Chronic Obstructive Pulmonary Disease: Prevalence, Characteristics, and Pharmacologic Treatment in Nursing Home Residents with Cognitive Impairment

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ABSTRACT

BACKGROUND: Chronic obstructive pulmonary disease (COPD) is prevalent in nursing home residents. National and international guidelines exist for management of COPD; however, little is known about "real-world" management of COPD in this population. Nursing home patients with significant cognitive impairment may have difficulty utilizing handheld device (HHD) formulations of respiratory medications and may be clinically appropriate candidates for nebulized therapy.

OBJECTIVES: To determine (a) the prevalence, clinical characteristics, and treatment of patients with a diagnosis of "emphysema/COPD" per Minimum Data Set (MDS) version 2.0 records in U.S. nursing homes and (b) the relationship of nebulized versus HHD formulations of medication to prevalence of shortness of breath in a cohort of cognitively impaired nursing home residents.

METHODS: In a descriptive, retrospective analysis of a large data repository of skilled nursing home residents with COPD, prescription claims and MDS data from October 1, 2009, through September 30, 2010, were extracted, linked, and de-identified. Measures included medications, diagnoses, and selected outcome parameters from the MDS. Cognitive impairment was defined as a score of 3-6 on the Cognitive Performance Scale derived from MDS records. A proxy of ≤ 14 -day courses of respiratory antibiotics, oral corticosteroids, or both was used to identify COPD exacerbations. Shortness of breath (SOB) in the last 7 days was captured from Section J1.I. of the MDS.

RESULTS: The total number of unique patients with at least 1 MDS record during the study period was 126,121. Of those, 27,106 (21.5%) had COPD. The prevalence rates of diagnoses concurrent with COPD were as follows: asthma = 8.6%, Alzheimer's disease or other dementia = 37.2%, congestive heart failure = 37.5%, anxiety disorder = 23%, depression = 50.1%, pneumonia = 21.2%, and respiratory infection = 9%. 58% of patients with COPD were white females aged 75 years or older. According to the MDS, 62% of COPD patients had a short-term memory problem, while 43.3% of patients had moderately or severely impaired cognitive skills for daily decision making. 83% of COPD patients with pharmacy claims (17,395/27,106) received at least 1 medication used to treat COPD; 9,711 (17.1%) received no respiratory medications. Use of beta-agonists (53.9%), anticholinergic medications (41.2%), long-acting beta-agonist/corticosteroid (LABA/ICS) combinations (28%) in HHD, and nebulized beta-agonist/anticholinergic combinations (26.6%) was prevalent. Inhaled LABA/ICS and long-acting anticholinergic therapy was received by 28% and 22% residents, respectively. 22% ($n=5,085$) of patients exhibited at least 2 exacerbations of COPD, and 33% were noted to have SOB. Monotherapy with short-acting beta-agonists (SABA) was evident in 48.7% of cognitively impaired COPD patients. SOB within the previous 7 days was noted in 39.1% of cognitively impaired COPD patients treated with nebulized SABA monotherapy. 38% of these patients exhibited 2 or more COPD exacerbations, and 57.9% were hospitalized at least once during the 12-month period. LABA monotherapy or combined LABA/SABA use represented $\leq 1\%$ of beta-agonist use for unique COPD patients with cognitive impairment.

CONCLUSIONS: In this retrospective analysis of administrative data, 21.5% of nursing home residents had a diagnosis of COPD, and 17% of these residents received no respiratory medications. These residents had significant cognitive and functional impairment and concurrent diagnoses. 22% of residents experienced at least 2 exacerbations of COPD during the 12 months of study. As many as 60% were not receiving inhaled LABA/ICS or inhaled tiotropium, and 33% exhibited SOB. There is significant use of nebulized SABA monotherapy, which may be contributing to SOB and exacerbations or hospitalizations in nursing home residents with COPD.

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What is already known about this subject

- Little is known about the way that chronic obstructive pulmonary disease (COPD) medications are utilized in nursing home residents. Given the prevalence of Alzheimer's disease and non-Alzheimer's dementia in nursing homes, cognitive and physical function is moderately to severely impaired. Allen et al. (2009) noted that subjects older than 70 years of age with moderate dementia were unable to learn and coordinate 3 stages of inhalation techniques using metered dose inhalers.
- COPD has been identified as one of 5 conditions responsible for potentially avoidable hospitalizations in nursing home residents (Walsh et al. 2012). Age >70 years has been associated with increased all-cause hospitalization and high financial burden in Medicare beneficiaries with COPD patients residing in nursing homes.
- Monotherapy with short-acting beta-agonists for management of COPD is discouraged in the Global Initiative for Chronic Obstructive Lung Disease guidelines.

