

Impact of Educational Intervention on Preventive Strategies for Cardiovascular Disease Risk Modification among Patients with Type II Diabetes Mellitus



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Abstract

Objective: The Type II Diabetes mellitus (DM) patients were stratified into CVD risk categories. The lifestyle and prescription pattern of DM patients was studied. Also, impact of educational intervention on preventive strategies for CVD risk modification was assessed.

Methods: The WHO Cardiovascular disease (CVD) risk prediction charts were used to categorize DM into various CVD risk categories and were imparted education intervention based on WHO Guidelines for Assessment and Management of CVD Risk.

Results: 67.5 % of DM had low, 15 % medium, 15 % high and 2.5 % had very high CVD risk. 100 % of DM patients with high CVD risk profile were on antihypertensive and antiplatelet drugs though only 50 % were on hypolipidemic agents. Educational intervention improved the knowledge regarding preventive strategies for CVD Risk modification {weight control ($p < 0.05$), glycemic control ($P < 0.01$), benefits of hypolipidemic agents ($p < 0.01$) and antiplatelet drug aspirin ($P < 0.001$) usage}.

Conclusion: 32.5 % Type 2 diabetic patients have medium to very high risk of developing a cardiovascular event. There is a scope to increase the prescription of hypolipidemic drugs for CVD risk modification. Educational intervention resulted in a significant increase in knowledge regarding preventive strategies for CVD Risk modification.

Keywords: Cardiovascular disease; Risk prediction charts; Diabetes mellitus; World health Organization

Abbreviations: CVD: Cardiovascular disease; DM: Type II Diabetes mellitus; WHO: World Health Organization; ICMR: Indian Council of Medical Research

Introduction

Cardiovascular disease (CVD) is the major cause of death in patients with type 2 diabetes mellitus (DM), as majority of DM patients' die of myocardial infarction (MI) or stroke, and an even greater proportion of patients have serious burdensome complications [1-3]. Recent large clinical trials, the Action in Diabetes and Vascular Disease (ADVANCE), Action to Control Cardiovascular Risk in Diabetes (ACCORD) reported no significant decrease in primary cardiovascular endpoints with solely intensive glucose control as besides blood glucose, other variables: age, gender, high blood pressure, smoking and dyslipidemia are the other major contributing risk factors for developing CVD. Thus, besides good glycemic control comprehensive risk factor management, including blood pressure control, lipid management,

weight reduction in overweight or obese individuals, and smoking cessation, are also needed [4-10].

Therefore, development of strategies for the control of CVD risk factors and primary prevention of cardiovascular complications in diabetes remains the most important clinical objective. To address this issue, various multivariable CVD risk prediction algorithms such as Framingham Risk score, UKPDS Risk Engine, WHO charts have been developed that can be used by primary care physicians to assess in individual patients the risk of developing of CVD [4]. Risk factor modification can reduce clinical events and premature death in people with established cardiovascular disease as well as in those who are at high cardiovascular risk due to one or more risk factors.

Several studies including WHO Guidelines for assessment and management of CVD risk have shown that besides anti-diabetic drugs: antihypertensive hypolipidemic, antiplatelet drugs are the pharmacological agents that can be prescribed for CVD risk modification based on the individuals CVD risk profile. Additionally, non-pharmacological recommendations focusing on diet, smoking cessation and regular physical activity will provide guidance on self-management strategies to DM patients (with risk factors who have not yet developed clinically manifest cardiovascular disease) to prevent adverse CVD outcomes in the future (primary prevention).

With this point of view the present study was designed. The primary objective was to use the WHO/ISH CVD risk prediction charts to categorize the DM patients as having very high, high, medium and low CVD risk. The WHO/ISH risk prediction charts indicate 10-year risk of a fatal or nonfatal major cardiovascular event (myocardial infarction or stroke), according to age, sex, blood pressure, smoking status, total blood cholesterol and presence or absence of diabetes mellitus.

The patient profile, cardiovascular risk factors and prescription pattern among diabetic patients of various CVD risk categories was determined. Results would provide baseline information based on which future intervention can be planned to mitigate CVD risk among diabetic patients by following the WHO Pharmacological and Non-Pharmacological recommendation for CVD risk modification.

