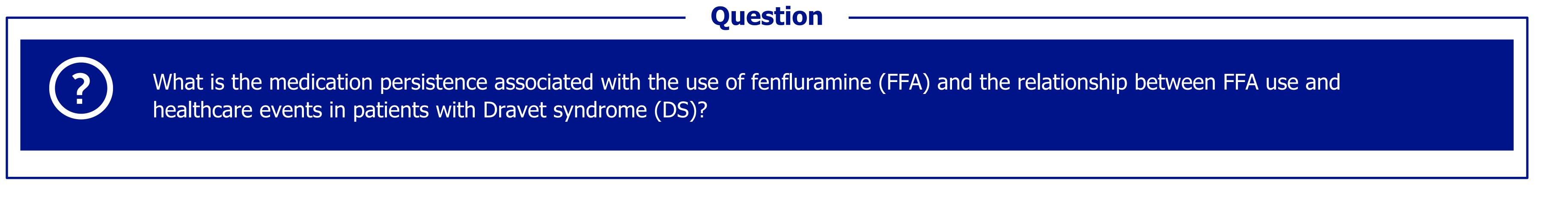
Healthcare Utilization and Persistence in Patients With Dravet Syndrome: A Retrospective Analysis Using US Claims Data Derek Ems, MPH¹, Srihari Jaganathan¹, Rob Sederman², Chen Chen², Amélie Lothe³; Shuang Wu²

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Investigation

- We analyzed the Komodo Healthcare claims database for individuals with DS who received FFA from Oct 1, 2020, to June 30, 2023
- Reductions were observed in all healthcare claims between the pre- and post-index period in individuals using FFA in both STP/CBD inclusive and exclusive regimens

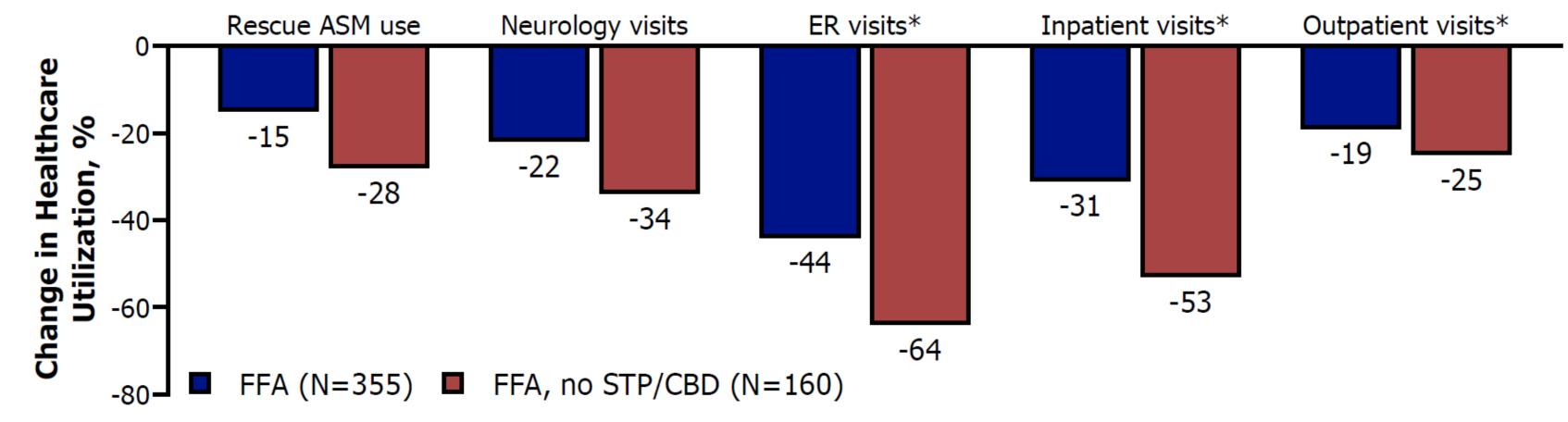
Figure 3. Percentage Change in HCRU Claims During the First 6 Months of FFA Use in FFA-Persistent Individuals

Methods

- Continuous claims data were required for 6 months before (pre-index period) and after (post-index period) FFA initiation
- Individuals were permitted to use other ASMs concomitantly (except where indicated)
- Persistence was assessed in individuals with continuous FFA claims data (no gap in claims >90 days) during the combined 6-month pre-index and 6-month post-index periods: A) regardless of stiripentol (STP) or cannabidiol (CBD) claims; and B) without STP/CBD claims
- A Kaplan-Meier survival analysis was used to assess persistence from FFA initiation (Day 0) to 6 months (Day 180)
- In those individuals with persistent FFA use at Day 180, post- vs pre-index healthcare resource utilization (HCRU) claims data were analyzed
- Measured by mean difference in number of events between post- and pre-index periods using a 2-tailed paired t-test

Figure 1. Study Design

FFA i	initiation			
6-month pre-index period ^a	6-month post-index period			
	Persistence analysis ^b			
Healthcare resource utilization (HCRU) analysis post- vs pre-index claims				
Analyzed in individuals with persistent FFA use ^b				
Cohorts of interest				
FFA: individuals with FFA claims regardless of concomitant STP/CBD				



*Seizure-related visits.

