A Stratified Analysis of Efficacy and Safety of Fenfluramine in Patients With Dravet Syndrome

Poster 1.401

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Background

- Fenfluramine (FFA) is approved for the treatment of seizures associated with Dravet syndrome (DS) in the United States,[1] European Union,[2] United Kingdom,[3] Japan,[4] and Israel[5] in patients ≥2 years of age
- Three pivotal phase 3, double-blind, placebo-controlled, randomized controlled trials (RCTs) have previously shown the safety and efficacy of FFA added to the antiseizure medication (ASM) regimens of patients with DS 2-18 years old[6-8]

Objective

- To better understand the potential impact of clinical characteristics on the safety and efficacy of FFA in patients with DS, patient data from all three pivotal phase 3 RCTs were pooled and stratified by age, disease severity as assessed by number of failed ASMs, and *SCN1A* status

Methods

- Patient data from 3 RCTs (NCT02682927, NCT02826863, NCT02926898)[6-8] were pooled by dose group and stratified by baseline characteristics of age, disease severity (# of failed ASMs), and *SCN1A* status
  - Stiripentol (STP) inhibits the metabolism of FFA and increases FFA bioavailability; in patients taking concomitant STP + FFA regimens, 0.4 mg/kg/day FFA has similar efficacy and safety profiles as 0.7 mg/kg/day FFA without STP[7,9]
  - Concomitant STP was an exclusion criterion in NCT02682927 and NCT02826863 and an inclusion criterion in NCT02926898[6-8]
- Safety (analyzed by dose group)
  - Treatment-emergent adverse events (TEAEs; proportion, %)
- Efficacy endpoints (analyzed by dose group and stratified by baseline characteristic):
  - Change in monthly convulsive seizure frequency (MCSF; % change, median)
  - Longest interval between seizure-free days (median, in days)
  - Clinically meaningful change in Clinical Global Impression—Improvement (CGI-I) scores evaluated by investigators or parents/caregivers (Much Improved or Very Much Improved; proportion, %)

Statistics:

- Change in MCSF:
  - *P*-value results were obtained from an ANCOVA model with treatment group and age group (<6 years, ≥6 years) as factors, study as an additional factor for the Overall group, log baseline convulsive seizure frequency as a covariate and log convulsive seizure frequency (Titration + Maintenance) as response
  - The estimate of % difference from placebo was obtained from the least-squares means (LS Means) on the log scale as follows: 100 x [1 - exp(LS Mean active - LS Mean placebo)]
- Interval between seizure-free days: estimate of median treatment difference with confidence intervals based on Hodges-Lehmann estimator of treatment difference and *P*-values from Wilcoxon rank test comparing overall FFA groups with placebo
- Clinically meaningful change in CGI-I: Odds Ratios vs placebo (95% CI) with *P*-values from Cochran-Mantel-Haenszel test controlling for age group
- All hypothesis tests are post-hoc in nature; *P*-values are considered nominal due to small n

Results

BASELINE CHARACTERISTICS

- A total of 348 patients with DS aged 2-18 years were included in the analysis across 3 RCTs (**Table 1**)
  - Most patients were ≥4 years (83.7%-89.4% across groups)
  - Most patients were *SCN1A*+ (84.7%-87.5%)
  - Many patients failed 4-6 (31.8%-48.8%) or 7+ ASMs (34.8%-57.6%); however, no patients treated with 0.4FFA+STP failed 7+ ASMs prior to FFA initiation
    - Overall, the median ages of patients in the 1-3, 4-6, and 7+ ASM failure groups were 7.0, 7.5, and 11.0 years, respectively

Overview

QUESTION

What baseline characteristics affect the safety and/or efficacy of add-on fenfluramine (FFA) treatment in patients with Dravet syndrome (DS) in randomized controlled trials (RCTs)?

