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Original Research Article

DISPARITIES IN PHYSICIANS' KNOWLEDGE, ATTITUDES, AND PRACTICES REGARDING THE PRESCRIPTION OF FIXED-DOSE COMBINATIONS IN AN EASTERN INDIAN HOSPITAL

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Abstract

Background: This study aimed to assess the knowledge, attitude, and practice (KAP) regarding fixed drug combinations (FDCs) among the physicians of a super-facility tertiary care hospital in eastern India. **Materials and Methods:** Between November 2022 and May 2023, a cross-sectional KAP study with a questionnaire was carried out among practicing physicians. Data analysis has made use of descriptive statistics. **Result:** Most participants in the study (41.4%) were young practitioners, and 54.6% were junior residents. Of them, 40.8% had more than ten years of experience providing patient care. Of the participants, 91.5% knew that if a patient gets a dosage of FDCs, it is not necessary for them. Of the doctors, 46.7% are aware that 56% believe that FDCs can assist prevent anti-microbial resistance in cases of adverse drug reactions (ADRs). However, only 9.2% of people knew the names of FDCs. **Conclusion:** The outcome of this cross-sectional questionnaire based study reflects the disparities in the knowledge regarding FDCs, as well as incoherence among the knowledge, attitude, and prescription practice.

INTRODUCTION

The fixed dose combination (FDC) means combination of two different drugs in a single pharmaceutical formulation.[1] However, these combinations are only deemed reasonable if they meet specific requirements, such as having pharmacokinetic qualities and qualities that are on par with those of the individual drugs, improving efficacy, and lowering the incidence of side effects when the drugs are combined. FDCs have increased medication adherence rate among patients and improved response rate among them.[2] FDCs have shown beneficial effects in management of hypertension, tuberculosis, HIV, malaria and in some bacterial infections etc.[3] The rational use of FDCs has many advantages, including increased adherence, better compliance, and affordability. But if not properly prescribed, irrational use of FDCs can lead to undesirable side effects along with drug resistance.[4] Approximately one-third of all newly added medicines to the market in the past decade consist of FDCs.[5] Concern over the increase in irrational FDCs and the ensuing rise in the frequency of negative effects is growing in developing countries. In order the purpose of managing the health care system and assisting physicians in prescribing rational combinations, the government published the Essential Medicine List. There are 384 medications on the 22nd national list of essential medicines, but only 22 of them have set dosage combinations and approved by FDA and 39 by WHO.[6,7] Nonetheless, some contentious prohibited ingredients continue to be found in over the counter FDCs across India, including chlorpheniramine with dextromethorphan and phenylephrine in suspension as a cough suppressant.[8,9] Therefore, it is imperative that all healthcare professionals have adequate knowledge of the Essential Medicine List and illogical or banned FDCs, as well as follow a positive attitude and prescribe FDCs on a regular basis.[10] Therefore, it is beneficial to assess the actual circumstance with the objective to develop an awareness program which will cover in any knowledge gaps that the practicing physicians currently have concerning FDCs. Hence, the

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objective of the present studies was to evaluate knowledge, attitude, practice (KAP) of prescribing FDCs among practicing physicians in a tertiary care hospital.

MATERIALS AND METHODS

This questionnaire-based cross-sectional Knowledge, Attitude and Practice (KAP) study conducted among practicing physicians of out-patient and in-patient departments of Medicine, Surgery, Gynecology & Obstetrics, Pediatrics, Dermatology, Psychiatry, Chest Medicine, Orthopedics, ENT & Emergency of multidisciplinary Govt. Medical College & Hospital, Kolkata, from November 2022 to May 2023, after receiving approval from Institutional Ethics Committee (ECR/332/Inst/WB/2013/RR-20/RKC/400 dated 09.08.2023). A convenience sampling technique was used to select 152 practitioners, including faculties, post-graduate trainees, house-staff, and senior residents of different clinical departments of the hospital, in this study. They were enrolled after obtaining a written informed consent form (ICF).

The questionnaire module was developed by the authors following a comprehensive review of the FDC literature. After consulting with the faculties of the same tertiary care hospital, who each held a post-graduate degree in their respective specialties and a basic medical qualification, the questionnaire's contents were evaluated. A 4-point Likert scale was used to review and rate each question's component (1 = not relevant, 2 = slightly relevant, 3 = relevant, and 4 = highly relevant). Then, parameters were checked in accordance with the estimated Content Validity Index (CVI).

The responses from the participants were recorded using a pretested, closed-ended questionnaire. This module asked questions about their age, sex, years of experience, designation, and departments in addition to questions about their knowledge, attitudes, and practices around FDCs. Finally, they were asked to provide the names of the majority of FDCs that they frequently prescribe in their clinical practice. The obtained data were analysed by descriptive statistics using SPSS version 28.