Also, impact of educational intervention on preventive strategies for cardiovascular disease risk modification (Knowledge regarding Tobacco, Alcohol usage, Diet, Physical Activity, Weight control, Psychosocial factors, Multiple risk factor interventions) was assessed.

Materials and Methods

Necessary approval from the Institutional Ethics Committee was obtained before initiating the study.

- a) **Study design:** Prospective, Interventional
- b) **Study site:** Department of Pharmacology and Medicine, MGM Medical College, Kamothe, Navi Mumbai
- c) **Sample size:** Approximately 160 patients with type II Diabetes mellitus attending the Medicine OPD were enrolled in the study.
- d) **Study Population:** Type II diabetes mellitus patients who conformed to the specified Inclusion and Exclusion Criteria were enrolled for the study.
- e) **Inclusion criteria:**
Aged ≥ 18 years of age who were diagnosed with Type II DM
Patients on the Pharmacological agents for CVD risk modification for at least six months.

Patients who agree to sign the consent form

f) **Exclusion criteria:**

- Patients with Type 1 diabetes mellitus
 - Pregnant women, including those with gestational diabetes
 - People with established coronary heart disease (CHD), cerebrovascular disease (CeVD) and peripheral vascular disease
 - Patients who could not complete the questionnaire
- g) **Study Group:** Type II diabetic patients meeting the Inclusion and Exclusion criteria.

Case Record Form (CRF)

A CRF was prepared to record the following information on the Type II diabetes patient attending the medicine outdoor department.

- a. **Patient Profile:** Age, Gender, BMI and History of Smoking Intake was noted
- b. **Disease Profile:** Fasting and post prandial blood sugar values, duration of diabetes (5, 5-10, >10 years), Age of onset of diabetes (<50, 50-59, >60 years), presence of hypertension (BP recordings), presence of dyslipidemia (Lipid Profile (CH<180 mg/dl, HDL<45 mg/dl (Male), < 50 mg/dl (Female), LDL: >100 mg/dl and TG >150 mg/dl were recorded
- c. **Treatment Modality:** The various drugs (Anti-diabetic, Antihypertensive, Anti-platelet and Hypolipidemic agents) prescribed for cardiovascular disease modification were noted.
- d. **WHO Risk Prediction Chart for Assessment and Management of CVD Risk**

World Health Organization/International Society of Hypertension (WHO/ISH) risk prediction chart was used for the estimation of total cardiovascular risk of DM patients.

Study Procedure

The above-mentioned data and completed prescriptions were collected on predesigned case record form. All the diabetic patients attending the medicine outdoor department were screened and those eligible as per the inclusion and exclusion criteria were enrolled. Written informed consent was obtained from each patient. Subsequently the prescription details and the parameters mentioned on the CRF were filled up. The WHO Risk Prediction Chart for Assessment and Management of CVD Risk was used to stratify the patients into risk categories (Very high, high, medium and low). The patient's baseline knowledge on Preventive Strategies for CVD Risk modification was scored. Subsequently, the patients were counselled based on WHO CVD Risk Reduction Guidelines and thereafter re-administered the same questionnaire to assess the impact of structured counselling. The data was collected; analysed and appropriate statistics was applied to obtain meaningful information.

Data Analysis and Statistical Methods

Descriptive statistics was used to summarize patients' demographics and survey responses. Logistic regression models were used to assess the relationship between high CVD risk and potential influencing factors. P <0.05 was considered as statistically significant.

Results

Disposition summary of type II diabetic patients

One hundred sixty (160) diabetic patients who attended the medicine diabetic OPD received structured educational intervention for cardiovascular disease risk modification (Figure 1).

