

A prospective observational study on the off-label use of medications in the psychiatry outpatient department of a tertiary care hospital

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Abstract:

BACKGROUND: Off-label prescribing – using medications outside their approved indications, doses, or populations – is common in psychiatry, with Indian studies estimating a prevalence of 30%–40%. Despite this, data on prescribing patterns and associated factors remain limited.

AIM: This study aimed to assess the prevalence, pattern, and demographic factors associated with off-label prescribing in a psychiatric outpatient setting. The specific objectives included identifying common psychiatric conditions linked to off-label use and its correlation with patient age.

METHODS: A prospective, cross-sectional, and observational study was conducted over 3 months in the psychiatry outpatient department of a tertiary care hospital after ethics approval. Data on demographics, clinical history, and prescriptions were collected using a predesigned pro forma. Off-label status was determined using the National Formulary of India (NFI, 6th edition, 2021) and Central Drugs Standard Control Organization records. The Chi-square test was used for statistical analysis.

RESULTS: Among 500 patients (mean age 40.74 ± 15.49 years), 1197 drugs were prescribed, of which 417 (34.83%) were off-label. Clonazepam (40.28%) and lorazepam (15.35%) were the most frequently used off-label drugs, followed by risperidone and propranolol (4.32%). Depressive disorder was the most common condition linked to off-label use. Off-label prescribing was highest (49.6%) in the 21–40 years' age group. Inappropriate indications were the most frequent reason for off-label use.

CONCLUSION: Off-label prescribing is prevalent in psychiatric practice, with benzodiazepines and antipsychotics commonly involved. These findings highlight the need for improved awareness and regulation.

Keywords:

Clonazepam, observational study, off-label, psychiatry