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STUDY OF FIXED DOSE COMBINATION PATTERN AT TERTIARY CARE TEACHING HOSPITAL

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Abstract:
Background: Fixed dose combinations (FDCs) have different focal points and drawbacks. Fixed dose combinations (FDC) enhance the efficacy of individual drugs, decrease the chances of drug resistance, improve patient compliance and also decrease the pill burden on the patients. Studying the prescription pattern helps in developing national database which can be used to promote rational use of drugs.
Method: Prescriptions from various Outdoor Patient Department (OPD) during the study period were used for the study. The drugs were classified according to Anatomical Therapeutic Chemical (ATC) classification.
Results: The highest percentage of FDCs was seen in alimentary tract 35.78, followed by anti infective(20.21%). Among the alimentary drugs maximum number was of antacid combination followed by combination of proton pump inhibitors and prokinetic drugs. In anti-infective group mostly included amoxiclav, norfloxacin-tinidazole, ofloxacin-ornidazole.
Conclusions: A significant number of drugs are being prescribed as FDCs which also includes various irrational combinations.

Keywords: Fixed dose combination, prescribing pattern, irrational, ATC classification.

Introduction:

World Health Organization (WHO) defines Fixed Dose Combinations (FDCs) as combination of two or more active ingredients in a fixed ratio of doses[1]. It can be given as a sole agent given together or as a combined pharmaceutical product. Drug utilisation studies are powerful tools to ascertain the role of drugs in medical practice[2]. The ultimate goal of drug utilisation research is to assess whether drug therapy is rational or not. Various advantages associated with FDCs are synergistic action, improved efficacy, minimal adverse effects and good patient compliance. Disadvantages like cost, contra indication to one of the component, dose ratio. The FDC may not contain the specified amount of each individual medicine and the combination may not be synergistic. FDCs may expose patients to unnecessary risk of adverse drug reactions[3]. Most drugs should ideally be prescribed as single compounds, but doctors prescribe a lot of FDCs forwarding the argument of better patient compliance[4]. hundreds of irrational FDCs are being marketed in India under more than 1000 brand

names. Hence the knowledge about prescribing pattern of FDCs is important for better health outcomes. Tertiary care hospitals have a dual role to play in terms of educating post graduate students and providing health care facilities to the patients. The categories having large number of FDCs are cough, cold and fever medications; analgesics and muscle relaxants; antimicrobials; drugs for hypertension, dyslipidemia, diabetes and psychiatric drug and vitamins and minerals. The estimated number of FDCs in India is over 6000[5].

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. Drug controller of *India (CDSCO) came out with the arrangement rules for the endorsement of FDCs in 2013[6]. CDSCO has intermittently prohibited different FDCs . Despite many interventions, irrational FDCs are still available in the market and are used extensively. Hence the present study was conducted with the objective of studying the pattern of prescribing pattern of FDCs especially in tertiary care center as less data is available despite high prescribing trends.

Methods: A cross-sectional descriptive study was done for one year in tertiary care centre. Prescriptions from Out-patient departments especially Medicine and Pediatrics were collected and analyzed. The prescribed fixed dose combination drugs and other drugs were categorized according to Anatomical Therapeutic Chemical classification (ATC classification). The list of Fixed drug combinations that are currently banned were also identified. Over 1000 prescriptions were collected and analysed. Out of these 1000 prescriptions about 2800 drugs were prescribed. Among these drugs, about 950 were FDCs, and rest 1850 were others. The data was entered, stored and evaluated using Microsoft excel 2016. Data was calculated according to the percentages.

Result:

Most common FDCs in elderly age group belonged to Gastrointestinal system and in Pediatric population mainly respiratory system. The highest percentage of FDCs were seen in alimentary tract (35.78%), followed by anti infective (20.21%), respiratory system (10.73%), (Table 1). The maximum number of FDCs was of antacid combination followed by combination of proton-pump inhibitors and prokinetic drugs in the alimentary tract. 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 (Table 2).

Table 1: The group wise distribution of drugs, according to ATC classification and FDCs in that category.

S.no.	ATC classification	No. of FDCs	Percentage
1	Alimentary tract	340	35.78
2.	Blood and blood forming organs	18	01.89
3.	CVS	6	0.63
4.	Dermatology	1	0.1
5.	Genitourinary	95	10.00
6.	Systemic hormones	6	0.63
7.	Anti infective	190	20.21
8.	Musculoskeletal	88	9.26
9.	Nervous	85	8.94
10.	Anti parasitic	16	01.68
11.	Respiratory system	102	10.73
12.	Others	3	0.31

Table 2: The ATC classification and various FDCs.

S.no	ATC classification	Name of drugs	No. of prescriptions
1.	Alimentary tract	Simethicone Alum.hydroxiode Mag .hydroxide	90
		Pantoprazole Domperidone	75
2.	Anti infective	Amoxiclav	70
		Norfloxacin Tinidazole	35
3.	Respiratory	Pseudoephedrine Guaifensin	50
		Dextromethorphan Phenylephrine chlorphenarimine	45
4.	Nervous sytem	Paracetamol Tramadol	40
		Paracetamol Codeine Caffeine	45
5	Musculoskeletal	Mafenamicacid, paracetamol	70
		Mefenamic acid, dicycloverine	55

Discussion:

The Indian medicine market has become the world leader of FDCs and number of estimated FDCs in India is over 6000. There is no database of currently available FDCs in the market, their sales turnover and use pattern[7]. Poly-pharmacy is common and there is an increasing inclination to combine drugs, more often than not without a sound rational basis for doing so[8]. This is a prospective observational study done in a tertiary care hospital done using prescriptions of patients attending OPD during the study period. Our study found that a total of 33.9% drugs were FDCs. A study conducted by Biswadeep das MD et al[9], had 64.8% as FDCs which is high compared to our study. Highest number of FDCs belonged to alimentary system followed by drugs belonging to anti-infective. 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[10]. Wide scale studies on FDC usage in various clinical departments to help build national database may go long way in promoting rational drug use. Some of these drugs were recently banned combinations because of their irrationality[11.]

Conclusion:

A significant number of drugs are being prescribed as FDCs which also includes various irrational combinations. 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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