THERAPEUTIC MANAGEMENT OF HYPERTENSION AND HYPERLIPIDEMIA IN TYPE-2 DIABETES MELLITUS PATIENTS IN SOUTHWESTERN REGION OF SAUDI ARABIA: A PHARMACIST PERSPECTIVE

NOOHU ABDULLA KHAN[1]*, VENKATACHALAM VV[2], KHALED M AL-AKHALI[1] SIRAJUDEEN S ALAVUDEEN[1], DHANAPAL CK[2], SHAIK MOHAMMAD ASIF ANSARI[1]

[1]Department of Clinical Pharmacy, King Khalid University, Abha, Kingdom of Saudi Arabia. [2]Department of Pharmacy, Annamalai University, Annamali Nagar, Chidambaram, Tamil Nadu, India. Email: shanoohu@yahoo.co.in

ABSTRACT

Objective: The main objective of this study was to evaluate the therapeutic management of hypertension (HTN) and hyperlipidemia in Type 2 diabetes mellitus (T2DM) patients in Aseer Diabetic Center, southwestern region of Saudi Arabia.

Methods: This is a cross-sectional retrospective study in adult T2DM patients. A total number of 343 patient's records was randomly selected from the patient medical records section. Among the 343 T2DM patients, all were hyperlipidemics, and only 228 patients were Hypertensive. The collected raw data were recorded and statistically analyzed with Windows Microsoft Excel 2007. Descriptive statistics of mean, standard deviation, and frequencies were performed on the sample, one-way ANOVA was used to analyze the continuous data by using Graphpad software version-5; p≤0.05 was considered statistically significant.

Result: The systolic blood pressure (BP) was found to have statistically significant difference (p≤0.0320) after treatment, but there is no statistical difference in diastolic BP. Glycemic control was found to have statistically significant difference (p≤0.0039). Most of the patients were treated with captopril −25 mg (angiotensin-converting enzyme inhibitor class drug). All the lipid profile high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, and total cholesterol showed statistically significant difference after treatment except triglycerides. Most of the patients were prescribed with statins for hyperlipidemia.

Conclusion: In this study, systolic HTN is better controlled with statistically significant difference compared to diastolic HTN. In the current study, lipid control was better than glycemic control. Updating of the drug formulary to have new therapeutic agents can improve the current status.

Keywords: Hyperlipidemia, Hypertension, Saudi Arabia Southwestern region, Therapeutic management, Type 2 diabetes.

INTRODUCTION

According to International Diabetes Federation, the prevalence estimates of diabetes Type 2 in Saudi Arabia year 2007 was the highest (~20%) compared to other countries and it is expected to increase by the year 2025 [1]. The explosive increase in the prevalence of diabetes and the consequences of its complications are challenge facing the world today [2]. Type 2 diabetes mellitus (T2DM) and hypertension (HTN) frequently coexist, and patients with this combination are at a higher risk for cardiovascular events [3]. Strict blood pressure (BP) control in this population, as advised by The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High BP and American Diabetes Association, with a target BP lower than 130/80 mmHg is difficult to obtain, therefore, multiple medications are often required [4-6]. United Kingdom Prospective Diabetes Study (UKPDS) concluded that tight BP control in patients with T2DM and HTN is able to reduce micro and macrovascular diabetic complications [7].

The evaluation of drug use in given health care against predetermined criteria and standards is crucial to assess the appropriateness of drug therapy. Moreover, these studies create a sound socio-medical and health economic basis for healthcare decision making [8]. According to World Health Organization, drug utilization studies serve as an important marker to measure the clinical and inappropriate drug use over the time and as a control tool in health facilities as well as to measure the effect of a therapeutic intervention [9]. Several problems in drug use patterns have been reported worldwide [10].

