

COMPARISON BETWEEN PAIN RELIEF ACHIEVED BY DICLOFENAC ALONE AND THE COMBINATION OF DICLOFENAC AND HYOSCINE IN THE SHORT-TERM TREATMENT OF URETERIC COLIC

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ABSTRACT

Object: This study aims to determine whether the combination of diclofenac and hyoscine gives superior pain relief than diclofenac sodium alone.

Design: A prospective, non-randomized comparative study.

Place and Duration of Study: The study was conducted in the Emergency Department of Surgical Unit III at Combined Military Hospital, Rawalpindi from October 31, 2004 to May 01, 2005.

Patients and Methods: A total of 100 patients were included in the study and distributed between two equal groups. Assessment of pain relief was done at 30 and 60 minutes after the administration of drugs. The diagnosis of ureteric colic was confirmed using urine analysis, plain radiography and ultrasonography. It was a prospective non-randomized comparative trial without blinding. A quasi-experimental study.

Results: A significantly ($p < 0.05$) greater number of patients treated with a combination of diclofenac and hyoscine achieved pain relief after 30 minutes as compared to those treated with diclofenac alone. No significant difference was found between the treatment groups after 60 minutes of drug administration.

Conclusion: The combination of diclofenac and hyoscine gave a faster pain relief as compared to diclofenac alone in patients of ureteric colic.

Keywords: Diclofenac, hyoscine, ureteric, colic.

INTRODUCTION

Ureteric colic is an acute pain felt in the loin and radiating to the ipsilateral iliac fossa and genitalia. It is usually caused by the passage of a stone through the ureter.

Ureteric colic is a frequent presenting complaint in the surgical outpatient department [1,2]. The use of non-steroidal anti-inflammatory drugs, especially diclofenac, is well established in pain relief in these patients [3,4]. The role of antispasmodics in relief of ureteric colic has been the subject of many international studies

[5,6]. Despite these clinical trials the role of antispasmodics in relief of ureteric colic is still considered debatable [7-10].

A study conducted by Ali [11] comparing tenoxicam, an NSAID, with buscopan showed that 80% of patients treated with tenoxicam achieved pain relief after one hour as compared to 86% in this study.

Another study conducted by Kumar, et al [12] compared the effect of diclofenac with hyoscine in the symptomatic treatment of acute colic. They showed that 91.7% of patients treated with diclofenac were completely relieved of pain after one hour.. However both of the above-mentioned studies compared the effects of NSAIDS with

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that of hyoscine alone, not with a combination of diclofenac and hyoscine. Ali [11] and Kumar et al [12] demonstrated 72.7% and 69.4% pain relief respectively after one hour of administration of hyoscine alone.

Objective of the Study:

To compare the pain relief achieved by diclofenac alone and the pain relief achieved by a combination of diclofenac and hyoscine in patients of ureteric colic after 30 and 60 minutes of administration of drugs.

PATIENTS AND METHODS

It was a prospective, non-randomized, comparative trial without blinding, a quasi-experimental study. The study was conducted in the Emergency Department of Surgical Unit III at Combined Military Hospital, Rawalpindi. A total of 100 patients having ureteric colic were included in the study. Non-probability convenient sampling was used to place the patients alternately in two groups. The study was conducted from October 31, 2004 to May 01, 2005 (6 months).

Inclusion Criteria:

The inclusion criteria were:

- Adult patients of both sexes, from 18 to 70 years of age.
- A provisional diagnosis of ureteric colic.
- Presence of at least one of the confirmatory criteria for ureteric colic.
- Patients who gave a written informed consent.

Ureteric Colic:

A provisional diagnosis of ureteric colic was based on a history of colicky pain in the flank radiating to the ipsilateral iliac fossa and/or the genitalia.

Confirmatory Tests:

The diagnosis was confirmed in every case by at least one of the following criteria:

- Visualisation of ureteric calculus or indirect evidence of its presence

(Hydronephrosis and/or proximal ureteric dilatation) on ultrasonography of ureter, kidney and bladder.

