Survey Study to Describe Burden of High Dose Insulin Use among Patients with T2D on U-100 Insulins

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OBJECTIVE

The purpose of this study was to describe the burden of high dose U-100 basal-bolus insulin therapy in people with type 2 diabetes (T2D) and the associated dosing behaviors:

1. To understand the burden of disease management
2. To understand and describe the consequences of the burden of high dose insulin
3. To describe patients' satisfaction with high dose insulin therapy and burden of high dose insulin therapy on patients' daily life routine and other social activities using the Treatment Related Impact Measure for Diabetes (TRIM-D)

CONCLUSIONS

- Most patients reported to be compliant with the daily amount of basal-bolus insulin doses prescribed by their physician.
- However, there were patients who reported missing/skipping doses as well as underdosing for a variety of reasons, such as forgetting or being too busy, as well as concerns regarding low blood sugar.
- Patients reported above mid-range satisfaction with insulin treatment based on TRIM-D scores.
- Study results provide a better understanding of patient adherence and the burden associated with high dose U-100 basal-bolus regimens and can help address treatment concerns, motivations, barriers, and satisfaction of patients on high dose insulin.

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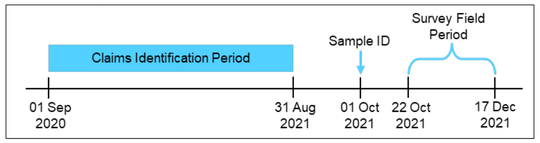
BACKGROUND

- Despite the importance of adhering to prescribed insulin regimens, patients with T2D undergo instances of missing doses and underdosing.
- Little is known about the degree to which patients are adherent to high dose basal-bolus insulin (>200 units daily) and the reasons for non-adherence.
- A better understanding of the burden associated with high dose U-100 basal-bolus regimen is required to adequately address the treatment concerns, motivations, barriers, and satisfaction of patients on high dose insulin.
- The goal of this survey-based study was to assess patient attitudes and concerns, providing guidelines for subsequent interventions.

METHODS

Study design



METHODS

Participants

- Patients were identified using enrollment, medical, and pharmacy records from the **Optum Research Database** during the identification period, September 2020 – August 2021.

Main eligibility criteria:

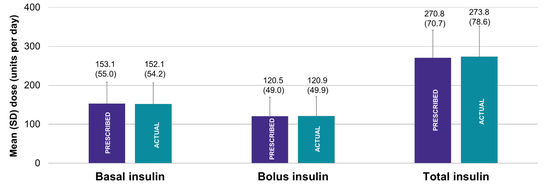
- ≥1 medical claim with a diagnosis for T2D
- ≥18 years old as of the first T2D claim
- ≥2 pharmacy claims for U-100 basal insulin and ≥2 pharmacy claims for U-100 bolus insulin. High dose U-100 bolus insulin and U-100 basal insulin (total daily dose >150 units*) were identified by reviewing strength and day supply information to calculate a daily average consumption
- No pharmacy claims for inhaled insulin, U-100 combination basal insulin, U-200 or U-300 or U-500 basal or bolus insulin, pre-mixed insulin, or pump during the identification period
- No more than 1 claim for T1D during the identification period

*Priority was given to patients with a total daily dose >200 units, as the goal was to identify patients on >200 units. If there were not enough patients on >200 units, then patients with a total daily dose >150 units and ≤200 units were selected.

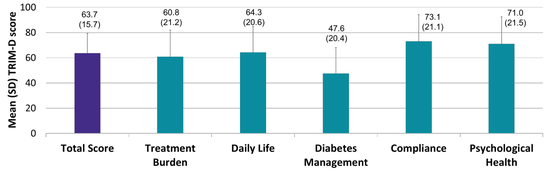
Patients with commercial insurance were selected first to obtain as many commercial patients as possible, since there were fewer commercial patients than Medicare Advantage. The remaining Medicare Advantage patients were randomly sampled to obtain a total of 2,000 patients. If possible, minority groups were selected first to increase representation in the sample.

KEY RESULTS

Mean daily dose prescribed for basal and bolus insulin did not differ from insulin that was actually taken.



Mean TRIM-D scores ranged from 48 to 73, with higher scores indicating a better health state and lesser negative impact of insulin therapy.



	Total Score	Treatment Burden	Daily Life	Diabetes Management	Compliance	Psychological Health
Median	65.2	62.5	65.0	45.0	75.0	71.9
IQR	52.8, 73.7	45.8, 75.0	50.0, 80.0	35.0, 60.0	56.3, 87.5	56.3, 87.5

METHODS

Survey

- Of the 2000 patients invited by mail to participate, 207 responded and were included in the analysis.
- The survey was developed specifically for this study to collect the patients' experience with high dose insulin injections, including:
  - Daily dose compliance
  - Missing/skipping an entire dose: Any time a patient may have intentionally or unintentionally not taken any insulin for that dose
  - Underdosing: Any time a patient 1) may have taken a partial dose of insulin by injecting fewer units in an injection than they were supposed to take (e.g., taking 30 units instead of 40 units in one injection) or 2) missed or skipped an injection by only taking 1 injection when they were supposed to take 2 injections to get a full dose of insulin
  - Reasons for non-adherence
  - Blood glucose monitoring including missed testing
- A validated TRIM-D instrument was used to measure the patient's satisfaction, functioning, and wellbeing.
- Patients confirmed that they were prescribed high dose U-100 bolus and U-100 basal insulin (total daily dose >200 units) and that they self-administered their insulin injections.

