

ORIGINAL ARTICLE

A Randomized Double Blind Controlled Trial of Ringers Lactate Versus Normal Saline Among Pediatric Patients with Acute Severe Diarrhea

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ABSTRACT

Objective: To compare ringer's lactate versus normal saline as a fluid replacement therapy among pediatric patients with acute severe diarrhea and dehydration.

Study Setting: A quasi experimental study was undertaken at Paediatric medicine department, "Peoples university of medical and health sciences for women Nawabshah during April to September 2021".

Material and Methods: A quasi experimental study was conducted. Randomly participants were divided in two groups, in group A Ringer lactate was given while in group B normal saline was given for fluid replacement. Detailed history, clinical findings, demographic details and the serum electrolytes, renal parameters and acid-base status of participants of both groups were noted on a pre-formed proforma, before and after 6 hours of starting fluid replacement therapy. Data was analyzed by using SPSS V-20.

Results: Mean age of the study participants of RL groups was 3.35 ± 1.22 and 3.39 ± 1.19 of NS group with male predominance. At the time of admission, there was no significant association of demographic and clinical characteristics between RL and NS groups. After starting treatment, at the end of 6 hours the status of dehydration and pH were improved more in the participants of RL group. The change in serum electrolytes comprising potassium, chloride and sodium were greater in groups RL, on the other hand, significant p-values were noted only with sodium and potassium. Looking over the acid-base status, the alteration in pH and serum bicarbonate was greater in group RL as compared to group NS with significant p-value.

Conclusion: It can be concluded that the ringer's lactate is superior to normal saline as a fluid replacement therapy in pediatric patients of acute gastroenteritis.

Keywords: Acute watery diarrhea, Severe dehydration, Ringer's lactate, Normal saline, Fluid replacement therapy

INTRODUCTION

Acute watery diarrhea is defined as more than three loose stools per 24 hours with softer consistency for the period of < fourteen days⁽¹⁾. Diarrhea is considered as the 2nd most common reason of increased mortality among the children, approximately two billion children are affecting annually out of which about 1.5 million leads to death. It is worldwide increasing the burden of disease⁽²⁾. Among the developing countries like Pakistan, there is a very high morbidity and mortality rate, it has been estimated that about 500 children die because of diarrhea daily and average of about 5-6 episodes of diarrhea have been occurred in a child within one year^(2,3).

Severe diarrhea always leads to dehydration which need intravenous fluid replacement on urgent basis. WHO recommends the ringer's lactate (RL) and normal saline (NS) fluid for correcting dehydration immediately and this is commonly practiced worldwide⁽⁴⁾. Very few of the studies have been found in the literature to compare the efficacy of RL and NS fluid for correcting dehydration. It has been reported that after 6 hours of fluid replacement therapy, the RL is more effective than NS in correcting serum potassium, serum bicarbonate concentration and regulating pH within normal range, beside this RL is safer and does not cause acidosis⁽⁵⁾. Due to lack of literature there is conflict regarding serum bicarbonate concentration and pH regulation by two different fluids^(6,6), so the current study aims to compare ringer's lactate versus normal saline as a fluid replacement therapy among pediatric patients with acute severe diarrhea and dehydration.

MATERIAL AND METHODS

This quasi experimental study was undertaken at Paediatric medicine department, "Peoples university of medical and health sciences for women Nawabshah during April to September 2021". Sample size was calculated by using OpenEpi calculator and was 220. Those patients were included in the study who were presented with acute watery diarrhea and severe dehydration and from age between 1-5 years. Acute watery diarrhea was labelled

when more than three stools per 24 hours with softer consistency and was for less than 14 days while severe dehydration included drowsy, skin pinch and sunken eyes goes back gently. Those patients were excluded who either having persistent diarrhea or blood in stool or malnourished or hypoglycemic or parents refused to give consent. The informed consent was taken from the parents.

The participants were randomly divided into two treatment groups, Group A had Ringer lactate as a replacement fluid while Group B had Normal saline for fluid replacement. Each group contained equal number of 110 participants. Detailed history, clinical findings, demographic details and the serum electrolytes, renal parameters and acid-base status of participants of both groups were noted on a pre-formed proforma. The fluid replacement therapy was started soon after the presentation and after 6 hours of therapy again patients were analyzed clinically and serum electrolytes and acid-base status were noted.

Statistical Package for Social Science (SPSS) version-20 was used to analyse the data. Quantitative data was analysed using the mean and standard deviation, whereas qualitative data was analysed using frequency and percentage. Independent sample t-test was applied for comparing mean values of serum electrolytes, renal parameters and acid-base status between the two groups. Chi square was applied to compare categorical variables including gender, symptoms and improvement after fluid replacement. p-value less than 0.05 was considered as significant.

RESULTS

Mean age of the study participants of RL groups was 3.35 ± 1.22 and 3.39 ± 1.19 of NS group but this variation was of no significant value. Males were predominant in both groups but had no significance. Symptoms were almost similar in both groups but the duration of symptoms were slightly more in the RL group. Demographic and clinical characteristics of study participants of both groups and their associations were separately mentioned in Table 1. At the time of admission, there was no significant association of demographic and clinical characteristics between RL and NS groups as the p-values were non-significant (p-value ≥ 0.05).

After starting treatment, at the end of 6 hours the status of dehydration and pH were improved more in the participants of RL group but this difference was non-significant. The variation in serum electrolytes were higher in RL groups, on the other hand, significant p-values were noted only with sodium and potassium i.e. 0.04 and 0.01 respectively but not significant with the chloride (0.32). Looking over the acid-base status, the alteration in pH and serum bicarbonate was maximum in group RL as compared to group NS with significant p-value. Beside this the base deficit was more in group NS than the group RL, but this differences between RL group and NS group were not significant as p-values were more than 0.05.

