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ORIGINAL ARTICLE

Use of Drotaverine 80mg with Paracetamol 500mg in Patients with Acute Bacterial Gastroenteristis

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ABSTRACT

Objective: This study's goal is to see whether drotaverine 80 mg and paracetamol 500 mg are as effective and safe as each other in treating individuals with acute gastroenteritis.

Study Design: Randomized control trial

Place and Duration: The study was conducted at the medicine department of Lahore General Hospital and Ittefaq Hospital Trust, Lahore for the period of five months from April 2021 to August 2021.

Methods: Total one hundred and eighty patients of both genders with ages 17-60 years were presented. Patients had acute infectious gastroenteritis with abdominal pain from last 24 hours were included. To obtain comprehensive demographic information, including age, gender, height/weight, and BMI (body mass index), informed written permission was obtained from each patient. A total of two groups of patients were created: I and II. It took two days to provide 80mg drotaverine, together with 500 mg paracetamol, to patients in group I, while it took two days to administer 500 mg paracetamol, along with the same number of patients, in group II. A visual analogue scale (VAS) was used to measure the severity of pain in both groups after treatment to determine efficacy and safety. SPSS 24.0 was used to analyze the data. For categorical data, frequency and percentage were employed.

Results: Mean age of the patients in group I was 30.07±4.28 years with mean BMI 23.07±4.32 kg/m^2 and in group II 28.17±9.88 years was the mean age with mean BMI 22.44±8.21 kg/m^2. Majority of the patients were males 59 (65.6%) in group I and 54 (60%) in group II. Intensity of pain was significantly decreases after 8hrs in group I 1.01±2.17 as compared to group II 4.09±11.34. Post treatment effectiveness among patients in group I was 84 (93.3%) greater than that of group II 54 (60%). The most prevalent side effects in both groups were nausea, vomiting, and dizziness, however the frequency was considerably lower in group I than in group II with a p value of 0.005.Frequency of satisfaction in group I was 88 (97.8%) higher than that of group II 60 (66.7%).

Conclusion: In this study we concluded that the combination of 80mg drotaverine with 500mg paracetamol was effective and safe in terms of pain control and control of infection as compared to the paracetamol alone in the treatment of patients with acute gastroenteritis.

Keywords: Acute Gastroenteritis, Drotaverine, Paracetamol, Efficacy

INTRODUCTION

Many people across the world suffer from acute infectious gastroenteritis. There's a high probability that a virus is at blame. In wealthy nations, acute diarrhoea may be self-limiting, but in children and the elderly, it may cause significant morbidity. In impoverished countries, viral diarrheal diseases, especially in neonates, are the primary cause of death. [1,2] Centers for Disease Control estimates that viral gastroenteritis illnesses kill more than 200,000 children globally each year. [3] In developed nations like the United States, the illness usually goes away on its own in one to three days. However, hospitalisation may lead to increased morbidity and mortality in patients who are vulnerable, such as small children, the elderly, and those who are immunocompromised. [4,5]

As many as half of the population suffers from abdominal pain, cramps, or discomfort. In addition, nearly one in ten patients in general practise experience gastrointestinal complaints [6]. For example, menstrual discomfort, renal colic, biliary colic and spasms in the genitourinary tracts are all thought to be caused by the contraction of smooth muscle fibres. These drugs are safe and generally accessible over the counter, therefore antispasmodics are often utilised for pain management in these situations. Drotaverine, scopolamine, mebeverine, papaverine, and hyoscine are some of the most widely prescribed antispasmodics. Contrary to popular belief, different drugs seem to be favoured in different nations despite the fact that these agents appear to have equal effectiveness and safety across a wide range of stomach symptoms.

