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RESEARCH

Transforaminal epidural steroid injections for the treatment of lumbosacral radicular pain in a Nigeria tertiary hospital: observational study

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Background: Lumbosacral radicular pain is a common cause of chronic low back pain. Despite published reports of effectiveness of transforaminal epidural steroid for lumbosacral radicular pain, it is underutilised in many tertiary hospitals in sub-Saharan Africa. This study assessed the clinical effects of transforaminal epidural steroid injections in patients with lumbosacral radicular pain at a major tertiary health facility in Nigeria.
Methods: This is a prospective observational study carried out between March 2012 and February 2016. Under fluoroscopy, the epidural space was accessed through the neuroforamen using 22G spinal needles in 47 adult patients with lumbosacral radicular pain; and a mixture of 10 mg triamcinolone acetonide and 0.25% plain bupivacaine (2 mLs per level) was injected. Pain intensity and functional impairment were assessed with the Numeric Pain Rating Scale (NPRS) and the Oswestry Disability Index (ODI) scores respectively at three and six months.
Results: The pain and ODI scores at baseline and at six months' follow-up improved significantly; 8.49 ± 1.28 vs. 3.6 ± 1.5 ($p = 0.002$) and 45.1 ± 11.5 vs. 32.4 ± 11.5 ($p = 0.001$) respectively.
Conclusion: Transforaminal epidural steroid injections provided significant pain relief and improved function in patients with lumbar radicular pain due to intervertebral disc herniations.

Keywords: herniated intervertebral disc, lumbosacral radicular pain, Nigeria, pain relief, transforaminal epidural steroid injection

Introduction

Lumbar radicular pain secondary to lumbar disc herniation is an important cause of disabling chronic low back pain. The mechanism of the pain is due to the inflammation of the affected nerve roots by the disc contents.[1–3] Epidural steroid injections are one of the most utilised therapeutic interventions for treatment of chronic low back with or without lower extremity pain[4,5] but are rarely offered to patients in most hospitals in the West African sub-region. Until recently, patients with chronic low back pain in most African healthcare institutions were being managed with non-steroidal anti-inflammatory medications (NSAIMs), bed rest, low-potency opioids and sessions of physiotherapy but without achieving significant pain relief.[6] We evaluated the outcomes of transforaminal epidural steroid injections, which are believed to guarantee deposition of the medication closer to the inflamed nerve roots compared with the traditional interlaminar approach, for lumbosacral radicular pain at a University Teaching Hospital in Nigeria.

Materials and methods

This prospective observational study was carried out in a tertiary health centre after approval by the institutional ethical review committee. All the patients were referred from orthopaedic and neurosurgical clinics, consented to participate and were enrolled into the study (from March 2012 to February 2016). Before intervention, patients were educated on the use of Numeric Pain Rating Scale (NPRS) for pain and Oswestry Disability Index (ODI) for functional status. Information on co-morbid medical conditions, previous history of back surgery and reports of magnetic resonance imaging (MRI) of the lumbar spine were obtained and recorded.

Patients with presence of lumbosacral radicular pain unresponsive to at least 12 weeks of conservative treatment, pain severity score of ≥ 5, magnetic resonance imaging of the lumbosacral spine and intact motor or bladder/bowel function, and the cognitive competence to participate in outcome measurements were recruited into the study. All the patients had magnetic resonance imaging (MRI) of the lumbar spine that confirmed herniation of disc(s) at the segmental levels consistent with the clinical features.

Patients with any of the following conditions were not enrolled into the study: previous lumbar surgery, uncontrolled psychiatric disorders, uncontrolled acute or chronic medical illness, local infection around the back, adverse reactions to local anaesthetic or steroid, pregnant or lactating women and patients on anticoagulants with a history of chronic low back pain.

Technique of injection

The patients were placed in the prone position on a fluoroscopic table. The back area was cleaned with povidone iodine and covered with a sterile drape, which was fenestrated over the lumbar region. Using the fluoroscope in an AP view, the pedicle corresponding to the targeted foramen was identified and the image intensifier was moved in cephalo-caudal direction until the inferior end plate was seen as a line rather than an oval, that is the X-ray beam passes tangentially. Then, the image intensifier was rotated to 20–30° in the oblique position on the side of the pathology and a 22G spinal needle was advanced towards the neuroforamen through the skin just below the 6 o'clock position of the pedicle. The needle advancement was stopped when the tip was subpedicular in the 'safe triangle' of the neuroforamen, approximately halfway between the ventral and dorsal extent of the pedicle when imaged in a true lateral view. The needle was aspirated for blood or cerebrospinal fluid (CSF) and a negative aspirate was obtained before a non-

ionic contrast medium (omnipaque iohexol 240 mg) was injected under continuous fluoroscopy to confirm proximal spread and exclude vascular uptake. The injection of the contrast was completed in AP view. If vascular uptake was noticed, the needle tip was repositioned until appropriate contrast spread was observed. For the confirmation of anterior epidural spread, a lateral fluoroscopic image was obtained and 2 ml of a mixture of 10 mg triamcinolone acetonide and 0.25% plain bupivacaine was injected per affected level with not more than four levels during a treatment session, Figure 1.

