Safety of Deutetrabenazine Above Food and Drug Administration Maximum Recommended Dose in Huntington's Disease Chorea

Kayla Dodson, PharmD Candidate[1]; Sabrina Livezey, PharmD, CSP[2]; Kayla Johnson, PharmD, BCPS, BCPP[2]; Josh DeClercq, MS[3]; Autumn Zuckerman, PharmD, BCPS, CSP[2]

[1]University of Tennessee Health Science Center College of Pharmacy; [2]Vanderbilt Specialty Pharmacy, Vanderbilt University Medical Center; [3]Department of Biostatistics, Vanderbilt University Medical Center

QR Code

VANDERBILT UNIVERSITY MEDICAL CENTER

CONCLUSION

Deutetrabenazine (DBZ) dosed greater than 48 mg/day appears to be safe in patients with Huntington's Disease (HD) chorea.

Although adverse events (AE) were common, they resolved after dose change without requiring discontinuation of DBZ.

PURPOSE

Describe AE and discontinuation rates in patients treated with DBZ doses greater than 48 mg per day

METHODS

HD Society of America Center of Excellence outpatient clinic at an academic medical center

Adult patients with HD chorea taking DBZ between April 2017 – July 2022

Retrospective chart review to look at dose changes, AE, safety monitoring, and discontinuation

Minimum of 6-months of therapy at a DBZ dose greater than 48 mg/day

Exclusion criteria: concurrent use of strong CYP2D6 inhibitors, deceased or lost to follow-up before study outcomes were evaluated, previous enrollment in clinical trial on DBZ greater than 48 mg/day when moving to commercial product

RESULTS

Screened 32 Patients
- 17 patients included

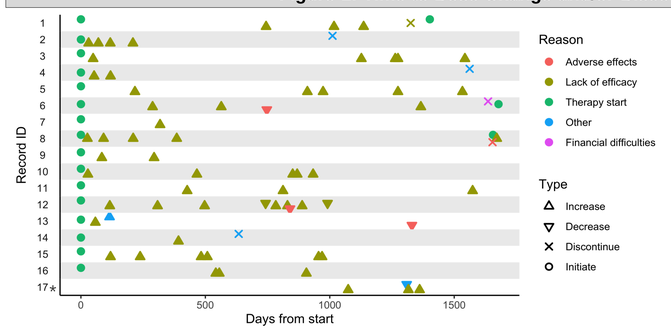
Excluded 15 Patients
- 5: strong CYP2D6 inhibitor use
- 5: deceased or lost to follow-up
- 5: prior DBZ use > 48 mg/day

Table 1: Baseline Demographics (N=17)

Age, years, median (IQR)	55 (48-66)
Gender, male, n (%)	8 (47)
Race, White, n (%)	17 (100)
Ethnicity, Non-Hispanic, n (%)	17 (100)

IQR: interquartile range

Figure 1: Time to Dose Change and/or Discontinuation with Rationale



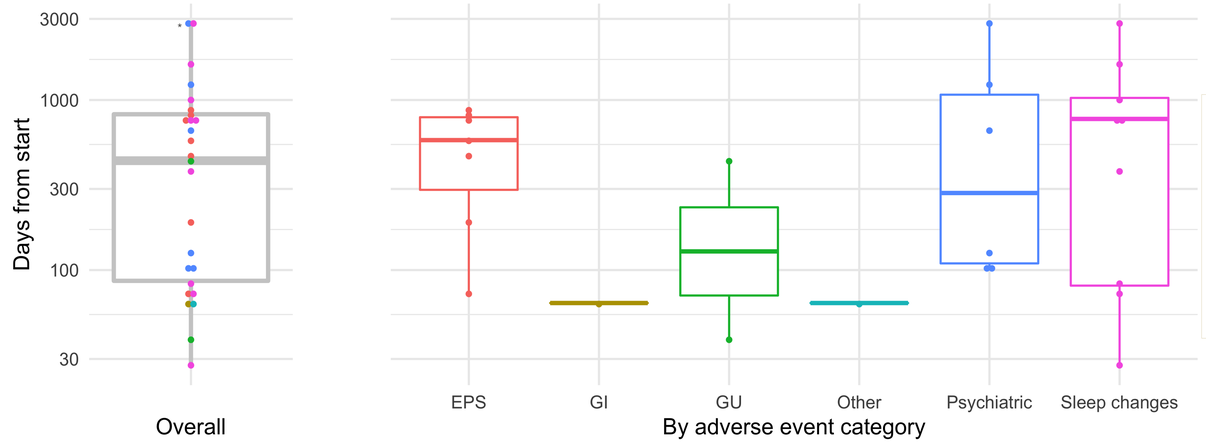
* Patient converted from DBZ clinical trial at < 48 mg/day

Overall, **26 AEs were reported** and **4 (15%) were associated with dose changes**

DBZ discontinuation was required in 4 patients (24%) due to **deceased status (n=2), lack of efficacy (n=1)**, or **formulation incompatibilities (n=1)**

The **median dose of DBZ at study close was 54 mg/day (IQR 42 – 60)** with a **maximum dose of 72 mg/day**

Figure 2: Time to AE



Of the 11 patients monitored with an EKG, **18% (2) had QT prolongation**

Of the 10 patients monitored with LFTs, **20% (2) had elevated liver enzymes**

Out of 26 total AE reports, **akathisia and insomnia were most common with each reported 5 (19%) times**

Disclosures

Autumn Zuckerman, PharmD, BCPS, CSP receives research support unrelated to this project from AstraZeneca, Pfizer, and BeiGene.

aapp / apnp