Available online at
SciVerse ScienceDirect
www.sciencedirect.com

Elsevier Masson France
EM|consulte
www.em-consulte.com/en

Diabetes & Metabolism 38 (2012) 523–530

Original article

GERODIAB: Glycaemic control and 5-year morbidity/mortality of type 2 diabetic patients aged 70 years and older: 1. Description of the population at inclusion

J. Doucet [a,*], J.-P. Le Floch [b], B. Bauduceau [c], C. Verny [d], the SFD/SFGG Intergroup

[a] *Service de médecine interne gériatrie thérapeutique, hôpital Saint-Julien, Rouen University, CHU de Rouen, 76031 Rouen cedex, France*
[b] *Service de diabétologie-endocrinologie, clinique médicale de Villecresnes, 8, boulevard Richerand, 94440 Villecresnes, France*
[c] *Service d'endocrinologie, hôpital Bégin, 69, avenue de Paris, 94160 Saint-Mandé, France*
[d] *Service de gérontologie, CHU de Bicêtre, 12, rue Séverine, 94276 Le Kremlin-Bicêtre cedex, France*

Received 17 April 2012; received in revised form 6 July 2012; accepted 6 July 2012

Abstract

Aims. – The GERODIAB study is the first French multicentre, prospective, observational study that aims, through a 5-year cohort follow-up, to evaluate the link between glycaemic control and morbidity/mortality of type 2 diabetic (T2D) patients aged 70 years and older. This first report describes the study population at inclusion.

Patients and methods. – A total of 987 T2D autonomous patients, aged ≥ 70 years, were recruited between June 2009 and July 2010 at 56 investigator centres. Their general parameters, diabetes characteristics and standard geriatric parameters were recorded.

Results. – The patients' mean age was 77 ± 5 years, with 65.2% aged 75 years or more. The mean BMI was close to 30 kg/m^2. Hypertension was found in 89.7% of patients, and 85.0% had at least one cholesterol abnormality. The mean duration of the diabetes was around 18 years, and the mean HbA_{1c} level was about 7.5%. During the previous six months, 33.6% of patients had experienced one or several hypoglycaemias. Also, 26% of patients presented with diabetic retinopathy, 37.3% had a GFR < 60 mL/min, 31.2% had coronary insufficiency, 10.1% had heart failure, 15.8% had cerebrovascular involvement and 25.6% had peripheral vascular disease of the lower extremities. In addition, 30.5% of patients had orthostatic hypotension, 12.4% had malnutrition and 28.8% had cognitive impairment, all of which were often diagnosed at inclusion. Three-quarters of patients were taking an oral antidiabetic drug and nearly six in every 10 patients were using insulin.

Conclusion. – This population can be considered representative of elderly, autonomous T2D patients, and its follow-up should clarify the link between glycaemic control and mortality/morbidity.

Keywords: Type 2 diabetes; Elderly patients; Geriatric tests; Cohort; Mortality; Morbidity; Epidemiology; GERODIAB

Résumé

GERODIAB : équilibre glycémique et morbi-mortalité à cinq ans des diabétiques de type 2 de 70 ans et plus : 1. Description de la population à l'inclusion.

L'étude GERODIAB est la première étude multicentrique française observationnelle prospective de suivi de cohorte dont l'objectif est d'évaluer le lien entre l'équilibre glycémique et la morbi-mortalité à cinq ans de diabétiques de type 2 de 70 ans et plus. Ce premier rapport décrit la population à l'inclusion.

Patients et méthodes. – Neuf cent quatre-vingt-sept patients diabétiques de type 2 âgés de 70 ans et plus, autonomes, ont été inclus de juin 2009 à juillet 2010 dans 56 centres investigateurs. Les paramètres généraux, les caractéristiques du diabète et les paramètres gériatriques habituels ont été enregistrés.

Résultats. – L'âge moyen était de 77 ± 5 ans et 65,2 % des patients avaient 75 ans ou plus. L'IMC moyen était proche de 30 kg/m^2. Une HTA était notée chez 89,7 % des patients et 85,0 % avaient au moins une anomalie du cholestérol. La durée moyenne d'évolution du diabète était proche de 18 ans. Le taux moyen d'HbA_{1c} était proche de 7,5 %. Au cours du semestre précédant l'inclusion, 33,6 % des patients avaient eu une ou

* Corresponding author. Tel.: +33 2 32 88 65 52; fax: +33 2 32 88 68 64.
E-mail address: jean.doucet@chu-rouen.fr (J. Doucet).

1262-3636/$ – see front matter © 2012 Elsevier Masson SAS. All rights reserved.
http://dx.doi.org/10.1016/j.diabet.2012.07.001

plusieurs hypoglycémies. Vingt-six pour cent des patients présentaient une rétinopathie diabétique, 37,3 % avaient un DFG estimé inférieur à 60 ml par minute, 31,2 % avaient une insuffisance coronarienne, 10,1 % une insuffisance cardiaque, 15,8 % une atteinte cérébrovasculaire et 25,6 % une artériopathie oblitérante des membres inférieurs. Parmi les patients, 30,5 % avaient une hypotension orthostatique, 12,4 % une dénutrition protéino-énergétique et 28,8 % avaient une altération cognitive souvent diagnostiquée à l'inclusion. Trois quarts des patients recevaient un médicament antidiabétique oral et près de six sur dix de l'insuline.

