ORIGINAL ARTICLE

OUTCOME ANALYSIS OF TWO DIFFERENT INJECTION SOLUTIONS FOR EPIDURAL INJECTION IN RADICULAR LUMBAR BACKACHE SYNDROMES

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Background: Backache is a significant source of disability and suffering in our society. The treatment modalities need continued enhancement in order to achieve the desired goals of lowering morbidity and financial losses while improving the response of the patient. **Methods:** This prospective comparative study was conducted at the department of Orthopaedics and Spine Surgery, Khyber Teaching Hospital Peshawar from July 2013 to June 2015. Two interventional groups were designated; Group 1 was comprised of 54 patients who were injected with epidural bupivacaine plus methylprednisolone while Group 2 included 55 patients who were injected with bupivacaine only. Outcome was assessed using the visual analogue scale and Oswestry disability index (ODI). **Results:** Fifty-five female and 54 male patients with mean age 49.37 years±10.46 SD, Mean symptoms duration was 15.01 months±9.32 SD. Common presenting symptoms were backache (77.1%), lower limbs pain (66.1%), dermatomal paresthesias (54.1%) and neurogenic claudication in 57.8% patients. The mean visual analogue score (VAS) after injection was 3.18±1.29 while mean ODI after injection was 23.615. There was a statistically significant reduction in VAS scores (2-sided p=0.003, OR =4.03, 95% CI: 1.535–10.60) following the injection. **Conclusion:** An epidural spinal injection is a viable option for achieving relief of pain & improves functioning in individuals with radicular backache. However, further research is advised in order to clarify the role of ESI for long-term relief.

Keywords: Backache, Outcome; Epidural steroid injection; Local anaesthetic

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INTRODUCTION

Ridiculer backache is a significant medical problem which affects about 4.8% of male and 2.5% of female population beyond the age of 35 years. It has been estimated that 75% of patients who experience acute radicular back pain (sciatica) will improve within 10–30 days of the onset of symptoms. Those patients who eventually become candidates for surgical intervention actually make up less than 20% of the backache population.[1]

Patient outcome has improved significantly over the previous two decades owing to advancement in the clinical knowledge, investigative techniques, pharmacological improvement and good medical and interventional procedures.[2–4] Despite the common use of epidural steroid injections (ESI), debate is still ongoing as to the efficacy of the procedure and its long-term benefits.[5]

There is a diversity of anatomical abnormalities detectable clinically radiologically which may cause patients' symptoms. However, a large proportion of asymptomatic individuals also have a diverse array of anatomical aberrations which warrant caution while evaluating such cases, so as to differentiate them from true symptomatic patients with discrete pathology.[6]

The rationale for epidural injections therefore is diagnostic, for identifying nerve roots involved in diffuse radicular pain involving multiple dermatomes, where it is injected with a short-acting local anaesthetic and if relief is obtained, the root is identified, and therapeutic purposes in radicular backache.[7] The rationale for therapeutic intervention is the control of local inflammation which give rise to noxious inflammatory substances.[7] Newer techniques such as CT guided transforaminal, Doppler guided caudal injection of steroids, local anaesthetic or their combination has shown improved outcome results both in their rapid onset of action and prolonged treatment effects.[8,9] However, many other studies and clinical reviews have shown that these procedures are of little or no value in management of radicular backache and instead must be strictly reserved for very mild cases of backache.[7,9–11]

The purpose for our study was therefore, to ascertain whether or not our patients would be benefited in terms of short pain relief with quantification of the pain relief and functional effects? The goal therefore was first to achieve an

effective relief of pain, which would be a decrease of 50% or more reduction in pain scoring and second the attainment of functional improvement to the degree where pain medication and disability are reduced to acceptable levels.

MATERIAL AND METHODS

The study was commenced after the Institutional Ethical Review Committee approval. It was conducted from July 2013 to June 2015 at the department of Orthopaedic & Spine Surgery, Khyber Teaching Hospital Peshawar. It was a quasi-experimental, prospective interventional study where we randomised patients to the treatment groups after taking their consent for inclusion into the study.

