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ORIGINAL ARTICLE

Patterns and Predictors of Psychiatric Polypharmacy and Fixed-Dose Combination Use: A Cross-Sectional Study from a Tertiary Care Hospital in Eastern India

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ABSTRACT

Psychiatric polypharmacy and fixed-dose combination (FDC) prescribing are frequently observed in tertiary care psychiatry. While appropriate in selected scenarios such as treatment-resistant illness or comorbidities, both practices carry risks of adverse drug reactions, drug–drug interactions, and poor adherence. To determine the prevalence, patterns, and predictors of psychiatric polypharmacy and FDC use among psychiatric outpatients in a tertiary care hospital in Eastern India. A three-month cross-sectional study was conducted in the Psychiatry Outpatient Department of a government tertiary hospital. Prescriptions containing at least one psychotropic drug were obtained by convenience sampling. Socio-demographic, clinical, and prescribing details were recorded using a structured form. Psychiatric polypharmacy was defined as ≥2 psychotropics per prescription; general polypharmacy as ≥5 drugs. Associations were tested using chi-square and logistic regression. Among 150 prescriptions, psychiatric polypharmacy was present in 67.3%, general polypharmacy in 41.3%, and FDC use in 41.3%. Psychotropic FDCs accounted for 22.7% of prescriptions. Polypharmacy was significantly associated with age (p=0.048), socio-economic status (p=0.032), and diagnosis (p=0.001). Logistic regression confirmed schizophrenia spectrum disorders (OR=2.91, 95% CI: 1.24–6.83) and middle socio-economic status (OR=2.37, 95% CI: 1.02–5.49) as independent predictors. High rates of psychiatric polypharmacy and FDC use, particularly in schizophrenia, highlight the need for regular prescription audits, prescriber education, and stricter regulation of irrational FDCs. Limitations include convenience sampling, modest sample size, and single-centre design. Multicentric, longitudinal studies are needed to evaluate outcomes and guide rational psychotropic prescribing.

Keywords: Psychiatry, Polypharmacy, Fixed-dose combinations, Psychotropic drugs, Prescription audit, Rational prescribing

INTRODUCTION

Mental disorders impose a substantial health, social, and economic burden worldwide, contributing significantly to disability-adjusted life years (DALYs) lost. According to the Global Burden of Disease Study, depressive disorders, schizophrenia, and bipolar affective disorder remain among the leading causes of disability globally [1, 2]. In India, psychiatric disorders form a major component of the non-communicable disease burden, yet service coverage, access to care, and rational drug use remain major challenges [3].

Psychotropic medications are the cornerstone of treatment for most psychiatric illnesses. However, in real-world practice, concurrent use of multiple psychotropic agents—referred to as psychiatric polypharmacy—is common [4]. While such combinations may be justified in situations such as treatment-resistant schizophrenia, acute exacerbations, or psychiatric comorbidities [5, 6], inappropriate use can increase the risk of adverse drug reactions, drug–drug interactions, treatment costs, and non-adherence [7]. Schizophrenia spectrum disorders, in particular, have been strongly linked with higher rates of polypharmacy, often involving antipsychotic combinations [8, 9].

Fixed-dose combinations (FDCs) are also encountered in psychiatry, intended to simplify regimens and potentially improve adherence [10]. However, irrational psychotropic FDCs remain prevalent in some markets, despite recommendations from the World Health Organization (WHO) and the Indian Psychiatric Society discouraging their routine use without strong supporting evidence [11, 12].

Previous Indian studies have examined either psychiatric polypharmacy or FDC use in isolation [9, 13]. Very few have assessed both together while also exploring socio-demographic and diagnostic predictors of prescribing patterns. Moreover, data from Eastern India are limited, despite differences in prescribing culture, availability of psychotropic FDCs, and variability in access to private versus public psychiatric care.

This study was therefore undertaken to:

1. Determine the prevalence and patterns of psychiatric polypharmacy and FDC use in a tertiary care psychiatry outpatient department.

2. Identify socio-demographic and clinical predictors associated with psychiatric polypharmacy.

METHODS

This was a hospital-based, cross-sectional observational study conducted in the Psychiatry Outpatient Department (OPD) of Calcutta Pavlov Hospital, Kolkata, a government-run tertiary care mental health institute in Eastern India. The study was carried out in collaboration with the Department of Pharmacology, Calcutta National Medical College, Kolkata. Data collection was undertaken over a three-month period from March to May 2023.

