

Taiwan Clinical Practice Guidelines for Myasthenia Gravis

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Abstract

Myasthenia gravis (MG) is an autoimmune neuromuscular disorder characterized by muscle weakness and fatigue due to autoantibodies impairing neuromuscular transmission. With a global prevalence of 40–180 per million, Taiwan has seen a rise in MG cases from 4476 in 2013 to 5752 in 2019, with generalized MG (GMG) prevalence increasing significantly, whereas GMG patients incur substantially higher medical costs and resource utilization compared to non-MG patients. To standardize MG management, the Society formed an expert committee of 37 MG specialists and a patient representative, tasked with developing evidence-based guidelines. The committee, organized into 11 thematic subgroups, conducted a systematic review of literature from 2015 to 2024 and employed a Modified Delphi method to achieve consensus on clinical guidance statements. Recommendations cover diagnosis (e.g., antibody testing and electrophysiological tests), treatment (e.g. thymectomy, steroids, and novel biologics), and management of specific MG subtypes, including ocular, early- and late-onset, muscle-specific tyrosine kinase-related, and refractory MG, as well as myasthenic crisis and neonatal MG. The guidelines emphasize early diagnosis, integrated management of comorbidities, and long-term care strategies, including patient support and tailored exercise programs. These consensus statements aim to enhance care quality, improve patient outcomes, and guide future research and pharmaceutical development in Taiwan's medical community.

Keywords: Autoimmune disorder, consensus guidelines, myasthenia gravis, neuromuscular junction, Taiwan

INTRODUCTION

Myasthenia gravis (MG) is an autoimmune disorder affecting the neuromuscular junction, characterized by autoantibodies targeting the acetylcholine receptor (AChR), muscle-specific tyrosine kinase (MuSK), or low-density lipoprotein receptor-related protein 4 (LRP4), which impair

neuromuscular transmission and cause skeletal muscle weakness and fatigue.^[1] MG impacts various muscles, including those controlling eye movement, facial expression, chewing, swallowing, limb movement, and respiration.

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Common symptoms include ptosis, diplopia, slurred speech, dysphagia, and fluctuating limb weakness.^[2]

MG can affect individuals of any age (predominantly women under 40 and men over 60), ethnicity, or gender, and may be triggered by stressors, with infections being the most frequent cause. The global prevalence of MG ranges from 40 to 180 cases per million, with an annual incidence of 4–12 per million.^[3] In Taiwan, the number of MG patients rose from 4476 in 2013 to 5752 in 2019, with prevalence increasing from 19 to 24 per 100,000 individuals.^[4] Generalized MG (GMG) cases grew from 1,576 in 2009 to 2,638 in 2019, with prevalence rising from 6.83 to 11.18 per 100,000 ($P < 0.0001$).^[5] A retrospective matched study using Taiwan's National Health Insurance Research Database assessed healthcare resource utilization and costs for GMG patients, revealing that in 2019, GMG patients had, on average, 10 additional outpatient visits, 0.62 more hospitalizations, and 0.49 more emergency visits compared to non-GMG patients ($P < 0.0001$). The average cost difference was New Taiwan Dollar (NTD) 94,997 ± 76,431 (USD 3,133 ± 2,521), with significantly higher expenses across all categories (outpatient, inpatient, emergency, and medication) ($P < 0.0001$).^[6]

The rising prevalence of MG in Taiwan and its substantial burden on the healthcare system underscore the importance of early diagnosis and treatment. To address this, the Taiwan Neuroimmunology Medical Society established an expert committee to standardize MG management based on the latest scientific evidence and Taiwan's clinical context. The committee aims to provide a comprehensive guideline for MG diagnosis and treatment for physicians and healthcare professionals in Taiwan, improve the quality of care and health outcomes for MG patients, and foster further research and pharmaceutical development in the field within Taiwan's medical community.

