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CLINICAL RESEARCH

Clinical Study on Drug Utilization Pattern and Quality of Life Assessment in Diabetic Patients: A prospective Study

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ABSTRACT

BACKGROUND

Diabetes mellitus (DM) impacts over 500 million individuals globally, accounting for approximately 10% of the population. This study analyzed antidiabetic drug utilization patterns and assessed the quality of life in diabetic patients during disease management using specific evaluation indicators.

METHODOLOGY

A prospective observational study involving 180 diabetic patients was conducted at a multispecialty hospital. Demographic information was gathered, and drug utilization patterns were analyzed following WHO guidelines. The MDQoL quality of life questionnaire was employed to assess general health perceptions in diabetic patients.

RESULTS

Of the 180 participants, males (n = 101) outnumbered females (n = 79), with a mean age of 58.34 years. Fasting blood sugar (FBS) and postprandial blood sugar (PP2BS) levels were 194.1 mg/dl and 288.40 mg/dl in males and 183.37 mg/dl and 288.03 mg/dl in females, respectively. Metformin emerged as the most frequently prescribed antidiabetic agent, both as monotherapy and in combination with glimepiride, with oral administration being predominant. Newly diagnosed cases accounted for 36 patients. Hypertension, neuropathy, and retinopathy were the most prevalent comorbidities. Most respondents indicated an improved quality of life.

CONCLUSIONS

Diabetic neuropathy and retinopathy were prevalent among patients with poorly controlled diabetes. Metformin monotherapy was frequently associated with palliative benefits. Overall, diabetes management led to enhancements in health-related quality of life.

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KEYWORDS

Diabetes mellitus; Quality of life; Neuropathy; Metformin; Glimepiride

INTRODUCTION

The American Diabetes Association defined diabetes mellitus as a group of metabolic diseases characterized by an increased level of glucose in the blood (hyperglycemia) manifested by alterations in insulin secretion and/or action [1]. Diabetes affects 537 million individuals (20 years - 79 years old), and one out of every ten people suffers from it. By 2030, this number is expected to climb to 643 million and, by 2045, to 783 million [2]. DM (32%) was found to be a prominent comorbid condition in cardiovascular diseases [3,4].

Type-1 DM is an auto-immune disorder involving the destruction of β-cells in pancreatic islets mediated through T lymphocytes and macrophages [5]. It is also known as insulin-dependent DM (IDDM) or juvenile-onset DM. [6,7] Type-2 can be termed non-insulin-dependent DM (NIDDM) or maternity-onset DM [7] and is characterized by different defects such as insulin resistance, impaired insulin secretion, decreased insulin release due to reduced incretin effect, excess glucagon secretion, and up-regulation of sodium-glucose cotransporter-2 (SGLT-2), 90% of DM cases belong to type 2 DM [8,9]. Gestational DM is experienced during pregnancy's second or third trimester [10], mimicking type-2 DM.

Diabetes serves as a reservoir for many fatal diseases, and its progression brings life-threatening conditions. Major complications during DM include microvascular and macrovascular associations. Microvascular problems involve retinopathy, neuropathy, and nephropathy, as well as diabetic foot syndrome [11], where small blood vessels get affected for prolonged periods of time [12]. It is also correlated with an increased risk of atherosclerosis and type-2 DM [13]. Macrovascular damage involves cardiovascular diseases such as coronary artery disease, stroke, peripheral artery disease, atherosclerosis, hypertension, dyslipidemia, and venous thromboembolism [14]. DKA (diabetic ketoacidosis) and HHS (hyperglycemic hyperosmolar state) are life-threatening metabolic complications during both type 1 and type 2 DM [15]. DKA is manifested by three disorders: metabolic acidosis, elevated blood ketones, and hyperglycemia. It is the result of declining insulin levels in the blood and the counteraction of hormones, resulting in altered glucose production and disposal and elevated lipolysis and ketone production [16]. HHS is an acute hyperglycemic condition indicating hyperglycemia, hyperosmolality, and dehydration in the absence of ketoacidosis [17].

