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RESEARCH LETTER

Patient perspectives and experiences with basal insulin titration in type 2 diabetes in the United States: A cross-sectional survey

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1 | INTRODUCTION

The treatment goals for type 2 diabetes (T2D) are to prevent or delay complications and maintain quality of life. This is best achieved through glycaemic management using a patient-centred approach based on careful consideration of individual patient factors and preferences.[1,2] For many people with T2D, addition of long-acting basal insulin (BI) to oral therapy becomes necessary within 5 to 10 years of diagnosis.[1] However, titration following BI initiation is needed to determine the optimal dose for each patient.[1-3] Insulin titration is a complex and iterative process that requires enhanced monitoring and tracking of blood glucose and eating behaviour.[3,4] Information about BI titration experience from the perspectives of patients or providers and their correlation to glycaemic control or hypoglycaemic events is limited. This cross-sectional survey sought to investigate patients' experience with BI initiation and titration among recent starters of BI treatment to better understand patients' unmet needs.

2 | MATERIALS AND METHODS

For this observational, cross-sectional survey, US adults with T2D who recently initiated BI were identified through diagnosis and prescription claims from April 2020 through April 2021 from the Optum Research Database during two waves of data collection to achieve an appropriate target sample size (Methods S1, Figure S1). Eligible individuals: had ≥2 T2D diagnosis claims and ≥1 BI prescription claims; were aged ≥18 years at index date (earliest BI prescription claim); had ≥12 months of pre-index continuous enrolment (baseline); had available mailing address and glycated haemoglobin (HbA1c) value (prioritized in Wave 2 only); were willing and able to complete the survey; and had a self-reported T2D diagnosis and confirmation of recent BI initiation. Individuals with any insulin claim (pre-index) or ≥1 diagnosis claim for type 1 diabetes during baseline were excluded. Eligible patients were invited to participate and return completed surveys by mail. The survey included an informed consent statement; consent was implied when patients returned the completed survey

TABLE 1 Self-reported demographic and clinical characteristics

Characteristic	N = 416
Age, years[a]	
Mean ± SD	70.1 ± 9.5
Distribution by age category, n (%)	
<55	25 (6)
55-64	73 (18)
65-74	184 (44)
>75	134 (32)
Sex, n (%)	n = 415
Female	204 (49)
Male	211 (51)
Race, n (%)[b]	n = 410
American Indian or Alaska native	7 (2)
Asian or Pacific islander	12 (3)
Black or African American	78 (19)
White	290 (71)
Other	28 (7)
Ethnicity, n (%)	n = 404
Hispanic or Latino	42 (10)
Non-Hispanic or Latino	362 (90)
Marital status, n (%)	n = 415
Married or living with partner	233 (56)
Widowed, divorced, separated, never married	182 (44)
Education level, n (%)	n = 411
Lower than high school	48 (12)
High school or equivalent (GED)	220 (54)
College graduate (2- or 4-year degree)	108 (26)
Graduate school	35 (9)
Body weight, kg	n = 408
Mean (SD)	93.0 (23.5)
Median (IQR)	88.7 (76.9, 106.6)
BMI, kg/m^2	n = 407
Mean (SD)	32.3 (7.2)
Median (IQR)	31.2 (27.2, 36.5)
Distribution by BMI categories, n (%)	n = 407
Underweight (<18.5)	3 (1)
Normal weight (18.5 to <25.0)	51 (13)
Overweight (25.0 to 30.0)	115 (28)
Obese (≥30.0)	238 (58)
Age at T2D diagnosis, mean (SD), years	n = 388
	51.3 (13.9)
Time since T2D diagnosis, n (%)[c]	n = 387
<5 years	48 (12)
5-10 years	61 (16)
>10 years	278 (72)
Last HbA1c measure before BI initiation, %	n = 45
Mean (SD)	9.4 (1.7)
Median (IQR)	9.1 (8.1, 10.7)
Time since BI initiation	
Among those who provided a date	n = 115
Mean (SD), days[d]	95 (31)
Among those who provided a date or categorical response, n (%)[e]	n = 350
< 2 months	26 (7)
2 to <3 months	72 (21)
3 to <4 months	92 (26)
≥ 4 months	125 (36)
Unknown	35 (10)
BI starting dosage, units/d[f]	n = 263
Mean (SD)	15.2 (6.8)
Median (IQR)	15.0 (10.0, 20.0)
Most recent HbA1c measure, %	n = 38
Mean (SD)	7.7 (1.3)
Median (IQR)	7.7 (6.8, 8.5)
Current BI dosage, units/d[g]	n = 352
Mean (SD)	28.5 (18.6)
Median (IQR)	23.0 (14.5, 40.0)