Glycosylated hemoglobin (HbA1c) is the test most widely used for assessment of blood glucose control. The current target level is approximately 7% with consideration of individualized care [11]. Standard diabetes care recommends drug therapy for control of BP, dyslipidemia, and assessment for the need for anti-platelets therapy [11-15]. HTN affects 60% of the population with T2DM. The high prevalence of undiagnosed nephropathy may still favor recommendations for the use of inhibitors of the renin-angiotensin system as first-line HTN therapy in people with diabetes [13]. Dyslipidemia is highly prevalent among the diabetic population [15]. Low-density lipoproteins (LDL) cholesterol-targeted statin therapy remains the preferred strategy for this condition [16]. Anti-platelet therapy for patients with previous cardiovascular disease (CVD) is highly recommended for secondary prevention. The current recommendation for primary prevention of CVD has been changed to be selective to women above 60 years of age with one additional risk factor [11,17].

Abnormal lipid metabolism, presented as hypercholesterolemia and hypertriglyceridemia, is a common finding among the diabetics [18], and it is considered a risk factor for premature atherosclerosis [19]. Increased oxidizability of LDL is believed to be partly responsible for the diabetic-related dyslipidemia [20]. The main objective of this study was to evaluate the therapeutic management of HTN and hyperlipidemia in T2DM patients in Aseer diabetic center (DC), southwestern region of Saudi Arabia.

METHODS

This is a cross-sectional retrospective study of patients which included all adult T2DM patients who were registered in the Aseer DC, Abha,

Aseer Region, and Kingdom of Saudi Arabia. This study was conducted from December 2012 to December 2013. A total number of 343 patient's records was randomly selected from the patient medical records section. Patients of T2DM of age group from 18 years to 80 years of either sex were included in the study. Medical record of the patients who fulfilled the criteria was reviewed, and the data were entered in the specifically designed data collection form. Data obtained from the patient records included: Age, duration of DM, body mass index, type of treatment for HTN, hyperlipedidemia. The HbA1c value, triglycerides (TGL), total cholesterol (TCL), LDL, and high-density lipoprotein (HDL) were considered as primary outcome measure. Current guidelines for glycemic control recommend HbA1c values <7% as a treatment goal for most DM patients. Controlled BP lower than 130/80 mm Hg [5], HDL cholesterol >40 mg/dl, TGL <150 mg/dl, LDL cholesterol <100 mg/dl, and TCL <200 mg/dl were considered normal lipid profile [21]. The whole study period was divided into four visits, each visit comprised of 3 calendar months. The visit 1 and visit 4 data were considered in this study to measure the status of the glycemic control and co-morbid disease of the patients starting of the study period (visit 1) and during the end of the study period (visit 4). Gestational DM, T1DM and patients <18 years, and more than 80 years were excluded from the study. Among the 343 T2DM patients, all were hyperlipidemics, and only 228 patients were hypertensive. 343 hyperlipidemics patients and 228 Hypertensive patient's data were analyzed for this study. The collected raw data were recorded and statistically analyzed with Windows Microsoft Excel 2007. Descriptive statistics of mean, standard deviation (SD), and frequencies were performed on the sample, one-way ANOVA was used to analyze the continuous data using Graph pad software version-5 (Graph pad software, Inc., USA); $p \leq 0.05$ was considered statistically significant. This study was formally approved by the University Research Ethics Committee (Approval number: REC#2013-05-05).

RESULTS

Among the total 343 patients, 96 patients were diagnosed with HTN during the visit 1 and 132 patients were with HTN during the visit 4. Among the 96 patients, 56 patients were male, and 40 patients were female, whereas 89 patients were male, and 43 patients were female in the visit 4 (Table 1). Male patients higher in number compared to female. The average age of patients was found to be 62.23±9.68 years, and the duration of DM was found to be 17.58±8.68 years. Majority of the male patients and female patients were in the age group above 60 years.

BP management among the HTN patients is represented in Table 2. The average systolic BP during the first visit was found to be 134.20±15.61 mmHg and 131.30±12.69 mm/Hg in the fourth visit. The diastolic BP was found to be 80.80±9.06 mm/Hg in first visit and 78.66±8.14 mmHg in the fourth visit. The systolic BP was found

to have statistically significant difference ($p \leq 0.0320$) but there is no statistical difference in diastolic BP. Glycemic control HbA1c was found to be 9.52±2.06 % in the first visit and 8.99±1.70% in the fourth visit. Glycemic control was found to have statistically significant difference ($p \leq 0.0039$) in the two major two visits and the fasting blood sugar was found to be 179.75±60.81 mg/dl and 168.8±56.24 mg/dl in the visit 4 which shows statistically significant difference ($p \leq 0.0071$).

