Medication Intervention for Chronic Kidney Disease Patients Transitioning from Hospital to Home: Study Design and Baseline Characteristics

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Key Words

Hospital admission · Primary diagnosis · Medication intervention · Pharmacist · Acute care utilization · Chronic kidney disease management · Elixhauser comorbidity measures

Abstract

Background: The hospital readmission rate in the population with chronic kidney disease (CKD) is high and strategies to reduce this risk are urgently needed. **Methods:** The CKD-Medication Intervention Trial (CKD-MIT; www.clinicaltrials.gov; NCT01459770) is a single-blind (investigators), randomized, clinical trial conducted at Providence Health Care in Spokane, Washington. Study participants are hospitalized patients with CKD stages 3–5 (not treated with kidney replacement therapy) and acute illness. The study intervention is a pharmacist-led, home-based, medication management intervention delivered within 7 days after hospital discharge. The primary outcome is a composite of hospital readmissions and visits to emergency departments and urgent care centers for 90 days following hospital discharge. Secondary outcomes are achievements of guideline-based targets for CKD risk factors and complications. **Results:** Enrollment began in February 2012 and ended in May 2015. At baseline, the age

of participants was 69 ± 11 years (mean $\pm$ SD), 50% (77 of 155) were women, 83% (117 of 141) had hypertension and 56% (79 of 141) had diabetes. At baseline, the estimated glomerular filtration rate was 41 ± 14 ml/min/1.73 m² and urine albumin-to-creatinine ratio was 43 mg/g (interquartile range 8–528 mg/g). The most frequent diagnosis category for the index hospital admission was cardiovascular diseases at 34% (53 of 155), but the most common single diagnosis for admission was community-acquired acute kidney injury at 10% (16 of 155). **Conclusion:** Participants in CKD-MIT are typical of acutely ill hospitalized patients with CKD. A medication management intervention after hospital discharge is under study to reduce post-hospitalization acute care utilization and to improve CKD management.

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Introduction

Patients with chronic kidney disease (CKD) experience high rates of hospitalization and readmission. An analysis of 676,343 adult patients admitted to hospitals in the Wash-

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ington state demonstrated markedly elevated risk for both total readmissions and readmissions resulting in death, with risks increasing progressively by severity of CKD [1]. The United States Renal Disease System reported 30-day readmission rates at 24% for Medicare-covered CKD patients compared with 18% for those without CKD [2]. This readmission rate exceeds even a combined rate of both death and re-hospitalization in non-CKD patients [2].

Adverse drug events are common after hospital discharge and increase risk for readmissions [3, 4]. Already complex medication regimens in patients with CKD are almost always adjusted during acute illness and hospitalization resulting in a frequent occurrence of adverse drug reactions [5]. In the general population of hospitalized patients, interventions consisting of medication reconciliation by a pharmacist in conjunction with patient counseling have reduced rates of adverse drug reactions, serious complications and readmissions [6–9]. Unfortunately, the CKD population has not been a focus of concerted efforts to improve outcomes after hospital-related care. As such, there are no effective strategies to reduce readmissions and improve quality of care for hospitalized patients with CKD. Furthermore, incomplete characterization of the acutely ill CKD population limits development of effective interventional strategies to reduce hospital readmissions.

The CKD-Medication Intervention Trial (CKD-MIT) is designed to test the efficacy of a pharmacy-led, home-based medication management intervention on acute care utilization (hospital readmissions, emergency department and urgent care center visits) and CKD management following hospitalization. The objectives of the present report are to describe the study design and baseline characteristics of hospitalized patients with CKD who participated in this study.

Methods

Study Design and Objectives

CKD-MIT is a single-blind (investigators), randomized, controlled clinical trial conducted at Providence Health Care in Spokane, Washington. The aim of the study is to determine effects of a home-based, pharmacist-led intervention to improve medication management administered within 7 days after discharge on the primary outcome of a composite of hospital readmissions, emergency department visits and urgent care visits for 90 days following hospital discharge. Secondary outcomes are achievements of guideline-based targets for CKD risk factors and complications [10–16]. CKD-MIT was reviewed and approved by the Institutional Review Board, Spokane, and adhered to the principles of the Declaration of Helsinki. All study participants provided written, informed consent to join the study.

