ORIGINAL ARTICLE

Type 2 Diabetes Mellitus - Linked with X chromosome? An epidemiological study

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ABSTRACT

T2 DM is emerging as a constant threat globally. It has more scope of development in developing countries like India. The objective of this study is to determine the drug utilization patterns and outcomes of treatment in terms of metabolic control in type 2 diabetics' patients, on oral hypoglycemic agent in the OPD, HAHC hospital in south Delhi, India. Patients with established type 2 diabetes (n=174) visiting the outpatient department were interviewed using a structured questionnaire over a period of 4 months. Results showed that prevalence of T2DM found to be more in female most of them from low cast as they are under poverty and low education Majority of patients in this setting were treated with a multiple oral hypoglycemic agent. The most commonly prescribed hypoglycemic agent was biguanides (metformin) insulin sulfonylureas (glimepiride), thiazolidinediones (pioglitazone), alpha-glycosidase inhibitor (miglitol) and dipeptidyl peptidase-4 inhibitor (sitagliptin). Whereas, the most prescribed combination was insulin + metformin. This study concludes that there is utmost need of patient education and focuses on patient counselling to enhance the patient's compliance for prescribed hypoglycemic agents and concomitant drug. There is a constant need for diet control and blood glucose and HbA1c monitoring. Metabolic control was found to be poor in the study population. Clinical monitoring of patients adherence to prescribed medicine to achieve good glycemic control is recommended. Measures should be taken to improve patient's adherence to the prescribed treatment.

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INTRODUCTION

Diabetes mellitus is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. The chronic hyperglycemia of diabetes is associated with long-term damage, dysfunction, and failure of various organs, especially the eyes, kidneys, nerves, heart, and blood vessels (Dipiro *et al.,* 2009).

Type 2 DM accounts for 90% of DM cases characterized by the presence of both insulin resistance and relative insulin deficiency (Dipiro *et al.,* 2009 & Janet B. McGill, 2011). Insulin resistance is manifested by increased lipolysis and free fatty acid production, increased hepatic glucose production,

and decreased skeletal muscle uptake of glucose. β-cell dysfunction is progressive and contributes to worsening blood glucose control over time. Type 2 DM occurs when a diabetogenic lifestyle (excessive calories, inadequate exercise, and obesity) is superimposed upon a susceptible genotype. Uncommon causes (1% to 2% of cases) endocrine disorders (e.g. acromegaly, Cushing's syndrome), gestational diabetes mellitus (GDM), diseases of the exocrine pancreas (e.g., pancreatitis), and medications (e.g. glucocorticoids, pentamidine, niacin, and α-interferon). *Impaired fasting glucose* and *impaired glucose tolerance* are term used to describe patients whose plasma glucose levels are higher than normal but not diagnostic of DM *(prediabetes)*. These disorders are risk factors for developing DM and cardiovascular disease and associated with the insulin-resistance syndrome.

The number of people affected with diabetes is projected to increase from 171 million in 2000 to 366 million in 2030. According to Indian diabetic federation (IDF), there is an estimated 40 million persons with diabetes in India in2007 and this number is predicted to rise to 70 million people in 2025 (IDF, 2013).

Drug utilization reviews of antidiabetic in health care setting can facilitate rational drug use in patients with diabetes (Mazze *et al.,* 2012). They provide useful insights into the current prescribing practices and also identify irrational prescribing. The study of prescribing pattern is a component of medical audit that does monitoring and evaluation of the prescribing practice of the prescribers as well as recommends necessary modifications to achieve rational and cost effective medical care and it help to evaluate and suggest modifications in prescribing practices of physicians to promote rational drug use. Drug utilization studies are powerful exploratory tools to ascertain the role of drugs in society (Parthasarathi G *et al.,* 2004). Hence the present study was carried out to assess the drug use pattern of antidiabetic among outpatients with diabetes visiting to a tertiary care hospital in south Delhi.

