(RESEARCH ARTICLE)

A pilot study: Drug utilization pattern and prevalence of micro and macrovascular complication in type 2 diabetes patient

N. VISHVA [1, *], M. VISHNUPRIYA [1], A. VASANTH [1], R. RAJAPANDI [2] and S. GOPIKRISHNAN [2]

[1] Clinical Clerkship, Doctor of pharmacy, Arulmigu Kalasalingam College of Pharmacy, Viruthunagar, Tamilnadu, India - 626126.

[2] Department of Pharmacology, Arulmigu Kalasalingam College of Pharmacy, Viruthunagar, Tamilnadu, India - 626126

Abstract

Background: Diabetes mellitus is a chronic metabolic disorder resulting from the deficiency of insulin secretion and insulin resistance. Currently, there is a death of nationwide data regarding the prevalence of micro and macro complications and drug utilization patterns. This study will help health-care professionals approach management more aggressively to prevent complications.

Objectives: To assess the risk factors associated with complications in diabetes patients, and to determine the pattern of drug prescription among type-2 DM patients patterns at Virudhunagar Medical College & Hospital.

Methods: This is a Prospective, prescription-based, and observational study. A sample size of 50 was selected systematically. Data were collected from patient case records and Prescriptions. The obtained data were entered in the structured patient profile form, and the filled forms were analyzed.

Results: Out of the total 50 cases evaluated, 60 (60%) were males and 20(40%) were females. The 28 patients (56%) had a family history of diabetes. The prevalence of the associated diabetic complications was as follows viz. Hypertension (17.65%), IHD (1.47%), retinopathy (17.65%), nephropathy (7.35%), Neuropathy (47.06%), Stroke (5.88%) and CHF (2.94%). The overall utilization pattern of drugs were as follows viz. anti-diabetics (28%), anti-hypertensive (9%), antiplatelets (4%), lipid lowering agents (7%), vitamins and minerals (17%),GI drugs (14%), antimicrobials(6%). Among anti-diabetic drugs 48(96%) biguanides and 44(88%) of sulfonylureas classes of antidiabetic drugs were utilized. Likewise, preferred drugs for the management of hypertension, IHD, dyslipidemia, and neuropathy were Diuretics (25.93%), Clopidogrel (66.66%), Atorvastatin (100%), and Acetominophine (67.74%) respectively.

Conclusion: The prevalence of micro and macro complications among type 2 diabetic patients was found to be high. Although polypharmacy was observed, drug utilization patterns can be rational owing to the higher prevalence of complications**.** Patient are not aware of the severity of the disease so complication makes the therapeutic more challenging. Patient education on disease severity and healthcare professionals need more focus on disease complications and severity to treat the disease earlier to improve patient health outcomes.

Keywords: Diabetes; Microvascular; Macrovascular; Drug Utilization.

---

* Corresponding author: N. VISHVA

1. Introduction

Diabetes mellitus is a chronic metabolic disorder resulting from the deficiency of insulin secretion and insulin resistance. It is one of the major global health problems and leads to an increased rate of morbidity and mortality (Sriram *et al.,* 2018).[1] Diabetes is characterised by high blood sugar, which raises the possibility of complications. Numerous issues could arise if high blood sugar levels are not controlled if diabetes is not well treated.. Hospitalization was the majorconcern among diabetic patients due to the severity of the disease. People with diabetes are more likely to be hospitalized because of both microvascular complications especially neuropathy, and nephropathy, and macrovascular complications involving stroke, and cardiac failure. Rational use of Oral Hypoglycaemic Agents and insulin helps in decreasing hospitalization (Tamoghna *et al.,* 2016).[2]

About 9.3% population was diagnosed with diabetes worldwide. This was reported as a riseof 62% in the past 10 years (Pauya Saeedi *et al.,* 2019).[3] International Diabetes Federation estimates the number of people with diabetes in India is expected to be 69.9 million by 2025. The prevalence rate of diabetes worldwide was estimated to be 2.6% in 2000 and it will increase to 4.4% in 2025. The overall prevalence of diabetes in all different states of India was estimated at 7·3%. Moreover, in urban areas, the diabetes prevalence rate is predominant in people with lower socioeconomic status compared with rural areas (Ranjit *et al.,* 2017).[4] The International Diabetes Federation reports that more than 463 million people were with diabetes as of2019 and it will rise to about 700 million by 2045. The World Health Organization estimatesthat 90 percent of people around the world who have diabetes belong to type 2 diabetes. Diabetes was the cause of 1.5 million deaths. The prevalence rate of diabetes worldwide was estimated to be 2.6% in 2000 and 4.4% in 2030.

