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EXAMINE THE EFFECTIVENESS OF DROTAVERINE WITH PARACETAMOL IN PATIENTS PRESENTED WITH MODERATE OR SEVERE ABDOMINAL PAIN ASSOCIATED WITH ACUTE INFECTIOUS GASTROENTERITIS

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Abstract:

Objective: *To examine the effectiveness and safety of drotaverine 80mg with paracetamol 500mg in patients presented with acute infectious gastroenteritis.*

Study Design: *Randomized controlled trial.*

Place & Duration of Study: *Department of Medicine, Chandka Medical College Hospital Larkana from 1st May 2019 to 31st October 2019.*

Materials and Methods: *Two hundred patients of both genders with ages 18 to 55 years presented with moderate to severe abdominal pain due to acute infectious diarrhea were included in this study. Patients were divided into two groups Group A consist of 100 patients and received drotaverine HCL 80mg and paracetamol 500mg thrice a day for three days, Group B contains 100 patients and received paracetamol 500mg alone with same compliance. VAS was used to examine the intensity of pain. Relief in pain, global assessment of pain relief, decrease of stool frequency and complications were examined and compare the findings between both groups.*

Results: *There were 58% males and 42% females in Group A with mean age of 29.55±10.45 years. In Group B 55% were males and 45% were females with mean age of 31.50±11.25 years. Pain frequency was significantly decreased in 30%, 65% and 90% at 1st, 2nd and 3rd days in Group A than 18%, 45% and 68% in Group B (p=<0.05). Pain severity significantly improved in Group A as compared to Group B (p=<0.05). Stool frequency improvement at2nd and 3rd day in Group A was 65% and 82% and in Group B it was 40% and 64%. Global improvement in abdominal pain by patients in Group A was 96% and in Group B it was 89% and by clinician it was 99% in Group A and 95% in Group B.*

Conclusion: *The use of fixed-dose combination of drotaverine HCL 80mg and paracetamol 500mg is safe and effective oral therapy in patients with moderate or severe abdominal pain due to acute infectious gastroenteritis.*

Keywords: *Abdominal pain, Infectious gastroenteritis, Drotaverine , Paracetamol.*

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INTRODUCTION:

Acute infectious gastroenteritis is a common illness seen around the world. Viral pathogens cause most of these cases. The acute diarrheal disease is generally self-limiting in industrialized nations but can have significant morbidity for young and elderly patients. In underdeveloped countries, viral diarrheal diseases are a significant cause of death, especially in infants.[1,2] According to the Centers for Disease Control, viral gastroenteritis infections can account for over 200,000 deaths of children per year worldwide.[3] In the United States and other industrialized countries, the disease is most often self-limited and resolves in 1 to 3 days. However, in susceptible patients including young children, elderly patients, and the immunocompromised, hospitalization can occur without proper supportive care leading to increased morbidity and mortality.[4,5]

The most common symptoms of acute infectious gastroenteritis are abdominal pain or discomfort often reported as cramping, bloating, gas, diarrhea, and/or constipation.[6] Abdominal pain is one of the most common reasons why people seek medical care and is the most bothersome symptom in patients of acute infectious gastroenteritis.[7] The cause of abdominal pain has traditionally been ascribed to smooth muscle spasm. Therefore, antispasmodics have been and remain the main stay of therapy, but clinical evidence supporting the use is limited. Antispasmodics, namely, hyoscyamine, dicyclomine, propantheline, and mebeverine are commonly used, but they are associated with lot of anticholenergic side effects, which restricts their use. Drotaverine, an antispasmodic, has a good relaxing effect on intestinal smooth muscle, which helps in alleviating pain and does not have side effects like anticholinergics.[8-10]

Present study has been conducted to examine the efficacy and safety of oral drotaverine HCL 80mg with combination of Paracetamol 500mg in patients with severe or moderate abdominal pain associated to acute infectious gastroenteritis.

MATERIALS AND METHODS:

This study was conducted at Department of Medicine, Chandka Medical College Hospital Larkana from 1st May 2019 to 31st October 2019. A total of 200 patients of both genders with ages 18 to 55 years presented with moderate to severe abdominal pain due to acute infectious diarrhea were included in this study. Patients detailed demographic including age, sex, body mass index were recorded after taking informed consent from all the patients. Pain intensity was recorded by using VAS (visual analogue scale). Pain severity score was examined (score 2 as moderate and score 3 as severe. Pregnant females, patients less than 18 years of age, blood in stool and patients with gastrointestinal tumor were excluded. Patients were divided into two groups Group A consist of 100 patients and received drotaverine HCL 80mg and paracetamol 500mg thrice a day for three days, Group B contains 100 patients and received paracetamol 500mg alone with same compliance. Relief in pain, global assessment of pain relief, decrease of stool frequency and complications were examined and compare the findings between both groups.

Statistical Analysis

All the data was analyzed by SPSS 20.0. P-value <0.05 was considered as significant.

