**To evaluate the outpatient department based prescribing pattern of Fixed Dose Combinations in a Tertiary Care Institute in Central India.**

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**ABSTRACT**

This study was done to evaluate the prescribing pattern of Fixed Dose Combinations (FDC) in a Tertiary Care Institute in Central India and help to formulate the institutional guideline for rational use of FDC. This was a prospective observational study conducted in All India institute of Medical Sciences, Bhopal, MP, India. We have collected 1008 prescriptions from in house pharmacy by convenience sampling method over a period of two months. The data was subjected to descriptive analysis using Microsoft excel and Graphpad Prism. Results were expressed in mean ± SD, percentages and 95% confidence interval. A total of 2496 drugs prescribed in 1008 prescriptions out of which 945(37.82 %) were FDC with an average of 0.93±0.94 (mean ± SD) per prescription. Out of which 67 (7.09 %) were included in National List of Essential Medicine 2015 considered as rational. Prescriptions containing one or more FDC were 629 (62.40 %). FDC were more frequently prescribed in male patients (54.92 %) and in age group of 18to 30 years (33.44 %). FDC containing Proton pump inhibitor were prescribed most frequently (16.29 %) followed by NSAID (13.96 %) and multivitamins (7.83 %). We observed that the prescribing irrational FDC are very common and hence there is obvious need to update our prescribers about the irrationality of FDC and motivate them to develop a habit of rational prescribing. Audit team should regularly review the prescriptions of their prescribers so as to identify the rationality and appropriateness of fixed dose combinations.

**Key words**: Prescription audit, Drug use pattern, Drug utilization study, Fixed dose combinations, Rational prescription

**INTRODUCTION**

New drug discovery and development is a cumbersome, time and money consuming process. Identifying a new lead, developing it into a molecule so that it becomes a potential drug in the market and then its marketing requires a lot of time and money. And hence, fixed dose combinations (FDC) of already available drugs are an attractive shortcut to new drugs in the market. FDC are pharmaceutical products containing two or more active drugs in a single dosage form. It is widely accepted that drug dosage forms should generally be composed of a single pharmacologically active compound. A fixed ratio combination is acceptable only when it meets the requirements of a defined population and when the combination has a proven advantage over single compound administered separately in terms of therapeutic effect, safety or compliance[1]. The active ingredients of a rational fixed dose combination should act by different mechanisms, their pharmacokinetics must not be widely different and they should not have supra-additive toxicity [2].

But the Indian market is flooded with a large number of FDC which do not fulfill the above criteria and can be considered to be irrational [3]. This is despite the fact that the National list of Essential Medicines (2015) contains only 14 FDC and the 19th WHO Model list of Essential Medicines (April 2015) contains 27 FDC [4,5]. In India FDC are available for the treatment of various disorders e.g. cardiovascular diseases, diabetes, infectious diseases (bacterial infections), gastro intestinal infections, orthopedic conditions, cough and cold, HIV infection, tuberculosis, psychiatric disorders and respiratory diseases. Many FDC available may contain banned or controversial active ingredients. Physicians are not aware about the concept of irrationality of FDC hence irrational FDC are being widely prescribed [6].

Thus, it is worthwhile to evaluate the pattern of FDC prescribing in a tertiary care teaching hospital in Central India. It is obligatory to understand various irrational fixed dose combinations in the market and to discourage their use [7].

**MATERIALS AND METHODS**

**Study design and site:** This was a prospective observational study conducted in All India institute of Medical Sciences (AIIMS) Bhopal.

**Sample size calculation***:* Sample size was calculated using an online available Raosoft sample size calculator for a population size of 20000 with 5% acceptable margin of error. It was come out to be 1000 with a margin of error of 3.02%.

**Data collection***:* We have collected 1008 prescriptions by convenience sampling method. One of our researchers went to in house pharmacy, 5 days a week at a chosen time and collected first 25 prescriptions came to pharmacy, over a period of two months. The essential information like patients OPD (outpatient department) number, age, sex, diagnosis, drugs prescribed, dosage form, frequency, duration and the treating department was recorded in Microsoft excel sheet. *Name of patient and treating physician was kept confidential*. The prescriptions containing fixed dose combinations were separated and analyzed in reference to its contents and strength of each component. FDC included in the National list of essential medicine of India (NLEM, 2015) were considered rational. Combinations prescribed from outside NLEM were analyzed for rationality. It was broadly decided to consider an FDC irrational if

1. One or more components were likely to be unnecessary for the majority of patients who were prescribed the FDC.
2. One or more component was present in a strength other than recommended strength.
3. One or more component may interfere with action of another.
4. One or more component may increase the adverse effects of another.

