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Primary care management of non-institutionalized elderly diabetic patients: The S.AGES cohort – Baseline data

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ABSTRACT

Aim: S.AGES is a multicenter prospective cohort study of non-institutionalized patients aged 65 and over with atrial fibrillation, type 2 diabetes or chronic pain. Its objective is to describe the medical management in primary care. This article presents the baseline characteristics of subjects in the diabetes subcohort and compares the results to those from cohorts of older diabetic patients.

Methods: From April 2009 to June 2011, 983 patients were included in the diabetes subcohort by 213 primary care providers. Demographic data, geriatric parameters and the history, characteristics and treatment of the diabetes were recorded at baseline.

Results: The mean age was 76.7 ± 5.9 years. Most patients were living independently, with no cognitive impairment and in relatively good health. The duration of diabetes was 11.3 ± 8.7 years with average HbA1c of 6.9 ± 1.0%. 20% of patients had macrovascular disease, 33% renal failure, 14.6% ocular complication and 7.1% neuropathy. The first-line antidiabetic treatment was metformin (61.2%) and 18% of patients had used insulin. Treatment intensified with the worsening of diabetic symptoms. When compared to those from French and North American cohorts, the results showed increased complications and use of insulin with age, disease duration and severity.

Conclusion: Due to the method of recruitment, S.AGES patients were generally healthy with well-controlled diabetes. However, the results were consistent with those from other cohorts. Three-year follow-up is expected to study the management of diabetic patients aged 65 and over in primary care.

1. Introduction

In France, type 2 diabetes affects 4.6% of the population, across all ages [1]. Its prevalence increases sharply after middle age to reach 14.2% in patients aged 65 and over [2], and 75-year-olds account for 25% of diabetic patients [3]. The figures in France are consistent with the European average [4]. In the US, diabetes is estimated to affect 15% of seniors [5]. Aging of the population and high levels of obesity result in an increased number of diabetic patients, particularly those aged 65 and over [6,7].

Diabetes leads to complications, notably micro and macrovascular problems. Diabetic patients tend to develop macrovascular disorders: coronary insufficiency, cerebrovascular involvement and heart failure [8].

The complications of diabetes are most frequent in the elderly and increase with age [2]: 45.3% of patients aged 65–74 experience vascular complications and this figure rises to 62.2% among patients aged 85 and over. Moreover, elderly diabetic patients are at a greater risk of developing other complications such as malnutrition, dementia, falls, fracture, depression and incontinence [9].

In France, type 2 diabetes is one of the main causes of healthcare expenditure [10]. Throughout the world, primary care providers are the first to support non-hospitalized patients [11] but few studies describe the medical management of elderly patients in the home. Despite international and national guidelines, little is known about the primary care of non-institutionalized elderly diabetic patients. The aim of this study is to describe the characteristics of non-institutionalized type 2 diabetics aged 65 and over participating in a primary care cohort study and to compare these characteristics to those of patients recruited in other cohorts of elderly diabetic subjects.

2. Patients and methods

In S.AGES [12], a prospective non-interventional multicenter cohort study conducted in France, the cohort of patients aged 65 or over, recruited in primary care practices and diagnosed with type 2 diabetes mellitus (T2DM), atrial fibrillation or chronic pain [13], was divided into three subcohorts. Primary care physicians could be included in one of 3 sub-cohorts, the choice of which was determined by drawing lots. Three-year follow-up was planned with visits to the primary care provider scheduled every six months. The main objective of S.AGES is to describe the primary care medical management of patients in each subcohort.

The secondary objectives common to all 3 cohorts are:

- To estimate resource consumption associated to the medical and paramedical care of the patients.
- To analyze the factors influencing the medical management.
- To describe the occurrence of major clinical events including hospitalizations and deaths during the 3 years follow up.

The secondary objectives specific of the T2DM sub cohort are:

- To describe the therapeutic strategies in relation with T2DM equilibrium (HbA1c).
- To analyze predictive factors of treatment response.
- To study pharmacogenetics geriatrics elements.

