In-patient comorbidities in inclusion body myositis: a United States national in-patient sample-based study

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Abstract

Objective

Inclusion body myositis (IBM) is the most common idiopathic inflammatory myopathy (IIM) above the age of 50 with a distinct clinical phenotype of progressive, painless, asymmetric weakness predominantly involving the long finger flexors and quadriceps. In this study, we compared comorbidities in IBM with other IIMs (i.e. dermatomyositis (DM) and polymyositis (PM)) from the United States National Inpatient Sample Database.

Methods

We identified patients with a primary diagnosis of IBM or IIM from the National Inpatient Sample (NIS) from 2012 to 2018. We then compared the rate of common inpatient comorbidities between the IBM and IIM.

Results

There were 18,819 admissions for patients with either IBM or IIM. IBM patients were older (72.9±10.7 years vs. 59.3±18.4 years for IIM, p<0.001), predominantly men (65.0% vs. 31.2% for IIM, p<0.001), and White Caucasians (82.5% vs. 58.4% for IIM, p<0.001). IBM patients had significantly more frequent events of aspiration pneumonia, atrial fibrillation, falls, and sepsis. The rate of PEG tube placement was also significantly higher. When performing multivariable logistic regression, we found that IBM is a risk factor for aspiration pneumonia (OR 3.03), PEG tube placement (OR 2.91), falls (OR 2.05), and sepsis (OR 1.30) but not for significant cardiovascular events.

Conclusion

IBM increases a patient's risk for dysphagia, falls, and infection as compared to other IIM patients. Further population-based studies are warranted to better elucidate the impact of these comorbidities in patients with IBM.

Key words

inclusion body myositis, dysphagia, idiopathic inflammatory myopathy, aspiration pneumonia

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Data availability statement
The NIS dataset is publicly available.

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Introduction

Sporadic inclusion body myositis (IBM) is the most common idiopathic inflammatory myopathy (IIM) in patients over the age of 50 and has a distinct clinical phenotype compared to other IIMs (1). IBM predominantly affects the long finger flexors and quadriceps muscles, and disease progression leads to the loss of hand function and independent ambulation (2, 3). IBM is also associated with swallowing dysfunction, falls, and significantly impaired quality of life. These events can present insidiously after limb weakness has already become apparent. About 40% of patients with IBM reported dysphagia at the time of diagnosis, and up to 80% develop dysphagia with disease progression. The incidence of dysphagia is much higher in IBM than in patients with other IIMs such as dermatomyositis (DM) and polymyositis (PM). While dysphagia is increasingly recognised as a significant morbidity of IBM, a detailed systematic examination of its burden is lacking (4-6). Similarly, the impact of other comorbidities in IBM compared to other IIMs (*i.e.* DM and PM) has not been explored in detail. Understanding the burden of dysphagia, falls, and other comorbidities in IBM is crucial as these events are often leading contributors to morbidity and mortality in patients with IBM and can lead to a multitude of complications such as malnutrition, dehydration, aspiration, injury, and systemic complications (7). To address this knowledge gap, we examined the United States (US) based National Inpatient Sample (NIS) database to understand the burden of dysphagia, falls, and medical comorbidities based on in-hospital events in patients with IBM compared to other IIMs.

Methods

The NIS is the largest in-patient healthcare database in the United States for estimating in-patient utilisation, quality, and outcomes (8). The NIS database estimates more than 35 million hospitalisations annually, representing approximately 20% of inpatient hospital admission in the USA. We queried the NIS database from years 2012 to 2018 for all patient discharges with prior diagnosis code of either IBM (ICD9: 359.71, ICD10: G72.41), DM (ICD9: 710.3, ICD10: M33.10), and PM (ICD9: 710.4, ICD10: M33.20). We grouped patients with either DM or PM into the IIM cohort and used them as the control group. To maintain homogeneity in analysis, we have used the database available from 2012 to the most recent available database (at the time of this analysis). We excluded patients with multiple diagnostic codes for inflammatory myopathies to have a clear delineation between the IBM and the IIM control group. We examined the burden of all the known common inpatient comorbidities and interventions found in patients with either IBM or IIM such as aspiration pneumonia, percutaneous endoscopic gastrostomy (PEG) tube placement, and falls, as well as other medical conditions such as chronic obstructive pulmonary disease (COPD), atrial fibrillation, congestive heart failure, sub-endocardial infarction, stroke, etc. The rate of occurrence for each comorbidity was compared between the IBM and IIM cohort. We further analysed the underlying variables that might explain the differences in incidence between the two cohorts.