The study population comprised adult patients attending the Psychiatry OPD during the study period who were prescribed at least one psychotropic medication by a qualified psychiatrist.

Inclusion Criteria

- Age ≥18 years
- Confirmed psychiatric diagnosis made by a consultant psychiatrist according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)
- Prescription containing at least one psychotropic drug
- Willingness to participate and provision of written informed consent

Exclusion Criteria

- Inpatients
- Patients diagnosed with epilepsy
- Patients with provisional or uncertain psychiatric diagnoses
- Prescriptions lacking complete drug information

A total of 150 prescriptions were included in the analysis. As no prior prevalence data on psychiatric polypharmacy and fixed-dose combination (FDC) use were available from this setting, formal sample size calculation was not feasible. Therefore, sample size was determined based on feasibility and patient flow during the study period.

Prescriptions were collected using convenience sampling. To minimize selection bias and ensure reasonable representation, data collection was performed twice weekly during routine OPD hours (10:00 AM–2:00 PM) until the target sample size was achieved. The limitations of this sampling approach are acknowledged.

Data were collected using a pretested, structured case record form (CRF). The following information was recorded:

- **Socio-demographic variables:** age, sex, and socio-economic status (SES), classified using the Modified Kuppuswamy Scale
- **Clinical variables:** primary psychiatric diagnosis as per DSM-5
- **Prescribing variables:** name of drugs (generic/brand), dosage form, strength, route of administration, frequency, and duration
- **Prescription indicators:**
  - Total number of drugs per prescription
  - Number of psychotropic drugs
  - Presence of fixed-dose combinations (psychotropic and/or non-psychotropic)
  - Use of injections and antibiotics

Operational Definitions

- **Psychiatric polypharmacy:** Prescription containing two or more psychotropic drugs
- **General polypharmacy:** Prescription containing five or more total drugs (psychotropic and non-psychotropic combined)

- **Fixed-dose combination (FDC):** A pharmaceutical product containing two or more active ingredients in a fixed ratio within a single dosage form

Data were entered into Microsoft Excel and analysed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA).

- **Descriptive statistics:** Categorical variables were expressed as frequencies and percentages. Continuous variables were summarized as mean ± standard deviation (SD) with 95% confidence intervals (CI).
- **Inferential statistics:** Associations between psychiatric polypharmacy and categorical variables (age group, gender, socio-economic status, and diagnosis) were assessed using the chi-square test or Fisher's exact test, as appropriate. Independent t-test or one-way ANOVA was used for comparison of continuous variables.
- **Multivariable analysis:** Binary logistic regression analysis was performed to identify independent predictors of psychiatric polypharmacy. Variables with $p < 0.10$ in univariate analysis were included in the regression model. Results were expressed as odds ratios (OR) with 95% confidence intervals (CI).

A p-value < 0.05 was considered statistically significant.

The study was conducted as a prescription audit using anonymized outpatient data, without any intervention or alteration of treatment. Ethical approval was obtained from the Institutional Ethics Committee prior to study initiation. Written informed consent was obtained from all participants. Patient confidentiality and anonymity were strictly maintained in accordance with the Declaration of Helsinki.

RESULTS

A total of 150 psychiatric outpatient prescriptions were analysed. The mean age of patients was 38.6 ± 13.9 years. The largest proportion of patients belonged to the 30–44-year age group (35.3%), followed by 18–29 years (28.0%), 45–59 years (22.7%), and ≥60 years (14.0%). Males constituted 52.7% of the study population. Most patients belonged to the middle socio-economic status (62.7%). Schizophrenia spectrum disorders were the most common diagnosis (38.7%), followed by depressive disorders (29.3%), bipolar affective disorder (18.0%), and anxiety disorders (14.0%) (Table. 1).

The mean total number of drugs per prescription was 4.8 ± 1.6, while the mean number of psychotropic drugs per prescription was 2.4 ± 0.9. General polypharmacy (≥5 total drugs) was observed in 41.3% of prescriptions, whereas psychiatric polypharmacy (≥2 psychotropic drugs) was present in 67.3%. Prescribing by generic name was limited, with only 15.8% of drugs written generically. The use of injectables (5.3%) and antibiotics (2.7%) was low (Table. 2).