2. Materials and methods

2.1. Study type

This was the Prospective observational study. All the patients who met the inclusion criteria were taken the as study population.

2.2. Study site

This study was conducted by observing case sheets of inpatients in a tertiarycare teaching hospital.

2.3. Study Population and Inclusion and Exclusion Criteria

The study population of this study was all diabetic patients having complete medical records. The patients who met the inclusion criteria were enrolled in the study. The inclusion and exclusion criteria were as follows.

2.3.1. Inclusion criteria

- Both the genders and age groups 30 – 90 years were included.
- .Patients with diabetes and complications were included after obtaining writteninformed consent.

2.3.2. Exclusion criteria

- Patients below 30 years & old who are not willing to participate were excluded.
- Pregnant Women.
- Patients with end-stage renal failure were excluded.

2.4. Sample Size

The study population is 50 patients.

2.5. Data Collection

A data collection form was developed to collect the data. There were two parts to the data collection form; the Pharmacist's patient profile form and the Medication study form.

2.6. Data Entry and Analysis

Data was entered into a Microsoft Office Excel worksheet and was analyzed. Approval for the study. The proposal for project work was approved by the Department of Pharmacy Practice, ARULMIGU KALASALINGAM COLLEGE OF PHARMACY. After that approval was taken from the hospitals where data collection was done.

2.7. Feasibility of the study (Pilot Study)

A pilot study was carried out for Two months. Necessary changes in the data collection forms and methods were made accordingly. Data collected during the pilot study are not included in the data analysis.

3. Results

Based on the study criteria, 50 cases were selected and taken for the study. Of the the total population majority were male (60%, N: 30) in comparison to female (40%, N: 20) and 16 (32%) were belonged to the age group 41-50 years and 14 (28%) were in the age group 61-70. According to the body mass index (BMI), 10 (20%) of the patient has normal weight followed by 24 (48%) were overweight and 16 (32%) patient were obese. (Table 1)

Table 1 Demographic Characteristics of Diabetic Patients (n=50)

Variable	Total Patient n (%)
Gender	
Male	30 (60)
Female	20 (40)
Age (years)	
18 – 30	0 (0)
31 – 40	5 (10)
41 – 50	16 (32)
51 – 60	9 (18)
61 – 70	14 (28)
>70	4 (8)
BMI (kg/m2)	
Normal	10 (20)
Overweight	24 (48)
Obese	16 (32)

BMI : Boby Mass Index

Of the 50 patient 28 (56%) shows familial association with type 2 diabetes and 23 (46%) were suffering from diabetes for 0-5 years followed by 16 (32%) and 6 (16%) had type 2 diabetes mellitus for 6-10 years and 16-20 years respectively. Patient were suffering from different types of complication. 1 (2%) patient do not shows any complication while majority shows single complication (N: 30, 60%) followed by two complication (N: 19, 38%) (Table 2).

(Table 3) shows the category wise prevalence of complication among the study population. Neuropathy complications were observed in majority of population with gross prevalence of 47.06% followed by diabetic retinopathy (N: 12, 17.65%) and cardiovascular (N: 12, 17.65%). Neuropathy is most prevalent among complication.

