

Spectrum of eye disorders in diabetes (SPEED) in India: Eye care facility based study. Report # 1. Eye disorders in people with type 2 diabetes mellitus

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Purpose: To document the spectrum of eye diseases in people with type 2 diabetes mellitus (T2DM) reporting to large eye care facilities in India. **Methods:** The selection of eye care facilities was based on the zone of the country and robustness of the programs. Only people with known T2DM certified by internist, or taking antidiabetes medications, or referred for diabetes related eye diseases were recruited. The analysis included the demographic characteristics, systemic associations, ocular comorbidities, and visual status. **Results:** People (11,182) with T2DM were recruited in 14 eye care facilities (3 in north, 2 in south central, 4 in south, 2 in west, and 3 in east zone); two were government and 12 were non-government facilities. Hypertension was the commonest systemic association ($n = 5500$; 49.2%). Diabetic retinopathy ($n = 3611$; 32.3%) and lens opacities ($n = 6407$; 57.3%) were the common ocular disorders. One-fifth of eyes ($n = 2077$; 20.4%) were pseudophakic; 547 (5.4%) eyes had glaucoma and 277 (2.5%) eyes had retinal vascular occlusion. At presentation, 4.5% ($n = 502$) were blind (visual acuity $<3/60$ in the better eye) and 9.6% ($n = 1077$) had moderate to severe visual impairment (visual acuity $<6/18 \rightarrow >3/60$ in the better eye). **Conclusion:** People with T2DM presenting at eye clinics in India have high rates of diabetic retinopathy and vision loss. Cataract is a very common occurrence. Advocacy, infrastructure strengthening, and human resource development are the key to address the growing threats of T2DM and eye care in India.

Key words: Clinic population, diabetes, eye disorders, India

Diabetes mellitus (DM) is a condition of growing concern with increasing worldwide prevalence and associated high mortality and morbidity.^[1] More people develop type 2 diabetes (T2DM) than type 1 diabetes (T1DM).^[2,3] The global diabetes population of 423 million in 2017 is likely to increase to 629 million by 2045.^[4] The Indian Council of Medical Research--India Diabetes (ICMR-INDIAB) study in 15 states reported a 7.3% (4.3%--10%) prevalence of diabetes (higher in urban, 11.2% than rural, 5.2%) and the prevalence of pre-diabetes (impaired fasting blood glucose and/or impaired glucose tolerance) was 10.3%.^[5] The global burden of disease (GBD) study has reported a 7.7% (6.9%--8.4%) prevalence of diabetes in India in year 2016 (higher in men, 9.6% than women 7.9%) and variations in different states of India.^[6]

DM affects many organs of the body. The acute complications include hypo- and hyperglycemia, and diabetic coma. Chronic complications occur due to micro- and macroangiopathy. Risk factors such as smoking, obesity, and hypertension compound the chronic complications of diabetes. The macrovascular complications lead to cardiovascular, cerebrovascular, and

peripheral vascular diseases. Microangiopathy affects all vital organs such as the kidneys, nerves, feet, and the eyes. While the retina (diabetic retinopathy) is invariably affected, other ocular tissue from cornea to optic nerve, and the cranial nerves, which control eye movement (III, IV, VI), also manifest a variety of disorders.^[7]

The spectrum of eye disease in diabetes (SPEED) study was designed to collect data from leading eye care facilities in India to determine the range of eye disorders in people with DM at their first presentation to the facility. This paper describes the profile of the patients with T2DM and the spectrum of eye disease in this hospital-based cohort. The subsequent papers will deal with specific eye disorders in people with T2DM.

Methods

The SPEED study collected data from all new people with known DM attending the retina clinics of participating eye care facilities spread across India. In order to select the eye care facility, we divided the country into 5 zones---the north, the south central, the south, the west and the east. We selected

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large eye care providers that receive a large number of people from the region. This study recruited people with known DM confirmed by their endocrinologist/physician and were currently using antidiabetic medications or were referred by their physicians for diabetes-related eye disorders. The health personnel in each eye care facility collected the data in a prescribed format. The questions were administered either in English or in local language. This was verified by the center Principal Investigator before depositing to a central repository at the Indian Institute of Public Health (IIPH), Hyderabad, India. The collected data included the demographics of the patient, the type and duration of DM, and record of all ocular conditions in the right and the left eye separately. The comprehensive examination, performed by the retina fellows-in-training (post-residency ophthalmologist) or fellowship trained retina physician, included measurement of presenting and corrected visual acuity, applanation intraocular pressure, slitlamp examination with grading of the lenticular opacity, indirect ophthalmoscopy, and fundus photography. Gonioscopy, fluorescein angiography, and optical coherence tomography were done as per the decision of the treating physician. Only the eyes where the fundus could be examined by indirect ophthalmoscope or photographed with a retinal camera were included for estimation and classification of retinal vascular disease including DR. Diabetes status was determined based on the Indian Council of Medical Research (ICMR) guidelines.^[8] We defined a good control of DM when the recent plasma glucose level was as follows: fasting: <110 mg/dL, 2-h post-load glucose <140 mg/dL and HbA1c <5.7%. We defined a person diabetic when the recent plasma glucose level was >126 mg/dL, 2-h post-load glucose >200 mg/dL random: >200 mg/dL, and HbA1c >6.5%.