Table 1: Parameters at the time of admission

	Ringer lactate group (n=110)	Normal saline group (n=110)	P-value
Age (years)	3.35 ± 1.22	3.39 ± 1.19	0.671
Gender			0.095
Male, n (%)	64 (58.2)	56 (50.9)	
Female n (%)	46 (41.8)	54 (49.1)	
Duration of symptoms	2.5 ± 0.7	2 ± 0.9	0.842
Symptoms			
Frequency of stools per day	10 ± 1.2	10 ± 1.1	0.923
Vomiting, n (%)	46 (41.8)	49 (44.5)	0.712
Unable to drink or drink poorly, n (%)	80 (72.7)	87 (79.1)	0.262
Lethargy or unconscious, n (%)	102 (92.7)	101 (91.8)	1.004
Sunken eyes, n (%)	110 (100)	110 (100)	1.019
Skin pinch goes back very slowly, n (%)	23 (20.9)	19 (17.3)	0.443
Serum electrolytes			
Sodium (mEq/L)	137.4 ± 5.0	135.9 ± 5.3	0.881
Potassium (mEq/L)	4.5 ± 0.8	4.4 ± 0.9	0.652
Chloride (mEq/L)	102.3 ± 1.4	101.7 ± 1.2	0.199
Renal parameters			
Blood urea (mg/dL)	51 ± 9.1	53 ± 11.5	0.245
Serum creatinine (mg/dL)	1.4 ± 0.7	1.5 ± 0.5	0.290
Status of Acid-base			
pH	7.12 ± 0.9	7.11 ± 0.10	0.501
Serum bicarbonate (mEq/L)	9.6 ± 2.8	8.9 ± 2.7	0.900
Base deficit (mMol/L)	17.4 ± 4.2	17.9 ± 4.9	0.898
Anion gap	25.4 ± 5.1	24.8 ± 5.3	0.110

Table 2: Parameters at the end of 6 hours

	Ringer lactate group (n=110)	Normal saline group (n=110)	P-value
Improved dehydration	42 (38.2)	25 (22.7)	0.189
Improved pH (≥7.35, n (%))	42 (38.2)	25 (22.7)	0.189
Serum electrolytes			
Sodium (mEq/L)	135.0 ± 3.3	131.5 ± 9.3	0.04
Potassium (mEq/L)	3.9 ± 0.6	3.6 ± 0.9	0.01
Chloride (mEq/L)	101.8 ± 1.6	101.5 ± 1.4	0.32
Status of Acid-base			
pH	7.46 ± 0.08	7.32 ± 0.07	0.001
Serum bicarbonate (mEq/L)	13.4 ± 2.1	9.3 ± 2.6	0.02
Base deficit (mMol/L)	15.3 ± 6.8	15.9 ± 5.7	0.72

DISCUSSION

The most common disease, the physicians are treating, is acute gastroenteritis leading to severe dehydration⁽⁷⁾. It is one of the leading cause of morbidity and mortality among neonatal and pediatric age groups and consumes major junk of healthcare cost⁽⁸⁾. American Academy of Microbiology presented a report on the burden of gastrointestinal diseases, which showed that about 6.6 billion cases per year was suffered from acute gastroenteritis worldwide⁽⁹⁾. Developing countries are facing higher prevalence of diarrhea, resulting in increased mortality rate. Frequent infectious diarrhea cause malnutrition so affecting the growth of children⁽¹⁰⁾. Not only the developing countries, the developed countries are also having increased morbidity rate due to infectious diarrhea among children⁽¹¹⁾.

Management plan depends upon the signs and symptoms of patient, as the aim is to recover from acute attack and prevent relapse⁽¹²⁾. It is one of the most common cause of severe dehydration as need immediate intravenous fluid replacement within 3-6 hours of illness^(4,13). It is still under discussion that what type of fluid should be given including colloid solution or crystalloid solution, depending upon the resuscitating property of solution that how fast the fluid can support the intravascular volume and tissue

perfusion without causing edema⁽¹⁴⁾. Literature review revealed that ringer's lactate fluid is superior to normal saline among children with acute gastroenteritis. Limited studies have been done and reported conflicted results about change in pH and serum bicarbonate^(5,6).

Current study reported that the mean age of the study participants of RL groups was 3.37 ± 1.14 with male predominance. Other studies also favor this finding by reporting increased incidence of diarrhea among male children^(15,16). Starting fluid replacement therapy, in the RL group, changes in pH and serum bicarbonate were greater than those in the NS group after six hours of incubation with significant p-value. The same is favored by another study done in Pakistani children by Rasheed et al.⁽¹⁷⁾. Mahajan et al also conducted a double blind controlled trial and found that there was rapid improvement among the patients of ringer's lactate group⁽⁵⁾. Cieza et al also reported that change in pH was more in ringer's lactate group (7.33 ± 0.05 versus 7.27 ± 0.08) with significant association⁽⁶⁾. Current study also found improved pH in ringer's lactate group (7.46 ± 0.08 versus 7.32 ± 0.07) with significant p-value (0.001).

Looking over the change in serum electrolytes the current study reported that sodium, potassium and chloride, were higher in RL groups, significant p-values were noted only with sodium and potassium but not with the chloride. Rasheed et al also found no significant results for serum potassium in normal saline and ringer's lactate group⁽¹⁷⁾, many other studies also favored the current findings^(6,18).

CONCLUSION

It can be concluded that the ringer's lactate is superior to normal saline as a fluid replacement therapy in pediatric patients of acute gastroenteritis. A rapid change in serum bicarbonate and pH was noted with ringer's lactate solution in comparison to normal saline solution after 6 hours of intravenous therapy.

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