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Hypoglycaemia Was Not Associated With Depression, Anxiety, Diabetes Distress or Fear of Hypoglycaemia Scores in People With Type 1 or Insulin-Treated Type 2 Diabetes in the Hypo-METRICS Study

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1 | Background

Hypoglycaemia is a common complication of insulin therapy. The relationship between hypoglycaemia and mood is not well understood, with conflicting evidence reported in the literature [1, 2]. Potential explanations for these conflicting data include the variation in hypoglycaemia definitions and thresholds. The strongest associations between hypoglycaemia and mental health appear to relate to severe hypoglycaemia (SH) [3], with impaired awareness of hypoglycaemia (IAH) being a major risk factor [4]. Using the dataset with which we previously demonstrated an association between IAH and a mental health burden

[5], this study provides an opportunity to explore whether this link operates through increased exposure to hypoglycaemia, using different common definitions of hypoglycaemia.

2 | Methods

Hypo-METRICS was a prospective, multi-country observational study of the hypoglycaemia experience. Adults with type 1 diabetes (T1D) or insulin-treated type 2 diabetes (T2D) were eligible for inclusion. Participants wore blinded study continuous glucose monitors (CGMs), continued with their usual method of glucose monitoring (CGM or capillary blood glucose [CBG]) and completed ecological momentary assessment (EMA) through a bespoke app for 10 weeks in real-time [6]. Participants completed patient-reported outcome measures (PROMs) at the beginning and end of the study to assess for depression (PHQ-9), anxiety (GAD-7), diabetes distress (PAID) and fear of hypoglycaemia (HFS-II [worry]) (Table S1). Hypoglycaemia was defined as time below range (TBR) < 3.9 mmol/L and TBR < 3 mmol/L, rate of sensor-detected hypoglycaemia (SDH) < 3.9 mmol/L and < 3 mmol/L and rate of person-reported hypoglycaemia (PRH). SDH was defined as glucose below the threshold for > 15 min, resolving after > 15 min above the threshold [7]. PRH was subdivided as symptomatic (resolved by carbohydrate ingestion), technology-detected (glucose ≤ 3.9 mmol/L on routine monitoring) and total PRH (combined symptomatic and technology-detected episodes) [6].

In this post hoc exploratory analysis, Chi-square, Fisher's exact and Mann–Whitney *U* tests were used to assess for differences in baseline characteristics and PROMs. Unadjusted and adjusted linear regression analyses with the Benjamini–Hochberg procedure were used to examine whether hypoglycaemia was associated with mental health scores after 10 weeks. Age, sex, ethnicity, diabetes duration, education, employment, CGM use and hypoglycaemia awareness status were variables in the adjusted analysis.

3 | Results

In total, 232 participants with T1D and 310 with insulin-treated T2D consented for inclusion in post hoc analyses. The baseline characteristics and prospectively-measured hypoglycaemia metrics are presented in Table 1. There were subtle but statistically significant differences in PROMs from week 0 to 10 (Table S2). There were no significant associations between any hypoglycaemia metric (TBR < 3.9 mmol/L, TBR < 3 mmol/L, SDH < 3.9 mmol/L, SDH < 3 mmol/L, symptomatic PRH, technology-detected PRH, total PRH) and any mental health score (PHQ-9, GAD-7, PAID, HFS-II [worry]) after 10 weeks in T1D or insulin-treated T2D in the linear regression analyses (all $p > 0.05$) (Figure 1; Tables S3 and S4).

4 | Conclusions

In summary, we report no evidence of a significant association between the experience of SDH and PRH documented prospectively over 10 weeks and depression, anxiety, diabetes distress and fear of hypoglycaemia scores at study end in Hypo-METRICS participants with T1D or insulin-treated T2D.

Firstly, these data suggest that it may not be the biological low glucose readings that drive the mental health burden. The psychological impact of hypoglycaemia may depend more on experience rather than frequency. Symptomatic hypoglycaemia, particularly when distressing, may have a greater impact on mental health than asymptomatic or technology-detected events. Individuals most impacted by hypoglycaemia can develop avoidant behaviours to minimise its occurrence [8], which may explain why we don't see a relationship between hypoglycaemia and poorer mental health. People living with diabetes who are less psychologically affected by hypoglycaemia may tolerate a greater number of events; consequently, in real-world settings, insulin is often titrated to the level of hypoglycaemia individuals are willing or able to tolerate.

