Research Paper

Age- and Sex-related Prevalence and Drug Utilization Pattern in the Management of Type 2 Diabetes Mellitus and its Comorbidity with Cardiovascular Diseases: A Comparative Study

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A cross-sectional study of 250 cases of type 2 diabetes management was conducted in a governmental tertiary care hospital of urban south India to determine the comparative prevalence of type 2 diabetes and its comorbidity with cardiovascular diseases in diabetic population, core drug use indicators and drug utilization pattern in the management of diabetics entirely and with cardiovascular diseases. Highest prevalent age group for type 2 diabetes/cardiovascular diseases (greater incidence in female than male) was 51-60 years. The 62.8% prevalence of cardiovascular diseases in the diabetic population ascertained in the study could provide an evidence-based rationale for the World Health Organization guidelines for the management of hypertension in type 2 diabetics. Incidence of polypharmacy (6.06, the mean number of total drug products prescribed); 59.26% of encounters prescribed antibiotics; 17.6 and 18.5 min of average consultation and dispensing time, respectively; 100% of drugs actually dispensed and adequately labeled; 81.26% of patients having knowledge of correct dosage and average drug cost of Indian Rupees 145.54 per prescription were the core drug use indicators found mainly. Moreover, drugs prescribed from the Essential Drug List were more than 90% and thereby indicated the drug use in this set-up quite rational. Around 71.09% of cardiovascular agents prescribed by generic name revealed the cost effective medical care. Among the agents in type 2 diabetes management, Actrapid® (35.43%) was the highest. Among the cardiovascular agents prescribed, lasix (19.37%) was the highest. Cardiovascular agents prescribed orally by 76.48% signified the good prescription habit indicating the improved patients' adherence to the treatment. The present study emphasizes the need of early detection of hypertension as a preliminary diagnostic parameter of cardiovascular diseases in diabetics and appropriate management through concomitant therapy of cardiovascular drugs to minimize the risks of death.

Key words: Diabetics, agents in type 2 diabetes mellitus management, drug utilization pattern, prevalence, cardiovascular diseases, hypertension

India leads the world with largest number of diabetic subjects earning the dubious distinction of being termed as the "diabetes capital of the world". According to the Diabetes Atlas 2006 published by the International Diabetes Federation, the number of people with diabetes in India, currently around 40.9 million is expected to rise to 69.9 million by 2025 unless urgent preventive steps are taken[1]. Type 2 diabetes mellitus (T2DM) is now the fourth leading cause of death, with 80% of patients having and/or dying of cardiovascular, cerebrovascular or peripheral arterial diseases in the Eastern Mediterranean Region[2]. Insulin resistance, the significant pathophysiological context of T2DM causes a sustained increase in the concentration of cytosolic malonyl CoA, a potent inhibitor of carnitine palmitoyl-transferase I (CPT-I) at outer mitochondrial membrane. As a consequence, an insulin resistant

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diabetic develops impaired β-oxidation of free fatty acids with esterification of surplus amount of acyl CoA to triglycerides transported out of the cell in very low density lipoprotein (VLDL) and is likely to progress into an initiation of hypertension, an element of CVS diseases[3-5]. In a case study of 1435 patients, 42.2% was found to have T2DM and among them 81.1% had uncontrolled systolic blood pressure where 76.2% had uncontrolled diastolic blood pressure[6].

In an epidemiological study of Chinese adults in Taiwan, the age- and sex-adjusted prevalence of hypertension among diabetic subjects was twice than that of non-diabetic subjects[7]. About 60% of patients with T2DM are known to have hypertension[2]. People with T2DM and hypertension have two-fold increased risk of cardiovascular mortality compared to the T2DM solely. It has been shown that each 10 mmHg decrease in systolic blood pressure leads to a decrease in diabetes-related mortality by 15%, diabetes-related diseases by 12% and myocardial infarctions by 11%[1]. An advanced randomized controlled trial of 11 140 patients with T2DM by 215 collaborating centers in 20 countries showed that the risk of death from cardiovascular (CVS) diseases could be reduced by 18% by taking a fixed-dose combination of the drugs perindopril [an angiotensin-converting enzyme (ACE) inhibitor] and indapamide (a thiazide-like diuretic)[8].

