Primary Care–based, Pharmacist–physician Collaborative Medication-therapy Management of Hypertension: A Randomized, Pragmatic Trial

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ABSTRACT

Purpose: A collaborative pharmacist–primary care provider (PharmD-PCP) team approach to medication-therapy management (MTM), with pharmacists initiating and changing medications at separate office visits, holds promise for the cost-effective management of hypertension, but has not been evaluated in many systematic trials. The primary objective of this study was to examine blood pressure (BP) control in hypertensive patients managed by a newly formed PharmD-PCP MTM team versus usual care in a university-based primary care clinic.

Methods: This randomized, pragmatic clinical trial was conducted in hypertensive patients randomly selected for PharmD-PCP MTM or usual care. In the PharmD-PCP MTM group, pharmacists managed drug-therapy initiation and monitoring, medication adjustments, biometric assessments, laboratory tests, and patient education. In the usual-care group, patients continued to see their PCPs. Participants were aged ≥18 years, were diagnosed with hypertension, had a most recent BP measurement of ≥140/≥90 mm Hg (≥130/≥80 mm Hg if codiagnosed with diabetes mellitus), were on at least 1 antihypertensive medication, and were English speaking. The primary outcome was the difference in the mean change from baseline in systolic BP at 6 months. Secondary outcomes included the percentage achieving therapeutic BP goal and the mean changes from baseline in diastolic BP and low- and high-density lipoprotein cholesterol.

Findings: A total of 166 patients were enrolled (69 men; mean age, 67.7 years; PharmD-PCP MTM group, n = 75; usual-care group, n = 91). Mean reduction in SBP was significantly greater in the PharmD-PCP MTM group at 6 months (–7.1 [19.4] vs +1.6 [21.0] mm Hg; $P = 0.008$), but the difference was no longer statistically significant at 9 months (–5.2 [16.9] vs –1.7 [17.7] mm Hg; $P = 0.22$), based on an intent-to-treat analysis. In the intervention group, greater percentages of patients who continued to see the MTM pharmacist versus those who returned to their PCP were at goal at 6 months (81% vs 44%) and at 9 months (70% vs 52%). No significant between-group differences in changes in cholesterol were detected at 6 and 9 months; however, the mean baseline values were near recommended levels. The PharmD-PCP MTM group had significantly fewer PCP visits compared with the usual-care group (1.8 [1.5] vs 4.2 [1.0]; $P < 0.001$).

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Implications: A PharmD-PCP collaborative MTM service was more effective in lowering BP than was usual care at 6 months in all patients and at 9 months in patients who continued to see the pharmacist. Incorporating pharmacists into the primary care team may be a successful strategy for managing medication therapy, improving patient outcomes and possibly extending the capacity of primary care. ClinicalTrials.gov identifier: NCT01973556. (*Clin Ther.* 2014;36:1244–1254) Published by Elsevier HS Journals, Inc.

Key words: collaborative care, hypertension, medication-therapy management, MTM, pharmaceutical care, pharmacist.

INTRODUCTION

Achieving blood pressure (BP) control is challenging for busy primary care providers (PCPs) and may become even more so because it is predicted there will be a shortage of 52,000 PCPs in the United States by 2015.[1] Pharmacists are an underutilized resource for extending the capacity of primary care with regard to medication-therapy management (MTM). In December 2011, the US Surgeon General released a letter supporting the greater involvement of pharmacists in patient care teams, stating, "policy makers should further explore ways to optimize the role of pharmacists to deliver a variety of patient-centered care and disease prevention, in collaboration with physicians or as part of the health care team."[2] In September 2013, the American College of Physicians issued a position paper that specifically included clinical pharmacists in the definition of *clinical care team*.[3] Evidence of favorable outcomes associated with the inclusion of pharmacists on the care team was reported in a systematic review of 298 studies and meta-analyses conducted using the outcomes of hemoglobin A1c and low-density lipoprotein cholesterol (LDL-C) concentrations, BP, and adverse events.[4] The review included data from studies of pharmacists who provided an array of MTM services, collaborative with physicians and stand-alone, in many settings (eg, inpatient hospitals, community pharmacies, outpatient clinics, emergency departments) and in many different types of patients (eg, those with diabetes, hypertension, asthma). A limitation of the report was that only a small percentage (7%) of the 298 studies were randomized controlled trials (RCTs).

Our literature review yielded 10 RCTs using a collaborative pharmacist–physician team approach in MTM in patients with hypertension.[5–14] The inclusion criteria varied, targeting different patient groups: patients using specific high-cost antihypertensive medications,[6] high-risk patients (ie, a large number of medications, doses per day, or medication changes, and/or poor adherence),[7] and patients with uncontrolled hypertension (with varying criteria on systolic and diastolic BP [SBP and DBP, respectively]).[5,8–14] The durations of intervention also varied, from 6 months (n = 5),[5,6,10–12] to 9 months (n = 1),[9] to 12 months (n = 4).[7,8,13,14] Despite these variances, all of the studies reported reductions in SBP and DBP that were greater with the team approach compared with usual care (range of mean differences: SBP, 5.5–12 mm Hg; DBP, 1.8–6.7 mm Hg). The between-group differences in the percentages of patients at BP goal ranged from 18% to 64%. Although pharmacists were integrated into the patient care team in each study, the role of the pharmacists differed. In 3 studies,[12–14] pharmacists independently initiated and changed medication therapy (with various levels of oversight and participation by the physician). Seven of the studies[5–11] included pharmacists only in an advisory role, that is, making recommendations on medication-therapy changes to physicians. Only 1 study involved the new implementation of a pharmacist into the patient-care team[7]; all others were conducted in environments with preexisting pharmacists' services.

A collaborative pharmacist–physician team model in which pharmacists independently initiate and change medication therapy and see patients at office visits separate from those with the PCP might result in time savings for PCPs as well as improved patient outcomes. However, little is known about this model that would be a likely scenario for many organizations wishing to newly integrate pharmacists into the care team for the treatment of hypertension.

We conducted a randomized, pragmatic trial examining the outcomes and processes of initiating and integrating a pharmacist–physician team model, with the pharmacist having ability to initiate and change medication therapy for the management of uncontrolled hypertension within a university-based internal medicine medical group. Our primary objective was to examine BP control in hypertensive patients who were collaboratively managed by a newly formed pharmacist–physician team versus those who were managed by solely their PCPs, over a 9-month period.