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Cognitive Impairment and Medication Complexity in Community-Living Older Adults: The Health, Aging and Body Composition Study

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Abstract

Background—Medication complexity is a large determinant of adherence. Few studies have explored the relationship between cognitive impairment and medication complexity.

Objective—To evaluate whether cognitive impairment is associated with medication complexity for prescription and over-the-counter (OTC) medications.

Methods—In this cross-sectional analysis, we studied the association between cognitive impairment and the complexity of prescription and OTC drug regimens. Baseline participants were from the Health, Aging and Body Composition study, consisting of 3075 well-functioning 70- to 79-year-old black and white men and women. Cognitive impairment was defined by having a Modified Mini-Mental State Examination score <80. The complexity of prescription and OTC (including supplements/herbals) medications was assessed using a modified version of the

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Medication Regimen Complexity Index (mMRCI). The mMRCI score increases with complexity of dosage forms, number of medications, pill burden, and nondaily dosing.

Results—The mean (SD) age was 74 (2.9) years (n = 3055; 52% female, 41% black). The median prescription mMRCI score was 6 (range 0–66). The median OTC mMRCI score was 4 (range 0–71). Adjusting for health status, demographics, and access to care, medication complexity was lower in participants with cognitive impairment for prescription (adjusted RR 0.89; 95% CI 0.80 to 0.99) and OTC medications (adjusted RR 0.76; 95% CI 0.64 to 0.93) compared to those without cognitive impairment. The number of prescription medications was not different, but the number of OTC drugs was lower for those with cognitive impairment.

Conclusions—In this cohort of well-functioning older adults, those with cognitive impairment had lower prescription complexity due to less-complex dosage forms, pill burden, or daily dosing. OTC complexity was also lower, primarily due to a lower number of OTC drugs. The results of this study show that further research on medication complexity and adherence and health outcomes in cognitively impaired individuals is warranted.

According to a World Health Organization (WHO) 2003 report, poor medication adherence is the primary reason for suboptimal clinical benefit, affecting morbidity and mortality for various chronic diseases such as hypertension and diabetes.[1] Poor adherence is commonly seen in older adults for a variety of reasons, including managing multiple chronic diseases, polypharmacy, and medication regimen complexity.[2] Poor adherence accounts for 33–69% of all medication-related hospital admissions, costing approximately $100 billion per year.[3] Medication complexity was one of the therapy-related factors that affect adherence to therapy that was identified in the WHO report and in other studies.[1,2]

Several factors affect the complexity of medication regimens, including polypharmacy, pill burden, and dosage form.[4] Persons with more complex medication regimens are less likely than those with simpler regimens to adhere to treatments.[5] Cognitive impairment is a known risk factor for medication-related problems in older adults. In addition, adherence is often poor in patients with cognitive impairment.[6] Interventions to improve adherence by decreasing complexity in individuals with normal cognitive function were successful.[5] However, limited data exist regarding the relationship between decreased cognitive status and medication complexity.

The objective of this study is to evaluate whether cognitive impairment is related to medication regimen complexity for both prescription and over-the-counter (OTC) medications. This study uses a validated instrument to assess medication complexity in a large cohort of community-living older adults. Medication complexity is assessed for both prescription and OTC medications.

Methods

STUDY DESIGN

This cross-sectional study included baseline participants who were enrolled in the Health, Aging, and Body Composition (Health ABC) Study. The Health ABC Study is a prospective cohort study sponsored by the National Institute of Aging. The Health ABC Study recruited 3075 men and women aged 70–79 years at 2 clinical centers in Memphis, TN, or Pittsburgh, PA, between April 1997 and June 1998. At baseline, participants had to be well-functioning: the participants had to be free of functional limitations, that is, had no difficulty in walking a quarter of a mile, walking up 10 steps without resting, getting in and out of bed or chairs, bathing or showering, dressing, or eating. They also could not use a cane, walker, crutches, or other assistive device to ambulate. The participants also had to be free of any life-threatening illnesses, such as cancer.