Studies regarding the prevalence and the drug utilization reviews of agents in T2DM management in different hospitals of India were reported in the recent past[9-11]. Present survey of 250 cases of T2DM management was undertaken in an urban south Indian hospital to determine the age- and sex-related comparative prevalence of T2DM and CVS diseases in the diabetic population and the core drug use indicators (CDUIs). Utilization patterns of therapeutic agents in the management of T2DM and CVS drugs in the diabetic population were also separately evaluated to explore the role of drug use in the society. Such study of prevalence in urban south India is helpful for assessing the age- and sex-related growing burden of T2DM and its comorbidity with CVS diseases, examining their trends and severity by comparing with the same of nationwide different populations and thereby helping the policy makers to adopt efficient preventive measures to stem the tide. The CDUIs, ascertained in the present study are helpful to determine the degree of polypharmacy (average drugs); cost-effectiveness (generics); use of two important, but commonly overused and costly forms of drug therapies (antibiotics and injections); rationality in prescribing (on Essential Drug List); patients' preparation to deal with the drugs, prescribed and dispensed as an experience gained at health facilities (average consultation/dispensing time, drugs actually dispensed/adequately labeled and knowledge of correct dosage) and prescribers' capability to provide curative care through non-pharmaceutical therapies (without drugs). If an intervention is undertaken for any inappropriate therapy, the CDUIs can be served as significant supervisory tools to measure the impact to improve the drug use practices. Drug utilization patterns of therapeutic agents in T2DM management and CVS drugs in diabetic population can also be served as documented ready reference to know the commonly used drugs with the corresponding frequencies, prescribed by generic and brand names with prescriber feedback and rationality in prescribing.

MATERIALS AND METHODS

A cross-sectional study was undertaken in a non-profit making governmental tertiary care hospital of urban south India. It is an 890 bedded health centre with super specialty blocks for paediatrics, plastic surgery, urology and neurology. Survey of 250 cases of T2DM management consisting of inpatients and outpatients (visiting every third Saturday) was accomplished over a period of 12 weeks (from November, 2012 to January, 2013). Once the consultation was over with the physician, patients were interviewed by the researchers based on the study objectives after receiving their verbal consents to determine the demographics of patient's details like age, sex, family history and educational status concerning the age- and sex-related prevalence of T2DM and its comorbidity with CVS diseases in diabetic population and therapeutic drug utilization data like name of drugs, doses, methods of administration and diagnostic observations. The details were enrolled and documented in the structured patient's profile form. Prescriptions were copied and evaluated as per the World Health Organization (WHO) guidelines to determine the CDUIs.

Prescribing indicators, CDUIs:
Average number of drug products per encounter was calculated by dividing the total number of drug products prescribed, by the number of encounters surveyed. Average number of each of therapeutic agents in T2DM management and CVS diseases was also separately designed. Percentage of encounters with an antibiotic was calculated by dividing the number of encounters prescribed an antibiotic by the total number of encounters, multiplied by 100. Percentage of drugs prescribed by generic name was calculated by dividing the number of drugs prescribed by generic name by the total number of drugs prescribed, multiplied by 100. Likewise, percentage of encounters with an injection was also calculated. Percentage of each of agents in T2DM management and CVS drugs prescribed from Essential Drug List (EDL) was calculated by dividing the number of products prescribed which are listed on the EDL by the total number of products prescribed, multiplied by 100.