Pharmacotherapy of Diabetes Mellitus

Insulin is mainly employed in cases of type 1 diabetes. Insulin analogs are prepared by DNA recombinant technology or chemistry modifications (by altering the amino acid sequence) of pork pancreas. Short-acting (Humulin R, Novolin R) works for 4 hours - 12 hours, and its onset is 30 minutes [18]. Rapid-acting insulin (insulin aspart (Novolog), insulin lispro (Humalog), and insulin glulisine (Apidra)) works for 2 hours - 4 hours, and its onset is 15 minutes [19]. Intermediate-acting insulin (Humulin-1, Hypurin isophane) starts acting in its initial hour of administration and lasts until 7 hours. Also known as isophane or NPH (neutral protamine Hagedorn), Long-acting insulins (insulin glargine, insulin detemir, and insulin degludec) are also known as basal or background insulins as they have a greater onset of action and can act for an entire day [20,21].

Sulfonylureas bind to sulfonylurea receptors (ATP-dependent potassium channels) and release potassium, resulting in depolarization. This causes calcium entry into the β-cells of the pancreas, and insulin exocytosis

occurs. SUR1 (located on β-cells) and SUR2 (smooth, cardiac, and skeletal muscles) are the receptors [22]. Drugs involved in this class are:

- ***First generation:*** Tolbutamide, chlorpropamide, tolazamide, acetohexamide, and carbetamide [23].
- ***Second generation:*** Glibenclamide, Glipizide, Gliclazide, Glimepiride, Glyclopyramide, Gliquidone, and Glibornuride [7,23].

Biguanides

Their mechanisms are not completely exposed but are presumed to act through elevating blood glucose uptake in muscles, declining synthesis of glucose in kidneys, and reducing glucose absorption in the intestine [24]. The drugs are metformin and phenformin.

α-Glucosidase Inhibitors

They are competitive inhibitors of the α-glucosidase enzyme at the carbohydrate-binding site. Oligosaccharides will not be able to bind to this site for their cleavage of monosaccharides. For example, Acarbose, Voglibose, and Miglitol [25].

Non-Sulfonylureas Insulin Secretagogues

They act in accordance with sulfonylureas by opening voltage-gated calcium channels and closing ATP-dependent potassium channels, ultimately elevating depolarization and exocytosis of insulin. SUR are the target receptors for these agents, but they bind to different sites than sulfonylureas [23]. Drugs like Repaglinide and Nateglinide fall into this class.

Thiazolidinediones

These agents bind to peroxisome proliferator activated receptor γ (PPAR γ) and induce conformational changes, forming the PPAR-γ and RXR (retinoid X receptor) complex. It binds to PPAR-γ response elements (PPRE) and alters the transcription of genes encoding for glucokinase and the GLUT4 glucose transporter. Drugs: rosiglitazone, pioglitazone, and troglitazone [26].

DDP-4 Inhibitors

DDP-4 inhibitors act by decelerating the incretin hormone destruction, which elevates the active GLP-1 levels and inhibits glucagon release from the α-cells of the pancreatic islet. These decrease glucose levels and increase insulin levels. Drugs: Vildagliptin, Saxagliptin, and Sitagliptin [27].

Drug Utilization Pattern

The drug utilization pattern was defined by the WHO as the trade, dispensation, direction, and application of drugs in society, with significance for therapeutic, civil, and commercial consequences [28]. Its purpose is to govern and analyze the usage of drugs at various degree of healthcare systems [29]. It demands proper knowledge of drugs, pharmacoeconomics, pharmacovigilance, and experience [30]. It provides perceptions on the pattern of prescribing, quality of drugs prescribed and their indices, determinants of use, consequences of drug therapy, efficacy of drugs, and rational use of drugs in the population [31,32].

METHODOLOGY

Study Detail

The prospective observational study was conducted at the CHARUSAT multispecialty hospital in Changa in the inpatient and outpatient departments of medicine from July 2019 to February 2020. A total of 180 patients gave their consent for the study. Patients were selected based on inclusion criteria as newly diagnosed and known cases of diabetic patients; pregnant women were excluded from the study. All relevant patient data was taken in a CRF (case record form) along with a consent form. The CRF includes age, date, ID number, gender, complaints, past and family history, comorbidities, medication, laboratory data, and a questionnaire. The majority of drugs were prescribed by their brand name and generic name.

The patients were administered the MDQOL-17 questionnaire (Table 1) and (Table 2). This questionnaire asks 17 questions, and it compares with seven domains: physical functioning, role limitation due to physical health problems, role limitation due to personal or emotional problems, emotional well-being, social functioning, energy fatigue, and general health perception. The score given per question was 0 (minimum) - 100 (maximum).

