Use of Fenfluramine and Cannabidiol in Daily Practice: A Retrospective Analysis of German Prescription Claims

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Background

- Lennox-Gastaut syndrome (LGS) is a rare, developmental and epileptic encephalopathy associated with high seizure burden by multiple seizure types and few seizure-free days, which adversely affects quality of life for patients and their caregivers[1]
- Dravet syndrome (DS) is a rare pharmacotherapy-resistant, developmental and epileptic encephalopathy that is typically diagnosed in early childhood. DS involves seizures accompanied by severe cognitive, behavioural, and motor impairments[2]
- Fenfluramine (FFA) is approved for the treatment of seizures associated with LGS and DS in patients ≥2 years of age in the US, EU, and UK[3,4]
- FFA and cannabidiol (CBD) are the latest two approved treatment options

Objective

- To describe the daily use of FFA and CBD in Germany based on prescriptions claims in terms of age and gender distribution, prior medication use, dosage, and medication persistence, in DS and LGS

Methods

- This was a retrospective analysis of German prescription data covering 64 million statutory health insured individuals from March 2020 until October 2023
  - Patient index date was the date of the first prescription of FFA or CBD
  - Patient numbers were extrapolated to the overall German statutory health insured population
- Patient groups were defined as follow:
  - DS: with Stiripentol (STP) and without Felbamate (FLB) or Rufinamide (RUF) at any time during study period
  - LGS: with FLB or RUF and without STP were assigned to LGS group at any time during study period
  - Undefined: without STP or FLB or RUF or with STP and FLB or RUF at any time during study period
  - Total: DS, LGS and undefined groups combined
- Prior anti-seizure medications (ASMs) were analyzed for up to 9 months prior to index
- Utilization of ASM co-medication was analyzed for the periods 180–15 days prior and 15–180 and 181–365 days after index using the time frame March 2020 to April 2024
- Persistence was analyzed for a follow-up period after index of up to 36 months and patients lost to follow-up due to end of database records were censored

Results

- A total of 303 (379 when extrapolated to statutory health insurance [SHI]) FFA (26.1% DS; 10.6% LGS; 63.3% undefined) and 1,918 CBD (4.6% DS; 17.2% LGS; 78.2% undefined) patients were identified in the database
- FFA patients at index had a mean age (standard deviation, SD) of 15.0 years (12.9) (DS: 14.7 (15.1); LGS: 17.8 (12.9); 40.9% were male (DS: 43.4%; LGS: 52.5%), 34.3% female (DS: 31.3%; LGS: 35.0%) and 24.8% unknown (DS: 25.3%; LGS: 12.5%)
- Patients with CBD (n=1,341; extrapolated to SHI: 1,918) had a mean (SD) age of 19.4 years (15.7) (DS: 16.5 (13.3); LGS: 18.5 (13.4)); 37.8% were males (DS: 49.4%; LGS: 41.3%), 34.8% females (DS: 32.6%; LGS: 28.6%), and 27.4% of unknown gender (DS: 18.0%; LGS: 30.1%)
- 93.7% of the FFA patients (DS: 97.5%; LGS: 100.0%) and 85.5% of the CBD patients (DS: 96.8%; LGS: 96.1%) received prior ASM (**Table 1**)

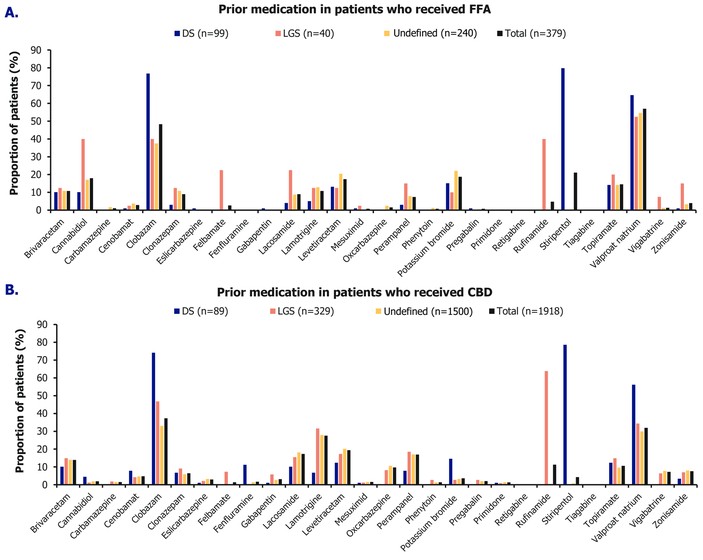
Table 1. Patient characteristics at date of first prescription of FFA or CBD (index date)

