CODEN [USA]: IAJPBB ISSN: 2349-7750

INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES
SJIF Impact Factor: 7.187
http://doi.org/10.5281/zenodo.3952216

Available online at: http://www.iajps.com Research Article

THE EFFICACY OF DIOSMECTITE IN ADMITTED CHILDREN HAVING ACUTE WATERY DIARRHEA WITH DEHYDRATION

[1]Dr Sikandar Arslan, [2]Dr Salman Zaffar, [3]Dr Abeer Mushtaq

[1]Hamdard Medical University, Karachi
[2]Continental Medical College, Lahore
[3]Quaid.e.Azam Medical College, Bahawalpur

Article Received: May 2020 **Accepted:** June 2020 **Published:** July 2020

Abstract:

Aim: *To determine the effect of diosmectite in reducing the duration of diarrhea in comparison with placebo.*

Method and material: *This open, randomized clinical trial held in the Pediatric Unit II of Jinnah Hospital Lahore for one-year duration from April 2019 to April 2020. The patients were allotted group A (Diosmectite group) or group B (placebo group) by the lottery method. After the initial hydration Diosmectite at a dose of one gram in children below 12 months of age and 1.5 grams in children 12-24 months of age three times a day diluted in water or other semi-solid food along with zinc sulphate was administered orally for 5 days to group A while group B was given placebo (oral zinc sulphate). All the study participants were followed from the beginning of therapy to normalization defined as the passage of first stool of pre-diarrheal consistency (hours) and maximally for six days from the beginning of therapy in case of failure to pass stool of pre-diarrheal consistency.*

Results: *There were 103 children in each group who were initially recruited into the study. 99 (96.12%) children in the diosmectite group and 97 (94.17%) children in the placebo group completed the study. Both groups had similar characteristics. There were 6 of 99 cases in the diosmectite group, while 7 of 97 in the placebo group that did not produce pre-diarrheal stools at the end of six days after starting treatment (p value 0.782). The time required to pass the first pre-diarrheal stool (hours) for the remaining 93 diosmectites was 58.935 ± 30.482, while the time to pass the first pre-diarrhea stool (hours) for the remaining 90 placebo patients was 76.511 ± 35.323 (value p 0.0004). This showed that the drug was moderately effective compared to placebo.*

Conclusion: *Smectite may be a useful addition to rehydration therapy in the treatment of acute watery diarrhea in children, but cost-effective tests are required before routine use is recommended.*

Key words: *randomized clinical trial of acute diarrhea, drug efficacy.*

Corresponding author:
Dr Sikandar Arslan,
Hamdard Medical University, Karachi

QR code

Please cite this article in press Sikandar Arslan et al, ***The Efficacy Of Diosmectite In Admitted Children Having Acute Watery Diarrhea With Dehydration.,*** *Indo Am. J. P. Sci, 2020; 07(07).*

INTRODUCTION:

Diarrhea is the second leading cause of death in young children, killing more than 1.5 million children under the age of 5 each year. It is estimated that there are approximately 4 billion cases of diarrhea in children under the age of 5 each year. Oral hydration is the cornerstone of treatment for acute diarrhea, but has no effect on the duration of the diarrhea or the volume of fluid lost. Diarrhea medication prescribing practices are very common among physicians in Pakistan. The ideal medicine for acute diarrhea is effective in a single application, reduces the loss of intestinal fluid, effective regardless of etiology, good taste, good taste, does not affect the absorption of nutrients, has no side effects, is widely available, stable (does not require cooling) and it's cheap but unfortunately no drugs. The main problem for most drugs is the lack of evidence of efficacy, and some p. Loperamide can even cause life-threatening side effects.

Diosmectite is a laminar, fibrous, crystalline, natural magnesium aluminosilicate clay that provides strong adsorption properties and is often used to treat acute diarrhea. Its mechanism of action has not yet been fully understood, but there are probably many. Diosmectite reduces inflammation, changes the rheological properties of mucus, prevents mucolysis and adsorbs bacteria, bacterial enterotoxins, viruses, and another potential diarrhea. As it is not absorbed from the gastrointestinal tract, it does not cause any systemic side effects. Szajewska et al. A 2006 meta-analysis found that diosmectitis was associated with a moderate reduction in diarrhea in children with acute infectious gastroenteritis. International studies have shown that in children treated with gastritis, diarrhea lasts 42-96 hours and 61.3-119 hours in children receiving placebo. WHO has not yet recommended this drug for the treatment of diarrhea in children under five years of age. Diarrhea is a very common problem in children in Pakistan, but research is still being done on this drug in other parts of Pakistan. The objective of this study is to determine the effect of diosmectite in reducing the duration of diarrhea in comparison with placebo.