METHOD

A prospective and observational study was conducted for 4 months at HAHC Hospital, to collect information from the patients attending to the outpatient department. The protocol was prepared as per the WHO guidelines (WHO booklet 2003). A total of 174 patients who satisfied the study criteria and consented to participate in this study were included. Prescriptions of outpatients were reviewed prospectively to study prescribing pattern of antidiabetic. Patient information such as name, age, sex, socioeconomic parameters, past medical history was collected. Therapeutic information

such as name of drugs, doses, route of administration, dosage schedule and the laboratory data were collected.

The drug utilization was assessed in terms of individual drugs used, its class and their percentage value was calculated. Values were expressed as mean ± standard deviation using Microsoft – Excel 2007 software.

RESULTS

A total of 174 prescriptions were collected in the study period of four months. Males were 33% (n = 57) and females were 67% (n = 117), this study supported by Khan et *al* and patel *et al* (Patel *et al.,* 2013 and Akila *et al.,* 2013) (Fig 1). Among these greatest number of patients were in the age group of 41-50 years (n = 74; 42.5%), followed by 51-60 years (n = 53; 30.5%), and 61-70 years (n = 17; 10 %). Least number of cases were found in the age group of 18-24 years (n = 6; 3.4%). The mean ± SD age of the patients was 50 ± 12.6 years. (Table 1)

Age of occurrence among T2DM Patients: Most diabetes patients who come to hospital having the disease from a period of time there are some patients started diabetes from young age18-24 (n: 4) the greatest number found to be among the age from 41-50 years (N: 55) followed by the patients age from 34-40; (N:42) after 60 years the number of patients decrease. (Fig 2). This study can be matched against the previous reports published by American Journal of Hospital Pharmacy (ASHP technical assistance bulletin on hospital drug distribution and control, 1980).

Family History among patients: large NO of T2DM patient does not have family history of diabetes mellitus 31 patients having family history from those 3 patients have both side from father and mother. (Fig 3). These results are in contrast with observations recorded by WHO Department of Noncommunicable Disease Management (Report of a World Health Organization and International Diabetes Federation meeting, 2003 & Vasamsetty *et al.,* 2011)

Effect of Life style on T2DM

Life style play important role as risk factor and as increase co-morbidity in T2DM most patient does not have basic education only 31.60% have basic education, poverty was major between them most of patient does not have proper food some of them miss breakfast and most of them have only 2 meal per day 74.13%, annual salary less than 10000 74.71%, smoking found to be between male only and consider rare 2.87%, alcohol intake found to be little high between male 8.62% , and most of pa- tient lacking to do daily exercise or routine work

Table 1: Age distribution among T2DM Patients

Age	Male	Females	Total	Percentage
18-24	0	6	6	3.4%
25-33	0	3	3	1.7%
34-40	9	12	21	12%
41-50	20	54	74	42.5%
51-60	25	28	53	30.5%
61-70	3	14	17	10%
Total	57	117	174	100%

Table 2: Effect of life style on T2DM

Life style	Female	Male	Total	Percentage
No of meal per day ≤ 2	89	40	129	74.13%
Smoking	0	5	5	2.87%
Alcohol intake	0	15	15	8.62%
Routine work out	35	27	63	36.20%
Basic Education	30	25	55	31.60%
Annual salary low income (≤10,000 pm)	100	30	130	74.71%

Table 3: Co-Morbid condition along with T2DM

Co-morbid condition	Female	Male	Total	Percentage
T2DM+HTN	35	17	52	56%
T2DM+TSH	6	0	6	6.5%
T2DM +HTN+ Dyslipidemia	4	4	8	8.6%
T2DM+Neuropathy	1	1	2	2%
T2DM+HTN+TSH	13	0	13	14%
T2DM+CAD+nephropathy	2	1	3	3.2%
T2DM+ HTN +Nephropathy	1	2	3	3.2%
T2DM + Nephropathy	2	2	4	4.3%
T2DM + cataract	2	0	2	2%
Total	66	27	93	53.5%