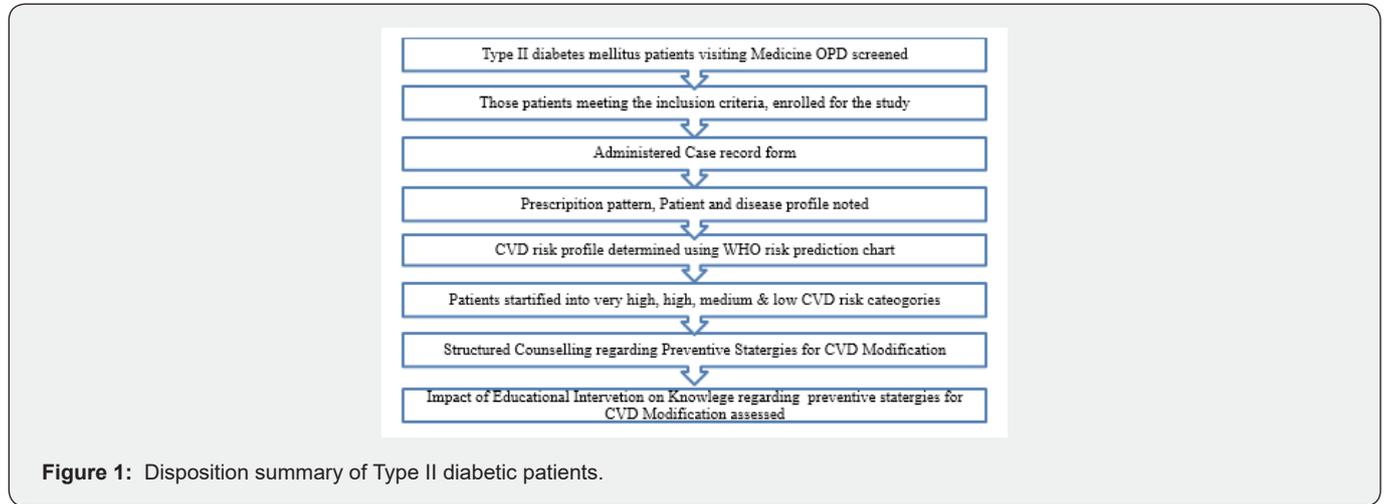


Figure 1: Disposition summary of Type II diabetic patients.

Patient profile of type II diabetic subjects

The age distribution of the Type II diabetic patients who were counselled for cardiovascular risk modification is depicted in

Table 1. Maximum (38.75 %) Type II diabetic patients were of the age group 50-59 years. Male/Female ratio was found to be 1.3. It was found that 16.3 % patients were obese (Table 1).

Table 1: Characteristics of type II diabetic patients enrolled for the study (N = 160).

S. No		N=160	Percentage (100%)
1	Age		
	<50	58	36.25%
	50-59	62	38.75%
	60-69	38	23.75%
	>70	2	1.25%
2	Gender		
	Male	90	56.25%
	Female	70	43.75%
3	BMI		
	Normal	92	57.50%
	Overweight	42	43.75%
	Obese	26	16.25%

Disease profile among type II diabetic subjects

Disease profile of the Type II diabetic patients who were counselled for cardiovascular risk modification is depicted in Table 2. Maximum (68.75 %) type 2 diabetic patients had diabetes for more than 7 years. Hypertension was encountered among 22.5 % patients and Dyslipidemia among 13.75 % patients. It was found that 52.5% patients had uncontrolled glycemic

control and 33 % had uncontrolled hypertension. Additional characteristics of these Type II diabetic subjects are presented in Table 2.

Cardiovascular risk stratification among Type II diabetic patients

Patients were stratified into cardiovascular risk categories. Out of the type 2 diabetic patients screened for CVD risk, 67.5 %

has low CVD risk (<10% scores), 15 % medium CVD risk (10 to 20 % scores), 15 % high CVD risk (20 to 30 % scores) and 2.5 % were categorized as having very high CVD risk (>30 % scores) (Figure 2).

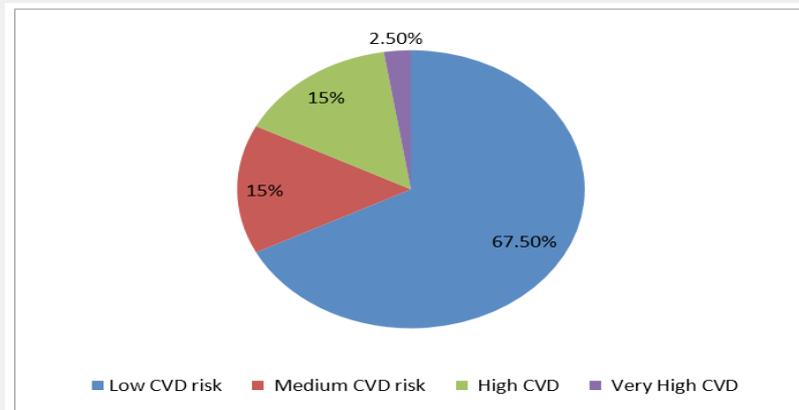


Figure 2: Cardiovascular Risk Stratification among Type II diabetic patients.