Patient care indicators:
Average consultation time was calculated by dividing the total time for a series of consultations, by the number of consultations. Average dispensing time was calculated by dividing the total time for dispensing drugs to a series of patients, by the number of encounters. Percentage of drugs actually dispensed was calculated by dividing the number of drugs actually dispensed at the health facility by the total number of drugs prescribed, multiplied by 100. Percentage of drugs adequately labeled was calculated by dividing the number of drug packages containing at least patient name, drug name and when the drug should be taken, by the total number of drug packages dispensed, multiplied by 100. Percentage of patients having the knowledge of correct dosage was calculated by dividing the number of patients who can adequately report the dosage schedule for all drugs, by the total number of patients interviewed, multiplied by 100.

Health facility indicators:
Availability of copy of EDL was shown whether yes or no per facility. Percentage of key drugs available for each of agents in T2DM management and CVS diseases was calculated by dividing the number of specified products actually in stock by the total number of drugs on the checklist, multiplied by 100.

Complementary indicators:
Percentage of patients without drugs was calculated by dividing the number of consultations in which no drug was prescribed by the number of consultations surveyed. Average drug cost per encounter was calculated by dividing the total cost of all drugs prescribed by the number of encounters surveyed. Percentage of drug cost spent on injection was calculated by dividing the cost for all injections, by the total drug costs, multiplied by 100.

Drug utilization patterns on the basis of generalized classes and individual drug by generic and brand name or combination of drugs prescribed under different brands by generic and brand name were determined separately for the therapeutic agents in T2DM management and CVS drugs prescribed for the diabetics with macrovascular and microvascular diseases. Data collected in the present study were statistically analysed and represented. Results concerning average value are expressed as mean±SD (min-max) and categorical measurements as number (%). The software for statistical calculation namely GraphPad InsTat3 was used for analysis of data indicated in the tables.

RESULTS

Demographics of study population:
Total number of diabetics treated solely with agents for the management of T2DM was 93, while concomitant therapy of CVS drugs was observed for 157 among 250 encounters. Literally, the prevalence of CVS diseases in diabetic population was 62.80%. Males were 44.80% (n=112) and females were 55.20% (n=138) in the diabetic population. The highest prevalence of T2DM of 33.60% [n=84 (male, 34 and female, 50)] was observed in the age group of 51-60 years. Among the diabetics with CVS diseases, male were 35.03% (n=55) and females were 64.97% (n=102). The highest prevalence of CVS diseases of 38.22% [n=60, male, 16 and female, 44] was observed in the age group of 51-60 years (Table 1).

Core drug use indicators:
Average numbers (mean±SD) of total drug products, agents in T2DM management and CVS drugs were 6.06±2.20, 1.52±0.72 and 2.01±1.22, respectively. The encounters prescribed antibiotics were 59.26%.

TABLE 1: PATIENTS' DEMOGRAPHICS CONCERNING THE DIABETIC POPULATION AND DIABETICS WITH CVS DISEASES

The diabetic population			
Age in years	Male *n* (%)	Female *n* (%)	Pooled *n* (%)
>70	7 (6.25)	2 (1.45)	9 (3.60)
61-70	32 (28.57)	21 (15.22)	53 (21.20)
51-60	34 (30.36)	50 (36.23)	84 (33.60)
41-50	23 (20.54)	49 (35.51)	72 (28.80)
31-40	12 (10.71)	13 (9.42)	25 (10.00)
21-30	4 (3.57)	3 (2.17)	7 (2.80)
Total	112 (100)	138 (100)	250 (100)
The diabetics with CVS diseases			
>70	4 (7.27)	Nil	4 (2.55)
61-70	17 (30.91)	15 (14.71)	32 (20.38)
51-60	16 (29.09)	44 (43.14)	60 (38.22)
41-50	12 (21.82)	33 (32.35)	45 (28.66)
31-40	6 (10.91)	9 (8.82)	15 (9.55)
21-30	Nil	1 (0.98)	1 (0.64)
Total	55 (100)	102 (100)	157 (100)

CVS: Cardiovascular

Total drug products, agents in T2DM management and CVS drugs prescribed by generic name were 41.41, 41.76 and 71.09%, respectively. Injectables prescribed as whole, injectables in T2DM management and CVS injectables were 71.76, 59.62 and 23.49%, respectively. Agents in T2DM management and CVS diseases prescribed from the EDL were 90.57 and 91.94%, respectively. Average consultation and dispensing time were found to be 17.60 and 18.50 min, respectively. Drugs actually dispensed and adequately labeled were found to be 100%. The patients having the knowledge of correct dosage were found to be 81.26%. Availability of key drugs listed on the readily available copy of EDL at the health facility was 100%. No patient was treated without drugs, but an average drug cost was found to be Indian Rupees 145.54 per prescription. Drug cost spent on injections was 85.00% (Table 2).

