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An audit of prescription for rational use of fixed dose drug combinations at a tertiary care dental setting

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Abstract

This study aimed to study about the rationality of various fixed dose combinations prescribed at a tertiary care dental setting, in Jaipur. After taking permission from the Institutional Ethical Committee, total 1654 prescriptions from all the clinical departments of the Rajasthan Dental College from December 2013 to September 2014 were analyzed. Our study revealed that 69.1% of the prescriptions contained fixed dose combinations, out of which majority of prescription (66.75%) had rational fixed dose combinations. Only 33.24% prescriptions had irrational fixed dose combinations. The average number of fixed dose combinations per prescription was 1.03. All the fixed dose combinations were prescribed by their brand names. 55.6% of the fixed dose combinations were prescribed by the oral route. The majority (37.1%) of the prescribed irrational fixed dose combinations were ofloxacin and ornidazole combinations, followed by non-steroidal anti-inflammatory combinations (24.7%). This study highlights the importance and need of awareness programs focusing on the deleterious consequences related to irrational use of medicines to ensure that the prescriber's knowledge and skills to prescribe rationally is updated frequently.

Keywords: Prescription audit, Irrational fixed dose combinations, Awareness programs.

Introduction

Combination products, also known as fixed dose drug combinations (FDCs), are combinations of two or more active drugs in a single dosage form. They are acceptable only when the dosage of each ingredient meets the requirement of a defined population group and when the combination has a proven advantage over single compounds administered separately in therapeutic effect, safety or compliance.[1] With the continuous and progressive increase in the usage of all sorts of bizarre combinations of drugs at present untoward adverse events, undesired monetary load on gullible patient and beyond all other considerations the emergence of drug-resistance strains of microorganisms have resulted.[1-2]

Over seventy dangerous FDCs are being sold in India despite the fact that National list of essential medicines of India includes only fourteen FDCs. [3] Measures and initiatives taken to curb their use have rattled even the central drug controlling authorities. It is obligatory to understand various irrational fixed dose combinations being prescribed and avoid their use by the clinicians.

Materials and Methods

It was a retrospective observational study conducted in all the clinical departments of Rajasthan Dental College, a tertiary care teaching dental hospital from December 2013 to September 2014. Prior to the study, approval of the institutional ethics committee was sought. All the prescriptions containing fixed dose combinations were separated. Of these, prescription containing irrational FDC were collated and analyzed. WHO Seventeenth Model List of essential medicines, the National list of essential medicine of India (NLEM, 2011) and

Medline Indexed journal articles which revealed evidence of benefit in combinations were referred to determine the rationality of the FDC prescribed. The data was subjected to descriptive analysis using Microsoft Excel and the results were expressed as percentages.

Results and Discussion

The majority of the prescriptions (n=1143, 69.1%) contained fixed dose combinations as depicted in figure-1.

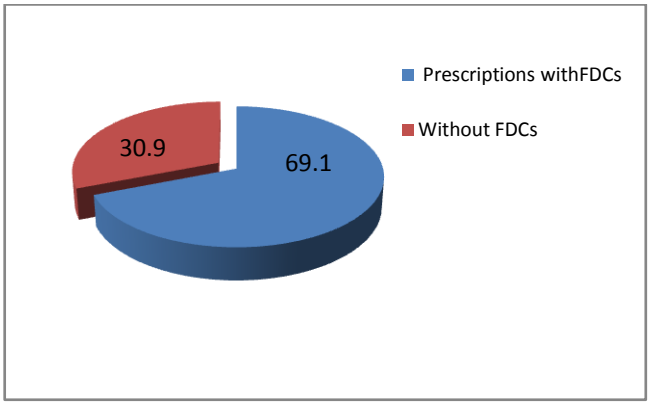

Figure 1: Percentage of prescriptions containing fixed dose combinations versus without fixed dose combinations

Rational fixed dose combinations were mostly prescribed (763, 66.8%) as compared to irrational ones (380, 33.2%). The average number of FDCs per prescription was 1.03 as illustrated in table-1.

Table 1: Details of the prescription analyzed

Variables	Number
Total no. of prescriptions analyzed	1654
Prescriptions with FDCs	1143
Prescriptions with rational FDCs	763
Prescriptions with irrational FDCs	380
Average no. of FDCs per prescription	1.03

Lignocaine and Epinephrine combination was the most frequently prescribed (66.6%) rational fixed dose combination, followed by the combination of amoxicillin and clavulanic acid (31.4%) as illustrated in table-2.

