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To study the effect of Triamcinolone injection for low back pain due to lumbar disc herniation

Tashi Wangchuk[1], Kuenza P. Wangmo[2], Thinley Norbu[3]

[1]*Khesar Gyalpo University of Medical Sciences of Bhutan, Thimphu, Bhutan*
[2,3]*Department of Anaesthesiology, Jigme Dorji Wangchuck National Referral Hospital, Thimphu, Bhutan*

ABSTRACT

Introduction: Low back pain is one of the most common complaints in the general population which represents a significant public health problem. Epidural Steroid Injection is being considered as a simple, effective and minimally invasive treatment modality for lumbar disc herniation. However, most studies only find a short-term benefit. In Bhutan, till date, no study has been done in Bhutan on this subject. The objective of our study was to find the effect of epidural steroid injection for low back pain due to lumbar disc herniation. **Methods:** An observational one-year-period study completed in Jigme Dorji Wangchuck National Referral Hospital. Symptomatic and positive Magnetic Resonance Imaging patients with lumbar disc herniation were included in our study. Pain scores were collected using Numeric Rating Scale at three different points of study. We also included patients' age, weight and trauma history as some of the independent variables to study their associations with pain scores. The data obtained were analyzed using the Stata software program. One way repeated measures ANOVA was used to assess the significant difference in pain score. **Results:** Out of 100 participants recruited for the study, 91 of them completed demographic data and only 81 patients completed follow-up till 4 weeks post-treatment for demographic analysis and analytical analysis, respectively. There was a significant difference in pain scores in all three different points of study ($p<0.01$). No significant difference was observed in the pain scores amongst different age groups, gender, occupation and trauma history ($p>0.05$) at all three points of study. **Conclusions:** Our study observed a significant short-term benefit from epidural Triamcinolone injection for symptomatic lumbar disc herniation.

Keywords: Bhutan; Epidural steroid injection; Low back pain.

INTRODUCTION

Low back pain (LBP) is one of the most common complaints and it is considered an important public health concern. It can cause major disability and increase the cost of health care[1-3]. It mostly affects those in a socially active age. With Bhutan being no exception, LBP has profound effects on the well-being of Bhutanese and is often the cause of significant physical and psychological health impairments. Prevalence of low back pain varies from country to country. According to Balagué F, Mannion AF, Pellisé F, & Cedraschi C, 2012, the lifetime prevalence of LBP is reported to be as high as 84% [4]. According to Krych AJ, et al., 2012, more than 70 % of the population in developed countries experience acute LBP at some time in their life[5]. Although risk factors and the health burden of LBP have not been studied in Bhutan, many cases of LBP are reported being managed in Bhutan.

Epidural Steroid Injection (ESI) is one of the most common treatment modalities for low back pain and it is being slowly established as a simple, effective and minimally invasive treatment modality[6]. It is however not without adverse events. Literature has described many side effects of epidural steroid injections some of which are minor and others are potentially life-threatening though very rare[7,8]. Minor complications includes; pain on the injection site, vasovagal syncope and weakness whereas some of the life-threatening complications are subdural haematoma, dural puncture, central nervous system infection and spinal cord damage.

There is little evidence which shows that one modality is superior to another. Many international and regional studies have been reported to have significant low back pain relief following ESIs. However, because their methods, findings, and conclusions were all different, the results were inconclusive. A study by Young IA, et al, 2007, stated that there were only a few prospective randomized controlled trials that had clearly demonstrated the positive effect of ESI[9] . The other advantages of ESIs was thought to be reducing the number of LBP patients going for surgery. Manchikanti L, et al., 2012, however, found that the ESIs did not reduce the incidence of Limber Disc Herniation (LDH) patients going for surgery [3]. In general, most of the studies on the effectiveness of ESI reported only short-time benefits[10].