Abbreviations: ADA, American Diabetes Association; BI, basal insulin; BMI, body mass index; FBG, fasting blood glucose; GED, General Educational Development test; HbA1c, glycated haemoglobin; IQR, interquartile range; T2D, type 2 diabetes.

[a]Based on patient-reported birth year used to calculate age in years as of calendar year 2021.

[b]Patients could select more than one response.

[c]Calculated by subtracting the age when T2D was first diagnosed (by a healthcare professional) from the respondent's current age as of calendar year 2021.

[d]Calculated among patients who reported their BI initiation date (n = 115) by subtracting patient-reported date of BI initiation from date of survey completion (using the 15th of the month if the day of BI initiation was not known but the month was known); set to missing if both day and month of BI initiation date were not known or if BI initiation date was earlier than January 1, 2021.

[e]Patients provided a date if known, or a categorical response if the actual date was unknown. For patients with a date, a category was calculated (n = 350).

[f]BI starting dosages <5 units/d (n = 11) and > 30 units/d (n = 85) were set to missing because they were considered to fall outside reasonable expected ranges (based on the ADA recommendations for BI initiation of 10 units/d or 0.1-0.2 units/kg/d,[4] and only nine patients who had a body weight > 150 kg).

[g]Current BI dosages <5 units/d (n = 6) and > 80 units/d (n = 17) were set to missing because they were considered to fall outside reasonable expected ranges (based on the ADA recommendations to adjust BI by 10%-15% or 2-4 units once or twice weekly to achieve FBG target[4]).

(compensated with a $25 debit card). The study received ethics approval and waiver of authorization from an institutional research board (WCG IRB).

Self-reported demographic and clinical characteristics related to T2D and BI treatment were documented (Methods S2). Patients'