Patient profile based on CVD risk profile

Maximum patients with medium, high and very high CVD risk

belonged to the age group 60-69 years. The gender distribution and characteristics of the Type 2 diabetic patients of various risk categories is depicted in table 3.

Table 2: Patient profile of Type II diabetic patients enrolled for the study.

S.No		N	Percentage
Diabetes			
A	Duration of diabetes		
	>7 years	50	31.25%
	<7 years	110	68.75%
B	Glycemic Control		
	Controlled	76	47.50%
	Uncontrolled	84	52.50%
Hypertension			
A	Presence of Hypertension	36	22.50%
	Controlled	24	66.60%
	Uncontrolled	12	33.30%
B	Family History	82	51.25%
Dyslipidemia			
	Presence of Dyslipidemia	22	13.75%

Table 3: Patient Profile based on CVD Risk Profile.

S. No		Low CVD Risk N=108	Medium CVD Risk N (%) N=24	High CVD Risk N (%) N=24	Very High CVD Risk N (%) N=04
1	Age				
	<50	54 (50 %)	4 (16.6 %)	0	0
	50-59	54 (50 %)	6 (25 %)	2(8.3 %)	0
	60-69	0	14 (58.3 %)	20 (83.3%)	4 (100 %)
	>70	0	0	2 (8.3 %)	0
2	Gender				

	Male	40 (38.4 %)	24 (100 %)	18 (75 %)	4 (100%)
	Female	64 (61.6 %)	0	6 (25 %)	0
3	BMI				
	Obese	8 (7.74%)	6 (25 %)	8 (33.3 %)	4 (100 %)

Disease profile based on CVD risk profile

Duration of diabetes more than 7 years (long standing diabetes) was encountered in 75 % belonging to medium CVD risk, 53.3 % high CVD risk and 50 % of very high CVD risk. Poor

glycemic control was noted among 66.6 % belonging to medium CVD risk, 75 % high CVD risk and 100 % of very high CVD risk. Hypertension was encountered in 50 % and 100 % of the type 2 diabetic patients and dyslipidemia among 33.3 % and 100 % respectively with high and very high CVD risk (Figure 3).

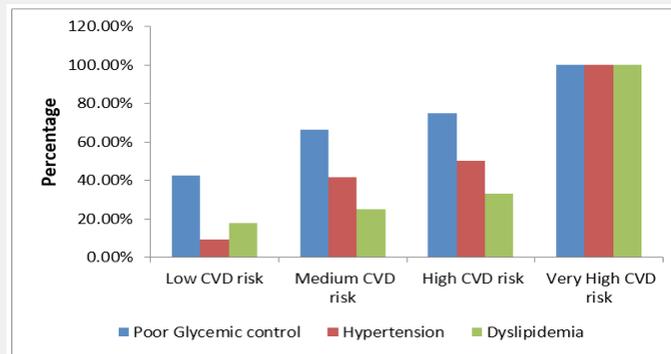


Figure 3: Risk factors present in patients based on CVD Risk Profile.

Drugs used for cardiovascular disease risk modification based on CVD Risk Profile

Antihypertensive drugs were prescribed among 41.6 % diabetic patients with medium CVD risk, 50 % with high CVD risk

and 100 % of very high CVD risk. Antiplatelet drug was prescribed among 100 % of diabetic patients with very high CVD risk. Hypolipidemic drug prescription was encountered among 25% and 50 % of the diabetic patients with high and very high CVD risk (Table 4).

Table 4: Drugs used for cardiovascular disease risk modification based on CVD Risk Profile.

