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A collaborative cardiologist-pharmacist care model to improve hypertension management in patients with or at high risk for cardiovascular disease

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ABSTRACT
Physician led collaborative drug therapy management utilizing clinical pharmacists to aid in the medication management of patients with hypertension has been shown to improve blood pressure control. With recommendations for lower blood pressures in patients with coronary artery disease, a cardiologist-pharmacist collaborative care model may be a novel way to achieve these more rigorous goals of therapy.

Objective: The purpose of this project was to evaluate this type of care model in a high cardiac risk patient population.

Methods: A retrospective cohort study determined the ability of a cardiologist-pharmacist care model (n=59) to lower blood pressure and achieve blood pressure goals (<130/80 mmHg) in patients with or at high risk for coronary artery disease compared to usual cardiologist care (n=58) in the same clinical setting.

Results: The cardiologist-pharmacist care model showed a higher percentage of patients obtaining their goal blood pressure compared to cardiologist care alone. 49.2% versus 31.0% respectively, p=0.0456. Greater reductions in systolic blood pressure (-22 mmHg versus -12 mmHg, p=0.0077) and pulse pressure (-15 mmHg versus -7 mmHg, p=0.0153) were noted in the cardiologist-pharmacist care model. No differences in diastolic blood pressure were found. There was a shorter duration of clinic follow-up (7.0 versus 13.2 months, p=0.0013) but a higher frequency of clinic visits (10.7 versus 3.45, p<0.0001) in the cardiologist-pharmacist care model compared to usual care. The number of antihypertensive agents used did not change over the time period evaluated.

Conclusion: This study suggests a team-based approach to hypertensive care using a collaborative cardiologist-pharmacist care model improves blood pressure from baseline in a high cardiac risk patient population and was more likely to obtain more stringent blood pressure goals than usual care.

It has been suggested that team-based approaches to the delivery of health care where physicians work collaboratively with allied health care professionals can significantly improve quality of care and clinical outcomes.\textsuperscript{3,10} In the summer of 2007 a cardiologist of the Texas Tech University Health Sciences Center’s University Cardiology Group collaborated with two faculty members of the Texas Tech University Health Sciences Center School of Pharmacy’s Ambulatory Care Division and initiated a physician-pharmacist collaborative practice model to facilitate the cardiologist’s care of patients with CAD or at high risk for CAD whose blood pressure was not optimally controlled. The intention of this model was to utilize the clinical pharmacist, under indirect supervision, in the more routine chronic disease / medication management of HTN the cardiologist would otherwise have to provide. This care model allows the physician to increase their time and focus on more acute and / or complex patient care issues. The objective of this study was to document the quality of care of this practice model and compare it to usual care in the same cardiology clinic in patients with HTN who have no clinical pharmacy intervention.

**METHODS**

**Clinical Practice Description**

At the time of this study, the TTUHSC’s University Cardiology Group included four full time cardiologists with clinical responsibilities for both in-patient and out-patient care. They all shared the same out-patient clinical facilities and staff. Only one of these physicians was involved in the collaborative practice model with the clinical pharmacists in the clinic. The other three physicians had their own separate established patients and received no clinical pharmacy services in the management of their patients with HTN. The cardiologist participating in the collaborative care model referred his patients with HTN to the HTN service at his discretion. The collaborative HTN service was staffed by two clinical pharmacists. The pharmacists shared the same clinical responsibilities and the same patients referred by the cardiologist and each separately staffed the service one morning a weekly basis. The primary concept of the cardiologist-pharmacist practice model was to optimize HTN medication management to improve blood pressure control through scheduled patient clinic appointments with clinical pharmacists. It was agreed upon between the cardiologist and pharmacists to use the blood pressure goal, if tolerated, of <130/80 mmHg for patients with established CAD or at high risk for such based on current guidelines at the time the service was implemented.\textsuperscript{2} Through written collaborative practice agreements, the pharmacists would adjust the drug regimens of patients on behalf of the physician by adding, deleting, or changing HTN medications, change dosages of existing HTN medications, obtain appropriate laboratory measurements when needed, provide limited physical assessment, and educate referred patients in an attempt to reach goal blood pressure goals (<130/80 mmHg) for this population high risk for such and set more stringent blood pressure medications necessary to obtain these goals and it is unknown how many patients remain above this goal despite antihypertensive therapy. This potential increase in medication use can influence patient adherence to drug therapy, increase the risk for medication related adverse effects or drug-drug interactions, and increase drug costs. This potential drawback to increased treatment to improve blood pressure control highlights the need for better vigilance on behalf of health care professionals and providers.
pressures. Patients could object to being cared for with this model and were simply deferred back to the referring cardiologist for follow-up of the HTN therapy. No specific formulary or algorithms were used by the clinical pharmacists. Rather, the pharmacists used their clinical judgment on a patient by patient basis on how best to optimize their HTN care. They had designated clinic space with their own clinic schedule and appointments to the HTN service were scheduled separate from the referring cardiologists and managed solely by the clinical pharmacists. The pharmacists had the autonomy in their decision making and were not required to obtain prospective approval from the cardiologist prior to implementing changes in patient HTN medications. The collaborating cardiologist would be consulted if alterations in other medications beyond HTN medications were recommended or as issues arose that were outside the pharmacists’ scope of practice. Documented patient encounters could be retrospectively reviewed by the cardiologist at any time but no specific frequency was delineated. The frequency of clinic or blood pressure assessment and scheduled follow-up appointments was left to the cardiologist’s or pharmacists’ discretion based on blood pressure control and adverse events. When changes to HTN medications were made in the HTN service due to poor BP control or other issues, subsequent follow-up visits were scheduled within 1-4 weeks depending on the clinical situation. If patients were found to be at their goal BP and without other complications related to their HTN therapy, they were scheduled for follow-up with the service in three months. In an effort to remain a productive and viable service, once blood pressure was determined to be under control during at least two follow-up visits to the service and subsequently maintained for several months the patients could be discharged from the care model and the patients resumed usual care with the referring cardiologist. The decision for discharge was discussed and agreed upon between the pharmacist and patient.