The present study centers on the T2DM subcohort at inclusion (T2DM S.AGES).

All French primary care physicians (N = 51,179) in private practice were invited to participate by mail. With their agreement, they were randomly assigned to one subcohort.

Each participating physician was required to recruit three to ten patients during a consultation or home visit, with a third of patients under the age of 75 and two thirds aged 75 and over. Data were collected using an electronic case report form.

Inclusion began in April 2009 and ended in June 2011.

The sample size was first calculated for each subcohort to meet the main objective of the study: to describe prevalence of at least 5% with absolute accuracy of 1%, particularly for the description of the different therapeutic strategies. The sample size was determined to obtain the required power for exploratory and explanatory analyzes, allowing a 13% rate of major clinical events in the follow-up. This sample size also had to make it possible to identify explanatory factors with a frequency of at least 10%, in order to achieve an odds ratio of approximately two with an alpha risk of 5% and 90%. To meet these conditions, the sample size was set at 2000 patients in the diabetic subcohort.

The inclusion criteria for the T2DM subcohort were: both male and female patients aged 65 or over, living in mainland France, diagnosed with T2DM, treated with an oral antidiabetic drug and/or insulin and affiliated to a national health insurance scheme. Patients had to agree to participate in the study and sign the informed consent form.

The exclusion criteria were as follows: patients living in nursing homes at the time of inclusion, patients unable to give consent, patients unable to take part in the follow-up procedures after inclusion, patients participating in clinical trials and patients presenting with life-threatening disease with less than three months life expectancy.

At inclusion, various information on the patients were recorded by the physicians:

- General parameters: age, gender, weight, body mass index (BMI) and living environment;
- Paramedical management (use and frequency): home assistance, nurse, physiotherapy and number of visits from a healthcare provider;
- Independence assessed by Activities of Daily Living (ADL) [14] and Instrumental Activities of Daily Activities (IADL) [15];
- Cognitive status evaluated by the Mini-Mental State Examination (MMSE) [16];
- Mood status evaluated by the fifteen-item Geriatric Depression Scale (GDS) [17];
- Smoking (never, past or present) and current alcohol consumption;
- Co-morbidities other than diabetes;
- Clinical and biological data: blood pressure, heart rate, glomerular filtration rate evaluated by Modification of Diet in Renal Disease (MDRD) and CKDepi formulas [18,19];
- A physiological age estimated by the physicians, defined as "less than, equal or more than chronological age";
- Number or drugs per day;
- T2DM characteristics: duration of diabetes, specific complications, glycemic control evaluated by HbA1c and treatment;
- A global health score adapted from the Short Emergency Geriatric Assessment (SEGA) [20] based on age, number of medical conditions, drugs and falls, living environment, mood and cognitive functions disorders, perception of health, IADL scale, mobility, continence and autonomy over food. Each item was scored from 0 to 2. If the score was less than 8, the subject was considered to be in good health; if the score was between 8 and 11, the patient was considered ill and if the score was over 11 the patient was considered severely ill.

The study was approved by the Ethics Committee and by the French Medicines Agency. The clinical trial reference of this study is: NCT01065909. Further details about the study have been provided in previously published papers [12,13].

2.1. *Statistical analyzes*

Qualitative variables and ordinal variables are presented in distribution of percentage and numbers. Quantitative variables are described as the mean, standard deviation and median.

Analyzes were performed with SAS software.

The characteristics at inclusion were presented and compared to the published results from other studies involving elderly diabetic patients. These publications were selected based on the search criteria in PubMed: elderly or older; diabetes in the title and/or abstract. The search was restricted with the filter publication dates from the twenty-first century in the English language on human species. Clinical trials were excluded. Articles were selected based on their title and abstract. Common data were sought and classified.

