# Original Article A randomized controlled trial to assess the effect of isotonic normal saline versus water post-Ryles Tube feeding for correcting hyponatremia among ICU patients at tertiary care hospital: a pilot study

Neetu Kataria<sup>1</sup>, Hoineiting Rebecca Haokip<sup>2</sup>, Vasantha C Kalyani<sup>3</sup>

<sup>1</sup>College of Nursing, All India Institute of Medical Sciences (AIIMS), Rishikesh, Uttarakhand, India; <sup>2</sup>Department Nursing, All India Institute of Medical Sciences (AIIMS), Kalyani, West Bengal, India; <sup>3</sup>College of Nursing, All India Institute of Medical Sciences (AIIMS), Deoghar, Jharkhand, India

Received November 18, 2022; Accepted March 20, 2023; Epub April 15, 2023; Published April 30, 2023

**Abstract:** Objectives: To assess the effect of isotonic normal saline (NS) versus water post-Ryles Tube (RT) feeding upon hyponatremia and blood parameters in Intensive Care Units (ICU) admitted patients. Methods: A parallel group randomized controlled trial design. The total sample size taken for this pilot trial was N = 50 as a thumb rule (n = 25 in each arm) selected by using a simple random sampling method. The sample was ICU-admitted patients with mild and moderate hyponatremia.at tertiary care hospital, Rishikesh. *Intervention*-20 mL Isotonic 0.9% normal saline (NS) among the experimental group vs. 20 mL water in the control group after each 9 am Ryles tube feeding respectively for three continuous days. At baseline and follow-up electrolytes, blood parameters, Glasgow Coma Scale (GCS), and blood pressures were assessed post-one hour of intervention daily for day-1, 2, 3 & 5. Data were analyzed by using descriptive & inferential statistics in the SPSS software 23.0 version. Results: There was a significant difference found between the experimental and control groups for the post-test value of serum sodium levels, GCS, Systolic Blood Pressure, and Diastolic Blood Pressure (DBP) at day 1 of administration of normal saline intervention with *p*-value < 0.0001. However, it was found significant at day 5 between both groups for the above-mentioned variables. Conclusion: The intervention of normal saline was found to be a cheaper and more effective remedy to treat hyponatremia and reduce mortality among ICU-admitted patients due to deterioration in bio-physiological parameters.

Keywords: Hyponatremia, Ryles tube feeding, isotonic, normal saline, intensive care unit

#### Introduction

Hyponatremia (< 135 mmol/L) is the single most frequent electrolyte disturbance encountered in the intensive care unit (ICU), affecting as many as 24.5% of the patients, depending on its biochemical definition. These previous studies evaluated hyponatremia during ICU admission, although new-onset hyponatremia is easily detected in clinical practice [1]. This ADH release may be related to stimuli such as pain, anxiety, fever, and vomiting, reducing the capacity to excrete free water and increasing the risk of hyponatremia in these patients [2, 3]. The complications of hypotonic hyponatremia are more severe when the decrease in serum sodium concentration is large or rapid (occurring over hours). The associated conditions are usually termed hypovolemic, isovolumic, and hypervolemic hyponatremia [4, 5]. The leakage moves proteins, electrolytes, and water from the intravascular compartment to the interstitial space. This allows immune mediators to reach the site of injury or infection, causing edema [6, 7].

Isotonic saline has been the most commonly used crystalloid for fluid resuscitation in ICUs [8]. Ryles tube (RT) feeding was primarily used in intensive care units to provide nutritional support for the patients. Normally, 20-30 ml of water is given after Ryles tube feeding in ICU patients to flush out the food materials. Hyponatremia in SIADH is characterized by an increase in total body water with decreased total body sodium [9, 10].

In the Northern India-Sub-Himalayan region, to per best of our knowledge, no randomized controlled trial online literature was found in this area for correcting hyponatremia by normal saline after Ryles tube feeding in critically ill patients. As nurses provide care, they give Ryles tube (RT) feedings to patients every day. The motivation to do this comes from day-today professional experiences working in critical care areas. The unnecessary pricking of the patients for correcting hyponatremia by IV route of normal saline administrations further requires proper monitoring and intake-output or can lead to the risk of phlebitis or infiltration of that area. Nurses are the best medium to provide this intervention smoothly as well as monitor the clinical parameters closely.

