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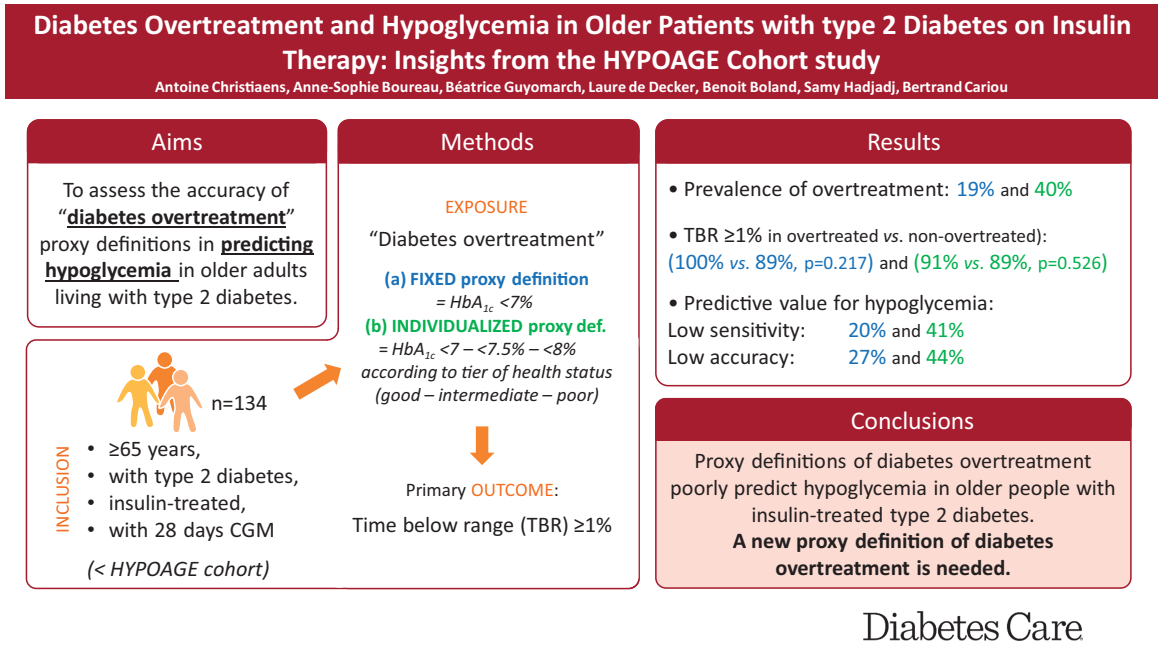

ARTICLE HIGHLIGHTS

- **Why did we undertake this study?**
  Diabetes overtreatment is a common condition in older people living with type 2 diabetes, tending to reflect the use of an overly intensive glucose-lowering treatment. However, the association between diabetes overtreatment and hypoglycemia has never been studied.
- **What is the specific question we wanted to answer?**
  We aimed at comparing the incidence of hypoglycemia in participants with or without diabetes overtreatment and investigating the predictive value of diabetes overtreatment for detecting hypoglycemia.
- **What did we find?**
  We find no association between diabetes overtreatment proxy definitions and hypoglycemia, with current proxy definitions showing low sensitivity and accuracy in predicting hypoglycemia.
- **What are the implications of our findings?**
  Current definitions of diabetes overtreatment are insufficient for managing hypoglycemia risk in older insulin-treated patients, necessitating the development of a new definition.

Diabetes Overtreatment and Hypoglycemia in Older Patients With Type 2 Diabetes on Insulin Therapy: Insights From the HYPOAGE Cohort Study

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OBJECTIVE

To assess the accuracy of "diabetes overtreatment" proxy definitions in predicting hypoglycemia in older adults with type 2 diabetes (T2D).

