

VALUE OF FLUOROSCOPICALLY GUIDED INJECTION OF BUPIVACAINE AND METHYLPREDNISOLONE IN PAIN RELIEF AND FUNCTION IMPROVEMENT IN PATIENTS WITH DIFFUSE DISC BULGE IN LUMBAR SPINE

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ABSTRACT

Background: Backache is one of the most common prevalent maladies of the mankind. TFESI has been used for symptomatic patients with radiculopathy since about half a century. The studies which have been done show conflicting evidence of efficacy of the treatment modality. **Objective:** To study changes in pain perception and functionality of the patients with MRI proven diffuse disc bulge in the lumbar spine using Visual analogue scale and revised Oswestry disability index after injecting with steroid and local anesthetic combination via transforaminal route. **Materials and Method:** 29 patients with radicular backache and MRI proven diffuse disc bulge were enrolled in the study. Their pre procedure VAS scores and revised ODI scores were calculated. Clinical and radiological evaluation of these patients was done prior to instillation of injection. Post injection, the patients were evaluated for pain relief immediately, at 3 months and 6 months. Change in function was evaluated at 3 months and 6 months. **Results:** The study showed male preponderance with mean age 40.7 years. There was a statistically significant pre and post intervention improvement (p value <0.05) in VAS and revised Oswestry disability index scores up to 6 months follow up. **Conclusion:** It was concluded that transforaminal epidural steroid injection is an effective management therapy for the patients with diffuse disc bulge even at 6 month of therapy with statistically significant improvement in pain and function at 6 months of follow up.

Key words: disc bulge, epidural injection, radicular back pain

INTRODUCTION

Back pain is one of the most common symptoms seen in populations. It is one of the major causes of disease and disability with resultant economic losses due to absenteeism and reduced quality of life. (1)

Backache has an estimated point prevalence of up to 42% (3,4). Jenkins has classified backache as simple mechanical, low back pain with radiculopathy, serious pathological low back pain and low back pain with psychological overlay.(2) Out of the various causes, disc degenerative changes remain the most common and important cause of low back pain with radiculopathy.(2)

Back pain is termed to be chronic when after 12 weeks of conservative management there is no therapeutic benefit. (4) Various treatment modalities are available which can be invasive or non-invasive. Noninvasive treatment modalities include pharmacological agents like NSAIDS or opioid analgesics. The practice of physical therapy, exercise or manipulation may also help in symptomatic relief. Epidural injections form minimally invasive type of management.

Invasive management includes surgical management e.g. surgical fusion with artificial disc placement. Other surgical managements include annuloplasty,

IDET, radiofrequency ablation. Percutaneous disc decompression may be achieved with the help of laser discectomy, radiofrequency coablation, mechanical disc decompression, endoscopic percutaneous discectomy, intradiscal methylene blue injection. (15)

Transforaminal epidural steroid injection is used for these patients after they fail conservative therapy. It acts by reducing pain perception by action of local anesthetic and reduced inflammation as a result of steroid action over the inflammation surrounding the sensory nerve root. This buys time for the action of physiotherapy and other therapeutic intervention.

There are multiple studies done on the transforaminal epidural steroid injections but they have failed to reach consensus on the efficacy of these injections for various causes of back pain, however they are the preferred choice of intervention in discogenic back pain. This study was planned to study changes in pain perception and function of the patients with MRI proven diffuse disc bulge in the lumbar spine using Visual analogue scale and revised Oswestry disability index after administration of steroid and local anesthetic combination through transforaminal route.

MATERIALS AND METHODS

A prospective study was conducted in the department of Radiodiagnosis at a tertiary care hospital from Dec 2014 to Jun 2016.

Sample

Assuming effect size of 0.55 [effect size 0.5 to 0.8 is considered large effect size for mean difference (of the paired differences from baseline to 6 months)] of the VAS score. At a minimum two sided 95% confidence interval and 80% power of the study, estimated sample size is 28. Sample size was estimated using software G Power version-3.1.9.2 (Dusseldorf University, Germany). 29 patients with diffuse disc bulge (proven on MRI) who failed conservative management for 6 weeks were referred to us. They were administered a combination of steroid and local anesthetic through transforaminal route in the epidural space in the lumbar spine after obtaining a valid consent. There were no drop outs from the study. Institutional ethics committee approval was taken.

Outcomes measured

Primary outcome – pain relief

Secondary outcome – functional change using the revised Oswestry disability index.

