



AN OBSERVATIONAL STUDY BETWEEN DICLOFENAC SODIUM, HYOSCINE N-BUTYL BROMIDE AND A COMBINATION OF HYOSCINE N-BUTYL BROMIDE WITH DICLOFENAC SODIUM IN PROVIDING PAIN RELIEF IN VARIOUS AGE GROUPS IN CASES OF ACUTE URETERIC COLIC

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ABSTRACT

Introduction: Pain associated with Ureteric colic is severe and excruciating in nature. Anti-spasmodic have logically been given, but the pain relief has not been satisfactory. This study makes an attempt to compare the effects of Diclofenac Sodium alone and in combination & Hyoscine N-Butyl Bromide, in pain relief from Ureteric colic.

Materials and Methods: A prospective, randomized controlled study was conducted with a total of 120 patients, aged between 18 and 50 years, suffering from acute ureteric colic were included in this trial and randomly assigned in three groups. Patients in the first group (A) received Diclofenac, 75mg intravenous. The second group (B) received Hyoscine N-Butyl Bromide, 10mg intravenous & the third Group (C) received Diclofenac (75mg) & Hyoscine (10mg), intravenous. The pain intensity and vital signs were measured at the time of presentation and was reassessed at 0, 15, 30 and 45 minutes on a VAS scoring scale.

Results: After analysis, it was found that the pain relief at 45 minutes with Diclofenac sodium alone or in combination with Hyoscine was better than with Hyoscine N-Butyl Bromide ($p = 0.001$). It was also noted that the onset of relief of the pain was much quicker with Diclofenac sodium alone or in combination with Hyoscine than with Hyoscine N-Butyl Bromide ($p = 0.013$).

Conclusion: Diclofenac, when given as monotherapy or in a combination, has a significantly greater and quicker pain relief as compared to Hyoscine when given alone.

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INTRODUCTION

Epidemiological studies in India have shown renal & ureteric colic to be most common in the dry regions of the country such as desert regions near Rajasthan, Kutch-Saurashtra & North Gujarat (Parikh & Shah 1960; Campbell 2011).

Due importance is given to the study of renal & ureteric colic. A major aspect of this is the immense pain causing severe patient discomfort. Another discrete, yet morbid aspect is the presence of a clinically silent calculi, gradually & insidiously destroying the renal parenchyma. Ureteric colic is characterised by the sudden onset of severe pain radiating from the flank to the groin. The pain is often described as the worst pain the patient has ever experienced & may be associated with nausea, vomiting, hypertension & haematuria (Campbell 2011).

As the majority of small ureteric calculi will pass spontaneously, the focus of acute management should be rapid pain relief, confirmation of the diagnosis & recognition of complications requiring immediate intervention. Conventionally, pain relief in ureteric colic have been achieved with spasmolytic agents either alone or sometimes in combination with opiate analgesics or NSAIDs (Uneno *et al* 1977).

An attempt has been made to compare the pain relief with Diclofenac Sodium, Hyoscine n-butyl bromide & a combination of Hyoscine n-butyl bromide with Diclofenac sodium in cases of acute ureteric colic.

Objectives

To compare the pain relief in patients of Ureteric Colic with Diclofenac Sodium alone, Diclofenac Sodium in combination with Hyoscine N-Butyl Bromide and with Hyoscine N-Butyl Bromide alone.

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MATERIALS AND METHODS

A total of 120 patients aged 20-50 years, presented to Shree Krishna Hospital with acute ureteric colic were included in the randomized, controlled clinical trial study. An approval from institutional ethics committee and written informed consent from the selected patients were obtained. The presence of calculi was confirmed using an ultrasonography. Admitted patients of either sex, diagnosed to have a single ureteric calculus on the basis of history, clinical examination & an ultra-sonographic scan, were included in the study. Patients having multiple calculi, taking treatment on OPD basis with a renal or urinary bladder calculus, with increased Serum Creatinine levels or with a known allergy to either Diclofenac or Hyoscine were excluded from the study. The position of a single calculus was classified within the ureter into the upper third (renal pelvis to the top edge of sacrum), middle third (top edge to the lower edge of sacrum), distal third (lower edge of sacrum to the urinary bladder) & vesico-urinary junction (VUJ).

