Original Research Article

Study of fixed dose combination pattern in rural hospital, Jammu

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Abstract

Background: Fixed dose combinations (FDCs) have different focal points and drawbacks. In nations like India there are various silly medicines as highlighted by the later prohibiting of FDCs in October 2018. Considering the medicine design makes a difference in creating national database which can be utilized to advance judicious use of drugs. **Method:** Outdoor Patient Department (OPD) prescriptions from various departments during the study period were used for the study. The drugs were classified according to Anatomical Therapeutic Chemical (ATC) classification. The whole data was described in percentage in table 1 and table 2. **Results:** The highest percentage of FDCs was seen in alimentary tract (37.5%), followed by anti infective(16.25%). Among the alimentary drugs maximum number was of antacid combination (26.6%) followed by combination of proton pump inhibitors and prokinetic drugs (Pantop D). In anti-infective group mostly included amoxiclav, norfloxacin-tinidazole, ofloxacin-ornidazole (46.15%). **Conclusion:** A multistep approach at different levels can curb the problems being faced by irrational FDCs prescribed in rural areas.

Key Words: Fixed dose combination, prescribing pattern, irrational, ATC classification.

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INTRODUCTION

Combination of two or more active ingredients in a fixed ratio is known as Fixed dose combination (FDC). It can be given as a sole agent given together or as a combined pharmaceutical product[1]. Various advantages associated are synergistic action and increased efficacy (e.g. cotrimoxazole), adverse effects are less (e.g. levodopa with carbidopa, thiazides with potassium sparing diuretics), less pill burden and hence better patient compliance (e.g. anti-tubercular drug combinations). Disadvantages are also there like incompatible pharmacokinetics, inflexible dose ratio, increased toxicity and cost, contraindication to one of the component. The FDC may not contain the specified amount of each individual medicine and the combination may not be synergistic. The most pressing concern with irrational FDCs is that they expose patients to unnecessary risk of adverse drug reactions[2]. In spite of the fact that FDCs are accessible in nearly all helpful categories, numerous of them are unusual combinations. The categories having large number of FDCs are cough, cold and fever arrangements; analgesics and muscle relaxants; antimicrobials; drugs for hypertension, dyslipidemia, diabetes and psychiatric drug ranges; vitamins and minerals. The FDC detailing may have up to 5 or indeed more fixings with or without judiciousness of their nearness and within the quantity. Notwithstanding the basic principle of formulating FDC, the Indian medicine market has become the world leader of FDCs. The estimated number of FDCs in India is over 6000[3]. Time and again, studies, editorials have shown violation of scientific merits in having many FDCs without adequate

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justification. Exploiting the liberal licensing system, many times bizarre FDCs find place. India today does not have the exact database of currently available FDCs in the market, their sales turnover and use pattern. The existence of unlimited brands of FDCs with different permutations and combinations leads to confusion rather than guiding the prescribing doctor. Many articles in print media and Non-Governmental Organizations addressed the levelheadedness of FDCs. Drug controller of *India (CDSCO) came out with the arrangement rules for the endorsement of FDCs in 2013[4]. CDSCO has intermittently prohibited different FDCs due to reasons such as need of basis or prove and potential security concern. In 2007, the Drugs Control General of India (DCGI) issued proclamations to State licensing authorities (SLAs) to pull back 294 FDCs which were not endorsed by CDSCO.[5]

Despite these interventions, irrational FDCs are still available in the market and are used extensively. The interventions are not successful due to several reasons. One such reason relates to exporting of FDCs that are banned in a particular country to the neighboring countries[6]. In spite of these intercessions, unreasonable FDCs are still accessible within the advertise and are utilized extensively. So it is necessary to study the pattern of prescribing pattern of FDCs especially in rural hospitals as less data is available despite of high prescribing trends.

METHODS

A cross-sectional descriptive study was done for one year in CHC Akhnoor. Prescriptions from Out-patient departments especially Medicine and Pediatrics were collected and analysed. The data was entered, stored and evaluated using Microsoft excel 2016. Data was calculated according to the percentages. Institutional ethical clearance was taken.

OBSERVATIONS AND RESULTS

The data was entered, stored and evaluated using Microsoft excel 2016. Descriptive statistics was used to analyze data. The prescribed fixed dose combination drugs and other drugs were categorized according to Anatomical Therapeutic Chemical classification (ATC classification). The percentage of Fixed drug combinations used in each class and their contribution to overall Fixed drug combinations were calculated. Numbers of Fixed drug combinations that are currently banned were also identified. Most of the prescriptions were collected from department of Medicine and Pediatrics followed by Obs and Gynae, Surgery and other allied branches. Over 1000 prescriptons were collected and analysed. Out of these 1000 prescriptions about 2300 drugs were prescribed. Among these drugs, about 800 were FDCs, and rest 1500 were others. Most common FDCs in elderly age group belonged to Gastrointestinal system and in Pediatric population mainly respiratory system. The group wise distribution of drugs, according to ATC classification and FDCs in that category, is listed in the Table 1.

