JAMDA 13 (2012) 390–393

JAMDA

journal homepage: www.jamda.com

Original Study

The Role of Cognitive Impairment in the Use of the Diskus Inhaler

Malcolm Fraser MD, FAAFP, CMD [a,*], Meenakshi Patel MD, FACP, CMD [b], Edward Paul Norkus PhD [c], Cyndi Whittington RN [d]

[a] University of South Florida, Department of Internal Medicine, Tampa, FL
[b] Wright State University, Director of Geriatrics, Miami Valley Hospital, Dayton, OH
[c] Montefiore Medical Center North, Bronx, NY
[d] Valley Medical Research, Dayton, OH

Keywords:
COPD
nursing home
Diskus
cognitive impairment

A B S T R A C T

Background and Purpose: Drugs delivered by metered-dose inhalers and dry powder inhalers (DPIs) are a mainstay in the treatment of chronic lung disease; however, previous studies suggest cognitive impairment hinders proper use of inhalers. The purpose of this study was to determine the relationship between the score on the Mini-Mental State Exam (MMSE) and the ability of nursing facility residents to complete the steps required for proper use of a multiunit-dose DPI (Diskus).

Methods: Nursing facility residents who had never used a multiunit-dose DPI (Diskus), who scored between 10 and 24 inclusive on the MMSE, and who were able to hold a breath for 10 seconds were recruited for an observational study to test their ability to use a placebo-loaded Diskus when supervised and assisted by personnel trained in the proper use the Diskus. Ability to use the DPI was assessed by the Diskus Evaluation Rating Scale (DERS), an instrument developed specifically for this study. Possible scores on the DERS ranged from 0 to 19, with a score of 0 indicating no limitations in any of the steps involved in using the Diskus and 19 indicating inability to do any of the steps after 3 supervised attempts.

Results: Forty Diskus-naïve nursing facility residents (86 ± 9 years of age; 32 women) with MMSE scores between 10 and 24 inclusive and the ability to hold a breath for 10 seconds were enrolled in the study. Mean MMSE scores were 17.4 ± 4.2, whereas the mean score on the DERS was 5.1 ± 3.2 (range 1–16). After controlling for age, gender, and education, a significant inverse relationship was noted between scores on the MMSE and the DERS such that for every 1-point increase on the MMSE, the subject's DERS score decreased by 0.345 points ($P = .003$). Overall, 38 of the 40 subjects with MMSE scores between 10 and 24 inclusive were able to use the Diskus successfully.

Conclusion: For MMSE scores, the better the performance on the MMSE, the better the performance on the DERS. More important, 95% of the subjects in this study could use the Diskus successfully when properly supervised. In contrast to earlier studies, these findings suggest that a multiunit-dose DPI can be prescribed as one component of the regimen for chronic lung disease in patients with substantial cognitive impairment.

When considering the relationship between chronic lung disease and cognitive impairment, there are 2 cohorts of patients requiring special attention when crafting the pulmonary treatment regimen. One cohort is composed of patients who develop cognitive impairment as a consequence of chronic obstructive pulmonary disease (COPD),[1] and the other is composed of people with Alzheimer's and related dementias who develop lung disease subsequent to onset of the dementing illness. In either case, determining how the patient's cognitive impairment affects adherence to the treatment plan should be an important clinical task in the care of older adults with COPD.

With regard to patients who develop cognitive impairment as a consequence of COPD, 3 studies are pertinent. The first, published more than a quarter century ago, reported that many of the patients with severe COPD who were enrolled in a trial to evaluate the efficacy of nocturnal oxygen therapy had significant cognitive impairment and that 42% of them showed improvement in cognitive function with nocturnal oxygen.[2] In a second study, almost half of COPD patients surviving their first episode of acute respiratory failure requiring mechanical ventilation had impaired cognitive function at the time of hospital discharge.[3] In the third publication, 4150 respondents who completed cognitive testing in 1996 and at least one subsequent survey, and excluding those with unknown

The authors have declared no conflicts of interest.

* Address correspondence to Malcolm Fraser, MD, FAAFP, CMD, Bay Geriatrics, 4905 34th Street, #610, St. Petersburg, FL 33711.
E-mail address: mf@baygeriatrics.com (M. Fraser).

