



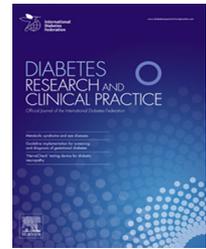
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The association between diabetes and cataract among 42,469 community-dwelling adults in six low- and middle-income countries

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ABSTRACT

Background: Cataract is a major cause of visual impairment in people with diabetes, yet a paucity of data is available in low- and middle-income countries (LMICs) on this comorbidity. Thus we assessed the association between diabetes and cataract in 6 LMICs.

Methods: Cross-sectional, community-based data from the Study on Global Ageing and Adult Health (SAGE) was analyzed (n = 42,469 aged ≥18 years). Five years information on self-reported diagnosis of cataract was collected. Three definitions for cataract were used: (a) Self-reported diagnosis and/or past 12-month symptoms; (b) Solely self-reported diagnosis; and (c) Surgical treatment for cataract in the past five years. Diabetes was based on self-reported diagnosis. Multivariable logistic regression was conducted to assess the associations.

Results: Overall, the prevalence of diabetes was 3.1% (95%CI = 2.7–3.5%) and that of cataract based on the three different definitions was: (a) 13.3% (95%CI = 12.4–14.3%); (b) 4.4% (95%CI = 3.9–4.8%), (c) 1.7% (95%CI = 1.5–2.0%). After adjustment the association was significantly elevated: (a) OR = 2.10 (95%CI = 1.59–2.76); (b) OR = 2.62 (95%CI = 2.00–3.42);

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(c) OR = 2.80 (95%CI = 1.78–4.40). These associations were particularly pronounced among those aged <50 years.

Conclusions: A strong association between diabetes and cataract was observed in LMICs.

Considering the impact on health and quality of life and the limited treatment options especially for cataract it is mandatory to promote the prevention through bi-directional screening and treatment.

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1. Introduction

It is estimated that approximately 314 million people are visually impaired globally, and this condition has a severe negative impact on quality of life and impairs an individual's ability to live independently. The leading causes of global blindness are cataract and refractive error [1]. It is estimated that about 95 million people are visually impaired due to cataracts and, usually, it is age related [2]. Cataract has a particularly devastating consequence in low- and middle-income countries (LMICs) where it remains the leading cause of blindness, accounting for 50% of blindness, whereas the corresponding figure is only 5% in developed countries [2]. Despite a general progress in the management of cataract, socioeconomic disparity in cataract burden remains a major concern for reducing global avoidable visual disability especially in LMICs [3]. Although it is possible to treat cataract by modern surgery, such interventions are not accessible to the majority of people in less-developed countries [4].

A well-known risk factor for cataract is diabetes mellitus [5]. In people with diabetes, cataract is a major cause of visual impairment with a three to four-fold increased risk of cataract in individuals with diabetes under the age of 65 years, and up to a two-fold excess risk in people above 65 years [6,7]. The global prevalence of diabetes has nearly doubled since 1980, rising from 4.7% to 8.5% in the adult population (estimated 422 million adults were living with diabetes in 2014) and it is increasing worldwide, in both developed and developing countries [5]. Especially in LMICs, diabetes has reached epidemic levels but prevention, diagnosis, and treatment are generally inadequate, leading to late stage complication manifestations [8,9]. Thus, this upward trend in diabetes may be driving a parallel increase in cataract in this setting.

Despite this, in LMICs, only a few studies have investigated the association between diabetes and cataract [10], and information from the general population is lacking. It is crucial to assess this association in LMICs for the increasing trend in diabetes and the lack of adequate treatment for cataract. It is also important to assess whether a stronger association between diabetes and cataract exists in the younger age group as has been reported from high-income countries considering the health and economic impact that cataract might have especially in the younger age group.

We therefore assessed the association between diabetes and cataract, using community-based, nationally representa-

tive data from 6 LMICs which participated in the Study on Global Ageing and Adult Health (SAGE) survey.

