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The Role of Clinical Pharmacists in Modifying Cardiovascular Disease Risk Factors

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Abstract

Objective: Assess the effect of intensive clinical and educational interventions aimed at reducing risk factors for Cardiovascular Disease (CVD), implemented by clinical pharmacists, on modifying risk factors in targeted patients at high risk for CVD.

Design: Patients with at least two risk factors for CHD were identified at two clinics by conducting a pre-intervention survey and were monitored over a period of 6 months with follow up conversations conducted every 4 weeks by phone and at subsequent physician visits. A post-intervention survey was conducted at the end of the study period to detect modified risk factors.

Setting: The Jefferson County Public Health Department (JCHD)

Participants: We followed a total of 47 patients over 6 months. The average age at baseline was 51 years old and 80% of the participants were female. The baseline average number of modifiable cardiovascular disease risk factors was 3.7.

Measurements: We assessed total number of CVD risk factors, smoking behavior, blood pressure, LDL, A1C, weight, and level of physical activity (major modifiable risk factors by the American Heart Association).

Results: Over a 6 month follow-up of 47 patients, statistically significant reductions occurred in total number of CVD risk factors, systolic and diastolic blood pressures, and A1C. Reductions also occurred in LDL level, weight, and changes in smoking behavior and physical activity were identified.

Conclusions: Results showed that increased patient counseling on adherence and lifestyle changes along with increased disease state monitoring and medication adjustment led by a clinical pharmacist can decrease risk factors in patients with multiple risk factors for cardiovascular disease.

Background

As Cardiovascular Disease (CVD) continues to be the leading cause of mortality in the United States, increasing efforts to decrease risk factors for CVD and overall mortality are crucial.[1] Modifiable risk factors for CVD include hypercholesterolemia, hypertension, physical inactivity, and smoking. The National Health and Nutrition Examination Survey (NHANES) III data reported that approximately 25% of adult Americans are at high risk for cardiovascular disease.[2] Intensive research in the area of CVD has shown the positive impact of identifying and targeting risk factors for the disease.[2-5] However, realistic and comprehensive ways to implement these recommendations have been less than forthcoming. As many clinical pharmacists in ambulatory care settings are trained in disease state management and medication therapy management, they provide an accessible, knowledgeable alternative in providing patient services that decrease CVD risk factors. Previous studies have demonstrated that involvement of clinical pharmacists in integrated patient care models can decrease CVD risk factors and improve outcomes.[6-10]

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The Jefferson County Department of Health (JCDH), located in Birmingham, AL, presents an excellent opportunity to implement CVD risk factor modifying techniques due to the high rates of CVD in the patient population as well as its integrated healthcare team approach. With over 300 deaths per 100,000 citizens in 2011, the state of Alabama ranks second among all US states and provinces in rates of CVD.[1] The following prospective clinical trial was conducted at JCDH to evaluate the outcomes of pharmacist-implemented clinical interventions in decreasing risk factors for cardiovascular disease in patients with two or more risk factors for CVD. The primary outcome being studied was a decrease in total number of CVD risk factors. Secondary outcomes include change in LDL leve, A_{1c} level, smoking status, physical activity, weight, and systolic and diastolic blood pressure.

Methods

After obtaining IRB approval from Samford University and JCDH, patients with at least two risk factors for CVD were identified at two JCDH clinics by conducting a pre-intervention survey. Upon providing written consent, patients agreed to be monitored over a period of six months with follow-up conversations conducted every four weeks by phone and at subsequent physician visits.

Inclusion criteria for the study included patients greater than 20 years of age, current patient at JCDH, greater than or equal to two risk factors for CVD, and one visit with a primary care physician in the past year. Exclusion criteria for the study included less than 20 or greater than 80 years of age, not a current patient at JCDH, and non-English speaking patients.

A total of 47 patients were enrolled into the study. Out of 47 patients, 16 were active smokers, 23 had uncontrolled hypertension, 17 had uncontrolled hyperlipidemia, 26 had uncontrolled diabetes mellitus, 46 were obese, and 40 were self-reportedly physically inactive. The average number of CVD risk factors was 3.7 and the average Framingham score was 4.6. The average age of enrolled patients was 51 years old and 80% of patients were female. See Table 1 for a review of baseline risk factors and patient characteristics.

