Immunobiological Therapies in the Drug Treatment of Myasthenia Gravis: Advances, Challenges and Therapeutic Perspectives

Terapias imunobiológicas no tratamento medicamentoso da miastenia gravis: avanços, desafios e perspectivas terapêuticas

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ABSTRACT

Introduction: Myasthenia Gravis is presented as an autoimmune disease traditionally treated with corticosteroids, highlighting its limitations such as worsening symptoms with initial treatment using high doses, underdosing, and even discontinuation of treatment. In this way, immunobiologicals emerge as an emerging therapy in comparison to conventional treatment with corticosteroids.
Objectives: To analyze the clinical importance of the alternative therapy with immunobiologicals in comparison to corticosteroids.
Methods: A qualitative integrative review was conducted with systematic searches in the PubMed and BVS databases, following strict eligibility criteria. The data were organized in a spreadsheet and analyzed by category, aiming to compare immunobiologicals and corticosteroids in the treatment of Myasthenia Gravis.
Results: Of the 1,936 articles initially identified, only 8 met the inclusion criteria and composed the final corpus of the review. The main findings of these studies were organized into tables, detailing titles, journals, methods, objectives, and results.
Discussion: Immunobiologicals stand out as a promising and safer alternative to corticosteroids in the treatment of Myasthenia Gravis, with good clinical efficacy and reduced adverse effects. However, challenges such as cost, accessibility, response variability, and the need for close monitoring still limit their widespread implementation.
Conclusion: Immunobiologicals are shown to be effective and safer than corticosteroids in the treatment of Myasthenia Gravis. However, their high cost and access limitations highlight the need for further research to expand their clinical use.

Keywords: Myasthenia Gravis. Immunobiologicals. Corticosteroids. Treatment.

RESUMO

Introdução: A Miastenia Gravis é apresentada como uma doença autoimune tratada tradicionalmente com corticosteroides, destacando seus limites como piora dos sintomas com tratamento inicial com altas doses utilizadas, subdosagem e até descontinuação do tratamento. Desse modo, os imunobiológicos surgem como terapia emergente em comparação ao tratamento convencional com os corticosteroides.
Objetivos: Analisar a importância clínica da terapia alternativa com imunobiológicos em comparação aos corticosteroides.
Metodologia: A abordagem utilizada foi através de uma revisão integrativa qualitativa, com buscas sistemáticas nas bases PubMed e BVS, seguindo critérios rigorosos de elegibilidade. Os dados foram organizados em planilha e analisados por categorias, visando comparar imunobiológicos e corticosteroides no tratamento da Miastenia Gravis.
Resultados: Dos 1.936 artigos inicialmente identificados, apenas 8 atenderam aos critérios de inclusão e compuseram o corpus final da revisão. As principais informações desses estudos foram organizadas em quadros, detalhando títulos, periódicos, métodos, objetivos e resultados.
Discussão: Destaca-se que os imunobiológicos oferecem uma alternativa promissora e mais segura aos corticosteroides no tratamento da Miastenia Gravis, com boa eficácia clínica e redução de efeitos adversos. No entanto, desafios como custo, acessibilidade, variabilidade de resposta e necessidade de monitoramento rigoroso ainda limitam sua ampla implementação.
Conclusão: Os imunobiológicos se mostram eficazes e mais seguros que os corticosteroides no tratamento da Miastenia Gravis. No entanto, seu custo elevado e limitações de acesso reforçam a necessidade de mais pesquisas para ampliar seu uso clínico.

Palavras-chave: Miastenia Gravis. Imunobiológicos. Corticosteróides. Tratamento.

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INTRODUCTION

Myasthenia Gravis (MG) is a rare autoimmune disease that affects the neuromuscular junction, resulting in muscle weakness and progressive fatigue[1]. This condition occurs due to the immune system's production of antibodies that attack acetylcholine receptors, impairing communication between nerves and muscles. Among the main symptoms are ptosis, diplopia, difficulties with chewing, swallowing, and speech, as well as weakness in the limbs and respiratory muscles[2].

