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STUDY ON ASSOCIATION OF DIABETIC FOOT ULCER WITH DIABETIC RETINOPATHY IN A UNIVERSITY TEACHING HOSPITAL

Ophthalmology

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ABSTRACT

AIM: To study the prevalence of diabetic retinopathy (DR) in patients with diagnosed diabetic foot ulcer (DFU) and correlations with other risk factors. **METHODS:** A cross sectional study was conducted in a university teaching hospital over six months. A complete ophthalmological evaluation with history, physical examination and investigations were done. RESULTS: 100 type 2 diabetes mellitus (DM) patients with DFU were included in this study with mean (SD) age being 55.74 ± 11.6140 years and of which 74% were males. Mean duration (SD) of DM was 10.16 ± 6.5945 years. 52% of patients showed various retinopathy changes. Statistics showed an increased association between presence of retinopathy with increase in severity of DFU ($p < 0.01$). **CONCLUSION**: The severity of retinopathy was greater in patients with increasing severity of DFU than in other associated risk factors. This association can help in future research on tackling these two devastating and crippling conditions.

KEYWORDS

Diabetic, foot ulcer, retinopathy, severity

INTRODUCTION

The diabetic population in the world is on a rapid rise with India bearing the impact of the global burden (1). This severity in the disease is also associated with conditions like nephropathy, neuropathy and retinopathy which are due to the changes in the microvasculature of the body. Diabetic foot ulcer (DFU) results in significant morbidity and mortality. Vascular insufficiency is the important pre- disposing factor for DFU, making it the common cause of non-traumatic foot amputation worldwide (2). The cultural practices in India such as barefootwalking, farming and agricultural injuries can contribute to the higher incidence of DFU, along with the rising standards of living (3,4) which is associated with poor standards of living. Our study tries to investigate the risk factors which contributes to the development of DR in patients with DFU from South India.

AIM

To evaluate, in diagnosed DFU patients, the extent of incidence and severity of DR and to compare all other risk factors like age, gender, duration of diabetes and hypertension, pulse pressure, presence of smoking, Body mass index, HbA1c, FBS, PPBS, duration of antidiabetic treatment, BUN and serum creatinine

MATERIALS

Type of study : Cross sectional study
Period of study : 6 months
Sample size: 100
Setting: Ophthalmology OPD in our University Teaching Hospital

INCLUSION CRITERIA:

- Type 2 diabetic patients diagnosed with a DFU which is based on the Wagner ulcer classification attending the General Surgery OPD

EXCLUSION CRITERIA:

- Patients with gestational diabetes
- Patients less than 18 years of ag
- Type 1 DM
- Patients whose retinopathy status can not be assessed due to hazy media

METHODS

100 patients suffering from DFU who have Diabetes Mellitus (DM) were enrolled from the General Surgery OPD. As per the guidelines of the Declaration of Helsinki, we explained the study and obtained a carefully explained informed written consent from the patients before they enrolled. Ethics was obtained from the ethics committee board of Sri Ramachandra Institute of Higher education and Research (SRIHER). Patients were asked in detail, about their diabetic history and other demographic details. Anthropological measurements like height, weight were collected and body mass index was calculated. We also noted the blood pressure and collected blood investigations like fasting blood sugar, post prandial blood sugar and glycated hemoglobin which was performed at the time of the study.

The Wagner ulcer classification system was used to classify foot lesions in these patients, which is as follows. There are 5 grades - grade 0 indicating no skin lesion with hyperkeratosis below or above bony prominences, grade 1 which indicated an ulceration of the skin and immediate subcutaneous tissue, grade 2 which denoted deeper lesions that may penetrate to the tendon, bone, or joint capsule, grade 3 denoting deep tissues are always involved, and osteomyelitis may be present, grade 4 indicating the presence of gangrene of some portion of the toes or forefoot, grade 5 denoting the entire foot is gangrenous.

We conducted visual acuity charting, slit-lamp biomicroscopy to evaluate the anterior segment, indirect ophthalmoscopy using a +90 D lens to examine fundus and intraocular pressure using Goldmann's applanation tonometry of each patient. In patients with asymmetrical DR, the rule was to consider and record retinopathy of greater severity. The grading of retinopathy was done as follows. There are 5 grades –

1. No Retinopathy changes
2. Mild Non Proliferative Diabetic Retinopathy (NPDR)
3. Moderate NPDR
4. Severe NPDR
5. Proliferative Diabetic Retinopathy (PDR)

The guidelines for retinopathy grading were as per the International Clinical Diabetic Retinopathy and Diabetic Macular Edema Severity scale.