Table 4: Percentage of Patient Improvement in T2DM

Fast Blood Glucose Range	Total Before Therapy	Total Improved blood glucose	Percentage of Improvements
125-140 mg/dl	26	20	76%
145-170 mg/dl	10	6	60%
175-210 mg/dl	8	5	62.5%
>210	6	3	50%

Table 5: Cost Effective Analysis

Drugs	Total	% of Patients	Mean cost	% Improved	Cost Effective Ratio
Biguanides	33	66	288	76%	3.78
Sulfonylurea	11	22	540	60%	9
DPP-IV inhibitors	6	12	2610	63%	41.4

out is very less in these population 36.2% only who do exercise (Wabe *et al.,* 2011) (Table 2)

Patient Classification as per Blood Glucose level : most patients not monitor blood glucose regularly so we could record only 124 patients, large no of patient does not have good blood glucose control 71 patients, 53 patients have good blood glucose control (clinical practice guidelines for the prevention and management of diabetes in Canada, 2008) (Fig 4)

**Patient's classification according to HbA1c parameter:** these another type of measurement to know exactly how much patient control blood glucose (ACE Diabetes Mellitus Clinical Practice Task Force, 2010). Large no of patient not taking regularly HbA1c (87 patients) only 18 patients have very good HbA1c. (Fig 5)

