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Original Research Article

A Randomized Clinical Trial to Evaluate Hypertension Control and Medication Adherence in Elderly Patients

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Abstract:

Background: High blood pressure is common in the older adult community and a major contributor to cardiovascular disease. There continues to be a significant barrier to achieving appropriate blood pressure (BP) control with adherence to medications.

Objectives: To assess the efficacy of a multicomponent intervention that involves the combination of EHR-based adherence alerts and team-based care for medication adherence and blood pressure control in elderly adults.

Methodology: A 12-months pragmatic, cluster-randomized controlled trial took place in Patna Medical College and Hospital, India, recruiting 400 patients ≥60 years old with uncontrolled hypertension and poor medication adherence (PDC <80%). Clinics were cluster-randomized to receive the intervention group with the TEAMLET program or the control group with usual care. Primary outcome was change in medication adherence (PDC); secondary outcome was changed in systolic BP. Data analysis was done using generalized linear mixed-effects models.

Results: Baseline characteristics were evenly split between groups. Mean PDC increased similarly in the two groups by 12 months (18.5% vs 18.2%; p = 0.94) and systolic BP decreased similarly (−11.6 vs −12.2 mmHg; p = 0.38). High patient activation on barrier questionnaires (79%) resulted but provider utilization of intervention tools was low (10–12%), and this presumably constrained clinical effects.

Conclusion: The TEAMLET intervention failed to significantly increase adherence to medications or BP control relative to usual care, a testament to the difficulty of translating process-level interventions to clinical end points in frail elderly patients.

Keywords: Hypertension, Elderly, Medication adherence, Blood pressure control, Randomized clinical trial, EHR-based intervention.

Introduction

Hypertension is the most common worldwide chronic disease and a top cause of cardiovascular morbidity and mortality, particularly in elderly individuals. Despite the efficiency of the current antihypertensive medications, optimal blood pressure (BP) is attained in fewer than half of the hypertensive patients. Nonadherence to medication—is the aspect of failure to take medications according to their prescription—is a key limitation for the attainment of target BP levels and the avoidance of related cardiovascular complications. Medication nonadherence has been found again and again to be prevailing in almost half of the hypertensive patients and a top cause of suboptimal blood pressure control [1,2].

Inadequate medication adherence is associated with a significantly increased risk of cardiovascular events, admissions to hospitals, and all-cause mortality. For example, a certain study estimated that a 15% increase in adherence to antihypertensive medication would result in a 9% drop in the number of stroke occurrences and a 7% reduction in the mortality rate [3]. These findings emphasize the substantial impact of even small levels of adherence on clinical endpoints for the broader population. However, medication adherence is a complicated problem that is impacted by various factors that include patient behavior, treatment regimen intensity, medication side effects, sociodemographic variables, and systemic weaknesses in the healthcare delivery system. [5].

In spite of the evidence that physician counseling and patient education improve medication adherence, their establishment in regular clinical practice remains limited. Physicians are ignorant of the inadequacy of their patients' adherence to antihypertensive treatment for over half the time [5]. Opportunities for intervention are thereby frequently ignored. Moreover, even when adherence issues are acknowledged, healthcare practitioners are often denied sufficient time to carry out extensive counseling and shared decisions with their patients [6]. Increasing complexity of clinical work and the limitation of time for appointments make adherence counseling a significant challenge in primary care settings.

In recent years, developments in health information technology have brought new potential for the improvement of medication adherence by integrating and automating data. Integration of the electronic health records (EHRs) and the dispensing systems of pharmacies has brought the possibility of real-time measurement of medication adherence at the point of care. Significantly, the composite EHR–pharmacy data are in a position to determine whether or not a patient has consistently filled prescribed medications—a reasonable and functional proxy for medication adherence [7]. This technology gives early warning for adherence pitfalls that could otherwise go undetected and thereby permits clinicians and caregiving teams to intervene sooner.

The TEAMLET (Putting EHR Technology and Team Care to Work for Medication Adherence) intervention illustrates a new approach to the management of hypertension by utilizing integrated data systems and models of collaborative care. Specifically, this intervention used interconnected EHR and pharmacy data to automatically alert PCPs and NPs when a patient was noted to have uncontrolled blood pressure and signs of medication nonadherence at the point of care [8]. By providing clinicians with actionable information at the time of the patient encounter, the intervention sought to close the gap between having the data and applying it to clinical management.