Study Design and Patient Identification

This study was approved by the Texas Tech University Health Sciences Center Institutional Review Board. This study was a retrospective cross-sectional study and conducted by medical chart review. Two separate groups of patients were identified, each with established CAD (or significant CAD risk equivalents, defined below) and uncontrolled blood pressure: 1) patients referred by the cardiologist to the clinical pharmacists for HTN management between July 2007 and April 2010 (experimental group) and 2) patients of the other cardiologists in the same clinic not referred to the HTN service during the same period (control group). Patients in the collaborative practice model were selected from an established list of patients referred by the collaborating cardiologist to the HTN clinic. All patients in the experimental group meeting the below inclusion/exclusion criteria were enrolled into the study and not randomly selected. The volume of patients enrolled in the practice model did not allow for adequate randomization. Patients in the control group meeting the same inclusion/exclusion criteria were identified by database query of the clinic’s appointment and billing system for patients of the University Cardiology group with ICD-9 codes consistent with CAD and randomly selected for review. No educational or clinical interventions regarding blood pressure goals, guideline updates, or HTN medication management were provided by the clinical pharmacists to the control group cardiologists.

Inclusion Criteria

Inclusion criteria for medical chart review were: a documented history of established coronary heart disease (defined as a history of myocardial infarction, coronary artery bypass graft surgery, angioplasty, coronary stent placement, stable angina, a cardioangiogram showing at least 50% stenosis of any major coronary artery, or a significant CAD risk equivalent [diabetes, carotid artery stenosis, or peripheral arterial disease]), a baseline systolic blood pressure greater than 135 mmHg during at least one clinic visit during the period of review, age between 40-85 years, established care with a physician of the TTUHSC University Cardiology Group for at least three months during the time period between July 2007 (the start of the HTN service) and April 2010, and a minimum of two visits with the clinical pharmacists in the experimental group or two visits with the cardiologist in the control group during the study time frame.

Exclusion Criteria

Exclusion criteria included a documented history of systolic heart failure (documented ejection fraction less than 40%), significant renal disease (defined as a creatinine clearance less than 30 ml/min), or documented consistent nonadherence with scheduled clinic appointments in either group (defined as <70% compliance with schedule clinic appointments during the period of review).

Outcomes

The primary outcome assessed was the difference within and between the two groups in percentage of patients who have obtained a blood pressure <130/80 mmHg at the last documented clinic visit within the time frame evaluated. Other secondary outcomes include changes in systolic, diastolic and pulse pressure from baseline, number of blood pressure medications used, pulse pressures, duration of study follow-up, and number of clinic appointments or documented blood pressure assessments (outside of scheduled appointments) during the time of follow-up.

