

# **BRIEF REPORT**

General Medicine



# Assessment of Patient Satisfaction Among Patients Treated With Intravenous vs Subcutaneous Insulin for Diabetic Ketoacidosis

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#### **Abstract**

Objectives: We previously implemented the subcutaneous (SQ) insulin in diabetic ketoacidosis (DKA) (SQuID) protocol, demonstrating safe, effective treatment of low to moderate (LTM) severity DKA in a non-intensive care unit setting. SQuID replaces intravenous (IV) insulin with SQ injections and reduces glucose checks from hourly to every 2 hours. We are not aware of any data on patient satisfaction with treatment in DKA. Our objective was to compare satisfaction in patients treated with IV insulin to that in patients treated with the SQ protocol.

Methods: We conducted a cross-sectional study in an urban academic hospital (March 2023 to March 2024) of emergency department patients treated for LTM DKA with SQ or IV insulin. Patients were contacted by phone in the hospital after the resolution of DKA. We used the validated 21-item Diabetic Treatment Satisfaction Questionnaire-Inpatient tool (DTSQ-IP) using 7-tier Likert-style options (0 = negative; 6 = positive) to assess patient satisfaction with treatment. We computed the DTSQ-IP composite treatment satisfaction score (using 15 of the 21 items), assessing differences between groups.

Results: Of the 60 patients contacted, 52 (87%) completed the questionnaire. Median DTSQ-IP satisfaction scores for SQuID and IV insulin patients were 86.0 (IQR, 79.0, 88.0) and 81.0 (IQR, 77.0, 88.0), respectively. We found no difference in satisfaction between groups (difference 5.0; 95% CI, -3.0, 10.0).

abstract continues

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JACEP Open 2025;6:100020. JACEPOpen.com 1 of 7

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## Abstract (continued)

Conclusion: In this single-center study, patient satisfaction with DKA care was high, with no differences observed between patients treated with SQ vs IV insulin protocols. This is the first study we are aware of on patient satisfaction with treatment in DKA or treatment with SQ insulin. Though the sample size is small, these findings suggest that patient satisfaction should not represent a barrier to the implementation of SQ protocols for LTM severity DKA.

Keywords: diabetic ketoacidosis, emergency, subcutaneous insulin, patient satisfaction

#### 1 INTRODUCTION

## 1.1 Background

Diabetic ketoacidosis (DKA) is a common, costly condition, and the major source of mortality in patients with diabetes that is on the rise. <sup>1–5</sup> Treatment involves fluid resuscitation, electrolyte replacement, and administration of intravenous (IV) insulin, typically requiring admission to an intensive care unit (ICU). <sup>6–8</sup> ICUs are a limited resource, with known variability in their use for DKA. <sup>8,9</sup>

# 1.2 Importance

Recently, as evaluated in a Cochrane review, fast-acting insulin analogs have been found safe and effective in replacing insulin infusions in low to moderate (LTM) DKA, obviating hourly blood glucose checks, and allowing treatment in non-ICU settings. We recently described the use of the subcutaneous (SQ) insulin in DKA (SQuID) protocol for LTM DKA, demonstrating safe and effective treatment, with improvements in emergency department (ED) length of stay. This protocol has been in continuous use in our hospital, at present in its fourth year.

Beyond questions of safety, efficacy, and impacts on operations or costs, patient satisfaction with SQ insulin as an alternate treatment pathway is important for this to be a viable path forward. Patient benefits of an SQ protocol may include a shorter ED length of stay compared with treatment with a traditional insulin infusion, which typically requires anion gap closure and discontinuation of IV insulin in the ED with admission to the medical floor. Benefits may also include less frequent glucose monitoring (possibly fewer fingerstick blood glucose checks) and potentially a quicker time to resolution of DKA. However, the use of an SQ protocol also means insulin injections up to every 2 hours, which could conceivably represent a patient dissatisfied.

# 1.3 Goals of This Investigation

Others have reported benefits of SQ protocols, such as reductions in ICU utilization and costs, <sup>12,13</sup> but we are not aware of any study to date that has evaluated patient satisfaction with an SQ protocol. Evaluating patient satisfaction was one of our objectives as part of a broad follow-up study.

Without a crossover study design, which is infeasible and would not provide any patient benefit, patients cannot weigh the benefits and dissatisfiers of one protocol vs the other, so our strategy was to measure and compare satisfaction in these 2 cohorts using a shared, validated instrument.

