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DIABETIC Medicine

REVIEW

Overtreatment of older people with type 2 diabetes—a high impact frequent occurrence in need of a new definition

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Abstract

Background: Diabetes overtreatment is a frequent and major issue in older people with type 2 diabetes but its definition is often inconsistent and may be misleading. This critical review has aimed at examining the definitions of diabetes overtreatment in older people used in research studies.

Methods: Studies addressing diabetes overtreatment in people aged 65 or older were identified by searching the PubMed database according to an extensive search equation.

Results: Twenty-two research studies providing a definition of diabetes overtreatment in people aged were found. Overall, 12 different definitions of diabetes overtreatment were used. All studies defined overtreatment according to a HbA_{1c} threshold (varying from <42 mmol/mol [<6.0%] to <64 mmol/mol [<8%]). Amongst them, 2 definitions had no consideration about glucose-lowering (GL) treatment, 6 required the prescribing of ≥1 GL agent(s), and 4 the prescribing of ≥1 GL agent(s) inducing the high risk of hypoglycaemia (i.e., sulfonylurea(s) or insulin(s)). Only 4 definitions (four studies) were individualised, using varying HbA_{1c} thresholds according to patients' age or health status.

Conclusions: Definitions of diabetes overtreatment are heterogeneous across research studies, which is confusing. A standardised definition, based on the individual risk of hypoglycaemia and/or its complications must be promoted in order to bring clarity and greater insight into this field, as well as to improve the quality of management of diabetes in older patients.

KEYWORDS

glucose-lowering drugs, older adults, overtreatment, review, type 2 diabetes

1 | INTRODUCTION

Type 2 diabetes (T2D) is one of the most prevalent chronic conditions in older people. In European countries, the prevalence of T2D in older people (aged 65 years or older) is estimated at 20.1% and is expected to rise in the next 25 years.[1,2] In older patients, T2D is often associated with multiple comorbidities, disability or functional impairment, promoting frailty and being complicated by more frequent hospitalisation, decreased quality of life and increased mortality.[3,4] T2D is, therefore, a real burden for patients, and public health due to the high health costs associated with T2D in older patients.[5] Appropriate therapeutic management of T2D is crucial in older people. Overtreatment should be avoided particularly when managing glycaemic control with glucose-lowering treatment (GLT).[6,7]

Given the wide heterogeneity of this population in terms of overall health status and life expectancy, the potential long-term benefits of an intensive GLT approach may differ considerably between patients. Furthermore, older patients are more sensitive and vulnerable to GLT adverse events (such as hypoglycaemia), which are particularly harmful to older patients and costly to the health care system.[8–11] Hypoglycaemic events have serious consequences for older patients, especially for more vulnerable patients with frailty or impaired awareness of hypoglycaemia, namely because of increases in cardiovascular events, cognitive impairment, frailty, falls with fracture, disability and mortality.[12–15] Hypoglycaemia occurs especially in the context of (too) intense treatment, which is referred to as 'diabetes overtreatment'.

Few clinical practice guidelines (CPGs) on the management of T2D in older people have been released by Scientific Societies. They all recommend the avoidance of hypoglycaemia.[16–19] However, none of these recent guidelines provides any precise definition of glycaemic overtreatment. Such a definition seems crucial for delivering quality research and appropriate management of older patients. This review aimed at reporting and critically discussing the definitions of diabetes overtreatment used in clinical research studies.

Novelty statement

- Type 2 diabetes overtreatment is a major issue for older people.
- This critical review aimed at reporting the definitions of diabetes overtreatment in older people used in research studies.
- Twelve heterogeneous definitions were identified across 22 studies, based on different criteria.
- A standardised definition of diabetes overtreatment based on the individual risk of hypoglycaemia must be promoted.

2 | METHODS

This review was conducted through a comprehensive search of the literature.

2.1 | Search strategy and inclusion criteria

The literature search was carried out on March 31 2021 using a search equation designed to identify the studies of interest (Appendix S1), in all scientific journals indexed in MEDLINE®. This search equation used keywords belonging to the field of 'older patient', 'diabetes' and 'overtreatment'. The search was not limited to some designs of studies, publication date or language. Duplicates were removed.

