NORDIC LONGITUDINAL DATA FROM ELECTRONIC MEDICAL RECORDS AND FULL POPULATION NATIONAL REGISTERS: UNIQUE OPPORTUNITIES FOR NEW INSIGHTS IN BENEFIT OF DIABETES PATIENTS

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OBJECTIVES

Detailed data on type 2 diabetes mellitus (T2DM) patients and treatment in clinical practice are scarce. The Nordic region offers unique opportunities for research on patient-level data from various complementary data sources, by utilizing the homogenous public healthcare systems with clinical information registered in electronic medical records (EMR) and mandatory national registers, and data linkage using the unique personal identification numbers.

This paper describes the implementation of a novel research methodology utilized in the Nordic countries to provide new T2DM insights based on a hybrid utilization of retrospectively collected EMR- and nationwide health register data to support an ongoing global non-interventional study describing T2DM disease reality, the DISCOVER program (NCT02322762).

The aim of the study is to describe patient characteristics when initiated on second-line glucoselowering treatment and to follow them up for three years, see DISCOVER study fact box.

METHODS

To enhance the data coverage and to obtain a 360 degree view of T2DM patients, additional secondary data collection is included in the DISCOVER Nordic study utilizing the unique and mandatory personal identification number (PIN) given at birth in the Nordic countries: Sweden, Norway, Denmark and Finland.1

Prospective cohort

As part of the worldwide DISCOVER study,2 the Nordic region is represented by three countries (Sweden, Norway and Denmark) involving a representative selection of approximately 70 primary care sites. Of the planned 15,000 patients worldwide, the Nordic region will contribute with at least 500 T2DM patients (Figure 1, upper pyramid segment) in the prospective cohort.

In addition to the prospective data collection, additional EMR data from the enrolled T2DM patients will be extracted in parallel by using the Pygargus Customized eXtraction Program (CXP), previously validated to adequately extract patient-level data.3 CXP provides robust, study-specific data including both structured and unstructured EMR data such as patient demographics, diagnoses, clinical notes, laboratory results, health care contacts and referrals. Using the unique PINs, data from all extracted patients identified in primary care will be linked with nationwide patient-, cause of death- and prescribed drug registers to obtain complete data on hospital care and detailed drug use.

To further facilitate prospective data collection completeness, electronic Case Report Forms (eCRFs) integrated in the EMRs can utilize EMR alerts for the enrolled patients to capture specific patient reported variables upon routine primary care visits (e.g. body weight and HbA1c).

Secondary data cohort – integrated EMR and national registry data

For the secondary cohort data collection, EMR patient level data from all T2DM patients at the included primary care sites will be extracted using the CXP tool as described above, and linked with the nationwide patient-, cause of death- and prescribed drug registers to obtain complete data (Figure 1, middle pyramid segment). This data collection method has previously been described and used in study T2DM registries in Sweden.4 Estimated number of T2DM patients included in the participating Nordic countries: 30,000.

Nordic nationwide registry data

In addition to the Nordic DISCOVER data collection described above, a separate full T2DM population based cohort will be extracted from the nationwide health care registries present in all Nordic countries - Sweden, Denmark, Norway and Finland (Figure 1, lower pyramid segment). As for the secondary data collection, this methodology has previously been utilized to describe T2DM disease and its treatment in Sweden.5 Estimated number of patients from the participating Nordic countries: >1 million.

RESULTS

This approach, bridging data from the enrolled T2DM patients in DISCOVER study to existing high quality health care registries, will generate extended observational data with high internal and external validity from approximately 1 million patients diagnosed with T2DM.

Details on the level of granularity for each extraction method, the non-interventional-, primary care- and nationwide data collection, respectively, is presented in Table 1. By utilizing iterative data collection spanning several years (2015 – 2017), interim analyses will be performed to provide contemporary, up-to-date insights of the disease progression and treatment development of patients with type 2 diabetes in the Nordic countries, Figure 2.

The treatment of diabetes is now changing fast, caused by recent introduction of several new drug classes and new important study results. This demonstrates the importance of iterative data collection to truly understand the modern development of treatment and disease.

CONCLUSIONS

This novel methodology presents a new era for observational research, providing efficient ways of generating comprehensive data with high completeness and minimal interference with ordinary clinical practice. By integrating the wealth of existing data, an enriched prospective study design can greatly increase the amount of information available and provide a 360 degrees view of the target population. This is highly relevant for diabetes but may also provide an important tool in the study of other diseases.

REFERENCES