

Knowledge, attitude and practice regarding use of fixed dose combination drugs among young prescribers a tertiary care teaching hospital in rural Bengal, India

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ABSTRACT

Background: Use of fixed dose combination (FDCs) is a double edged sword with scope for irrational prescribing on one hand and improved pharmacotherapy and patient compliance on the other hand. Irrational FDCs are being marketed aggressively and often young prescribers including Post Graduate Trainees fall prey to the lure of FDCs. This was a Knowledge-Attitude-Practice study regarding of FDC use among the resident doctors working at a tertiary care medical college of rural Bengal.

Methods: This was a cross-sectional, questionnaire based study including 50 resident doctors who were asked to fill a 10-question questionnaire on FDCs anonymously.

Results: Ninety two percent of the study participants were aware of the FDCs. The most commonly perceived advantages were better patient compliance and synergistic effects. Most (96%) cited problems of titrating dosages and problems of more side effects. Only 37.6% knew about the banned FDCs. Preferred FDCs among them were antibiotics (94%), cough syrups (80%) and NSAIDs (68%). Residents of dermatology, orthopaedics, surgery and medicine most commonly prescribed FDCs. Sources of knowledge regarding FDCs were CME (92%), medical representative (76%), colleagues (72%), internet (68%), journals (48%) and textbooks (36%).

Conclusions: The study showed that most participants were aware of the FDCs and also aware of the problems with irrational FDC use. Knowledge regarding banned drugs was poor as was the rationality of such combinations. More CMEs and inter department group discussions could be conducted to improve awareness and FDC prescribing practice among young prescribers.

Keywords: Fixed drug combinations, KAP study, Prescription, Rational drug use

INTRODUCTION

A combination of two or more actives in a fixed ratio of doses in a single dosage form is called Fixed dose combination (FDC).^{1,2} In past few years prescription of FDCs are flourishing in the Indian Pharmaceutical market. Currently the estimated number of FDCs in India is over 6000 though the exact number of FDC available in the

market is still lacking. This is despite the fact that the Government of India has introduced amendments and new rules to debar the ambiguity in FDC manufacturing and sales by extending its requirements for the approval of new FDCs. Despite these measures FDCs continued to be marketed without complying or having a record of central approval.³

This all has led the market of bizarre combination of FDCs flourish. The junior doctors including the interns, house staffs, postgraduate trainees and the resident's forms one of the main pillars in the healthcare system in India. Lack of sensitization toward the practice of rational prescribing in medical curriculum and in medical education had ended up in irrational prescribing practice due to inadequate knowledge. Knowledge, attitude and practice study on FDC forms an important device to understand the gaps related to FDC prescribing practice so that we can in future address the shortcomings.^{2,3} Our study was carried out to know about the existing scenario about Knowledge Attitude and Practice of FDC prescribing among the resident doctors working at Bankura Sammilani Medical College, Bankura which caters majority of rural population who are solely dependent on this hospital.

METHODS

This study was an observational cross sectional study undertaken in Bankura Sammilani Medical College. This is a tertiary care teaching hospital in rural Bengal that caters to a large population from three districts.

For our study 50 resident doctors belonging to Medicine, Surgery, Obstetrics and Gynaecology, Paediatrics and Orthopaedics were selected randomly to participate in this study. This study included young prescribers who were undergoing their postgraduate training at this Institute. Those unwilling to participate in the study were excused. The others were included in the study. We found that our study sample was representative all almost all medicine, medicine allied and surgical departments of the Institution.

This was a questionnaire based study. A predesigned pre validated close ended questionnaire containing ten questions on FDC addressing the knowledge, attitude and practice of junior doctors were supplied. They were asked to fill the questionnaire anonymously within 10 minutes. The department the students belonged to was asked to be specified at the top of the questionnaire. The study was conducted at the institution at a Pharmacology Lecture class taken for the post graduate trainees in January 2019. The study period was over that one lecture class where the questionnaire was supplied to the students to be filled over 10 minutes. Students from General Medicine, Pediatrics, Chest Medicine, Orthopedics, General Surgery, Obstetrics and Gynaecology, Radiology, Otorhinolaryngology and Anaesthesiology departments participated in the study. All the data were further analysed with the help of descriptive statistics. Results were expressed in figures, frequencies and percentages.

