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Review article

Single count breath test for the evaluation of respiratory function in Myasthenia Gravis: A systematic review

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ABSTRACT

Background: Myasthenia gravis (MG) can have a variety of respiratory presentations, ranging from mild symptoms through to respiratory failure. The evaluation of respiratory function in MG can be limited by accessibility to testing facilities, availability of medical equipment, and facial weakness. The single count breath test (SCBT) may be a useful adjunct in the evaluation of respiratory function in MG.
Method: A systematic review of the databases PubMed, EMBASE, and the Cochrane Library was conducted from inception to October 2022 in accordance with PRISMA guidelines and was registered on PROSPERO.
Results: There were 6 studies that fulfilled the inclusion criteria. The described method of evaluating SCBT involves inhaling deeply, then counting at two counts per second, in English or Spanish, sitting upright, with normal vocal register, until another breath needs to be taken. The identified studies support that the SCBT has a moderate correlation with forced vital capacity. These results also support that SCBT can assist the identification of MG exacerbation, including via assessment over the telephone. The included studies support a threshold count of ≥ 25 as consistent with normal respiratory muscle function. Although further analysis is needed, the included studies describe the SCBT as a quick bedside tool that is inexpensive and well tolerated.
Conclusions: The results of this review support the clinical utility of the SCBT in assessing respiratory function in MG and describe the most current and effective methods of administration.

1. Introduction

Myasthenia gravis (MG) is a neuromuscular disorder that is associated with a wide disease spectrum ranging from mild symptoms to life-threatening exacerbations and, in 15–20% of cases, respiratory failure [1–4]. When patients seek medical attention, either in an emergency department or outpatient setting, means of objectively evaluating their respiratory function are required. Traditionally, pulmonary function tests, namely forced vital capacity (FVC), are used to evaluate respiratory function in these patients [1–3,5,6]. However, the availability of spirometry equipment and patient facial weakness can limit evaluation. The single count breath test (SCBT) is a bedside test that overcomes these barriers and has been proposed as an assessment tool for respiratory function in MG [5,7–13].

Physiological measures of respiratory failure (e.g., low oxygen saturations) often fail to reflect underlying respiratory dysfunction until late in the course of MG. These delays can reduce the application and timeliness of appropriate respiratory supports [2,6,14,15]. Recent pilot studies have compared different tests against the current gold standard spirometry tests, to establish their accuracy in quantifying respiratory

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impairment in myasthenia gravis [5,9,13,16]. Bedside spirometry for patients with MG requires specialised equipment, which incurs an equipment cost and is not always available. Facial weakness and inexperience may preclude effective execution of spirometry due to an inability to make an effective seal on the mouthpiece. Peak expiratory flow rate monitoring has similar limitations, while other proposed strategies, such as neck flexion weakness testing, still require in-person evaluation. In the setting of COVID-19 and rural/remote telemedicine there is an increased need for a remote means of evaluating respiratory function in MG patients.

The use of SCBT as a measure of respiratory function has been studied in Guillain-Barré syndrome (GBS) and amyotrophic lateral sclerosis (ALS), and showed a high sensitivity and moderate correlation with FVC and other bedside predictors of respiratory function [10,12,17]. The evaluation of SCBT in the setting of MG is distinct because of fatigable bulbar weakness [18,19]. Previous pilot studies have described different evaluations of the test and produced varying thresholds as to what constitutes an abnormal reading [5,7,9,11,13,20].

The aims of this study were to (1) determine the best validated methods of performing the single count breath test (SCBT) for patients with MG, and (2) evaluate the effectiveness of this test in the assessment of respiratory status in MG.

2. Materials and methods

2.1. 2.1 Study design, search strategy, and selection criteria

The PRISMA guidelines were used in the development, conduct, and reporting of this systematic review (Supplementary Information 1) [21]. The systematic review was registered prospectively with the PROSPERO registry (CRD42022367198). The databases PubMed, EMBASE, and Cochrane library were searched for the systematic review. Studies were included from the date of inception of each of the databases to 14.10.2022. The search terms included: *(Myasthenia gravis OR Myasthen*) AND (single count breath test OR breath test OR count test OR spirometry OR pulmonary function test* OR pulmonary function* OR peak flow OR forced vital capacity OR respiratory monitoring OR peak expir*)*. The individual search strings employed for each database are listed in Supplementary Information 2. Additionally, the reference lists of included articles, and grey literature sources (medical magazines), were searched for relevant studies.