RESEARCH DESIGN AND METHODS

Inclusion of patients from HYPOAGE cohort with insulin-treated T2D, aged ≥75 years, and using a continuous glycemic monitoring (CGM) device for 28 days. "Diabetes overtreatment" was defined as HbA_{1c} <7.0% (fixed proxy definition) or as HbA_{1c} <7.0%, 7.5%, and 8.0% according to patient's health status (individualized proxy definition). The primary outcome was time below range (TBR) ≧1%.

RESULTS

Of the 134 patients included (81.6 ± 5.4 years, 59% male), 25 (19%) and 53 (40%) were overtreated, based on fixed and individualized proxy definitions, respectively. CGM data showed TBR >1% in nearly all patients regardless of overtreatment status. Both proxy definitions had low sensitivity (20% [14; 29] and 41% [32; 50]) and accuracy (27% [20; 35] and 44% [35; 53]) in predicting hypoglycemia.

CONCLUSIONS

A revised definition of diabetes overtreatment is needed to better manage older insulin-treated patients and protect them from hypoglycemia.

Recent clinical practice guidelines recommend to avoid "diabetes overtreatment" in older people living with type 2 diabetes (T2D), conceptually corresponding to an inappropriate level of glycemia that places the patient at high risk of unwanted side effects of glucose-lowering treatment (e.g., hypoglycemia), without providing a clinically implementable definition of this concept (1,2). To assess the prevalence and consequences of diabetes overtreatment, several studies used "proxy definitions of diabetes overtreatment," based on thresholds of HbA_{1c} (3–6); there is no evidence on the predictive value of these proxy definitions to detect hypoglycemia. This study used data from the HYPOAGE cohort to assess the incidence and predictive value of hypoglycemia associated with proxy definitions of diabetes overtreatment in older insulin-treated patients living with T2D.

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A.C. and A.-S.B. have equal authorship.

**A complete list of HYPOAGE Study Group members can be found in the supplementary material online.*

See accompanying article, p. 47.

RESEARCH DESIGN AND METHODS

Study Design and Population

This ancillary study of the HYPOAGE prospective cohort (6), conducted from November 2017 to March 2020 in six French diabetes clinics, included outpatients aged ≥75 years, with T2D (duration of ≥1 year), treated by a glucose-lowering therapy including insulin for ≥6 consecutive months, with an HbA_{1c} measurement at baseline and with ≥2 self-monitoring blood glucose (SMBG) measurements per day (Supplementary Table 1).

Continuous Glycemic Monitoring Metrics

All patients agreed to place a continuous glycemic monitoring (CGM) device (FreeStyle Libre Pro [FSLP] Sensor; Abbott Diabetes Care, Wiesbaden, Germany) for 28 consecutive days. CGM data were collected in double-blind conditions.

CGM data are reported as a percentage of the total time spent in different ranges (7): time above range (TAR) for glycemia >180 mg/dL (level 1 TAR [glycemia 181–250 mg/dL] and level 2 TAR [glycemia >250 mg/dL]), time in range for glycemia 70–180 mg/dL, and time below range (TBR) for glycemia <70 mg/dL (level 1 TBR [glycemia 54–69 mg/dL] and level 2 TBR [glycemia <54 mg/dL]). We differentiated diurnal (6 A.M. to midnight) and nocturnal (midnight to 6 A.M.) time.

Measurements at Baseline

Sociodemographic (age, sex), clinical, biological, and comprehensive geriatric assessment data were collected at baseline. HbA_{1c} was expressed as percent (National Glycohemoglobin Standardization Program) and millimoles per mole (International Federation of Clinical Chemistry). Health status was defined according to the three-tiered Blaum classification (8) (Supplementary Fig. 1).

Definitions of Diabetes Overtreatment

We used two different proxy definitions of diabetes overtreatment from previous studies (1):

- "Fixed proxy definition" (9): HbA_{1c} <7.0% (<53 mmol/mol)
- "Individualized proxy definition" (3,10): HbA_{1c} <7.0% (53 mmol/mol), <7.5% (58 mmol/mol), and <8.0% (64 mmol/mol) for patients in good, intermediate, and poor health status, respectively (Supplementary Fig. 1)

Outcomes

The primary outcome was the TBR ≥1% (i.e., ≥15 min/day).