Data collection instruments and analysis

Ethics committees at each study center approved the study and written informed consent was taken from all the participants. The Ethics Committee at IIPH, Hyderabad ratified these approvals. Participants were not provided any financial assistance. The study followed the Declaration of Helsinki on human research. Participants were administered a pretested questionnaire. An online data collection software and app base using Java was supplied to all participating centers. Stata14SE for Windows (Stata Corp., TX, USA) was used for statistical analysis. Frequencies of the variables were tabulated. Means and standard deviations for continuous variables and percentage or proportion for categorical variables were compiled.

Results

There were 14 study locations, which included two large government facilities, one tertiary diabetes care facility with integrated diabetic eye care, and 11 non-government not-for-profit eye care facilities. The centers included 3 in North India (1 in Chandigarh and 2 in Delhi), 2 in South Central India (both in Hyderabad), 4 in South India (1 in Angamaly, Kerala; 2 in Chennai and 1 in Madurai, Tamil Nadu), 2 in West India (1 each in Pune, Maharashtra and Surat, Gujrat), and 3 in East India (1 each in Bhubaneswar, Odisha, East Midanapur, Bengal and Guwahati, Assam) [Fig. 1].

The average new outpatient footfall in these facilities was 287 (± 51.9) people daily, 54.2 (± 5.9) of whom attended the retina service. Data collection spanned 6 months (August 2016

to January 2017). The study recruited 11,390 people satisfying all the inclusion criteria. After excluding 208 people with T1DM, this report includes 11,182 people with T2DM. There were 6,620 (59.2%) males and 4,562 (40.8%) females; and the average age was 58.2 years (± 10.6 years; range 39–96 years). The majority of people were ≥ 60 years ($n = 5388$; 48.2%) in age. The duration of known DM could be elicited from 11,173 (99.9%) people and in 4,727 (42.3%) it was ≤ 5 years. In a quarter ($n = 2949$; 26.4%), the diabetes duration was 6–10 years.

The diabetes treatment consisted of oral hypoglycemic agents (9169; 82%), insulin injection (865; 7.7%), combination of the two (1,010; 9.0%), and others (138; 1.23). Only 3,593 (32.1%) people had good control of diabetes; 1,237 (11.1%) people admitted to regular glycated hemoglobin (HbA_{1c}) testing. Half of the available HbA_{1c} values were in the range of 6–8%. More than half (6,484; 58%) people had systemic disorders and hypertension (5,550, 49.2%) was the commonest systemic association [Table 1].

Some form of diabetic retinopathy (32.3%) and some degree of lens opacity (57.3%) were the common ocular disorders. Other disorders included glaucoma, vascular retinopathy, optic nerve disorder, corneal disorder, and muscle palsy [Table 2]. The details of these disorders will be described in subsequent reports. At presentation to the eye care facility, 1,343 (12.01%) right eye and 1,238 (11.07%) left eye had a visual acuity of <3/60 and 1,467 (13.13%) right eye and 1,517 (13.57%) left eye had a visual acuity of <6/18->3/60. At presentation 502 (4.5%), people were blind (<3/60 in the better eye) and 1,077 people had moderate to severe visual impairment (MSVI; visual acuity <6/18->3/60 in the better eye) [Table 3].

Discussion

The current series is a large cohort of people collected from large eye care facilities located at different regions of India.

