COMPARISON OF OUTCOME BETWEEN RINGER'S LACTATE AND NORMAL SALINE FLUID REPLACEMENT IN PEDIATRIC PATIENTS WITH ACUTE WATERY DIARRHOEA

Shahzad Rasheed, Saima Rafique, Abdul Wahid Hussain, Munir Akmal Lodhi

Pak Emirates Military Hospital/National University of Medical Sciences (NUMS) Rawalpindi Pakistan

ABSTRACT

Objective: To compare ringer's lactate and normal saline fluid replacement in pediatric patients with acute watery diarrhoea in terms of mean serum bicarbonate, potassium and pH.

Study Design: Quasi experimental study.

Place and Duration of Study: This study was conducted at the department of Pediatrics, Pak Emirates Military Hospital, Rawalpindi from Feb 2015 to Jul 2015.

Methodology: This study involved 206 children of both genders aged between 1-5 years with watery diarrhoea and severe dehydration. These patients were randomly divided into two treatment groups each comprising of 103 patients. Patients in group-A received ringer's lactate while group-B patients were given normal saline as replacement fluids.

Results: The mean age of the patients was 3.34 ± 1.19 years and there were 112 (54.4%) male and 94 (45.6%) female patients. Both the groups were comparable in terms of mean age (p=0.861) and gender distribution (p=0.576). After 6 hours of initiating fluid therapy, mean serum bicarbonate (13.61 ± 2.41 vs. 9.72 ± 2.07 meq/l; p<0.001) and mean blood pH (7.46 ± 0.02 vs. 7.38 ± 0.03; p<0.001) were significantly higher in children treated with ringer's lactate as compared to normal saline. While there was no significant difference between the two groups (4.35 ± 0.61 vs. 4.27 ± 0.58 meq/l; p=0.319) in terms of mean serum potassium level.

Conclusion: Fluid replacement with ringer's lactate was superior to normal saline in terms of significantly higher mean serum bicarbonate and mean blood pH after 6 hours of initiating therapy while it was equally safe and only caused insignificant increase in mean serum potassium level.

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

INTRODUCTION

Acute watery diarrhoea may be defined as "three or more loose or liquid stools per day, or stools which are more frequent than usual for the individual of less than 14 days duration[1]. A treatable as well as preventable disease, diarrheal illness is the 2nd leading cause of childhood mortality responsible not only for two billion cases of diarrhoea worldwide but also results in 1.5 million deaths annually[2]. Pakistan is a country with very high mortality of 500 deaths per day and almost every Pakistani child suffers from five to six episodes of diarrhoeal illness on yearly basis[2,3].

Correspondence: Dr Shahzad Rasheed, Child Specialist, Combined Military Hospital, Sialkot Pakistan
Email: drshahzadrashid@gmail.com
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Acute watery diarrhoea causes severe dehydration which necessitates urgent intravenous fluid therapy over three to six hours duration. According to WHO recommendations, ringer's lactate (RL) and normal saline (NS) can be transfused for rapid correction of dehydration which is a common practice in tertiary care hospitals around the globe and in Pakistan[4].

Very limited data is available which compares the role of RL and NS in fluid replacement. Mahajan *et al*. in 2011 in a randomized controlled trial showed that ringer's lactate replacement was superior to normal saline in terms of mean serum bicarbonate (13.4 ± 2.1 vs. 9.3 ± 2.6 mEq/L; p=0.03) and mean serum potassium (3.9 ± 0.6 vs. 3.6 ± 0.9; p=0.03) measured after 6 hours of initiation of treatment. At the same time they observed that ringer's lactate was equally safe

and was not associated with acidosis; mean blood pH was (7.28 ± 0.09 vs. 7.21 ± 0.09; p=0.17)[5]. Cieza *et al*. in 2013 documented that ringer's lactate was even superior to normal saline in terms of mean blood pH (7.33 ± 0.05 vs. 7.27 ± 0.08; p<0.01). But they didn't observe any significant difference between the two groups in terms of mean serum potassium (5.1 ± 1.4 vs. 4.5 ± 1.3 mEq/L; p>0.05)[6].

The above mentioned studies highlighted the benefit of ringer's lactate over normal saline in fluid replacement in pediatric patients with acute watery diarrhoea. However the evidence was currently limited and contained conflicting results about the serum bicarbonate level and pH[5,6].

