

Research paper

Electrodiagnostic criteria for neuromuscular transmission disorders suggested by a European consensus group

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ABSTRACT

Objective: Electrodiagnostic testing plays an important role in diagnosing disorders of neuromuscular transmission (NMT), especially in seronegative myasthenia gravis. However, electrodiagnostic criteria for the diagnosis are sparse. This study aimed at inferring evidence-based recommendations for the electrodiagnostic examination of NMT disorders.

Methods: A total of 164 cases with a consensus diagnosis of NMT disorder obtained by peer review by eight experienced neurophysiologists were analysed for differences in examination strategy, the sensitivity of different tests, and inferring minimal criteria. The diagnostic performance of the suggested criteria was validated on 24 MG patients and 50 patients with neuropathy (17), myopathy (15), or fatigue (18).

Results: We recommend as minimal electrodiagnostic criteria for NMT disorders, either (a) 2 abnormal repetitive nerve stimulation (RNS), (b) 1 abnormal RNS and 1 abnormal single fiber electromyography (SFEMG) or (c) 2 abnormal SFEMG. These showed a good diagnostic performance with a sensitivity of 87.5 % and a specificity of 100 %.

Conclusion: Recommendations with high diagnostic sensitivity and specificity for the minimum number of RNS and SFEMG studies to diagnose NMT disorders developed by an international consensus group are suggested.

Significance: The suggested electrodiagnostic recommendations for diagnosing NMT disorders are reliable and suitable for use at different centres.

1. Introduction

Despite advances in antibody testing, electrodiagnostic testing still plays an important role in diagnosing disorders of neuromuscular transmission (NMT) (Clifford et al., 2023; Tomschik et al., 2023; Yoganathan et al., 2022; Haran, 2014). Myasthenia gravis (MG), the most common disorder of the NMT, may be straightforward to diagnose in the presence of a typical clinical picture associated with abnormally elevated titers of the anti-acetylcholine receptor (AChR), anti-muscle

specific kinase (MuSK) or anti-LRP-4 antibodies. However, in seronegative patients, the clinical picture may be insufficient for reaching the diagnosis.

In 2001, the American Association of Neuromuscular & Electrodiagnostic Medicine (AAEM) published a practice parameter for the electrodiagnosis of MG and Lambert-Eaton myasthenic syndrome (LEMS) based on a retrospective literature review of 34 articles (AAEM Quality Assurance Committee. American Association of Electrodiagnostic Medicine, 2001a; AAEM Quality Assurance Committee.

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American Association of Electrodiagnostic Medicine, 2001b). An update in 2015 including a review of the literature from the intervening years concluded that repetitive nerve stimulation (RNS) studies and single-fiber EMG (SFEMG) were still useful in the diagnosis of NMT disorders (Chiou-Tan and Gilchrist, 2015). Although stating limits for abnormality in RNS and SFEMG in NMT disorders, the practice parameter did not give detailed electrodiagnostic criteria. Thus, electrodiagnostic criteria for NMT disorders are sparse and derived from literature review consensus, while no evidence-based criteria have been published.

We aimed in this study to develop evidence-based recommendations for the electrodiagnosis of NMT disorders and to evaluate the sensitivity and specificity of RNS and SFEMG under various circumstances. The recommendations were based on the electrophysiological studies and clinical diagnosis of a set of patients in the database, and developed in collaboration amongst experienced neurophysiologists from six different European countries in the European Standardised Telematic tool to Evaluate Electrodiagnostic Methods (ESTEEM) (Vingtoft et al., 1994; Fuglsang-Frederiksen et al., 1995). Thereafter, we tested the sensitivity and specificity of ESTEEM Groups recommendations and AAEM guidelines on a second set of data.

2. Methods

2.1. Multicenter data collection and peer review

Physicians from six different European countries (Great Britain, France, Germany, Italy, Portugal, and Denmark) submitted samples of consecutive electrodiagnostic examinations of patients with a clinical suspicion of NMT disorder. Since electrophysiological examinations were performed as a part of the diagnostic work-up, ethical committee approval was waived for this study.