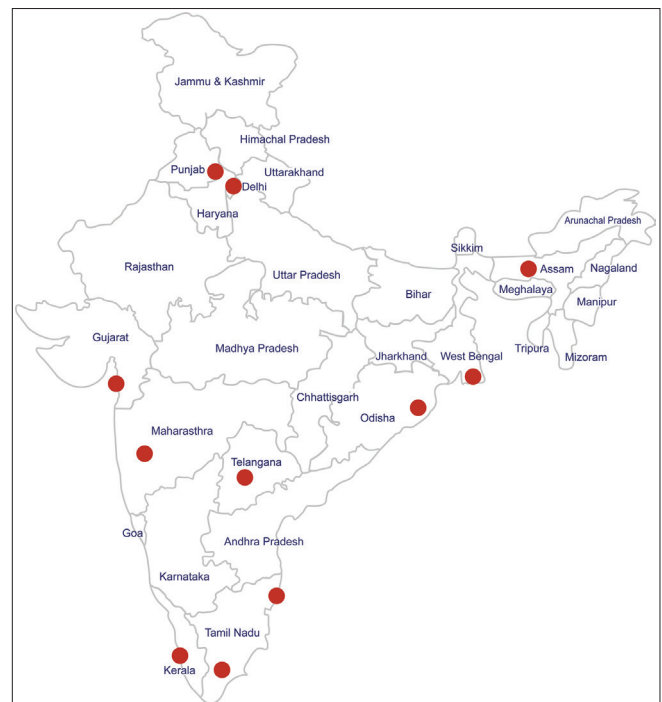


Figure 1: Participating centers in the SPEED Study

The common disorders were lens opacity and diabetic retinopathy (DR).

DR is the most common ocular complication in people with diabetes. Globally, 0.8 million people were blind and 3.7 million people were visually impaired in 2010 due to DR, with an alarming increase of 27% and 64%, respectively, from 1990 to 2010.^[9] The prevalence of both blindness and moderate to severe visual impairment was higher in sub-Saharan Africa and South Asia. The reported prevalence of DR among people with diabetes in India ranges from 9.6% to 28.2%.^[10-17] In a meta-analysis of 35 published population-based studies that included studies from India, the overall prevalence of any DR was 34.6% and the prevalence of vision threatening DR, including diabetic macular edema (DME), was 10.2%.^[18] In a meta-analysis of 62 published studies, that included population, diabetes clinics, and eye care facilities in 21 countries in Africa,

the prevalence of DR was 30.2--31.6% in population-based studies and 7.0--60.4% in clinic-based studies.^[19] A global analysis has also shown that the crude prevalence of visual impairment and blindness secondary to DR in 2015 has increased by 7.7% and 28.8%, respectively, from 1990 baseline while the crude prevalence of other major eye disorders have actually decreased.^[20]

Lens opacity is a common associated eye disorder in people with DM. Three population-based studies, the Beaver Dam Eye Study, Wisconsin Epidemiological Study of Diabetic Retinopathy, and the Barbados Eye Study, have documented association between DM and cataract.^[21-24] The surgical technique for cataract in people with DM is no different than in people without DM, although the people with DM are more at risk of postoperative complications including cystoid macular edema, worsening of DR, capsular contraction, neovascular glaucoma and, in worst cases, increased postoperative inflammation and/or endophthalmitis.^[25-28] It is imperative to control both DME and proliferative diabetic retinopathy (PDR) before planning for cataract surgery. There are few guidelines for diabetes management before and after cataract surgery.^[29,30] HbA1c rather than random blood sugar is considered a better indicator for ambulatory surgery such as cataract.^[31] The British Diabetes Society^[32] and the American Diabetes Association^[33] recommend a blood glucose level of 140-180 mg/dL in the perioperative period. There is no conclusive evidence to postpone cataract surgery in the face of less stringent diabetes control although it might be prudent to reasonably control diabetes in perioperative period of cataract surgery.

Vascular occlusion, either branch or central retinal vein occlusion, was the second most frequent retinal vascular lesion after DR in this study. Epidemiological studies have not shown a consistent relationship between diabetes and retinal vein occlusion (RVO).^[34,35] RVO in people with diabetes is more likely to cause retinal neovascularization that could result in vitreous hemorrhage and neovascular glaucoma if not adequately treated.^[36] RVO is more often seen in people with T2DM, and is often in association with hypertension and hyperlipidemia.^[37] People with diabetes (Odds 1.74) and hypertension (Odds 2.16) are associated with an increased risk of developing branch retinal vein occlusion (BRVO) within 10 years of diagnosis. BRVO is also associated with an increased risk of developing hypertension (Odds 1.37) and diabetes (Odds 1.51) in subsequent years.^[38]

Table 1: Systemic co-morbidities (n=11,182)

Systemic factor	n	%
Hypertension	5500	49.2
Cardiovascular disorder	672	6.0
Renal disorder	162	1.4
Neuropathy	86	0.8
Stroke	52	0.5
Limb amputation	12	0.1
No systemic association	4698	42.0

Table 2: Ocular comorbidities n=11,182

Tissue specific ocular disorder	Any eye* n (%)	Both Eyes n (% of specific disorder)
Lens opacity	6407 (57.3)	5105 (79.8)
Diabetic retinopathy	3611 (32.3)	3084 (85.4)
Pseudophakia	2077 (20.4)	909 (48.6)
Glaucoma	547 (5.4)	420 (76.7)
Vascular retinopathy	277 (2.5)	54 (19.5)
Optic nerve	105 (0.9)	39 (37.1)
Cornea	68 (0.6)	16 (23.5)
Nerve palsy	26 (0.2)	1 (3.8)

*Addition is more than 11,182 since more than one disorder was seen in the eyes.