**Statistical Analysis***:* The data was subjected to descriptive analysis using Microsoft excel and online software Graph pad prism. Results were expressed in mean ± SEM (standard error of mean), Standard Deviation (SD), percentages and 95% confidence interval.

**RESULTS**

Total number of prescriptions analyzed was 1008, which contained a total of 2496 drugs with an average of 2.47± 1.22 (mean ± SD). Prescriptions containing one or more Fixed Dose Combination (FDC) were 629 (62.40 %).

Total FDC written were 945 [37.82 %, (95% CI 0.359 - 0.397)] out of which 67 [7.09 % (95% CI (0.056 - 0.089)] were included in NLEM 2015 considered as rational FDC and rest 878 [92.91 %, (95% CI 0.911 - 0.944)] were irrational. Average number of FDC per prescription was 0.93± 0.94 (mean ± SD). (Table 1)

The number of FDC prescribed in male patients was 519 (54.92 %) and in female patients 422 (44.65 %). FDC were most commonly prescribed in age group of 18 to 30 years (33.44 %) followed by age group of 31 to 49 years (32.38 %) and 50 to 69 years (20.32 %). Patients below 18 years and above 70 years of age were prescribed 8.46 % and 4.34 % FDC respectively. (Table 2)

There were 395 (62.79 %) prescriptions containing one FDC followed by 169 (26.86 %), 52 (8.26 %), 9 (1.43 %) and 4 (0.63%) prescriptions containing two, three, four and five FDC respectively. (Table 3)

Amongst all the prescriptions containing FDC, department of General Medicine wrote maximum 144 (22.89 %) followed by department of Dermatology 100 (15.89 %), Community and Family Medicine (CFM) 57 (9.06 %) and Dentistry 50 (7.94 %). FDC prescriptions per department was maximum in department of Neurosurgery (96.66 %) followed by Dentistry (87.72 %), PMR (86.66 %), Orthopedics (84.90 %) and ENT (75.55 %). (Table 4)

The most frequently prescribed FDC that is 154 (16.29 %) comprised of a proton pump inhibitor (PPI) with an ant-emetic. Rabeprazole was the PPI most frequently included (75, 48.70 %), while Domperidone was the most common ant-emetic. Non-Steroidal Anti-inflammatory Drugs (NSAID) were a component of 132 (13.96 %) FDC, the most common NSAID being paracetamol, present in 73 (55.30 %) preparations. There were 74 (7.83 %) fixed dose combinations of vitamins and micronutrients. Other FDC included combinations containing steroids (61, 6.45%), calcium and vitamin D combinations (60, 6.34 %) and combinations containing an antibacterial with an antiprotozoal (22, 2.32 %). We found only 1 (0.10 %) combination of cefuroxime with clavulanic acid. FDC of Antitussive and expectorant like dextromethorphan with ammonium chloride and chlorpheniramine with bromhexine were 54 (5.71 %). FDC containing Lactobacilli at a dose of 20 million units per day were 11 (1.16 %) (Table 5)

Rational FDC included Amoxicillin plus Clavulanic acid (38, 56.71%), Oral Rehydration Solution (10), Formoterol plus Budesonide (7), Ferrous salt plus Folic acid (6), Levonorgesterel plus Ethinylestradiol(2), Cotrimoxazole(2), Lidocaine plus Prilocaine(1) and Levodopa plus Carbidopa(10). (Table 6)

**DISCUSSION**

Fixed dose combinations of drugs do have certain advantages like reduced number of pills to be taken, leading to simpler medication regimens which in turn may improve patient compliance. Some FDC are designed such that the individual components act synergistically to increase desirable pharmacological effects, or to reduce adverse effect/s. They may sometimes also be less expensive than individual component formulations [8-11]. But common limitations of FDC include the inability to adjust doses of individual components, inadequate doses of components and presence of a component which may be unnecessary in a particular patient [12-14]. Inappropriate use of FDC has been reported to increase the incidence of adverse events, escalated drug costs and, in case of antimicrobials, encourage emergence of drug-resistant strains of microorganisms [15].

