Type 2 Diabetes Mellitus - Patient Demographics, Risk Factors, Complications and Management: A Cross Sectional Field Survey

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Research Article

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Abstract

Objective: The objective of this study was to evaluate the demographics, risk factors, admission causes, diabetic complications and medical management associated with Type 2 Diabetes Mellitus patients admitted in a semi-urban city in South India. This study followed the Danish Diabetes Risk Score and validated the linkage between Type 2 diabetes and risk factors.

Methods: This study was carried out at Kovai Medical Center and Hospital, Coimbatore, Tamilnadu, India. A total of 270 patients, comprising of both male and female patients diagnosed as Type 2 Diabetes Mellitus with or without co-morbidities admitted and treated as an in-patient basis were included in this study.

Results: Out of 270 patients studied most of patients were in the age groups 60-79 years and 40-59 years, constituting 42.22% and 41.85%. Obesity, the conventional risk factor for diabetes, was observed in 32.22% of total population and another 13.33% were pre-obese. The most prevalent macro vascular complication observed was Cardio vascular, 20.37% and among the micro vascular complications, diabetic nephropathy was most prevalent. During hospitalization, the past medication history of 68.53% of the patients were not available. And at discharge, 39.25% were advised Insulin only, 30.37% were advised both Insulin & Oral Hypoglycemic Agents and 27.03% were prescribed Oral Hypoglycemic Agents (OHA) only. Only 3.33% were on diabetic diet.

Conclusion:
Among the surveyed population, risk factor, macro vascular and micro vascular complications confirms with the earlier

study reports. Also, medical regimens observed in this study confirms that while short acting insulin is the preferred insulin for immediate management, intermediate acting insulin still remains the most trusted insulin for long term diabetes control.

Introduction

Clinical features similar to diabetes mellitus were described 3000 years ago by the ancient Indians, Egyptians, Greeks and Persians. The term "diabetes" was first coined by Araetus of Cappodocia (81-133AD). Later, the word mellitus (honey sweet) was added by Thomas Willis (Britain) in 1675 after rediscovering the sweetness of urine and blood of patients (first noticed by the ancient Indians). It was only in 1776 that Dobson (Britain) firstly confirmed the presence of excess sugar in urine and blood as a cause of their sweetness. In modern time, the history of diabetes coincided with the emergence of experimental medicine [1].

Globally, as of 2010, an estimated 285 million people had diabetes, with type 2 making up about 90% of the cases [2]. Its incidence is increasing rapidly, and by 2030, this number is estimated to almost double. The greatest increase in prevalence is, however, expected to occur in Asia and Africa, where most patients will probably be found by 2030 [3]. According to the International Diabetes Foundation, India has more diabetics than any other country in the world [4].

The first documented study on diabetes in India was a hospital based study from Kolkata in 1938 showing a prevalence of glycosuria (glucose in urine) as 1.3 per cent. The first multi-centric study in India done by the Indian Council of Medical Research (ICMR) between 1972 and 1975, reported a prevalence of 3.0 % in urban areas and 1.3% in rural areas [5]. The rise in prevalence of type 2 diabetes was reported in 1980s, which accelerated after 1990s, showing rapid rises in the southern parts of the country [6].

International Diabetic Federation's projection estimates in 2006 show that the number of people

with diabetes in India is 40.9 million and is expected to rise to 69.9 million by 2025. And as per ICMR study in 2004 on Assessment of Burden of Non Communicable Diseases (NCDs) in India it is estimated that the overall prevalence of diabetes is 62.47 per 1000 population of India [5].

However, in the ICMR study on Assessment of Burden of Non-Communicable Diseases in India [7], the prevalence rates of diabetes were as high as 103 per thousand to 124 per thousand. It was estimated that there are 37.77 million diabetics in India in 2004; 21.4 million in urban areas and 16.36 million in rural areas. Prevalence, increasing in both urban and rural areas, is in the range of 5–15 percent among urban populations, 4–6 percent in semi-urban populations, and 2–5 percent in rural populations [5].