Secondly, the lack of evidence of an association between hypoglycaemia and mental health scores may reflect prior, rather than current, hypoglycaemic exposure. Individuals with poorer mental health may have previously experienced substantial hypoglycaemia but subsequently undergone treatment optimisation, such as access to CGM. While these interventions may reduce current hypoglycaemia frequency, the psychological impact of prior hypoglycaemia may persist, thereby weakening any observable relationship between current hypoglycaemia metrics and mental health. This interpretation aligns with our previous work, in which we suggest that the neurobiological state of IAH may be a key determinant of psychological well-being [5], and also aligns with findings from the HARPdoc programme, which showed that a hypoglycaemia-focused psychoeducational intervention improved anxiety and depression in people with recurrent SH and IAH more than standard education, despite similar reductions in SH [9].

Thirdly, rates of SH captured both retrospectively and prospectively were low in our study cohort, although similar to those observed in the general diabetes population [10]. As the strongest associations between hypoglycaemia and mental health relate to SH, this may have limited our ability to detect such relationships. While the risk of SH is unevenly distributed, with 10% of individuals experiencing 70% of episodes [11], studies demonstrating associations between SH and poorer mental health are often conducted in populations selected based on their history of SH [12]. As our study population was relatively psychologically healthy with low rates of SH, this may enhance generalisability by reflecting a more typical diabetes population compared with other studies.

Fourthly, it is important to consider this work in the context of previous publications from the Hypo-RESOLVE consortium, which demonstrated that a single PRH event can lead to transient reductions in mood using EMA data [2]. Our findings extend this by showing that cumulative hypoglycaemia exposure was not associated with overall mental health using standardised, validated questionnaires, consistent with our previous analysis demonstrating that achieving consensus guideline targets for TBR was not associated with mental health scores at study end [13]. This may reflect limitations of CGM-derived metrics and conventional PROMs used in clinical medicine and research to assess

TABLE 1 | Baseline characteristics and glycaemic metrics captured prospectively over 10 weeks in individuals with type 1 or insulin-treated type 2 diabetes in the Hypo-METRICS study.

Baseline characteristic	T1D ($n=232$)	Insulin-treated T2D ($n=310$)	p
Age (years)	49 (30–58)	63 (55–69)	<0.001
Duration of diabetes (years)	20 (10–35)	19 (13–25)	0.243
Ethnicity, *n* (%)			0.053
White	223 (96)	284 (91.6)	
Other[a]	9 (4)	26 (8.4)	
Sex, *n* (%)			<0.001
Women	123 (53)	116 (37.4)	
Men	108 (46.5)	194 (62.6)	
Employment, *n* (%)			<0.001
Retired	44 (19)	159 (51.4)	
Employed	158 (68)	111 (35.8)	
Unemployed	16 (7)	35 (11.2)	
Full-time education	14 (6)	5 (1.6)	
Highest level of education achieved, *n* (%)			<0.001
Primary school	4 (1.7)	36 (11.6)	
Secondary school	58 (25)	99 (32)	
College/undergraduate degree	99 (42.7)	107 (34.5)	
Postgraduate degree: Masters/PhD/MBA	58 (25)	36 (11.6)	
Other	13 (5.6)	32 (10.3)	
Glucose monitoring, *n* (%)			<0.001
CBG monitoring	61 (26)	183 (59)	
Flash/CGM	171 (74)	127 (41)	
HbA1c (mmol/mol)	56 (50–62)	58 (51–67)	0.005
Gold score	2 (1–3)	2 (1–4)	0.445
Severe hypoglycaemia in the past year[b], *n* (%)			0.90
No	226 (97.4)	302 (97.4)	
Yes	6 (2.6)	8 (2.6)	
PHQ-9 score	3 (1–6)	4 (2–9)	0.005
GAD-7 score	3 (1–6)	3 (1–7)	0.431
PAID score	18 (8–33)	20 (9–37)	0.327
HFS-II (worry) score	12 (5–22)	9 (3–19)	0.029
Hypoglycaemia and other glycaemic metrics recorded prospectively over 10 weeks			
Total PRH per week	3.9 (2.3–5.9)	1.1 (0.5–2)	<0.001
Symptomatic PRH per week	2.9 (1.6–4.6)	0.8 (0.3–1.5)	<0.001
Rate of SDH 3.9 mmol/L per week	6.5 (3.8–10.3)	2 (0.8–3.8)	<0.001
Rate of SDH 3.0 mmol/L per week	1.1 (0.4–2.4)	0.2 (0–0.5)	<0.001
Time in range (3.9–10 mmol/L)	60.5 (51.5–71.8)	66.6 (52.2–80.4)	0.003