Conclusion. – La population étudiée peut être considérée comme représentative des patients diabétiques de type 2 âgés autonomes. Son suivi pendant cinq ans devrait permettre de préciser le lien entre l'équilibre glycémique et la morbi-mortalité.

Mots clés : Diabète de type 2 ; Patients âgés ; Évaluation gériatrique ; Cohorte ; Morbi-mortalité ; Épidémiologie ; GERODIAB

1. Introduction

The prevalence of diabetes in the elderly is growing due to increases in both life expectancy and incidence of diabetes in the general population [1–3]. Compared with younger diabetic patients, the consequences of diabetes and ageing accumulate in the elderly, and exacerbate degenerative complications and the effects of co-morbidities [4,5]. Elderly diabetic patients also constitute a heterogeneous population that cannot be compared with younger diabetic patients and requires 'individualized' management [6,7].

Most studies that have demonstrated the effects of glycaemic control on the morbidity/mortality of diabetes were conducted in diabetic patients < 70 years of age [8–12]. There is therefore no clear evidence that elderly and younger diabetic patients should all share the same therapeutic targets [13,14], and recent studies of the potential risks of glycaemic control intensification have added further doubts [15–18]. Thus, it has yet to be determined whether glycaemic control in elderly diabetic patients plays a role not only in the acute and degenerative complications of diabetes, but also in the classical geriatric parameters used to evaluate risk factors for decreased autonomy [7,19,20].

The GERODIAB study is the first multicentre, prospective, observational study that aims, through a 5-year cohort follow-up, to evaluate the link between glycaemic control and the morbidity/mortality of type 2 diabetes (T2D) patients aged ≥ 70 years in France. The objective of this first report is to describe the study population at inclusion.

2. Patients and methods

T2D patients aged ≥ 70 years were included in the study irrespective of their treatment (for insulin-treated diabetic patients, the time between the diagnosis of diabetes and initiation of insulin therapy was at least 2 years). Diabetes had to have been diagnosed for at least 1 year, and the patients had to have sufficient autonomy, as defined by a score ≥ 3 out of 6 on the Activities of Daily Living (ADL) scale. They also all had to be available for follow-up on an outpatients basis for the next 5 years, and should all have agreed to participate in the study after being fully informed of the risks and benefits.

The reasons for patient exclusion included the presence of type 1 diabetes or secondary diabetes, loss of autonomy (ADL score < 3/6), acute disease stage (transitory exclusion criterion) and refusal to participate in the study.

The primary endpoint of the study was the 5-year mortality in two patient subgroups compared according to their mean HbA_{1c} levels over 5 years, using survival curves for those less than vs greater than, or equal to, 7.5% [21,22]. The secondary endpoint analyses included comparisons of the survival curves for each HbA_{1c} subgroup, investigation of an optimal threshold and the influence of other individual parameters on mortality, as well as diabetes complications or worsening of geriatric functional assessment tests.

The number of subjects to be included was evaluated according to the primary endpoint, using a log-rank model with an estimated 20% mortality at 5 years in well-controlled diabetic patients, a risk ratio of 1.5 in poorly controlled diabetic patients with quarterly follow-up, a 5% α risk and 90% power [22–24]. Furthermore, the population had to be a representative sample able to describe events with sufficient accuracy (< 5%). For this reason, a sample of 900 to 1000 patients, representing about 0.5% of diabetic patients aged 70 years or older, was selected. Information on the study was sent to members of the SFD (French-Speaking Diabetes Society) and the SFGG (French Society of Gerontology and Geriatrics). After a feasibility study and stratification according to geographical distribution, 56 centres were randomly selected for the study (Fig. S1; see supplementary material associated with this article online).

These centres were part of a network of diabetes/geriatric clinicians throughout the country, with each including a physician investigator and one or several physician co-investigators (with a total of 163 investigators and co-investigators). To maintain homogeneity and feasibility, only metropolitan centres were selected.

Each centre was initially asked to include between 10 and 30 patients (20 on average). Inclusion was systematically proposed to patients meeting the inclusion criteria in the sequential order in which they were seen as outpatients until the allocated number of subjects for each centre was reached. As some centres had difficulty in recruiting, other centres were authorized to include up to 40 patients to compensate.

At inclusion, three types of information were recorded to serve as a basis for comparisons throughout the follow-up:

- general parameters, including demographic data, socioeconomic level and cardiovascular risk factors;
- diabetes characteristics, such as time since diagnosis, glycaemic control, and treatment and specific complications of diabetes preexisting at inclusion or found during the initial