ORIGINAL RESEARCH

Normoglycemia and Weight Reduction: Perspectives of People with Type 2 Diabetes in Australia

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Purpose: As more treatments become available to normalize glycated hemoglobin (HbA1c) levels and reduce weight, it is important to understand the meaningfulness of achieving target HbA1c levels and weight reduction from the perspective of people with type 2 diabetes.

Patients and Methods: This is a cross-sectional survey of 300 Australians with type 2 diabetes.

Results: Achieving target HbA1c levels was meaningful to 90.0% (n=198) and moderately/very/extremely important to 94.5% (n=208) of the 220 participants with HbA1c >6.0%. Over half of the participants were dissatisfied with their current weight (n=158, 52.7%) and underreported their body mass index category (n=160, 53.3%). For 59.0% (n=177), a mean (±standard deviation) of 17.2 (±20.6) kg of weight loss was meaningful. Of these participants, 10.7%, 30.5%, 21.5%, and 37.3% viewed 5%, 5–10%, 10%-15%, and >15% of weight reduction as meaningful, respectively.

Conclusion: According to this survey, achieving target HbA1c levels is both meaningful and important to most people with type 2 diabetes. Achieving weight reduction is also seen as important despite frequent underrating of body mass index. Therapies targeting both target HbA1c levels and weight reduction may be of interest to people with type 2 diabetes in Australia, and this could impact medication adherence and health outcomes.

Keywords: adherence, HbA1c, patient voice, body mass index

Introduction

Worldwide, there are approximately 537 million people with diabetes, and prevalence rates are increasing rapidly.¹ In Australia, 8.2% of adults aged 20–79 years were diagnosed with diabetes in 2021,¹ and based on national data from 2021, type 2 diabetes (T2D) accounted for 85.5% of all cases of diabetes.²

T2D is a chronic and complex metabolic disease characterized by insulin insufficiency and resistance.^{3,4} T2D is associated with chronic and severe complications, including elevated rates of macrovascular and microvascular diseases, which lead to increased morbidity and mortality among people with T2D (PwT2D).⁵

Moreover, 90% of PwT2D have overweight or obesity.⁶ These conditions are also independently correlated to serious chronic disorders such as dyslipidemia, hypertension, and cardio- and cerebrovascular disease, which further reduce patients' life quality and expectancy.⁷

Additionally, T2D is associated with high health costs; for example, the annual direct diabetes-related health expenditure per person in Australia in 2021 was AUD 9,400.88, the highest amount in the Western Pacific region.¹

Considering the above-mentioned factors, the American Diabetes Association (ADA) recommends opting for medicines with both high glycemic and weight efficacy in PwT2D who have overweight or obesity.⁸ Indeed, the ADA has provided robust evidence that losing weight for PwT2D, in proportion to the percentage of body weight lost, conveys

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a wide range of benefits from improving glycemia, thus potentially reducing the number and complexity of anti-diabetic therapies, to achieving diabetes remission and ameliorating the outcomes of the comorbidities previously listed.⁹

The Royal Australian College of General Practitioners in collaboration with Diabetes Australia has reiterated these recommendations by advising a weight loss of 5%-10% of the current weight in PwT2D who have overweight or obesity as well as individualized glycemic targets.¹⁰

Moreover, both diabetes societies recommend a target glycated hemoglobin (HbA1c) level of <7.0% for PwT2D.^{10,11} Despite the breadth of available treatments, management of T2D remains difficult, with nearly half of PwT2D having an HbA1c level $\geq 7.0\%^{12}$ and the associated risk of significant morbidities¹³ and premature death.¹²

Therefore, understanding the perceptions of PwT2D on normoglycemia and weight reduction as well as their unmet needs may improve medication adherence and lead to better overall health outcomes. This information may also be helpful in clinical practice for healthcare practitioners who may not always be aware of patients' perspectives. However, there is a gap in the available literature regarding the perspective of PwT2D in Australia regarding normoglycemia and weight reduction, as in the last ten years only one study was conducted in this patient population, and it was focusing only on the self-management of hypoglycemia.¹⁴

Consequently, this study aimed to fill the gap by understanding the importance of achieving normoglycemia and weight reduction from the perspective of PwT2D in Australia.

