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RESEARCH ARTICLE
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EVALUATION OF PRESCRIPTION PATTERN AND RATIONALITY OF FIXED DRUG COMBINATIONS (FDCS) IN A TERTIARY CARE TEACHING HOSPITAL: RETROSPECTIVE OBSERVATIONAL STUDY

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Abstract

Background:
Fixed drug combinations (FDCs) are widely prescribed to improve patient compliance, enhance therapeutic efficacy, and minimize pill burden. However, irrational and indiscriminate use of FDCs can lead to adverse drug reactions, drug interactions, and antimicrobial resistance.

Objective:
To evaluate the prescription pattern, rationality, and regulatory status of fixed drug combinations prescribed in a tertiary care teaching hospital with reference to WHO and Central Drugs Standard Control Organization (CDSCO) guidelines.

Methods:
A retrospective observational study was conducted over six months (January–June 2023) among 400 prescriptions collected from the outpatient departments (OPDs) of Medicine, Surgery, ENT, and Dermatology. Data were analysed for FDC usage, drug class, indication, rationality (as per WHO criteria), and approval status from CDSCO.

Results:
Out of 400 prescriptions, **220 (55%)** contained at least one FDC. The average number of FDCs per prescription was **1.4 ± 0.6**.

Commonly prescribed FDC categories included:

- **Antimicrobial combinations:** 28% (Amoxicillin + Clavulanic acid most common)
- **Analgesic/antipyretic combinations:** 22% (Paracetamol + Ibuprofen)
- **Antihypertensive and antidiabetic combinations:** 18% (Amlodipine + Telmisartan, Metformin + Sitagliptin)
- **Gastrointestinal agents:** 16% (Pantoprazole + Domperidone)
- **Respiratory agents:** 10% (Levosalbutamol + Ambroxol)
- **Vitamins/mineral combinations:** 6%

Rationality assessment (WHO criteria):

- Rational FDCs: 72%
- Irrational/unapproved combinations: 18%
- Insufficient data to judge: 10%

Adverse events were reported in **6%** of patients, mainly gastritis and mild hypersensitivity.

Conclusion:

FDCs were widely prescribed, particularly for infectious and chronic conditions. While most combinations were rational and CDSCO-approved, the presence of irrational or non-approved FDCs underscores the need for continuous prescription audit and clinician education to ensure safe and rational use.

Keywords: Fixed drug combinations, rationality, CDSCO, WHO guidelines, prescription pattern, pharmacovigilance

Introduction

Fixed Drug Combinations (FDCs) are formulations containing two or more active ingredients in a fixed ratio of doses. They are commonly used to enhance therapeutic efficacy, improve patient adherence, and reduce pill burden, especially in chronic diseases such as hypertension, diabetes, and tuberculosis (1,2).

However, irrational FDCs—those lacking pharmacological justification, safety, or regulatory approval—pose significant risks, including drug–drug interactions, adverse effects, and increased resistance in case of antimicrobials (3,4).

In India, the proliferation of irrational FDCs led the **CDSCO** to review and ban several unapproved combinations (5). Therefore, assessing the prescription pattern and rationality of FDCs in clinical settings is essential for promoting rational use and ensuring patient safety.

This study aims to evaluate the prescription pattern, therapeutic rationale, and regulatory approval status of FDCs prescribed in a tertiary care hospital and to identify areas needing improvement in prescribing practices.

Materials and Methods

Study Design and Setting:

A retrospective observational study was conducted in the Department of Pharmacology in collaboration with Medicine, Surgery, ENT, and Dermatology departments of a tertiary care teaching hospital.

Study Duration: January–June 2023

Sample Size: 400 prescriptions randomly selected from OPDs.

Inclusion Criteria:

- Prescriptions containing at least one FDC
- Adult patients (≥18 years)

Exclusion Criteria:

- Incomplete prescriptions
- Topical-only preparations

Data Collection:

Prescription details were collected and recorded in a structured proforma, including patient demographics, diagnosis, FDC composition, and indication. Each FDC was evaluated for:

- **Therapeutic class**
- **Rationality (WHO criteria)**
- **Approval status (CDSCO database)**

Statistical Analysis:

Data were analysed using SPSS version 26. Results were expressed in percentages and mean ± SD. Chi-square test was used for categorical variables; $p < 0.05$ was considered statistically significant.

