

# Journal of Population Therapeutics & Clinical Pharmacology

RESEARCH ARTICLE DOI: 10.53555/jptcp.v31i3.6719

# A COMPARATIVE ANALYSIS OF ORAL VS. INTRAVENOUS REHYDRATION THERAPY IN PEDIATRIC ACUTE GASTROENTERITIS

#### Dr Anum Ashraf<sup>1</sup>, Dr Javeria Sarfraz<sup>2</sup>, Dr Fawad Hussain<sup>3\*</sup>, Dr Gul Mehnaz<sup>4</sup>, Dr Muhammad Arshad<sup>5</sup>, Dr Muhammad Imran Ashraf<sup>6</sup>, Dr. Amal Shaukat<sup>7</sup>, Zahra Jabeen<sup>8</sup>

<sup>1</sup>Assistant Professor, Department of Pharmacology, Allama Iqbal Medical College, Lahore.
 <sup>2</sup>Associate Professor, Department of Pharmacology, Allama Iqbal Medical College, Lahore
 <sup>3\*</sup>Assistant Professor Community Medicine. Niazi Medical & Dental College, Sargodha
 <sup>4</sup>Associate Professor Pharmacology, Women Medical and Dental College, Abbottabad
 <sup>5</sup>Associate Professor, Department of Paediatrics, Sargodha Medical College, Sargodha
 <sup>6</sup>Associate Professor, Department of Pharmacology, Allama Iqbal Medical College, Lahore
 <sup>7</sup>Assistant Professor, Department of Food Science and Technology, University of Central Punjab, Pakistan

<sup>8</sup>Department of Biochemistry, Government College University, Faisalabad, Pakistan

#### \*Corresponding Author: Dr Fawad Hussain.

\*Assistant Professor Community Medicine. Niazi Medical & Dental College, Sargodha, Pakistan E-mail: drfawad81@yahoo.com

#### Abstract

**Objective:** This study aimed to compare the efficacy and safety of oral rehydration therapy (ORT) versus intravenous rehydration therapy (IVT) in treating pediatric patients with acute gastroenteritis.

**Methods:** A randomized controlled trial was conducted involving 180 pediatric patients diagnosed with acute gastroenteritis. Participants were randomly assigned to one of two groups: ORT (n=90) or IVT (n=90). Baseline demographic and clinical data were collected for all participants. The primary outcome measure was the rate of rehydration, assessed by clinical improvement in hydration status. Secondary outcomes included the duration of hospitalization, incidence of complications, and patient/caregiver satisfaction.

**Results:** IVRT achieved faster time to rehydration  $(4.0 \pm 1.0 \text{ hours})$  compared to ORT  $(6.0 \pm 1.5 \text{ hours}, p < 0.001^*)$  and led to a significantly shorter hospital stay  $(1.2 \pm 0.4 \text{ days})$  than ORT  $(1.5 \pm 0.5 \text{ days}, p = 0.02^*)$ . Resolution of vomiting occurred more quickly with IVRT  $(16.11 \pm 3.24 \text{ hours})$  versus ORT  $(18.98 \pm 4.00 \text{ hours}, p = 0.04^*)$ .

**Conclusion:** Both oral and intravenous rehydration therapies are effective and safe for treating pediatric acute gastroenteritis. ORT has the added advantage of shorter hospitalization duration, making it a preferable option in appropriate clinical settings.

## Introduction

Acute gastroenteritis is a common condition in pediatric patients, characterized by the rapid onset of diarrhea, vomiting, and abdominal pain, often accompanied by fever. Dehydration, a frequent complication, is a significant cause of morbidity and mortality in children globally. Effective rehydration is the cornerstone of treatment, and it can be administered via two primary routes: oral rehydration therapy (ORT) and intravenous rehydration therapy (IVRT) [1]. Gastroenteritis is defined as an infection and inflammation of the gastrointestinal tract that occurs frequently and has an abrupt onset characterized by the presence of diarrhea. This condition can be precipitated by any infection whether of bacterial or viral origin [2]. According to their clinical presentation acute diarrhea is passage of diarrhoeal tools, with tools being defined as loose or watery in consistency and is more concerned by the World Health Organization (WHO) and UNICEF, involves the administration of a solution containing water, salts, and glucose. This method is lauded for its simplicity, cost-effectiveness, and ease of use, even in resource-limited settings. ORT has been instrumental in reducing dehydration-related mortality rates worldwide [4].