Patients were observed for one hour post-intervention and assessed for any adverse effects such as nausea, vomiting and lethargy. At the discretion of the patients, the injection was repeated once or twice 10–14 days after the last injection in order to boost the response. Patients were sent for physiotherapy after the interventions.

Patients who reported at least 2 points reduction in their pain intensity after the treatment were followed up and assessed at 3 and 6 months after the last injection. The outcome measures were NPRS and ODI scores; and the proportion of patients who attained clinically relevant success in terms of pain relief and functional status were determined. The quantity of analgesic consumption was also assessed at the end of the six months' follow-up. Clinically relevant treatment success was deemed to have been achieved when patients reported a drop in the NPRS score $\geq$ 2.5 or a reduction in the ODI score of 10 or greater.[7,8]

Data analysis

Data analyses were carried out using SPSS® software for Windowa (version 20.0, SPSS Inc, Chicago, IL, USA). Data on baseline features and outcomes were collected and recorded. Means and standard deviations were calculated for continuous variables that described outcomes in the treated patients at baseline, three and six months. Results for proportions are reported as percentages and nonparametric tests were applied when the data obtained were not normally distributed. For comparisons of baseline values with the parameters obtained after the intervention, a paired *t*-test was used; a *p*-value of < 0.05 was considered to be statistically significant.

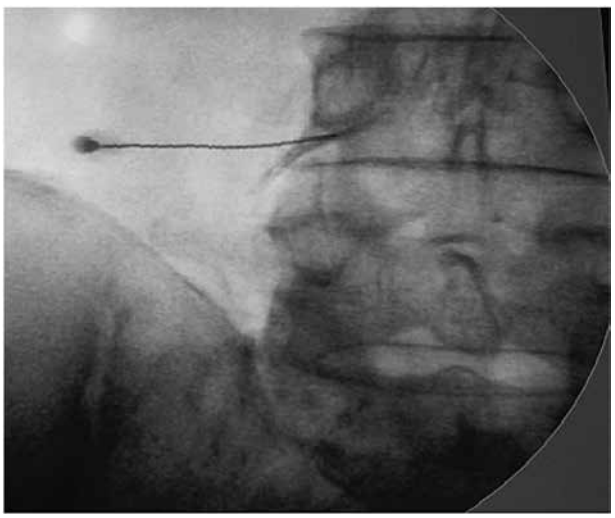

Figure 1: Anterior-posterior fluoroscopic image of an injection of contrast medium before transforaminal injection of a mixture of tiamcinolone acetonide and plain bupivacaine on the right L4 nerve root.

Results

A total of 68 patients diagnosed with lumbosacral radicular pain received transforaminal epidural steroid injections. After the first injection and prior to assessing their response to the treatment, 21 patients were excluded from this study due to geographical relocations and co-morbid depressive disorder (19 vs. 2 patients, respectively). The remaining 47 patients, 26 males (55.3%) and 21 (44.7%) females, who completed the study were analysed. The mean age, weight and height of the patients were 58.2 ± 11.6 years, 78.5 ± 8.2 kg and 1.68 ± 0.02 m respectively. The mean duration of pain before the patients were offered the treatment was 4.5 ± 4.7 months and the sites of radicular pain affected the left lower limb, both lower limbs and right lower limb in 8 (17%), 15 (31.9%) and 24 (51.1%) patients respectively (Table 1).

The lumbar spine MRI showed disc herniation at more than one intervertebral level in 39 (83%) patients and only 8 (17%) patients had single-level disc herniation. Prior to intervention, pain intensities were of severe and moderate scores respectively in 45 (94%) and 2 (4%) of the patients evaluated. Similarly, 21 (45%) patients were observed to be functionally compromised with ODI of severe and moderate scores respectively.