What this study adds

- Consequences of nebulized short-acting beta-agonists (SABA) monotherapy in nursing home residents have not been previously characterized. This study indicates that shortness of breath (SOB) and exacerbations are common in this population and may be related to use of SABA in the absence of long-acting beta-agonists (LABA) or long-acting anticholinergic agents. Between 33.9% and 39.8% of patients with moderate to very severe cognitive impairment treated with SABA monotherapy exhibited SOB. Additionally, 17% of patients with a diagnosis of COPD received no medications.

What this study adds (*continued*)

- Twenty-two percent of nursing home residents with COPD experienced at least 2 exacerbations of COPD, and as many as 60% were not receiving a long-acting agent. Over 55% were hospitalized at least once, and 11.3% had at least 1 emergency room visit.
- Nebulization is a common route of administration for respiratory medications in nursing home residents independent of their cognitive function. Thirty-nine percent of residents with moderate to very severe cognitive impairment received SABA monotherapy.

The prevalence of chronic obstructive pulmonary disease (COPD) in the nursing home setting is approximately 10%-20%.¹ The Global Initiative for Chronic Obstructive Pulmonary Disease (GOLD), the American Medical Directors Association (AMDA) Clinical Practice Guidelines, and the guidelines by the American College of Physicians, American College of Chest Physicians, American Thoracic Society, and European Respiratory Society recommend the use of long-acting beta-agonists and/or anticholinergics for management of patients with moderate and more severe COPD.²⁻⁴ Among nursing home patients with COPD, there is variation in the medication class, route of administration, and formulation used to treat this condition. For example, some patients require nebulized therapy due to comorbidities or functional impairment, while others prefer the nebulized route of administration for these medications because they feel they are more effective.⁵

The GOLD and AMDA guidelines recommend a stepwise approach to therapy for patients with COPD.^{2,3} While short-acting bronchodilators are recommended on a “when needed” basis beginning in mild disease and throughout the course of the disease, the addition of routine treatment with 1 or more long-acting bronchodilators should occur beginning in moderate disease, and inhaled corticosteroids should be added for those with severe or very severe disease if repeated exacerbations occur. The addition of long-term oxygen therapy is recommended for those with very severe disease.²⁻⁴ For exacerbations of COPD, the GOLD and AMDA guidelines recommend increasing the dose or frequency of short-acting inhaled bronchodilators, considering short-course systemic corticosteroid therapy, and utilizing short-term antibiotic therapy for patients with clinical signs of airway infection, such as increased sputum purulence.

The multiple medical conditions, complicated medication regimens, and high prevalence of cognitive impairment add to the challenge of the risk-benefit assessment that clinicians face when treating COPD in nursing home patients. It is estimated that between 50% and 70% of patients in nursing facilities have some degree of dementia. In 2008, 68% of all nursing home patients had some degree of cognitive impairment, the

majority of which was moderate to severe,⁶ while 2009 data showed that 47% of all nursing home patients had a diagnosis of Alzheimer’s disease or other dementia in the nursing home record.⁷

The standardized assessment tool for patients in nursing facilities, the Minimum Data Set (MDS) version 2.0, contains individual items that can identify patients with cognitive impairment.⁸ The Cognitive Performance Scale (CPS) score is a measure of cognition that is calculated from 5 unique MDS version 2.0 items (item B1: Comatose; item B2a: Short-Term Memory; item B4: Cognitive Skills for Daily Decision Making; item C4: Making Self Understood; and item G1ha: Eating). The CPS has been shown to have a significant positive correlation with the Mini-Mental State Examination (MMSE) and is scored on a 0-6 scale, with 0 corresponding to No Impairment (intact) and 6 corresponding to Very Severe Impairment.⁹⁻¹¹ Nursing home patients with significant cognitive impairment may have difficulty utilizing handheld device (HHD) formulations (metered-dose or dry powder inhalers) of COPD medications and may be clinically appropriate candidates for nebulized therapy.¹²

The objective of this study was to develop a “profile” of patients in nursing homes with a diagnosis of COPD, including but not limited to pertinent demographic information, concurrent diagnoses, medications used in the treatment of COPD, other concomitant medications, and numerous functional (e.g., ability to ambulate independently) and quality of life (e.g., oxygen use) parameters extracted from the MDS and pharmacy claims data. Further, we sought to determine the relationship of short-acting beta-agonists (SABA) versus long-acting beta-agonists (LABA) and handheld devices (HHD) versus nebulized medication use to prevalence of shortness of breath (SOB) in a cohort of cognitively impaired nursing home residents.