After careful clinical history and examination, the patients were investigated with lumbar spine MRI study. All patients were assessed for clear surgical indications by using the clinical red flags for spine patients. Pre-injection Visual Analogue Score (VAS) and Oswestry Disability Score (ODS) were recorded. The same scores were also recorded post-injection. All data was collected using digital charts designed in Microsoft Excel 2016.

We selected patients specifically with a diagnosis of chronic backache, i.e., >12 week duration.

- All the patients who came to the backache specialty care service with a confirmed diagnosis of lumbar spine disorders such as stenosis and prolapsed intervertebral discs and those who opted for the epidural steroid injections for their backache were included.
- Patients with multilevel root involvement on MRI, equivocal cases with non-specific radicular leg pain, central spinal stenosis and those who were either not willing for surgery or due to high anaesthesia risk could not be operated safely were included.
- A sample size of 120 patients was calculated using MedCalc version 14.8.1 and utilising the estimated EPR of 86% in group 1 and 50% in group 2,[12] keeping alpha at 0.01 and beta at 0.05.
- 11 patients were ultimately operated for their backache conditions on emergent basis.
- We decided to include patients only with herniated discs or spinal stenosis so as to minimise the confounding effect of the causes of non-specific backache or other pathologies. Red flag signs for serious spinal disease were associated fever, unexplained weight loss, known history of cancer, use of intravenous drugs, severe or rapidly progressive pain and motor deficit and features of cauda equina.
- Similarly, patients with pain attributable to facet joints pathology were excluded due to variable responses and different injection techniques requirement.
- Backache due to facet joint disease usually present with moderate to severe mechanical back pain which in majority of cases do not present as radicular pain. Similarly, on lumbar spine CT or MRI, facet joint hypertrophy or cyst. Those patients who were straight-forward candidates for surgical intervention such as those with acute foot drop, cauda equina syndrome, tumours, cysts and vascular pathologies were also excluded.
- Also patients with established diabetic neuropathy or peripheral vascular disease were excluded.
- Immunocompromised patients, those with coagulation defects, those with local infection or those with bony spinal deformities were also excluded.

We used the fluoroscopy guided interlaminar injection technique for all patients. Patients were positioned in a lateral recumbent position with the side of pain downwards. Careful marking was performed for the injection level intervertebral space using the anatomical landmarks and fluoroscopy. Injection was performed one level above the involved level in a prolapsed intervertebral disc (PID) or one level above in a multiple level stenosis patient. Drugs used in Group 1 were 40 mg of Methylprednisolone in a 2.5 mL normal saline solution and 1.5-2 mL of 0.25% Bupivacaine. In Group 2 bupivacaine solution of 0.25% concentration was used. An 18/20-Gauge Tuohy type spinal needle was used for the injection using direct fluoroscopy and the loss of resistance technique.

After aseptic technique the marked site was injected with local anaesthetic (2% Lignocaine). The spinal needle was connected to a 3 cc syringe with 1 mL of air. Maintaining pressure on the plunger, the needle was advanced through the interspinous space. Once a loss of resistance was felt the position of the needle was confirmed using the C-arm fluoroscope. The syringed with prepared solution was attached to the spinal needle and the solution was slowly injected. After the injection the patient was kept in supine position for 10 minutes and his vitals monitoring was done. Any complaint was recorded and managed accordingly. After the injection the patient was sent home with oral medications (Paracetamol + Tramadol TDS, and Naproxen 500 mg BD) for local pain relief and was called for follow up at 4-week duration. The patient was also provided emergency contact number in case of reporting any complications arising during the stay period.

Patients were followed and examined in the outpatient department at the end of 4th week after injection. Complete neurological examination was performed and attention was paid to the local injection site for any infective complications or CSF leaks. VAS and OSD were recorded and further treatment advised if necessary.

