



An Observational Study of DM Complications and their Clinical Outcomes

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Abstract

Aim: The purpose of the study is to examine the complications, their associated clinical characteristics and health related quality of life in DM patients.

Objectives: To evaluate and analyse the clinical outcomes of diabetes mellitus complications.

1. To identify the prevalence of DM complications.
2. To identify about complication percentage (%) in type-1 and type-2 DM.
3. To determine HRQL of patients with diabetes mellitus complications.

Methodology: A prospective observational study was carried out at Departments of in and out patients at Gandhi hospital and BBR hospital, for a period of 6 months (July 2017 to December 2017). All the patients who are diagnosed with DM complications were included in this study. Patients between ages of 18 - 90 yrs were considered. Patients with comorbidities of DM were excluded in the study.

Results: During the study period, a total of 400 cases of suspected Diabetes complications were recorded from July 2017 to December 2017. The total of 400 cases was analyzed, among them the prevalence % was found to be more in Diabetic nephropathy (33%), in which prevalence rate in males was found to be (71.96%) than females (28.03%). According to the age wise distribution, maximum patients belonged to age group 40-60 years. The occurrence of DM complications was identified more in Type-2 DM patients (273) than in Type-1 DM patients (127).

Conclusion: The suspected complication cases were analyzed, among them type 2 DM is more predominant than type 1. In type 2 Males are at more risk than females in nephropathy and in males are at more risk than females in DKA. So, 40-60 age group were highly affected with complications. Clinical outcome measures of GRBS levels was found to be more in patients with GRBS levels of 200 - 300 (42.5%), FBS levels was found to be more in patients with FBS levels of 120 - 130 (39.5%), HbA1C levels was found to be more in patients with HbA1C levels of 7.5 - 8.0 (39.5%), BP levels was found to be more in patients with BP levels of stage 2 (46%), lipid levels was found to be more in patients with lipid levels of 50 - 100 (55%).

Keywords: Diabetes Mellitus; Type-2 DM; HbA1C

Definition

Diabetes mellitus is a heterogeneous group of diseases characterized by chronic elevation of glucose in the blood. It arises because the body is unable to produce enough insulin for its own needs, either because of impaired insulin secretion, impaired insulin action, or both. Chronic exposure to high blood glucose is a leading cause of renal failure, visual loss and a range of other types of tissue damage. Diabetes also predisposes to arterial disease, not least because it is often accompanied by hypertension, lipid disorders and obesity [1].

Etiologic classification of diabetes mellitus:

1. Type 1 DM (10%) [Earlier called Insulin dependent or juvenile onset diabetes]
2. Type 1A: Immune mediated
3. Type 1B: Idiopathic
4. Type 2 DM (80%) [earlier called non-insulin dependent or maturity onset diabetes]
5. Other specific types of diabetes (10%)

6. Genetic defect of beta cell function due to mutations in various enzymes [MODY] (e.g. hepatocyte nuclear transcription factor HNF, glucokinase)
7. Genetic defect in insulin action (e.g. type A insulin resistance)
8. Diseases of exocrine pancreas (e.g. chronic pancreatitis, pancreatic tumours, post pancreatectomy)
9. Endocrinopathies (e.g. acromegaly, cushings syndrome, pheochromocytoma)
10. Uncommon forms of immune mediated DM (stiffman syndrome, anti-insulin receptor antibodies)
11. Other genetic syndromes (e.g. downs syndrome, Klinefelter's syndrome, turners syndrome)
12. Gestational diabetes mellitus.

Action of insulin: Half of insulin secreted from beta-cells into portal vein is degraded in liver while the remaining half enters the systemic circulation for action on the target cells. Insulin from circulation binds to its receptor on the target cells.

These reactions on the target cells are responsible for the main mitogenic and anabolic actions of insulin-glycogen synthesis, glucose transport, protein synthesis, lipogenesis. Besides the role of glucose in maintaining equilibrium of insulin resistance, low insulin level in the fasting state promotes hepatic gluconeogenesis and glycogenolysis, reduced glucose uptake by insulin-sensitive tissues and promotes metabolism of stored precursors, so as to prevent hypoglycaemia [2].

