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Early detection of Diabetic Retinopathy through active screening of out-patients at ESI facility in Hyderabad

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ABSTRACT

Background: Diabetes Mellitus is one the major non-communicable diseases in India. ESI State Hospital, Nacharam, Hyderabad, India with the support of Novartis under its Public Health Initiatives, has implemented screening camps for early detection of Diabetic Retinopathy (DR). **Objectives:** In this analysis, we aim to identify the utility of the camps in early detection of Diabetic complications like DR. **Methods:** Twenty-four camps were conducted in the facility during Jun 2018 to Aug 2019. Subjects were screened and shortlisted for HbA_1c and Fundoscopy in an algorithm based screening protocol on predetermined camp schedule as per non-financial collaboration. **Results:** Of 2676 (male=1458; female=1218) subjects utilizing the camp services, 70% (1884) were referred to avail HbA_1c testing in the camps, which consisted of 55% (1041) known diabetics. Fifty seven percent of the subjects belonged to age group 40-59 years (range: 15-86). Nearly one-third (34%) had HbA_1c levels >7%. Nearly half (47%) of the known Diabetic subjects had HbA_1c >7% indicating the need for strengthening treatment adherence ($p<0.05$). Among subjects with HbA_1c >7%, twenty seven percent (38/142) had abnormal Fundoscopy results indicating need for regular screening for DR. More than a quarter (28%; 122/434) of the Fundoscopy results shown abnormalities in the fundus. **Conclusions:** The observations suggest that there is high probability of early detection of Diabetic Retinopathy if proper screening methods are implemented. Results also indicate the need for regular treatment adherence counseling for prevention and early detection of DR.

Key word: Diabetes, Diabetic Retinopathy, Fundoscopy, Early Detection, Active Screening

INTRODUCTION

In India, According to National Family Health Survey (NFHS-4) Report 2,172 women of age 15-49 and 2,137 men of age 15-49 per 100,000 have self-reported diabetes. Three percent of women and 2% of men age 15-49 in Telangana have high blood glucose levels while 2% of women and men of 15-49 age have high blood glucose in India. Prevalence of high blood glucose generally increases with age and is higher in urban than rural areas for both women and men [1]. Health promotion mechanisms is one of the envisaged roles to be played by the public and private sectors in achieving the goals of National Program for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) as per the National Multi-sectoral Action Plan (NMAP) for Prevention and Control of Common Non-Communicable Diseases (NCDs) (2017-22), revised in October 2017 [2]. The framework also enlists the desired achievement of reduction in premature mortality due to NCDs by 10% by 2020 and by 25% by 2025.

Towards preventing the complications due to common NCDs, especially Diabetes, the ESIS (Employee State Insurance Corporation-State) of Telangana State has made a non-financial agreement with Novartis Healthcare Private Limited (Novartis) to utilize the support from Novartis Public Health Initiatives in 5 identified ESI Hospitals/dispensaries in the state. As part of the agreement, Novartis supported ESI State Hospital in Nacharam, Hyderabad through arranging an algorithm based screening camps at stipulated frequency.

Employee's State Insurance (ESI) is a self-financing social security and health insurance scheme for workers or employees of firms in India [3]. Employees' State Insurance Act, 1948 (ESI Act), by the Parliament was the first major legislation on social Security for workers in independent India. It encompasses certain health related eventualities that the workers are generally exposed to; such as sickness, maternity, temporary or permanent disablement, Occupational disease or death due to

employment injury, resulting in loss of wages or earning capacity-total or partial [4]. Employees' State Insurance Corporation (ESIC) is an autonomous corporation, which is maintained by the central government under the Ministry of Labour and Employment, Government of India. ESI State Hospital in Nacharam is a one-stop super-specialty destination for patients from Hyderabad and nearby districts. Major services available round the clock at this hospital are Orthopedic, General Physician, Ophthalmology and Diabetes clinic among others [3].