The data were stored in a standardised data format in a web database and peer-reviewed following the procedure described in detail elsewhere (Pugdahl et al., 2017). In short, for the discussion of each patient at the in-person consensus meetings, the case was displayed on a screen as a starting point for an open discussion among the group with the aim of obtaining consensus on the diagnosis. First, an agreement among the group of physicians on the diagnosis that could be determined solely on the electrodiagnostic finding, termed the **EMG-diagnosis**, was reached,

prior to checking the laboratory tests and treatment response. The consensus EMG diagnosis was categorised as definite, probable and possible based on the electrodiagnostic findings. These categories were agreed on consensus considering the degree of probability, following the decision of the majority. Then, a **final consensus diagnosis** was derived by reviewing the full set of clinical information, including neurophysiological tests, imaging of the thorax, antibody tests (AChR, MuSK, calcium channels), response to edrophonium test, response to treatment and clinical follow-up (Fig. 1). The **final consensus diagnosis** was the gold standard for the present study.

2.2. Testing sensitivity and specificity

As a reference standard for testing the sensitivity and specificity of the recommendations, a second set of data was collected (Fig. 1). For testing sensitivity, each lab was asked to submit their last ten consecutively examined patients with 1) clinically confirmed MG defined as (clinical presentation) AND (abnormal antibody titres AND/OR positive response to treatment). The established diagnosis of NMT disorders was not based on the ESTEEM group's recommendations for minimum electrodiagnostic criteria used by the physicians who submitted the cases. To avoid selection bias, neurophysiological examinations performed by an independent physician were preferably selected. The examinations in the first and second sets were performed using the same techniques, criteria, and reference values used in that lab. Additionally, a final consensus diagnosis has been provided for both sets. For testing specificity, each lab submitted its last 5 patients with suspected MG and a final clinical diagnosis of neuropathy, myopathy, and unspecified fatigue.

2.3. Statistical analysis

The sensitivity and specificity of ESTEEM recommendations and AAEM guidelines have been compared using a Mc Namer test. A p-value < 0.05 has been accepted as significant.

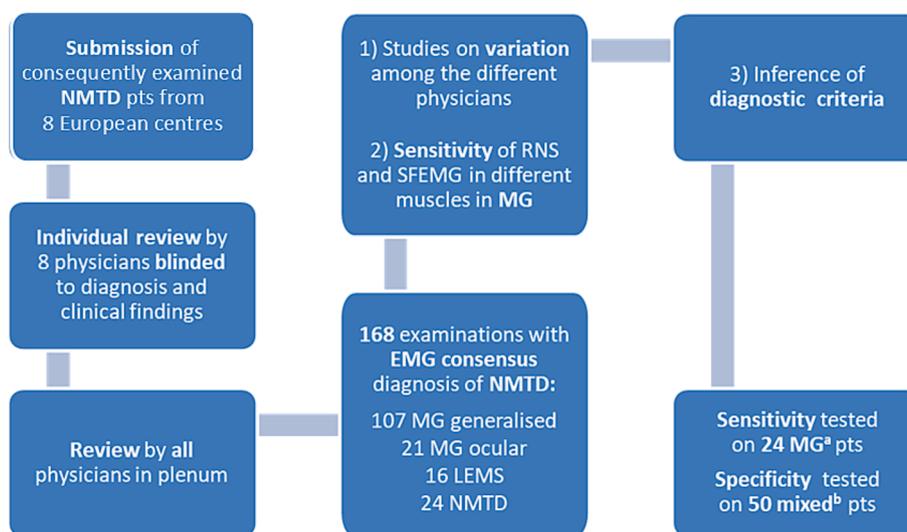


Fig. 1. Flowchart illustrating the study design. Electrodiagnostic examinations of patients with neuromuscular transmission disorders (NMTD) obtained from eight European centres were reviewed and discussed in plenum by experienced neurophysiologists. The result was an EMG consensus diagnosis using only the EMG data. Then, final clinical consensus diagnoses were reached by inferring the laboratory data and clinical data including response to treatment and confirmation of the diagnosis by clinical follow-up. This data on 164 cases was basis for studies on variation and for suggesting diagnostic criteria. The sensitivity and specificity of the suggested criteria were tested on another set of data. See text for details. MG: Myasthenia Gravis. **a**12 generalised MG, 12 ocular MG, **b**17 neuropathy, 15 myopathy, 18 fatigue.