	FFA				CBD			
	DS	LGS	Undefined	Total	DS	LGS	Undefined	Total
N in database	79	32	192	303	62	230	1,049	1,341
Extrapolated to SHI	99	40	240	379	89	329	1,500	1,918
Adult patients, n (%)	29 (29.3)	18 (43.9)	81 (33.8)	128 (33.7)	30 (34.1)	134 (40.9)	649 (43.3)	814 (42.4)
Sex, %								
Female	31.3	35.0	35.4	34.3	32.6	28.6	36.3	34.8
Male	43.4	52.5	37.9	40.9	49.4	41.3	36.3	37.8
Unknown	25.3	12.5	26.7	24.8	18.0	30.1	27.3	27.4
Mean age (SD), years	14.7 (15.1)	17.8 (12.9)	14.6 (11.9)	15.0 (12.9)	16.5 (13.3)	18.5 (13.4)	19.8 (16.3)	19.4 (15.7)
With ASM before index*,%	97.5	100.0	91.1	93.7	96.8	96.1	82.6	85.5

*Within 9 months prior to index. Data source: Patient Insights Analytics, Insight Health 2024.
ASM, antiseizure medication;CBD, cannabidiol; DS, Dravet syndrome; FFA, fenfluramine; LGS, Lennox-Gastaut syndrome, SD, standard deviation; SHI, statutory health insurance.

- Most frequently used prior ASMs (**Figure 1A**) in the total FFA patient population were valproate (57.0%), clobazam (48.3%), STP (21.1%) and potassium bromide (18.7%). Patients on CBD (**Figure 1B**) received clobazam (37.3%), valproate (32.0%), lamotrigine (27.6%) and levetiracetam (19.4%) as most frequent prior ASMs

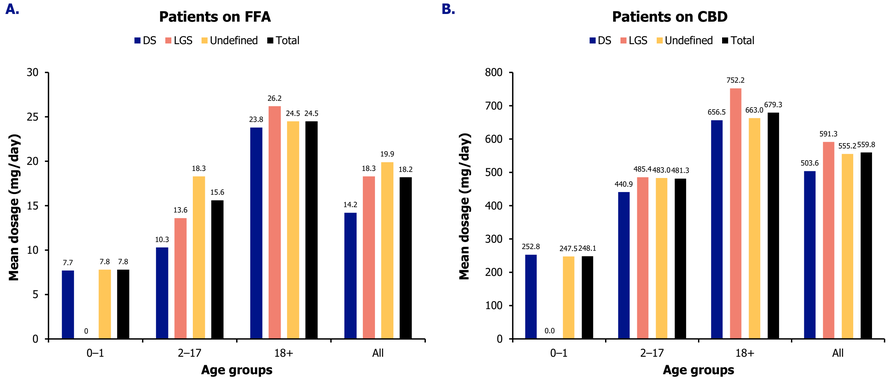
Figure 1. Prior medications in patients who received FFA (A) and CBD (B) within 9 months prior to index



Data source: Patient Insights Analytics, Insight Health 2024.
CBD, cannabidiol; DS, Dravet syndrome; FFA, fenfluramine; LGS, Lennox-Gastaut syndrome.