In our study we found that around 67% prescriptions contain FDC suggesting higher rate of prescribing FDC. This proportion is less as compare to the study done in Ahmadabad (80 %) [9] while more as compare to the study done in Nepal (39 %) [16]. The inconsistency in result is because in Ahmadabad, study included three seasons over the period of two years and Nepal being different country might be having different drug preparation available.

Out of total drug prescribed around 38% were FDC which is lower as compare to study done in Ahmadabad (50 %) [9]. Amongst these only 7.09% FDC were included in the latest version of the National List of Essential Medicines, which is similar to the proportion reported from Ahmadabad (9.8 %) [9] while more than that from Nepal (1%) [16].

The number of FDC prescribed in male patients was 1.22 times more than in female patients, and the most common age groups in whom FDC were prescribed was 18- 30 years and 31 -49 years which is consistent with the observation of studies done in Ahmadabad [9] and Uttaranchal [17].

In our study we found that the Prescriptions containing one, two and three FDC were 62.79 %, 26.86 % and 8.26 % respectively which is different than the results obtained from a study done in Nepal, where these were 82.4 %, 14.4 % and 3.0 %, respectively [16]. We observed in our study that maximum (96 %) of the prescription written by department of Neurosurgery contains at least one FDC, followed by department of Dentistry (87.72 %), PMR (86.66 %) and Orthopedics (84.90 %) while Department of Psychiatry wrote minimum (25 %) such prescriptions.

Our study showed that amongst all FDC prescribed, the maximum (16.29%) were combinations of proton pump inhibitor (PPI) with ant-emetics. The results are not consistent with a study from Ahmadabad where 5.7 % such FDC were prescribed [9]. FDC of proton pump inhibitor (PPI) or H2 receptor blockers with antiemetics are not rational as they have incompatible pharmacokinetics [18]. Non-steroidal anti-inflammatory drugs (NSAIDs) are commonly combined with other NSAIDs, skeletal muscle relaxants and enzymes, which are irrational, as they do not provide any therapeutic advantage of the FDC in a therapy [2] [18]. There is no synergism when two drugs acting on the same enzyme are combined. Thus combining two NSAIDs does not and cannot improve the efficacy of treatment. It only adds to the cost of therapy and more importantly, to the adverse effects [19] and the ‘muscle relaxants’ in some of these combinations are of questionable efficacy. Our study showed that the combinations containing NSAIDs were the second most commonly prescribed FDC. The most commonly used NSAID in various FDC was paracetamol, while in a study in Nigeria showed that the most common NSAID prescribed was aspirin [20].

Irrational use of FDC of antimicrobial is also very common. Clavulanic acid and sulbactam are useless in combination with cephalosporins since these β-lactamase inhibitors are not effective against Class-I chromosomal β-lactamases produced by gram negative bacilli [2, 21]. Our study showed that the prescribers are well aware in writing antimicrobial FDC as we found only 1 irrational combination of cephalosporin (cefuroxime) and Clavulanic acid. FDC containing an antibacterial with an antiprotozoal are prescribed frequently. In majority of cases of dysentery, mixed infection (bacillary and amoebic) do not occur simultaneously, making one of the ingredients not only unnecessary, but also contributing to increase in medication costs as well as adverse effects [22]. In our study we did find a small percentage (2.32%) of prescriptions containing such combinations. Although the recommended dose of probiotics for treatment of diarrhea is 5 billion per day, many FDC have the strength of lactobacillus in the range of 20 to 60 million bacilli, which is not sufficient [22]. In our study we observed 11 FDC containing lactobacilli at a dose of 20 million were prescribed.

The combinations of vitamins B1, B6 and B12 have been banned for human use in India [23]. Various combinations of vitamins with or without minerals are prescribed as nutritional supplements. However, a deficiency of all the ingredient vitamins or minerals may not be present in the given patient. Also the dose of different vitamins/minerals in the FDC may not be the same as recommended therapeutic doses. Multivitamin and mineral preparations were the third most commonly prescribed FDC (7.83%) in our study after PPI and NSAIDs, although this proportion was much less than that reported at another tertiary care institute where 31.3% multivitamin combinations were prescribed [16].