Diabetes mellitus is responsible for 11.57 lakh years of life lost due to the disease, and for 22.63 lakh DALYs (Disability-Adjusted Life Years) during 2004. The estimated number of DALYs attributable to diabetes was 20.72 lakh in the year 2000. As per the ICMR study in 2004 on Assessment of Burden of NCDs in India, the estimates of number of DALYs were 22.63 lakh [5].

Among the risk factors associated with Type 2 Diabetes, while Danish Diabetic Risk Score captures variables age, sex, family history of DM, physical activity, hypertension and obesity; Cambridge Diabetic Risk Score captures smoking too as an additional variable. Since literature showed that the percentage area under the receiver operating characteristic curve (AUC ROC, a standard measure of the ability of a screening test to distinguish cases from no cases) under Danish Diabetic Risk Score was as high as 80.3% [8], we followed the same in this study.

World Health Organization (WHO) defines obesity as BMI of 30 or more and pre-obesity as BMI between 25 and 30 [9]. The association of obesity with type 2 diabetes has been recognized for decades, and the major basis for this link is the ability of obesity to engender insulin resistance [10].

Diabetes substantially increases the propensity to macrovascular and microvascular complications, such as cardiovascular disease, cerebrovascular disease, retinopathy, nephropathy, neuropathy and peripheral vascular complications, all of which account for considerable mortality and morbidity [11].

Diabetic retinopathy was estimated to be 17.6% in a populations based study in Chennai, India in 2005, the prevalence of [12] neuropathy in urban population was 26.1% and the prevalence of coronary artery disease was 21.4% among diabetic subjects compared to 9.1% in subjects with normal glucose tolerance, whereas the prevalence of overt nephropathy was found to be 2.2% and that of micro-albuminuria was 26.9% 22. In addition, a third of the heart attack patients in India have concurrent diabetes [13]. Diabetes also increases the risk of stroke particularly ischemic type of stroke.

A review of published literature has highlighted several barriers in addressing the growing burden of diabetes [14]. Only 12% of the general population is aware of the risk factors of diabetes. Even among those with established diabetes only 40.6% were aware that it could result in organ damage [5].

Even in tertiary care centers, poor glucose control was observed in half of the patients highlighting poor management of individuals with diabetes. Managing multiple risk factors in subjects with diabetes and other established Cardio Vascular Disorder (CVD) complications adds to heavy financial burden and also is particularly challenging to both the households and the health system [5].

Material and Method

This study was carried out at Kovai Medical Center and Hospital, Coimbatore, Tamilnadu, India. A total of 270 patients, comprising of both male and female patients diagnosed as Type 2 Diabetes Mellitus (DM) with or without co-morbidities admitted and treated as an in-patient basis were included in this study.

Data Collection and Evaluation

After obtaining due approvals from the ethics committee, data were collected from the inpatient settings of Endocrinology Department, using a specially designed data collection form. The main sources of this data collection form were patient counseling center, patient specific medical case notes and treatment chart.

Details regarding past medical history, past medication history, present medical complaints, present medications and patient demographics such as name of the patient, age, sex, occupation, smoking, alcoholism, tobacco chewing and dietary habits were collected. Known risk factors like family history of Type 2 Diabetes and body mass index (BMI) were also collected. After thorough review, data of all 270 subjects were compiled and tabulated for assessment.

Informed Consent, Ethical Approvals

The study was approved by the Ethics committee of Kovai Medical Center and Hospital, Coimbatore, India.

Results and Discussion

Demographics

Out of 270 patients studied 61.86% (n=167) were males and 38.14% (n=103) were females.

Age wise distribution shows that most of patients were in the age groups 60-79 years and 40-59 years, constituting 42.22% (n=114) and 41.85% (n=113) of the total patient population. This data proves that diabetes can no longer be branded as an old age disease and clearly reveals that the old age and middle-aged populations constitutes the major chunk of the diabetic population. The much feared concern of rising prevalence of Type 2 Diabetes in young population is confirmed by the presence of 15.93% (n=43) of such patients in the age group of 20-39 years.