(Continues)

TABLE 1 | (Continued)

Baseline characteristic	T1D ($n = 232$)	Insulin-treated T2D ($n = 310$)	p
Time in level 1 hypoglycaemia (< 3.9 mmol/L)	4.3 (2.4–7.8)	1.3 (0.5–3.2)	< 0.001
Time in level 2 hypoglycaemia (< 3 mmol/L)	0.5 (0.02–1.3)	0.1 (0–0.3)	< 0.001
Time in level 1 hyperglycaemia (> 10 mmol/L)	31.5 (19.5–44.6)	29.9 (15.5–46.5)	0.397
Severe hypoglycaemia, *n* (%)			0.86
0	224 (96.6)	298 (96.1)	
≥ 1	8 (3.4)	12 (3.9)	

Note: Data is presented as medians (IQR) or *n* (%) as appropriate. In the study cohort with T1D, there were three participants who were missing HbA1c data, and one participant did not identify as male or female. In the study cohort with insulin-treated T2D, there was one participant missing HbA1c data, and one participant missing baseline HFS II (worry) data. Chi-square, Fisher's exact and Mann–Whitney *U* tests were used to assess for differences in baseline characteristics between participants with T1D and insulin-treated T2D.

[a]'Other' included individuals of Asian and Black ethnicities and mixed ethnic backgrounds.

[b]Severe hypoglycaemia is defined as cognitive impairment requiring external assistance for recovery [3].