Body Mass Index: it is having great value in determine the risk factor and co morbidity in T2DM.Half of our population study are overweight (n; 42), only 18 patients are obese, very few patients are underweight (Kamrai *et al.,* 2010) (Fig 6)
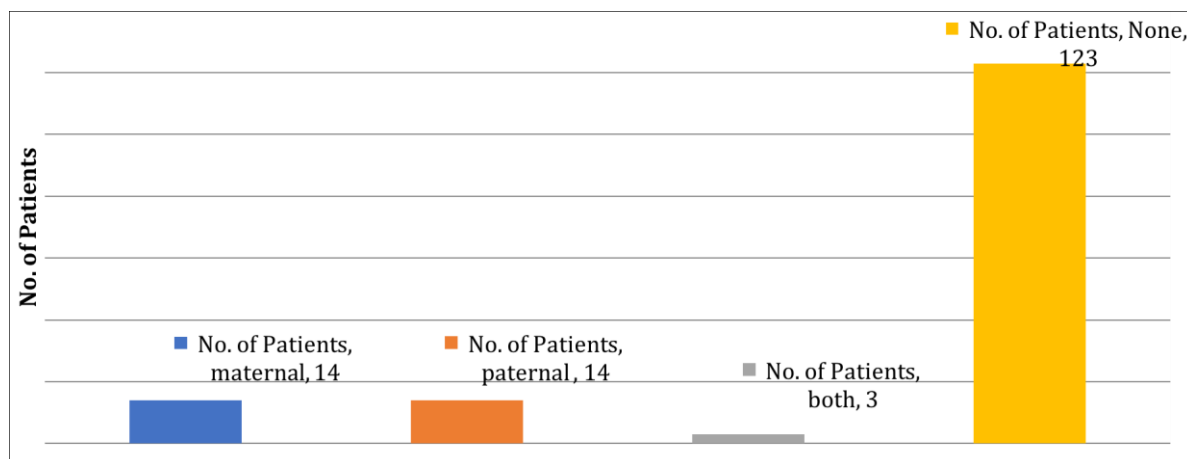
Indication of co-morbid condition: More than (n: 90; 53.5%) patients have co morbid condition.
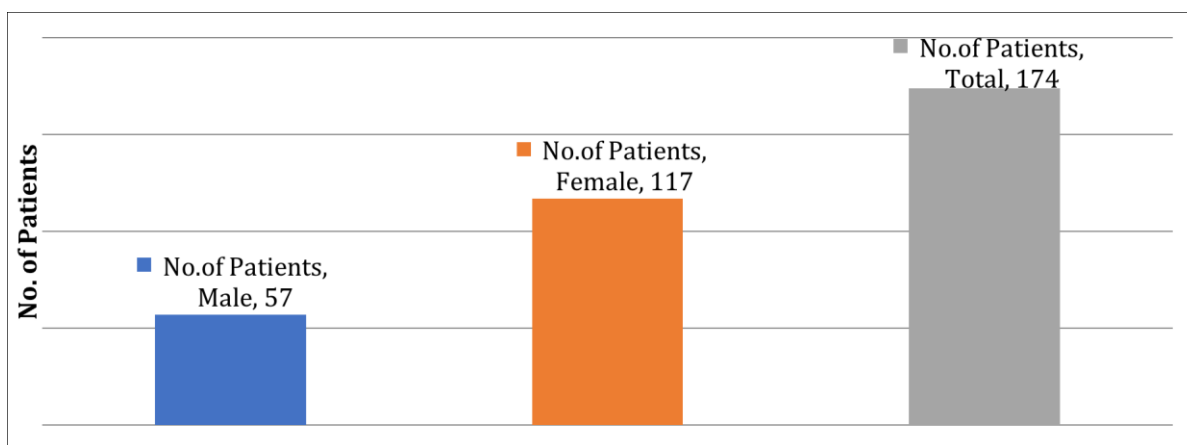
Figure 1: Gender distribution of patients
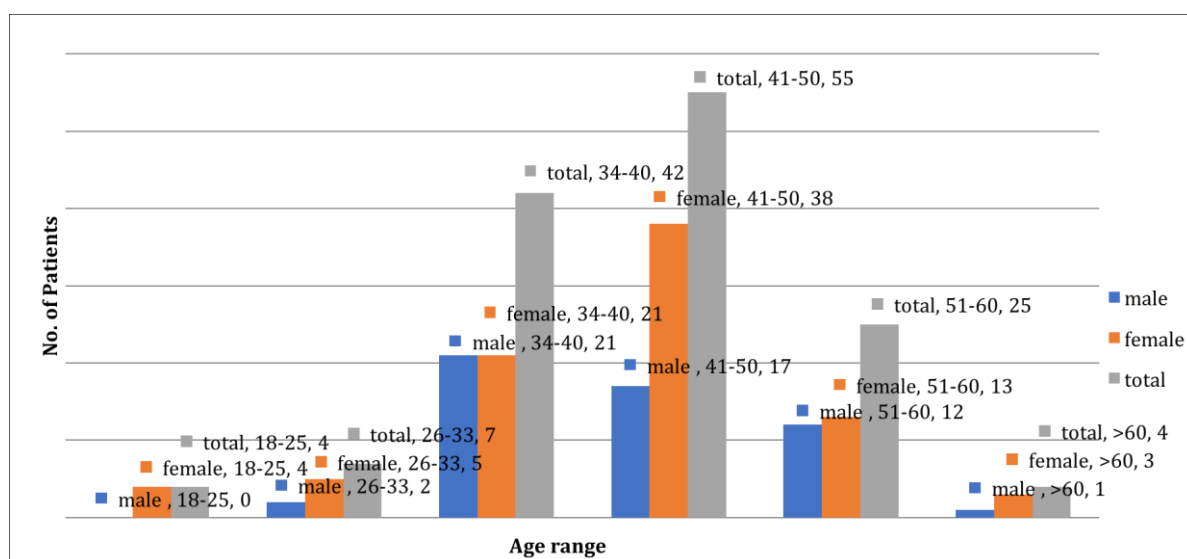
**Figure 2: Age of occurrence of T2DM among Patients**

**Figure 3: Family history among T2DM patients**

most co morbid is hypertension (no: 52; 56%), followed by hypertension and hypothyroidism together (no: 13; 14%), there are some cases of hypothyroidism alone along with T2DM 6.5%, followed by Neuropathy 2%, nephropathy 4.3%, cataract 2%, and dyslipidemia 8.6% together with hypertension (Kamrai *et al.,* 2010) (Table 3)

