Pharmacy-Based Intervention Improves Medication Adherence and Chronic Disease Outcomes

Lee JK, Grace KA, Taylor AJ. Effect of a pharmacy care program on medication adherence and persistence, blood pressure, and low-density lipoprotein cholesterol: a randomized controlled trial. JAMA 2006;296:2563–71.

Study Overview

Objective. To evaluate the effectiveness of a comprehensive pharmacy-based program to improve blood pressure (BP) and hyperlipidemia medication adherence.

Design. Single-center, multiphase, prospective study.

Setting and participants. Patients aged ≥ 65 years who were taking at least 4 chronic medications daily and living independently were recruited from the Walter Reed Army Medical Center. The study had 3 sequential phases: a 2-month run-in (n = 200), a 6-month uncontrolled intervention (phase 1; n = 174), and a 6-month randomized controlled study (phase 2; n = 159) in which patients were randomized to continued intervention or return to usual care (total study duration, 14 months). The intervention consisted of individualized medication education (1 hr at baseline and 30 min thereafter), use of a medication adherence aid (blister packs), and follow-up with a clinical pharmacist every 2 months.

Main outcome measures. The primary endpoint for phase 1 was the change in medication adherence from run-in to 8 months, measured by pill counts (percentage of pills taken); secondary outcomes were changes in BP and low-density lipoprotein (LDL) cholesterol. The primary endpoint for phase 2 was persistence of medication adherence.

Main results. Medication adherence significantly improved from 61.2% (standard deviation [SD], 13.5%) at baseline to 96.9% (SD, 5.2%) after completion of phase 1 (P < 0.001). After phase 2, the continued intervention group maintained an adherence rate of 95.5% (SD, 7.7%), whereas the usual care group's adherence rate declined to 69.1% (SD, 16.4%; P < 0.001). Among participants being treated for hypertension, mean systolic BP decreased 3.3 mm Hg at the end of phase 1 (baseline BP, 133.2 mm Hg; P < 0.02); at the end of phase 2, mean systolic BP decreased 6.9 mm Hg in the continued intervention group versus 1 mm Hg in the usual care group (P < 0.04). Among those being treated for hyperlipidemia, mean LDL cholesterol declined 4.8 mg/dL at the end of phase 1 (baseline LDL, 91.7 mg/dL; P < 0.001), but there was no significant difference in LDL cholesterol between the continued intervention and usual care groups at the end of phase 2.

Conclusion. A pharmacy-based intervention using patient education, blister packaging, and frequent intensive follow-up substantially improved medication adherence for chronic illness; clinically meaningful reductions in BP and LDL cholesterol were also achieved. However, these effects did not persist after the intervention was withdrawn.

Commentary

Suboptimal adherence to chronic medications, particularly medications for cardiovascular disease, represents a significant source of morbidity, mortality, and cost. Estimates of statin adherence suggest that more than half of new patients started on a statin will be nonadherent after 1 year [1]. A similarly high rate of medication nonadherence has been reported in patients being treated for other diseases with long asymptomatic periods, such as hypertension and diabetes [2]. Unfortunately, interventions aimed at reducing medication nonadherence have been only marginally effective [3].

The study by Lee and colleagues (the FAME [Federal Study of Adherence to Medications in the Elderly] trial) represents a potentially significant step in the effort to improve medication adherence. The authors' approach used a 3-level intervention involving intensive patient education and follow-up by trained clinical pharmacists along with use of blister packaging for all medications. The result was an impressive achievement of nearly perfect (96.9%) adherence after 6 months. However, the adherence rate quickly returned close to baseline in the group randomized to return to usual care.

Although these results are encouraging, there are several important limitations that must be noted. The population studied is atypical, considering that the trial was conducted in a military setting and that 200 of 208 patients approached agreed to enroll. More importantly, the usual care group no longer received frequent follow-up, and this lower level of attention is a significant source of bias and limits the interpretation of the intervention's efficacy. The lack of a guiding

theoretical model and process measures inhibits meaningful insight into the impact of each intervention component and how these components might be integrated into other interventions.

Applications for Clinical Practice

This study establishes a proof of concept that in the right setting and with intensive efforts, a persistent and important clinical problem can be ameliorated. Although blister packaging and intensive follow-up may be impractical, elements of these intervention components can be tailored and incorporated into daily practice.

—Review by Devin M. Mann, MD, MS (Mount Sinai School of Medicine, New York, NY), and Salomeh Keyhani, MD, MPH

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