S. No	Drug Class	Low CVD risk N=108	Medium CVD Risk N=24	High CVD Risk N=24	Very High CVD Risk N=04
1	Antidiabetic	108 (100%)	24 (100%)	24 (100%)	4 (100%)
2	Antihypertensive	10 (9.2%)	10 (41.6 %)	12 (50 %)	4 (100%)
3	Antiplatelet	0 (0 %)	0 (0%)	0 (0%)	2 (50%)
4	Hypolipidemic	10 (9.2 %)	4 (16.6 %)	6 (25 %)	2 (50 %)

Impact of counselling on knowledge related to risk factors associated with cardiovascular disease

The WHO Risk Prediction Chart for Assessment and Management of CVD Risk was used to stratify the patients into risk categories (Very high, high, medium and low). The patient’s baseline knowledge on Preventive Strategies for CVD Risk modification was scored. Subsequently, the patients were counselled based on WHO CVD Risk Reduction Guidelines and thereafter re-administered the same questionnaire to assess the impact of structured counselling. Counselling resulted in a significant increase in knowledge regarding preventive Strategies

for CVD Risk modification. The baseline total knowledge score increased significantly related to items: body weight (p<0.05), glycemic control (P<0.01), benefits of hypolipidemic agents (p<0.01) and antiplatelet drug aspirin (P<0.001) usage (Figure 4). Majority of the type 2 diabetic patients found the counselling to be useful, complete and balanced.

Discussion

Diabetes is fast gaining the status of a potential epidemic in India with more than 62 million diabetic individuals currently diagnosed with the disease [11-13]. In 2000, India (31.7 million)

topped the world with the highest number of people with diabetes mellitus. Cardiovascular disease (CVD) is the major cause of death in patients with type 2 diabetes mellitus (DM) [14]. The myriad of

cardiovascular complications associated with diabetes will make the disease a public health emergency in the future [1].

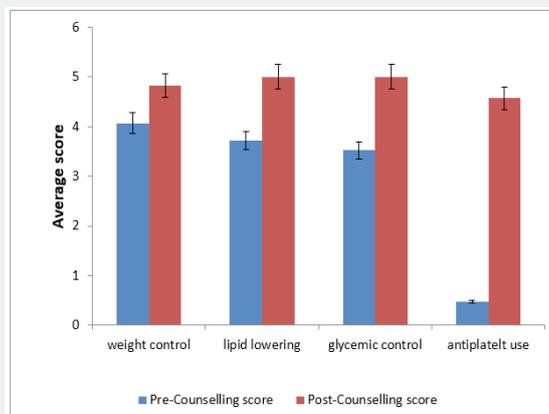


Figure 4: Impact of Educational Intervention on knowledge related to CVD prevention strategies.

Among diabetic patients, the impact of sole glucose lowering on cardiovascular complications is a hotly debated issue. The United Kingdom Prospective Diabetes Study (UKPDS) was the first clinical trial to provide key evidence of the importance of using intensive therapy for diabetes control in individuals with newly diagnosed DM. Recent large clinical trials, the Action in Diabetes and Vascular Disease (ADVANCE), Action to Control Cardiovascular Risk in Diabetes (ACCORD), and the Veterans Affairs Diabetes Trial (VADT), reported no significant decrease in primary cardiovascular endpoints with intensive glucose control [15-17]. Therefore, glycemic control is not the only factor to be considered to decrease the risks of cardiovascular complications.

It is widely accepted that besides blood glucose, other variables: age, gender, high blood pressure, smoking and dyslipidemia are the major risk factors for developing CVD. Thus, comprehensive risk factor management, including blood pressure control, lipid management, weight reduction in overweight or obese individuals, and smoking cessation, are also needed. The results of the ACCORD and ADVANCE studies and the VADT should be interpreted in the context of comprehensive care of patients with diabetes [18]. Therefore, Interventions for simultaneous optimal control of co-morbidities often present in DM, such as hypertension and hyperlipidemia, have been shown to be a more effective strategy in reducing cardiovascular risk than targeting only blood glucose levels per se.

Several large randomized trials and systematic reviews have shown the benefit of drugs such as statins in patients with high cardiovascular risk. Anti-platelets are capable of reducing major cardiovascular events, and many antihypertensive drugs, mainly angiotensin-converting enzyme inhibitors (ACEI), have the potential to reduce cardiovascular events. Additionally, non-

pharmacological interventions, such as cardioprotective diets, smoking cessation and regular physical activity, although the data are less robust than those in studies with pharmacological therapies, are also associated with a reduction in clinically relevant CVD outcomes [19].