1525-8610/$ - see front matter Published by Elsevier Inc. on behalf of the American Medical Directors Association, Inc.
doi:10.1016/j.jamda.2011.04.004

history of COPD, were surveyed; 12% of participants had COPD. Of these, 29% had severe COPD and those with severe COPD showed significant cognitive decline.[4]

The other cohort, patients with Alzheimer's and related dementias who develop lung disease, is described in a report from the Alzheimer Disease Research Center at the University of California, Los Angeles. Findings from this study indicate that COPD was a comorbid condition in 36.5% of demented patients who underwent complete autopsies supplemented with premorbid clinical findings.[2]

Optimal treatment of COPD usually involves drugs delivered by metered-dose inhalers (MDIs) and various types of dry powder inhalers (DPIs).[5] However, previous studies suggest cognitive impairment hinders proper use of inhalers, thereby compromising their potential benefit for people with Alzheimer's disease and related dementias and patients who have developed cognitive impairment as a consequence of COPD.[6] A 1997 report suggested that patients with moderate dementia were unable to learn 3 inhaler techniques of increasing levels of complexity.[6] Ability to use MDIs and Turbohalers was correlated with performance on the Mini-Mental State Examination (MMSE) and EXIT 25 (the executive interview for mild dementia developed by Dr Royall in San Antonio, TX) in a study published in 2003, which concluded that acquisition and short-term retention of MDI and Turbohaler techniques is unlikely to be successful in frail elderly people who have an MMSE lower than 23 of 30 and/or an abnormal EXIT 25.[7] An abnormal EXIT 25 was proposed to be the superior predictor of inability to learn inhaler techniques.[7] Several years later, the same group of researchers reported that most patients with an MMSE lower than 24 or the inability to copy a figure of 2 intersecting pentagons will not be able to learn MDI technique.[8] Furthermore, inability to copy a figure of 2 intersecting pentagons had the best overall predictive value.[8] Another group of investigators have reported that an MMSE lower than 24 and dependence in at least one instrumental activity of daily living had the best sensitivity and specificity in identifying cognitive impairment sufficient to adversely impact adherence to recommended treatment regimens.[9]

The purpose of this study was to determine the relationship between the score on the MMSE and nursing facility residents' ability to complete the steps required for the proper use of a multiunit-dose DPI (Diskus) when supervised by facility staff.

Methods

Nursing facility (NF) residents with dementia but not with COPD were randomly selected from 4 long term care nursing facilities (2 in Ohio and 2 in Florida). These subjects had never used a multiunit-dose DPI (Diskus). Those who scored between 10 and 24, inclusive, on the MMSE and were able to hold a breath for 10 seconds were recruited for an observational study to test their ability to use a placebo-loaded Diskus when supervised and assisted by nursing facility personnel trained in the proper use of the Diskus. The placebo-loaded Diskus was provided by GlaxoSmithKline. There was no control group in this study. The study was approved by the New England IRB, an independent institutional review board for sponsors, CROs, and individual researchers that is accredited by the Association for the Accreditation of Human Research Protection Programs. Appropriate procedures for consent and assent were in place.

Subjects had to have dementia to be included in the study. The power of attorney as determined by the respective state laws was consented. If the participants were able to understand the study by verbalizing understanding, they were assented.

After informed consent was obtained, investigators met with each subject and reviewed the subject's chart to confirm eligibility.

Table 1
Patient Characteristics

No. of subjects	40
Male/Female	8/32
Mean age, y	86 ± 9 (SD), Range 51–100
Age range, y	51–100
Race	American Indian: 2.5% (1/40) Asian: 5% (2/40) African American: 2.5% (1/40) White: 90% (36/40)
Mean years of education	12 ± 2 (SD), Range: 8–20
Mini-Mental State Examination	17.4 ± 4.2 (SD), Range 10–24
Mean Diskus Evaluation Rating Scores	5.1 ± 3.2 (SD), Range 1–16

The subject was asked to take a deep breath and hold it while the investigator counted to 10. If the subject was able to hold a breath for 10 seconds, then an MMSE was administered. If the score on the MMSE was between 10 and 24 inclusive, the subject was instructed on the use of the Diskus, including demonstration of the "open, click, inhale, and close" steps, followed by asking the subject to repeat the steps. The investigator could repeat the demonstration 2 more times, for a total of 3 demonstrations if necessary, for the subject to complete all 4 steps successfully. The demonstration took less than 5 minutes on average.

