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Original Article

Internal Medicine Section

Complications in Advanced Diabetics in a Tertiary Care Centre: A Retrospective Registry-Based Study

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ABSTRACT

Introduction: Diabetes is a major public health problem in our country and complications of diabetes are a major cause of morbidity and mortality. There is a need to quantify the complications in order to improve our strategies for prevention and management.

Aim: To measure the prevalence of complications in type 2 diabetics following up at a tertiary care centre and to study its association with the socio-demographic and clinical parameters.

Materials and Methods: A retrospective record based study was conducted on 3261 type 2 diabetic patients on insulin therapy, recorded in the diabetic registry maintained at Goa Medical College from Aug 2009 to May 2012. Data on anthropometric measurements, demographic characteristics, complications and other details were extracted from these records.

Results: Out of the 3261 patients 1025 (31.4%) had macrovascular complications and 1122 (34.4%) had at least one microvascular complication. The prevalence of peripheral vascular disease, coronary artery disease and stroke were 6.7%, 21.3% and 6.6% respectively and were significantly higher in males. The prevalence of diabetic retinopathy, nephropathy and neuropathy were 16.7%, 16.5% and 16.3% respectively with diabetic nephropathy being significantly higher in males. Trend analysis showed significant association of rising prevalence of all complications with age ($p<0.05$). Duration of diabetes also showed significantly positive trend for all complications ($p<0.05$) except stroke.

Conclusion: The study presents the prevalence of diabetic complications in patients reporting to a tertiary hospital in Goa. Coronary artery disease was found to be the most common complication. As age and duration of diabetes were found to be significantly associated, efforts should be made towards promoting earlier diagnosis of diabetes so as to improve management and decrease the chances of complications.

Keywords: Diabetes mellitus, India, Registry

INTRODUCTION

Diabetes mellitus is one of the most important non-communicable disease of public health concern today [1]. According to the International Diabetes Federation (IDF), the estimates of diabetics in India in the 2015 was 69.2 million, which is predicted to rise to 123.5 million by 2040, next only to China. The same atlas also reported national prevalence as 8.7% (7.0 - 10.6) and 1,027,911.6 diabetes related deaths in the 20-79 year age group [2]. There are 350 million people with diabetes worldwide and the numbers are expected to double in the next 20 years. It is with this in mind that the World Health Organisation has declared 'beat diabetes' as the central theme for World Health Day 2016 [3].

Goa, where the current study is based, is a small state on the west coast of India which is reported to have one of the highest GDP in the country and it also has an affluent lifestyle. This provides a fertile ground for lifestyle diseases such as diabetes [4]. A recent study [5] on diabetes in rural Goa revealed a prevalence of 10.3% in >20-year-old, which is similar to the reported prevalence of 8.6% from the neighbouring Malwan area in Sindhudurg, Maharashtra [6]. At the most humble estimates India is projected to spend 4.8 billion USD in 2030 on diabetes accounting for 11% of health expenditure, which will be a considerable burden on a country already battling with tuberculosis, malnutrition, infant and maternal mortality superimposed on poverty [7]. A large amount of this will be spent on direct costs like drugs and management of chronic debilitating complications of diabetes [8,9]. The present situation makes it all the more important that we make attempts to understand the prevalence of these complications and possible risk factors in order to develop potential preventive programmes.

On 15th August 2009, Government of Goa launched a program of supplying free insulin to all patients following up at government hospitals [10]. The prerequisite for a patient to be provided insulin is to get registered at the diabetic clinic and should be on insulin prescription from the institution doctors. At the diabetic clinic anthropometric data, family history, medical history, status of complications and type of insulin prescribed were recorded. This study is an analysis of the captured data in the records as an attempt to understand the prevalence of various macrovascular and microvascular complications in that population.

MATERIALS AND METHODS

Study population

Data for this study was collected from the Insulin prescription registry set up at the diabetic clinic, Goa Medical College. This service included all patients seen at Goa Medical College. Goa Medical College is a government tertiary care hospital which provides free services to the people of Goa.