INVESTIGATION

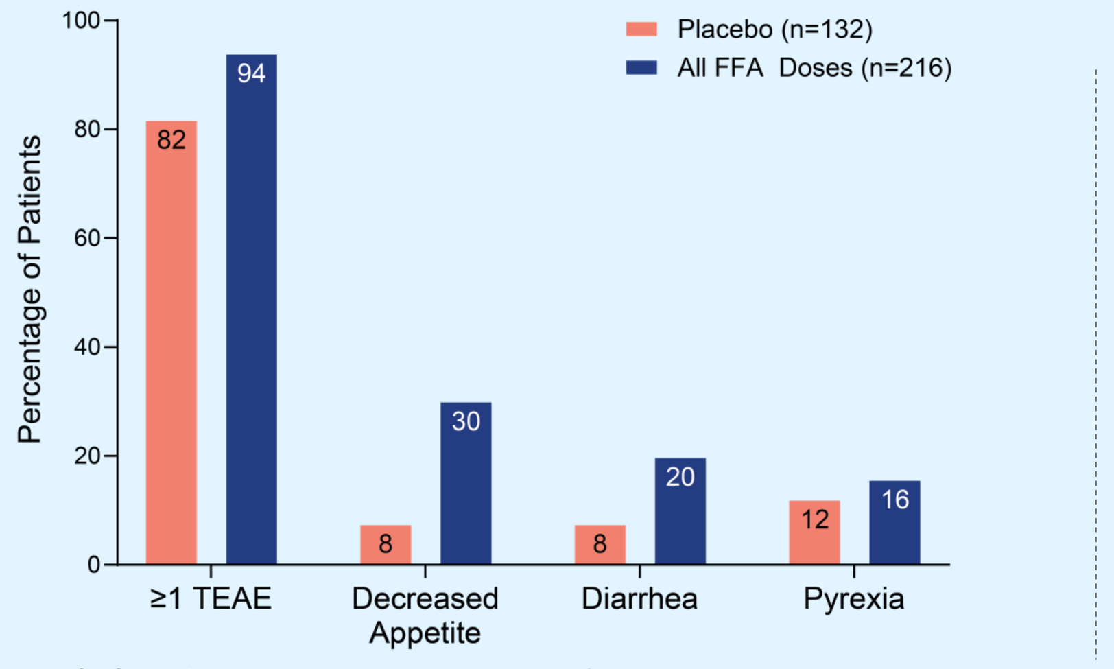
Patients from 3 published RCTs were stratified by age at FFA initiation, number of failed antiseizure medications (ASMs), and *SCN1A* status. Efficacy endpoints were median percentage change in monthly convulsive seizure frequency (MCSF), median longest interval of convulsive seizure-free days, and proportion of patients with clinically meaningful improvement on Clinical Global Impression—Improvement (CGI-I) scores. Safety endpoints were assessed as proportions of patients with treatment-emergent adverse events (TEAEs) by dose group.

RESULTS

- Total number of patients included in the analysis: placebo (n=132) and FFA (n=216, all doses)

Safety

- No cases of valvular heart disease or pulmonary hypertension were reported in any patient at any time in the analysis
- One death was reported in the placebo group in one of the studies (probable sudden unexpected death in epilepsy); no deaths were reported in the FFA groups in any study
- Most common TEAEs were decreased appetite, diarrhea, and pyrexia

