Felner 2001

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Bibliographic Reference	Felner EI; White PC; Improving management of diabetic ketoacidosis in children.; Pediatrics; 2001; vol. 108 (no. 3)

Study details

Study type	**Retrospective cohort study**
Study location	USA

Study type	**Retrospective cohort study**
Study setting	Children's medical centre. Study states at almost all patients admitted with DKA were initially evaluated in the emergency department. They patients were admitted to a regular hospital floor when stable. Patients who are obtunded, have severe acidosis were admitted to the intensive care unit.
Study dates	Group 1: September 1st 1994 to June 30th 1997. Group 2: July 1st 1997 to March 31st 2000.
Duration of follow-up	During treatment.
Sources of funding	The work was supported by the National Institutes of Health Grants.
Inclusion criteria	Patients within insulin-dependent diabetes mellitus who received DKA therapy under a traditional fluid protocol (group 1)were identified from a list of patients at Children's Medical Centre of Dallas who has discharge diagnoses of 'diabetic ketosis/ ketoacidosis" and admission dates from September 1st 1994 to June 30th 1997, whereas patients treated under the revised fluid protocol (group 2) were identified from a list of patients admitted from July 1st 1997 to March 31st 2000.
Exclusion criteria	Not reported
Sample size	60
Loss to follow-up	Not reported
Condition specific characteristics	No definition provided for DKA.
Interventions	**Fast rate** On presentation to the emergency department, all patients received a 20 mL/kg bolus infusion of 0.9% NaCl (normal saline, 150 mmol/L of Na) over 30 to 45 minutes. This was repeated if necessary to maintain adequate peripheral perfusion, defined as normal peripheral pulses and normal capillary refill time. After completion of bolus infusions, patients from both treatment groups received regular human insulin in a premixed solution at a rate of 0.1 U/kg/hour IV. The fluid deficit was calculated by multiplying the percentage of dehydration (7-10%, determined clinically on initial presentation) by the patient's weight. The fluid deficit was added to 1.5 times the patient's total fluid requirement. Half of the total required fluid was ordered over the first 12 hours of treatment and the remaining 50% over the next 24 hours. In both groups patients were changed to subcutaneous insulin regimen and allowed to eat and drink ad libitum at the first meal time after resolution of acidosis, defined as a venous pH >7.30. After initial fluid bolus infusions, patients in group1 received 0.45% NaCl. **Slow rate** On presentation to the emergency department, all patients received a 20 mL/kg bolus infusion of 0.9% NaCl (normal saline, 150 mmol/L of Na) over 30 to 45 minutes. This was repeated if necessary to maintain adequate peripheral perfusion, defined as normal

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	peripheral pulses and normal capillary refill time. After completion of bolus infusions, patients from both treatment groups received regular human insulin in a premixed solution at a rate of 0.1 U/kg/hour IV. Total fluids were delivered at 2.5 times the maintenance rate regardless of the degree of dehydration. Fluid were decreased to 1 to 1.5 times the maintenance rate after 24 hours of treatment (or earlier if acidosis resolved) until urine ketones were negative. In both groups patients were changed to subcutaneous insulin regimen and allowed to eat and drink ad libitum at the first meal time after resolution of acidosis, defined as a venous pH >7.30. After initial fluid bolus infusions, patients in group1 received 0.675% NaCl.
Outcome measures	**Time acidosis resolved (hours)** **Change in sodium concentration** **Change in chloride concentration**

Study arms

Fast rate (N = 30) Group 1 was further divided into group 1A (the initial 0.45% NaCl solution was discontinued and replaced with an identical solution containing an appropriate amount of glucose to provide 4:1 glucose to insulin ratio, and this was changed as necessary to control the level and rate of decrease of serum glucose. 2 bag system. In group 1B, 10g/dL of glucose was added to separate solution that was otherwise identical to the initial fluid. the rate of infusion of each of the 2 solutions was varied as necessary to control the level and rate of decrease of serum glucose, with both the insulin and total fluid delivery remaining constant. Therefore 3 separate IV solutions including the insulin solution (3-bag protocol) were needed. Data from group 1B was used as comparator group also used a 3 bag protocol.
Slow rate (N = 30) The use of 3 bag protocol was mandated.

Characteristics

Arm-level characteristics

	Fast rate (N = 30)	Slow rate (N = 30)
Age (years) Mean/SD	10.9 (4.5)	11.4 (4.6)
% Female No of events	n = 16; % = 53.3	n = 14; % = 46.6

	Fast rate (N = 30)	Slow rate (N = 30)
New onset diabetes (%) No of events	n = 8; % = 26.7	n = 9; % = 30

ROBINS-I Tool		
Section	Question	Answer
1. Bias due to confounding	Risk of bias judgement for confounding	Moderate (Appropriate analysis to control confounding not conducted.)
2. Bias in selection of participants into the study	Risk of bias judgement for selection of participants into the study	Moderate (Adjustment techniques were not used to correct the presence of selection bias.)
3. Bias in classification of interventions	Risk of bias judgement for classification of interventions	Low
4. Bias due to deviations from intended interventions	Risk of bias judgement for deviations from intended interventions	Low
5. Bias due to missing data	Risk of bias judgement for missing data	Low
6. Bias in measurement of outcomes	Risk of bias judgement for measurement of outcomes	Low
7. Bias in selection of the reported result	Risk of bias judgement for selection of the reported result	Low
Overall bias	Risk of bias judgement	Serious (Appropriate analysis to control confounding not conducted. Adjustment techniques were not used to correct the presence of selection bias.)
	Directness	Partially Applicable (Type of fluid used were different between the two groups. Definition of DKA not provided.)