ABSTRACT

Objectives To determine the prevalence of diabetes mellitus (DM), prevalence of diabetic retinopathy (DR) and sight-threatening conditions among persons with DM aged 50 years and older in Sohag governorate in Upper Egypt. Design Population-based, cross-sectional survey using the standardised Rapid Assessment of Avoidable Blindness with the addition of the Diabetic Retinopathy module methodology. Settings Sohag governorate in Egypt where 68 clusters were selected using probability proportional to population size. Households were selected using the compact segment technique. Participants 4078 people aged 50 years and older in 68 clusters were enrolled, of which 4033 participants had their random blood sugar checked and 843 examined for features of DR. Primary and secondary outcomes The prevalence of DM and DR; secondary outcome was the coverage with diabetic eye care. Results The prevalence of DM was 20.9% (95% CI 19.3% to 22.5%). The prevalence in females (23.8%; 95% CI 21.4% to 26.3%) was significantly higher than in males (18.9%; 95% CI 17.1% to 20.7%) (p=0.0001). Only 38.8% of persons diagnosed with diabetes had good control of DM. The prevalence of DR in the sample was 17.9% (95% CI 14.7% to 21.1%). The prevalence in females was higher (18.9%; 95% CI 14.0% to 23.8%) than in males (17.1%; 95% CI 13.0% to 21.2%). Up to 85.3% of study participants have never had eye examination. Sight-threatening DR (R4 and/or M2) was detected in 5.2% (95% CI 3.4% to 7.0%) with only 2.3% having had laser treatment. Conclusion The prevalence of uncontrolled DM in Sohag governorate in Egypt is higher than the national prevalence. There is a high prevalence of sight-threatening retinopathy and/or maculopathy with few people having access to diabetic eye care. A public health approach is needed for health promotion, early detection and management of DR.

INTRODUCTION

Diabetic eye disease stands as the most common microvascular complication of diabetes mellitus (DM), and includes diabetic retinopathy (DR) and diabetic macular oedema (DMO). Proliferative diabetic retinopathy (PDR) is the most common vision-threatening complication of DM, while DMO is the main cause of visual loss among patients with diabetes. Multifactorial interventions are found to be more effective in reducing the risk of developing and progression of DR than targeting the control of one risk factor only like controlling serum glucose, blood pressure or diet.

Estimating the global prevalence of DR—the principal cause of vision loss among working-age adults—is challenging, as there is great diversity in methodologies, variance in the study populations and grading criteria. In 2015, DR was the cause of moderate to severe visual impairment (SVI) in 2.6 million people, with a higher burden among women than men. The global prevalence of DR and DMO for the period of 2015–2019 was 27%. Due to increasing life expectancy of persons living with DM and ageing of the population, the prevalence of DR is expected to increase. Awareness about DR is still insufficient in both developed countries and low and middle-income countries, and it is associated with low socioeconomic status and poor health literacy.

The prevalence of DR in Egypt is understudied and various prevalence estimates are found.
have been provided using diverse methodologies and in different populations studied. For instance, Herman et al. showed that 42% of patients with diabetes in households had retinopathy,19 while a hospital-based study in 2011 in the Egyptian capital, Cairo, showed that DR was found in 20.5% of patients with diabetes.9 The Egyptian Ministry of Health and Population (MOHP) ran the STEPwise household population-based survey of non-communicable diseases in 2005 and 2006, and in 2012, and included Sohag governorate. The prevalence of DM was 16% and 17%, respectively.10 11 In 2019, Egypt ranked ninth among countries with the highest numbers of adults (aged 20–79) with DM, this is expected to shift up to eighth in 2030 and seventh in 2045.12 In 2019, Egypt ranked third among the countries of the Eastern Mediterranean Region (EMR) with a prevalence of DM reaching up to 17.2%.12

Due to the scarcity of population-based data on DR in Egypt generally, and in Sohag governorate specifically one of the least fortunate governorates in the country,13 we chose this study site. The study aimed at determining the prevalence of diabetes, prevalence of DR and sight-threatening conditions among persons with DM aged 50 years and older in Sohag governorate in Upper Egypt. We also sought to estimate access to diabetic care and eye examination in this population with a view to come up with data for planning diabetic eye care services.