Table 2 Clinical characteristics of Diabetic Patients (n=50)

Variable	Total Patient n (%)
Family history of diabetes	28 (56)
Duration of diabetes (years)	
0 -5	23 (46)
6 – 10	16 (32)
11 – 15	5 (10)
16 – 20	6 (16)
Prevalence of complication	
No complication	1 (2)
Single complication	30 (60)
Two complication	19 (38)

Table 3 Category Wise Prevalence of Complications

Complication	Frequency (%)
CARDIO VASCULAR	12 (17.65)
IHD	1 (1.47)
CHRONIC HEART FAILURE	2 (2.94)
NEPHROPATHY	5 (7.35)
RETINOPATHY	12 (17.65)
STROKE	4 (5.88)
NEUROPATHY	32 (47.06)

During the study period, a total of 112 OHAs were prescribed to the patient. Biguanides (N: 48, 42.85%) were the most commonly prescribed class, followed by sulphonylureas (N: 44, 39.28%) and sitagliptin (N: 2, 1.78%). (Table 4) shows that 18 of the studied patient received insulin alone or in combination with oral antidiabetic drugs (16) (Table 5). Details of the class of antidiabetic drugs and combination prescription pattern for enrolled patients are presented in Table 4 and 5 respectively.

Table 4 Type of Hypoglycemic Agents Prescribed (n=50)

Class	Frequency (%)
Insulin	18 (16.07)
Biguanides	48 (42.85)
Thiozolidinediones	0
Sulphonylureas	44 (39.28)
Sitagliptin	2 (1.78)
Alpha – Glucosidase Inhibitors	0

Table 5 Pattern of Anti-Diabetic Combinations used in Study Population (n=50).

Combination (s)	Frequency (%)
Glimepiride + Metformin	33 (60)
Glibenclamide + Metformin	4 (7)
Metformin + Acarbose	0
Metformin + Insulin	9 (16)
Sitagliptin + Metformin	2 (4)
Glimepiride + Metformin + pioglitazone	0
Metformin + Glipizide	7 (13)

3.1. Management of complications

Table 6 Management of Complications.

		Class	No.Of. Prescriptions	Percentage of total numbers
Cardiovascular drugs	Anti-hypertensives	ACEI	6	22.22
		CCB	11	40.74
		B- Blocker	3	11.11
		Diuretics	7	25.93
		Total	**27**	
	IHD drugs	Aspirin	5	33.33
		Clopidogrel	10	66.67
		Total	**15**	
	Dyslipedemic drugs	Atorvastatin	12	100
		Total	**12**	
Peripheral Neuropathy		Amitriptyline	3	9.68
		Pregabalin	7	22.58
		Acetaminophen	21	67.74
		Total	**31**	

NOTE: Angiotension-converting enzyme inhibitor, ARB: Angiotensin Receptor Blocker, CCB: Calcium Channel Blocker.

3.2. Management of cardiovascular complications

3.2.1. Hypertension

Calcium channel blockers (40%) were the most preferred agents in treatment of diabetic hypertensive followed by diuretics (25%), Angiotensin converting Enzyme inhibitors (22%), Beta Blocker (11%). Calcium channel blockers / Diuretics was the most commonly prescribed drug class both in mono and combination therapy.
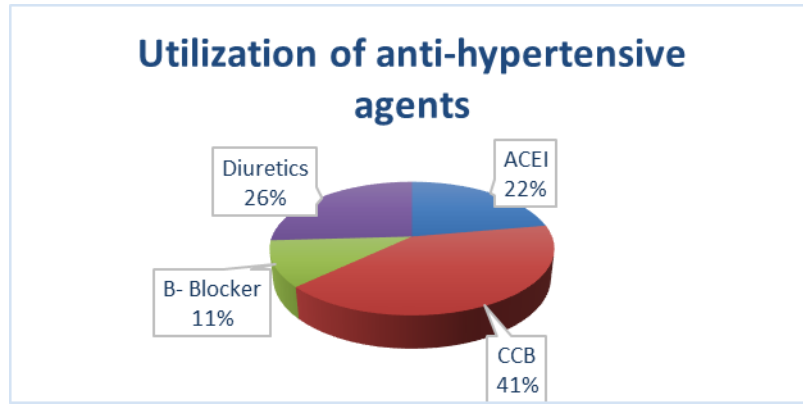
Figure 1 Utilization of Anti-Hypertensive Agents

