ORIGINAL ARTICLE

Assessment of Clinical, Risk Factors Profile and Clinical Pharmacist Care Services on Management and Prevention of Coronary Artery Disease Complications Among Diabetic Patients in a Tertiary Care Hospital Practice

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ABSTRACT

Introduction: Diabetes is a chronic metabolic disease and noted to be incidence is intensifying globally and contemplated as epidemic. The study is aimed to assess the coronary artery disease risk profile associated diabetes mellitus patient and to identify the clinical pharmacist care services in the management and to control the risk burden in the clinical practice. **Method:** A prospective observational study was conducted among the consecutive patients of coronary artery disease associated diabetic patients in a tertiary care teaching hospital over 6 months period. A sample of 150 patients was recruited in the study. Data analysis was done with graph pad prism software 5.01. **Results:** The present study revealed that coronary artery disease in diabetes was more prevalent in age group between 41-50 years. About 54.66% patients with hyperlipidemia were at risk to develop the coronary artery disease complication. Glycated hemoglobin test was detected in 40% of the patient showing abnormal levels and around 43.33% of patient had an abnormal fasting blood sugar level. The study showed only 32% of patients was prescribed Insulin & oral hypoglycemic agents and 13 % were treated with statins. **Conclusion:** It could be concluded that the causative factors should be controlled and treated with an early need for amalgamation of clinical pharmacist care services with the health care team on life style modification counseling could ultimately improve the patient health outcomes and also lowers progression of coronary artery disease risk complications among diabetic patients.

Keywords: Coronary artery disease, Diabetes mellitus, Hyperlipidemia, Clinical pharmacist, Care services.

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INTRODUCTION

Diabetes mellitus has a broad range of complications which includes macro vascular and micro vascular complications which lead to develop severe coronary artery diseases amongst the diabetes mellitus affected patients rather than non-diabetic patients. The release of inflammatory cells, proliferation of vascular smooth muscle cells led to endothelial dysfunction can cause the plaque instability and thrombus formation can lead to development of coronary artery disease. Diabetic patients can increase two to four folds of developing coronary artery disease risk. Cardiovascular diseases are creating primary health problem and causing mortality and morbidity in worldwide. Around 17.9 million people die from cardiovascular disease every year and accounts for 31% death globally (1-3). Recent statement from the International Diabetes Federation estimated that people around 387 million affected with diabetes mellitus in 2013 and which may to rise 592 million by 2035. The health care cost of diabetes mellitus is largely attributed to many complications such as hypertension, coronary artery disease, peripheral vascular disease, neuropathy, retinal problems and renal failure (4-5).

Cardiovascular diseases consist of congestive heart failure, congenital heart disease, cardiomyopathy, cardiac arrhythmia, coronary heart disease, rheumatic heart disease, stroke, and peripheral arterial disease etc. The etiology of coronary artery disease is a complex process following a series of coronary artery disease development with severe risk factors. Coronary artery disease comprises an array of manifestations which extend from stable angina, unstable angina, ST-elevation myocardial infarction non-ST elevation myocardial

infarction. A major determinant of cardiovascular disease includes smoking, alcohol, physical inactivity, consuming high fat diet, hypertension, obesity and diabetes mellitus which lead to progression of coronary artery disease risk complications and also contribute more health care cost to the individual patients. Coronary artery disease is a leading cause of mortality and morbidity in both developed and developing countries. The incidence of coronary artery disease is likely to increase because of quick urbanization and its accompanying lifestyle changes. The greater incidence of risk factors in a population determines the future burden of health care services and also it would impose the economy of the affected patients (6-10). Previous research studies have reported that controlling of coronary artery disease risk factors and evidence based therapeutic practices can efficiently reduce the coronary artery disease progression.

The screening modalities for coronary artery disease complications in diabetes include electrocardiogram, coronary angiogram, echocardiogram, treadmill test, coronary angiogram, coronary computed tomography, lipid test, and blood sugar test are useful tool for enhancement of better therapeutic outcomes and also prediction of coronary risk characteristics of affected patients.

