment of Low Backache through the Caudal Route

Col Rashmi Datta*, Brig KK Upadhyay, VSM+

Abstract

Background: Although epidural steroids are commonly used for conservative management of sciatica, controversies exist regarding optimal approach, type and dose of steroids, volume of injectate and frequency of administration. This randomized comparative blinded study was undertaken to compare the efficacy of caudal methylprednisolone acetate with triamcinolone acetonide and dexamethasone acetate, for pain relief for sciatica associated with lumbar-disk herniations.

Methods: A Total of 163 patients with radicular pain due to lumbar-disk herniations, between 27-70 years of age were randomly divided into four groups: three were given epidural steroid injection therapy (methylprednisolone acetate, triamcinolone acetonide and betamethasone acetate) with bupivacaine; one group received bupivacaine alone via caudal approach. Injections were repeated every three weeks till a total of 210 mg of methylprednisolone (and equivalent) or three injections. Pain relief, disability and activity levels were assessed at 3, 6, 9 and 12 weeks interval.

Result: Pain relief was present in all four groups by three weeks with no difference between the groups ($p=0.006$; 0.005; 0.0045; 0.005 respectively to baseline). By the 6 and 12 week, the three steroid groups had significant pain relief ($p<0.001$). Among these, both methylprednisolone and triamcinolone groups showed greater improvement in the finger-to-floor distance ($p=0.006$). A smaller proportion of patients in this group had residual sensory deficits ($p=0.03$) as compared to dexamethasone but difference was statistically insignificant. Overall pain relief was significantly better at all follow-up evaluations in the steroid group than in the control group ($p<0.001$ at all evaluations).

Conclusion: Short-term improvement in leg pain and sensory deficits was observed in patients with sciatica due to a herniated nucleus pulposus with both epidural bupivacaine and steroids. All long-acting steroids had no statistically significant difference between their efficacy in pain relief but methylprednisolone and triamcinolone were more effective by the second injection as compared to dexamethasone which required a third injection in a significant number of cases. Differences between methylprednisolone and triamcinolone were insignificant. Complications were negligible and temporary.

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Key Words : Epidural steroid injections; Methylprednisolone; Triamcinolone; Dexamethasone; Sciatica

Introduction

Chronic low back pain (LBP), defined as pain persisting >12 weeks, is commonly caused by nerve-root inflammation with/ or without mechanical factors secondary to extrusion of nucleus pulposus. Theories for this induced inflammation include mechanical compression from the herniated disc, direct chemical irritation of the nucleus pulposus of the herniated disc, autoimmune response to material of extruded nucleus pulposus or combination [1]. Suppression of the biochemical factors of inflammation is the rationale behind the use of corticosteroids in LBP leading to reduction in soft-tissue swelling, oedema, pressure, soft adhesions and slow regression of disc herniation [2,3].

Epidural steroid injections (ESIs) localize the drug around the area of affected nerve roots, thereby decreasing systemic effects and side-effects. Caudal route with or without fluoroscopy is a popular approach for the lumbar region [4]. Agents commonly used are methylprednisolone acetate, triamcinolone acetonide and betamethasone acetate [5,6]. Hydrocortisone and prednisolone have significantly less anti-inflammatory potency and higher mineralocorticoid effects (sodium retention with a tendency for hypertension). Hydrocortisone is additionally irritant to the nerves, meninges and can precipitate grand-mal epilepsy [7,8].

ESIs are administered with or without dilution using local anesthetics or isotonic saline solution. Local anesthetics are advantageous in providing temporary pain relief by means of analgesic effects exerted by blocking nerve conduction and suppressing ectopic signal

*Senior Advisor, (Anaesthesiology), Army Hospital (R&R), New Delhi-10. +Commandant, MH Secunderabad, PIN-900453.
Received : 18.09.2009; Accepted : 21.10.2010 E-mail : rashmidatta@rediffmail.com

generation in injured nerves. Prolonged benefits may occur by putatively interrupting the spasm-ischemia-pain cycle, thus favoring muscle relaxation. These also help in confirming whether the steroids have reached the clinical site [6].

In the Armed Forces, a number of backache patients are admitted every year leading to high bed occupancy. The aim of this study was to determine the efficacy and safety of ESIs given through the caudal approach for out-hospital management of sciatica, thereby avoiding hospital admission for the treatment of sciatica. Also, the comparative efficacy of available steroid formulations keeping the availability and cost-effectiveness of the three drugs with the null hypothesis that these are of equal efficacy was determined.