Ability to complete the steps in the proper use of the DPI was assessed by the Diskus Evaluation Rating Scale (DERS), an instrument developed specifically for this study. The DERS was developed using the number of steps required for successful use of the Diskus inhaler and the number of attempts that were made to use it successfully. Possible scores on the DERS range from 0 to 19 with a score of 0 indicating complete success (no limitations) in any of the steps involved in the use of the Diskus and 19 indicating inability to do any of the steps after 3 cycles of supervision and assistance. The DERS is shown in Appendix 1. Finally, the investigator completed a global assessment of the use of the Diskus, indicating whether the subject's overall ability to use the Diskus was adequate or inadequate.

The data collected on each subject were entered into a Microsoft Excel spreadsheet. Statistical analysis was conducted using a commercially available software package (STATA, 10.0).

Results

Table 1 provides a description of the subjects in the study. The 40 Diskus-naïve NF residents had a mean age 86 ± 9 years and included 32 women. MMSE scores for subjects included in the study were between 10 and 24 inclusive, and each subject was able to hold a breath for 10 seconds. Overall, 38 of the 40 subjects were able to use the Diskus successfully (Table 2). MMSE scores had a mean of 17.4 ± 4.2 with a range of 10 to 24, whereas the mean score on the DERS was 5.1 ± 3.2 with a range of 1 to 16. After controlling for age, gender, and education, a significant inverse relationship was noted between scores on the MMSE and the DERS such that for every 1-point increase on the MMSE, the subject's

Table 2
Success Rates of Using the Diskus Inhaler

	%	No.
1st attempt: subjects who were successful	0	0/40
2nd attempt: subjects who were successful	52.5	21/40
3rd attempt: subjects who were successful	42.5	17/40
Failure after 3 attempts	5	2/40

Ninety-five percent (38/40) of subjects were able to successfully use the Diskus within 3 tries (2 failures in 40 subjects).

Table 3
Relationship between Diskus Evaluation Rating Scale (DERS) and MMSE Score*

Independent Variables	Dependent Variable
	Diskus Evaluation Rating Scale (0–19 range)
y-intercept	−0.51188 (.927)
Age, y	0.08149 (.1110)
Gender (0=F/1=M)	−0.42813 (.728)
Schooling, y	0.37455 (.106)
MMSE Score (0–30 range)	−0.34521 **(.003)**
R^2	0.3335
F	4.25
P value	**.00676**

This analysis examined the potential relationship between a subject's Diskus Evaluation Rating Scale and his or her MMSE score. In this analysis, subject age, gender, and years of education also were examined to determine if one or all could have an independent or confounding effect on the suspected relationship.

*These calculations show a significant inverse relationship between a patient's Diskus Evaluation Rating Scale and MMSE score such that for every 1-unit increase in MMSE Score the patient's Diskus Evaluation Rating Scale decreases by 0.345 units (ie, for every 3-unit increase in MMSE the Diskus Evaluation Rating Scale decreases by 1-unit; $P = .003$).

DERS score decreased by 0.345 points ($P = .003$). Table 3 and Figure 1 describe this relationship in more detail.

Discussion

For NF residents with MMSE scores between 10 and 24 inclusive, the better the performance on the MMSE, the better the performance on the DERS. More important is the finding that 95% of subjects in this cohort of NF residents with cognitive impairment who could hold a breath for 10 seconds when prompted, could successfully use the Diskus.

In contrast to previous studies, the main findings in this study are more encouraging. In a study of acquisition and short-term retention of Turbohaler techniques, one-third of patients with an MMSE of 23 or lower were unlikely to be successful, whereas all patients with an MMSE higher than 23 retained the ability to use the Turbohaler over the short term.[6] Another study reported that most patients with an MMSE lower than 24 would not be able to learn MDI technique.[10] In the study described herein, patients with MMSE scores as low as 10 were able to use a device such as a Diskus when properly supervised.

This study is similar to previous reports in that sample size is small. An additional limitation is that the DERS has not been validated elsewhere. However, the study was conducted in 4 nursing facilities, 2 in Ohio and 2 in Florida. The fact that we used trained research staff to conduct this study may have played a role in the successful use of the Diskus inhaler; however, it may take no more than 10 minutes to train the trainer in most nursing facilities. It also took more than one attempt to get subjects to use the Discus successfully. The challenges faced by NFs are turnover and time constraints; however if a facility is interested in quality improvement and a potential for reducing COPD exacerbations, it could be time well invested to produce better outcomes.

