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## Original Contributions

### THE TWO-BAG METHOD FOR TREATMENT OF DIABETIC KETOACIDOSIS IN ADULTS

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**Abstract—Background:** The “two-bag method” of management of diabetic ketoacidosis (DKA) allows for titration of dextrose delivery by adjusting the infusions of two i.v. fluid bags of varying dextrose concentrations while keeping fluid, electrolyte, and insulin infusion rates constant. **Objective:** We aimed to evaluate the feasibility and potential benefits of this strategy in adult emergency department (ED) patients with DKA. **Methods:** This is a before-and-after comparison of a protocol using the two-bag method operationalized in our adult ED in 2015. A retrospective electronic medical record search identified adult ED patients presenting with DKA from January 1, 2013 to June 30, 2016. Clinical and laboratory data, timing of medical therapies, and safety outcomes were collected and analyzed. **Results:** Sixty-eight patients managed with the two-bag method (2B) and 107 patients managed with the one-bag method (1B) were identified. The 2B and 1B groups were similar in demographics and baseline metabolic derangements, though significantly more patients in the 2B group received care in a hybrid ED and intensive care unit setting (94.1% vs. 51.4%;  $p < 0.01$ ). 2B patients experienced a shorter interval to first serum bicarbonate  $\geq 18$  mEq/L (13.4 vs. 20.0 h;  $p < 0.05$ ), shorter duration of insulin infusion (14.1 vs. 21.8 h;  $p < 0.05$ ), and fewer fluid bags were charged to the patient (5.2 vs. 29.7;  $p < 0.01$ ). Frequency of any measured hypogly-

cemia or hypokalemia trended in favor of the 2B group (2.9% vs. 10.3%;  $p = 0.07$ ; 16.2% vs. 27.1%;  $p = 0.09$ ; respectively), though did not reach significance. **Conclusions:** The 2B method appears feasible for management of adult ED patients with DKA, and use was associated with earlier correction of acidosis, earlier discontinuation of insulin infusion, and fewer i.v. fluid bags charged than traditional 1B methods, while no safety concerns were observed. © 2018 Elsevier Inc. All rights reserved.

**Keywords—**diabetic ketoacidosis; DKA; endocrine; critical care

#### INTRODUCTION

Diabetic ketoacidosis (DKA) is a common and severe complication of diabetes mellitus, with the incidence increasing in the United States over the past 2 decades from 80,000 reported cases in 1988 to 140,000 reported cases in 2009 (1). Most cases of DKA occur in adult patients, with 80% of cases occurring between the ages of 18 and 65 years (2). Management of DKA requires close laboratory monitoring with frequent titration of fluid, electrolyte, and dextrose therapies. Outcomes do not

appear to be affected by the managing physician's specialty (i.e., family physician vs. internist vs. endocrinologist), as long as standard written therapeutic guidelines are followed; therefore, standardized or protocolized management is appealing in the care of patients with DKA (3,4).

Insulin is required to clear hyperglycemia and acidosis and to suppress ketone formation. As hyperglycemia clears faster than acidosis, insulin is continued past euglycemia, and dextrose is added to prevent hypoglycemia. It is recommended that DKA patients be given dextrose-containing fluids as their blood glucose (BG) falls into high-normal range (2). The two-bag (2B) method of fluid management maintains constant fluid and insulin infusion rates, while the concentration of dextrose administered is titrated by adjusting the infusion rates of two bags of i.v. fluids, one with dextrose and one without, in response to changing BG measurements. This variation of the euglycemic clamp technique allows for rapidly titratable and customizable dextrose infusion rates, while keeping fluid, insulin, and electrolyte delivery constant (5).

The 2B method has been studied in pediatric populations, and has been weakly associated with faster response time in i.v. fluid therapy changes; earlier correction of serum bicarbonate, ketones, and pH; and more cost-effective care in small studies (6–8). However, this method has not been studied previously in adult patients. We aimed to evaluate the feasibility of the 2B method in the treatment of adult emergency department (ED) patients with DKA, and to assess for potential association with improvement in metabolic and resource utilization outcomes. We hypothesized that use of the 2B method would be associated with fewer episodes of hypoglycemia and shorter duration of insulin infusion compared to the traditional one-bag (1B) method with a titratable insulin infusion.

## MATERIALS AND METHODS

### *Study Design and Setting*

A protocolized 2B method for management of adult ED patients with DKA was developed, with the working hypothesis that implementation would be associated with earlier correction of metabolic acidosis and resource preservation, and implemented in August 2015. This was a before-and-after comparison study of the initiation of this protocol using the 2B method with the hypotheses mentioned. It was reviewed and approved by the Institutional Review Board at the University of Michigan, and was granted exception from informed consent. All subjects were treated in the adult ED at a large tertiary referral center with > 100,000 annual ED visits from January 1, 2013 to June 30, 2016.

### *Selection of Participants*

Patients were included if they were at least 18 years of age with an ED clinical impression or admission diagnosis of DKA, as identified by an electronic medical record (EMR) search, and either the 1B or 2B order set was used. Patients were excluded if they did not meet diagnostic criteria on manual chart review, which included hyperglycemia plus initial pH < 7.30, initial bicarbonate ( $\text{HCO}_3$ ) < 18 mEq/L, initial anion gap > 14, if neither order set was used, or if both order sets were used. Before implementation of the 2B method, 120 patients were excluded due to no protocolized care plan being used. After implementation of the 2B method, 25 patients were excluded, as both order sets were utilized at some point. All data were obtained from the EMR. A computerized search algorithm was used to identify data points of interest. As the search criteria were developed and refined, the authors reviewed charts from 10-patient sample groups to ensure accuracy and inter-abstractor reliability in an iterative fashion. Data unable to be obtained by computerized search were abstracted manually.

### *Interventions (1B and 2B Methodology)*

Patients managed with the 1B method were treated with a hospital-wide DKA protocol, which included a continuous insulin infusion with titration instructions to adjust the insulin rate depending on the magnitude and rate of change of BG on hourly checks, and a written prompt to providers to initiate 5% dextrose-containing i.v. fluids when glucose dropped below 250 mg/dL (Figure 1). Laboratory draws and electrolyte replacement were at the discretion of the physician. Patients managed with the 2B method were treated with an ED-specific DKA protocol, which included a non-titratable continuous insulin infusion at 0.1 U/kg/h, combined with a constant fluid infusion rate of two bags of 0.45% saline, one with 10% dextrose and the other with no dextrose, the ratio of which was adjusted based on hourly BG checks to maintain a total fluid rate of 250 mL/h (Figure 2). Laboratory draws were performed every 2 h, alternating between venous blood gas and basic chemistries. Electrolyte replacement was guided by a nurse-initiated electrolyte protocol identical to that used in the inpatient intensive care units (ICUs). In both groups, long-acting insulin was routinely given when the patient met the following parameters: BG < 200 mg/dL, anion gap < 14,  $\text{HCO}_3 \geq 15$  mEq/L, pH > 7.3, and tolerating a diet by mouth. The insulin infusion was continued for an additional 2 h once these parameters were met before transitioning to subcutaneous insulin therapy. Patients in both cohorts with unique circumstances (i.e., renal failure, fluid overload) were excluded from protocolized

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