METHODOLOGY

It was a quasi experimental study. Research was conducted at department of Pediatrics, Pak Emirates Military Hospital, Rawalpindi. Duration of study was 6 months from February 2015 to July 2015.

Sample size of 206 cases (103 in each group) was calculated with 80% power of test and 95% confidence level taking expected mean serum potassium level to be 3.9 ± 0.6 with ringer lactate and 3.6 ± 0.9 with normal saline in pediatric patients with acute watery diarrhoea[5]. Patients were selected by non-probability, consecutive sampling. Children of both genders aged between 1-5 years with watery diarrhoea and severe dehydration were taken as subjects. Watery diarrhoea was defined as the passage of ≥3 stools/24 hours which were softer than normal consistency as per history from the mother while the severe dehydration was labeled if there was drowsiness, sunken eye and decreased skin turgor (pinched skin goes back >1 sec) on clinical examination. Patients who presented within first 96 hours of diarrhoea were included.

Children with bloody diarrhoea and those with severe malnutrition (weight for height below -3 z-scores of the median WHO growth standards) were excluded.

Approval from hospital's ethical review committee was taken. Written informed consent and detailed history was taken from each patient. Their demographic details were also noted. The patients were then randomly divided into following two treatment groups using lottery method.

Group A. Replacement Fluid: Ringer's lactate (103 cases)

Group B. Replacement Fluid: Normal saline (103 cases)

Fluid replacement required was calculated as per operational definition and each group received corresponding treatment starting with in 5 minutes of presentation. Serum bicarbonate, potassium and pH level were acquired after 6 hours of initiating fluid replacement. Patient's demographic details along with serum bicarbonate, potassium and blood pH level were noted and recorded into the attached proforma.

All the patients were managed by a single resident and all the laboratory reports were acquired from a single laboratory to eliminate bias. Confounding variables were controlled by exclusion. Data were analyzed with SPSS version 22.0.

Numerical variables were presented by mean ± SD. Independent sample t-test was used to compare mean serum bicarbonate, mean serum potassium and mean blood pH between the two groups taking p-value ≤0.05 as significant. Categorical variables were presented by frequency and percentage. Post-stratification independent sample t-test was applied taking p-value ≤0.05 as significant.

RESULTS

The age of the patients ranged from 1 year to 5 years with a mean of 3.34 ± 1.19 years. There were 112 (54.4%) male and 94 (45.6%) female patients in the study cohort as shown in table-I. Both the groups were comparable in terms of mean age (p=0.861) and gender distribution (p=0.576) as shown in table-II.

After 6 hours of initiating fluid therapy, mean serum bicarbonate (13.61 ± 2.41 vs. 9.72 ± 2.07 meq/l; p<0.001) and mean blood pH (7.46 ± 0.02 vs. 7.38 ± .03; p<0.001) were significantly higher in children treated with Ringer's Lactate as compared to Normal Saline. While there was no significant difference between the two groups (4.35 ± 0.61 vs. 4.27 ± 0.58 meq/l; p=0.319) in terms of mean serum potassium as shown in table-III.

Table-I: Baseline characteristics of the study population.

Characteristics	Participants (n=206)
Age (years)	3.34 ± 1.19
Gender	
Males	112 (54.4%)
Females	94 (45.6%)

Table-II: Baseline characteristics of the study groups.

Characteristics	Ringer Lactate (n=103)	Normal Saline (n=103)	*p*-value
Age (years)	3.33 ± 1.28	3.36 ± 1.10	0.861
Gender			
Males	54 (52.4%)	58 (56.3%)	0.576
Females	49 (47.6%)	45 (43.7%)	

Independent sample t-test, observed difference was statistically insignificant

Table-III: Comparison of mean serum sodium, potassium and pH between the study groups.

	Study Groups		*p*-value
	Ringer Lactate (n=103)	Normal Saline (n=103)	
Mean Serum Bicarbonate (meq/l)	13.61 ± 2.41	9.72 ± 2.07	<0.001*
Mean Blood pH	7.46 ± 0.02	7.38 ± 0.03	<0.001*
Mean Serum Potassium (meq/l)	4.35 ± 0.61	4.27 ± 0.58	0.319

Independent sample t-test, *observed difference was statistically significant.