**Evaluation of Therapy in T2DM:** Very good blood glucose control was obtained from the range of 140-125 mg/dl as out of 26 patient we got 20 patients (76%) good control, due to short of period of research we could follow 50 T2DM patients, they are using mono therapy of antidiabetic drug, and the drug is biguanides, sulfonylurea, and dipeptidyl peptidase inhibitor. followed by another group 170-145 mg/dl out of 10 patients before therapy 6 patient got improved (60%), from another group 210-175mg/dl out of 8 patients we got
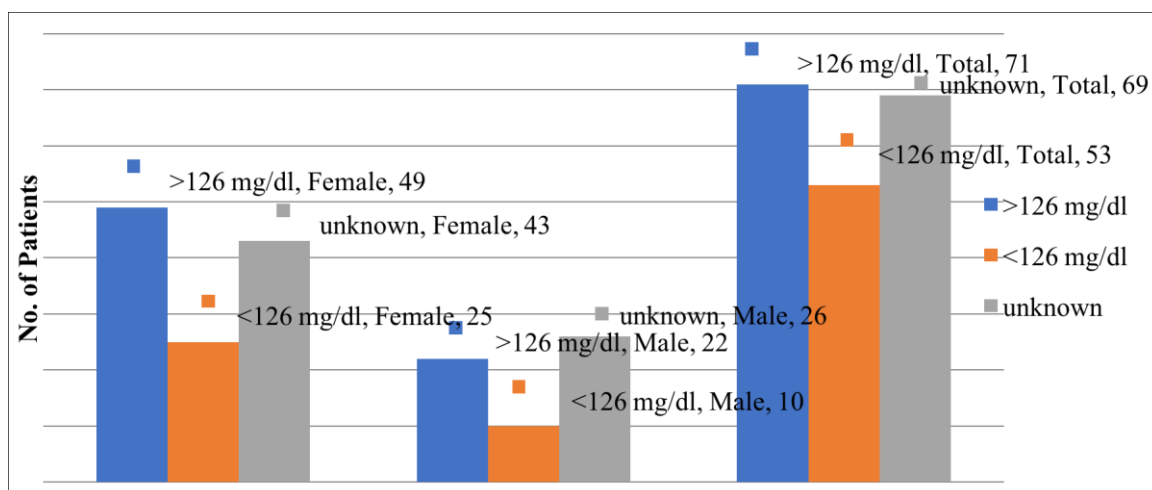
Figure 4: Patient Classification as per Blood Glucose level
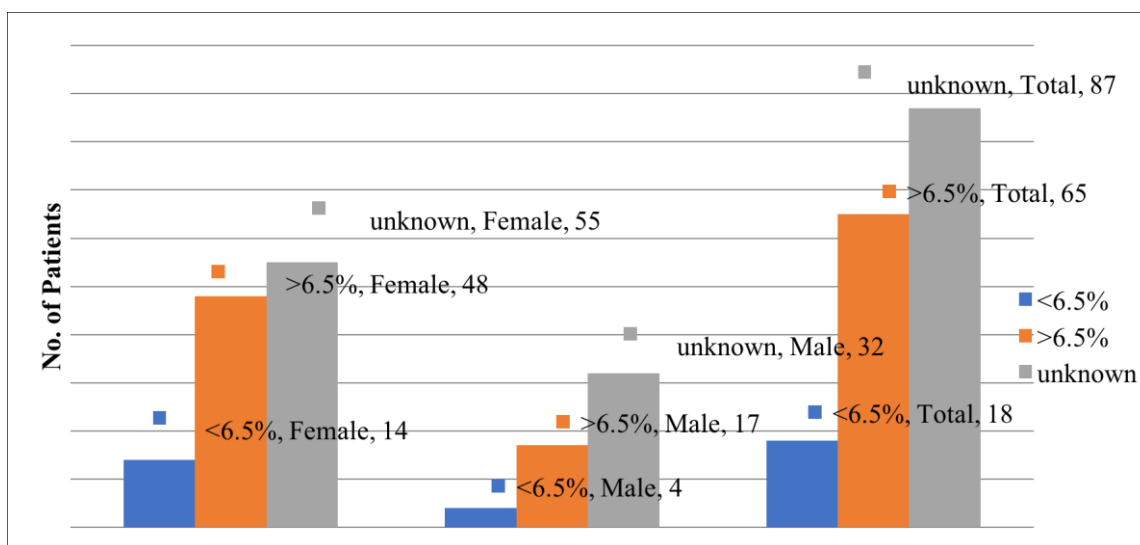
Figure 5: Patient's classification according to HbA1c parameter
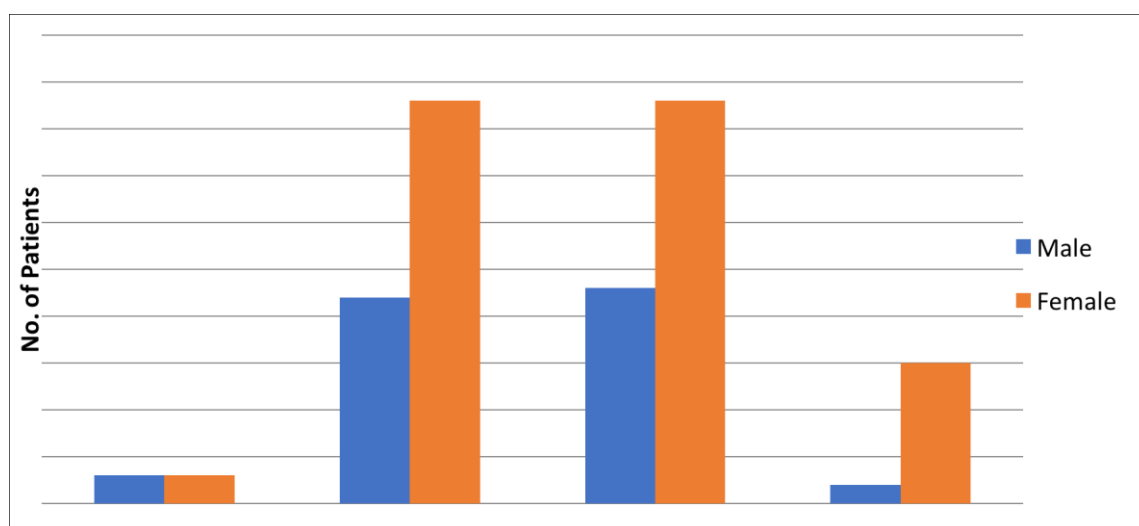
Figure 6: Body Mass Index distribution among T2DM patient