Inclusion criteria were original research studies addressing diabetes overtreatment in older people (65 years or older) with type 2 diabetes and providing a clear definition of 'overtreatment'. 'Diabetes overtreatment' was understood as 'overtreatment by glucose-lowering drugs'.

The selection of the studies followed a 2-step process and was carried out by one author (AC). First, the titles and abstracts were screened and all records not meeting the inclusion criteria were excluded. Second, the full papers of the remaining studies were examined. Studies were included if they were confirmed to be eligible on the basis of the inclusion criteria.

2.2 | Data extraction

General information was extracted from the included studies (year of publication, country, study design, setting, patients' inclusion criteria, number of patients). Definitions of diabetes overtreatment were extracted and summarised. Amongst existing glucose-lowering agents, those inducing a high risk of hypoglycaemia were insulins, sulfonylureas and glinides.

3 | RESULTS

A total of 248 records were identified. After the removal of 1 duplicate, titles and abstracts of 247 records were screened, of which 216 were excluded (Figure 1). Of the 31 full texts further assessed for eligibility, 22 fitted with the inclusion criteria.

3.1 | Characteristics of the studies

The majority of the 22 studies were from Europe ($n = 13$) and North America ($n = 6$). None was published before 2010 and three-quarters were from the last 5 years (Table 1). Thirteen studies (59%) were conducted in outpatient settings (geriatric medicine units, diabetes centres or general practice). Sample sizes varied widely across studies, with three of them (registered-based, from North America) including a very large number of patients (42,000—108,000). All but two were cross-sectional or retrospective cohort studies. All but one study had a retrospective design (cross-sectional or cohort).

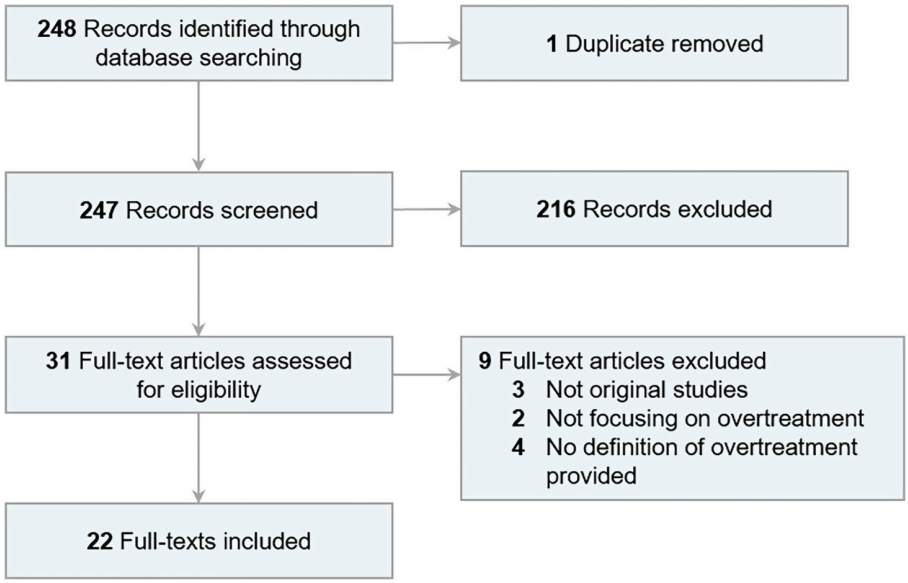

FIGURE 1 PRISMA flow diagram.

3.2 | Definitions of overtreatment

Overall, the 22 studies used 12 different definitions of diabetes overtreatment. The definitions were classified into non-individualised definitions ('the same for all patients': 8 definitions shared by 18 studies) and individualised definitions ('the definition varied according to patient's characteristics': 4 definitions used in four studies).