The determination of whether studies met inclusion criteria was performed with a standardised form and in duplicate. The inclusion criteria were (1) Studies published in English (including case reports, case series, and conference abstracts); (2) Primary research publication (reviews were excluded); (3) Included adult (≥18 years of age) patients with myasthenia gravis; (4) evaluated MG patients with the SCBT; and (5) was available in full-text. Eligibility was determined in duplicate (N. D., S.T., L.X., A.V., S.B.) and disagreement was resolved through input from a third author. The Johanna Briggs Institute Critical Appraisal Checklists for cohort studies, cross-sectional studies, and case reports were used for risk of bias analysis [22–24]. This risk of bias analysis was performed in duplicate.

2.2. 2.2 Data extraction and analysis

Data were extracted from included studies with a standardised form. Extracted data included patient factors (including age, gender, and comorbidities) and MG factors (type, severity, means of diagnosis, and treatment). Extraction of data for multiple aspects of the SCBT were performed, including: language in which counting occurs; whether assessed in person or via another modality (such as telehealth); rate of counting; means of standardisation; volume of counting; instructions presented to patient; patient position while performing SCBT (e.g., lying, sitting or standing); repetition of SCBT during a single evaluation (e.g., best of three); repetition of SCBT over multiple evaluations (e.g., longitudinal assessment); SCBT timing in relation to pyridostigmine (or other medications); SCBT threshold for an abnormal result; SCBT performance in the prediction of multiple factors related to respiratory function (FVC, PEFR, other spirometry features, exacerbations including respiratory exacerbations, intensive care unit admission, intubation/ventilation, and mortality); adverse events with SCBT; time taken to perform SCBT; and the cost of performing SCBT.

3. Results

3.1. 3.1 Search results and study characteristics

The search initially returned a total of 900 results (Fig. 1). After title/abstract screening 100 articles underwent full-text review. At the completion of this process there were 8 studies included in the review. These studies included 1 cohort study [25], 6 cross-sectional studies [5,9,11,13,20,26], and 1 case report [27] (Table 1). Three studies were considered likely to describe the same cohort of patients, and are therefore not presented separately, although all fulfilled the inclusion criteria [11,20,26]. Therefore, the results of 6 studies are presented [5,9,11,13,25,27].

Risk of bias analysis of the included studies showed most studies had moderate risk of bias (Supplementary Information 3). In one study, reporting was limited due to the fact that the research was published as an abstract [13].

3.2. 3.2 Described methods of performing SCBT

The most commonly used method for performing SCBT involved patients taking a 'deep breath', and then counting in a 'normal voice' at approximately 2 counts per second, to the maximum number possible before requiring another breath [25]. Often the position of the patient and the language in which the counting occurred was not specified. However, in Kukulka et al. it was specified that the patient be seated upright and count in English, and in Aguirre et al. a video was included of a patient performing the SCBT in Spanish [5,11]. In certain studies, it was described that two attempts be provided, and to then take the highest count of the two attempts [5,11].

One study described a series of SCBT performed on the same group of patients over 24 months [25]. The study used SCBT to evaluate the effect of eculizumab on a retrospective cohort of MG patients. The serial SCBT showed improvement following the commencement of eculizumab (mean SCBT prior 28.13 [standard deviation 0.33] to post 50.26

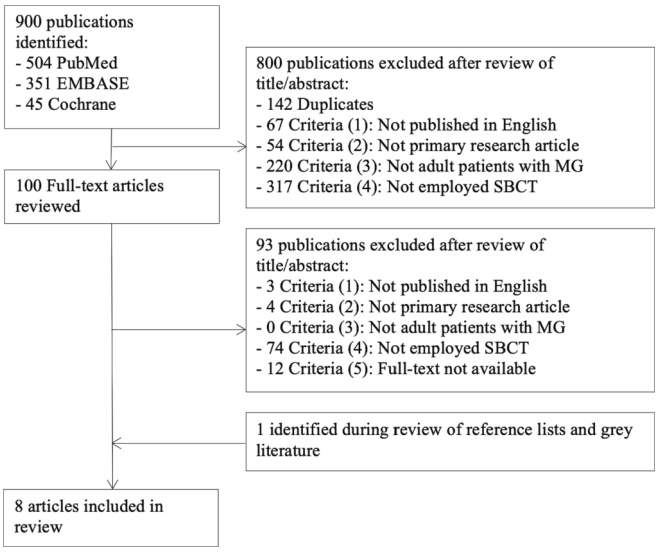

Fig. 1. Study selection.