Data collection and analysis

The retrospective chart review occurred in the spring of 2010. Data in both groups were collected at the earliest time within the above mentioned time frame though the initial date for each patient varied depending on when they were referred to the HTN service for the experimental group or when they established care with the control group physicians if that occurred after July 2007. Data collection on individual patients was completed after two years.
consecutive blood pressures were at goal. For patients who did not reach the pre-specified goal, data collection continued until April of 2010. Data were evaluated with the Excel statistics add-on package Analyze-it v 2.07 ©1997-2007, Analyze-it Software, Ltd., Leeds, England, United Kingdom. The continuous data were evaluated with the Shapiro-Wilk test for normality and all were non-parametric therefore all central tendencies are presented as medians and 95% confidence intervals. The 95% confidence intervals of the medians were calculated by the binomial method. Mann Whitney U, Kruskal Wallis, and Wilcoxon Signed Rank tests were utilized for continuous data and Pearson Chi Square and Fisher’s Exact Tests for nominal data as appropriate. Alpha level of significance was set at 0.05.

RESULTS
A total of 58 subjects were included in the control group and 59 in the experimental group (Table 1). The groups were well matched in age, gender and pulse pressure. Baseline median systolic blood pressure was identical in both groups (148 mmHg), median diastolic blood pressures and pulse pressure were similar and not statistically different between the two groups. The experimental group included fewer white patients but significantly more Hispanic and black subjects. The majority of subjects in both groups had established CAD and diabetes mellitus was the most common CAD risk equivalent. Overall the number of subjects with diabetes regardless of CAD status was higher in the experimental group (49% vs 36% respectively) and may explain the high percent of patients receiving ACE-inhibitor therapy. The median number of medications at baseline was significantly higher in the experimental group. No changes implemented by the clinical pharmacists were overturned by the supervising cardiologist.

The median duration of follow-up was nearly 50% shorter in the experimental group compared to the control group while the frequency of patient visits or blood pressure assessments per year was greater than two fold higher in the experimental group over the study period. The experimental group showed a significantly higher percent of patients obtaining the goal blood pressure of <130/80 mmHg at the last recorded clinic visit / blood pressure assessment (49.2% versus 31.0% in the control group, p=0.0456). Systolic blood pressure decreased over the study period significantly in both groups (-12 mmHg in the control group, -22 mmHg in the experimental group) but was significantly lower in the experimental group (p<0.0077) (Table 1). The percent of subjects with a systolic blood pressure <130 mmHg at the final visit or assessment was statistically higher in the experimental group compared to the control group. While the median diastolic blood pressure decreased in both the control and experimental groups (-5 mmHg and -10 mmHg respectively) it was only statistically different from baseline in the experimental group (p<0.001). There was no significant difference in diastolic blood pressure between groups at the final assessment. The median number of medications used did not change from baseline in either group though there was a larger percent of patients in the experimental group receiving three or more blood pressure medications (Table 3). The median pulse pressure decreased significantly in both groups (-12 mmHg in the experimental groups and – 7 mmHg in the control group) but was significantly lower in the experimental group compared to the control at the final visit (p=0.0153).

Table 1: Baseline patient characteristics

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Experimental</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>58</td>
<td>59</td>
</tr>
<tr>
<td>Age (year, median)</td>
<td>72</td>
<td>70</td>
</tr>
<tr>
<td>Gender (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>62.1</td>
<td>57.6</td>
</tr>
<tr>
<td>Female</td>
<td>37.9</td>
<td>42.4</td>
</tr>
<tr>
<td>Race (%)</td>
<td></td>
<td></td>
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<tr>
<td>White</td>
<td>77.8</td>
<td>47.4 *</td>
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<tr>
<td>Black</td>
<td>0.0</td>
<td>15.2</td>
</tr>
<tr>
<td>Hispanic</td>
<td>22.2</td>
<td>37.3</td>
</tr>
<tr>
<td>Systolic BP (median mm Hg)</td>
<td>148</td>
<td>148</td>
</tr>
<tr>
<td>Diastolic BP (median mm Hg)</td>
<td>75</td>
<td>78</td>
</tr>
<tr>
<td>Pulse pressure (median mm Hg)</td>
<td>74</td>
<td>73</td>
</tr>
<tr>
<td>Cardiovascular Disease (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Established CAD</td>
<td>87.9</td>
<td>78.0</td>
</tr>
<tr>
<td>Diabetes</td>
<td>8.6</td>
<td>22.0</td>
</tr>
<tr>
<td>Peripheral Artery Disease</td>
<td>3.4</td>
<td>0.0</td>
</tr>
<tr>
<td>Diabetes with or w/o established CAD (%)</td>
<td>36.2</td>
<td>49.1</td>
</tr>
<tr>
<td>Number of antihypertensive agents (median)</td>
<td>2.0</td>
<td>3.0 *</td>
</tr>
<tr>
<td>Antihypertensive Medications (%)</td>
<td></td>
<td></td>
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<tr>
<td>Thiazide diuretic</td>
<td>20.7</td>
<td>40.7 *</td>
</tr>
<tr>
<td>Calcium Channel Blocker</td>
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<tr>
<td>Beta-blocker</td>
<td>55.2</td>
<td>89.8 *</td>
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<tr>
<td>ACE-Inhibitor</td>
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<td>ARB</td>
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<tr>
<td>Direct Renin Inhibitor</td>
<td>0.0</td>
<td>13.5</td>
</tr>
<tr>
<td>Other</td>
<td>13.8</td>
<td>15.2</td>
</tr>
</tbody>
</table>