Data collected in the digital charts was uploaded into IBM SPSS version 22.0. Patient demographics, presenting features and clinical findings were all displayed using frequency tables and charts. Chi-square analysis and Mann-Whitney U tests were used for testing the categorical data. A binary logistic regression and paired samples t-test were performed taking into account the effect of predictor variables on the outcome variables. Results were considered significant if p was ≤0.05.

RESULTS

Due to the loss to follow-up of 11 patients, we were left with 55 patients in Group 1 (local anaesthetic+steroids) and 54 patients in Group 2 (local anaesthetic only). There were 55 (50.5%) female patients and 54 (49.5%) male patients with a male to female ratio of 0.9:1. Mean age through both groups was 49.37 years±10.46 SD. Mean symptoms duration was 15.01 months±9.32 SD.

The common presenting symptoms were backache (77.1%), lower limbs pain (66.1%), dermatomal paresthesias (54.1%) and neurogenic claudication in 57.8% patients. The straight leg raise (SLR) test was positive in 59.6% patients while none of the patients were having motor weakness, bowel bladder loss or significant muscle atrophy as such cases were excluded from the sample. Prolapsed intervertebral disc (PID) was diagnosed in 72.5% while 27.5% patients were having spinal canal stenosis. More than 70% (n=77) patients had positive history of medical treatment for the same problem. (Table-1)

The mean VAS before injection was 7.48±0.918 SD (median=7.0) while mean Oswestry Disability Index (ODI) before injection was 52.35 (mean ODS=26.18)±6.19 (median=54.0). (Table-2) The mean VAS after injection was 3.18±1.29 (median=3.0) while mean ODI after injection was 23.615 (mean ODS=11.81)±7.62 (median=22.0).

Overall there were 27 (24.8%) patients who were ranked in the unfavourable group due to suboptimal EPR while 82 (75.2%) patients achieved favourable outcome (p=0.003). Similarly, 49.5% (n=54) patients achieved the minimal disability score (ODI = 0–20%) while 50.5 % (n=55) patients achieved the moderate disability score (ODI=21–40%).

31.2% (n=34) patients had favourable outcome according to VAS pain score while 18.3% (n=20) patients had unfavourable outcome in Group 1 (Bupivacaine+Methylprednisolone). Similarly, 44% (n=48) patients had favourable outcome according to VAS pain score while 6.4% (n=7) had unfavourable outcome in Group 2 (Bupivacaine only).

26.6% (n=29) patients achieved a minimal disability score (ODI=0–20%) and 22.9% (n=25) achieved a moderate disability score (ODI=21–40%) in Group 1. Similarly, 22.9% achieved the minimal disability score (ODI=0–20%) and 27.5% (n=30) achieved a moderate disability score (ODI=21–40%) in Group 2. The Chi-square analysis, however, did not show a significance of association between the two groups in terms of functional improvement (p=0.38, OR=1.39, 95% CI: 0.65–2.96). (Figure-1)