Methods

Study Design

This was a cross-sectional, non-interventional, web-based survey, programmed and hosted by a third-party recruitment vendor, which sent an Email invitation to subjects who had previously opted to be contacted for future research and who had self-reported having T2D. If interested, invitees were screened to confirm eligibility, as listed in the successive section, and if they were eligible, participants provided informed consent before proceeding to the main study questionnaire.

All the sections of the web-based survey study were programmed to ensure only valid responses were provided and to prevent the participant from moving on to the next question before completing the previous item.

Participants were fully informed through a research participation privacy notice before they were included in the study. This study was conducted in accordance with the Declaration of Helsinki, the Good Pharmacoepidemiology Practices, and applicable laws and regulations of Australia. The Bellberry Human Research Ethics Committee (Bellberry) has reviewed and approved this study in accordance with the National Statement on Ethical Conduct in Human Research (2007).

The web-based survey study was launched on December 2, 2022, and completed by December 14, 2022.

Study Population

PwT2D were recruited from the Australian general population using qualified and validated patient panels. Panelists provided demographic and clinical information to the panel provider upon registration and consented to be contacted for research. The following inclusion criteria were applied:

- Age ≥ 18 years
- Australian residency
- T2D for at least 3 months, diagnosed by a medical professional (self-report checked by study screener)
- Use of at least one glucose-lowering therapy (oral/tablet/injection)
- Ability to self-report their last HbA1c level that was recorded in the past 12 months
- Ability to read, understand, and speak English at the level needed to complete a web-based survey with no assistance.

Participants were excluded if they had gestational diabetes, were pregnant, had type 1 diabetes, or were currently using basal insulin. We also included soft quotas to promote the diversity and inclusion of our sample. We aimed to have at

least 50% of the population with overweight/obesity, approximately 20% who live in rural settings, and approximately 20% to be non-Caucasian.

Variables

The variables collected in the web-based survey study included data on sociodemographics, overall health and general T2D, perception of HbA1c, and perception of weight.

Statistical methods

Analyses were all descriptive and noncomparative in nature, and therefore sample size and power calculations were not applicable. Nonetheless, the expected sample size of 125-300 participants was estimated to allow reasonable precision for the categorical outcomes of this study. Descriptive summary statistics included the number (n) of patients, mean, and standard deviation (SD) for continuous variables, and percentages [n (%)] for categorical variables.

The analysis was conducted in participants who met the eligibility criteria and completed the web-based survey. Participants who did not meet the eligibility criteria or who terminated the survey before completing it were excluded from the study. Analyses were conducted using SAS Software version 9.4 (SAS Institute, Cary, North Carolina, USA).

Results

A total of 1013 subjects responded to the invitation to participate, and 300 participants qualified and were included in the study. Most individuals were excluded from the study for screen failure (n=499, 49.3%), with the primary reasons being no T2D (n=174, 17.2%), no "exercise or diabetic medications" or "oral/tablets or non-insulin injection" to control diabetes (n=123, 12.1%), and no recent HbA1c level (n=105, 10.4%). Other reasons for exclusion from the study were partial completion (n=119, 11.7%), reluctance to participate (n=62, 6.1%), and exceeding the 300-participant recruitment target (n=33, 3.3%), as per protocol.

Participants' Sociodemographic and Disease Characteristics

The mean (SD) age of the sample was 55.7 (15.60) years, and most participants were male (n=190, 63.3%), Caucasian (n=251, 83.7%), and from a major city or suburban area (n=248, 82.7%; Table 1). This was relatively aligned to the soft targets of 20% for the non-Caucasian (n=49, 16.3%) and rural or country area (n=52, 17.3%) population.

The mean (SD) body mass index (BMI) at baseline was 30.9 (11.87) kg/m², with 213 (71.0%) having BMI \geq 25 kg/m²; this met the soft quota of \geq 50% with BMI \geq 25.0 kg/m². Most participants had HbA1c \geq 7.0% (n=126, 42.0%) or \geq 6.0% to <7.0% (n=113, 37.7%). Most participants (n=254, 84.7%) had been diagnosed with T2D more than 1 year before study enrollment, with 133 (44.3%) reported being diagnosed >5 years before study enrollment.