**METHODS**

**Study design**

We undertook a population-based, cross-sectional survey following the standardised Rapid Assessment of Avoidable Blindness with the addition of the Diabetic Retinopathy module (RAAB+DR) methodology.14 The prevalence of blindness and cataract services coverage have been reported in separate publication.15

**Sampling and sample size calculation**

Details of the sample size calculation and sampling methodology have been provided elsewhere.14 In brief, we calculated a sample size of 4080 individuals based on an expected prevalence of DR of 4.25%, a precision of 20%, at 95% confidence level, non-compliance rate of 15% and a design effect of 1.6 to compensate for clustering.

**Settings and participants**

We selected 68 clusters using probability proportional to cluster size and selected households using the compact segment technique, where 60 persons aged 50 years and above were enrolled for examination.

**Survey teams**

There were six survey teams, each composed of an ophthalmologist, ophthalmology assistant and local community worker. Teams were trained by a certified RAAB+DR trainer using the Scottish grading scheme for DR and maculopathy on a photoset of 40 retinal images. These photos were referred to as ‘Gold Standard’ to which the grades of each ophthalmologist were compared. A minimum kappa score of 0.6 in the interobserver variation test was required before proceeding with the fieldwork.

**Examination protocol**

Presenting visual acuity (PVA) for right and left eyes was measured in ambient illumination, with a 6/60 tumbling E optotype at 6, 3 or 1 m, and 6/18 and 6/12 tumbling E optotypes at 6 m. Pinhole VA was measured where PVA was less than 6/12 in any eye. All participants had a lens examination by an ophthalmologist using direct ophthalmoscope. Fundus examination using an indirect ophthalmoscope was undertaken by an ophthalmologist to determine the cause of PVA less than 6/12 where appropriate. Dilated fundus examination using two drops of tropicamide 0.5% was carried out where the cause of visual impairment was not uncorrected refractive error, or an obvious corneal or lens opacity. Participants were asked about a history of diabetes and underwent a random blood glucose test using Accu-chek digital glucometers if they consented. Persons known to have DM were asked about the type of treatment for glycaemic control, age at diagnosis and if they had previous eye examination. Ophthalmologists examined all diabetic participants using the indirect ophthalmoscope after pupil dilation, and recorded grading for DR in the survey forms. Fundal photos for subjects with DR were taken with mydriatic fundus camera in a local eye care facility. Retinal pictures were graded using the Scottish DR grading system by a retina specialist at office to confirm the field grading. There was no discrepancy between field and office grading.

**Study definitions**

Visual impairment and blindness were defined according to the WHO definitions based on PVA in the better eye. The cut-off for blindness was PVA less than 3/60, SVI was PVA 3/60 or better but less than 6/60, moderate visual impairment (MVI) was PVA 6/60 or better but less than 6/18 and early visual impairment was PVA 6/18 or better but less than 6/12. Sight-threatening conditions were defined as grade R4 (PDR was diagnosed if there were active new vessels or vitreous haemorrhage) or grade M2 (lesions seen within a radius of ≤1 disc diameter at the centre of the fovea, or with the presence of any hard exudates) based on the Scottish DR grading scheme.

Persons without a history of DM were considered to be newly diagnosed patients with diabetes if the random blood glucose level was found to be >200 mg/dL (11.1 mmol/L). Known diabetics were considered to have poor control if the random blood glucose level was found to be >200 mg/dL (11.1 mmol/L) while good control of DM was defined as random blood sugar less than 200 mg/dL (11.1 mmol/L) among persons with DM.
Data collection and statistical analysis
Fieldwork was completed over 23 days in February 2019. Two teams attended one cluster per day, with each team examining 30 participants. Data were collected door to door following the standardised RAAB6 two-page survey form and cross-checked daily to identify missing data and correct errors. Survey teams revisited the homes of enrolled participants who were not available at the first visit. Two data entry clerks used the RAAB6 software for consistency checks during data entry. Standardised survey reports were generated by RAAB6 software which accounts for the clustered survey design. Adjusted prevalence estimates were weighted to age and sex-disaggregated population data from the 2016 census. \( \chi^2 \) test was used to determine the relationship between sex and prevalence of DM, and relationship between control of DM and prevalence of DR, with significance level of 0.05. Simple logistic regression was used to determine if there is a relationship between self-report duration of DM and having DR. SAS statistical software (V.9.04, SAS Institute) was used to run these tests using data modified from RAAB6 standardised reporting output.

