

## Original Research Article

# Assessment of clinical efficacy of nefopam hydrochloride in lumbar disc prolapse patients in secondary care hospital

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**Received:** 01 May 2021

**Revised:** 07 June 2021

**Accepted:** 08 June 2021

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## ABSTRACT

**Background:** In this study assessing the efficacy of 30 mg of nefopam hydrochloride in lumbar disc prolapse patients.

**Methods:** This was a prospective observational study. This study was carried out about 6 months in secondary care hospital. 100 patients are involved in this study. Patient documentation forms, visual analogue scale, patient counselling forms are the materials for this study. In this study patients visiting the Hospital with low back pain patients are included in the study. Pregnancy patients and failed back syndrome are excluded in the study.

**Results:** In this study different age groups of patients as follows 21 patients in 20-30 years of age, 31 patients in 30-40 years of age, 37 patients in 40-60 years of age, 11 patients in 60-80 years of age.

Percentage of pain relief of Nefopam hydrochloride drug therapy as follows, 23 patients in 10-20%, 16 patients in 20-40%, 38 patients in 40-60%, 16 patients in 60-80%, 7 patients in 80-100%. Assessing pain intensity in no. of patients after nefopam hydrochloride drug therapy are as follows 10 patients has no pain, 28 patients has mild pain, 34 patients moderate pain, 15 patients has severe pain, 13 patients are worst pain.

**Conclusions:** In current study demonstrated that the analgesic efficacies of nefopam hydrochloride in low back pain patients. Nefopam shows better action in mild, moderate, severe and worst pain. Nefopam shows high efficacy.

**Keywords:** Visual analogue scale, Patient counselling, Patient Document form

## INTRODUCTION

Globally number of people affected with lumbar disc prolapse. Low back pain is defined as a pain or discomfort located below the margin of the 12th rib and above the inferior gluteal fold, with or without leg pain. The low back that can be related to symptoms in this region include the bony lumbar spine, disc between the vertebrae, ligaments around the spine and discs, spinal cord and nerves, muscles of the low back, internal organs of the pelvis and abdomen, and the skin covering the lumbar area.<sup>1-3</sup> The discs are pads that serve as “cushions” between

the individual vertebral bodies.<sup>4,5</sup> They help to minimize the impact of stress forces on the spinal column. Each disc is designed like a jelly donut with a central, softer component (nucleus pulposus) and a surrounding, firm outer ring (annulus fibrosus). The central portion of the disc is capable of rupturing (herniating as in a herniated disc) through the outer ring, causing irritation of adjacent nervous tissue and sciatica.<sup>6,7</sup>

Nefopam 30 mg sold under the brand names Acupan and Nefopammedisol. It is a pain reducing medication. It is mainly used to moderate to treat acute or chronic pain. It

is believed to work in the brain and spinal cord to relieve pain. Primarily it increases the activity of the serotonin, nor-epinephrine and dopamine neurotransmitters.<sup>8,9</sup> Secondly it modulates sodium and calcium channels thereby inhibiting the release of glutamate a key neurotransmitter involved in pain processing.

Its analgesic effects are not well understood, although inhibition of the reuptake of serotonin, nor-epinephrine and to a lesser extent dopamine is involved. It also reduces glutamate signalling via modulating sodium and calcium channels.<sup>10</sup>

Pain is measured by using the visual analogue scale and statistical analysis are used by the ethical approval of the committee.

### **Aim**

The study is to assess the efficacy of Nefopam HCL and Etodolac in lumbar disc prolapse patients.

### **Objectives**

To assess the efficacy of two drugs between Nefopam Hcl and Etodolac.

To assess the intensity of pain relief in lumbar disc prolapse patients by using visual analogue scale.

### **METHODS**

The study design was prospective observational study. The study was conducted at Sai Nursing home, Yemmiganur, Kurnool, Andhra Pradesh, India. The study period from August 2019 to January 2020.

Sample size of 100 patients for nefopam hydrochloride. Patient documentation form, VAS (visual analogue scale) questionnaire, patient counseling form.

### **Inclusion criteria**

The patients visiting the Hospital with low back pain patients are included in the study. All the patients of either sex, aged above 20years would be included. Patients who are willing to participate only included.

### **Exclusion criteria**

Pregnancy patients and failed back syndrome are excluded in the study. Patients who are willing to participate only included.