To address barriers to clinician time and bandwidth, TEAMLET had an EHR-enabled workflow that the intervention incorporated, in which adherence counseling and follow-up were delegated to a team of staff members [9,10]. A team-based care model aligns with current approaches to chronic disease management that are designed around the work of a team-based approach consisting of physicians, nurses, pharmacists, and others to maximize treatment outcomes. By employing EHR data, automation, and structured communication approaches, TEAMLET sought a sustainable approach to adherence and BP control applicable across varied clinical contexts.

Earlier research has shown the potential benefit of health information technology and multidisciplinary approaches for improving medication adherence. However, there are relatively few randomized clinical studies to evaluate these approaches for the elderly population who is at the greatest risk for both hypertensive events and problems related to medication adherence. Elderly adults often face other barriers including the effects of polypharmacy, cognitive impairment, physical limitation, and complex medication schedules that create havoc with adherence. It will indeed require coordinated patient-centered approaches that combine technology, effective communication, and a coordinated health care system.

This randomized clinical trial aimed to assess the efficiency of a multimodal intervention combining EHR-enhanced adherence reminders and team-based collaborative care for the enhanced management of hypertension and medication adherence in older adults. By testing this intervention against standard care controls, the research tries to generate evidence for the hypothesis that such a structured, technology-enhanced, and team-based intervention may generate superior clinical and behavioral outcomes in this high-risk population.

Methodology

Study Design: This study is a pragmatic, two-arm, cluster-randomized clinical trial conducted to evaluate the effectiveness of a multicomponent intervention on medication adherence and blood pressure control among elderly patients diagnosed with hypertension. The trial followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

Study Area: The study was conducted in the Department of Geriatric Medicine, Patna Medical College and Hospital (PMCH), Patna, Bihar, India.

Study Duration: The study was conducted over a period of 12 months from January 2024 to December 2024, including patient recruitment, intervention, follow-up, and data analysis phases.

Study Population: The study included older patients (aged ≥60) attending the OPD (Outpatient Department) of Geriatric Medicine at the PMCH with a clinical diagnosis of hypertension, and who were prescribed a minimum of one antihypertensive medication.

Sample Size: The estimated sample size of approximately 400 participants (200 per arm) for an 80% power to detect a 20% difference (proportion of days covered, PDC) in medication adherence between intervention and control groups, when assuming a 30% attrition rate at a 5% significance level ($\alpha = 0.05$). To reduce contamination between study groups, cluster randomization was performed at the outpatient clinic level.

Sampling and Randomization

Eligible patients were enrolled using a cluster randomization technique based on clinic days. Clinics were randomized to either:

- **Intervention group:** Received the multicomponent adherence program.
- **Control group:** Received standard care.

Randomization was computer-generated, and allocation concealment was ensured by an independent data manager.

Inclusion Criteria

Participants were included if they met the following criteria:

- Aged 60 years or older.
- Diagnosed with hypertension by a physician.
- Prescribed at least one antihypertensive medication for the past 6 months.
- Had uncontrolled blood pressure, defined as systolic ≥140 mmHg or diastolic ≥90 mmHg on two consecutive OPD visits.
- Demonstrated low medication adherence, defined as PDC < 80% over the preceding 6 months, calculated from pharmacy refill records.

Exclusion Criteria

Patients were excluded if they:

- Had severe cognitive impairment or dementia preventing informed participation.
- Had terminal illnesses (life expectancy <6 months).
- Were bedridden or institutionalized (e.g., nursing home residents).
- Were participating in another interventional clinical study.
- Refused to participate or withdraw consent at any time.

Data Collection: Data was extracted using the hospitals' electronic health record (EHR) system in combination with structured patient interviews. The major dataset consisted of demographic features (age, gender, and socioeconomic position), clinical indicators (presence of comorbidities, number of antihypertensive medications, initial blood pressure, and initial PDC), and health service utilization information. The EHR and pharmacy refill histories were combined to calculate the PDC for assessing the adherence to medication by dividing the number of days that medications that were actually dispensed covered by the total duration of the observation. Follow-up data were extracted over a period of 12 months and consisted of repeat assessments for blood pressures, new medication adherence data, and the number of subsequent clinical visits. All the data were extracted by research staff trained to remain blind to the allocations in the groups so that the possibility of information bias could be minimized.