Participants with missing medication data (n = 20) were excluded from this analysis, leaving 3055 participants in the analytic sample. All participants signed an informed written consent form and study protocols were approved by the institutional review boards of University of Tennessee and University of Pittsburgh. The analysis protocol was approved by the institutional review board of Yale University, where this analysis was performed.

DATA COLLECTION AND MANAGEMENT

Participants underwent a baseline home visit followed by a clinic visit. At the home visit, participants were given a bag and asked to bring in all medications to a clinic visit. Reminder calls were made the day before the clinic visit, and they were reminded again to bring their medications. Information about the medications was collected at the clinic visit and additional questions were asked to elicit information on any missing or forgotten medications. If any medications were missing at the clinic visit, a follow-up phone interview was performed to collect the medication information.

COGNITIVE IMPAIRMENT

There were no entry criteria based on cognitive impairment, but the participants had to be considered well-functioning to be enrolled in the study. Cognitive impairment was assessed by the Teng Modified Mini-Mental State Examination (3MS).[7,8] The 3MS was administered by a trained technician during the clinic visit. The 3MS is a rescaling of the Folstein Mini-Mental State Examination with scores ranging from 30 to 100 and is more sensitive than the Folstein Mini-Mental State Examination in older adults. Cognitive impairment was defined as a dichotomous variable, with a score <80 on the 3MS indicating cognitive impairment.[7,8]

COVARIATES

At the home and clinic visits, the baseline questionnaire assessed demographic and health history information. Clinical assessments included vital measurements and blood analysis. Presence of disease was assessed by self-report of a physician-diagnosed condition, use of a medication specific to that disease, and/or by physiologic or psychological measures.[9–12] Low self-perceived health status was defined as the participants self-rating their health as poor or fair, compared to good, very good, or excellent. The demographic variables included age, sex, race, and education. Access to health care was defined by dichotomous variables for supplemental medication insurance (self-report), greater than 2 outpatient visits in the last year, and prior hospitalization in the last 5 years; outpatient visits and prior hospitalization were determined by administrative or fiscal records.

Medication use was determined through examination of all prescription and nonprescription medications used by participants in the 2 weeks preceding the baseline clinic visit. Self-reporting of medications by older adults has been validated by several different methods, including comparison of serum concentrations of cardiovascular medications,[13] pharmacy data,[14] and pharmaceutical claims data.[15] The short recall period was designed to limit recall bias. The medication name, strength, and dosage form were recorded. Additional information obtained included categorizing the drug as either prescription or OTC and whether it was taken on an as-needed basis. OTC medications included herbals and supplements. The dosage frequency was recorded as the total number of doses taken on a daily, weekly, or monthly basis.

OUTCOME MEASURE

Drug therapy complexity was assessed using a modified version of the Medication Regimen Complexity Index (MRCI), originally developed by George et al.[16] The main modification was that we did not have information about additional preparation instructions (eg, mixing

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the medication with apple juice). The modified MRCI (mM-RCI) score was calculated using the number of medications, dosage forms, pill burden, and increased complexity for nondaily dosing. The modifications to the MRCI resulted in a more conservative (lower) complexity score compared to the full MRCI score since additional instructions were not included. Higher mMRCI scores indicate greater medication complexity.

Dosage forms were scored as described by George et al.[17] In short, oral tablets and capsules were scored a 1, topical creams were scored a 2, inhalers were scored a 3, and injections were scored a 4. For dosage frequency, medications taken on a daily basis were scored a 1, medications taken on a weekly and monthly basis were scored a 2 (ie, medications taken less often than daily were considered more complex to administer). To account for pill burden, if more than 1 tablet was taken in a day, 1 was added to the score. If the medication was taken on an as-needed basis, the dosage frequency and pill burden scores were divided by half.

The medication complexity was scored by a computer algorithm as described above. A random sample of 250 medications was reviewed by the pharmacist co-authors with geriatrics training (DSHL, SMJ, and JTH) to insure the fidelity of the mMRCI scores. In short, the dosage form, daily pill burden, and nondaily dosing schedule were printed for the 250 medications along with the score generated by the algorithm and manually checked for the correct score being assigned.

