



Intravenous fluid-related symptomatic acute hyponatremia

PROTOCOLS

Principal investigator

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Background

Maintenance fluid requirements, published in 1957 (Holliday, Segar), are based on the study of healthy children and indicate the use of hypotonic saline solutions. Recent literature has questioned the routine use of hypotonic maintenance solutions, in light of reports of significant morbidity and mortality (seizures, respiratory arrest, neurologic dysfunction, death) amongst children who developed hospital-acquired hyponatremia while receiving intravenous (IV) fluids. Children are at higher risk than their adult counterparts. Currently, there is wide international variation in the prescribed tonicity of paediatric IV fluids.

While the estimated incidence of clinically significant, symptomatic cases of hospital-acquired acute hyponatremia is relatively low (0.07%), the severity of the associated outcomes has brought the issue to light in the patient safety literature. Given that approximately 280,000 paediatric acute care hospital discharges occur annually across Canada and that the majority of hospitalized patients receive IV fluids, the potential burden of illness is striking.

There is little data regarding the incidence and epidemiology of acute IV fluid-related hyponatremia in hospitalized children. Available prospective literature does not study clinically significant acute hyponatremia; such an infrequent but important outcome is more appropriately addressed by surveillance methodology.



Methods

Through the established methodology of the CPSP, over 2,500 paediatricians and paediatric subspecialists will be actively surveyed on a monthly basis for new cases of Intravenous fluid-related symptomatic acute hyponatremia (HNA). For each reported case, participants will be asked to complete a detailed clinical questionnaire to ensure that the case definition is met.

Case definition

Report all children and youth less than 18 years of age, receiving IV fluid, who develop symptomatic acute hyponatremia during their hospitalization, including those who receive IV fluids from a referring hospital, during transfer, in the emergency department or operating room.

Symptomatic acute hyponatremia is defined as:

- 1) A fall in serum sodium from the normal range (135–145 mmol/L) to <130 mmol/L within 48 hours. (In the case of a previously healthy child hospitalized for elective reasons, in whom baseline laboratory values were not drawn, a serum sodium <130 mmol/L, within 48 hours of IV fluid initiation, will be accepted.)

AND

- 2) Temporally accompanied by one or more of the following manifestation(s):
 - Seizures
 - Decreased level of consciousness
 - Loss of consciousness
 - Respiratory arrest
 - Cardiac arrest
 - Death

Exclusion criteria

- 1) Preterm infants <37 weeks
- 2) Patients on diuretic therapy
- 3) Patients with severe gastrointestinal losses (e.g., diarrhea, nasogastric or ostomy output >50% of total enteric intake or >15 mL/kg/day if NPO)
- 4) Patients with cardiac or renal failure
- 5) Patients with known diabetes insipidus
- 6) Patients with diabetic ketoacidosis
- 7) Patients with chronic hyponatremia due to other etiologies

Objectives

- 1) To determine the incidence of symptomatic acute hyponatremia in hospitalized children receiving intravenous (IV) fluids, not otherwise explained by their pre-existing medical condition.
- 2) To explore potential risk factors associated with symptomatic hospital-acquired acute hyponatremia in this population.
- 3) To describe the clinical manifestations and sequelae of symptomatic hospital-acquired acute hyponatremia in these children.



Intravenous fluid-related symptomatic acute hyponatremia (continued)

Duration

March 2012 to February 2014

Expected number of cases

The expected incidence for this study is approximately 200 cases per year.

Ethical approval

Research Ethics Board, The Hospital for Sick Children, Toronto

Analysis and publication

The incidence rate of symptomatic hospital-acquired acute hyponatremia will be calculated as the number of cases reported, divided by the number of children hospitalized over the study period, determined by using Canadian Institute for Health Information (CIHI) data. Patient and hospital level factors associated with symptomatic hospital-acquired acute hyponatremia in this population will be explored using descriptive statistics. Clinical manifestations and sequelae of symptomatic hospital-acquired acute hyponatremia in these children will be described using proportions. Study results will be published in a peer-reviewed journal and presented at national and international conferences.

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