The clinical significance includes the nasogastric route of administration via Ryles Tube, which will help reduce the need for close monitoring of intravenous interventions for corrections of fluid and electrolyte imbalances, ultimately reducing the prevalence of IV site infections, phlebitis, or any other complications.

Therefore, we aim to conduct this study in ICU patients by assessing the effect of normal saline (0.9%) vs. free water post-RT feeding upon hyponatremia and blood parameters.

#### Methodology (CONSORT-2010 guidelines)

#### Study design

A parallel group randomized Controlled Trial design was adopted for the present study.

# Study sample and setting

The participants for the study were adults with mild to moderate hyponatremia admitted to an Intensive Care Unit at a tertiary care hospital in Rishikesh, Uttarakhand.

*Eligibility criteria*: Inclusion criteria were patients with age > 18 years, ICU stays > 48 hours, and mild hyponatremia (130-134 mEq/L), as well as moderate hyponatremia (125-130 mEq/L), who were included in the study. Exclusion criteria were patients with any history of pituitary adenoma disease, chronic kidney disorders (CKD), and chronic liver disease (CKD), and any history of intake of drugs such as ACE inhibitors, Heparin, diuretics, antidepressants, antipsychotics, and antiepileptics.

#### Sample size calculation

The sample size was estimated using the Winpepi® program (http://www.brixtonhealth. com/pepi4windows.html).

Required sample size = 24 (for each arm) [Inflated to compensate for the loss of 10% of subjects], to estimate a mean (simple random sample): Confidence level = 95%; acceptable error = 5; assumed S.D. = 11; expected loss of subjects = 10%. The final sample size was calculated at 50 (25 in each arm) because it was a pilot trial (using the rule of thumb technique) collected within six months.

*Randomization:* Randomization was done by using a simple random sampling technique of a computer-generated random number table with a block size of 4 as 52 and SEED no.: 15881205688032 from an independent person outside the research team was used for the study.

Allocation: It was done by using the sealed envelope method (SNOSE) with a ratio of 1:1 into each arm for the study.

*Blinding:* Participants and the outcome assessor were blinded in this pilot trial, but the investigator was not.

Interventions: The experimental group received a maintenance dose of 20 mL of isotonic 0.9% normal saline, whereas the control group received 20 mL of free water post-Ryles Tube feeding daily at 9 a.m. for three continuous days (day 1 to day 3). Then intervention stopped on the fourth and fifth days; only free water was given to both groups along with measurements of electrolytes and blood parameters post-Ryles tube feeding, as mentioned in **Figure 1**: CONSORT flow chart.

# Blood investigations

Blood parameters include serum sodium (Na), chloride (Cl), urea, creatinine, calcium (Ca), uric

Effect of isotonic NS versus water post-Ryles Tube feeding for correcting hyponatremia



acid, potassium (K), and other parameters include systolic blood pressure (SBP) and diastolic blood pressure (DBP), the Glasgow coma scale (GCS) (Total score: 15). The grading of GCS includes: mild GCS = 13-15, moderate GCS = 9-12, and severe GCS = 3-8. The use of GCS was suggested in a previous study to assess the impact of early correction of hyponatremia on overall prognosis as well as neurological outcomes due to brain edema among ICU-admitted patients [11]. The purpose of this tool was to check for any deterioration in consciousness or improvement due to intervention among hyponatremia participants.

#### Data collection procedure

Participants in both groups were screened for eligibility criteria and enrolled in the study by giving informed consent, then socio-demographic and clinical variables and blood parameters were taken. The total duration of the study was five days at baseline with follow-ups one hour post-intervention on all days 1, 2, 3, and 5 for measuring serum electrolytes such as Na, Cl, GCS, SBP, and DBP. At baseline, blood samples were taken to measure electrolytes, and blood parameters were recorded before and after one hour daily for three days