The patients' demographic details, risk factors, past medical history and complications are presented in Figure 1.

Table 1: Past Medication History

Past Medication History	Number	Percentage (%)
Oral Hypoglycemic Agents (OHA)	42	15.55
Insulin	30	11.11
Oral Hypoglycemic Agents with Insulin	13	4.81
Unknown	185	68.53

Table 2: During Hospitalization

During Hospitalization		Number	Percentage (%)
For Immediate Control of Hyperglycemia	Short acting insulin	192	71.11
	Intermediate acting insulin	70	25.93
	Long acting insulin	8	02.96
After Immediate Control of Hyperglycemic	Intermediate acting insulin	265	98.15
	Long acting insulin	5	01.85

Table 3: Discharge Advice

Discharge Advice	Number	Percentage (%)
Insulin	106	39.26
Insulin +OHA	82	30.37
OHA alone	73	27.04
Diabetic diet	9	03.33

Dietary and other habits
Among the 270 patients, 64.07% (n=173) follows non-vegetarian and rest 35.93% (n=97) vegetarian diets. 87.41% (n=236) of the surveyed population are habituated with tea or coffee drinking habit.
Among the other habits, 20.37% (n=57) had tobacco usage habits and 7.78% (n=21) were alcoholics. Of the tobacco usage habits, predominant was smoking, 79.63% (n=43) and the rest 20.37% (n=11) had tobacco chewing habits.

Risk Factors: Danish Diabetes Risk Factors
Among the surveyed population, the disease was found to be predominant in male population, 61.86% (n=167). Though no sex bias has been proven among the Indian population, male: female ratio almost 3:2 ratio observed in this study matches with that of European population [15].
Among other risk factors Obesity/Pre-obesity together (45.55%) came as a close second. Obesity, the conventional risk factor for diabetes, was observed in 32.22% (n=87) of total population and another 13.33% (n=36) were pre-obese. This is

followed by hypertension found in 40.37% (n=109), a family history of diabetes in 37.77% (n=102) and smoking habit in 15.93% (n=43).
Since we couldn't get reliable information on the physical activity of the patients, we had to avoid the assessment on this risk factor.

Admission causes
From the data evaluation, the most prevalent medical complication that led to the in-patient admission of the diabetic patients was Uncontrolled Diabetic Status 36.66% (n=99), followed by Surgical procedure 14.81% (n=40). Ischemic Heart Disease accounted for 13.33% (n=36) and Coronary Artery Disease accounted for 7.03% (n=19) from total studied population.

Diabetic Complications: Macro vascular and Micro vascular
Of the 270 patients, the most prevalent macro vascular complication observed was Cardio vascular, 20.37% (n=55), followed by 15.18% (n=41) were having Peripheral Vascular Complications. Of the 41 subjects with Peripheral Vascular Complications, 68.29% (n=28) were admitted to undergo surgical procedures (like distal toe amputation, cellulitis debridement etc).
Though a small portion, but definitely a matter of concern was the prevalence of cerebrovascular stroke in 3.7% (n=10) of the total population.
And among the micro vascular complications, diabetic nephropathy was the most observed, 9.25% (n=25), followed by diabetic neuropathy, 4.07% (n=11), and diabetic retinopathy, 1.85% (n=05).
The presence of co-morbidities affecting the macro and micro vasculature alike, i.e., Hypertension in 40.37% (n=109) and Hypercholesterolemia in 26.29% (n=71) must have compounded the occurrence of these complications.