Antitussives are used for the treatment of dry cough while expectorants are useful for cough with expectoration. Both the conditions do not coexist. Hence, it is irrational to use both antitussive and expectorant in combination. In addition, a centrally active antitussive agent may antagonize the supposed expectorant effect of expectorants that may lead to atelectasis [23]. In our study we found that 5.71% of all drugs prescribed were combination of antitussive and expectorant which was lesser than the study done in Nepal (17 %) [16].

FDC containing corticosteroids are not always rational but ICS (inhalational corticosteroids) can rationally be combined with other inhalational agents for treatment of Asthma and COPD [24]. Our study showed that out of the entire FDC containing steroid only 11.47 % were rational (Budesonide + Formoterol combination).

Calcium supplementation, with concomitant vitamin D supplementation, is supported for patients at high risk of calcium and vitamin D insufficiency, and in those who are receiving treatment for osteoporosis [25]. Our study showed that the all the calcium containing FDC were irrational either due to content or the doses.

**Limitation of study:** The study has been carried out in two consecutive months so seasonal variation of prescribing FDC cannot be analyzed. Diagnosis based prescription audit was not done and hence could not comment on the reason of prescribing FDC.

**CONCLUSION**

There is obvious need to update our prescribers about the irrationality of FDC and motivate them to develop a habit of rational prescribing. Awareness of irrationality of antimicrobial FDC was found out to be adequate but on the other hand prescribing irrational FDC of PPI, NSAID and Multivitamins is common and we need to spread awareness regarding reduction in their use. Apart from that reducing the prescribing habit of Antitussive and expectorants combinations also need to address. Steroids and calcium containing combinations should be prescribed in appropriate doses. Department wise audit helped us to focus on the prescribers writing excessive number of irrational FDC. Most importantly audit team should regularly review the prescriptions of their prescribers so as to identify the rationality and appropriateness of fixed dose combinations.

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**Conflict of Interest**: The authors declare that they have no conflict of interest.

**Ethical approval**: This study protocol was approved by Institutional Human Ethics Committee*,* All India Institute of Medical Sciences, Bhopal, Madhya Pradesh, India. Approval no. **IHEC-LOP/2016/IM0091.**

**Informed consent:** For this type of study formal consent is not required.

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**TABLE 1: PRESCRIPTIONS ANALYSIS**

|  |  |  |  |
| --- | --- | --- | --- |
|  | N (%) [CI (95%)] | | MEAN ±SEM, SD |
| Total number of prescriptions | 1008 (100) | |  |
| Total number of drugs prescribed | 2496 (100) | |  |
| Prescriptions containing 1 or more FDCs | 629 (62.40) | |  |
| Total FDCs written | 945 (37.82)[0.359 - 0.397] | |  |
| \*RATIONAL | \*IRRATIONAL |  |
| 67 (7.09)[0.056 - 0.089] | 878 (92.91)[0.911 - 0.944] |
| Average number of drugs per prescription |  | | 2.47±0.038, 1.22 |
| Average number of FDCs per prescription |  | | 0.93±0.029, 0.94 |

\*Rational/irrational on the basis of included/not included in NLEM 2015 respectively. NLEM: National List of Essential Medicine 2015[9]. CI is confidence interval. SEM is standard error of mean. SD is standard deviation.

**TABLE 2: DEMOGRAPHIC DISTRIBUTION OF PRESCRIPTIONS CONTAINING FDC.**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Prescriptions | | | FDCs | | |
|  | N (629) | % (100) | | N (945) | % (100) | |
| Sex | | | | | | |
| Male | 349 | 55.48 | M:F Ratio 1.25 : 1 | 519 | 54.92 | M:F Ratio 1.22 : 1 |
| Female | 278 | 44.19 | 422 | 44.65 |
| NA | 2 | 0.32 | | 4 | 0.42 | |
| Age group | | | | | | |
| <18 | 56 | 8.90 | | 80 | 8.46 | |
| 18 – 30 | 211 | 33.54 | | 316 | 33.44 | |
| 31 – 49 | 199 | 31.63 | | 306 | 32.38 | |
| 50 – 69 | 126 | 20.03 | | 192 | 20.32 | |
| ≥ 70 | 28 | 4.45 | | 41 | 4.34 | |
| NA | 9 | 1.43 | | 10 | 1.06 | |

