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Dararat Chiewchalernsri

Department of Medicine, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok 10400, Thailand

Chayanin Wanittansirichok

Department of Medicine, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok 10400, Thailand

Chutintorn Sriphrapadang

Department of Medicine, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok 10400, Thailand, chutintorn.sri@mahidol.ac.th

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Subcutaneous Insulin Aspart Every 4 Hours in the Treatment of COVID-19 Patients With Mild-to-Moderate Diabetic Ketoacidosis: A Case Series

Dararat Chiewchalernsri, Chayanin Wanittansirichok, Chutintorn Sriphrapradang* 

Department of Medicine, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok 10400, Thailand

Abstract

This case series evaluates the efficacy and safety of subcutaneous (SC) insulin Aspart administered every 4 h for managing mild-to-moderate diabetic ketoacidosis (DKA) in COVID-19 patients, addressing a current evidence gap. We conducted a retrospective review of confirmed COVID-19 patients over 15 years old who developed mild to moderate DKA between July 2020 and October 2021. Insulin Aspart was administered at 0.4 units/kg SC every 4 h, reduced to 0.2 units/kg when blood glucose (BG) decreased to <250 mg/dL, and SC basal insulin was initiated at 0.15–0.2 units/kg at DKA diagnosis. A total of seven patients, with a mean age of 67.4 ± 13.2 years, predominantly female (71.4 %), and all with pre-existing type 2 diabetes mellitus, were analyzed. Initial biochemical parameters included BG of 449 ± 157.3 mg/dL, HbA1c of 10.6 ± 2.8 %, pH of 7.34 (range, 7.26–7.45), beta-hydroxybutyrate of 4.0 ± 1.5 mmol/L, and bicarbonate of 15.5 ± 2.2 mmol/L. The time to resolution of hyperglycemia (BG < 250 mg/dL) and DKA was 8.0 ± 3.1 and was 12.7 ± 5.8 h, respectively. During DKA resolution, one patient experienced hypoglycemia (47 mg/dL) and later developed recurrent DKA as COVID-19 infection worsened. Three deaths occurred due to COVID-19-related complications following DKA recovery. While SC insulin Aspart administered every 4 h shows promise, careful monitoring for recurrent DKA and septic shock is essential for optimal management.

Keywords: Diabetic ketoacidosis, Diabetes mellitus, Hyperglycemic crises, Insulin analog, SARS-CoV-2

1. Introduction

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) causes COVID-19, a respiratory illness associated with high morbidity and mortality, especially in patients with diabetes mellitus.¹ COVID-19 can worsen hyperglycemia,^{2,3} leading to hyperglycemic crises such as diabetic ketoacidosis (DKA) and hyperosmolar hyperglycemic state (HHS) in both diabetic and nondiabetic patients.^{4,5} DKA, typically treated with intravenous (IV) insulin, often necessitates intensive care unit (ICU) admission.^{6,7} However, during the COVID-19 pandemic, minimizing healthcare resource utilization and reducing exposure to healthcare workers were crucial.

Several studies have shown that subcutaneous (SC) rapid-acting insulin analogs administered every 1–2 h may be effective as IV regular insulin for mild to moderate DKA.^{8–11} In response to the pandemic, professional recommendations have suggested using SC rapid-acting insulin analogs every 4 h to manage DKA in COVID-19 patients.¹² The National Diabetes Inpatient COVID-19 Response Group recommends this approach for treating mild to moderate DKA when IV insulin infusion is not possible.¹³ In alignment with these recommendations, our institution implemented a protocol using rapid-acting insulin administered every 4 h to treat mild to moderate DKA. This protocol aims to avoid ICU admission and limit

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* Corresponding author at: Department of Medicine, Faculty of Medicine Ramathibodi Hospital, Mahidol University, 270 Rama VI Road, Ratchatewi, Bangkok 10400, Thailand.
E-mail address: chutintorn.sri@mahidol.ac.th (C. Sriphrapradang).