Pathogenesis

Complications of diabetes

The diabetic foot

Diabetic foot infections are the most common skeletal and soft-tissue infections in patients with diabetes. Both types of diabetes confer a 30-fold higher risk of lower extremity amputation due to infection compared with patients without diabetes. Diabetic foot complications can range from cellulitis to chronic osteomyelitis. These complications arise with local trauma in the setting of neuropathy, compromised vascular supply, and immunosuppression (complications-of-diabetes-mellitus/article/605171/),

Diabetic nephropathy

Increased urinary protein is the first clinical finding of diabetic nephropathy. The major manifestation of diabetic nephropathy is albuminuria, which is further separated into microalbuminuria (urinary albumin excretion of 30 - 300 mg on 24-hour urine collection or 30 - 300 mg/g Cr on a spot urine sample) and macroalbuminuria (urinary albumin excretion over 300 mg on 24-hour urine collection or over 300 mg/g Cr on spot urine). Microalbuminuria is less severe but predicts high risk for future nephropathy [3].

Diabetic ketoacidosis

Diabetic ketoacidosis (DKA) is a major acute metabolic complication of T1D that is typically marked by acidosis, ketosis and usually hyperglycaemia. The symptoms of uncontrolled diabetes that may lead to development of DKA are typically of short duration and include polyuria, polydipsia, polyphagia, weight loss, vomiting, abdominal pain and fatigue. Diabetic ketoacidosis is diagnosed in different ways, but typically the following three factors are present: elevated plasma glucose (> 250 mg/dL), ketones in serum or urine and acidosis (serum bicarbonate < 18 mEq/L and/or pH < 7.30).

Diabetic retinopathy

Diabetic retinopathy is a condition that occurs in people who have diabetes. It causes progressive damage to the retina, the light-sensitive lining at the back of the eye. Diabetic retinopathy is a serious sight-threatening complication of diabetes. Diabetes interferes with the body's ability to use and store sugar (glucose).

Diabetic retinopathy is classified into two types:

1. Non-proliferative diabetic retinopathy
2. Proliferative diabetic retinopathy [4].

Cardiovascular disease

Hyperglycemia and insulin resistance, among various other factors, are thought to contribute significantly to atherosclerotic changes and the pathogenesis of macrovascular complications in diabetes. Though both are commonly observed in diabetic patients, insulin resistance usually develops years before hyperglycemia becomes clinically significant.

Diabetic neuropathy

Depending on the affected nerves, symptoms of diabetic neuropathy can range from pain and numbness in your extremities to problems with digestive system, urinary tract, blood vessels and heart. For some people, these symptoms are mild; for others, diabetic neuropathy can be painful, disabling and even fatal. Diabetic neuropathy is a common serious complication of diabetes.

Aim of the Study

The purpose of the study is to examine the complications, their associated clinical characteristics and health related quality of life in DM patients.

Objectives

1. To evaluate and analyse the clinical outcomes of diabetes mellitus complications.
2. To identify the prevalence of DM complications.
3. To identify about complication percentage (%) in type-1 and type-2 DM.
4. To determine HRQL of patients with diabetes mellitus complications.

How data is collected and interpreted

For this aim, we have to collect the data about occurrence of different complications of DM at the study site. After the collection of data, we have to interpret the data by using the necessary statistics.

Strategical Outcome

As data is collected and interpreted, outcomes of different types of DM complications are found with respect to age and gender are obtained.

The clinical outcome measures and clinical process measures of the study are obtained.

The prevalence, % complications in type-1 and type-2 DM and HRQL of patients with DM complications are obtained.

Methodology

It is a Prospective observational study carried for a period of 6 months (July 2017 to December 2017). Patients diagnosed with type I Diabetes mellitus and type II Diabetismellitus complications were enrolled into the study. The proposed study was carried out in inpatient and outpatient wards of various departments

of Endocrinology, Nephrology, Neurology, General medical ward, Cardiology and General surgical wards in BBR multi-speciality Hospital- 250bedded and Gandhi hospital, Secunderabad by considering following inclusion and exclusion criteria.

Inclusion criteria

1. Patients who were diagnosed with diabetes mellitus complications like Diabetic nephropathy, diabetic retinopathy, diabetic foot ulcers, stroke, cardiovascular diseases, diabetic ketoacidosis
2. Patients of either sex.
3. Patients who are above 18 years and below 80 years.