The epidemiology of MG shows significant regional variations. In the United States[3], a standardized incidence rate of 68.5 new cases per million person-years and an adjusted prevalence of 316.4 per million was estimated among individuals with commercial insurance and Medicare. Among Medicaid beneficiaries, these numbers were lower, with 49.7 new cases per million person-years and a prevalence of 203.7 per million. Overall, it is estimated that in 2021, approximately 82,715 adults in the U.S. were living with MG, which corresponds to 320.2 cases per million. The study also highlighted epidemiological differences related to sex and age, with higher incidence observed in young women and a marked increase in older men, showing a general upward trend with aging[3].

In Latin America, the epidemiology of MG remains under-researched, and many countries lack comprehensive data. According to[4], available information generally comes from referral hospitals, which hinders comparisons across different regions. In general, MG prevalence in Latin America is below 100 cases per million inhabitants, while in the Iberian Peninsula, the numbers exceed that threshold. Moreover, there is a female predominance in early-onset cases (<50 years), and a rising prevalence among the elderly (>65 years), especially men[4].

MG treatment commonly involves the use of corticosteroids, which have shown high efficacy in symptom improvement and can induce remission in up to 75% of cases, particularly when administered in high doses and maintained over the medium to long term[5]. However, prolonged use of these drugs is associated with considerable adverse effects, which drives the search for alternative therapeutic strategies, including immunosuppressants, plasmapheresis, intravenous immunoglobulin, and more recently,immunobiological therapies[6]. Additionally, initial worsening of symptoms has been reported with the start of corticosteroid therapy, especially at high doses, which may lead to underdosing or even treatment discontinuation[7]. To mitigate the risks of long-term use, clinical guidelines, such as the Japanese 2014 guidelines, recommend reducing the dose of prednisolone to 5 mg/day or less whenever possible[8].

In recent years, immunobiological therapies have gained prominence as a promising alternative in the treatment of MG. These therapies offer greater specificity and fewer adverse effects compared to corticosteroids. Drugs such as eculizumab, zilucoplan, efgartigimod, and rituximab have shown positive results in clinical trials, expanding the treatment options for patients who are refractory to the conventional therapy[9]. These advances represent new perspectives for a more effective and personalized management of the disease.

Therefore, the objective of this study was to analyze the clinical importance of alternative therapy with immunobiologicals in comparison to corticosteroids.

METHODOLOGICAL APPROACH

TYPE OF STUDY

This article presents an integrative literature review aimed at gathering and synthesizing research findings that analyzed the clinical importance of alternative immunobiological therapies in comparison to corticosteroids for the treatment of Myasthenia Gravis. The main focus was to consolidate knowledge about genetic mutations and their implications in the development of this condition. An integrative review, with a qualitative approach, seeks to evaluate data from various scientific studies, enabling the aggregation and synthesis of findings on a specific topic. This process involves exposing, comparing, and interpreting data, culminating in the production of new insights and a deeper understanding of the investigated subject[10].

The quality of this article was guaranteed through the rigorous fulfillment of five fundamental steps: 1 - formulation of the central question or main research hypothesis, which guided the entire work; 2 - definition of an exhaustive approach to the literature search and well-defined criteria for inclusion and exclusion of sources in the bibliographic survey, in order to ensure the relevance and quality of the references gathered; 3 - collection, organization, and systematic summary of the information found, structuring them into a consistent database; 4 - deep analysis and careful interpretation of the findings in light of the parameters initially established; and 5 - clear and synthetic presentation of the results obtained, through consistent and well-defined analytical categories[10].

The descriptors used for the search of scientific articles were cataloged in the Medical Subject Headings (MeSH) and Health Sciences Descriptors (DeCS) systems. These platforms are essential tools in scientific research, as they provide standardized terminology for indexing and retrieving articles, making the search more efficient and increasing the accuracy of the results. MeSH, maintained by the National Library of Medicine (NLM), is widely used in international databases such as PubMed. DeCS, developed by BIREME, is focused on scientific literature from Latin America and is applied in databases such as LILACS and the Biblioteca Virtual em Saúde (BVS).