■ Methods

The MDS is a comprehensive, standardized resident assessment instrument that is utilized in nursing facilities to develop care delivery and planning; monitor clinical indicators such as falls, fractures, cognition, and behavior; and determine payment from Medicare. The MDS assessment is conducted for all residents of nursing facilities upon admission, quarterly, annually, and when the resident has a significant change in status. Version 2.0 of the MDS was used for this study. The MDS data elements have been validated, and there is evidence for inter-rater reliability.¹³ Over 85% of MDS data elements have been found to be reliable with adequate inter-rater reliability and overall good agreement.^{13,14} The strongest reliability was with elements related to activities of daily living (ADL). ADL, pain, distressed mood, behavioral disturbances, and social engagement elements of the MDS have manifested discriminant validity.¹⁵ Validity problems have been reported with MDS data

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elements of visual acuity, pain frequency and intensity, and resident incontinence, all of which were excluded as measures of interest for this study.¹⁵ The instrument has been criticized by some for data discrepancies that occur due to miscoding. Agreement rates for a number of data elements have been reportedly poor but reliability adequate when calculated using a weighted kappa statistic.¹⁴ While there are limitations to this caregiver-related assessment instrument, it is a standardized tool that provides the “best available evidence” of resident status and outcomes in the nursing facility setting.

Information for this study was gleaned from Omnicare Senior Health Outcomes (OSHO) Data Warehouse of resident records (demographic and admission tables), resident MDS records, prescription records, drug data and prescriber specialty records, facility records, and prescriber records. Most of the data in the OSHO Data Warehouse is refreshed on a daily basis, with the exception of resident MDS records and drug data records (data dictionary).

The real-time data is collected from about 200 pharmacies serving more than 1.4 million residents in about 19,000 long-term care and other health care facilities in 48 states (excludes Hawaii and Alaska) and Canada. The database stores over 600 million pharmacy (Rx) claims processed within the last 6 years. All de-identifiable datasets carry a unique resident identification key that allows longitudinal tracking at the prescription claims level. The prescription data can be analyzed by National Drug Code (NDC), brand name, strength, dosage form, individual ingredient, and drug therapeutic class. Resident MDS records are available for residents in facilities that use the AccuMed electronic MDS system, a small subset (estimated to be 10%-15%) of the residents within the Omnicare network.

Within the OSHO Data Warehouse are 2 datasets: pharmacy claims data for residents in Omnicare-serviced nursing homes and MDS data for residents in nursing homes that are clients of AccuMed's electronic MDS application. Omnicare is the owner of the pharmacy claims data and a processor of the MDS data. To perform the data match, prescription claims data were obtained from the warehouse, and MDS data were obtained from the warehouse for the time period of October 1, 2009, through September 30, 2010. Once the 2 datasets were extracted, they were matched using resident demographics. Then, the matched records were de-identified using a “safe harbor” method in which all 18 identifiable data elements listed in section 164.514(b)(2) of the HIPAA Privacy Rule were removed and replaced with internal identifiers. The internal identifier is a randomly generated number that is not derived from or related to the information about the individual and is not otherwise capable of being translated to identify the individual. In addition, all internal identifiers were encrypted using a 128-bit, one-way hashing algorithm to further ensure that identifiers cannot be traced to individuals.

FIGURE 1 Patient Selection Flow Diagram

^aMedications listed in Table 3.

COPD=chronic obstructive pulmonary disease; Dx=diagnosis;
HCR ManorCare=nursing home company; MDS=Minimum Data Set;
Rx=pharmacy; SAVA=nursing home company.