The mean score of the NPRS for pain and ODI score were 8.5 ± 1.3 and 45.1 ± 11.5 respectively at first presentation. The commonest co-morbid medical condition was hypertension in 15 patients, with an incidence of 31.9% (see Table 1).

The most injected nerve roots were L4 and L5, and the transforaminal epidural steroid injections were given to 29 (61.7%), 13 (27.7%) and 5 (10.6%) patients once, twice or three times

Table 1: Baseline sociodemographics and clinical data

Variables		Frequency (%)
Sex:		
Male		26 (55.3)
Female		21 (44.7)
Age (years):		
Mean ± SD	58.2 ± 11.6	
Weight:		
Mean ± SD	78.5 ± 8.2	
Height:		
Mean ± SD	1.68 ± 0.02	
Duration of pain (months):		
Mean ± SD	4.47 ± 4.74	
Pain distribution:		
Unilateral		32 (68.1)
Bilateral		15 (31.9)
Back pain distribution:		
Back pain more than leg pain		14 (30)
Leg pain more than back pain		27 (57.5)
Both equal		6 (12.5)
Numeric Pain Rating Scale:		
Mean ± SD	8.49 ± 1.28	
Oswestry Disability Index:		
Mean ± SD	45.1 ± 11.5	
Total dose of triamcinolone used:	40 mg:	5 (10.6%)
	80 mg:	42 (89.4%)
Co-morbidity hypertension		15(31.9)

respectively. Two intervertebral levels on one side, were injected in all the 29 patients who had the injection once; two intervertebral levels on both sides were injected in the 13 patients who received the injection twice, and two intervertebral levels on both sides were injected in the 5 patients who received the injections three times in this study.

There were 29 and 33 (62% and 70% respectively) patients who achieved 50% or more reduction in their NPRS pain scores from the baseline at 3 and 6 months follow-ups. Observed changes in functional performance were concordant with changes in the pain scores; 36 (77%) and 34 (72%) of the patients improved 10 points or more on the ODI scale at 3 and 6 months follow-up respectively, Table 2.

Overall, statistically significant improvements were obtained and maintained in the patients: the mean reduction in NPRS pain score and mean improvement in ODI score, from the baseline parameters, was 4.9 ± 1.5 and 13 ± 7 respectively, ($p = 0.0001$) at the end of 6 months' follow-up (Table 3).

There was an approximately 50% reduction in total analgesic consumption at the end of 6 months' follow-up ($p < 0.001$). Headache after the injection of contrast medium (1 ml omnipaque iohexol 240 mg) occurred in one patient but resolved within 30 minutes of observation in the recovery room.

Discussion

This prospective observational study shows that patients with lumbar radicular pain achieved significant pain relief and improved performance following fluoroscopic-guided transforaminal lumbar epidural injection of a mixture of steroid and local anaesthetic agent. The results showed that 29 (62%) and 33 (70%) patients achieved a drop in NPRS pain score of 2.5 or more from baseline at 3 and 6 months' follow-up respectively. We chose NPRS pain scores drop of 2.5 or more because studies have shown that clinically relevant success was deemed to have occurred when such a level of reduction is obtained by patients.[7,8] This degree of reduction in pain scores has been shown to correspond to 'much improved' on a patient global impression of change (PGIC) scale for pain.[9] These findings are similar to results of some studies on transforaminal lumbar epidural steroid injection for radicular pain.[7–12] Previous studies on the outcomes of transforaminal and interlaminar epidural steroid injections focused on changes in pain intensity only[13–17] and the impact of radicular pain on functional status, with a validated questionnaire, was not evaluated. In contrast, the data of the present study and that of Rados *et al*.[9] included information on pain intensity, functional impairment, and correlation between pain and performance. Whereas, our study evaluated the clinical effectiveness of epidural injection in radicular pain; Rados *et al*. compared the efficacy of depositing the steroid into the lumbar epidural space through transforaminal and interlaminar routes. The two studies revealed that long-term (greater than six weeks) pain relief and clinically relevant improvement in functional status of significant proportion of the patients followed transforaminal steroid injections. Furthermore, reductions in pain scores and enhanced performance of daily activities obtained in the present study are similar to the results of some previous studies.[15–18] Pain relief achieved by patients in our study facilitated compliance with physiotherapy, which further enhanced functionality. High treatment success rate was noticed among the patients who received more than one injection and this was supported by the findings from the works of Lutz *et al*. and Riew *et al*.[17,19] The patients achieved better pain control and regained their mobility faster with improved independence. These findings could be explained by the ability of bupivacaine to instantly block nociceptive signals from the inflamed nerve or its roots and the slow anti-inflammatory effect of steroid in reversing the phospholipase A2-induced inflammatory process.