Thus, it is critical that therapy should also be directed towards aggressive modification of the cardiovascular risk factors in diabetic patients. Therefore development of strategies for the primary prevention of cardiovascular complications in diabetes remains the most important clinical objective. To address this issue, various multivariable CVD risk prediction algorithms such as Framingham Risk score, UKPDS Risk Engine, WHO charts have been developed incorporating these risk factors, that can be used by primary care physicians to assess in individual patients the risk of developing of CVD, ie, coronary heart disease, stroke, peripheral vascular disease, or heart failure [20]. Risk factor modification can reduce clinical events and premature death in people with established cardiovascular disease as well as in those who are at high cardiovascular risk due to one or more risk factors.

The estimated absolute CVD event rates predicted based on Prediction tools can be used to quantify risk and to guide preventive primary care among DM patients. Individuals with a high global CVD risk scores (eg, a 10-year risk of a CVD event (coronary, cerebrovascular, and peripheral artery disease and heart failure) more than 20%) require more aggressive risk factor modification. The goal of therapy of dyslipidemia, diabetes, and hypertension should be linked to the global CVD risk. In the future the use of CV risk prediction tools may be used to estimate overall CV risk in order to decide on treatment. When resources are limited, individual counselling and provision of care may have to be prioritized according to cardiovascular risk [21].

With this point of view the present study was designed. The WHO CVD risk prediction charts were used to categorize the DM patients as having very high, high, medium and low CVD risk. The patient profile, cardiovascular risk factors and prescription pattern among diabetic patients of various CVD risk categories was determined. Also, impact of structured counselling on preventive strategies for cardiovascular disease risk modification was assessed.

Maximum Type II diabetic patients who were counselled for cardiovascular risk modification were of the age group 50-59 years. A large proportion of the type 2 diabetic patients had long standing diabetes for more than 7 years. Hypertension was encountered among 22.5% patients and dyslipidemia among 13.75% patients. It was found that 52.5% patients had uncontrolled glycemic control and 33% had uncontrolled hypertension. Studies have shown that uncontrolled glycaemia and hypertension are the major culprits precipitating a cardiovascular event such as myocardial infarction and stroke. Therefore, efforts should be directed to keep blood sugar and blood pressure under clinically permissible limits.

WHO Guidelines for CVD Prevention recommends the use of antihypertensive, hypolipidemic and antiplatelet drugs besides antidiabetic drugs for CVD risk modification [4,10]. The drug therapy of dyslipidemia, diabetes, and hypertension should be linked to the global CVD risk. In the present study it was found that for the management of diabetes maximum (97.5%) type 2 diabetic patients were prescribed oral hypoglycemic agents alone. Aspirin was prescribed only in 1.25% cases and hypolipidemic agents (statins) among 13.75% type II diabetic patients.

The WHO Risk Prediction Chart for Assessment and Management of CVD Risk was used to stratify the patients into risk categories (Very high, high, medium and low) [4]. Out of the type 2 diabetic patients screened for CVD risk, 67.5% has low CVD risk (<10% scores), 15% medium CVD risk (10 to 20% scores), 15% high CVD risk (20 to 30% scores) and 2.5% were categorized as having very high CVD risk (>30% scores). Thus 32.5% of the diabetic patients have medium to very high risk of developing a cardiovascular event in the near future. Therefore, these diabetic patients need to be monitored more closely and an intervention to modify these CVD risk factors needs to be addressed.

The prevalence of WHO/ISH "high CVD risk" ($\geq 20\%$ chance of developing a cardiovascular event over 10 years) was studied in Mongolia, Malaysia and Cambodia. Results showed that majority of people in all three countries has a low (<10%) 10-year CVD risk ranging from 89.6% in Mongolia to 94.4% in Malaysia to 97% in Cambodia. The percentage of population at a high CVD risk ($\geq 20\%$) was the greatest at 6% in Mongolia, compared with 2.3% in Malaysia and 1.3% in Cambodia. In all the three countries, a higher proportion of men had moderate or high total CVD risk than women, though in none of the countries were the differences

statistically significant, and the risk among both women and men increased significantly with age [10].