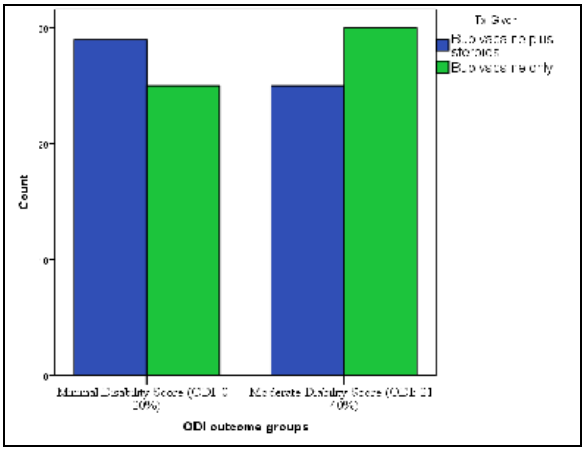

Figure-1: Oswestry Disability Index (ODI) outcome between treatment groups

Table-1: Clinical variables and their frequencies

Variable	Frequency	Percentage	Significance
Gender			0.45
Male	54	49.5	
Female	55	50.5	
Backache	84	77.1	0.87
Lower limbs pain	72	66.1	0.007
Dermatomal paresthesias	59	54.1	0.91
Claudication	63	57.8	0.053
Positive SLR	65	59.6	0.61
Diagnosis			0.38
PID	79	72.5	
Stenosis	30	27.5	
Comorbidities	46	42.2	0.61
Past Treatment	77	70.6	
Complications			
Local pain	15	13.8	
Headache	10	9.2	
Urinary retention	8	7.3	
Arachnoiditis	5	4.6	
Transient weakness	4	3.7	
Haematoma	3	2.8	
Outcome (VAS)			
Favourable	82	75.2	
Unfavourable	27	24.5	

Table-2: Quantitative variables and their statistical representation

	Patient Age	Symptoms Duration	VAS before Injection	VAS after Injection	ODI before Injection	ODI After Injection
Mean	49.37	15.018	7.477	3.183	52.349	23.615
Median	47.00	12.000	7.000	3.000	54.000	22.000
Mode	38	6.0[a]	7.0	3.0	60.0	16.0
Std. Deviation	10.461	9.3254	.9189	1.2484	6.1934	7.6181
Minimum	32	3.0	6.0	1.0	40.0	14.0
Maximum	70	36.0	10.0	6.0	60.0	40.0
a. Multiple modes exist. The smallest value is shown						

Table-3: Paired Samples Test for before and after injection pain and disability scores

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	SD	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	**VAS before Injection - VAS after Injection**	4.2936	1.4096	0.13	4.02	4.56	31.800	108	<0.0001
Pair 2	**ODI before Injection – ODI after Injection**	28.7339	9.6366	0.92	26.90	30.56	31.130	108	<0.0001

Table-4: Analysis of mean scores before and after injections with their independent samples t-test significance and confidence intervals

	Bupivacaine+Steroids (mean±SD)	Bupivacaine only	*p* for treatment groups	Mean Difference	95% Confidence Interval of the Difference
VAS before inj.	7.33±0.75	7.62±1.05	0.10	-0.28	-0.63–0.06
VAS after inj.	3.33±1.44	3.03±1.02	0.21	0.29	-0.18–0.77
ODI before inj.	51.29±6.41	53.38±5.84	0.79	-2.08	-4.42–0.24
ODI after inj.	23.11±7.81	24.11±7.46	0.49	-0.99	-3.89–1.90

The data was checked for normality using the Smirnov-Kolmogorov method and tests of significance were applied. On Chi-square analysis between the treatment groups (Group 1 & 2) versus unfavourable/favourable outcome in terms of effective pain relief (EPR) of ≤50% reduction on VAS, there was a statistically significant association (2-sided p=0.003, OR=4.03, 95% CI: 1.535–10.60).

After performing a Paired Sample t-test for the VAS scores, before and after injection (mean difference=4.29, 95% CI: 4.03–4.56) and ODI before and after injection (mean difference=28.73, 95% CI: 26.90–30.56) it was found that the mean difference between pre- and post-injection VAS and ODI was statistically significant (p<0.001) irrespective of the injection solution as is shown in table-3. However, by comparing the two solutions in an independent samples *t*-test, no significant difference was noted for the two groups of injection solutions as is shown in table-4

These results show that the two treatment methods are comparable to each other, however, the steroid + bupivacaine (Group 1) combination is associated with more favourable outcome. Moreover, it shows that though there has been significant improvement on functional scales, both of the treatment methods are efficacious. (Figure-1)

The most common complications were local pain (13.8%), headache (9.2%) and urinary retention (7.3%). Almost all of the complications were transient in nature and resolved within 3 hours of the procedure. Three (2.8%) patients developed a spinal epidural hematoma; however, all were managed conservatively.

