

ACUTE RENAL COLIC; COMPARISON OF NELBUPHINE HYDROCHLORIDE WITH DICLOFENAC SODIUM DURING EMERGENCY MANAGEMENT

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ABSTRACT: Objective: To compare the efficacy of Nelbuphine hydrochloride (opioid) and Diclofenac Sodium (NSAID) in management of Acute renal pain. **Design:** Prospective non-randomized quasi experimental study. **Setting:** This study was conducted in Emergency department (ED) of Combined Military Hospital, Lahore. **Period:** From 1st April 2008 to 31 July 2009. **Patients and Method:** A Total of 100 patients presenting in emergency department with a clinical diagnosis of renal and Ureteric colic were studied. They were randomly divided in to equal and comparable groups, Group A & B. Severity of pain was assessed using a Visual Analogue scale (VAS). Group A was treated with Intravenous Nelbuphine 10mg and group B was given intramuscular Diclofenac Sodium 75mg. Assessment of Pain relief, both onset and complete response was assessed in both groups. In addition to the pain relief, side effects like Nausea, vomiting, respiratory depression, drowsiness and injection site pain were also assessed. **Results:** Nelbuphine was found significantly superior ($p=0.05$) to Diclofenac, both for time of onset of pain relief and complete pain relief. Moreover less patients required rescue analgesia in Group A ($p=0.05$). Only one patient treated with Group A had respiratory depression which was statistically insignificant ($p=0.05$). There was a 3.5% increase in Nausea and vomiting in Nelbuphine treated patients. **Conclusion:** Nelbuphine is a safe and rapid acting Opioid with few side effects. It should be preferred over Diclofenac sodium in treatment of Acute Renal pain.

Key words: Nelbuphine, Diclofenac Sodium, Ureteric, Renal pain.

INTRODUCTION

Renal pain is one of the most common acute emergencies encountered in an emergency Department (ED)¹. Up to 12 percent of the population will have a urinary stone during their lifetime, and recurrence rates approach 50 percent². The risk is approximately 12% for men and 4% for women in the life time³. Having a family member with a history of stones doubles these rates. Peak incidence occurs in people aged 35-45 years but the stone disease can occur in any age group⁴. At average, usual Emergency departments treat at least one patient with acute renal pain every day but this can be more depending upon the prevalence of stone disease in a population⁵.

Renal pain is a syndrome of flank pain which classically presents as sudden severe, colicky pain at the costovertebral angle often radiating to the groin. Usually the patient is keeping one of his hands on the flank and is sometimes tossing in the bed to seek relief. It is one of the most agonizing pains that a human being can ever experience. The role of NSAIDS as well as Opioids is

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well established in emergency treatment of this condition⁶. A number of studies and reviews have been published on the emergency treatment of acute renal pain, mostly comparing NSAIDs with opioids^{7,8,9}. Most of these studies have preferred Diclofenac (NSAID) over Morphine and Pethidine⁶, and the main reason for this is the side effects associated with opioids. Nelbuphine hydrochloride is a relatively newer synthetic opioid agonist-antagonist analgesic of the phenanthrene series. It is chemically related to the widely used opioid antagonist, naloxone, and the potent opioid analgesic, oxymorphone. Its analgesic potency is essentially equivalent to that of morphine on a milligram basis. The onset of action of Nelbuphine hydrochloride occurs within 2 to 3 minutes after intravenous administration, and in less than 15 minutes following subcutaneous or intramuscular injection. Diclofenac Sodium is given via intramuscular injection only.

OBJECTIVES

The purpose of the study was to compare relative efficacy of Diclofenac and Nelbuphine and to document the side effect encountered while the drugs are being administered.

MATERIALS AND METHODS

It was a prospective non-randomized quasi experimental study conducted in the Emergency Department of Combined Military Hospital, Lahore from 1st April 2008 to 31 July 2009. A total of 121 patients with a clinical diagnosis of Renal/Ureteric colic were included in the study and 100 patients were finally selected. In 21 patients the diagnosis of Renal/Ureteric Calculi could not be established on later investigations and were excluded from study. Non probability convenient sampling was used and patients were alternatively placed in to two groups.

INCLUSION CRITERIA

1. All Patients between 18 and 60 years with Radiation Flank pain from loin to groin.
2. Patients with flank pain and haematuria (microscopic/Gross).
3. All Patients which were previously diagnosis case of renal and Ureteric Calculi, or those

who recently had ESWL therapy

EXCLUSION CRITERIA

1. Patients who already had taken analgesic at home or from a general practitioner.
2. Patients with signs of Peritonism i.e. Tenderness and guarding in the abdomen with a suspected diagnosis of Appendicitis, Diverticulitis, Torsion and ruptured ovarian Cyst.
3. Pregnant patients or those with a known history of drug allergy and Bronchial Asthma, chest infections.

All the patients presenting in emergency department with suspected diagnosis of Renal and Ureteric colic were included in the study. Patients were explained about the risks and benefits of both treatment options and informed consent was taken.