Procedure: The intervention was developed with the Capability–Opportunity–Motivation Behavior (COM-B) framework and implemented in four major steps. First, a systematic assessment of patients with uncontrolled hypertension and poor adherence was conducted using an electronic health record (EHR)-based algorithm that flagged patients with two elevated blood pressure consecutive readings, and a proportion of days covered (PDC) less than 80%. Second, medical assistants (MAs) gave patients a brief structured questionnaire made to elicit barriers to adherence, e.g. side effects, forgetting to take medications, cost, or the complexity of the therapeutic regimen. Third, primary care physicians (PCPs) received an EHR alert that summarized the patient's barriers to adherence and provided recommended steps physicians could use to engage patients in conversations about adherence. Finally, physicians engaged in short counseling involving educational materials developed to discuss the barriers to adherence identified from the MA questionnaire.

The intervention group physicians and the medical assistants received standardized training before the onset of the trial and were focused on adherence counseling, health coaching, and the use of electronic clinical decision support (CDS) tools. On the other hand, the control group physicians received standard care that consisted of traditional hypertension management such as consultation by physicians, refill of medications, and advice on lifestyle but without any additional intervention for adherence.

Outcome Measures: The primary result of the study was the change in medication adherence, which was evaluated using the Proportion of Days Covered (PDC), from the initial assessment to the 12- Months point. The PDC was established by an analysis of antihypertensive refill prescription data extracted from the electronic health record-pharmacy connection system. An 80% or greater PDC by the 12-months point was considered to represent adequate adherence. The secondary result included the change in the systolic blood pressure (SBP) from baseline to 12 months and was reported for a continuous variable. Baseline SBP was recorded upon the initial consultation, while the follow-up reading came from the average of the final two charted outpatient measurements during the 12-months period. Other exploratory endpoints included the proportion of patients achieving the blood pressure goal threshold (<140/90 mmHg) and the number of occurrences for the follow-up clinic attendances during the course of the study.

Statistical Analysis: Data analysis was carried out using R version 4.3.0 software developed by the R Project for Statistical Computing. Descriptive statistics were used to summarize the baseline demographic and clinical features, where categorical measures were expressed as frequencies along with percentages, and continuous measures were defined as means ± standard deviations or medians ± interquartile ranges, respectively, depending on suitability. Generalized linear mixed models (GLMMs) were utilized for evaluating the change in PDC and in systolic blood pressure between the intervention and comparison groups. The models included fixed effects related to the study group, time (baseline vs. 12 months post-baseline), and interaction effects, along with random effects included at the clinic level to accommodate for the effects of clustering. Covariables that showed imbalance during baseline were controlled for in the models. The subgroup analysis was carried out according to category of age (60–74 years vs. ≥75 years), gender, and number of follow-up visits." All statistical comparisons were two-tailed, and a p-value threshold of below 0.05 was defined to indicate statistical significance.

Result

Table 1 briefly tabulates the base patient characteristics between the intervention (n = 200) and control (n = 200) groups. Mean age was matched between groups (67.6 ± 14.3 vs 66.6 ± 13.5 years). Sex breakdown was roughly evenly split but somewhat higher for females for the intervention group (54.0% vs 48.5%). Most subjects were Non-Hispanic White (51.0% intervention, 59.0% control), followed by Non-Hispanic Black or African American (24.0% vs 18.5%). Mean active medications were similarly matched (≈2.08–2.09), and insurance plans were highly Medicare or commercial. Comorbid conditions were similarly matched between groups but somewhat higher for diabetes for the controls (30.0% vs 24.5%) and somewhat higher for obesity for the intervention group (22.0% vs 20.0%). Mean PDC was 32.4% vs 34.0%, and blood pressures similarly matched (systolic 149.0 vs 148.0 mmHg, diastolic 84.7 vs 84.4 mmHg). Both groups were overall similarly matched in demographics and base clinical conditions.