The patients included in the study were the ones with established diagnosis of Type 2 diabetes mellitus and were prescribed insulin with or without oral hypoglycaemic agents. Type 2 diabetics otherwise controlled on oral hypoglycaemics but temporarily on insulin, Type 1 diabetics, gestational diabetes mellitus, other causes of diabetes like fibrocalcific pancreatic diabetes and cases under investigation were excluded from the study.

The Institutional Review Board (IRB) of Goa Medical College approved the study protocol. Records of all eligible patients who were registered at diabetic clinic, Goa Medical College between Aug 2009 and May 2012 were included in the study. 3261 patient records out of total 3361 (96.45%) satisfied the inclusion criteria. These records included existing as well as new insulin prescribed patients during the study period.

Data collection

Anthropometric data in the registry was collected by a nurse measuring height weight, waist circumference and hip circumference following the standardized guidelines. The variables recorded in the registry were age of diagnosis of diabetes mellitus and years since prescribed insulin. If the patients were aware of the diabetic history of their family members, the same was recorded. The type of insulin, prescribed insulin regimen and last lab report values were also recorded.

Diabetic complications were recorded as macrovascular (coronary artery disease, peripheral vascular disease and stroke) and microvascular (diabetic retinopathy, diabetic nephropathy and peripheral neuropathy).

Coronary artery disease was defined on basis of changes in 12 lead resting echocardiogram and any documented past event of myocardial infarction, coronary artery bypass grafting or any other invasive procedure to treat the coronary artery disease. Peripheral vascular disease was defined as absent pedal pulses or history of a past event of gangrene, amputation, vascular surgery or ischemic foot ulcer. Stroke was defined as a recorded past event of transient ischemic attack or cerebral vascular accident.

Diabetic retinopathy was defined by fundoscopy (direct ophthalmoscopy) performed on dilated pupils by ophthalmologists. Diabetic nephropathy was diagnosed on basis of presence of urinary albumin in range of 30-300mg/day on repeated testing. Peripheral neuropathy was defined by history of pain, tingling numbness.

Data Management and Statistical Analysis

All patient records were available as individual MS Word files containing a semi-structured, close-ended proforma. The relevant data like socio-demographic characteristics, years since diagnosis, complications were subsequently transferred into an MS Excel file using scripts to avoid inadvertent errors of manual entry.

STATISTICAL ANALYSIS

Tests such as χ^2 tests and Independent t-test were used to analyse categorical and continuous variables, respectively. Mantel-Haenszel linear-by-linear association chi-squared test was used for trend analysis. Binomial logistic regression was performed to see predictive models. All statistical testing was two-tailed with significance level of 0.05. The statistical analysis was performed using IBM SPSS Statistics (v 19) and MS Excel 2007.

RESULTS

General Characteristics

A total of 3261 recorded entries were analysed after applying the inclusion/exclusion criteria. Of these, 837 (25.7%) patients were enrolled in 2009 (from Aug), 1319 (40.4%) in 2010, 725 (22.2%) in 2011 and 380 in 2012 (till May). There were 1991 (61.1%) males as compared to 1270 (38.9%) females. The mean age recorded was 57±11 years (median: 58 years; interquartile range: 16 years), with mean duration of being diabetic when enrolled in study was 9.1±7.6 years (median: 8.0 years; interquartile range: 11 years). There was a statistically significant difference in mean Body Mass Index (BMI) between males and females, with females BMI higher than males, 1.74 (95% CI, 1.41 to 2.06), t(2393.265) = 10.468, $p < 0.001$. When asked about family history of diabetes, 971 (29.8%) gave a positive family history out of which 299 (9.2%) reported only father as diabetic, 514 (15.4%) reported only mother and 158 (4.8%) reported both parents as diabetic. There was no statistically significant association between gender and family history of diabetes, χ^2 (3) = 1.047, p = 0.790.

