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## A study on drug utilization pattern of fixed dose combinations in the department of medicine in Gauhati Medical College Hospital

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### Abstract

**Background:** Fixed Dose Combinations (FDCs) are being widely used now-a-days. The use of FDCs has decreased the incidence of drug resistance, improved patient compliance, has made individual drugs more efficacious and there has been a decline on pill burden on patients. But there is an impending threat to health and economy sector of a country leading to drainage of resources due to irrational prescribing practice of FDCs. For limiting irrational FDCs prescribing, a proper prescription audit is mandatory.

**Objectives:** This study is aimed to study about the drug utilization pattern of fixed dose combination and to evaluate the rationality of FDCs prescriptions in the department of Medicine in Gauhati Medical College and Hospital; Guwahati.

**Methods and Materials:** This study is a prescription based non-comparative, observational prospective study. After taking permission from the Institutional Ethical Committee; a total of 600 prescriptions of patients were analysed for over a period of 6 months from 1<sup>st</sup> August 2016 to 31<sup>st</sup> January 2017. The rational use of FDCs was evaluated by analyzing the drug prescriptions. Data was analysed by descriptive studies.

**Results:** Amongst the total 600 prescriptions evaluated, FDCs were prescribed in 524 (87.3%) prescriptions with an average of 1.8 per prescription. The age group in which FDCs were most commonly prescribed is 31 to 40 years (26.33%). FDCs were prescribed in higher number in case of male patients (54.58%). The most common route of administration of FDCs was oral route (54.45%). FDCs were most commonly prescribed for respiratory and gastro-intestinal system ailments. Out of the 944 FDCs only 23.41% FDCs were included in WHO Essential Medicines Lists (EML) (2017) and National List of Essential Medicines (2015). Nutritional supplements were the most commonly prescribed FDCs (66.53%). While evaluating the prescribed FDCs, 66.31% were irrational FDCs while 33.69% were considered as rational. Adverse drug reactions in the form of diarrhea (6 no. of cases) has been observed upon administration of Amoxycillin-Clavulanic acid. The management of these 6 cases have been done conservatively.

**Conclusion:** Our study on FDCs have emphasized upon the fact that it is of utmost necessity both on the part of health care professionals as well as patients to follow proper prescription writing format, adhere to Essential List of Medicines, dispose proper dosages of FDC and prescribing generic names as far as practicable. Health care professionals should have regular orientation programme regarding recent upcoming changes in Essential List of Medicine and acquire recent inputs from relevant journals, newsletters and gather all sorts of recent information regarding drugs and their pharmacokinetic, pharmacodynamic properties and various interactions.

**Keywords:** Fixed dose combinations, Medicine, Drug Utilization Pattern

### 1. Introduction

A 'Fixed Dose Combination' (FDC) is a combination of two or more active ingredients in a fixed ratio of doses. This term means active ingredients of different formulations or brands are combined in a particular combination or fixed ratio<sup>[1]</sup>. For the approval of the FDCs, each active ingredient of an FDC should fulfill the need of a defined population group. Simultaneously, the combination needs to have a proper documented advantage in comparison to single compounds given individually in terms of the therapeutic effect, safety or compliance<sup>[2]</sup>.

On using FDCs the incidence of drug resistance has declined, patient compliance has improved, individual drugs have become more efficacious and there has been a decline on pill burden on patients.

FDCs are being widely used now-a-days to treat some major infectious diseases in world like HIV/AIDS, malaria and TB. From public health point of view, the use of FDCs is increasing rapidly.

However, FDCs has certain disadvantages like incompatible pharmacokinetics, fixed dosage, adverse drug reactions, increasing cost or inevitable contraindication of a particular component of FDC in certain physiological and pathological condition of patient.

Sometimes, such adverse drug reactions become potentially serious and needs urgent identification and proper management.

The Seventeenth WHO model list of essential medicines (March 2011) has enlisted 25 approved FDCs however, in India, National List of Essential Drugs has enlisted 354 essential drugs out of which 14 are FDCs and in market over seventy dangerous FDCs are sold [3, 4, 5] So, recently there is a marked increase in use of irrational FDCs and many of them are dispersed at present as over the counter (OTC) drugs.