Table 1: Based on this MDQoL -17 the questionnaire is evaluated.

Domains	Number of Items	Item Number
Physical Health Functioning	3	4,5,6
Role Limitation Due to Physical Health	1	7
Role Limitation Due to Emotional	2	11,12
Energy Fatigue	1	17
Emotional Well Being	3	8,9,10
Social Functioning	4	13,14,15,16
General Health	3	1,2,3

Table 2: Response category and scores of MDQoL -17.

Item No.	Response Category and Scores
1,2,7,13	1→100, 2→75, 3→50, 4→25, 5→0
3	1→0, 2→25, 3→50, 4→5, 5→100
4,5,6	1→0, 2→50, 3→100
10,11,12,14,15,16	1→0, 2→20, 3→40, 4→60, 5→80, 6→10
17	1→100, 2→80, 3→60, 4→40, 5→20, 6→0

Data Analytics

The data were analyzed using Microsoft Excel for various demographic variables: Age, gender, duration of diabetes, history, drug prescribed to the patient, laboratory test, and quality of life in diabetes patients using MDQoL-17. Those patients who scored more than 70 had better QoL, 50-70 had moderate QoL, and less than 50 had poor QoL.

RESULTS

Demographic Details

Total patients and study duration

Study duration was 8 months with 180 patients' enrollment.

Age group

The patient's age ranged from 18 to 80 years. The mean age was 58.34 ± 13.07 years. The most common age group was 61 years - 80 years (45.55%), followed by 41 years - 60 years (35.55%), 21 years - 40 years (14.44%), more than 80 years (3.88%), and 18 years - 20 years (0.55%).

Gender wise distribution

Out of 180 patients 101(56.2%) were male and 79 (43.47%) were female.

FBS and PP2BS levels

During the study, it was found that FBS and PP2BS were 194.1 ± 90.44 and 288.40 ± 92.05 mg/dl in males and 183.37 ± 60.01 and 289.03 ± 96.97 in females.

Co-existing illness

Twelve different comorbidities were listed among diabetic patients: hypertension (HTN) (40.55%), neuropathy (6.66%), gastritis (6.11%), COPD (4.44%), stroke (4.44%), IHD (3.88%), hypothyroidism (3.33%), thrombocytopenia (3.33%), CKD (2.22%), hyperlipidemia (2.22%), retinopathy (2.22%), and DKA (1.33%). Another common complication includes chest pain, heartburn, viral fever, nausea and vomiting, hyperacidity, weakness, difficulty breathing, giddiness, slurry speech, and drowsiness (Table 3).

Out of 180 patients, 36 were newly diagnosed with DM; 53 had one comorbidity with DM (HTN, hypothyroidism, etc.); 57 had more than one (HTN, neuropathy, liver diseases); and 26 patients had more than two (HTN, neuropathy, retinopathy, hyperlipidemia, IHD, etc) (Table-3).

Table 3: Socio-demographic data of the patients.

Gender Wise Distribution	Male	101
	Female	79
Age Group Wise Patient	18-20	1
	21-40	26
	41-60	64
	61-80	82
Distribution	>80	7
Comorbid Condition with DM	HTN	73
	Neuropathy	12
	Gastritis	11
No. of Complication with DM	Having only DM	36
	DM + 1	53
	DM + 2	57
	DM + 3	26
	DM + 4	8
Patient Affected based on Heredity	Family History (Yes)	118
	Family History (No)	62
History of Patients	Newly Diagnosed	36
	01-05	80
	06-10	38
	11-15	9
	16-20	9
	21-25	8

Family history and past of patient

Out of 180 patients, 118 (65.55%) had a positive family history. Maximum patients 80 (44.44%) were diagnosed between 1 and 5 years, followed by 38 (24.11%) between 6 and 10 years (Table 3).

Drug utilization of antidiabetic drugs

Monotherapy: Metformin was used in 45 patients, Teneligliptin in 27, Glimepiride in 9, and Voglibose in 7.

2 drug combinations- Metformin + Glimepiride was used in 71 patients; Metformin + Glipizide in 15, Metformin + Teneligliptin in 11, Metformin + Voglibose in 3, Metformin + Sitagliptin in 2 - were used as dual drug therapy.