Complications

In [Table/Fig-1] we see, overall 1025 (31.4%) patients had one or more macrovascular complications. The prevalence of individual complications, Peripheral Vascular Disease (PVD), Coronary Artery Disease (CAD) and stroke were 6.7%, 21.3% and

Variables	n	PVD	CAD	Stroke	Macrovascular	Diabetic Retinopathy	Diabetic Nephropathy	Diabetic Neuropathy	Microvascular
Sex									
Male	1991	168 (8.4)	457 (23.0)	149 (7.5)	699 (35.1)	350 (17.6)	358 (18.0)	339 (17.0)	708 (35.6)
Female	1270	51 (4.0)	236 (18.6)	67 (5.3)	326 (25.7)	194 (15.3)	180 (14.2)	194 (15.3)	414 (32.6)
Total	3261	219 (6.7)	693 (21.3)	216 (6.6)	1025 (31.4)	544 (16.7)	538 (16.5)	533 (16.3)	1122 (34.4)
χ^{2a}		24.20	8.85	6.11	32.05	2.96	8.16	1.74	3.01
p-value		<0.001	0.003	0.013	<0.001	0.085	0.004	0.187	0.083
Duration of Diabetes, (in years)									
≤ 5	1301	65 (5.0)	205 (15.8)	79 (6.1)	319 (24.5)	144 (11.1)	155 (11.9)	154 (11.8)	339 (26.1)
5-10	913	76 (8.3)	198 (21.7)	71 (7.8)	312 (34.2)	158 (17.3)	156 (17.1)	164 (18.0)	332 (36.4)
10-15	486	28 (5.8)	122 (25.1)	34 (7.0)	167 (34.4)	116 (23.9)	120 (24.7)	88 (18.1)	204 (42.0)
15-20	320	29 (9.1)	92 (28.8)	19 (5.9)	127 (39.7)	69 (21.6)	55 (17.2)	66 (20.6)	135 (42.2)
>20	241	21 (8.7)	76 (31.5)	13 (5.4)	100 (41.5)	57 (23.7)	52 (21.6)	61 (25.3)	112 (46.5)
Total	3261	219 (6.7)	693 (21.3)	216 (6.6)	1025 (31.4)	544 (16.7)	538 (16.5)	533 (16.3)	1122 (34.4)
χ^2 trend[b]		6.911	52.462	0.058	47.599	50.256	27.884	36.128	68.700
p-value		0.009	<0.001	0.810	<0.001	<0.001	<0.001	<0.001	<0.001
Age, (when collecting data, in years)									
≤ 40	290	9 (3.1)	7 (2.4)	12 (4.1)	25 (8.6)	16 (5.5)	23 (7.9)	25 (8.6)	51 (17.6)
41-50	626	37 (5.9)	73 (11.7)	29 (4.6)	129 (20.6)	79 (12.6)	56 (8.9)	82 (13.1)	161 (25.7)
51-60	1021	77 (7.5)	206 (20.2)	57 (5.6)	307 (30.1)	175 (17.1)	168 (16.5)	192 (18.8)	364 (35.7)
61-70	955	66 (6.9)	281 (29.4)	75 (7.9)	387 (40.5)	203 (21.3)	204 (21.4)	155 (16.2)	385 (40.3)
>71	369	30 (8.1)	126 (34.1)	43 (11.7)	177 (48.0)	71 (19.2)	87 (23.6)	79 (21.4)	161 (43.6)
Total	3261	219 (6.7)	693 (21.3)	216 (6.6)	1025 (31.4)	544 (16.7)	538 (16.5)	533 (16.3)	1122 (34.4)
χ^2 trend[b]		5.647	169.095	22.375	187.160	40.499	67.030	18.140	81.68
p-value		0.017	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

[Table/Fig-1]: Diabetic Complications.
PVD- Peripheral vascular disease CAD- Coronary artery disease. a. Pearson's Chi square test b. Mantel-Haenszel linear-by-linear association chi-squared test.

6.6% respectively. With 34.4% patients showing microvascular complications, the prevalence were much closer with diabetic retinopathy (DR), Diabetic Nephropathy (DNP) and diabetic Neuropathy (DNR) showing prevalence of 16.7%, 16.5% and 16.3% respectively. All the three macrovascular complications were significantly higher among males (all p-values < 0.05) and so was the overall macrovascular complications prevalence (χ^2 = 32.05, p < 0.001). But there was no statistically significant association with gender in overall microvascular complications (χ^2 = 3.01, p = 0.083). Although diabetic nephropathy was significantly higher among males (χ^2= 8.16, p = 0.004).

