

Epidemiological aspects of diabetes mellitus and diabetes-related eye complications in Hungary

PhD thesis

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Budapest
2021

1. Introduction

The prevalence of diabetes mellitus (DM) and diabetic retinopathy (DR) is rapidly increasing worldwide. It is estimated that in 2015, 415 million people in the world had DM, and that number will increase to 642 million by 2040. It was reported in 2015 that 52 million persons are living with DM in Europe, an average prevalence of 9.1%. Prevalence of DM is growing continuously worldwide due to the aging of the population and increasing rate of obesity.

The prevalence of DR is estimated to be 34.6% in people with DM and DR is responsible for 1.0–4.8% of blindness globally. It is one of the leading causes of blindness among middle-aged persons in developed countries.

With screening programs, regular control of DM and timely treatment of DR, visual impairment and blindness due to DM and its complications can largely be prevented. VISION 2020: the Right to Sight and, the more recent initiative, the World Health Organization (WHO) Global Action Plan 2014–2019 are global initiatives to eliminate avoidable blindness by the year 2020. The first step in achieving this target among persons with DM is to obtain baseline data on the prevalence of DM, DR, and ophthalmological status of patients with DM for planning and monitoring eye care programs. For this reason, a population-based survey is needed to estimate both the prevalence and pattern of DM and DR. Population-based surveys on DM and DR are rare because it is thought that data collection is difficult and expensive.

The rapid assessment of avoidable blindness (RAAB) is a quick and efficient population-based survey technique to estimate the prevalence and causes of blindness among people aged 50 years and older in a defined geographic area. Estimation of prevalence of DM and DR is possible with the optional diabetic retinopathy module (DRM).

2. Objectives

The objective of our research was to survey the epidemiological aspects of DM and diabetes-related eye complications using the standardized RAAB + DRM methodology in Hungary. In order to achieve this objective, the aims of the present study were:

1. To estimate the prevalence of DM, DR and diabetes-related blindness in persons aged 50 years and older in Hungary.
2. To estimate the prevalence of DM in the adult population of Hungary.
3. To analyse a special subgroup of survey participants whose random blood glucose was found to be between 140-200 mg/dl.

3. Methods

Rapid assessment of avoidable blindness

The RAAB + DRM survey was conducted by Semmelweis University in Hungary between April and July 2015.

Training

Prior to the fieldwork, the participating doctors (senior residents or specialized ophthalmologist) were trained in the use of the binocular indirect ophthalmoscope. The five teams, each consisting of one doctor, one nurse, and one assistant were trained for 5 days in the use of the eye examination protocol, blood sugar testing, grading of DR according to the Scottish DR grading scheme, and uploading data to the RAAB software.

Sampling

A sample size of 3675 individuals, corresponding to 105 clusters of 35 people, was calculated with RAAB software version 6 (ICEH, LSHTM, London, United Kingdom), based on an expected prevalence of blindness of 2.5% among people aged 50 years and older, with a variation of 25%, confidence level of 95%, and an estimated non-response rate of 10%. The Hungarian Central Statistical Office has used the RAAB algorithm to randomly select 105 census enumeration areas from the list of all enumeration areas of the 2011 population census in Hungary with a probability proportional to size to ensure a representative sample. It also provided the corresponding maps for each selected enumeration area. The teams then selected 35 residents aged 50 years or older within each selected enumeration area, using the compact segment sampling method.

Both for the clinical examination of RAAB as well as for the DR grading, inter-observer variation assessment tests were conducted until a required agreement was achieved (Kappa at least 0.75).

Each survey team went from house to house in the selected enumeration area until 35 eligible residents were examined using the standard RAAB + DRM protocol. People who were still unavailable after two visits were considered non-responders, and neighbors were asked about the status of non-responders.

Diabetes mellitus and diabetic retinopathy in people aged 50 years and older

All participants underwent a finger-prick random blood glucose test, using a digital glucometer (Dcont[®] Trend, 77 Elektronika Kft., Hungary). They were considered as having DM if they were previously diagnosed with DM, if they took medicine for DM, or if their actual blood glucose test showed a glucose level higher than 200 mg/dl (11.1 mmol/l).

Participants with known DM diagnosis were asked about their last fundus examination for DR. All participants with DM who agreed underwent a dilated fundus examination to assess presence and grade of DR with a portable indirect ophthalmoscope. DR was graded according to the Scottish DR grading system.