2. Methods

2.1. The survey

Data from the SAGE were analyzed. This survey was undertaken in China, Ghana, India, Mexico, Russia, and South Africa between 2007 and 2010. Based on the World Bank classification at the time of the survey, all of these countries were LMICs [11]. Details of the survey methodology have been published elsewhere [12]. In brief, in order to obtain nationally representative samples, a multistage clustered sampling design method was used. The sample consisted of adults aged ≥ 18 years with oversampling of those aged ≥ 50 years. Trained interviewers conducted face-to-face interviews using a standard questionnaire. Standard translation procedures were undertaken to ensure comparability between countries. The survey response rate ranged from 51% (Mexico) to 93% (China). Sampling weights were constructed to adjust for the population structure as reported by the United Nations Statistical Division. Ethical approval was obtained from the WHO Ethical Review Committee and local ethics research review boards. Written informed consent was obtained from all participants.

2.2. Cataract (Outcome)

Cataract was assessed in several ways. First, the participants were asked "In the last 5 years, were you diagnosed with cataracts in one or both of your eyes (a cloudiness in the lens of the eye)?" Those who answered affirmatively were then asked "In the last 5 years, have you had eye surgery to remove this cataract(s)?" Apart from these questions, two questions on typical symptoms of cataract [13] in the past 12 months were asked: (1) cloudy or blurry vision; and (2) vision problems with light, such as glare from bright lights, or halos around lights. Based on these questions, we created three different variables for cataract: (a) self-reported diagnosis and/or symptoms; (b) solely self-reported diagnosis; and (c) self-reported diagnosis and surgery. As for the symptoms, as in publications using the same survey questions, we assumed that those who claimed to have both of the above-mentioned symptoms have cataract [14,15]. We also relied on symptoms to identify individuals with cataract as

under-diagnosis is likely to occur in areas with limited resources [16].

2.3. Diabetes (Exposure)

Those who answered affirmatively to the question “Have you ever been diagnosed with diabetes (high blood sugar)?” were considered to have diabetes. This did not include diabetes associated with pregnancy.

2.4. Co-variables

The selection of the control variables was based on past literature [17,18]. Sociodemographic variables included age, sex, education, wealth, and setting (rural or urban). Education was based on the highest educational level achieved and was categorized as \leq primary, secondary, and \geq tertiary. Wealth quintiles were created based on country-specific income. A stadiometer and a routinely calibrated electronic weighting scale were used to measure height and weight respectively. Body mass index (BMI) was calculated as weight in kilograms divided by height in meters squared. Obesity was defined as BMI \geq 30 kg/m². Blood pressure was measured three times with a one-minute interval with the use of a wrist blood pressure monitor. The average of three measurements was calculated. Hypertension was defined as having at least one of: systolic blood pressure \geq 140 mmHg; diastolic blood pressure \geq 90 mmHg; or self-reported diagnosis. Smoking was categorized as never, current smoking, and former smoking. Individuals who consumed alcohol in the last 30 days were considered current drinkers.

2.5. Statistical analysis

The statistical analysis was performed with Stata 14.1 (Stata Corp LP, College station, Texas). The difference in the prevalence of cataract (based on self-reported diagnosis and symptoms) by sample characteristics was tested by Chi-squared tests. We conducted multivariable logistic regression analysis to assess the association between diabetes (exposure) and cataract (outcome). We used three different definitions for cataract (i.e., self-reported diagnosis and/or symptoms, self-reported diagnosis only, and surgical treatment). Analyses using the overall sample, and by subgroups (age groups and country) were conducted. We conducted age-stratified analyses as previous studies have shown that the association between diabetes and cataract may differ by age [19,20]. Age groups of 18–49, 50–64, and \geq 65 years were used for this analysis. Further stratification for the youngest age group was not possible given that this study involved oversampling of individuals aged \geq 50 years and the number of individuals aged 18–49 years was relatively small. The analyses were adjusted for age, sex, education, wealth, setting, obesity, hypertension, smoking, and alcohol consumption, with the exception of the county-wise analysis which was not adjusted for country. We also tested for interaction by age using the overall sample by including an interaction term in the model [i.e., diabetes \times age (18–49, 50–64, \geq 65 years)]. All variables were included in the models as categorical variables with the exception of age (continuous variable) apart from the interac-

tion analysis where age was included as a categorical variable. Country adjustment was done by including dummy variables for each country. Under 3% of the data were missing for the variables used in the analysis with the exception of obesity (5.8%). Complete-case analysis was done. The sample weighting and the complex study design were taken into account in the analyses. Results from the regression analyses are presented as odds ratios (ORs) with 95% confidence intervals (CIs). The level of statistical significance was set at $P < 0.05$.

