



Original Article

Evaluation of knowledge on Fixed Dose Combinations, Concept of P Drugs and Essential Medicines List among Interns and Residents

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Abstract

Background: Fixed dose combinations (FDC) is a combination product of two or more active pharmacological ingredients (API) in a single dosage form. Rational use of medicines (RUM) as defined by WHO requires that “patients receive medications appropriate to their clinical needs, in doses that meet their individual requirements, for an adequate period of time, and at the lowest cost to them and their community.” Essential medicines, a corner stone of RUM is defined as those that satisfy the health care needs of the majority of a population. Treating a particular ailment with effective, safe and good quality drugs is the basic aim of drug therapy. Irrational drug usage can lead to reduction in quality of drug therapy, increased risk of side effects and drug resistance. Hence the present study was conducted to assess the knowledge of FDCs, Concept of P drug and Essential medicine list among interns and residents.

Methods: The questionnaire based study was conducted at Dhanalakshmi Srinivasan Medical College hospital during the month of November – December 2018. A total of 101 participants comprising of interns and residents were included in the study. The study was conducted using a questionnaire about FDC, P drug concept and Essential medicine list. Data was entered in Microsoft excel and data analysis was done using SPSS.

Results: Out of the 101 participants, 80 (79.2%) were interns, 21(20.8%) were residents. Among this, 65% of participants were aware of fixed dose combinations. But 90% of them were unaware of Irrational combination of FDC's. Only 50% participants had knowledge on essential medicine List. Also knowledge on concept of P-drugs and rational use of medicines were lacking.

Conclusion: Knowledge about FDC, essential medicine list and P drug concept about was very little among interns and residents. Hence educational interventions like Continuous Medical Education (CME) programmes should be implemented at different levels of undergraduate curriculum to improve rational prescribing among future clinicians for their Good Clinical Practice.

Keywords: Fixed dose combinations, P-drug, Interns, Essential Medicines List, Residents.

Introduction

Medicines are an integral part of healthcare. More than one drug is frequently used for treatment of either single ailment or multiple comorbid conditions. Sometimes, two or more drugs are combined in a fixed ratio into a single dosage form, which are termed as fixed dose combinations (FDC) [6]. FDC enhance the efficacy of individual drug, decrease the incidence of drug resistance, improve patient compliance and also decrease the pill burden on the patients. Some disadvantages associated with the use of FDC are irrational prescription, unsafe and ineffective treatment, prolongation or exacerbation of illness, higher cost of treatment [1].

In developing countries, there is a growing concern about the expanding number of irrational FDCs increasing the incidence of Adverse Drug Reaction (ADR) like allergy etc which necessitates hospitalisation imposing unnecessary financial burden and ultimately the quality of life is reduced. Combining two or more drugs in a single formulation causes changes in its safety, efficacy and bioavailability profile, hence FDC is treated as a new drug. [2]

Although FDC are available in almost all therapeutic categories, many of them are bizarre combinations. The therapeutic categories having high number of FDCs are for cough, antipyretic preparations, analgesics, muscle relaxants, antimicrobials, drugs for hypertension, dyslipidemia, diabetes and psychiatric disorders along with vitamins and minerals. The FDC formulation may have up to 5 or even more ingredients with or without rationality of their presence and quantity. [3]

Essential medicines are those that satisfy the priority health care needs of the population and intended to be available at all times, in adequate amount and at affordable price. The list is prepared with due consideration to disease prevalence, efficacy, safety, and comparative cost-effectiveness of medicines. [4] Out of the 414 medicines included in the 19th WHO List of

Essential Medicines, only 27 are approved FDCs. [4]

In our country we included 24 FDCs out of 376 entities in the National List of Essential Medicines of India (NLEM) 2015. These FDCs were included after due deliberations in national consultations with scientific justifications. Majority of the FDCs in both the lists belong to antimalarial, antitubercular and antiretroviral drug category which emphasize the importance of FDC use in treatment adherence and prevention of drug resistance. [3]

According to a report by World Health Organization (WHO), 50% of all medicines are prescribed, dispensed or sold incorrectly while 50% of patients fail to take their medicines satisfactorily. Rational use of medicine (RUM) as defined by WHO requires that patients receive medications appropriate to their clinical needs, in doses that meet their own requirements, for an adequate period of time, and at the lowest cost to them and their community. Increase in irrational use of medicines is due to factors such as misleading/false beliefs, inadequate knowledge on part of the consumers and prescribing pressures, professional, profit driven approach of prescribers, lucrative promotional activities by pharmaceutical industry and lack of enforcement of regulations by regulatory authorities. [5]

Objective of the study

To elicit the knowledge on Fixed Dose Combination, Concept of P drug and Essential Medicines List and to find out their practices among interns and residents at a tertiary care teaching hospital.

