ISSN (P) : 2589-9120 / (O) : 2589-9139
PubMed-National Library of Medicine - ID: 101773527

International Journal of Medical Science and Applied Research (IJMSAR)

Available Online at: https://www.ijmsar.com

Volume – 5, Issue – 6, November – 2022, Page No. : 37 – 46

To Study the Weight Changes and Adverse Events Associated with Infusion of Isotonic Saline (0.9%NS) Compared with Hypotonic Saline (0.45%NS) As Maintenance Fluids in Children

[1]Dr. Ashutosh Sharma, [2]Dr. D.K. Bhagwani, [3]Dr. Rajiv Kumar Ranjan

[1]PG Scholar, Department of Paediatrics, Gajra Raja Medical College, Gwalior (M.P.), India

[2]Specialist, Department of Paediatrics, Hindu Rao Hospital NDMC Medical College Delhi, India

[3]Specialist, Department of Biochemistry, Hindu Rao Hospital NDMC Medical College Delhi, India

Citation of this Article: Dr. Ashutosh Sharma. Dr. D.K. Bhagwani, Dr. Rajiv Kumar Ranjan, "To Study the Weight Changes and Adverse Events Associated with Infusion of Isotonic Saline (0.9%NS) Compared with Hypotonic Saline (0.45%NS) As Maintenance Fluids in Children,'' IJMSAR – November – 2022, Vol. – 5, Issue - 6, Page No. 37-46.

Corresponding Author: Dr. Ashutosh Sharma, [1]PG Scholar, Department of Paediatrics, Gajra Raja Medical College, Gwalior (M.P.), India

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Background

The purpose of intravenous (IV) fluid therapy is replacement of water and mineral of the body fluids in patients who could not maintain hydration orally.[1] For almost half a century, pediatricians have ordered "maintenance" intravenous (IV) fluids for children according to the guidelines set out by Holliday and Segar:.[2] Based on these recommendations for water intake, and on the estimated daily sodium and potassium needs of 3 milliequivalents and 2 milliequivalents per 100 kcal per day respectively, a hypotonic solution (0.2% saline) was recommended.[3,4] The wisdom of this approach to IV maintenance fluid therapy has been questioned recently. Several authors have argued that administration of hypotonic fluids to hospitalized children [13].Although the best choice of solution for IV maintenance needs has not yet been defined, many clinicians commonly prescribe 0.45% saline as a sort of 'compromise' between the traditional 0.18% saline and a complete switch to isotonic fluids. Therefore, we chose to compare 0.9% saline in 5.0% dextrose to 0.45% saline in 5.0% dextrose.

Material and Methods

Prospective and Interventional Randomized

single blinded Comparative study (computerized block randomization). Was carried out in Department of pediatrics Hindu Rao Hospital from 2108 to 2019 The objectives were to compare weight changes in both groups after24 hrs., and 48 hrs., of initiation of therapy, compare incidence of weight gain study signs of fluid overload.

Children of age group 1 year to 12 years suffering from Severe Pneumonia, meningitis, encephalitis, Meningoencephalitis, hepatitis and infections admitted in pediatric emergency and ward requiring IV maintenance fluid having normal serum sodium levels were included All eligible patients were randomized to receive either Isotonic (0.9% NS in 5% Dextrose), at the rate of standard maintenance volume or hypotonic (0.45%NS in 5% Dextrose), at rate of standard maintenance volume. Randomization sequence was generated using Technique computerized block randomization. The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0.