METHODS

The expert committee comprised 37 MG experts and one patient representative (the chairperson of the MG association of Taiwan). The committee was divided into groups based on 11 distinct themes: diagnosis, thymectomy, ocular MG (OMG), early-onset GMG, late-onset and very late-onset GMG, MuSK MG and double-negative MG (DNMG), myasthenic crisis (MC), neonatal and juvenile MG, MG with autoimmune diseases, refractory MG, and long-term management and patient support groups.

Each consensus subgroup began by searching the MEDLINE database for literature from the past decade (2015–2024). After thoroughly reviewing the retrieved studies, the subgroups drafted clinical guidance statements for MG management. Through in-person and virtual discussions, the statements were refined, followed by a first round of voting. The voting used a 5-point Likert scale, where all committee members anonymously rated each statement: 5 for complete acceptance, 4 for acceptance with minor reservations, 3 for acceptance with major reservations, 2 for rejection with reservations, and 1 for complete rejection. A statement achieved consensus if ≥75% of experts rated it 4 or 5. Statements with 60%–74%

agreement were revised by the responsible subgroup, whereas those with <60% agreement were discarded. A second round of voting evaluated the revised statements, with consensus achieved if ≥75% of experts rated them 4 or 5; statements with <75% agreement were excluded from the study. The consensus level is established through a Modified Delphi method, with agreement above 90% classified as strong, 70%–90% as moderate, and below 70% as weak. The original consensus statements, presented in this article, are in English. A Chinese edition of this work has been published.^[7] Grok 3 (version 3.0, developed by xAI) was used to translate the Introduction and Methods sections from Chinese to English, with prompts specifying accurate medical terminology; authors reviewed and edited the output for accuracy and clarity.

RESULTS

Consensus guidance treatment statements

Diagnosis

1. Serum antibody testing, such as AChR antibody, is recommended for patients suspected of MG, as it can assist in confirming the diagnosis when combined with the clinical presentations. However, due to occasionally positive results appearing in non-MG patients, careful interpretation and longitudinal monitoring are crucial.^[8–10] (Level of consensus: 100%; average score: 4.84; strength of recommendation: strong)
2. To achieve an accurate diagnosis of fatigable muscle weakness, clinicians are advised to employ electrophysiological tests, such as repetitive nerve stimulation (RNS) or single fiber electromyography (SFEMG). These tools enhance sensitivity, aid in differentiating between disease severities, minimize misdiagnoses, and track disease progression.^[11–14] (Level of consensus: 100%; average score: 4.92; strength of recommendation: strong)
3. In patients presenting with ocular symptoms, the ice pack test is recommended for the early and accurate diagnosis of OMG. RNS and SFEMG may correlate with MG severity.^[15–18] (Level of consensus: 97%; average score: 4.83; strength of recommendation: strong)
4. In patients with suspected MG, screening for autoimmune thyroid diseases, including Graves' disease, is recommended due to their high prevalence. The presence of thyroid-stimulating hormone receptor autoantibodies may be indicative of the presence and severity of Graves' disease.^[19–23] (Level of consensus: 96%; average score: 4.54; strength of recommendation: strong)
5. For patients with MG, it is recommended to perform computed tomography (CT) imaging to rule out thymic diseases, including thymoma and thymic hyperplasia. CT images provide crucial information about tumor characteristics, enabling the distinction between low-risk and high-risk thymomas, and guiding the appropriate surgical approach.^[24] (Level of consensus: 100%; average score: 4.81; strength of recommendation: strong)