**TABLE 3: NUMBER OF FDC PER PRESCRIPTION**

|  |  |  |
| --- | --- | --- |
| NO. OF FDCS/prescription | NO. OF PRESCRIPTIONS, N= 629, (100%) | Total FDCs (945) |
| 5 | 4 (0.63) | 20 |
| 4 | 9 (1.43) | 36 |
| 3 | 52 (8.26) | 156 |
| 2 | 169 (26.86) | 338 |
| 1 | 395 (62.79) | 395 |

**TABLE 4: DEPARTMENT WISE DISTRIBUTION OF PRESCRIPTIONS CONTAINING FDCS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Department** | **Total prescriptions** | | **Prescriptions containing FDCs** | | **FDC prescriptions per Department (%)** |
| **N (= 1008)** | **%** | **N (= 629)** | **%** |
| GENERAL MEDICINE | 226 | 22.42 | 144 | 22.89 | 63.71 |
| DERMATOLOGY | 206 | 20.43 | 100 | 15.89 | 48.54 |
| \*CFM | 97 | 9.62 | 57 | 9.06 | 58.76 |
| DENTISTRY | 57 | 5.65 | 50 | 7.94 | 87.72 |
| ORTHOPEDIC | 53 | 5.25 | 45 | 7.15 | 84.90 |
| \*\*ENT | 45 | 4.46 | 34 | 5.40 | 75.55 |
| GENERAL SURGERY | 45 | 4.46 | 30 | 4.76 | 66.66 |
| NEUROLOGY | 46 | 4.56 | 29 | 4.61 | 63.04 |
| NEUROSURGERY | 30 | 2.97 | 29 | 4.61 | 96.66 |
| #OBGY | 54 | 5.35 | 29 | 4.61 | 53.70 |
| PULMONARY MEDICINE | 40 | 3.96 | 28 | 4.45 | 70 |
| PEDIATRICS | 55 | 5.45 | 27 | 4.29 | 49.09 |
| ##PMR | 15 | 1.48 | 13 | 2.06 | 86.66 |
| OPHTHALMOLOGY | 21 | 2.08 | 9 | 1.43 | 42.86 |
| PSYCHIATRY | 16 | 1.58 | 4 | 0.63 | 25 |
| BURNS & PLASTIC SURGERY | 2 | 0.19 | 1 | 0.16 | 50 |

\*CFM- Community and Family Medicine.

\*\* ENT- Ear, Nose and Throat.

#OBGY- Obstetrics and Gynecology.

## PMR- Physical Medicine and Rehabilitation

**TABLE 5: FREQUENTLY PRESCRIBED FIXED DOSE COMBINATIONS (FDCS).**

|  |  |  |
| --- | --- | --- |
| **Drug group/ name** | **N** | **%** |
| PPI\* + ant-emetic | 154 | 16.29 |
| NSAID \*\* containing combinations | 132 | 13.96 |
| Multivitamins and micronutrients | 74 | 7.83 |
| Steroidal# Combinations | 61 | 6.45 |
| Calcium with Vitamin D | 60 | 6.34 |
| Antitussive plus Expectorants | 54 | 5.71 |
| Amoxicillin Clavulanic acid | 38 | 4.02 |
| Antibacterial + Antiprotozoals | 22 | 2.32 |
| Lactobacilli (20 million units) | 11 | 1.16 |
| Cefuroxime + Clavulanic acid | 1 | 0.10 |

\*Rabeprazole [75/154 (48.70%)] was the most commonly used PPI in FDCs.

\*\*Paracetamol [73/132 (55.30 %)] was the most commonly used NSAID in FDCs.

# Budesonide [7/61 (11.47 %)] was the only Inhalational Corticosteroid (ICS) included in NLEM.

**TABLE 6: FDCS INCLUDED IN NLEM 2015 (RATIONAL FDCS)**

|  |  |
| --- | --- |
| Amoxicillin + Clavulanic Acid | 38 |
| Oral Rehydration Solution | 10 |
| Budesonide + Formoterol | 7 |
| Ferrous Salt+ Folic Acid | 6 |
| Cotrimoxazole | 2 |
| Levonorgesterel + Ethinylestradiol | 2 |
| Levodopa + Carbidopa | 1 |
| Lidocaine + Prilocaine | 1 |
| **Total** | **67** |