3. Results

The analytical sample consisted of 42,469 adults (China 14,811; Ghana 5108; India 11,230; Mexico 2742; Russia 4355; South Africa 4223) aged \geq 18 years. The mean (SD) age of the sample was 43.8 (14.4) years and 50.1% were females. The overall prevalence of diabetes was 3.1% (95%CI = 2.7–3.5%), while the figures for cataract were: 13.3% (95% CI = 12.4–14.3%), 4.4% (95%CI = 3.9–4.8%), and 1.7% (95% CI = 1.5–2.0%) for (a) self-reported diagnosis and/or symptoms; (b) solely self-reported diagnosis; and (c) surgical treatment for cataract, respectively. Overall, the prevalence of cataract based on self-reported diagnosis and/or symptoms among those with and without diabetes was 12.8% and 31.8%, respectively. A linear increase in the prevalence of cataract was observed among those with and without diabetes with increasing age (Fig. 1). Based on unadjusted estimates, advanced age, female sex, lower education and wealth, rural location, hypertension, smoking, and less alcohol consumption were associated with significantly higher prevalence of cataract (Table 1). In the adjusted overall analysis, diabetes was associated with significant 2.10–2.80 times higher odds for cataract (Table 2). Age-stratified analyses showed that the association between diabetes and cataract is strongest among the youngest age group regardless of the definition used for cataract (Table 3). The youngest age group had significantly higher ORs compared to either those aged 50–64 years or \geq 65 years based on the interaction analysis. With the exception of surgical treatment for cataract in Russia, diabetes was significantly associated with cataract in all countries regardless of the definition of cataract used (Table 4).

4. Discussion

The current work is the first population study to investigate the association between diabetes and cataract using representative data from LMICs. Our results show that diabetes is associated with an approximately 2–3 times higher odds for cataract, after adjustment for potential confounders. Diabetes was associated with higher odds for cataract in all the countries, with the sole exception of Russia where Regardless of the definition for cataract used, the association between diabetes and cataract was strongest in the youngest age group (18–49 years). This finding is in agreement with previous studies from high-income countries [6,21]. As reported by Hodge and colleagues, cataract occurs more frequently in LMICs while early onset is also common possibly due to limited access to health care and more intense exposure to risk factors [22].