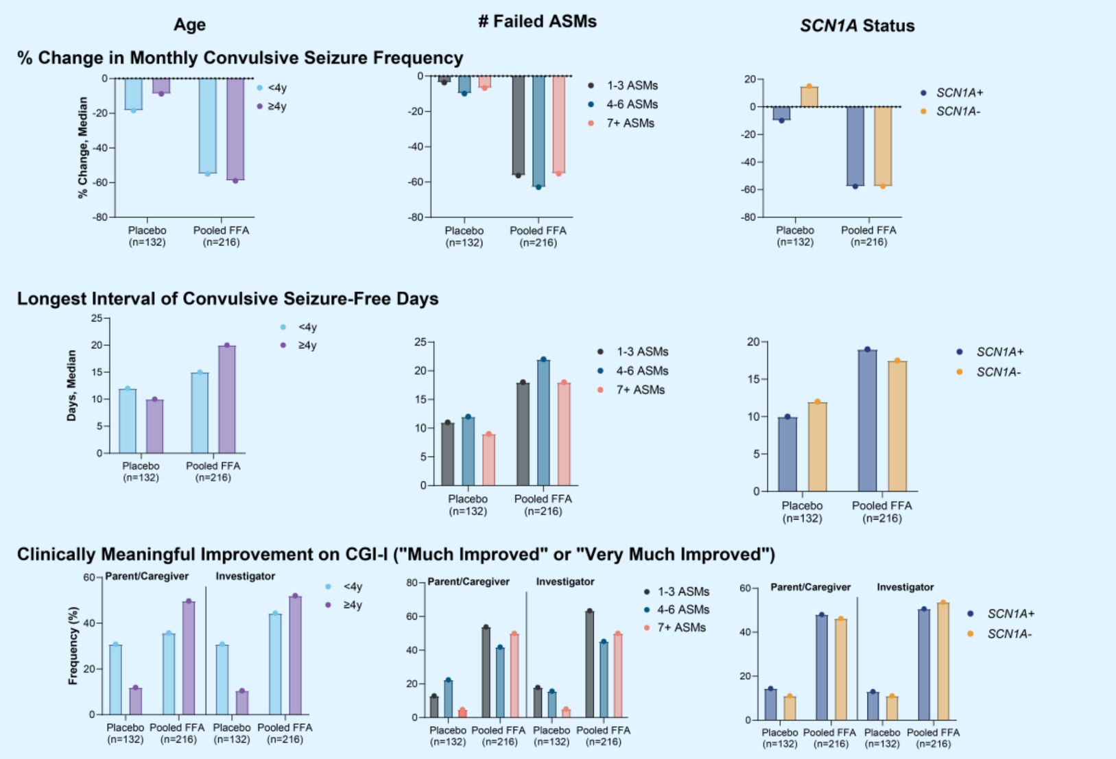


FFA, fenfluramine; TEAE, treatment-emergent adverse event.

Efficacy

- Overall, compared with placebo, FFA treatment resulted in: (a) greater decline in MCSF, (b) greater increase in longest interval between seizure-free days, and (c) higher proportion of parent/caregivers and investigators reporting clinically meaningful improvement in CGI-I scores regardless of age, disease severity, and *SCN1A* status

n per group: placebo (n=132); FFA (n=216).
ASM, antiseizure medication; CGI-I, Clinical Global Impression—Improvement scale; FFA, fenfluramine.



CONCLUSIONS

- FFA was generally well tolerated; the most common TEAEs were decreased appetite, fatigue, and pyrexia
- FFA treatment was numerically superior to placebo after stratification by age, disease severity (number of failed ASMs), and *SCN1A* status
- Larger sample sizes and inferential statistical analyses are needed to confirm

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Table 1. Baseline Characteristics, Combined From Patients Enrolled in Three Pivotal Trials (N=348)

	Placebo (n=132)	FFA 0.2 mg/kg/d Without STP (n=85)	FFA 0.4 mg/kg/d With STP (n=43)	FFA 0.7 mg/kg/d Without STP (n=88)	Total FFA (n=216)
Sex, n (%) female	57 (43.2)	39 (45.9)	20 (46.5)	45 (51.1)	104 (48.2)
Age group, n (%)					
<4 years	15 (11.4)	9 (10.6)	7 (16.3)	13 (14.8)	29 (13.4)
≥4 years	117 (88.6)	76 (89.4)	36 (83.7)	75 (85.2)	187 (86.6)
Race, n (%)					
White	96 (72.7)	70 (82.4)	23 (53.5)	67 (76.1)	160 (74.1)
Asian	12 (9.1)	7 (8.2)	2 (4.7)	9 (10.2)	18 (8.3)
Other or Unknown	10 (7.6)	6 (7.1)	5(11.6)	7 (8.0)	18 (8.3)
Not reported[a]	14 (10.6)	2 (2.4)	13 (30.2)	5 (5.7)	20 (9.3)
***SCN1A*+, n (%)**	113 (85.6)	72 (84.7)	37 (86.0)	77 (87.5)	186 (86.1)
Number of previously failed ASMs, n (%)[b]					
1-3	32 (24.2)	7 (8.2)	22 (51.2)	13 (14.8)	42 (19.4)
4-6	54 (40.9)	29 (34.1)	21 (48.8)	28 (31.8)	78 (36.1)
7+	46 (34.8)	49 (57.6)	0	47 (53.4)	96 (44.4)
Number of concomitant ASMs, n (%)					
1-3	101 (76.5)	69 (81.2)	20 (46.5)	78 (88.6)	167 (77.3)
4-6	31 (23.5)	15 (17.6)	23 (53.5)	10 (11.4)	48 (22.2)
Concomitant ASMs in ≥10% of any group, n (%)					
Valproate, all forms	96 (72.7)	58 (68.2)	38 (88.4)	61 (69.3)	157 (72.7)
Clobazam	96 (72.7)	43 (50.6)	40 (93.0)	53 (60.2)	136 (63.0)
Clonazepam	10 (7.6)	14 (16.5)	2 (4.7)	13 (14.8)	29 (13.4)
Levetiracetam	29 (22.0)	25 (29.4)	6 (14.0)	17 (19.3)	48 (22.2)
Stiripentol	44 (33.3)	0	43 (100)	0	43 (19.9)
Topiramate	29 (22.0)	20 (23.5)	14 (32.6)	26 (29.5)	60 (27.8)
Zonisamide	14 (10.6)	8 (9.4)	0	7 (8.0)	15 (6.9)
Baseline MCSF					
Mean ± SD	30.1 ± 36.2	58.3 ± 175.5	27.9 ± 36.9	67.5 ± 288.1	56.0 ± 214.7
Median (Range)	14.8 (2.7, 229.3)	17.5 (4, 1464)	14.0 (2.7, 213.3)	16.9 (2.7, 2700.7)	16.3 (2.7, 2700.7)