* = statistical difference between groups (p<0.02)

CAD = Coronary artery disease, ARB = Angiotensin Receptor Blocker

DISCUSSION
Pharmacists have many roles in improving HTN-related outcomes through various methods including patient counseling, blood pressure
screening, blood pressure monitoring, providing recommendations to providers, and collaborative drug therapy management.12-17 This last method of intervention aids a physician’s care of patients through direct patient contact and pharmacist management in the clinic setting to optimize drug therapy in an effort to better meet treatment goals. While the literature has examples that show the benefits of collaborative physician-pharmacist care of patients with high blood pressure,13,17-20 little data is available in patients with established CAD21 and none have been published in this patient population using the more stringent AHA recommendations.

This study examined the potential benefit in blood pressure control of using a cardiologist-pharmacist care model in patients with established or at high risk for CAD. The care model was associated with significant improvements from baseline in systolic, diastolic blood, and pulse pressure. When compared to cardiologist care within the same clinic setting, the cardiologist-pharmacist model was more likely to get patients to an aggressive goal blood pressure. The frequency of clinic visits or blood pressure assessments was higher in the cardiologist-pharmacist care model than usual care while the median quantity of medications used to treat blood pressure was not different over the study period.

It is likely the higher frequency of clinic visits or blood pressure assessments had an influence on the differences observed between the two groups. A higher frequency of encounters is associated with faster blood pressure reductions and earlier control but may not be feasible in many clinic settings.22 Since this collaborative clinic model discharged patients from further follow-up with the clinical pharmacists after they obtained and maintained blood pressure control this may explain the shorter duration of follow-up in the experimental compared to the control group. It should also be noted the experimental group had a higher percentage of African-American subjects and patients receiving numerous blood pressure medications. Both potentially more difficult to control patient populations but this did not seem to affect the ability to reduce systolic blood pressure. Neither the frequency of clinic visits nor dosage adjustments of medications were controlled for in the data analysis.

The particular care model used in this study specifically used the AHA goal of <130/80 mmHg rather than other US guideline goals. The differences in blood pressures at the final blood pressure assessment may have been influenced by cardiologist preference of goal pressures. For a variety of reasons the cardiologists in the control group may not have accepted the more stringent proposed goals. Position statements that recommend more stringent goals for patients with established CAD or at risk for such do not appear to derive this goal from specific prospective, randomized studies evaluating one blood pressure goal versus another.5,7,8 Rather the goals are derived primarily from epidemiological studies. A review of the literature assessing HTN trials suggests there is no clear benefit of reducing blood pressures <135/85 mmHg compared to <140/90 mmHg.23 Recent data from prospective studies in diabetes with or without CAD also question the
need for more aggressive blood pressure control and at least one organization has retracted their more stringent goal. In addition to this, the cardiologists in the control group may not have aggressively treated the blood pressures observed during scheduled clinic appointments but recommended the patients to consult with their primary care physician instead. The reasons for not increasing antihypertensive therapy in either group for uncontrolled blood pressures were not evaluated.

Reviews of the literature evaluating quality improvement strategies in HTN management suggest the addition of other health care personnel, in particular pharmacists, to a physician-led team is associated with significant improvements in blood pressure control. Today’s pharmacists with their extensive knowledge in medications and therapeutics combined with essential patient care training make them a logical choice for clinic collaboration with physicians. Shared HTN management between pharmacists and physicians has been shown to improve blood pressure control using a variety of techniques or care models. In the community pharmacy setting, pharmacists can help physicians through various activities including, but not limited to, screening patients with or without hypertension to identify those with uncontrolled BPs, provide patient education, assess HTN medication adherence, and review medication regimens for agents that may adversely affect a patient’s BP. Other models have utilized pharmacists in initiating home BP monitoring and informing patients’ physicians when BPs were not optimally controlled and deliver therapeutic recommendations. Other roles for pharmacists in HTN management have been described in more detail in the literature.

