INTERNATIONAL JOURNAL OF STUDENTS' RESEARCH
Volume 5 Issue 1 Year 2015 www.ijsronline.com

RESEARCH

Current inclination of the clinicians for prescribing various fixed dose combinations: a retrospective, obsevational study in medicine outpatient department at a tertiary care hospital in Jaipur

Angelika Batta[1], Pushpawati Jain[1], Kopal Sharma[1], Mohammed Shoaib[1], Prerna Upadhyaya[1]

ABSTRACT

Introduction: Rational use of drugs is mandatory for improving the quality of life, optimal utilization of our meagre financial resources, and better community healthcare fulfilling the "rule of right and need, efficacy, suitability, safety, and affordability criteria." Despite this many irrational fixed dose combinations (FDCs) are continuously springing up in the Indian pharmaceutical market. Hence, it becomes crucial to evaluate the prescribing patterns of FDCs - the current trends and the loopholes. **Methodology:** This study was carried out in the outpatient department of medicine at Mahatma Gandhi Medical College and Hospital, Jaipur. Total 500 prescriptions were collected for the duration of 6 months, starting from February 2014 and assessed. The data was analyzed using Microsoft Office Excel® version 2007. **Results:** The data analysis reflected that 60% of prescriptions analyzed contained FDCs; revealing that significantly high number of patients received FDCs. The total number of FDCs in a prescription was also greater (mean = 1.82). Out of 60 FDCs prescribed only three of them were enlisted in the Essential Medicine List of World Health Organization and Government of India. **Conclusion:** The increased trend in using irrational FDC warrants a drug regulatory body in every hospital to ameliorate the free flow of irrational FDCs. Awareness programs focusing on deleterious consequences related to irrational use of medicines should be made.

Key words: Irrational fixed dose combinations, prescription, rational drug use

Introduction

A well-structured healthcare delivery system is vital for well-being of everyone. "Medicines are nothing in them but are the very hands of God if employed with reason and prudence" [1]. Fixed-dose combinations (FDCs) is a combination of two or more active ingredients in fixed ratio of doses which can either be administered as single entity product given concurrently or as finished pharmaceutical product [2]. FDCs are accessible for the treatment of various disorders including cardiovascular diseases, diabetes, infectious diseases (bacterial infections), gastrointestinal infections, cough and cold, HIV infection, tuberculosis, psychiatric disorders, and respiratory diseases [3]. Nowadays in clinical practice, prescriptions with irrational FDCs are a common occurrence. The large proportions of the drugs that are currently available in the market today cater little to the needs of primary healthcare. There are loopholes within the Indian laws which deal with approval and marketing of FDCs [4]. It is now mandatory that the concepts of rational FDCs which are still unknown to most of the prescribers should be inculcated in them. Thus, it is worthwhile to evaluate the current trends in prescribing of FDCs.

[1]Department of Pharmacology, Mahatma Gandhi Medical College, Jaipur Mahatma Gandhi University of Medical Sciences and Technology, Jaipur, Rajasthan, India

Corresponding Author:
Dr. Kopal Sharma, E-mail: sharmakopal85@gmail.com

Methodology

This was a retrospective observational study carried out at the outpatient medicine department of Mahatma Gandhi Medical Hospital, Jaipur from February 2014 to July 2014. Prior to the study approval of the Institutional Ethics Committee was sought. Five hundred prescriptions were scrutinized and screened for the presence of FDCs in them. The data pertinent to our study was recorded. The rationality of FDCs was determined based on the 18th WHO Essential Medicine List and National List of Essential Medicine (NLEM) of India 2014.

Results

Five hundred prescriptions were collected and analyzed during the study period. Three hundred two (60.4%) prescriptions had FDCs [Figure 1]. The average number of FDCs per prescription was also higher that is 1.82 [Table 1]. All the antiulcer and antihistaminic FDCs prescribed were irrational [Table 2]. The most commonly prescribed FDCs were aceclofenac and paracetamol combination followed by salbutamol, bromhexine, guaiphenesin, and menthol combination [Table 3]. Table 4 depicts the banned/controversial FDCs prescribed during the study. Only 2.3% of the prescribed FDCs were rational [Figure 2]. Ninety-seven