In Bhutan, ESI was first started about 10 years ago in JDWNRH. It still remains the only center providing this service. The coverage of ESI has remained unchanged partly because the effectiveness of the ESI in Bhutan is unclear. There is no similar

Corresponding author:
Tashi Wangchuk
dr.tashiwangchuk@yahoo.com

study done in Bhutan on the effectiveness of ESI. The ESI record in JDWNRH indicates that some patients receive only one single injection while others receive either two or three injections. Only 20 % of total cases who receive ESI complete their full course of three injections. The remainder of the patients opted for either one or two injections. These discrepancies of injections indicated that the benefit among the patients receiving the injections was not uniform and clear. Therefore, we need to find out if a Bhutanese population presenting with LBP would benefit from ESI.

There are reports of gender being an influencing factor for the response to pain treatment from ESI. Some factors found to influence the incidence of sciatica included increased height, age, genetic predisposition, and physical occupations[11].

The objective of this study was to find the effectiveness of our routine Triamcinolone injection in the management of symptomatic lumbar disc herniation in JDWNRH. We suspected to find only a short-term benefit from epidural 80mg Triamcinolone injection. As some factors were reported to have an influence in the treatment response of ESI**,** an assessment was also done to find any differences in the treatment outcomes with the injection between gender, age groups, occupation, and trauma history.

METHODS

This study was an observational study to assess the effectiveness of epidural Triamcinolone injection for patients with symptomatic LDH**.** It was carried over a period of one year from January 2016 to January 2017 at the department of anesthesiology in JDWNRH, Bhutan**.** Follow-up was done in week two and four following the epidural Triamcinolone injection.

The primary outcome variable was pain score at pre-injection and post-injection at week two and four. Other variables were age, sex, weight, occupation, history of trauma and geographical distribution of the patients.

The study proposal was developed as per the guidelines of the Khesar Gyalpo University of Medical Sciences of Bhutan (KGUMSB). The research ethics approval was accorded vide REBH Approval Letter No. REBH/Approval/2015/029 dated 14th December 2015.

Inclusion criteria

1. Patients who were advised ESI by orthopedic surgeons
2. Both male and female
3. Age between 17 and 80 years old
4. Both literate and illiterate
5. New case not responding to conservative treatment
6. Clinical and radiologic (MRI) diagnosed case of LDH

Exclusion criteria

1. Patient not consenting to participate in the study
2. Patient with uncontrolled co-morbidities
3. Patients who had already received ESI
4. Patients with other skeletal diseases
5. Mentally and physically challenged patients
6. Patients who have not completed conservative treatment
7. Patients who underwent lumbar surgeries

Sampling Size

The sample size was calculated empirically based on the following parameters.

1. The estimated population who would come for ESI in a year was taken as a round up number of 300 (ESI in 2014 at JDWNRH was 219 patients).
2. The margin of error taken was 10.
3. Confidence level and response distribution were empirically taken as 95% and 50% respectively.

Using these baseline data, the sample size was seventy three. We also verified the sample size through sample sizes used in other similar studies. A very similar study in Nepal on 'The effectiveness of ESI for the management of symptomatic herniated lumbar disc' by Baral BK, et al., 2011, collected sixty two patients[6]. Whereas in another similar study on 'Our experience with ESI in the management of LBP and sciatica' also done in Nepal, fifty two patients were used[12]. Based on the baseline data and the sample sizes used in other similar studies, we aimed for one hundred participants, a number large enough to represent and compensate for a few dropouts in the due process of the study.

Sampling technique

It was non-randomized sampling. We included all those participants meeting the inclusion criteria. The method of sample recruitment is shown in Figure 1.

Procedure

As routinely done for the ESI in JDWNRH, all equipment necessary for ESI were prepared before a patient was brought into the recovery room. A questionnaire was developed to collect all necessary information. After the general demographic information, each patient was given NRS of pain and asked to grade his/her average pain scores in numbers from 0 to 10 where '0' signified no pain and '10' the worst pain possible. As the intensity of pain felt by the participant is not same throughout the day, weeks and months, we took their average pain score instead of one particular point of the period. Follow-up interview for pain score was done in week two and four via telephone after the first dose of ESI.