Clinical interventions including medication adjustment and/or initiation, patient education and counseling, and support in accessing pharmacologic therapy through medication assistance programs were implemented based on patient-specific risk factors. CVD risk factors assessed included: smoking, hypertension (measured by systolic and diastolic blood pressures), hyperlipidemia (measured by calculated LDL level), obesity (measured by weight and BMI), physical inactivity and diabetes (measured by A_{1c}). The following risk

factor-specific interventions were made over the course of six months. Every patient with a positive smoking status was counseled by a pharmacist in the JCDH smoking cessation clinic. Eligible positive smoking status patients also received Nicotine Replacement Therapy (NRT) through the Alabama Tobacco Quitline and/or varenicline through the Pfizer Patient Assistance Program®. All patients with diabetes and patients with uncontrolled dyslipidemia and/or hypertension were counseled by a pharmacist on lifestyle modifications. Pharmacist-directed disease state-specific medication adjustments were made in 70% of diabetic patients , 23% of dyslipidemia patients, and 60% of hypertensive patients followed. All patients with obesity and/or physical inactivity were counseled by a pharmacist on weight loss, exercise, and lifestyle modifications.

Patients were followed by clinical pharmacists through either appointments in the pharmacist run Diabetes Clinic, pharmacist run Smoking Cessation Clinic, primary care physician visits, or telehealth visits. During follow-up conversations, patients were assessed based on change in smoking status, physical activity, systolic and diastolic blood pressure, current lipid panel, fasting plasma glucose levels, A_{1c} levels, weight, and Body Mass Index (BMI). Initially, current aspirin therapy was assessed, but was not evaluated for the six month period. Clinical pharmacists educated patients during these conversations and ascertained the need for any adjustments in medication therapy. Recommendations for medication adjustments were communicated to the patient's primary care physician at JCDH for implementation.

A post-intervention survey was conducted at the end of the study period by either telephone or primary care visit to detect the number and degree of change in CVD risk factors. A risk factor was considered at goal if it met the following criteria: smoking cessation, a blood pressure of less than 140/90 mmHg or less than 130/80 mmHg in patients with diabetes and/or chronic kidney disease, an LDL below 100 mg/dL, a BMI below 25 kg/m², an A1c below 7%, and physical activity of at least 30 minutes per day, most days of the week. An intervention was considered successful if at least one risk factor was modified. Data management and analysis was conducted using Microsoft EXCEL® and Minitab 16.2.2.

Results

Over the course of six months, communication was maintained at least every four weeks with all 47 patients initially enrolled. Overall, statistically significant decreases were seen in total number of CVD risk factors, systolic blood pressure, diastolic blood pressure, and A_{1c}. There were no statistically significant changes in LDL, weight, BMI, smoking

behavior, or physical activity (Table 2). The primary outcome being studied, number of total CVD risk factors significantly decreased from 3.74± at baseline to 3.06± (0.49, 0.87, p<0.001) post-intervention. Notably, at baseline four patients (8%) had all six CVD risk factors targeted, ten patients (20%) had five, and ten patients (20%) had four. Following intervention, only one patient (2%) still had all six CVD risk factors, five (10%) had five risk factors, and nine (19%) had four risk factors.

Mean systolic blood pressure (SBP) post-intervention was 126.72±18.49 mmHg compared to baseline SBP of 134.92±21.58 mmHg. This represented a difference of 8.2±6.1 mmHg (2.11, 14.28, p = 0.009). Similarly, diastolic blood pressure (DBP) averaged 80.34±9.63 mmHg post-intervention compared to 86.85±12.35 mmHg at baseline. Change in DBP was calculated as 6.51±2.9 mmHg (3.63, 9.39, p<0.001). Average A_{1c} was decreased from 9.44±2.19% to 8.49±1.67% (0.37, 1.53, p=0.002).

Out of ten baseline smokers, seven decreased smoking frequency and two patients stopped smoking altogether. At baseline, 41 patients reported that they were physically inactive. After clinical pharmacist intervention, only 4 patients reported having less than 30 minutes per day most days of the week of physical activity.