	een both group	3 (11 - 30)	
	Experimental	Control group	n
Variables	group (n = 25)	(n = 25)	value
	f (%)	f (%)	value
Age (in years)	41.7±10.07	41.6±10.37	0.99
Sex			
Male	13 (52%)	16 (64%)	0.59
Education			
Uneducated	5 (20%)	5 (20%)	0.58
Primary school	13 (52%)	11 (44%)	
Secondary school	6 (24%)	10 (40%)	
Habitat			
Rural	18 (72%)	21 (84%)	0.62
BMI			
Normal	17 (68%)	21 (84%)	0.41
Underweight	7 (28%)	5 (20%)	
Hypertensive			
Yes	15 (60%)	13 (52%)	0.37
Diabetes Mellitus			
Yes	13 (52%)	14 (56%)	0.98
History of heart disease			
Yes	6 (24%)	5 (20%)	0.62
Type of tobacco abuse			
Non-user	13 (52%)	12 (48%)	0.72
Tobacco Smoking	6 (24%)	6 (24%)	
Both	5 (20%)	8 (32%)	
Pattern of alcohol use			
User	5 (20%)	6 (44%)	0.84
Baseline urea	60.5±51.60	33.35±42.55	0.09 <sup>@</sup>
Baseline creatinine	1.61±1.70	2.19±1.79	0.25
Baseline potassium	3.41±0.76	3.21±0.65	0.32
Baseline calcium	8.47±2.77	8.20±1.32	0.66
Baseline uric acid	5.65±3.16	5.33±2.38	0.66®
Length of hospital stay	8.91±5.23	9.55±3.90	0.62

Table 1. Baseline distribution of socio-demographic and
clinical variables between both groups ( $N = 50$ )

Note: Chi-square test and <sup>@</sup>Mann-Whitney U test,  $^*p$  value considered as significant < 0.05.

with interventions. The last venous blood sample was taken on the fifth day without any intervention provided to any group for assessing any relapse of hyponatremia among samples.

#### Ethical approval

Ethical approval was obtained from the institutional ethical committee (IEC), a tertiary care hospital in Rishikesh (AIIMS/IEC/19/1298), and the Clinical Trial Registry of India (REF no= CTRI/2021/06/044318). All participants filled out an informed consent form, and their confidentiality and anonymity were well maintained. All ethical standards of the IEC, Declaration of Helsinki, ICMR, and good clinical practices were followed in the study.

## Statistical methods

The data were analyzed using SPSS 23.0 version software (IBM, Chicago) with appropriate descriptive and inferential statistics to generate results. The normality of data regarding blood parameters had been assessed using the Kolmogorov-Smirnov test, with a p-value > 0.05 showing data as normally distributed and proceeding for the parametric test, and vice versa, All socio-demographic and clinical variables were tabulated as frequency percentages, and the Chi-Square or Fisher exact test was used where appropriate. The continuous data of the blood parameters were analyzed using parametric testing (independent t-test or Mann-Whitney U test as appropriate) and RM-ANOVA testing for the timeseries measurements of values, with a *p*-value considered significant < 0.05and 95% confidence intervals. The primary outcome was a change in sodium levels, and the secondary outcomes were a change in selected blood parameters (CI, SBP, DBP, and GCS status). If any harmful effect due to the intervention of normal saline occurred, it would be reported to the IEC (Institutional Ethical Committee) of the hospital, and the trial would be stopped. However, in our study, no harmful effect was reported.

# Results

No drop-outs were reported in the study; hence, N = 50, and all participants entered the analysis phase. The study results were divided into two main sections: Section 1 (socio-demographic and clinical profiles) and Section 2 (outcome variables for Na, Cl, GCS, SBP, and DBP).

# Section 1: socio-demographic and clinical profiles of participants

 Table 1 presents the baseline distribution of socio-demographic and clinical characteristics

Variable	Experimental group (n = 25) (Mean ± SD)	Control group (n = 25) (Mean ± SD)	95% Lower C.I.	95% Upper C.I.	t value (p value)
Baseline	127.12±26.42	127.96±18.86	-2.13	0.46	-1.26 (0.20)
Immediate post-test	129.12±20.62	126.12±26.95	-4.66	-1.94	-4.89 (< 0.0001*)
Day-2 post-test	130.35±18.96	126.80±24.45	-4.76	-2.28	-5.72 (< 0.0001*)
Day-3 post-test	131.12±16.08	126.62±23.18	-5.61	-3.36	-8.01 (< 0.0001*)
Day-5 post-test	126.97±15.72	126.89±20.69	-1.11	0.96	-0.15 (0.88)