Exclusion criteria

1. Patients with cancer and psychiatric disorders.
2. Paediatric patients.
3. Pregnancy and lactating women.

Study procedure

Study was conducted in Endocrinology, Nephrology, Neurology, General medical ward, Cardiology and General surgical ward departments. Diabetes mellitus complications patients admitted to hospital have been reviewed on daily basis and those patients who met the study criteria were enrolled into the study.

For the identification of type I and type II DM complications among DM patients, we have developed a data collection form consisting of a check list of commonly occurring DM complications in patients.

All the cases were reviewed and those who met the study criteria were followed after getting drug therapy. Details were recorded in the suitable designed data collection form including the past medical history, and past medication history, laboratory parameters, and treatment chart as per the need of the study to improve the patient condition. We monitor the patients with type I and type II DM and its complications. The identified DM complications were recorded.

Source of data

All the relevant and necessary data was collected from the following: Patients case records-demographics, past medication history, past medical history, laboratory investigations and treatment chart.

Plan of work

1. Literature review was carried out.
2. Ethical committee approval.
3. Collection of data.
4. Compilation of various patient populations with different types of DM complications and who are undergoing treatment for DM complications.
5. Analysis of data.
6. Report the data.

Parameters considered for analysis of data collection

1. Age wise distribution of patients.
2. Gender wise distribution of patients.
3. Clinical process measurement
4. Clinical outcomes
5. Prevalence of DM complications
6. HRQL for DM with complications
7. Distribution of patients based on type 1 and type 2 DM and their complications.

Result

During our study period (July 2017 to December 2017) 400 patients were enrolled according to the inclusion criteria.

Types	No. of Patients	Male	Female
Type 1-DM	127	109	18
Type 2-DM	273	173	100

Table 1: Types of DM.

The above table shows that out of 400 patients enrolled in our study, the occurrence of DM complications were identified more in Type-2 DM patients (273) than in Type-1 DM patients (127).

DM Complications	Type-1 (%)	Type-2 (%)
Nephropathy	18	82
Neuropathy	34	66
Foot Ulcer	20	80
Retinopathy	24	76
CV Disease	30	70
DKA	62	38
Neuropathy and Nephropathy	25	75
Retinopathy and Nephropathy	15	85
DKA and Foot ulcer	11	89

Table 2: Complications (%) With Type-1 and TYPE-2 DM.

The above table shows that out of 400 patients enrolled in our study, DM complications in Type-1 DM patients was found to be more in DKA (62%) and DM complications in Type-2 DM patients was found to be more in Nephropathy (82%).

Age	No. of Patients	Percentage (%)
0 - 20	4	1
20 - 40	42	10.5
40 - 60	206	51.5
60 - 80	132	33
80 - 100	16	4
Total	400	100

Table 3: Distribution of Patients Based on Age.

The above table shows that out of 400 patients enrolled in our study, the occurrence of DM complications were identified in age group of 40 - 60 years (51.5%), followed by 60 - 80 years (33%).

Gender	No. of patients	Percentage (%)
Males	282	70.5
Females	118	29.5
Total	400	100

Table 4: Distribution of Patients Based on Sex.

The above table shows that out of 400 patients enrolled in our study, the occurrence of DM complications was found to be more in 282 males (70.5%) then 118 females (29.5%).

DM Complications	Total (n = 400)	Male	Female
Nephropathy	33	71.96	28.03
Neuropathy	20	77.5	22.5
Stroke	28	58.92	41.07
Foot ulcer	6	83.33	16.66
DKA	6.5	76.92	23.07
Retinopathy	2.5	60	40
Retinopathy and Nephropathy	2	75	25
Neuropathy and Nephropathy	1	100	0
DKA and Foot ulcer	1	100	0

Table 5: Prevalence (%) of Diabetes Complications in Individuals.

The above table shows the prevalence (%) of DM complications in male and female patients. The prevalence % was found to be more in Diabetic nephropathy (33%), in which prevalence rate in males was found to be (71.96%) than females (28.03%).