### **Study procedure**

Study was done on the representative of nefopam hydrochloride with lumbar disc prolapse patients. An informed consent from the patient was taken before

performing the procedure. We collected data from patient case sheet and noted at patient documentation form. We asked some question regarding the visual analogue scale and we provide patient counselling regarding usage of drug. After completing the data collecting discussing with physician and interpret data.

It is ethically cleared by Institutional review board (IRB)

### **Statistical analysis**

In this study we used MS office, mean and standard deviation as a statistical tool used to analyze the data.

## **RESULTS**

The study was carried out for a period of six months in Sai ram orthopaedic hospital. A total number of 100 patients for Nefopam. In this study males are 46 and females are 54 is displayed in Table 1.

**Table 1: Percentage of males and females suffering from lumbar disc prolapse.**

Percentage of males	Percentage of females
46%	54%

**Table 2: Different age groups of number of patients of lumbar disc prolapse.**

Age group (in years)	Number of patients
20-30	21
30-40	31
40-60	37
60-80	11

**Table 3: Percentage of pain relief of Nefopam hydrochloride drug therapy in lumbar disc prolapse patients.**

Pain relief (in %)	Number of patients
0-20	23
20-40	16
40-60	38
60-80	16
80-100	7

In this study different age groups of patients as follows 21 patients in 20-30 years of age, 31 patients in 30-40 years of age, 37 patients in 40-60 years of age, 11 patients in 60-80 years of age. In the study lumbar disc prolapse patients are between the 30 to 60 years age groups are most effected it is showed in Table 2. Percentage of pain relief of Nefopam hydrochloride drug therapy as follows, 23 patients in 10-20%, 16 patients in 20-40%, 38 patients in 40-60%, 16 patients in 60-80%, 7 patients in 80-100%. while using the nefopam hydrochloride drug 60% pain relief in most of the patients displayed in Table 3. Measuring pain intensity in the patients of Nefopam

hydrochloride drug therapy in lumbar disc prolapse patients only 13% patients having worse pain and 10% patients having severe pain and remaining patients are having less pain it is represented in Table 4. In our study nefopam hydrochloride showed a mean score and standard deviation of VAS to the extent were  $52 \pm 0.27$  respectively. This indicates that nefopam shows more efficacy showed in Table 5.

**Table 4: Measuring pain intensity in number of patients of Nefopam hydrochloride drug therapy in lumbar disc prolapse patients.**

Pain Intensity	Percentage (%)
No Pain	10
Mild pain	28
Moderate pain	34
Severe pain	15
Worst pain	13

**Table 5: Mean and standard deviation of nefopam hydrochloride by using visual analogue scale.**

Visual analogue scale
Nefopam hydrochloride
Mean $\pm$ S.D = $52 \pm 0.27$

## DISCUSSION

Current study was carried out to assess the efficacy of Nefopam HCL and Etodolac in lumbar disc prolapse patients. In this study, it was found that almost 60% patients are relieved from pain while using Nefopam hydrochloride. Nefopam was first introduced as an antidepressant, then it was reported to be efficacious in preventing postsurgical hyperalgesia. It is considered a potent nonopioid analgesic with supraspinal and spinal sites of action.<sup>11,12</sup> The present data indicate that nefopam has a favourable safety profile in relation to many systemic organs of patients who undergo lumbar disc prolapse.<sup>13</sup> Only two previous studies found no analgesic effect of nefopam, and both used continuous administration, after urological surgery and after childbirth, respectively.<sup>14,15</sup> Based on the previous study data, it can be said that combinations drugs with nefopam HCl in human subjects did not induce unexpected side-effects or significant laboratory abnormalities.<sup>16-18</sup>

## Limitations

Limitations of the study were subjects were collected from only one orthopedic hospital; may not represent the whole population of the country; sample size was not enough for the study to find out clinical efficacy of nefopam hydrochloride among lumbar disc prolapse patients due to short duration.

## CONCLUSION

In current study demonstrated that the analgesic efficacies of nefopam hydrochloride in low back pain patients. Nefopam shows better action in mild, moderate, severe and worst pain. Nefopam shows high efficacy.

## ACKNOWLEDGEMENTS

Authors are thankful to giving support to do study.

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: The study was approved by the Institutional Ethics Committee*

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**Cite this article as:** Samarpana S, Chamundeswari Y, Jagadeesh K, Venkatesh C, Vinod G, Kodiganti R. Assessment of clinical efficacy of nefopam hydrochloride in lumbar disc prolapse patients in secondary care hospital. *Int J Res Med Sci* 2021;9:1935-8.