Table 2. Change in blood sodium (Na) (in mEq/L) levels between both groups (N = 50)

Note: Independent 't' test used, \*p value considered as significant < 0.05.

of the 50 participants in the experimental and control groups. The mean age matches between the experimental and control arms were  $41.7\pm10.07$  and  $41.6\pm10.37$  years, respectively, with a *p*-value of 0.99. The current study matched the age, sex, education, and habitat of both groups with a *p*-value > 0.05. Similarly, all the clinical characteristics, including body mass index (BMI), the status of hypertensive, diabetes mellitus, history of heart disease, type of tobacco abuse, alcohol abuse, baseline serum urea, creatinine, potassium, calcium, uric acid levels, and length of hospital stay, were matched between the two groups with a *p*-value > 0.05.

# Section 2: outcome variables of participants

**Table 2** shows that, in the experimental group, there was a significant improvement in the mean change in blood sodium level from baseline to immediate post-test day 1 (127 vs. 127), at day 2 (129 vs. 126), and at day 3 follow-up (131 vs. 126) compared to the control group, respectively, with a *p*-value of < 0.0001. Although this change was not reported on day 5 without any intervention in any group, it was found to be similar to 126 vs. 126 in the experimental and control groups, respectively, with a *p*-value of 0.88. Hence, normal saline was found to be effective in improving sodium levels compared to free water post-RT feeding on days 1, 2, and 3.

**Table 3**, the Repeated Measures ANOVA test was used for continuous time series data for serum sodium levels in the control group and showed only a significant difference from baseline to day 1 but not in other time series of days 2, 3, and 5 at a *p*-value < 0.05.

However, the RMANOVA continuous time series for serum sodium level of the experimental

group was found to be significant from baseline to days 1, 2, and 3, but not on day 5. Similarly, on day 5, serum sodium was significantly different from days 1, 2, and 3 and not on the baseline at a p-value < 0.05.

**Table 4** findings reported that, in the experimental group, there was a significant improvement in the mean change in GCS score from baseline to immediate post-test (6.2 vs. 8.13) compared to the control group with a *p*-value < 0.0001. Although this change was not reported on day 2 (7.08 vs. 6.56), day 3 (7.08 vs. 6.23), and day 5 (7.12 vs. 5.96) were found to be similar in the experimental and control groups, respectively, with a *p*-value > 0.05. Hence, normal saline was only found to be effective in improving GCS scores immediately after intervention compared to free water post-RT feeding.

**Table 5** findings suggested that, in the experimental group, there was a significant maintenance of mean change in SBP (mmHg) from baseline to immediate post-test (119 vs. 130) with a *p*-value < 0.0001. Although this change was not reported on day 2 (123 vs. 130), day 3 (124 vs. 133) and day 5 (126 vs. 131) were found to be similar in the experimental and control groups, respectively, with *p*-values > 0.05. Hence, normal saline was only found to be effective in maintaining SBP immediately after intervention compared to free water post-RT feeding.

In **Table 6**, findings suggested that, in the experimental group, there was significant maintenance of the mean change in DBP (mmHg) from baseline to immediate post-test (78 vs. 72) with a *p*-value < 0.0001. Although this change was not reported on day 2 (84 vs. 87), day 3 (86 vs. 88) and day 5 (85 vs. 88) were