RESULTS

The collected data were analysed with IBM.SPSS statistics software 23.0 Version. The probability value .05 was considered as significant level. 100 patients with DFU were included in this study. Their mean (SD) age was 55.74 ± 11.6077 years. 74% were males. The mean duration (SD) seen in these diabetic patients was 10.16 ± 6.94505 years. DR was seen in 52 patients. A significant association was seen between the duration of diabetes mellitus, severity of diabetic foot ulcer and the presence of retinopathy, as seen by the Chi square test (p .021)

In patients with Grade 1 DF, 45% % had mild NPDR, 18.18% had mild NPDR + CSME, 27.27% showed moderate NPDR + CSME, 9.09%

had severe NPDR + CSME and 72.91% showed no DR. In patients with Grade 2 DF, 61.53% had mild NPDR, 23.07% had moderate NPDR, 15.38% had only CSME and 16.66% had no DR. In patients with Grade 3 DF, 58.82% suffered from mild NPDR, 29.41% from moderate NPDR, 11.76% from moderate NPDR + CSME, and 2.08% had no DR. In patients with Grade 4 DF, 18.18% had mild NPDR, 27.27% had moderate NPDR, 54.54% had moderate NPDR + CSME, and 8.33% had no DR.

The increasing severity of DFU and the severity of stage of DR showed a statistical significance, given by Chi-square test (P 0.002). No patients had PDR. No significance was found to associate serum creatinine, glycated hemoglobin or serum urea with various stages of DF or DR, statistically. Glycated hemoglobin was found to have a mean of 10.327 ± 2.7835%, serum urea a mean value of 12.14 ± 10.5747 mg/dL and serum creatinine 1.033 ± 1.1104 mg/dL.

CLINICAL PROFILE OF DR PATIENTS VS NON DR PATIENTS				
PARAMETER		NON DR	DR	TOTAL
SEX	FEMALE	18 (37.5%)	8 (15.38%)	26
	MALE	30 (62.5%)	44 (84.61%)	74
AGE	<40 YEARS	8 (16.66%)	11 (21.15%)	19
	41-50 YEARS	12 (25%)	12 (23.07%)	24
	51-60 YEARS	22 (45.83%)	16 (30.76%)	38
	>60 YEARS	6 (12.5%)	13 (25%)	19
DURATION OF DIABETES	<5 YEARS	15 (31.25%)	12 (23.07%)	27
	5-10 YEARS	18 (37.5%)	27 (51.92%)	45
	>10 YEARS	15 (31.25%)	13 (25%)	28
HYPERTENSION	NO	28 (58.33%)	36 (69.23%)	64
	YES	20 (41.66%)	16 (30.76%)	36
SMOKING	NO	37 (77.08%)	39 (75%)	76
	YES	11 (22.91%)	13 (25%)	24
BMI	18.5–23 KG/M2	8 (16.66%)	18 (34.61%)	26
	23 – 25KG/M2	31 (64.58%)	18 (34.61%)	49
	25 - 30KG/M2	9 (18.75%)	16 (30.76%)	25
HBA1C	<8 %	12 (25%)	13 (25%)	25
	8– 9 %	8 (16.66%)	7 (13.46%)	15
	>9%	28 (58.33%)	32 (61.53%)	60
ORAL DRUGS	NO	17 (35.41%)	20 (38.46%)	37
	YES	31 (64.58%)	32 (61.53%)	63
INSULIN	NO	37 (77.08%)	30 (57.69%)	67
	YES	11 (22.91%)	22 (42.30%)	33
BUN	<7MG/DL	8 (16.66%)	8 (15.38%)	16
	7-18MG/DL	31 (64.58%)	26 (50%)	57
	>18MG/DL	9 (18.75%)	18 (34.61%)	27
CREATININE	<0.6MG/DL	9 (18.75%)	7 (13.46%)	16
	0.6-1.3MG/DL	32 (66.66%)	31 (59.61%)	63
	>1.3MG/DL	7 (14.58%)	14 (26.92%)	21

