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ORIGINAL RESEARCH ARTICLE

Dysphagia in Inclusion Body Myositis

Clinical Features, Management, and Clinical Outcome

ABSTRACT

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Objective: To evaluate the clinical features, treatment strategies, and outcome of dysphagia in patients with inclusion body myositis.

Design: Retrospective review of all 26 patients (20 women, 6 men, mean age of 72.2 yrs) with inclusion body myositis-associated dysphagia seen in 1997–2001 at our institution.

Results: Twenty-four patients (92%) had a dysphagia evaluation. Cricopharyngeal muscle dysfunction was noted in all nine patients who had barium swallow studies. Eighteen patients (69%) underwent one or more interventional procedures: cricopharyngeal myotomy (10), pharyngoesophageal dilation (6), percutaneous endoscopic gastrostomy (6), and botulinum injection of the upper esophageal sphincter (2). Dysphagia tended to worsen with time. Symptomatic improvement was noted with cricopharyngeal myotomy (63%) and pharyngoesophageal dilation (33%). The Mendelsohn maneuver seemed helpful in maintaining oral intake in the three patients in whom it was recommended. Thirteen patients died during follow-up at a mean age of 81 yrs. The cause of death was identified in eight and in all cases was because of the respiratory complications of aspiration.

Conclusions: Dysphagia is a progressive condition in patients with inclusion body myositis and often leads to death from aspiration pneumonia. Treatment targeting cricopharyngeal muscle dysfunction, such as the Mendelsohn maneuver, will benefit from further investigation.

Key Words: Dysphagia, Inclusion Body Myositis, Swallowing Rehabilitation, Cricopharyngeal Myotomy, Aspiration Pneumonia

Inclusion body myositis (IBM) is a chronic, progressive, acquired myopathy, which usually occurs in patients older than 50 yrs of age.[1,2] It is characterized by an insidious onset and slow progression of painless muscle weakness of the proximal and distal muscles.[3–6] Although immunosuppressive therapies may provide transient benefits, there is no known effective treatment for this condition.[7,8]

Dysphagia is more common in IBM than in the other inflammatory myopathies[9] and is reported to be occurring in 38–84% of patients.[2,3,10–13] Moreover, its outcome is worse in patients with IBM than in those with either poly- or dermatomyositis[14] and its contribution to aspiration pneumonia associated respiratory failure may be the most common cause of death in people with IBM.[15]

Surgical interventions such as cricopharyngeal (CP) myotomy[8,13,16–19] and upper esophageal dilation[20] as well as botulinum injections of the upper esophageal sphincter (UES)[21] have been studied in patients with IBM, but a comprehensive evaluation of treatment modalities and their outcomes has not been reported.

Useful swallowing therapy methods in patients with neurological disorders causing CP dysfunction included the Mendelsohn maneuver, supraglottic swallowing, dietary adjustments, and change of head positioning.[22] CP dysfunction has been reported as the primary finding of modified barium swallow studies in patients with IBM-associated dysphagia;[2,3] however, it is not known whether the above swallowing therapy is beneficial in them. In particular, the Mendelsohn maneuver, prolonged laryngeal elevation to prolong the UES opening during swallowing[23,24] may have a role, but its effectiveness has not been established in patients with IBM-associated dysphagia.

In this study, we aimed to examine the clinical characteristics, management strategies, and outcome of the patients with IBM and dysphagia.

METHODS

This study involves a subgroup analysis of data that was previously reported by our group as part of a more general investigation of the presence and relative incidence of dysphagia in the inflammatory myopathies.[14] The database review began with the identification of all 783 patients diagnosed with inflammatory myopathy at our institution between January 1, 1997 and December 31, 2001. A second search resulted in the identification of 62 patients with dysphagia associated with a diagnosis of an inflammatory myopathy. The last search included a chart review of the selected records by one of the investigators (T.H. Oh) who used the criteria of Griggs et al.[6] to confirm the diagnosis of IBM.

Data collected included demographic information, patients' clinical examinations, biopsy and electromyographic confirmation of diagnosis, muscle enzyme activities, clinical dysphagia examinations, videofluoroscopic studies, other dysphagia-related diagnostic and therapeutic procedures, medical treatment, swallowing rehabilitation treatment, outcome of dysphagia, and cause of death. Follow-up data were collected through January 2006. Survival status was assessed where available from the medical record and from an institutionally approved fee-based Internet research and location service (Accurint) in seven patients who did not return for follow-up. Death certificates were ordered to determine the cause of death in two patients.