Clinical measures	Daily	1 week	Once a month
Patient examination	70	20	10
Physician performed examination	70	20	10
Eye/Neuro/Nephro/foot examination	70	20	10
B.P measurement	70	20	10
Lipid profile	-	70	30
HbA1c	-	-	100

Table 6: Percentage (%) of clinical process measures during the study.

GRBS Levels	No. of patients	Percentage (%)
0 - 100	18	4.5
100 - 200	56	14
200 - 300	170	42.5
300 - 400	94	23.5
400 - 500	42	10.5
500 - 600	12	3
600 - 700	6	1.5
Above 700	2	0.5
Total	400	100

Table 7: Clinical measures of GRBS levels in individuals.

The above table shows that out of 400 patients enrolled in our study, the occurrence of DM complications was found to be more in patients with GRBS levels of 200 - 300 (42.5%), then followed by patients with GRBS levels of 300 - 400 (23.5%).

FBS levels	Frequency	Percentage (%)
110 - 120	4	1
120 - 130	158	39.5
130 - 140	138	34.5
140 - 150	100	25
Total	400	100

Table 8: Clinical measures of FBS levels in individuals.

The above table shows that out of 400 patients enrolled in our study, the occurrence of DM complications was found to be more in patients with FBS levels of 120 - 130 (39.5%), then followed by patients with FBS levels of 130 - 140 (34.5%)

HBA1C Levels	No. of Patients	Percentage (%)
6 - 6.5	4	1
6.5 - 7	114	28.5
7 - 7.5	118	29.5
7.5 - 8	158	39.5
Above 8	6	1.5
Total	400	100

Table 9: Clinical measures of HBA1c levels in individuals.

The above table shows that out of 400 patients enrolled in our study, the occurrence of DM complications was found to be more in patients with HbA1C levels of 7.5 - 8.0 (39.5%), then followed by patients with HbA1C levels of 7 - 7.5 (29.5%).

Lipid levels	No. of patients	Percentage (%)
Above 200	220	55
150 - 200	84	21
100 - 150	52	13
50 - 100	44	11
Total	400	100

Table 10: Clinical measures of lipid levels in individuals.

The above table shows that out of 400 patients enrolled in our study, the occurrence of DM complications was found to be more in patients with lipid levels of above 200 (55%), then followed by patients with lipid levels of 150 - 200 (21%).

BP Levels	Frequency	Percentage (%)
Normal	48	12
Stage-1	76	19
Stage-2	184	46
Stage-3	92	23
Total	400	100

Table 11: Clinical measures of BP Levels in individuals.

The above table shows that out of 400 patients enrolled in our study, the occurrence of DM complications was found to be more in patients with BP levels of stage-2 (46%), then followed by patients with BP levels of stage-3 (23%).

Factors	Nephro-Pathy	Neuropathy	CV Disorder	Foot ulcer	Retinopathy
Physical Functioning	30 ± 34.96029	80 ± 25.81989	45 ± 36.89324	25 ± 35.35534	55 ± 43.77975
Emotional Well being	40 ± 37.41657	60 ± 14.14214	68 ± 10.95445	20 ± 0	72 ± 17.88854
Social Functioning	37.5 ± 17.67767	50 ± 0	37.5 ± 17.67767	37.5 ± 53.03301	75 ± 0
General Health	10 ± 12.24745	30 ± 11.18034	35 ± 25.4951	15 ± 13.69306	65 ± 13.69306

Table 12: HRQL for DM with complications.

The above table shows among 400 patients, the mean of patients.

- Physical functioning in nephropathy 30 ± 34.96029 (mean ± Sd), neuropathy 80 ± 25.81989 (mean ± Sd), cv disorders 45 ± 36.89324 (mean ± Sd), foot ulcers 25 ± 35.35534 (mean ± Sd), retinopathy 55 ± 43.77975 (mean ± Sd).
- Emotional wellbeing in nephropathy 40 ± 37.41657 (mean ± Sd), neuropathy 60 ± 14.14214 (mean ± Sd), cv disorders 68 ± 10.95445 (mean ± Sd), foot ulcers 20 ± 0 (mean ± Sd), retinopathy 72 ± 17.88854 (mean ± Sd).
- Social functioning in nephropathy 37.5 ± 17.67767 (mean ± Sd), neuropathy 50 ± 0 (mean ± Sd), cv disorders 37.5 ± 17.67767 (mean ± Sd), foot ulcers 37.5 ± 53.03301 (mean ± Sd), retinopathy 75 ± 0 (mean ± Sd).
- General health in nephropathy 10 ± 12.24745 (mean ± Sd), neuropathy 30 ± 11.18034 (mean ± Sd), cv disorders 35 ± 25.4951 (mean ± Sd), foot ulcers 15 ± 13.69306 (mean ± Sd), retinopathy 65 ± 13.69306 (mean ± Sd).