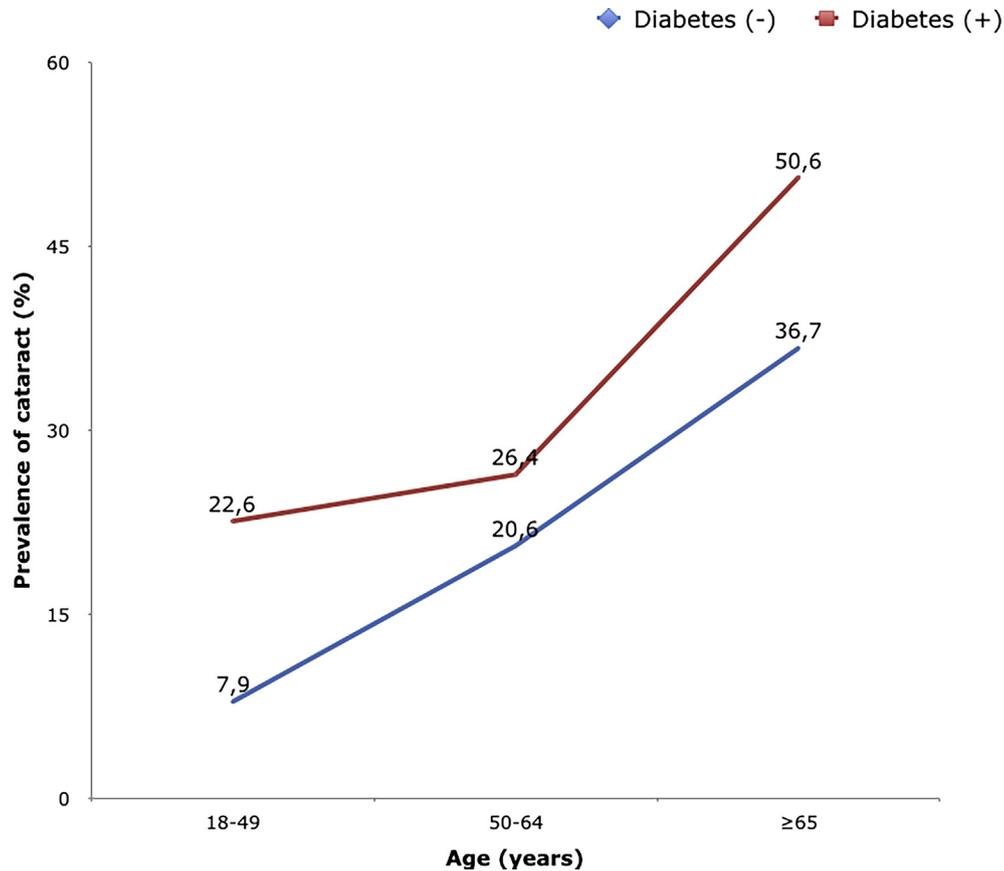


Fig. 1 – Prevalence of cataract based on self-reported diagnosis and symptoms by the presence or absence of diabetes and by age groups. Estimates are based on weighted sample. Cataract was based on self-reported diagnosis in the past five years and/or typical symptoms of cataract in the past 12 months (i.e., cloudy or blurry vision, and vision problems with light, such as glare from bright lights, or halos around lights).

4.1. Previous research

It is widely known that cataract occurs more frequently and with earlier onset and more rapid progression in people with diabetes compared to those without diabetes with a three to fourfold increased prevalence under 65 years, and up to a twofold increase above 65 [19,23]. Furthermore, among individuals with cataracts, the prevalence of diabetes has been reported to be 15–25 times higher than in the general population [24]. The main difference between high-income countries and LMICs is access to health care both for diabetes and cataract. Considering the limited access to care for people with diabetes in LMICs [25] and the increased risk of cataract development in individuals with longer duration of diabetes and with poor metabolic control [6], it is plausible that the risk for developing diabetes-related cataracts is higher in low resource settings. On the other hand, the low accessibility for diagnosis and surgery and the gender inequality in LMICs may also lead to a particularly heavy burden of cataract in this setting [2].

4.2. Interpretation of the findings

The pathophysiologic mechanism by which diabetes increased cataract risk has been described previously [26].

Indeed, hyperglycemia implies a rise in glucose in the aqueous humor that spreads into the crystalline. In the lens, glucose is metabolized to sorbitol and galactose to sugar alcohol galactitol, both by aldose reductase, but they are only poorly further metabolized. Sorbitol and galactitol thus accumulate in the crystalline and causes osmotic hyper hydration of the lens and oxidative stress. Furthermore, increased glucose levels in the aqueous humor, may induce generation of free radicals and advanced glycation end-products, leading to increased oxidative stress, exacerbated by the impaired antioxidant capacity of diabetic lenses [27]. This mechanism may partly explain our findings, however, multiple risk factors act in cataract etiology especially in LMICs. Specifically, malnutrition (low protein and antioxidant consumption), exposure to ultraviolet radiation, dehydration, sequelae of infectious diseases and low socioeconomic status are all possible causes of cataract development [22]. Besides, three single-nucleotide polymorphisms in chromosome 3p14.1-3p14.2 which relates to functions of voltage-dependent anion-selective channel protein, long myosin light chain kinase, adenylyl-cyclase associated protein, and retinoic acid receptor were significantly different in diabetes patients with cataract compared to these without cataract, suggesting also a genetic susceptibility [28]. Moreover, it is also possible that detection bias plays a role in the higher prevalence of cataract

Table 1 – Sample characteristics.

