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One-Year Follow-Up of Medication Management Capacity in Highly Functioning Older Adults

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Background. We tested the hypothesis that impairment in the ability to take medication independently predicts early functional decline.

Methods. A 12-month, prospective cohort study was performed at two continuing-care retirement facilities using the Drug Regimen Unassisted Grading Scale (DRUGS). This geriatric screening tool utilizes a stepwise progression of four tasks: (i) identification, (ii) access, (iii) dosage, and (iv) timing.

Results. Forty-seven (86%) of the eligible participants completed the 12-month follow-up assessment; three were transferred to skilled nursing facilities. The mean age at study entry was 84.2 ± 5.1 years; 72% of the participants were women, and 68% were college educated. At 12 months there was a decline in the Mini-Mental State Examination (MMSE) score ($p = .029$), an increase in the timed "Up and Go" test ($p = .023$), and a decline in the DRUGS score ($p = .029$). Nine (18%) of the participants resided in assisted- versus independent-living situations compared with three participants (5%) at study entry ($p = .031$). Both 12-month DRUGS score and 12-month self-reported medication management capacity were associated with 12-month MMSE ($p = .0001$ and $p = .019$, respectively). Baseline DRUGS score was associated with 12-month MMSE and Geriatric Depression Scale scores ($p = .0002$ and $p = .002$, respectively). Both baseline DRUGS score and self-reported medication management capacity were also associated with residence in assisted-living communities at 6 months ($p = .029$ and $p = .040$, respectively). MMSE was not associated with any of the clinical outcomes.

Conclusions. The DRUGS tool may predict functional decline in highly functioning older adults.

ALTHOUGH population-based screening data suggest that needing or receiving assistance with medication management may predict increased risk of frailty, previous studies of medication management have not extensively explored the relationship between medication management, functional status, and the risk of functional decline (1–5). Cognitive impairment has been associated with the inability to take medications independently, as well as with gait disorders, falls, and functional impairment. (2–4,6–10). The onset of functional impairment and disability may be heralded by subtle changes in either cognitive or physical status.

We recently developed and tested a geriatric screening tool, the Drug Regimen Unassisted Grading Scale (DRUGS) to assess medication management and various aspects of function in the ambulatory setting (11). An extension of one item of the Instrumental Activities of Daily Living (IADL) scale and the "brown-bag" test, the DRUGS tool was developed as a performance-based, individualized measure of the patient's capacity to manage his or her own medication regimen (11,12). The purpose of this study is to determine if an impairment in the ability to take medications independently, measured by the DRUGS tool, correlates with overall functional status and predicts future functional disability.

METHODS

Geriatric Screening Tools

Self-report.—Modified Katz Activities of Daily Living (maximum score = 6) and Lawton IADL (maximum score = 8) scales were used to assess basic and instrumental activities of daily living, respectively (12,13). In addition, each participant was asked a series of medication management questions (11): (i) Do you take your own medication without help?; (ii) Does someone remind you to take your medication on a regular basis?; and (iii) Does someone set up your medication in advance?

DRUGS tool.—The DRUGS tool was employed as previously described (11). Briefly, this tool involves a stepwise progression of four medication management tasks: (i) identification, or showing the appropriate medications; (ii) access, or opening the appropriate containers; (iii) dosage, or taking out the correct number per dose; and (iv) timing, or demonstrating the timing of doses. The subject is asked to perform these tasks for each of the prescription and nonprescription medications that he or she plans to take on the day

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of the evaluation, including PRN or "as needed" medications, using the DRUGS tool. A visual aid, in the form of a sheet of paper marked with a grid labeled "time" (7 AM–11 PM), "meal," and "medications," is employed to standardize the process. The DRUGS tool is an easy-to-administer individualized measure that examines medication self-administration. It takes approximately 4 to 5 minutes, and interrater and test-retest reliability of the DRUGS tool are >.90 (11).

Standard Measures of Functional Status

The results of these geriatric screening tools were compared with a complement of previously validated standard measures of functional status, which were categorized for clinical relevance. There were tests of cognitive status (Mini-Mental State Examination [MMSE]), affective status (15-item Geriatric Depression Scale), physical function (timed "Up and Go" test), medical conditions (Jaeger card to test near vision, Charlson Comorbidity Index), medication-specific factors (number of medications, number of doses), and social factors (living alone or with a partner) (14–18). Covariates included age, gender, and level of education.

Patients and Setting

This prospective cohort study was conducted at two continuing-care retirement facilities in the greater Boston area. Patients were recruited from the Beth Israel Deaconess Gerontology Group practice between October 10, 1996, and January 27, 1997. All ambulatory community-dwelling patients aged 70 years and older who presented to one of the study sites were eligible for the study. Patients were excluded if they were currently not taking any prescription or nonprescription medications or if they refused to participate.