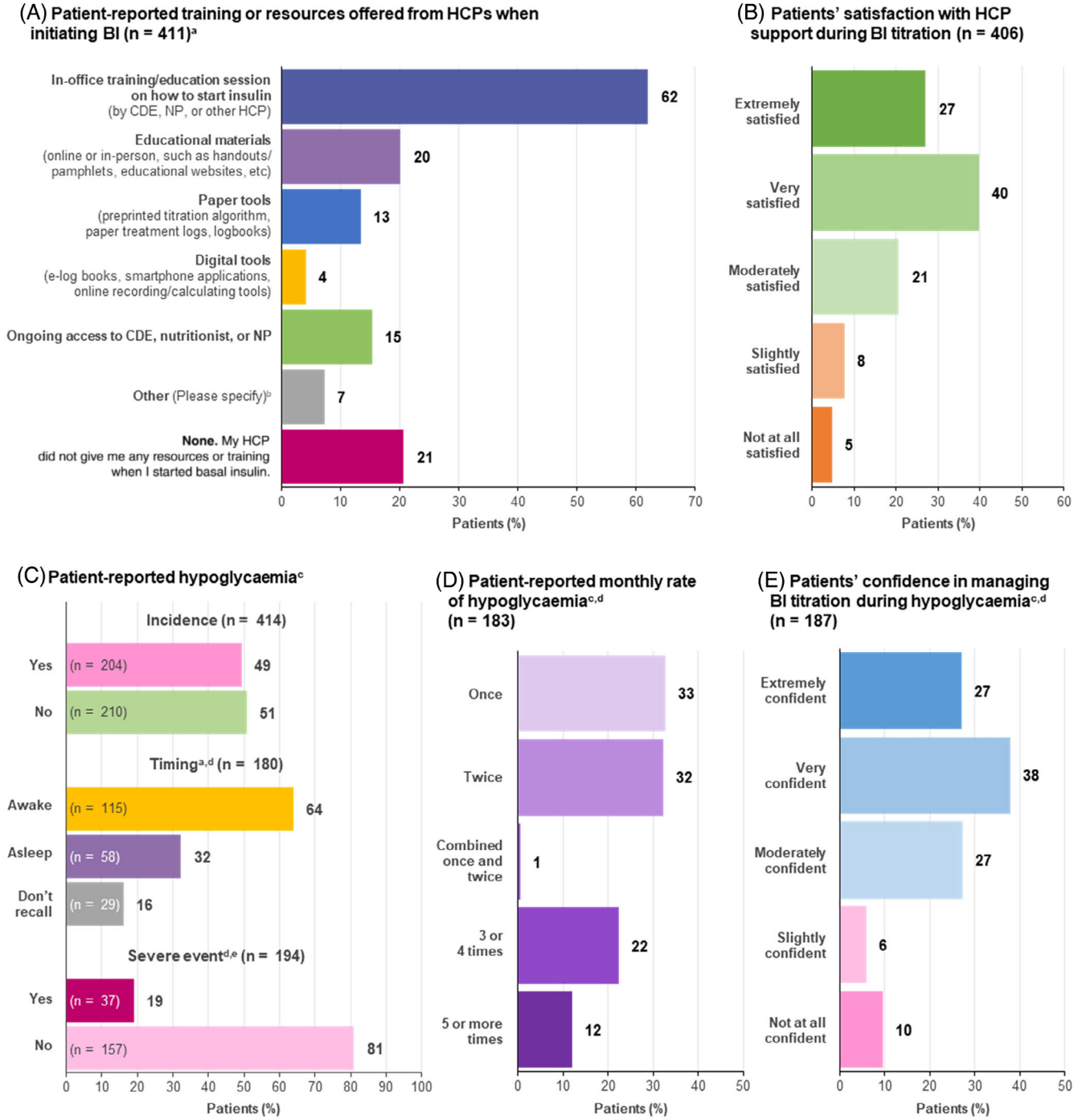

FIGURE 1 Patients' experience with basal insulin (BI) titration. [a]Patients could select more than one response. [b]Other resources included had prior experience; patient or spouse is a healthcare professional (HCP) and knows what to do; I ask how to adjust; daily log on blood sugar; help from family member; nurse at facility administers medication; pharmacist; was able to use instructions myself; telehealth appointment; at regular checkups; nutritionist. [c]Hypoglycaemia was assessed by asking: "Have you experienced low blood sugar (hypoglycaemia)? This is when your blood glucose levels have fallen low enough (usually <70 mg/dL) that you need to take action to bring them back to your target range while titrating." [d]Among patients who reported having experienced hypoglycaemia. [e]Severe hypoglycaemia was assessed by asking: "Have you experienced any severe low blood sugar (or severe hypoglycaemia) episode, that is, when you needed someone to help you manage it?". Abbreviations: CDE, certified diabetes educator; NP, nurse practitioner.

experience was assessed according to: patient-reported education received from healthcare professionals (HCPs) at BI initiation; interactions with their HCPs and satisfaction with HCP support during BI titration; diabetes self-management measures tracked (fasting blood glucose [FBG], non-FBG, BI dose, and other lifestyle measures [carbohydrate intake, caloric intake, and physical activity]), including tracking frequency and tools used; and patient-reported satisfaction with tracking tools and confidence in tracking diabetes measures accurately

(Methods S3). Patients' clinical experience was evaluated by self-reported hypoglycaemic events and BI titration status (Methods S4). All survey variables were analysed descriptively.

3 | RESULTS

From 2 408 662 patients with T2D identified, 2200 were eligible and selected for survey participation, including 1932 (88%) with Medicare Advantage and 268 (12%) commercially insured (Figure S2). Overall, 416 patients (Table 1) returned completed surveys on time (response rate 19%; 416/2200).

When they initiated BI, 74% (302/406) of respondents reported being explained BI titration by their HCPs, most often during in-office training or education sessions (62%), although 21% were not provided any resources or training (Figure 1A). During BI titration, patients interacted with various HCP types, most commonly every 2 to 3 months (Figure S3). Most patients were very or extremely satisfied with their HCP's support (Figure 1B). Almost all patients (90%; 376/416) tracked their FBG, but fewer tracked BI dosage (75%; 312/416), non-FBG (67%; 278/416), and other lifestyle measures (42%; 174/416). Among those who tracked these measures, most patients did so daily for FBG (80%; 295/367), BI (89%; 276/309), and lifestyle measures (61%; 99/162), but only 35% (96/275) tracked non-FBG daily. Across all measures tracked, most patients used paper logs, followed by other tools that were used but not captured by the survey (Figure S4). Almost half of patients were very satisfied with their tracking tools (39% to 45%) and felt very confident in their ability to use tracking tools (40% to 47%).