3. Results

3.1. Variation studies and minimal criteria for NMT disorder diagnosis

A total of 165 examinations were collected with the number of examinations from eight physicians ranging between 13 and 36 per physician (P1: 18, P2: 24, P3: 13, P4: 15, P5: 25; P6: 36; P7: 18, P8: 21). One case was excluded for incomplete data set. This left 164 cases that reached a consensus diagnosis of definite (105), probable (44), or possible (15) NMT disorder based on the electrodiagnostic findings, thus termed the EMG-diagnosis.

After reviewing the full set of clinical information and laboratory information antibody tests, response to edrophonium test or response to treatment and clinical follow-up in addition to neurophysiological data, the cases received final consensus diagnoses. Among the 164 cases, 104 had generalised MG, 20 had ocular MG, and 15 had LEMS. However, in 25 cases, it was possible to diagnose a neuromuscular transmission defect, but further specification was not possible.

3.1.1. Variation in the number of examined and abnormal tests between centres

There was a large variation among physicians on the number of performed RNS and SFEMG tests. The average number of performed RNS studies per patient from each of eight physicians ranged from 1.9 to 5.2, while the average number of abnormal RNS studies ranged from 0.7 to 3.2. For SFEMG, the average number ranged from 1.0 to 1.6 for performed studies and from 0.9 to 1.5 for abnormal studies (Fig. 2).

3.1.2. Number of abnormal tests required for NMT disorder diagnosis

When RNS and SFEMG tests were considered together, if there was no abnormal SFEMG, 3 abnormal RNS tests were required for the category of definite NMT disorder, while for probable NMT disorder 2 abnormal RNS tests were needed. In case of abnormal SFEMG in 1–3 muscles, one or less abnormal RNS in average was found enough for definite or probable NMT disorder diagnosis (Fig. 3).

Based on these findings, the ESTEEM group recommends as minimal electrodiagnostic criteria, that either a) 2 abnormal RNS studies, or b) 1 abnormal RNS study and 1 abnormal SFEMG study, or c) 2 abnormal SFEMG should be required to diagnose a NMT disorder. To classify the individual electrodiagnostic tests abnormal, the routinely used limits for decrement at the different centres should be applied (Table 1).

3.2. The sensitivity and specificity of ESTEEM Groups recommendations and AAEM guidelines

For the sensitivity analysis, 25 patients (Lisbon [10], St. Etienne [10], Aarhus [5]) with an established diagnosis of MG (13 generalised and 12 ocular), were collected. Mean age: 58.7 years; range: 16–84 years, 15 males; 10 females. Mean disease duration: 17.8 months; range: 1–200 months. Fluctuating muscle weakness was seen in 24 patients (96 %), fatigue in 17 (68 %), ptosis in 20 (80 %). AChR antibodies were positive in 15 (60 %) and negative in 10 (40 %) whereas MuSK antibodies researched in 12 patients were negative (100 %). There was a positive response to Pyridostigmine bromide in 22 (88 %) patients and thymectomy was done only in one 1 (4 %).

For the specificity analysis, 50 patients were collected from 3 centres (Lisbon [18], St. Etienne [6] and Aarhus [25]). Of the 50 patients, 17 had neuropathy, 15 had myopathy and 18 had unspecified fatigue. The distribution of age and disease duration is shown in Fig. 4. The mean age was similar in all patient groups while for the disease duration, myopathy patients had a longer duration (Fig. 4).

The sensitivity and specificity of AAEM guidelines and ESTEEM recommendations were compared in MG and patient control (neuropathy, myopathy and fatigue) groups. The AAEM guidelines and ESTEEM recommendations are summarised in Table 1.