The prescribing pattern of antihypertensive drugs in T2DM, HTN patients is represented in Table 3. Most of the patients were treated with captopril - 25 mg an angiotensin-converting enzyme (ACE) inhibitor class drug. About 80.21% of patients were prescribed with captopril then it was followed by a combination of ACE Inhibitors and β blocker (captopril + atenolol) 10.42% and β blocker (atenolol) alone in 9.37% patients in first visit. Even in the fourth visit, the ACE inhibitor classification drug captopril was prescribed in large number and about 53.79% of patients were treated by this drug and followed by lisinopril - 10 mg which was about 15.91%, this drug was prescribed in patients during the first visit. There is raise in β blocker usage in the fourth visit compared to first visit. β blocker is followed by thiazide diuretic (6.06%). combinations of ACE inhibitor+ β blocker (6.06%) and ACE inhibitor + loop diuretic (4.55%) were mostly used. ACE inhibitor+ β blocker (bisoprolol) combination was less (2.27%) used in this group of patients. The other micro and macrovascular complication therapy data were not available in the DC file and the details are available only in the Aseer Central Hospital medical record (main file) and in electronic database i.e., health information system. The authors do not have access to the electronic medical record database so the other cardiovascular complication therapy cannot be represented and analyzed in this study.

The demographic characters of the patients of T2DM with dyslipidemia are represented in Table 4. Among the total 343 patients, 213 were male and 130 were females, average age was found to be 60.45±10.15 years and the average duration of DM was found to be 15.96±7.71 years. Abnormal lipid profile was found in both sexes. Elevated TG was found to be in 105 men and 68 women from, elevated LDL levels were found to be in 97 men and 69 women, reduced HDL level were found to be in 156 men and 119 women from the total study population.

The hyperlipidemia data mean ± SD are represented in the Table 5. TCL was found to be 190±53.68 mg/dl in visit 1 and 175.7±43.27 mg/dl in visit 4 which shows statistically difference ($p \leq 0.0001$) between the two visits. TGL was found to be 186.7±113.8 mg/dl in visit 1 and 172.5±91.22 mg/dl in visit 4 which does not have any statistically significant difference ($p \leq 0.0721$) between the two visits. LDL was found to be 172.5±91.22 mg/dl in visit 1 and 104.94±34.60 mg/dl in visit 4, which shows statistically difference ($p \leq 0.0001$) between the

Table 1: The demographic characters of T2DM patients with HTN

Parameter/variables/ characteristics	Visit 1		Visit 4	
	N	%	N	%
N	96 (27.99%)	100	132 (38.48%)	100
Male	56	58.33	89	67.42
Female	40	41.67	43	32.58
BMI	30.21±6.01 kg/m²		31.13±6.81 kg/m²	
Duration of DM in years (mean±SD)	17.58±8.68			
Age in years (mean±SD)	62.23±9.68			

Age distribution	Visit 1		Visit 4	
	Males	Females	Males	Females
<40 years	1	1	1	1
40-50 years	4	3	12	3
51-60 years	12	17	22	18
>60 years	39	19	54	21
Total	56	40	89	43

SD: Standard deviation, DM: Diabetes mellitus, BMI: Body mass index, T2DM: Type 2 diabetes mellitus

two visits. HDL was found to be low in all the men and women which is an alarming sign for the DC to start proper therapeutic regimen in the study population. The Mean and SD value for HDL was found to be 39.92±9.59 mg/dl in visit 1 and 38.31±10.28 mg/dl in visit 4 which shows statistically difference (p≤0.0340) between the two visits. There is a statistically difference (p≤0.0009) between the two visits in very LDL also.