Table 1
Study characteristics.

	Katyal et al. 2021 [25]	Aguirre et al. 2020 [5]	Elsheikh et al. 2016 [9]	Kukulka et al. 2020 [11]	Ramsewak & Wong 2021 [13]	Shahul et al. 2021 [27]
Number of MG patients	15	45	31	25	212 patients (171 had SBCT results recorded)	1
Subtypes of MG included	Treatment-refactory AChR + GMG	AChR + 40 (89%), MuSK + 2 (4%), double seronegative 3 (7%)	all AChR+	seropositive 17/25 (68%), AChR + 15 (60%), MuSK + 2 (8%)	seropositivity not specified	seropositivity not specified
Reference standard for MG diagnosis	positive antibody serology	Positive results in one of the following: 1) anti-AChR or anti-MuSK 2) repetitive nerve stimulation test showing decrement of at least 10% in motor potentials 3) single-fibre EMG study showing increased jitter 4) clear clinical response to acetylcholinesterase inhibitors	positive antibody serology	"Final diagnosis of MG exacerbation was at the discretion of a board-certified neurologist on call."	N/A	Repetitive nerve stimulation test
MGFA clinical classification	9 were class II, 6 were class III	2 were class I, 35 class II, 7 class III, and 1 class IV	8 were class I, 20 class II, 3 class III	11 were class IIa (44%), 6 class IIb (24%), 7 class IIIa (28%), 1 class IIIb (4%)	N/A	N/A
MG treatment details	All patients on pyridostigmine at doses 60 mg three times per day. All patients on immunosuppressants (prednisolone, azathioprine, mycophenolate, and/or intravenous immunoglobulin) and subsequently treated with eculizumab.	N/A	90% were on immunosuppressants	N/A	N/A	Pyridostigmine and tapering of steroids for initial steroid dependent asthma diagnosis. Monitoring with SCBT and muscle power charts.
Mean age in years (SD)	47.4 (14.9)	40.7, range 18–82	mean 57 (19), range 20–85	42.92 (18.46)	N/A	52
Gender (female number (%))	60%	78%	48%	60%	N/A	100%
Comorbidities	N/A	N/A	N/A	N/A	N/A	steroid-dependent asthma
SCBT language	N/A	Spanish	N/A	English	N/A	N/A
SCBT in person or via other modality	N/A	In person	In person	Telephone	In person	In person
SCBT rate of counting	2 counts per second	2 counts per second	2 counts per second	2 counts per second	N/A	N/A
SCBT standardisation of rate of counting method	N/A	N/A	N/A	N/A	N/A	N/A
SCBT volume of counting	normal voice	not specified	normal voice	normal voice	N/A	N/A
SCBT described instructions to patient	asking patients to take deep breath and count as far as possible'	take deep breath and count aloud until they need to take another breath	N/A	(1) asking the patient to sit upright, (2) inhale deeply, and (3) count out loud in English for as long as possible in their normal voice at a rate of two counts per second	N/A	N/A
SCBT described patient position at time of assessment	N/A	N/A	N/A	Sit upright	N/A	N/A
SCBT repeated tests in one evaluation	N/A	2 attempts, using highest value	2 attempts	2 attempts and recorded the highest count	N/A	N/A
SCBT repeated tests over time	Yes: 3 monthly over a 2 year period	N/A	N/A	N/A	N/A	Monitored with SCBT, unknown number of repeats

(*continued on next page*)

Table 1 (*continued*)