Results

Table 1. Demographic Characteristics

Parameter	Value
Total prescriptions analysed	400
Mean age (years)	45.6 ± 13.2
Male: Female ratio	1.1: 1
Average drugs per prescription	5.6 ± 1.8
Average FDCs per prescription	1.4 ± 0.6

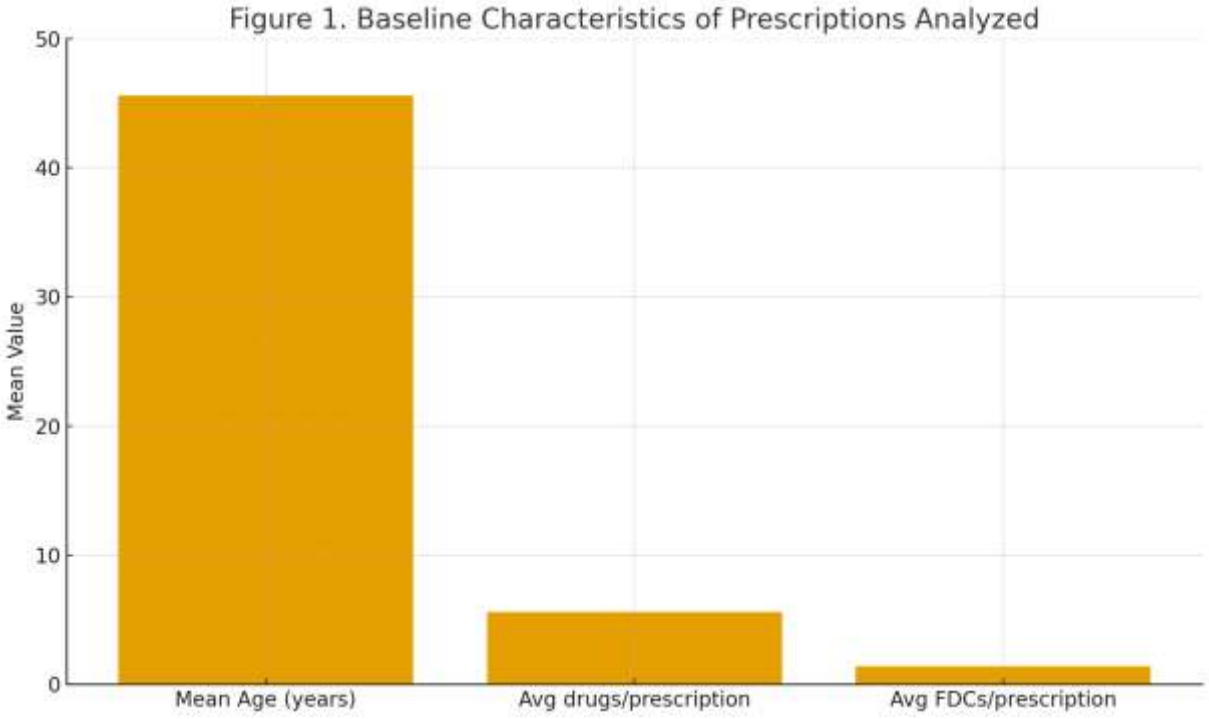


Table 2. Distribution of Fixed Drug Combinations by Therapeutic Class

Drug Category	% Of Prescriptions	Commonly Used FDCs
Antimicrobials	28%	Amoxicillin + Clavulanic acid
Analgesic/Antipyretic	22%	Paracetamol + Ibuprofen
Antihypertensive/Antidiabetic	18%	Amlodipine + Telmisartan, Metformin + Sitagliptin
Gastrointestinal	16%	Pantoprazole + Domperidone
Respiratory	10%	Lev salbutamol + Ambroxol
Vitamins/Minerals	6%	Multivitamins + Zinc