The mMRCI scores for all prescription medications were summed for a total prescription complexity score. This was repeated for OTC drugs. Thus, the total participant mMRCI score is a composite of the number of medications, complexity of dosage forms, daily pill burden, and nondaily dosing. If the dosage form was not recorded, the 3 pharmacist coauthors assigned a dosage form score based on known dosage forms (n = 49). If multiple dosage forms existed, the more conservative (lower) score was assigned. In the analysis, the mMRCI was used as a continuous variable.

STATISTICAL ANALYSIS

Multivariable linear models with a negative binomial distribution were used to estimate the relative risk of medication complexity by cognitive impairment. The dependent variable was cognitive impairment. The first primary independent variable was prescription medication complexity. We present 4 linear models to examine the association between cognitive impairment and prescription complexity. The first model presents the unadjusted relative risk and 95% confidence intervals for the association of cognitive impairment and prescription mMRCI score; model 2 presents relative risk adjusted for health status (hypertension, cardiovascular disease, diabetes, arthritis, pulmonary disease, depressive symptoms, heart failure, and self-perceived health status); model 3 estimates the relative risk adjusted for health status and demographics (age, race, sex, and education); model 4 presents the relative risk adjusted for all potential confounding variables by including access to health care (supplemental medication insurance, more outpatient visits, hospitalization in the last 5 years). A relative risk greater than 1 is associated with higher medication complexity, and a relative risk less than 1 is associated with lower medication complexity. The same analysis was performed on OTC complexity, the second primary independent variable.

Since the coexistence of a cognitive impairment and chronic condition may alter medication complexity, we also examined all 2-way interactions between cognitive impairment and any chronic condition left in the final model. The 2-way interaction was to test if any chronic condition changed the association of mMRCI with cognitive impairment. If no 2-way interactions were observed, this would suggest that the other chronic conditions did not change the association between mMRCI and cognitive impairment.

Since the number of medications can increase complexity, we conducted a second analysis to assess the association between the number of medications and cognitive impairment. All statistical analyses were performed with SAS Statistical Software, version 9.2 (SAS Institute, Cary, NC).

Results

PARTICIPANTS' CHARACTERISTICS

Baseline characteristics are listed in Table 1. The mean (SD) age was 74 (2.9) years, 52% were female, and 41% were black; 10% of the participants had cognitive impairment. Hypertension was the most prevalent disease (61%) followed by cardiovascular disease (25%). Approximately one quarter of the participants had more than 2 outpatient visits in the last year, and 38% were hospitalized in the last 5 years. The number of prescription medications ranged from 0 to 23, with a median of 3 (interquartile range 1 to 5). The number of OTC medications ranged from 0 to 27, with a median of 2 (interquartile range 1 to 4).

COGNITIVE IMPAIRMENT AND PRESCRIPTION COMPLEXITY

The prescription complexity score ranged from 0 to 66, with a median of 6 (interquartile range 2 to 11.5). Table 2 shows the results of the association between cognitive impairment and prescription complexity. Cognitive impairment was associated with lower prescription complexity after adjusting for other health status, demographics, and access to health care in the fully adjusted model (RR 0.89; 95% CI 0.80 to 0.99). In contrast to complexity, the number of prescription medications was not significantly different between cognitively impaired and cognitively normal individuals after controlling for health status, demographic, and access to health care variables. The 2-way interaction between cognitive impairment and each of the chronic conditions was not significant and indicates that the decrease in prescription complexity was observed regardless of which chronic condition was present.