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TABLE 1 Long-Term Care Patients with COPD Diagnosis from MDS Records and Other Concurrent Diagnoses

Diagnosis	Total Number ^a	Percentage ^b
Asthma (MDS item I1hh)	2,335	8.6
Alzheimer disease (MDS item I1q)	2,499	9.2
Dementia other than Alzheimer's disease (MDS item I1u)	7,595	28.0
Congestive heart failure (MDS item I1f)	10,169	37.5
Anxiety disorder (MDS item I1dd)	6,247	23.0
Depression (MDS item I1ee)	13,582	50.1
Pneumonia (MDS item I2e)	5,736	21.2
Respiratory infection (MDS item I1f)	2,447	9.0
Diabetes mellitus (MDS item I1a)	10,794	39.8
Cerebrovascular accident (MDS item I1t)	5,071	18.7
Arthritis (MDS item I1l)	7,481	27.6
Hypertension (MDS item I1h)	18,419	68.0
Osteoporosis (MDS item I1o)	4,511	16.6
Cerebral palsy (MDS item I1s)	78	0.3
Multiple sclerosis (MDS item I1w)	137	0.5
Parkinson's disease (MDS item I1y)	1,129	4.2
Quadriplegia (MDS item I1z)	89	0.3
Traumatic brain injury (MDS item I1cc)	114	0.4
Anemia (MDS item I1oo)	8,365	30.9
Cancer (MDS item I1pp)	2,630	9.7
Total unique patients with diagnosis of COPD	27,106	

^aTotal number of unique patients in MDS database with COPD diagnosis and listed concurrent diagnosis.

^b $[(\text{Unique patients with diagnosis of COPD and listed concurrent diagnosis in MDS database}) \div \text{unique patients with COPD diagnosis in database}] \times 100$.

COPD=chronic obstructive pulmonary disease; MDS=Minimum Data Set.

Figure 1 depicts the patient selection algorithm for this study. Initially, a count of unique patients for whom MDS data existed in the database was obtained and served as the denominator for determining the prevalence of COPD. The diagnosis of emphysema/COPD was made if the presence was noted on MDS item I1.ii and asthma if so noted by item I1.hh. The unique number of patients with a diagnosis of COPD in MDS records ($n=27,106$) was then used as the denominator for all nonmedication-related calculations. However, for the medication data, the denominator used was the total number of unique patients with a diagnosis of COPD in MDS records who had at least 1 pharmacy claim ($n=20,978$). Not all residents with a diagnosis of COPD received treatment with respiratory medications, despite having other prescription claims in the OSHO Data Warehouse. Additionally, not all residents with a diagnosis of COPD had their medications supplied by Omnicare. Therefore, in order to calculate the percentage of treated patients, the denominator of patients for whom pharmacy records are available ($n=20,978$) was used.

For patients who had more than 1 MDS assessment during the 12-month study period, MDS results were compared, and

the answer representing the more severe condition was used. For example, if MDS item C1 (hearing) was scored a 0 ("hear adequately") in one assessment and 2 ("hear in special situations only") in another, then the latter score was used for that patient.

SOB was defined by positive selection of J1.b and J1l on the MDS. An exacerbation of COPD was defined as an episode in which a patient received either a short course (≤ 14 days) of "respiratory" antibiotics¹⁶ or oral corticosteroids or both. We calculated the percentage of patients with 2 or more exacerbations in 12 months. Respiratory antibiotics, identified by First DataBank's specific therapeutic classification (GC3), were denoted as azithromycin, levofloxacin, moxifloxacin, amoxicillin/clavulanate, doxycycline, cefuroxime, cefdinir, cefpodoxime, gemifloxacin, amoxicillin, trimethoprim-sulfamethoxazole, clarithromycin, cefprozil, cefditoren, cefepime, ceftazidime, imipenem/cilastatin, meropenem, piperacillin/tazobactam, vancomycin (parenteral only), linezolid, gentamicin, tobramycin, and amikacin for the purposes of this investigation. Descriptive statistics were performed for all data fields.

Results

The total number of unique patients with at least 1 MDS assessment during the study period was 126,121. Of those, a total of 27,106 unique patients had a diagnosis of COPD indicated on MDS records, resulting in a COPD prevalence of 21.5%.

Concurrent Diagnoses

In patients with a diagnosis of COPD, the prevalence of an asthma diagnosis per MDS records was 8.6%; Alzheimer's disease or other dementia was 37.2%, congestive heart failure 37.5%, anxiety disorder 23%, depression 50.1%, pneumonia 21.2%, and respiratory infection 9% (Table 1).