Inclusion and exclusion criteria

Patients more than or 18 years of age (who could give a valid consent and were able to respond to questionnaire) with MRI proven diffuse disc bulge who complained of radicular symptoms despite 12 weeks of conservative treatment were included in the study. Patients who were unable to provide informed consent, patients with coagulopathy/ using anticoagulant, patient with history of allergy to contrast media/steroid/local anesthetic, patients with unstable spine, compression fracture, spondylolisthesis, cauda equina syndrome, facet joint arthropathy, arachnoiditis, vertebral osteomyelitis and patients with sensory/ motor deficit were excluded from this study.

Technique of administration of the steroid and local anesthetic injection

Under fluoroscopy guidance the epidural space surrounding the effected nerve root was accessed using spinal needles. The epidural space surrounding the nerve root was delineated using iohexol, the spread of contrast was confirmed and documented. A mixture of local anesthetic and steroid was injected in the delineated epidural space after vascular exclusion.

Test of statistical significance

Assuming effect size of 0.55 [effect size 0.5 to 0.8 is considered large effect size for mean difference (of the paired differences from baseline to 6 months)] of the VAS score. At a minimum two sided 95% confidence interval and 80% power of the study, estimated sample size is 28. Sample size was estimated using software G Power version-3.1.9.2 (Dusseldorf University, Germany). We received 29 patients, these patients were evaluated using Visual analogue scale and revised Oswestry disability index for low backache prior to injection, immediately after the injection, at 3 and 6 months of follow up after thorough explanation of the procedure and obtaining informed consent. The scores were subjected to one way ANOVA, F value and P value were calculated and inferences were drawn.

RESULTS

29 patients were enrolled; all patients were evaluated prior to procedure, immediately after the procedure, at 3 months and at 6 months for pain relief and for functional benefit prior to the procedure and 3 month and 6 month. There were no drop outs from the study. Patients with diffuse disc bulge had a mean age of 40.7 years .(Table 1) The minimum age was 24years and maximum age was 73 years (table 1),

median age was 36 years. Sex distribution showed a male predisposition with male=21 (72.4%) and female =8(27.6%). (Table1)

The pre procedure VAS score was maximum 10 and minimum 5 with mean 7.4, median 8, standard deviation 1.29. Immediate post procedure the VAS was calculated as maximum 8, minimum 0, standard deviation 2.2, mean 2, median 2. On 3 month follow up the maximum VAS was 8, minimum 0, mean 1.37, median 0, standard deviation 2.4. On 6 month follow up the scores were maximum 8, minimum 0, mean 1.79, median 0 and standard deviation 2.8. The group showed mean rank= 3.97 pre- procedure, which fell to 2.19 on table it further reduced to 1.81 at 3 month and at 6 month it stood at 2.03. The F value of 64.703 with a p value < 0.0001 was suggestive of statistically significant change in VAS values before and after the intervention. (Table 2)

ODI scores pre-procedure were maximum 43, minimum 13, standard deviation7.27, mean 29.4 and median 32. At 3 months follow up ODI scores were maximum 32, minimum 0, standard deviation 8.9, mean 6.0 and median 3. At 6 months follow up ODI scores were maximum 40, minimum 0, standard deviation 10.8, mean 8.1 and median 5. ODI scores were not calculated immediately after the procedure because it was not feasible to assess these scores immediately after instillation of the drug. Revised Oswestry disability index scores were, mean rank pre TFEI ODI was 29.48, at 3 months it was 6.04, and at 6 month follow up it rose to 8.14. F value was 58.287 with a p value <0.0001 showing significant change in ODI values pre and post intervention. (Table 3)

Correlation with contrast spread

The end point of the study was even opacification of the epidural space. (Figure 1)

Figure1



Fluorospot showing opacified epidural space prior to injection.

DISCUSSION

Our study revealed that local anesthetic and steroid combination is effective in providing pain relief for a period of at least six months. Functional improvement is seen at 6 months of follow up. The benefits are statistically significant (p value <0.05).

Transforaminal epidural steroid injection targets the dorsal root ganglion. Image guidance is necessary for adequate needle placement and drug deposition and to avoid inadvertent intravascular particulate steroid injection

Epidural injections were first tried using cocaine. First epidural injection with steroid was given in 1952. Three different approaches to epidural space have been described namely transforaminal, interlaminar and caudal.(16)

NASS 2012 (North American Spine Society) guidelines recommend MRI as an appropriate preliminary, non-invasive investigation (grade of recommendation A). It also shows insufficient evidence to favor the use of intravenous steroid, gabapentine, or amytriptiline for radicular low backache. NASS 2012 recommends (grade of recommendation A) in favor of contrast enhanced transforaminal epidural steroid injection for guiding and providing short term pain relief treatment of lumbar disc herniation with radiculopathy.