Figure 2. Distribution of Fixed Drug Combinations by Therapeutic Class

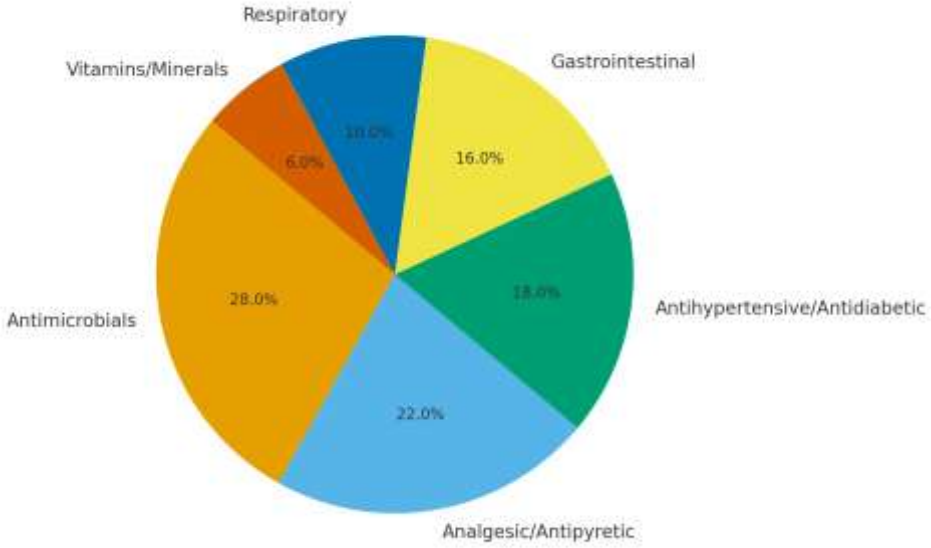


Table 3. Assessment of Rationality and Approval

Parameter	Percentage
Rational (WHO criteria met)	72%
Irrational combinations	18%
Insufficient data	10%
CDSCO-approved FDCs	82%
Non-approved FDCs	18%

Figure 3. Rationality, Approval, and Adverse Effects of FDCs

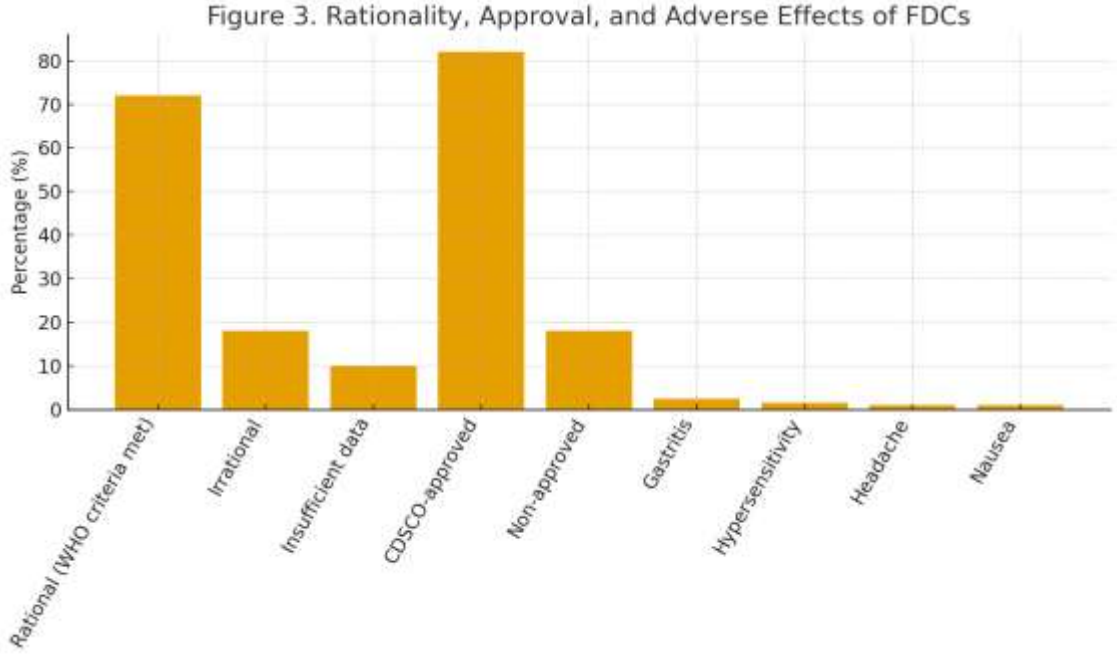
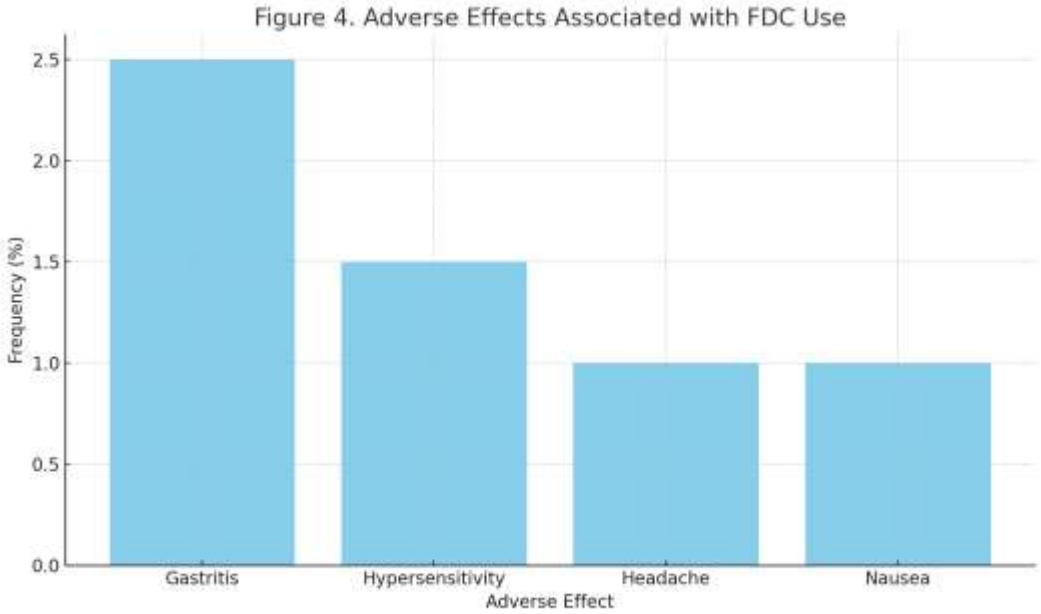