RESULTS

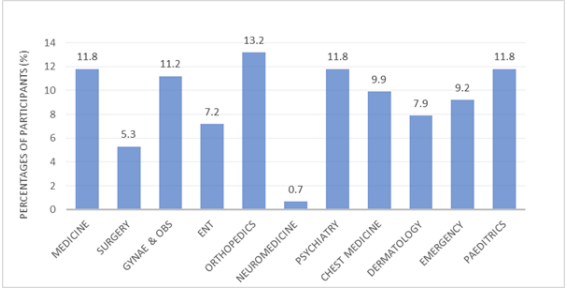

Figure 1: Participants distribution among disciplines

The questionnaire involved 152 doctors in total. The age group of 30–40 years accounted for 41.4% of the study participants, while, with the age group under 30 years ensuring up 35.5%. Most of the doctors participated in the study working as Junior Residents (54.6%) and majority of participants have >10 years of experience (40.8%) in patient care. Department wise distribution shown in [Figure 1].

All the participants have knowledge of the concept of FDCs. Within the respondents, 91.5% were aware that if a patient receives a dosage of FDCs that is unnecessary for them, the combination of ingredients may still be harmful. 85.5% of respondents were aware that not all FDCs on the market are reasonable. 46.7% physicians have knowledge that in case of adverse drug reactions (ADR), determination of the culprit component is being prevented by using FDCs. 56% stated that FDCs may be helpful in controlling anti-microbial resistance. While 94% were familiar with the term "Essential Medicine List," but only 9.2% were acquainted with the names of FDCs included on that list [Table 1]. Textbooks account for 81.6 percent of knowledge acquisition, followed by seminars (12.5%), DPL (4.6%), and the internet (1.2%), in that order.

All participants agreed that prescription should be necessary to obtain FDCs from pharmacy. 85.53% physicians prefer to prescribe FDCs instead of individual medicine and agreed that FDCs can control antimicrobial resistance. 98.7% physicians admitted the necessity of knowing of National List of Essential Medicines (NLEM). 97.4% believed that FDC can decrease pill burden. [Table 2]

Regarding practice, 45.4% physicians always counsel the patients before prescribing FDCs, whereas 40.1% & 34.9% physicians always write generic names as well as dosage of FDCs in the prescription.42.1 % & 33.6 % always prescribe FDCs from current national list of essential medicines and check rationality of FDCs before prescribing [Table 3].

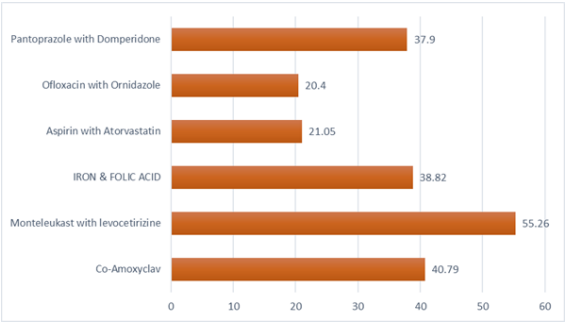

Figure 2: Distribution of commonly prescribed FDCs by participants

40.79% physicians commonly prescribed Co-amoxiclav for respiratory tract infections. Some other commonly prescribed medicines among physicians are Montelukast with Levocetirizine (55.26%), Iron & Folic Acid (38.82%), Aspirin with Atorvastatin (21.05%), Ofloxacin with Ornidazole (20.4%) &

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Pantoprazole with Domperidone (37.9%). 43% of participant physicians unable to name any banned FDCs.

Table 1: Distribution of positive responses on knowledge domain questions regarding FDCs

Knowledge questions	Number of Positive responses	Percentage (%)
Are you aware of fixed dose combinations?	152	100
Do you know FDCs may be harmful where all the ingredients are not needed in the dosage they are combined in a particular patient?	139	91.5
Do you know all FDCs available in the market are not rational?	130	85.5
Do you know in case of ADRs, FDCs cannot determine the culprit component?	71	46.7
Do you know some fixed dose combination may be helpful in controlling antimicrobial resistance?	85	56
Are you aware of the term 'Essential medicine list'?	143	94
Do you know 2022 National list of essential medicine contain 384 medicines of them only 22 are fixed dose combination?	14	9.2

Table 2: Distribution of positive response Attitude domain questions

Attitude Questions	Number of Positive responses	Percentage
Do you agree that prescription is necessary to avail a Fixed Dose Combination from pharmacy?	152	100
Do you prefer to prescribe two or more drugs as a fixed-dose-combination rather than prescribing these dividually?	130	85.5
Do you agree that use of fixed dose combination can control antimicrobial resistance?	130	85.5
Do you agree that all health care professionals should be aware of National list of essential medicine?	150	98.7
Do you believe that FDC have a role in decreasing pill burden among patients?	148	97.4

Table 3: Distribution of practice regarding FDCs among participants

Practice Questions	Always No (%)	Sometimes No (%)	Never No (%)
Do you counsel the patients properly before prescribing fixed dose combination?	69(45.4)	71(46.7)	12(7.9)
Do you write generic names of a fixed dose combination in the prescription?	61(40.1)	86(56.9)	5(3.3)
Do you mention dosage of fixed dose combination in the prescription?	53(34.9)	96(63.2)	3(1.9)
Do you prescribe FDCs from Current national list of essential medicine?	64(42.1)	81(53.3)	7(4.6)
Do you check rationality of fixed dose combination before prescribing?	51(33.6)	93(61.2)	8(5.3)