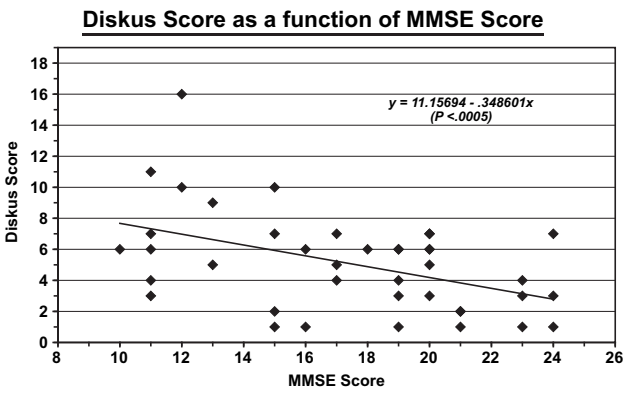

Fig. 1. Diskus score as a function of MMSE score.

Conclusion

For MMSE scores between 10 and 24 inclusive, the better the performance on the MMSE, the better the performance on the DERS. More important, 95% of the subjects in this study were able to use the Diskus successfully when properly supervised. In contrast to earlier studies, these findings suggest that a multiunit-dose DPI can be prescribed as one component of the regimen for chronic lung disease in patients with substantial cognitive impairment. Based on this work in NFs, similar studies could be conducted in the assisted living setting to determine the appropriate amount of supervision or assistance required for residents with varying degrees of cognitive impairment to use a multiunit-dose DPI (Diskus).

References

1. Liesker JJ, Postma DS, Beukema RJ, et al. Cognitive performance in patients with COPD. Respir Med 2004;98:351–356.
2. Heaton RK, Grant I, McSweeny AJ, et al. Psychologic effects of continuous and nocturnal oxygen therapy in hypoxemic chronic obstructive pulmonary disease. Arch Intern Med 1983;143:1941–1947.
3. Ambrosino N, Bruletti G, Scala V, et al. Cognitive and perceived health status in patients with chronic obstructive pulmonary disease surviving acute on chronic respiratory failure: A controlled study. Intensive Care Med 2002;28: 170–177.
4. Hung WW, Wisnivesky JP, Siu AL, Ross JS. Cognitive decline among patients with chronic obstructive pulmonary disease. A J Respir Crit Care Med 2009; 180:134–137.
5. Celli BR, Macnee W. ATS/ERS Task Force. Standards for the diagnosis and treatment of patients with COPD: A summary of the ATS/ERS position paper. Eur Respir J 2004;23:932–946.
6. Allen SC. Competence thresholds for the use of inhalers in people with dementia. Age Ageing 1997;26:83–86.
7. Allen SC, Jain M, Ragab S, Malik N. Acquisition and short-term retention of inhaler techniques require intact executive function in elderly subjects. AgeAging 2003;32:299–302.
8. Allen SC, Warwick-Sanders M, Baxter M. A comparison of four tests of cognition as predictors of inability to learn to use a metered dose inhaler in old age. Int J Clin Pract 2009;63:1150–1153.
9. Antonelli-Incalzi R, Corsonello A, Trojano L, et al. Screening of cognitive impairment in COPD. Dement Geriatr Cogn Disord 2007;23:264–270.
10. Fu C, Chute DJ, Farag ES, et al. Comorbidity in dementia: An autopsy study. Arch Pathol Lab Med 2004;128:32–38.

Appendix 1

Diskus Evaluation Rating Scale

		Completed by (1)	Subject Score	Possible Score	Guide
A- Open Phase					
1.	Can Subject open the DISKUS cover?			0–3	0 = successful 1st attempt 1 = successful 2nd attempt 2 = successful 3rd attempt 3 = not successful.
2.	How many efforts until the mouthpiece snaps into position?			0–3	Same as 1 above
Open Phase Score				**0–6**	
B-Click Phase					
3.	Is the lever slid away?			0–3	Same as 1 above
4.	How many efforts until it clicks?			0–3	Same as 1 above
Click Phase Score				**0–6**	
C-Inhale Phase					
5.	Is DISKUS kept horizontal?			0–1	0 = Yes 1 = No
6.	Is DISKUS spontaneously put to lips?			0–1	0 = Yes 1 = No
7.	Does the subject breathe in quickly and deeply on the first effort? If not, how many efforts are required to breathe in deep and quick?			0–3	Same as 1 above
8.	Is breath held for 10 seconds?			0–1	0 = Yes 1 = No
9.	Is DISKUS closed?			0–1	0 = Yes 1 = No
Inhale Phase Score				**0–7**	
Total Score				**0–19**	

(1) PU = Patient Unassisted. N = Nurse or other Health Care Professional. PA = Patient with Assistance.

Rater:_____ _____ _____ (Printed Name) (Signature) (Date)