The distribution of participants across states was proportional to the state population, with an expectedly larger proportion based in New South Wales (n=87, 29.0%), Queensland (n=74, 24.7%), and Victoria (n=68, 22.7%).

Diabetes Health and Methods for Evaluating T2D Treatment Success

Most of the participants were primarily treated for diabetes by a general practitioner (n=195, 65.0%), and most saw their primary healthcare provider once every 2–3 months (n=137, 45.7%) or one or more times per month (n=76, 25.3%).

Over two-thirds (n=210, 70.0%) of the participants reported experiencing at least one T2D-related complication, with high blood pressure (n=146, 48.7%), neuropathy (n=73, 24.3%), and eye (n=64, 21.3%), foot (n=64, 21.3%), and skin (n=54, 18.0%) complications being the most prevalent. Less severe complications (eg, gum disease, slower healing) were reported by 66 (22.0%) and diabetic ketoacidosis by 31 (10.3%) participants (Table S1).

When participants were asked about ways in which T2D treatment success is evaluated, the most endorsed methods were lower HbA1c levels (n=178, 59.3%), comments from doctors (n=173, 57.7%), lower blood glucose levels (n=166, 55.3%), and general feeling of well-being (n=157, 52.3%; <u>Table S2</u>).

	Participants (N=300)
Age (years), mean (±SD)	55.7 (±15.6)
Gender	
Male	190 (63.3)
Female	109 (36.3)
Other	I (0.3)
Caucasian	
Yes	251 (83.7)
No	49 (16.3)
Way to control diabetes ^{a,b}	
Diabetic oral/tablet medication	289 (96.3)
Diet and exercise	221 (73.7)
Bolus insulin injection (typically multiple times a day)	65 (21.7)
Non-insulin injection	47 (15.7)
Other	3 (1.0)
Time since diabetes diagnosis	
<i td="" year<=""><td>46 (15.3)</td></i>	46 (15.3)
≥l year	254 (84.7)
Recent HbAIc level (%)	
<7.0	174 (58.0)
≥7.0	126 (42.0)
Body mass index (kg/m²) ^c	
<25	87 (29.0)
≥25 to <30	89 (29.7)
≥30 to <35	58 (19.3)
≥35 to <40	31 (10.3)
≥40	35 (11.7)
State	
New South Wales	87 (29.0)
Queensland	74 (24.7)
Victoria	68 (22.7)
South Australia	31 (10.3)
Western Australia	27 (9.0)
Tasmania	7 (2.3)
Australian Capital Territory	5 (1.7)
Northern Territory	I (0.3)
Geographic area	
Major city or suburb (≤60 km from a major city)	248 (82.7)
Rural or country (>60 km from a major city)	52 (17.3)

 Table I Sociodemographic and Disease Characteristics of the Participants

Notes: ^aPercentages may add up to more than 100%, as patients may be counted in more than one category. ^bThe number of patients presented for "Oral/tablets and" as well as "Non-insulin injection and" include all patients receiving the respective category regardless of whether is it taken as a monotherapy or combination therapy. ^cParticipants were asked to report height and weight, then investigators would use the data to calculate the BMI.

Abbreviations: BMI, body mass index; HbA1ctable, glycated hemoglobin; kg, kilograms; m, meters; N, total number of participants; n, number of participants; SD, standard deviation.



Figure I Participants' perception of the meaningfulness (a) and importance (b) of safely lowering their HbA1c level to near normoglycemia. The figure is property of the authors.

Abbreviation: HbAIc, glycated hemoglobin.

Perceptions of HbAIc

As illustrated in Figure 1, participants with HbA1c >6% (n=220) were asked 2 questions about whether safely achieving near normoglycemia would be meaningful and important. Their responses were stratified according to their HbA1c level: 6.0% <HbA1c <7.0%, HbA1c ≥7.0%, and overall. At least 86.2% in all categories indicated that achieving near normoglycemia was meaningful, and for 94.5% (n=208) of the participants, achieving near normoglycemia was moderately, very, or extremely important. For 48.4% and 37.3% of those with HbA1c ≥7.0% safely lowering their HbA1c level to near normoglycemia was very and extremely important, respectively.