[a]Not reported or missing: privacy laws in some regions and countries preclude disclosure of certain personal information.
[b]Previously failed ASMs do not include concomitant ASMs.
ASM, antiseizure medication; FFA, fenfluramine; MCSF, monthly convulsive seizure frequency; SD, standard deviation; STP, stiripentol.

SAFETY

- Most patients in all groups experienced at least 1 TEAE (81.8%-97.7%; **Table 2**)
  - The most common TEAEs in the FFA groups were decreased appetite (with or without weight loss), diarrhea, and pyrexia
- No cases of valvular heart disease or pulmonary hypertension were reported in any patient at any time in the analysis
- One death was reported in the placebo group in one of the studies (probably sudden unexpected death in epilepsy); no deaths were reported in the FFA groups in any study

Table 2. TEAEs From 3 RCTs Combined

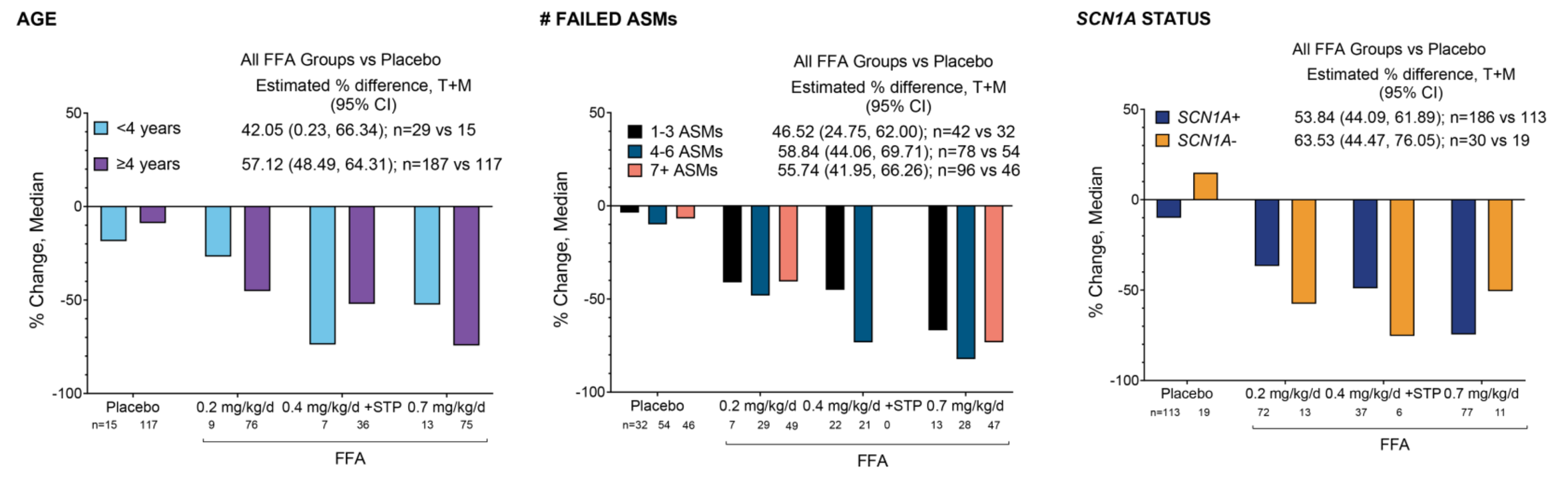
	Placebo (n=132)	FFA 0.2 mg/kg/d Without STP (n=85)	FFA 0.4 mg/kg/d With STP (n=43)	FFA 0.7 mg/kg/d Without STP (n=88)	Total FFA (n=216)
Patients with ≥1 TEAE, n (%)[a]	108 (81.8)	79 (92.9)	42 (97.7)	82 (93.2)	203 (94.0)
Decreased appetite	10 (7.6)	18 (21.2)	17 (39.5)	30 (34.1)	65 (30.1)
Diarrhea	10 (7.6)	19 (22.4)	10 (23.3)	14 (15.9)	43 (19.9)
Pyrexia	16 (12.1)	12 (14.1)	11 (25.6)	11 (12.5)	34 (15.7)
Somnolence	11 (8.3)	11 (12.9)	3 (7.0)	14 (15.9)	28 (13.0)
Fatigue	4 (3.0)	7 (8.2)	11 (25.6)	9 (10.2)	27 (12.5)
Blood glucose decreased	8 (6.1)	11 (12.9)	6 (14.0)	8 (9.1)	25 (11.6)
Nasopharyngitis	25 (18.9)	8 (9.4)	7 (16.3)	8 (9.1)	23 (10.7)
Upper respiratory tract infection	10 (7.6)	11 (12.9)	4 (9.3)	4 (4.6)	19 (8.8)
Tremor	2 (1.5)	2 (2.4)	5 (11.6)	7 (8.0)	14 (6.5)
Bronchitis	2 (1.5)	1 (1.2)	5 (11.6)	0	6 (2.8)
Days to onset of earliest occurrence of common TEAEs, mean ± SD[b]	41.0 ± 38.4	30.1 ±31.2	26.2 ± 27.6	24.1 ±29.9	26.9 ± 29.8
Patients with ≥1 serious TEAE, n (%)	12 (9.1)	8 (9.4)	6 (14.0)	8 (9.1)	22 (10.2)
Patients with any TEAE resulting in discontinuation of treatment, n (%)	2 (1.5)	1 (1.2)	2 (4.7)	7 (8.0)	10 (4.6)
Patients with any TEAE resulting in death, n (%)	1 (0.8)	0	0	0	0