There was no significant difference on the sensitivity between the ESTEEM recommendations and AAEM guidelines for the whole MG group nor when the group has been divided as generalised and ocular MG (McNemar test, $p > 0.1$) (Fig. 5) whereas the specificity was significantly higher (100 %) than AAEM guidelines (88 %) (McNemar test, $p < 0.05$) (Fig. 6).

4. Discussion

In this study, we compared the sensitivity and specificity of evidence-based criteria recommended by the European multicentre ESTEEM study group with the AAEM guidelines for the diagnosis of NMT disorders. The ESTEEM groups recommendations had similar sensitivity as AAEM guidelines but higher specificity.

Antibody testing has been an important development in the diagnosis of MG. However, electrodiagnostic testing still plays a role in diagnosing NMT disorders (Tomschik et al., 2023; Katzberg and Abraham, 2021; Sanders et al., 2019; Ueta et al., 2024; Oh et al., 2005, 2007; Tim et al., 2000). There is also scientific evidence for the continued use of RNS and SFEMG as valid clinical laboratory studies for confirming the clinical diagnosis of NMT disorders and for differential

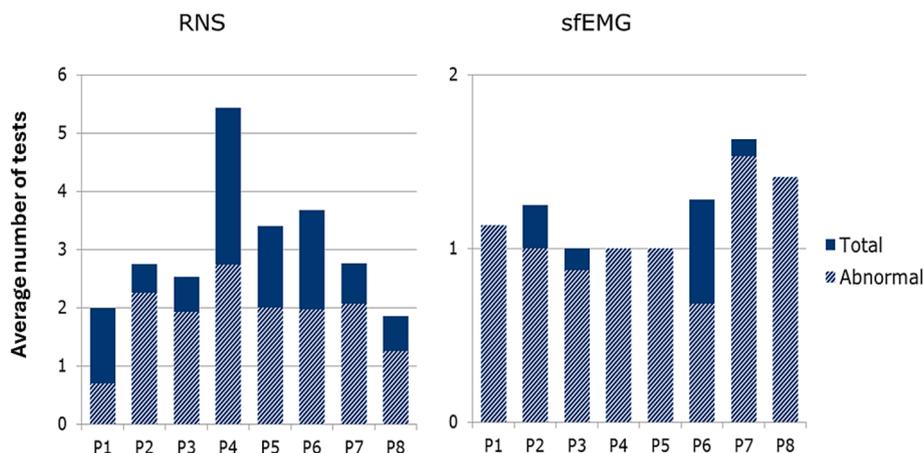


Fig. 2. The average number of examined and abnormal tests at each lab for a) repetitive nerve stimulation (RNS) and b) Single fiber electromyography. There is a large variation among the eight physicians (P1-P8) particularly in the number of examined RNS tests. The striped column indicates the number of abnormal tests while the entire column (dark blue) indicates the number of examined test. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

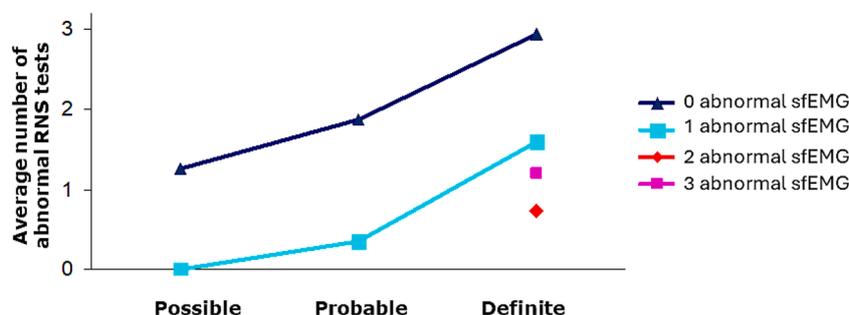


Fig. 3. The correlation between the number of abnormal repetitive nerve stimulation (RNS) tests and diagnostic certainty as possible, probable and definite myasthenia gravis when RNS and single fibre electromyography (SFEMG) tests are taken together. If there were no abnormal SFEMG tests, 3 abnormal RNS tests in average were required for definite NMT disorder diagnosis while for probable NMT disorder 2 abnormal tests were needed. In case of abnormal SFEMG in 1–3 muscles, one or less abnormal RNS in average was found enough for definite diagnosis.