3. Results

Overall 213 primary care practitioners agreed to participate (170 men and 43 women) and included 983 patients (47% women); 86% of patients were recruited by male physicians. On average, the physicians were aged 50 ± 7 years and had been practicing for over twenty years; 41% worked alone and 53% were based in an urban area.

At inclusion, the average age of patients was 76.7 ± 5.9 years with 29.5% under 75. Half were women. The diabetes had been evolving for 11.3 ± 8.3 years on average. Overall 161 patients (17%) had a bachelor's degree or higher level of education. A third of the study population (N = 306) lived alone at home. Past or present tobacco consumption was relevant to 30% of patients, of whom 4% were still active smokers, and 30% also regularly consumed alcohol.

Concerning health status, 22% of the patients were estimated as presenting with a physiological age lower than their chronological age, 70% equal to it and 8% above it. According to the global health score, almost nine in ten patients were in good health (87.4%), 9.1% were ill and 3.5% severely ill.

The patients' baseline clinical parameters are presented in Table 1.

Table 1 – Clinical parameters at inclusion, N = 983.

	Mean ± SD	Median (interquartile range Q1–Q3)	Missing data
Age (years)	76.7 ± 5.9	77.0 (73–80)	–
Weight (kg)	77.5 ± 15	76.0 (68–86)	13 (1%)
Body mass index (kg/m^2)	28.9 ± 4.9	28.2 (25.4–31.5)	39 (4%)
Waist circumference (cm)	102.0 ± 13	102.0 (94–110)	223 (23%)
Duration of diabetes (years)	11.3 ± 8.7	9.5 (5–15)	12 (1%)
SBP sitting (mmHg)	135.2 ± 11.9	135.0 (130–140)	7 (1%)
SBP standing (mmHg)	134.4 ± 11.7	130.0 (130–140)	102 (10%)
DBP sitting (mmHg)	76.4 ± 7.6	80.0 (70–80)	7 (1%)
DBP standing (mmHg)	76.9 ± 7.5	80.0 (70–80)	102 (10%)
Heart rate (min^{-1})	71.6 ± 8.7	72.0 (67–76)	17 (2%)
HbA1c (%)	6.9 ± 1	6.7 (6.3–6.7)	46 (5%)
GFR MDRD (mL/min/1.73 m^2) [18]	69 ± 21	68 (55–81)	264 (27%)
GFR CKD-epi (mL/min/1.73 m^2) [19]	67 ± 18	68 (55–82)	264 (27%)
HDL (g/l)	0.5 ± 0.2	0.5 (0.4–0.6)	234 (24%)
LDL (g/l)	1.0 ± 0.3	1.0 (0.81–1.2)	238 (24%)

Most of the recruited patients were living independently (85.6% had a normal ADL score) and more than a third presented with moderately impaired cognitive functions (MMSE [10–27]). Only 12.5% had home assistance (Table S1) and 8% at least one daily visit from a healthcare provider.

Supplementary Table S1 related to this article can be found, in the online version, at http://dx.doi.org/10.1016/j.pcd.2014.07.004.

Mean glycated hemoglobin (HbA1c) was 6.9% ± 1 (Fig. S1) at inclusion.

Supplementary Fig. S1 related to this article can be found, in the online version, at http://dx.doi.org/10.1016/j.pcd.2014.07.004.

Table 2 details the micro and macrovascular complications of T2DM, as well as the major medical history of the participating patients. In the year prior to inclusion, 18 patients (2%) experienced at least one severe hypoglycemic episode (<0.6 g/l glucose, which necessitated outside assistance). Among the patients of the T2DM sub-cohort, 9.6% presented atrial fibrillation and 39.5% chronic pain.

Unstable and stable angina pectoris was observed in 10.8% and 35% of the patients with a history of coronary disease respectively and 30.5% had already experienced at least one myocardial infarction. Cerebrovascular disease was noted in 45 patients, including 16 definitive strokes and 23 transient strokes. Among 112 patients with heart failure, none suffered from NYHA Class IV heart failure, whereas 29%, 54% and 18% presented with NYHA class I, II and III heart failure respectively.