Table 1: ATC Class of drugs prescribed.

S.no.	ATC classification	No. of FDCs	Percentage
1	Alimentary tract	300	37.5
2.	Blood and blood forming organs	20	2.5
3.	CVS	2	0.125
4.	Dermatology	0	0
5.	Genitourinary	70	8.75
6.	Systemic hormones	8	1
7.	Anti infective	130	16.25
8.	Musculoskeletal	70	8.75
9.	Nervous	90	11.25
10.	Anti parasitic	8	1
11.	Respiratory system	100	12.5
12.	Others	3	3.75

The highest percentage of FDCs were seen in alimentary tract (37.5%), followed by anti infective (16.25%). The next high number was seen in respiratory system (12.5%) which was also high in pediatric population followed by nervous system(11.25%), then musculoskeletal (8.75%) and genitourinary (8.75%). It was followed by systemic hormones (1%) and antiparasitic (1%) then CVS (0.125%). Among the alimentary drugs maximum number was of antacid combination followed by combination of proton pump inhibitors and prokinetic drugs (Pantop D). In case of respiratory drugs maximum number was of antihistaminics, anticholinergics followed by antiasthamatics. In nervous system combination of paracetamol, tramadol followed by paracetamol, codeine and caffeine. In antiinfective group mostly amoxiclav, norfloxacin-tinidazole, ofloxacin-ornidazole. The ATC classification and various FDCs, their number and percentage is shown in table 2.

Table 2: ATC classification, no. of prescriptions and percentage

S.no	ATC classification	Name of drugs	No. of prescriptions	%age
1.	Alimentary tract	Simethicone Alum.hydroxiode Mag .hydroxide	80	26.6%
		Pantoprazole Domperidone	65	21.6%
2.	Anti infective	Amoxiclav	60	46.15%
		Norfloxacin Tinidazole	45	34.61%
3.	Respiratory	Pseudoephedrine Guaifensin	40	40%
		Dextromethorphan Phenylephrine chlorphenarimine	30	30%
4.	Nervous sytem	Paracetamol Tramadol	35	38.89%
		Paracetamol Codeine Caffeine	30	33.3%

DISCUSSION

The Indian pharmaceutical industry has ended up the world pioneer of FDCs and various considers have appeared infringement of logi cal merits without satisfactory defense among accessible FDCs. The re's no database of currently available FDCs within the showcase, their deals turnover and use pattern[7]. Polypharmacy is exceptionally common and there's an expanding slant to combine drugs, more regularly than not without a sound premise for doing so. As per the Rule 122E of Drugs and Cosmetics Act 1940, the FDCs are considered as New Drugs and the Central Drugs Standard Control Organization (CDSCO), after due examination of data on rationality, safety, and efficacy, issues approval. On the basis of this, the State Licensing Authority (SLA) gives the manufacturing and marketing permission. Incidentally, in the past, SLAs issued the license to manufacture and market without asking for no-objection from CDSCO. Thus, the efficacy, safety, and rationality of such FDCs remain questionable. This "disconnect" between the CDSCO and SLAs has precipitated a roadblock in the action against irrational FDCs. In September 16, 2014, Service of Wellbeing and Family Welfare (MOH and FW) constituted a committee for looking at the applications for soundness, security, and viability of the FDCs.[8] Based on discoveries of the master board, on Feb 10, 2016, 344 FDCs were precluded beneath Segment 26A of Drugs and Makeup Act, 1940.[9] Authors have found that a total of 34.78% drugs were FDCs. A study conducted by Biswadeep das MD *et al.*, had 64.8% as FDCs which is high compared to our study.[10] Highest number of FDCs belonged to alimentary system followed by drugs belonging to anti-infective, Blood and blood forming organs and respiratory system. In a study done in various clinical departments by Deepak *et al.*, percentage of FDCs prescribed were 64.29% and most of them belonged to antimicrobial class[11]. This study finds that FDCs constitute a significant portion of drugs that are prescribed in the department of OBG. Many of these drugs were recently banned combinations because of their irrationality[12]. Wide scale studies on FDC usage in various clinical departments to help build national database may go long way in promoting rational drug use.

SUMMARY AND CONCLUSION

To control the unreasonable utilization of FDC in India, a multistep approach including all partners including customers, doctors, administrative specialist, industry and the academicians is required. The authorization instrument by the controllers has to be reinforced. Both the central and state controllers must harmonize their methods for permitting FDCs. Pharmacovigilance also plays an important role in curbing the irrational use of FDCs. A multipronged corrective approach involving regulator, academia, industry, physicians, and public is needed to correct the dismal FDC scenario in the country.

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