Study Participants and Enrollment

Patients with CKD were recruited from the inpatient units of a large, tertiary referral hospital between February 2012 and February 2015 with follow-up assessments completed between May 2012 and May 2015. Patients >21 years of age were eligible to be enrolled if they were hospitalized for an acute illness and had CKD stages 3 through 5 (not treated with kidney replacement therapy) identified by at least 2 measures of estimated glomerular filtration rate (eGFR) <60 ml/min/1.73 m² for >3 months during the year prior to the index hospital admission. For study eligibility, eGFR was based on local laboratory reports using the Modification of Diet in Renal Disease calculation. Main exclusion criteria were the following: planned admission; kidney transplant or maintenance dialysis treatment; discharge to an extended care facility or rehabilitation unit; or medication management by a healthcare professional in the home.

Randomization, Assessments and Intervention

Study participants were randomized in a 1:1 ratio to the usual care discharge process alone or intervention plus usual care by means of a computer-generated random allocation sequence, stratified by diabetes status. Participants had 3 assessment visits: baseline within 7 days after hospital discharge and 2 follow-up assessments at 30 and 90 days after hospital discharge. The assessments consisted of health history, depressive symptom screening (patient health questionnaire-9), resource utilization review (emergency department visits, hospitalizations, dialysis treatment, home health services visits, rehabilitation/skilled nursing facility admissions), physical examination, health literacy screening (Rapid Estimate of Adult Literacy in Medicine – revised), cognitive screening (MINI-COGTM), clinical laboratory testing (complete metabolic panel, hemoglobin (Hb), lipid profile, parathyroid hormone (PTH), phosphorus (PO₄), urine albumin-to-creatinine ratio (UACR) and, for those with diabetes, HbA1c) and review of the medication list. Based on a pre-specified classification system, the primary diagnosis for hospitalization was adjudicated by 2 physician investigators (R.Z.A. and K.R.T.) in a blinded manner (online suppl. table 1; for all online suppl. material, see www.karger.com/doi/10.1159/000447019). To ascertain the study participants' awareness of their kidney disease, they were asked if they knew of having 'kidney disease' or 'problems with their kidneys' at the time they consented to participate in the study. Healthcare provider awareness was assessed by identifying the diagnosis of kidney disease on the electronic health record including CKD, chronic kidney failure, acute kidney diseases, acute worsening of CKD or chronic kidney failure or specific kidney diseases. Comorbidity status of the study participants was quantified by calculating the Elixhauser comorbidity score using International Classification of Disease – 9th Revision, Clinical Modification (ICD9-CM) diagnostic codes [1, 17, 18].

In the usual care group, participants received a medication list and discharge prescriptions with instructions presented by a nurse at the time of discharge from the hospital. They also received clinical education from the hospital staff using teach-back to verify understanding of 'red flag' signs and symptoms, filling new prescriptions right away and the importance of follow-up and review of their discharge medication regimen with their primary care provider. In addition to this usual discharge process, participants in the intervention group received a medication management intervention delivered by a home visit from a pharmacist within 7 days after hospital discharge. This intervention was previously validated

Fig. 1. CONSORT flow diagram.

ed in a general population of hospitalized patients [6]. The pharmacist-led, in-home medication management intervention is based on the Chronic Care Model and the ‘5As’ model of behavior change.

- (1) Assessment: identify medication problems and discrepancies.
- (2) Advice: answer questions or concerns, advice to carry an updated medication list, advice on medicines to avoid, resolve medication discrepancies, adjust doses for kidney function.
- (3) Agreement: agree upon medications that will be taken regularly and strategies to manage the medication list and keep it updated.
- (4) Assistance: develop plans for medication-taking, inform prescribers about medications that are taken differently than prescribed, create strategies to overcome barriers to keeping medication list updated.
- (5) Arrangements: assistance from family or caregivers to take medicines as prescribed, keep medication list updated, obtain medications, address unresolved discrepancies, visit prescriber regarding dose adjustments or report other concerns discussed with the participant’s prescriber [19, 20].

Statistical Analyses

A power estimate indicated that recruitment of 120 study participants would detect a 50% reduction in the primary outcome at 90 days based on a pilot study that included a subset of participants with CKD [6]. The resulting power for use of a Kaplan–Maier survival log-rank test (a 2-tailed test, and alpha of 0.05) was estimated at 81%. Due to the loss of some enrollees prior to active study participation during the recruitment phase (CONSORT diagram; fig. 1), the sample size was subsequently increased to approximately 140 randomized participants. For baseline data analyses, eGFR was calculated from the serum creatinine concentration using the CKD epidemiology collaboration equation. Data are presented as mean $\pm$ SD for symmetrically distributed continuous variables or median and interquartile ranges for skewed variables. Frequencies and percentages are presented with n/N for categorical data. The comorbidity score was calculated for each participant by summing the equally weighted number of ICD9-CM diagnoses determined by Elixhauser comorbidity measures method [1, 17, 18]. In an exploratory analysis, analysis of variance and correlation coefficients were used to test the magnitude of associations between comorbidity status (Elixhauser score) and the UACR. Due to skewness, the UACR was log-transformed for analyses. All statistics were computed using the SPSS program version 22 (IBM SPSS).