DISCUSSION

Diarrhea is one of the most common presentations seen by primary care physicians and contributes major proportion of referrals to gastroenterologists[7]. Acute gastroenteritis (AGE) complicated by dehydration continues to be the major cause of childhood morbidity and mortality, necessitating substantial healthcare costs across the world[8]. In a report by the American Academy of Microbiology in 2002 on the worldwide load of gastrointestinal diseases, it was assessed that 6.60 billion cases of gastrointestinal diseases occur through out the world annually[9]. A latest World Health Organization (WHO) report claims that in 2005 1.8 million people died from diarrheal diseases worldwide[10]. Although the approximates of worldwide mortality from diarrhoea dropped from roughly 4.6 million annual deaths in the mid-1980s[5] to the current assessment of 1.8 million[4], the morbidity of this syndrome is still considerable[5]. Moreover, most of the morbidity estimations do not consider the malnutrition produced by persistent diarrhea and enteropathy subsequent to chronic and recurrent enteric infections and its associated influence on growth and development[9]. Thus the actual morbidity may be much higher than estimated[9]. In developing countries, infectious diarrheas are frequently disabling and contribute significantly to malnutrition and mortality in children[10], while in the USA and other western countries; they are a major cause of morbidity, physician visits/ hospitalizations, and loss from work or school[11].

The treatment of diarrhoea remains empirical and depends on the clinical status of the patient. Certain manifestations and complications must be identified in order to determine the goals

of therapy. Treatment is directed at terminating an acute attack and inducing remission, preventing relapse and controlling chronic symptoms[12]. Acute watery diarrhoea causes severe dehydration which necessitates urgent intravenous fluid therapy over three to six hours duration[4]. Fluid management is perhaps the most permeating therapeutic intervention in such dehydrated children[13]. The debate as to which fluid, how much, and when to give it was originally focused around the option between colloid or crystalloid solutions, evaluating which was a better resuscitation fluid regarding its capacity to firstly support intravascular volume and endorse tissue perfusion, without producing interstitial edema[14]. Recent studies claimed the benefit of ringer's lactate over normal saline in fluid replacement in pediatric patients with acute watery diarrhoea. However the evidence was currently limited and contained conflicting results about the serum bicarbonate level and pH[5,6]. Also there was no such local published material which necessitated the present study.

In the present study, the mean age of the patients was 3.34 ± 1.19 years and there were 112 (54.4%) male and 94 (45.6%) female patients. A similar male predominance among diarrhea children has also been reported in other local studies by Habib *et al*[15] in 2014 (60% vs. 40%) and Zahoor *et al*[16] in 2010 (66.7% vs. 33.3%). After 6 hours of initiating fluid therapy, mean serum bicarbonate (13.61 ± 2.41 vs. 9.72 ± 2.07 meq/l; p=0.000) was significantly higher in children treated with ringer's lactate as compared to normal saline. Our results match with those of Mahajan *et al*[5] in 2011 who also observed fluid replacement with ringer's lactate to be superior to normal saline in terms of mean serum bicarbonate (13.4 ± 2.1 vs. 9.3 ± 2.6 mEq/L; p=0.03). Mean blood pH (7.46 ± 0.02 vs. 7.38 ± .03; p=.000) was also significantly higher in children treated with ringer's lactate as compared to normal saline. Cieza *et al*[6] in 2013 also observed similar results in terms of mean blood pH (7.33 ± 0.05 vs. 7.27 ± 0.08; p<0.01). However there was no significant difference between the two groups (4.35 ± .61 vs. 4.27 ± .58 meq/l; p=.319) in terms of mean serum potassium. Here our observation is in line with that of Cieza *et al*[6] in 2013 who also didn't observe any significant difference between ringer's lactate and normal saline (5.1 ± 1.4 vs. 4.5 ± 1.3 mEq/L; p>0.05) in terms of mean serum potassium. In a recent randomized controlled trial, Kartha *et al*.[17] (2017) however observed insignificant difference in the mean serum potassium (4.2 vs. 4.1; p=0.768) and blood pH (7.32 vs. 7.30; p=0.428) between children receiving ringer's lactate and normal saline for rehydration[18]. However, the study was conducted over a limited sample size of 68 children compared to 206 children in the present study which support the current observations.

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CONCLUSION

Fluid replacement with ringer's lactate was superior to normal saline in terms of significantly higher mean serum bicarbonate and mean blood pH after 6 hours of initiating therapywhile it was equally safe and only caused insignificant increase in mean serum potassium level.

CONFLICT OF INTEREST

This study has no conflict of interest to be declared by any author.

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