[a]Listed TEAEs occurred in ≥10% of any treatment group.
[b]Common TEAEs are those occurring with a frequency of at least 5% across all subjects.
ASM, antiseizure medication; FFA, fenfluramine; RCTs, randomized clinical trials; SD, standard deviation; STP, stiripentol; TEAE, treatment-related adverse event.

Efficacy

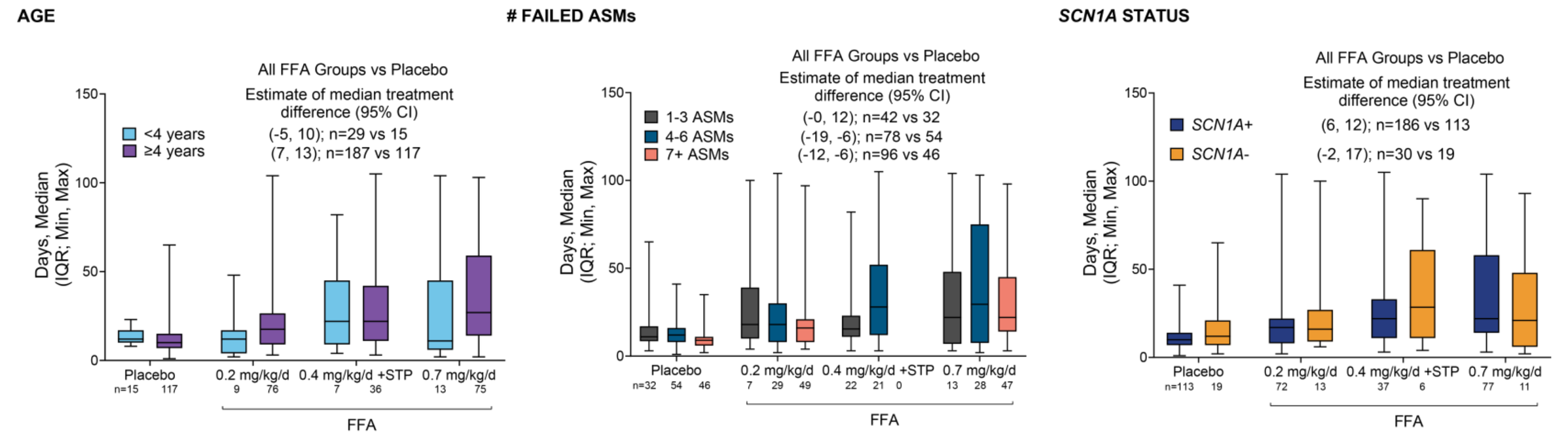
- Overall, the differences between all FFA treatment groups combined and placebo showed:
  - Significant reduction in % MCSF in all subgroups (**Figure 1**)
  - Significant increase in longest seizure-free interval for:
    - ≥4 years group
    - All ASM groups
  - Increase that was not significant for the groups <4 years and *SCN1A*-, possibly due to small n (n=29 and n=30, respectively) (**Figure 2**)
- Compared to placebo, patients in the highest dose group (0.4 mg/kg/d FFA+STP and 0.7 mg/kg/d FFA) experienced:
  - Greatest numerical percentage MCSF reduction (**Figure 1**)
  - Greatest numerical increase in median convulsive seizure-free days (**Figure 2**)
- FFA treatment was associated with increased frequency in clinically meaningful improvement on CGI-I scores relative to placebo (**Figure 3**)
  - Significant clinically meaningful improvement on CGI-I scores was consistently reported by parents/caregivers and investigators across stratified groups in FFA-treated cohorts relative to placebo except for the <4 years group (n=15 placebo; n=29 FFA); notably, the placebo effect was substantially higher for patients in the <4 years group than the ≥4 years group for both parents/caregivers and investigators