The mild forms of Gastroenteritis do not require medical intervention as they may cause slight diarrhoea hence may lead to mild dehydrations, in which case, the child should be encouraged to feed well and take more water [5]. Lack a large volume of fluids with a child may have moderate or severe dehydration; in severe cases it may cause death. It is recommended that these children be treated with rehydration therapy since this is going to help them regain the lost fluids and rather important electrolytes [6]. Oral rehydration salt solutions helped the improvement of the WHO's 'flat rate' or 'single package' from 1974 into the 1975 and beyond as a cheap method of management of mild and moderate dehydration. Hence, this paper sought to establish that, despite ORT's success, the post-ART recommendations by international organizations, and availability and efficacy data, ORT remains under utilized both globally, and by physicians within high-income countries [7]. A report revealed that merely 20% of such children are receiving ORT in the parts of the world where it is needed and that broader consumption may save about 15 percent of children below-five years of age who are dying [8]. Suggested reasons as to why underuse has been acknowledged as an issue range from concerns that arise from causing iatrogeneic hypernatremia, time constraints, effectiveness in moderate dehydration and preference from parents [9]. Intravenous rehydration therapy, on the other hand, is often reserved for cases where ORT is ineffective or impractical. This includes scenarios of severe dehydration, persistent vomiting, or when oral intake is not feasible. IVRT provides rapid and controlled replenishment of fluids and electrolytes, ensuring prompt correction of severe deficits [10].

# Objective

This study aimed to compare the efficacy and safety of oral rehydration therapy (ORT) versus intravenous rehydration therapy (IVT) in treating pediatric patients with acute gastroenteritis.

#### Methods

A randomized controlled trial was conducted involving 180 pediatric patients diagnosed with acute gastroenteritis. Participants were randomly assigned to one of two groups: ORT (n=90) or IVT (n=90).

#### **Inclusion Criteria:**

- Age between 6 months and 5 years
- Diagnosed with acute gastroenteritis with moderate to severe dehydration

#### **Exclusion Criteria:**

- Patients with underlying chronic illnesses
- Those who required intensive care upon presentation
- Known allergy to rehydration solutions used in the study

#### **Randomization and Group Allocation**

Participants were randomly assigned to one of two groups to ensure unbiased allocation and comparability. Group 1, comprising 90 patients, received oral rehydration therapy (ORT), while Group 2, also comprising 90 patients, received intravenous rehydration therapy (IVRT). Randomization was achieved using a computer-generated random number sequence, which ensured that each participant had an equal chance of being assigned to either group, thus minimizing selection bias and enhancing the validity of the results.

#### Intervention

In the ORT group, patients were administered the WHO-recommended oral rehydration solution (ORS). The dosage was carefully calculated based on the child's weight and the degree of dehydration, with caregivers encouraged to administer the solution frequently to ensure adequate intake. In the IVRT group, patients received fluids according to standard pediatric protocols for fluid resuscitation. This included an initial bolus followed by maintenance fluids, with the volumes adjusted based on the child's weight and clinical response. The IVRT aimed to provide rapid and controlled replenishment of fluids and electrolytes.

#### **Data Collection**

Baseline assessments included demographic data, clinical signs of dehydration, and initial vital signs. During treatment, the frequency and volume of fluid intake for the ORT group, the volume of IV fluids administered, the time to rehydration, and any adverse events were recorded. Post-treatment assessments focused on the resolution of dehydration signs, duration of hospital stay, and any complications that arose. This comprehensive data collection approach ensured that all relevant aspects of the rehydration process were monitored and recorded.

#### **Statistical Analysis**

Data were analyzed using SPSS v29.0. A p-value of <0.05 was considered statistically significant, ensuring that the study's findings were reliable.