Table 1: Patient-Level Baseline Characteristics

Characteristic	Intervention (n = 200)	Control (n = 200)
Age mean (SD) y	67.6 (14.3)	66.6 (13.5)
Sex No (%)		
Female	108 (54.0)	97 (48.5)
Male	92 (46.0)	103 (51.5)
Race and ethnicity		
Hispanic	22 (11.0)	17 (8.5)
Non-Hispanic Black or African American	48 (24.0)	37 (18.5)
Non-Hispanic White	102 (51.0)	118 (59.0)
Non-Hispanic other	9 (4.5)	9 (4.5)
Unknown	19 (9.5)	20 (10.0)
Active medication count mean (SD) No	2.08 (0.97)	2.09 (1.00)
Insurance No (%)		
Medicare	105 (52.5)	102 (51.0)
Commercial	79 (39.5)	82 (41.0)
Medicaid	14 (7.0)	15 (7.5)
Missing	1 (0.5)	2 (1.0)
Comorbidities		
Cerebrovascular disease	15 (7.6)	12 (6.0)
Heart failure	11 (5.7)	7 (3.5)
Dementia	3 (1.5)	2 (1.0)
Depression	13 (6.5)	11 (5.5)
Diabetes	49 (24.5)	60 (30.0)
Obesity	44 (22.0)	40 (20.0)
Peripheral vascular disease	17 (8.5)	14 (7.0)
Kidney disease and failure	22 (11.0)	21 (10.5)
Alcohol abuse	2 (1.0)	2 (1.0)
Cardiovascular disease	28 (14.0)	23 (11.5)
PDC mean (SD) %	32.4 (30.4)	34.0 (30.6)
Blood pressure mean (SD) mm Hg		
Systolic	149.0 (14.3)	148.0 (12.3)
Diastolic	84.7 (11.6)	84.4 (10.5)

Table 2 summarizes the 12-month changes in medication adherence and blood pressure between the intervention and control groups (n = 200 each). The mean change in proportion of days covered (PDC) was similar in both groups (18.5 ± 41.1 vs 18.2 ± 40.9 percentage points), with an adjusted estimate of −0.15 (95% CI −4.06 to 3.76, p = 0.94), indicating no significant difference. The proportion of patients achieving PDC ≥80% was also comparable (35.0% vs 37.0%, OR 1.03, 95% CI 0.63–1.69, p = 0.89). Similarly, systolic blood pressure decreased from baseline in both groups (−11.6 ± 17.8 vs −12.2 ± 16.8 mmHg), with an adjusted difference of 0.75 mmHg (95% CI −0.94 to 2.44, p = 0.38). Overall, the intervention did not produce a statistically significant improvement in medication adherence or systolic blood pressure compared with usual care over 12 months.

Table 2: Change in Medication Adherence (PDC) and Blood Pressure Over 12 Months

Outcome	Intervention (n = 200)	Control (n = 200)	Adjusted estimate or odds ratio (95% CI)	P value
PDC change from baseline to 12 mo mean (SD) percentage points	18.5 (41.1)	18.2 (40.9)	−0.15 (−4.06 to 3.76)*	0.94
Patients with PDC ≥80% No. (%)	70 (35.0)	74 (37.0)	1.03 (0.63 to 1.69)b	0.89
Systolic blood pressure changes from baseline to 12 mo mean (SD) mm Hg	−11.6 (17.8)	−12.2 (16.8)	0.75 (−0.94 to 2.44)*	0.38

Note: *Adjusted mean difference (intervention − control).

b Adjusted odds ratio.

Table 3 presents the penetrance and adoption of the TEAMLET intervention among 200 patients in the intervention group. Most patients (96.5%) had a medical assistant (MA) receive the barrier questionnaire, with 79.0% completing it. Uptake by primary care providers (PCPs) was lower: the order set was opened in 12.0% of cases, documentation added to the PCP progress note in 10.5%, and patient education handouts added to the after-visit summary in 9.0%. These findings indicate high initial engagement at the MA level but limited downstream adoption by PCPs, highlighting a gap between intervention delivery and clinical implementation.