Lifestyle modification and drug therapy are the mainstay in the hyperlipidemia therapy for T2DM patients. Therapeutic management for dyslipidemia is represented in the Table 6. Statins (3-hydroxy-3-methylglutaryl-coenzyme reductase inhibitor) such as simvastatin-10 mg and 20 mg and rosuvastatin-10 mg were prescribed for most of the patients. Among the 213 male patients, 155 patients were prescribed for antihyperlipidemic agents. Among the 155 patients, 132 were prescribed with simvastatin and 23 were prescribed with rosuvastatin. Among the 130 female patients, 100 patients were prescribed for antihyperlipidemic agents. Among the 100 patients, 83 patients were prescribed with simvastatin and 17 were prescribed with rosuvastatin. Antiplatelet aggregator, aspirin - 81 mg an adjuvant therapy in hyperlipidemic patients to avoid platelet aggregation in the vascular system was prescribed only to 160 men and 101 women.

DISCUSSION

Achieving targeted glycemic control (HbA1c <7%) is a challenging task for the health care providers. DM communities participation and cooperation with health care providers and comply with the therapeutic plan or management is an important factor in the treatment of T2DM. Patient compliance will do better glycemic control.

In this current study, the various parameters of national T2DM prevalence rate in Kingdom was reflected, such as age and glycemic control (HbA1c <7%). Al-Nozha et al. in 2004 [22] represented in their study that the average age in T2DM in the Kingdom was found to be 30-70 years, men with T2DM are higher in number compared to women with T2DM this current study is consistent with that report. After a successful initial response to oral therapy, patients fail to maintain target HbA1c levels <7% at a rate of 5-10% per year, a report in United Kingdom by UKPDS [23-25] which is consistent with this current study.

More than one-third of the patients in the present study were not adequately controlled and this represents a serious problem because diabetes is a very prevalent disease (23.7%) [22] in the Saudi community. The poor control of the disease has shown an increasing prevalence of diabetic complications and high morbidity and mortality.

Studies by Alwakeel et al. in 2008 and Akbar in 2001 [26,27] found that HTN to be present in 78% and 60%, respectively, among diabetic patients, which is consistent with this current study (66.47%). Systolic HTN is better controlled with statistically significant difference compared to diastolic HTN in this study which is a good sign for the T2DM community compared to other study done by Vijan and Hayward in 2003 [28]. An ACE inhibitor or an angiotensin receptor blocker is a potential first-line therapy in all people with HTN and diabetes, in the current study prescribing pattern for HTN had the same pattern as represented by Campbell, et al. in 2011 [29] a study from Canada. According to most of the guidelines ACE inhibitor therapy, should be an integral component of any antihypertensive regime in patients with diabetes. These agents have demonstrated a significant role in reducing coronary vascular disease and renal disease a statement by Supratim datta and Udupa in 2010 [30], and this has been reflected in our study.

Table 4: The demographic characters of patients with hyperlipidaemia

Parameter/variables/characteristics	N (%)	
N	343 (100)	
Male	213 (62.10)	
Female	130 (37.90)	
Age in years (mean±SD)	60.45±10.15	
Duration of DM in years (mean±SD)	15.96±7.71	
	Male n (%)	**Female n (%)**
Abnormal lipid profile[22]		
Elevated TG (≥150 mg/dl)	105 (49.29)	68 (52.31)
Elevated LDL (≥100 mg/dl)	97 (45.54)	69 (53.01)
Reduced HDL (<40 mg/dl in men and <50 mg mg/dl for women)	156 (73.23)	119 (91.54)

DM: Diabetes mellitus, SD: Standard deviation

Table 5: The hyperlipidemia target achieved in T2DM patients in two major visits

Lipid profile (mean±SD)	Visit 1	Visit 4	p value
TCL mg/dl	190±53.68	175.7±43.27	0.0001*
TGL mg/dl	186.7±113.8	172.5±91.22	0.0721
LDL mg/dl	172.5±91.22	104.94±34.60	0.0001*
HDL mg/dl	39.92±9.59	38.31±10.28	0.0340*
VLDL mg/dl	31.67±14.8	28.96±12.7	0.0009*

*Statistically significant (p<0.05 was considered as significant), VLDL: Very low density lipoprotein, HDL: High-density lipoprotein, LDL: Low density lipoprotein, TGL: Triglycerides, TCL: Total cholesterol, SD: Standard deviation

Table 2: The glycemic control and BP management in hypertensive T2DM patients in two major visits