Demographic and Clinical Profile from Minimum Data Set

Demographically, the majority of patients with a diagnosis of COPD were white females (82%, 58.4%, respectively) and aged 75 years or older (64.7%). Approximately 16% of patients were between the ages of 75-79 years; the prevalence of those 80-84 years, 85-89 years, and 90 years or older was 19.2%, 17.5%, and 12.1%, respectively. Blacks made up 9.8% of the COPD population, while Hispanics accounted for 5% of patients. In the year prior to admission, tobacco products were used at least daily in 9.4% of patients.

Clinically, 62% of COPD patients had a short-term memory problem, while 43.3% of patients had moderately or severely impaired cognitive skills for daily decision making (Table 2). This is in agreement with CPS scores for the study sample in which 41.8% of patients had CPS scores of 3-6, indicating moderate to very severe impairment. Conversely, nearly 60% of patients with COPD had none-to-mild cognitive

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TABLE 2 Long-Term Care Patients with COPD Diagnosis with Selected MDS Data Elements

MDS Data Element	Total Number	Percentage	MDS Data Element	Total Number	Percentage
Gender (MDS item AA-2 from BATF)			Respiratory infection (I2f=checked)	2,447	9.0
Male (MDS item AA-2=1)	11,283	41.6	Septicemia (I2g=checked)	895	3.3
Female (MDS item AA-2=2)	15,823	58.4	Health conditions (Section J)		
Age category (from birth date in MDS item AA-3 from BATF)			Problem conditions (J1)		
<65 years	3,800	14.0	Inability to lie flat due to shortness of breath (J1b=checked)	3,348	12.4
65-69 years	2,612	9.6	Shortness of breath (J1l=checked)	8,953	33.0
70-74 years	3,162	11.7	Stability of conditions (J5)		
75-79 years	4,299	15.9	Conditions/diseases make resident's cognitive, ADL, mood, or behavior unstable (J5a=checked)	6,809	25.1
80-84 years	5,215	19.2	Resident experiencing an acute episode or flare-up of a recurrent or chronic problem (J5b=checked)	12,990	47.9
85-89 years	4,741	17.5	End-stage disease, 6 or fewer months to live (J5c=checked)	1,211	4.5
>90 years	3,277	12.1	Weight change (K3)		
Race/ethnicity (MDS item AA-4 of BATF)			Weight loss (5% or more in last 30 days or 10% or more in last 180 days)		
Unknown	331	1.2	No (K3a=0)	20,654	76.2
American Indian/Alaskan native	180	0.7	Yes (K3a=1)	5,824	21.5
Asian/Pacific Islander	362	1.3	Weight gain (5% or more in last 30 days or 10% or more in last 180 days)		
Black, not of Hispanic origin	2,660	9.8	No (K3b=0)	22,884	84.4
Hispanic	1,353	5.0	Yes (K3b=1)	3,597	13.3
White, not of Hispanic origin	22,220	82.0	Special treatments and procedures (Section P)		
Memory (section B2 of MDS Full Assessment Form)			Special care (P1a)		
Short-term memory			Chemotherapy (P1a a=checked)	222	0.8
memory okay (item B2a=0)	10,210	37.7	Dialysis (P1a b=checked)	818	3.0
memory problem (item B2a=1)	16,784	61.9	IV medication (P1a c=checked)	14,828	54.7
Long-term memory			Monitoring acute medical condition (P1a e=checked)	18,261	67.4
memory okay (item B2b=0)	16,949	62.5	Oxygen therapy (P1a g=checked)	14,325	52.8
memory problem (item B2b=1)	10,051	37.1	Suctioning (P1a i=checked)	568	2.1
Cognitive skills for daily decision making (Section B4)			Tracheostomy care (P1a j=checked)	500	1.8
Independent (item B4=0)	8,289	30.6	Ventilator or respirator (P1a l=checked)	301	1.1
Modified independence (item B4=1)	7,022	25.9	Respiratory therapy (P1b d A does not=0)	2,748	10.1
Moderately impaired (item B4=2)	9,390	34.6	Hospital stays (P5)		
Severely impaired (item B4=3)	2,363	8.7	None (P5=0)	10,403	38.4
Making self understood (Section C4)			One (P5=1)	12,958	47.8
Understood (item C4=0)	17,866	65.9	Two (P5=2)	1,826	6.7
Usually understood (item C4=1)	5,169	19.1	Three (P5=3)	291	1.1
Sometimes understood (item C4=2)	2,858	10.5	Four (P5=4)	57	0.2
Rarely/never understood (item C4=3)	1,178	4.3	Five (P5=5)	12	0.0
Ability to understand others (Section C6)			More than five (P5>5)	14	0.1
Understands (C6=0)	16,333	60.3	Total unique patients with diagnosis of COPD	27,106	
Usually understands (C6=1)	6,358	23.5			
Sometimes understands (C6=2)	3,405	12.6			
Rarely/never understands (C6=3)	968	3.6			
Disease diagnoses (Section I)					
Infections					
Pneumonia (I2e=checked)	5,736	21.2			