There is an impending danger to health and economy sector of a country leading to drainage of resources due to irrational prescribing practice [6]. It is therefore very essential to constitute proper guidelines for use of FDCs in order to limit their irrational prescribing and this goal can be achieved only through a proper prescription audit [7, 8, 9].

With this aim, the present study has been planned to study the prescription pattern of FDCs in Gauhati Medical College, India and thereby to determine whether there is any need for any sort of educational intervention.

## 2. Materials and methods

This prescription based non-comparative, observational, prospective study was conducted in the In-patient Department of Medicine of Gauhati Medical College Hospital, Guwahati. The study was conducted for over a period of 6 months from 1<sup>st</sup> August 2016 to 31<sup>st</sup> January 2017 after taking approval from Institutional Ethical Committee. Drug usage pattern of fixed dose combinations

was evaluated by analyzing the drug prescriptions. A total of 600 prescriptions of patients were analysed. Prescriptions containing fixed dose combinations of patients of either sex and all ages were considered, whereas prescriptions without fixed dose combinations and with incomplete information and case notes were excluded. Throughout the study the names of the patients and prescribing doctors were kept confidential. To evaluate the drug utilization pattern of fixed dose combinations total number of drugs prescribed, average number of fixed dose combinations drugs per prescription, most common route of administration were noted. Data was analysed by descriptive statistics.

## 3. Results

In this study, a total of 600 prescriptions were evaluated from the In-patient Department of Medicine in Gauhati Medical College Hospital. Out of these 600 prescriptions, FDCs were prescribed in 524 (87.3%) prescriptions with an average of 1.8 per prescription [TABLE-1]. Out of the total 2756 formulations prescribed, 944(34.25%) formulations were FDCs.

The age group in which FDCs were most commonly prescribed is 31 to 40 years (138, 26.33%) followed by 41 to 50 years (126, 24.05%) and 51 to 60 years (118, 22.52%). FDCs prescribed in male patients (286, 54.58%) was higher than in female patients (238, 45.42%). FDCs were most commonly prescribed by oral route (514, 54.45%) followed by intravenous route (430, 45.55%). FDCs were most commonly prescribed for respiratory and gastro-intestinal system ailments.

It was observed that out of the 944 FDCs prescribed, only 221 (23.41%) FDCs were included in WHO Essential Medicines Lists (EML) (2017) and National List Of Essential Medicines (2015). Nutritional supplements were the most commonly prescribed FDCs (628, 66.53%) followed by antimicrobials (228, 24.15%) and proton-pump inhibitors (88, 9.32%) [FIGURE-1]. Out of 944 FDCs prescribed, 626 (66.31%) were irrational FDCs [FIGURE-2] while 318 (33.69%) FDCs were considered rational [TABLE-2].

Drug associated diarrhea (6 cases) has been observed with the administration of Amoxycillin – Clavulanic acid, which was managed conservatively.

**Table 1:** Details of the prescription analyzed

S.no	Variables	Number
1.	Total no. of prescriptions analyzed	600
2.	Prescriptions with FDCs	524
3.	Prescriptions with rational FDCs	182
4.	Prescriptions with irrational FDCs	342
5.	Average no. of FDCs per prescription	1.8

**Table 2:** Frequency of rational FDCs prescribed

S.no	Formulations	Number
1.	Tablet Ferrous salts + Folic Acid	108
2.	Inj. Piperacillin + Tazobactam	28
3.	Inj. Amoxycillin + Clavulanic Acid	42
4.	Inj. Ceftriaxone + Sulbactam	81
5.	Inj. Cefotaxime + Sulbactam	16
6.	Tab. Amoxycillin + Clavulanic Acid	43