Secondary outcomes were ≥1% of level 1 TBR, ≥1% of level 2 TBR, and the occurrence of ≥1 confirmed hypoglycemic event (<70 mg/dL) measured by SMBG.

Statistical Analyses

Continuous data were expressed as means ± SD or medians [interquartile range], while categorical data were shown as number (percent). Comparisons between overtreated and non-overtreated groups used Student *t* test or Wilcoxon rank sum test for continuous variables, and Pearson χ^2 test, or Fisher exact test for categorical variables. The diagnostic performance of overtreatment proxy definitions was assessed using measures of sensitivity, specificity, and accuracy (Supplementary Table 1). Statistical analyses were conducted with SAS version 9.4 (SAS Institute, Cary, NC), with *P* value <0.05 considered statistically significant.

RESULTS

Of the 141 patients with full follow-up of the HYPOAGE cohort, 134 had HbA_{1c} measurement at baseline and were included in this ancillary study (Supplementary Fig. 2).

Baseline Patients' Characteristics

Among the 134 patients aged 81.6 ± 5.4 years, with 41% female, 67 (54.5%) met the Fried criteria for frailty, 57 (42.5%) had malnutrition, and 29 (21.6%) were nursing home residents (Table 1). According to Blaum classification, global health was good in 16 (12%), intermediate in 67 (50%), and poor in 51 (38%) patients (criteria provided in Supplementary Fig. 1).

At baseline, the mean HbA_{1c} was 7.9 ± 1% (63 ± 11 mmol/mol). All participants were on insulin therapy, and the glucose-lowering regimen is detailed, with 22 (16%) on sulfonylurea or repaglinide (Supplementary Table 2).

Overall, 25 patients (18.7%) were classified as overtreated based on the fixed proxy definition and 53 patients (39.6%) based on the individualized proxy definition (Table 1).

The overtreated patients (for both definitions), as compared with the other patients, had lower HbA_{1c}, lower eGFR, and lower use of metformin. Overtreated patients according to the individualized proxy definition also showed lower functional independence (by definition). No other significant difference was observed between overtreated and non-overtreated patients (Table 1 and Supplementary Table 2).

CGM Metrics

Figure 1 (and Supplementary Table 2) shows the CGM metrics according to the presence or the absence of diabetes overtreatment. Trends for higher median TBR were observed in overtreated patients compared with non-overtreated patients using the fixed proxy definition (6.3% [1.1; 12.1] vs. 2.6% [0.9; 6.4]; *P* = 0.059) and the individualized proxy definition (4.1% [1.1; 12.1] vs. 2.6% [0.9; 5.1]; *P* = 0.070). Statistically significant differences were observed between overtreated participants and non-overtreated ones in the median time spent in level 1 TBR using the fixed definition (4.3% [1.1; 6.1] vs. 2.0% [0.6; 4.1]; *P* = 0.034) and the individualized proxy definition (3.6% [0.9; 6.1] vs. 2.0% [0.6; 3.6]; *P* = 0.038). The median time in range was higher in overtreated patients than in non-overtreated patients using the fixed proxy definition (82.4% [73.1; 90.0] vs. 65.7% [50.0; 78.3]; *P* < 0.001), and the individualized proxy definition (79.6% [64.2; 86.1] vs. 62.6% [46.7; 75.6]; *P* < 0.001). The median TAR was lower in overtreated patients than in non-overtreated patients using the fixed definition (5.9% [2.7; 16.6] vs. 28.0% [15.4; 44.7]; *P* < 0.001) and the individualized definition (15.4% [4.0; 26.7] vs. 29.9% [18.3; 51.2]; *P* < 0.001). The same pattern of CGM metrics distribution was found for level 1 TAR and level 2 TAR.

In overtreated participants, the median coefficient of variation indicating glycemic variability was 31.7% [29.0; 35.7] and 32.6% [29.2; 37.7] using the fixed and individualized proxy definitions, respectively, not significantly different from non-overtreated participants (Supplementary Table 2).