Results

Baseline Characteristics

A total of 421 patients were approached to participate in the study prior to hospital discharge (CONSORT diagram; fig. 1). Of them, 262 declined to participate and 159 who consented to participate were randomly assigned to 1 of the 2 groups of the CKD-MIT trial. The most frequent reasons enrollees exited the study before the baseline visit were reaching a primary outcome (end point) event and severe illness or admission to extended care facilities (n = 18). Baseline demographic data and patient and provider awareness of kidney disease was available for 155 participants and a full data set was available for 141 of them.

The distribution of men and women who entered the study was nearly equal: 78 men and 77 women of a total 155 participants (table 1). Most participants, 66% (103 of 155), were aware of their diagnosis of kidney disease. Healthcare providers noted a diagnosis of kidney disease in 79% (123 of 155) of participants. The average age of study participants was 69 ± 11 years. The racial distribution reflected the local community, largely of white race [21]. The baseline eGFR of the study participants was 41 ± 14 ml/min/1.73 m² with a median UACR of 43 mg/g (interquartile range 8–528). The majority of participants had hypertension 83% (117 of 141), and 56% (79 of 141) had diabetes. The most frequent categories of primary di-

Table 1. Baseline characteristics of CKD-MIT participants

Characteristics/attributes	n/N	Means/median	%/SD/IQR
Age, years		69	11
Gender			
Women	77/155		50
Men	78/155		50
Race			
White	138/155		86
American Indian	9/155		6
Black	7/155		4
Others	6/155		4
Education			
Some high school, high school	45/151		30
Some college, college graduate	84/151		56
Graduate school	22/151		14
Diabetes (yes)	79/141		56
Hypertension (yes)	117/140		83
SBP, mm Hg	117/140	131	21
Diastolic blood pressure, mm Hg	117/140	73	11
eGFR (CKD-EPI), ml/min/1.73 m ²	134/141	41	14
CKD stage 2 (60–89 ml/min/1.73 m ²)	10/134		8
CKD stage 3A (45–59 ml/min/1.73 m ²)	38/134		28
CKD stage 3B (15–29 ml/min/1.73 m ²)	54/134		40
CKD stage 4 (15–29 ml/min/1.73 m ²)	29/134		22
CKD stage 5 (<15 ml/min/1.73 m ²)	3/134		2
UACR, mg/g	106/141	43	8,528
Normal albuminuria (<30 mg/g)	45/106		42
Moderately increased albuminuria (30–300 mg/g)	29/106		27
Severely increased albuminuria (≥300 mg/g)	32/106		30
Potassium, mEq/l	134/141	4.6	0.5
Blood urea nitrogen, mg/dl	134/141	37	21
Creatinine, mg/dl	134/141	1.7	0.7
Hemoglobin, g/dl	133/141	11.6	1.9
PTH, pg/ml	127/141	76	62
PO ₄ , mg/dl	132/141	3.6	0.7
HbA1c (diabetic subgroup), %	77/141	7.0	1.3
Fasting glucose (diabetic subgroup), mg/dl	78/141	157	77

agnoses for hospitalization were cardiovascular disease 34% (53 of 155), infections 19% (29 of 155) and kidney diseases 13% (21 of 155; table 2). The single most frequent primary diagnosis for hospitalization was acute kidney injury (AKI) 10% (16 of 155).

The study participants had 2.0 ± 1.6 (mean $\pm$ SD) hospitalizations within 12 months before the index hospitalization and an Elixhauser comorbidity score of 4.6 ± 2.5 (mean $\pm$ SD; online suppl. table 2). A linear relationship was observed between severity of albuminuria status and the Elixhauser comorbidity score (fig. 2). In addition, a correlation ($r = 0.23$; $p = 0.02$) was found between the continuous variable of the log of ACR at baseline and the number of comorbidities measured by the Elixhauser method.