Material and Methods

Two hundred seven patients in ASA grade I-II who presented to the Pain Clinic in a tertiary care service hospital for sciatica were included in this double blind, randomized, comparative study after taking approval from hospital ethical committee and an informed consent. Sciatica was defined as the presence of constant or intermittent pain in one or both legs, radiating below the knee.

Eligibility criteria included (a) age 20-70 years inclusive, at the time of informed consent (b) body mass index (BMI) between 18-30 kg/m^2 (c) recurrent episodes of sciatica > four weeks but < one year with failure of, at least, six weeks of conservative therapy (including all the episodes) (d) computed tomographic (CT) evidence of a herniated nucleus pulposus at a level corresponding to symptoms and clinical findings (e) >20 score on the Roland-Morris Disability Questionnaire [9, 10]. CT scan was chosen over MRI because the service hospital had only a CT scan.

Patients were excluded if they had: (a) symptoms requiring early surgical treatment (severe motor weakness, cauda equina syndrome, hyperalgic sciatica) (b) structural spinal deformities (scoliosis >40°, spondylolisthesis) (c) symptoms from causes other than herniated nucleus pulposus (d) received any spinal injection in the past year (e) undergone low back surgery, chemonucleolysis, or nucleotomy (f) pregnancy (g) known allergy to corticosteroids (h) ongoing treatment with tricyclic antidepressant drugs or lithium.

A sample size calculation was done to look for clinically relevant difference of 30% between the success rate of steroid groups (70%) Vs. control group (40%) keeping a two-sided alfa of 5% and power of 80%. A sample size of 39 per group was calculated; keeping in mind a 10% loss to follow up it was decided to enroll 50 patients in each group.

Patients fulfilling criteria were randomly allocated to the four groups using block randomization sequence generated by the computer and instituted by the study nurse using sealed envelopes:

Group A - Caudal injection of 10-15 ml 0.125% bupivacaine alone.

Group B - Caudal injection of 10-15 ml 0.125% bupivacaine and 80 mg methyl prednisolone.

Group C - Caudal injection of 10-15 ml 0.125% bupivacaine and 80 mg triamcinolone.

Group D - Caudal injection of 10-15 ml 0.125% bupivacaine and 15 mg dexamethasone.

The initial level of pain and functional disability was monitored using a Visual Analogue Scale (VAS) and Roland Morris low-back-pain disability questionnaire (Table 1). Nerve-root irritation and/or compression were evaluated by Lasègue's sign (reproduction of radicular pain by elevation of the leg) and the angle of leg noted by a goniometer for Straight Leg Raising (SLR) test. Finger-to-floor distance (FTFD) was also measured. Presence or absence of paraspinal muscle spasm was documented. Motor and/or sensory deficits were recorded.

The caudal block was performed under strict aseptic precautions with all resuscitative equipments kept standby. 2cc of air was injected through the caudal hiatus and area over the thoraco-lumbar spine auscultated for a 'swoosh' (modified 'Whoosh Test') [11]. The anaesthesiologists making the assessments were not the same as those giving the injections.

Follow up: Patients were discharged after an hour of observation following ESI. Re-evaluation was done after 1

Table 1

The Roland - Morris Disability Questionnaire

- I stay at home, most of the time because of my back.
- I change position frequently to try and get my back comfortable.
- I walk more slowly than usual because of my back.
- Because of my back, I am not doing any of the jobs that I usually do around the house.
- Because of my back, I use a hand rail to get upstairs.
- Because of my back, I lie down to rest more often.
- Because of my back, I have to hold on to something to get out of an easy chair.
- Because of my back, I try to get other people to do things for me.
- I get dressed more slowly than usual because of my back.
- I only stand for short period of time because of my back.
- Because of my back, I try not to bend or kneel down.
- I only walk short distances because of my back.
- I sleep less well on my back.
- Because of my back pain, I get dressed with help from someone else.
- Because of my back pain, I am more irritable and bad tempered with people than usual.
- Because of my back, I go upstairs more slowly than usual.
- I stay in the bed most of the time because of my back.
- I sit down for most of the day because of my back.
- I avoid heavy jobs around the house because of my back.
- I find it difficult to get out of chair because of my back.
- My back is painful almost all the time.
- I find it difficult to turn over in the bed because of my back.
- My appetite is not very good because of my back pain.
- I have trouble putting on my socks (stocking) because of pain in my back.

Total = The score is the total number of the items checked and will range from 0 to 24.