Characteristic	Category	Unweighted N	Column %	% with cataract ^a	P-value ^b
Age (years)	18–49	8340	72.7	8.1	<0.001
	50–64	19,544	17.0	20.9	
	≥65	14,585	10.3	37.9	
Sex	Female	24,137	50.1	14.6	<0.001
	Male	18,324	49.9	12.1	
	Missing	8			
Education	≤Primary	25,451	43.1	19.8	<0.001
	Secondary	13,231	46.5	8.8	
	≥Tertiary	2935	10.4	7.8	
	Missing	852			
Wealth	Poorest	7954	14.9	20.0	<0.001
	Poorer	8292	17.8	15.0	
	Middle	8259	18.8	14.3	
	Richer	8758	21.1	11.2	
	Richest	9026	27.3	9.7	
	Missing	180			
Location	Rural	22,182	55.6	15.1	<0.001
	Urban	20,283	44.4	11.2	
	Missing	4			
Obese (BMI ≥ 30 kg/m ²)	No	34,785	93.0	13.4	0.557
	Yes	5229	7.0	14.3	
	Missing	2455			
Hypertension	No	19,690	65.3	12.2	<0.001
	Yes	22,356	34.7	15.4	
	Missing	423			
Smoking	Never	27,312	60.5	12.0	0.001
	Current	11,275	35.2	15.1	
	Former	3,179	4.3	18.3	
	Missing	703			
Alcohol Consumption	No	34,041	78.1	14.6	<0.001
	Yes	7805	21.9	8.8	
	Missing	623			

Abbreviation: BMI Body Mass Index.

Estimates are based on weighted sample with the exception of the unweighted N.

^a Percent of individuals with that sample characteristic who have cataract. Cataract was based on self-reported diagnosis in the past five years and/or typical symptoms of cataract in the past 12 months (i.e., cloudy or blurry vision, and vision problems with light, such as glare from bright lights, or halos around lights).

^b P-value was calculated with Chi-squared tests.

among diabetic patients as they are more likely to receive regular eye examinations for the increased risk of eye diseases such as diabetic retinopathy [22]. We should also consider the possibility that medication for diabetes, and not diabetes *per se* may have increased the risk of cataract or, that lack of physical activity (due to lower vision) post cataract may have increased the risk of diabetes. Finally, in LMICs, access to diagnosis is a major issue and it is likely that certain sections of the population were more likely to have access to both diabetes and cataract diagnosis leading to a higher likelihood of identifying the diabetes-cataract comorbidity.

4.3. Clinical and policy implications

The results of our study highlight the potential importance of diabetes prevention and treatment to prevent cataract and its devastating consequences in LMICs. In LMICs, addressing the

risk factors of cataract, especially at younger age, is important given that gold standard treatment for cataract such as phacoemulsification surgery is often not available. Moreover, effective strategies for prevention, control and treatment of diabetes, could avoid other severe complications, common in LMICs, such as, kidney failure, cardiovascular disease, sexual dysfunction, and premature death [25,29]. Particularly in LMICs, diabetes self-management education should be considered a crucial approach to avoid complications [30]. However, it requires constant aid and follow-up by health professionals and, thus, improved access to care and increased health care staff are also essential.

5. Strength and limitations

This is the first study specifically on diabetes and cataract using nationally representative data from LMICs. The

Table 2 – Association of diabetes and other covariates with cataract (outcome) estimated by multivariable logistic regression.