Frequency of use of angiotensin II receptor blocker (ARB) agents and renin angiotensin converting enzymes (ACE) inhibitors was 47% (66 of 141; fig. 3). Of all participants, 69% (97 of 141) met the clinical goal of systolic blood pressure (SBP) <140 mm Hg, and 51% (72 of 141) met the goal of SBP of <130 mm Hg. Goals of diastolic blood pressure <90 or <80 mm Hg was achieved in most participants, 92% (130 of 141) and 74% (104 of 141), respectively. Hb was >11 g/dl in 59% (79 of 133). Almost all, 98% (129 of 132), had PO₄ <5 mg/dl and 56% (71 of 127) had PTH <65 pg/ml. HbA1c was <7% in 53% (41 of 77) and <7.5% in 69% (53 of 77) of study participants with diabetes. Goals were based on current clinical practice guidelines at the time of study [10–16].

Table 2. Adjudicated primary diagnosis for index hospitalization

Diagnosis category (by system)	n/N (n = 155)	%
Cardiovascular diseases	53/155	34
Heart failure	13/155	8
Ischemic heart disease	13/155	8
Arrhythmias	8/155	6
Hypertension	7/155	4
Hypotension	2/155	1
Syncope	2/155	1
Pericarditis	1/155	1
Valvular abnormalities	3/155	2
Abdominal aortic aneurism	2/155	0.6
Peripheral vascular disease	2/155	0.6
Infections	29/155	19
Soft tissue/bone/joint	9/155	6
Urinary tract infection	6/155	4
Pneumonia	7/155	4
Gastrointestinal infections	5/155	3
Sepsis	1/155	1
Acute cholecystitis	1/155	1
Kidney system diseases	21/155	13
AKI	16/155	10
Nephrotic syndrome	2/155	1
Volume depletion	3/155	2
Central nervous system diseases	12/155	8
Stroke	4/155	3
Encephalopathy	4/155	3
Seizures	1/155	0.6
Intracerebral hemorrhages	1/155	0.6
Transient ischemic attack	2/155	1
Respiratory system diseases	11/155	7
Respiratory failure	5/155	3
Pleural effusion	2/155	1
Pulmonary embolism	3/155	2
Acute asthma exacerbation	1/155	0.6
Gastrointestinal system diagnosis	10/155	6
Bleeding from gastrointestinal tract	7/155	4
Cirrhosis	1/155	0.6
Small bowel obstruction	2/155	1
Miscellaneous	19/155	12
Atypical chest pain	5/155	3
Musculoskeletal	5/155	3
Malignancies	3/155	2
Hypoglycemia	2/155	1
Vasculitis	1/155	0.6
Epistaxis	1/155	0.6
Deep venous thrombosis	1/155	0.6
Revision of fistula	1/155	0.6

Discussion

The CKD-MIT clinical trial is designed to test the efficacy of a pharmacist-led, home-delivered medication management intervention on acute care utilization and CKD care in patients recently discharged from hospital-

Fig. 2. Average number of Elixhauser comorbidities (with the 95% CIs) by albuminuria category (<30, 30–300, ≥300 mg/g). The probability level refers to the linear component of the association by analysis of variance.

to-home after acute illness. One of the many challenges the CKD population faces during and after hospitalization are fluctuations in kidney function related to acute illness. Declining eGFR, in particular, adds additional complexity to medication management and warrants focused attention to avert unintended consequences and complications. In the general population of hospitalized patients, tremendous clinical and administrative resources have been directed toward reducing readmission rates while improving quality of care and controlling costs. The main emphasis has been placed on sentinel conditions such as pneumonia, heart failure and myocardial infarction [22]. Although patients with CKD may have been inadvertently included in such studies, to our knowledge, this will be the first prospective, randomized, controlled clinical trial to focus an intervention on this particularly high-risk group.

The participants enrolled in CKD-MIT are older, mostly white and equally distributed between women and men. Their mean eGFR at baseline was 41 ml/min/1.73 m² and most had CKD stages 3b–5. As to be expected, hypertension and diabetes are very common in the study participants. In contrast to low rates of CKD awareness in observational studies, awareness of kidney disease by CKD-MIT participants and their healthcare providers was relatively high, suggesting that those who are more likely to enroll in clinical trials are more aware of their

Fig. 3. Frequency of study participants achieving goals for CKD risk factor control, complications and use of ACE inhibitors and ARB medications at baseline. DBP = Diastolic blood pressure.

condition [23]. The most frequent primary diagnostic categories for hospital admission were cardiovascular diseases followed by infections and kidney diseases. Community-acquired AKI was the most common single primary diagnosis for hospitalization. Patients with CKD are known to be at higher risk of AKI [24, 25]; however, identification of community-acquired AKI as the most common primary diagnosis for admission in hospitalized patients with CKD is a unique finding that was captured by classification with an adjudication system rather than use of only administrative coding data.