For this study, NRS was used as it was easy and more comprehensible and required no additional training to record it accurately. VAS was not a feasible option for telephonic follow-up, unlike NRS. Data collection was done over the period of one year.

Statistical analysis and software used

The data collected were analyzed using Stata version 13.2 (StataCorp. 2011. Stata Statistical Software: Release 13. College Station, TX: StataCorp LP). A descriptive analysis was done to assess the normality of the pain scores and other continuous variables. The unconditional or univariable association between the outcome variable (pain scores) and each explanatory variable (variables that may affect the efficacy of the treatment outcome) were assessed. The effect of the ESI on pain scores was assessed using One-way ANOVA with repeated measures as each patient was assessed repeatedly at three-time intervals (pre-ESI, week two and week four post ESI treatment). The pairwise comparison of the pain scores among the three-time point was assessed using post hoc test. The statistical significance of the one-way repeated measures ANOVA was assessed at 5% significance.

RESULTS

Out of 100 participants recruited for the study, 91 of them, 55 (60.44%) male and 36 (39.56%) female completed the demographic data, and only 81 of them, 35 (43.21%) male and 46 (56.79%) patients completed follow-up till 4 weeks post-treatment (Figure 1). 9 patients refused to participate in the study. ESI was not given to 2 participants because one had elevated blood pressure and one refused to receive it inside the procedural room. 7 of them could not be contacted during follow up at week-two and one of them could not be contacted during follow up at week-four.

The result of One-way ANOVA with the repeated measure is shown in Figure 2. There was a significant beneficial effect of ESI treatment on reducing the pain score in the patient with low back pain caused by lumbar disc herniation. The average pain score decreased by 1.92 and 2.46 at week two and week four post- ESI treatment compared with pre-treatment, respectively (Table 1). Although statistically significant, the average pain score decreased by only 0.54 units at week four compared with week two post-ESI treatment (Table 1). The pain score to ESI treatment did not differ by age (p= 0.461), weight (p= 0.462), gender (p= 0.795), history of trauma (p= 0.747), occupation (p= 0.261) and regions (p= 0.410).

The 91 participants were analyzed for demographic parameters. The median age was 38 years old, with minimum, 1st quartile, 3rd quartile and maximum age of 17, 25, 50 and 78 years, respectively. The median body weight was 65 kg, with minimum, 1st quartile, 3rd quartile, and the maximum weight of 41, 59, 75, and 100 kg, respectively. The majority of patients who received ESI were male and with no history of trauma (Table 2). The distribution of different occupation of patients who received ESI during the study period is shown in Figure 3.