3.2.2. Management of Ischemic Heart disease / CV events prophylaxis
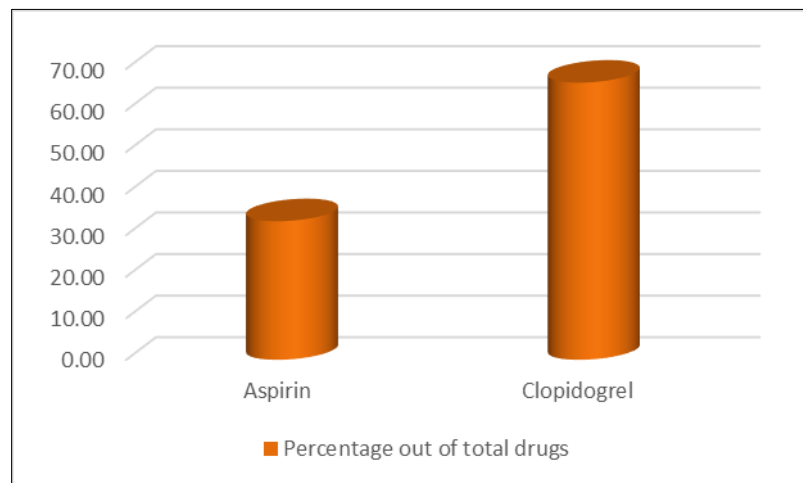

Figure 2 Utilization of Anti-Platelet Agents

Patients received one or more anti-platelet agents for ischemic heart disease or prevention of cardiovascular complications. From this study, it was discovered that clopidogrel was preferred agent (66% out of total anti-platelet agents) as mono-therapy used among Type II Diabetes Mellitues (T2DM) patients followed by a combination of aspirin and Clopidrogel.
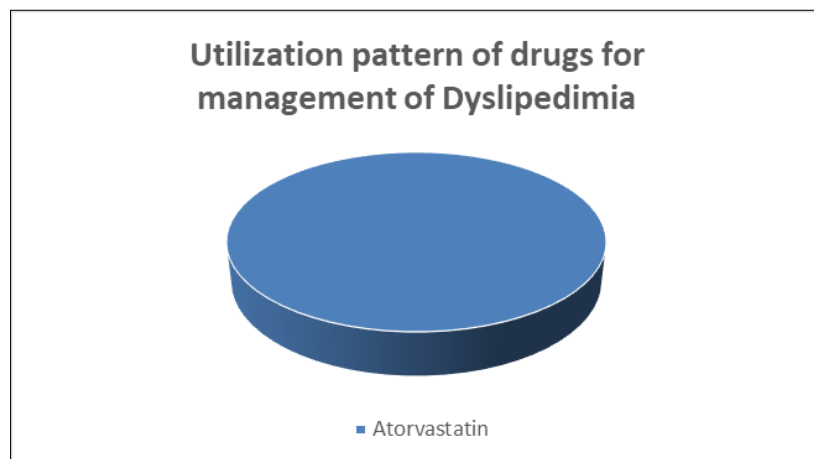
3.2.3. Management of Dyslipidemis.

Figure 3 Utilization of Hypolipidemic Agents.

The drug use evaluation studies of hypolipidemic agents showed that 100 % of the patients received statins. Among statins, atorvastatin was most commonly used.

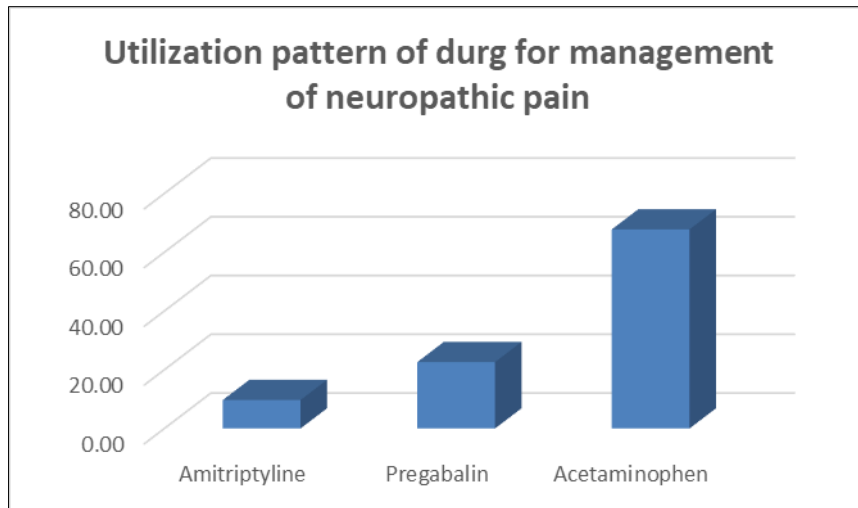### 3.2.4. Management of diabetic neuropathic pain

Figure 4 Utilization Pattern of Drugs for Management of Neuropathic Pain.