Hypoglycemia

In participants with diabetes overtreatment, the incidence of hypoglycemia, defined as TBR ≥1%, was 100% using the fixed proxy definition and 94.3% using the individualized proxy definition. A significant

Table 1—Baseline patient's characteristics according to the fixed and the individualized proxy definitions of diabetes overtreatment

	Diabetes overtreatment, fixed proxy definition			Diabetes overtreatment, individualized proxy definition		
	No, *n* = 109 (81.3%)	Yes, *n* = 25 (18.7%)	*P* value	No, *n* = 81 (60.4%)	Yes, *n* = 53 (39.6%)	*P* value
Age, years	81.7 ± 5.5	80.8 ± 4.9	0.417	81.4 ± 5.4	81.8 ± 5.5	0.608
Female	48 (44.0%)	7 (28.0%)	0.142	37 (45.7%)	18 (34.0%)	0.178
BMI ≥30 kg/m^2	42 (40.0%)	14 (58.3%)	0.102	32 (40.5%)	24 (48.0%)	0.403
Diabetes duration, years	26.0 ± 11.4	22.2 ± 11.8	0.150	26.9 ± 11.7	22.8 ± 10.8	0.059
History of severe hypoglycemia*	9 (8.3%)	0 (0%)	0.363	7 (8.6%)	2 (3.8%)	0.482
HbA_{1c}, % [mmol/mol]†	8.2 ± 0.8 [66 ± 9]	6.5 ± 0.5 [48 ± 5]	<0.001	8.5 ± 0.8 [69 ± 9]	7.0 ± 0.6 [53 ± 7]	<0.001
CKD-EPI, mL/min	63.2 ± 20.5	48.2 ± 25.4	0.003	63.9 ± 20.0	55.4 ± 24.2	0.033
CIRS-G score (0–56)	12.0 ± 4.6	13.1 ± 5.6	0.317	11.6 ± 4.6	13.1 ± 5.0	0.101
Diabetes comorbidities						
Macrovascular diseases	68 (63.0%)	14 (58.3%)	0.672	52 (65.0%)	30 (57.7%)	0.398
Chronic kidney disease	49 (45.4%)	18 (75.0%)	0.009	34 (42.5%)	33 (63.5%)	0.019
Retinopathy	34 (36.2%)	6 (27.3%)	0.429	26 (36.6%)	14 (31.1%)	0.543
Neuropathy	52 (51.0%)	12 (52.2%)	0.918	36 (48.0%)	28 (56.0%)	0.381
Geriatric syndromes						
ADL dependence (0–6)	4.7 ± 1.6	4.5 ± 1.8	0.654	4.9 ± 1.4	4.3 ± 1.9	0.040
Nursing home	25 (22.9%)	4 (16.0%)	0.448	18 (22.2%)	11 (20.8%)	0.840
Frailty (Fried)	54 (53.5%)	13 (59.1%)	0.631	38 (50.7%)	29 (60.4%)	0.290
MMSE score (0–30)	23.0 ± 5.3	24.5 ± 5.6	0.226	23.0 ± 5.5	23.8 ± 5.1	0.383
Cognitive impairment‡	90 (84.9%)	16 (66.7%)	0.076	64 (82.1%)	42 (80.8%)	0.854
Risk of depression	49 (47.6%)	10 (40.0%)	0.496	36 (45.6%)	23 (46.9%)	0.880
Malnutrition§	47 (46.1%)	10 (41.7%)	0.696	34 (44.7%)	23 (46.0%)	0.889
Global health status						
Good	12 (11.0%)	4 (16.0%)	0.632	12 (14.8%)	4 (7.5%)	0.252
Intermediate	54 (49.5%)	13 (52.0%)		42 (51.9%)	25 (47.2%)	
Poor	43 (39.4%)	8 (32.0%)		27 (33.3%)	24 (45.3%)	
Use of GLD classes (added to insulin)						
SU or repaglinide	21 (19.3%)	1 (4.0%)	0.075	17 (21.0%)	5 (9.4%)	0.078
Metformin	54 (49.5%)	6 (24.0%)	0.021	44 (54.3%)	16 (30.2%)	0.006
DPP-4 inhibitors	26 (23.9%)	6 (24.0%)	0.988	19 (23.5%)	13 (24.5%)	0.887
GLP-1 RAs	9 (8.3%)	2 (8.0%)	0.999	6 (7.4%)	5 (9.4%)	0.752