Most participants noted that the doctor said that their HbA1c level was good or well-controlled (n=152, 50.7%), while 135 (45.0%) reported that their doctor said that their level was not where it should be. Overall, 129 (43.0%) reported no change to HbA1c from the previous level, while 93 (31.0%) and 74 (24.7%) noted an increase and decrease in HbA1c levels, respectively. Of the participants, 164 (54.7%) were somewhat or very satisfied with their most recent HbA1c level. Regardless, 202 (67.3%) noted that they wanted to reduce their HbA1c level, with a mean (\pm SD) goal of HbA1c = 5.8% (\pm 0.79).

Perceptions of Weight

Most participants were somewhat or very dissatisfied with their weight (n=158, 52.7%) and characterized their weight as overweight or obese (n=176, 58.7%). For 177 (59.0%) participants, reducing weight was meaningful; for 54 (30.5%) and 66 (37.3%) of these participants, meaningful weight reduction equaled \geq 5.0% to <10.0% and \geq 15% of their current weight, respectively. Moreover, for 72 (40.7%) and 52 (29.4%) of those participants, lowering their weight was very and extremely important, respectively (Table 2).

When gauging perception of weight compared to actual BMI—calculated from self-reported weight and height—there was a great extent of underreporting of weight categorization, particularly for the participants with obesity class III (<u>Table S3</u>).

Perception of Weight Items, n (%) if not Otherwise Specified	Participants (N=300)
Self-reported BMI category ^a	
Underweight	43 (14.3)
Normal	81 (27.0)
Overweight	126 (42.0)
Obesity	37 (12.3)
Severe obesity	13 (4.3)
Concerned about the impact of current weight on health	
An extreme amount	42 (14.0)
A lot	90 (30.0)
Somewhat	77 (25.7)
A little	62 (20.7)
Not at all	29 (9.7)
Satisfaction with current weight	
Very satisfied	27 (9.0)
Somewhat satisfied	78 (26.0)
Neither satisfied nor dissatisfied	37 (12.3)
Somewhat dissatisfied	99 (33.0)
Very dissatisfied	59 (19.7)
Is weight reduction meaningful?	
No	85 (28.3)
Not sure	38 (12.7)
Yes	177 (59.0)
Weight reduction is meaningful	Participants (N=177)
Meaningful weight reduction (kg)	
Mean (±SD)	17.2 (±20.6)
Meaningful weight reduction (% of current weight)	
<5.0	19 (10.7)
≥5.0 to <10.0	54 (30.5)
≥10.0 to <15.0	38 (21.5)
≥15.0	66 (37.3)
Importance of lowering weight by noted amount	
Not at all important	I (0.6)
	9 (5.1)
Slightly important	
Signtly important Moderately important	43 (24.3)
	43 (24.3) 72 (40.7)

Table 2 Participants' Perceptions of Their Weight

Notes: ^aParticipants were asked to report their BMI category without interference of the investigators.

Abbreviations: BMI, body mass index; N, total number of participants; n, number of participants, SD, standard deviation.

Discussion

To the best of our knowledge, this is the first study in Australia to elicit the perceptions of PwT2D on achieving near normoglycemia and weight reduction, a relatively new concept for this population.

This study showed that despite current treatment options, 42.0% of participants had an HbA1c value above target ($\geq 7.0\%$); for 92.9% of them, achieving near normoglycemia was meaningful, while for 96.0% of them, it was moderately,

very, or extremely important. More than half of the participants identified lower HbA1c levels as the primary method to evaluate diabetes management success.

These results are aligned with those of other publications,^{15,16} even if they were not conducted in Australia, which showed that PwT2D are conscious of the meaningfulness and importance of achieving normoglycemia, and more importantly, that prolonged suboptimal glycemic level may lead PwT2D to non-adherence and alternative medications, thus leading to worse health outcomes.¹⁶

Weight reduction was also reported as meaningful for 177 (59.0%) participants; for 72 (40.7%) and 52 (29.4%) of these participants, lowering their weight was very and extremely important, respectively. Notably, weight reduction was considered meaningful for most participants despite the underreporting of their BMI compared to their actual BMI.