FFA-persistent individuals are defined as individuals with continuous FFA claims with no gap >90 days over 6 months following FFA initiation. ASM, antiseizure medication; CBD, cannabidiol; ER, emergency room; FFA, fenfluramine; HCRU, healthcare resource utilization; STP, stiripentol.

Table 2. Post- vs Pre-Index HCRU Claims in Individuals With Persistent FFA Use at Day 180

	FFA N=355			FFA, no STP/CBD N=160			
	Mean Change	P-value	% Change	Mean Change	<i>P</i> -value	% Change	
Rescue ASM use <i>(Unique days)</i>	-0.3	0.010	-15	-0.6	0.001	-28	
Neurology visits (Unique days)	-0.4	<0.001	-22	-0.6	0.001	-34	
Seizure-related ER visits (Unique visits)	-1.0	<0.001	-44	-1.7	<0.001	-64	
Seizure-related inpatient visits (Unique visits)	-1.3	0.111	-31	-3.1	0.018	-53	

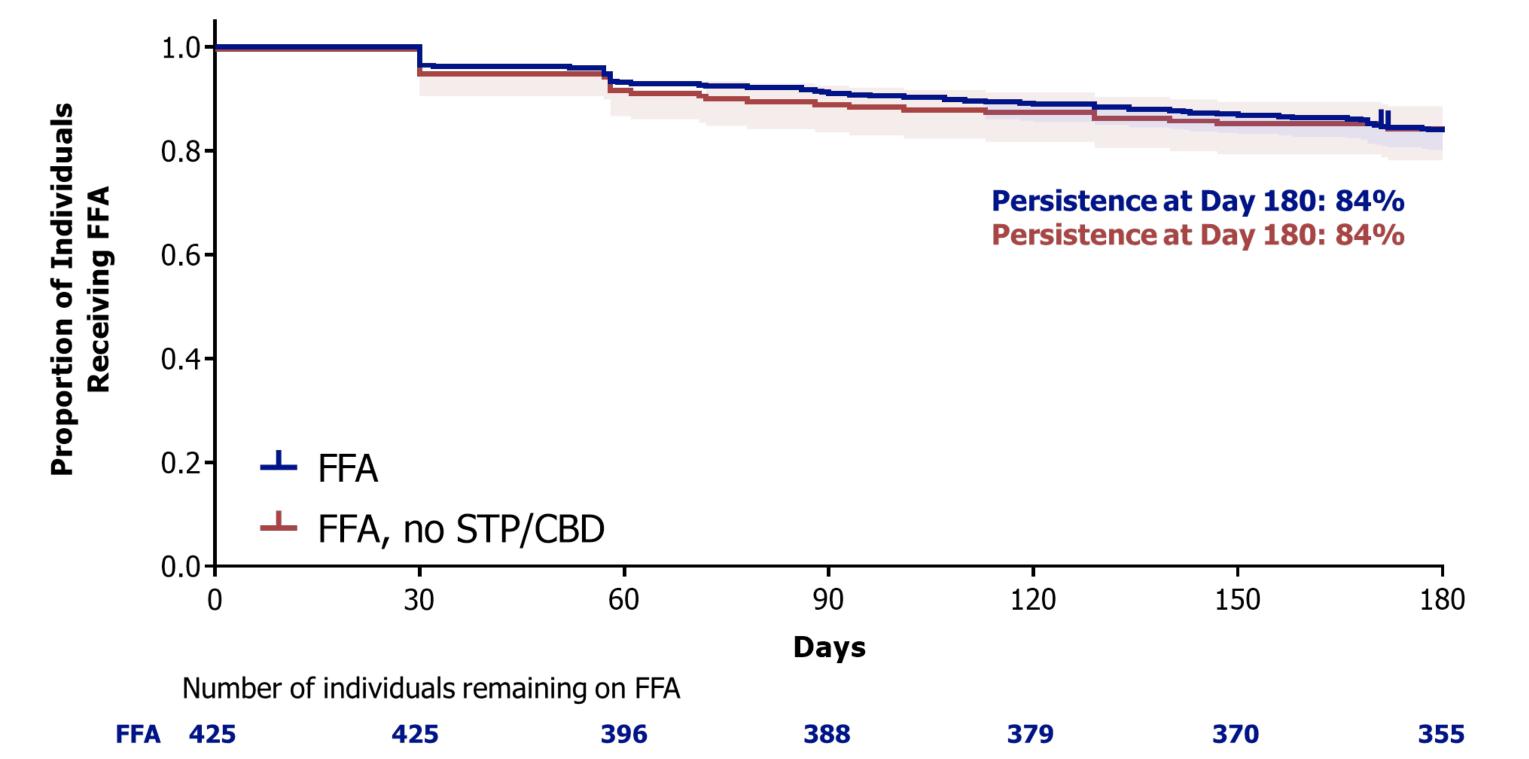
FFA, no STP/CBD: individuals with FFA claims *without* concomitant STP/CBD during the pre- and post-index periods