DISCUSSION

In clinical practice, the practice of prescribing FDCs is rising. The application of FDCs has many benefits, but when they are used negligently or inappropriately because of insufficient knowledge, it might result in irrational prescriptions. Unfortunately, a significant number of FDCs on the healthcare market are legitimate and not authorized by the FDA or the WHO.[2,6] Usually, a community's knowledge reflects how well they understand a certain topic; their attitude describes how they feel about it; and their practice describes how they show their knowledge and attitude by acting in certain ways. Hence, the knowledge, attitude, and practice (KAP) study help us to understand deficiencies present regarding a subject.[11] The present study assessed knowledge, attitude, and practices among the practicing doctors in this institution.

Majority of physicians are aware of the term FDC and National List of Essential Medicine (NLEM). But only few of them (9.2%) have knowledge of the drugs included in NLEM. In case of any adverse drug reaction occurs after using FDCs, it is very difficult to correctly determine the offender component, only 46.7% have knowledge regarding this. Whereas a significant proportion of participants knew advantages of FDC like control antimicrobial resistance. It was also observed that common sources of knowledge regarding FDCs are mostly textbooks (81.6%) that differ from a study conducted by Goswami et al in Western India tertiary teaching hospital where the major source of knowledge is form Medical Representative and Drug Promotional Literature (2) indicating Governments policy of restricting Medical Representatives access to physicians in Govt. set up. Another similar study published in 2016 showed that sources of knowledge about FDCs (10) came from textbooks (43%), and journals (34%), rest from internet and others which corroborate our findings.

Majority of participants believed that FDCs decrease pill burden which is particularly true in case of elderly persons who often take several medications for different coexisting illness like diabetes, hypertension, cardiac failure etc.[12] All physicians agreed on the requirement of proper prescription to obtain FDCs from pharmacy. Thus, FDCs availability by Over- the- counter selling can be minimized cutting down irrational use.[3,13] Majority of participants preferred to prescribe FDCs over individual drugs to increase patient compliance and financial affordability.[14]

A proper counselling needed from doctors to patients regarding FDCs use, advantages, disadvantages and

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it was revealed from the study that 45.4% physicians always practice that before prescribing FDCs. A similar study in 2022 stated that 53% of doctors educated their patients on the benefits and drawbacks of FDCs.[7] 40.1% always write generic names of FDCs along with proper dosage (34.9%). 42.1% prescribe FDCs from current NLEM and 33.6 % do checking of rationality of FDCs before prescribing. These practices are necessary to promote rational use of medicine & preventing undue use of irrational FDCs.

One of the most common FDCs prescribed by the participants is Montelukast with Levocetirizine in Asthma, viral respiratory tract infection. Montelukast, a leukotriene antagonist, has a half-life of around 3-6 hours, whereas Levocetirizine, a second-generation antihistaminic, has a half-life of approximately 6–10 hours. Since there is no rationale for this combination, it is deemed irrational.[14] Other notable FDCs used by participants, Ofloxacin with Ornidazole (20.4%) for treatment of diarrhoea. This combination is irrational as ofloxacin works to treat bacterial diarrhoea while ornidazole treats intestinal amoebiasis.[9] Another FDC commonly used Pantoprazole & Domperidone also is an irrational combination because a peptic ulcer is not always accompanied by vomiting.[9,15] In a similar study done in Western India most common FDC prescribed was Amoxicillin Clavulanic acid.[16] In a similar study conducted in Western India stated that 58% of respondents lacked awareness about banned FDC (2), although in our study 43% were unable to name a single current banned FDC in India. This unawareness is because of not being able to keep oneself updated with the current edition of NLEM because time constraints and partially because of unavailability of hard copy of NLEM in Wards and OPDs.

Prescribing rational FDCs should be practiced for optimum therapeutic benefit along with lowering ADRs. Use of FDCs can also improve availability of drugs for patients. Undergraduates should have proper knowledge of rational FDCs, so they can rightly prescribe right medicine in time of need. Awareness programmes like Seminars, CMEs, workshop should be arranged to keep medical students and practicing doctors updated on rational, irrational/banned FDCs. Central and state drug regulatory authorities should also be vigilant about the marketing of irrational FDCs by pharmaceutical company.

CONCLUSION

Almost all study participants had the basic knowledge of definition and terminology of FDC and essential medicine list. But we detect a knowledge gap regarding disadvantages and rationality of commonly prescribed FDCs. Most of them are not aware about the banned FDCs and FDCs which are included in NLEM. Rational and judicious use of FDCs can save patients; on the other hand, injudicious and irrational combinations can give rise to anti-microbial resistance and serious adverse-drug-reactions. There we suggest awareness programmes like seminars, CMEs to raise the awareness about optimal and rational uses of FDC. Educational improvisations are of utmost necessity in different levels of post-graduate and undergraduate training in every field. In future we also suggest further research on determining effect of use of FDCs on the compliance and clinical outcome in the patient as well as cost effectiveness.

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