The selected descriptors were: Immunoglobulins (corresponding in Portuguese: Imunoglobulinas), Myasthenia Gravis (corresponding in Portuguese: Miastenia Gravis), and Drug Therapy (corresponding in Portuguese: Tratamento Farmacológico). These terms were chosen to cover the main variables of the research, ensuring the relevance of the retrieved articles. Searches were conducted in the following databases:

PubMed: An international reference database in the biomedical field, known for the quality and scope of the published articles. The search strategy applied was: ((Immunoglobulins) AND (Myasthenia Gravis)) AND (Drug Therapy) NOT case report. The period was limited to the last 5 years to ensure the timeliness of the results.

Biblioteca Virtual em Saúde (BVS): A platform that compiles scientific literature from the Americas, including databases such as LILACS and SciELO. The search strategy used was: ((Imunoglobulinas) OR (Immunoglobulins)) AND ((Miastenia Gravis) OR (Myasthenia Gravis)) AND ((Tratamento Farmacológico) OR (Drug Therapy)). The period was limited to the last 5 years to ensure the timeliness of the results.

ELIGIBILITY CRITERIA

Strict inclusion and exclusion criteria were established for the selection of articles to be analyzed in the research. The inclusion criteria were: articles addressing alternative therapy withimmunobiological and their implications in the treatment of myasthenia gravis compared to corticosteroids; articles published in Portuguese, English, or Spanish; studies published in the last 5 years (2020–2025); publications available in full text, both free and paid; and studies with a clear methodology applicable to an integrative literature review.

The exclusion criteria were: duplicate studies found in more than one database; articles that addressed topics unrelated to the research objective; case reports, since this type of study has limitations in providing consistent and generalizable evidence due to its descriptive nature and small sample sizes.

DATA SYNTHESIS AND ANALYSIS

To organize and summarize the selected articles, two tables were created, in which the fundamental data of each study were recorded, such as: article title, journal, year of publication, type of study, objective, methodology, and main findings. This organization enabled a structured analysis of the content, allowing for the identification of the studies that best addressed the research question proposed in this review.

The selection of studies followed the use of the previously defined descriptors and inclusion and exclusion criteria. Initially, the titles were reviewed to exclude duplicate articles found in different databases. Next, the abstracts of the remaining articles were read, and those not aligned with the research topic or not meeting the established criteria were excluded. Finally, the articles that passed the title and abstract screening were thoroughly analyzed, and the final selection was based on the previously established inclusion and exclusion criteria. The selection process was illustrated by a flowchart (Figure 1), which details the number of studies at each stage.

To facilitate understanding and presentation of the data in the results and discussion section, the most relevant information was organized into tables (Table 1 and Table 2), highlighting the essential findings. These categories structured the analysis and will be further explored in the results, emphasizing the most relevant findings.

RESULTS

The initial search identified 1,936 records, with 520 from the Biblioteca Virtual em Saúde (BVS) and 1,416 from PubMed. After applying the time filter (2020–2025), 1,365 records were excluded. Of the remaining 571 articles, 232 were eliminated because they were case reports, which offer low-quality evidence to support an integrative review. Next, from the 339 remaining articles, 5 were excluded due to duplication. After this step, of the 334 remaining articles, 313 were discarded based on the reading of the title and abstract. Finally, of the 21 articles submitted to full-text reading, 13 were excluded. Thus, 8 articles were selected to compose the research corpus, as illustrated in the flowchart (Figure).