Statistical Analysis

- Descriptive analyses reported categorical variables as number and percentage and continuous variables as mean, median, standard deviation, interquartile range (IQR), minimum, and maximum.

RESULTS

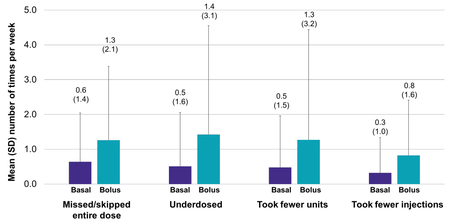
Table 1. Demographics and clinical characteristics

Variables	Total	Commercial	Medicare Advantage
Age, years, N | mean (SD)	207 | 63.9 (8.8)	26 | 56.6 (8.6)	181 | 65.0 (8.3)
Gender, N | n (%)			
Female	206 | 92 (44.7)	26 | 10 (38.5)	180 | 82 (45.6)
Race, N | n (%)	204	26	178
American Indian or Alaska Native	4 (2.0%)	0 (0)	4 (2.2%)
Asian	3 (1.5%)	0 (0)	3 (1.7%)
Black/African American	23 (11.3%)	0 (0)	23 (12.9%)
White	160 (78.4%)	24 (92.3%)	136 (76.4%)
Other	5 (2.5%)	2 (7.7%)	3 (1.7%)
Unknown	13 (6.4%)	1 (3.8%)	12 (6.7%)
Highest level of education, N | n (%)	202	26	176
Some high school	16 (7.9%)	1 (3.8%)	15 (8.5%)
High school or equivalent	59 (29.2%)	4 (15.4%)	55 (31.3%)
Some college but no degree	52 (25.7%)	8 (30.8%)	44 (25.0%)
Two-year college	25 (12.4%)	2 (7.7%)	23 (13.1%)
Four-year college	28 (13.9%)	9 (34.6%)	19 (10.8%)
Graduate school	22 (10.9%)	2 (7.7%)	20 (11.4%)
BMI, kg/m^2, N | mean (SD)	205 | 41.0 (9.2)	26 | 41.8 (12.2)	179 | 40.9 (8.7)
HbA1c at goal set by HCP, N | n (%)	201	26	175
Yes	133 (66.2%)	15 (57.7%)	118 (67.4%)
No	46 (22.9%)	9 (34.6%)	37 (21.1%)
No goal set	11 (5.5%)	2 (7.7%)	9 (5.1%)
Unknown	11 (5.5%)	0 (0)	11 (6.3%)
Current HbA1c level, %, N | mean (SD)	190 | 7.6 (1.4)	24 | 7.5 (1.2)	166 | 7.7 (1.4)
Hypoglycemia episodes/week, N | mean (SD)	202 | 1.4 (2.1)	25 | 1.9 (1.8)	177 | 1.3 (2.2)
Blood glucose testing device, N | n (%)	206	26	180
CGM	52 (25.2%)	11 (42.3%)	41 (22.8%)
Fingerstick Glucose Monitor	170 (82.5%)	19 (73.1%)	151 (83.9%)
Fingerpick frequency/day, N | n (%)	154	15	139
0 time	6 (3.9%)	3 (20.0%)	3 (2.2%)
1 time	13 (8.4%)	3 (20.0%)	10 (7.2%)
2–3 times	70 (45.5%)	5 (33.3%)	65 (46.8%)
4–5 times	59 (38.3%)	3 (20.0%)	56 (40.3%)
>6 times	6 (3.9%)	1 (6.7%)	5 (3.6%)

Abbreviations: N, valid cohort size for each variable; n, sample size; SD, standard deviation; BMI, body mass index; HbA1c, glycated hemoglobin; CGM, continuous glucose monitoring

Consequences of the burden of high dose insulin

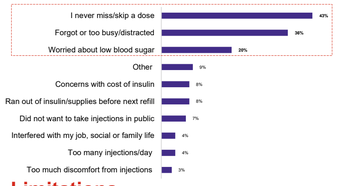
Self-reported missed/skipped entire doses and underdosing (overall and by type of underdosing), basal versus bolus insulin



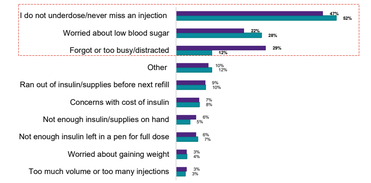
Missed/skipped: Mean (SD) calculated total missed/skipped doses of basal *or* bolus insulin was 1.9 (2.9) times per week (range: 0 to 14) (data not shown).

Underdosing: Mean (SD) calculated total times underdosing basal *or* bolus insulin was 1.9 (3.8) times per week (range: 0 to 22) (data not shown).

Reasons for missed/skipped entire insulin dose (percentage of patients)



Reasons for underdosing by taking fewer injections or fewer insulin units per injection (percentage of patients)



Limitations

- The results may not be generalizable to the overall T2D population as the study population had a mean age of 64 years and were predominantly insured through Medicare Advantage.
- This is a survey study based on self-reported data, and the impact of recall bias must be considered when interpreting the results.

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