The American diabetes association suggested that routine screening of high-risk profile patients and treated with anti-diabetic and cardiovascular medications can reduce the incidence of cardiovascular events. People need primary prevention who have abnormal clinical risk profile for developing coronary artery disease and secondary prevention to reduce the recurrence of the coronary artery disease. Recent research evidence demonstrates that Indian population is more vulnerable to develop coronary artery disease manifestations. The main strategy in the primary prevention of coronary artery disease include early risk factor detection and control as anticipated by the American heart association and American college of cardiology guidelines. There is a huge advance in the secondary prevention of coronary artery disease as witnessed by the various research studies of prescribing antiplatelets, statins, angiotensin-converting enzyme inhibitors could impact the better clinical outcomes in affected patients (11-13).

The continuous progression of coronary artery disease incidences can reduced by approaching effective treatment strategies and also regular implementation of clinical pharmacist counseling programmes on lifestyle modifications which includes adherence to medications and physical exercises, smoking, alcohol cessation and maintaining controlled levels of lipid, blood pressure and diabetes can lower the risk of coronary artery disease complications.

Rejuvenation of awareness programmes on coronary artery disease prevention and management by the clinical practitioners, clinical pharmacist and nurse in the clinical settings can be helpful for successful control of alarming incidences of coronary artery disease events. In high-income countries effective screening for prevention and management of coronary artery disease is well established, but such treatment strategies have not yet been implemented developing countries like in India.

The risk of coronary artery disease complications among diabetic patients is the major disease burden amongst the population. The care of this complicated cases is of the need along with the physician, the clinical pharmacist association can bring forth an effective changes which eventually can countdown the number of the disease complication causes.

We hypothesized that as a keystone for our research, the study could attempt to evaluate the coronary artery disease risk profile associated diabetes mellitus patient and to identify the clinical pharmacist care services in the management and to control the treatment associated economic burden in the clinical practice. The clinical pharmacist care services can bring drastic change in the treatment modalities being one among in the effective health care team of these complicated patients.

The primary objective of our study was to identify coronary artery disease risk factors, clinical profile and to evaluate the clinical pharmacist care services in the management and prevention of coronary artery disease complications amongst the diabetic patients. The secondary objective of the study was to analyze the drug medication prescribing practice and to control the disease burden.

MATERIALS AND METHODS

Study design and location
A prospective observational study was conducted for a period of 6 months in the cardiology outpatient department, SRM Medical College Hospital and Research Center after obtaining the Institutional human ethical committee clearance (No.1329/IEC/2017). The patients visiting to the cardiology out department were screened according to inclusion and exclusion criteria and 150 patients were selected for the study.

Inclusion criteria
The patients above 18 years of age, type 1 and type 2 diabetic patients diagnosed with coronary artery disease associated complications were admitted included in the study based on inclusion criteria.

Exclusion criteria
The subjects with pregnancy, lactation, chemotherapy treatment, cognitive impairment, non-diabetic patients were excluded from the study.

Source of data

Patients case sheets containing demographic details, laboratory test report and drug treatment prescription.

Data collection

The study data was collected from individual patient case sheets and conducting patient interviews. The collected data having characteristics of the patients such as age, gender, social habits, type of diabetes, duration of diabetes, risk factors, length of stay, co-morbid conditions, coronary artery disease complications, laboratory findings including glycated hemoglobin (HbA1c) level, fasting blood sugar, random blood sugar value, lipid level, echo cardiogram, electrocardiogram, coronary angiogram, left ventricular ejection fraction profiles of the patients were collected.

The collected data from each patient was documented and sent for evaluating the clinical study parameters. The research data was assessed from the identified domains include risk factors, diagnosis, patient care services, prevention and management were indicated by American heart association guidelines and American diabetes association guidelines as the necessities for coronary artery disease in diabetes management in the current health care practice.

Statistical analysis

The graph pad prism software version 5.01 was applied for statistical analysis. The descriptive analysis was used for describing socio-demographic criteria using number and percentage (%). Mean and standard deviation were also determined for all the patients. The one sample t-test was performed to determine the significant difference between the variables. P-valve of less than 0.05 was considered as statistically significant.

RESULTS

The sample size of 150 consecutive patients visiting the cardiology outpatient department in SRM Medical College Hospital and Research Centre, Kattankulathur, India. The data collected using patients socio-demographic parameters include age, gender, social habits, marital status, BMI, diabetes and coronary artery disease duration residential status, risk factors, co-morbid conditions, diagnosis of coronary artery disease, complications, laboratory findings include coronary angiogram, echo cardiogram, fasting blood sugar (FBS), postprandial blood sugar (PPBS), random blood sugar (RBS), cholesterol levels and drug prescribing pattern in clinical practice.