Results

No Significant changes were observed in weight , mean weight in isotonic group was more as compared to hypotonic group at 24 and 48 hrs of IV fluid administration .No adverse events were seen in either group

Keyword

Isotonic, Hypotonic, Weight Gain and Fluid Overload

Introduction

The purpose of intravenous (IV) fluid therapy is replacement of water and mineral of the body fluids in patients who could not maintain hydration orally.[1]For almost half a century, pediatricians have ordered "maintenance" intravenous (IV) fluids for children according to the guidelines set out by Holliday and Segar: 100 ml/kg/day for the first 10 kg, plus 50 ml/kg/day for the next 10 kg, plus 20 ml/kg/day for each remaining kilogram.[2] Based on these recommendations for water intake, and on the estimated daily sodium and potassium needs of 3 milliequivalents and 2 milliequivalents per 100 kcal per day respectively, a hypotonic solution (0.2% saline) was recommended.[3]administration of hypotonic fluids to hospitalized children - many of whom have a non-osmotic stimulus for anti-diuretic hormone (ADH) secretion - may lead to clinically important hyponatremia[4].· Iatrogenic hyponatremia has been the reported cause of neurological injury or death in more than 50 cases[5.]Concerns regarding hyponatremia have led some authors to recommend using isotonic saline as the routine maintenance solution for hospitalized patients, reserving hypotonic fluids for exception al situations. Isotonic saline administration may result in an increase in weight, but has not been shown to increase the risk for hypernatremia. [5].Although the best choice of solution for IV maintenance needs has not yet been defined, many clinicians commonly prescribe 0.45% saline as a sort of 'compromise' between the traditional 0.18% saline and a complete switch to isotonic fluids. Therefore, we chose to compare 0.9% saline in 5.0% dextrose to 0.45% saline in 5.0% dextrose respectively.

Material and Methods

Prospective and Interventional Randomized single blinded Comparative study was carried out in Department of pediatric and pediatric emergency Hindu Rao hospital (a tertiary care hospital in north

Delhi from Nov 2018 to May2019 in 1 to 12 years Age group. Main Objectives were To compare mean weight in both groups after 24 hrs. and 48 hrs., of initiation of therapy and to study incidence of weight and fluid overload. After obtaining clearance from institutional ethical committee, Children of age group 1 years to 12 years admitted in Pediatric emergency and ward requiring IV maintenance fluid having normal serum sodium levels, and suffering from Severe Pneumonia, meningitis, encephalitis, Meningoencephalitis, hepatitis and infections were included Children with hemodynamic instability, and suffering from Acute or chronic Kidney Disease, Acute gastroenteritis, and cardiac dysfunction were excluded.

65 Patients each in Isotonic and hypotonic group were included sample size was derived from Statistical formula. All eligible patients were randomized to receive either Isotonic or Hypotonic at the rate of standard maintenance volume. Randomization sequence was generated using Technique computerized block randomization.

Maintenance fluid volume for administration was calculated using Holliday and Segar formula. Both groups received 1 ML of potassium chloride per 100 ML of intravenous fluids.