Table 1

AAEM Guidelines and ESTEEM Groups recommendation for electrodiagnostic examination of neuromuscular transmission (NMT) disorders.

	AAEM Guidelines	ESTEEM recommendations
Combining RNS and SFEMG	No	Yes
Criteria for abnormal NMT failure	≥1 abnormal RNS or ≥1 abnormal SFEMG	≥2 abnormal RNS if no abnormal SFEMG or ≥1 abnormal RNS, if ≥ 1 abnormal SFEMG or ≥2 abnormal SFEMG
Criteria for the definition of decrement	≥10 % decrement	Abnormal decrement according to the labs local reference value

Optional AAEM single fiber EMG (SFEMG) criteria: 1) Patients with mild or solely ocular symptoms and repetitive nerve stimulation (RNS) believed to be normal, or if discomfort prevents completion of RNS => SFEMG may be performed as the initial test, 2) In laboratories with SFEMG capability, SFEMG may be performed as the initial test for disorders of neuromuscular transmission.

diagnosis. RNS and SFEMG may indicate a dysfunction in the neuromuscular junction, either pre- or post-synaptic, and then the results of laboratory tests may add positive information for the clinical diagnosis. RNS and SFEMG are not specific tests, and their specificity is particularly low when the changes are mild. For instance, a slight increase in jitter may result from various conditions other than MG, such as myopathy, denervation, reinnervation, botulinum toxin effects, peripheral neuropathy, or drug effects. Therefore, performing RNS, SFEMG, conventional EMG, and nerve conduction studies is crucial in these conditions.

We showed a large variation between laboratories in the number of RNS and SFEMG tests performed for diagnosis of NMT disorders. In earlier studies, we showed large variation in electrodiagnostic practice for the diagnosis of polyneuropathies (Tomschik et al., 2023), amyotrophic lateral sclerosis (Pugdahl et al., 2010) and myopathy (Pugdahl et al., 2010). The cause of large variations may be the clinical

presentations of the patients or the electrodiagnostic examination routine and the techniques used at each lab. Similarly, there may be differences in the referral pattern from lab to lab. Another reason for the large variations may be the lack of reliable criteria for the minimum number of tests to perform or to accept for a diagnosis which has been the main purpose of the present study.

Up to date, the only recommendations were the AAEM guidelines on the electrodiagnosis of MG and LEMS. These guidelines are based on a retrospective literature review (Committee, 2001a, 2001b), and in 2015 updated (Chiou-Tan and Gilchrist, 2015) but the sensitivity and specificity of these guidelines have never been tested. In the present study, we showed a high sensitivity and specificity of the AAEM guidelines. Evidence-based ESTEEM Groups recommendations showed a similar high sensitivity but higher specificity (100 %).

A diagnostic gold standard is not available for MG, creating a methodological problem when estimating the sensitivity and specificity of an index test. When a conclusive MG diagnosis is not reached at initial evaluation, a period of clinical observation evaluating the response to therapy alongside the results of different diagnostic procedures may be

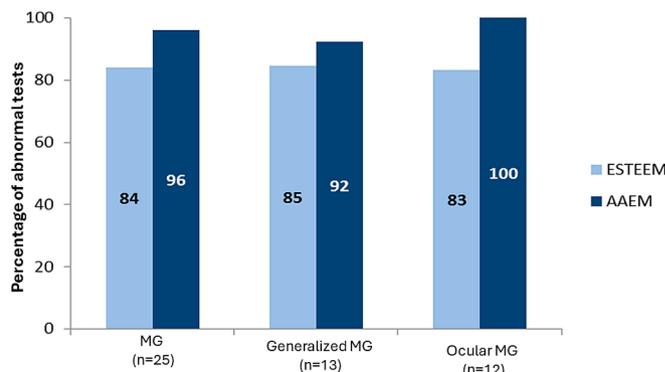


Fig. 5. Comparison of the sensitivity between AAEM criteria and ESTEEM recommendations. MG = myasthenia gravis.