Table 3: Penetrance and Adoption of TEAMLET Intervention — Intervention Group Patients (n = 200)

Intervention activity	Intervention patients No. (%)
MA received barrier questionnaire	193 (96.5)
MA completed barrier questionnaire	158 (79.0)
PCP opened order set	24 (12.0)
Documentation added to PCP progress note from order set	21 (10.5)
Patient education handout added to after-visit summary from order set	18 (9.0)

Table 4 provides a summary of EHR documentation of intervention adoption in a random 20% sample from each arm (n = 40). The proportion of patients with hypertension documented in the progress note was similar between intervention and control (72.5% vs 75.0%, p = 0.97) and the proportion with handling of elevated BP was also similar (37.5% vs 32.5%, p = 0.59). The other identified interventions in the EHR, including new medication, dose adjustment, medication switch and lifestyle recommendations, had low documentation in both groups. The most notable finding was that adherence was documented at least twice as often in the intervention group compared to control (27.5% vs 17.5%, p = 0.05) suggesting a small improvement in adherence documentation but the other measures that were documented showed no meaningful differences in the arms.

Table 4: Electronic Health Record Documentation of Intervention Adoption in a Random 20% Sample (n = 40 per arm)

Patients No. (%)	Intervention (n = 40)	Control (n = 40)	P value
Hypertension indicated in progress note	29 (72.5)	30 (75.0)	0.97
Addressed elevated blood pressure	15 (37.5)	13 (32.5)	0.59
New medication added	5 (12.5)	3 (7.5)	NA
Medication dose increased	3 (7.5)	3 (7.5)	NA
Medication changed	2 (5.0)	1 (2.5)	NA
Lifestyle recommendations	6 (15.0)	8 (20.0)	NA
Patient refused treatment	1 (2.5)	0 (0.0)	NA
Adherence indicated in progress note	11 (27.5)	7 (17.5)	0.05

Discussion

Our research assessed the effects of the TEAMLET intervention when given to elderly patients having hypertension. The intervention was administered in a group of 400 patients divided equally between the intervention and the control arms. The mean ages were similar (67.6 years in the intervention group and 66.6 years in the controls), and the sex distribution also balanced, albeit slightly higher for females in the intervention group (54.0% vs. 48.5%). Race and ethnic distribution were also homogeneous, the majority being non-Hispanic White, followed by non-Hispanic Black or Black or African American, Hispanic, and a very small percentage of other or unknown races. Baseline comorbidities were also fairly consistent, especially the prevalence of diabetes and cardiovascular conditions, and the average number of active medications for the patients were around two reflecting characteristic polypharmacy for this population. Insurance coverage for the majority of the patients was through Medicare and commercial plans; fewer being enrolled in Medicaid. Baseline adherence levels were low, PDC being around 32–34% and mean systolic and diastolic blood pressures high at around 149/85 mm Hg."

At 12-month follow-up, adherence increased for both groups. The mean PDC increased by 18.5 percentage points for the intervention group and 18.2 percentage points for the control group and the proportion of patients having high adherence (PDC ≥80%) levels were 35.0% and 37.0% respectively. We conclude that although the intervention was successfully implemented at the patient level, especially a 79% completion rate for the barrier questionnaire, the take-up by the providers themselves proved a poor one. A total of only 12% of the primary care providers (PCPs) opened the order set, 10.5% attached documentation to the progress note, and 9% included the patient education handout in after-visit summaries. Minimal clinical actions such as medication initiation or change in dose were few, and so were the interventions for lifestyle counseling. This poor take-up by the providers most likely eclipsed the minimal between-group differences in the adherence and blood pressure outcomes because patient-level intervention alone may be insufficient to have significant clinical impacts in real-world settings.

Comparable results have also been the outcome of prior research. A pragmatic cluster-randomized clinical trial by Choudhry et al. (2022) [11] in patients with chronic hypertension and poor initial adherence showed that multicomponent, practice-based interventions failed to produce significant advantages in terms of adherence or blood pressure versus usual care. Baseline adherence in that study, by assessment using PDC, was also correspondingly poor around a third of the days covered, and while modest increments over the duration of follow-up ensued, these were not significantly larger in the intervention when contrasted with the control cohorts. The research also noted the difficulties of the implementation of team-based interventions in everyday practice and noted that the most important determinant of success remains the physician or caregiver level of commitment.