Statistical Analysis

Descriptive statistics were reported using means, medians, ranges, or percentages as appropriate. Groups were compared using Wilcoxon's rank-sum tests for continuous variables and Fisher's exact tests for categorical variables. The Kaplan-Meier method and log-rank test were used to analyze survival data. The observed number of deaths was compared with the expected number of deaths for a cohort of United States' whites with the same age and gender distribution and same follow-up.[25] $P < 0.05$ was considered statistically significant. Analyses were performed using JMP statistical software (version 6, SAS Institute Inc., Cary, NC) and SAS (version 9, SAS Institute Inc.).

RESULTS

Patient Population and Clinical Presentation

Among the 62 patients with inflammatory myopathy and dysphagia,[14] 26 (6 men and 20 women) met the diagnostic criteria of definite (10) and possible (16) IBM.[6] Mean age at presentation to our institution was 72.2 yrs (range, 54.6–84.5), and the mean age at IBM diagnosis was 68.7 yrs (range, 53.8–84.3). The mean age of patients with "possible" IBM was 5 yrs older than the "definite" group ($P = 0.02$) at presentation. There were no other statistical differences in demographics and clinical features among the definite and possible IBM groups.

The median duration of weakness was 48 mos (range, 0–180) and median duration of dysphagia was 36 mos (range, 1–240) at the time of diagnosis. Dysphagia was an initial presenting symptom in 11 (42.3%) patients (2 men and 9 women), with these patients exhibiting a significantly longer duration of dysphagia (median 120 mos *vs.* 24 mos, $P < 0.001$) and shorter duration of weakness (median 18 mos *vs.* 60 mos, $P = 0.03$) compared with others

who did not have dysphagia as a presenting symptom. Two of the 11 patients who had dysphagia as an initial presenting symptom demonstrated no limb weakness at the time of presentation, but each was noted to display limb weakness at a subsequent visit (8 mos and 2 yrs later).

Diagnostic Studies

All but one patient had at least one neurology evaluation in our institution and was confirmed to have either definite or possible IBM. The one patient who did not have a neurology evaluation at our institution had a neurology evaluation elsewhere with biopsy proven IBM and was referred for evaluation of dysphagia.

All patients had at least one muscle biopsy. Eight had a second and one had a third. Those 10 patients diagnosed with definite IBM had both rimmed vacuoles and congophilic inclusions. Those 16 patients diagnosed with possible IBM had characteristic clinical findings of IBM, but their muscle biopsy could not histologically confirm the diagnosis. Advanced disease with muscles replaced by fat and fibrous tissue was noted in two specimens on those who were diagnosed with possible IBM. CP muscle biopsies were obtained in two patients during CP myotomy and showed findings of chronic inflammatory myopathy in one and fibrous tissue in the other.

Electromyography was obtained in 24 patients with the studies showing both myopathic and neurogenic findings characterized by a mixed pattern of short and long duration, low and high amplitude with often polyphasic motor unit potentials, and increased spontaneous activity with fibrillation potentials. The muscles examined included limb muscles in all patients and paraspinal and cranial muscles in 17 and 4 patients, respectively. None had examination of the swallowing muscles. The remaining two patients also had electromyography, but one patient could not tolerate a needle examination and other patient had it elsewhere.

The median serum creatine kinase concentrations at the time of presentation (normal values <336 in men and <176 in women) was 296 U/L (range, 23–1125) and were similar in the two groups, 296 U/L (range, 178–1125) in definite IBM and 298 U/L (range, 23–767) in possible IBM ($P = 0.55$). Eighteen patients had elevated serum creatine kinase values at the time of presentation with a median of 421 U/L (range, 188–1125).

Dysphagia Evaluation

Twenty-four patients (92%) received a clinical dysphagia evaluation by either an occupational or speech therapist and all but one of these underwent videofluoroscopy. Two patients had a videofluoroscopy without involvement of a therapist. Additional studies included upper endoscopy (16), barium swallow (9), pharyngoesophageal manometry (12), and fiberoptic nasopharyngeal endoscopy (7).