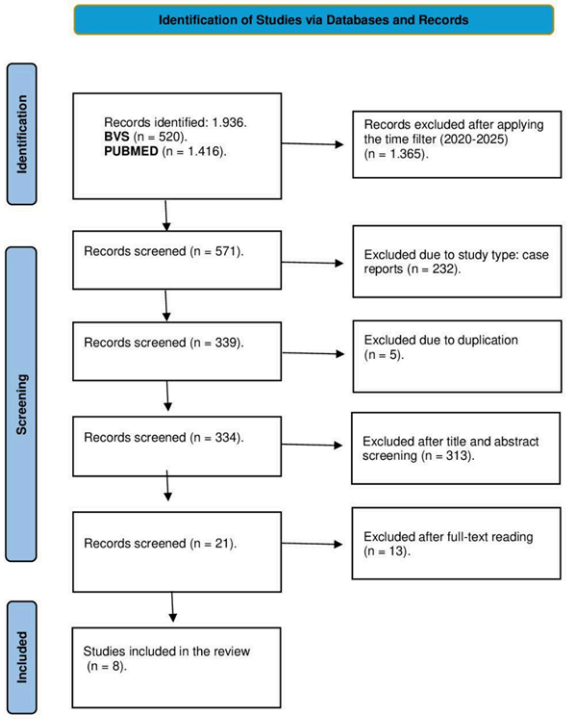

Figure. Flowchart of the study material selection.
Source: authorship.

The following tables were prepared with the aim of presenting, in an organized manner, the main information from the articles included in this review. Table 1 presents the titles of the articles, the journals in which they were published, the year of publication, and the type of study. Table 2 describes the objectives, the methods employed, and the main findings of each analyzed work.

Table 1. Characterization of the Study Material.

Article Title	Journal	Year	Type of Study
Efficacy and safety of immunosuppressants and monoclonal antibodies in adults with myasthenia gravis: a systematic review and network meta-analysis.	Front Immunology.	2023	"This is a systematic review and network meta-analysis based on randomized clinical trials."[11].
Risk-Benefit Analysis of Novel Treatments for Patients with Generalized Myasthenia Gravis.	Advances in Therapy	2024	This is a network meta-analysis (NMA) based on previously published phase III randomized clinical trials.[12]
Efficacy of innovative therapies in myasthenia gravis: A systematic review, meta-analysis and network meta-analysis.	Eur J Neurol.	2023	"This systematic review and network meta-analysis was conducted in accordance with the PRISMA guidelines."[13]
Efficacy and safety of the innovative monoclonal antibodies in adults with generalized myasthenia gravis: a Bayesian network analysis.	Frontiers in Immunology.	2023	The study is a systematic review with network meta-analysis (NMA) based on randomized clinical trials (RCTs) and conducted within a Bayesian framework.[14]
IgG regulation through FcRn blocking: A novel mechanism for the treatment of myasthenia gravis.	Journal of the Neurological Sciences.	2021	The article is a scientific review that discusses the mechanisms and clinical data of FcRn blockade as a therapeutic approach for myasthenia gravis.[15]
Randomized Double-Blind Placebo-Controlled Trial of the Corticosteroid-Sparing Effects of Immunoglobulin in Myasthenia Gravis.	American Academy of Neurology.	2023	The study was a randomized, double-blind, placebo-controlled clinical trial.[16]
Progress in the therapy of myasthenia gravis: getting closer to effective targeted immunotherapies.	Current Opinion in Neurology.	2020.	"This is an updated review on targeted immunotherapies for the chronic treatment of myasthenia gravis."[9]
Maintenance immunosuppression in myasthenia gravis, an update.	World Federation of Neurology.	2020	The article is an evidence-based review on immunosuppressive treatments for MG.[17]

Source: authorship.

Table 2. Characterization of the Study Material.