Diabetic retinopathy (DR) is one of the leading causes of visual impairment and blindness globally [5]. Globally, it is estimated that the DR cases would increase from 126.6 million to 191 million from 2010 to 2030 [6]. The prevalence of DR in India is reported to be between 17.6% to 28.2% [7-10] which is lower than high-income countries ranging between 30% to 50% [11]. There are several factors, which influence incidence of DR such as duration and type of DM, blood pressure and serum lipid etc. After onset of non-insulin dependent DM, the DR develops generally in 4-7 years. Hence, Ophthalmologists advise a comprehensive eye examination including dilated fundus examination for all subjects with diabetes on regular basis [12]. With the improvement in life expectancy in India [13], the individuals with DM are expected to live longer than before and as the DM occurs at younger age in Indians compared to Caucasians [14-15] the DM complications such as DR are bound to increase in the coming years. Early detection of DR is critical in preventing vision loss. Poor knowledge about DM and inequitable availability of diagnostic services are major challenges in early detection of DR in India [16].

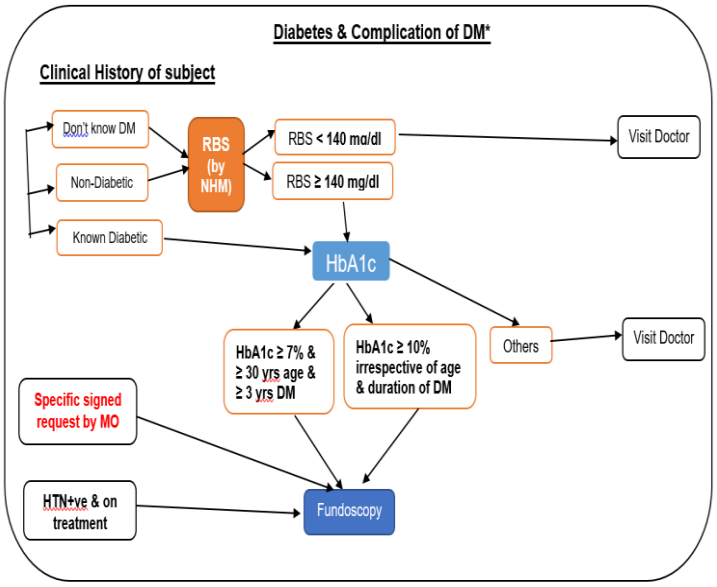
In current study, we present the observations from our intervention, which add value to the existing knowledge on role of regular screening and early detection of diabetes and its complications towards achieving the goals of NPCDCS.

SUBJECTS, MATERIAL AND METHODS

ESI State Hospital, Nacharam, is one of the 5 hospitals/dispensaries identified for implementation of the non-financial collaboration between ESIS DIMS, GoTS and Novartis under its Public Health Initiatives. The visitors to the out-patient department of ESI Nacharam were screened for history of Diabetes and tested for Random Blood Sugar (RBS) levels using the rapid test kits on the finger prick whole blood samples. The known diabetics and the new suspects for DM with RBS >140 mg/dl were referred to the NCD screening camps arranged at the Ophthalmology out-patient area in the hospital.

According to the pre-decided camp calendar, the Novartis team provided the screening tests along with necessary test kits as per the attached screening algorithm (Figure 1) on the camp day. Diabetes and its complications related to Retina were covered through these camps.

Figure 1 – Screening algorithm for Diabetes and Complications of DM



RBS: Random Blood Sugar, HbA1c: Glycosylated Hemoglobin, DM: Diabetes Mellitus

HbA_1c results were generated using rapid test kit (SD Multicare), which generates results within 3 minutes, and the same were shared with the subjects attending the camps on the spot. If the HbA_1c was >7% and based on other criteria of algorithm, the Medical Officer (MO) in the ESI Nacharam recommended further testing with Fundoscopy (Figure 1). Fundus assessment was performed using Bosch fundus camera and the image was shared immediately with the MO in the camp for an immediate counseling to the subject. However, a printed copy of the image with reporting by a qualified ophthalmologist was shared in courier to the health facility within 7 days for data updation in the patient treatment card and further distribution to the subjects.

RESULTS

Twenty four secondary screening camps were conducted in the hospital during Jul 2018 to Aug 2019. Of 2676 (male=1458; female=1218) subjects utilizing the camp services, 70% (1884) have utilized the HbA_1c testing in the camps. Number of HbA_1c tests conducted in one camp ranged from 43 to 250 (Table 1).