Materials and Methods

A cross-sectional questionnaire based study was conducted among interns and residents of Dhanalakshmi Srinivasan Medical College & Hospital, Perambalur, Tamil Nadu, India. The study was conducted after obtaining permission from the Institutional Research Committee of Human Subjects (IRCHS) followed by ethical

approval from the Institutional Ethics Committee Of Human Subjects (IECHS), DSMCH. Objectives and procedure of the study was explained to the participants and those willing to participate in the study were gathered at a lecture hall. Those who were not willing to give consent were excluded from the study.

A questionnaire covering the knowledge aspects of FDCs, Concept of p-drug and Essential Medicines List, that contained a total of 20 questions was distributed among the participants. They were given one hour time for filling the questionnaire without discussing with other participants and collected after the allotted time.

The filled questionnaire feedbacks were retrieved from the participants. Quality control was maintained as per the standard protocol. The returned questionnaires were checked for completeness of the data and the descriptive data were expressed in percentages.

Results

The present study was carried out among the resident doctors and interns at a tertiary care hospital. A total of 101 participants were involved in the study, of which 80 (79.2%) were interns and 21(20.8%) were residents.

Figure 1 Designation of Respondents

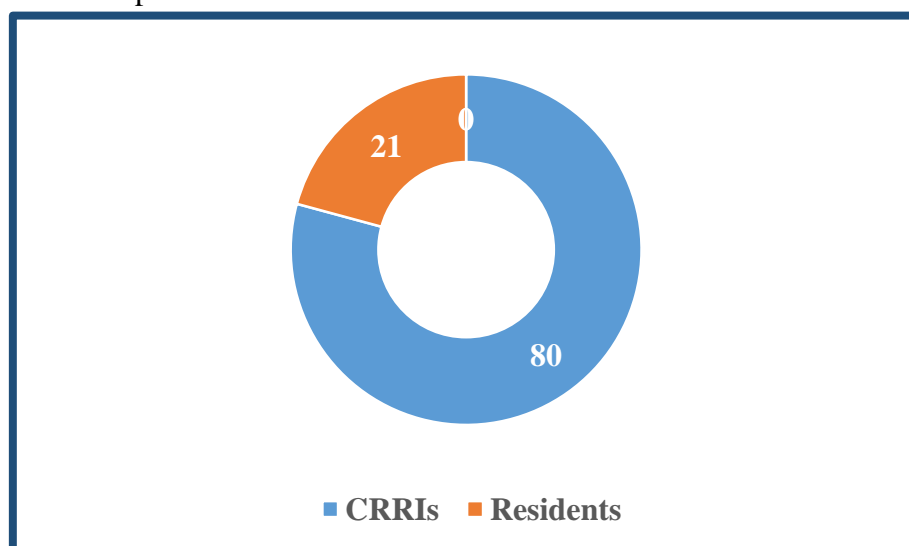


Table 1 Knowledge about FDC

Q.NO	QUESTIONS	YES		NO	
		NO	%	NO	%
1	“FDC” stands for	65	64.4	36	35.6
2	Features of FDC are all except	65	64.4	36	35.6
3	“DCGI” means	56	55.4	45	45.6
4	Do you know that DCGI have banned 344 FDCs in 2016	71	70.3	30	29.7
6	FDCs are included in WHO list of essential medicines	80	79.2	21	20.8

Table 2 Knowledge about Rationality of Drugs

Q.NO	QUESTIONS	OPTIONS	NO	%
5	Choose the irrational combination of FDCs among the following (multiple choice)	a. Diclofenac + Rabeprazole	48	24
		b. Isoniazid+ Rifampicin	16	8
		c. Nimesulide + Diclofenac/Paracetamol	54	27
		d. Amoxicillin+ Potassium clavulanate	30	15
		e. Sulfamethoxazole+ Trimethoprim	13	6.5
		f. Ornidazole+ Ofloxacin	39	19.5