RESEARCH

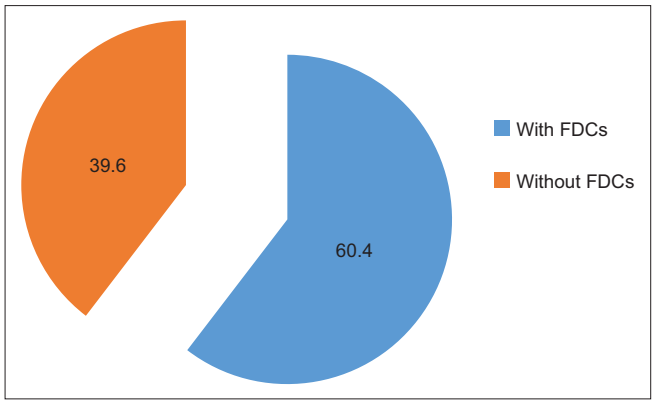

Figure 1 Percentage of prescriptions with and without fixed dose combinations

percent of FDCs were prescribed by their brand names while only 3% were prescribed by their generic names [Figure 3]. The majority (97.3%) of the FDCs were prescribed by the oral route and only 2.6% were prescribed by parenteral route [Figure 4]. Banned or controversial FDC prescribed is depicted in Table 4.

Discussion

Rational use of FDCs ensures better community healthcare fulfilling the need, efficacy, suitability, safety, and affordability criteria. It is astonishing to state that many irrational FDCs are favored by the clinician's all across our country, despite of the fact they have no mention in NLEM of India as well as the World Health Organization (WHO) Model List of essential medicines [5,6]. Cursory survey of the studies conducted in the past throws up a wealth of data which is consistent with our study. Irrational FDC prescribing is a common and rampant feature, leading to unnecessary drainage of resources in developing country, like India.

About 91.1% of the prescription in our study had irrational FDCs. Almost similar findings were reflected in the previous studies [4,7]. The average number of FDCs per prescription was a bit higher in our study (1.82) in contrast to previous studies [7,8]. As per the drug category analysis, more analgesics were prescribed (24.8%) followed by cough and cold agents (23.2%) in our study. However, Vitamin B-complex preparation was the highly prescribed FDC in many previous studies [7,8].

It was observed that nonsteroidal anti-inflammatory drugs (NSAIDs) were combined with other NSAIDs (aceclofenac, diclofenac with paracetamol) which is irrational as they do not provide any therapeutic advantage of the FDCs in the therapy, on the contrary increases the chances of nephrotoxicity [9]. Similarly FDCs of proton pump inhibitors and H2 receptor blockers with antiemetics do not have any advantage as they have incompatible

Table 1: Demographic data of the study population

Characteristics	Estimate
Number of prescriptions analyzed	500
Total number of FDC prescribed (%)	302 (60.4)
Demographic details	
Age (years)	
Mean±SD	29±0.75
Range	16-70
Sex ratio	
Male: female	2:1
Males (%)	66.7
Females (%)	33.3

SD: Standard deviation, FDC: Fixed dose combination

Table 2: Categorization of different classes of fixed dose combinations prescribed

Classes of FDC	*n* (frequency)	Rational	Irrational	Banned/ controversial
Anti-inflammatory agents	75	0	70	5
Cough and cold agents	70	0	64	6
Antimicrobials	47	5	42	
Anti histaminics	42	0	42	
Nutritional supplements	34	2	23	9
Antiulcer drugs	34	0	34	

FDC: Fixed dose combination

Table 3: Frequency of the prescribed irrational FDC

Irrational FDCs prescribed during the study	Co-morbid conditions for prescribing FDCs	Frequency
Aceclofenac + paracetamol	Myalgia Polyarthritis Pyrexia of unknown origin Allergic rhinitis	67
Diclofenac + paracetamol	Headache Fever with chills	3
Salbutamol + bromhexine + guaiphenesin + menthol	Allergic bronchitis Bronchial asthma	64
Ofloxacin + ornidazole	Gastroenteritis Diarrhoea	38
Cefexime + ornidazole	Gastroenteritis	4
Levocetirizine + montelukast	Bronchial asthma Acute bronchitis	42
Multivitamin preparations	Anorexia	23
Pantoprazole + domperidone	Acid peptic disease	28
Esomeprazole + domperidone	Acid peptic disease	6

FDCs: Fixed dose combinations

Table 4: Banned/controversial fixed dose combinations prescribed
Banned/controversial active ingredients
FDC of vitamin B1 + B6 + B12 for human use
FDC with paracetamol 500 mg
FDC containing phenylpropanolamine

FDCs: Fixed dose combinations

pharmacokinetics [7]. An irrational use of FDCs of antimicrobials is also evident from our study. For all types of diarrhea and dysentery, the prescriptions with the FDCs of fluoroquinolones and nitroimidazoles is quite rampant, turning a blind eye to the fact that fluoroquinolones have no role in amoebic dysentery and similarly nitroimidazoles are ineffective in bacterial dysentery. Both these conditions exist side-by-side seldomly [10]. In our study, 38 prescriptions contained this irrational ofloxacin and ornidazole combination and four prescriptions had cefexime and ornidazole combination. As the pharmacokinetic and pharmacodynamic profiles of antimicrobial and antiprotozoal groups do not match, these combinations are not justifiable for the treatment of dysentery [11].