Table 2: Summaries of Numeric Pain Rating Scale for pain and Oswestry Disability Index scores at three different times

Time points	Numeric Pain Rating Scale (Mean ± SD)	Oswestry Disability Index (Mean ± SD)
Baseline	8.49 ± 1.28	45.1 ± 11.5
3 months	3.98 ± 1.31	33.4 ± 11.1
6 months	3.55 ± 1.46	32.4 ± 11.5

*Outcome measurements were achieved by NPRS: Numeric Pain Rating Scale; ODI: Oswestry Disability Index.
**Based on Student's paired *t*-test.
***Based on NPRS and ODI.

Choi *et al*.[20] showed that lumbar transforaminal epidural steroid injection was more effective for a contained herniated disc or when the disc content is abutting on the spinal nerve. The evaluation of the MRI findings of our patients at presentation showed anterior impingement on the thecal membrane by the intervertebral disc content, which was assumed to be confined to within the neuroforamen, a prerequisite to achieving good response in radicular pain after steroid injection. The results of our study are consistent with findings of a systematic review[15] on the effectiveness of the treatment of radicular pain with steroid injections.

Our study assessed the effectiveness, and not the efficacy, of an intervention. This is pertinent in that practical studies that measure effectiveness are considered more appropriate than explanatory trials that assess efficacy[22–24] because they highlight the benefits of such interventions. Interestingly, healthcare policy is now being formulated from the outcomes of comparative effectiveness and evidence-based medicine.[25–32]

Aside from the dose of steroid, clinician's experience and training, patient selection, symptom duration, underlying pathophysiology, epidural steroid injection approach, and use of fluoroscopy, vocational and socioeconomic status, and possible psychological issues within the patient group undergoing such conservative treatment have been identified as other factors that may influence long-term and short-term outcomes of the epidural steroid injections.[10] In our study, fluoroscopy was used, a transforaminal approach was employed and only patients with radicular pain from disc herniation were treated in order to ensure maximal benefits from the intervention.

In contrast to non-particulate steroids, triamcinolone was chosen because its large particles, relative to red blood cells, are slowly cleared from the spinal canal[33] and thus it acts longer on the inflamed spinal nerve leading to better pain relief. However, serious complications can occur when particulate steroids act as an embolus[34] during transforaminal epidural technique causing spinal cord infarction and consequent paraplegia. Cortical blindness,[35] paraplegia,[36–40] quadriplegia and death[41–43] immediately after a transforaminal technique as a result of embolisation of particulate corticosteroid in the vertebral artery or radicular artery that reinforces the spinal artery

Table 3: Comparisons of NPRS pain and ODI scores at six months post interventions

Outcome[a]	Mean baseline Value ± SD	Mean six-month value ± SD	Statistically[b] significant difference	Six-month change from baseline	Clinically meaningful[c]
NPRS	8.49 ± 1.14	3.55 ± 1.46	Yes ($p < 0.001$)	4.94 ± 1.48	Yes
ODI	45.1 ± 11.5	32.4 ± 11.5	Yes ($p < 0.001$)	12.7 ± 6.5	Yes

[a]Outcome measurements were achieved by NPRS: Numeric Pain Rating Scale; ODI: Oswestry Disability Index.
[b]Based on Student's paired *t*-test.
[c]Based on NPRS and ODI.

have been reported by some authors. In our study, headache and lethargy, which resolved spontaneously, were observed in two patients. Continuous fluoroscopy during and throughout the injection of omnipaque iohexol contrast medium was utilised to exclude intra-arterial flow away from the site of injection after which the triamcinolone/bupivacaine mixture was injected onto the target nerve roots to prevent any such serious complications.

The weakness of this study is the lack of a placebo or control group. However, studies on interventional procedures where placebos were used led to conflicting outcomes due to inappropriate methodology.[24,25] Nevertheless, the placebo agent was found to be significantly ineffective in a properly designed clinical trial[31] and, with this finding, absence of a placebo group in our study may not cast a serious aspersion on the clinical validity of our results. For now, there is no agreed position on what volume and dose of steroid should be injected in epidural steroid injection.[11–13]

In conclusion, this study demonstrated that fluoroscopic-guided transforaminal epidural injection of a mixture of steroid and local anaesthetic agent is effective in controlling pain, enhancing functionality and improving independence of patients with lumbar radicular pain secondary to intervertebral disc herniations.

Disclosure statement – No potential conflict of interest was reported by the authors.

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