Out of 150 patients 29 (19.33%) patients were in the age group of 30-40years, 82(54.66%) patients were in the age group of 41-50 years, 23(15.33%) patients were in the age group of 51-60 years and 16(10.66%) patients were in the age group of 61-70 years. Out of 150 patients 17(11.33%) were body mass index (BMI) of

Table I: Age wise distribution and BMI of study patients

Age (years)	No of patients N=150	Percentage (%)	Mean ± SD
30-40	29	19.33	36.03±2.44
41-50	82	54.66	46.06±2.06
51-60	23	15.33	55.52±2.31
61-70	16	10.66	65.88± 2.98
Total	150		*P<0.0001
BMI	**No of patients N=150**	**Percentage (%)**	
18.5-24.9	17	11.33	21.79 ±2.00
25.0-29.9	35	23.33	27.51±1.47
30.0-34.9	98	65.33	32.40±1.61
Total	150		*P<0.0001

18.5-24.9, 35(23.33%) patients were BMI of 25.0-29.9, 98(65.33%) patients were BMI of 30.0-34.9. The results were shown in Table I.

From the total sample size of 150 patients, men were around 127 (84.66 %) and 23 (15.33%) were women among the admitted patients. Present study total sample size of 150 patients Non vegetarian patients were 85 (56.66%) and vegetarian patients were 65 (43.33%). Present study total sample size of 150 patient's marital status of patients includes single patients were 12(8%), married patients were 138(92%).Out of 150 patients in the study urban locality patients were 117(78%) and rural locality patients were 33(28%). The results were summarized in Table II.

In our study diabetes mellitus duration ranges from 1-3 years duration patients were 45(30%), 4-5 years duration patients were 67(44.66%) and 6-7 years duration patients were 38(25.33%).Coronary artery disease duration ranges from 1-3 years duration patients

Table II: Demographic characteristics of study patients

Gender	No of patients N=150	Percentage (%)
Male	127	84.66
Female	23	15.33
Total	150	
Social habits	**No of patients N=150**	**Percentage (%)**
Non vegetarian	85	56.66
Vegetarian	65	43.33
Total	150	
Marital status	**No of patients N=150**	**Percentage (%)**
Single	12	8
Married	138	92
Total	150	
Residential status	**No of patients N=150**	**Percentage (%)**
Urban	127	84.66
Rural	23	15.33
Total	150	

were 65(43.33%), 4-5 years duration patients were 33(22%), 6-7 years duration patients were 52(34.66%). Present research study identified risk factors amongst the recruited patient's having coronary artery disease revealed family history of coronary artery disease 16 (10.66%), smoking and alcohol habitual patients were 15(10%), hypertension patients were 21(14%), diabetes > 10 years patients were 16(10.66%), hyperlipidemia patients were 82(54.66%). The results were depicted in Table III.

Table III: Duration of diabetes mellitus and coronary artery disease and Risk factors of coronary artery disease

Duration of DM (Years)	No of patients N=150	Percentage (%)
1-3	45	30
4-5	67	44.66
6-7	38	25.33
Total	150	
Duration of CAD (Years)	**No of patients N=150**	**Percentage (%)**
1-2	65	43.33
2-4	33	22
4-5	52	34.66
Total	150	
Risk factors	**No of patients N=150**	**Percentage (%)**
Family history of coronary artery disease	16	10.66
Smoking and alcohol	15	10
Hypertension	21	14
Diabetes > 10 years	16	10.66
Hyperlipidemia	82	54.66
Total	150	

A total sample size of 150 patients was evaluated for various diagnostic investigations which includes stable angina patients were 65(43.33%), unstable angina patients were 45(30%), ST-Elevation Myocardial Infarction (STEMI) patients were 28(18.66%) and Non-ST-elevation myocardial infarction (NSTEMI) patients were 12(8%). The coronary angiogram test showed single vessel patients were 66(44%), double vessel disease patients were 34(22.66%) and triple vessel disease patients were 50(33.33%). Echocardiogram left ventricular ejection fraction (LVEF) findings include 20-25% LVEF patients were 42 (28%), 26-30% LVEF patients were 21(14%), 30-35% LVEF patients were 33(22%), 36-45% LVEF patients were 54(36%). The results were shown in Table IV.