Article Title	Objetives	Methods	Results
Efficacy and safety of immunosuppressants and monoclonal antibodies in adults with myasthenia gravis: a systematic review and network meta-analysis.	"We evaluated and compared the efficacy and safety of immunosuppressants and monoclonal antibodies in the treatment of myasthenia gravis (MG) through a systematic review and network meta-analysis."[11]	"Data were extracted from randomized trials published between 2000 and 2024, available in PubMed, Embase, Web of Science, and the Cochrane Library. Statistical analysis was performed using R (version 4.2.3), JAGS, and STATA (version 15.0). Drug ranking was based on the Surface Under the Cumulative Ranking Curve (SUCRA)."[11]	"Batoclimab showed the best therapeutic effects with SUCRA values of 99% and 92% for the QMG and MG Composite scales, respectively." "Rozanolixizumab was the most effective in the MG Activities of Daily Living score (85%)." "Eculizumab demonstrated the greatest positive impact on quality of life (MG-QoL 15r) with a SUCRA of 96%." "Belimumab had the lowest probability of adverse events (SUCRA of 85%)." "Rozanolixizumab had a higher incidence of adverse events than placebo."[11]
Risk-Benefit Analysis of Novel Treatments for Patients with Generalized Myasthenia Gravis.	The study used a network meta-analysis (NMA) to compare the number needed to treat (NNT), the number needed to harm (NNH), and the cost per improved clinical outcome (CPIO) of recently approved treatments for generalized myasthenia gravis (gMG) associated with anti-acetylcholine receptor antibodies (anti-AChR Ab+). Investigated hypothesis: Neonatal Fc receptor (FcRn) inhibitors, intravenous efgartigimod and rozanolixizumab, and complement inhibitors, ravulizumab and zilucoplan, demonstrate different efficacy, safety, and cost profiles, with intravenous efgartigimod being the therapy with the best benefit-risk ratio.[12]	Design: Network meta-analysis comparing the efficacy and safety of treatments. Outcomes analyzed: **Efficacy**: Reduction of ≥3 and ≥5 points in Quantitative Myasthenia Gravis (QMG) and Myasthenia Gravis–Activities of Daily Living (MG-ADL) scores. **Safety**: Serious adverse events (SAEs) and treatment-emergent adverse events (TEAEs). **Cost**: Comparison of CPIO (cost per improved outcome) among treatments. Citation: "Efficacy outcomes included MG-ADL and QMG scores. Safety outcomes assessed included the proportions of patients with any serious AE (SAE) and any treatment-emergent AE (TEAE)."[12]	Efgartigimod IV apresentou o menor NNT para ≥3 e ≥5 pontos no QMG e MG-ADL. Rozanolixizumab teve o menor NNT para ≥3 pontos no MG-ADL. Todos os tratamentos tiveram perfis de segurança aceitáveis com NNH semelhantes. Efgartigimod IV teve o menor CPIO, sugerindo melhor relação custo-benefício. Citação: "Efgartigimod IV had the lowest NNT versus placebo for achieving a ≥3- and ≥5-point reduction in QMG, as well as a ≥5-point reduction in MG-ADL, whereas rozanolixizumab had the lowest NNT for a ≥3-point reduction in MG-ADL."[12]
Efficacy of innovative therapies in myasthenia gravis: A systematic review, meta-analysis and network meta-analysis.	"The objective of this study was to perform a meta-analysis and a network meta-analysis of randomized, placebo-controlled clinical trials on innovative therapies for myasthenia gravis with available efficacy data."[13]	"Treatment efficacy was assessed through changes in the MG-ADL, QMG, MGC, and MG-QoL15 scales. Statistical heterogeneity among trials was evaluated using the Cochrane Q test and I^2 values. Mean differences were pooled using a random-effects model."[13]	"The overall mean change in the MG-ADL scale was -2.17 points (95% CI: -2.67 to -1.67; p < 0.001) compared to placebo. The reduction in the QMG score was -3.46 (95% CI: -4.53 to -2.39; p < 0.001). Rituximab did not show significant improvement in MG-ADL scores (-0.92; p = 0.17) or QMG (-1.90; p = 0.07)."[13]
Efficacy and safety of the innovative monoclonal antibodies in adults with generalized myasthenia gravis: a Bayesian network analysis.	The study conducted a network meta-analysis (NMA) to quantitatively compare the efficacy of multiple interventions, combining results from direct and indirect comparisons. The goal was to determine the priority of new therapeutic agents for generalized myasthenia gravis, in the absence of head-to-head randomized clinical trials[14].	Data were collected from phase III randomized clinical trials and analyzed using Bayesian meta-analysis. The main outcomes analyzed were: **Efficacy**: Measured by MG-ADL, QMG, MGC, and MG-QoL 15r scores. **Safety**: Assessment of adverse events (AEs), serious adverse events (SAEs), and all-cause mortality. The analyses were conducted using R software (package 'gemtc') and Review Manager 5.4.[14]	**Efficacy**: The treatments rozanolixizumab 10 mg/kg, batoclimab 680 mg, and eculizumab showed greater reductions in MG-ADL, QMG, and MGC scores compared to placebo (Chen et al., 2023). **Safety**: Rozanolixizumab presented a higher incidence of adverse effects than other monoclonal antibodies. **Most common adverse effects**: Headache, diarrhea, and nausea. **Impact on quality of life**: Significant improvements in MG-QoL 15r scores were observed with efgartigimod and eculizumab treatments.[14]
