

A Survey on Awareness of Fixed Dose Combinations (FDCs) among Patients, Physicians and Pharmacists at Pune and Beed (India)

Patil PJ*, Patil MJ¹, Patil VR², Deshmukh TA², Band SS¹

¹Department of Pharmacology, Marathwada Mitra Mandal's College of Pharmacy, Pune – 411 033(M. S.)

²Tapi Valley Education Society's Hon. Loksevak Madhukarrao Chaudhari College of Pharmacy, Faizpur Dist.: Jalgaon- 425503 (M. S.)

ABSTRACT

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Fixed dose combinations (FDCs) of pharmaceutical products are flourishing in the Indian pharmaceutical market. It was found out that many FDCs were irrational. In consequence to that, some FDCs have been withdrawn from the market. This paper aims to evaluate awareness about the FDC among patient, pharmacist and physicians and to create awareness in society in general. Also, opinion regarding rationality and safety of FDCs were determined.

Three different questionnaires containing different questions were prepared for patient, pharmacist and physicians. Surveys were conducted among patients (n=50), pharmacists (n=55) and physicians (n=40). Questionnaires having different questions were presented to respective personnel individually. Collected data was tabulated and percentage responses were compared.

It was found that there was contrast in the thinking of physician and pharmacist vs patient on rationality of FDCs. Majority of the physicians and pharmacists thought that FDCs are rational, whereas patients thought FDCs as irrational. In general, it was found out that there was no specific storage condition for FDCs as compared to single drug formulation. Physicians and pharmacists agreed that FDCs are more convenient to patient, whereas there is tie on these issues among patients. All physicians, pharmacists and patients unanimously agreed on the issue that FDCs are more cost effective than single drug.

Keywords: Awareness, Fixed dose combinations, Patients, Pharmacists, Physicians, Rational Drug Therapy, survey.

INTRODUCTION

FDC is a combination of two or more active ingredients in a fixed ratio of doses. This term is generically used to mean a particular combination of active ingredient irrespective of the formulation or brand. It may be administered as single entity products given along with or as a finished pharmaceutical product.¹

It is an accepted fact that an FDC be treated as a new drug, because by combining two or more drugs, the safety, efficacy, and bioavailability of the individual Active Pharmaceutical Ingredient (API) may change. As per the Drugs and Cosmetic Act, 1940, any new drug and the permission to market a drug is to be given by the Drugs Controller General of India (DCGI). As per rule 122(E) of the Drugs & Cosmetic Rules, 1945, the same criteria holds good for US markets as well. More than one-third of all the new drug products introduced worldwide during the last decade were fixed dose combination (FDCs) preparations. The trend varied from country to country. In Japan, only 10 percent of the new products were fixed dose combinations, whereas, in European countries like Spain, it was up to 56 percent. However, such statistical data are lacking for the developing countries.²

Presently, there is lot of debate over rationality and irrationality of FDCs. As, there are two sides of each coin FDCs do also have advantages and disadvantages. It is up to the stakeholder to misuse it or use it judiciously by maintaining the balance. Considering, the present scenario it is observed that the balance is tilting towards misuse of the concept of FDC. The reasons for misuse are: most commercial approach of industry, casual approach of all the stakeholders of health care regarding the rational drug therapy. Also, there is lack of awareness and orientation among patient, pharmacist and physician.^{2,3,4,5}

CIMS list more than 100 irrational drug combinations which are not approved in any developed country but are being marketed in India. These facts have to be taught to undergraduate medical and pharmacy students in their formative years of learning. Hence, when they address the disease like malaria, tuberculosis, AIDS, hypertension etc. they should be logical in selecting appropriate FDCs and shall not get influenced by the marketing trick and false claim made by pharmaceutical industry. Moreover, medical and pharmacy undergraduate curriculum shall also include rational use of FDCs and implementation of good ethical practices for use of FDCs.⁶

Hence, the present survey was undertaken to address the issue of lack of understanding and awareness among all stakeholders of health care i.e. patient, pharmacist and physician.