Drug utilization pattern:

Prescription pattern of agents for the management of T2DM under different generalized classes was determined to represent the total number of diabetics prescribed, % of drugs in each prescription and drugs among agents in T2DM management for each class (Table 3). Total numbers of diabetics treated solely with oral hypoglycemics and antidiabetic injectables were 75 and 172, respectively, while combinations were prescribed to 29 among 250 encounters. Oral hypoglycemics, antidiabetic injectables and injectables prescribed for diabetic hypoglycemia (25% dextrose) were 40.38, 52.75 and 6.87%, respectively. Among the oral hypoglycemics prescribed, biguanides were the highest (24.92%) followed by sulfonylureas (17.03%) and thiazolidinediones (1.83%). Among the antidiabetic injectables prescribed, short-acting insulin- Actrapid® was the highest (35.43%) followed by intermediate-acting insulin- Mixtard® 30/70 (14.70%) and short-acting insulin- Humulin (2.62%). Noteworthy, the average of drugs from three major classes such as oral hypoglycemics, intidiabetic injectables and injectables prescribed in diabetic hypoglycemia was 23.48% which in turn indicated the average of drugs prescribed other than those for the management of T2DM was 76.52% in each prescription.

Furthermore, the utilization pattern of individual drug by generic and brand names and combination of drugs prescribed under different brands for the management of T2DM was shown to represent the % of drugs among the agents in T2DM management and diabetics prescribed for each individual or combination drug therapy (Table 4). Among the agents in the management of T2DM, Actrapid® was the highest (35.43%) prescribed to the highest frequency of diabetics (54.00%).

Similarly in the 157 concomitant drug therapies, class wise prescription pattern of CVS drugs was calculated to indicate the total number of diabetics prescribed, % of drugs in each prescription and drugs among CVS agents by oral administration and injection under each class of drugs (Table 5). Among the CVS agents, collective % of drugs (oral administration and injection) was the highest for the class diuretics [27.93%; lasix (19.37%), mannitol (7.30%), aldactone and furosemide (0.63%)]. Moreover, each CVS drug prescribed by generic and brand name was calculated to indicate the % of drugs among CVS agents and encounters among diabetics with CVS diseases (Table 6). Among the diabetics with CVS diseases, % of encounters received lasix (38.85%) was the highest.

DISCUSSION

The first and second highest age groups of diabetic prevalence in this study were 51-60 and 41-50 years, respectively which correlate well with the same of

TABLE 2: DETAILS OF CORE DRUG USE INDICATORS

	Data		
	Different drug products	Agents in T2DM management	CVS agents
Prescribing indicators			
Average drugs prescribed (mean±SD)	6.06±2.20	1.52±0.72	2.01±1.22
Antibiotics (%)	59.26	-	-
Generics (%)	41.41	41.76	71.09
Injections (%)	71.76	59.62	23.49
On EDL	-	90.57	91.94
Patient care indicators			
Average consultation time (min)	17.60		
Average dispensing time (min)	18.50		
Drugs actually dispensed (%)	100		
Drugs adequately labeled (%)	100		
Knowledge of correct dosage (%)	81.26		
Health facility indicators			
Availability of EDL	Yes		
Key drugs available (%)		100	100
Complementary indicators			
Without drugs		No prescription	
Average drug cost (Rs. per prescription)		145.54	
Drug costs on injections (%)		85.00	