Descriptive statistics were represented as percentages or mean ± standard deviation (SD) as applicable. We performed two-sided t-tests to compare normally distributed continuous variables between two groups, z-test for proportions, and chi-square analyses for categorical variables. We included cases with a complete dataset for age, gender, race, and hospital admission details for the regression analysis. A multivariable logistic regression analysis was performed to identify associations between age, gender, and underlying diagnosis with adverse hospital events that were more frequently found in the IBM cohort. We used Holm's method to adjust for multiple comparisons (9). A p-value <0.05 was considered to be statistically significant. All data processing and statistical analyses were performed with Python (2.7.16), R (3.6.2), and SPSS (26.0).

Our dataset was de-identified, so no informed consent from patients was necessary. This study received exemption

from the IRB at the Yale University School of Medicine.

Results

Between 2012 and 2018, there were a total of 18,819 admissions for patients with a primary diagnosis of IBM (2020), DM (6997), or PM (9802). We grouped the study population into two cohorts: the first for patients with IBM and the second for other IIM patients with either DM or PM. The mean age for patients in the IBM cohort was 72.9±10.7 years compared to 59.3±18.4 years for patients in the other IIM group ($p<0.001$). IBM patients were predominantly men (65.0%) as compared to the other IIM group being mostly female (68.8%) ($p<0.001$). Patients with IBM were predominantly White Caucasian (82.5%). In contrast, the IIM cohort had a much more diverse population with lower frequency of White Caucasians (58.4%) and a higher frequency of African American (25.6%) and Hispanic (10.7%) populations (Table I, Supplementary Table S1).

We noted significantly higher frequency of atrial fibrillation (16.8% *vs*. 11.3%), aspiration pneumonia (14.3% *vs*. 3.6%), falls (10.7% *vs*. 4.1%), unspecified septicaemia (6.4% *vs*. 4%), sub-endocardial infarction (4.8% *vs*. 2.6%), and stroke (1.6% *vs*. 0.9%) in the IBM cohort as compared to IIM (Suppl. Table S2). Given the known risk for dysphagia in IBM patients and PEG tube placement being a very common procedure performed in patients with aspiration risks, we compared the rate of in-patient PEG placement between the two cohorts. There was a significantly higher incidence of in-hospital PEG tube placement in the IBM group (6.6%) as compared to the other IIM cohort (2.4%) ($p<0.0001$) (Table II).

We performed a multivariable logistic regression analysis for each significant in-hospital complication among the patients combined across the IBM and IIM cohort. Furthermore, we assessed the degree in which an IBM diagnosis and other variables such as age and gender influence the likelihood of a certain complicating event. Men were 1.3 times more likely than women to develop aspiration pneumonia during their admission (OR=1.305, 95% confidence interval (CI): 1.131–1.505), and age only had a minimal effect (OR=1.026, 95% CI: 1.02–1.032). IBM increased the risk of aspiration pneumonia 3.0 times (OR=3.026, 95% CI: 2.574–3.558). We found a similar result for the PEG tube placement. Men had higher odds of undergoing PEG placement (OR=1.223, 95% CI: 1.011–1.481). And patients with IBM were 2.9 times more likely to receive PEG tube placement then IIM patients (OR=2.909, 95% CI: 2.323–3.644). Patients with IBM were also much more susceptible to falls compared to patients in the IIM cohort (OR=2.048, 95% CI: 1.723–2.433), but male gender (OR=1.326, 95% CI: 1.141–1.535), and increased age (OR=1.039, 95% CI: 1.035–1.044) also contributed to elevated fall risk. Similarly, an IBM diagnosis mildly increases the risk for sepsis (OR=1.300, 95% CI 1.058–1.598). While the absolute incidence for cardiac and vascular complications were higher in IBM, the multivariable logistic regression analysis revealed that an IBM diagnosis itself does not significantly contribute to such complications. Such elevated cardiovascular risk was primarily driven by an increased proportion of males in the IBM cohort (OR=1.588, 95% CI: 1.445–1.745, for atrial fibrillation, OR=1.683, 95% CI 1.408–2.012 for sub-endocardial infarction). Similarly, older age was the primary driver of increased stroke among IBM patients (OR=1.036, 95% CI 1.024–1.047) (Table II).

Table I. Comparison of demographics between IBM and IIM cohorts.

