Geriatric Nursing xx (2017) 1–6

Contents lists available at ScienceDirect

Geriatric Nursing

journal homepage: www.gnjournal.com

Identification of pseudobulbar affect symptoms in the nursing home setting: Development and assessment of a screening tool

Carrie Allen, PharmD [a,*], Barbara Zarowitz, PharmD [1,a], Terrence O'Shea, PharmD [a], Edward Peterson, PhD [b], Charles Yonan, PharmD [2,c], Fanta Waterman, PhD, MPH [c]

[a] Omnicare Senior Health Outcomes – a CVS Health Company, Cincinnati, OH, USA
[b] Henry Ford Health System, Detroit, MI, USA
[c] Avanir Pharmaceuticals, Inc., Aliso Viejo, CA, USA

ARTICLE INFO

Article history:
Received 29 November 2016
Received in revised form
2 June 2017
Accepted 9 June 2017
Available online xxx

Keywords:
Pseudobulbar affect
Nursing home
Screening
Dextromethorphan hydrobromide/quinidine sulfate
Long-term care

ABSTRACT

Pseudobulbar Affect (PBA) is a neurologic condition characterized by involuntary outbursts of crying and/or laughing disproportionate to patient mood or social context. Although an estimated 9% of nursing home residents have symptoms suggestive of PBA, they are not routinely screened. Our goal was to develop an electronic screening tool based upon characteristics common to nursing home residents with PBA identified through medical record data. Nursing home residents with PBA treated with dextromethorphan hydrobromide/quinidine sulfate (n = 140) were compared to age-, gender-, and dementia-diagnosis-matched controls without PBA or treatment (n = 140). Comparative categories included diagnoses, medication use and symptom documentation. Using a multivariable regression and best decision rule analysis, we found PBA in nursing home residents was associated with chart documentation of uncontrollable crying, presence of a neurologic disorder (e.g., Parkinson's disease), or by the documented presence of at least 2 of the following: stroke, severe cognitive impairment, and schizophrenia. Based on these risk factors, an electronic screening tool was created.

Introduction

Pseudobulbar Affect (PBA) is a neurologic condition characterized by involuntary outbursts of laughing and/or crying incongruous with, or disproportionate to, the patient's emotional state.[1] PBA is hypothesized to arise from disruption of brainstem structures from cortical inhibition and is associated with several predisposing central nervous system disorders, including stroke, traumatic brain injury (TBI), dementia, amyotrophic lateral sclerosis (ALS), Parkinson's disease (PD), Huntington's disease (HD) and multiple sclerosis (MS).[1] The prevalence of PBA is estimated at about 2 million in the United States.[1] In 2013, a retrospective database study was conducted to assess the potential prevalence of PBA in nursing home residents (NHR) using documented presence of "crying/tearfulness" as a proxy measure. This study found that almost 1 in 10 residents had "crying, tearfulness" documented on the Minimum Data Set 2.0 (MDS), a uniform assessment tool for NHR used in facilities certified to receive payment from Medicare and/or Medicaid.[2] Additionally, identified residents with "crying, tearfulness" exhibited a higher prevalence of all other MDS mood and behavioral indicators, and greater psychopharmacological medication use compared with matched control residents without documented "crying, tearfulness".[2] Likewise, a 2015 study of 811 residents from 9 nursing homes in Michigan found a similar 9% prevalence of potential PBA (based on a rating scale measure), and a higher use of anxiolytic and antipsychotic medications.[3]

Patients with PBA symptoms report impaired social and occupational functioning, and when compared with patients without these symptoms, they have more neurological comorbidities, a higher medication burden, adverse medical outcomes (e.g. falls), and a lower quality of life (QOL).[1–4] To date, few studies have explored NHR prescribed dextromethorphan hydrobromide/quinidine sulfate (DM/Q) for treatment of PBA, and there is no simple method to identify residents who may be suffering with PBA. Two

Abbreviations: ALS, Amyotrophic lateral sclerosis; BIMS, Brief Interview for Mental Status; CP, consultant pharmacists; DM/Q, dextromethorphan hydrobromide/quinidine sulfate; HD, Huntington's disease; MARS, medication administration records; MDS, Minimum Data Set; MS, multiple sclerosis; NH, nursing home; NHR, nursing home residents; PBA, Pseudobulbar Affect; PD, Parkinson's disease; POS, physician orders sheet; QOL, quality of life; SCI, severe cognitive impairment; TBI, traumatic brain injury.

* Corresponding author. Omnicare Senior Health Outcomes – a CVS Health Company, 900 Omnicare Center, 201 East Fourth Street, Cincinnati, OH 45202, USA.
E-mail address: Carrie.Allen@omnicare.com (C. Allen).

[1] Former employee of Omnicare Senior Health Outcomes - a CVS Health Company

[2] Former employee of Avanir Pharmaceuticals

0197-4572/$ – see front matter © 2017 Elsevier Inc. All rights reserved.
http://dx.doi.org/10.1016/j.gerinurse.2017.06.002

screening assessments are available to screen patients for PBA. The Center for Neurologic Study-Lability Scale (CNS-LS), a 7-item scale used to assess the frequency of PBA symptoms, has been validated in patients with MS and ALS.[5,6] The Pathological Laughter and Crying Scale (PLACS), a 16-item quantitative scale that measures the severity of PBA, has shown high reliability and has been used to effectively rate PBA in patients with stroke and traumatic brain injury.[7,8] Although these screening tools are commonly used to assess PBA symptoms, they are more suited for community use and may be burdensome when applied to the NH setting.