	Katyal et al. 2021 [25]	Aguirre et al. 2020 [5]	Elsheikh et al. 2016 [9]	Kukulka et al. 2020 [11]	Ramsewak & Wong 2021 [13]	Shahul et al. 2021 [27]
SCBT other details regarding method	N/A	N/A	N/A	SCBT was administered by trained nurses during the pilot study. The training included: (1) A 1-hr overview of MG, (2) learning to recognize the key symptoms of MG and MG exacerbation, (3) administering the SCBT over the telephone, and (4) interpreting the SCBT. (last two parts assessed by neurologist)	N/A	N/A
SCBT timing in relation to pyridostigmine (or other anticholinesterase medication) specified	N/A	N/A	N/A	N/A	N/A	N/A
SCBT threshold for abnormal result	N/A	N/A	< 25 counts			
	< 25: likely MG exacerbation, directed to come into ED	N/A	N/A			
SCBT prediction of FVC	N/A	r = 0.56P= <0.001	good positive correlation (r = 0.554, P < 0.01)	N/A	Correlation between SCBT and FVC (r = 0.542, p = 0.0001); paired *t* test showed a decrease in SCBT prior to onset of respiratory symptoms	N/A
SCBT prediction of PEFR	N/A	N/A	N/A	N/A	N/A	N/A
SCBT prediction of other MGFA classification	N/A	N/A	SCBT correlation with MGFA classification (r= −0.480 and p= <0.01). SCBT correlation with neck flexion (r = 0.519, p=<0.01). 11 patients had a SCBT of < 25, of these were; all patients of class 3 MGFA and 8 of class II MGFA	N/A	N/A	N/A
SCBT prediction of respiratory exacerbation	N/A	N/A	N/A	cut off 25 to diagnose exacerbation: sensitivity 80%, specificity 60%	N/A	N/A
SCBT prediction of ICU	N/A	N/A	N/A	N/A	N/A	N/A
SCBT prediction of intubation	N/A	N/A	N/A	N/A	N/A	N/A
SCBT prediction of mortality	N/A	N/A	N/A	N/A	N/A	N/A
SCBT description of any adverse events	N/A	N/A	N/A	N/A	N/A	N/A
SCBT description of time taken to perform test	N/A	N/A	N/A	N/A	N/A	N/A
SCBT description of cost to perform test	N/A	N/A	N/A	N/A	N/A	N/A

Legend: OMG, ocular myasthenia gravis; GMG, generalized myasthenia gravis; AChR, anti-acetylcholine receptor antibodies; MuSK, anti-muscle-specific kinase; MGFA, Myasthenia Gravis Foundation of America; SD, standard deviation.

[standard deviation 2.86], statistical significance not presented). These results suggest that longitudinal SCBT assessment may be useful in evaluating response to therapy in MG patients with baseline respiratory involvement. The included case report described serial SCBT being used to monitor a patient with both asthma and MG, which again supports the potential utility of serial assessments [27].

3.3. 3.3 Performance in the prediction of FVC and other respiratory parameters

In a study of 45 individuals, Aguirre et al. identified a significant positive correlation using linear regression analysis between FVC and SCBT performance ($r = 0.57$, $p < 0.001$) [5]. These results were supported by the largest study, with a sample size of 171 patients who had SCBT, which found again a moderate correlation between SCBT and FVC ($r = 0.542$, $p = 0.0001$), although the risk of bias analysis of this study was limited by the poster format [13]. Similarly, Elsheikh et al. also described a moderate correlation between SCBT and FVC ($r = 0.554$, $p < 0.01$) [9].

3.4. 3.4 Cut-off score selection and performance in identifying MG exacerbation

Given that SCBT provides a discrete continuous score, defined cut-offs may be clinically useful to predict different outcomes. However, the included studies only evaluated the ability to identify the presence of an exacerbation or abnormal respiratory muscle function and not outcomes such as intubation and ventilation. Included studies suggested a cut-off score of 25 as indicative of normal respiratory function. Elsheikh et al. described a cut-off score of ≥ 25 as being indicative of normal respiratory muscle function. This suggested threshold was supported by the results in their study in which all patients with MGFA-3 (Myasthenia Gravis Foundation of America class 3) and 40% of MGFA-2 MG failed to count to this number, while all MGFA-1 were able to count beyond this number. Kukulka et al. also described the use of a cut-off of 25 [11]. When using this cut-off count of 25, this study found that the SCBT had a sensitivity of 80% and specificity of 60% for an MG exacerbation (as compared to the gold standard of the on-call neurologist opinion) [11]. With a cut-off count of 28 this study found a sensitivity of 100% with a specificity of 55% for MG exacerbation. With a cut-off count of 21 this study found a sensitivity of 64% and specificity of 100%.