Demographic characteristics			
Characteristics	IBM (n=2020)	IIM (n=16799)	*p*-value
Women (%)	707 (35.0)	11560 (68.8)	<0.0001
Age, mean (SD), year	72.9 (10.7)	59.3 (18.4)	<0.0001
Race (%)			<0.0001
White	1667 (82.5)	9816 (58.4)	
Black	213 (10.5)	4297 (25.6)	
Hispanic	77 (3.8)	1793 (10.7)	
Asian	22 (1.1)	360 (2.1)	
Native American	7 (0.3)	81 (0.5)	

Discussion

The NIS database provides a large, comprehensive, and representative survey of disease burden across the United States, especially when examining rare diseases such as IBM and IIM where single centre studies may not yield required clinical insights that are generalisable to the entire patient population. The NIS has been reliably used to address some important clinical knowledge gaps in patients with IIM. Several studies on DM and PM based on the NIS database have shown a high rate of infection, cardiopulmonary and rheumatological comorbidities, and increased resource utilisation through imaging studies (10-13). However, large national scale studies on IBM are lacking.

In this study, we confirmed significant dysphagia-related in-patient complications in patients with IBM as compared to those with DM/PM (5). Furthermore, we identified falls to be another significant risk factor in the IBM cohort. Certain treatable medical comorbidities such as sepsis were also more common in IBM patients.

Dysphagia can severely reduce the quality of life and lead to serious medical complications; however, the impact of dysphagia in IBM has gained attention only in the recent past. (14, 15). Many early clinical trials in IBM ignored swallowing dysfunction, and only three randomised clinical trials have used stand-alone outcome measures of swallowing dysfunction in IBM (16-18). There was also limited knowledge on the mechanistic details of dysphagia in IBM. A recent study using real-time MRI showed that the pharyngeal transit time is about 2-fold longer in patients with IBM, and there are morphologic abnormalities in muscle (19, 20). While Rosenbek penetration-aspiration scale is used to classify the degree of dysphagia in IBM, and vide-

Table II. Comparison of in-hospital complications. Multivariate logistic regression to assess the degree in which age, gender, and diagnosis (IBM *vs*. IIM) influences the likelihood of common medical comorbidities. (Odds ratio and 95% confidence interval applies to each covariate age, gender, and diagnosis for each comorbidity).

Odds ratio for in-hospital complications (IBM *vs*. IIM)			
PEG Tube placement	6.6% (IBM)	2.1% (IIM)	
	OR	95% CI	*p*-value
Age	1.005	1.000 - 1.011	0.072
Gender (male)	1.223	1.011 - 1.480	0.038
Diagnosis (IBM)	2.909	2.323 - 3.644	<0.001
Aspiration pneumonia	14.3% (IBM)	3.6% (IIM)	
	OR	95% CI	*p*-value
Age	1.026	1.021 - 1.032	<0.001
Gender (male)	1.305	1.131 - 1.505	<0.001
Diagnosis (IBM)	3.026	2.574 - 3.558	<0.001
Atrial fibrillation	16.8% (IBM)	11.3% (IIM)	
	OR	95% CI	*p*-value
Age	1.050	1.046 - 1.053	<0.001
Gender (male)	1.588	1.445 - 1.745	<0.001
Diagnosis (IBM)	0.844	0.738 - 0.967	0.014
Sub-endocardial infarction	4.8% (IBM)	2.6% (IIM)	
	OR	95% CI	*p*-value
Age	1.031	1.024 - 1.037	<0.001
Gender (male)	1.683	1.408 - 2.012	<0.001
Diagnosis (IBM)	1.156	0.910 - 1.468	0.234
Stroke	1.6% (IBM)	0.9% (IIM)	
	OR	95% CI	*p*-value
Age	1.036	1.024 - 1.047	<0.001
Gender (male)	1.249	0.921 - 1.694	0.152
Diagnosis (IBM)	1.184	0.792 - 1.770	0.409
Sepsis	6.4% (IBM)	4.0% (IIM)	
	OR	95% CI	*p*-value
Age	1.011	1.007 - 1.016	<0.001
Gender (male)	1.271	1.096 - 1.474	0.001
Diagnosis (IBM)	1.300	1.058 - 1.598	0.013
Falls	10.7% (IBM)	4.1% (IIM)	
	OR	95% CI	*p*-value
Age	1.039	1.034 - 1.044	<0.001
Gender (male)	1.326	1.141 - 1.535	<0.001
Diagnosis (IBM)	2.048	1.723 - 2.433	<0.001

ofluoroscopy (VF), flexible endoscopic evaluations of swallowing (FEES), and real time MRI are used as a quantitative measure of swallowing dysfunction in IBM, there is a lack of a validated objective outcome measure (21, 22).