At hospital discharge, most participants were at recommended blood pressure targets for the less stringent goal and more than half met the more intensified goal. ACE inhibitor or ARB use was less than 50%, but these medicines are commonly stopped during acute illness and hospitalization. Recommended goals for PTH and

Hb were reached in more than half of participants despite acute illness and nearly all had adequate control of serum PO4 levels. HbA1c levels in patients with diabetes and CKD indicated acceptable glycemic control in the majority, but are more reflective of the previous 3 months of glycemic control rather than their levels of glycemia during acute illness.

In the general population, proven strategies to reduce hospital readmission rates and improve transition of care remain to be identified and validated [26–28]. A systemic review and meta-analysis of 42 trials testing interventions designed to prevent 30-day hospital readmissions found that studies published before the year 2002 were more likely to report positive results than those reported later [28]. Comprehensive interventions involving multidisciplinary care and support for self-management may be more effective than single interventions and pharmacist-

led interventions show particular promise [7–9]. Most previously tested medication interventions took place in-hospital or were conducted by a telephone call after hospital discharge. A recent study that evaluated effects of an in-person, pharmacist-led intervention performed soon after discharge in a general population of hospitalized patients showed improvements in medication management and reduced rates of acute care utilization within 30 days [3]. Additionally, a collaborative pharmacist-nurse medication intervention performed through home health services in older adults produced significant reductions in medication discrepancies [29]. CKD-MIT will provide new knowledge about the efficacy of an in-person, pharmacist-led intervention performed soon after hospital discharge on subsequent acute care utilization and CKD care.

This study population has multiple comorbidities as determined by the Elixhauser score. Of note, there was a significant relationship between severity of albuminuria and number of comorbidities, which is a novel finding from this study of patients with CKD. Similarly, in a recent study, kidney transplant recipients were found to have multiple comorbidities by the Elixhauser score [18]. Albuminuria is a well-known biomarker for kidney disease, cardiovascular disease and mortality that adds to conventional risk prediction in diabetic and non-diabetic populations alike [30, 31]. The larger implications of the relationship between severity of albuminuria and the Elixhauser comorbidity score will be further evaluated in a longitudinal manner in the CKD-MIT clinical trial.

The study design for CKD-MIT has many strengths, but also some limitations. First, focusing on the CKD population is considered as strength because of the population's high risk for post-hospitalization complications and readmissions [1]. Second, this study offers tremendous opportunity to better characterize the hospitalized population with CKD. For example, the high frequency of community-acquired AKI as a primary cause for hospital admission points toward focus on AKI prevention among patients with CKD to avoid acute illness requiring hospitalization. Third, most research in this area has been dominated by studies of administrative claims data, whereas CKD-MIT study has an abundance of direct observations and adjudicated events that allows greater delineation and knowledge about the hospitalized population with CKD. Fourth, the medication intervention is based on direct interaction with a pharmacist in the home after discharge from the hospital. Face-to-face interactions in the patient's home environment are likely to be more comprehensive than a simple phone call conducted

from a distance. Pharmacists have the opportunity to review not only medication lists, but also the actual medication available in the home and observe the way patients self-administer their medicines. The pharmacist will have an opportunity to address multiple stressors that patients encounter after the hospital stay (e.g., disruption of sleeping and eating, changes in daily schedule, understanding diagnoses and health conditions). Finally, longitudinal follow-up in CKD-MIT will provide insight into medication management as well as CKD care over the 90 days after hospitalization. Limitations of the study include that it is a single-center trial, enrolling a predominantly older, well-educated, white population in the Northwestern United States. The high rate of kidney disease awareness among CKD-MIT participants and providers likely reflects selection bias for study enrollment, which is inherent to clinical trial populations and contrasts with lower reported rates of awareness in observational studies [23]. Therefore, large more diverse groups of hospitalized patients with CKD should eventually be studied to broaden generalizability of the findings.

In conclusion, the CKD-MIT is a prospective, randomized, controlled clinical trial evaluating the effect of a pharmacist-led, home-based medication management intervention during the transition of care from hospital-to-home for patients with CKD. This study will determine whether the medication management intervention reduces subsequent acute care utilization and improves CKD management. The baseline findings of CKD-MIT reveal novel findings about the hospitalized CKD population, including a high prevalence of community-acquired AKI and an association between severity of albuminuria and multiple comorbidities. The study results will be relevant to advanced care of acutely ill hospitalized patients with CKD.

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