#### 2 METHODS

# 2.1 Study Design, Setting, and Selection of Participants

We conducted a cross-sectional study in an urban academic hospital (March 4, 2023, to March 4, 2024) of ED patients treated for LTM DKA with either SQ or IV insulin. A trained research coordinator contacted patients for consent and enrollment during their hospitalization following the resolution of DKA (anion gap  $\leq$  16) by administering a survey by phone. This study was approved by our hospital institutional review board.

#### 2.2 Study Protocol

The SQuID protocol is for patients with LTM DKA. Severity was determined with a widely-used scheme endorsed by the American Diabetes Association, with severe DKA defined as having an HCO<sub>3</sub> < 10 mmol/L or pH < 7.0.<sup>7</sup> Exclusion criteria for the SQuID protocol included severe DKA, <18 years old, end-stage renal disease, congestive heart failure, pregnancy, high-risk cardiology admission, left ventricular assist device, tracheostomy, organ transplant recipient, oncologic emergency, sodium-glucose cotransporter-2-inhibitor use, and physician discretion. We also excluded from this study those with communication barriers, altered mental status, those who had switched protocols for any reason, and those who were transferred from other facilities and had been started on treatment.

Details for the process of identifying patients and details of the SQuID and traditional IV insulin protocols have been previously described. Patients were assigned at the discretion of the treating team. However, SQuID has emerged as the default pathway for ~75% of LTM DKA patients in our hospital (those without exclusion criteria and not requiring the ICU for non-DKA reasons). This reflects that nearly 100% of eligible LTM DKA patients not needing an ICU are treated with SQ insulin. Patients on SQuID were admitted to either

2 of 7 GRIFFEY ET AL.



# The Bottom Line

Does patient satisfaction differ between patients with diabetic ketoacidosis (DKA) treated with subcutaneous (SQ) vs intravenous insulin protocols? This single-center study provides the first data we are aware of attempting to address this question. Researchers found that patient satisfaction with DKA care was high, with no differences observed between patients treated with SQ vs intravenous insulin protocols. Though the sample size is small, this preliminary signal suggests that patient satisfaction should not represent a barrier to implementation of SQ protocols for DKA.

an inpatient observation floor or a medical floor, where patients were treated by hospitalist physicians and with nurses trained on the use of the protocol. Patients with any exclusions were started on an IV insulin protocol and could be admitted to the medical floor (after anion gap closure and discontinuation of the insulin infusion) or to the ICU, depending on bed availability and concomitant non-DKA indications for an ICU admission.

#### 2.3 Measurements

We collected sociodemographic information and used the validated 21-item Diabetic Treatment Satisfaction Questionnaire-Inpatient tool (DTSQ-IP) to compare patient satisfaction between SQuID and IV insulin cohorts. The DTSQ-IP uses 7-tier Likert-style response options (0 = negative; 6 = positive) covering a total of 21 items impacting patient satisfaction. The proprietary nature of the DTSQ-IP instrument prevents our disclosure of its exact language, but we are able to present topic areas as has been done in other publications and do not believe this represents a barrier to understanding or validity.

#### 2.4 Outcomes

Our primary outcome was the DTSQ-IP composite score, which uses 15 of the 21 items in the tool, comparing cohorts on this score. 14

### 2.5 Data Analyses

This was part of a broader project powered for other outcomes. Our analysis is descriptive, in which we report medians and IQRs for continuous variables (all were nonnormal) and frequencies and proportions for categoric variables. We evaluated for potential demographic differences between the IV insulin and SQuID groups, employing the Mann-Whitney U test and Fisher's exact test for comparing age, patient-identified sex, and race at  $\alpha$  = .05. We computed the DTSQ-IP composite treatment satisfaction score, which is defined as the sum of the responses to 15 of the 21 items, with each question scored 0 to 6. Patients who did not answer all 15 questions were dropped

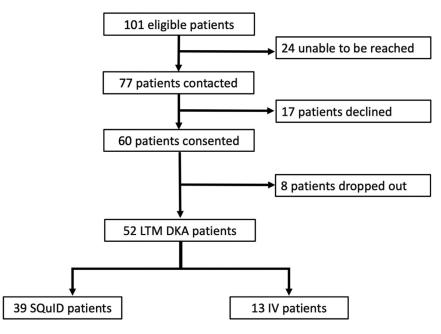


FIGURE 1. Flow diagram. DKA, diabetic ketoacidosis; IV, intravenous; LTM, low to moderate; SQuID, subcutaneous insulin in diabetic ketoacidosis.