Among those utilizing the screening camps, 54.6% (1029/1884) were males and 45.4% (855/1884) were females. Of them 1041 (55%) were known diabetic subjects and 843 (45%) did not know their DM status or were known non-diabetic. Age of the subjects ranged from 15 to 86 years, while majority (56.6%) of the subjects belonged to 40-59 years age group (Table 2). The mean age of the subjects was 48.94 years with standard deviation of 11.94 years. As the age increased, there was significant higher utilization of screening camps by men compared to similar age group of women ($p<0.001$) (Table 2).

Table 1 – Camp wise details of subjects utilizing the secondary screening camps

Date	Camp OP	Males	Females	HbA_1c	Fundoscopy
01-Jun-18	51	24	27	40	0
15-Jun-18	62	28	34	35	8
29-Jun-18	43	28	15	33	7
13-Jul-18	60	32	28	30	9
27-Jul-18	86	52	34	46	19
25-Sep-18	55	31	24	44	2
09-Oct-18	60	39	21	50	9
23-Oct-18	89	50	39	89	27
20-Nov-18	53	31	22	53	16
04-Dec-18	71	49	22	71	23
18-Dec-18	63	35	28	63	20
22-Jan-19	106	70	36	90	16
05-Feb-19	97	47	50	70	27
19-Feb-19	148	75	73	118	30
05-Mar-19	161	88	73	111	50
19-Mar-19	93	48	45	86	49
14-May-19	220	100	120	81	25
28-May-19	158	91	67	56	14
11-Jun-19	150	90	60	60	7
25-Jun-19	120	57	63	117	20
09-Jul-19	250	133	117	137	25
23-Jul-19	150	69	81	144	8
06-Aug-19	180	115	65	117	12
20-Aug-19	150	76	74	143	11
Total	**2676**	**1458**	**1218**	**1884**	**434**

The abnormal HbA_1c results were significantly higher among men compared to women ($p<0.05$). Nearly 47% of the known diabetic subjects had HbA_1c >7% that indicates the treatment adherence needs to be strengthened ($p<0.05$). Nearly one-third (34%) had HbA_1c levels >7%. Higher proportion of subjects with high HbA_1c level were found among known diabetics compared to the subjects without prior diabetes or unknown status ($p<0.05$) (Table 3 & Figure 2).

Among 648 subjects with HbA_1c >7%, 434 (67%) could have Fundoscopy test during the camps of which 122 (28%) had abnormal Fundoscopy results indicating need for regular screening for diabetic retinopathy (Table 4). There was no significant difference in Fundus abnormalities across gender (Table 2). Fundus abnormalities did not differ significantly across known or unknown status of diabetes (Table 4). Abnormal fundus status has significantly increased with the increase in age of the subject between 20 to 80 years age (Table 5).

Table 2 – Demographics of study subjects tested for HbA_1c

Variable	Gender		Total	Pearson X^2 statistic and *p-value*
	Female n (row %)	Male n (row %)	n	
Total	**855 (45.4%)**	**1029 (54.6%)**	**1884**	
Age Category				
0-19	3 (100.0%)	0 (0.0%)	2	39.967* ***p<0.001***
20-39	247 (57.7%)	181 (42.3%)	428	
40-59	466 (43.7%)	601 (56.3%)	1067	
60-79	139 (36.4%)	243 (63.6%)	382	
>=80	1 (20.0%)	4 (80.0%)	5	
Diabetes Status prior to camp				
Known Diabetic	440 (42.3%)	601 (57.7%)	1041	9.102 ***P=0.002***
Unknown status/ Non Diabetic	415 (49.2%)	428 (50.8%)	843	
HbA_1c Results				
Normal (<6%)	384 (51.3%)	365 (48.7%)	749	24.559 ***p<0.001***
Good Control (6-7%)	214 (43.9%)	273 (56.1%)	487	
Fair Control (7-8%)	120 (38.3%)	193 (61.7%)	313	
Unsatisfactory Control (8-10%)	91 (37.3%)	153 (62.7%)	244	
Poor Control (>10%)	46 (50.5%)	45 (49.5%)	91	
Fundoscopy				
Abnormal	53 (43.4%)	69 (56.6%)	122	0.656 ***p=0.418***
Normal	149 (47.8%)	163 (52.2%)	312	
Total Fundoscopy	202 (46.5%)	232 (53.5%)	434	