Data Collection

Data for all participants were collected at the time of the initial outpatient office visit (HE, ES) and at a 6-month follow-up visit. The initial contact was used to obtain written informed consent and collect clinical data. The chart review data included the list of medications and the 19 variables that constitute the Charlson Comorbidity Index (18). Test status was ascertained by an investigator (HE, ES) who was blinded to health status and sociodemographic factors. An additional office visit was scheduled at 6 months. Data were obtained regarding predefined clinical outcomes: interim clinic visits (0, ≥2), emergency room visits (0, ≥1), acute care hospitalizations (0, ≥1), institutionalization, and death. This information was confirmed by chart review. The institutional review board of the Beth Israel Deaconess Medical Center approved the protocol.

Data Analysis

Univariate and multivariate analyses were performed using the SAS statistical package for Windows, version 6.12 (SAS Institute Inc., Carey, NC). Univariate associations between the continuous outcomes (DRUGS summary score, change in DRUGS summary score) and continuous variables were examined by Spearman correlation. Student's *t* test was used to compare the DRUGS score and change in DRUGS score between two groups for binary predictors. Bonferroni correction was applied to multiple comparisons. The Spearman correlation, Fisher's exact, chi-square, and Wilcoxon rank sum tests were employed to examine the relationships between predictors.

New variables were derived to control for baseline values by calculating the mathematical difference between values at either 6 or 12 months and baseline values. Multivariate models were derived using stepwise linear regression in which the dependent variable was either baseline DRUGS summary score or 6- or 12-month change in DRUGS summary score. Age, sex, and covariates with $p < .2$ on univariate analysis were entered into the models, and variables with $p < .05$ were retained in the models. Additional statistical analyses were performed to explore whether changes in self-reported medication management capacity or MMSE were also associated with the standard measures or clinical outcomes. Stepwise logistic regression models were derived using baseline self-reported medication management capacity as the dependent variable. Collinearity diagnostics were performed on the final models. Nonsignificant predictors were entered into the final models to check for uncontrolled confounding (change in β coefficient of >10%). Residual and regression diagnostics were performed.

RESULTS

Study Population

A total of 67 patients were approached. Four were ineligible, two did not take any medications, one lived in a different facility at the time of the study, and five declined to participate (these individuals were more cognitively and functionally impaired than those who agreed to participate). A total of 58 subjects were enrolled in the study and completed the baseline assessment. At 6 months, three patients had moved from independent apartments to an on-site skilled nursing facility (study endpoint). Fifty-three of the 55 community-dwelling patients (96%) completed the 6-month follow-up assessment; one refused to participate and another did not complete the DRUGS test. Forty-seven (86%) of the 55 eligible participants completed the 12-month follow-up assessment; five refused to complete the study, and three were lost to follow-up.

The mean age at study entry was 84.2 ± 5.1 years; 72% of the participants were women, 68% were college educated. There was no significant difference between the patients who participated in the baseline, 6-month, and 12-month assessments in terms of age, gender, living arrangement, or level of education (Table 1).

Table 1. Demographic Data at Baseline, 6, and 12 Months

	Baseline	6 Mo	12 Mo
Number of participants (%)	59	53 (90)	47 (81)
Mean age, y (*SD*)	84.2 (5.1)	84.1 (4.9)	85.2 (5.3)
Gender, number women (%)	43 (72)	37 (70)	31 (70)
Living arrangement, number alone (%)	44 (73)	37 (70)	31 (70)
Level of education, number completed college (%)	41 (69)	36 (68)	30 (4)
Assisted living, number (%)	3 (5)	5 (8)	9 (18)
Nursing home, number (%)	0 (0)	3 (5)	3 (6)

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Change in Functional Status

The baseline, 6-, and 12-month mean values for standard measures of cognitive, affective, physical, and functional status, medication-specific factors, and DRUGS summary scores are presented in Table 2. There was a decline in MMSE (27.2 to 26.4, $p = .029$), an increase in the timed "Up and Go" test (13.1 to 18.6 s, $p = .023$), and a decline in the DRUGS score (93.2 to 81.1, $p = .029$). The increase in the timed "Up and Go" was also evident at 6 months (13.1 to 17.5 s, $p = .0008$). There was no change in the Geriatric Depression Scale, Jaeger score, or Charlson Comorbidity Index. Self-reported IADL and activities of daily living (ADL) scores did not change over the 12-month follow-up period. At 12 months, nine (18%) of the participants resided in assisted-living rather than independent-living housing units, compared with three participants (5%) at study entry ($p = .031$).

Baseline, 6-, and 12-Month Correlates

At baseline, 6, and 12 months, there was a positive association between the DRUGS tool and MMSE scores ($r = .42$, $p = .0008$; $r = .34$, $p = .003$; and $r = .35$, $p = .018$, respectively). Controlling for medication-specific factors in a multivariate model, both 12-month DRUGS score and 12-month self-reported medication management capacity were associated with 12-month MMSE ($p = .0001$, $p = .019$, respectively).

There was a significant association between the 6-month DRUGS tool and 6-month self-reported ADL capacity ($p = .025$). Both 12-month DRUGS scores and 12-month self-reported medication management capacity were associated with 12-month IADL capacity ($p = .026$, $p = .007$, respectively). Neither DRUGS performance nor self-reported medication management capacity was associated with the total number or total dose of medication at baseline, 6, or 12 months.