Characteristic	Definition of cataract	Definition of cataract					
		(a) Self-report and/or symptoms ^a		(b) Self-report only ^b		(c) Surgical treatment ^c	
Diabetes	Yes vs. No	2.10 ^{***}	[1.59,2.76]	2.62 ^{***}	[2.00,3.42]	2.80 ^{***}	[1.78,4.40]
Age (years)	Per unit increase	1.07 ^{***}	[1.06,1.07]	1.09 ^{***}	[1.08,1.10]	1.09 ^{***}	[1.08,1.10]
Sex	Male vs. Female	0.70 ^{***}	[0.58,0.85]	0.85	[0.63,1.14]	0.88	[0.67,1.16]
Education	≤Primary	1.00		1.00		1.00	
	Secondary	0.90	[0.72,1.12]	1.08	[0.75,1.55]	1.38	[0.95,2.00]
	≥Tertiary	0.81	[0.56,1.19]	1.00	[0.60,1.66]	0.80	[0.42,1.55]
Wealth	Poorest	1.00		1.00		1.00	
	Poorer	0.79 [*]	[0.63,0.99]	1.04	[0.76,1.43]	1.35	[0.81,2.25]
	Middle	0.82	[0.66,1.01]	0.97	[0.74,1.28]	0.78	[0.53,1.15]
	Richer	0.68 ^{***}	[0.54,0.85]	1.03	[0.76,1.39]	1.35	[0.90,2.03]
	Richest	0.64 ^{***}	[0.49,0.82]	0.99	[0.70,1.38]	1.06	[0.69,1.64]
Setting	Urban vs. Rural	1.08	[0.89,1.30]	1.32 [*]	[1.03,1.71]	1.02	[0.69,1.51]
Obesity	Yes vs. No	1.43 [*]	[1.06,1.92]	1.32	[0.96,1.81]	1.40	[0.85,2.32]
Hypertension	Yes vs. No	0.94	[0.79,1.13]	1.30 ^{**}	[1.07,1.58]	1.26	[0.94,1.68]
Smoking	Never	1.00		1.00		1.00	
	Current	1.08	[0.90,1.30]	0.98	[0.76,1.27]	1.05	[0.71,1.55]
	Former	1.61 [*]	[1.01,2.56]	1.04	[0.73,1.48]	0.90	[0.60,1.35]
Alcohol consumption	Yes vs. No	1.10	[0.86,1.41]	0.84	[0.60,1.17]	0.58	[0.32,1.04]

Estimates are odds ratio [95% confidence interval].

Models are adjusted for all variables in the Table and country.

^a Having had cataract diagnosis in the past 5 years and/or having typical symptoms of cataract in the past 12 months (i.e., cloudy or blurry vision, and vision problems with light, such as glare from bright lights, or halos around lights).

^b Having had cataract diagnosis in the past 5 years.

^c Having had cataract diagnosis in the past 5 years and having had eye surgery to remove the cataract.

^{*} p < 0.05.

^{**} p < 0.01.

^{***} p < 0.001.

Table 3 – Association between diabetes and cataract (outcome) by age groups estimated by multivariable logistic regression.

Age (years)	Definition of cataract					
	(a) Self-report and/or symptoms ^a		(b) Self-report only ^b		(c) Surgical treatment ^c	
18–49	2.62 ^{**}	[1.40,4.93]	4.17 ^{**}	[1.59,10.97]	7.36 ^{**}	[1.82,29.84]
50–64	1.42 ^{*,d}	[1.06,1.91]	1.93 ^{***,d}	[1.38,2.70]	2.56 ^{**}	[1.43,4.59]
≥65	2.20 ^{***}	[1.74,2.78]	2.36 ^{***}	[1.86,2.98]	1.94 ^{***,d}	[1.32,2.84]

Estimates are odds ratio [95% confidence interval].
 Models are adjusted for age, sex, education, wealth, setting, obesity, hypertension, smoking, alcohol consumption, and country.
^a Having had cataract diagnosis in the past 5 years and/or having typical symptoms of cataract in the past 12 months (i.e., cloudy or blurry vision, and vision problems with light, such as glare from bright lights, or halos around lights).
^b Having had cataract diagnosis in the past 5 years.
^c Having had cataract diagnosis in the past 5 years and having had eye surgery to remove the cataract.
^d Odds ratio is significantly lower than those aged 18–49 based on interaction analysis ($P < 0.05$).
^{*} $p < 0.05$.
^{**} $p < 0.01$.
^{***} $p < 0.001$.

Table 4 – Association between diabetes and cataract (outcome) by country estimated by multivariable logistic regression.