Diabetic neuropathic pain was managed by Acetaminophen (67%) in majority of cases, followed by the anticonvulsants Pregabalin (22%), Amitriptyline (10%)

3.2.5. Overall Utilization Patterns of Drugs

Table 7 Overall Utilization Pattern of Drugs.

Drugs	Frequency (%)
Anti-diabetic	50 (28)
Lipid-lowering agent	13 (7)
Anti-hypertensive	16 (9)
Analgesics	28 (15)
Anti-platelet	8 (4)
Antimicrobial	11 (6)
GI Drugs	25 (14)
Vitamins	30 (17)
Total	181

Anti-diabetic drugs accounted for almost 30% of the prescribed drugs followed by anti-hypertensive medications, which might be due to higher prevalence of hypertension (9%) among diabetic patients. The utilization of lipid lowering drug and anti-platelet drug was 7% and 4% respectively.

4. Discussion

From the above graphical representation, A total of 50 diabetic patients were evaluated during the study period male (62%) was found to be predominant over female (38%), similar to the study conducted, by Maskey et al., [5].

Majority of the patient n=16(32%) were found to be in 41-50 years and 15 (30%) were of the age 61-70 years of age group and 9 (18%) were of the age 51-60 years indicating that the risk of type 2 diabetes increases after the age of 40. Roy V et al.,[7] shows similar result in age wise prevalence of type 2 diabetes.

This studies found out the prevalence of obesity and hypertension among 16(32%) and 18(36%) were at high prevalence. In this study prevalence of dyslipidemia (26%) which is contrast to the study conducted by Abdel aal NM et al.,[13] shows (90%). Hypertension is the major comorbid condition associated with type 2 diabetes increases the risk of cardiovascular complications reported the findings of the study conducted by Colosia AD et al.,[12]. Obesity (32%) and overweight (48%) are at higher prevalence. Obesity is the major potentially modifiable risk factor for type 2 diabetes similar to the study conducted by pinkney J et al., [10].

Out of 50 patient,28 patients (56%) had a family history of diabetes compared to the study conducted by Patel PS et al.,[13]. From this study,32 (64%) were observed with neuropathy is at higher risk than other microvascular complications was significantly reported by the study by Ashok s et al,.[14]. and n=12 (24%) are at high risk for cardiovascular disease than other macrovascular complication.

Out of 50 patient n=48 (96%) of biguanides and 44(88%) of sulfonylureas classes of antidiabetic drug were utilized similar to the findings reported by Upadhyay DK et al ,[11] and Sultana G et al., [12]. Overall 33 patient (66%) had utilized metformin + glimiperide combinational drug and followed by 9 (18%) had utilised metformin + insulin. Overall utilization of drugs antidiabetic drug (100%) along with vitamins (60%) and analgesic (56%) has been prescribed. Furthermore. the lipid lowering agent prescribed to 13 patient (26%) is almost contrast to the similar study conducted by Enwere OO et al., [14] which shows (5.5%)

5. Conclusion

This study concludes that Lack of awareness, ineffective diagnosis, uncontrolled disease, and poor compliance to therapy lead to serious outcomes progressing to micro and macrovascular complications and worsening of the disease. This leads to increases the mortality and hospitalization rates. The study indicates that the above 40 years of age group has more risk and we observed that neuropathy and cardiovascular disease are the most prevalent micro and macrovascular complication which requires the implementation of the most effective therapy. Metformin is a first-line drug along with glimiperide to treat type 2 diabetes. Insulin was used only in severe glycemic levels and is found to be more effective in achieving the target in hospitalized patients. Patient are not aware of the severity of the disease so complication makes the therapeutic more challenging. Patient education on disease severity and healthcare professionals need more focus on disease complications and severity to treat the disease earlier to improve patient health outcomes.