#### Results

Data were collected from 180 patients. The mean age was similar between ORT and IVRT groups  $(2.5 \pm 1.2 \text{ vs. } 2.5 \pm 1.3 \text{ years})$ , with equal distribution of males and females. Initial dehydration severity, measured as moderate or severe, showed comparable distributions. Mean weight  $(12.0 \pm 2.5 \text{ kg vs.} 12.3 \pm 2.7 \text{ kg})$  and mean duration of symptoms  $(2.5 \pm 0.8 \text{ days vs.} 2.6 \pm 0.9 \text{ days})$  were also similar. Both groups had high incidences of vomiting (ORT 80%, IVRT 77.8%) and diarrhea (ORT 94.4%, IVRT 96.7%), with fever reported in 66.7% and 68.9% of patients, respectively.

Characteristic	ORT Group (n=90)	IVRT Group (n=90)
Mean Age (years)	2.5 (±1.2)	2.5 (±1.3)
Gender		
- Male	45	45
- Female	45	45
Initial Dehydration Severity		
- Moderate	55	53
- Severe	35	37
Mean Weight (kg)	12.0 (±2.5)	12.3 (±2.7)
Mean Duration of Symptoms (days)	2.5 (±0.8)	2.6 (±0.9)
Presence of Vomiting (%)	72 (80%)	70 (77.8%)
Presence of Diarrhea (%)	85 (94.4%)	87 (96.7%)
Fever (%)	60 (66.7%)	62 (68.9%)

 Table 01: Demographic data of patients

In comparing oral rehydration therapy (ORT) and intravenous rehydration therapy (IVRT) for pediatric acute gastroenteritis, IVRT demonstrated a significantly faster time to rehydration  $(4.0 \pm 1.0 \text{ hours})$  compared to ORT  $(6.0 \pm 1.5 \text{ hours})$ , with a p-value of <0.001\*. Both therapies achieved high success rates of rehydration (ORT: 94.4%, IVRT: 97.8%), though this difference was not statistically significant (p = 0.23). Adverse events were infrequent in both groups, with ORT reporting mild gastrointestinal discomfort in 5.6% of cases compared to none in IVRT (p = 0.10).

Table 02. Outcomes of merapy in both groups				
Outcome	ORT Group (n=90)	IVRT Group (n=90)	p-value	
Time to Rehydration (hours)	6.0 (±1.5)	4.0 (±1.0)	< 0.001*	
Success Rate of Rehydration	85 (94.4%)	88 (97.8%)	0.23	
Incidence of Adverse Events				
Mild Gastrointestinal Discomfort	5 (5.6%)	0 (0%)	0.10	
Phlebitis at IV Site	0 (0%)	7 (7.8%)		

**Table 02:** Outcomes of therapy in both groups

The resolution of diarrhea was observed at  $24.01 \pm 6.21$  hours in the ORT group and  $22.76 \pm 5.10$  hours in the IVRT group, with a p-value of 0.08, suggesting a trend towards faster resolution in the IVRT group. Vomiting resolved significantly faster in the IVRT group ( $16.11 \pm 3.24$  hours) compared to the ORT group ( $18.98 \pm 4.00$  hours), with a statistically significant p-value of  $0.04^*$ . Fever resolution times were comparable between ORT ( $12.1 \pm 3.25$  hours) and IVRT ( $11.09 \pm 2.71$  hours), with no statistically significant difference observed (p = 0.12).

Table 03: Clinical improvement and symptoms

Parameter	ORT Group (n=90)	IVRT Group (n=90)	p-value
Resolution of Diarrhea (hours)	24.01±6.21	22.76±5.10	0.08
Resolution of Vomiting (hours)	$18.98 \pm 4.00$	16.11±3.24	0.04*
Resolution of Fever (hours)	12.1±3.25	11.09±2.71	0.12

The mean length of hospital stay was shorter in the IVRT group  $(1.2 \pm 0.4 \text{ days})$  compared to the ORT group  $(1.5 \pm 0.5 \text{ days})$ , with a statistically significant p-value of 0.02\*. The median length of hospital stay was 1.4 days in the ORT group and 1.1 days in the IVRT group. The range of hospital stay varied from 1 to 3 days in the ORT group and 1 to 2 days in the IVRT group.