ADL=activities of daily living; BATF=Basic Assessment Tracking Form; COPD=chronic obstructive pulmonary disease; IV=intravenous; MDS=Minimum Data Set.

impairment. Physical impairment was very common in this population (Figure 2), with greater than 65% of patients requiring extensive assistance or noted to be totally dependent on staff assistance in the areas of bed mobility, transfer, dressing, and personal hygiene. Twenty-four percent of patients required extensive assistance or were totally dependent on staff for assistance with eating.

Related specifically to COPD symptomatology, one-third of patients were noted to have SOB, and 12.4% of patients were unable to lie flat due to SOB. Additionally, 52.8% of patients required oxygen therapy; however, only 10.1% received respiratory therapy services. Comorbidities commonly associated with COPD were highly prevalent in these patients, including depression (50.1%), anemia (30.9%), diabetes mellitus (39.8%),

FIGURE 2 Percentage of Long-Term Care Patients Requiring Extensive Assistance or Totally Dependent for Activities of Daily Living

and congestive heart failure (37.5%). Although osteoporosis is known to be associated with COPD, only 16.6% of patients had this diagnosis in MDS records. Osteoporosis and possible skeletal muscle dysfunction (which is not captured in MDS data) may have contributed to the prevalence of falls (70.3% of patients within a 180-day period) and fractures (13.7% of patients within a 180-day period) that were noted. A weight loss of 5% or more in the previous 30 days or 10% or more in the previous 180 days was noted in 21.5% of patients, while 13.3% had a corresponding weight gain.

Regarding the overall stability of conditions for the patients with COPD, 47.9% were noted to be experiencing an acute episode or flare-up of a recurrent or chronic problem, although the MDS does not specify the exact nature of the acute problem. Nearly 5 percent (4.5%) of patients with COPD were noted to be end stage (defined as 6 or fewer months to live). The diseases responsible for this end-stage designation were not captured by MDS data. Finally, during the study period, 47.8% of patients required 1 hospital stay; 6.7% required 2 hospital stays; and 9.8% required at least 1 emergency room visit.

Medication Use

Among the 27,106 unique patients with a diagnosis of COPD, 17,395 (82.9%) received at least 1 medication used to treat COPD. Those patients with a diagnosis of COPD who received no respiratory medications for this condition numbered 9,711 (17.1%). Table 3 provides a summary of medication use.

The use of nebulized dosage forms of SABA (48.6%) and short-acting anticholinergic (23.4%) medications was more

common than SABA (15.1%) and short-acting anticholinergic (1.9%) medications delivered via HHD. Using less than or equal to 14-day courses of respiratory antibiotics, oral corticosteroids, or both as a proxy for an acute exacerbation of COPD, there were 5,085 of 23,022 unique COPD patients (22.1%) with 2 or more exacerbations.

Table 4 depicts the percentage of patients with moderate to very severe cognitive impairment receiving monotherapy with SABA, LABA, or the combination in HHD and nebulized formulations with the corresponding presence of SOB, exacerbations, and hospitalizations. In the 48.7% of cognitively impaired patients that received SABA monotherapy, SOB was noted in 39.1%, while 59.1% had 1 or more hospitalizations over the 12-month period. Nebulized SABA monotherapy was the most common form of COPD treatment in these cognitively impaired individuals. Patients receiving LABA monotherapy were less likely to have SOB (25%) or an exacerbation (26.9%), but the number of patients receiving LABA monotherapy is too small to draw conclusions.

Discussion

This is a real-world look into the clinical characteristics and treatment of nursing home residents with COPD. Because of the frailty, underlying concomitant illness, and prevalence of cognitive impairment of patients in this health care setting, treatment decisions are based commonly on information deduced from family, medical records, facility staff, and the MDS data. While portable spirometry can be performed in the nursing home, based on the limitations in accuracy of

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spirometry in this population, diagnosis is usually based on symptoms and history.¹⁷ In light of these considerations, a real-world investigation performed retrospectively using a large data repository contributes substantial information about the management of COPD in nursing home residents.