3.2.1 | Non-individualised definitions ($n = 8$)

The 8 non-individualised definitions of diabetes overtreatment were all based on a HbA_{1c} threshold and for 6 of them, additionally on the presence of a GLT (Table 2). Indeed, 2 definitions took only HbA_{1c} values into account,[28,29,31,40] 4 definitions required the use of any GL agent(s)[22,23,25,27,34] and 2 definitions required the use of a GLT inducing a high risk of hypoglycaemia, i.e. a GLT including insulin, sulfonylurea or a glinide.[15,20,24,30,32,35,37–39] The HbA_{1c} threshold considered by the different definitions varied from <42 mmol/mol (6.0%) to <58 mmol/mol (7.5%). The most frequent definition of diabetes overtreatment, shared by eight different studies, was $HbA_{1c} < 53$ mmol/mol (7.0%) in patients prescribed a GLT inducing a higher risk of hypoglycaemia.

3.2.2 | Individualised definitions ($n = 4$)

Four studies provided individualised definitions of diabetes overtreatment,[21,26,33,36] i.e. definitions with different criteria according to patients' characteristics (Table 3). These studies defined diabetes overtreatment as a HbA_{1c} value lower than a given threshold in the presence of a GLT (with high hypoglycaemic risk for 2 studies).[21,26] In the individualised definitions, this HbA_{1c} threshold varied according to specific patient characteristics: patients' age[26] or patients' health status.[21,33,36] Each of the three latter definitions was based on the recommendations of clinical practice guidelines for the treatment of type 2 diabetes in older patients (American Diabetes Association 2020,[18] Nederlands Huisartsen Genootschap—Standaard 2013[41] and the American Endocrine Society 2019[17]).

4 | DISCUSSION

This study found that 12 different definitions of diabetes overtreatment were used in the 22 original research articles addressing diabetes overtreatment. These definitions were all based on the HbA_{1c} threshold and, for most of them, on a glucose-lowering drug regimen. Amongst these 12 definitions, 8 were non-individualised definitions (the same definition for all patients), whereas 4 definitions were individualised according to the patient's characteristics (age or health status).

The studies were all published after 2010. This observation probably results from the beginning of the medical consideration of a potential risk of too strict glycaemic control in older patients with T2D.[8,42] The concept of diabetes overtreatment in older patients is, therefore, relatively recent. Nevertheless, in the past 10 years of clinical research, only 22 publications addressed diabetes overtreatment in older people, despite the high relevance of this issue for patients and public health. The lack of research on this

TABLE 1 Characteristics of the 22 clinical research studies addressing diabetes overtreatment

		Inclusion criteria					
Author, Year	**Country**	**Age (years)**	**Having T2D**	**Other**	**Setting**	***N***	**Study type**
Lega, 2021[20]	Canada	≥75	T2D Treated by GLT		GP	108,620	RCS
Christiaens, 2020[21]	Belgium	≥75	T2D Treated by GLT		Inpatients (Geriatrics)	318	RCS
Gotfredsen, 2020[22]	Denmark	>80	T2D		Inpatients	5172	RCS
Niznik, 2020[23]	USA	Veteran	T2D	limited LE and/or advanced dementia	LTC	6960	RCS
Quilot, 2020[24]	France	≥65	T2D		LTC	148	RCS
Sonmez, 2020[25]	Turkey	≥65	T2D		Inpatients (DbC)	1264	CSS
Tran, 2020[26]	Norway	≥65	T2D		GP	10,233	CSS
Akin, 2019[27]	Turkey	≥65	T2D of ≥5 years	perfect attendance in controls (<2 years)	Outpatients (DbC)	755	CSS
Wojszel, 2019[28]	Poland	[a]	T2D		Inpatients (Geriatrics)	213	CSS
Wojszel, 2019[29]	Poland	[a]	T2D		Inpatients (Geriatrics)	213	CSS
Arnold, 2018[30]	USA	≥75	T2D		Outpatients (DbC)	42,669	CSS
Bruce, 2018[15]	Australia	≥75	T2D		GP and Outpatients (DbC)	367	PCS
Formiga, 2017[31]	Spain	≥65	T2D		GP	7269	CSS
Hambling, 2017[32]	UK	≥70	T2D treated by SUH of insulin		GP	1379	RCS
Hart, 2017[33]	The Netherlands	≥70	T2D		GP	1002	RCS
Maciejewski, 2017[34]	USA	≥65	T2D		Outpatients	78,792	RCS
Vimalananda, 2017[35]	USA	>74 OR dementia	T2D treated by SUH or insulin	$HbA_{1c} < 53$ mmol/mol (7.0%)	Outpatients	2830	Uncontrolled interventional study
Deletre, 2016[36]	Switzerland	≥75	T2D treated by GLT		Inpatients (Geriatrics)	257	RCS
Müller, 2016[37]	Germany	≥65	T2D		Outpatients	4459	CSS
Lipska, 2015[38]	USA	≥65	T2D		GP	1288	CSS
Penfornis, 2015[39]	France	≥75	T2D	CKD	GP and Outpatients (DbC)	980	CSS
Bouillet, 2010[40]	France	≥65	T2D		LTC	100	CSS