COGNITIVE IMPAIRMENT AND OTC COMPLEXITY

The complexity score for OTC medications ranged from 0 to 71, with a median of 4 (interquartile range 1.5 to 8). Table 3 shows the results of multivariable regression model for the OTC medications. Cognitive impairment was associated with lower OTC complexity and remained statistically significant when controlled for health status, demographics, and access to health care in the fully adjusted model (RR 0.76; 95% CI 0.64 to 0.93). The number of nonprescription drugs was also lower for those with cognitive impairment when controlled for health status, demographics, and access to health care (RR 0.76; 95% CI 0.66 to 0.88). Thus, the decreased OTC complexity likely reflects a decreased number of OTC medications, rather than complexity. The only remaining health status characteristic was arthritis. The 2-way interaction between cognitive impairment and arthritis was not significant and indicates that the decrease in OTC complexity was observed regardless of whether arthritis was present or not.

Discussion

This is, to the best of our knowledge, the first study to describe the relationship between medication complexity and cognitive impairment in a community-living older population. Cognitive impairment was associated with lower prescription and OTC complexity. The lower prescription complexity was not due to lower prescription usage, but rather due to decreased complexity in dosage form, daily pill burden, and nondaily dosing. In contrast, the decreased OTC complexity was primarily due to decreased OTC usage, and is consistent with other reports.[18] These decreases were observed regardless of which chronic condition was present.

Medication complexity may be lower in the presence of cognitive impairment for a variety of reasons. Clinicians may simplify regimens once patients demonstrate functional impairments resulting from cognitive decline. This could occur either by decreasing the number of medications in a patient's regimen (eg, reducing polypharmacy) or by adopting strategies that reduce complexity (eg, decrease pill burden). Furthermore, as cognitive impairment worsens, clinicians may reevaluate the need for certain drugs, thereby reducing complexity. Prior reports have indicated both increased[19] and decreased[20] prescription drug use in cognitively impaired persons, but neither was seen in this study. This study shows the number of prescription medications used was not different for those with cognitive impairment, suggesting that the complexity was lower due to simpler dosage forms, decreased pill burden, or dosing daily rather than weekly or monthly. Additionally, patients and/or their caregivers may request a less complex prescription regimen in response to subclinical or overt cognitive impairment.

On the other hand, the number of OTC medications was lower for those with cognitive impairment, suggesting that those participants simply took fewer OTC medications, similar to what has been reported previously.[18] OTC medications, by FDA definition, must be easy to administer. Thus, taking fewer OTC drugs is one of the only ways to decrease OTC complexity and therefore is expected.

The implications of this research are 2-fold: first, prescription complexity may be decreased for older adults with cognitive impairment, possibly in an attempt to improve adherence or decrease pill burden. However, the number of prescriptions may not be decreased. Pharmacists should be aware that because the number of prescriptions was not decreased, and each chronic condition increases medication complexity, even if the patient had cognitive impairment, this would suggest that they are still being treated and quality of care has not been compromised. Second, the number of OTC medications used was decreased in participants with cognitive impairment. Therefore, pharmacists should pay extra attention to those with cognitive impairment to be sure that OTC symptomatic treatment, such as for pain, is still received.

This study is also among the first to describe other key covariates important to prescription MRCI. Not surprisingly, other diseases increased the complexity of prescription medications, but this study shows that conditions with complex therapies, such as pulmonary disease, diabetes, and heart failure, were more strongly associated with higher prescription complexity. Hypertension was also strongly associated with higher prescription complexity, most likely due to multiple agents being used to control blood pressure. Female participants had more complex prescription regimens, perhaps due to greater utilization of health services.[21] Access to health care variables, such as more outpatient visits, most likely increased complexity by increasing the number of prescribed medications. Finally, the prescription regimens for participants in Pittsburgh were associated with lower complexity, perhaps reflecting better health status and a different demographic.

OTC medication complexity was associated only with arthritis, most likely due to increased OTC analgesic use.[20] Black participants had lower OTC complexity, which may indicate less use of OTC drugs in this population.[22] Similar to prescription complexity, being female was associated with higher OTC complexity because of more OTC usage.[21] A prior hospitalization was associated with lower OTC complexity.