RESULTS:

There were 58% male and 42% females in Group A with mean age of 29.55±10.45 years. In Group B 55% were males and 45% were females with mean age of 31.50±11.25 years. Mean BMI in Group A was 22.65±2.44 and in Group B it was 22.94±2.55. 70%, 20% and 10% in Group A and 68%, 18% and 14% patients in Group B had diffuse, umbilical and other pain sites. All the patients had initial pain intensity VAS >50. According to the pain severity score 85% and 15% had score 2 and 3 in Group A and 87% and 13% had score 2 and 3 in Group B (Table 1).

Pain relief frequency was significantly decreased in 30%, 65% and 90% at 1st, 2nd and 3rd days in Group A than 18%, 45% and 68% in Group B (p=<0.05). Pain severity significantly improved in Group A as compared to Group B (p=<0.05). Stool frequency improvement at2nd and 3rd day in Group A was 65% and 82% and in Group B it was 40% and 64%. Global improvement in abdominal pain by patients in Group A was 96% and in Group B it was 78% and by clinician it was 99% in Group A and 85% in Group B (Table 2)

Table 1: Demographic information of the patients

Variable	Group A	Group B	P value
Age (years)	29.55+10.45	31.50+11.25	>0.05
Gender			
Male	58 (58%)	55 (55%)	>0.05
Female	42 (42%)	45 (45%)	
Mean BMI	22.65+2.44	22.94+2.55	>0.05
Pain site			
Diffuse	70 (70%)	68 (68%)	>0.05
Umbilical	20 (20%)	18 (18%)	
Other	10 (10%)	14 (14%)	
Pain intensity			
VAS >50	100 (100%)	100 (100%)	>0.05
Pain Severity			
Moderate	85 (85%)	87 (87%)	>0.05
Severe	15 (15%)	13 (13%)	

Table 2: Comparison of outcomes between both groups

Variable	Group A	Group B	P value
Pain Relief (days)			
1st	30 (30%)	18 (18%)	>0.05
2nd	65 (65%)	45 (45%)	
3rd	90 (90%)	68 (68%)	
Pain Severity			
None	50 (50%)	30 (30%)	>0.05
Mild	45 (45%)	36 (36%)	
Moderate	5 (5%)	30 (30%)	
Severe	0	4 (4%)	
Stool Frequency Improvement (days)			
2nd	65 (65%)	40 (40%)	>0.05
3rd	82 (82%0	64 (64%0	
Global assessment pain relief			
By patient	96%	78%	<0.05
By clinician	99%	85%	

DISCUSSION:

Acute infectious gastroenteritis is one of the most common disorders found all over the world and abdominal pain is the most common symptoms in patients with acute infectious gastroenteritis. Many of medications has been used for the treatment of abdominal pain associated to infectious gastroenteritis.[11,12] Drotaverine HCL 80mg considered as the medicine for choice in abdominal pain.[13] Present study was conducted aimed to examine the efficacy and safety of drotaverine HCL 80mg with combination of Paracetamol 500mg in patients with moderate or severe abdominal pain due to infectious gastroenteritis. We performed a randomized controlled trial to examine the outcomes. In this study total 200 patients with moderate or severe abdominal pain due to acute infectious gastroenteritis were included. All the patients were equally divided in to two groups. There were 58% male and 42% females in Group A (Drotaverine 80mg+PCM 500mg) with mean age of 29.55±10.45 years. In Group B (PCM 500mg alone) 55% were males and 45% were females with mean age of 31.50±11.25 years. These results were similar to some other studies in which male patients were high in numbers as compared to females and mostly patients were ages 30 to 50 years.[14,15]

In the present study we found that all of the patients of both groups had VAS >50 pain intensity at initial diagnosis and most of the patients had pain severity score 2 that was considered as moderate pain. We prescribed medication thrice a day for three days and advice strictly for follow-up on 2nd and 3rd day. We found that Pain relief frequency was significantly decreased in 30%, 65% and 90% at 1st, 2nd and 3rd days in Group A than 18%, 45% and 68% in Group B (p=<0.05). 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.[16]

This study showed that pain severity significantly improved in Group A as compared to Group B (p=<0.05). Stool frequency improvement at2nd and 3rd day in Group A was 65% and 82% and in Group B it was 40% and 64%. Global improvement in abdominal pain by patients in Group A was 96% and in Group B it was 78% and by clinician it was 99% in Group A and 85% in Group B. These results were comparable to some other studies.[17,18] In our study we found 3 patients in Group A and 5 patients in group B had mild adverse effects. These results showed similarity to other study in which 4 patients had mild symptomatic adverse effects such as nausea and headache.[19,20]

CONCLUSION:

The use of fixed-dose combination of drotaverine HCL 80mg and paracetamol 500mg is safe and effective oral therapy with no adverse effects in patients with moderate or severe abdominal pain due to acute infectious gastroenteritis.

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