SD: Standard deviation, T2DM: type 2 diabetes mellitus, EDL: essential drug list, CVS: cardiovascular

TABLE 3: PRESCRIPTION PATTERN OF AGENTS IN T2DM MANAGEMENT FROM DIFFERENT GENERALIZING CLASSES

Class	Total number of diabetics prescribed	Percentage of drugs in each prescription	Percentage of drugs among agents in T2DM management
Oral hypoglycemics	104	35.97	40.38
Biguanides	95	24.37	24.92
Sulfonylureas	65	23.08	17.03
Thiazolidinediones	7	18.75	1.83
Antidiabetic injectables	201	19.34	52.73
Short-acting insulin (actrapid®)	135	20.17	35.43
Intermediate-acting insulin (mixtard® 30/70)	56	16.05	14.70
Short-acting insulin (humulin)	10	12.86	2.62
25% dextrose (in diabetic hypoglycemia)	26	15.15	6.87

T2DM: Type 2 diabetes mellitus

TABLE 4: SINGLE AND COMBINATION OF AGENTS IN T2DM MANAGEMENT PRESCRIBED BY GENERIC AND BRAND NAMES

Single and combination of agents in T2DM management (generic and brand-name drugs)	Percentage of drugs among agents in T2DM	Percentage of diabetics prescribed
Metformin	22.31	34.00
Innomet SR (metformin)	0.52	0.80
Glibenclamide	9.71	14.80
Daonil (glibenclamide)	1.05	1.60
Glucored forte (glibenclamide + metformin)	0.26	0.40
Glimepiride	1.57	2.40
Blisto (glimepiride)	0.52	0.80
Gepride (glimepiride)	1.05	1.60
Glypride (glimepiride)	0.26	0.40
Euglim-M (glimepiride + metformin)	0.26	0.40
Blisto 1 MF (glimepiride + metformin)	0.26	0.40
Trigem (glimepiride + metformin + pioglitazone)	1.31	2.00
Gliclazide	0.26	0.40
Tolbutamide	0.52	0.80
Pioglitazone	0.52	0.80
Actrapid®	35.43	54.00
Mixtard® 30/70	14.70	22.40
Humulin	2.62	4.00
25% dextrose	6.87	10.40

T2DM: Type 2 diabetes mellitus

a global statistical report of working age, between 40 and 60 years in the countries of the developing world[12]. The finding of 62.80% prevalence of CVS diseases in the diabetic population ascertained in the present study could provide an evidence-based rationale for the WHO guidelines for management of hypertension, an element of CVS diseases in patients with T2DM[2]. Among the oral hypoglycemics, 22.83% utilization of metformin was found to be the highest including its generic and brand name drugs. Hence it could be the rationale for the guidelines of different official publications and monographs as the first drug of choice for the treatment of T2DM[13-15]. This study revealed the 1.23-fold greater prevalence of T2DM in female than male and such evidence-based observation

TABLE 5: CLASS WISE PATTERN OF DRUGS PRESCRIBED FOR DIABETICS WITH CVS DISEASES

Class (collective percentage of drugs among CVS agents)	Method of administration	Diabetics prescribed CVS drugs	Percentage of drugs in each prescription	Percentage of drugs among CVS agents
Diuretics (27.93)	O.A.	22	13.98	6.66
	Injection	66	13.95	21.27
Antithrombotic agents (18.09)	O.A.	56	17.01	17.77
	Injection (heparin)	1	14.28	0.32
Calcium channel blockers (13.65)	O.A.	43	16.23	13.65
	Injection	N.D.P	N.D.P	N.D.P
HMG-CoA reductase inhibitors (12.70)	O.A.	40	13.77	12.70
	Injection	N.D.P	N.D.P	N.D.P
ACE inhibitors (7.62)	O.A.	40	13.77	7.62
	Injection	N.D.P.	N.D.P.	N.D.P.
Coronary vasodilators (6.34)	O.A.	18	12.71	5.71
	Injection	2	15.38	0.63
β-blockers (5.71)	O.A.	18	16.13	5.71
	Injection	N.D.P.	N.D.P.	N.D.P.
Angiotensin II antagonist (4.44)	O.A.	14	20.34	4.44
	Injection	N.D.P.	N.D.P.	N.D.P.
In heart failure (2.86)	O.A. (digoxin)	5	15.12	1.59
	Injection (dopamine)	4	16.67	1.27
α-blockers (0.63)	O.A.	2	13.33	0.63
	Injection	N.D.P.	N.D.P.	N.D.P.