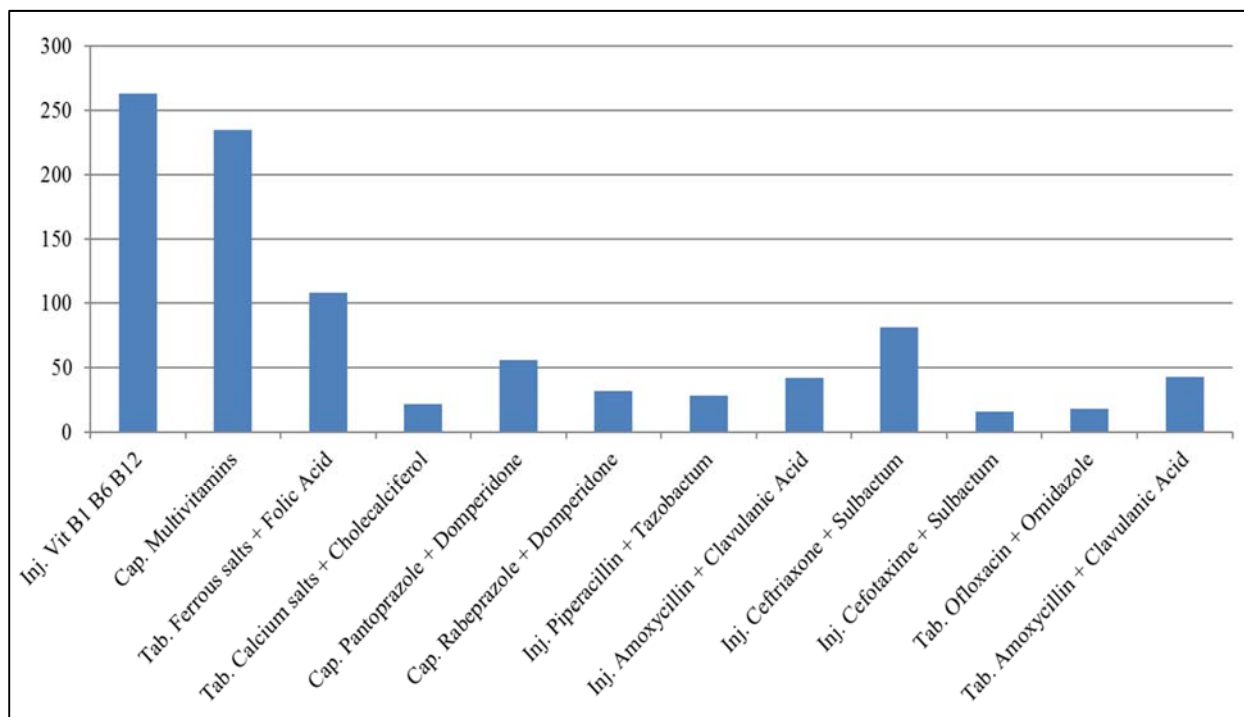


Fig 1: Frequency of various FDCs prescribed

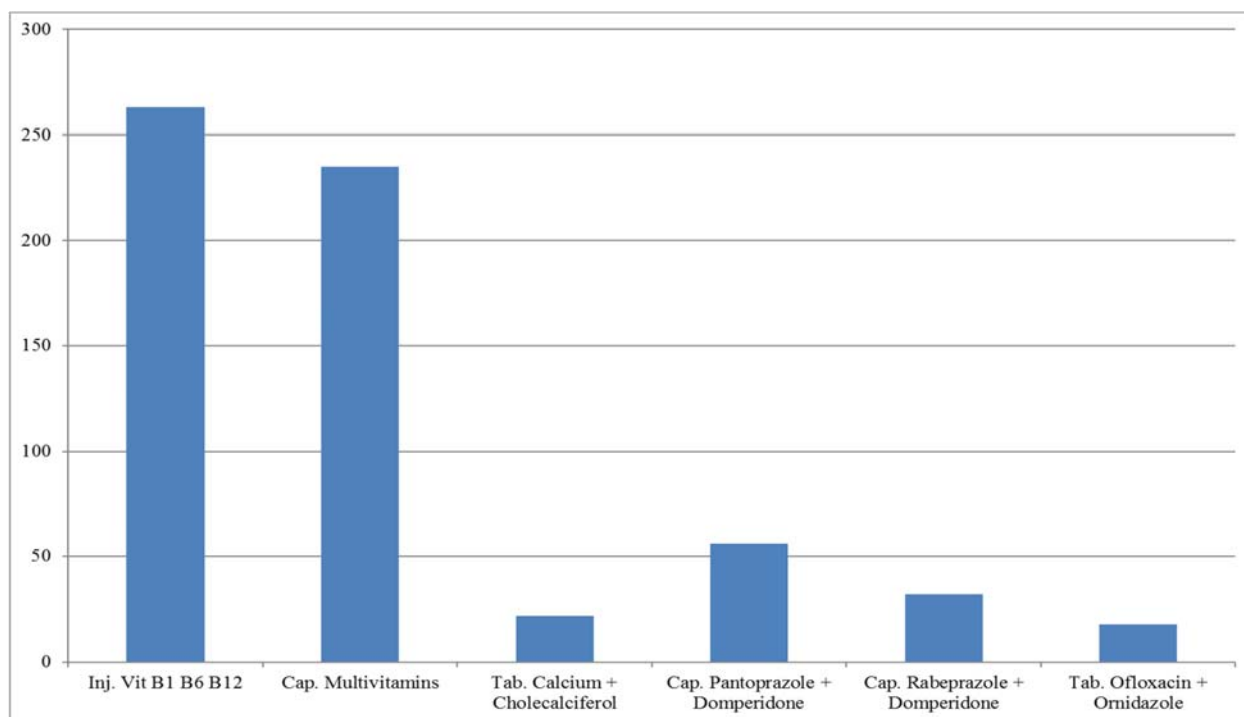


Fig 2: Frequency of irrational FDCs prescribed

**4. Discussion**

In third world countries, due to irrational prescription pattern there is an wastage of 30-40% of the total health budget of those countries upon drugs [10]. There has been an increasing trend of prescribing FDCs amongst the health care professionals [11, 12]. In our present study, the average number of FDCs prescribed per prescription was 1.8 (as shown in table no. 1) as compared to 1.3 in Kopal Sharma *et al* [13].

After analyzing the results of our study we got drugs prescribed from Essential Drug List was only about 23.41% however, in other studies it was reported as 95.78% by Biswas *et al*. [14] and 51% by Georgekutty *et al* [15]. There is a lack of knowledge of rational use of FDCs amongst the prescribing clinicians in our study. The present study showed 66.31% irrational FDCs (Fig. 2) use while 33.69% rational FDCs use (Table 2). So, there is a need of proper educational intervention amongst the healthcare

professionals of the hospital included in our study regarding rational prescription pattern of FDCs [11, 16, 17].

As per WHO guidelines, vitamin combinations should not be used frequently [2]. Combination of H-2 blockers and proton pump inhibitors with antiemetic drugs is an irrational use [18]. Injudicious use of antibiotic FDCs should be stopped as soon as possible because it will lead to development of resistant strains of organisms and the pipeline of new antibiotic regimens will decline [2,19]. In our study, the most commonly prescribed are the nutritional supplements (66.53%) followed by antimicrobials (24.15%) and PPI's (9.32%). So, after nutritional supplements antimicrobials has been widely prescribed in this study which needs to be limited to rational usage only.