Medical Management: At admission, post admission and on discharge

While analyzing the past medication history of diabetic patients at admission, it was observed that, 15.55% (n=42) were on Oral hypoglycemic agents and 11.11% (n=30) were on Insulin. Only 4.81% (n=13) were using Insulin and Oral hypoglycemic agents together. But the alarming finding was that the past medication history of remaining 185 patients (68.53%) were not available. This shows a lack of awareness among the population about the severity of the disease and its proper therapeutic management.
During hospitalization, for immediate control of the glycemic status, the most preferred insulin was short acting insulin, 192 patients (71.11%), followed by

Total number of subject enrolled = 270
Gender distribution
-Male 61.85% (n=167)
-Female 38.15% (n=103)
Age distribution (in years)
-20 to 39 15.93% (n=43)
-40 to 59 41.85% (n=113)
-60 to 79 42.22% (n=114)

Risk factors
-Age (40-79) 84.07% (n=227)
-Obesity 32.22% (n=87)
-Pre-obesity 13.33 (n=36)
- Hypertension 40.37% (n=109)
- Family history of diabetes 37.77% (n=102)
-Smoking habit 15.93% (n=43)

Dietary and other Habits
-Vegetarian 35.93% (n=97)
-Non-vegetarian 64.07 (n=173)
-Cofee/Tea Drinkers 87.41% (n=236)
-Smokers 15.93% (n=43)
-Tobacco chewers 4.44% (n=11)
-Alcoholics 7.78% (n=21)

Admission Causes
-Uncontrolled Diabetic status 36.66% (n=99)
-Clinical Surgery 14.81% (n=40)
-Ischemic Heart Disease 13.33 (n=36)
-Coronary Artery Disease 7.04% (n=19)

Macrovascular Complications
-Cardio vascular 20.37% (n=55)
-Peripheral Vascular 15.18% (n=41)
-Cerebro vascular 3.7% (n=10)

Microvascular Complications
-Nephropathy 9.26% (n=25)
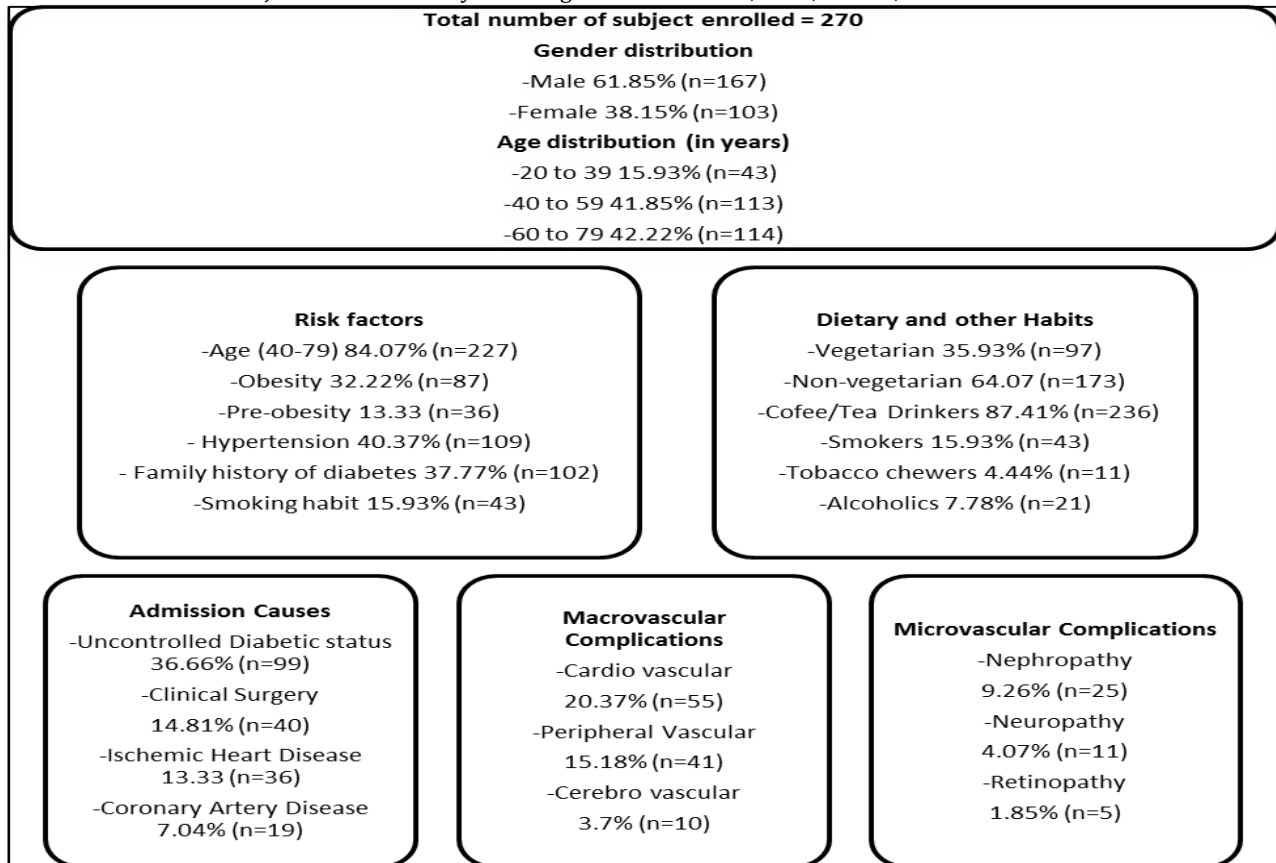-Neuropathy 4.07% (n=11)
-Retinopathy 1.85% (n=5)