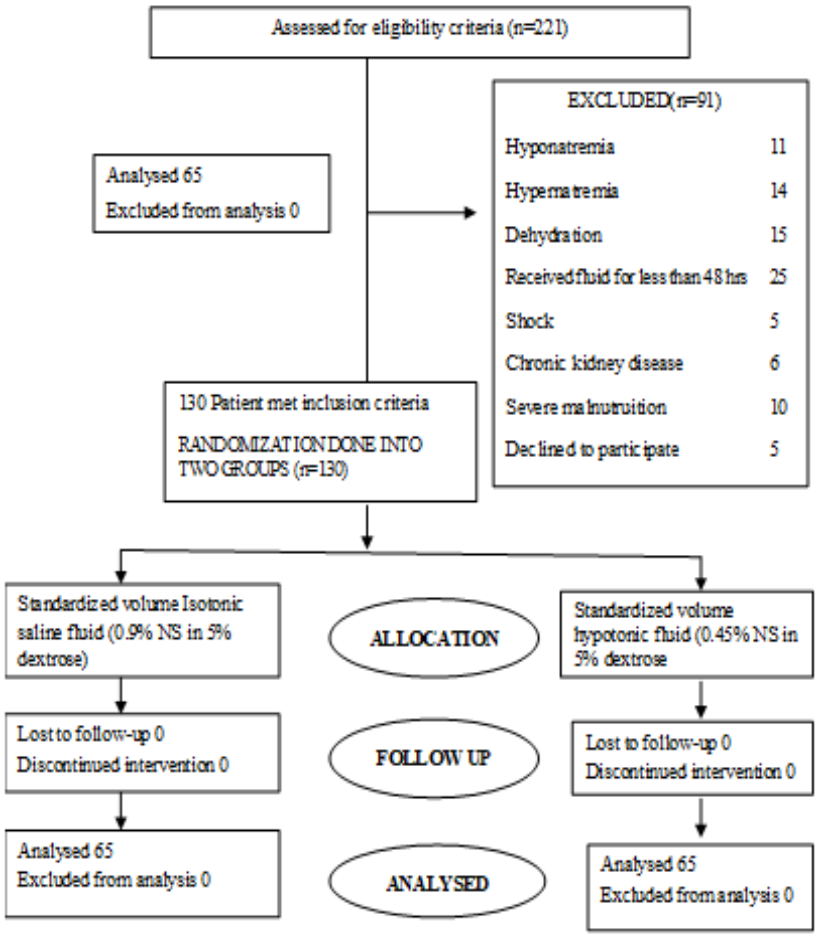
Baseline demographic and laboratory characteristics were noted at enrolment. All patients were monitored clinically for symptoms and signs of dysnatraemias and signs of fluid overload or dehydration throughout the study period. Clinical assessment, including Weight and Blood pressure were done every 24 hours. Measurement of Weight in Kg by digital weighing scale at an interval of 0 hrs, 24 hrs and 48 hrs.

Approximately 2 ml of Venous blood sample was withdrawn at 0 hrs., 24hrs.and 48 hrs of starting of IV fluid for measurement of serum sodium, potassium, blood urea, creatinine.

During Intravenous fluid therapy, children were observed for clinical features of Dyselectrolytemia (Seizures, letharginess, irritability, coma) and fluid overload (weight gain>10 % from the base line) and outcome, duration of hospitalization were observed at the time of discharge.

In case of any clinical features of hyponatremia / hypernatremia or fluid overload, plan was to manage according to standard protocol and exclusion from the study. Categorical variables were presented in number and percentage (%) and continuous variables was presented as mean ± SD and median Data was entered in MS EXCEL Spreadsheet and analysis was done using SPSS Version 21.0.

