Real-World Use of Fenfluramine in patients with Lennox-Gastaut Syndrome

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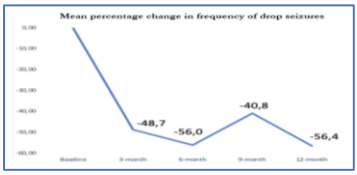
Objectives: We evaluated the effectiveness and tolerability of fenfluramine (FFA) in children and adults with LGS treated according to routine clinical practice.

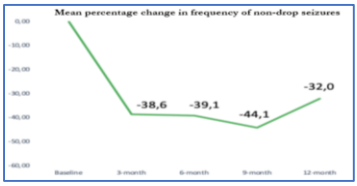
Materials and Methods: This was a real-world, multicenter, retrospective cohort study conducted across 27 clinical sites in Italy. Seizure related and non seizure related outcomes were evaluated at 3, 6, 9, and 12 months following initiation of FFA treatment.

62 pts	
Male N (%)	32 (54.8%)
Age (years)	17(11-32)*
Age at epilepsy onset (months)	7.5 (2-24)*
ASMs failures (N)	10 (8-13)*
ASMs concomitant (N)	3 (3-4)*
2	15 (24%)
3	21 (34%)
>4	26 (42%)
Vagus Nerve Stimulation	22 (35%)
Ketogenic diet	10 (16%)
Severe intellectual disability	34 (55%)
Behavioral disorder	40 (64%)

*median (interquartile range)

Results: Sixty-two patients (54.8% males, 34 adults) were included. The median number of concomitant ASMs was 3 (IQR: 3–4).

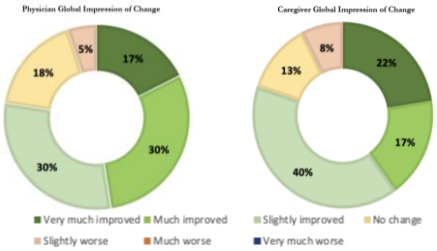




The median number of drop and non drop seizures in the 3 months prior to FFA initiation was 16 (IQR: 0–120) and 100 (IQR: 60–180), respectively. The mean percentage reduction in frequency of drop seizures was 48.7%, 56.0% and 56.4% at 3, 6, and 12 months following FFA treatment. The corresponding values for non drop seizures were 38.6%, 39.1%, and 32.0%. A ≥50% reduction in frequency of drop seizures was observed in 50% of the participants at 3, 6, and 12 months; a ≥50% reduction in frequency of non drop seizures was reported by 42.9%, 45.9% and 41.7% of subjects.

At 6-month follow-up, the median number of 3-month days free of drop seizures increased from a median of 55 to a median of 84 days. Discontinuation of at least one concomitant ASM occurred in 12 cases.

Subjects rated as slightly improved, much improved, or very much improved for overall condition from baseline to 6 months as measured by the Physician Global Impression of Change scale and Caregiver Global Impression of Change were 77% and 79%.



The 12-month retention rate was 72.6% and at least one adverse event (AE) was reported in 24 patients (38.7%). Most common AEs included somnolence and decreased appetite. Treatment discontinuation due to AEs occurred in 9 subjects

Conclusions: Adjunctive FFA was well tolerated and effective in reducing seizure frequency and improving non-seizure-related outcomes in a real-world cohort of patients with LGS.

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