TABLE 1 Videofluoroscopic findings ($n = 23$)

Impaired Findings	n (%)
Tongue control	9 (39)
Bolus control	12 (52)
Tongue base retraction	17 (74)
Laryngeal elevation	10 (43)
Pharyngeal constrictor contraction	13 (57)
Residual pharyngeal pooling	21 (91)
Cricopharyngeal dysfunction	13 (57)
Penetration	16 (70)
Aspiration	8 (35)

Common dysphagia symptoms were sensation of food sticking in the throat and coughing during meals. The patients noted difficulty with dry foods, solids, and thin liquids most frequently. Clinical oral examination findings typically showed normal lingual range of motion, strength, and coordination. Reduced laryngeal elevation was noted in eight patients.

The most common videofluoroscopic abnormalities are summarized in Table 1 and were residual pharyngeal pooling, tongue base weakness, airway penetration, reduced pharyngeal constrictor contraction, CP muscle dysfunction described as a prominent CP muscle with poor relaxation and narrowing in the upper esophagus, and impaired laryngeal elevation. Aspiration was revealed in eight patients (35%). Prominent, tight CP muscle was noted in all nine patients who underwent a barium swallow. Common pharyngoesophageal manometry findings included low amplitude pharyngeal constrictor contraction (75%), normal resting tone and relaxation of the UES (82%), and diminished inferior esophageal sphincter pressure (42%).

Follow-up dysphagia evaluations were completed on nine patients (five after a myotomy) 4 mos to 6 yrs following their initial evaluations at the clinic. Three reported increasing symptoms of sticking and coughing with oral intake. Two, both of whom had undergone myotomy, reported an improvement in symptoms despite the fact that videofluoroscopy revealed a progressive worsening of their dysphagia. All but one of nine patients was maintained on oral intake with a modified diet. Two were encouraged to use a modified diet in addition to enteral nutrition, and enteral nutrition was declined by one to whom it was recommended.

Treatment

Immunosuppressive Treatment

Twenty patients received immunosuppressive therapy: 19 corticosteroids, 10 azathioprine, 9 methotrexate, 2 mycophenolate mofetil, and 1 intravenous immunoglobulin. Treatment was not judged beneficial by either the patient or their physician except in one patient with definite IBM who remained medically stable and reported a subjective functional benefit from prednisone and azathioprine over a 6-yr period.

Swallowing Rehabilitation

All 23 patients who underwent a clinical dysphagia evaluation and videofluoroscopy received swallowing rehabilitation which involved one or more of the following: diet modification (23), feeding strategies (13), compensatory techniques (13), and exercises (8). An oral diet was recommended for 61% (14), a combination of oral and enteral nutrition for 9% (7) and exclusive enteral nutrition for 30% (2). Feeding and compensatory treatments were suggested for 13 patients following trials during their videofluoroscopic studies. Feeding strategies included one or more of the following: chew food well (10), swallow twice (12), small bites (12), alternate solids and liquids (8), and sit upright during meals (7). Compensatory techniques included chin tuck (8), head turn (2), effortful swallow (2), the Mendelsohn maneuver (2), and supraglottic swallow (1). Swallowing exercises were provided on the basis of swallowing dysfunction noted during videofluoroscopy and included one or more of the following: tongue base retraction (4), effortful swallow (4), the Mendelsohn maneuver (3), Falsetto (2), and supraglottic exercises (2).[24] All three patients receiving the Mendelsohn maneuver as an exercise or compensatory technique reported maintaining oral intake (1–5 yrs) without aspiration related illness or weight loss.

Only three patients who received one or more of the above mentioned exercises had follow-up videofluoroscopic data. The studies showed persistent or increased residual pharyngeal pooling, penetration, and aspiration. None of the patients who were recommended to use the Mendelsohn maneuver as an exercise had a follow-up videofluoroscopy.

Interventional Measures

Eighteen patients (69%) underwent one or more interventional procedures: 10 CP myotomy, 6 pharyngoesophageal dilation, 2 botulinum injection, and 6 percutaneous endoscopic gastrostomy. Clinical findings in the 10 patients who had a CP myotomy are summarized in Table 2. Three patients had a myotomy performed at another institution, with two occurring 1 and 4 yrs before their diagnosis of IBM. Eight patients had a median postmyotomy follow-up period of 35 mos (range, 2–132): one patient had repeat myotomy at 46 mos and 23 additional months of follow-up after the second myotomy. Seven patients noted symptomatic improvement: five continued to experience benefit and two had recurrent problems in 2 yrs. Benefits included improvements in swallowing (5), voice (3), secretion (1), and weight gain (4). Minor complications occurred in 2 of the 10 patients: one an esophageal perforation during operation and one a pharyngeal leak immediately after operation thought because of excessive coughing. Both recovered and repeat videofluoroscopy did not show leaking. Seven had postmyotomy videofluoroscopy,