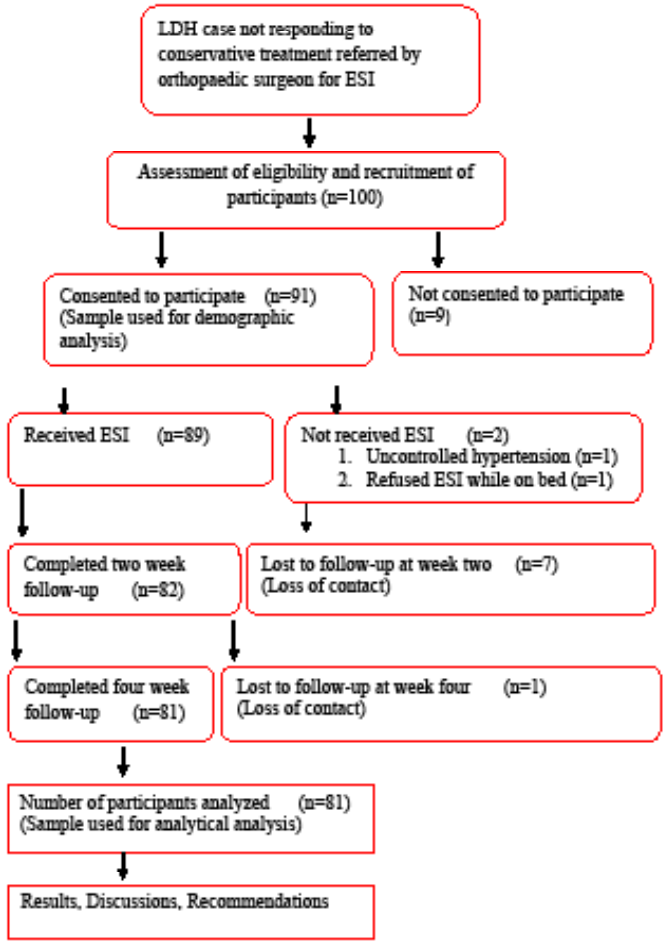

Figure 1. Flow chart of the study

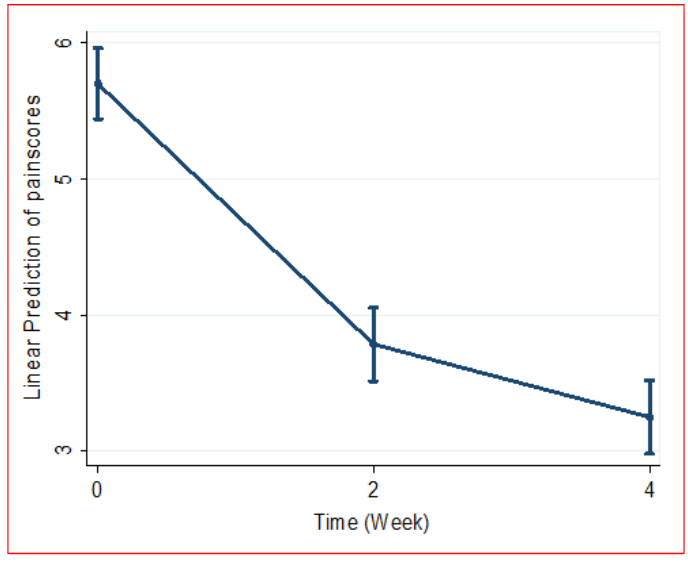

Figure 2. Predicted margin of mean pain scores at three different time points (week zero pre-treatment, week two and week four post-ESI treatment) in 81 patients with low back pain due to lumbar disc herniation at JDWNRH during January 2016 to January 2017. The error bar shows the 95% confidence interval of mean pain scores

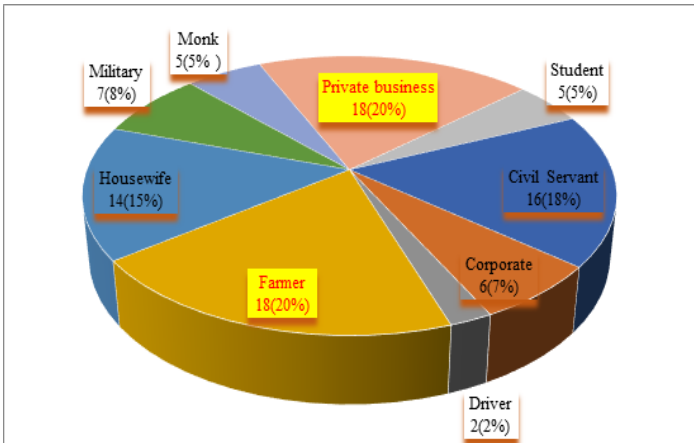

Figure 3. Distribution of 91 patients by different occupation groups who received epidural steroid injection for lower back pain due to lumbar disc herniation at JDWNRH during January 2016 to January 2017