Country	Definition of cataract					
	(a) Self-report and/or symptoms ^a		(b) Self-report only ^b		(c) Surgical treatment ^c	
China	1.80 ^{**}	[1.26,2.56]	2.56 ^{***}	[1.72,3.81]	4.48 ^{***}	[1.94,10.37]
India	2.19 ^{***}	[1.38,3.48]	2.38 ^{***}	[1.51,3.76]	2.89 ^{**}	[1.53,5.44]
Ghana	3.48 [*]	[1.02,11.89]	6.71 [*]	[1.38,32.57]	14.84 ^{**}	[2.78,79.34]
Mexico	3.91 ^{***}	[2.06,7.44]	2.85 ^{**}	[1.42,5.72]	3.39 ^{**}	[1.35,8.55]
Russia	1.76 [*]	[1.11,2.81]	2.18 ^{**}	[1.38,3.43]	0.94	[0.41,2.17]
South Africa	5.98 ^{***}	[3.06,11.69]	4.43 ^{***}	[2.08,9.45]	4.59 ^{**}	[1.56,13.49]

Estimates are odds ratio [95% confidence interval].
 Models are adjusted for age, sex, education, wealth, setting, obesity, hypertension, smoking, and alcohol consumption.
^a Having had cataract diagnosis in the past 5 years and/or having typical symptoms of cataract in the past 12 months (i.e., cloudy or blurry vision, and vision problems with light, such as glare from bright lights, or halos around lights).
^b Having had cataract diagnosis in the past 5 years.
^c Having had cataract diagnosis in the past 5 years and having had eye surgery to remove the cataract.
^{*} $p < 0.05$.
^{**} $p < 0.01$.
^{***} $p < 0.001$.

strengths of the study include the large sample size and the use of nationally representative data from six countries which collectively represent nearly half of the world population [12]. However, the study results should be interpreted in the light of several limitations. First, diabetes was based solely on a lifetime self-reported diagnosis. Thus, under-diagnosis is possible, and results may have differed if data from blood samples were available. However, self-reported diagnosis of diabetes is the main method for determining diabetes in large-scale epidemiological studies including those from LMICs [31–35]. Second, we included self-reported diagnosis of cataract in the definitions of cataract and no objective data based on eye examinations were available. However, previous studies have shown that self-reported diagnosis of cataract is often accurate with high specificity [36,37]. Third, self-reported diagnosis of cataract and surgical treatment was based on experiences in the past five years. Next, in order to minimize under-diagnosis of cataract, we also used symptom-based diagnosis of cataract for some analyses. Although the algorithm used is not validated, this was based on typical symptoms of cataract [13] used in previous SAGE

publications or studies using data with the same questions [14,15]. In addition, we used three different definitions for cataract (i.e., self-report and/or symptoms, self-report only, surgical treatment) but the results were largely comparable, suggesting that the results are likely to be robust. Finally, due to lack of data, we were unable to adjust for steroid use which is associated with a higher risk for both cataract and diabetes. However, given that this was a population-based study conducted in LMICs, we believe that the prevalence of individuals taking steroids (especially for long term) was very low. Despite these limitations, considering the lack of studies in LMICs and that epidemiological data on the diabetes and cataract comorbidity are crucial to improve clinical outcomes for these diseases, we can consider this study a mile stone to approach, develop and improve focused and effective health policies.

6. Conclusions

In conclusion, considering the strong association between diabetes and cataract in LMICs, it is mandatory to introduce

health policies for prevention, early diagnosis, and treatment of diabetes, as well as its complications such as vision diseases. First of all, a bi-directional screening of these two conditions is recommended. Besides, since diabetes is a chronic disease requiring therapy compliance and adequate follow up in order to obtain effective long-term control, it will be crucial to organize a multidisciplinary approach which takes into account of all aspects of comorbidity.

Authors contribution

Conception and design: DP, NV, GQ
 Acquisition and analysis: AK
 Interpretation of data: FDG, DD, BS
 Draft the manuscript: DP, NV, FDG, DD
 Manuscript revision: GQ, BS, AK
 Given final approval: DP, NV, GQ, FDG, DD, BS, AK
 Agreed to be accountable for all aspects of the work: DP, NV, GQ, FDG, DD, BS, AK.

Conflict of interest

All authors declare no conflict of interest.

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Appendix A. Supplementary material

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.diabres.2018.12.001>.

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