Amongst the patients with a history of cancer, almost nine in ten (88%) were in remission at inclusion.

Sixty seven (7%) patients had chronic obstructive pulmonary diseases and 39 patients (4%) sleep apnea.

On average, patients were taking 6 ± 3 different drugs per day; 69 patients (7%) were taking only one drug but 106 (11%) were taking ten or more different drugs per day. Most patients received cardiovascular drugs, which is not surprising given that most were hypertensive.

Metformin was the most prescribed antidiabetic drug, followed by sulfonylureas and insulin (Table 2). At inclusion, 17 patients were not taking any drug for the treatment of diabetes. Monotherapy with oral antidiabetic drugs (OADs) was prescribed in 44% of patients whilst combined therapy (OAD combinations or oral OADs with insulin) was prescribed in 36% and 12% of patients respectively. Insulin alone or in combination with OAD was prescribed in 18.6% of patients. Amongst patients treated with OADs, metformin was prescribed in 57% and sulfonylureas in 29%.

Capillary blood glucose monitoring was carried out in 48% of patients.

The most effective diabetes management was observed in patients treated with a single OAD, followed by OAD combinations, insulin alone and insulin combined with OADs (Fig. 1).

Three French and one North American cohort have studied diabetes in the elderly (Table 3). These studies have common characteristics relating to elderly diabetic patients and have been conducted in the twenty-first century.

The objective of the GERODIAB study [21] was to evaluate the link between glycemic control and morbidity/mortality. The aim of the Diabetes and Aging study [22] was to evaluate the relationships between baseline HbA1c and subsequent outcomes. The ENTRED study [23] used a French cross-sectional representative survey and aimed to characterize the socio-demographic data, health status and quality of care.

In two cohorts, patients were recruited in medical practice (primary care physicians and specialists). In the two other cohorts, patient data were obtained from registries. The

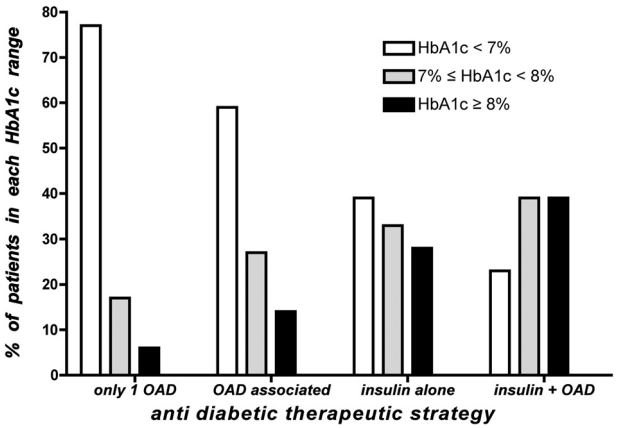

Fig. 1 – Type 2 diabetes management by antidiabetic strategy.

Table 2 – Previous medical history and treatment at inclusion.