Figure 2 Knowledge about irrational combination of FDCs

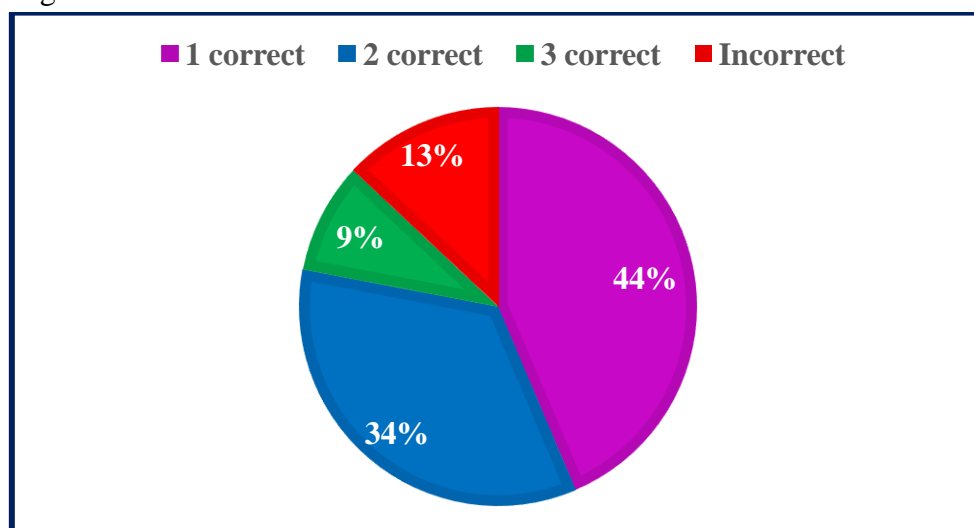


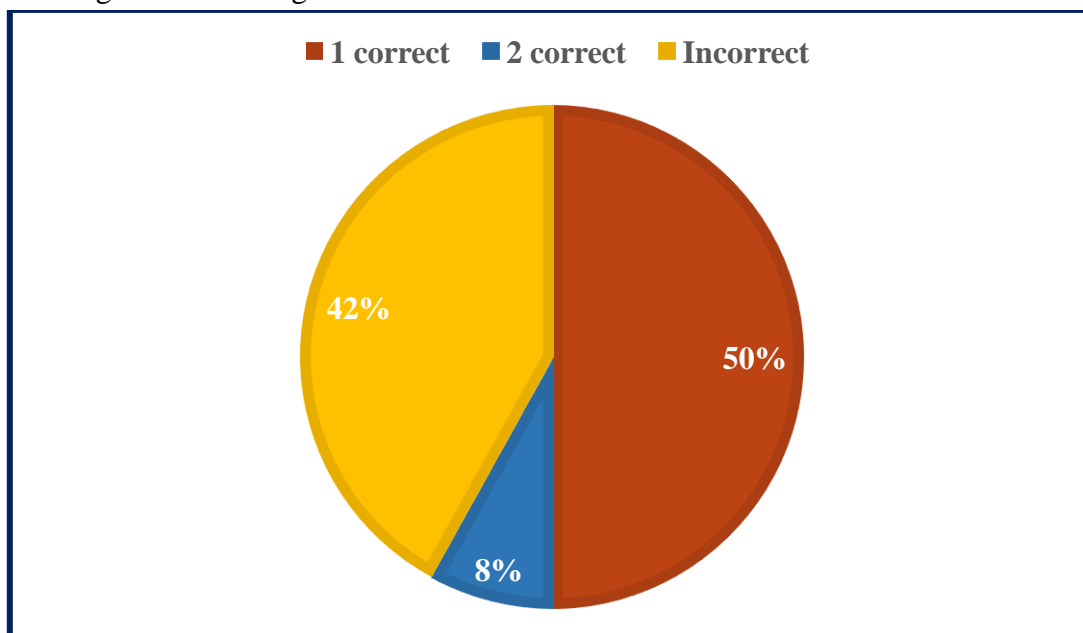
Table 3 Knowledge about essential medicines list