While there is no approved therapy for IBM or dysphagia in IBM, several exercises such as the Mendelsohn manoeuvre have been shown to help early-stage IBM patients with swallowing and maintaining nutrition without aspiration (23, 24). A recent study on using an expiratory muscle strength trainer device showed no improvement in swallowing function but it may have some preventative role (25). While one randomised clinical trial initially reported some objective improvement in dysphagia with intravenous immunoglobulin (IVIg) treatment, the results were not reproducible in the subsequent clinical trial (16). A series of studies have also shown evidence of IVIg coinciding with some improvement in dysphagia symptoms, some requiring multiple treatments to yield temporary effects for two months (26, 27). Invasive treatment with balloon dilation of the pharyngoesophageal segment to dilate the upper oesophageal sphincter and cricopharyngeal myotomy can be beneficial (27, 28).

Not surprisingly, falls were more frequent in patients with IBM, and a part of it stems from its distinct clinical phenotype. IBM predominantly affects the quadriceps and ankle dorsiflexion also can be affected. (15) Given the distribution of affected muscles, IBM patients are more susceptible to knee buckling and fall. About 73% of patients with IBM report frequent fall, and number of falls increases with disease progression (29). Usually, majority of patients with IBM require a cane about 7.5–10 years from symptom onset, and use wheelchair within 13–15 years from symptom onset (29, 30). Apart from standard fall precautions, there are no definitive guideline to avoid falls in IBM. Ankle foot orthoses are used by some patients in IBM (8.5%), and stance control orthosis was evaluated in a small number of patients, but their impact on preventing fall is not established (31, 32).

In this study, the rate of atrial fibrillation, sub-endocardial infarction, and strokes were higher in IBM patients. While higher frequency of hypertension, hyperlipidaemia, myocardial infarction, and congestive heart failure in IBM patients was reported in a single study, focused studies did not find any definitive cardiac involvement in IBM patients (33, 34). On the other hand, higher rates of atrial fibrillation in patients with IIM compared to patients with other autoimmune diseases has been reported (35, 36). There have been reported findings that patients with different IIM subtypes exhibited different levels of myocardial damage and that whereas elevated cardiac troponin may be due to elevated expression in skeletal muscle for IBM patients, it often represents actual inflammatory processes in the heart for patients with PM or DM (37, 38). In our cohort, the higher rate of cardiovascular comorbidities was related to male gender and age. Furthermore, the incidence of stroke was higher in IBM patients than DM/PM, yet it remains unclear if atrial

fibrillation is a contributing factor for the increased stroke burden. Whereas stroke can lead to dysphagia and may necessitate PEG tube placement, the incidence of stroke was lower than that of PEG tube placement. It is unlikely that stroke was a significant direct contributor to the burden of dysphagia in IBM patients. Overall, we identified the degree in which an IBM diagnosis directly contributes to the risk of modifiable complications such as dysphagia, falls, and sepsis and its lack of influence on other cardiac and vascular complications such as atrial fibrillation, cardiac infarction, and stroke. Having such knowledge can inform providers on ways to intervene with procedures, fall precautions, or infectious rule out and treatment in a proactive manner.

Despite providing valuable information, there are several limitations to our study. First, the NIS provides a weighted estimate of admissions rather than individualised patient information. This makes it difficult to draw conclusions for individual patients. In this study, we relied on diagnostic codes to identify patients with IBM and DM/PM and ICD diagnostic codes may not necessarily be fully reliable in correctly labelling the diagnostic subtype of inflammatory myopathies given the variability of clinical presentation and diagnostic criteria for IIMs. However, the large size of the NIS database dilutes the impact of possible diagnostic error. Furthermore, there is very limited clinical information provided other than basic demographic identifiers. Many possible contributing factors towards comorbidities in IBM could not be incorporated in the regression model given the unknown contribution from pre-existing medical and surgical conditions prior to the hospital admission. While some details regarding the social history can be inferred from income brackets and the type of hospital the patient was admitted to, there are many variables regarding barriers to health that are not represented in this dataset alone. That is, we could not rule out the possibility of biased results due to significant residual confounding. Finally, given the structure of the dataset, we compared the other comorbidities in IBM with DM/PM rather than healthy controls thus introducing some limitations to our conclusions. However, such a comparison helped in side-by-side assessment of comorbidities of IBM with common subtypes of IIM, and further reinforced the distinct nature of this debilitating disease (5).

Patients with IBM are prone to in-hospital complications related to dysphagia, falls, and infection. Overall, these complicating events are significant contributors to a reduction in quality of life for IBM patients (39). Recognising the associated co-morbidities is important as it reflects upon the magnitude of the knowledge gap regarding associated disabilities in IBM, this should stimulate further intellectual dialogue to develop meaningful interventions for these debilitating complications of IBM.

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