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healthcare provider exposure, reducing the risk of COVID-19 transmission. However, the efficacy and safety of this approach remain uncertain. This case series reports the outcomes of this protocol in COVID-19 patients with mild to moderate DKA.

2. Case series presentation

This retrospective review, conducted between July 1, 2020, and October 31, 2021, included patients with laboratory-confirmed COVID-19 and mild to moderate DKA. Patients under 15 years old, those with severe DKA or mixed DKA and HHS, severe metabolic derangements ($\text{pH} < 7.0$, bicarbonate < 10 mmol/L, or potassium < 3.5 mmol/L), impaired consciousness, and pregnancy were excluded.

DKA was defined as a blood glucose concentration > 250 mg/dL, a blood ketone concentration of > 3.0 mmol/L or significant ketonuria, a bicarbonate concentration of < 18.0 mmol/L, an anion gap > 10 mEq/L, and/or venous $\text{pH} < 7.3$.⁶ The criteria for DKA severity were based on the American Diabetes Association's definition of mild (pH 7.25 to 7.3 or bicarbonate 15–18 mEq/L), moderate (pH 7.0 to < 7.24 or bicarbonate 10 to < 15 mEq/L), or severe DKA ($\text{pH} < 7.0$ or bicarbonate < 10 mEq/L).⁶ All patients received SC insulin Aspart every 4 h according to the protocol for the treatment of mild to moderate DKA.¹³ Treatment included normal saline solution or isotonic solution (500–1000 ml) based on volume status, SC basal insulin (0.15–0.2 units/kg) and SC insulin Aspart (0.4 units/kg) every 4 h until blood glucose levels dropped below 250 mg/dL, followed by a reduced dose (0.2 units/kg) until DKA resolution. Capillary blood glucose levels and plasma electrolytes were measured every 4 h, with additional assessments of arterial blood gas and beta-hydroxybutyrate as needed. Data collected included demographic characteristics, baseline clinical parameters, laboratory results, and COVID-19 severity. Primary outcomes were the time to hyperglycemia resolution, the time to DKA resolution, and total insulin dosage. Secondary outcomes included treatment-related complications, treatment failure (switch to IV regular insulin infusion), length of hospitalization, ICU admission, mortality, and health care worker exposure frequency.

We defined hyperglycemia resolution as blood glucose < 250 mg/dL. DKA was considered resolved when blood glucose < 200 mg/dL, serum bicarbonate ≥ 15 mEq/L, $\text{pH} > 7.30$, and anion gap ≤ 12 mEq/L, according to the American Diabetes Association⁶; or when ketones < 0.6 mmol/L and venous $\text{pH} > 7.3$ or bicarbonate > 15 mEq/L, according to the Joint British Diabetes Society-Inpatient Care Group.¹⁴

Hypoglycemia is defined as blood glucose levels below 60 mg/dL. The severity of COVID-19 infection ranged from mild to critical illness according to the COVID-19 Treatment Guidelines from the United States National Institutes of Health.¹⁵

2.1. Study population characteristics

Seven patients with confirmed COVID-19 and mild to moderate DKA received SC insulin Aspart every 4 h. [Table 1](#) summarizes the baseline characteristics. The mean age was 67.4 ± 13.2 years, and the mean BMI was 25.5 ± 3.4 kg/m². The majority of patients were female (71.4 %), and all had type 2 diabetes mellitus. None had previously been treated with an SGLT2 inhibitor. Other underlying diseases included hypertension, dyslipidemia, chronic obstructive pulmonary disease, and chronic kidney disease. Two patients received insulin treatment for type 2 diabetes.