RESULTS

On analysis of their knowledge regarding FDC, authors found 92% percent of the study participants were aware of the concept of FDC. The rest did not know the term FDC but were aware of combination of drugs used in their day to day practice. We noted that 96% of the respondents were

aware of the EDL (Essential drug list). However, when asked to write 3 banned FDCs only 37.6% responded.

All participants accepted that FDC reduces the pill burden of the patient and most of them (92%) felt that improved patient compliance was the main reason why FDCs are being prescribed. Dose adjustment is one of the major problems with FDC use. This was agreed upon by 96% of the participants. We noted that 88% prescribers in our study felt that FDCs increase the efficacy of the drugs and 72% felt that FDCs can reduce the adverse effects of the drugs in the combination. We noted that only 68% of the participants knew about the concept of FDCs preventing drug resistance and 64% were aware that FDCs help in reducing the cost of treatment. Knowledge and perception regarding FDCs among the participants has been depicted in Figure 1.

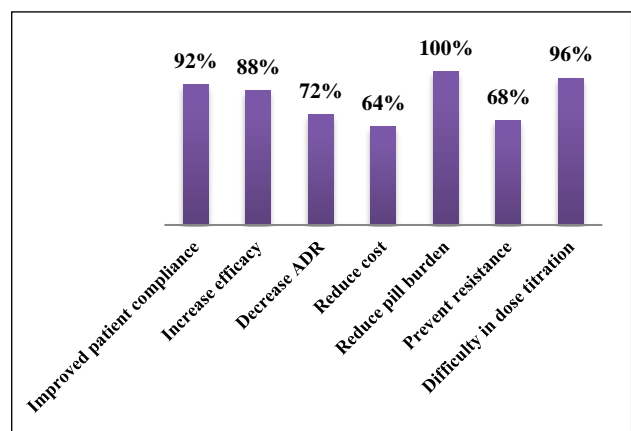


Figure 1: Knowledge and perception regarding FDCs among the participants.

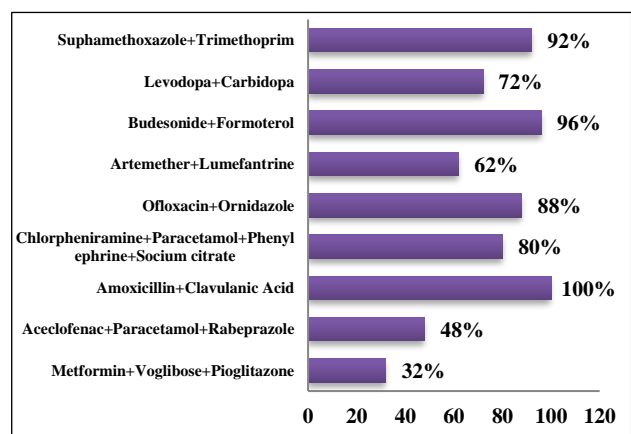


Figure 2: Perception regarding some commonly used fixed dose combinations in the hospital.

On assessing the individual perception regarding rationality of commonly used FDCs we noted that all students identified some of the rational FDCs like amoxicillin-clavulanic acid, budesonide-formeterol and ofloxacin-ornidazole to be rational. These combinations are taught in the undergraduate classes with emphasis.

Irrational combinations such as those of NSAIDs with Proton Pump Inhibitors were also considered to rational by many of the participants. The general perception regarding rationality of the commonly used FDCs is shown in Figure 2.

It was disappointing to find that 76% accepted their source of information regarding the FDCs to be medical representatives followed by colleagues and internet. Nearly half of the respondents have the habit of critically analysing it from CME, textbook and journals. Figure 3 shows the source of information used by the participants in this study.