Table 3: Presenting and best- corrected visual acuity at presentation

Vision	Right eye		Left eye		Better eye vision Corrected (%)
	Presenting	Corrected	Presenting	Corrected	
6/6 -6/12 Good vision	4552	7055	4638	7100	8595 (76.9)
<6/12 -6/18 Mild VI	1675	1025	1707	1044	922 (8.2)
<6/18 ->3/60 MSVI	3059	1467	3058	1517	1077 (9.6)
<3/60- LP Blind	1604	1343	1496	1238	502 (4.5)
Unreliable	292	292	283	283	86 (0.8)

MSVI=Moderate to severe visual impairment; VI=Visual impairment

People with diabetes are at risk of developing two types of glaucoma—primary open angle glaucoma (POAG) and neovascular glaucoma (NVG). Several large epidemiological studies have reported positive associations between diabetes and POAG.^[39-41] It is reported that between 32% and 43% of NVG is caused by PDR.^[42]

Most ocular complications of diabetes cause visual impairment and when neglected could lead to blindness. With possible disproportionate rise in number of people with diabetes in India (from 73 million in 2017 to 134 million in 2045; a 83.5% rise),^[4] one has to pay special attention to the care of diabetes and diabetic eye disease.

Primary prevention is the main strategy for control of visual loss from many of the diabetes-related eye diseases. This can be done through improved control of glycemia and hypertension. Secondary prevention entails regular eye examinations, including dilated fundus evaluation, and timely treatment. It was a surprise that nearly 9.6% people had moderate to severe visual impairment and 4.5% were blind in this cohort at the time of presentation, similar to an earlier study in India.^[43] This is evidently related as much to lack of eye care infrastructure and human resources, as much to incorrect perception and practices in people with diabetes.^[44,45] While clinical trials have demonstrated that good glycemic control reduces the incidence and progression of diabetic retinopathy,^[46] it is unclear whether the same beneficial effect applies to other diabetes-related ocular conditions.^[47]

Study limitations

This was a facility-based study, and so the findings cannot be generalizable to the population. Many of the disorders identified were associated with loss of vision, which would have prompted for an eye checkup, or referral from other centers. Only people with known diabetes were recruited, possibly leaving out those who did not know their diabetes status. Those that were missed may have been more likely not to have the recognized eye complications, so the findings may have been biased.

Study strengths

This was a large cohort of patients collected prospectively from different areas of India. The collection of data and analysis thereafter were uniform.

Conclusion

In view of the increasing number of people with diabetes in India, the number of people requiring diagnosis and treatment for eye disorders is also likely to increase, adding to the workload of already over-stretched facilities. Hence, India should have a sound plan and policy to contain this new and emerging burden. Efforts are required in areas of advocacy, infrastructure placement and/or strengthening, and trained human resources development.

SPEED study participating clinical facility organizations and investigators

1. Aravind Eye Hospital, Madurai (Dr. Kim Ramasamy, MD)
2. Divyajyoti Trust, Surat, India (Dr. Rohan Chariwala, MD; Dr. Uday Gajiwala, MD)
3. Dr Mohan's Diabetes Specialities Centre and Madras Diabetes Research Foundation, Chennai, India (Dr. R Rajalakshmi, MD)
4. Dr. Rajendra Prasad Center for Ophthalmic Sciences, New Delhi (Dr. Rohan Chawla, MD; Dr Atul Kumar, MD)

5. Dr. Shroff's Charity Eye Hospital, Delhi, India (Dr. Manisha Agarwal, MD)
6. H V Desai Eye Hospital (Dr. Kuldeep Dole, MD; Dr. Madan Despande, MD)
7. Little Flower Eye Hospital, Angamaly, India (Dr. Thomas Cherian, MD)
8. L V Prasad Eye Institute, Bhubaneswar, India (Dr. Umesh C Behera, MD)
9. L V Prasad Eye Institute, Hyderabad, India (Dr. Rajeev Reddy, MD; Dr. Taraprasad Das, MD)
10. Netra Nirmay Niketan, Purba Midnapur, Bengal (Dr Asim Sil, MD)
11. Post Graduate institute of Medical Education and Research, Chandigarh, India (Dr. Ramandeep Singh, MD; Dr. Mangat Dogra, MD)
12. Pushpagiri Eye Institute, Hyderabad, India (Dr. K Viswanath, MD)
13. Sankara Nethralaya, Chennai, India (Dr. Muna Bhende, MD)
14. Sri Sankaradeva Netralaya, Guwahati, India (Dr. Harsha Bhattacharjee, MS)

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Conflicts of interest

There are no conflicts of interest.

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