DISCUSSION

Backache is a highly prevalent medical condition which ranges from 60–90% in various meta-analysis.[13] Similarly, various reviews have shown that imaging features of degenerative spine disorders are highly prevalent and ranges from 37% in the 2nd & 3rd decade to more than 90% at the 8th and 9th decade of life.[6] The impact of such a diverse disorder are predictably immense in terms of individual morbidity and economic losses.[14] The estimated economic impact of pain ranges from $261 to $300 billion.[15] Among these more than $80 billion are paid in backache and spinal problems care.[16] Such higher costs also demand establishing the right diagnosis and judicious treatment approach.

Epidural steroid injections are one of the most commonly practiced treatment modalities and a lot of research has been focussed to study their effectiveness.[5,7,11,17] Despite such a wide use, however, there is no consensus among the pain experts as to the true role of spinal epidural injections. Although it is not approved by FDA, it is still widely used for the early or short-term relief of back pain in selected patient populations.[17,18,19] Despite the ongoing debate, no consensus guidelines are established, however, it has been advised that in

carefully selected patients, better benefits can be achieved.[11]

In a systematic review of 31 well designed randomised controlled trials which investigated the use of epidural steroids, local anaesthetics, normal saline or a combination of some of these, Manchikanti L *et al*[18] has concluded that epidural steroid injections are successful both in short- and mid- to long-term relief of pain utilising any of the above stated solutions. This level I evidence also suggested that local anaesthetic, steroids or saline were all effective, however, the steroids or mixture of local anaesthetics with a steroids were more effective in radicular pain due to prolapsed intervertebral disc.[18] Moreover, the same systematic review has also shown that transforaminal injections with fluoroscopic or CT guidance were even more effective than the interlaminar or facet joints injection techniques.[18] These findings are concurrent with the results of our study where we observed improved VAS pain scores at the end of 4-week follow-up period (p<0.0001, mean difference=4.29, 95% CI: 4.03–4.56).

Another systematic review involving 11 randomised controlled trials of epidural injections, Abdi S et al[5] concluded that almost all patients reported positive short term relief (<6 week) while two studies reported long term relief (>6 week). Only 3 trials reported negative short or long-term relief of radicular symptoms.[5] However, the authors are of view that evidence for epidural steroid injections in the management of lumbar radicular pain is moderate for short-term while weak for long-term benefits.[5] Epstein NE[20] in a review of literature has outlined the risks and complications of epidural steroid injections. The author has identified a high number of infectious complications and risks associated with the chemical nature of the injection solution and advised that patient should not be exposed to such high risks for a short-term relief from pain.[20] Complications described in this review were concurrent with our study where we found local pain (13.8%), headaches (9.2%), urinary retention (7.3%) and spinal haematoma (2.8%). Although we observed cases of chemical arachnoiditis (4.6%), there were no cases of septic meningitis, wound infections, epidural abscess or CSF leaks. (Table-1) All of the complications in our study were transient and symptoms of local pain, headaches and urinary retention were resolved within 3 hours of the injections. However, it is prudent to state that withdrawing a therapeutic modality due to the occurrence of transient and rare complications is injudicious, because even the surgical interventions for radicular backache are not free of complications and risks.

The notion of short-term relief and no long-term benefits of the procedure should be looked in the light of alleviating patient symptoms shortly in order to provide time for the spontaneous improvement in radicular symptoms, which occur in more than 75% of patients. Miller *et al*[19] has shown that such procedures should be performed within the emergency department for those patients in whom aggressive medical treatment has failed. They have shown that these procedures can cut hospital length of stay, cost of treatment and provide early pain relief.[19]

The major weaknesses of our study were no control groups, no blinding and a limited sample size. These weaknesses can be improved by designing studies with large sample size for better extrapolation for the population, blinding the treatments and instituting control groups. All these measures will help improve for better delineating the role of epidural steroid injections in lumbar radicular pain relief.

CONCLUSION

Lumbar epidural steroid injections are safe and effective for short-term pain relief and modest functional improvement although transient complications of local pain and headaches are common. Bupivacaine plus steroid combination is equally efficacious to bupivacaine injection. Further studies are required in order to improve the evidence base for these procedures.

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