Fig.1: Algorithm of Methodology



Results

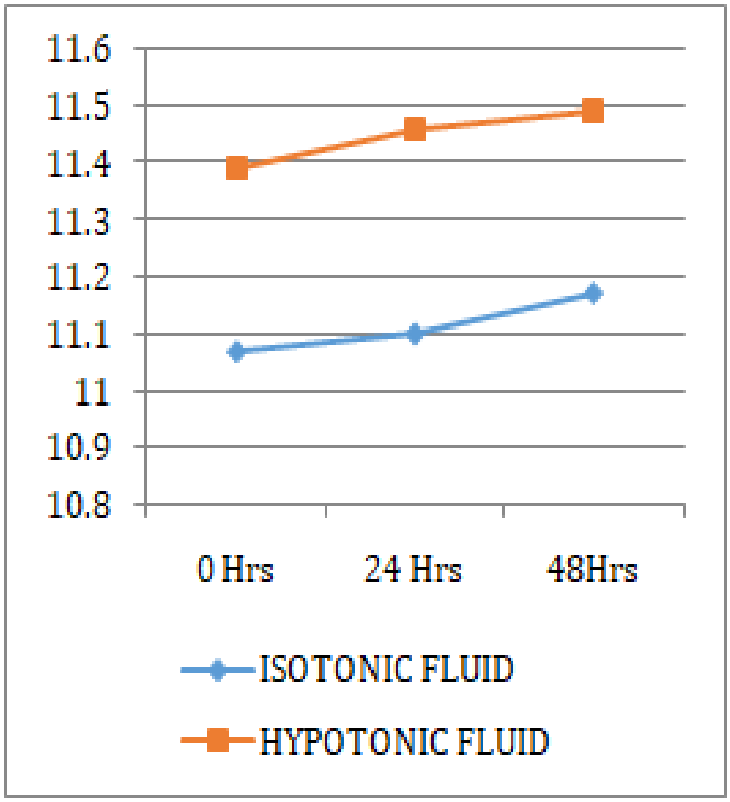
1. Weight Distribution in Toddlers

Table and line graph showing weight distribution in Toddlers age group (3-6 years age group) over a duration of 48 hrs. Mean weight in isotonic group was 11.07 at 0 hrs 11.10 at 24hrs and 11.17 at 48 hrs, in hypotonic group it was 11.39 at 0 hrs, 11.46 at 24 hrs, and 11.49 at 48 hrs. Graph clearly indicates no significant weight gain in isotonic and hypotonic group (FIGURE 2 AND GRAPH1

Fig. 2: Weight distribution in toddler group (1-3 years age group) (mean + SD)

N=15		0hrs	24hrs	48hrs	ANOVA p value
Weight (kg)	Isotonic (0.9%NS in 5% Dextrose)	11.07±1.355	11.10±1.370	11.17±1.347	>0.05
	Hypotonic (0.45% NS in 5% Dextrose)	11.39±1.453	11.46±1.461	11.49±1.488	

Graph 1: Line diagram depicting weight distribution in toddlers age group



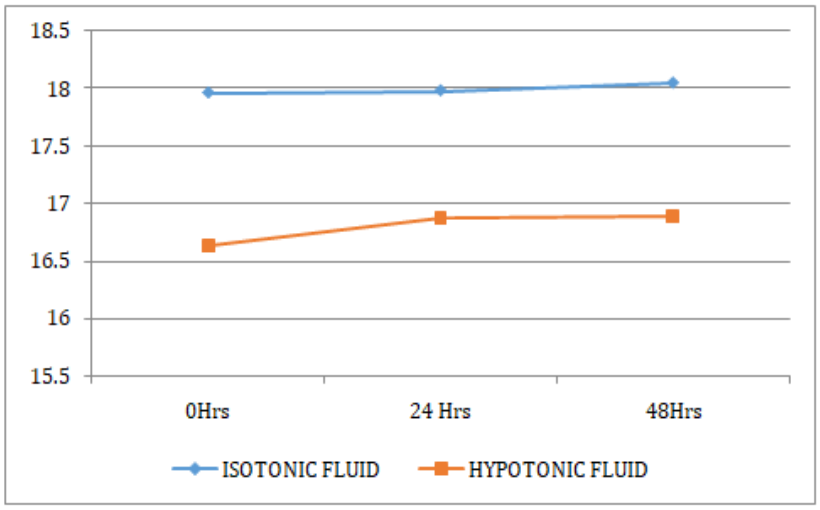
2. Weight Distribution in Early Childhood Age Group (4-6 years age group)

Table and line diagram showing age wise distribution of weight in early childhood (3-6 years age group) mean weight of children receiving isotonic was 17.96 at 0 hrs and 18.05 at 48 hrs and hypotonic group was 16.63 at 0 hrs and 16.88 at 48 hrs. There was no significant weight gain in isotonic and hypotonic group($p>.05$) **(**FIGURE 3 and Graph2)

Figure 3: Weight distribution in early childhood group (mean + SD)

N=25		0hrs	24hrs	48hrs	ANOVA p value
Weight (kg)	Isotonic (0.9%NS in 5% Dextrose)	17.96±4.224	17.98±4.239	18.05±4.25	>0.05
	Hypotonic (0.45% NS in 5% Dextrose)	16.63±1.992	16.86±1.953	16.88±1.945	