On performing trend analysis of prevalence of complications, we observed that there was a statistically significant increase in prevalence of macrovascular complications (χ^2trend = 47.599, p < 0.001) as well as microvascular complications (χ^2trend = 68.700, p < 0.001) with duration of diabetes. This was observed in PVD (χ^2trend = 6.911, p = 0.009), CAD (χ^2trend = 52.462, p < 0.001) but not with stroke (χ^2trend = 0.058, p = 0.810). Similarly, trend analysis in relation with age showed a statistically significant trend both in overall macrovascular complications (χ^2trend = 187.160, p < 0.001) and microvascular complications (χ^2trend = 81.68, p < 0.001) as well for individual macrovascular and microvascular complications (all p-values < 0.05).

A logistic regression was performed to ascertain the effects of sex, BMI, age and duration of diabetes on the likelihood that the patients had macrovascular complication [Table/Fig-2] and microvascular complications [Table/Fig-3]. The logistic regression was statistically significant for both macrovascular (χ^2 (4) = 244.006, p < 0.001) and microvascular (χ^2 (4) = 133.028, p < 0.001) complications. Increasing age, BMI and duration of diabetes were associated increased likelihood of exhibiting macrovascular complication with males 1.697 times more likely to exhibit macrovascular complications. However, only increasing age and duration of diabetes were associated with increased likelihood of exhibiting microvascular complication.

DISCUSSION

This paper describes the prevalence of various diabetic complications from a retrospective record based study in a large sample of advanced diabetics following up as outpatients in a tertiary care centre. Goa Medical College being the only tertiary care centre in the state, provides healthcare to its 1.458 million (census 2011) [11] people and also serves the adjacent bordering regions of Maharashtra and Karnataka.

Few studies have been done to describe the prevalence of multiple diabetic complications in a single setting. An overview of such studies can be seen in [Table/Fig-4] [12-18].

The lower prevalence of PVD (6.7%) is consistent with similar lower prevalence of 3.9% [19], 4.0% [13] and 5% [20] and reported from South India respectively in hospital based studies and a prevalence of 6.3% in population based study [21]. Similar lower incidence was reported among Asians (3.7% Asian, 9.3% Caucasian, p< 0.05) in a study in Leicester, U.K [22].

Six hundred ninety three (21.3%) had evidence of CAD. Hospital based study from South Glamorgan (Wales) found this to be 25.2% [16]. Also, a similar prevalence of 19.2% was found in a study from North West India [14] but a lower prevalence of 11.4% was found in South India [13]. The prevalence of stroke 6.6% in our study is consistent with findings in Asians [17] of 6.7% which was done in 13 tertiary hospitals of Korea (n = 5652) and also 6.8% [18] from endocrinology departments of 15 general hospitals in China. The increase in prevalence of PVD and CAD with age and duration of diabetes was found to be similar to other studies [13,18,21]. There was no association of Stroke with increasing duration. This could be because of sampling variation as our study included advanced diabetics and also due to survival bias. We also found statistically

Independent variable	Coefficient	Standard Error	Odds ratio	95% C.I.	p-value
Sex	.529	.085	1.697	1.437 - 2.005	< 0.001
BMI	.022	.009	1.022	1.005 - 1.040	0.014
Age	.047	.004	1.048	1.040 - 1.057	< 0.001
Duration of Diabetes	.015	.005	1.015	1.005 - 1.026	0.005

[Table/Fig-2]: Binomial logistic regression on likelihood of having macrovascular complication.
χ^2 (4) = 244.006, p < 0.001

Independent variable	Coefficient	Standard Error	Odds ratio	95% C.I.	p-value
Sex	.138	.080	1.149	0.983 - 1.343	0.082
BMI	.003	.009	1.003	0.986 - 1.020	0.762
Age	.025	.004	1.026	1.018 - 1.033	< 0.001
Duration of Diabetes	.032	.005	1.032	1.022 -1.033	< 0.001

[Table/Fig-3]: Binomial logistic regression on likelihood of having microvascular complication.
χ^2 (4) = 133.028, p < 0.001