A three-drug combination - metformin, glimepiride, and pioglitazone - was used in nine patients as triple-drug therapy.

Insulin therapy: Out of 180 patients, injection of human actrapid 40 IU was used in 18 patients, mainly for patients with uncontrolled diabetes, retinopathy, neuropathy, etc.; injection of human insulin 100 units/ml in 7; injection of human mixtard 30/70 40 IU in 4; and injection of human glargine 100 IU in 3 (Table 4).

Table 4: Drug utilization of antidiabetic and non-anti-diabetic drugs.

No. of Antidiabetic Drug Prescribed as Monotherapy	Metformin	45
	Glimepiride	9
	Voglibose	7
	Teneligliptin	27
No. of Antidiabetic Drug Prescribed as Two-Drug Combination Therapy	Metformin + Glimepiride	71
	Metformin + Glipizide	15
	Metformin + Voglibose	3
	Metformin + Teneligliptin	11
	Metformin + Sitagliptin	2
No. of Antidiabetic Drug Prescribed as Three-Drug Combination Therapy	Metformin + Glimepiride + Pioglitazone	9
Injectable Antidiabetic Drug Prescribed as Insulin	Injection Human Insulin 100 Unit/ ml	7
	Injection Human Actrapid 40 IU	18
	Injection Human Mixtard 30/70 40 IU	4
	Injection Human Glargine 100 IU	3
No. of Cardiovascular Drug Prescribed	Antiplatelet	20
	HMG Co Enzyme Reductase Inhibitors	33
	Beta Blockers	24
	Calcium Channel Blockers	7
	ACE Inhibitors	14
Drugs Prescribed other than Antidiabetic Drugs	Antiemetic	80
	Antibiotic	63
	NSAIDS	28
	Folic acid	10
	Anti-Asthmatic	7
	Anti-Thyroid	5
	Pregabalin + Methyl-Cobalamin	3

Drug utilization of other medications

Cardiovascular agents: Out of 98 agents, HMG coenzyme reductase inhibitors (rosuvastatin, atorvastatin) were prescribed in 33 patients; beta blockers (atenolol, bisoprolol, carvedilol, and metoprolol) were prescribed in 24; antiplatelets (aspirin and clopidogrel) were prescribed in 20; ACE inhibitors (Ramipril, captopril, lisinopril, enalapril) were prescribed in 14; and calcium channel blockers (amlodipine, nifedipine, and verapamil) were prescribed in 7 cases.

During this study, we also recorded drugs other than anti-diabetic (pantoprazole, domperidone, and ondansetron) in 80 patients, antibiotics (Augmentin) in 63 cases, NSAIDS (paracetamol, ibuprofen, diclofenac, and tramadol) in 28 cases, folic acid in 10 cases, etc.

Assessment of health-related quality of life in Diabetic patients

From 180 patients, only 25 experienced a better quality of life, of which 12 suffered from DM and 13 from DM and comorbidities; 100 patients had a moderate quality of life from those 17 patients with DM and 83 patients

with DM and coexisting illnesses; 55 patients had a poor quality of life from those 7 patients with DM and 48 patients with DM and coexisting illnesses (Table 5).

Table 5: Assessment of quality of life in diabetic patients.

QoL score	Having only DM (n = 36)	DM with co-existing illness (n = 118)	No. of patients (n = 180)
Less than 50	7	48	55
50-70	17	83	100
More than 70	12	13	25