Table 1. Socio-demographic and Clinical Characteristics of Study Participants (n = 150)

Variable	Category	n	%
Age group (years)	18–29	42	28.0
	30–44	53	35.3
	45–59	34	22.7
	≥60	21	14.0
Gender	Male	79	52.7
	Female	71	47.3
Socio-economic status	Upper	18	12.0
	Middle	94	62.7
	Lower	38	25.3
Primary psychiatric diagnosis	Schizophrenia spectrum disorders	58	38.7
	Depressive disorders	44	29.3
	Bipolar affective disorder	27	18.0
	Anxiety disorders	21	14.0

Table 2. Prescribing Indicators and Drug Utilization Pattern (n = 150 prescriptions)

Prescribing Indicator	Value	95% CI
Mean total drugs per prescription	4.8 ± 1.6	4.6 – 5.1
Mean psychotropic drugs per prescription	2.4 ± 0.9	2.2 – 2.6
General polypharmacy (≥5 drugs)	62	41.3%
Psychiatric polypharmacy (≥2 psychotropics)	101	67.3%
Drugs prescribed by generic name	118	15.8%*
Prescriptions with ≥1 injectable drug	8	5.3%
Prescriptions with ≥1 antibiotic	4	2.7%

*Percentage calculated from total number of drugs prescribed.

Fixed-dose combinations (FDCs) were identified in 41.3% of prescriptions. Psychotropic FDCs alone accounted for 22.7% of prescriptions, non-psychotropic FDCs alone for 12.7%, and both psychotropic and non-psychotropic FDCs for 6.0% (Table. 3).

Table 3. Fixed-Dose Combination (FDC) Use in Prescriptions (n = 150)

Type of FDC	n	%
Psychotropic FDCs only	34	22.7
Non-psychotropic FDCs only	19	12.7
Both psychotropic and non-psychotropic FDCs	9	6.0
At least one FDC in prescription	**62**	**41.3**

Table 4. Association Between Psychiatric Polypharmacy and Patient Characteristics (n = 150)

Variable	Polypharmacy Present (n=101)	Polypharmacy Absent (n=49)	p-value
Age group (years)			**0.048***
18–29	22 (21.8%)	20 (40.8%)	
30–44	39 (38.6%)	14 (28.6%)	
45–59	26 (25.7%)	8 (16.3%)	
≥60	14 (13.9%)	7 (14.3%)	
Gender			0.524
Male	55 (54.5%)	24 (49.0%)	
Female	46 (45.5%)	25 (51.0%)	
Socio-economic status			**0.032***
Upper	7 (6.9%)	11 (22.4%)	
Middle	69 (68.3%)	25 (51.0%)	
Lower	25 (24.8%)	13 (26.5%)	
Primary diagnosis			**0.001***
Schizophrenia spectrum disorders	47 (46.5%)	11 (22.4%)	
Bipolar affective disorder	18 (17.8%)	9 (18.4%)	
Depressive disorders	25 (24.8%)	19 (38.8%)	
Anxiety disorders	11 (10.9%)	10 (20.4%)	

*Chi-square test; Fisher's exact test applied where appropriate *p < 0.05 considered statistically significant

Psychiatric polypharmacy showed statistically significant associations with age group (p = 0.048), socio-economic status (p = 0.032), and primary psychiatric diagnosis (p = 0.001). Polypharmacy was most frequent among patients aged 30–44 years and those belonging to the middle socio-economic category. Schizophrenia spectrum disorders accounted for the highest proportion of polypharmacy cases (46.5%). Gender did not show a significant association with psychiatric polypharmacy (p = 0.524) (Table. 4).

On binary logistic regression analysis, schizophrenia spectrum disorders emerged as an independent predictor of psychiatric polypharmacy (OR = 2.91, 95% CI: 1.24–6.83; p = 0.014). Middle socio-economic status was also independently associated with polypharmacy (OR = 2.37, 95% CI: 1.02–5.49; p = 0.046). Age group did not retain statistical significance after adjustment for confounding variables (Table. 5).

Table 5. Binary Logistic Regression Analysis of Predictors of Psychiatric Polypharmacy (n = 150)

Predictor Variable	Odds Ratio (OR)	95% CI	p-value
Age 30–44 years vs others	1.72	0.83 – 3.57	0.144
Middle SES vs others	2.37	1.02 – 5.49	0.046*
Schizophrenia spectrum disorders vs others	2.91	1.24 – 6.83	0.014*

*Statistically significant (p < 0.05)

DISCUSSION

This cross-sectional study demonstrated a high prevalence of psychiatric polypharmacy (67.3%) and fixed-dose combination (FDC) use (41.3%) in a tertiary care psychiatry outpatient setting in Eastern India. Independent predictors of psychiatric polypharmacy were schizophrenia spectrum disorders and middle socio-economic status (SES), while age showed a non-significant trend after adjustment.