Serum Sodium levels of control group (free water) (n = 25)						
S. No	Baseline	Day-1	Day-2	Day-3	Day-5	
Baseline	-	0.30 (0.004*)	0.22 (0.15)	0.37 (0.37)	0.41 (0.66)	
		[0.34; 1.56]	[0.13; 0.79]	[-0.46; 1.18]	[-0.68; 1.04]	
Day-1	0.30 (0.004*)	-	0.32 (0.058)	0.32 (0.07)	0.40 (0.06)	
	[-1.56; -0.345]		[-1.2; 0.02]	[-1.27; 0.05]	[-1.6; 0.04]	
Day-2	0.22 (0.15)	0.32 (0.058)	-	0.33 (0.93)	0.36 (0.68)	
	[-0.79; 0.13]	[-0.024; 1.29]		[-0.65; 0.71]	[-0.89; 0.59]	
Day-3	0.39 (0.36)	0.32 (0.07)	0.33 (0.93)	-	0.28 (0.54)	
	[-1.18; 0.46]	[-0.05; 1.27]	[-0.71; 0.65]		[-0.76; 0.41]	
Day-5	0.41 (0.66)	0.40 (0.06)	0.36 (0.68)	0.28 (0.54)	-	
	[-1.04; 0.68]	[-0.04; 1.61]	[-0.59; 0.89]	[-0.41; 0.76]		
Serum Sodium I	evels of experimenta	l group (Norma salir	ne) (n = 25)			
S. No	Baseline	Day-1	Day-2	Day-3	Day-5	
Baseline	-	0.58 (0.04*)	0.42 (0.001*)	0.43 (0.001*)	0.52 (0.06)	
		[-2.43; 0.04]	[-3.2; -1.4]	[-4.0; -2.2]	[-0.05; 2.11]	
Day-1	0.58 (0.04*)	-	0.47 (0.02*)	0.46 (0.001*)	0.45 (0.001*)	
	[0.04; 2.4]		[-2.09; -0.15]	[-2.8; -0.92]	[1.33; 3.21]	
Day-2	0.42 (0.001*)	0.47 (0.025*)	-	0.19 (0.001*)	0.36 (0.0001*)	
	[1.48; 3.23]	[0.15;2.09]		[-1.16; -0.36]	[2.63; 4.15]	
Day-3	0.43 (0.001*)	0.46 (0.001*)	0.19 (0.001*)	-	0.34 (0001*)	
	[2.21; 4.02]	[0.92; 2.83]	[0.36; 1.16]		[3.44; 4.6]	
Day-5	0.52 (0.06)	0.45 (0.001*)	0.36 (0.001*)	0.344 (0.001*)	-	
	[-2.11; 0.05]	[-3.21; -1.3]	[-4.15; -2.63]	[-4.86; -3.44]		

 Table 3. Repeated measure ANOVA for Serum Sodium for control and experimental group (n = 25 each)

RMANOVA for measurements at continuous time points, standard error (p value), [95% Confidence interval] = lower Cl; Upper Cl; \*p value < 0.05 considered as significant.

Table 4. Change in GCS	Glasgow coma	scores levels be	etween both groups (N = 5	iO)
------------------------	--------------	------------------	---------------------------	-----

0	( U )		0		,
Variable	Experimental group	Control group (n =	95% Lower	95% Upper	t value (n value)
	(n = 25) (Mean ± SD)	25) (Mean ± SD)	C.I.	C.I.	
Baseline	6.20±4.13	5.11±3.82	-1.17	3.35	0.97 (0.123&)
Immediate post-test	6.20±4.13	8.13±1.43	-81.2	-69.0	-24.76 (< 0.0001*.&)
Day-2 post-test	7.08±4.43	5.65±3.58	-0.85	3.71	1.25 (0.195*)
Day-3 post-test	7.08±4.26	6.23±3.69	-1.40	3.11	0.75 (0.49%)
Day-5 post-test	7.12±4.37	5.96±3.42	-1.06	3.38	1.05 (0.25 <sup>&amp;</sup> )

Note: <sup>&</sup>Mann Whitney U test, <sup>\*</sup>p value considered as significant.

Table 5. Change in	N Systolic blood pressure	(SBP) (in mmHg)	between both grou	ups (N = $50$ )
--------------------	---------------------------	-----------------	-------------------	-----------------

Variabla	Experimental group (n	Control group (n =	95% Lower	95% Upper	t value (p value)
	= 25) (Mean ± SD)	25) (Mean ± SD)	C.I.	C.I.	t value (p value)
Baseline	120.88±19.6	116.04±20.27	-6.52	16.1	0.85 (0.39)
Immediate post-test	119.29±20.1	130.3±37.4	106.1	122.3	0.86 (< 0.0001*.&)
Day-2 post-test	123.33±19.31	130.54±18.18	-17.8	3.40	-1.36 (0.17)
Day-3 post-test	124.38±18.69	133.19±18.10	-19.2	1.64	-1.69 (0.09)
Day-5 post-test	126.04±18.26	131.65±20.51	-16.6	5.46	-1.01 (0.31)

Note: <sup>&</sup>Mann Whitney U test, Independent 't' test used, <sup>\*</sup>p value considered as significant.

found to be similar in the experimental and control groups, respectively, with p-values > 0.05.