Thymectomy

1. A combination of thymectomy and pharmacotherapy is recommended for the management of newly diagnosed MG, particularly in adults aged 18–50 years and in patients with AChR antibody-positive GMG. This approach has been demonstrated to improve clinical outcomes, reduce the necessity for immunosuppressive therapy, and increase the likelihood of complete prednisolone withdrawal.^[25–28] In particular, patients with thymic hyperplasia, early-onset MG (EOMG, defined as MG diagnosed before age 50), and a short disease duration are more likely to achieve complete and stable remission postthymectomy.^[29] For those with generalized juvenile MG, thymectomy may offer benefits. This recommendation should be applied judiciously in patients with late-onset MG (LOMG, defined as MG diagnosed after age 50), advanced age, higher body mass index, dysphagia, or extended disease duration, as these factors have been linked to a suboptimal response to thymectomy.^[25,30,31] (Level of consensus: 100%; average score: 4.97; strength of recommendation: strong)
2. Clinical studies suggest that thymectomy using either video-assisted thoracoscopic surgery or robot-assisted thoracoscopic surgery yields comparable outcomes for patients with MG. Both methods are safe and effective, improving neurological outcomes, reducing the dosage of steroid therapy, and potentially leading to complete stable remission. Although there might be some complications, most patients showed improvement after thymectomy.^[32,33] (Level of consensus: 94%; average score: 4.50; strength of recommendation: strong)
3. Preoperative short-term plasmapheresis can improve clinical outcomes, especially in early-onset cases of GMG undergoing thymectomy.^[34] Intravenous immunoglobulin (IVIG) is a potential alternative, with potentially consistent response rates and fewer postoperative complications.^[35] (Level of consensus: 96%; average score: 4.54; strength of recommendation: strong)
4. For patients diagnosed with MuSK MG, thymectomy is not recommended due to insufficient evidence of significantly improved clinical outcomes.^[36–38] (Level of consensus: 96%; average score: 4.73; strength of recommendation: strong).

Ocular myasthenia gravis

1. Pyridostigmine, an acetylcholinesterase inhibitor, is the recommended first-line treatment for patients with ophthalmoplegia due to OMG. In more severe cases, steroids may be required.^[24,39] (Level of consensus: 96%; average score: 4.81; strength of recommendation: strong)
2. A low-dose prednisolone regimen of up to 15 mg/day is a commonly utilized treatment for OMG. Furthermore, higher doses of prednisolone and other types of steroids, such as methylprednisolone, have also been demonstrated to be effective.^[40] Nevertheless, it is important to note that potential side effects, such as impaired glucose tolerance and reduced bone mineral density, necessitate careful

monitoring.^[41] (Level of consensus: 100%; average score: 4.81; strength of recommendation: strong)

3. The administration of steroids in the early stages of OMG may be associated with a reduced risk of progression to GMG.^[42] (Level of consensus: 97%; average score: 4.89; strength of recommendation: strong)
4. For patients with OMG who are intolerant or unresponsive to prednisolone, steroid-sparing agents such as azathioprine (AZA), mycophenolate mofetil (MMF), and tacrolimus may be considered as safe, tolerable, and effective options. These agents may reduce the need for high steroid doses, mitigate the side effects of prolonged steroid use, maintain the disease stage, and improve overall symptoms.^[43–47] (Level of consensus: 100%; average score: 4.81; strength of recommendation: strong).

Early-onset generalized myasthenia gravis

1. Oral steroids may provide symptom control benefits in patients with early-onset GMG, defined as GMG diagnosed before age 50. Earlier intervention may result in more favorable long-term outcomes and reduced maintenance doses.^[48,49] (Level of consensus: 100%; average score: 4.84; strength of recommendation: strong)
2. Alternate-day prednisolone therapy is an effective strategy for managing early-onset GMG, with a reduced incidence of adverse effects and superior symptom control.^[3,50–52] (Level of consensus: 100%; average score: 4.70; strength of recommendation: strong)
3. Patients with GMG may experience a temporary exacerbation of weakness when initiating high-dose prednisolone therapy (40–80 mg daily). This phenomenon is more prevalent in older patients, those with severe bulbar symptoms, and those with a low MG Severity Scale score. Therefore, it is crucial to closely monitor patients during this period.^[39,50,53] (Level of consensus: 100%; average score: 4.86; strength of recommendation: strong)
4. AZA is a highly effective treatment for managing symptoms of MG, whether used alone or in combination with prednisolone. It reliably results in improved functional states and reduced bulbar involvement, and significantly aids in decreasing the maintenance dose of prednisolone. The effect of AZA may be delayed. For optimal results in the treatment of moderate-to-severe MG, it is recommended to administer AZA at a dosage of 2–3 mg/kg/day in combination with prednisolone.^[3,54–57] (Level of consensus: 100%; average score: 4.73; strength of recommendation: strong)
5. MMF may be considered in certain scenarios, particularly for patients who are intolerant to other immunosuppressants, and it may result in a reduction in the dosage of steroids needed.^[58,59] (Level of consensus: 100%; average score: 5.00; strength of recommendation: strong)
6. In cases of early-onset generalized nonthymomatous MG, an early response (defined as a positive response to treatment within the first two years after disease onset, specifically achieving freedom from symptoms lasting