Comparison with Previous Studies

The prevalence of psychiatric polypharmacy in our study aligns with earlier Indian reports (50–70%) [9, 13, 19], and is slightly higher than the 64% documented by Das *et al.* [4] in a similar Eastern Indian setting. Internationally, rates vary widely (10–50%), depending on diagnostic profile, availability of treatment options, and local prescribing culture [8, 20]. Higher rates are generally seen in tertiary centres managing treatment-resistant or complex cases, which may explain the magnitude observed here.

Antipsychotics were the most frequently prescribed class, with a marked preference for atypical agents, consistent with the global shift towards second-generation drugs due to their broader efficacy and lower risk of extrapyramidal symptoms [14-16]. The relatively high use of anticholinergics likely reflects prophylaxis against extrapyramidal side effects from typical antipsychotics, though routine use is discouraged.

Fixed-Dose Combination (FDC) Use

Psychotropic FDCs were found in nearly one-quarter of prescriptions. This is comparable to other Indian studies (20–30%) [17, 19]. While certain FDCs, such as antipsychotic–anticholinergic combinations, may improve adherence in selected patients, many available formulations in India lack robust evidence of clinical advantage [11, 12]. Their continued availability despite discouragement by WHO and the Indian Psychiatric Society underscores the need for stronger regulatory oversight.

Socio-Economic Status and Polypharmacy

The association between middle SES and higher polypharmacy is notable. A possible explanation is that this group has better affordability and access compared with lower SES patients but continues to rely on public-sector facilities more than upper SES groups who may seek private care. Similar patterns have been noted in limited Indian studies [9, 13], but the mechanisms remain speculative. Future qualitative research should explore whether affordability, prescriber preference, or patient demand influences these patterns.

Other Prescribing Indicators

Generic prescribing was strikingly low (15.8%), despite national emphasis on promoting generics through initiatives such as Jan Aushadhi. This gap highlights the need for targeted educational and institutional interventions. Similarly, the low use of injectables and antibiotics is encouraging, but continued vigilance is required given the risks of irrational use in psychiatry.

Strengths and Limitations

Key strengths include the real-world setting, use of standardized definitions, and combined evaluation of polypharmacy and FDCs, an approach rarely reported in Indian psychiatric practice. The inclusion of socio-economic data adds useful insights into prescribing disparities. However, limitations must be acknowledged: the modest sample size (n=150) may limit statistical power; convenience sampling introduces selection bias; the single-centre, short-duration design restricts generalizability; and outcomes such as adherence, adverse events, or prescriber rationale were not captured. Variability between psychiatrists, an important confounder, was also not assessed.

Implications for Clinical Practice and Policy

At the clinical level, polypharmacy should be reserved for evidence-based indications such as treatment-resistant schizophrenia or comorbid psychiatric illness. Regular prescription audits and continuing medical education (CME) sessions can reinforce rational use. Patient engagement through education on risks and benefits of multiple medications may further improve adherence.

At the policy level, prescription audits should be prioritized as the most feasible immediate step. Regulatory agencies such as the Drug Controller General of India (DCGI) should continue banning irrational FDCs, while professional bodies like the Indian Psychiatric Society can promote adherence to national guidelines. Integrating rational prescribing metrics into hospital accreditation and electronic prescribing systems could help institutionalize good practices.

CONCLUSION

This study revealed a high prevalence of psychiatric polypharmacy (67.3%) and fixed-dose combination (FDC) use (41.3%) among outpatients in a tertiary care psychiatry setting in Eastern India. Schizophrenia spectrum disorders and middle socio-economic status emerged as independent predictors of polypharmacy.

While certain combinations may be clinically justified, the extent of polypharmacy observed raises concerns regarding safety, cost, and adherence. The findings highlight the need for regular prescription audits, targeted prescriber education, stricter regulation of irrational FDCs, and patient engagement to ensure rational use of psychotropics.

Future research should adopt multicentric, longitudinal designs to assess adverse outcomes, treatment adherence, and prescriber rationale, thereby strengthening the evidence base for safer and more cost-effective psychiatric prescribing in India.

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