During BI titration, almost half (49%) of patients experienced hypoglycaemia, of whom 19% experienced severe hypoglycaemia (Figure 1C). Among those who experienced hypoglycaemia, 32% experienced it while asleep, 33% experienced it once and 32% twice a month (Figure 1D), and 38% were very confident in managing their titration/adjusting their BI dosage (Figure 1E). Among patients who reported their BI titration status, 35% (127/359) had met their FBG goal and were maintaining their BI dosage, 58% (207/359) had not met their goal and were still titrating, and 7% (25/359) had stopped using BI. Few patients reported the date of goal attainment (n = 27) or their most recent HbA1c value (n = 45) or date (n = 38).

4 | DISCUSSION

The majority of patients surveyed were offered training and resources in support of BI titration and were very to extremely satisfied with their HCP's support. Patients who tracked diabetes measures used paper logs most often and were satisfied and confident with their tracking tools, as previously reported.[5] However, approximately half of patients in this survey experienced hypoglycaemia during BI titration, including one-third during nighttime, with one-fifth being severe. Self-reports of hypoglycaemia in real-world settings are usually higher than in clinical trials and close to our findings,[6-9] with a reported range of 37% to 64%.[6] More than half of patients in this survey felt very or extremely confident managing titration/adjusting their BI dose when experiencing hypoglycaemia. While patients' confidence in T2D self-management is encouraging, the high rates of hypoglycaemia that accompany it suggest this perceived confidence may be preventing optimal titration, raising the potential need for optimized communication and titration support tools to foster efficient clinical management.

Potential limitations of this study include a low response rate, although ranges of 20% to 40% have been observed in mail surveys administered among Optum enrollees with various conditions.[10,11] A lower response rate might be expected among older adults with significant disease burden (T2D with recent BI initiation) during the COVID pandemic. Nevertheless, results may not be generalizable to non-responders, even though high response rates do not prevent a lack of non-response bias.[12] Nonetheless, missing information such as satisfaction level among non-responders is an inherent bias of satisfaction surveys. The predominantly Medicare Advantage proportion of participants may also limit the generalizability of our results to the overall T2D population. The poor glycaemic control and high hypoglycaemia observed might be explained in part by the lack of non-FBG monitoring in some patients, as well as unknown timing of BI injections or specific concomitant medications more frequently covered under Medicare (not captured in this survey). Finally, the study aimed to identify patients who recently initiated BI so that they could receive the survey within 10 to 12 weeks of initiation to limit recall bias, but this bias may still exist. The accuracy of reported BI dosages and HbA1c values cannot be confirmed, limiting interpretation.

In conclusion, although many patients with T2D initiating BI received training and support, nearly half experienced hypoglycaemia, including almost one-fifth with severe hypoglycaemia during BI titration. A discrepancy may exist in real-world clinical practice between standard HCP-offered insulin titration training and support and the inability to avoid hypoglycaemia during BI titration. These findings suggest the need for novel tools and strategies to empower patients to attain effective BI titration self-management.

AUTHOR CONTRIBUTIONS

Stewart B. Harris, Monica Bertolini, John White, Valery Walker and Fang Liz Zhou were responsible for the study concept and design. John White and Valery Walker were responsible for data acquisition and statistical analysis, and had full access to all data. All authors interpreted the data, critically revised, and approved the final version of the manuscript and take responsibility for the integrity of the data and the accuracy of the data analysis.

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CONFLICT OF INTEREST

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PEER REVIEW

The peer review history for this article is available at https://publons.com/publon/10.1111/dom.14973.

DATA AVAILABILITY STATEMENT

The data contained in our database contains proprietary elements owned by Optum, and therefore cannot be broadly disclosed or made publicly available at this time. The disclosure of this data to third-party clients assumes certain data security and privacy protocols are in place and that the third-party client has executed our standard license agreement, which includes restrictive covenants governing the use of the data.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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