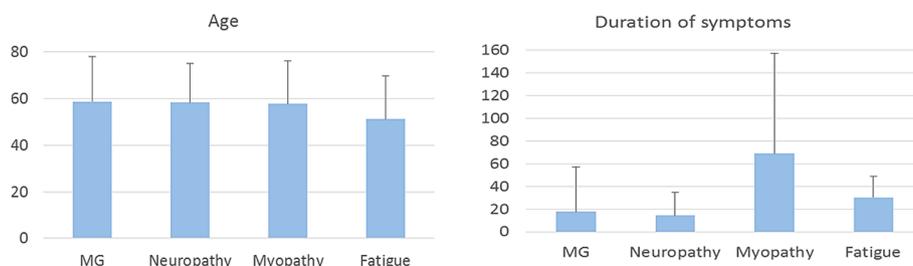


Fig. 4. Comparison of age and symptom duration in myasthenia gravis (MG) and patient controls.

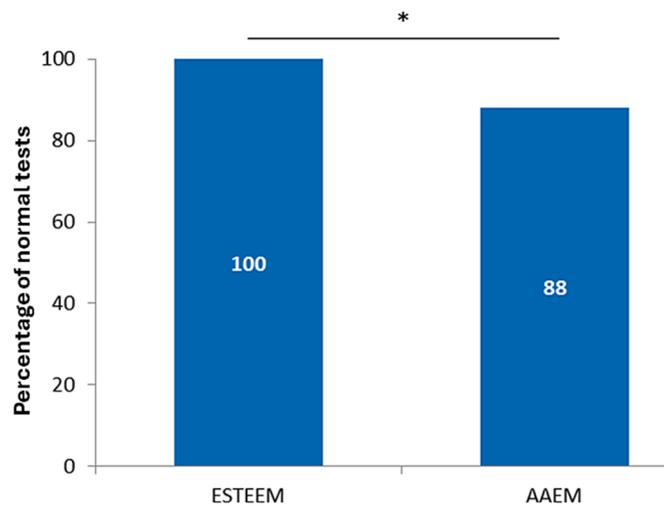


Fig. 6. Comparison of the specificity between AAEM criteria and ESTEEM recommendations. MG = myasthenia gravis.

of help in defining the disease (Padua et al., 2014). In our study, our reference standard (gold standard) was the consensus diagnosis made by experienced clinical neurophysiologists from 6 different countries based on both electrodiagnostic and clinical findings including follow-up. Therefore, we believe the diagnoses for the reference standard were robust.

Our study has some limitations. First, the number of patients for the sensitivity and specificity analyses was limited. Second, our recommendations cover only MG but LEMS and other NMT disorders could not be included due to the limited number of patients in these groups. Further studies are required for these disorders. Third, we cannot evaluate the sensitivity of individual muscles because not the same muscles were examined in all patients. We want to emphasize that abnormalities need to be identified in different nerves and muscles. Finally, the patients should be questioned for Botulinum toxin injections before SFEMG testing not only in facial muscles but also in the extremity muscles (Punga and Liik, 2020; Punga et al., 2023). We do not have any data on this.

5. Conclusion

Electrodiagnostic consensus recommendations for the minimum number of RNS and SFEMG studies to diagnose disorders of the neuromuscular junction are suggested. The recommendations encourage using different limits of normality according to the specific muscle examined and age group, and obtained locally at each diagnostic centre or in multicentre studies.

Electrodiagnostic consensus recommendations for the minimum number of abnormal RNS and SFEMG studies may serve as a first step towards evidence-based guidelines for diagnosing NMT disorders.

Author Contributions

KP and AFF contributed to the conception and design of the study. BJ, JPC, MdeC, PF, ALV, RL, WN, IS and AFF contributed to the acquisition of data. KP contributed to the analysis of data. HT and KP contributed to drafting the text and preparing the figures. All authors reviewed and edited the manuscript.

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.

Data availability

Data will be made available on request.

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