MATERIALS AND METHODS:

This open-label randomized clinical trial was conducted in the Pediatric Unit II of Jinnah Hospital Lahore for one-year duration from April 2019 to April 2020. Children 6 to 24 months of age taken with acute watery diarrhea (three or more loose stools for 24 hours) if duration is ≤ 72 hours but ≥24 hours and mild dehydration (child has two or more of the four symptoms i.e. irritated, sunken eyes, increased urge to drink, skin slowly returns) or severe dehydration (if the child has two or more of four symptoms, namely numbness, sunken eyes, unable to drink, skin returns very slowly). Flatulence, bloody diarrhea, history of any antibacterial / antidiarrheal drug use in the past 72 hours, severe protein malnutrition (defined as reference weight for age <60%) and systemic infection. Study Following informed consent from the parents / parents, patients were assigned either group A (Diosmectite group) or group B (placebo group) by lottery method. Demographic data (age, gender) and a brief history, severity and degree of dehydration were recorded. After the first rehydration with intravenous Ringer's lactate / oral rehydration salt, they are administered according to a WHO protocol for the treatment of acute watery diarrhea15. Children under 12 months of age were given 1 gram of diosmectite orally, diluted 3 times a day with 1.5 grams of water in children aged 12-24 months or zinc sulfate in other semi-solid foods, group A received placebo group B (oral zinc sulfate) for 5 days. All study participants were followed for up to six days from initiation of treatment to normalization, which is defined as the transition of the first stools (hour) of original consistency, and in the event of failure for no more than six days.

The mean, range and standard deviation (SD) were calculated for quantitative data by the online program available at: http://www.easycalculation.com/statistics/standard-deviation.php. The Fisher's test was used to compare qualitative and t test to compare quantitative data by the online program available at: http://www.graphpad.com/ quickcalcs/index.cf. The p value < 0.5 was taken as significant.

RESULTS:

There were 103 children in each group and initially recruited into the study. 4 cases in the diosmectite group (Group A) and 6 cases in the placebo group (Group B) left the study before termination. As a result, 99 (96.12%) children in the diosmectite group and 97 (94.17%) children in the placebo group completed the study. Table I shows a comparison of the characteristics of children from both groups who completed the study. There were 6 of 99 cases in the diosmectite group, while there were 7 of 97 cases in the placebo group that had not produced a pre-diarrheal stool at the end of six days after initiation of treatment (p-value 0.782). The time required to pass the first pre-diarrheal stool (hours) for the remaining 93 diosmectites was 58.935 ± 30.482, while the time to pass the first pre-diarrhea stool (hours) for the remaining 90 placebo patients was 76.511 ± 35.323 (value p 0.0004). This showed that

the drug was moderately effective compared to the placebo.

TABLE I: Comparison of Characteristics of the Children of Both Groups

Characteristic	Diosmectite Gp (Group A) (n= 99)	Placebo Gp (Group B) (n= 97)	P value
Sex Male (%)	52 (52.52%)	57 (58.76%)	0.392
Age (months)			
Mean±SD	11.081±5.104	10.753±5.498	0.665
Range	6-23 mo	6-23 mo	
Weight (Kg)			
Mean±SD	8.179 ±1.586	8.379±1.719	0.397
Range	5.8-11.9	5.7-13.7	
Breast fed	55(55.55)	59 (60.82%)	0.472
Duration of diarrhea before admission (hours)			
Mean±SD			
Range	43.515±17.157 24-72	41.268±17.048 24-72	0.359
Frequency of stool in the last 24 hours before admission			
Mean±SD			
Range	8.62±2.37 5-14	8.47±2.22 5-13	0.64
Children with severe Dehydration at the time of admission	27(27.27%)	23(23.71%)	0.624

DISCUSSION:

The study showed that in children treated with diosmectitis, the time from the start of treatment to the passage of the first granular stools was significantly shorter (58 vs 58.93 ± 30.48, 51 ± 35.32 hours). Other studies have produced similar results. Narkeviciute et al. A significantly shorter duration of diarrhea was found in the group of diosmectites from Lithuania (61.8 ± 33.9 vs 42.3 ± 24.7). Vivatvakin et al. The duration of diarrhea was significantly shorter in the diosmectite group in Thailand (43.3 ± 25.1 vs 84.7 ± 48.5). The Egyptian Madkour et al. Showed significantly shorter diarrhea in the diosmectite group (54.1 ± 2.35 compared to 72.1 ± 1.98). Mujawar et al. 2012 from India showed that the mean time needed to treat diarrhea was shorter in the treated group (64.34 ± 14.86 s) compared to the control group (82.37 ± 21.43). h). Guarino et al. From Italy, a significantly shorter duration of diarrhea was demonstrated in the treated group (96 ± 21 vs 119 ± 23). Lexomboon et al. They showed that the healing rate of diarrhea 72 hours after Thailand was significantly higher in the treatment group (71% vs 34%).