5 patients (62.5%), and last group was >210 out of 6 patients we got 3 patients improved blood glucose 50%. (Table 4)

Cost Effective Analysis of pharmacotherapy in T2DM: due to short of period of study we could fol-low 50 T2DM patients, they are using mono ther-apy of antidiabetic drug, and the drug is bigua-nides, sulfonylurea, and dipeptidyl peptidase in-hibitor (Naveed *et al.,* 2014). Out of 33 patients us-ing biguanides (metformin) the percentage of im-provement was 76% and cost effective ratio was

3.78, as the least ratio the drug is cost effective more (Nihar R. Desai *et al.,* 2011) (Table 5).

DISCUSSION AND CONCLUSION

This prospective observational study was performed among the South Delhi population visiting HAHC hospital, Jamia Hamdard. The main focus of the study was to find out the prevalence of T2DM, major co-morbid condition. To evaluate the prescription pattern in patients suffering from T2DM, to assess the cost- effectiveness relationship of the treatment. During the four months study period, 174 patients with T2DM meeting the criteria were evaluated. The present study observed that diabetes was more prevalent in females than in males. Out of 174 cases collected, the females account for 67% and males account for 33% of total cases. This gender distribution in this study is in agreement with other studies. Large number of patients does not have positive family history of T2DM, suggesting that T2DM not only genetically transmitted disease as there are many other important factors. Large number of patients found to be illiterate does not have basic education, poverty and irregular food intake (2meal per day) may cause stress increasing the prevalence of T2DM in this area. The associated Co morbid conditions seen with diabetes mellitus are hypertension, dyslipidemia, neuropathy, nephropathy and retinopathy. About 56% of diabetic patients are associated with hypertension as a co morbid condition. T2DM was found to be more prevalent in female (117) than in male (57). The most widely prescribed treatment as mono-therapy and combination therapy found to be metformin, and sulphonylureas. Cost Effective Analysis was performed on 50 patients the most common therapeutics prescribed to patients was biguanides (metformin) and sulphonylureas which found to be good cost effective ratio. Lower the CER values, better the treatment outcomes. According to this, other treatment was least effective, in term of cost effectiveness.