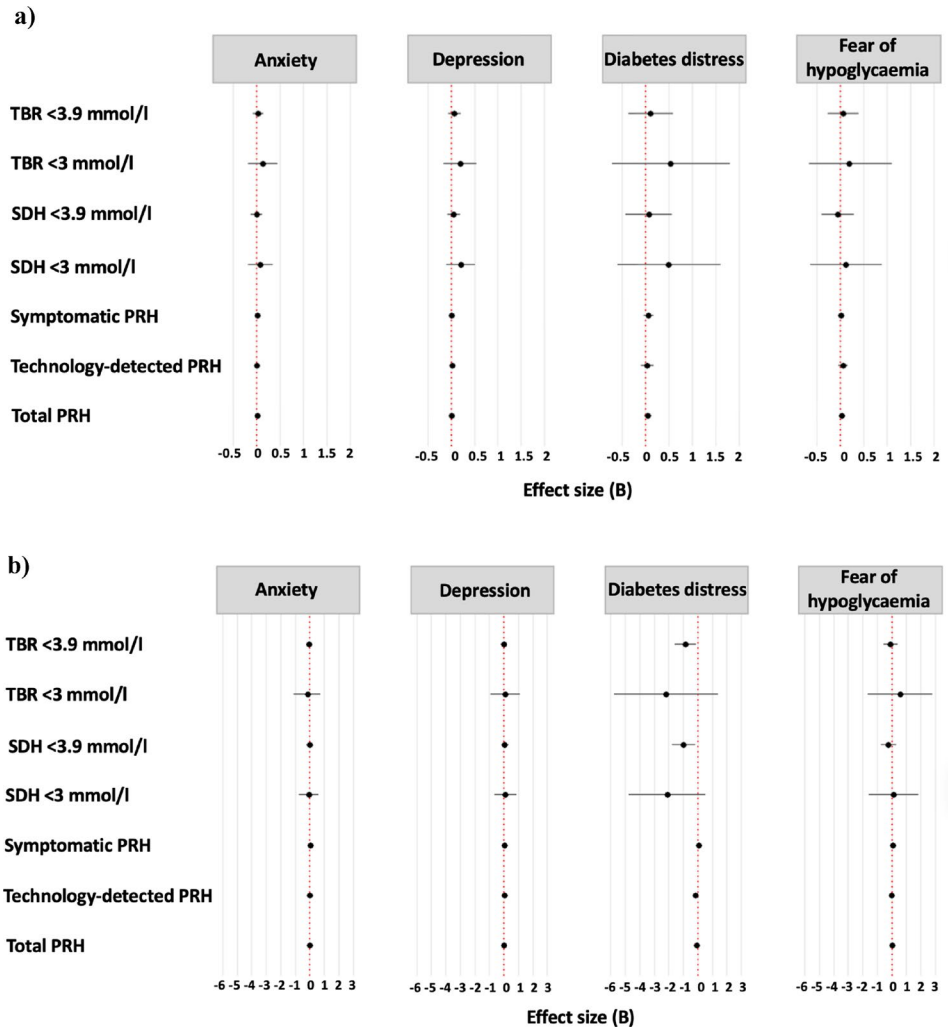

FIGURE 1 | Forest plots of the linear regression analyses, investigating the associations between sensor-detected (SDH, TBR) and person-reported (PRH) hypoglycaemia and depression, anxiety, diabetes distress and fear of hypoglycaemia scores after 10 weeks in individuals with type 1 (a) or insulin-treated type 2 diabetes (b) in the Hypo-METRICS study, with adjustment for age, sex, ethnicity, diabetes duration, level of education, employment status, CGM use and hypoglycaemia awareness status.

hypoglycaemia and mental health, which may be insufficiently sensitive to capture the dynamic and hypoglycaemia-specific psychological effects occurring in this population [14]. Standardised questionnaires assess experiences over longer periods and may therefore fail to capture the real-time impact of individual hypoglycaemic episodes and are prone to recall bias [14]. As such, these

tools may lack the granularity required for assessing the dynamic relationship between hypoglycaemia and mental health. In contrast, qualitative research consistently highlights hypoglycaemia, particularly symptomatic episodes, as a meaningful mental health burden [15]. Together, these findings suggest that EMA approaches may provide greater sensitivity for detecting the immediate effects of PRH than conventional CGM metrics and standardised questionnaires [2].

The strengths of this analysis include that it was based on a multinational study capturing over 100 years of lived patient experience. The use of blinded CGM and the Hypo-METRICS app allowed the evaluation of multiple objective and subjective measurements of hypoglycaemia. The limitations of this work include that it is a post hoc analysis, and the findings presented should be considered exploratory. The relatively short study duration may have limited sensitivity to detect changes or longer-term effects on mental health outcomes. The mental health scores were only measured at baseline and study end, which may limit sensitivity to temporal changes. The relatively low severity and frequency of SH in our cohort may also be insufficient to produce sustained changes in mental health.

In conclusion, none of the hypoglycaemia metrics assessed were associated with mental health scores after 10 weeks in Hypo-METRICS participants with T1D or insulin-treated T2D. Standardised mental health questionnaires may function like HbA1c, capturing cumulative burden over time, whereas EMA may be more akin to CBG, capturing real-time effects. As such, reliance on infrequent, questionnaire-based assessments may lack sensitivity to detect the nuanced and transient impact of hypoglycaemia on mental health.