Data are presented as mean ± SD or *n* (%). ADL, activities of daily living (from 0 [severe functional dependence] to 6 of 6 [full functional independence]); CIRS-G score, cumulative illness rating scale–geriatric (from 0 [light] to 56 [heavy]); DPP-4, dipeptidyl peptidase 4; GLD, glucose-lowering drug; GLP-1 RA, glucagon-like peptide 1 receptor agonist; MMSE, Mini-Mental State Examination; SUs, sulfonylureas. *Severe hypoglycemia is hypoglycemia requiring assistance of another person. †HbA_{1c} values were presented according to the standards of the National Glycohemoglobin Standardization Program (in percent) and those of the International Federation of the Clinical Chemists (in mmol/mol). ‡Cognitive impairment was defined as MMSE <24 of 30 and/or BREF (Batterie Rapide d'Efficience Frontale) score <16 of 18 (cutoff with high sensitivity and low specificity). §Risk or presence of malnutrition, based on BMI and Mini-Nutritional Assessment. As a reminder, all participants (100%) were treated by insulin.

difference in TBR ≥1% during nocturnal time between overtreated and non-overtreated patients was observed using the fixed proxy definition.

The incidence of level 1 TBR ≥1% was 100% and 92.5%, and of level 2 TBR ≥1% was 92.0% and 81.1%, respectively, according to the fixed and individualized proxy definitions (Table 2). Level 2 TBR ≥1% was more frequent in overtreated patients than in non-overtreated patients with the fixed proxy definition (92.0% vs. 72.5%, *P* = 0.039) but not with the individualized proxy definition (Table 2).

Predictive Value of Diabetes Overtreatment Definitions for Hypoglycemia

Overall, diabetes overtreatment based on an HbA_{1c} threshold had a low sensitivity, specificity, and accuracy for the prediction of hypoglycemia (e.g., TBR ≥1%). The individualized proxy definition of diabetes overtreatment, as compared with the fixed proxy definition, showed higher sensitivity and higher accuracy for the prediction of hypoglycemia (Table 3).

CONCLUSIONS

This analysis of the HYPOAGE cohort found no association between proxy definitions of diabetes overtreatment and occurrence of hypoglycemia in insulin-treated older adults living with T2D. Both fixed and individualized proxy definitions had low predictive value for hypoglycemia in this