Discussion

Our results revealed that most of the DM complications were identified in BP levels of stage-2 (46%), then followed by patients with BP levels of stage-3 (23%). whereas study conducted by patients in Addisu Y Mengesha shows that About two thirds of DM patients in the study had hypertension. The risk of HTN increased, as DM patients got older. Type 2 DM patients were affected by HTN

more than type1DM patients. On average, each 10 mm Hg reduction in systolic blood pressure was associated with a 12% decrease in the risk of any end point related to diabetes and a 15% reduction in the risk of death related to diabetes. Stroke and heart failure were the complications least strongly associated with glycaemia, suggesting that for these complications, by comparison, raised blood pressure is of greater pathogenetic importance [5].

Our results revealed that most of the DM complications was found to be more in patients with GRBS levels of 200 - 300 (42.5%), then followed by patients with GRBS levels of 300 - 400 (23.5%), DM complications were identified in age group of 40 - 60 years (51.5%), followed by 60 - 80 years (33%). DM complications was found to be more in 282 males (70.5%) then 118 females (29.5%). Whereas the study conducted by Stamler J, Vaccaro O, Neaton JD, shows an important association between the occurrence of each of the diabetic complications evaluated (except cataract extraction), including all-cause mortality, and systolic blood pressure exposure across the range observed in patients with type 2 diabetes. Stroke and cv disorders were the complications least strongly associated with glycaemia, suggesting that for these complications, by comparison, raised blood pressure is of greater pathogenetic importance [6].

Our results revealed that most of the DM complications was found to be more in patients with physical functioning in nephropathy 30 ± 34.960 (Mean ± SD), neuropathy 80 ± 25.819 (Mean ± SD), CV Disorders 45 ± 36.89 (Mean ± SD), Foot ulcers 25 ± 35.35534 (Mean ± SD), retinopathy 55 ± 43.7797 (Mean ± SD). The study conducted by Hansson L, Zanchetti A, Carruthers SG, Dahlöf B, Elmfeldt D, Julius S., et al. Tuomilehto J, Rastenyte D, Birkenhäger WH, Thijs

L, Antikainen R, Bulpitt CJ, *et al* shows the importance of early assessment of blood pressure in the course of diabetes. Improved control of blood pressure in diabetic patients has been shown to be effective in reducing the risk of cardiovascular complications and nephropathy [7].

Our results revealed that most of the DM complications was found to be more in DM complications in Type-1 DM patients was found to be more in DKA (62%) and DM complications in Type-2 DM patients was found to be more in Nephropathy (82%). The study conducted by Malone ML, Gennis V, and Goodwin shows that younger patients developed AKI in their study may be because most (56%) patients in this specific population of DKA were 18 - 44 years and 24% of patients were 45 - 65 years [8].

Our results revealed that most of the DM complications was found to be more in patients with HBA1C levels of 7.5 - 8.0 (39.5%), then followed by patients with HBA1C levels of 7 - 7.5 (29.5%). The study conducted by Lal B Rawal, Robyn j tapp., *et al.* shows that Maintaining glycemic control, in particular HbA1c levels lower than 7%, is important for preventing diabetes-related complications [9].

Our results revealed that the prevalence (%) of DM complications in male and female patients. The prevalence % was found to be more in Diabetic nephropathy (33%), stroke (28%), in which prevalence rate in males was found to be (71.96%) than females (28.03%). The study conducted by edurne alonso moran. *et al.* shows that Men had a higher prevalence than women of ischaemic heart disease and stroke. Indeed, sex was statistically significant for all analyses except foot ulcers and retinopathy; women reported approximately a 58%, 30%, 35% and 14% lower probability than men of developing ischaemic heart disease, renal failure, stroke and heart failure, respectively. Furthermore, the probability of suffering one of these complications increased significantly with age. The prevalence of two or more chronic diseases in addition to type 2 diabetes mellitus was 68.8% [10].