IgG regulation through FcRn blocking: A novel mechanism for the treatment of myasthenia gravis.	The study investigates the hypothesis that neonatal Fc receptor (FcRn) blockade may be an effective therapeutic approach for generalized myasthenia gravis (gMG). The research explores how FcRn inhibition can selectively reduce pathogenic IgG levels without affecting other immunoglobulins, thereby improving the clinical symptoms of the disease.[15]	The analyzed studies used clinical assessment methods, including scores such as MG-ADL (Myasthenia Gravis Activities of Daily Living) and MGC (Myasthenia Gravis Composite score). IgG concentrations were monitored over time, as well as the adverse effects of the treatments.[15]	Significant reduction in pathogenic IgG levels (~75% in some cases) without affecting other immunoglobulins. Improvement in clinical symptoms as assessed by MG-ADL and MGC scores. Good treatment tolerability, with few serious adverse events reported.[15]
Randomized Double-Blind Placebo-Controlled Trial of the Corticosteroid-Sparing Effects of Immunoglobulin in Myasthenia Gravis.	The study aimed to evaluate whether intravenous immunoglobulin (IVIG), 10% caprylate/chromatography-purified (IGIV-C), could facilitate corticosteroid (CS) dose reduction in corticosteroid-dependent myasthenia gravis patients. The hypothesis was that IGIV-C would allow a ≥50% reduction in CS dose without disease worsening.[16]	**Data collection**: Quantitative Myasthenia Gravis score (QMG), Myasthenia Gravis Quality of Life scale (MG-QOL 15), Myasthenia Gravis Activities of Daily Living scale (MG-ADL). **Primary outcome criterion**: Percentage of patients with ≥50% reduction in CS dose at week 39. **Secondary outcomes**: Percentage reduction in CS dose, time to first MG worsening, episodes of myasthenic crisis, and laboratory changes.[16]	**Efficacy**: There was no significant difference between IGIV-C and placebo in corticosteroid dose reduction (60% vs. 63.3%, p=1.00). **Safety**: IGIV-C was well tolerated, with adverse events similar to those of placebo. **Adverse effects**: Headache, respiratory infections, and MG worsening were the most common. **Impact on quality of life**: No significant improvement was observed with IGIV-C.[16]
Progress in the therapy of myasthenia gravis: getting closer to effective targeted immunotherapies.	"To provide an update on immunomodulatory and immunosuppressive therapies in myasthenia gravis and to highlight newly approved or pending approval therapies with novel biologic agents."[9]	Data were collected from randomized clinical trials and observational studies. The analyses involved clinical outcomes related to the efficacy of immunobiologicals, reduction of myasthenic crises, impact on quality of life, and biomarkers of treatment response.[9]	"Eculizumab resulted in a 75% reduction in exacerbation rate and sustained improvement in daily activities of patients with myasthenia gravis." "Treatment with Rituximab led to sustained remission in 35% of patients over two years, without the need for additional immunotherapies." "Patients treated with Zilucoplan, Efgartigimod, and Rozanolixizumab demonstrated promising clinical responses in phase II trials."[9]
Maintenance immunosuppression in myasthenia gravis, an update.	The study critically reviews the practical aspects of long-term immunosuppression in myasthenia gravis (MG), assessing the efficacy and safety profile of various immunosuppressive and immunomodulatory agents, including corticosteroids, azathioprine, mycophenolate mofetil, cyclosporine, tacrolimus, methotrexate, rituximab, cyclophosphamide, eculizumab, intravenous immunoglobulin, subcutaneous immunoglobulin, plasmapheresis, and thymectomy.[17]	Data were collected from randomized clinical trials, observational studies, and literature reviews. The main outcome measures included clinical improvement of MG, reduction in the dose of immunosuppressants, and the adverse effects observed in patients.[17]	Eculizumab: 56% of patients achieved pharmacological remission or minimal manifestation status. IVIG: Resulted in clinical improvement and reduced the need for other immunosuppressants. SCIG: Showed similar benefit to IVIG with fewer systemic adverse effects. Tacrolimus: 92% of patients achieved remission or minimal manifestation status with adequate drug levels .[17]