In Poland, drotaverine is a popular antispasmodic. Drotaverine's effectiveness and safety have been shown in several controlled studies in patients with recurrent stomach pain, gastritis, IBS, menstrual pain, or renal colic [7-11]. But drotaverine is utilised on a wider range of individuals in clinical practise. Sadly, there are no published studies on drotaverine's usage in the real world. Drotaverine is an example of an over-the-counter medicine that benefits from real-world research. It is possible to find out whether a drug is really being taken in line with its stated purpose via such investigations. Furthermore, real-world studies give valuable information on product safety after launch [12]. Because of this, we investigated the patient profiles of those who had used drotaverine, as well as assessing the most prevalent causes for its usage, and evaluating the drug's efficacy and tolerance. Patients who bought drotaverine at pharmacies and doctors who often prescribe it to patients with abdominal problems were the subjects of this questionnaire-based research.

The purpose of this research was to evaluate the effectiveness and safety of drotaverine HCL 80mg with the combination of Paracetamol 500mg in patients with moderate or severe abdominal discomfort related to infectious gastroenteritis. Randomized controlled trials were used to analyze the results.

MATERIAL AND METHODS

This Randomized control trial was conducted at the medicine department of Lahore General Hospital and Ittefaq Hospital Trust, Lahore for the period of five months from April 2021 to August 2021 and comprised 180 patients. To obtain comprehensive demographic information, including age, gender, height/weight, and BMI (body mass index), informed written permission was obtained from each patient. Participants under the age of 18, had blood in their stool, or who had a gastrointestinal tumour were not included in the study.

Patients having acute infectious gastroenteritis with abdominal pain from the last 24 hours were included. A total of two groups of patients were created: I and II. It took two days to

provide 80mg of drotaverine, together with 500 mg paracetamol, to patients in group I, while it took two days to administer 500 mg paracetamol, along with the same number of patients, in group II. A visual analogue scale (VAS) was used to measure the severity of pain in both groups after treatment to determine efficacy and safety. SPSS 24.0 was used to analyze the data. For categorical data, frequency and percentage were employed.

RESULTS

Mean age of the patients in group I was 30.07±4.28 years with mean BMI 23.07±4.32 kg/m^2 and in group II 28.17±9.88 years was the mean age with mean BMI 22.44±8.21 kg/m^2. Majority of the patients were males 59 (65.6%) in group I and 54 (60%) in group II.(table 1)

Table-1: Baseline characteristics among both groups

Variables	Group I	Group II
Mean age (years)	30.07±4.28	28.17±9.88
Mean BMI (kg/m^2)	23.07±4.32	22.44±8.21
Gender		
Male	59 (65.6%)	54 (60%)
Female	31 (34.4%)	36 (40%)

Intensity of pain was significantly decreases after 8 hrs in group I 1.01±2.17 as compared to group II 4.09±11.34 with p value <0.004.(table 2)

Table-2: Comparison of pain intensity among both groups

Variables	Group I	Group II
Pain Intensity		
2 hrs	8.15±9.56	8.04±13.23
4 hrs	5.8±15.76	6.12±5.25
6 hrs	3.17±12.87	5.5±6.43
8 hrs	1.01±2.17	4.09±11.34

Post treatment effectiveness among patients in group I was 84 (93.3%) greater than that of group II 54 (60%) in terms of pain relief.(fig 1)

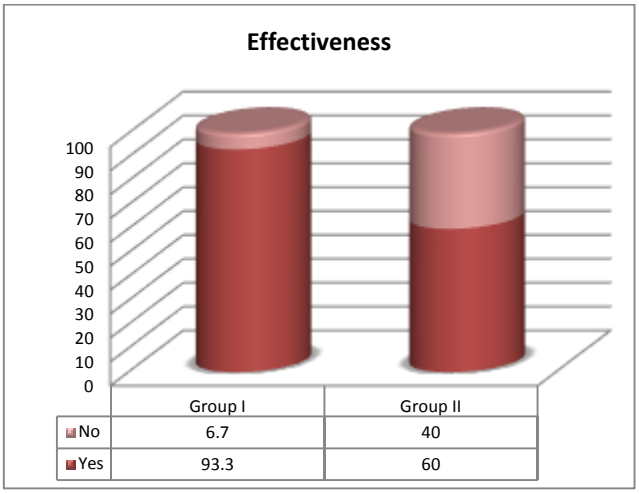

Figure-1: Comparison of efficacy among both groups

The most prevalent side effects in both groups were nausea, vomiting, and dizziness, however the frequency was considerably lower in group I than in group II with a p value of 0.005.(table 3)

