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VEDOLIZUMAB INDUCED CACHEXIA: A NOVEL SIGNAL IDENTIFIED THROUGH US FOOD AND DRUG ADMINISTRATION ADVERSE EVENT REPORTING SYSTEM (FEARS) DATABASE

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INTRODUCTION

Vedolizumab, an integrin receptor antagonist is indicated for the treatment of moderate to severe ulcerative colitis or Crohn's disease, in case of development of treatment resistance to other medications. Signal detection and disproportionality analysis helps to identify an unidentified adverse drug reaction (ADR).

OBJECTIVE

The study aimed to identify novel signals associated with vedolizumab by analyzing reports in the USFDA Adverse Event Reporting System (FAERS) database, focusing on previously unrecognized adverse drug reactions (ADRs), particularly cachexia. This research is essential for improving the safety profile of vedolizumab and guiding clinical practices.

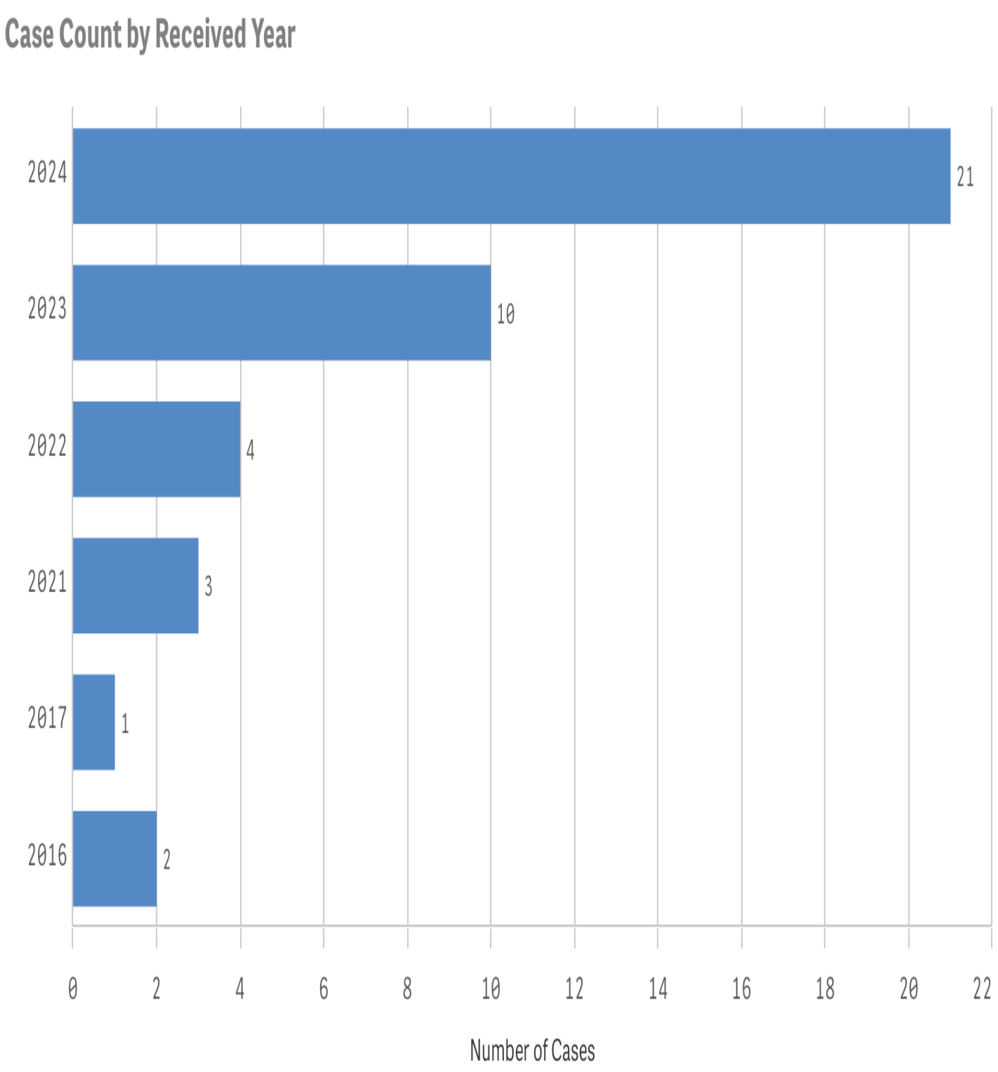
METHOD

An in-depth case/non-case retrospective disproportionality analysis was conducted in the publicly available FAERS database for vedolizumab. Vedolizumab was approved by FDA in the year 2014. All the reports of vedolizumab were analysed. The investigation delved into the USFDA adverse event reporting system database, employing the top 2 data mining algorithms in widespread use for signal detection such as Reporting Odds Ratio (ROR) and Proportional Reporting Ratio (PRR) from the Open Vigil database. A value of PRR≥2 and ROR-1.96SE>2 was considered as positive signal.

RESULTS

Among the total 27,634,809 FAERS reports, 54,173 were related to vedolizumab. The vedolizumab reports(45,909) were classified as serious and many fatal reactions were reported. The total number of adverse events reported for Cachexia is 41. On analysis, data mining algorithms showed the results as ROR of 4.60 (3.23 ; 6.56) and PRR 4.60(3.231 ; 6.559)The ROR and PRR confirmed the occurrence of the adverse reaction cachexia for Vedolizumab.

Data Mining Results for Vedolizumab induced Cachexia	values
Total FAERS Reports Analysed	27,634,809
Vedolizumab Reports	54,173
Serious Vedolizumab Reports	45,909
Total Adverse Events Reported for Cachexia	41
Reporting Odds Ratio (ROR)	4.607
Proportional Reporting Ratio (PRR)	4.604



CONCLUSIONS

This study revealed that Cachexia is likely to occur among patients administered with Vedolizumab. The authors conclude that the health care practitioners should monitor for the occurrence of cachexia among patients administered with Vedolizumab. The epidemiological studies should be conducted to validate the identified novel signal among a larger population.

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