2.2. DKA and COVID-19 parameters ([Table 1](#))

At the diagnosis of DKA, the biochemical parameters were as follows: capillary blood glucose of 449.3 ± 157.3 mg/dL, hemoglobin A1c of 10.6 ± 2.8 %, pH of 7.34 (range, 7.26–7.45), beta-hydroxybutyrate of 4.0 ± 1.5 mmol/L, and bicarbonate of 15.5 ± 2.2 mmol/L ([Table 1](#)). The effective serum osmolality was 298 ± 9.6 mOsm/kg, measured sodium levels were 136.5 ± 1.2 mmol/L, serum potassium levels were 4.7 ± 0.9 mmol/L, and the estimated glomerular filtration rate was 67.4 ± 51.7 ml/min/1.73 m². The majority of patients (71.4 %) had severe to critical COVID-19 infection. Three patients required ventilators, and all patients received high-dose systemic corticosteroids, either dexamethasone or methylprednisolone. C-reactive protein levels were 88.6 ± 46.8 mg/L, lactate dehydrogenase was 413.8 ± 146.6 U/L, and absolute lymphocyte counts were 742.9 ± 450.4 cells/ μL . Detailed characteristics of each patient are presented in [Table 2](#).

2.3. Outcomes ([Table 3](#))

The mean time to hyperglycemia resolution was 8.0 ± 3.1 h, and the time to DKA resolution was 12.7 ± 5.8 h. The total insulin dosage until hyperglycemia and DKA resolution were 55.1 ± 16.8 and 76.9 ± 34.9 units, respectively.

Four patients were admitted to the non-critical ward, while the remaining patients were admitted to the ICU. The mean hospital length of stay was 13.9 ± 6.9 days. The average frequency of health care worker exposure for blood draws and SC insulin

Table 1. Baseline characteristics included DKA and COVID-19 parameters.

Baseline characteristics (N = 7)	
Age, years	67.4 ± 13.2
Female, no. (%)	5 (71.4 %)
Weight, kg	63.5 ± 12.8
BMI, kg/m ²	25.5 ± 3.4
Co-morbidities no. (%)	
Hypertension	5 (71.4 %)
Dyslipidemia	5 (71.4 %)
Chronic kidney disease	3 (42.8 %)
COPD	2 (28.5 %)
Types of DM, no. (%)	
Type 2 DM	7 (100 %)
Current medications, no. (%)	
Metformin	2 (28.5 %)
Sulfonylurea	2 (28.5 %)
Thiazolidinedione	1 (14.3 %)
Insulin	2 (28.5 %)
Antihypertensive drugs	4 (57.1 %)
Statin	3 (42.8 %)
Severities of DKA, no. (%)	
Mild	3 (42.9 %)
Moderate	4 (57.1 %)
Laboratory parameters at diagnosis of DKA	
Hemoglobin A1c, %	10.6 ± 2.8
Capillary blood glucose, mg/dL	449.3 ± 157.3
pH	7.34 (7.26–7.45)
Beta-hydroxybutyrate, mmol/L	4.0 ± 1.5
Bicarbonate, mmol/L	15.5 ± 2.2
Anion gap, mmol/L	19.0 ± 3.9
Severities of COVID-19, no. (%)	
Mild	1 (14.3 %)
Moderate	1 (14.3 %)
Severe	2 (28.6 %)
Critical	3 (42.9 %)
Oxygen therapy, no. (%)	
No	1 (14.3 %)
Oxygen cannula	2 (28.6 %)
HFNC	1 (14.3 %)
Ventilator	3 (37.5 %)
Glucocorticoid therapy, no. (%)	
Dexamethasone	2 (28.6 %)
Methylprednisolone	5 (71.4 %)
Antiviral treatment and immunomodulators, no. (%)	
Favipiravir	4 (57.1 %)
Remdesivir	3 (42.9 %)
Baricitinib	1 (14.3 %)
Tocilizumab	2 (28.6 %)

Abbreviations: BMI, body mass index; COPD, chronic obstructive pulmonary disease; DKA, diabetic ketoacidosis; DM, diabetes mellitus; DPP4, dipeptidyl peptidase 4; HFNC, high-flow nasal cannula; SGLT2, sodium-glucose cotransporter 2.

administration was 4.4 ± 1.7 times/day. No patient required switching to IV regular insulin infusion, and no hypokalemia occurred. One patient developed hypoglycemia (blood glucose of 47 mg/dL) during DKA resolution and subsequently experienced recurrent DKA due to worsening COVID-19. Three patients died from COVID-19-related complications, despite recovering from DKA. The

clinical features and disease progression of all patients are described in Table 2.