Figure 1 : Clinical profile of non DR versus DR patients

	Non DR	DR
I	72.91%	21.15%
II	16.66%	25%
III	2.08%	32.69%
IV	8.33%	21.15%

Figure 2 : Percentage of non DR and DR cases among various grades of DFU

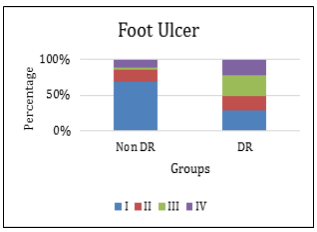

Figure 3 : Graph depicting the maximum DR cases in foot ulcer grade 3

	B	Standard Error (S.E.)	p value	Odd's ratio (OR)	95% C.I.for OR	
					Lower	Upper
HB1AC	-.032	.113	.774	.968	.776	1.208
CREATININE	.852	.493	.084	2.344	.891	6.164
AGE	.024	.030	.416	1.025	.966	1.087
BMI	-.019	.208	.928	.981	.653	1.474
SEX	.737	.770	.338	2.090	.462	9.449
DIABETES	-.141	.061	.021	.869	.771	.979
HTN	.472	.681	.488	1.604	.422	6.094
SMOKING	.182	.837	.828	1.200	.232	6.191
INSULIN	.329	.614	.592	1.389	.417	4.625
FOOTULCER	.890	.293	.002	2.436	1.371	4.328
CONSTANT	-2.696	5.834	.644	.067		

Figure 4 : Correlation of DR with various factors

DISCUSSION

An association of increasing DR and DFU, as seen in our study, was found in a similar study conducted by Hwang et al. An increased oxidative stress occurring in the later stages of diabetes, leading to an endothelial damage was hypothesized in his study(2). However no PDR was seen here. Shahbazian et al. showed that 33.3% of their patients with a DFU of grade 1 or higher had presence of DR (5), while ours showed 52 DFU patients having DR. An increased presence of nephropathy and HTN was seen in a study conducted by Venkatesh et al. (6). This was not seen in our study, probably due to the smaller sample size. Advanced age and higher HbA1c levels was seen as risk factors in a study conducted by Shahbazian et al(5). However, these risk factors had no significance in our study. Boyko et al. also reported risk factors such as HbA1c and serum creatinine levels for development of DFU (7), which did not occur in our study.

A study conducted by Nadarajan et al, showed that the duration of diabetes accelerated the development and progression of DR (8). The Wisconsin epidemiological study revealed the prevalence of DR varied from 28.8% in diabetic patients with duration <5 years to 77.8% in diabetic patients with duration of more than 15 years (9). Gadkari et al. conducted a study in 2014, showing a variation between 9.23% in newly diagnosed diabetics <6 months to 35.12% at >5 years (10)

Agarwal S et al. proved that the incidence of DR was more in long standing diabetics (13%) than in those who were newly diagnosed (2.8%)(11). The CURES study showed an overall prevalence of DR as 17.6% including 20.8% in known diabetic patients and 5.1% in newly detected diabetics. Also, they noticed that the prevalence of DR was considerably higher in men than in women. In their study, it showed an increased risk of DR ie. 1.89 fold for every 5-year increase in the duration of diabetes (12) . Yet again, as seen before, the major risk factors for DR in these studies by Agardh E et al, Cohen O et al, Yoshida Y et al were the duration of diabetes and degree of glycemic control (13), (14), (15) . A study conducted in Punjab revealed that 33.98 percent of T2DM subjects above 45 years had NPDR and 31.50 percent of type 2 diabetic patients had PDR respectively (16) .

CONCLUSION

An establishment of an association between DR and DFU could help in better screening protocols to be followed, so as to detect and manage both the diseases in a timely fashion. Retinopathy speeds up the progression of DFU, and viceversa, the presence of DFU can forsee a possible progression to the advanced stages of DR. A limited data on the association between DFU and DR is seen. A well-planned strategy in providing an integrated approach to the workup of diabetic patients

in the early stages itself should be in place and is the need of the hour. An ophthalmological opinion in case of detection of DFU and viceversa, ie a prompt referral of DR patients to a general surgeon specializing in DFU is of paramount importance, for better outcomes.

FUTURE SCOPE

Our study had limitations such as small sample size as compared to other studies. Also, the population demographics was largely restricted to the local area thus extrapolation to the Indian population might not be accurate.

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