TABLE 2 Clinical findings in patients who underwent cricopharyngeal myotomy

Patients	Age at Time of Myotomy	Sex	Cricopharyngeal Dysfunction	Duration from Diagnosis to Myotomy (mos)	Surgical Result	Duration of Myotomy Follow-up (mos)	Time to Death from Myotomy (mos)	Cause of Death
1	80	F	Yes	37	Recurred	103	103	Aspiration pneumonia
2	73	F	Yes	44	Improved	22	NA	
3	76	M	Yes	147	Unknown	0	20	Unknown
4	82 and 84[a]	F	Yes	50 (73)[a]	Recurred	46 (23)[a]	NA	
5	73	F	Yes	12	Improved	24	89	Unknown
6	77	M	Yes	49	Unknown	0	100	Unknown
7	57	F	Unknown	−12	Improved	23	NA	
8	50	F	Yes	−48	No benefit	132	NA	
9	68	F	Yes	4	Improved	60	NA	
10	71	F	Yes	107	Improved	2	NA	

[a] Second myotomy. Time to death from myotomy. NA (not applicable) = patient alive.
M, male; F, female. Follow-up duration 0 = no clinical follow-up postmyotomy.

and CP tightness was noted in four, with one patient proceeding to repeat myotomy.

Only two of the six patients receiving pharyngoesophageal dilations reported benefit (one "excellent," one "partial"), with the patient with the excellent result undergoing a second dilation after about 3 yrs, again with an excellent result. Three patients had three dilations, only one receiving partial benefit. Two patients had botulinum injections of the UES (one at our institution and one elsewhere) with neither reporting benefit.

Six patients (23%) ultimately received a PEG placement at times ranging from 9 to 138 mos (mean 67 mos) after the diagnosis of IBM as the result of aspiration pneumonia in five and swallowing difficulty in one. All six died during the study period because of aspiration and respiratory failure in five and the cause of death of remaining one patient was not known: three within 1 mo and one each in 5, 29, and 41 mos of placement. Two patients declined PEG.

Outcome

Clinical follow-up data were available on 19 patients at a median of 50 mos (range, 11–108). Twelve had progressive dysphagia, one was unchanged and six had improved. None reported resolution. All of the six noting improvement had undergone an interventional treatment (five myotomy, one dilation). Among those seven who did not have follow-up, five were found to have died via an Accurint search. There were no statistically significant differences in gender, age, and duration of dysphagia between those who had and did not have follow-up with the exception that those with follow-up had a shorter duration of weakness at the time of diagnosis (median 36 mos *vs.* 84 mos, $P = 0.03$).

Thirteen patients died at a mean age at death of 81 yrs (range, 74–88) and a median time from diagnosis of 134 mos (range, 30–184). The cause of death on eight was known with all dying as a result of the complications of aspiration. Kaplan-Meier overall survival estimates were 84% ± 7% at 5 yrs and 72% ± 10% at 10 yrs. Stratified by age, however, we found 100% survival at 5 and 10 yrs among those diagnosed before the age 70 ($n = 13$). Among those older at diagnosis ($n = 13$), 5-yr survival was 69% ± 13% and 10-yr survival was 45% ± 17% ($P = 0.03$). There was no difference in survival between diagnoses of definite and possible IBM ($P = 0.39$). In the general United States population with this age and sex distribution and the same follow-up, we would have expected 86% survival at 5 yrs and 70% survival 10 yrs: this was compared with the observed survival in this group of patients with IBM and dysphagia of 84% (95% confidence interval: 70–100%) at 5 yrs and 72% (95% confidence interval: 55–95%) at 10 yrs. Overall, the observed number of deaths (13) did not differ significantly from the expected number of deaths (11) in a cohort of United States' whites with the same age and sex distribution ($P = 0.44$).

DISCUSSION

In this study, we reviewed how dysphagia in patients with IBM was presented, managed, and what course it took. Dysphagia was frequently the presenting clinical symptom in patients who had IBM-associated dysphagia, observed more often in women and was usually refractory to medical and nonsurgical treatment. Over three fourths of the patients received aggressive immunosuppression, but the benefit seems to be ineffective consistent with literature.[7,8]

CP dysfunction was a frequent finding, and treatment strategies targeting the problem seem to provide some symptomatic benefit despite videofluoroscopic evidence of a continued worsening of pharyngeal function.