Diabetes mellitus in people aged 18 years and older

To estimate the number of people with DM in the adult population, the results of the Hungarian RAAB + DRM survey was used. The estimation of the number of people with DM between the ages of 18 and 49 years was carried out using the DM age distribution of a recently published survey by Domján et al. The estimated number of adult people with DM (DM) was calculated as follows:

$$\mathbf{DM} = [\mathbf{Pop}_{\geq 50;2015} \times (\mathbf{Pre}_{\text{Tóth};\geq 50} / 100)] / [(100 - \mathbf{Rat}_{>18 \text{ and } <50;2012}) / 100]$$

where $\text{Pop}_{\geq 50;2015}$ is the population of people aged 50 years or older in Hungary in 2015, $\text{Pre}_{\text{Tóth};\geq 50}$ is the age- and sex-adjusted DM prevalence according to Tóth et al. (19.3%) in persons aged 50 years or older in Hungary, and $\text{Rat}_{>18 \text{ and } <50;2012}$ represents 10.1% of all DM prevalence rates found in 2012 according to Domján et al. among people between the ages of 18 and 50 years in Hungary.

Statistical analysis

RAAB 6 software was used for the standard statistical analysis. It allows data entry, validation of data, sample size calculation, and standardized data analysis. The prevalence estimates provide 95% confidence intervals for cluster sampling. Statistica 11.0 (StatSoft Inc., Tulsa, OK, USA) and Chi-square test was used for more detailed analysis of DM and DR data. P values <0.05 were considered statistically significant.

4. Results

Study population

In total, 3675 people aged 50 years or older were included in the RAAB + DRM survey, of whom 3523 (95.9%) were examined (1273 males and 2250 females).

Diabetes mellitus in people aged 50 years and older

Of the 3523 examined persons, 705 had DM (known or new), thus prevalence of DM in people aged 50 years and older was 20.0% (95% CI: 18.5 to 21.5). There were 661 known cases (93.8%) and 44 new cases (6.2%). There was no significant difference in DM prevalence by gender. Among known diabetic participants, the mean duration of diabetes was 11.0 years [standard deviation (SD) 10.0 years]. Prevalence of DM was the lowest between 50-59 year-old participants and increased with age.

The age- and sex-adjusted prevalence of DM was estimated to be 19.3% in the population aged 50 years or older in Hungary.

Diabetic retinopathy in people aged 50 years and older

Of the participants with known DM, 302 (45.7%) had an ophthalmological examination for DR once during the past 12 months, 66 (10.0%) 13–24 months ago, 112 (16.9%) more than 24 months ago, and 181 (27.4%) had never had an eye examination.

Of the 705 participants who had DM (known and new cases), 561 (79.6%) agreed to have a fundus examination. Among them, 142 [20.1% (16.4 to 23.9)] showed any sign of retinopathy, and 56 [7.9% (5.7 to 10.2)] showed any sign of diabetic maculopathy (DMP). The remaining 144 participants (20.4%) did not agree to pupil dilatation and fundus examination. Prevalence of any DR and/or DMP was 20.7% (16.9 to 24.5). Prevalence of DR and/or

DMP was a slightly higher among males in every age group, but the difference was never significant. Prevalence of DR was 4.0% (3.3–4.8) among all participants.

Sight-threatening DR [STDR; R4 (proliferative retinopathy) and/or M2 (referable maculopathy)] was seen in 30 [(4.3% (2.8 to 5.8)] patients with DM. Prevalence of STDR was 0.9% (0.5–1.2) among all participants. Two (0.3%) participants with DM were blind due to DM [Pinhole corrected visual acuity (PCVA) <3/60] and 10 (1.4%) patients with DM had any visual impairment (PCVA <6/18 and \geq 3/60).

Diabetes mellitus in people aged 18 years and older

Based on our results and considering the earlier published Hungarian DM age distribution data by Domján et al., the number of people with DM was estimated to be 807885, and the DM prevalence was 9.9% in the adult population of Hungary.

People with random blood glucose level between 140-200 mg/dl

Among participants without DM, 322 (9.1%) had a blood glucose level \geq 140 mg/dl and < 200 mg/dl. The possible number of such prediabetic patients in the Hungarian population was 380920 persons, with a 4.3% prevalence.

5. Conclusions

- The current thesis sought to estimate the prevalence of DM and diabetes-related eye complications in Hungary:
- The estimated prevalence of DM was in line with findings of other RAAB+DM surveys and slightly lower than those recently published for the adult population of Hungary. However, if we extend our estimation, prevalence of undiagnosed DM may be higher and thus prevalence of DM may reach a higher value, even up to 14.2%.
- Prevalence of DR in people aged older than 50 years was slightly lower than expected. Optimizing the availability of eye care would be essential to decrease the high proportion of uncontrolled ophthalmological effects of DM. Primary prevention, as well as collaboration among primary eye care doctors, diabetologists, and ophthalmologists should be intensified to increase eye-fundus screening activity and follow-up of patients to decrease the prevalence of STDR and DR-induced blindness.
- Due to the large number of DM patients, there is an urgent need for the start of a nationwide, well-organized, and financed telemedical eye-screening program.

6. Bibliography of the candidate's publications

Thesis related publications

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