Discussion

We found that interventions implemented by clinical pharmacists at JCDH significantly decreased total number of patient risk factors for cardiovascular disease in patients with two or more baseline risk factors. Major risk factors that were modified include systolic and diastolic blood pressures and A_{1c}. Medication adjustment occurred in 70% of diabetic patients and 60% of uncontrolled hypertensive patients. These adjustments were made based on the pharmacists' assessment of outcomes on current therapy. While blood pressure can respond promptly to medication changes, a significant change in A_{1c} level over six months is less quickly achieved. This change was most likely a result of intensive counseling along with oral and insulin medication adjustments.

Risk factors that were not modified during the course of this study include obesity, physical inactivity, smoking behavior, and LDL levels. One possible reason for the lack of change in obesity and physical inactivity is that they are less easily targeted by medication adjustment. While structured counseling was provided on dietary and lifestyle changes, no medication was initiated to modify these risk factors. Varenicline was provided to 38% of active smokers enrolled. Varenicline is currently the only FDA approved partial

nicotine agonist and may take up to 12 weeks of compliant administration for positive outcomes to occur. However, many patients are unable to complete the full course due to side effects such as abnormal dreams, headache, and insomnia. Similar to A_{1c} levels, LDL levels can take an extended period of time in which to see reductions.[11] Medication adjustment only occurred in 25% of patients with uncontrolled dyslipidemia. The low percentage of changes could have resulted from the average LDL level at baseline being within the ATPIII goal of <100 mg/dL in diabetic patients at 96.96 mg/dL. Patients who met this goal were less likely to be initiated on or have changes in hyperlipidemia medication therapy.

All patients enrolled in the study received written and oral education on their baseline risk factors and improving these through lifestyle modifications. Patient education provided by clinical pharmacists was thorough, comprehensible, and structured. Clinical pharmacists monitored patients for medication adjustments to improve current therapy. From the success of this study, it can reasonably be concluded that frequent follow-up and communication with high risk patients improves outcomes by decreasing CVD risk factors. While studies have shown the correlation between increased monitoring of risk factors and improved outcomes, this study uniquely demonstrates that the clinical pharmacist can be integral and advantageous when implementing such interventions.[6-10] Recently the U.S. Surgeon General, Dr. Regina Benjamin, outlined that "health leaders and policy makers need to support evidence-based models of cost effective patient care that utilizes the expertise and contributions of our nation's pharmacists as an essential part of the healthcare team." Clinical pharmacists are trained as medication experts and are in an optimal position to lead such interventions as those implemented in this study in ambulatory care settings.

Limitations to this study included the short study duration of only six months, lack of comparator group which limits the study's ability to attribute outcomes solely to pharmacist's interventions, and self-reported estimates of smoking status and frequency and duration of exercise.

Conclusion

Statistically significant results showed that increased patient counseling on adherence and lifestyle changes along with increased disease state monitoring and medication adjustment led by a clinical pharmacist can decrease risk factors in patients with multiple risk factors for cardiovascular disease. Clinical pharmacists are in an optimal position to provide effective interventions aimed at decreasing risk factors for cardiovascular disease. Increased monitoring for

cardiovascular disease presence and progression is recommended in both symptomatic and asymptomatic adults.[2] Further research and consideration into the role of the clinical pharmacists in implementing interventions targeted at decreasing risk factors for cardiovascular disease is warranted.

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Table 1: Baseline Characteristics

Characteristic	Average at Baseline
Age (years)	51
Female (%)	80
Average Framingham Risk Score	4.6
Average number of CVD Risk Factors	3.7
Smoker	16
Blood Pressure (mmHg)	135/87
LDL (mg/dL)	97
A_{1c} (%)	9.4
Weight (kg)	95
BMI (kg/m^2)	34
Physical Inactivity (%)	85

Table 2: Risk Factor Assessment

Characteristic	Average at Baseline	Average at Study Completion	Mean Difference	P-Value	95% Confidence Interval
Total number of CVD Risk Factors	3.7	3.1	0.68	<0.001	0.49, 0.87
Systolic Blood Pressure (mmHg)	135	126	8.19	0.009	2.1, 14.28
Diastolic Blood Pressure (mmHg)	86.9	80.3	6.51	<0.001	3.63. 9.39
A_{1c} (%)	9.4	8.5	0.95	0.002	0.37, 1.53
Weight (kg)	210	208	1.79	0.089	-0.28, 3.87
BMI (kg/m^2)	34	34	0.21	0.346	-0.23, 0.66
LDL (mg/dL)	97	94	2.65	0.283	-2.72, 7.58