Abbreviations: CCS, Cross-sectional study; DbC, Diabetes Centre; GLT, Glucose-lowering treatment; GP, General practice; LE, Life expectancy; LTC, Long term care; PCS, Prospective cohort study; RCS, Retrospective cohort study; SUH, Sulfonylureas; T2D, Type 2 diabetes.

[a]Age not provided.

TABLE 2 Summary of the 12 definitions of diabetes overtreatment (22 studies)

		Criterion = Glucose-lowering treatment		
		No consideration about GLT	GLT use, any	GLT inducing high risk of hypoglycaemia
Criterion = HbA_{1c} values	HbA_{1c} < 42 mmol/mol (6.0%) for all patients		●[22]	
	HbA_{1c} < 48 mmol/mol (6.5%) for all patients	●[40]	●●[25,34a]	
	HbA_{1c} < 53 mmol/mol (7.0%) for all patients	●●●[28,29,31]	●[27]	●●●●●●●[15,20,24,30,32,35,37,38]
	HbA_{1c} < 58 mmol/mol (7.5%) for all patients		●[23]	●[39b]
	Individualised thresholds of HbA_{1c}		●[33] ●[36]	●[21] ●[26]

Note: ●: a study included in the review. GLT: Glucose-lowering treatment.

[a]In Sonmez et al.[25]: GLT including ≥2 glucose-lowering agents.

[b]In Perfornis et al.[39]: GLT including ≥2 glucose-lowering agents, including at least 1 agent inducing high risk of hypoglycaemia (Sulfonylurea and/or insulin).

issue is correlated with the overall paucity of research on diabetes in older patients.[43,44]

The definitions of overtreatment used by the 22 studies are very heterogeneous, being based on different combinations of various criteria. Amongst those, a HbA_{1c} value below a defined threshold (i.e., a 'too tight glycaemic control') is shared by all definitions. However, the recent major clinical practice guidelines on T2D management in older patients,[16] recommend the individualisation of the treatment goal for each patient by setting the HbA_{1c} target according to her/his health status. It would, therefore, seem logical to consider an individualised definition of a 'too tight glycaemic control' according to the patient's health status, as proposed in only 3 of the 12 definitions reported.[21,33,36]

The majority of the 22 studies also included the presence of a glucose-lowering treatment as a required condition to define diabetes overtreatment. This is expected since overtreatment first requires being pharmacologically treated. Moreover, four definitions considered overtreatment only when a glucose-lowering agent with a high risk of causing hypoglycaemia (insulin, sulfonylureas or glinides) was prescribed.