*** X^2 test performed only for 3 age-groups 20-39, 40-59 and 60-79 years as both the extreme age groups have very minimal subjects.**

Table 3 – HbA_1c results versus Diabetes Mellitus status before testing in the camp

	Normal (<6 %)	Good Control (6-7%)	Fair Control (7-8%)	Unsatisfactory Control (8-10%)	Poor Control (>10%)	Total
Known Diabetic	240	304	225	192	80	1041
DM status not known	509	183	88	52	11	843
Total	749	487	313	244	91	1884

Pearson X^2 statistic is 301.81 p<0.001

DISCUSSION

Complication of diabetes is one the major contributing to preventable blindness in India. By 2030, it is estimated that 79.4 million people in India would have DM and 22.4 million DR [17]. Though prevalence of DM (10%) and DR (12%) has been lesser in rural India compared to urban India, the subset population can never to be ignored as majority of Indian population (70%) resides in rural India [18,19]. Abysmally low confirmation DM in rural India was found to be due to 'low risk perception' in a study,

Table 4 – Fundus abnormalities in comparison with Diabetes Mellitus Status

Fundus Results	DM Status Known	DM Status Unknown	Total	Pearson X^2 statistic is
Abnormal	38	84	122	0.1903
Normal	104	208	312	***p=0.662***
Total	**142**	**292**	**434**	

Table 5 – Fundus abnormalities with Age-group (in years)

Fundus Results/ Age-group	0-19	20-39	40-59	60-79	>=80	Total
Abnormal	0	16	48	55	3	122
Normal	3	57	189	61	2	312
Total	**3**	**73**	**237**	**116**	**5**	**434**

Pearson X^2 statistic is 30.123 p<0.001. * X^2 test performed only for 3 age-groups 20-39, 40-59 and 60-79 years as both the extreme age groups have very minimal subjects.

Figure 2 – HbA1c results

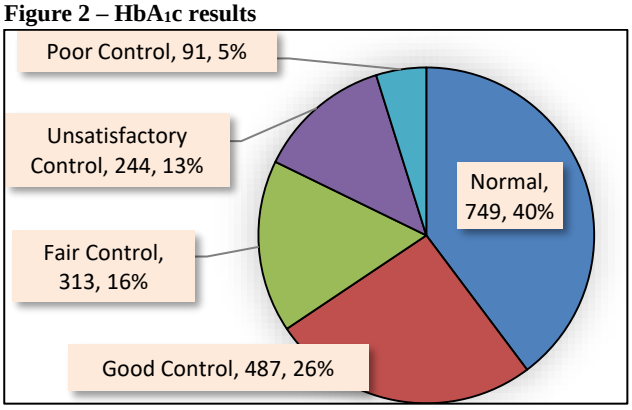
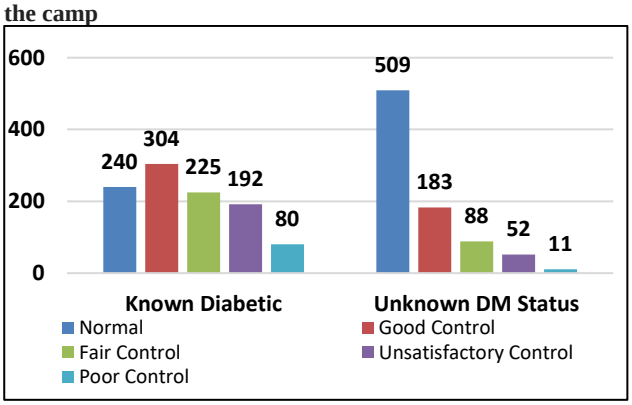


Figure 3 – HbA1c results versus DM status before testing in the camp



which recommended community-focused risk communication interventions to increase the uptake of DM confirmatory tests [20]. A population-based study from India reported <1% uptake of confirmatory tests by the DM high risk patients identified through screening [21]. However, some other studies reported varied uptake of confirmatory tests ranging from 30% [22] to 50% [23]. Uptake of HbA_1c as confirmatory was observed to be at 70% (1884/2676) in our hospital-based algorithm-based screening of high risk subjects.