Narkeviciute et al. Children 6-48 months, Vivatvakin et al. 1 to 24 months, Madkour et al. 3 to 24 months, Mujawar et al. 2012 to 5 years. Guarino et al. From 3 months to 5 years and Lexomboon et al. From 1 to 24 months. This study has some limitations. This is a hospital examination and only includes children with dehydration. No further studies on the cause of diarrhea have been performed. This study does not concern profitability analysis.

CONCLUSION:

Smectitis can be a useful complement to rehydration therapy in treating acute watery diarrhea in children. Cost-effectiveness studies should be performed prior to recommending routine drug treatment for proctitis.

REFERENCES:

1. Florez, Ivan D., Laura F. Niño-Serna, and Claudia P. Beltrán-Arroyave. "Acute infectious diarrhea and gastroenteritis in children." *Current Infectious Disease Reports* 22, no. 2 (2020): 4.
2. Tishin, Anton N., Uliana A. Krut, Olga M. Tishina, Evgeniya Alexandrovna Beskhmelnitsyna, and Vladimir I. Yakushev. "Physico-chemical properties of montmorillonite clays and their application in clinical practice." (2017).
3. Szymański, Henryk, and Hania Szajewska. "Efficacy of Lactobacillus Reuteri DSM 17938 for the treatment of acute gastroenteritis in children: protocol of a randomized controlled trial." *JMIR research protocols* 6, no. 8 (2017): e164.
4. Serban, Elena D., and Mihai Manolache. "Gelatin tannate versus other antidiarrheal medication in children with acute gastroenteritis: a retrospective, observational study." *Journal of comparative effectiveness research* 8, no. 3 (2018): 187-194.
5. Beskhmelnitsyna, E. A., and V. I. Yakushev. "PHYSICO-CHEMICAL PROPERTIES OF MONTMORILLONITE CLAYS AND THEIR APPLICATION IN CLINICAL PRACTICE."
6. Aloi, Marina, and Maurizio Mennini. "Efficacy of gelatin tannate for acute diarrhea in children: a systematic review and meta-analysis." *Journal of comparative effectiveness research* 8, no. 2 (2019): 91-102.
7. Szajewska, Hania. "Efficacy of Lactobacillus Reuteri DSM 17938 for the Treatment of Acute Gastroenteritis in Children: Protocol of a Randomized Controlled Trial."
8. Motaze, Nkengafac V., Chukwuemeka E. Nwachukwu, and Eliza H. Humphreys. "Treatment interventions for diarrhoea in HIV-infected and HIV-exposed children." *The Cochrane Database of Systematic Reviews* 2018, no. 1 (2018).
9. Liu, Zhe, Ke-yu Yao, Hui-ru Wang, Meng-ling Li, Jian-ping Liu, and Shuang-qing Zhai. "Acupoint herbal patching at Shenque (CV8) as an adjunctive therapy for acute diarrhea in children: A systematic review and meta-analysis." *European Journal of Integrative Medicine* 10 (2017): 25-37.
10. do Carmo, Monique Santos, Camilla itapary dos Santos, Mizael Calácio Araújo, Jorge Alberto Girón, Elizabeth Soares Fernandes, and Valério Monteiro-Neto. "Probiotics, mechanisms of action, and clinical perspectives for diarrhea management in children." *Food & function* 9, no. 10 (2018): 5074-5095.
11. Eutamene, Helene, Catherine Beaufrand, Cherryl Harkat, and Vassilia Theodorou. "The role of mucoprotectants in the management of gastrointestinal disorders." *Expert review of gastroenterology & hepatology* 12, no. 1 (2018): 83-90.
12. Braghero, Marco, Annamaria Staiano, Eleonora Biasin, Patrizia Matarazzo, Silvia Einaudi, Rosaria Manicone, Francesco Felicetti et al. "72nd Congress of the Italian Society of Pediatrics." In *Italian Journal of Pediatrics*, vol. 43, no. 1, p. 21. BioMed Central, 2017.
13. MÁCHALOVÁ, Alena, Zuzana BABINSKÁ, Jan JUŘICA, Gabriela DOVRTĚLOVÁ, Hana KOSTKOVÁ, Leoš LANDA, Jana MERHAUTOVÁ et al. "Pharmacology for students of bachelor's programmes at MF MU (special part)."
14. McKenzie III, Harold C. "Diagnosis of Enteritis and Colitis in the Horse." *The Equine Acute Abdomen* (2017): 376.
15. Mutura, Alice Wairimu. "Geophagy and Parasitic Infections in Pregnant Women attending an Ante-Natal Clinic in Thika Level-5 Hospital, Kiambu County, Central Kenya." PhD diss., JKUAT COHES, 2017.