Hence, normal saline was only found to be effective in maintaining DBP immediately after

## Effect of isotonic NS versus water post-Ryles Tube feeding for correcting hyponatremia

•				<b>U</b>	,
Variable	Experimental group	Control group (n =	95% Lower	95% Upper	t value (n value)
	(n = 25) (Mean ± SD)	25) (Mean ± SD)	C.I.	C.I.	
Baseline	78.62±13.61	79.46±14.80	-8.94	7.27	-0.20 (0.83)
Immediate post-test	78.3±13.4	72.3±19.3	106.1	122.3	-9.46 (< 0.0001*)
Day-2 post-test	84.75±12.52	87.69±10.79	-9.57	3.69	-1.36 (0.37)
Day-3 post-test	86.87±14.85	88.11±10.63	-8.54	6.06	-0.34 (0.73)
Day-5 post-test	85.50±11.25	88.84±14.90	-10.9	4.21	-0.89 (0.37)

Table 6. Change in Diastolic blood pressure (DBP) (in mmHg) between both groups (N = 50)

Note: Independent 't' test used, \*p value considered as significant < 0.05.



Figure 2. Day-1 post-test Sodium levels positive correlation with GCS, chloride, DBP and negative correlation with SBP levels (N=50).

intervention compared to free water post-RT feeding.

In Figure 2, post-test day 1, serum chloride levels, GCS scores, and DBP levels showed a positive correlation with post-test day 1 serum sodium levels. In contrast, systolic blood pressure showed a negative deflection in the graph with relation to post-test serum sodium levels, suggesting that after treatment of hyponatremia, there will be a decrease in the chances of hypertension occurrence.

#### Discussion

Hyponatremia is one of the most common electrolyte imbalances in patients admitted to the intensive care unit. In this study, it is reported that more than two-thirds of the patients (77.8%) developed delirium after 72 hours of mechanical ventilation.

In this pilot randomized controlled trial, we have seen an increase in serum sodium concentration after giving isotonic 0.9% normal saline post-Ryles tube feeding to treat hyponatremia among patients admitted to the intensive care unit.

A significant difference was found in the experimental groups compared to the control groups for the post-test value of serum sodium levels, GCS scores, SBP, and DBP at day 1 (immediate post-test one hour) of administration of normal saline post-RT feed at a *p*-value of 0.0001. However, no significant difference was found for GCS, SBP, and DBP levels on days 2, 3, and 5, and for serum sodium, only on day 5, no difference was found between both groups at a *p*-value of > 0.05. Similarly, serum chloride was not found to be significantly affected on days 1, 2, 3, or 5 (data not shown).

Previous studies [12-14] showed that hyponatremia is present in 5.2% of total admissions. The medical emergency of severely symptomatic hyponatremia includes signs of somnolence, obtundation, coma, seizures, and cardiorespiratory distress.

These findings concur with the existing studies on the effectiveness of isotonic normal saline, which reported that 30 patients were included, aged 72 years (60-80), of which 50% were women. 24 Na was  $\geq$  8 mmol/L/24 hrs in 33%,  $\geq$  6 mmol/L/24 hrs in 50%, and < 4 mmol/L/24 hrs in 30 [15]. Likewise, another study from Belgium reported that mild hyponatremia increased from baseline NA levels to post-test (128-135 mEg/L), whereas, in the second group, Na increased from 111 to 122 mEq/L in one day with a p-value < 0.001 [16]. Additionally, according to one interventional study comparing isotonic 0.9% normal saline with 0.45% saline to correct hyponatremia, the results indicate that there was no significant difference between the two groups in sodium (P = 0.94), systolic (P = 0.81), or diastolic (P = 0.94)0.73) blood pressure. So, the results of this study showed that the administration of hypotonic fluids was an appropriate treatment strategy for patients who would not face the risk of hyponatremia [17].