Our analysis of 1884 subjects utilizing the screening camps at ESI State Hospital, Nacharam, Hyderabad through 24 focused screening camps had observed that 34% of the subjects screened (648/1884) had HbA_1c >7%. However, it is interesting to find that of those with HbA_1c >7%, approximately one fourth (23%; 151/648) were either not aware of their DM status or they were found to be non-diabetic earlier, while 77% (497/648) were known Diabetic subjects. It implies that the blood sugar maintenance in the known diabetic needs a drastic improvement who are prone for all complications of DM unless the treatment adherence is achieved through proper counselling and management.

If detected early, Diabetic Retinopathy is a preventable complication among the patients with diabetes. In a study conducted on rural Indian population, 49.9% subjects had knowledge of DM and only 37.1% about DR, while knowledge and belief about controlling blood sugar can avoid DR was limited to only 36.5% [24]. Only one-third (34%) decided to visit an ophthalmologist for eye check-up when they had any problems with eyesight [25]. Besides other factors such as poor doctor-patient communication, cultural beliefs, poor literacy and misconceptions about treatment, Lack of awareness about DR was the prime reason for the delay in investigation for complication of DM especially for DR [25, 26].

Our analysis also observed that around 28% (122/434) had abnormal retina in Fundoscopy testing. Interestingly the abnormalities in fundus were seen in higher proportions in those without prior DM diagnosis 29% (84/292) compared to those in known DM cases 27% (38/142). This result implies that there is higher proportion of abnormal fundus cases even before the subjects are identified with Diabetes. In line with general expectations, with age the abnormal fundus results have increased from 0% (0/3) in 0-19 years age group, 21.9% (16/73) in 20-39 years, 20.3% (48/237) in 40-59 years, 47.4% (55/116) in 60-79 years and 60% (3/5) in subjects with >80 years age group. However, interestingly, there was no gender difference in fund results with 26.2% (53/202) abnormality in females and 29.7% (69/232) in males.

Some of the strengths of our study are that, firstly, for the first time in Telangana State ESIS, the secondary screening support provided through a non-financial collaboration was effectively integrated into regular clinical services. Secondly, a structured planning of schedule of the camps was done and the same was informed to people visiting the Ophthalmology out-patient department. Thirdly, the report of confirmatory test for DM was instantaneous which helped the Medical Officer (MO) in the facility to take immediate necessary actions in terms of counseling and treatment modifications besides identifying candidates for further testing related to complications of DM. Results of Fundoscopy were also instantaneous through images which helped the MO for providing further counselling and referral to higher centers for further management.

Limitations: One major limitation in our study is that, only 67% of subjects with HbA_1c >7% could utilize Fundoscopy. Higher proportion of fundus abnormalities could probably be because the hospital is a referral center which needs to be explored through similar screening protocol in peripheral hospitals/dispensaries.

Conclusion: The observations suggest that there is high probability of undetected Diabetes cases with or without complications in the field, which might be missed during routine population based screening. Our results indicate the abnormality in fundus due to DM is higher (28.1%) than generally expected which emphasizes the need forregular and structured counseling on treatment adherence to those who are already diagnosed with DM towards prevention and early detection of diabetic retinopathy.

Acknowledgements: We acknowledge the support rendered by ESI Hospital administration and staff in organizing the screening camps as per schedule. Also acknowledge the support in arranging for the digital educational kiosk on the camp days for awareness on DM and DR among the patients and their attendants visiting the hospital.

Disclosure/ Conflict of Interest: There is no conflict of interest declared as the screening camps arranged by Novartis were as per the non-financial MoU between ESIS DIMS, GoTS and Novartis and as per mutually agreed screening camps schedule and algorithm. Novartis has not collected/ gathered any individual/ personalized data from the screening camps. Support by Novartis was limited to the arrangement of camps only. Data collection, analysis and further intervention based on the screening camps results were solely owned by ESI Hospital, Nacharam, Hyderabad.

Ethical considerations: Since all the provided services were part of implementation of the national program, NPCDCS, in accordance to the non-financial agreement, and no therapeutic or clinical interventions were made in the study, there was no breach of ethical issues of the subjects who were part of the analysis.

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