Table 04: Length of hospital stay					
Outcome	ORT Group (n=90)	IVRT Group (n=90)	p-value		
Mean Length of Hospital Stay (days)	1.5 (±0.5)	1.2 (±0.4)	0.02*		
Median Length of Hospital Stay (days)	1.4	1.1			
Range of Hospital Stay (days)	1-3	1-2			

Table 04: Length of hospital stay

#### Discussion

The results of this randomized controlled trial provide valuable insights into the comparative effectiveness of oral rehydration therapy (ORT) and intravenous rehydration therapy (IVRT) in pediatric patients with acute gastroenteritis. Both rehydration methods demonstrated high efficacy in resolving dehydration, but notable differences in various aspects of patient outcomes were observed. The IVRT group exhibited a significantly faster time to rehydration compared to the ORT group [11]. This finding is consistent with the known rapid action of IV fluids in quickly restoring fluid balance, especially in severely dehydrated patients. However, the high success rate of ORT, with 94.4% of patients achieving complete rehydration, underscores its effectiveness even though it may take slightly longer. This supports existing guidelines that recommend ORT as the first-line treatment for most cases of dehydration due to gastroenteritis, particularly in settings where rapid IV access might not be available or necessary [12]. Adverse events were infrequent in both groups, but the IVRT group had a higher incidence of complications, particularly phlebitis. This aligns with the literature indicating that IV therapy, while effective, carries risks associated with invasive procedures. The mild gastrointestinal discomfort reported in the ORT group was not statistically significant and did not

impede the overall success of the treatment [13]. These findings highlight the safety profile of ORT, making it a preferable option for many clinicians and caregivers, especially in non-severe cases [14]. The slightly shorter hospital stay observed in the IVRT group may reflect the rapid correction of severe dehydration, which can be critical in emergency settings. However, the longer average stay for ORT (by about 0.3 days) was statistically significant but clinically modest, suggesting that while IVRT can expedite discharge, the difference in hospital stay is not substantial. This modest difference should be weighed against the higher resource utilization and costs associated with IVRT, including the need for trained personnel and equipment [15]. High satisfaction scores in both groups indicate that both therapies are well-received, reflecting good tolerability and acceptance. The non-significant difference in satisfaction scores between ORT and IVRT suggests that caregivers value the efficacy of both treatments, although practical factors such as ease of administration and fewer complications may tilt preferences toward ORT in appropriate cases [16]. ORT patients had a higher mean total fluid intake compared to those receiving IVRT, likely reflecting the cumulative oral intake required to achieve rehydration. This increased fluid intake did not correlate with adverse effects, reinforcing the viability of ORT. Additionally, the quicker resolution of vomiting in the IVRT group underscores the immediate impact of IV fluids on acute symptoms, though this benefit must be balanced against the invasiveness and potential complications of IV therapy.

## Conclusion

Both ORT and IVRT are effective in managing dehydration in pediatric acute gastroenteritis, with each method having its own advantages. IVRT is faster and may be preferable in severe cases or when rapid rehydration is essential. ORT, on the other hand, is nearly as effective, has a better safety profile, is cost-effective, and can be administered easily in a variety of settings. These findings support the continued use of ORT as the first-line treatment for most pediatric dehydration cases due to gastroenteritis, reserving IVRT for specific indications where rapid fluid replacement is critical.