GRIFFEY ET AL. 3 of 7

# **JACEP OPEN**

from the analysis. We also report the scoring of one individual question (regarding the frequency with which patients felt they were hypoglycemic) that did not contribute to the composite score. As this question is scored in the opposite order from other questions, we reversed its scoring for interpretability. We computed 95% CIs for the differences in median scores using percentile bootstrapping (N = 1000). Differences with 95% CIs not crossing zero were considered significant. We used R, version 4.4.0, for all analyses and figures, employing the packages tidyverse version 1.3.0, table1 version 1.4.3, and boot version 1.3-30.  $^{16-19}$ 

#### 3 RESULTS

In this 1-year study period, we identified 101 eligible patients with LTM DKA, 17 of whom declined to participate. We were able to contact 60 of the remaining 84 patients, 52 of whom (87%) completed the questionnaire; 13 (25%) patients were treated with IV insulin, and 39 (75%) were treated with SQuID (Fig 1). The median age was 46 (IQR, 28, 54); 60% were male, and 77% were Black, with no differences between

cohorts (Table). The median DTSQ-IP satisfaction scores among SQuID and IV insulin patients were 86.0 (IQR, 79.0, 88.0) and 81.0 (IQR, 77.0, 88.0), respectively. We found no significant difference in the median DTSQ-IP composite score (difference 5.0; 95% CI, -3.0, 10.0) in the median score for the question about self-perceived frequency of hypoglycemia (difference 0; 95% CI, -1.0, 3.0), satisfaction with monitoring (difference 0; 95% CI, 0, 0), timing of medication relative to meals (difference 0; 95% CI, 0, 0.5), or overall satisfaction between the 2 groups (difference 0; 95% CI, 0, 0.5; Fig 2). We observed no significant variability in responses or between groups over time (Fig 3).

# **4** LIMITATIONS

This was a single-center study that may impact generalizability. Although limited by the sample size and imbalance between groups, these data nevertheless still provide a preliminary signal that patients treated with SQ insulin are no less satisfied with their hospital experience and add value to what is currently known, which essentially consists of no published data on this

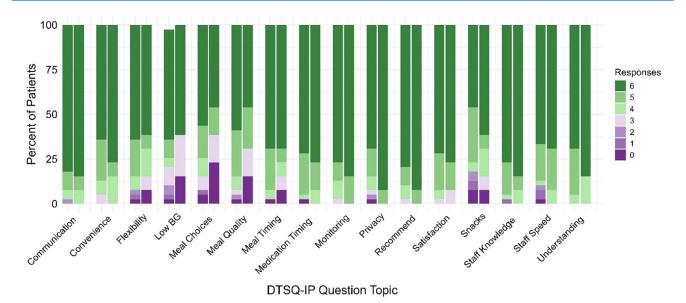
TABLE. Patient demographics.

Demographic or clinical descriptor	SQuID (n = 39)	Traditional (n = 13)	P value
Age (y), median (IQR)	41.8 (25.3, 53.9)	51.1 (43.8, 53.2)	.36
Sex, n (%)			1.0
Male	23 (59.0)	8 (61.5)	
Female	16 (41.0)	5 (38.5)	
Race, n (%)			.08
Black/African American	32 (82.1)	8 (61.5)	
White/Caucasian	6 (15.4)	2 (15.4)	
Other	0 (0)	1 (7.7)	
Not available	1 (2.6)	2 (15.4)	
ESI, median (IQR)	2.00 (2.00, 3.00)	2.00 (2.00, 3.00)	.60
HLOS (h), median (IQR)	50.6 (28.3, 96.6)	102 (78.4, 129)	.004
Not admitted	5 (12.8)	O (O)	
ED disposition, n (%)			<.001
Discharged from the ED	5 (12.8)	O (O)	
Admitted to observation floor	25 (64.1)	1 (7.7)	
Admitted to medical floor	9 (23.1)	O (O)	
Admitted to ICU	0 (0)	12 (92.3)	
Initial bicarbonate, median (IQR)	18.0 (14.0, 23.5)	18.0 (16.0, 20.0)	.66
Missing	1 (2.6)	O (O)	
Initial pH, median (IQR)	7.29 (7.21, 7.30)	7.22 (7.12, 7.26)	.06
Missing	1 (2.6)	0 (0)	
DKA severity, n (%)			.053
Mild	25 (64.1)	4 (30.8)	
Moderate	14 (35.9)	9 (69.2)	

DKA, diabetic ketoacidosis; ED, emergency department; ESI, Emergency Severity Index; HLOS, hospital length of stay; ICU, intensive care unit, SQuID, subcutaneous insulin in diabetic ketoacidosis. "Other" race categories included: "missing" or "not available." P values are from Mann-Whitney U tests for all continuous variables and Fisher's exact tests for all categoric variables.

4 of 7 GRIFFEY ET AL.