Additionally, a randomized, controlled open study conducted in which the use of isotonic fluid as maintenance therapy prevents iatrogenic hyponatremia in pediatrics reported that at the time of admission to the hospital, no differences in hyponatremia or the percentage of hyponatremia were found between groups at baseline. At 24 hrs, the percentage of hyponatremia in the hypotonic group was 20.6% as opposed to 5.1% in the isotonic group (P = 0.02). The use of isotonic fluids decreases the risk of hyponatremia compared with hypotonic fluids at 24 hrs following infusion, which aligns with the present study findings [18].

In the case of moderate-to-severe hyponatremia, CNS symptoms were most common and were present in 61% of the patients. Among 100 patients, 52% of the patients were conscious, while 48% of the patients presented with altered sensorium. Seeing the comorbidity, hypertension was present in 49% of patients, whereas diabetes mellitus was noted in 29% of patients. The most common system involved was the CNS (43%), followed by the abdominal (21%), renal (15%), cardiovascular (12%), and respiratory (9%) systems [19].

A recent meta-analysis revealed that balanced fluids showed more benefits than isotonic saline in maintaining electrolytes and acidbase balance postoperatively among patients undergoing the non-renal surgical procedure. However, a meta-analysis comparison between isotonic saline and balanced fluids in ICUs and operating rooms showed no difference in AKI or in-hospital mortality between the two fluid types [20].

According to a study [21], the administration of isotonic saline in the maintenance of parenteral fluids is the most important preventive measure that can be taken to prevent hyponatremia in children receiving parenteral fluids. Isotonic saline is also more beneficial to patients than free water.

# Strengths and limitations

The parameters used in this methodologically strong RCT to assess the outcome are highly specific and sensitive. It includes a nasogastric route of administration via the Ryles Tube, which will help reduce the need for intravenous interventions for corrections of fluid and electrolyte imbalances, ultimately reducing the prevalence of IV site infections, phlebitis, or any other complications. Although the study had a limited sample size, as it was just a pilot trial at a single center, it included multiple disease factors.

## Conclusion

Our study generated quality evidence that indicates that the cheap, safe, and easily available intervention of isotonic, 0.9% normal saline, which was given through the Ryles tube route, was effective for treating hyponatremia among the patients admitted to the intensive care unit without any harmful effects reported. The researcher recommended that this study be a multicentered trial with a larger sample size for better clarity in this area. A future trial can be done to assess the effectiveness of hyponatremia-corrective interventions with isotonic fluids through the Ryles tube versus intravenous (IV) routes.

#### Acknowledgements

The authors would like to thank all participants, nursing staff, and residents who cooperated in the study.

#### Disclosure of conflict of interest

None.

Address correspondence to: Dr. Neetu Kataria, College of Nursing, All India Institute of Medical Sciences (AIIMS), Rishikesh 249203, Uttarakhand, India. ORCID: 0000-0002-0956-5361; E-mail: neetukataria31@gmail.com; Dr. Vasantha C Kalyani, Department of Nursing, All India Institute of Medical Sciences (AIIMS), Deoghar 814142, Jharkhand, India. ORCID: 0000-0003-1075-9208; E-mail: vasantha.nur@aiimsdeoghar.edu.in

# References

- [1] Sim JK, Ko RE, Na SJ, Suh GY and Jeon K. Intensive care unit-acquired hyponatremia in critically ill medical patients. J Transl Med 2020; 18: 268.
- [2] Padhi R, Panda BN, Jagati S and Patra SC. Hyponatremia in critically ill patients. Indian J Crit Care Med 2014; 18: 83-87.
- [3] Fernández-Sarmiento J, Pérez A, Echeverri MA, Jimenez P, Joachim MA and Andrés-Jagua. Association between hyponatremia and maintenance intravenous solutions in critically ill

children: a retrospective observational study. Front Pediatr 2021; 9: 691721.