Graph 2: Line diagram depicting weight distribution in early childhood age group



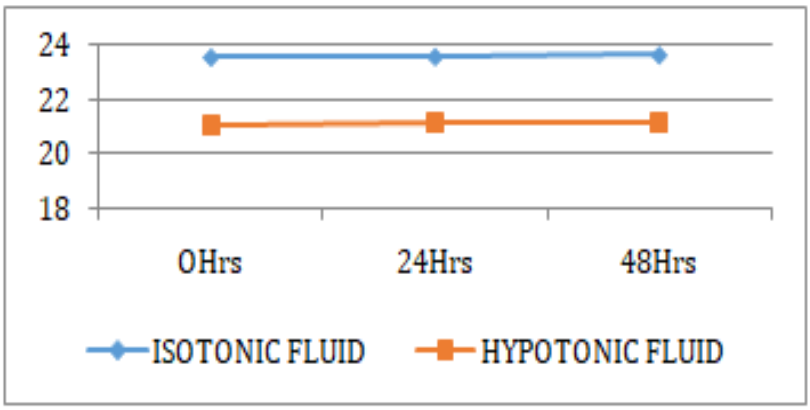
3. Weight Distribution in Middle Childhood Age group (7-11 years age group)

Table and line diagram showing mean weight of middle childhood (6-11 years age group) over a duration of 48 hours there was no significant weight gain.(p>.05) mean weight of patients receiving isotonic fluid was 23.54 at 0 hrs, 23.56 at 24 hrs and 23.63 at 48 hrs, in hypotonic group it was 21.04 at 0 hrs 21.11 at 24 hrs and 21.14 at 48 hrs (Figure4 and Graph 3).

Figure 4: Weight distribution in middle childhood (6-11 years) group

N=15		0hrs	24hrs	48hrs	ANOVA
					p value
Weight (kg)	Isotonic (0.9%NS in 5% Dextrose)	23.54±2.816	23.56±2.814	23.63±2.807	>0.05
	Hypotonic (0.45% NS in 5% Dextrose)	21.04±3.880	21.11±3.910	21.14±3.961	

Graph 3 Line diagram depicting weight distribution in middle childhood age group



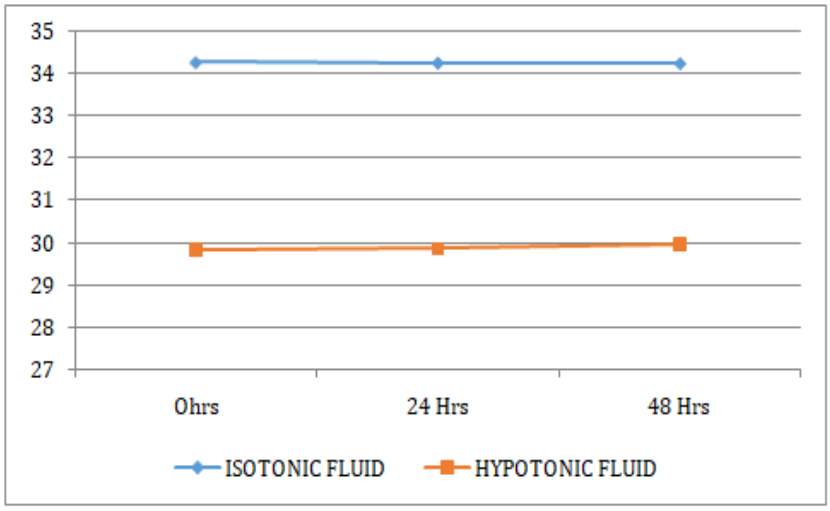
3. Weight Distribution in Early Adolescent Age Group (12 years age group)

Mean weight of children receiving isotonic fluid was 34.27, 34.26 and 34.25 at 0, 24 and 48 hrs respectively where as mean weight of children receiving hypotonic fluid was 29.81 29.85, and 29.96. in this study it was found that there was no significant change in weight in either age group(p>.05). Line diagram showing distribution of weight in Early Adolescent age group (12 years age group) (Figure 5 and Graph 4).