	Percentage	Numbers
Related to type 2 diabetes mellitus		
Arterial disease	19.0	185
Coronary event	10.5	102
Cerebrovascular involvement	4.7	45
Peripheral vascular disease of the lower extremities	7.2	70
Infection	2.7	26
Proteinuria	19.7	193
Glomerular filtration rate (ml/min/1.73 m²) MDRD		
Stage I ≥90	14.8	106
Stage II [60–90]	52.4	377
Stage III [30–60]	29.8	214
Stage IV [15–30]	2.6	19
Stage V [0–15]	0.4	3
Dialysis	0.3	3
Ocular complications	14.6	141
Cataract	9.5	92
Retinopathy or blindness	5.4	52
Peripheral neuropathy	7.1	69
Foot wound/amputation	1.2	12
Unrelated to type 2 diabetes mellitus		
Thromboembolic disease	6.3	61
Hypertension	90.0	880
Atrial fibrillation	9.6	94
Heart failure	11.5	112
Dyslipidemia	62.5	610
Falls	6.3	62
Osteoarticular disease[a]	45.2	437
Cancer	13.7	134
Chronic pulmonary disease[b]	10.2	100
History of depression	18.0	176
Treatment at inclusion		
Oral antidiabetic		
Metformin and other biguanides	61.7	607
Sulfonylureas	39.8	391
Repaglinide	11.0	108
Thiazolidinedione	10.6	104
Alpha-glucosidase inhibitors	7.1	70
Dipeptidyl peptidase-4 inhibitors	8.2	81
GLP-1 analogs (Exenatide, Liraglutide)	1.4	14
Insulin	18.3	180
Cardiovascular drugs		
Beta-blockers	32.2	316
Calcium-channel blockers	24.9	245
Diuretics	21.8	214
ACE inhibitors and AT1 receptor antagonists	64.6	635
Statins	45.8	450
Fibrates	6.3	62
Oral anticoagulants	11.0	108
Anti-platelet drugs	36.1	355

[a] Osteoarticular disease = symptomatic arthrosis, hip or knee prosthesis, osteoporosis, inflammatory rheumatic and/or vertebral fracture.
[b] Chronic pulmonary disease = sleep apnea, chronic obstructive pulmonary and/or pulmonary fibrosis.
GLP1 = Glucagon-Like Peptide-1 agonist.
ACE = Angiotensin-converting enzyme.
AT1 = Angiotensin type 1.

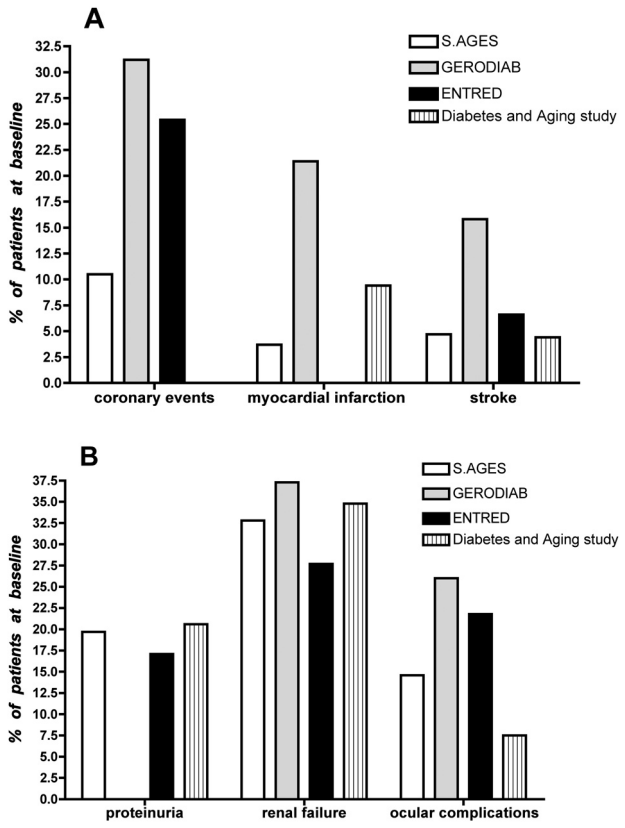

Fig. 2 – Macrovascular and microvascular complications.

observational prospective study GERODIAB [21] recruited a similar number of diabetic patients through diabetologists or gerontologists.

In GEROBIAD, the patients were about the same age as in T2DM SAGES and older than in the Diabetes and Aging study and their average duration of diabetes was longer than in other studies. The diabetes was often less controlled. Patients in the Diabetes and Aging study, however, were younger with a shorter duration and well-controlled diabetes.

In the French cohorts, approximately 40% of patients were treated with oral monotherapy. Metformin was used in between 39% and 54% of patients. In GERODIAB, six in ten patients were treated with insulin. In the other studies, this proportion was between 17.5% and 20.0%.