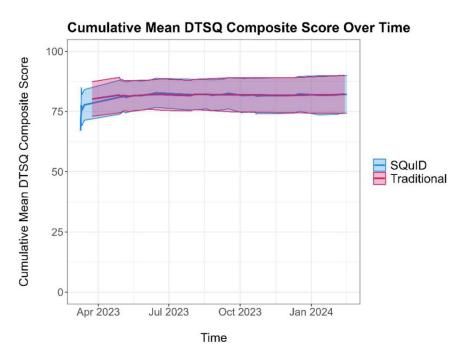




**FIGURE 2.** Responses to 7-point Likert scale (0 = most negative; 6 = most positive) Diabetic Treatment Satisfaction Questionnaire-Inpatient (DTSQ-IP) questions. The left bar corresponds to the subcutaneous insulin in diabetic ketoacidosis group; the right bar corresponds to the intravenous insulin group. BG, blood glucose.

topic. Our sample size does reflect a year of data collection, and our allocation is driven largely by the popularity of the SQuID protocol. We experienced lower DKA patient volumes than anticipated based on historical numbers. Though our prior research experience has been that phone contact was more practical than in-person attempts, we encountered some difficulties contacting eligible patients, which likely resulted in

a smaller sampling frame. We observed a high level of stability and lack of variability in responses to the DTSQ-IP (Fig 3), suggesting that additional data collection would not yield a meaningful increase in information. This supported truncating data collection at 1 year with the end of our funding period. It is possible that the DTSQ-IP, which is validated for evaluation of satisfaction with treatment in the inpatient setting, may not



**FIGURE 3.** Cumulative mean Diabetic Treatment Satisfaction Questionnaire-Inpatient (DTSQ-IP) composite scores with SD over time. SQuID, subcutaneous insulin in diabetic ketoacidosis.

GRIFFEY ET AL. 5 of 7

# **JACEP OPEN**

be as focused on issues specific to treatment in DKA. We are not aware of another instrument that is better suited for this assessment or that has undergone prior testing.

#### 5 DISCUSSION

A Cochrane review on SQ insulin in DKA indicated that no study included in their review evaluated patient satisfaction as part of their outcomes. <sup>10</sup> We aimed to provide data on this important topic using the only validated instrument we are aware of for assessing treatment satisfaction, the DTSQ-IP instrument. The DTSQ-IP assesses a variety of aspects of care, not just the medication route, and includes questions assessing satisfaction with aspects of glycemic control, monitoring, and medication management relevant to our intervention. We found that patients had very high satisfaction with their care on both the SQuID and the IV pathways across all domains assessed, with no differences noted between arms.

Patients on the IV pathway were almost all treated in the ICU. As is the case in many facilities, for well-reasoned safety considerations, insulin infusions are disallowed on the medical floor, which is one of the reasons we developed the SQ protocol in the first place. Patients treated with IV insulin thus either complete their treatment in the ED prior to admission to the floor or are admitted on IV insulin to the ICU (for reasons unrelated to their DKA). Although this presents the opportunity for some confounding because of issues apart from treatment with SQ vs IV insulin, it allows the best comparison possible.

Although the numbers are small and there are acknowledged limitations to this assessment, these are the only data we are aware of providing any information on this topic. Future studies assessing and comparing patient satisfaction with treatment regimens in DKA might ask more pointed questions about specific potential benefits and disadvantages of the respective treatment regimens, presenting those items separately from other shared comparators. Alternately, other methods, such as qualitative approaches or questions assessing patient prioritizations or trade-offs, may help better inform patient preferences. A related but separate issue is an assessment of costs, which may impact satisfaction and estimates of the relative value of treatment approaches.

In summary, in this single-center study, patient satisfaction with DKA care was high, and we observed no differences between patients treated with SQ and IV insulin protocols. This is the first study we are aware of on patient satisfaction with treatment in DKA or treatment with SQ insulin. Though the sample size is small, these findings suggest that patient satisfaction should not represent a barrier to the implementation of SQ protocols for LTM severity DKA.

## **AUTHOR CONTRIBUTIONS**

R.M.S. was responsible for data collection and data integrity. R.A. performed programming and established data management. R.A. and T.K. were responsible for data analysis. R.M.S. and R.T.G. performed the primary drafting of the manuscript. R.M.S., R.A., T.K., M.G., and P.C.B. performed critical editing. R.T.G. was responsible for the study overall.

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#### **CONFLICT OF INTEREST**

All authors have affirmed they have no conflicts of interest to declare.

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6 of 7 GRIFFEY ET AL.



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GRIFFEY ET AL. 7 of 7