For the patients of asthma FDCs of Montelukast and Levocetirizine is often prescribed, which is irrational. Levocetirizine belongs to the antihistaminic group and has no role in human asthma where the main mediators are leukotrienes and platelet activating factors. In mild and persistent asthma cases, montelukast is recommended only if inhaled steroids cannot be prescribed for some suitable reasons [12]. In this study, 42 prescriptions had this irrational montelukast and levocetirizine combination.

As per WHO guidelines, the combination of vitamins are a key component of balanced diet and their use as FDCs is not justified [13]. In FDCs the dosage of Paracetamol should be 325 mg as recommended by the WHO and Central Drugs Standard Control Organization, but in our study, we observed paracetamol in the dosage of 500 mg in FDC which is again not justified [14]. Similarly, phenylpropanolamine is banned in other countries due to the risk of stroke. However, the FDCs containing these controversial active ingredients, nimesulide, and phenylpropanolamine are yet freely available and prescribed in India [15].

In this study, the oral route was the common route of administration for the majority of the FDCs (97.3%) in comparison to the parenteral route (2.7%). Significantly, higher percentage (97%) of the FDCs were prescribed by their brand names in contrast to 3% FDCs which were prescribed by their generic names. The FDCs prescribed by their generic names were combinations of amoxicillin and clavulanic acid. Similar findings were mirrored in the previous study also [16].

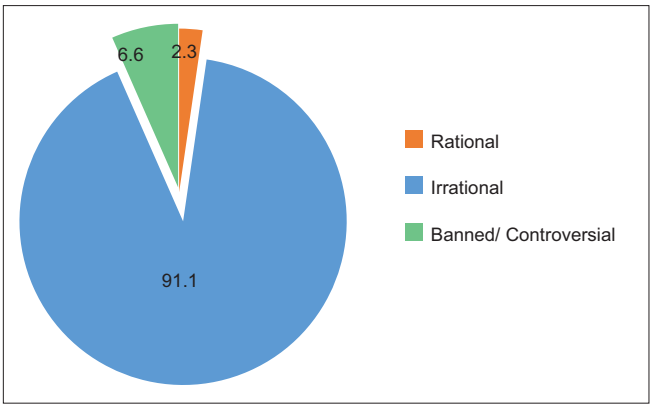

Figure 2 Percentage wise categorization of fixed dose combinations based on their rationality

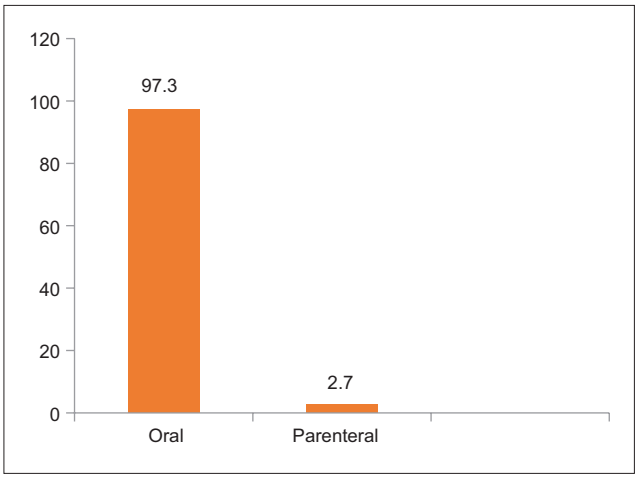

Figure 3 Routes of administration for the various fixed dose combinations prescribed

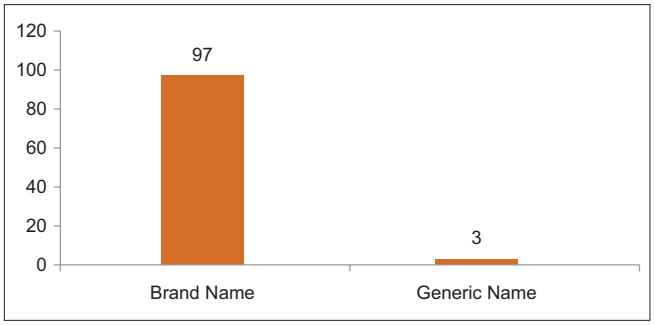

Figure 4 Comparison of fixed dose combinations prescribed as brand names and generic names

Our study reveals the current trends of prescribing irrational FDCs. The responsibility of clinicians does not end with the task of prescribing drugs but to understand and use medicines rationally by implicating their relevant knowledge, skills, and competencies in the interest of their patients. There should be proper drug information centers providing all the relevant, unprejudiced, and current information on the drugs

and its serious adverse effects, where the clinicians, medical students, health care providers, and the patients can enrich their knowledge on any aspect of drug use.