O.A.: Oral administration, N.D.P.: no drugs prescribed, HMG-CoA: 3-hydroxy-3-methylglutaryl coenzyme A, CVS: cardiovascular, ACE: angiotensin-converting enzyme

TABLE 6: CVS DRUGS PRESCRIBED BY GENERIC AND BRAND NAMES

CVS agents (generic and brand-name drugs)	Percentage of drugs among CVS agents	Percentage of encounters among diabetics with CVS diseases
Furosemide	0.63	1.27
Lasix (furosemide)	19.37	38.85
Mannitol	7.30	14.65
Aldactone (spiranolactone)	0.63	1.27
Aspirin	13.33	26.57
Clopidogrel	4.44	8.92
Heparin	0.32	0.64
Amlodipine	13.33	26.75
Nifedipine	0.32	0.64
Atorvastatin	12.38	24.84
Tonact (atorvastatin)	0.32	0.64
Enalapril	6.03	12.10
Enam (enalapril)	1.59	3.18
Isosorbide dinitrite	1.27	2.55
Sorbitrate (isosorbide dinitrite)	4.44	8.92
NTG (nitroglycerin)	0.63	1.27
Atenolol	2.85	5.73
Aten (atenolol)	1.27	2.55
Metoprolol	1.59	3.18
Losartan	4.44	8.92
Digoxin	1.59	3.18
Dopamine	1.27	2.55
Prazopress (prazosin)	0.63	1.27

CVS: Cardiovascular

agrees well with that of different multicentre studies in developing nations[16,17]. Furthermore, female with greater rate of increased glucose tolerance in an epidemiological study in Kashmir also supports the sex-related diabetic prevalence of the present study[18]. However, the rate is slightly lower for diabetic female than male in developed nation like USA[19]. Concomitant drug therapy also revealed the 1.85-fold higher prevalence of CVS diseases in female than male. Highest prevalence of T2DM and CVS diseases in the diabetic population was observed in the age group of 51-60 years. Moreover, the average of drugs prescribed except those for the management of T2DM was greater than 75% in each prescription which sequentially signifies the extent of drugs for the treatment of cardiovascular diseases, retinopathy, nephropathy, obstructive pulmonary diseases, diabetic foot, inflammations and infections associated as a rationale for commonly occurring comorbidities of secondary and tertiary illness. Consequently, the incidence of polypharmacy [average drugs prescribed (mean±SD): 6.06±2.20] was higher. Percentage of each of agents in T2DM management and CVS diseases prescribed from the EDL was more than 90 and thereby indicated the drug use in this set-up quite rational. Though the oral drugs prescribed for the management of T2DM were 40.38%, but those for CVS drugs were 76.48%. This literally indicated the good prescription habit indicating the improved patients' adherence to the treatment. Though, total drug products and agents in T2DM management

prescribed by generic name were 41.41 and 41.76%, respectively, but those for CVS drugs were 71.09% which revealed the cost effective medical care achieved through the prescribing practices.

The present survey indicates the burden of type 2 diabetes and its comorbidity with cardiovascular diseases in India as existing in the countries of the developing world. It emphasizes the pressing need of early detection of hypertension as a preliminary diagnostic parameter of CVS diseases in diabetics, proper attention to be paid to other coexisting CVS risk factors such as obesity, dyslipidaemia and appropriate management of these conditions to be instituted through concomitant therapy of CVS drugs to minimize the risks of death. The findings of the study will definitely have far-reaching implications for diabetes care in the country.

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