The study showed that oral route of administration has been the most commonly used route of administration for FDCs and the age groups who have been most commonly prescribed FDCs was in the range of 31-40 years (26.33%). In our study, the irrational use of multivitamins as nutritional supplements in form of FDCs was 52.75% in comparison to 7.4% in another study by Kopal Sharma *et al.* and in many more previous studies where such irrational prescription of multivitamins in form of FDCs have been done [20, 21, 22].

In addition our study showed that an adverse drug reaction in the form of diarrhea has been manifested in six number of patients upon administration of Amoxycillin-Clavulanic acid combination.

So our present study suggests that health care professionals should have regular orientation programme regarding recent upcoming changes in Essential List of Medicine and acquire recent inputs from relevant journals, newsletters and gather all sorts of recent information regarding drugs and their pharmacokinetic, pharmacodynamic properties and various interactions.

## 5. Conclusion

Our study on FDCs have focused on the point that it is beneficiary both on the part of health care professionals as well as patients to follow proper prescription writing format, adhere to Essential List of Medicines, dispose proper dosages of FDC and prescribing generic names as far as practicable.

All this will lead to rational prescription pattern and events of Adverse Drug Reactions monitoring, drug resistance etc. will be reduced to a great extent. Moreover, proper awareness programmes should be routinely held for the health care professionals and their sources of information regarding various drugs needs neither be implemented nor be influenced by external irrelevant sources.

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