Figure 5: Weight distribution in early adolescent group (12 years) (mean + SD)

N=10		0hrs	24hrs	48hrs	ANOVA p value
Weight (kg)	Isotonic (0.9%NS in 5% Dextrose)	34.27±3.514	34.26±3.520	34.25±3.468	>0.05
	Hypotonic (0.45% NS in 5% Dextrose)	29.81±1.90	29.85±1.93	29.96±1.86	

Graph 4: Line diagram depicting weight distribution in early adolescent age group



Outcome of Study Subjects

Out of 130 patients who received iv fluid there were two mortalities reported which were not attributed to dyselectrolytemia and fluid overload. One patient was of disseminated Koch's where as the other one was of Acute Febrile Meningoencephalitis syndrome with ARDS. Both child had normal serum sodium throughout the study period both deaths occurred during observation period after 48 hrs of IV fluid therapy.

Discussion

This is one among the few studies done prospectively to assess the impact of prescribing isotonic intravenous maintenance fluids on weight changes and other associated complications in the age group between 1 and 12 years.

In a population of general pediatric patients outside the PICU, there was no significant difference in weight at 24 and 48 hours between those administered

isotonic or hypotonic IV maintenance fluids in early childhood middle childhood and early adolescent period .

In this study no adverse events of fluid overload weight gain oedema complications due to dyselectrolytemia was noted out of 65 child 27 child developed mild hyponatremia in HT group, after 48 hours of receiving Intravenous fluid was asymptomatic and did not require any intervention during observation period.

1 Death reported in each group was due to long term morbidity of underlying disease and was not related to type of fluid administered and dysnatraemias. Both child had normal serum sodium throughout the study period both deaths occurred during observation period after 48 hrs of IV fluid therapy. one child was having disseminated Koch's and other one was having acute febrile Meningoencephalitis with ARDS .

Kannan et al.[6] in their RCT observed 2 adverse events one patient developed hypernatremic encephalopathy this child was having Acute intermittent porphyria . Another Child expired cause of death was ARDS and he had normal serum sodium throughout the study period.

Similar to present study

Montanana et al.[7] did not observed any adverse effects other then hyponatremia in any other group.

Saba TG et al.[8] did not observed any adverse events in their RCT.

Fahimi et al.[9] in their RCT did not observed any symptomatic hyponatremia or hypernatremia in 24 hours following the IV therapy treatment.

Shamim A et al.[10] did not observed any adverse events related to dysnatraemias in either intervention group. No mortality occurred during the observation period.

Almeida Hl et al.[11] also did not observed any adverse events in their Prospective RCT.

However **Yung et al.**[12] in their RCT observed one patient receiving normal saline at restricted rate.

Developed Asymptomatic hypoglycemia this child was 10 moth old premature child recovering from craniofacial surgery

Padua et al.[13] in their systematic review did not observed any mortality attributed to dysnatraemias.

Friedman et al.[14] **i**n their randomized control trail conducted in 110 children observed that 2 patient in each group developed hypertension and 2 in the isotonic group developed oedema however these adverse effects were unrelated to volume and type of fluids administered.

Choong et al.[15] in their systematic review of six studies adverse events in three studies Wilkinson reported seizures in 2/26 patients receiving hypotonic fluids .Hoons reported nausea and vomiting more commonly in patients with hypotonic fluids then isotonic fluids. Burrows observed increase pulmonary interstitial fluid on Chest X -ray in hypotonic group as compared to isotonic group .

Foster et al.[16] in their meta analysis of 10 independent randomized controlled trail observed neurologic impairment in 4 out of 10 studies, edema secondary hypertension in their 4 studies.

Thus most of these studies which included RCT and meta analysis including present study noted that there was no adverse events attribute to administration of isotonic fluids in the form of hypertension oedema weight gain. Mortality that occurred was due to underlying disease and not due to adverse events associated with intravenous fluids.

