

Prescription pattern of fixed dose drug combinations in obstetrics and gynecology department of a tertiary care hospital in Puducherry, India: an observational study

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ABSTRACT

Background: Fixed drug combinations (FDCs) have various advantages and disadvantages. In countries like India there are numerous irrational prescriptions as highlighted by the recent banning of FDCs in October 2018. Studying the prescription pattern helps in developing national database which can be used to promote rational use of drugs.

Methods: All the Outdoor Patient Department (OPD) prescriptions from department of Obstetrics and Gynecology (OBG) during the study period were used for the study. The drugs were classified according to Anatomical Therapeutic Chemical (ATC) classification. Other data studied were the number of FDCs and the number of currently banned combinations which were used during the study period.

Results: The 41% of the drugs prescribed as FDCs. Most FDCs belonged to alimentary system followed by anti-infectives and blood and blood forming organs group. Vitamin D3 and Calcium combination was the most commonly prescribed FDC. Approximately 20% of these prescribed drugs are currently banned.

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

Keywords: Fixed drug combinations, Prescription, irrational, ATC classification

INTRODUCTION

The term FDC is synonymous with fixed-ratio combination. Both terms refer to a product that contains two or more active ingredients. World Health Organization (WHO) defines Fixed Dose Combinations (FDCs) as combination of two or more active ingredients in a fixed ratio of doses.¹ Some advantages of fixed-dose combinations are better patient compliance and economical. They also have some disadvantage like they discourage adjustment of doses according to patient's need.² Numerous irrational fixed drug combinations are

prescribed in India. The most pressing concern with irrational FDCs is that they expose patients to unnecessary risk of adverse drug reactions.³

This study becomes even more relevant in the context that as many as 328 fixed drug combinations have been banned after a prolonged battle between pharmaceutical industry and regulatory bodies in September 2018. This shows how rampant is the menace of irrational fixed drug combination.⁴ Prescription pattern monitoring studies focus mainly on prescribing, dispensing and administering of drugs. They promote appropriate use of monitored

drugs and reduction of abuse or misuse of monitored drugs.⁵

Obstetrics and Gynecology (OBG) is one such department where FDCs are commonly used and there is need to monitor the prescription pattern of such FDCs to promote rational use of medications.

METHODS

This is a prospective and observational study done in a tertiary care hospital of Pondicherry institute of medical sciences, a six hundred and forty bedded hospital, in Pondicherry, India.

All the patients attending Obstetrics and Gynecology Outdoor patient department were selected.

Inclusion criteria

Prescriptions of all patients attending Obstetrics and Gynecology Outpatient department during the study period were included in this study.

Exclusion criteria

Indoor patients attending Obstetrics and Gynecology Outdoor patient department were excluded from this study.

The study was conducted during the period of April - October, 2016. Patients attending Obstetrics and Gynecology Outdoor patient department from in and around Pondicherry.

A total of One thousand four hundred and eighty two prescriptions were collected and analyzed prospectively. All the Outdoor patient department Prescriptions from Obstetrics and Gynecology department over a period of 6 months were collected.

Data analysis

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.

The percentage of Fixed drug combinations used in each class and their contribution to overall Fixed drug combinations were calculated. Number of Fixed drug combinations that are currently banned were also identified.

Since this is an Observational study where data was obtained using Outdoor Patient Department prescriptions of Obstetrics and Gynecology Department, without any risk associated with interventional human studies and hence there are no ethical considerations.

RESULTS

In 1482 prescriptions, a total of 2787 drugs were prescribed. Of this, 1166 were FDCs and 1621 were others. 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.

