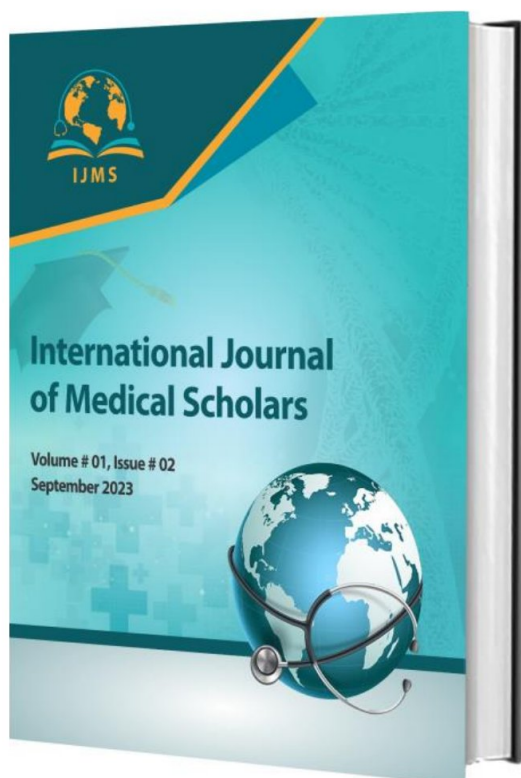


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**Ringers lactate versus normal saline among pediatric patients with acute severe diarrhea**

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**ABSTRACT**

**Objective:** This study compares Ringer Lactate (RL) and normal saline (NS) effectiveness in treating pediatric acute severe diarrheal dehydration.

**Methods:** The study was conducted in Agha Khan University Hospital, Karachi, Pakistan from 1<sup>st</sup> March 2022 to 30 February 2023 in one-year duration. Patients were divided into two equal groups (group RL and group NS) by simple randomization. The randomization process was carried out by a person who was not involved in the study to minimize bias and maintain the integrity of the randomization process.

**Results:** Primary and secondary outcomes at the end of six hours shown in table. II. Improvement in clinical status and pH ( $\geq 7.35$ ) in RL group was most common 50.0% as compare to the NS group 27.8%, the difference was statistically significant, ( $p < 0.010$ ).

**Conclusion:** Resuscitation with Ringer's lactate (RL) and normal saline (NS) yields comparable resolution of biochemical and improvement in clinical signs in children with acute severe diarrheal dehydration, with NS showing a trend toward lower creatinine, blood urea, and lactate levels, as well as offering advantages of lower cost and greater availability, thus positioning NS as the preferred fluid choice based on considerations of clinical efficacy, cost-effectiveness, and accessibility.

**Keywords:** Acute severe diarrhea, Ringer's Lactate, Normal Saline, Pediatrics, Electrolytes imbalance

## 1. INTRODUCTION

Diarrhea is a highly prevalent and deadly disease, especially in developing countries<sup>1</sup>. It's caused by a parasitic, bacterial and viral infections. It is the second leading cause of death among children under the age of five years globally<sup>2</sup>. The primary reason for this high mortality rate is the rapid loss of fluids and electrolytes, leading to dehydration. In case of acute diarrhea, the intestinal epithelial barrier can become compromised<sup>3</sup>. This leads to the loss of water and electrolytes (such as sodium and potassium) from the gut, resulting in fluid imbalance and dehydration<sup>4</sup>.

1<sup>st</sup>step in managing acute severe diarrhea dehydration in children is to assess the severity of dehydration. This assessment includes evaluating clinical signs and symptoms such as the degree of dehydration, heart rate, respiratory rate, capillary refill time, and other relevant clinical parameters<sup>5</sup>. The cornerstone of managing diarrheal dehydration is the administration of ORS. In cases of severe dehydration or when a child is unable to drink ORS due to lethargy, vomiting, or other reasons, intravenous rehydration may be necessary<sup>6</sup>. Intravenous fluids (IVF), usually isotonic solutions like normal saline, are administered to rapidly correct dehydration<sup>7</sup>.

Ringer's Lactate is an IV fluid that contains electrolytes (sodium, potassium, calcium) and lactate. It is often used in cases of dehydration and various medical conditions. RL is considered suitable for correcting dehydration because it helps replace lost fluids and electrolytes. Lactate can be converted to bicarbonate in the body, which can help in maintaining acid-base balance<sup>8</sup>.

Normal Saline, also known as isotonic saline or NS, is an IV fluid that contains a concentration of sodium chloride (salt)

similar to that of normal blood plasma<sup>9</sup>. It is used to treat dehydration, restore electrolyte balance, and dilute or administer medications. NS is commonly used when there is a need to increase circulating volume or when patients have specific electrolyte imbalances<sup>10</sup>.