Participant and public involvement in the research
We did not directly include participants in the design of the research; however, policymakers in the MOHP and local community leaders were consulted about the survey design, questionnaire and approaches to facilitate the implementation of the study. In partnership with the MOHP, we will disseminate a plain language summary of the findings to the public.

RESULTS

Age and gender distribution
Among the 4078 people aged 50 years and older enrolled, a total of 4033 participants were examined, with a response rate of 98.9%. Thirteen persons (0.3%) were unavailable for examination, 18 (0.4%) refused examination while 14 (0.3%) persons were unable to communicate. A total of 3874 (97.3%) respondents accepted the random blood glucose check, while 159 (3.9%) refused. Seven hundred and twenty-nine persons with diabetes accepted DR examination (86.5%), while 114 (13.5%) refused as they felt no need for examination since they could still see very well.

Prevalence of DM
DM was diagnosed in 843 persons giving a prevalence of 20.9% (95% CI 19.3% to 22.5%), of which 707 (83.9%) were known diabetics and 136 (16.1%) were newly discovered. The prevalence of DM in females was significantly higher (23.8%; 95% CI 21.4% to 26.3%) than in males (18.9%; 95% CI 17.1% to 20.7%) (p=0.0001) (table 1). A total of 76.8% of participants with known DM used oral hypoglycaemic drugs to control their blood sugar, while only 17.8% were on insulin. Only 38.8% of known diabetics had random blood sugar that was less than 200 mg/dL. The majority (85.3%) never had an eye examination for DR.

Distribution of DM by age and gender
More females had DM at 23.8% (21.4–26.3) than males at 18.9% (17.1–20.7) with diabetes being more common in the age group of 60–69 years closely followed by the youngest age group (50–59 years). In all age groups, there were more females with DM than males. Females had 1.26 (95% CI 1.12 to 1.42; p=0.0001) times the prevalence of DM in males (table 1).

Visual status of study participants and causes of visual impairment among persons with DM
The prevalence of blindness among persons with DM was 6.2% (95% CI 4.5% to 7.8%) vs 6.4% (95% CI 5.2% to 7.5%) in persons without diabetes (table 2). Cataract remained the major cause of blindness (44%) and SVI (48%) in persons with DM, followed by other posterior segment diseases (34%) and other miscellaneous eye conditions (25%) (table 3).

In the whole sample and based on PVA, DR was responsible for 0.4%, 2.0% and 1.8% of causes of blindness, SVI and MVI, respectively. In persons with DM, DR constituted 1%, 10% and 7% of causes of blindness, SVI and MVI, respectively. The major cause of early visual impairment in persons with DM was refractive error (43%) followed by other posterior segment diseases (25%) (table 3).

| Table 1 Prevalence of DM by age and gender in the sample |
|-----------------------------|-----------------------------|-----------------------------|
| Age groups (years)          | Males n %                  | Females n %                 | Total n %                     |
| 50–59                       | 198 19.9% (17.2–22.6)       | 169 23.1% (20.3–25.9)       | 367 21.3% (19.3–23.3)         |
| 60–69                       | 183 21.6% (18.6–24.6)       | 145 25.5% (21.8–29.3)       | 328 23.2% (20.9–25.5)         |
| 70–79                       | 59 14.4% (11.0–17.8)        | 67 25.7% (19.3–32.1)        | 126 18.8% (15.2–22.3)         |
| 80+                         | 11 8.0% (3.8–12.3)          | 11 13.1% (5.6–20.6)         | 22 10.0% (6.3–13.6)           |
| Total                       | 451 18.9% (17.1–20.7)       | 392 23.8% (21.4–26.3)       | 843 20.9% (19.3–22.5)         |

DM, diabetes mellitus.
Prevalence of DR
The age and sex-adjusted prevalence of DR among persons with DM was 17.9% (95% CI 14.7% to 21.1%) with more females affected (18.9%; 95% CI 14.0% to 23.8%) than males (17.1%; 95% CI 13.0% to 21.2%). On average, the odds of DR increases by 1.27 times (95% CI 1.13 to 1.44) for additional 5 years of DM (table 4). Sight-threatening DR (R4 and/or M2) was detected in 5.2% (95% CI 3.4% to 7.0%). Laser scars were found in only 2.3% (95% CI 1.2% to 3.5%) (table 5). In the sample, there was significant association between the duration of DM and DR (p<0.0001). Poorly controlled diabetic participants had 1.65 (95% CI 1.17 to 2.34) times the prevalence of DR compared with participants with controlled blood sugar (p=0.0046). The prevalence of DR among participants with controlled blood sugar was 15.4% (95% CI 10.7% to 20.1%), while poorly controlled diabetic participants had a prevalence of DR of 25.5% (95% CI 21.2% to 29.8%) (p=0.0033).