In our research study from the blood sample analysis of the recruited patients fasting blood sugar levels (110-170) mg/dl patients were 65 (43.33%), postprandial blood sugar (PPBS) (160-200) mg/dl patients were 39(26%), and random blood sugar (RBS) (190-270) mg/dl patients were 46 (30.66%). Glycated hemoglobin (HbA1c) 7-8 patients were 54(36%), 8-9 patients were 36 (24%) and

Table IV: Coronary artery disease diagnostic investigations profile of study patients

Diagnosis	No of patients N=150	Percentage (%)
Stable angina	65	43.33
Unstable angina	45	30
STEMI	28	18.66
NSTEMI	12	8
Total	150	
Coronary angiogram	**No of patients N=150**	**Percentage (%)**
Single vessel disease	66	44
Double vessel disease	34	22.66
Triple vessel disease	50	33.33
Total	150	
Echocardiogram findings (LVEF) %	**No of patients N=150**	**Percentage (%)**
20-25	42	28
26-30	21	14
30-35	33	22
36-45	54	36
Total	150	

9-12 patients were 60 (40%). Cholesterol levels was found to be total cholesterol ranges from (170-200) mg/dl patients were 34(22.66%), triglycerides ranges from (150-185) mg/dl patients were 31(20.66%), very low density level lipoproteins ranges from (30-41) mg/dl patients were 13(8.66%),low density level lipoprotein ranges from (130-160) mg/dl patients were 53(35.33%), high density level lipoprotein ranges from (25-35) mg/dl patients were 19(12.66%). The results were summarized in Table V and Figure 1.

Table V: Biochemical parameters profile of study patients

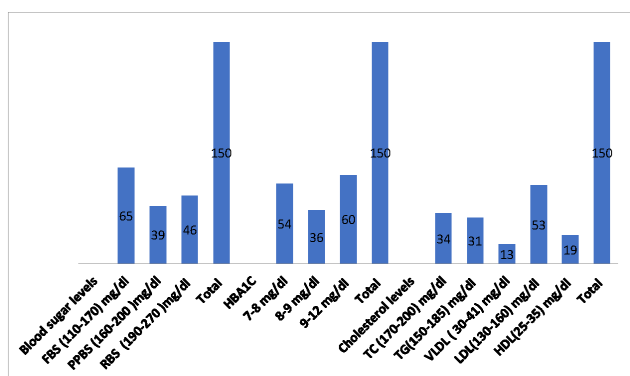| Biochemical parameters	No of patients N=150	Percentage (%)	Mean ± SD
Blood sugar levels			
FBS (110-170) mg/dl	65	43.33	146.4±15.41
PPBS (160-200)mg/dl	39	26	182.1±10.59
RBS (190-270)mg/dl	46	30.66	245.8±22.97
Total	150	100	*P<0.0001
HBA1C			
7-8 mg/dl	54	36	7.55±0.28
8-9 mg/dl	36	24	8.57±0.24
9-12 mg/dl	60	40	10.65±0.89
Total	150	100	*P<0.0001
Cholesterol levels			
TC (170-200) mg/dl	34	22.66	185.2±8.26
TG (150-185) mg/dl	31	20.66	168.1±10.51
VLDL (30-41) mg/dl	13	8.66	35.62±3.15
LDL (130-160) mg/dl	53	35.33	147.5±8.87
HDL (25-35) mg/dl	19	12.66	30.63±3.40
Total	150	100	*P<0.0001

Figure 1: Biochemical parameters

Present study coronary artery disease associated complications includes heart failure patients were 11(7.33%), stroke patients were 16(10.66%),Cardiac Arrhythmia patients were 26(17.33%), Acute coronary syndrome patients were 51(34%), Myocardial infarction patients were 21(14%), Cardiomyopathy patients were 18(12%) and Peripheral arteriopathy patients were 7(4.66%). Present study total sample size of 150 patients Insulin & oral hypoglycemic agents prescribed patients were 48(32%), antiplatelets 50(33.33%), beta blockers 5(3.33%), statins prescribed patients were 20(13.33%), nitrates prescribed patients were 9(6%), diuretics prescribed patients were 8(5.33%) and calcium channel blockers prescribed patients were 10(6.66%). The results were shown in Table VI.

