THYROID EYE DISEASE

Adding mycophenolate to infusions of methylprednisolone improves treatment of Graves’ eye disease.

BACKGROUND

Thyroid eye disease is most often associated with Graves’ disease, so much so that it is usually referred to as Graves’ ophthalmopathy (GO). GO is an autoimmune disorder that ranges from mild to severe disease. In its most severe form, GO causes bulging of the eyes, blurry or double vision, pain and swelling around the eyes and altered eye movement. Moderate-to-severe GO is usually associated with poor clinical outcomes and impaired quality of life as treatment is limited. GO is currently treated with a course of steroids, particularly intravenous methylprednisolone, but response is often limited and there are significant side effects to high dose steroids. Mycophenolate is an immunosuppressive medication that showed clinical efficacy in GO treatment in previous studies. This study aimed to compare the efficacy and safety of combination therapy of mycophenolate and intravenous methylprednisolone to the standard regimen of methylprednisolone alone.

THE FULL ARTICLE TITLE


SUMMARY OF THE STUDY

This study compared combined mycophenolate with intravenous methylprednisolone therapy versus intravenous methylprednisolone alone in active moderate-to-severe GO. A total of 81 out of 164 patients from four European centers received treatment with methylprednisolone alone (weekly infusions for 3 months) and 83 received combination of methylprednisolone with mycophenolate (weekly infusions for 3 months and twice daily tablet for 6 months).

Response to therapy was defined as improvement in eye findings. Symptoms measured by a standardized clinical activity score and severity of GO were assessed at 3, 6 and 9 months. Patients also filled out quality of life questionnaire at 3, 6 and 9 months. Relapse defined as worsening of symptoms that occurred after a response was assessed at 6 and 9 months. Safety of the medications was monitored during time of the study.

Response to therapy was observed in 36 of 73 (49%) patients in the methylprednisolone alone group and 48 of 76 (63%) patients in the combination group. At 6 months, 38 of 72 (53%) patients on methylprednisolone and 53 of 75 (71%) patients on combination therapy responded to treatment. At 9 months, 46% of patients on methylprednisolone compared to 67% on methylprednisolone with mycophenolate continued to respond to therapy. At 6 months, relapse occurred in 4 of 38 (11%) patients in the monotherapy group and 4 of 53 (8%) patients in the combination group. At 9 months, relapse occurred in additional 3 (8%) patients in the monotherapy group and 2 (4%) patients in the combination group. Drug-related adverse events were similar in both groups.

Although no significant difference was seen in the response rate at 3 months or relapse rate at 6 and 9 months, advanced analysis suggested that addition of mycophenolate to treatment with methylprednisolone improved response rate to therapy by 6 months in patients with active and moderate-to-severe GO.

WHAT ARE THE IMPLICATIONS OF THIS STUDY?

This study suggests that combination therapy of mycophenolate and methylprednisolone compared to methylprednisolone alone is more efficient in treatment of moderate-to-severe GO. This is an important result as moderate-to-severe GO is usually associated with poor clinical outcomes as treatment is limited. Indeed, this study shows that been in the group that responded the best, 30-40% of patients did not respond to treatment. More effective therapy is needed but this study is encouraging for patients with moderate-to-severe GO.

—Valentina D. Tarasova, MD
THYROID EYE DISEASE, continued

ATA WEB BROCHURE LINKS:
Graves' Disease: https://www.thyroid.org/graves-disease/

ABBREVIATION AND DEFINITIONS:

Clinical Activity Score: a scoring system used to evaluate patients with Graves’ ophthalmopathy, and is based on classical signs of inflammation (pain, redness, swelling and function) and that helps predict which patients will benefit from immunosuppressive treatment.

Graves’ disease: the most common cause of hyperthyroidism in the United States. It is caused by antibodies that attack the thyroid and turn it on.

Graves' ophthalmopathy (GO): is most often seen in patients with Graves’ disease but also can be seen with Hashimoto’s thyroiditis. GO includes inflammation of the eyes, eye muscles and the surrounding tissues. Symptoms include dry eyes, red eyes, bulging of the eyes and double vision.

Steroids/Glucocorticoids: general anti-inflammatory and immunosuppressive drugs that are commonly used for the treatment of many autoimmune diseases associated with inflammation.

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