## 2. METHODOLOGY

The study was conducted in a Agha Khan University Hospital, Karachi, Pakistan from 1<sup>st</sup> March 2022 to 30 February 2023 in one year duration. Study received approval from the Institute Ethics Committee (IEC) and before enrolling participants into the study, written informed consent was obtained from the parents or caregivers of the participants. Acute diarrhea is defined as having three or more episodes of loose, watery, or semisolid stools within a 24-hour period for seven days or less. The assessment of severe dehydration in children using the WHO (World Health Organization) scale involves evaluating several clinical signs and symptoms. Presence of two of following signs among, lethargy (unconsciousness), sunken eyes, poor drinking and loss of skin turgor (skin may take more than 2 seconds to return to its normal position after pinching) was considered as severe dehydration. Severely malnourished children, diarrhea above 7 days, chronic systemic illness, bloody stool and who received intravenous fluids just 24 hours before enrollment in study.

Patients were divided into two equal groups (group RL and group NS) by simple randomization. The randomization process was carried out by a person who was not involved in the study to minimize bias and maintain the integrity of the randomization process. The study fluids, RL (presumably a study fluid) and NS (presumably another study fluid), were placed in identical-looking bottles. After filling the bottles with the study

fluids, they were packed into sequentially numbered boxes. Each box appears to contain a specific number of bottle-sets, where one bottle-set consists of 10 bottles, each containing 500 mL of the respective study fluid. Before packaging the bottles into boxes, the previous labels were replaced with new labels bearing the study name and box number. Each eligible child enrolled in the study was associated with a specific serial number, and the study fluid was administered from boxes with serial numbers corresponding to the enrolled child.

Hydration status in a child was assessed, likely due to acute diarrhea, at the end of administering 100 mL/kg of intravenous fluid (IVF) therapy. The subsequent management of the child's condition was based on the World Health Organization (WHO) plan for the management of acute diarrhea. This plan likely includes guidelines for treating diarrhea, which can be quite serious, especially in children. Blood samples were taken from the child both before the start of IVF therapy and at the end of six hours. This could be to monitor electrolyte levels, blood counts, or other parameters to assess the child's response to treatment. The amounts of fluids given (input) and the fluids lost (output) were recorded. The duration of the child's hospital stay was noted. The length of stay can provide insights into the severity of the condition and the effectiveness of treatment.

SPSS version 23 was used for data analysis, mean and SD was calculated for numerical data and frequency (percentages) were calculated for categorical data. After applying test of significance p value less than or equal to 0.05 was taken as significant.

### 3. RESULTS

Overall, 144 patients were included in this study, both genders. All the patients were divided into two equal groups

(RL Group & NS Group). The mean age of RL and NS group was 16.52±2.36 months and 15.48±2.12 months, respectively, (p=0.941). There were 37 (51.4%) males in RL group and 47 (65.3%) males in NS group, (p=0.091). The mean weight of RL and NS group was 9.68±79 kg and 10.29±1.95 kg, respectively, (p=0.053). The clinical and biochemical characteristics of both the groups were almost equal and statistically insignificant, (p>0.050). (Table. I).

Primary and secondary outcomes at the end of six hours shown in table. II. Improvement in clinical status and pH (≥7.35) in RL group was most common 36 (50.0%) as compare to the NS group 20 (27.8%), the difference was statistically significant, (p<0.010). Whereas, in secondary outcomes, electrolytes, renal parameters, AKI, time to start oral feeds and length of hospital stay in RL and NS group was almost equal, with statistically insignificant difference, (p>0.050). (Table. II).

**Table. I**  
**Demographic and baseline characteristics at the start of the study**

Variable	RL Group	NS Group	p-value
Age (month)	16.52±2.36	15.48±2.12	0.941
Gender			
Male	37 (51.4)	47 (65.3)	0.091
Female	35 (48.6)	25 (34.7)	
Weight (kg)	9.68±79	10.29±1.95	0.053
Duration of symptoms (days)	2.12±0.96	2.00±1.06	0.461
loose stools per day	22 (30.6)	23 (31.9)	0.857
Vomiting	26 (36.1)	34 (47.2)	0.176
Drinks poorly or not able to drink	53 (73.6)	50 (69.4)	0.580
Lethargy or unconscious	62 (86.1)	61 (84.7)	0.813
Sunken eyes	62 (86.1)	65 (90.3)	0.438
Skin pinch goes back very slowly	9 (12.5)	10 (13.9)	0.806
Electrolytes			
Serum Sodium (mmol/L)	136.65±2.32	137.21±3.56	0.741
Serum Potassium (mmol/L)	4.25±0.1	4.23±1.06	0.919