- Presence of radio-opaque stone on plane radiography of ureter, kidney and bladder.
- Passage of renal calculus in urine.
- More than 3 red blood cells per high-powered field in the urinary analysis.

Intervention:

Administration of Diclofenac alone

The patients treated with diclofenac alone were each given one dose of Diclofenac sodium, 75 milligrams intramuscularly.

Administration of combination of Diclofenac and Hyoscine

The patients in this group were each given one dose of diclofenac sodium, 75 milligrams intramuscularly, along with one dose of hyoscine-N-butyl bromide, 20 milligrams intravenously.

STATISTICAL ANALYSIS

Data was analyzed using the computer software Statistical Package for the Social Sciences (SPSS) for Windows, Version 10. Chi Square Test was used to compare the nominal data of pain relief achieved in the two unpaired groups. The level of statistical significance was considered as $p < 0.05$. Descriptive statistics like mean, standard deviation, frequency and percentage were used to present data regarding the age, sex and laboratory investigations used.

RESULTS

Patient Information:

A total of 126 patients were included in the study. 100 patients completed the study and their data was included in the analysis. The causes of dropping out of 26 patients during study (table). The major reasons were incomplete filling of Data Collection Proforma and because the diagnosis of

ureteric colic could not be confirmed on investigations. The mean age of the patients was 34.36 years. Out of the total 100 patients, 90 were males and 10 females. In the majority of patients, the diagnosis of ureteric colic was confirmed by Ultrasonography as described (fig. 1).

Efficacy Results:

The pain relief assessment showed that 30 minutes after the administration of drugs, 40 patients (80%) treated with a combination of diclofenac and hyoscine achieved pain relief as compared to 31 patients (62%) treated with diclofenac alone. The Chi-square value was 3.93, which is greater than $\chi^2_{0.05}$ value of 3.84, which is statistically significant ($p < 0.05$). This indicates that the combination of Diclofenac and Hyoscine produced a significantly greater pain relief than Diclofenac alone after 30 minutes of drug administration (fig. 2).

After 60 minutes of drug administration, 46 patients (92%) treated with a combination of diclofenac and hyoscine achieved pain relief as compared to 43 patients (86%) treated with diclofenac alone. The chi square value of 0.919 is less than $\chi^2_{0.05}$ which is 3.84 and hence ($p > 0.05$) not statistically significant. This implies that there was no significant difference in pain relief produced between the two groups of patients after 60 minutes of drug administration (fig. 3).

Table: Causes of dropping out of patients during study.

Diagnosis of ureteric colic could not be established by investigations	7
Rescue medication necessitated due to severe persistent pain	4
Left against medical advice	3
Complete data could not be collected	9
Adverse effects of drugs	3
Total	26

DISCUSSION

The study showed that there was a significantly greater pain relief in patients of ureteric colic treated with a combination of diclofenac and hyoscine as compared to those

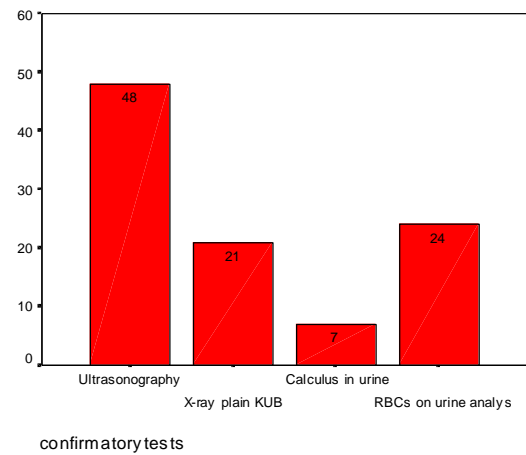


Fig. 1: Confirmatory tests used for diagnosis.