A detailed history was taken about the pain as well as associated features like nausea and vomiting, any previous history of such pain episodes, treatment given and any previous diagnosis established. Severity of Pain was documented with VAS by the emergency physician or nurse. Patients sample were taken for blood complete examination, Urine Routine examination and pregnancy test (wherever appropriate). X-Ray KUB was also taken. Intravenous access was obtained through an IV cannula in both the groups and IV hydration was started.

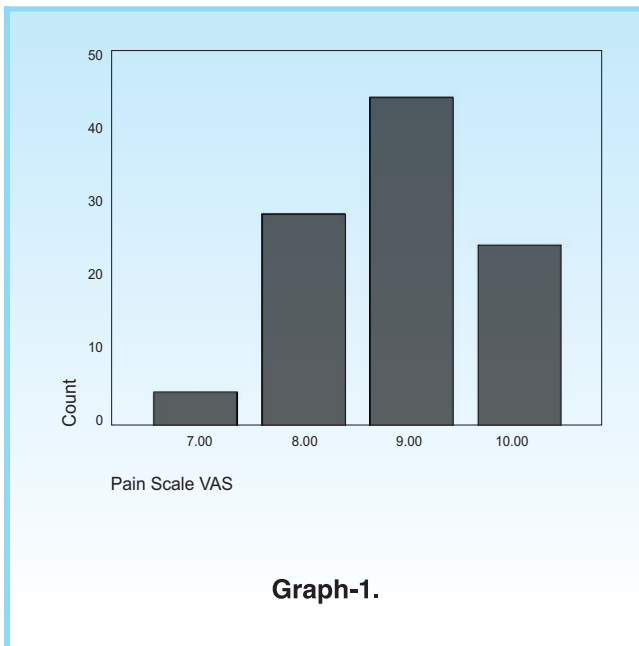
Patients were randomly divided in to two groups, Group A would receive Nelbuphine where as Group B was to be treated with Diclofenac. All the patients were admitted and were detained in ED till complete pain relief. Group A was given Injection Nelbuphine 10 mg via slow intravenous injection while group B was given 75 mg Injection Diclofenac Sodium via Intramuscular route. Those patients who were experiencing significant nausea or vomiting were given Injection Metoclo-peramide 10mg via slow IV injection. Patients were asked to give an estimate of the onset of pain relief (in minutes). Patients were reassessed at 5, 15, 30 and 45 minutes for the onset of pain relief till they achieve complete pain relief. Patients were also closely monitored for side effects like respiratory depression, nausea, vomiting and

drowsiness. Those patients which did not show any response to pain after a lapse of 30 minutes were given rescue analgesia which was Injection Morphine 0.1mg/kg slow Intravenous route.

Ultrasound KUB was done once the patient was pain free and was able to be taken to Radiology Department.

RESULTS

Data was analyzed using SPSS 10.0 for windows. A total of 100 patients were finally analyzed, out of which 13 were females and 87 were males. 19 patients were already diagnosed cases of Renal calculi disease and have had previous episodes of such pain. 57 Patients (57%) rated it to be the most severe pain they have ever experienced with a max VAS value of 10 and the minimum score of pain was 7 which were seen in only 1 patient (1%.) Graph-1.

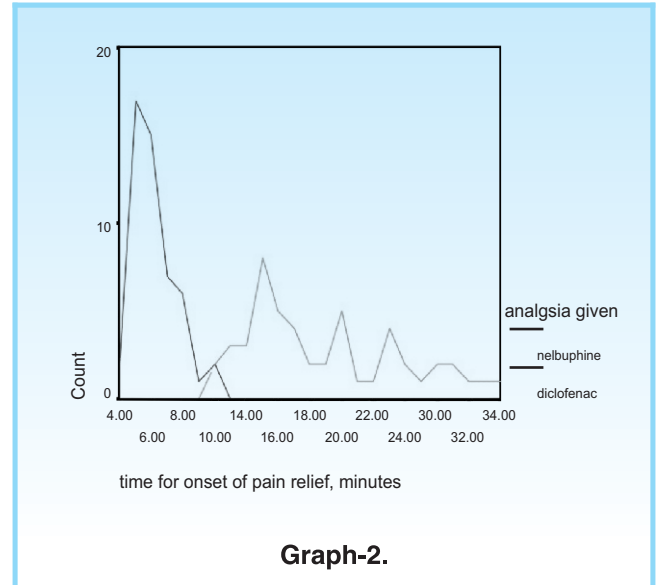


Graph-1.