The modest provider uptake that we noted is typical of the experience documented in the systematic reviews of clinical decision support systems (CDSS). Kouri et al. (2022) [12] and Kwan et al. (2020) [13] commented that although CDSS holds the promise of enhanced care in highly regulated environments, real world adoption by providers has generally been low, with adoption between 10% and 40%. PCP uptake in the current study came in below this estimate, underscoring the importance of the need to generate interventions that are smoothly integrated into day-to-day workflows and supported by regular audit and feedback mechanisms. This limitation could very well explain why the TEAMLET intervention failed to lead to increased adherence or blood pressure reduction relative to controls.

Regression to the mean and awareness regarding studies might also have explained the observed improvements in the second group. Umair et al. (2024) [14] detail the way statistical regression may generate false positives for improved outcomes over time when the initial measurements are extreme. Further, initial training of PCPs and awareness that they are being observed may have enhanced vigilance around adherence by the control group and result in improved charting and perhaps dampening group effects. In the analysis of subgroups, it was noted that participants with lower follow-up appeared to benefit most from the intervention and that interventions for the patients with limited healthcare access may have greater effects in agreement with the earlier observational studies that related frequent physician visits to greater adherence (Brookhart et al., 2007; Hamo et al., 2024; Faridi et al., 2016) [15,16,17].

In the background of modest success in our pilot, past evidence makes the case for the effectiveness of team-based care and the contribution of pharmacists to the management of hypertension. The deployment of pharmacists in care teams has the tendency to increase adherence to medications and blood-pressure levels (Choudhry et al., 2022; Whelton et al., 2018) [11,18]. Multicomponent adherence interventions are further found by other Cochrane reviews to be more effective when individualized feedback, real-time patient information presentations, and regular follow-up are implemented (Nieuwlaat et al., 2014; Zaugg et al., 2018) [19,20]. Patient-level and provider-level challenges are addressed by these interventions that are likely to increase the effectiveness of future interventions.

Our results also emphasize the need for EHR-pharmacy integration for the purpose of poor adherence

risk identification for patients. Linked EHR-pharmacy data utilization allowed for real-time triggering of intervention and post-intervention assessment of outcomes, and it captured almost all of the patients eligible. This facilitates the accurate measurement of PDC and blood-pressure outcomes. This aligns with guidelines for scalable, pragmatic interventions in the clinic (Al Ani et al., 2022) [21]. But our results indicate that alone, data integration is inadequate if the providers themselves are not actively using intervention tools. Future initiatives need to improve the adoption of providers, possibly by the use of automated reminders, task-shifting to pharmacist staff or by incentivizing documentation in order to achieve the full potential of such interventions.

In summary, the TEAMLET intervention effectively engaged patients and utilized EHR-connected data, but restrained provider adoption most likely limited its effects on adherence to medications and blood pressure control. As in prior studies, clinically relevant improvements in blood pressure in older adults with hypertension require strategies that combine patient activation with strong provider integration, team care with pharmacists, and plan for follow-up. Addressing these multispectral barriers is central to improving adherence and achieving the best cardiovascular outcomes in real-world practice.

Conclusion

The analysis assessing hypertension control and medication adherence in elderly patients showed that the intervention wasn't associated with important differences relative to usual care during the 12-month duration. Both the intervention and control groups experienced moderate increments in medication adherence and blood pressure reduction, reflecting the benefit experienced by patients in both arms from typical clinical management. Despite strong participation in the intervention activities, such as completion of the barrier workups by the medical assistants and negligible uptake of the order sets and educational brochures by the primary care physicians, these process measures failed to result in measurable clinical benefits. Documentation in the electronic health records noted that hypertension was routinely noted and treated in the participants across both arms but modifications in therapy, recommendations for lifestyle change, and adherence monitoring were also equally absent and reflected the negligible impact of the intervention on typical clinical practice. Generally speaking, the results indicate that the intervention represented a feasible and nicely integrated activity at the process level but failed to add benefit for hypertension management or adherence outcomes beyond the standard care in this population group and reflected the difficulties associated with achieving significant clinical impact through supplementary intervention where elderly patients have a multitude of documented disease states.

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