ATC Class of drugs	FDC	Non-FDC
Alimentary tract	552 (36.70%)	952 (63.3%)
Blood and blood forming organs	49 (13.53%)	313 (86.47%)
CVS	0 (00.00%)	6 (100%)
Dermatology	1 (16.66%)	5 (83.34%)
Genitourinary	38 (19.89%)	153 (80.11%)
Systemic hormones	0 (00.00%)	21 (100.00%)
Anti-infective	188 (47.95%)	204 (52.05%)
Musculoskeletal	29 (72.50%)	11 (27.50%)
Nervous system	69 (72.63%)	26 (27.37%)
Anti-parasitic	0 (00.00%)	79 (100.00%)
Respiratory system	49 (55.68%)	39 (44.32%)
Others	1 (33.33%)	2 (66.67%)

The highest percentage of FDCs were seen in Alimentary tract and metabolism (56.61%), followed by anti-infective (19.28%), Nervous system (07.07%), Blood and blood forming organs (05.02%) and Respiratory system (05.02%) as shown in the Table 2.

Table 2: Percentage of different FDCs prescribed.

ATC Class of drugs	FDC	Percentage
Alimentary tract	552	56.61%
Blood and blood forming organs	49	05.02%
CVS	0	00.00%
Dermatology	1	00.102%
Genitourinary	38	03.89%
Systemic hormones	0	00.00%
Anti-infective	188	19.28%
Musculoskeletal	29	02.97%
Nervous system	69	07.07%
Anti-parasitic	0	00.00%
Respiratory system	49	05.02%
Others	1	00.102%

Among drugs affecting the Alimentary system, the most common FDC was a combination of Vitamin D3 and Calcium (97.46%) followed by antacid combination of Oxethazaine+ magnesium hydroxide+aluminium hydroxide (0.90%) and Ascorbic acid + sodium ascorbate (0.04%) as shown in the Figure 1.

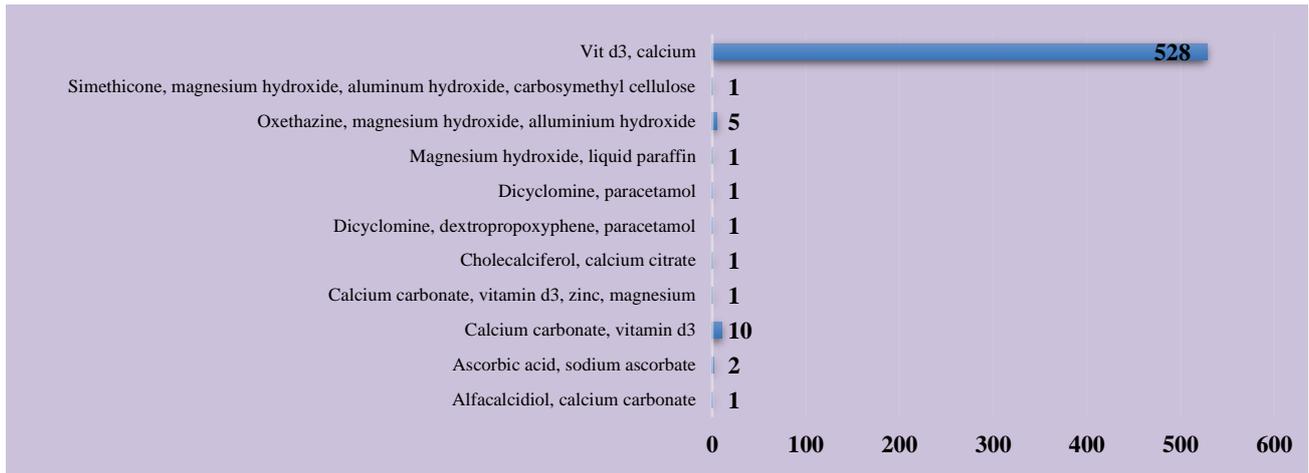


Figure 1: Number of different FDCs prescribed in alimentary system.

