

## STUDY OF FIXED DOSE COMBINATIONS IN A TERTIARY CARE HOSPITAL

SHAUNAK A PISAL<sup>1</sup>, SUJATA A JADHAV<sup>2\*</sup>, CHITRA C KHANWELKAR<sup>2</sup>, VANDANA M THORAT<sup>2</sup>,  
SOMNATH M MATULE<sup>2</sup><sup>1</sup>Department of Third Phase UG Student, Krishna Institute of Medical Sciences, Karad, Maharashtra, India. <sup>2</sup>Department of Pharmacology, Krishna Institute of Medical Sciences, Karad, Maharashtra, India. Email: drjadhavsujata@gmail.com

Received: 05 May 2016, Revised and Accepted: 25 August 2016

## ABSTRACT

**Objective:** To study and analyze the pattern of fixed dose combinations (FDCs) in medicine outpatient clinic.**Methods:** The study is prospective cross-sectional study was conducted for 2 months in medicine outpatient clinic in tertiary care hospital. After taking approval from Institutional Ethics Committee, the data were collected on every working day of the hospital. Prescriptions from the patients coming to medicine outpatient clinic outpatient department were taken and required information is filled in data record form.**Results:** A total of 83 prescriptions were included in the study. Out of 287 drugs, 111, i.e., 39.92% were fixed dose formulations. As per drug category analysis, nutritional supplements were used (47.74%). While 27.02% and 9.03% of FDCs were given for cardiovascular complains and respiratory complains, respectively. FDCs used for other conditions were 16.21%. About 29.72% of total FDCs are included in approved list of FDCs by Drugs Controller General of India (DCGI), November 2014.**Conclusion:** 39.92% drugs are FDCs out of total prescribed drugs. Nutritional supplements are prescribed in higher concentrations. Out of total FDCs only 29.72% were included in DCGI approved list of FDCs and only four FDCs are found in the WHO list of essential drugs.**Keywords:** Fixed dose combinations, Prescriptions, Approved, Drugs Controller General of India.© 2016 The Authors. Published by Innovare Academic Sciences Pvt Ltd. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>) DOI: <http://dx.doi.org/10.22159/ajpcr.2016.v9s3.12615>

## INTRODUCTION

Fixed dose combination (FDC) is a combination of drugs that includes two or more active pharmaceutical ingredients combined in a single dosage form. Such combination of drugs are being used in wide range of conditions and are also used in the treatment of HIV/AIDS, tuberculosis, malaria, etc., which are considered to be foremost infectious disease threats in the world [1]. The Food and Drug Administration, the USA defines a combination product as a product composed of any combination of a drug and a device or a biological product and a device or a drug and a biological product or a drug, device, and a biological product [2].

Fixed ratio combination products are acceptable only when the dosage of each ingredient meets the requirement of a defined population group and when the combination has a proven advantage over single compounds administered separately in therapeutic effect, safety or compliance [3]. The use of FDCs is associated with many advantages such as synergistic action, increased efficacy, improved patient compliance, and reduced adverse effects. However, it also has some disadvantages such as additional side effects and mismatched pharmacokinetics; different clinical indications for different ingredients, delayed action of components, contraindications of one compound can cause contraindication of whole product, etc. [4].

Because of advantages, FDCs are accepted worldwide and used widely. The WHO has prepared some guidelines for the use of FDCs and also have declared a list of it [5]. However, many irrational FDCs are also present in the market and are used rampantly [6]. The rationality of FDCs is based on certain aspects which are as follows [7].

- The drugs in the combination should act by different mechanisms
- The pharmacokinetics must not be widely different

- The combination should not have supra-additive toxicity of the ingredients.

Studies regarding the use of FDCs have been conducted in Gujarat [8] and other states of India. Some meta-analysis studies are also done for this topic. As no such studies have been conducted in this area, we conducted this study in our teaching hospital. The study aims to collect information about the use of FDCs in medicine outpatient clinic in the Krishna Hospital, Karad. The study is conducted over a period of 6 weeks. This study would help us - to evaluate prescribing pattern of FDCs and to analyze their rationality.