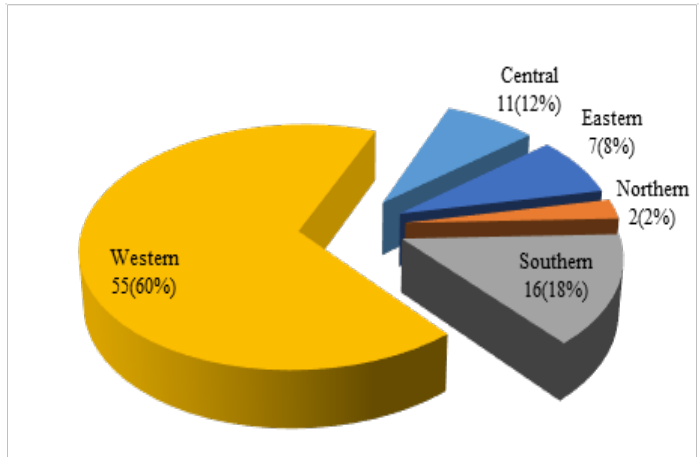

Figure 4. Regional distribution of 91 patients who received epidural steroid injection of lower back pain due to lumbar disc herniation at JDWNRH during January 2016 to January 2017

Table 1. Result of post hoc pairwise comparison of pain scores between three different points of study using One-way ANOVA with repeated measure for 81 patients who received ESI treatment at JDWNRH during January 2016 to January 2017

Comparison between three points of study	Mean predicted difference	p value
Week two versus week zero	1.92 (95% CI 1.54-2.30)	0.000
Week four versus week zero	2.46 (95% CI 2.08-2.84)	0.000
Week four versus week two	0.54 (95% CI 0.16-0.92)	0.006

Table 2. Distribution of 91 patients by history of trauma who received epidural steroid injection for lower back pain due to lumbar disc herniation at JDWNRH during January 2016 to January 2017

Variables	Category	Frequency	Percent
Past History of Trauma	No Trauma	76	83.52
	Fall Injury	10	10.99
	Road Traffic Accident	5	5.49

DISCUSSION

Our study found that after ESI treatment, there was a significant short-term beneficial effect of epidural Triamcinolone injection. It agreed with other research findings[13,14]. Our study, different to some expert opinions in JDWNRH, found that there was no difference in the response to ESI treatment by age, weight, gender, occupation, history of trauma and regions (all *p*-value >0.05).

Our study also showed that lumbar disc herniation mostly affected a younger and male population. It is believed that physical activity and poor postural habits may have contributed to this finding. Generally, in Bhutan, most manual labor requiring physical stress is usually done by men.

Among various occupations, nearly 20% of respondents were either from private business or farmers which represents the highest percentage among occupational groups. While it is unclear why the private business group is affected the most, farmers may be at risk due to the nature of physical stress they undergo while in the fields and farms. We also found that two-thirds of patients in our study were from the western regions. The possible reason may be due to better accessibility and awareness of ESI in these regions. This needs further study. Our study, except for two cases who presented with mild form of vasovagal attack, did not have any life-threatening complications.

The study was one-centered and its result may not represent the situation of whole country. NRS was the only outcome measure used to assess the effect of ESI. The study also had the limitation with the duration of follow up. We took week two and four as the only two points of pain assessment which was very short to interpret its long-term beneficial effect. In the future, a randomized controlled trial with long-term follow-up study is recommended. The radiological classification of disc herniation

may be used as variable to find if it influences the response to ESI.

CONCLUSIONS

There was a short-term improvement of pain from ESI in the management of symptomatic lumbar disc herniation. We also found that unconditional associations between main outcome variable versus independent variables were all insignificant with all *p*-values >0.05. In future, more similar studies on ESI are recommended in Bhutan.

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AUTHORS CONTRIBUTION

The following authors have made substantial contributions to the manuscript as under:

TW: Concept, study design, analysis of data, manuscript drafting and critical reviews
KPW: Concept, samples testing, samples shipment and critical reviews
TN: Concept, samples testing, samples shipment and critical reviews
Authors agree to be accountable for all respects of the work in ensuring that questions related to the accuracy and integrity of any part of the work are appropriately investigated and resolved.

CONFLICT OF INTEREST

None

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