Address for Correspondence:

P. J. Patil, Department of Pharmacology, Marathwada Mitra Mandal's College of Pharmacy, Thergaon (Kalewadi), Pune-411 033 (M.S.)

E-mail: pravin2k2001@yahoo.com

MATERIAL AND METHODS

Literature survey was carried out to design questionnaires for survey on FDCs. Based on present need; three different questionnaires containing different questions were prepared for patient, pharmacist and physicians. Questionnaires were presented in Table No. 1, 2, 3 for patient, pharmacist and physician respectively. Questionnaires were finalized after pilot study conducted on five patients, pharmacists and physicians. Questionnaire contains questions seeking information on various aspects of FDCs. Survey was conducted at Beed Dist. Beed, Maharashtra, India for patients and physicians. Survey was extended to Pune Dist. Pune, Maharashtra, India for pharmacists. Survey was conducted during November, 2011 to January, 2012 among 50 patients, 55 pharmacists and 40 physicians.

Questionnaire was presented personally by a trained pharmacist. Survey on patient was conducted on the patients attending clinics. Survey on pharmacists was conducted on community pharmacists while survey for physicians were conducted on private general practitioners. Patients lacking the technical understanding were given a prior brief introduction about FDCs. Personal details viz. name; contact number address etc. and technical answer were acquired in the questionnaire. Data was compiled in tabular form and percentage responses were compared.

RESULTS

Survey on Patient:

Among surveyed patients, there was tie about awareness for the concept of FDCs. Ninety percentage of them responded that the FDCs are not rational. It was found out that there was tie (50%:50%) over the question of whether they have faced any adverse effects of FDCs and about safety of FDC. Also it was found out that majority i.e. 94% of them were reported any queries about the FDCs to physicians. There was also tie

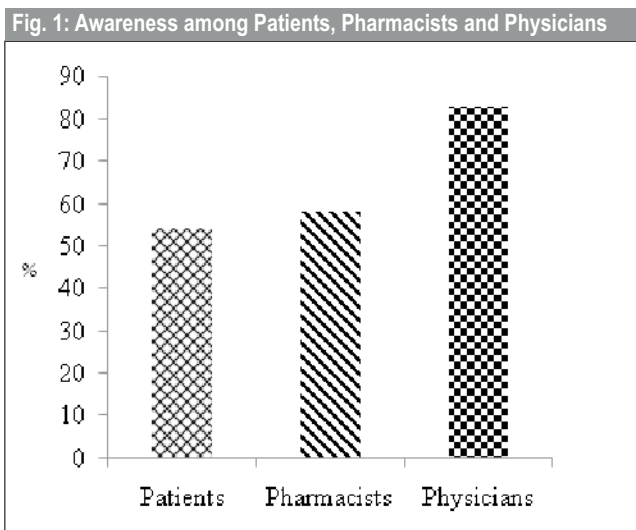


Table 1: Result of Survey on Patient

Sr. No.	Question	% Response	
		Yes	No
1.	Are you aware about FDC?	58	42
2.	Do you think FDC are rational?	08	92
3.	Have you face adverse effects during treatment by FDC?	26	74
4.	Do you think FDC are safe /not?	50	50
5.	Have you reported any incidence during use of FDC?	06	47
6.	Are you aware that these drugs may interact with each other?	50	50
7.	Do you think that FDC have more adversely effects as compared to single drug dose?	50	50
8.	Do you think FDC are more convenient for patients?	50	50
9.	Do you think with FDC patient compliance is more?	50	50
10.	Do you think FDC are cost effective?	56	44

Table 2: Result of Survey on Pharmacist

Sr. No.	Question	% Response	
		Yes	No
1.	Do you FDC are more effective than single drug?	94	05
2.	Do FDC are rational?	69	31
3.	Whether FDC/Single drugs have more demand at OTC?	82	18
4.	Whether doctors prescribe more FDC as compared to single?	87	13
5.	Whether FDC are safe as compared to single drug?	67	33
6.	Do you think that FDC have more stringent storage conditions?	58	42
7.	Do you think FDC are more convenient for patients?	93	07
8.	Do you counsel patient about FDC?	35	65
9.	Do you think FDC are cost effective?	85	15