Table 2. Standard Measures, Self-Report and DRUGS Tool at Baseline, 6, and 12 Months

	Baseline DRUGS Mean (*SD*)	6-Mo DRUGS Mean (*SD*)	12-Mo DRUGS Mean (*SD*)
Standard			
Charlson Index	1.3 (1.2)	1.4 (1.4)	1.2 (1.2)
Jaeger score	5.4 (3.7)	4.6 (3.8)	5.0 (3.9)
MMSE	27.2 (2.4)	26.8 (3.5)	26.4 (4.1)*
Geriatric Depression Scale	3.6 (3.1)	3.7 (2.8)	3.9 (2.9)
Timed "Up and Go," s	13.1 (5.9)	17.5 (10.8)*	18.6 (16.3)*
Self-report			
ADLs capacity	5.8 (0.4)	5.8 (0.5)	5.7 (0.7)
IADLs capacity	6.4 (1.9)	6.3 (2.3)	6.6 (2.3)
MM capacity, number (%)†	48 (81.4)	41 (75.9)	38 (80.9)
DRUGS tool			
Total medications	6.6 (3.0)	6.4 (3.7)	7.6 (3.6)
Total doses	9.3 (5.3)	9.1 (6.0)	10.3 (5.4)
Summary score	93.2 (11.2)	87.9 (20.3)	81.1 (29.3)*
Time to completion, min	4.2 (2.9)	3.3 (2.3)	4.4 (4.4)

Note: MMSE = Mini-Mental State Examination; ADLs = activities of daily living; IADLs = instrumental activities of daily living; MM = medication management.

*Denotes statistically significant change compared with baseline, $p \leq .05$.

†Able to take medication independently by self-report.

Change in DRUGS score between baseline and 6 months was associated with an increased frequency of emergency department visits ($p = .024$), whereas change in self-reported medication management capacity was associated with an increased frequency of ambulatory clinic visits ($p = .024$). Change in DRUGS summary score and in self-reported medication management capacity between baseline and 12 months was associated with residence in assisted- versus independent-living situations at 12 months ($p = .049$, $p = .030$).

Predictive Value

Both baseline DRUGS score and self-reported medication management capacity were also associated with residence in assisted-living situations at 6 months (summary score, 80.2 vs 94.4 for those in assisted- vs independent-living situations at 6 months; $p = .029$, $p = .040$, respectively). There was no association between either the performance-based or self-reported measures of medication management capacity and the 12-month clinical outcomes. MMSE was not associated with any of the 6- or 12-month clinical outcomes.

Multivariate analyses, adjusted for age, gender, living arrangement, and medication-specific factors, demonstrated a statistically significant association between baseline DRUGS summary score (dependent variable), change in MMSE ($\beta = 1.69$, $p = .0002$), and change in Geriatric Depression Scale ($\beta = 1.93$, $p = .002$) over time. The logistic regression model with baseline self-reported medication management capacity as the dependent variable, adjusted for age, gender, living arrangement, and medication-specific factors, included change in Geriatric Depression Scale (odds ratio = 0.99, 95% confidence interval = 0.62, 1.57; $p = .965$).

There was no evidence of collinearity between the variables in the model by Belsey-Kuh-Welch criteria. Outliers (data points with jackknife residuals >3 or <-3) were removed, and the model was rerun without significant change in the β coefficients. There were no influential points (Cook's distance >1).

Discussion

This study had three major findings. First, the DRUGS tool has face validity as a measure of medication management capacity over time. Second, the DRUGS tool provides information about functional correlates, particularly cognitive status. Finally, the DRUGS score is apparently associated with subsequent transfer from an independent-living to an assisted-living situation.

The DRUGS tool has implied functional significance. It has intrinsic value in assessing medication management capacity. Short-term follow-up data confirm the relationship between self-reported ADL and IADL scores and self-reported and performance-based medication management capacity. Irrespective of the actual summary score, the DRUGS tool is designed to provide valuable information regarding the patient's ability to manage his or her own medication regimen without assistance.

There is a robust association between the DRUGS tool and cognitive status as measured by the MMSE. Unlike the MMSE, however, change in DRUGS score is associated

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with the need for increased home services (i.e., assisted living) and multiple emergency room visits. This study did not explore the specific reasons for the transfer. The DRUGS score may reflect deterioration in health or functional status. Alternatively, mismanagement of medications, with or without subsequent adverse drug events, may have precipitated the move. Medication management capacity as measured by the DRUGS tool may provide a key to understanding the patient's ability to live independently.

There are several limitations to this study. This was a small cohort of highly functioning, well-educated individuals. The power of the study was insufficient to detect differences in clinical outcomes, such as institutionalization or death. In addition, the results are not readily generalizable to the population at large, and the DRUGS tool needs to be validated in a larger, ethnically and socioeconomically diverse population of older adults. Nevertheless, the DRUGS tool appeared to identify highly functioning individuals who are at risk of functional decline in this sample population. These findings may actually strengthen the validity and comparative value of the DRUGS tool as a measure of medication management capacity and functional status.

In conclusion, the DRUGS tool, a performance-based screening tool that relies on direct observation, may complement self-report measures of medication management capacity and may be useful in predicting functional decline.

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