DISCUSSION
This study contributes to bridging the considerable gap of knowledge about DR in Egypt including its prevalence, severity of cases, health-seeking behaviour and coverage of diabetic health services. Through a representative population-based standardised method, the study allows comparisons with other RAAB+DR surveys. The study attained high response rate (98.9%), as the survey teams revisited eligible subjects who were not available at first visit. There is a potential to underestimate the prevalence of DR in this study as persons with undiagnosed DM with normal random blood sugar and vision would have been missed just as persons with other diseases like cataract which preclude retinal examination would have been missed.16

In this study, the prevalence of DM was 20.9%. Though Sohag governorate shares many demographic and cultural features with the region of Upper Egypt, we cannot generalise our results widely. The most recent population-based survey in Egypt was run in 2012 and showed a prevalence of 20.9% and 34.3% among the age groups 45–54 and 55–64, respectively.11 The difference in the cut-offs between the two study designs would justify this variance. The prevalence of DM was higher in females (23.8%) than males (18.9%) affected. The 2012 STEPwise survey showed that the prevalence of DM reached 17%, but with more males (21%) than females (13%) affected.11 The 2012 STEPwise survey included nine more governorates besides Sohag. This might explain the difference in prevalence by gender.

In contrast to other middle-income countries in the region, the prevalence of DM in Sohag was less than that

| Table 2 | Visual status of study participants |
|---------|------------------------------------|
|         | Persons with DM | Persons without DM |
|         | n | % (95% CI) | n | % (95% CI) |
| **Normal vision** | 438 | 52.0 (47.0 to 56.9) | 1605 | 50.3 (46.4 to 54.2) |
| **Early VI** | 138 | 16.4 (13.6 to 19.1) | 597 | 18.7 (16.8 to 20.6) |
| **Moderate VI** | 176 | 20.9 (16.9 to 24.8) | 624 | 19.6 (17.6 to 21.5) |
| **Severe VI** | 39 | 4.6 (3.2 to 6.0) | 161 | 5.0 (4.1 to 6.0) |
| **Blindness** | 52 | 6.2 (4.5 to 7.8) | 203 | 6.4 (5.2 to 7.5) |
| **Total** | 843 | 100% | 3190 | 100% |

DM, diabetes mellitus; VI, visual impairment.

| Table 3 | Causes of visual impairment and blindness among participants by diabetic status |
|---------|----------------------------------|
|         | Blinding | Severe VI | Moderate VI | Early VI |
| **Causes** | DM | Non-DM | DM | Non-DM | DM | Non-DM | DM | Non-DM | DM | Non-DM |
| **Refraction error** | 0 | 0 | 1 | 0 | 0 | 3 | 1 | 26 | 14 | 83 | 13 | 61 | 44 | 333 | 55 |
| **Cataract** | 23 | 44 | 82 | 40 | 19 | 48 | 102 | 63 | 57 | 32 | 309 | 49 | 30 | 21 | 121 | 20 |
| **DR** | 1 | 1 | 0 | 0 | 4 | 10 | 0 | 0 | 14 | 7 | 0 | 0 | 5 | 3 | 0 | 0 |
| **Other PSD** | 18 | 34 | 46 | 22 | 6 | 15 | 26 | 16 | 50 | 28 | 154 | 24 | 35 | 25 | 97 | 16 |
| **Other** | 10 | 19 | 74 | 36 | 10 | 25 | 30 | 18 | 29 | 16 | 78 | 12 | 7 | 5 | 46 | 7 |
| **Total** | 52 | 100 | 203 | 100 | 39 | 100 | 161 | 100 | 176 | 100 | 624 | 100 | 138 | 100 | 597 | 100 |

DM, diabetes mellitus; DR, diabetic retinopathy; PSD, posterior segment disease; VI, visual impairment.
in northern Jordan that showed 28.6% (95% CI 26.9% to 30.3%), and higher than Peshawar district in Pakistan that showed a prevalence of 18.6% (95% CI 16.8% to 20.5%). In the three RAAB+DR surveys, women were more vulnerable to DM than men. In northern Jordan, women showed a prevalence of 30% vs 26.8% in men, and in Peshawar, women had a prevalence of 23.2% vs 14.2% in men.17 18

In our study, 83.9% of persons with diabetes were aware about their diabetic status, reflecting significantly higher percentage than that reported in the International Diabetes Federation report in 2019 (45.5%), and 37.2% in 2012. However, the control of diabetes in our study was poor as only 38.8% of known cases of diabetes had random blood sugar that is less than 200 mg/dL. This may be attributed to the presence of other comorbidities such as obesity (32%), overweight (63.5%), raised blood pressure (25%) and insufficient physical activity.