Source: authorship.

DISCUSSION

Myasthenia Gravis (MG) is a chronic autoimmune disease characterized by impaired neuromuscular transmission, resulting in progressive muscle weakness and fatigability. Its therapeutic management has traditionally relied on the use of corticosteroids and immunosuppressants—drugs that, although effective in alleviating symptoms, are associated with substantial adverse effects, including osteoporosis, arterial hypertension, weight gain, and metabolic disorders such as

diabetes mellitus. These limitations pose significant challenges to treatment adherence and long-term disease control, making it imperative to seek innovative therapeutic strategies that offer greater efficacy and a more favorable safety profile. In this context, biologic therapies have emerged as a promising therapeutic alternative, with the potential to modify the course of the disease by acting more specifically on the pathophysiological mechanisms of MG, reducing the production of pathogenic autoantibodies, and minimizing the risks inherent to systemic immunosuppression.

One of the key aspects to consider in the introduction of immunobiologicals for the treatment of MG is the impact of these therapies on reducing the need for corticosteroids and other traditional immunosuppressants. The studies analyzed demonstrated that drugs such as eculizumab, efgartigimod, and rozanolixizumab allow for a progressive reduction in corticosteroid dependency, thus reducing the adverse effects associated with long-term use, as highlighted by[11] and[17]. This transition represents a significant advance in the quality of life of patients, enabling more stable disease control without the metabolic and systemic impacts characteristic of prolonged corticosteroid use. However,[16] pointed out that this replacement is not yet fully feasible for all patients, as the response to immunobiologicals can vary, requiring a personalized approach to MG management. This necessity reinforces the importance of new clinical studies investigating therapeutic combinations and strategies to optimize the transition between treatments, ensuring that the reduction of corticosteroids does not compromise disease control.

In recent years, immunobiologicals have emerged as promising alternatives for the treatment of MG, offering greater specificity in modulating the immune response and a more favorable safety profile. The results of the studies analyzed in this review support this trend, showing that biologic therapies demonstrate significant efficacy in clinical improvement of the disease. The study by[11] reported that batoclimab was one of the most effective immunobiologicals, leading to expressive reductions in MG clinical scores. Similarly,[12] highlighted intravenous efgartigimod as the most efficient treatment, presenting the lowest number needed to treat (NNT) to achieve significant clinical improvement—an indicator of its high therapeutic potential. Moreover,[13] demonstrated that complement and FcRn inhibitors resulted in considerable improvements in MG-ADL and QMG scores, suggesting a positive impact not only on motor symptoms but also on functionality and patient quality of life. These findings reinforce the importance of transitioning to immunobiological therapies, considering their clinical benefits and lower risk of adverse effects compared to corticosteroids. It is important to note that this transition does not imply an abrupt replacement of conventional treatments, but rather a gradual integration in which Immunobiologicals may act as adjuvants or enable the progressive reduction of corticosteroid doses, thereby decreasing associated side effects.

Beyond efficacy, the safety ofimmunobiologicals was a widely discussed aspect in the analyzed studies. Although corticosteroids have a well-established role in treatment, they are frequently associated with metabolic and cardiovascular complications, making their prolonged administration a clinical challenge. In contrast, immunobiologicals were developed to act more specifically within the immune system, reducing the production of pathogenic autoantibodies without causing generalized immunosuppression. The study by[15] emphasized that FcRn blockade can be an effective therapeutic strategy by selectively reducing pathogenic IgG levels while preserving other immunoglobulins essential for immune defense. However, immunobiologicals are not without risks, as[11] identified an increased incidence of meningococcal infections among patients treated with ravulizumab. This highlights that, despite their promising therapeutic potential, immunobiologicals must be accompanied by monitoring and prevention strategies to ensure patient safety, making it necessary to implement preventive measures such as prior vaccination and close medical follow-up.