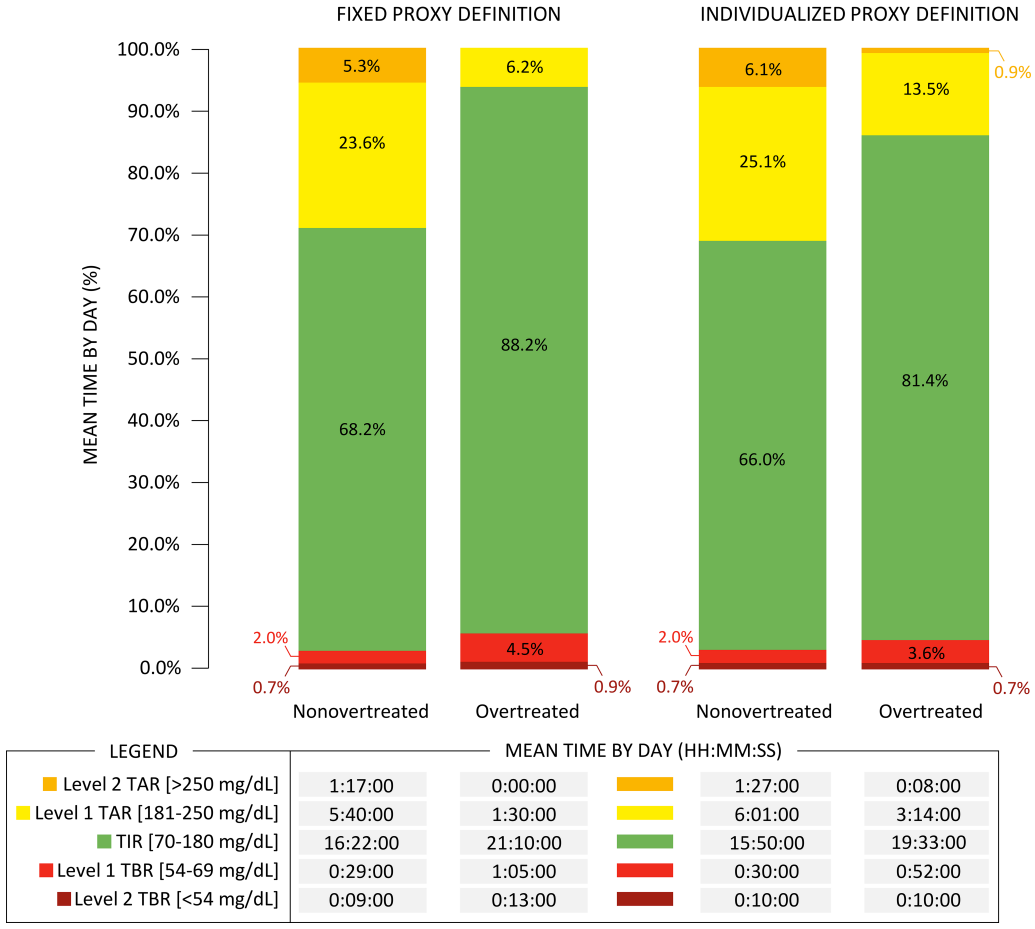

Figure 1—Time spent (percent) in different ranges of glycemia, based on CGM metrics, according to the fixed and individualized proxy definitions of diabetes overtreatment. TIR, time in range.

population. Our findings align with previous studies on diabetes overtreatment prevalence (3,9,11) but contradict those associating overtreatments with hypoglycemia (12). The high prevalence of hypoglycemia we found may be attributed to our use of CGM, differences in study population, settings, or outcomes definitions.

Our results therefore challenge the use of these proxy definitions of diabetes overtreatment for the detection of hypoglycemia, which is nevertheless assumed

Table 2—Occurrence of hypoglycemic events detected by CGM according to the two proxy definitions of diabetes overtreatment

	Diabetes overtreatment, fixed proxy definition, *n* (%)			Diabetes overtreatment, individualized proxy definition, *n* (%)		
	No, *n* = 109 (81.3)	Yes, *n* = 25 (18.7)	*P* value	No, *n* = 81 (60.4)	Yes, *n* = 53 (39.6)	*P* value
TBR ≥1% (glycemia <70 mg/dL)	98 (89.9)	25 (100.0)	0.217	73 (90.1)	50 (94.3)	0.526
Nocturnal TBR ≥1%	89 (81.7)	25 (100.0)	0.025	68 (84.0)	46 (86.8)	0.652
Diurnal TBR ≥1%	98 (89.9)	24 (96.0)	0.464	73 (90.1)	49 (92.5)	0.763
Level 1 TBR ≥1% (54 mg/dL < glycemia < 70 mg/dL)	97 (89.0)	25 (100.0)	0.122	73 (90.1)	49 (92.5)	0.763
Level 2 TBR ≥ 1% (glycemia <54 mg/dL)	79 (72.5)	23 (92.0)	0.039	59 (72.8)	43 (81.1)	0.271
≥1 Hypoglycemic episode (SMBG <70 mg/dL)	42 (38.5)	9 (36.0)	0.814	31 (38.3)	20 (37.7)	0.950

The glucose concentration values corresponding to the TBR was <70 mg/dL, to the level 1 TBR was between 54 and 69 mg/dL, and to the level 2 TBR was <54 mg/dL. Values are based on data from the 28-day CGM. Nocturnal time was between midnight and 6:00 A.M. Diurnal time was between 6:00 A.M. and midnight.