^aNo prescription claims for FFA during the 6 months prior to FFA initiation (index). ^bPersistent FFA use defined as continuous FFA claims with no gap >90 days over 6 months following FFA initiation. CBD, cannabidiol; DS, Dravet syndrome; FFA, fenfluramine; STP, stiripentol.

Results

- We identified 425 individuals with DS who received FFA; 190 individuals without concomitant STP/CBD
- The 6-month persistence for both the STP/CBD inclusive and exclusive groups was 84%

Figure 2. 6-Month FFA Persistence Data in Individuals With DS



Seiz	ure-	rela	ated	
		_		

outpatient visits	-2.8	0.003	-19	-3.8	0.007	-25
(Unique visits)						

P-values were calculated using 2-tailed paired t-tests: mean difference in number of days/visits with claims post- vs pre-index. Persistent FFA use defined as continuous FFA claims with no gap >90 days over 6 months following FFA initiation. ASM, antiseizure medication; CBD, cannabidiol; ER, emergency room; FFA, fenfluramine; HCRU, healthcare resource utilization; STP, stiripentol.

Data caveats

- Prescription claims do not necessarily indicate treatment use
- FFA initiation as determined here may not be the first use for a given individual; FFA use prior to the 6-month pre-index period is possible
- Safety data are not available in the claims database and have not been reported
- Selection bias may be introduced when patients without 6 months of continuous post-index claims are excluded

Conclusions

- Individuals with DS receiving FFA that had 6 months of pre- and post-index claims data demonstrated a strong persistence over a 6-month period, regardless of concomitant STP/CBD use
- Strong persistence is typically associated with improved effectiveness and tolerability for chronic medications,⁷ suggesting real-world benefits of FFA use in this population
- Reductions in HCRU claims observed over 6 months, regardless of concomitant STP/CBD use, suggests improved outcomes in this population
- Differences in HCRU between the STP/CBD inclusive and exclusive groups may be due to clinical differences between the groups
- Selection bias may be introduced due to exclusion of individuals without 6 months of post-index data, thus overestimating persistence and HCRU and limiting generalizability
 Future analyses may include individuals without 6 months of post-index claims data

FFA, no STP/CBD190175170167163

Discontinuation is defined as not having a treatment claim within 90 days following the last day of supply of a previous treatment claim. Shaded areas indicate 95% confidence interval. Individuals are censored if their last day of FFA claim is \leq 90 days prior to the end of the study period. Note: FFA, no STP/CBD data has been adjusted downward by 0.01 units for visibility.

CBD, cannabidiol; DS, Dravet syndrome; FFA, fenfluramine; STP, stiripentol.

 Individuals with persistent FFA use at Day 180 in the STP/CBD inclusive cohort (N=355) and exclusive cohort (N=160) were included in the HCRU analysis

Table 1. Baseline Characteristics of Individuals With Persistent FFA Use at Day 180

	FFA N=355	FFA, no STP/CBD N=160
Age at FFA initiation, median (range), years	10 (1-42)	9 (1-42)
Gender, male, %	48	47
Treatment history ^a , %		
Any ASM	94	91
Valproate ^b	49	54
Levetiracetam	31	34
CBD	39	0
STP	19	0

Persistent FFA use defined as continuous FFA claims with no gap >90 days over 6 months following FFA initiation. ^aTreatment history here is defined as any prescription claim made during the 6-month pre-index period. ^bIncluding divalproex and valproic acid. ASM, antiseizure medication; CBD, cannabidiol; FFA, fenfluramine; STP, stiripentol.

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DISCLOSURES

SJ, DE: Employee of UCB Pharma. **RS, CC, SW:** Employee of Ambit, Inc., which has a contractual relationship with UCB Pharma. **AL:** Employment/Stock Ownership: UCB Pharma.



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160