



THE IMPACT OF FLUPHENAZINE DECANOATE DISCONTINUATION – A RETROSPECTIVE COHORT STUDY

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BACKGROUND

- Fluphenazine decanoate (Modecate) is a first generation antipsychotic (FGA) introduced to the Irish market in a long-acting injectable format in the 1950's
- In 2018, it was announced by the pharmaceutical company, Sanofi, that Modecate was to be withdrawn from the market in the Republic of Ireland.
- When thioridazine, another FGA, was withdrawn from the market in 2005, high rates of relapses for many patients with psychotic disorders including those who had maintained mental health stability for many years was noted (Purhonen et al., 2012).

AIMS

- To ascertain if patients demonstrating mental health stability experienced a relapse in psychosis in a 2-year period following discontinuation of fluphenazine decanoate in a West of Ireland catchment region.
- To examine if particular alternate antipsychotic treatments prescribed were associated with lower levels of relapse of psychosis.

METHODS

- Semi-structured interviews were conducted in person (n = 4) or by telephone (n=10) with participants by the first author (SM) who provided written informed consent between June X and August X, 2021.
- Relapse rates were determined review of all clinical notes, with rates of associated hospitalisation or additional supports also assessed.
- The number and type of replacement antipsychotic treatments required secondary to a relapse of psychosis was attained.
- Additional information pertaining to participants own experience with fluphenazine decanoate and its discontinuation was discussed, including both positive and negative experiences
- Established psychometric instruments with known high reliability and validity indices were also utilised to measure current functioning:
 - Global Assessment of Functioning Scale (GAF, Hall 1978)
 - Clinical Global Impression (CGI-S, Guy 1976).

REFERENCES

- Purhonen M, Koponen H, Tiihonen J, Tanskanen A. Outcome of patients after market withdrawal of thioridazine: a retrospective analysis in a nationwide cohort. *Pharmacoepidemiol Drug. Saf.* 2012;21(11): 1227-31.
- Hall R. Global Assessment of functioning: A modified scale. *Psychosomatics* 1995; 36: 267-275.
- Guy W. ECDEU Assessment manual for Psychopharmacology – Revised (DHEW Publ No ADM 76-338). Rockville, MD, U.S. Department of Health Education, and Welfare, Public Health Service, Alcohol, Drug Abuse, and Mental Health Administration, NIMH Psychopharmacology Research Branch, Division of Extramural Research Programs 1976, pp218-222.

INCLUSION CRITERIA

- participants that attended Galway Mental Health services
- had been in receipt of fluphenazine decanoate for at least 12 months prior to its withdrawal
- over 18 years of age
- have capacity to provide written informed consent for study participation
- have a diagnosis of schizophrenia, schizoaffective disorder or bipolar affective disorder.

Participants were excluded if they had a confirmed diagnosis of intellectual disability or dementia.

RESULTS

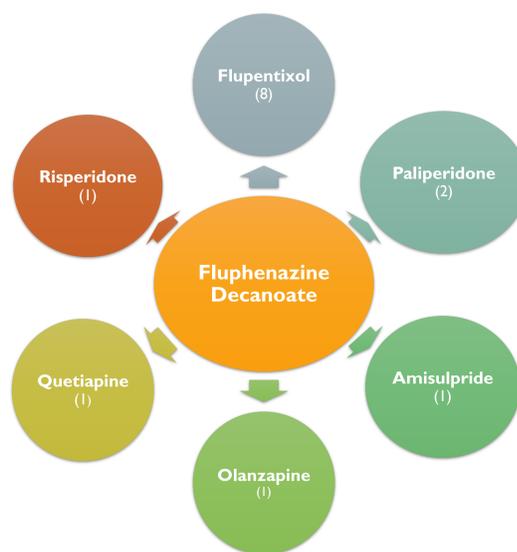
Table 1: Clinical Variables

GAF, median range	61-80	
CGI, mean (SD)	5.3	
Fluphenazine Dosage (mg)	12.5	2
	25	8
	50	1
	75	2
	87.5	1
Fluphenazine Frequency	1x every 2 weeks	6
	1x every 3 weeks	5
	1x every 4 weeks	2
	1x every 6 weeks	1

Table 2: Demographic Factors

Age in years, mean (SD)		60.07
Gender n(%)	Male	8 (57.1%)
	Female	6 (42.9%)
Marital Status n(%)	Single	12 (85.8%)
	Married	1 (7.1%)
	Widowed	1 (7.1%)
Occupation n(%)	Unemployed	13 (92.9%)
	Employed	1 (7.1%)
Diagnosis n(%)	Paranoid Schizophrenia	9 (64.3%)
	Schizoaffective Disorder	4 (28.6%)
	Avoidant Personality Disorder	1 (7.1%)
Duration of illness in years, mean (SD)		32.6

First change options after fluphenazine withdrawal



- In total, 71.4% (n=10) of our participants had relapse significant of noting since fluphenazine decanoate withdrawal.
- Though the number of study participants was small (n=14), the effects on individual participants were highly clinically significant.
- Utilisation of the FGA flupentixol as an alternate antipsychotic medication was associated with lower rates of relapse than others (62.5%; versus relapse rate of 100% in risperidone, paliperidone and olanzapine).
- Flupentixol should be considered as a therapeutic option if other FGAs are also withdrawn from the Irish market.

CONCLUSION

- The discontinuation of fluphenazine decanoate was associated with significant rates of relapse in psychosis, including in individuals with lengthy periods of pre-treatment alteration stability
- This review highlights the relationship between disease stability and effective, long-term treatment and the need for careful planning around potential change of treatment for those maintained on long acting depot medications.