Another critical factor in the adoption of immunobiologicals is the issue of cost and accessibility. Although these therapies present evident clinical benefits, their high cost still represents a significant challenge for large-scale implementation. The study by[12] demonstrated that, despite its superior efficacy, intravenous efgartigimod still has a high cost, which may hinder its incorporation into public healthcare systems. Similarly,[9] noted that complement and FcRn inhibitors, although promising, still face economic and regulatory barriers that limit their access to a small portion of the population. This reinforces the need for cost-effectiveness studies to assess the financial impact of these therapies and explore strategies to make their use more viable, such as subsidy programs, public-private partnerships, and the production of biosimilars.

In addition to the issues of efficacy, safety, and cost, individual patient response to immunologicals was also a relevant aspect identified in the analyzed studies. MG is a heterogeneous disease, with different clinical subtypes and variable treatment responses. The study by[16] showed that intravenous immunoglobulin (IVIG-C) did not present a statistically significant difference compared to placebo in reducing the need for corticosteroids, suggesting that this therapy may not be equally effective for all patients. This underscores the importance of personalized treatment, taking into account factors such as age, disease severity, comorbidities, and genetic profile to select the most appropriate therapeutic approach. Personalized medicine strategies, such as identifying predictive biomarkers of treatment response, may play a key role in optimizing MG management.

Although immunobiologicals have a more favorable safety profile than corticosteroids, other adverse

reactions are still a concern and must be closely monitored. The study by[15] showed that FcRn blockade selectively reduces pathogenic IgG levels without affecting other essential immunoglobulins, which may minimize the immunosuppressive impact of therapy. Furthermore,[16] reported that intravenous immunoglobulin (IVIG-C) did not prove more effective than placebo in reducing corticosteroid requirements and was associated with adverse events such as headache and respiratory infections. These data reinforce the need for strict patient monitoring during the use of immunobiologicals, as well as the development of specific guidelines for managing adverse effects to ensure safe and effective treatment for MG.

LIMITATIONS OF THE STUDY

Based on what was presented in the Results and Discussion sections, it is concluded that there were some limitations in the construction of this article. Initially, the differences between the clinical trials analyzed may impact the comparison of results, since each study included different inclusion and exclusion criteria regarding aspects such as population characteristics, disease severity, and evaluated outcomes. These particularities hinder the generalization of findings and may introduce bias in the results of meta-analyses, influencing the interpretation of the efficacy and safety of biologic treatments for myasthenia gravis. Furthermore, some studies included a limited number of clinical trials or small sample sizes, which may compromise the statistical robustness of the presented results.

Additionally, another observed limitation is the absence of direct comparisons between some pharmacological treatments, making it difficult to determine which therapeutic option would be the most effective in different clinical scenarios. As a result, many studies used network meta-analyses, which rely on indirect comparisons and complex statistical models to estimate the superiority among treatments. Although this approach is valid, it may be influenced by factors such as differences in the protocols of the original clinical trials. Lastly, some of the reviewed studies are based on systematic reviews rather than primary data, which may introduce selection bias by including only published studies.

FINAL CONSIDERATIONS

Based on the objective of this study to analyze the clinical importance of alternative therapy with immunobiologicalsin comparison to corticosteroids, it is concluded that immunobiologicals are established as a promising therapeutic alternative for Myasthenia Gravis. Accordingly, immunobiologicals offer superior efficacy and a more favorable safety profile compared to corticosteroids. However, challenges such as high cost to the patient, limited accessibility to major research centers, and individual variability in treatment response still limit their widespread implementation as a standardized pharmacological protocol.

Finally, the aforementioned factors reinforce the need for more randomized clinical trials and direct comparative studies, especially those focused on cost-effectiveness and long-term outcomes, which are essential to determine the viability of these agents in clinical practice based on evidence regarding their use and incorporation into global therapeutic guidelines. In this way, advances in treatment personalization and the broader availability of these therapies may represent a milestone in improving the quality of life of MG patients, ensuring more effective and safer disease management.

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