Author Contributions

All authors made substantial contributions to the conception and design of this manuscript. A.M., P.C., P.D., F.P. and U.S. developed the plan for this manuscript with input and advice from the remaining co-authors. S.A.A., P.C., U.P.-B. and N.Z. advised on the analysis plan, and A.M. conducted all analyses. A.M. prepared the first manuscript draft, with critical feedback from S.A.A., P.C., P.D., M.E., B.E.d.G., S.H., J.K.M., R.M., E.R. and A.A.V. A.M. prepared subsequent revisions with feedback from all authors. All authors approved the final draft of the manuscript. A.M. is the guarantor of this work and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Conflicts of Interest

S.A.A. has received consultation fees from NIH (CLEAR study); served as an advisory board member for Novo Nordisk and Medtronic; spoken at educational events sponsored by Novo Nordisk and Sanofi. P.C. has received personal fees from Abbott Diabetes Care, Insulet, Dexcom, Novo Nordisk, AstraZeneca, Medtronic, Roche Diabetes Care and Sanofi Diabetes; research funding support from Abbott Diabetes Care, Medtronic and Novo Nordisk. P.D. reports consulting fees from Dexcom, honoraria from Novo Nordisk and Grunenthal and travel support from Novo Nordisk. M.L.E. has received institutional payments for clinical trial work from Abbott Diabetes Care, Novo Nordisk, ITB Medical and Lexicon; research funding from Novo Nordisk; personal speaker fees from Abbott Diabetes Care, Novo Nordisk and Eli Lilly; serves on the advisory board roles with Pila Pharma, Zucara, vTv Therapeutics, Medtronic, Sanofi and Vertex. B.E.d.G. is a member of the Data Safety Monitoring Board for the DARE study. S.H. reports EU HypoRESOLVE MMI support (institution); research funding from Dexcom (institution); honoraria from Medtronic and Novo Nordisk (institution); advisory board participation for Eli Lilly (institution). R.M. has served on advisory boards and received research support from Sanofi and Novo Nordisk. J.K.M. is an advisory board member for Abbott Diabetes Care, Becton-Dickinson/embecta, Biomea Fusion, Boehringer Ingelheim, Eli Lilly, Medtronic, Novo Nordisk, Roche Diabetes Care, Pharmasens, Prediktor SA, Sanofi, Viatris; received speaker honoraria from Abbott Diabetes Care, AstraZeneca, Becton-Dickinson/embecta, Eli Lilly, Dexcom, Medtronic, Medtrust, Menarini, Novo Nordisk, Roche Diabetes Care, Sanofi, Servier, Viatris, Ypsomed; shareholder of decide Clinical Software GmbH and Elyte Diagnostics GmbH. F.P. has received funding for research from Novo Nordisk, Eli Lilly and Sanofi-Aventis Deutschland GmbH. U.P.-B. received honoraria for lectures from Abbott, Novo Nordisk and Tandem, and provided expert testimony for Novo Nordisk. E.R. has served as consultant/advisor for Abbott, Air Liquide SI, AstraZeneca, Boehringer-Ingelheim, Dexcom, Eli Lilly, Hillo, Insulet, Medirio, Novo Nordisk, Roche, Sanofi-Aventis Deutschland GmbH and Tandem; received research support from Dexcom, Insulet and Tandem. U.S. is a former employee of Novo Nordisk, Denmark. The other authors declare that there are no relationships or activities that might bias, or be perceived to bias, their work.

Data Availability Statement

Data are accessible by application to the Hypo-RESOLVE data access committee (Pratik Choudhary [pratik.choudhary@leicester.ac.uk] or Bastiaan de Galen [bastiaan.degalan@radboudumc.nl]).

Peer Review

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Supporting Information

Additional supporting information can be found online in the Supporting Information section. **Table S1:** Mental health scoring tools and ecological momentary assessment. **Table S2:** Mental health scores at the beginning (visit 1) and end (visit 5) of the study in Hypo-METRICS participants with type 1 or insulin-treated type 2 diabetes. **Table S3:** Linear regression analyses with the Benjamini–Hochberg procedure assessing associations between hypoglycaemia and mental health scores in individuals with type 1 diabetes in the Hypo-METRICS study. **Table S4:** Linear regression analyses with the Benjamini–Hochberg procedure assessing associations between hypoglycaemia and mental health scores in individuals with insulin-treated type 2 diabetes in the Hypo-METRICS study.