Table3: Result of Survey on Physician			
Sr. No.	Question	% Response	
		Yes	No
1.	Do you explain patient about FDC?	75	25
2.	Is there any specific storage condition that you are using for FDC as compared to single?	40	60
3.	Do you provide any directions regarding the use of FDC?	97	03
4.	Are you aware whether the FDC is rational or not before prescribing?	95	05
5.	Is there any specific type of category in FDC that you are prescribe mostly(name)	48	52
6.	Have you come across any FDC in which drug interacts?	08	92
7.	Do you think FDC's are more effective as compared to single?	65	35
8.	Do you think FDC's convenience to use as compared to single?	85	15
9.	Do you check patient compliance regarding FDC?	100	00
10.	Do you think FDC are cost effective?	70	30
11.	Do you take care of queries about FDC from patient?	90	10

on whether they are aware about the interactions of active ingredient in the FDCs, whether the FDCs are more convenient for them and cost effectiveness of FDCs. Results were presented in the Table1.

Survey on Pharmacists:

It was found out that majority, i.e. 86% of pharmacists agreed that FDCs are more effective than single drug. Majority, i.e. 70% of pharmacist thinks that FDCs were rational. Majority, i.e. 87% of pharmacists indicated that FDCs were sold more as compared single drug. Moreover, majority i.e. 87% of them agreed that physicians prescribe more FDCs as compared to single drug. Many, i.e. 67% of surveyed pharmacist believe that FDC are safer. There is tie among pharmacist regarding stringent storage condition as compared to single drug. Majority, i.e. 93% of pharmacist agreed that FDCs were more convenient for patient. Majority, i.e. 86% of surveyed pharmacist believes that the FDCs were cost effective as compared to single drugs. Results were presented in the Table 2.

Fig. 2: Opinion of Patients, Pharmacists and Physicians on Rationality of Fixed Dose Combinations

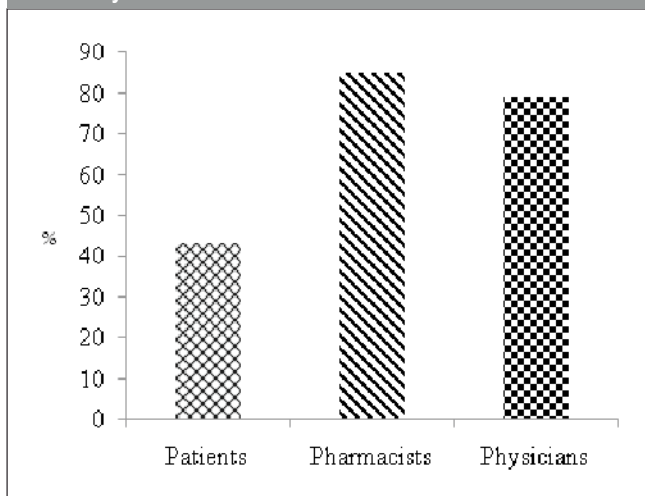
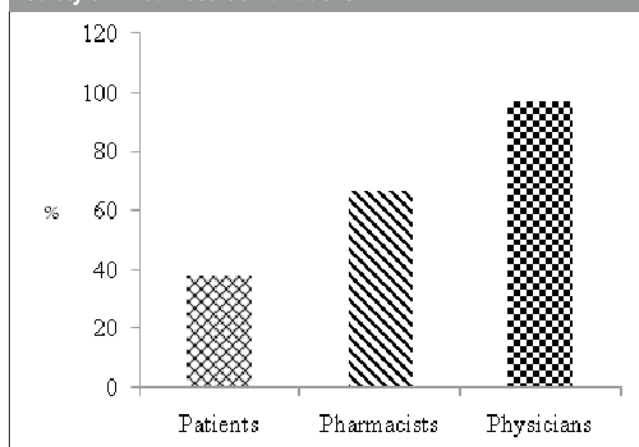


Fig. 3: Opinion of Patients, Pharmacists and Physicians on Safety of Fixed Dose Combinations.