Figure 1: The patients' demographic details, risk factors, past medical history and complications

intermediate acting insulin in 70 patients (25.93%). Only 8 patients (2.96%) received long-acting insulin.

Further during the hospital stay, after the immediate management of glycemic status, 98.15% (n=265) of the patients on short acting insulin were shifted to intermediate acting insulin and the rest 1.85% (n=5) were on long acting insulin. From the published literature, it's understood that though both intermediate-acting insulin and the long-acting insulin have long served as the standard basal insulin, the latter being known for its erratically absorption is less preferred [16]. Thus, the present study confirms the predominant utilization of intermediate acting insulin while hospitalization. Further assessing the prescribed advice at discharge, it was observed that of these 270 patients 39.25% (n=106) were advised Insulin only, followed by 30.37% (n=82) were advised both Insulin & Oral Hypoglycemic Agents and 27.03% (n=73) were prescribed Oral Hypoglycemic Agents (OHA) only. Only 3.33% (n=9) were on diabetic diet.
Medications details regarding past, during hospitalization and discharge advice is presented in Tables 1-3.

Conclusion

Type 2 diabetes is an epidemic that is affecting an ever-increasing proportion of the global population. And the rising proportion of Type 2 diabetes cases in our country coupled with the lack of awareness among the diseased and differing

treatment modalities among the physicians together makes it a definitely very dangerous epidemic. This cross-sectional field survey has validated our concerns.

The observation that the past medication history of about 68 % of the patients surveyed was unknown strongly substantiate the lack of awareness among the patients about the disease's severity and essentiality of maintaining a strict treatment regimen. Also the fact that almost 37% of the type 2 diabetic patients got admitted for uncontrolled diabetic status strengthens the observation and validates the importance of proper glycemic control through a strict treatment regimen. This necessitates the need of immediate implementation of country-wide awareness programs.

Another highlight of this study was that it not only validated that the middle and late age groups together, i.e, 40-79 years, constitutes the major proportion of patients but also depicted that about 15% of the patients were of the age group 20-39 years. Like in the developed countries, a steady decrease in the presenting age of the disease cannot be ruled out. However, similar studies across all the age groups, including the paediatrics, should be done to correctly validate this concern.

Knowing the link between obesity and insulin resistance, the observation that more than 45% of

the patients were either obese or pre-obese, strengthens the theory that insulin resistance may be the most important role player in the cause behind Type 2 diabetes patients. With almost 40% of patients having Hypertension and 37% with a positive family history of Diabetes, the linkage of these risk factors to diabetes is also confirmed. Population should be sensitized about these risk factors and should be advised from young age for periodic check-ups and necessary lifestyle modifications so that they can delay or even avoid the occurrence of the disease.