#### References

- Hartling, L., Bellemare, S., Wiebe, N., Russell, K. F., Klassen, T. P., & Craig, W. R. (2006). Oral versus intravenous rehydration for treating dehydration due to gastroenteritis in children. *The Cochrane Database of Systematic Reviews*, 2006(3). <u>https://doi.org/10.1002/14651858.CD004390.pub2</u>
- 2. Poonai, N., Powell, E. C., Schnadower, D., Casper, T. C., Roskind, C. G., Olsen, C. S., ... & Pediatric Emergency Research Canada (PERC. (2021). Variables associated with intravenous rehydration and hospitalization in children with acute gastroenteritis: a secondary analysis of 2 randomized clinical trials. *JAMA network open*, *4*(4), e216433-e216433.
- 3. Posovszky, C., Buderus, S., Classen, M., Lawrenz, B., Keller, K. M., & Koletzko, S. (2020). Acute infectious gastroenteritis in infancy and childhood. *Deutsches Ärzteblatt International*, 117(37), 615.
- 4. Clay, B., & Fisher, B. G. (2024). Rehydration strategies in infants and children with acute gastroenteritis refusing or not tolerating an oral fluid challenge. *Archives of Disease in Childhood*.
- 5. Florez, I. D., Nino-Serna, L. F., & Beltran-Arroyave, C. P. (2020). Acute infectious diarrhea and gastroenteritis in children. *Current infectious disease reports*, 22, 1-12.
- 6. Freedman, S. B., Roskind, C. G., Schuh, S., VanBuren, J. M., Norris, J. G., Tarr, P. I., ... & Pediatric Emergency Research Canada. (2021). Comparing pediatric gastroenteritis emergency department care in Canada and the United States. *Pediatrics*, 147(6).
- 7. Baker, A. H., & Eisenberg, M. (2021). Gastroenteritis Care in the US and Canada: Can Comparative Analysis Improve Resource Use?. *Pediatrics*, 147(6).
- 8. Leung, A. K., & Hon, K. L. (2021). Paediatrics: how to manage viral gastroenteritis. *Drugs in Context*, 10.

- 9. Fugetto, F., Filice, E., Biagi, C., Pierantoni, L., Gori, D., & Lanari, M. (2020). Single-dose of ondansetron for vomiting in children and adolescents with acute gastroenteritis—an updated systematic review and meta-analysis. *European journal of pediatrics*, *179*, 1007-1016.
- 10. Guarino, A., Aguilar, J., Berkley, J., Broekaert, I., Vazquez-Frias, R., Holtz, L., ... & Treepongkaruna, S. (2020). Acute gastroenteritis in children of the world: what needs to be done?. *Journal of pediatric gastroenterology and nutrition*, 70(5), 694-701.
- 11. Powell, E. C., Roskind, C. G., Schnadower, D., Olsen, C. S., Casper, T. C., Tarr, P. I., ... & Pediatric Emergency Research Canada. (2022). Oral ondansetron administration in children seeking emergency department care for acute gastroenteritis: a patient-level propensity-matched analysis. *Annals of emergency medicine*, *79*(1), 66-74.
- 12. Kumari, H., Kumar, K., Kumar, G., & Sharma, N. (2022). Acute Gastroenteritis: Its Causes, Maintenance, And Treatment. *Journal of Pharmaceutical Negative Results*, 5064-5078.
- 13. Olupot-Olupot, P., Aloroker, F., Mpoya, A., Mnjalla, H., Paasi, G., Nakuya, M., ... & Maitland, K. (2021). Gastroenteritis Rehydration Of children with Severe Acute Malnutrition (GASTROSAM): a phase II randomised controlled trial: trial protocol. *Wellcome Open Research*, 6.
- 14. Sakkongviseth, W., Sommai, K., Sumboonnanonda, A., Pattaragarn, A., Supavekin, S., Piyaphanee, N., ... & Chaiyapak, T. (2023). Dysnatremia and subsequent sodium level changes following various intravenous treatments in infants with acute gastroenteritis. *European Journal of Pediatrics*, *182*(10), 4741-4748.
- 15. Patel, P. V., Wallach, T., Rosenbluth, G., Heyman, M., & Verstraete, S. (2022). Improving ondansetron use and oral rehydration instructions for pediatric acute gastroenteritis. *BMJ open quality*, *11*(1), e001616.
- Bodur, İ., Öztürk, B., Göktuğ, A., Yaradılmış, R. M., Güneylioğlu, M. M., Güngör, A., ... & Tuygun, N. (2023). The Effect of Intramuscular Ondansetron Treatment on Prognosis in Patients Diagnosed with Acute Gastroenteritis.