Conclusion

This Study demonstrates that standard volume maintenance isotonic fluid does not lead to significant weight changes in comparison to hypotonic maintenance fluid in children without inducing a higher incidence of side effects

Recommendation

Use of isotonic saline solution as maintenance fluid therapy is safe in 1-12 years Age group.

Limitation of Study

Sample size of this study was small and hence the results of this study could not be extrapolated to the whole population.

References

1. Baron FA, Meregalli CN, Rombola VA, Bolasell C, Pigliapoco VE, Bartoletti SE, Debaisi GE. Hypotonic versus isotonic intravenous maintenance fluids in critically ill pediatric patients: a randomized clinical trial. Arch Argent Pediatr. 2013;111(4):281-7.
2. Holliday MA, Segar WE. The maintenance need for water in parenteral fluid therapy. Pediatrics 1957;19(5):823-832.
3. Hatherill M. Rubbing salt in the wound. Arch Dis Child .2004; 89(5):414-8.
4. Hoorn EJ, Geary D, Robb M, Halperin ML, Bohn D. Acute hyponatremia related to intravenous fluid administration in hospitalized children: an observational study. Pediatrics. 2004; 113(5):1279-84.
5. Paut O, Remond C, Lagier P, Fortier G, Camboulives J. [Severe hyponatremic encephalopathy after pediatric surgery: report of seven cases and recommendations for management and prevention]. Ann Fr Anesth Reanim. 2000; 19(6):467-73.
6. Kannan L, Lodha R, Vivekanandhan S, Bagga A, Kabra SK, Kabra M. Intravenous fluid regimen and hyponatraemia among children: a randomized controlled trial.Pediatr Nephrol. 2010;25(11):2303-9.
7. Montañana PA, Modesto i Alapont V, Ocón AP, López PO, López Prats JL, 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(6):589-97.
8. Saba TG, Fairbairn J, Houghton F, Laforte D, Foster BJ. A randomized controlled trial of isotonic versus hypotonic maintenance intravenous fluids in hospitalized children. BMC Pediatr. 2011;11:82.
9. Fahimi D, Delavar M A, Karahoudi M, Honarmand M, Eghbalkhah A. Comparison of Two Intravenous Fluid Maintenance Therapy with Different Sodium Concentrations in Hospitalized Children: A Randomized Trial Study. Pediatr Nephrol. 2014;2(3):110-5.
10. Shamim A, Afzal K, Ali SM. Safety and efficacy of isotonic (0.9%) vs. hypotonic (0.18%) saline as maintenance intravenous fluids in children: a randomized controlled trial. Indian pediatrics. 2014;51(12):969-74.
11. Almeida HI, Mascarenhas MI, Loureiro HC, Abadesso CS, Nunes PS, Moniz MS et al. The effect of NaCl 0.9% and NaCl 0.45% on sodium, chloride, and acid-base balance in a PICU population. Jornal de pediatrica. 2015;91(5):499-505.
12. Yung M, Keeley S. Randomized controlled trial of intravenous maintenance fluids. J Paediatr Child Health. 2009; 45(1-2):9-14.

13. Padua AP, Macaraya JR, Dans LF, Anacleto FE Jr. Isotonic versus hypotonic saline solution for maintenance intravenous fluid therapy in children: a systematic review. Pediatr Nephrol. 2015;30(7):1163-72.
14. Friedman JN, Beck CE, DeGroot J, Geary DF, Sklansky DJ, Freedman SB. Comparison of isotonic and hypotonic intravenous maintenance fluids: a randomized clinical trial. JAMA Pediatr. 2015;169(5):445-51.
15. Choong K, Kho ME, Menon K, Bohn D. Hypotonic versus isotonic saline in a hospitalised children: a systematic review. Arch Dis Child .2006; 91(10):828-35.
16. Foster BA, Tom D, Hill V. Hypotonic versus isotonic fluids in hospitalized children: a systematic review and meta-analysis. J Pediatr. 2014;165(1):163-169.