This analysis revealed that 21.5% of nursing home residents had a diagnosis of COPD, and 17% of those with COPD received no respiratory medications. Our sample depicts a population with significant cognitive and functional impairment, serious comorbid illness, and the presence of conditions that make the patient's cognition, functionality, mood, or behavior unstable. At least 20% of residents treated for COPD experienced at least 2 acute exacerbations of COPD during the 12 months of study, and as many as 60% were not receiving long-acting beta-agonist/corticosteroid (LABA/ICS) HHD combination therapy. Despite the prevalence of exacerbations requiring treatment with a respiratory antibiotic or respiratory antibiotic and oral corticosteroid, only 5,863 patients (28%) received inhaled LABA/ICS combination therapy as recommended by the GOLD and AMDA guidelines.^{2,3}

Along with Pleasants (2009), we found that more than a quarter of nursing home residents with COPD have comorbidities such as cardiovascular disease, diabetes, osteoporosis, and dementia complicating their treatment and adding to the burden of illness.¹ The results of a quality improvement project identified COPD as one of the most prevalent conditions leading to 7-day and 30-day hospital readmission rate of 23% in a sample of patients discharged from a community hospital to a nursing home.¹⁸ Simoni-Wastila et al. (2009), using a retrospective analysis of a large administrative claims database, reported that 43.3% of long-term care residents with COPD had at least 1 hospitalization, and 90% had at least 1 emergency room visit.¹⁹ Age greater than 70 years was associated with an increase in all-cause hospitalization and increased burden of illness. COPD has recently been identified as 1 of 5 conditions associated with potentially avoidable hospital admissions of dually eligible Medicaid and Medicare beneficiaries, 20%-60% of which could be prevented.²⁰

Limitations

The limitations of this study are characteristic of retrospective database analyses. Claims prescription data accurately reflect dispensed medications as they are adjudicated online and represent information 6 months or longer post-reconciliation. However, not all patients received their medications from Omnicare, and medication consumption may be over-represented, using prescription claims data in nursing home residents who may refuse or spit out doses, resulting in waste. There are potential inaccuracies in coding of MDS data due to poor medical historical data and inter-rater variability. When reviewed by others, MDS data have been reported to have

TABLE 3 Medication Use in Long-Term Care Patients with COPD

Group	Total Patients	Percentage
Inhaled beta-agonists	11,303	53.9
Short-acting beta-agonists, HHD	3,172	28.0
Short-acting beta-agonists, nebulized	10,189	90.1
Long-acting beta-agonists, HHD	440	3.9
Long-acting beta-agonists, nebulized	230	2.0
Inhaled anticholinergics	8,654	41.3
Short-acting anticholinergics, inhalers	400	1.9
Short-acting anticholinergics, nebulized	4,906	23.4
Long-acting anticholinergics, HHD	4,610	22.0
Inhaled corticosteroids	2,363	11.3
Oral corticosteroids	6,203	29.6
Oral theophylline	587	2.8
Leukotriene inhibitors	1,644	7.8
Cromolyn/necromodil	3	0.01
Beta-adrenergic/anticholinergic HHD combos	1,764	8.4
Beta-adrenergic/anticholinergic nebulized combos	5,586	26.6
Beta-adrenergic/corticosteroid HHD combos	5,695	27.2
Selected "nonfixed" combinations		
Beta-adrenergic HHD/anticholinergic inhaler	1,381	6.6
Beta-adrenergic HHD/anticholinergic nebulized solution	686	3.3
Beta-adrenergic nebulized solution/anticholinergic HHD	2,608	12.43
Beta-adrenergic nebulized solution/anticholinergic nebulized solution	4,605	22.0
Beta-adrenergic HHD/corticosteroid inhaler	495	2.4
Beta-adrenergic nebulized solution/corticosteroid nebulized solution	767	3.7
Subtotal of unique patients with at least 1 claim for a COPD medication	17,395	
Patients with at least two $\leq$ 14-day courses of respiratory antibiotics and/or oral corticosteroids	5,085	22.1
Oral beta-blockers	10,836	51.7
Oral beta-blockers, selective	7,713	71.2
Oral beta-blockers, nonselective	3,527	32.6
Total unique patients	20,978	

COPD = chronic obstructive pulmonary disease; HHD = handheld device.

moderate to moderately high validity and reliability.²¹ The linking of these datasets allows investigators to ask questions that can be viewed as hypothesis generating for future studies rather than conclusive or causative.