The patients were randomly divided into 3 groups with Group A receiving Diclofenac, 75mg intravenous, Group B receiving Hyoscine N-Butyl Bromide, 10mg intravenous & Group C receiving both Diclofenac (75mg) & Hyoscine (10mg), intravenous. The pain intensity was then assessed and recorded on a 10-cm linear vertical numeric rating scale (VAS Scale), defined as “10” representing the worst pain the patient has ever suffered and “0” describing the absence of pain. Pain intensity and vital signs were measured at the time of presentation and was reassessed at 15, 30 and 45 minutes (P_0, P_15, P_30 & P_45). Pain at 45 minutes (P_45) was taken as the end point. The criteria for pain intensity were assessed using a standard questionnaire validated by a classic visual analog score. Data were also gathered to determine how rapidly each method of treatment became effective and to what extent was the relief of pain at the end of 45 minutes. If the pain was not reducing within the first 20 minutes or not relieved to 70% of the original, an intravenous injection of 50mg Tramadol diluted in 100ml Normal Saline was prescribed, and the patient would be excluded from the study. Side effects such as dryness of the mouth, vomiting and nausea were strictly observed, and, if required, immediate treatment was administered. Statistical analysis was carried out using the independent T test. The Chi-square test was used to estimate the statistical significance between baseline characteristics and the success of treatment in both groups.

OBSERVATIONS AND RESULTS

In this study we observed that majority (53%) of the patients presenting with ureteric calculi were between the ages of 20 & 29 (Table 1) while none of them below the age of 20yrs or above 50yrs. We also observed that 83% of them being males (Table 2). Majority of the calculi (64.2%) were in & mid ureter and upper ureter while the rest (35.8%) were in lower ureter and vesico-ureteric junction (Table 3).

Results, when compiled, showed that the Mean VAS Score at 45 minutes was significantly lower with Diclofenac & Hyoscine and Diclofenac alone (Fig1) 0.67 (SD=0.8706) & 0.68 (SD=0.7642) as compared to 1.85 (SD=1.2342) with Hyoscine alone. Even the percentage of pain relief achieved by Diclofenac alone or its combination at 15 minutes was 41.50 (SD=20.4613) and 38.98 (SD=20.0216) as compared to 19.71

(SD=11.7667) for Hyoscine. And the percentage of pain relief achieved by Diclofenac alone or its combination at 45 minutes was 89.07 (SD=12.2817) and 89.80 (SD=13.3327) as compared to 70.88 (SD=15.5676) for Hyoscine suggesting that pain relief was quicker and near complete with Diclofenac alone or in combination as compared to Hyoscine alone.

Table 1 Age wise distribution of the patients

Age	Frequency	Percentage
20-29	64	53.3
30-39	24	20.0
40-50	32	26.7
Total	120	100.0

Table 2 Gender wise distribution of the patients

Gender	Frequency	Percent
Females	38	31.7
Males	82	68.3
Total	120	100.0

Table 3 Distribution of calculi according to site

Site in Ureter	Frequency	Percent
Upper	39	32.5 %
Mid	38	31.7 %
Lower	28	23.3 %
VUJ	15	12.5 %
Total	120	100

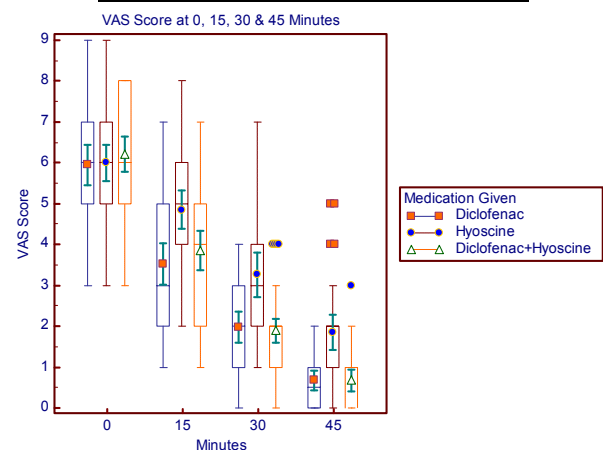


Fig 1 Graphical representation of mean VAS Score of the three groups at 0, 15, 30 and 45 minutes.