Several controlled studies have documented that pharmacists working jointly with physicians in the clinical setting and making drug therapy recommendations leads to significant blood pressure reductions and most often obtaining blood pressure goals over usual care. When allowed to make appropriate changes in antihypertensive medications through collaborative drug therapy management, controlled studies have also shown pharmacists improve control and increase the ability to reach blood pressure goals. Most of these studies, however, have been focused on essential hypertension or are collaborative models in general or primary care clinics. McConnell et al evaluated a pharmacist-managed, physician-supervised care model using interventions both in-person or by telephone to control blood pressure in patients with CAD and uncontrolled hypertension. The mean age and baseline systolic blood pressures observed in that study were very similar to our own. They found a greater than 16 mmHg decrease in systolic blood pressure from baseline and gained control in 47.6% of subjects which is similar to the control we were able to obtain. This particular study did not have a control group for comparison.

Novel patient care models such as the one used in this study may be cost effective. Using pharmacists as mid-level providers for more routine disease / drug therapy management costs significantly less from a salary perspective than physician time performing similar duties. By taking responsibility for the more routine management of some aspects of patient care, the physician has more time to focus on more complex or acute patient care activities. The cost effectiveness of this type of model in cardiology clinics has not been evaluated and was not assessed in this study. However, Okamoto et al in a prospective, randomized study comparing pharmacist-managed HTN care to physician-managed care found the cost effectiveness ratios per mmHg decrease in both systolic and diastolic blood pressure were significantly less in the pharmacist-managed model.

Our current study has several limitations. First, its retrospective cohort design is not as robust as a prospective, randomized study. The latter study design is difficult to implement in the average clinical setting. The results of our data may also be skewed by the exclusion of subjects with too few patient care visits or poor compliance with clinic appointments. Also, one group of patients, the control group, was randomly selected while the other group was not. This was due to the overall number of patients seen in the cardiologist-pharmacist care model who fit the inclusion criteria was not of a sufficient volume to adequately randomize. In addition and for reasons mentioned above, there was no specific goal blood pressure expected of the cardiologists in the control group and as such is not an ideal control. Lastly, this study focused on surrogate markers of disease rather than concrete clinical outcomes. It is anticipated that improved blood pressure and pulse pressure control in the cardiologist-pharmacist care model will reduce subsequent or initial CAD events but this has not been evaluated.

Finally, there are numerous challenges in establishing a clinical service and research project such as this. From a clinical standpoint, it is essential to work within a legal and institutional scope of practice and that varies significantly from state to state and within various institutions. Another hurdle is establishing appropriate relationships with the physicians and other healthcare professionals in the clinical setting. The various professionals must agree on the initiation and management of clinical pharmacy services in this setting and work together to understand and appreciate the various roles each provider has in patient care. The pharmacists and cardiologist in this clinical service agreed upon the more aggressive BP goal for both the clinical service as well as the research project. Setting specific goals of therapy is crucial to any collaborative practice such as this. However specific goals are rather black and white and clinicians are often faced with treating patients who are more or less complex than the average patient in a particular clinic setting and treatment must be individualized. In this service and research project the patient characteristics are quite complex and adds to the difficulty in making clinical decisions to optimize hypertension control. The patients in this study either had a history of CAD or presented with
multiple other comorbidities. They were also older on average and already receiving two or more medications to treat their high BP. Given the age and complexity of the patients being aggressive with BP goals and implementing additional medication management to obtain those goals is not without risk for such things as hypotension, electrolyte abnormalities, and medication adherence issues to mention a few.

From a research standpoint there are other challenges to overcome as well. This study would have more robust if it were designed to be prospective and randomized to either a cardiologist or a cardiologist/pharmacist team. However it is difficult in the normal clinic setting to design such studies and often times retrospective analysis despite its potential flaws is easier to accomplish. Even if a retrospective approach is taken, finding an adequate control group for comparison is also difficult for reasons mentioned above.

**CONCLUSIONS**

Pharmacists have many roles in helping to optimize the treatment and management of hypertension. Using collaborative drug therapy management is one role pharmacists can play in working as a team with physicians to improve blood pressures and obtain goal blood pressures in both essential hypertension as well as those with existing CAD.

More stringent goals for blood pressure control has several implications that increase the risk for problems with adherence, adverse events, contraindications, and medications costs. This is the first study to document the effectiveness of a cardiologist-pharmacist care model to control hypertension in patients with or at high risk for CAD using more stringent blood pressure goals and comparing that control to usual care within the same clinic setting.

**ACKNOWLEDGEMENTS**

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**CONFLICT OF INTEREST**

This data has been presented in poster/abstract form at the 2010 Annual Seminar of the Texas Society of Health System Pharmacists in Galveston, TX April 2010 and at the 2010 Annual Meeting of the American College of Clinical Pharmacy in Austin, TX October 2010.

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References