These findings indicate that PwT2D in Australia may be open to treatments targeting both normoglycemia and weight loss, which would match the recommendations provided by the diabetes guidelines,^{8,10} and which would convey several benefits to the outcomes of not only T2D and overweight or obesity, but also of the other comorbidities such as cardiovascular, lipid, and sleep disturbs.⁹ Moreover, targeting both T2D and overweight or obesity simultaneously would bring an enhanced benefit given the interrelationship between these diseases. Indeed, obesity is a key contributor to diabetes onset and progression, by aggravating hyperglycemia, microvascular and macrovascular complications. Furthermore, both the pathophysiological nature of diabetes and several of its first-line treatments, such as insulin, can worsen the damages caused by obesity, thus further complicating the clinical conditions of PwT2D with overweight or obesity.⁹ Consequently, ameliorating the outcomes of one condition would positively reflect on the other, and therefore, providing PwT2D in Australia with more effective treatment options may help with patient adherence and overall better health outcomes.

The authors acknowledge some limitations. First, data from this study were self-reported and relied on participants' knowledge and recollection regarding medical care. Second, participants in this study were not a true random sample of all eligible patients, as they were younger, had lower HbA1c, were diagnosed more recently, and by design did not take basal insulin as compared to the T2D sample in the Australian National Diabetes Audit-Australian Quality Clinical Audit 2021 results,¹⁷ which may limit the generalizability of the results to all PwT2D in Australia. However, soft quotas were applied for race and geographic locations to promote the diversity of the sample. Third, all questions were close-ended, and no additional data were collected regarding participants' perspectives, which may limit qualitative assessments of perspectives. Nevertheless, the data collection tool was informed from both literature and expert opinion, and therefore, data capture is robust.

Conclusions

According to this survey, achieving target HbA1c levels was both meaningful and important to most PwT2D. Achieving weight reduction is also seen as important despite frequent underrating of BMI. This study showed that many PwT2D in Australia are underrating their BMI levels, thus indicating that patient education is required. Moreover, these findings show that therapies targeting both optimal HbA1c levels and weight reduction may be of interest to PwT2D, and this could impact medication adherence and health outcomes.

Abbreviations

BMI, body mass index; HbA1c, glycated hemoglobin; PwT2D, people with T2D; SD, standard deviation; T2D, type 2 diabetes.

Data Sharing Statement

All information about this observational study and individual participant medical information resulting from this study are considered confidential, and disclosure to third parties is prohibited except for regulatory authorities and as applicable by law.

Compliance with Ethics Guidelines

This study was conducted in accordance with the Declaration of Helsinki, the Good Pharmacoepidemiology Practices, and applicable laws and regulations of Australia. The Bellberry Human Research Ethics Committee (Bellberry) has reviewed and approved this study in accordance with the National Statement on Ethical Conduct in Human Research (2007).

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Author Contributions

All named authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this article, take responsibility for the integrity of the work, and have given their approval for this version to be published.

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

Rachel S Newson is an employee and minor shareholder in Eli Lilly and Company. Helen Barraclough is an employee and minor shareholder in Eli Lilly and Company. Jennifer Lapthorn received consulting fees as a Fortrea employee, which was contracted by Eli Lilly and Company to conduct the study. Martin Stewart received consulting fees as a Fortrea employee, which was contracted by Eli Lilly and Company to conduct the study. Sam Colman received consulting fees as a Fortrea employee, which was contracted by Eli Lilly and Company to conduct the study. Sam Colman received consulting fees as a Fortrea employee, which was contracted by Eli Lilly and Company to conduct the study. Michael D'Emden received honoraria for presentations at medical meetings from Eli Lilly and Company, Boehringer Ingelheim, and Novo Nordisk; received support to attend medical meetings from Eli Lilly and Company; received support from Boehringer Ingelheim, Novo Nordisk, Astra Zeneca, and Pfizer; and has been a member of an Advisory Board for Eli Lilly and Company. The authors report no other conflicts of interest in this work.

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