- Mean±SD prescribed FFA dosage per day (**Figure 2A**) was 18.2±35.2 mg (DS: 14.2±15.5; LGS: 18.3±11.6), 15.6±40.8 mg and 24.5±18.8 mg in the overall population, in patients aged 2–17 years and ≥18 years, respectively. Mean±SD prescribed daily doses of CBD (**Figure 2B**) were 559.8±718.2 mg, 481.3±870.8 mg and 679.3±418.7 mg in the overall population, in patients aged 2–17 years and ≥18 years, respectively

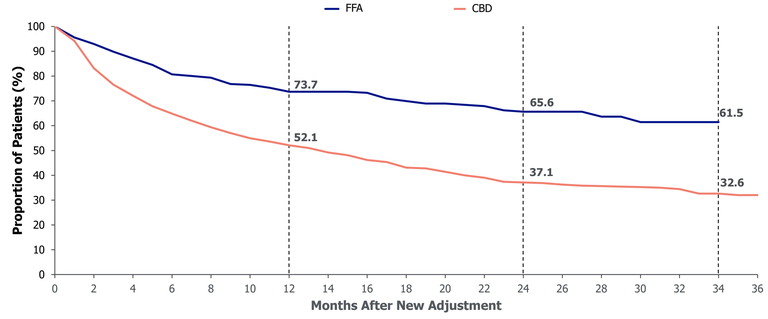
Figure 2. Prescribed daily dosage of FFA (A) and CBD (B) by age group and by indication



Data source: Patient Insights Analytics, Insight Health 2024.
CBD, cannabidiol; DS, Dravet syndrome; FFA, fenfluramine; LGS, Lennox-Gastaut syndrome.

- The persistence after 12, 24, and 34 months was 73.7%, 65.6% and 61.5% for FFA, and 52.1%, 37.1% and 32.6% for CBD in the total populations (**Figure 3**), respectively

Figure 3. Persistence with FFA (blue) and CBD (grey) in the total population[a]



[a]Patients lost to follow-up due to end of database were censored

Table 2. Number of ASM co-medication prescriptions in defined pre- and post-index timelines in patients who received FFA or CBD

Analytic Cohort	Time frame relative to index	Number of co-medication prescriptions, mean (SD)	
		FFA	CBD
Total	**-180 to -15**	11.6 (8.9)	10.4 (10.4)
Total	**15 to 180**	9.5 (8.3)	10.2 (9.9)
Total	**181 to 365**	8.2 (8.3)	10.4 (11.0)

Data source: Patient Insights Analytics, Insight Health 2024.
ASM, antiseizure medication; CBD, cannabidiol; DS, Dravet syndrome; FFA, fenfluramine; LGS, Lennox-Gastaut syndrome; SD, standard deviation.

- Patients with FFA had a mean of 11.6±8.9 (DS: 13.7±7.1 / LGS: 15.9±10.7) ASM co-medication prescriptions within the 180–15 days before index, which reduced to 9.5±8.3 (DS: 10.7±7.0; LGS: 13.3±10.8) in the period 15–180 days and 8.2±8.3 (DS: 10.5±8.5; LGS: 8.9±9.7) 181–365 days after index, respectively. In contrast, mean number of ASM co-medication prescriptions remained stable in patients who received CBD with 10.4±10.4 (DS: 12.9±8.1; LGS: 14.4±10.5) 180–15 days before, 10.2±9.9 (DS: 11.7±7.9; LGS: 13.5±9.7) 15–180 days and 10.4±11.0 (DS: 12.1±8.6; LGS: 15.3±12.3) 181–365 days after index, respectively

Limitations

- Assumptions were made regarding indication assignment and the proportion of patients with undefined indication is high
- The dosage calculation could not take into account the weight of the patients

Conclusions

- This analysis suggested that prescribed daily dosage for FFA and CBD was in line with the SmPC recommendations
- Prior medication use was numerically greater in patients who received FFA vs CBD
- After the index date, the number of prescriptions for concomitant ASMs appeared to have reduced to a greater extent in patients who received FFA vs CBD
- The overall (not indication specific) medication persistency can be considered numerically higher in patients who received FFA vs CBD

References

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