Table 4. Adverse Effects Associated with FDC Use

Adverse Effect	Frequency (%)
Gastritis	2.5
Hypersensitivity	1.5

Adverse Effect	Frequency (%)
Headache	1.0
Nausea	1.0



Discussion

The widespread prescription of FDCs (55% of total prescriptions) observed in this study indicates their increasing popularity in clinical practice due to better compliance and perceived convenience (6,7).

Antimicrobial and analgesic FDCs were most frequently prescribed, consistent with previous Indian studies (8,9). The predominance of **amoxicillin + clavulanic acid** and **paracetamol + ibuprofen** reflects commonly used evidence-based combinations.

However, **18% of prescriptions contained irrational or unapproved FDCs**, particularly among gastrointestinal and respiratory agents, similar to findings reported by Sharma et al. (10).

Rational combinations were identified by fulfilling pharmacokinetic compatibility, synergistic action, and safety criteria as per WHO guidelines (11). The presence of non-approved FDCs highlights the need for stronger regulatory enforcement and periodic prescription audits.

Adverse effects were mild and infrequent, aligning with reported literature (12).

Conclusion

Fixed drug combinations are extensively used across multiple therapeutic areas. Most prescribed combinations were rational and approved by CDSCO; however, irrational and non-approved formulations persist. Regular training of prescribers, enforcement of regulatory policies, and promotion of evidence-based therapy are essential to ensure rational use and safeguard patient health.

References

1. World Health Organization. Rational use of drugs: report of the conference of experts. Nairobi: WHO; 1985.
2. CDSCO. Fixed Dose Combinations approved by DCGI. Govt. of India; 2023.
3. Hazra A, et al. Rationality of fixed-dose combinations: An Indian perspective. Indian J Pharmacol. 2020;52(5):341–347.
4. Tripathi KD. Essentials of Medical Pharmacology. 9th ed. Jaypee Brothers; 2022.

5. Ministry of Health and Family Welfare. Ban on irrational FDCs in India: Gazette Notification, 2022.
6. Shankar PR, et al. Fixed-dose combination use in clinical practice: Trends and challenges. Int J Basic Clin Pharmacol. 2021;10(3):201–208.
7. Gupta R, et al. Pattern of fixed dose combination prescriptions in India. J Family Med Prim Care. 2022;11(4):1331–1336.
8. Chatterjee S, et al. Prescribing pattern of FDCs in a tertiary hospital: A cross-sectional study. Indian J Pharm Pract. 2020;13(1):25–30.
9. Banerjee S, et al. Evaluation of FDC rationality using WHO criteria. Int J Pharm Sci Rev Res. 2022;74(2):49–55.
10. Sharma M, et al. Regulatory assessment of fixed-dose combinations: Indian scenario. Clin Ther. 2021;43(9):1592–1600.
11. WHO. Model List of Essential Medicines: Guidance on fixed-dose combinations. Geneva: WHO; 2023.
12. Deshpande K, et al. Adverse drug reactions associated with FDCs: A pharmacovigilance perspective. J Clin Pharmacol. 2022;62(11):1378–1384.