3. Discussion

This case series suggests that SC insulin Aspart administered every 4 h could be an effective and safe treatment for mild to moderate DKA in COVID-19 patients. Our findings did not show a significant difference in the time to resolve hyperglycemia and DKA compared to previous studies.^{8,11} This approach may reduce ICU admissions and health-care worker exposure. However, our study population was older, had more severe comorbidities compared to those in previous studies,^{8,11} and the requirement for corticosteroid treatment further complicated glucose management. Despite these challenges, there were no significant differences in treatment outcomes (such as time to hyperglycemia and DKA resolution, as well as total insulin dosage until hyperglycemia and DKA resolution) compared to previous findings.^{8,11} This suggests that SC insulin Aspart every 4 h is effective, even in individuals with severe comorbidities and glucocorticoid use.

The lower severity of DKA in our patients compared to previous studies^{8,11} may be attributed to the early collection of blood samples during their COVID-19 illness, enabling rapid diagnosis and favorable outcomes. All our patients had type 2 diabetes, not type 1 diabetes, possibly contributing to the milder DKA observed.¹⁶

Standard DKA management involves continuous IV regular insulin infusion, but SC rapid-acting insulin analogs every 1–2 h are also accepted for mild, uncomplicated DKA.^{10,17} The prospective study by Griffey et al. in an academic setting found that using a SC rapid-acting insulin analog protocol for mild-to-moderate DKA was effective, safe, and associated with a reduced emergency department length of stay.¹⁸ Data from a health care system in California demonstrated that the SC insulin protocol for DKA management reduced the need for ICU admission without increasing adverse events.¹⁹ This approach could be particularly useful in pandemics, as it limits patient contact frequency. Although our patients with end-stage renal disease received this SC insulin approach, it is important to emphasize that this SC approach is not recommended for individuals with mixed DKA/HHS, pregnancy, severe metabolic derangement, impaired consciousness, and other significant co-morbidities, such as chronic kidney stage 4 or end-stage liver disease, acute coronary syndrome.¹³ In a limited resource setting in Ethiopia, a retrospective study on the treatment of DKA in children with type 1 diabetes in Ethiopia

Table 2. Characteristics and outcomes of each subject.

Subjects	1	2	3	4	5	6	7
Age, years	54	71	60	67	82	52	86
Sex	Female	Male	Female	Male	Female	Female	Female
Co-morbidities	None	HT, DLP, ESRD, COPD	DLP	HT, DLP, CKD stage 3b	HT, DLP, ESRD	HT	HT, DLP, COPD, CAD
BMI, kg/m ²	20.4	29.7	22.0	27.6	28.0	26.7	24.0
eGFR by CKD-EPI	120.6	3.9	109.6	36.9	4.8	116	80.6
HbA1c, %	13.2	10.8	11.3	9.2	5.0	12.9	11.6
Severity of COVID-19 infection	Moderate	Critical	Severe	Critical	Critical	Severe	Mild
Severity of DKA	Mild	Moderate	Moderate	Moderate	Moderate	Mild	Mild
pH	7.37	7.26	7.36	7.33	7.26	7.34	7.45
Bicarbonate, mmol/L	18.5	13.8	14.4	13.2	13.9	17.5	17.3
Beta-hydroxybutyrate, mmol/L	2.3	2.6	6.6	5.1	4.3	4.0	3.4
Blood glucose, mg/dL	648	310	502	656	267	353	409
Anion gap, mmol/L	16.5	20.2	24.6	21.8	20.1	17.5	12.7
Time to resolve hyperglycemia, hours	5	8	12	8	10	10	3
Time to resolve DKA, hours	5	19	12	16	10	20	7
Diabetic complications	None	None	None	Hypoglycemia, recurrent DKA	None	None	None
Frequency of healthcare worker exposure, times/day	2	4	5	7	4	6	3
Outcomes at discharge	Improved	Death	Improved	Death	Death	Improved	Improved