BP	Visit 1	Visit 4	p value
BP systolic (mean±SD) mm/Hg	134.20±15.61	131.30±12.69	0.0320*
BP diastolic (mean±SD) mm/Hg	80.80±9.06	78.66±8.14	0.0705
HbA1c %	9.52±2.06	8.99±1.70	0.0039*
FBS mg/dl	179.75±60.81	168.8±56.24	0.0071*

*Statistically significant, BP: Blood pressure, HbAlc: Glycosylated hemoglobin, T2DM: Type 2 diabetes mellitus, SD: Standard deviation, FBS: Fasting blood sugar

Table 3: The HTN therapeutic management in T2DM patients

Sl. no	Drug classification/ combination	Drug name/drug combination name	No (%)	
			Visit 1 (n=96)	**Visit 4 (n=132)**
1	ACE inhibitors	Captopril - 25 mg	77 (80.21)	71 (53.79)
		Lisinopril - 10 mg	-	21 (15.91)
2	ACE inhibitor+β blocker	Captopril+atenolol-50 mg	10 (10.42)	8 (6.06)
	ACE inhibitor+β blocker	Captopril - 25 mg+bisoprolol - 10 mg	-	3 (2.27)
3	β blocker	Atenolol - 50 mg	9 (9.37)	15 (11.36)
4	ACE inhibitor+Loop diuretic	Furosemide - 40 mg	-	6 (4.55)
5	Thiazide diuretic	Hydrochlorthiazide - 25 mg	-	8
	Total		96 (100)	132 (100)

ACE: Angiotensin-converting enzyme, DM: Diabetes mellitus

Table 6: Therapeutic management in hyperlipidemia patients with T2DM

Serial number	Drug classification/ combination	Drug name	Males	Females
1	Statins (HMG Co-A reductase inhibitor)	Simvstatin - 10 mg and 20 mg	132	83
		Rosuvastatin - 10 mg	23	17
2	Antiplatelet aggregator	Aspirin - 81 mg	160 (75.12% of total male patients)	101 (77.69% of total female patients)

T2DM: Type 2 diabetes mellitus, HMG Co-A: 3-hydroxy-3-methylglutaryl-coenzyme

In the current study, lipid control was somewhat better than glycemic control. TCL and LDL had statistically significant reduction compared to glycemic control which is consistent with other study conducted by Al-Rowais in 2013 [31]. T2DM is, usually, associated with low plasma levels of HDL [32] which has been seen in this current study too. Decrease in HDL also seen in T2DM patients, a study in Ghana done by Adinortey, et al. in 2011 which is consistent with this study [33]. And another study in Nigeria done by Bello-Sani et al. in 2011 is consistent with this current study [34]. The HDL fraction gives protection from atheroma formation and thus ischemic heart disease is prevented [35], but the current study T2DM patients have low rate of HDL which may give rise to macrovascular complication which is a serious issue in which the healthcare sector should concentrate.

DM has a profound impact on life expectancy. T2DM patient has other metabolic complication like hyperlipidemia has to properly treat with proper selection of lipid-lowering agent. In this current study, all the patients were treated with statins, fibrates (gemfibrozil) is the drug of choice in DM patients [36] was not prescribed, because either the drug is not available in the DC or the treating physicians are not having awareness about this drug. Further studies are required to confirm the low rate of glycemic, lipid control; this might be due to poor compliance from the patients or low awareness about the disease.

CONCLUSION

Many factors may account for poor glycemic control, the first and foremost is poor patient compliance with the treatment. In addition to these, others factors are lifestyle modifications. The increase in dyslipidemia according to duration of DM in T2DM is challenging to the health care team, dyslipidemia will have an alteration in vascular function integrity in T2DM population. In this study, systolic HTN is better controlled with statistically significant difference compared to diastolic HTN. In the current study, lipid control was better than glycemic control. According to Ramesh Adepu and Madhu in 2011, a study in Bulgaria in 2002, has shown a significant improvement in HbA1c after patient education programs [37], this strategy can also followed to improve the glycemic control and HTN. Updating of the drug formulary to have new therapeutic agents can improve the current status.

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