3.5. 3.5 Adverse events, time involved, and cost of SCBT

Although no formal evaluations were reported, the included studies described that the SCBT was efficient and well-tolerated. Although not formally evaluated, Aguirre et al. endorsed that the SCBT is brief to administer and incurs no or low cost [5]. While mild neck pain was described in one study, in the setting of neck flexion testing, no adverse effects of SCBT were described [9].

4. Discussion

The studies included in this review support that SCBT has a moderate correlation with FVC and may aid in the identification of MG exacerbation, including via assessment over the phone. There is preliminary evidence that SCBT may also provide a simple method of reviewing response to treatment over time in generalised MG. The most clearly described method for testing involved counting at two counts per second, in English or Spanish, sitting upright, with a normal voice (Table 2). The included studies describe a threshold count of ≥ 25 as representative of normal respiratory muscle function. SCBT is described as a quick, inexpensive bedside test, which is well tolerated, although formal analyses are lacking. Collectively, these results support SCBT as a clinically useful screening tool in assessing respiratory function in MG.

These findings have several practical implications.

Table 2
Current recommendations for the evaluation of SCBT.

Component of test	Recommendation
Position	Sitting upright
Instructions	'Take a deep breath, then count out loud at two numbers per second until you need to take another breath'
Rate of counting	Two counts per second
Volume of counting	'Normal voice'
Language of counting	English or Spanish
Number of attempts	Two
Attempt which should be scored	Highest of the two attempts
Threshold for an abnormal result	Counts to < 25 considered abnormal

Recommendations regarding the testing of the SCBT for MG are summarised in Table 2. These recommendations also highlight the limitations of the current evidence. For example, validation in languages other than English and Spanish, which may have phonetically distinct numerals and differing syllable totals, are required. The language in which the SCBT was undertaken was not specified in most studies, whilst two studies used English and Spanish [5,11]. It is important to note that the interpretation of the SCBT may be hypothesised to vary by language. For example, agglutinative languages (Finnish, Hungarian) containing polysyllabic words may require a greater respiratory reserve to count to a given number compared to analytic languages with free morphemes (Thai, Vietnamese, or Chinese). Patients who are unwell with MG may have difficulty with positioning, and suboptimal position may limit performance. It is also important to note that vocal cord weakness in patients with MG may also limit phonation.

There are several settings in which SCBTs are at times employed clinically, which are not described in the available studies. While a threshold for normal respiratory function has been described, none of the available studies examined the extreme of near respiratory failure and SCBT in this setting. There is limited evidence regarding aspects of the threshold for intensive care unit admission, and intubation and ventilation in these patients [6,28]. This lack of evidence regarding the SCBT in this setting should be acknowledged when integrating SCBT results into critical care decision-making processes. There are limited data regarding the monitoring of SCBT over time. Given that significant value in objective measures of respiratory function in MG exacerbations hinge on being able to evaluate a trajectory, this area requires further examination. There is a lack of information regarding the timing of administration of anticholinesterase medication in the included studies. Since the onset of medications such as pyridostigmine is typically <30 min, and peaks at approximately 2 h, the timing of the most recent dose likely significantly influences the results of SCBT. Future studies evaluating the SCBT should describe the duration of time between the most recent anti-cholinesterase dose and SCBT evaluation.

This review has several limitations that should be acknowledged, including the exclusion of non-English articles. The exclusion of several articles due to an inability to access full-text articles is also a limitation. Additionally, noting the small study sizes of the included studies, publication bias may have influenced the results of the review.

Further research in this area should seek to evaluate serial SCBT, including over the course of an inpatient admission. Similarly, the evaluation of SCBT in the extremes of respiratory function, nearing respiratory failure, would be useful. Evaluation of thresholds for which intensive care should be considered may provide benefit. Further evaluation regarding using SCBT to monitor response to therapies such as intravenous immunoglobulin and plasmapheresis is also required. Future studies should also seek to validate the SCBT in languages other than English and Spanish.

5. Conclusion

The SCBT has a moderate correlation with FVC and can assist in the identification of MG exacerbation. The test is well-tolerated, quick, and inexpensive. Further studies may improve the utility of SCBT through the description of serial assessments and SCBT evaluation in languages other than English and Spanish.

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Informed consent

Formal consent was not required for this type of study.

Ethical approval

Ethical approval was not required for this type of study.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jocn.2023.04.011.

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