DISCUSSION

The present study analyses drug utilization patterns among diabetic patients in the outpatient and inpatient departments of medicine at a multispecialty hospital. The study represents eighty enrolments of diabetic patients, and data were collected in case record form. Demographic details showed 101 (56.2%) males and 79 (43.47%) females. A retrospective study also showed ninety-one (52%) males and eighty-four (48%) females out of 175 patients [33,34]. In a prospective study of 250 patients, both male and female ratios were almost the same [35]. Age distribution postulates that 61 years - 80 years (45.55%) of the age group was involved most. A study showed similar results, with 142 patients out of 300 falling into this age group [36]. Another study showed that, 156 (62%) of the 250 admitted patients were male, while 94 (38%) were female and the preponderance of patients, 79 (32%), were between the ages of 20 and 40 [37]. Twelve comorbid conditions were experienced. Hypertension (73, 40.55%) was the most common comorbid condition, followed by neuropathy (12, 6.66%). Similar findings were obtained: hypertension was accompanied by a comorbidity with DM [33,36,38]. Fifty-three patients had a single complication (HTN, hypothyroidism, etc.); fifty-seven patients had more than one complication (HTN, neuropathy, and liver diseases); and 26 patients had more than two complications (HTN, neuropathy, retinopathy, hyperlipidemia, etc.). It was demonstrated that low socio-economic conditions can increase the risk of complications in type-1 DM, whereas in type-2 DM, obesity can result in fatal consequences [39,40]. A study concluded that neurovascular complications include retinopathy, neuropathy, nephropathy, and neurological disorders [41]. Out of 180 patients, 118 (65.55%) had a family history of DM. Genetic association was also evidenced in a study where the majority of subjects had a family history of DM. Eighty patients (44.44%) have been diagnosed with DM for 1 years - 5 years. Results are sustained by 5 years - 15 years of DM history in a study [35]. 100 patients have been diagnosed with DM for 1 years - 5 years [42]. Out of 180 patients, metformin was used in 45 patients as monotherapy. Similar outcomes were obtained; out of 180 patients, 106 used metformin as monotherapy [1,33,43,44], followed by glimepiride [33,36]. Monotherapy was dominant in this study. Similar results were obtained where, out of 175 patients, 136 were prescribed monotherapy [33,34]. Metformin and glimepiride were used in 71 patients as dual-drug therapy. The study showed that metformin and glimepiride are the most commonly used dual-drug therapies [34,35,42]. Metformin and glimepiride are the drugs also employed during cardiovascular comorbidities [3].

Out of 180 patients, metformin, glimepiride, and pioglitazone were used in nine patients as triple-drug therapy. The study showed that out of 144 patients, eight were treated with three drug combinations, followed by metformin, glimepiride, and sitagliptin [33]. Injection of human actrapid 40 IU was used in 18 patients with uncontrolled diabetes, retinopathy, neuropathy, etc. Insulin injection was found to be inefficient due to the absence of a gold chain during transportation. The second complication was bruising [46]. Insulin degludec is a novel insulin preparation comprising recombinant DesB30 human insulin acylated at the LysB29 residue with a

hexadecandioyl-gamma-L-Glu side chain that has a unique mode of protraction. Others are pegylated insulin Lispro (LY2605541), Glargine U300, and ultra-rapid-acting insulin analogues. The oral route was preferable to intravenous or systemic administration in the study. Out of all drugs 326 drugs were oral dosage forms, and 63 were injectables [47,48].

A HMG coenzyme reductase inhibitor (rosuvastatin, atorvastatin) was prescribed as a commonly used CV agent in 33 patients. A study had similar results. HMG coenzyme reductase inhibitors (rosuvastatin, atorvastatin) and antiplatelets (aspirin and clopidogrel) are the most commonly prescribed adjuvant drugs [33]. ARBs and diuretics were prescribed for CVD [44].

During this study, antiemetics in 80 patients, antibiotics in 63 patients, NSAIDs in 28 patients, and folic acid in 10 patients were prescribed [49]. Cephalosporin was widely used in an observational study [44]. The present study found that out of 180 patients, only 25 improved quality of life, out of which 100 had moderate quality of life and 55 had poor quality of life. Out of 250 patients, 106 had moderate QoL, 103 had better life quality, and 40 had poor quality of life [48].

CONCLSUION

There is an increased propensity for the development of Type 2 Diabetes Mellitus (T2DM) among elderly individuals. Diabetes mellitus (DM) can give rise to a range of issues that are associated with the cardiovascular system, among other systems. The study revealed a high prevalence of hypertension. Type 2 diabetes mellitus (DM) primarily arises from genetic factors, according to the findings of the research study. During the course of this study, metformin was administered as a monotherapy, whereas a combination of metformin and glimepiride was employed as a dual-drug therapy. Oral medications are generally favoured over injectable formulations, such as insulin. During the research, a comparison was made between the quality of life of individuals diagnosed with diabetes and those diagnosed with DM, while also considering the presence of comorbidities. The findings of the study indicate that a significant proportion of patients had a moderate quality of life.

CONFLICT OF INTEREST

No conflict of interest between authors.

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