A better control of serum glucose occurs with addressing these comorbidities. It is also possible that most patients are either not compliant with their medications or appointments with their managing physicians.

The prevalence of DR was 17.9%, with more females (18.9%) affected than males (17.1%). The 2005 STEP-Wise survey reported that 20.7% of diabetics showed more ocular complications in female diabetics (27.9%) versus (11.6%) in males. DR was responsible for 3.9% of functional low vision with significantly more women (6.8%) affected than men (1.5%), consistent with the significantly higher prevalence of SVI and MVI among women than men in the main study. Compared with other RAAB+DR surveys from middle-income countries in the EMR, DR contributed to SVI by 2% in Sohag, like northern Sudan (2.2%), and higher than White Nile state in Sudan (1.1%). Districts in other lower middle and upper middle-income countries in the region showed higher contribution of DR to SVI such as Peshawar district in Pakistan (6.7%), Varamin district in Iran (5%), Libya (16.6%) and northern Jordan (20.6%). This difference may be due to the difference in the level of control of DM, duration of disease and the age of the study populations.

The majority (85.7%) of persons with DM in the study never had an eye examination for DR. This is consistent with findings by Macky et al which showed that 82% of patients in Cairo University Hospitals were not aware of ocular complications of diabetes. In this study, up to 5.2% of participants have sight-threatening retinopathy or maculopathy which should have been treated but only 2.3% had evidence of previous laser treatment, which denotes insufficient coverage of DR services. Several barriers exist including the cost of eye examination, lack of written guidelines and protocols for detection and management of DR besides scarce training for ophthalmologists in DR. The mean diabetes-related expenditure per person with diabetes in both private and public hospitals in Egypt in 2019 was US$279 compared with US$475.3 in the EMR. This amount is above what most people can afford in Egypt, considering that the gross domestic product per capita in 2019 in Egypt was US$3020 in comparison to US$8104.5 in the EMR. Furthermore, DR is almost asymptomatic at early stages, so most people only have their first eye examination with...
the onset of symptoms. Considering the poor control of DM as reflected in our study, and the high number of people with sight-threatening DR and maculopathy, the need for a public health approach for screening for DR is dire. Successful strategies to reduce the cost and increase the efficiency of the screening include the usage of non-mydriatic fundus camera by mid-level ophthalmic personnel and using the advantages of teledmedicine in remote areas. Despite the initial and maintenance costs needed for such model, it has the potential to be cost-effective and enhance the quality of life of patients with diabetes especially in low-income countries.

CONCLUSION
The prevalence of DM in Sohag governorate in Egypt is higher than the national prevalence with a high prevalence of sight-threatening retinopathy and/or maculopathy. Few people have access to diabetic eye care. Women continue to be more vulnerable to DM and DR.

Key challenges include the poor control of DM, insufficient coverage of DR services, late eye examination among people with diabetes, besides low health expenditure. A public health approach is needed for health promotion, early detection and management of DR.

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Contributors HA, MS and GE conceived and planned the presented study. OS and AA worked on funding. CDM (a certified Rapid Assessment of Avoidable Blindness trainer) oversaw the delivery of the survey methodology and training of fieldwork teams. HA was responsible for data acquisition and handling. IH provided needed statistical analysis. HA, CDM, GE and IH reviewed the survey findings and wrote the manuscript.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval Ethical approval for the study was obtained from the Egyptian Ministry of Health and Population (approval number 32019). The participant data were confidentially handled. The field teams oriented the participants about the purpose of the study and asked for written consent prior to data collection, ophtalmic examination and blood sugar measurement (online supplemental file 1). Participants identified with eye conditions were counselled and referred for further care.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available in a public, open-access repository. The data of the study will be available through the RAAB repository at http://raabdata.info/repository/.

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