## METHODS

The study was conducted in the Department of Medicine, Krishna Hospital, Karad. This is a prospective cross-sectional study which was conducted over a period of 6 weeks in the medicine outpatient department (OPD) from May 2015 to June 2015.

The patients for the study were selected by following criteria.

**Inclusion criteria**

Patients who visited the medicine outpatient clinic in the study period, prescription given only by the consultant and patients who agreed to give informed consent are included in the study.

**Exclusion criteria**

Patients not willing to give the informed consent are excluded from the study.

The data were collected on every working day of the hospital. This cross-sectional study was started after approval by the institutional ethical committee. We got 83 patients according to our inclusion and exclusion criteria. All patients visiting the medicine OPD during the study period

and the prescriptions from consultants only were considered. The data were collected on data record form. The sociodemographic details such as age, sex, occupation, chief complaints, and prescribed drugs with dosage were recorded. The total number of FDCs prescribed was calculated. The data obtained were subjected to descriptive statistical analysis using Microsoft Excel.

## RESULTS

A total of 83 patients included in the study according to inclusion and exclusion criteria. Percentage of prescribed FDCs as compared to total drug prescribed is shown in Table 1. Rationality of FDCs calculated as per the WHO list of essential drugs and the results of this are shown in Table 2. In Table 3 system wise distribution of prescribed FDCs is shown.

## DISCUSSION

The objective was to study the prescription pattern of FDCs in medicine outpatient clinic at Krishna Hospital, Karad and also to find out the rationality of prescribed FDCs.

According to our study, out of 83 prescriptions, 64 prescriptions had FDC formulations. Thus 77.13% of prescriptions contain FDC formulations. The total number of FDCs prescribed is about 39.92%, i.e., out of 287 drugs (from 83 prescriptions) 111 are FDCs. In a similar study conducted in Gujarat, out of 1170 prescriptions, 941 contained FDC formulations, i.e., 80.3%. Therefore, comparison of both the studies shows that the percentage of use of FDCs is nearly the same [8]. As our study was conducted in OPD, the majority of prescriptions were given by oral route. Some were topical preparations.

As per drug category analysis, a higher number of FDCs containing nutritional supplements were used (47.74%). While, 27.02% of FDCs were given for cardiovascular complains. Our results differ from the study by Balat *et al.* as their study concludes that 20.2% FDCs contains nutritional supplements and 18.1% for central nervous system complains [8].

Among all the FDCs, about 70.28% of them were irrational according to the list of FDCs approved by Drugs Controller General of India, November 2014. This number is higher by 10% from the study conducted in Gujarat [8]. From the prescribed FDCs only 4 are included in the WHO list of essential drugs, 2015. In the study conducted by Bangalore *et al.*, it was found that compliance of patient is better with the use FDCs [9]. Our study was conducted for short duration; it will not represent the entire population. There is no follow-up in our study, so we could not compare the compliance and adverse drug reaction profile of two types of formulations. We will extend this study to observe the compliance, efficacy, and adverse drug reaction profile of FDCs for long duration.

## CONCLUSION

FDCs used are about 39.92%. Most of the FDCs are used as nutritional supplements. Out of total FDCs used, 29.72% FDCs are rational and 70.28% FDCs are irrational. While prescribing these drugs, precaution should be taken as there are rational as well as irrational combinations available in the market.

**Table 1: Percentage of FDCs prescribed in total number of drugs**

Total number of drugs	Number of FDCs	Percentage of FDCs	Other (%)
287	111	39.92	60.08

FDC: Fixed dose combination

**Table 2: Rationality of the prescribed FDCs**

Number of FDCs	Rational FDCs	Percentage of rational FDCs
111	33	29.72

FDC: Fixed dose combination

**Table 3: System-wise classification of FDCs**

System	Number of FDCs	Percentage of FDCs
Nutritional	53	47.74
CVS	30	27.02
RS	10	9.03
Others	18	16.21

FDC: Fixed dose combination, CVS: Cardiovascular system, RS: Respiratory system

## ACKNOWLEDGMENT

Authors wish to acknowledge the Medical Director of Krishna Hospital and Research Center, Karad. Furthermore, we wish to thank Head of Department of Medicine as well as all consultants of Medicine Department for their cooperation. We also extend thanks to the patients involved in the study.

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