Table 3—Accuracy of proxy definitions of diabetes overtreatment for detecting patients with hypoglycemia defined as TBR (glycemia <70 mg/dL) ≥1% (≥15 min/day)

	Hypoglycemic event, *n* (%) or % [95% CI]						
	Fixed proxy definition of diabetes overtreatment			Individualized proxy definition of diabetes overtreatment			
	Yes	No	Total	Yes	No	Total	*P* value
Overtreated	25 (100)	0 (0)	25	50 (94)	3 (6)	53	—
Non-overtreated	98 (90)	11 (10)	109	73 (90)	8 (10)	81	—
Total	123 (92)	11 (8)	134	123 (92)	11 (8)	134	—
Predictive performance							
Sensitivity	20 [14; 29]			41 [32; 50]			<0.001
Specificity		100 [71; 89]			73 [39; 94]		0.083
Accuracy			27 [20; 35]			44 [35; 53]	<0.001

Sensitivity $\left[\frac{TP}{TP+FN}\right]$, specificity $\left[\frac{TN}{TN+FP}\right]$, and accuracy $\left[\frac{TP+TN}{TP+TN+FP+FN}\right]$, considering true positive (*TP*) as the proportion of hypoglycemic patients with overtreatment, true negative (*TN*) as the proportion of non-nonhypoglycemic patients without overtreatment, false negative (*FN*) as the proportion of hypoglycemic patients without overtreatment, and false positive (*FP*) as the proportion of nonhypoglycemic patients with overtreatment. All measures of diagnostic performances were presented with their 95% CI. *P* values for comparisons of predictive performance between fixed and individualized proxy definitions of diabetes overtreatment were assessed using McNemar test.

by various studies (1,3,9,11). One of the main issues of these proxy definitions is their reliance solely on (sometimes physiological) HbA_{1c} levels. While HbA_{1c} is effective for monitoring glycemic control over several weeks, previous research has demonstrated the weak link between low HbA_{1c} and hypoglycemia (13,14). Furthermore, recent evidence and progress in glucose-lowering treatment, including insulin therapies, allow for improved glycemic control (with lower HbA_{1c}) without significantly increasing hypoglycemia risk (15–17).

This finding underscores the necessity for a revised proxy definition of diabetes overtreatment. The prospect of a new CGM-based proxy definition is promising, yet it is premature to assert its validity. Our results require further validation, and the association between CGM metrics and adverse clinical outcomes must be thoroughly explored in this older population.

This study is the first to use CGM data to explore diabetes overtreatment and hypoglycemia in older adults with T2D, benefiting from prospective high-quality multicenter cohort data. However, all patients were treated with insulin, possibly underestimating the predictive values of overtreatment definitions. Moreover, the used CGM device might have introduced a measurement bias, overestimating hypoglycemia prevalence (18). Nevertheless, this bias is consistent across all patients, likely having minimal impact on outcomes. In addition, similar conclusions were found when using SMBG-confirmed hypoglycemia.

In conclusion, this study underscores the urgent need to explore alternative approaches for identifying older patients with T2D at risk for hypoglycemia from intensive glucose-lowering therapy. Addressing these issues is pivotal in optimizing the management of diabetes in older patients and mitigating the adverse consequences of glucose-lowering treatment.

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Author Contributions. A.C., A.-S.B., S.H., and B.C. designed the ancillary study. A.C. and B.G. performed the statistical analyses. A.-S.B., L.d.D., S.H., and B.C. recruited and followed study patients. A.C. drafted the first version of the manuscript. All coauthors critically reviewed and edited the manuscript. B.C. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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