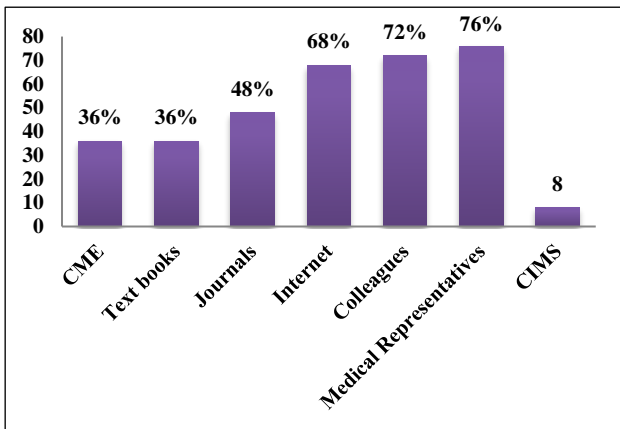


Figure 3: Source of information regarding fixed dose combinations among participants.

From the questionnaire we noted that 98% of the participants think that prescribing FDCs is a rational practice and 60% agree that FDCs are superior to individual drugs when prescribed separately. The attitude towards superiority of FDCs is shown in Figure 4.

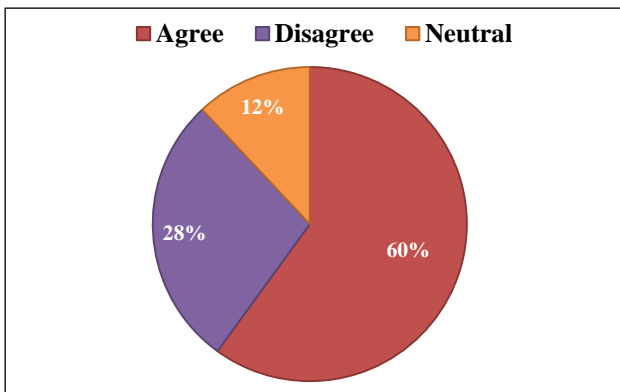


Figure 4: Attitude towards superiority of fixed drug combinations over individual drug prescriptions.

The participants were aware of the regulations encouraging generic prescriptions but 92% said that prescribing FDCs in generics is a challenge. We felt that generic prescribing should be encouraged, and the senior

faculties need to be more involved in building the generic prescribing habit.

Regarding practice of FDC use, a list of common clinical ailments was supplied, and the participants were asked to indicate if FDC prescription in these conditions was rational. We noted that all participants agreed about FDC prescription in tuberculosis, asthma, diabetes mellitus and cough. Surprisingly, only 64% thought use of combined hormonal contraceptives to be rational. Figure 5 shows the general practice adopted by the participants regarding FDC use in common disease conditions.

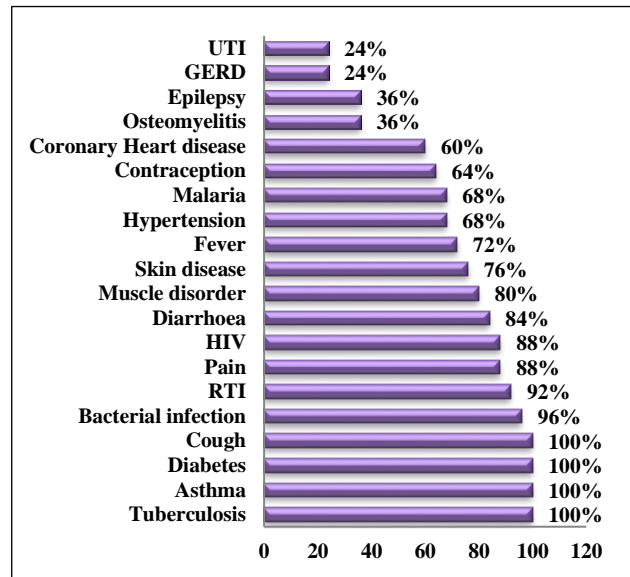


Figure 5: General practice adopted by the participants regarding FDC use in common disease conditions.

