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Factors associated with Prolonged Inaction in the hypoglycaemic treatment in people with non-insulin dependent Type 2 Diabetes and elevated glycated haemoglobin: A registry-based cohort study

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ABSTRACT

Aims: To assess factors associated with Prolonged Inaction (PI) in insulin-naïve patients with Type 2 Diabetes Mellitus (T2DM). PI was defined as the absence of treatment initiation or intensification for ≥12 months despite HbA1c >7% (53 mmol/mol).

Methods: A retrospective cohort study was conducted based on data from Intego, a Flemish General Practice registry. The study period ranged from January 1, 2006 to December 31, 2013. Patients with insulin therapy before the start of the study period were excluded from the analysis. A mixed effects logistic regression was used to assess the association of PI with the presence of co-morbidities, co-medications, process parameters and bio-clinical parameters.

Results: In a population of 2265 patients with T2DM, 578 insulin-naive patients presented with an HbA1c >7% (53 mmol/mol) for ≥12 months. Median follow-up was 1.2 years, median age 67 years, 55% were male. PI was present in 340 patients (59%) and associated with moderate to severe Chronic Kidney Disease, absence of a mental health disorder, less frequent HbA1c measurements, lower HbA1c values and a smaller number of co-medications.

Conclusions: PI is highly prevalent in primary care, particularly in patients with less complex disease status and with less intensive follow-up.

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1. Introduction

Clinical Inertia (CI) was defined in 2001 as a failure to initiate or intensify a treatment when indicated: "*recognition of the problem, but failure to act*" [1]. This definition is articulated on the definition of "quality of care", expressed by the Institute of Medicine: "*The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."(Institute of Medicine (U.S.). Committee on Quality of Health Care in America. 2001 #303)* and may be considered as a clinical error [2,3].

CI arises from the comparison between 'real' and 'best' practices and can only be identified if three additional conditions are present according to well-documented clinical guidelines: (1) the presence of evidence-based and measurable targets; (2) the presence of an evidence-based and measurable therapy; (3) a time window for initiation or intensification of treatment [2,3].

CI is associated both with preventable medical consequences for patients, and with a high economic burden in terms of national health care expenditure [4,5] T2DM is a progressive disease with deteriorating glycaemic (HbA1c) levels. The natural history of the disease imposes regular and stepwise treatment intensification in order to maintain HbA1c-levels under the treatment target. As to the treatment, guidelines recommend metformin as first-line therapy. Additional oral anti-diabetics and/or injectable incretin mimetics and/or insulin therapy are recommended if the HbA1c-level exceeds the defined target.

CI is widely prevalent and includes patients in all treatment phases [6]. Barriers for necessary treatment intensification have previously been studied and are divided into those related to the provider (knowledge, attitude, clinical judgement), those related to the patient (compliance, health literacy, medication side effects, preferences) and those related to the health system (costs, reimbursement systems, availability of guidelines, decision support). These factors should be considered together – rather than separately – as a complex and cumulative pattern of barriers [7].

The treatment target for HbA1c levels was previously set at 7% (53 mmol/mol). However, recent guidelines indicate a window for individual adaption related to additional factors such as co-morbidity, age, compliance, diabetes duration, diabetes complications and financial resources [8].

Moreover, Aujoulat et al. added an important element to the debate on CI, i.e. the difference between 'true CI' and 'apparent CI' [9]: in complex clinical situations, e.g. in patients with co-morbidities, elderly patients, patients who are already on a number of medications, inaction may to some extent be more appropriate than intensifying treatment. Their study emphasized the need to aggregate all treatment-related information, including justification of treatment choices, in order to understand the modifiable and non-modifiable factors of CI. The term 'apparent CI' may be misleading, because CI is per definition 'true', namely the failure to intensify the treatment *if indicated*. However, it is reasonable to introduce the distinction between unjustified inaction – ('true') CI – and justified inaction—'apparent CI'.

The evaluation of "real practice" in primary care is preferentially based on routinely collected data. Including general practitioners in a prospective cohort study risks to induce a Hawthorne effect, to alter GPs attitude and thus to bias the results. Ongoing General Practice Morbidity registers such as Intego dealing with routinely collected data are excellent tools for evaluating real practices. However, in these registries, it is not possible to make the distinction between 'justified' and 'unjustified' inaction. It is yet possible to picture 'inaction'. Therefore we introduced the concept of 'Prolonged Inaction' (PI). PI was defined as the absence of treatment adjustments (no start/addition of a new non-insulin medication, no start of insulin treatment) in spite of indications based on patients' HbA1c values, i.e. the presence of HbA1c >7% (53 mmol/mol) for a period of ≥1 year.

The concept of PI allows investigators to analyse routinely collected data and to bring into picture objective conditions that are associated with PI. To our knowledge, little research has focused on non-behavioural patient factors associated with the lack of hypoglycaemic treatment intensification in patients with T2DM.

We conducted a retrospective cohort study in patients with T2DM on non-insulin glucose-lowering therapies in order to assess the occurrence of PI in these patients and to evaluate factors associated with PI. More precisely the presence of co-morbidity, co-medication, process parameters and bio-clinical parameters

2. Subjects, materials and methods

2.1. Study design

Data were obtained from Intego, a Flemish general practice-based morbidity registration network at the Department of General Practice of the University of Leuven [10]. One hundred and eleven general practitioners (GPs), all using Medidoc software (Corilus NV, Aalter, Belgium), collaborated in the Intego project. They work in 48 practices evenly spread over Flanders, Belgium. GPs applied for inclusion in the registry. Before acceptance of their data, registration performance was audited using a number of algorithms that compared their results with those of all other applicants. Only the data of the practices with an adequate registration performance were included in the database. The Intego GPs prospectively and routinely registered all new diagnoses, new drug prescriptions, as well as laboratory test results and some background information (including gender and year of birth), using computer-generated keywords internally linked to codes; new data were encrypted with especially framed extraction software; collected from the GPs' personal computers and entered into a central database. Registered data were continuously updated and historically accumulated for each patient. New diagnoses were classified according to a very detailed thesaurus automatically linked to the International Classification of Primary Care (ICPC-2) and International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10). Drugs were classified according to the WHO's Anatomical Therapeutic Chemical (ATC) classification system.

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