Duration of diabetes more than 7 years (long standing diabetes) was encountered in 75% belonging to medium CVD risk, 53.3% high CVD risk and 50% of very high CVD risk. Poor glycemic control was noted among 66.6% belonging to medium CVD risk, 75% high CVD risk and 100% of very high CVD risk. Hypertension was encountered in 50% and 100% of the type 2 diabetic patients and dyslipidemia among 33.3% and 100% respectively with high and very high CVD risk. Thus the various CVD risk factors such as poor glycemic control, hypertension, dyslipidemia was encountered in majority of the diabetic patients belonging to high and very high CVD risk profile.

Drug used for the cardiovascular risk modification among the various CVD risk categories was also assessed. It was found that antihypertensive drugs were prescribed among 41.6% diabetic patients with medium CVD risk, 50% with high CVD risk and 100% of very high CVD risk. Antiplatelet drug was prescribed among 100% of diabetic patients with very high CVD risk. Hypolipidemic drug prescription was encountered among 25% and 50% of the diabetic patients with high and very high CVD risk. The WHO Guidelines for Assessment and Management of CVD Risk recommends the use of various classes' drugs for CVD risk modification depending upon the risk category. Those with higher CVD risk need to be treated more aggressively. Thus, there exists a scope to increase the usage of hypolipidemic drugs in patients with high and very high CVD risk category.

Reducing cigarette smoking, body weight, blood pressure, blood cholesterol, and blood glucose all have a beneficial impact on major biological cardiovascular risk factors [22-24]. Behaviors such as stopping smoking, taking regular physical activity and eating a healthy diet promote health and have no known harmful effects. They also improve the sense of well-being and are usually less expensive to the health care system than drug treatments, which may also have adverse effects. Observational studies have found that other behavioral modifications, in particular cessation of smoking, are associated with a reduction in cardiovascular disease mortality [25]. In men in the United Kingdom, a healthy lifestyle and increased physical activity have been shown to reduce the chances of developing cardiovascular disease. Therefore, interventions targeted at individuals could be expected to bring about behavioural changes and modify the CVD risk factors.

The type II diabetic patients were imparted educational intervention based on WHO Guidelines for Assessment and Management of CVD Risk on Knowledge regarding Tobacco, Alcohol usage, Diet, Physical Activity, Weight control, Psychosocial factors and Multiple risk factor interventions [4,10]. The patient's knowledge on Preventive Strategies for CVD Risk modification was scored. Subsequently, the patients were counselled based on WHO CVD Risk Reduction Guidelines and thereafter re-

administered the same questionnaire to assess the impact of structured counselling. The knowledge pre and post educational intervention was compared among type II diabetic patients to assess the impact of structured counselling.

Counselling resulted in a significant increase in knowledge regarding preventive Strategies for CVD Risk modification. The baseline total knowledge score increased significantly related to items: weight control ($p < 0.05$), glycemic control ($P < 0.01$), benefits of hypolipidemic agents ($p < 0.01$) and antiplatelet drug aspirin ($P < 0.001$) usage. Majority of the type 2 diabetic patients found the counselling to be useful, complete and balanced. If knowledge related to benefits of weight control and maintaining good glycemic control translates to self-corrective behavior, it would be very beneficial in modifying the preventable CVD risk factors.

Results of the present study have provided baseline information on the CVD risk profile, drug therapy, disease, risk factor profile among diabetic patients with variable CVD risk profile. The purpose of emphasizing the recommendations elaborated in the WHO guidelines through structured counselling is to motivate and assist high-risk diabetic individuals to lower their cardiovascular risk by: quitting tobacco use, making healthy food choice, being physically active, reducing body mass index, lowering blood pressure, lowering blood cholesterol, controlling glycaemia. Data will provide future guidance on specific preventive actions to initiate at the level of patient, physician and Institute for CVD risk modification.

Conclusion

WHO CVD risk prediction charts demonstrated that one third of the Type 2 diabetic patients have medium to very high risk of developing a cardiovascular event in the near future. Education intervention resulted in a significant increase in knowledge {related to weight control, glycemic control, benefits of hypolipidemic agents and antiplatelet drug aspirin usage} regarding preventive strategies for CVD Risk modification.

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