REFERENCES

ACE Diabetes Mellitus Clinical Practice Task Force. American Association on Clinical Endocrinologists medical guidelines for clinical practice for the management of diabetes mellitus. *Endocr Pract*. 2010; 16 Suppl 1:270–283

Akila,Sandozi, Kumar, Balasubramanian, Rani,Drug Utilization Study of Oral Anti-Diabetic Drugs at a Tertiary Care (SRM medical college) Hospital in Chennai. *InternationalJournal of Medicobiological Research,2011; 1(3):177-182*

American Society of Hospital Pharmacist. ASHP technical assistance bulletin on hospital drug distribution and control. *American Journal of Hospital Pharmacy*.1980; 37:1097-1103.

Canadian Diabetes Association Clinical Practice Guidelines ExpertCommittee. Canadian Diabetes Association 2008 clinical practice guidelines for the prevention and management of diabetes in Canada.*Can J Diabetes 2008*; 32: S95-S98.

Dipiro,Schwinghammer, V. DiPiro,Wells,Pharmacotherapy hand book, 7thEdition. Chapter 19, Pg 210.

International Diabetic federation (IDF), Diabetes Atlas I Sixth edition.2013

Introduction to drug utilization research. WHO booklet 2003 ISBN 94

Janet B. McGill. The Washington Manual of Medical therapeutics: diabetes mellitus and related disorders; 33rd Edition; Wolter Kluwern Pvt Ltd 2011, pg 793

Kamrai, Sachdeva, Prescribing Trends Of Antidiabetic In Diabetic Patients And Hypertensive Diabetic Patients In An Urban Secondary Care Hospital.2010 *International Journal of Pharmaceutical & Biological Archives* 2010; 1(2): 249 – 255, ISSN 0976-3333.

Mazze *et al* Staged Diabetes Management third edition, International Diabetes Center, 2012 Wiley-Blackwell, ISBN: 3528-6.

Naveed, Badar,Rehman, Abbas, Khalid, Qayam. Drug prescribed to diabetic patients and effectiveness of combination and monotherapy. *Mintage Journal of Pharmaceutical and Medical Science* 2014; 3(2), 26-31.

Nihar R. Desai, MD *et al* Patterns of Medication Initiation in Newly Diagnosed Diabetes Mellitus: Quality and Cost Implications *the American Journal of Medicine* 2011; 07.033.

Parthasarathi G, Hansen KN, Nahata. MC. "Text Book of clinical pharmacy practice: Essential Concepts and skills" Orient Longman Private limited 2004, P. 363

Patel, Oza, Patel, Malhotra, Patel,Pattern of antidiabetic drugs use in type-2 diabetic patients in a medicine outpatient clinic of a tertiary care teaching hospital. *International Journal of Basic & Clinical Pharmacology2013; 2(4):485-491*.

Vasamsetty, Rao peri, Rao, Srinivas, Someswararao. Gene Expression Analysis for Type-2 Diabetes Mellitus – A study on diabetes with and without parental history. *Journal of Theoretical and Applied Information Technology*; 2011; vol. 27 NO. 1; p 43:53.

Wabe, Angamo, Hussein, Medication adherence in diabetes mellitus and self management practices

among type-2 diabetics in Ethiopia. *North American Journal of Medical Sciences 2011;* Vol 3. No. 9.413-423.

World Health Organization. Screening for type 2 diabetes. Report of a World Health Organization and International Diabetes Federation meeting. WHO/NMH/MNC/03.1 Geneva: *WHO Department of Noncommunicable Disease Management*; 2003.