This wide variety of definitions can be confusing for clinicians and researchers working in the area of diabetes overtreatment. At the very least, this unmasks a lack of consistency and comparability amongst studies where different definitions of overtreatment are used. The prospect of a consensual definition of overtreatment, therefore, seems attractive. In our view, the *new definition of diabetes overtreatment should correspond to a level of glycaemia that is inappropriate to a patient's health status that places a high risk of unwanted side effects of GLT, such as hypoglycaemia and/or its harmful consequences.*

At this stage, we can only speculate on what might be the additional criteria that could be used for defining overtreatment. Amongst these, known risk factors for hypoglycaemia in older patients could be indeed used as criteria to modulate the definition of diabetes overtreatment, such as frailty, care home residency, polypharmacy (≥10 drugs/day) or undernutrition.[9,13] This would enable the overtreatment of some patients to be considered more severe than that of others, alerting them to the greater risk of hypoglycaemia which overtreatment exposes.

This new definition should be developed carefully, based on the strongest available evidence. Research in this field needs to progress to provide new evidence.[44,45] Furthermore, it is essential that this new definition also takes into account patient preferences. The participation of the patient in therapeutic decision-making is indeed central and is part of the recent recommendations.[16–19] This new definition should clearly be developed from both a patient-centred, and diabetes-centred perspective to emphasise the importance of considering the quality of life of older people with diabetes. In addition, any new definition will require validation through the clinical trial process to achieve an evidence-based footing which will serve to distinguish it from existing empirical definitions as we have now.

Finally, it should be remembered that the concept of 'overtreatment of diabetes' we have discussed here relates only to the glycaemia perspective of overtreatment. Overtreatment with anti-hypertensive or lipid-lowering therapy is also possible and may also have adverse consequences for older patients, but is not the subject of this review.

In conclusion, the prospect of a new consensual definition of overtreatment is attractive, especially given the heterogeneity

TABLE 3 Summary of the 4 individualised definitions of diabetes overtreatment (four studies)

Studies	Individualised definitions of diabetes overtreatment
Christiaens et al. (2020)[21]	Use of sulfonylurea or/and insulin + HbA_{1c} cut-off individualised according to patient's health status tier: • Poor health: < 64 mmol/mol (8.0%) • Intermediate health: < 58 mmol/mol (7.5%) • Good health: < 53 mmol/mol (7.0%) [Based on American Endocrine Society 2019 targets and health status classification][17]
Deletre et al. (2016)[36]	Use of any GLT + HbA_{1c} cut-offs individualised according to patient's health status tier: • Poor health: < 64 mmol/mol (8.0%) • Intermediate health: < 58 mmol/mol (7.5%) • Good health: < 53 mmol/mol (7.0%) [Based on American Diabetes Association 2020 guidelines: (targets – 0.5%) and health status][18]
Hart et al. (2017)[33]	Use of any GLT + HbA_{1c} cut-offs individualised according to patient's health status tier: • ≥ 70 years + GLT other than metformin monotherapy + T2D duration ≥10 years: < 53 mmol/mol (7.0%) • ≥ 70 years + GLT other than metformin monotherapy + T2D duration <10 years: < 53 mmol/mol (7.0%) • < 70 years or Metformin monotherapy or no GLT: No overtreatment [Based on Nederlands Huisartsen Genootschap 2013 guidelines][41]
Tran et al. (2020)[26]	Use sulfonylurea or/and insulin + HbA_{1c} cut-offs individualised according to patient's age only: • > 75 years: < 53 mmol/mol (7.0%) • 64–75 years: < 48 mmol/mol (6.5%)

Abbreviations: ADA20, American Diabetes Association 2020; ES19, Endocrine Society 2019; GLT, Glucose-lowering therapy; SUH, Sulfonylureas; T2D, Type 2 diabetes.

of definitions in the current scientific literature. We believe that this advance would contribute to better evidence in the field of diabetes in older people, whilst directly improving the quality of therapeutic management for those patients.

AUTHOR CONTRIBUTIONS

AC designed the study. AC carried out the search. AC extracted and synthesised the data. AC drafted the manuscript under the supervision of SH, BB and AJS. SH, BB and AJS reviewed the manuscript. All authors read and approved the final manuscript.

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CONFLICTS OF INTEREST

The authors have no conflict of interest to report.

DATA AVAILABILITY STATEMENT

I confirm that my Data Availability Statement (pasted below) complies with the Expects Data Policy. Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

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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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