There is insufficient evidence (I) for or against 12 month efficacy of TFESI, and in favor of method of approach for accessing the epidural space. (5) However some studies show persistent improvement till 24 months.

Our study revealed a statistically significant reduction in pain up to 6 months follow up. These patients also showed improved functional outcome at 3 and 6 months of follow up. All patients showed good epidural spread of contrast. These patients reported good pain relief till 6 months of follow up after which the follow up was discontinued .The findings are in agreement with NASS 2012 guidelines.

The most common post procedural complication was local pain due to minimally invasive nature which usually subsided after few hours. No intrathecal injection/ intravascular injections were reported, these were avoided by use of fluoroscopy guidance.

The results of our study match those of Adiguzel et al in that we also demonstrate a homogenous improvement in pain scores and revised ODI scores till three months follow up. Our research however

states that this benefit can be seen at 6 months of follow up also.(6)

The RCT published by Ghahreman et al indicates that > 54% patients who were injected with TFESI showed > 50 % reduced pain score at one month follow up, these gains are well corroborated with reduced disability scores. The effectiveness of the injections is reduced at 12 month follow up. (7) Our study reveals improved pain scores and improved function till 6 months of follow up and it is limited to patients with disc bulge as a primary pathology.

Ng et al state that there is no significant difference seen between the outcomes in the steroid, local anesthetic combination v/s local anesthetic only injection, at 3 month follow up. (8) We on the other hand have found a statistical significant reduction in the patients with disc bulge the difference in outcome may be due to a fact that our patients were only those with diffuse disc bulge, also that our protocol of injection was not restricted to only one injection and that we used 80 mg of methyl prednisolone as against 40 mg by this study. Further studies may be done on the variable steroid doses.

Vad et al report 84 % of patients showing an improved outcome after TFESI as also indicated by our study.(9)

Systematic reviews done by Benny et al and Roberts et al both favor the injection in epidural space for pain relief in patients suffering from backache due to herniated nucleus pulposus.(10,11)

WEST trial states that TFESI amount to transient relief at 3 weeks but not later. Their definition of pain relief was >75% relief.(12) We believe it is arbitrary and too high a cut off. The difference may be related to different patient selection criteria.

Karppinen et al believe that the transforaminal injections are helpful in the management of the contained herniation as in our study.(13)

Carette et al in their popular RCT state that over a 12 month follow up, there is no significant change seen in the function or the need for surgery is not reduced. (14) However the select population in this study was derived by using CT scan as the initial modality for screening the population, as against current gold standard of MRI.

CONCLUSION

Fluoroscopically guided transforaminal epidural steroid injection is an effective treatment modality for pain relief and functional improvement in patients with diffuse disc bulge up to six months of

follow up after obtaining a good spread of contrast in the epidural space. Further studies may be done to determine the dose of steroid and local anaesthetic to be injected. Studies are needed to establish long term efficacies of TFESI. Further research is also needed for establishing the efficacy of the transforaminal epidural steroid injections in various other causes of radicular back pain.

Conflict of interest: none to declare

Economic affiliation: none

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Tables :

Table 1: Distribution of age and sex in study population

	Total	Minimum age	Maximum age	Mean age	Standard deviation	Male	Female
Age	29	24	73	40.7	15.15		
Sex	29					21(27.6%)	8 (72.4)

Table 2: Distribution of VAS in different time Periods

	Mean	Median	Standard deviation	Minimum	maximum	Mean Rank	F value	P value
Pre TFEI VAS	7.44	8	1.29	5	10	3.97	64.7	<0.0001
Post TFEI VAS	2.0	2	2.21	0	8	2.19		
VAS 3 month	1.3	0	2.45	0	8	1.81		
VAS 6 month	1.79	0	2.82	0	8	2.03		

Table 3: Distribution of ODI in different time periods

	Mean	Median	Standard Deviation	Maximum	Minimum	F value	P value
Pre TFEI ODI	29.48	32	7.27	43	13	58.28	<0.0001
ODI 3 months	6.03	3	8.91	32	0		
ODI 6 months	8.13	5	10.9	40	0		

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