The proportion of complications is detailed in Fig. 2.

4. Discussion

The aim of our work was to describe the baseline characteristics of non-institutionalized patients aged 65 and over with type 2 diabetes, participating in a cohort study and recruited in primary care practices and to compare these characteristics to those of patients recruited in other cohorts of elderly diabetic subjects.

Only 983 patients were recruited in the T2DM S.AGES subcohort; the rate of inclusions was lower than expected.

As previously reported [12], the geographic distribution of physicians in the study was representative of primary care physicians throughout France: low in the center of the coun-

Table 3 – Baseline characteristics of the patients included in older type 2 diabetic cohorts.

		S.AGES	GERODIAB	ENTRED	Diabetes and Aging study
Year of publication		2009–2011	2009–2010	2007	2004
Country		France	France	France	EU (California)
Recruitment		Primary care provider	Endocrinologist or gerontologist	Registry data	Registry data
Data collection		Medical provider questionnaire	Medical provider questionnaire	Medical provider and patients questionnaire	Registry provider questionnaire
Number of subjects		983	987	1766 983	71,092
Gender (% women)		47.00%	52.1%	45.00%	47.4%
Age					
Mean in years		76.7 ± 5.9	77 ± 5.0		71 ± 7.4
Breakdown	<75 years	29.5%	34.8%		
	Between 75 and 80 years	40.0%	36.7%		
	>80 years	30.5%	28.5%		14.6%
Education		17.0% higher education	12.7% higher education	10% higher education	
Duration of diabetes (years)					
Mean		11.3	18		8.3
<5 years		24.7%	10.6%	20%	43%
Between 5 and 10 years		28.5%	14.2%	20%	24.1%
Between 10 and 19 years		32.6%	37.2%	32%	23.2%
>20 years		14.2%	38.0%	28%	9.7%
Past or present tobacco consumption		30.0%	35.8%		
HbA1c %		6.9%	7.5%	7.1%	7.00%
BMI	Mean	29	30		
kg/m^2	>30	34.8%	48.5%	34.9%	
DFG MDRD < 60 ml/min/1.73 m^2		32.8%	37.3%	27.7%	34.8%
Strategy of treatment					
1 OAD		44.8%	39.3%	40.0%	
>1 OAD		36.5%		34.0%	
OAD + insulin		12.0%	28.9%	10.0%	
Insulin		6.7%	25.4%	10.0%	
Treatment					
Use of insulin		18.3%	57.5%	20.0%	17.5%
Metformin and biguanides		61.7%	48.8%	54.0%	37.7%
Sulfonylureas		39.8%	28.6%	52.0%	50.6%
Repaglinide		11.0%	14.6%	8.0%	0.1%
Thiazolidinedione		10.6%	7.3%	10.0%	9.3%
Alpha-glucosidase inhibitors		7.1%	5.00%	9.0%	0.7%
Dipeptidyl peptidase-4 inhibitors		8.2%	10.00%		
Severe hypoglycemia		1.8% (last twelve months)	3.3% (last six months)		

try and high in the Mediterranean region. The average age of investigators was similar to that of physicians in France (50 years in T2DM S.AGES versus 52 throughout France). Male physicians were overrepresented: 80% in T2DM S.AGES compared to 58% throughout the country [23].

At inclusion, the average age of patients was 76.7 ± 5.9 years with 29.5% under 75. Half of the patients were women. The diabetes had been evolving for eleven years on average and was well controlled. Most patients were living independently (85.6% had normal ADL scores) and presented with no cognitive disorders. These results can be explained by the inclusion criteria. Patients were living at home, were able to give informed consent and had no fatal disease with less than three months life expectancy. As patients had to be non-institutionalized to participate in the study, it is not surprising that their autonomy assessments (ADL and IADL scale) were relatively good. Furthermore, an additional selection bias due to enrollment by physicians, which may have included less severe patients, cannot be ruled out.