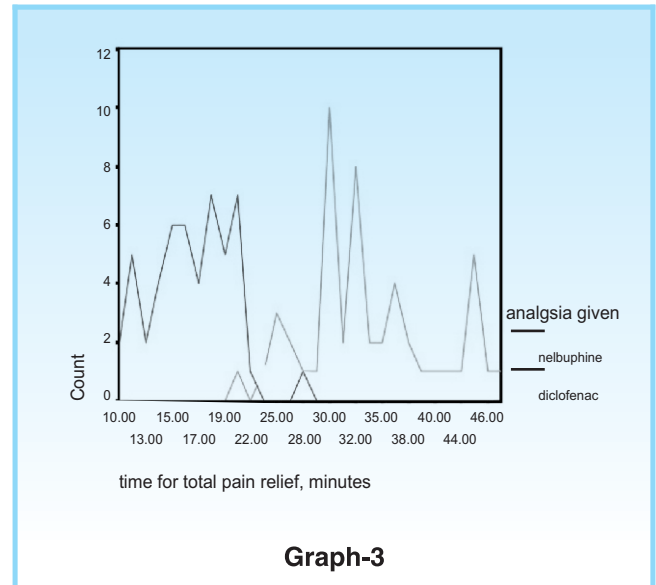
Forty four patients (44%) of the patients were already experiencing nausea and a few have had one or more vomiting episodes, during the pain event, even before any medication was administered.

The pain relief assessment showed that Nelbuphine treated group had much quicker onset of pain relief with

17 ((34%) patients in group A had an onset of pain relief within 5 minutes where as none from Group B had a response till 10 minutes which was significant statistically ($p < 0.05$) Graph-2.



Graph-2.



Graph-3

Mean time for complete pain relief in Group A was 16.54 minutes where as in Group B it was 33.72 minutes (Table-I) Graph-3.

Table-I. Time for total pain relief, minutes

Analgesia given	Mean time (Minutes)	No. of patients	Std. Deviation
Nelbuphine	16.5400	50	3.3394
Diclofenac	33.7200	50	6.6395
Total	25.1300	100	10.0932

Only 1 (0.5%) patient experienced certain degree of respiratory depression which was insignificant statistically with a $p > 0.05$ (Table-II).

Table-II. Respiratory depression after treatment

Analgesia		Resp. depression		Total
		Yes	No	
	Nelbuphine	1	49	50
	Diclofenac	-	50	50
Total		1	99	100

9 (4.5%) patients in Nelbuphine treated group experienced or had an increase in nausea and vomiting (Table-III).

Table-III. Increase in nausea or vomiting after treatment

Analgesia		Increase nausea vomiting after analgesia		Total
		Yes	No	
	Nelbuphine	5	43	50
	Diclofenac	-	50	50
Total		5	93	100

8 (4%) patients treated in Group A experienced drowsiness. Injection site pain was observed in 18 (36%) patients treated with Diclofenac with a significant p value < 0.05 and none was seen in Nelbuphine group.

DISCUSSION

Acute ureteric colic is the most common urological emergencies encountered in most of emergency departments. Gross or microscopic haematuria occurs in approximately 70-80% of patients; however, the absence of haematuria does not preclude the presence of stones¹⁰. Nausea and vomiting are often associated with acute renal pain and occur in at least 50% of patients¹¹.

Diagnosis of renal colic is based on clinical features alone. However best imaging study to confirm the diagnosis of a urinary stone in a patient with acute flank pain is non enhanced, helical CT of the abdomen and pelvis¹², where as previously the gold standard was Intravenous urography¹¹. Pain associated with renal calculi has been managed with both Opioids and NSAIDs^{13,14}. Although NSAIDs are less likely than narcotics to cause nausea, but a significant portion of patients (up to 50%) are already experiencing this and usually require Anti-emetics like Metocloperamide. NSAIDs may further diminish renal function in patients with an obstruction, particularly those with pre-existing renal impairment¹⁵. Most of the studies that have been done previously have compared NSAIDs with Opioids like Morphine, Meperidine and Pethidine⁶⁻⁹ but no comparative study have been found in literature on the use of Nelbuphine in acute renal pain. Nelbuphine hydrochloride is a potent analgesic. Its analgesic potency is essentially equivalent to that of morphine on a milligram basis.

The onset of action of Nelbuphine hydrochloride occurs within 2 to 3 minutes after intravenous administration, and in less than 15 minutes following subcutaneous or intramuscular injection. One of the main advantages of using this drug is the very rapid onset of action and hence a very quicker pain relief as compared to Diclofenac sodium. In our study this drug showed many benefits as compared to Diclofenac and there was no rescue analgesia required and there was no injection site pain in the Nelbuphine treated group which is significantly observed with Diclofenac Sodium. There was a slight increase in the incidence of Nausea and vomiting in the Nelbuphine treated group but we do not consider this single side effect it to be statistically so significant as to

render it inferior to Diclofenac. There is a risk of respiratory depression with Nalbuphine but only one case in our study had this side effect. This drug is associated with sedation and may impair mental and physical abilities required for the performance of potentially dangerous tasks such as driving a car or operating machinery, so patient has to be informed about it.

Limitations of Study: Although Nelbuphine is a widely used potent analgesic but no comparative study has been done between Nelbuphine and Diclofenac previously so we were not able to compare our results with other study. Further studies are needed to be done to draw a final conclusion.

CONCLUSIONS

Nelbuphine Hydrochloride easily available opioid with much quicker in onset, brings about very efficient pain relief in acute renal pain. It has relatively fewer side effects and hence is a safe and effective option in emergency treatment of Acute renal pain. It should be a preferred analgesic in acute renal pain.

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