Table-3: Post-treatment complications among all cases

Variables	Group I	Group II
Complications		
Nausea	12 (13.3%)	16 (17.8%)
Vomiting	7 (7.8%)	14 (15.6%)
Dizziness	5 (5.6%)	10 (11.1%)

Frequency of satisfaction in group I was 88 (97.8%) higher than that of group II 60 (66.7%).(table 4)

Table-4: Patients satisfaction between both groups

Variables	Group I	Group II
Satisfaction		
Yes	88 (97.8%)	60 (66.7%)
No	2 (2.2%)	30 (33.3%)

DISCUSSION

People suffering from acute infectious gastroenteritis are more likely to have stomach discomfort than those who do not have this illness. Infectious gastroenteritis-related abdominal discomfort has been treated with a wide variety of medicines. [13,14] When it comes to treating stomach pain, Drotaverine HCL 80mg is generally regarded the best option. [15]

One hundred and eighty individuals of both sexes between the ages of 17 and 60 were included in this research. A total of two groups of patients were created: I and II. Group I's average patient age was 30.07±4.28 years with mean BMI 23.07±4.32 kg/m^2 and in group II 28.17±9.88 years was the mean age with mean BMI 22.44±8.21 kg/m^2. Majority of the patients were males 59 (65.6%) in group I and 54 (60%) in group II. These results were comparable to the previous researches.[16,17] In this research, we observed that all of the patients in both groups had a VAS >50 pain intensity at first diagnosis, and that most of the patients had a pain severity score 2 that was deemed moderate. For the next three days, we prescribed medicine three times a day and advised only for follow-up appointments on the second and third days. Intensity of pain was significantly decreases after 8 hrs in group I 1.01±2.17 as compared to group II 4.09±11.34 with p value <0.004. Post treatment effectiveness among patients in group I was 84 (93.3%) greater than that of group II 54 (60%) in terms of pain relief. These results were similar to the study India in which drotaverine 80mg group patients had a significant improvement in relief in pain frequency than the placebo group p=<0.05.[18]

Drotaverine was rated excellent or good by virtually all of the patients who took part in the study because it decreased the intensity of all the symptoms. If drotaverine is acquired without a physician's advise, it is equally effective at all dosages for all people. Overwhelmingly, most patients were pleased with the results of the therapy, which significantly reduced their daily struggle with symptoms. 90% of patients said that drotaverine's start of action was quick or quite quick (similarly to all GPs). Drotaverine has a high rate of patient satisfaction, which indicates that it may enhance quality of life in patients. As a result, further research is needed to determine the influence of drotaverine on quality of life in primary care settings and among patients who self-administer the medication [19].

The most prevalent side effects in both groups were nausea, vomiting, and dizziness, however the frequency was considerably lower in group I than in group II with a p value of 0.005. Frequency of satisfaction in group I was 88 (97.8%) higher than that of group II 60 (66.7%). The findings of this investigation indicated that they were comparable to those of another study in which four individuals had moderate symptomatic side effects such as nausea and headache. [20,21]

In our study, we found that most patients used drotaverine on their own to alleviate symptoms such as stomach pain, menstrual pain, or abdominal cramps. For all symptoms for which it was prescribed, drotaverine had a significant impact on their severity. In general practise, it was the most often prescribed antispasmodic. Patients and GPs found the medication to be effective and acceptable. There were no new safety concerns discovered over the course of therapy.

CONCLUSION

In this study we concluded that the combination of 80mg drotaverine with 500mg paracetamol was effective and safe in terms of pain control and control of infection as compared to the

paracetamol alone in the treatment of patients with acute gastroenteritis.

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