Conclusion

Clinicians increasing inclination for FDC products warrant a functioning drug regulatory body in every hospital. Continuous medical education programs emphasizing all the deleterious consequences related to the irrational use of medicines should be made mandatory at undergraduate levels itself. Awareness and education about irrational FDCs, FDCs containing banned or controversial ingredients will help develop rational prescribing practices among prescribers. Unaware general public, unintentional yet malicious prescribing practices of the doctors and loopholes in our present clinical drug policy are the obstacles, without eliminating them we cannot possibly achieve our goals.

References

1. Ambwani S, Mathur AK. Rational drug use. *Health Adm* 2007;19(1):5-7.
2. Jayasheel BG. Regulatory requirements for marketing fixed dose combinations. *Perspect Clin Res* 2010;1(4):120-3.
3. Panda J, Tiwari P, Uppal R. Evaluation of rationality of some FDC: focus on antihypertensive drugs. *Indian J Pharm Sci* 2006;68:649-52.
4. Rayasam SP, Dudhgaonkar SS, Dakhale GN, Hire RC, Deshmukh PS, Gaikwad NN. The irrational fixed dose combinations in the Indian drug market: an evaluation of prescribing pattern using WHO guidelines. *Int J Basic Clin Pharmacol* 2013;2(4):452-7.
5. World Health Organization. (WHO) Model List of Essential Medicines. 18th List (Updated); April, 2014. Available from: http://www.who.int/medicines/publications/essentialmedicines/en/index.html. [Last accessed on 2014 Jan 04].
6. National list of Essential Medicines. (2011) Govt. India, Ministry of Health and Family welfare, Directorate General of Health Services, New Delhi; 2003. Available from: http://www.cdsco.nic.in/nedl.pdf. [Last accessed on 2014 Jan 16].
7. Balat JD, Gandhi AM, Patel PP, Dikshit RK. A study of use of fixed dose combinations in Ahmedabad, India. *Indian J Pharmacol* 2014;46(5):503-9.
8. Hindoliya M, Sharma PK, Dhaneria SP. Prescribing trends of fixed dose combinations in teaching and non teaching hospitals of Ujjain District. *J Pharm Res* 2012;5(7):3503-5.
9. Gulhati CM. Monthly index of medical specialities, India. *MIMS INDIA*. 2005;25:81-94.
10. Chakraborti A. Prescription of FDC drugs for diarrhea. *Indian J Med Ethics* 2007;4:165-7.
11. Anand S, Asha AN, Bhosale U, Sarasija S. Emergence of irrationality of fixed dose combinations. *Pharm Times* 2008;40:17-21.
12. Hair PI, Scott LJ. Levocetirizine: a review of its use in the management of allergic rhinitis and skin allergies. *Drugs* 2006;66:973-96.
13. Gautam CS, Saha L. Fixed dose drug combinations (FDCs): rational or irrational: a view point. *Br J Clin Pharmacol* 2008;65:795-6.
14. CDSCO. Limitations of Acetaminophen (Paracetamol) in Prescription Combination Products and Giving Box Warning About its Liver Toxicity. New Delhi: CDSCO; 2011. Available from: http://www.cipi.in/DCGI%20CIR23092011.pdf. [Last accessed on 2015 Jan 20].
15. Drugs Banned in India. Available from: http://www.cdsco.nic.in/drugs%20banned%20in%20th%20ed%20country.pdf. [Last accessed on 2013 Feb 20].
16. Patel V, Vaidya R, Naik D, Borker P. Irrational drug use in India: a prescription survey from Goa. *J Postgrad Med* 2005;51:9-12.

Author's Contributions

KS, PJ, AB, and PU conceptualized the study. KS, PJ and PU contributed to data collection, analysis and drafting the manuscript. KS, MS and PU provided critical inputs and helped in revising the manuscript. All authors have read and approved the final version.

Ethical Approval

Institutional ethical committee approval was sought prior to the start of the study.

Competing Interest

The authors declare that they have no competing interests.

Funding

Sources of funding: None.

Please cite this paper as: Batta A, Jain P, Sharma K, Shoaib M, Upadhyaya P. Current inclination of the clinicians for prescribing various fixed dose combinations: a retrospective, obsevational study in medicine outpatient department at a tertiary care hospital in Jaipur. *Int J Stud Res* 2015;5(1):3-6.

Received: 22 Jan 2015, Accepted: 14 Aug 2015

Access this article online

Quick Response Code:

Website: www.ijsronline.com

DOI: 10.4103/2230-7095.180078