for more than 12 months by year two) to intensive immunotherapy, including steroids, steroid-sparing immunosuppressants, and rituximab, may indicate a benign disease course and better outcomes. This highlights the potential for tailored medication strategies.^[60] (Level of consensus: 97%; average score: 4.92; strength of recommendation: strong)

7. For patients with MG who are on long-term steroid therapy, supplementation with alendronate and alfacalcidol may improve bone mineral density. Regular monitoring of bone mineral density and bisphosphonate use may preserve bone health.^[61] (Level of consensus: 97%; average score: 4.94; strength of recommendation: strong).

Late- and very late-onset generalized myasthenia gravis

1. Patients with EOMG and LOMG respond to similar therapeutic approaches. The appropriate dosage should be determined based on individual characteristics.^[60,62,63] (Level of consensus: 100%; average score: 4.92; strength of recommendation: strong)
2. For patients with very late-onset MG, defined as MG diagnosed after age 65, prednisolone may be a potential treatment. It is recommended that the dosage of prednisolone be individualized, considering the severity of the disease and the patient's underlying conditions.^[64-66] (Level of consensus: 100%; average score: 4.86; strength of recommendation: strong)
3. Limited research suggests that prednisolone alone, AZA alone, and their combination have beneficial effects in the treatment of LOMG. However, the combination therapy of prednisolone and AZA appears to result in significant positive outcomes and improvement in patient condition.^[67,68] (Level of consensus: 100%; average score: 4.76; strength of recommendation: strong)
4. Rituximab may be a potential therapeutic option for late-onset generalized nonthymomatous MG. It is important to highlight that an early response to treatment can indicate a favorable disease course.^[69] (Level of consensus: 97%; average score: 4.68; strength of recommendation: strong)
5. Patients aged 65 years and older who are newly diagnosed with MG may experience more life-threatening events early in the disease course. Compared to younger patients, they may require less medication to achieve favorable outcomes. However, the lack of immunotherapy may be associated with a poor prognosis.^[70,71] (Level of consensus: 92%; average score: 4.78; strength of recommendation: strong)
6. The evidence is limited but suggests that tacrolimus, with or without steroids, may be effective and safe for very late-onset MG. In some patients, symptom control has been achieved with an initial dosage of 1.0 mg/day.^[64,72] (Level of consensus: 100%; Average score: 4.56; strength of recommendation: strong).

Muscle-specific tyrosine kinase myasthenia gravis and double-negative myasthenia gravis

