Bakes 2016

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Bibliographic Reference	Bakes, Katherine; Haukoos, Jason S; Deakyne, Sara J; Hopkins, Emily; Easter, Josh; McFann, Kim; Brent, Alison; Rewers, Arleta; Effect of Volume of Fluid Resuscitation on Metabolic Normalization in Children Presenting in Diabetic Ketoacidosis: A Randomized Controlled Trial.; The Journal of emergency medicine; 2016; vol. 50 (no. 4); 551-9

Study details

Study type	**Randomised controlled trial (RCT)**
Study location	USA
Study setting	Paediatric emergency department and inpatient units of an academic freestanding children's hospital
Study dates	December 2007 until June 2010
Duration of follow-up	Variables measured included demographic characteristics (i.e., age, sex, and race/ethnicity) and laboratory values. Laboratory values, which included venous blood gas, basic chemistries (i.e., glucose, sodium, chloride, bicarbonate, potassium, blood urea nitrogen, creatinine, magnesium, phosphate, and b-hydroxybutyrate) were sent hourly during the first 4 h.
Sources of funding	Not specified.
Inclusion criteria	Children were eligible for participation if they were between 0 and 18 years of age, had type 1 diabetes mellitus plus the presence of DKA
Exclusion criteria	Patients were excluded from the study if they 1) required additional fluid resuscitation for treatment of hemodynamic instability, given at the discretion of the treating attending physician; or 2) weighed >70 kg.
Sample size	50
Loss to follow-up	No loss to follow up.
Condition specific characteristics	DKA defined as glucose >250 mg/dL, presence of ketone bodies in the blood, and metabolic acidosis (venous pH < 7.30 or serum bicarbonate < 15 mmol/L)

Study type	Randomised controlled trial (RCT)
	DKA severity was classified according to the Lawson Wilkins Pediatric Endocrine Society Consensus Statement: severe DKA (venous pH < 7.10 or bicarbonate < 5 mmol/L), moderate DKA (venous pH 7.10 to7.19 or bicarbonate 5 to < 10 mmol/L), and mild DKA (venous pH 7.20 to 7.29 or bicarbonate between 10 and < 15 mmol/L)
Interventions	**High volume IV fluid** The high-volume IV fluid group, received a 20 mL/kg of IV 0.9% saline bolus over the first hour followed by 0.675% saline + potassium replacement at 1.5 times maintenance. In both groups, dextrose was added to the IV fluids when serum glucose values reached 250–300 mg/dL. Dextrose content in IV fluids was adjusted depending on hourly glucose measurements. Potassium replacement was conducted as per International Society for Pediatric and Adolescent Diabetes (ISPAD) guidelines. Both groups received an insulin infusion (0.1 U/kg/h) upon completion of the initial saline bolus. If safe glucose levels could not be maintained by adjusting dextrose (5%–10%), insulin infusion was adjusted per protocol. **Low volume IV fluid** Low-volume IV fluid group, received a 10 mL/kg of IV 0.9% saline bolus over the first hour followed by 0.675% saline + potassium replacement at 1.25 times maintenance. In both groups, dextrose was added to the IV fluids when serum glucose values reached 250–300 mg/dL. Dextrose content in IV fluids was adjusted depending on hourly glucose measurements. Potassium replacement was conducted as per International Society for Pediatric and Adolescent Diabetes (ISPAD) guidelines. Both groups received an insulin infusion (0.1 U/kg/h) upon completion of the initial saline bolus. If safe glucose levels could not be maintained by adjusting dextrose (5%–10%), insulin infusion was adjusted per protocol.
Outcome measures	**Cerebral oedema** **Time to metabolic normalisation** serum bicarbonate >15 mmol/L and pH> 7.30. **Healthcare utilisation - length of treatment** Defined as the duration of hospital stay after the start of IV fluid infusion. **Time to discharge**

Study arms

High volume infusion (N = 25)
Low volume infusion (N = 25)

Characteristics

Arm-level characteristics

	High volume infusion (N = 25)	Low volume infusion (N = 25)
Age (years) MedianIQR	9 (6 to 12)	10 (8 to 13)
% Female No of events	n = 18; % = 72	n = 12; % = 48
New onset DM No of events	n = 12; % = 48	n = 15; % = 60
Severity of DKA		
Mild		
Number (%)	n = 9; % = 36	n = 12; % = 48
Moderate		
Number (%)	n = 9; % = 36	n = 11; % = 44
Severe		
Number (%)	n = 7; % = 28	n = 2; % = 8

Cochrane risk of bias tool 2.0 (RoB 2.0)		
Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	High (Study states that the treating attending physician identified potential subjects, followed by laboratory confirmation of

Cochrane risk of bias tool 2.0 (RoB 2.0)		
		DKA. Additionally there were more children with severe DKA in the high volume arm. Furthermore the study states that there is a possibility of selection bias, as many potential study patients were initially fluid resuscitated at an outside facility before transfer to our study site, thus making them ineligible for study enrolment.)
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High (Study states that the treating attending physician identified potential subjects, followed by laboratory confirmation of DKA. Additionally there were more children with severe DKA in the high volume arm. Furthermore the study states that there is a possibility of selection bias, as many potential study patients were initially fluid resuscitated at an outside facility before transfer to our study site, thus making them ineligible for study enrollment.)
	Overall Directness	Indirectly applicable (Rate of infusion of maintenance dose was different in the two groups. Outcome time to metabolic normalisation not specified in review protocol)