Table VI: Coronary artery disease associated complications of study patients

Coronary artery disease complications	Number of patients N=150	Percentage (%)
Heart failure	11	7.33
Stroke	16	10.66
Cardiac Arrhythmia	26	17.33
Acute coronary syndrome	51	34
Myocardial infarction	21	14
Cardiomyopathy	18	12
Peripheral arteriopathy	7	4.66
Total	150	
Drugs prescribed	**No of patients N=150**	**Percentage (%)**
Insulin & OHA	48	32
Antiplatelets	50	33.33
Beta blockers	5	3.33
Statins	20	13.33
Nitrates	9	6
Diuretics	8	5.33
Calcium channel blockers	10	6.66
Total	150	

DISCUSSION

The present study demonstrates the comprehensive summary of coronary artery disease risk factors profile in a tertiary care hospital. In our study 41-50 years age patients were 82(54.66%) more as compared with other age groups (Table I). Maximum patients were from age group of 41-50 years. The body mass index (BMI) ranges from 30.0-34.9 patients were more 98(65.33%) as compared with other BMI values. Our study results (Table II) similar with other study (14), the male patients were more 127(84.66%) as compared with female patients. Our study results complied with (15), and (16), revealed the incidences of coronary artery disease were higher in males as compared to females. In our study non veterinarian food habits patients were more 85(56.66%) as compared with Vegetarian patients (Table III). The married patients were more 138(92%) as compared with single patients. The urban area patients were more 117(78%) as compared with rural locality patients. Diabetes mellitus duration ranges from 4-5 years of patients were more 67(44.66%) as compared with other duration patients. Coronary artery disease duration ranges from 1-2 years of patients were more 65(43.33%) as compared with other patients (Table IV). Hyperlipidemia risk factor patients were more 82(54.66%) as compared with other risk factors. Male patients have higher tendency to develop coronary artery disease in comparison to female patients due to unhealthy social activity like alcohol intake, smoking habits, diverse lifestyle practice and stress. Tobacco contains various carcinogenic chemicals which damage the vascular smooth muscles and entire blockage of coronary artery walls results in increase risk incidence of coronary artery disease. World health organization said that the tobacco is the major risk contributing factor in the development of coronary artery disease in India. Present study smoking and alcohol habitual was observed in 10% of the study patients. The various published research literatures showed the classical risk factors of coronary artery disease towards a higher incidence of coronary artery disease and which includes smoking, alcohol, obesity, diabetes mellitus and hypertension. The Framingham study showed that the hypertension was one of the risk factors for coronary artery disease. In the present study the hypertension was found in 14% of the patients which increased with the advancement of age and these results found congruence with (17). Diabetes mellitus is a complex metabolic disorder which is associated with insulin resistance and genetic abnormalities and highly seen in Indian population. In our study diabetes mellitus patients were 10.66%. The alarming risk incidence of diabetes mellitus with aging factor was previously reported by Ramachandran et al., The stable angina patients were more 65(43.33%) as compared with other diagnosis (18). The coronary angiogram revealed that single vessel disease patients

were more 66(44%) as compared with other coronary angiogram results. Our study results similar with other study conducted by (19), coronary angiogram results determined that the incidence of single disease was most commonly seen in the coronary artery disease patients (19).

Echocardiogram findings showed that left ventricular ejection fraction (LVEF) ranges from 36-45% patients were more 54(36%) as compared with other LVEF results. Acute coronary syndrome complicated patients were more 51(34%) as compared with other complications. The fasting blood sugar levels more than 110 mg/dl patients in were more 65(43.33%) as compared with other blood glucose parameters. The glycated hemoglobin (HbA1c) ranges from 9-12 mg/dl patients were more 60(40%) as compared with other HbA1c values (Table V). The low-density level lipoprotein more than 130 mg/dl patients in the intervention group were more 56(37.33%) as compared with control group. In our study the triglycerides, total cholesterol, low density level lipoproteins were found high and high density lipoproteins was low. The elevated triglycerides and LDL levels were extensively enhancing the risk of coronary artery disease. Our results were meeting with similar study conducted by (20). Present study total sample size of 150 patients Insulin & OHA prescribed patients were 48(32%), statins prescribed patients were 20(13.33%). The study showed only 32% of patients was prescribed Insulin & oral hypoglycemic agents and 13 % were treated with statins revealing an improved effective drug prescribing pattern was needed (Table VI). In this study antiplatelet drugs were prescribed. According to the American college of cardiology guidelines in the management of coronary artery disease patients with prescribing of antiplatelet therapy is recommended for better outcomes of patients. Our study results contrast with similar study was conducted by Masoudi et al. (2005), reported that aspirin is available as least price and effective for treatment of coronary artery disease (21).