The purpose of this study was to use descriptive data from NHR medical records, to develop a preliminary list of characteristics to facilitate identification of PBA in NHR. This is a starting point to guide future studies in the development of a validated screening tool. Residents treated with DM/Q and a diagnosis of PBA (n = 140), were compared with an age range-, gender-, and dementia-diagnosis matched control group without PBA or DM/Q treatment (n = 140). Multivariable logistic regression and a best decision rule analysis were performed to determine what characteristics were associated with a risk of PBA.

Methods

Design

A non-interventional, cross-sectional, case-control methodology was used to compare the case cohort, NHR treated with DM/Q who had a documented diagnosis of PBA, with an age range-, gender-, and dementia-diagnosis matched control group without PBA or DM/Q treatment during the study period of 4/28/2015–8/03/2015. Age range groupings for matching were defined as <65 (not elderly), 65–74 (young-old), 75–84 (middle old), ≥85 (old-old or oldest-old) based on age groupings meaningful in geriatrics/sociology for disease burden and overall experience.

Sample

The study design included a 1:1 ratio of PBA cases to controls. Inclusion criteria are described in Table 1. It was assumed *a priori* that the minimum number of residents needed for sufficient power (80%) was 220; and that the percent of controls exposed was 20% and the two-sided alpha value was 0.05. This resulted in the test being able to detect an odds ratio of 2.22 or higher. The cases and controls were a convenience sample of NHR across 22 states, with selection based on the inclusion criteria listed in Table 1, availability of charts, and consent by the facility to collect data.

Measures

Data collection form

An electronic data collection form (see Appendix) was developed to systematize the data collection from medical records, as there is poor documentation of PBA and associated symptoms in the nursing home (NH) setting. PBA, if documented, is usually found in the diagnosis list or healthcare providers' notes, as section I of the MDS (diagnoses) does not have a designated checkbox for PBA.[9] Based on the literature, the form focused on comorbid neurologic and psychiatric conditions, severe cognitive impairment, behaviors specific to PBA, presence of severe agitation/aggression, and psychopharmacologic medication use. The PRISM registry informed question 8 regarding most common neurological conditions associated with PBA.[1] In addition to PRISM, specific predisposing neurologic diagnoses (e.g. traumatic brain injury), the presence of severe agitation, severe cognitive impairment, medication use, and presence of crying or laughing uncontrollably and/or inconsistent with surroundings (PBA behaviors) were based on the work of Brooks et al., 2013, Foley et al., 2015, and Colamonico et al., 2012.[1,3,4] Other questions regarding medications of interest and comorbidities/behaviors associated with PBA were informed by Zarowitz et al., 2013 and Work et al., 2011.[2,10]

Data collection

A data analyst queried Omnicare's national prescription claims database and identified residents who had a persistent prescription for DM/Q (≥100 days, no more than a 2-day gap in therapy at any time). Once identified, local consultant pharmacists (CP) were recruited to participate in data collection. CP who agreed to participate were trained to perform data collection and how to select appropriately matched controls at each nursing home (NH). Training was self-paced and on-line, with ongoing individual support from the study investigator. Written consent was obtained from each facility to allow data collection by CP. The CP confirmed that each identified patient had a documented diagnosis of PBA, selected an appropriate matched control, completed the data collection forms, and submitted these data to the study investigator. Data were aggregated and submitted to a statistician for analysis. This protocol qualified for an IRB exemption and a waiver of informed consent requirements upon review by Sterling IRB.

Clinical data

Clinical data included diagnoses/documentation of the following conditions in the medical record or MDS: dementia, MS, HD, PD, TBI, ALS, brain cancer, stroke, psychosis/psychotic disorder, schizophrenia, schizophreniform or schizoaffective disorder. Additionally, the presence of severe cognitive impairment (SCI) was recorded by the CP if it was documented in the chart or if the Brief Interview for Mental Status (BIMS) score on MDS indicated it was present.[9,11–13] Behaviors/emotional outbursts that may be characteristic of PBA were recorded if there was documentation of: 1) crying, sobbing or wailing uncontrollably, 2) inappropriate laughing, or laughing uncontrollably, inconsistent with environment or surroundings, or 3) both. Routine use of psychiatric medications in the 30 days prior to chart review was recorded for five categories: antidepressants, antipsychotics, anticonvulsants (used for mood stabilization), anxiolytics, and sedative/hypnotics.

Data analysis

Multivariable logistic regression, followed by a best decision rule analysis were performed to determine a short list of potential indicators of PBA in NHR from the data collected. First, clinical data were analyzed using a backwards, stepwise, multivariable logistic regression to determine which variables correlated with PBA.[14] The multivariable analysis examined each variable in the context of the other variables and averaged these strata to find risk factors for PBA that were conditionally significant. Odds ratios and their 95% confidence intervals were calculated. Dementia was excluded from this process, as it was a matched variable. Following the multivariable logistic regression, MS, HD, PD, TBI, ALS, and brain cancer were pooled into a single variable termed "neurologic disorder" for the best decision rule analysis. Aggregation of these specific variables occurred because the prevalence of each condition in the NH was too small to carry weight in a final screening tool. All other variables remained separate as they had a prevalence that was high enough to evaluate separately.

Then data from the multivariable analysis were used to inform a best-decision rule calculation, which identified the most parsimonious set of individual predictors of PBA from these data in the NH setting.[14] The individual predictors were then developed into a