Table 2: Frequency prescribed rational FDCs

FDCs	No. of times prescribed
Lignocaine + Epinephrine	508
Amoxicillin + Clavulanic acid	240
Ferrous salts + Folic acid	15
Total	763

The majority (37.1%) of the prescribed irrational fixed dose combinations were ofloxacin and ornidazole combined, followed by non-steroidal anti-inflammatory combinations (24.7%) as depicted in table-3 and figure-2.

Table 3: Category wise distribution of irrational FDC prescribed

Drug category	Group	Combination with	No. of times prescribed
CNS	NSAIDs	a) NSAID	94
		b) Skeletal muscle relaxant	20
		c) Anti-inflammatory enzyme	35
GIT	Antiemetic	a) PPIs	42
		b) H2 receptor blocker	10
Anti infective	a) FQs	Antiamoebic	141
	b) Cephalosporins	Probiotic	10
Nutritional supplements	Vitamin	Vitamin	28

NSAIDs = Non-steroidal anti-inflammatory drugs, PPIs = Proton pump inhibitors, FQs = Fluoroquinolones, CNS = Central nervous system, GIT = Gastrointestinal tract

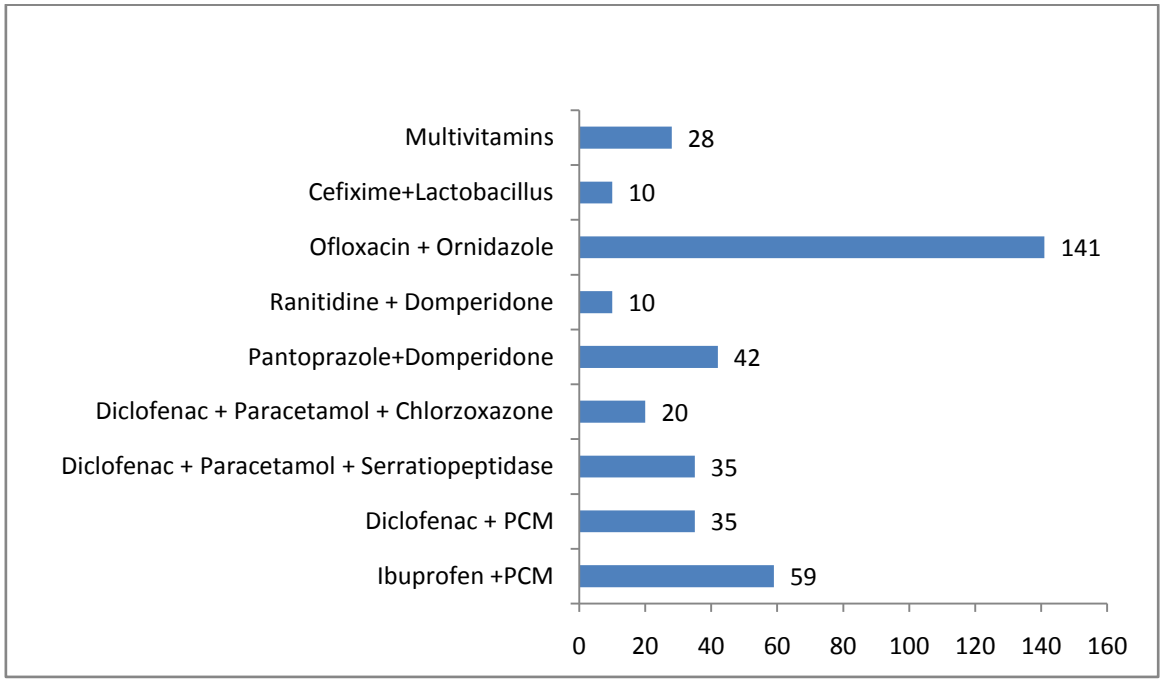

Figure 2: Frequency of various irrational FDC prescribed

Fixed dose combinations are available for the treatment of various ailments ranging from nutritional deficiency to cardiovascular, tubercular diseases, thereby extending the range of treatment options for such diseases. However irrational FDCs are a menace worldwide. [4] A sordid fact behind this burgeoning list of irrational and inconsistent fixed dose combination is the huge profits, which the pharmaceutical manufacturers continue to procure and therefore the vicious cycle of manufacturing and marketing of such products goes on.