This study has several potential limitations. This study was cross-sectional and did not explore the change in medication complexity over time. There may be some historical differences in treatments, which may limit the results; overall, while specific treatment choices have changed over time, the complexity of treatments has not dramatically changed and many complex diseases, such as pulmonary diseases, are still complex to treat. Some diseases and other factors used to control for confounding were self-reported by the participants. Due to limitations of available data, the complete medication complexity score could not be calculated; thus, the modified complexity score did not account for additional instructions but represents an estimate that incorporates the number of medications, dosage form, daily pill burden, and nondaily dosing. Additional instructions could not be included, so the mMRCI would be a conservative measure of medication complexity. Further, there may be residual confounding not accounted for in the model, such as acute medical problems, injuries, or infections that may affect medication complexity. The study sample consisted of well-functioning older adults, and may represent only mild cognitive impairment, and may not be representative of the general population of 70- to 79-year-old adults because they are well functioning with higher education levels. Despite these limitations, this study describes how prescription and OTC complexity is associated with cognitive impairment in a large cohort of well-functioning older adults using multivariable linear regression to control for potential confounders by other diseases, demographic factors, and access to care.

In conclusion, this study found that prescription complexity was lower in cognitively impaired older adults compared to those without impairment, and was independent of the number of prescription medications. Chronic conditions, especially those with complex therapies such as pulmonary disease and heart failure, had the most influence on prescription complexity. The implication is that prescription complexity may be decreased, but the number of drugs may not be decreased, which may affect both adherence and quality of care, but more research is needed in this area. OTC complexity was also lower in cognitively impaired older adults but appeared to be primarily due to less use of OTC medications. This result is expected since OTC drugs are generally not complex to administer; thus, the only way to decrease complexity for OTC medications is to use fewer of them. The implication is that cognitively impaired older adults may be using fewer OTC drugs, and may not be treating symptoms as readily as cognitively normal older adults.

Our next area of research is to explore the effect of medication complexity on adherence in community-living older adults with and without cognitive impairment. Additional longitudinal analyses will explore the effect of complexity on clinically relevant outcomes, such as falls and cardiovascular events.

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Table 1

Baseline Characteristics of the Analytic Sample (N = 3055)

Cognitive impairment, n (%)	303 (10)
Health status, n (%)	
hypertension	1854 (61)
cardiovascular disease	744 (25)
diabetes	575 (19)
osteoarthritis	513 (17)
pulmonary	355 (12)
depressive symptoms	144 (5)
heart failure	40 (1)
low self-perceived health status	493 (16)
Chronic conditions, n (%)[a]	
0	645 (21)
1	1188 (38)
2	844 (28)
3	315 (10)
≥4	63 (2.1)
Demographics	
age (years), mean (SD)	74 (2.9)
female, n (%)	1574 (52)
black, n (%)	1266 (41)
high school education or greater, n (%)	2281 (75)
Pittsburgh, n (%)[b]	1516 (49)
Access to care, n (%)	
supplemental medication insurance	1873 (63)
>2 outpatient visits in last year	834 (27)
prior hospitalization in last 5 years	1159 (38)
Prescription medications (n), median (IQR)	3 (1 to 5)
OTC medications (n), median (IQR)	2 (1 to 4)

IQR = interquartile range; OTC = over-the-counter.

[a]Conditions include hypertension, cardiovascular disease, diabetes, osteoarthritis, pulmonary disease, and heart failure.

[b]Pittsburgh, PA, compared to Memphis, TN.

Table 2

Association of Cognitive Impairment with Prescription Medication Complexity Adjusted for Key Covariates (N = 3055)