Three French and one North American cohort of elderly diabetic patients were identified through a search in Pubmed.

At inclusion, the patients in GERODIAB had more severe diabetes defined by longer duration, poorer control (HbA1c) and higher complications. With the exception of renal failure (i.e. GFR < 60 ml/min/1.73 m^2), for which the proportion of patients was similar in the different cohorts, more patients presented with diabetic complications.

For patients aged 65 years or older, the duration of diabetes was longer in ENTRED than in T2DM S.AGES. The control of diabetes was similar compared to T2DM S.AGES. Similar microvascular complications, neuropathy, renal failure and proteinuria were observed in T2DM S.AGES and ENTRED patients: approximately two in ten patients. In macrovascular complications, T2DM S.AGES patients presented with fewer coronary events whereas cerebrovascular events were in similar proportions.

While patients in the Diabetes and Aging study were younger with shorter duration and similar control of diabetes compared to T2DM S.AGES patients, they presented with few complications, giving similar rates of stroke, myocardial infarction and proteinuria compared to T2DM S.AGES patients.

In summary, the results of different studies conducted in non-institutionalized elderly diabetic patients are consistent. Increased complications are associated with age and disease duration, as recently observed in the follow-up of the Diabetes and Aging cohort [24].

In the three French cohorts, the proportion of patients treated with oral monotherapy was similar. The first-line oral treatment of diabetes was metformin, which was used alone or in combination. The proportion of patients treated with sulfonylurea was greater in ENTRED. In addition, the percentage of patients treated with insulin was different and far larger in GERODIAB compared to T2DM S.AGES and ENTRED. This could explain the difference observed between T2DM S.AGES and GERODIAB in severe hypoglycemia. In the Diabetes and Aging study, the percentage of patients treated with insulin was similar but the first-line oral treatment was sulfonylurea instead of metformin. Changing diabetes management guidelines over the last decade, the time needed to introduce them in clinical practice and the discrepancies between countries could explain the different uses of sulfonylurea in cohorts.

Antidiabetic therapeutics seemed mainly to follow recent international guidelines [25]. As discussed above, the use of insulin increases with worsening control of diabetes, longer disease duration and higher rate of complication.

The T2DM S.AGES study has some limitations. The study patients seem to have a low rate of diabetic complications and their diabetes appears to be extremely well managed based on their HbA1c level. There might be a selection bias due to enrollment by primary care providers (versus endocrinologists or gerontologists), which may have included less severe diabetic patients. Furthermore, additional patient selection may have occurred by recruiting non-institutionalized patients with no cognitive impairment, allowing them to understand the goals of the study and sign the informed consent form. Therefore, physicians did not give all their diabetic patients the opportunity to participate in the study.

However, the results presented here are consistent with those obtained in other European and North American cohorts of elderly diabetic patients. It is likely that older diabetics in France are somewhere between those of T2DM S.AGES (with less severe diabetes) and GERODIAB (with more severe diabetes), although ENTRED is the most representative as the data are derived from reimbursement databases.

S.AGES is one of the few cohorts making it possible to study the medical and paramedical management of elderly patients with common conditions such as diabetes. A special feature of this study was its conduct in primary care with recruitment by primary care providers, who are the main healthcare providers to elderly patients. Three-year follow-up is planned, which may identify new interactions. It is intended as a first step in studying the risk factors for hospitalization, management of elderly patients and major clinical events in diabetes.

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Ethical approval

The study was approved by the Ethics Committee and by the French Drug Agency. The clinical trial reference of this study is: NCT01065909.

Conflict of interest

Sophie Bucher, Benattar-Zibi L, Delespierre T, Ourabah R, Piedvache C and Ringa V have no conflict of interest.

Bauduceau B received consulting fees from Sanofi-Aventis, Bristol-Myers Squibb, Merck Sharp and Dohme, Roche and Novo Nordisk.

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