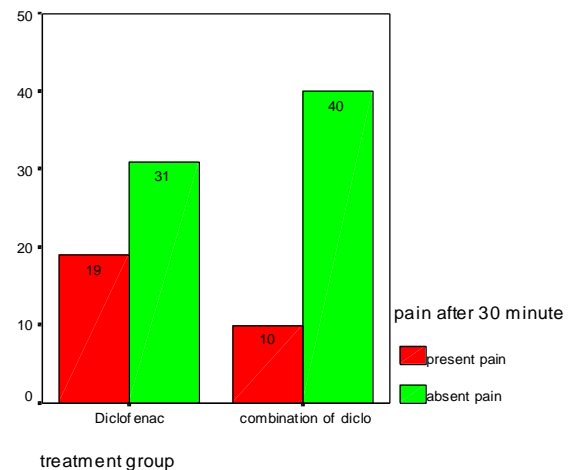


Fig. 2: Relief of Pain after 30 minutes.

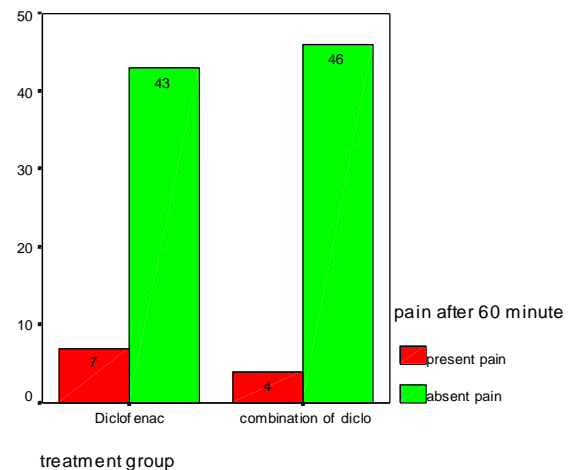


Fig. 3: Relief of Pain after 60 minutes.

patients who were treated with diclofenac alone, after 30 minutes of drug administration. However, no significant difference was found between the pain reliefs

achieved in each group after 60 minutes of drug administration.

The study indicates that the use of hyoscine is beneficial in patients of ureteric colic. Ureteric colic is a very intense pain and rapid relief is important. Therefore even a small increase in effectiveness is desirable. This is also appropriate because hyoscine is a low cost drug. The improvement in pain relief compensates for the slight increase in cost and the discomfort of intravenous administration of hyoscine.

Both treatment groups were similar in terms of demographic features. The mean age of the patients in this study was 34.36 years, which is slightly less than the peak age of incidence described for this condition in the literature [4,5] and the results obtained by other studies [11,12].

The study has certain limitations. The major one is that the study was conducted on a non-representative sample. Thus the conclusions of the study cannot be generalized to the whole population. A possible source of bias in this study is that young overall healthy males are over-represented in the sample because only soldiers and their families are entitled to treatment in CMH. But most of the soldier's families are in villages, so they do not reach CMH for acute short-term illnesses. The soldiers themselves tend to report early for any medical complaint and may exaggerate their symptoms to get excused from their tough routine. Therefore the pain relief may be overestimated due to exaggerated initial pain.

Further research is required using a larger representative sample to enable us to generalize the results obtained in this study. Future studies should be conducted using a quantitative scale of pain intensity instead of the qualitative values used in the study. The quantitative pain scale will allow the measurement of different grades of pain intensity and variable degrees of pain relief obtained in different patients.

CONCLUSION

The combination of diclofenac and hyoscine provides greater pain relief as compared to diclofenac alone after 30 minutes of administration in patients of ureteric colic. This suggests a more rapid onset of action of the combination therapy. After 60 minutes of drug administration, the combination therapy gives a superior pain relief than diclofenac alone but this does not reach statistical significance. The combination of diclofenac and hyoscine can therefore be considered a superior alternative for the management of pain in patients of ureteric colic, where obtaining a rapid as well as prolonged analgesic effect is of particular importance.

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