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Adverse Event Types and Discontinuation Rate of Alzheimer's Medication Approved By United States Food and Drug Administration (USFDA)

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CONCLUSION

Immunotherapies had the most common AEs as infusion-related reactions managed by other treatments.

Background

Alzheimer's disease (AD) constitute a public health crisis affecting the US aging population and society.

- An estimated 6.7 million Americans aged 65 years and older are living with AD in 2023. Seventy-three percent are age 75 or older.[1]
- By 2050, the total estimated prevalence of AD is expected to be 12.7 million.[1]
- The pharmacological managements of AD include two symptomatic approaches: The inhibition of acetylcholinesterase and the inhibition of N-methyl-D-aspartate receptors.
- Acetylcholinesterase inhibitors (AChEIs) such as donepezil, galantamine, and rivastigmine are the recommended treatments for managing mild to moderate AD.[1,2,3]
- In 2023, AD and other dementias will cost the nation $345 billion — not including the value of unpaid caregivers.[1]
- Medicare and Medicaid are expected to cover $222 billion.[1]

OBJECTIVE

This study aims to identify Discontinuation Adverse Events (AEs) type per treatment for all formulations of Drugs approved by the US FDA for treating AD as of May 31, 2023.

Methodology

- The safety information about Adverse Events (AEs), discontinuation types, and rates were collected from FDA product labels and clinical trial data for Alzheimer's disease.
- Descriptive analyses were used to classify AEs resulting in product discontinuation.
- AE rates were calculated by dividing the number of events by the sample size for a specific period.

RESULTS

- ADA-approved NMEs between 2001 and 2023.
- Cholinesterase inhibitors (3, 42.8%) were the most common therapeutic category.
- . The largest number of AEs leading to discontinuation occurred in Galantamine (7), Donepezil (4), Rivastigmine (4), and Lecanemab (1).
- The most common AED management has three main classes, including 6 Fs were GI upset (nausea, vomiting, diarrhea), CNS AEs (dizziness).
- Cholinesterase inhibitors were the most common class leading to AEs discontinuation
- Memantine has not reported discontinuation due to AEs.

Table: Discontinued AEs list & annual rates per AD treatment

Adverse Events	Galantamine	Rivastigmine	Rivastigmine tdm	Donepezi 5 to 10 mg	Donepezi 23 mg	Lecanemab	Aducanumab
Anorexia	0.0%	3.7%	0.0%	0.0%	0.0%	0.0%	0.0%
Decreased appetite	0.6%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Decreased weigh	0.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Diarrhea	0.3%	0.0%	0.0%	1.6%	1.1%	0.0%	0.0%
Dizziness	0.5%	2.5%	0.0%	0.0%	0.5%	0.0%	0.0%
Headache	0.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Infusion-related reactions	0.0%	0.0%	0.0%	0.0%	0.0%	1.8%	0.0%
Nausea	2.5%	9.9%	0.6%	1.6%	1.1%	0.0%	0.6%
Vomiting	1.3%	6.2%	1.3%	1.1%	1.6%	0.0%	0.0%

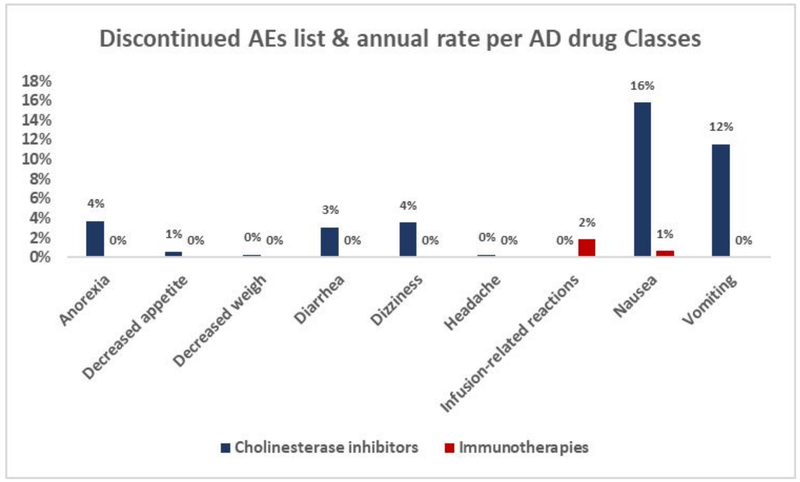

Figure: Discontinued AEs annual rates per Rx classes

Discussions

- This study identify type and rate of discontinuation adverse event among drugs and pharmacological classes.
- The study evaluated FDA discontinuation type and rate of adverse events but did not assess a effect on the utilization of those drugs in clinical practice.
- Future research is needed to address this limitation.

References

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Disclosure