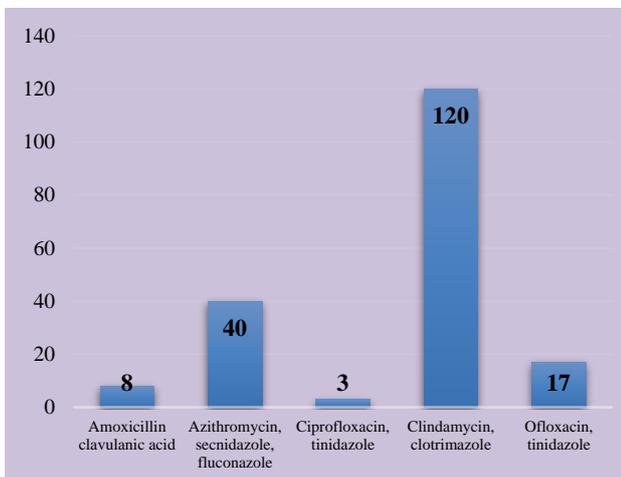


Figure 2: Number of different FDCs prescribed in anti-infectives.

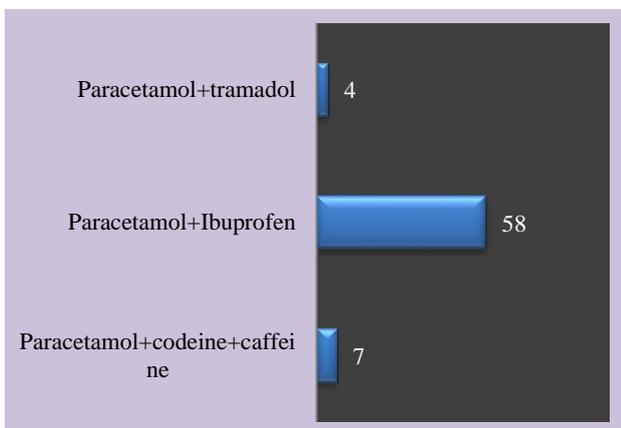


Figure 3: Number of FDCs prescribed in nervous system.

In the anti-infective class of drugs, the most common FDCs prescribed were combinations of

clindamycin+clotrimazole (63.82%), followed by combination of Azithromycin+secnidazole+ fluconazole (21.27%) and ofloxacin+tinidazole (09.04%) as shown in the Figure 2.

Among drugs affecting the Nervous system combination of Paracetamol + ibuprofen was the most commonly prescribed FDC as shown in Figure 3.

No FDCs belonging to systemic hormonal preparations, cardiovascular system and antiparasitic group were used. Approximately 20% of the FDCs are currently banned and that list is shown in Table 3.

Table 3: FDCs prescribed in the study which are currently banned.

ATC class	FDC	No of prescriptions
Anti-infective	Azithromycin, secnidazole, fluconazole	40
	Clindamycin, clotrimazole	120
Musculoskeletal	Mafenamicacid, paracetamol	1
	Mefenamic acid, dicycloverine	27
Nervous system	Paracetamol, codeine, caffeine	7
	Paracetamol, tramadol	4
Respiratory system	Diphenhydramine, ammonium chloride, sodium citrate, menthol	1
	Doxylamine, pyridoxine	36
Total		236

DISCUSSION

The Indian medicine market has become the world leader of FDCs and number of estimated FDCs in India is over 6000. Numerous studies have shown violation of scientific merits without adequate justification among available FDCs. There is no database of currently available FDCs in the market, their sales turnover and use pattern.⁶ Poly-pharmacy is very common and there is an increasing inclination to combine drugs, more often than not without a sound rational basis for doing so.⁷

This is a prospective observational study done in a tertiary care hospital done using prescriptions of patients attending OBG OPD during the study period.

Authors have found that a total of 41% drugs were FDCs. A study conducted by Biswadeep das MD et al, had 64.8% as FDCs which is high compared to our study.⁸ 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.⁹ Vitamin D3 and Calcium combination was the most commonly prescribed FDC. This is probably explained by the use of this FDC to prevent osteoporosis IN POST-MENOPAUSAL WOMEN. 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.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.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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