Serum Chloride (mmol/L)	104.45±5.42	106.38±5.24	0.297
Hyperchloremia	53 (73.6)	55 (76.4)	0.700
Renal parameter			
AKI	57 (79.2)	61 (84.7)	0.386

**Table. II**  
**Primary and secondary outcomes at the end of six hours**

Variable	RL Group	NS Group	p-value
<b>Primary outcome</b>			
Improvement in clinical status (disappearance of signs of severe dehydration) and pH ( $\geq 7.35$ )	36 (50.0)	20 (27.8)	0.006
Improvement in clinical status (disappearance of signs of severe dehydration)	66 (91.7)	65 (90.3)	0.771
<b>Secondary outcome</b>			
<b>Electrolytes</b>			
Serum Sodium (mmol/L)	139.05±6.62	140.77±635	0.114
Serum Potassium (mmol/L)	4.03±0.94	3.90±1.03	0.427
Serum Chloride (mmol/L)	112.18±8.91	112.17±9.15	0.993
Hyperchloremia	2 (2.8)	1 (1.4)	0.560
<b>Renal parameter</b>			
AKI	50 (69.4)	46 (63.9)	0.480
Time to start oral feeds (hours)	1.95±0.68	1.97±0.69	0.903
Length of stay hospital (days)	2.25±1.03	2.59±1.04	0.057

#### 4. DISCUSSION

The study found that patients in both groups NS and RL experienced a similar improvement in clinical status. The change in serum electrolytes and blood gas parameters was similar in both groups. This indicates that the alterations in these physiological measures were consistent between the groups. In our study RL group have 139.05±6.62mmol/L sodium after six hours and in NS group it was 140.77±635mmol/L. Similar ratio was found in other electrolytes.

In this study 51.4% children were male in R/L group and in N/S group 65.3% were male. Another study conducted by Habib et al<sup>11</sup> shows male predominance among children with diarrhea in 2014. In that study, 60% of the children with diarrhea were male, while 40% were female. This suggests that there was a higher incidence of diarrhea among boys compared to girls in the study population. Similarly, Zahoor et al<sup>12</sup> observed male dominance 66.7% and female 33.3% in study group.

Study by Mahajan et al<sup>13</sup> had 22 participants and did not find any significant difference in pH and had a worse baseline mortality risk score. This suggests that study did not show a correlation between pH and baseline mortality risk score. In another study by Kartha et al<sup>14</sup> reported that there was no significant difference regarding electrolyte imbalance and start of feeding time 1 hour in RL and 1.5 hours in NS group.

Cieza et al<sup>15</sup> found that RL was superior to NS in terms of the time it took for patients to resolve their symptoms of cholera. The mean (average) volume of fluid needed for rehydration in the RL group was 6.25 liters with a standard deviation of ±1.39, while in the NS group, it was 6.51 liters with a standard deviation of ±2.47. Juca et al<sup>16</sup> describe that normal saline can replace body fluids easily but worsen the metabolic imbalances, particularly in individuals who may already have electrolyte abnormalities or underlying health issues.

A study was conducted by Rasheed et al<sup>17</sup> in 2020 and reported that in the group treated with Ringer's lactate, the mean serum bicarbonate level was 13.61 ± 2.41 meq/l and group treated with normal saline, the mean serum bicarbonate level was 9.72 ± 2.07 meq/l that indicate a significant difference (p<0.001) between groups. Shaikh et al<sup>18</sup> concluded in a study on fluid replacement therapy in acute peritonitis and

reported that ringer's lactate is much better than normal saline.

An Indian study by Naseem et al<sup>19</sup> also reported similar finding, increase in sodium, potassium and chloride was observed in ringer group but correlation with chloride was not significant. There were a total of 70 children who participated in the study, with 35 children in each of the RL and NS groups. In the RL group, the mean change in serum sodium levels from baseline was 1.4 mEq/L, with a standard deviation (SD) of 4.5 mEq/L. In the NS group, the mean change in serum sodium levels from baseline was 2.1 mEq/L, with a standard deviation (SD) of 4.9 mEq/L. Similar findings were reported by Hasman et al<sup>20</sup> on effect of crystalloid solution on acid base balance.

## 5. CONCLUSION

Resuscitation with Ringer's lactate (RL) and normal saline (NS) yields comparable resolution of biochemical and improvement in clinical signs in children with acute severe diarrheal dehydration, with NS showing a trend toward lower creatinine, blood urea, and lactate levels, as well as offering advantages of lower cost and greater availability, thus positioning NS as the preferred fluid choice based on considerations of clinical efficacy, cost-effectiveness, and accessibility.

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