Our results revealed that most of the DM complications was found to be more in Type-2 DM patients (282) than in Type-1 DM patients (118). DM complications in Type-2 DM patients was found to be more in CVD (70%) and neuropathy (66) than type-1 DM. The study conducted by Soon H Song, *et al.* shows that CVD and

neuropathy were substantially higher in T2D and occurred at an earlier stage than T1D. Despite the similar glycemic control and diabetes duration, neuropathic complication was higher in T2D diabetes. Luk, *et al.* [8] showed that CVD (coronary heart disease and stroke), nephropathy (albuminuria and end-stage renal disease), neuropathy, and retinopathy complications were higher in young-onset T2D (age of diagnosis above 33 years). In contrast, microvascular complications were strongly associated with hyperglycemia in this study cohort. Second, there is a suggestion that lifestyle intervention has a minimal impact on weight loss, glycemic control, and dyslipidemia in young patients with T2D [11].

Our results revealed that the mean of patients physical functioning in neuropathy is 80 ± 25.819 , whereas the study conducted by Goutam, *et al.* shows that the most complication was neuropathy. The present study demonstrates that overall HRQL is poor in people with diabetes. In this study among 8 domains of QOL physical functioning, general health, social functioning, emotional wellbeing was observed in DM complications. Duration of diabetes is negatively associated with physical functioning, general health. The most complication observed in diabetic patients were with neuropathy [12].

Conclusion

Over a 6 months period of study, 400 of suspected DM complications cases were analysed and studied. Out of this we had concluded the following outcomes. They are:

- Occurrence of DM complications such as diabetic neuropathy, nephropathy, retinopathy, foot ulcers, CV disorders, DKA among the study population were done. Out of 400 cases collected, nephropathy- 33%, DKA- 6.5%, neuropathy- 20%, stroke- 28%, foot ulcer- 6%, retinopathy- 2.5% were observed.
- Comparison of type 1 and type 2 DM, complications were found more in type 2 DM patients (273) than in type 1 DM (127).
- During a 6 months period of study we found that complications of type 1 DM patients were found to be more in DKA (62%) and in type 2 DM were found to be more in nephropathy (82%).

- Distribution of complications are more in 40-60 age group compared to other age groups which are included in the study.
- According to gender wise distribution, out of 400 cases 118 are females and 282 are males. As per these values males are more prone to be affected with complications than that of females.
 - Out of 33% cases of nephropathy, 71.96% were males and 28.03% were females.
 - Out of 20% cases of neuropathy, 77.5% were males and 22.5% were females.
 - Out of 28% cases of CV disorders ,58.92% were males and 41.07% were females.
 - Out of 6% cases of foot ulcers, 83.33% were males and 16.66% were females.
 - Out of 6.4% cases of DKA, 76.92% were males and 23.07% were females.
 - Out of 2.5% of cases of retinopathy, 60% were males and 40% were females.
- Clinical outcome measures of GRBS levels was found to be more in patients with GRBS levels of 200 - 300 (42.5%), FBS levels was found to be more in patients with FBS levels of 120 - 130 (39.5%), HbA1C levels was found to be more in patients with HbA1C levels of 7.5 - 8.0 (39.5%), BP levels was found to be more in patients with BP levels of stage 2 (46%), lipid levels was found to be more in patients with lipid levels of 50 - 100 (55%).
- HRQL for dm with complications patients in 400 patients, the mean of patients
 - Physical functioning in nephropathy 30 ± 34.96029 (mean \pm Sd), neuropathy 80 ± 25.81989 (mean \pm Sd), cv disorders 45 ± 36.89324 (mean \pm Sd), foot ulcers 25 ± 35.35534 (mean \pm Sd), retinopathy 55 ± 43.77975 (mean \pm Sd).
 - Emotional wellbeing in nephropathy 40 ± 37.41657 (mean \pm Sd), neuropathy 60 ± 14.14214 (mean \pm Sd), cv disorders 68 ± 10.95445 (mean \pm Sd), foot ulcers 20 ± 0 (mean \pm Sd), retinopathy 72 ± 17.88854 (mean \pm Sd).

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