Unfortunately, the degree of pulmonary functional or symptomatic impairment cannot be quantified using administrative data only. Thus, disease severity cannot be evaluated as a variable affecting product choice in these patients. Furthermore, disease staging through spirometry has limitations in frail elderly adults for whom respiratory effort can be severely compromised and lung volumes reduced.¹²

Chronic Obstructive Pulmonary Disease: Prevalence, Characteristics, and Pharmacologic Treatment in Nursing Home Residents with Cognitive Impairment

TABLE 4 Inhaled Beta-Agonist Therapy and Shortness of Breath in Long-Term Care Patients with Moderate to Very Severe Cognitive Impairment and COPD Diagnosis

Beta-Agonist Type	Number of Patients Receiving	Percentage	Number of Patients with SOB	Percentage	Number of Patients with EXACERB Either/Or ^a	Percentage	Number of Patients with HOSP ^b	Percentage
Cognitive impairment, CPS=3-6	8,476		2,673		2,470		4,560	
Total number of patients and existence of Rx claims for study-selected medications ^c								
SABA monotherapy ^c								
SABA HHD	450	5.3	121	26.9	25	5.6	268	59.6
SABA nebulized	3,311	39.1	1,296	39.1	1,262	38.1	1,916	57.9
SABA HHD+nebulized	364	4.3	197	54.1	154	42.3	253	69.5
Total SABA monotherapy	4,125	48.7	1,614	39.1	1,441	34.9	2,437	59.1
LABA monotherapy ^d								
LABA HHD	28	0.3	5	17.9	6	21.4	18	64.3
LABA nebulized	23	0.3	8	34.8	8	34.8	13	56.5
LABA HHD+nebulized	1	0.0	0	0.0	0	0.0	0	0.0
Total LABA monotherapy	52	0.6	13	25.0	14	26.9	31	59.6
Combination therapy ^e								
SABA HHD+LABA HHD	15	0.2	5	33.3	3	20.0	11	73.3
SABA HHD+LABA nebulized	10	0.1	7	70.0	5	50.0	5	50.0
SABA nebulized+LABA HHD	38	0.4	18	47.4	18	47.4	26	68.4
Nebulized SABA and LABA	46	0.5	24	52.2	23	50.0	28	60.9
Total combination therapy	109	1.3	54	49.5	49	45.0	70	64.2
Total of SABA/LABA with CPS=3-6	4,286	50.6	1,681	39.2	1,504	35.1	2,538	59.2

^aEXACERB=exacerbation as defined by 2 or more $\leq$ 14-day courses of either oral corticosteroids or respiratory antibiotics or both.

^bHOSP=1 or more hospitalizations over the entire year.

^cMedications listed in Table 3.

^dMonotherapy=not receiving combination SABA/LABA therapy concurrently.

^eCombination therapy=receiving combination SABA/LABA therapy concurrently.

COPD=chronic obstructive pulmonary disease; CPS=Cognitive Performance Scale; HHD=handheld device; LABA=long-acting beta-agonist; Rx=pharmacy;

SABA=short-acting beta-agonist; SOB=shortness of breath.

Lastly, the use of short-course antibiotic and/or corticosteroid therapy as a proxy for COPD exacerbations may overestimate the actual number of exacerbations given that these therapies are prescribed for other indications as well. In our search of the literature, we could find no similar studies of nursing home residents with COPD and view an understanding of these findings as a necessary first step in improving the quality of care and reducing COPD exacerbations in this population. Despite the potential limitations described, this real-world examination provides meaningful insight regarding several key observations.

Conclusions

Nursing home patients with COPD and cognitive impairment are a special population for whom optimal management of COPD is challenging. Monotherapy with HHDs or nebulized SABAs is prevalent and can be a sign of, or contributor to, unstable disease that may help explain SOB in nearly one-third of all treated patients and COPD exacerbations in 22.1% of patients. Undertreatment with a LABA, whether by HHD or

nebulization in those with moderately severe or severe cognitive impairment, was evident.

In this population of patients with moderately severe and severe cognitive impairment, nebulized LABA, long-acting inhaled anticholinergic, and the combination of LABA/ICS therapy should be considered to align treatment with practice guidelines, reduce the prevalence of SOB, and reduce COPD exacerbations.

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