DISCUSSION

To treat a single ailment or existing co morbid conditions, very often more than one drug is prescribed. To reduce the pill burden and to have a better compliance FDCs are preferred. But due to lack of time and negligent attitude from junior doctors to critically analyse the mammoth claims by pharmaceutical companies, irrational FDCs take up a big proportion of the market. The annual turnover statistics show a trend of their growth.

In the 19th list of WHO List of Essential Medicines, there are only 27 FDCs included among the 414 medicines. In the National List of Essential Medicines of India (NLEM) 2015, only 24 FDCs are included among the 376 entities. These approved FDCs include antimalarials, antitubercular and antiretroviral drugs aiming for better treatment adherence and reducing emergence of drug resistance.³⁻⁵ Unfortunately, due to lack of supervision regarding the marketed drugs in India, irrational drug combinations are easily available some being sold as OTC drugs.^{6,7} According to the Rule 122E of Drugs and Cosmetics Act 1940, the FDCs are considered as New

Drugs. After due examination of data on rationality, safety, and efficacy, Central Drugs Standard Control Organization (CDSCO) issues approval based on which the State Licensing Authority (SLA) gives the manufacturing and marketing permission. Unfortunately, due to the laxity of SLA and lack of alignment with CDSCO many irrational FDC finds a place in the market.³

In September 2018, the Ministry of Health and Family Welfare has prohibited the manufacture and marketing of 328 FDC and restricted the manufacture, sale and distribution of 6 FDCs subjected to certain conditions with immediate effect. A report by a Supreme Court mandated an expert's panel that concluded that there is no therapeutic justification for the ingredients in these drugs, but they can in fact pose health risks. Things are getting worse when these banned FDCs are getting exported to African and other Asian countries thus jeopardizing their health system.^{4,8,9}

The rationality of FDC stands on that the combination is to act in different ways thus enhancing the efficacy, with close pharmacokinetics properties and should not include any supra additive toxicity of the ingredients.¹⁰ Apart from increasing the compliance by decreasing the pill burden with reduced emergence of resistance and adverse effects thus bringing down the cost it also has some existing demerits like difficulty in dose adjustment of individual drug, difficulty in identifying the source of side effects and chances of increased drug interaction.^{3,8} Irrational fixed drug combinations can lead to mismatch in pharmacodynamics and pharmacokinetics leading to decreased shelf life along with increased risk of adverse drug reaction.

The pharmacovigilance programme in India is currently running successfully across the nation but the physicians have not yet imbibed the habit of spontaneous reporting of adverse drug reaction. India being the huge market for generic drug has led the pharmaceutical company to publicize spurious claim to gain profits in these irrational FDCs.

Though 100% was expected to know what is FDC and EDL but we found a fair percentage of having such knowledge which differed from a similar study undertaken in Ahmedabad.⁷ It was disheartening to find that only 37.6% in our study could name the recently banned FDCs thus the need for change in behaviour of continuous up gradation of medical knowledge was felt.

Almost everybody accepts that reducing pill burden and improved patient compliance are the main grounds for their FDC prescribing practice whereas finer dose titration of individual drug remained to be the main disadvantage. Our result regarding the knowledge on rationality of FDC prescribing bears slight resemblance with the result of similar study.⁷ Similar trends were also seen in the study regarding source of information for the junior doctors.⁷

Unjustifiable combinations like aceclofenac and paracetamol are considered rational by 92% of our junior doctors. Authors noted that most young prescribers in our study were unaware that these two drugs working by same mechanism would only increase the adverse drug effects along with escalating the dose.^{4,7,8} Apart from antimicrobials and drugs used in gastrointestinal disorders, the antipsychotics and antidepressants are other classes where abundant irrational FDCs are available helping the companies for huge turnover.^{4,6,8,9}

CONCLUSION

From this study we noted that most participants were aware of the FDCs and also aware of the problems with irrational FDC use. However, their individual knowledge of the FDCs was poor and there was a gap in their source of knowledge acquisition on FDCs. We conclude that more interdepartmental activities and awareness programmes regarding FDC prescriptions are necessary to ensure safe and rational FDC use among the young prescribers.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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