1. For patients with MuSK MG, steroids are an effective treatment option. A maintenance dose of 30 mg prednisolone daily is commonly used, although dosages range from 10 to 60 mg daily.^[73-76] (Level of consensus: 94%; average score: 4.62; strength of recommendation: strong)
2. For patients with MuSK MG, evidence suggests that pyridostigmine monotherapy may not achieve clinical improvement.^[38,77] (Level of consensus: 100%; average score: 4.73; strength of recommendation: strong)
3. For patients with MuSK MG who have shown a poor response to previous treatments, rituximab can be a treatment option due to its proven effectiveness and safety. An initial induction regimen of rituximab at 375 mg/m² weekly for four consecutive weeks is advised, or two 1 g doses bi-weekly. Following rituximab induction in MuSK MG patients, clinical studies consistently report a significant decrease in the mean dose of prednisolone and other immunosuppressants.^[78-84] (Level of consensus: 97%; average score: 4.68; strength of recommendation: strong)
4. A limited case series indicates that plasma exchange (PE) and double filtration plasmapheresis (DFPP) may be beneficial for MuSK MG patients. PE demonstrated greater clinical improvement than IVIG and may be preferred for acute exacerbations. Maintenance PE may provide prolonged symptom control.^[38,85-87] (Level of consensus: 100%; average score: 4.73; strength of recommendation: strong)
5. In the management of patients diagnosed with DNMG, inclusive of LRP4 and cortactin, prednisolone is a recommended treatment option. However, clinicians should be aware that the effectiveness of this therapeutic approach may vary. Evidence suggests that some patients may experience remission following prednisolone use, whereas others may exhibit drug refractoriness.^[88-90] (Level of consensus: 94%; average score: 4.61; strength of recommendation: strong)
6. For patients diagnosed with DNMG, immunosuppressive agents may be considered to potentially improve long-term prognosis.^[60,91] (Level of consensus: 97%; average score: 4.59; strength of recommendation: strong).

Myasthenic crisis

1. For the management of MC or MG with acute exacerbations, it is recommended to initiate DFPP or PE. These treatments have demonstrated improved patient outcomes. Therapeutic PE or DFPP has proven effective in improving physical and mental functioning and is considered cost-effective.^[92-99] (Level of consensus: 97%; average score: 4.86; strength of recommendation: strong)
2. IVIG is an efficacious treatment for patients experiencing MC or acute exacerbations of MG. IVIG may induce

remission, reduce the need for immunosuppressive drugs, and improve muscle strength and function. IVIG at a total dose of 1–2 g/kg given over several days may be sufficient for the treatment of MG exacerbations.^[92,100–104] (Level of consensus: 100%; average score: 4.81; strength of recommendation: strong)

3. Both IVIG and PE are viable options for managing moderate to severe MG crises, with comparable efficacy and similar durations of effect. While PE or DFPP may have a higher complication rate, it is associated with better respiratory outcomes. IVIG can be considered as an alternative, or when PE is not accessible.^[105–109] (Level of consensus: 100%; average score: 4.86; strength of recommendation: strong)
4. In the event of a MC, IVIG and DFPP or PE are the recommended first-line options for the management of MC. The combination of DFPP/PE or IVIG with intravenous steroids injection may be a more effective approach to managing MC and preventing its recurrence than steroids alone, as it may decrease the initial worsening caused by steroids.^[110,111] (Level of consensus: 97%; average score: 4.86; strength of recommendation: strong)
5. Noninvasive ventilation may be considered a potential option for the management of MC due to its potential cost benefits and ability to prevent intubation and reintubation.^[112–114] (Level of consensus: 100%; average score: 4.84; strength of recommendation: strong)
6. For patients presenting with a sudden worsening of symptoms related to MG, diagnostic tools may include the assessment of AChR or MuSK antibodies, RNS, and SFEMG. These tools can be employed to confirm the diagnosis of MG.^[115,116] A diagnosis of MC is made when the appearance of respiratory failure due to weakness of respiratory and bulbar (oropharyngeal) muscles is confirmed by reduced forced vital capacity, maximal inspiratory pressure, and maximal expiratory pressure.^[117] (Level of consensus: 93%; average score: 4.68; strength of recommendation: strong)
7. To manage MG patients at risk of a MC, it is recommended to identify potential triggers such as infections (including coronavirus disease-2019), stress, certain medications, and comorbidities. Significant risk factors for MC include EOMG, respiratory infection, cardiac comorbidities, high-dose pyridostigmine use, poor MG Foundation of America clinical classification, and a history of previous MC.^[94,118,119] (Level of consensus: 96%; average score: 4.73; strength of recommendation: strong).