	RR (95% CI)[a]			
COVARIATE	COGNITIVE IMPAIRMENT ALONE	COGNITIVE IMPAIRMENT AND HEALTH STATUS	COGNITIVE IMPAIRMENT, HEALTH STATUS, AND DEMOGRAPHICS	FULLY ADJUSTED MODEL
Cognitive impairment	1.00 (0.89 to 1.12)	0.87 (0.78 to 0.96)	0.89 (0.89 to 0.99)	0.89 (0.80 to 0.99)
Health status				
hypertension		1.45 (1.36 to 1.56)	1.46 (1.36 to 1.56)	1.45 (1.35 to 1.55)
cardiovascular disease		1.48 (1.39 to 1.57)	1.54 (1.44 to 1.64)	1.40 (1.31 to 1.50)
diabetes		1.45 (1.40 to 1.56)	1.50 (1.40 to 1.64)	1.46 (1.36 to 1.56)
arthritis		1.28 (1.18 to 1.38)	1.25 (1.135 to 1.35)	1.21 (1.12 to 1.31)
pulmonary		1.73 (1.59 to 1.89)	1.75 (1.60 to 1.91)	1.71 (1.57 to 1.88)
depressive symptoms		1.20 (1.10 to 1.38)	1.18 (1.03 to 1.35)	1.15 (1.01 to 1.31)
heart failure		1.64 (1.43 to 1.87)	1.68 (1.48 to 1.93)	1.53 (1.36 to 1.73)
lower self-perceived health		1.26 (1.16 to 1.37)	1.29 (1.18 to 1.40)	1.28 (1.17 to 1.40)
Demographics				
age (years)			NS	NS
female			1.22 (1.14 to 1.30)	1.18 (1.12 to 1.27)
black			0.92 (0.86 to 0.98)	0.93 (0.87 to 0.99)
high school education or greater			NS	NS
Pittsburgh[b]			0.87 (0.82 to 0.92)	0.80 (0.75 to 0.85)
Access to care				
supplemental medication insurance				1.23 (1.14 to 1.30)
more outpatient visits[c]				1.17 (1.10 to 1.26)
prior hospitalization[d]				1.21 (1.13 to 1.30)

NS = not significant with a 2-sided p value <0.05

[a]Adjusted relative risk (95% CI) in generalized linear models with negative binomial error distribution fit by backwards elimination.

[b]Pittsburgh, PA, compared to Memphis, TN.

[c]More than 2 outpatient visits in the last year.

[d]Hospitalization in the last 5 years.

Table 3

Association of Cognitive Impairment with OTC Medication Complexity Adjusted for Key Covariates (N = 3055)

	RR (95% CI)[a]			
COVARIATE	**COGNITIVE IMPAIRMENT ALONE**	**COGNITIVE IMPAIRMENT AND HEALTH STATUS**	**COGNITIVE IMPAIRMENT, HEALTH STATUS, AND DEMOGRAPHICS**	**FULLY ADJUSTED MODEL**
Cognitive impairment	0.55 (0.46 to 0.65)	0.59 (0.49 to 0.70)	0.77 (0.64 to 0.93)	0.76 (0.64 to 0.93)
Health status				
hypertension		NS	NS	NS
cardiovascular disease		NS	NS	NS
diabetes		0.79 (0.71 to 0.88)	0.90 (0.81 to 1.00)	NS
arthritis		1.29 (1.18 to 1.41)	1.17 (1.07 to 1.28)	1.19 (1.06 to 1.31)
pulmonary		NS	NS	NS
depressive symptoms		NS	NS	NS
heart failure		NS	NS	NS
lower self-perceived health		NS	NS	NS
Demographics				
age (years)			NS	NS
female			1.27 (1.17 to 1.38)	1.26 (1.16 to 1.37)
black			0.63 (0.58 to 0.69)	0.62 (0.57 to 0.68)
high school education or greater			1.10 (1.01 to 1.20)	1.11 (1.03 to 1.21)
Pittsburgh[b]			NS	NS
Access to care				
supplemental medication insurance				NS
more outpatient visits[c]				NS
prior hospitalization[d]				0.87 (0.80 to 0.94)

NS = not significant with a 2-sided p value <0.05

[a] Adjusted relative risk (95% CI) in generalized linear models with negative binomial error distribution fit by backwards elimination.

[b] Pittsburgh, PA, compared to Memphis, TN.

[c] More than 2 outpatient visits in the last year.

[d] Hospitalization in the last 5 years.