Compliance with ethical standards

Acknowledgment

Disclosure of conflict of interest

No conflict of interest is to be disclosed.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

Reference

[1] Sriram A, Dhanapal CK and Junior Sundresh N. Drug use pattern involved in diabetic with hypertension patents in a tertiary care teaching hospital. The Pharma Innovation Journal 2018; 7(7): 535-538 .

[2] Tamoghna Maiti, Sourav Chakrabarty, Sonai Mandal, Amrita Panda, TanmoyGangopadhyay, Satrajit Dan ,A Study On Drug Utilization Pattern In Patients Of Type II Diabetes Mellitus Attending Referral Diabetic Clinic At A

Tertiary Care Teaching Hospital In Rural Bengal. European Journal of Pharmaceutical and Medical Research, 2016:3(9):641-64.

[3] Pouya Saeedi, Inga Petersohn, Paraskevi Salpea, Belma Malanda**,** Suvi Karuranga**,** Nigel Unwin**,** Stephen Colagiuri**,** Leonor Guariguata**,** Ayesha A Motala**,** Katherine Ogurtsova**,** Jonathan E Shaw**,** Dominic Bright, Rhys Williams**,** IDF Diabetes Atlas Committee. Global and regional diabetes estimates for 2019 and projection for 2030,International diabetes federation, Diabetes atlas, 2019; edition 9. Diabetes Research and Clinical Practice, 2019;157:107843.

[4] Ranjit Unnikrishnan, Rajendra Pradeepa, Shashank R Joshi, Viswanathan Mohan.Type 2Diabetes: Demystifying the Global Epidemic. Diabetes, 2017;66(6):1432-1442.

[5] Maskey R, shakya DR, sharma SK, karki P, et al. (2011). Diabetes mellitus related complications in out- patient clinic of tertiary care hospital Journal of College of Medical Sciences-Nepal. 7(2).

[6] Pinkney J, Wilding J, Williams G and Macfarlane I. (2002). Hypothalamic obesity in humans: what do we know and what can be done? Obes Rev. 3(1): 27-34

[7] Roy V and Rewari S. (1998). Ambiguous drug pricing: A physician's dilemma. Indian J Pharmacol. 30(6): 404-407.

[8] Colosia AD, Palencia R and Khan S. (2013). Prevalence of hypertension and obesity in patients with type 2 diabetes mellitus in observational studies: a systematic literature review. Diabetes Metab Syndr Obes. 6: 327-338.

[9] Patel PS, Sharp SJ, Luben RN, khaw KT, et al. (2009). Association between type of dietary fish and seafood intake and the risk of incident type 2 diabetes: the European Prospective Investigation of Cancer (EPIC)-Norfolk cohort study. Diabetes Care. 32(10): 1857-1863.

[10] Ashok S, Ramu M, Deepa R and Mohan V. (2002). Prevalence of neuropathy in type 2 diabetic patients attending a diabetes centre in South India. J Assoc Physicians India. 50: 546-550.

[11] Upadhyay DK, Palaian S, Ravi Shankar P, Mishra P, et al. (2007). Prescribing Pattern In Diabetic Outpatients In A Tertiary Care Teaching Hospital In Nepal. Journal of Clinical and Diagnostic Research. 1(4): 248-255.

[12] Sultana G, Kapur P, Aqil M, Alam MS, et al. (2010). Drug utilization of oral hypoglycemic agents in a university teaching hospital in India. J Clin Pharm Ther. 35(3): 267-277.

[13] Abdel-Aal NM, Ahmad AT, Froelicher ES, Batieha AM, et al. (2008). Prevalence of dyslipidemia in patients with type 2 diabetes in Jordan. Saudi medical journal. 29(10): 1423-8.

[14] Enwere OO, Salako BL and Falade CO. (2004). Prescription at a Diabetic Clinic in Ibadan, Nigeria: A Report, Annals of Ibadan Postgraduate Medicine. 4(2): 35-39