Year	Author	Place	n	Prevalence					
				PVD	CAD	Stroke	DR	DNP	DNR
India									
1989	Patel JC [12]	Bombay (West)	8793	4.2%	27.2%	9.2%	-	-	-
1999	Ramachandran et al., [13]	Chennai (South)	3010	4.0%	11.4%	0.9%	23.7%	19.7%	27.5%
2000	Agrawal et al., [14]	Bikaner (North West)	4067	18.1%	19.2%	-	28.9%	32.5%	30.1%
2012	Kumar et al., [15]	Lucknow (North)	1529	-	-	-	16.7%	19.4%	37%
Other countries									
2000	Morgan et al., [16]*	South Glamorgan (Wales)	10709	-	25.2%	9.6%	16.5%	2.0%	-
2006	Lim et al., [17]	13 tertiary hospitals in Korea	5652	3.0%	8.7%	6.7%	38.3%	44.6%	-
2010	Liu et al., [18]**	Shanghai, Chengdu, Beijing and Guangzhou	1524	-	30.1%	6.8%	14.8%	10.7%	17.8%

[Table/Fig-4]: Studies showing prevalence of multiple diabetic complications in hospital/outpatient settings.
PVD – Peripheral vascular disease; CAD – Coronary artery disease; DR – Diabetic retinopathy; DNP – Diabetic nephropathy; DNR – Diabetic neuropathy
* Included diagnosis of peripheral vascular disease and diabetic neuropathy as foot ulcer. ** Mentions only foot ulcers.

significant higher prevalence in males than females in overall and each macrovascular complication with men having increased likelihood was also seen in binary logistic regression, in spite of available evidence that diabetes erases the female advantage of lower coronary artery disease risk [23]. Smoking could be a possible factor responsible for this, but as data regarding the same was not recorded, we cannot comment on this.

More than a third of the patients (34.4%) had microvascular complications, but individual complications were fairly uniform. Diabetic retinopathy as diagnosed with stereoscopic retinal photography was reported as 18% [24] and 17.6% [25] from South India and our finding of 16.7% is close to this, but unlike both of these studies we didn't find any increased likelihood associated with gender nor was there any increased prevalence, although there was increased prevalence with age and duration of diabetes here as well. In a study from North India where direct ophthalmoscopy was used [15] as in this study, it reported a similar prevalence of 17%. The prevalence of diabetic nephropathy in this study(16.5%) was lower than that which has been reported from North India(26.6%) [26] as well as South India (26.9%) [27]. A greater prevalence was observed in males in this study. Prevalence of diabetic neuropathy as reported using Biothesiometry studies on a thousand type 2 diabetics [28] was reported to be 19.1% which is similar to the observed prevalence in our study (16.3%) and also showed association with age and duration of diabetes, but was lower than that recorded in U.K (32.1%) [29].

Epidemiological studies have shown that there is a large burden of undiagnosed patients with diabetes mellitus [30]. Lack of screening opportunities coupled with non-specific symptoms of the disease is mainly responsible for this. A significant proportion of patients present with microvascular or macrovascular complications at the first detection of diabetes. Our health care delivery system has to be able to focus on prevention of diabetes and its complications in primary care to decrease the burden on the tertiary health care system. There is certainly a need to scale up the strategies for prevention of diabetes, strengthen care and enhance surveillance of diabetes in the community if we have to achieve the third goal in the list of the Global Sustainable Development Goals [31]. The aim is to reduce by one third the premature mortality due to non communicable diseases by the year 2030, which can only be done by focussing on diabetes.

LIMITATION

The study isn't without its limitations. Apart from being a retrospective record based study there are two major factors which possibly contribute to the possible overestimation of the prevalence. The study was conducted in outpatients following up at a tertiary care centre which brings in the possibility of a referral bias. HbA1c could not be studied as an independent variable as the test was not performed on a majority of patients.

CONCLUSION

The study provides prevalence of diabetic complications from a large hospital based setting. The rising trend of complications with age and duration of diabetes makes early diagnosis imperative for better management and prevention of complications. Building capacity of the primary health care system for early detection of diabetes, proper management and prevention would go a long way in preventing the complications due to diabetes as described in this study. Further research is needed to understand the cause for difference in prevalence of complications in males, taking in consideration factors like smoking, diet while also exploring the role of possible genetic predisposition. Research is also needed to develop evidence based practices through primary health care for the adequate management of diabetes and its complications.

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