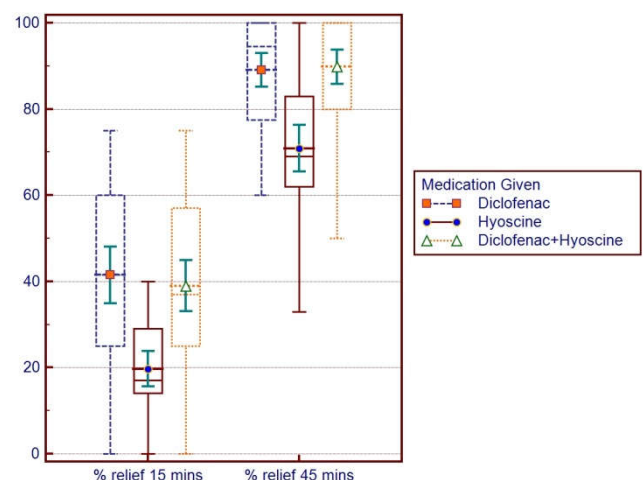


Figure 2 Graphical representation of percentage pain relief at 15 and 45 minutes in three groups

DISCUSSION

This study makes an attempt to find the group which gives better and quicker pain relief. Anti-spasmodics should be the logical choice for pain relief but use of NSAIDs has been seen with encouraging results even without anti-spasmodics (Afshar *et al* 2015).

The current study showed a decrease of mean pain by 4.1 on the VAS scale when monitored 30 minutes after administration of Hyoscine (Group B), which was similar to the study done by Papadopoulos in 2014 [3.3] and Gurbuz in 2011 [3.5] (Abou-Auda 2003, Al-Waili 1999, Yencilek 2008).

Patients in Groups A & C, who were given only intravenous Diclofenac alone or in combination, showed a reduction in pain of 5.3 on the VAS scoring which was very similar to study done by Holdgate in 2004 who obtained a reduction by 4.6.

Abou-Auda (2003) obtained a reduction on the VAS scoring by only 1.6 with Diclofenac.

There was no correlation found between the site of calculus, Age and sex with the pain relief achieved by medications of any group (Holdgate 2004, Roshani 2010).

It was evident that the analgesic effect of Hyoscine was inferior to Diclofenac in this study but its inferior analgesic effect compared to NSAIDs and Opioids has also been suggested in the literature (Papadopoulos 2014).

CONCLUSION

NSAIDs, such as Diclofenac, and anti-spasmodics, such as Hyoscine N-Butyl Bromide, are often used in the management of acute urological conditions such as Ureteric Colic. It was previously thought that as urinary tract smooth muscle spasm is thought to be part of the pathophysiological process, Hyoscine, being an anti-spasmodic, would have a significant effect on pain relief. As per the current study, Diclofenac, when given as monotherapy or in a combination with Hyoscine, has a significantly greater pain relief as compared to Hyoscine when given alone. The results of Diclofenac as monotherapy or combination therapy, on pain relief are comparable. There also appears to be a time-dependent relation to pain reduction following parenteral administration of Diclofenac, with the relief achieved within a shorter duration.

LEGEND/Abbreviations used

VAS	Visualized Analogue Scale
mg	Milligram
USG	Ultrasonography
D	Diclofenac
H	Hyoscine N-Butyl Bromide
D + H	Diclofenac and Hyoscine N-Butyl Bromide
VUJ	Vesico-Ureteric Junction
NSAIDs	Non-Steroidal Anti Inflammatory Drugs
IM	Intramuscular
IV	Intravenous
P_0	Pain at 0 Minutes
P_15	Pain at 15 Minutes
P_30	Pain at 30 Minutes
P_45	Pain at 45 Minutes
Pain_R	Total Pain Relief at 45 Minutes
Pain_R 15	Total Pain Relief at 15 Minutes

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