Survey on Physicians:

Physician's survey was carried out at Beed (India). It was found out that about 75% of physician explains about the FDCs to patient. It is found out that the storage condition for FDCs was not specific and it is more or less similar to their single counterpart. It was observed that 98% of physician provides direction for the use of FDCs. Majority i.e. 95% surveyed physicians think on rationality and irrationality of drugs before prescribing it. Majority, i.e. 93% of physicians agreed that the active ingredient in the FDCs does not interact with each other. Many, i.e. 65% of physicians indicate that FDCs are more effective as compared to single. All surveyed physicians agreed that they check patient compliance regarding the prescribed FDCs. Majority, i.e. 70% of surveyed physicians agreed that FDCs are cost effective as compared to single drug. Majority, i.e. 90% of surveyed physicians take note of queries of patient regarding FDCs. Results were presented in the Table No. 03.

Various questions were clubbed in three sub-groups: 1. Awareness 2. Rationality 3. Safety of FDCs. Graphs were presented based on these sub-groups in the figure numbers 1,

2, 3 respectively. It was found that physicians (83%) are the most aware about FDCs as compared to pharmacist (58%) and patients (54%). Majority of pharmacist (85%) and physicians (79%) agreed that FDCs are rational, whereas majority of patients (57%) indicated that FDCs are irrational. Majority of pharmacists (67%) and physicians (97%) agreed that FDCs are safe whereas majority of patients (62%) gave the opinion that FDCs are not safe.

DISCUSSION

As there are two sides of each coin, on one hand FDCs give convenience and cost effectiveness to patients. On contrary, it brings patient safety in jeopardy. This is due to various reasons viz. interactions of drugs in the FDCs, injudicious inclusion of various active ingredients, additive toxicity and using FDCs as marketing and advertising strategy by companies for the sake of commercial purpose only.

This scenario brought the attention of regulatory authorities worldwide. And concept of rationality and irrationality of FDCs has come up. FDCs, should always be based on convincing therapeutic justification. Each fixed dose combination should be carefully justified and clinically relevant (e.g. in cases when each component of the FDCs has several possible dosages, dosages that have shown benefit on clinical outcomes may be preferable).^[7] Even though, use of FDCs is common in practice, the selection of optimum dose and appropriate combination remained largely a matter of trial and error. In a survey in the U.S. on internists and general practitioners (GPs), it was found that: Majority GPs prescribed more FDCs than single drug; physician generally acknowledges both the advantages and disadvantages of FDCs.^[8] As compared to the survey in the U.S. it was found out in this survey that physician prescribes more FDCs similar to U.S. but they are unaware of the advantages and disadvantages of the FDCs. The basis of many FDCs being taught to undergraduate and also being prescribed popularly appears to be irrational to pharmacologist.^[6] Lack of technical understanding about FDCs among patient may be the limitation for the study. Presently, pharmaceutical market is overflow with irrational FDCs. Due to lack of awareness and understanding about the irrational FDCs there is lack of understanding of present scenario of FDCs among society in general. The present study may create the awareness among all stakeholder of health care i.e. patient, pharmacist, physician and society in general. Also, these surveys help to develop judicious mind among patient, pharmacist and physician regarding rational use of FDCs. Hence, similar survey at national level shall be conducted to ignite the consciousness about rational use FDCs.

CONCLUSION

It was found out that there was a contrast in the thinking of physicians, pharmacists vs patients on rationality of FDCs. Majority of physicians and pharmacists think that FDCs are

rational whereas majority of patients think that FDCs are irrational. In general, it was found that there were no specific storage conditions for FDCs as compared to single drug. Physicians and pharmacists agreed that FDC are more convenient to patient whereas there is tie on these issues among patients. All physicians, pharmacists and patients unanimously agreed that FDCs are more cost effective as compared to single drug.

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