The prevalence of macro vascular and micro vascular complications among these patients confirms with the earlier study reports and the observation that more than 66% of these patients had either Hypertension or Hypercholesterolemia confounds the importance of regular check-up, follow-up and control of these complications and co-morbidities .

The assessment of the treatment regimens confirm that while short acting insulin is the preferred insulin for immediate management of hyperglycemic state in these patients, it has also confirmed that among the physicians intermediate acting insulin still remains the most trusted insulin for long term diabetes control. Equally trusted are the OHAs but more preferred as in combination with Insulin. The treatment regimen rightly varies as per the patient's condition, but it's worth noting that only 3% were not on medications and were advised diabetic diet only. Though this study didn't capture the exact duration of disease, co-morbidities and also that the earlier medication history of most of the subjects were missing; it's certainly not a good note to observe that of the population which had almost 15% in young age group only 3% were advised diabetic diet. May be an aggressive management with medications were given more importance but then advises on lifestyle, diet and habit maintenance is important too and should be emphasized equally.

In general, the data from this field survey can be used by the medical fraternity to improve the patient's treatment outcomes and quality of life.

Acknowledgement

References

1. AM Ahmed., 2002. History of diabetes mellitus. Saudi Medical Journal;23(4):373-8.

2. Williams textbook of endocrinology (12th ed.), Philadelphia: Elsevier/Saunders. 1371–1435, ISBN 978-1-4377-0324-5.

3. Wild S, Roglic G, Green A, Sicree R, King H., 2004. Global prevalence of diabetes: Estimates for the year 2000 and projections for 2030". Diabetes Care; 27 (5): 1047–53.

4. Gale, Jason., 8 June 2012. India's Diabetes Epidemic Cuts Down Millions Who Escape Poverty, Bloomberg.

5. Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India., 2011. WG-3(2) Non-Communicable Diseases, Report of the working group on disease burden for 12th five year plan.

6. World Health Organisation., 2007. Development and updation of diabetes atlas in India.

7. ICMR study on Assessment of burden of Non-Communicable Diseases in India, 2004.

8. R Valdez., 2009. Detecting undiagnosed Type 2 diabetes: Family history as risk factor and screening tool. Journal of diabetes science and technology; Vol 3, Issue 4 : 722-26.

9. Obesity: preventing and managing the global epidemic., 1999. Report of a WHO convention, Geneva. World Health Organization;PMID 11234459.

10. Barbara B Kahn, Jeffrey S Flier., 2000. Obesity and insulin resistance. Journal of clinical investigation;106(4): 473-81.

11. Unnikrishnan R, Mohan V., 2007. Treatment of diabetes mellitus: beyond glycaemic control. NatlMed J India;20(6): 304-6.

12. International Institute for Population Sciences, Macro International., 2007. National Family Health Survey (NFHS-3) 2005-06: India. Mumbai, IIPS.

13. Xavier D, Pais P, Devereaux PJ, Xie C, Prabhakaran D, Reddy KS, Gupta R, Joshi P, Kerkar P, Thanikachalam S, Haridas KK, Jaison TM, Naik S, Maity AK, Yusuf S., 2008. Treatment and outcomes of acute coronary syndromes in India (CREATE): a prospective analysis of registry data. Lancet;371(9622):1435-42.

14. Raheja BS, Kapur A, Bhoraskar A, Sathe SR, Jorgensen LN, Moorthi SR, Pendsey S, Sahay BK., 2001. DiabCare Asia--India Study: diabetes care in India-current status. J Assoc Physicians India; 49: 717-22.

15. EAM Gale, KM Gillespie., 2001. Diabetes and gender. Diabetologia; 44: 3-15.

16. B. Hirsch, Insulin in the Hospital Setting, Adelphi Inc., New York, ISBN/0-9701451-8-7.

AUTHORS' CONTRIBUTIONS

Authors contributed equally to all aspects of the study.

PEER REVIEW

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CONFLICTS OF INTEREST

The authors declare that they have no competing interests.