Q. NO	QUESTIONS	YES		NO	
		No	%	No	%
7.	Criteria for selection of Essential Medicines list (EML)	33	32.7	68	67.3
8.	First model W.H.O. list of Essential drugs was published in which year	45	44.6	56	55.4
9.	National list of essential medicines in India was revised in which year	46	45.5	55	54.5
10.	Number of drugs in National (India) List of Essential Medicines currently is	45	44.6	56	55.4
11.	How many FDCs are included in the national list of essential medicines currently	48	47.5	53	52.5
12.	Regarding Essential Medicines list following is true except	<i>a. Vary from country to country</i>		52	51.4
		b. Same for all countries		32	31.6
		c. Same for developed countries		12	12
		d. Same for developing countries		5	5
13.	Purpose of Essential medicines list are all except	a. Promote rational drug use		14	13.8
		b. Development of standard protocols and rational prescribing policies		16	15.8
		<i>c. Individualizing drug usage</i>		52	51.4
		d. Serves as a tool for countries to identify and choose drug priorities		8	8
		e. Should be available in enough quantities in all health care facilities		10	10
14.	Components of WHO model list are all except	<i>a. Quantity information</i>		55	54.4
		b. Indicative cost		14	13.8
		c. WHO model Medicine Monographs		21	20.7
		d. Clinical guidelines		7	7
15.	Following are WHO core prescribing indicators except	a. Average number of drugs per prescription		27	26.7
		b. Percentage of drugs prescribed by generic name		11	10.8
		<i>c. Percentage of drugs adequately labelled</i>		51	50.4
		d. Percentage of drugs prescribed from Essential Drugs list		8	8
16.	In the development of Standard Treatment Guidelines which of the following is important consideration	a. Based on national disease factors		40	39.6
		b. Act independently		23	22.7
		<i>c. Use essential drug list drugs only</i>		26	25.7
		d. No need to involve clinicians		11	11

Table 4 Knowledge about concept of ‘P’ drug

Q. No	Questions	Yes		No	
		No	%	No	%
17.	Abbreviation for “P” in “P” drug concept	<i>a. Personal</i>		47	33.4
		b. Possible		54	38.2
		<i>c. Preferred</i>		20	14.2
		d. Probable		20	14.2
18.	Criteria to choose an effective group in P drug	44	43.6	57	56.4
19.	“RUM” stands for	67	66.3	34	33.7
20.	“Rule of RIGHT” is for	30	29.7	71	70.3

Figure 3 Knowledge about P-Drug



Discussion

The present study evaluates knowledge, attitude and practice about RUM in interns and post graduate medical students working in a tertiary care teaching hospital. Out of 80 participants, 66.74% of subjects had knowledge about FDCs. In a study conducted by Pallavi et al,⁽⁷⁾ it was observed that 76% of participants were aware of the concept of FDCs, a finding similar to our study. In our study, 79.2% had knowledge about FDC included in WHO EML. Pallavi et al found out that 48% of the participants had knowledge about FDCs in WHO Essential medicine list, which was comparatively much higher to our study.

In our study, 43% of the participants choosed atleast one correct FDC and 13% of the participants did not even choose one correct FDC.

Manu G et al⁽¹⁾ conducted a study in which it was found out that more than half of the participants were not able to mention a single banned FDC in India, a finding similar to our study.

In our study, nearly 45% of the participants were aware of the year in which national list of essential medicines was revised. In a study conducted by Hooli TV et al,⁽⁸⁾ it was observed that nearly 30% of the participants had the knowledge of the year in which list of EML was revised, a finding similar to our study. In our study, 47.5% of the participants had the knowledge of FDC’s included in national EML whereas Hooli TV et al found out that only 6% of the participants were aware of the FDC’s included in national EML, a finding contrast to our results.

The primary purpose of EML is to promote RUM consisting of the three important aspects, i.e.,

safety, efficacy and cost. Some studies have even reported that there is improvement in the quality of health care following use of EML and standard treatment guidelines. Hence, it is essential to adopt measures that will encourage their use. (Hooli tv et al). In our study, 43.6% of the participants were aware of the criteria to choose an effective group in P drug. In a study conducted by Manasa CR et al⁽⁹⁾, it was observed that 44% of the participants were aware of STEP criteria for selection of drug.

Conclusion

We found from our study, that the interns and residents had very little knowledge about FDC's, EML, RUM and P drug concept . Knowledge about FDC's, EML, RUM and P drug concept will make them more efficient in prescribing the right medicine. Considering the fact that respondents are future prescribers, they should be aware of all aspects about RUM and improper knowledge in certain areas of RUM is a matter of concern that needs to be addressed. So, it is the need of the hour to sensitize the doctors regarding the efficacy, safety, suitability and rationality of commonly prescribed FDCs through educational interventions like Continuous Medical Education (CME) programmes should be implemented at different stages of undergraduate curriculum to improve rational prescribing among future clinicians for their Good Clinical Practice.

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Declarations

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Conflict of Interest: None Declared

Ethical Approval: This study was registered with Institutional Human Ethical Committee.

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