Abbreviations: CAD, coronary artery disease; CKD, chronic kidney disease; CKD-EPI, chronic kidney disease epidemiology collaboration; COPD, chronic obstructive pulmonary disease; DKA, diabetic ketoacidosis; DLP, dyslipidemia; eGFR, estimated glomerular filtration rate; ESRD, end stage kidney disease; HT, hypertension.

Table 3. Outcomes.

Primary outcomes	N = 7
Time to hyperglycemia resolution, hours	8.0 ± 3.1
Time to DKA resolution, hours	12.7 ± 5.8
Total insulin dosage until hyperglycemia resolution, units	55.1 ± 16.8
Total insulin dosage until DKA resolution, units	76.9 ± 34.9
Length of hospital stays, days	13.9 ± 6.9
Frequency of healthcare worker exposure, times/day	4.4 ± 1.7
Secondary outcomes	N = 7
Switching to IV regular insulin fusion	0 (0 %)
Hypoglycemia	1 (14.3 %)
Hypokalemia	0 (0 %)
Rebound hyperglycemia	0 (0 %)
Recurrent DKA	1 (14.3 %)
Death	3 (42.9 %)

Hyperglycemia resolution is defined as blood glucose levels below 250 mg/dL.

Abbreviations: DKA, diabetic ketoacidosis; IV, intravenous.

suggests that administering six-hourly SC regular insulin may be a safe and effective alternative to IV insulin infusion.²⁰

Three patients in our study died due to COVID-19 complications after recovering from DKA. One patient developed recurrent DKA following the deterioration of their COVID-19 infection which led to

septic shock and acute respiratory distress syndrome. This recurrence might be linked to worsening COVID-19 infection, high doses of glucocorticoids, or decreased efficacy of SC insulin in patients with septic shock. Furthermore, most patients had poorly controlled diabetes prior to admission, with six out of the seven having a hemoglobin A1c level over 9 %. Therefore, assessing COVID-19 severity and predicting its progression are essential before initiating SC rapid-acting insulin in DKA patients. Furthermore, these two deceased patients had an estimated glomerular filtration rate (eGFR) < 15 ml/min/1.73 m², despite guidelines not recommending the use of SC insulin every 4 h in patients with CKD stages 4 or 5. Chronic kidney disease is also a major risk factor for COVID-19 mortality.²¹

Our study had several limitations, including a small sample size, lack of a control group, and the retrospective review. Further validation through a randomized controlled trial is necessary.

4. Conclusions

Our findings suggest that SC insulin Aspart administered every 4 h is a safe and effective treatment for mild to moderate DKA in COVID-19 patients, potentially reducing ICU utilization and healthcare worker exposure. However, larger,

prospective studies are needed to confirm these results and guide future treatment protocols.

Disclaimers

The abstract was presented at the ENDO 2023, in Chicago, Illinois (June 15-18, 2023).

Statement of authorship

The authors certified fulfillment of ICMJE authorship criteria.

CRedit author statement

DC: Conceptualization, Methodology, Validation, Formal analysis, Resources, Writing-original draft preparation, Writing-review and editing, Visualization; CW: Conceptualization, Methodology, Validation, Formal analysis, Resources, Writing-review and editing, Visualization; CS: Conceptualization, Methodology, Validation, Formal analysis, Resources, Writing-review and editing, Supervision, Project administration.

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Conflict of interest

The authors have nothing to disclose.

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