Figure 1. Percent Change in MCSF



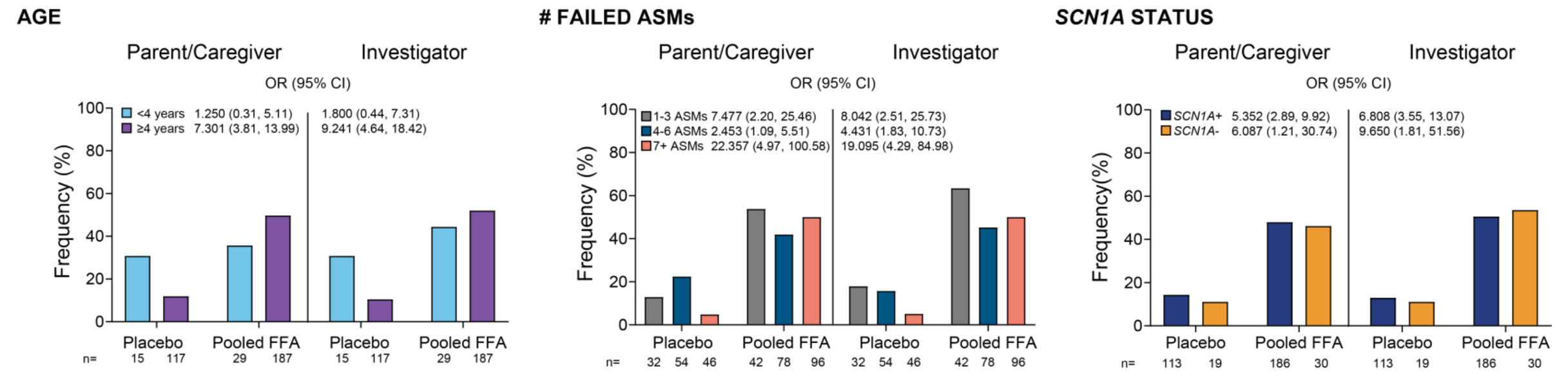
ASM, antiseizure medication; FFA, fenfluramine; MCSF, monthly convulsive seizure frequency; STP, stiripentol; T+M, titration and maintenance period.

Figure 2. Longest Interval of Convulsive Seizure-Free Days



95% CI based on Hodges-Lehman estimator of treatment difference.
ASM, antiseizure medication; FFA, fenfluramine; STP, stiripentol.

Figure 3. Clinically Meaningful Improvement on CGI-I Scores (Much Improved or Very Much Improved)



Clinically meaningful improvement: "Much Improved" or "Very Much Improved" on CGI-I. ASM, antiseizure medication; CGI-I, Clinical Global Impression-Improvement scale; FFA, fenfluramine; STP, stiripentol.

Conclusions

- FFA is associated with improved global functioning (seizure and non-seizure) outcomes relative to placebo, regardless of age, epilepsy severity (as estimated by number of failed ASMs), or *SCN1A* status in patients with DS
- Results should be interpreted with caution due to limitations of sample size and short treatment duration (2-3 weeks titration plus 12 weeks maintenance); additional studies are needed long-term
- Inferential analyses of stratified groups in larger populations may provide a better understanding of the increased benefits seen in different DS sub-populations and synergies with concomitant medications

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