Treatment options included swallowing strategies, CP myotomy, pharyngoesophageal dilation, botulinum injection of the UES, and PEG. Swallowing compensation and feeding techniques were recommended to over half of the patients, but their effectiveness remains uncertain. Swallowing exercise was recommended in one third of the patients with a suggestion that the Mendelsohn maneuver was beneficial in maintaining oral intake.

We observed 13 deaths during the observation period at a median time from diagnosis of 134 mos. Aspiration pneumonia was the most frequent cause, but it is interesting that the death rate in this group did not differ in a statistically significant manner from that expected from an age and sex-matched general population of United States' whites.[25]

Comparison with Other Studies

Several previous studies,[2,3,16–19] have reported CP dysfunction to be a frequent finding as we found in this study. It is notable that over two thirds of our patients had interventional procedures, with myotomies (40% of patients) being the most common. This finding corresponds to the findings of a number of other smaller studies in which 1–4 patients underwent myotomies with 67–100% reporting benefits.[13,16–19] Our finding of 63% of patients reporting benefits after surgery falls at the lower end of this range and possibly reflects our follow-up period relative to the shorter or unreported follow-ups of the other studies. Myotomy seems beneficial in appropriate cases, but its benefits may be transient as we observed recurrent symptoms in two of eight patients within 2 yrs.

Our investigation found that pharyngoesophageal dilations were performed in about one quarter of the patients; two thirds did not note any benefit despite a number of repeated procedures. The findings in the literature are scant in this area but tend to agree with ours. One study reported overall short (1 mo) and long-term (6 mos) response rates of 50% and 25% in eight patients with inflammatory myopathy[20] and another the lack of benefit of CP dilations in a single patient.[17] Botulinum injection of the UES occurred in two patients with neither noting benefit. PEG placement occurred in about one quarter of the patients without clear effect on outcome as all patients died during the study period and tended to be a sign of severe involvement. Whether earlier PEG placement would have been beneficial remains conjectural as PEG does not completely prevent aspiration.[26]

The Mendelsohn maneuver was recommended in only three patients and seemed beneficial in this small sample in maintaining oral intake. This maneuver is designed to prolong the UES opening during swallowing by voluntarily extending laryngeal elevation[23,27] and in comparison with other swallowing maneuvers such as the supraglottic and supersupraglottic swallows is associated with increased pharyngeal peak contraction and contraction duration and significantly longer bolus transit time.[23] Our assessment of the benefits of the Mendelsohn maneuver is necessarily limited by the small number involved. This approach may benefit from further investigation to determine the limited use of the approach (perhaps because of a lack of literature supporting its use in dysphagia of myopathic origin, the therapist's comfort with the patient's capacity to perform it successfully or a lack of clinical expertise in this uncommon condition). We found no evidence of the use of the Shaker maneuver[28] (an isometric-isokinetic head raising exercise that has been shown to improve the opening of the UES). The reason for this lack of use is unclear, but it may be due to a combination of factors, which include a limited published literature support for its effectiveness at the time of this study and a concern of fatigue. It is interesting that this maneuver was considered by an evaluating therapist as an exercise option but not recommended because of risk of fatigue. Further study of this maneuver as a treatment option seems worthwhile, but the exercise program would likely need to be modified and optimized to reduce the risk of fatigue.

Dysphagia in this study was far more common in women than men (20:6) with over three fourths of the patients being women even though IBM seems to be more common in men.[3,10–12,15] This finding, while seemingly surprising, is supported by the literature where reports indicate a preponderance of 56–75% in women.[16,29] Other reports add further support in that the initial presenting symptom occurs in a roughly 2:1 ratio of women to men.[12,16] Similarly, pharyngeal muscle involvement may be 1.5 to almost four times more common in women than men (8:5 and 19 *vs.* 5%).[11,12]

Our findings of death rate among the patients in our sample are similar to that of the general population, despite a high incidence of aspiration associated deaths agrees with the findings of a Dutch epidemiologic study[30] and may reflect either or both the small numbers of this study or the fact that IBM affects an older population whose elevated death rate obscures the incremental contribution because of IBM.[15] Additional limitations of this study are its retrospective nature, its potential tertiary care center subject bias, and limited follow-up duration. However, it is reassuring that there were no statistically significant differences in gender, age, and duration of dysphagia between those who had and did not have follow-up with the exception that those who had follow-up had a shorter duration of weakness at the time of diagnosis.

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