Many studies were undertaken previously in various medical hospitals and pharmacy stores evaluating the rationality of various fixed dose combinations prescribed by the clinicians. These studies throw light on a significantly higher number of irrational fixed dose combinations which were prescribed over the rational ones. [5-7] On the contrary, in our study, which was undertaken in tertiary care dental setting majority of the prescribed FDCs were rational. This might be due to the nature of dental diseases which often require interventional procedures than mere pharmacotherapy. Irrational use of medicine was reflected in this study also, though to a lesser extent. The Seventeenth WHO Model list of Essential Medicines for adults contains only 24 FDCs while only 18 FDCs are included in the National list of essential medicines (NLEM 2011).[8-9] Despite this fact over 70 irrational FDCs are sold in India under 1000 brand names. [10]

Irrational use of medicine was reflected in this study also. It was observed that non-steroidal anti-inflammatory drugs (NSAIDs) were combined with other NSAIDs, skeletal muscle relaxants, anti-inflammatory enzymes in our study, though there is no rational basis for such combinations. FDCs of diclofenac and serratiopeptidase do not offer any particular advantage over the individual drugs despite the claim that serratiopeptidase promotes more rapid resolution of inflammation. On the contrary, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration.[11] Skeletal muscle relaxants (chlorzoxazone, chlormezanone, methocarbamol) increase the risk of gastric adverse effects and provide no additional benefit to the patient. NSAIDs combination is associated with the increased risk of nephrotoxicity.[12]

Antiemetic domperidone was prescribed as fixed dose combinations with proton pump inhibitors and H2 blockers in our study. These fixed dose combinations has no rational basis as H2 blockers and proton pump inhibitors are effective in peptic ulcer and it is irrational to combine these drugs with an antiemetic as peptic ulcer is not always associated with vomiting.[4] The Drug Controller General of India (DCGI) has banned use of FDC of vitamin B1, vitamin B6 and vitamin B12 for human use as it has no therapeutic advantage over individual drugs.[5] In this study also 7.4% of the irrational FDC were multivitamin preparation in contrast to previous studies where majority of irrational FDCs prescribed were multivitamins preparations. [5-7]

Though fixed dose combinations of quinolones and nitroimidazoles (e.g. ofloxacin + ornidazole) have not been recommended in any standard books [13-14], but continue to be heavily prescribed drugs in dental infections. Similarly there is no rational in combining cephalosporins with probiotics. There are no controlled studies which prove the role of lactobacillus in its prevention of antibiotic-induced diarrhoea.[11] Such imprudent use of antibiotic FDCs can rapidly give rise to resistant strains of organisms. In our study 55.6% of FDCs were prescribed by oral route and rest 44.4% by topical route. All the FDCs in our study were prescribed by their brand names.

The present study showed a prevalence of prescribing of irrational fixed dose combinations and inclination of the clinicians to prescribe branded medicines. Prescribing behavior of a clinician not only governed by sound clinical knowledge, but at the same time also influenced by a large number of factors, including professional colleagues, academic literatures and government regulations.[15] Dependence on medical representatives for medical information by the prescribers, ultimately leads to an irrational use of medicines. This is mostly seen in private settings where the entry of medical representatives is not restricted, and clinicians fall prey to the persuasive behavior of medical representative.

The prescribers should undergo a continuing medical education (CME) course, once in a year on newer drug combinations introduced into the market and their adverse drug reactions, so that the prescribing practices become not only justifiable but evidence-based also. The drugs and therapeutics committee (DTC) of every hospital should actively involve in guiding and monitoring the drug use by conducting prescription audits regularly and monitoring adverse drug events encountered in their hospitals. Generic prescribing and generic substitution are mechanisms for reducing the cost of drug and should be encouraged at the tertiary care settings also.

The results of our study may vary from other studies that have been carried out at government hospitals or tertiary care settings where guidelines for the rational prescription of medicines are followed as per the standard guidelines like Essential Medicine List, drug formularies and Standard Treatment Guidelines (STG) that are available. Also, this was undertaken in dental tertiary care settings where pharmacotherapy is not the mere tool for curing the diseased patient, so the chances of irrational prescribing is also less frequent as the medical tertiary care center.

Conclusion

Awareness programs focusing on newer drug combinations introduced into the market and the adverse drug reactions associated with them should be made mandatory for all the clinicians to ensure that the their knowledge and skills to prescribe rationally is updated frequently. Extensive studies focusing on rational use of drugs could be fruitful besides public consciousness.

Conflict of Interest: None

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