- [4] Freund H, Atamian S and Fischer JE. Comparative study of parenteral nutrition in renal failure using essential and nonessential amino acid containing solutions. Surg Gynecol Obstet 1980; 151: 652-656.
- [5] Mirtallo JM. Introduction to parenteral nutrition. In: Gottschlich MM, Fuhrman MP, Hammond KA, Holcombe BJ, Seidner DL, editors. The science and practice of nutrition support. A case-based core curriculum. Dubuque, Ia: Kendall/Hunt Publishing; 2001. pp. 211-223.
- [6] Rocchi E, Cassanelli M, Gibertini P, Pietrangelo A, Casalgrandi G and Ventura E. Standard or branched-chain amino acid infusions as shortterm nutritional support in liver cirrhosis? JPEN J Parenter Enteral Nutr 1985; 9: 447-451.
- [7] Kanematsu T, Koyanagi N, Matsumata T, Kitano S, Takenaka K and Sugimachi K. Lack of preventative effect of branched chain amino acid solution on postoperative hepatic encephalopathy in patients with cirrhosis: a randomized, prospective trial. Surgery 1988; 104: 482-488.
- [8] Parekh NR and Seidner DL. Disease-specific nutrition. In: Irwin RS, Rippe JM, editors. Irwin and Rippe's intensive care medicine. 5th ed. Philadelphia, Pa: Lippincott, Williams & amp; Wilkins; 2003. pp. 2069-2080.
- [9] Sterns RH, Hix JK and Silver SM. Management of hyponatremia in the ICU. Chest 2013; 144: 672-679.
- [10] Madhuvan HS, Thimma Reddy SR, Ravishankar SN, Sadanand CD and Veerabhadra Goud GK. A prospective study on hyponatremia in intensive care unit (ICU) patients. Journal of Dental and Medical Sciences (IOSR-JDMS) 2019; 18: 17-20.
- [11] Ahmad K, Alrais ZF, Elkholy HM, Elkhouly AE, Beniamein MM, Hadi AA, Majeed S and Shoaib A. Effect of early correction of hyponatremia on neurological outcome in traumatic brain injury patients. J Intensive & Crit Care 2017; 3: 1.
- [12] Adrogué HJ, Tucker BM and Madias NE. Diagnosis and management of hyponatremia. JAMA 2022; 328: 280-291.
- [13] Uddin MS, Ahsan ASMA, Faria S and Sultana R. Frequency of hyponatremia and its outcome in critically ill patients. Bangladesh Crit Care J September 2021; 9: 68-73.
- [14] Pillai KS, Trivedi TH and Moulick ND. Hyponatremia in ICU. J Assoc Physicians India 2018; 66: 48-52.
- [15] Ruiz-Sánchez JG, Meneses D, Alvarez-Escola C, Cuesta M, Calle-Pascual AL and Runkle I. The effect of the dose of isotonic saline on the correction of serum sodium in the treatment of hypovolemic hyponatremia. J Clin Med 2020; 9: 3567.

- [16] Decaux G, Andres C, Gankam Kengne F and Soupart A. Treatment of euvolemic hyponatremia in the intensive care unit by urea. Crit Care 2010; 14: R184.
- [17] Sedaghattalab M, Khajezadeh S, Paymard A, Mansouri P, Larki RA and Manzouri L. Effect of isotonic and hypotonic fluid therapy on serum sodium: a randomized controlled trial. Acta Med Iran 2020; 58: 394-399.
- [18] Montañana PA, Modesto i Alapont V, Ocón AP, López PO, López Prats JL and Toledo Parreño JD. The use of isotonic fluid as maintenance therapy prevents iatrogenic hyponatremia in pediatrics: a randomized, controlled open study. Pediatr Crit Care Med 2008; 9: 589-597.
- [19] Babaliche P, Madnani S and Kamat S. Clinical profile of patients admitted with hyponatremia in the medical intensive care unit. Indian J Crit Care Med 2017; 21: 819-824.
- [20] Zayed YZM, Aburahma AMY, Barbarawi MO, Hamid K, Banifadel MRN, Rashdan L and Bachuwa GI. Balanced crystalloids versus isotonic saline in critically ill patients: systematic review and meta-analysis. J Intensive Care 2018; 6: 51.
- [21] Moritz ML and Ayus JC. Prevention of hospitalacquired hyponatremia: a case for using isotonic saline. Pediatrics 2003; 111: 227-230.