The Safety of Teprotumumab Administration Including Repeat Courses of Therapy

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Background

Thyroid Eye Disease (TED) is a rare autoimmune condition found in patients with Graves' disease where the eye muscles, eyelids, and tear glands become inflamed.[1] Teprotumumab is an insulin-like growth factor-1 receptor inhibitor and an IgG1 human monoclonal antibody. Teprotumumab is a novel treatment for TED.[2] The typical course of therapy of teprotumumab consists of eight infusions.[2]

The OPTIC study was a phase 3 randomized trial of teprotumumab vs placebo.[1] The primary outcome was reduction of proptosis at week 24. The percentage of patients with reduced proptosis was higher with teprotumumab than placebo.[1] This study was followed by OPTIC-X which studied retreatment in non-responders or patients who received placebo previously. OPTIC-X concluded that patients responded similarly to teprotumumab, and patients with flare ups may benefit from additional courses of therapy.[3]

Adverse drug reactions (ADRs) documented with teprotumumab include infusion reactions, hyperglycemia, exacerbation of inflammatory bowel disease, nausea, diarrhea, and fatigue.[2] Due to the potential ADRs, it is suggested to infuse teprotumumab in a controlled setting with a healthcare provider.

Purpose

The purpose of this study is to assess safety of teprotumumab, including safety data on additional courses of therapy.

Methods

A retrospective, multi-center chart review was performed evaluating patients who received teprotumumab. Electronic medical records and internal event reporting software were evaluated for adverse reactions. The primary outcome evaluated the safety profile with eight infusions of teprotumumab. The secondary outcome assessed the safety of additional courses of teprotumumab. Inclusion criteria were patients at least 18 years of age diagnosed with TED and receiving at least eight infusions of teprotumumab.

Results

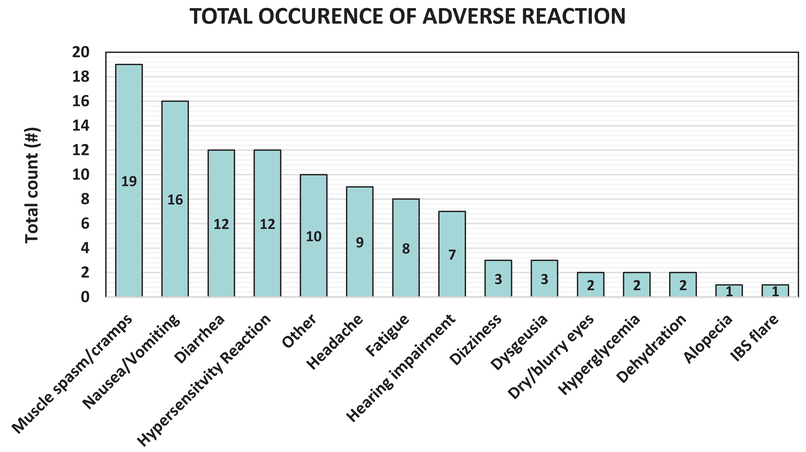
Between March 31, 2020 - February 23, 2022, two hundred fifty-seven patients received at least eight infusions of teprotumumab. Seven patients received more than eight infusions. Fifty-nine patients experienced ADRs; three of which received more than eight infusions of teprotumumab. Mean age of patients in this group was 52 years old, with 80% female. *[Table 1]*

No ADRs were reported in 77% (198) patients that received 8 infusions. Common ADRs reported in patients receiving eight infusions of teprotumumab included muscle spasms/cramping 32% (19), nausea/vomiting 27% (16), diarrhea 20% (12), hypersensitivity reaction 20% (12), headache 15% (9), fatigue 14% (8), hearing impairment 12% (7), and hyperglycemia 3% (2). *[Figure 1]*

Table 1:
Summary of Baseline Patient Demographics for Patients Experiencing Adverse Events

Variable	Total Patients	Patients with ADRs
Age, Average	53.4	53.3
Gender		
Male, n (%)	67 (26%)	12 (20%)
Female, n (%)	190 (74%)	47 (80%)

Figure 1:



(some patients may have experienced more than one type of reaction)

Results *(continued)*

No ADRs were reported in 57% (4) patients that received more than 8 infusions. ADRs reported in patients with additional courses of teprotumumab included headache 14% (1), nausea/vomiting 29% (2), and dizziness 14% (1).

Discussion

The incidence of ADRs was greater in the group of patients who received more than 8 infusions. Limitations of this study include the reliance on voluntary safety reporting and manual documentation in electronic medical records.

Conclusion

This study demonstrated a higher incidence of adverse reactions compared to product labeling. The findings demonstrated higher incidence of muscle spasms and cramps, nausea/vomiting, diarrhea, fatigue, and hearing impairment compared to clinical trials noted in the prescribing information. The results from this study may be utilized in future studies to evaluate the safety of additional courses of teprotumumab.

References

[1]Douglas RS, Kahaly GJ, Patel A, et al. Teprotumumab for the Treatment of Active Thyroid Eye Disease. N Engl J Med. 2020;382(4):341-352.
[2]TEPEZZA (teprotumumab-trbw) [prescribing information] Deerfield, IL: Horizon.
[3]Douglas RS, Kahaly GJ, Ugradar S, et al. Teprotumumab Efficacy, Safety, and Durability in Longer-Duration Thyroid Eye Disease and Re-treatment: OPTIC-X Study. Ophthalmology. 2022;129(4):438-449.

Disclosures

Authors of this presentation have the following to disclose concerning possible financial or personal relationshipswith commercial entities that may have a direct or indirect interest in the subject matter of this presentation: Ruba Samara, Jessica Fiant, Maria Giannakos, Suzanne Kluge. Nothing to disclose.

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