Neonatal and juvenile myasthenia gravis

1. Pregnant women diagnosed with MG may experience a worsening of symptoms, particularly if they have a shorter disease duration, higher clinical scores, or discontinue immunosuppressive treatment during pregnancy. Notably, unplanned pregnancies may lead to more MG exacerbations and hospitalizations. The decision for cesarean section should be based on obstetric indications. Despite these challenges,

infants of women with MG do not face higher risks of neonatal complications, even though they tend to be born on average two days earlier.^[120–128] (Level of consensus: 100%; average score: 4.92; strength of recommendation: strong)

2. Neonates born to mothers with MG have 6%–10% developing transient neonatal MG (TNMG). It is therefore recommended that these neonates be monitored until the 4th day of life to detect and treat any early signs of TNMG, particularly if they experience feeding difficulties or low muscle tone. It is important to note that despite the increased risk, TNMG symptoms are typically not life-threatening and usually self-limited after appropriate supportive care.^[129,130] (Level of consensus: 96%; average score: 4.76; strength of recommendation: strong)
3. For patients with juvenile MG, the first-line immunotherapy is steroids. In cases where long-term steroid therapy is necessary or the disease is refractory to conventional treatment, immunosuppressants such as AZA, rituximab, and tacrolimus may be considered.^[131,132] (Level of consensus: 100%; average score: 4.78; strength of recommendation: strong).

Myasthenia gravis with autoimmune diseases

1. It is recommended that the management of both MG and concurrent autoimmune diseases should be integrated, with the possible use of immunosuppressive therapies and thymectomy. Early intervention is particularly important in patients with a significant association between MG and systemic lupus erythematosus.^[133–141] (Level of consensus: 96%; average score: 4.81; strength of recommendation: strong).

Refractory myasthenia gravis

1. When managing refractory MG, clinicians should actively consider and monitor for comorbid conditions such as autoimmune diseases, renal disease, diabetes, and hypertension, as these may intensify the disease's severity. These comorbidities could increase hospital stays, the risk of death, and contribute to the development of refractory MG.^[142–145] (Level of consensus: 96%; average score: 4.73; strength of recommendation: strong)
2. Rituximab may be applied in patients with refractory MG who have positive antibodies against AChR or MuSK receptors. Its administration has been demonstrated to effectively reduce symptoms, lower the need for prednisolone, decrease hospital admissions, improve muscle function, and reduce disease severity.^[146–153] (Level of consensus: 100%; average score: 4.76; strength of recommendation: strong)
3. It is recommended that oral tacrolimus be considered as an adjunctive, long-term treatment option for patients with refractory MG, as it has been demonstrated to significantly improve symptoms, enhance quality of life, reduce prednisolone use, and exhibit a generally safe profile with few mild adverse events reported.^[132,154–156] (Level of consensus: 100%; average score: 4.61; strength of recommendation: strong)

4. Novel biological therapies, including eculizumab,^[157-161] efgartigimod,^[162,163] ravulizumab,^[164,165] rozanolixizumab,^[166] and zilucoplan,^[167] may be considered for the management of adult patients with GMG who are inadequately controlled by immunotherapies. These therapies have been validated by large-scale clinical trials and have been demonstrated to provide clinically meaningful improvements, while also exhibiting well-tolerated safety profiles.^[168,169] (Level of consensus: 97%; average score: 4.94; strength of recommendation: strong).

1. For the long-term management of MG, comprehensive support and tailored healthcare approaches are recommended, including structured and individualized exercise programs, patient support groups, and addressing emotional factors such as stress and depression.^[170-175] These interventions, when employed in conjunction with traditional therapies, can enhance health-related quality of life, augment muscle strength, improve functional capacity, diminish fatigue, and potentially alleviate depressive symptoms.^[176,177] Nevertheless, it is important to note that individual responses may vary, and that patients' conditions and safety should be considered when designing these programs.^[178-188] (Level of consensus: 100%; average score: 4.86; strength of recommendation: strong).

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