Clinical Pharmacist Care Services on Management and Prevention of Coronary artery Disease Complications among Diabetic Patients
Clinical pharmacy services are defined as a health care discipline where the pharmacist provides patient care that can improves health, wellness and to cure the disease. American College of Cardiology board of trustees designed and endorses the effective therapeutic care to address the budding cardiovascular disease complications. The lack of clinical practitioners in the patient care areas, there is a need for collaboration with non-physician health care practitioners, which includes clinical pharmacist, hospital pharmacist, community pharmacist, nurse, an efficiently to strengthen the patients care outcomes. Clinical pharmacist are the pharmacy practitioners who have advanced training, license and experience, skills, knowledge to offer the clinical pharmacy services to public and patients' domain. The clinical pharmacy services include adverse drug reactions monitoring, drug interactions monitoring, delivering drug based information to the diverse health care practitioners, complex disease management, educating the patients on medications utilization in appropriate schedules and designing policy, drug formulary and guidelines for prevention and management of communicable and non-communicable diseases and initiating awareness programmes on medication related problems management in hospitals and regular amalgamation of clinical pharmacist services in the cardiology care setup can reduce the coronary artery disease risk incidences (22-24). American college of cardiology survey reported that many cardiology physicians are arduous with surgery, patient visiting schedules and application of clinical pharmacist services to patient care areas could enhances the quality and safety of health care services.

Coronary artery disease patients are at high risk for developing medication related problems due to over utilization of medications. Therefore, application of evidence based therapies and prescribing of lest price medications having greater safety and efficacy can minimize the treatment based financial burden to the individuals. Clinical pharmacist is positioned in the various departments in the hospital to address the drug related issues, disease screening, educating the patients about disease risk factors, lifestyle modifications, diet, physical exercises, counseling the patients about medication utilization and medication adherence to reduce the cardiovascular events progression. The cardiovascular risk reduction can be achieved through targeting the high-risk profile patients and offering effective diagnostic, therapeutic modalities can promote the better health outcomes. Clinical pharmacist can practice as a health care consultant to evaluate the patient care services, designing clinical trials research protocols, prospective review of pharamcotherapies and guiding the health care team on disease state management and medication utilization care can benefit to the patient community and also to reduce the chronic disease burden in the health care setup. The management of chronic disease conditions such as dyslipidmeia, diabetes mellitus, hypertension, cardiovascular diseases could be directly allocated through clinical pharmacist care services under the supervision of medical practitioner. The utilization of clinical pharmacist care activities in the cardiology care is bountiful and adoption of these services in Indian health care scenario is impeded by lack of health care support.

CONCLUSION

In our study coronary artery disease complications in diabetes mellitus is more common in age group of 41-50 years. From our study we observed that hyperlipidemia,

diabetes mellitus, hypertension, smoking and alcohol is the major risk factor for developing coronary artery disease complications. Coronary angiogram is an effective diagnostic tool for detection of coronary artery disease complications. Antiplatelets, statins, insulin and anti-diabetic drugs are the effective therapeutic medications in the treatment of diabetic patients having coronary artery disease. The current study results identified a high incidence of coronary artery disease risk factor which alarms a rising trend in the study patients of Indian population. The primary prevention should be targeted to screen the risk factors to diminish the future episodes of coronary artery disease. The secondary prevention should rely on advanced treatment modalities can helps to prevent the coronary artery disease complications in diabetes mellitus. Previous studies have shown the identification of coronary artery disease risk factors, present study uniquely exhibits that clinical pharmacist care services in the prevention and management of coronary artery disease complications in diabetes mellitus is a huge advantageous when it is executing in the patient care areas.

From the study findings we confidently conclude and suggest that the clinical pharmacist care programmes plays a major role in early detection of risk factors and referring high risk patients to cardiac therapeutic modalities and regular implementation of these practices can targeted to minimize progression of coronary artery disease risk events in patient care settings. American college of cardiology advocate that the recommendation of clinical pharmacist medicated intervened care programmes to design newer coronary artery disease guidelines, newer cardiac risk screening tools could benefit to improve quality of cardiac care services as well as manage the high risk coronary artery disease patients in health care (25-26).

It could be concluded that the causative factors should be controlled and treated with an early need for amalgamation of clinical pharmacist care services such as life style modification counseling, patient referral services, drug problems identification and management could ultimately improve the patient health outcomes and also lowers progression of coronary artery disease risk complications among diabetic patients in cardiology practice (27).

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