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Original Research Article

Evaluation of Fixed Dose Combinations (FDCs) prescribing pattern in Tertiary care teaching Hospital and private sector

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Abstract: The study of prescribing pattern is a component of medical audit, which seeks monitoring, evaluation and necessary modification in the prescribing practices of prescribes to achieve rational and cost effective medical care. This study was conducted to evaluate the Fixed Dose Combinations (FDCs) prescribing pattern in Tertiary care teaching Hospital and private sector. This prospective study was designed to obtain statistical data on the prescribing pattern of FDCs in patients visiting either in the outpatient department or outside the hospital or clinics and also the patient admitted in the various specialties of S.V.B.P. hospital Meerut and other associated hospital/ clinics in the vicinity over a period of one year. Most of the prescriptions in both the sectors were incomplete with respect to the prescribing format. The prescribing error was maximum in the various department of surgery followed by medicine. Average number of FDCs per prescription was found to be 0.67, & 0.88 in government, & private sectors respectively. Average number of FDCs prescribed was highest 1.54 and 1.87 in skin of both the sectors. Average number of FDCs prescribed was lowest 0.13 and 0.21 in ophthalmology of both the sectors government and private sectors respectively. Percentages of prescriptions with FDCs were found to be 43.28, & 49.71 in government, & private sectors. The prevalence of prescribing of FDC is high. There is need to improve the rational use of FDC by providing feedback by educators, prescribers and other interventions like introduction of hospital formulary or control by institutional regularly authorities.
Keywords: Evaluation, Fixed Dose Combinations, prescription, pattern, Tertiary care teaching Hospital, private sector

INTRODUCTION

During the past several years there had been great concern by the government as well as public regarding safe, effective and rational use of drugs. Now-a-days the prescribing pattern is changing and it has become just an indication of medicine with some instructions of doses without considering its rationality [1]. Prescribing fixed dose drug combinations has become the "in thing" in medical practice. Using the excuse of better patient compliance, many doctors, both in private as well as government setup prescribe irrational fixed dose drug combinations. Quite a few infectious diseases are becoming resistant to treatment with a single drug. With the escalating cost of drugs, there is poor drug compliance, which further magnifies the problem, both for the prescriber as well the patient.

Manufacturers of drugs having quickly turned in to the potential golden egg are marketing fixed dose drug formulations for various diseases. Monitoring of prescriptions and drugs utilization studies could identify the associated problems and provide feedback to the prescribers, so as to create awareness about the irrational use of drugs [2]. Effort to reduce the number

of drug related adverse events due to misinterpretation, medical error, inappropriate or patient noncompliance could result in substantial saving and, more important improved patient health [3].

The study of prescribing pattern is a component of medical audit, which seeks monitoring, evaluation and necessary modification in the prescribing practices of prescribes to achieve rational and cost effective medical care. Quality life can be improved by enhancing the standard of medical treatment at all levels of health care delivery system. The present study indicates a considerable scope for improving the prescribing pattern of drugs and minimizing the misuse of FDCs. This can be facilitated by various interventions, strategies like improving feedback, prescriber education, and introduction of hospital formulary and control of institutional regulatory authorities.

MATERIAL AND METHODS

This prospective study was designed to obtain statistical data on the prescribing pattern of FDCs in patients visiting either in the outpatient department or outside the hospital or clinics and also the patient admitted in the various specialties of S.V.B.P. hospital Meerut and other associated hospital/ clinics in the vicinity over a period of one year. It was tried to collect the possible record from various specialty of MEDICINE: - Including –Cardiology, Gastroenterology, Resp. Medicine, Endocrinology, and Skin. SURGERY: - Including – Gen. Surgery, Ophthalmology, Otorhinolarygology, and Orthopedics, Obstetrics and Gynecology and Pediatrics.

The data consists of photocopies of prescriptions. The total study sample size was of 614 prescriptions. Out of these 439 prescriptions were from government sector, 175 prescriptions from private sectors.

The data was evaluated for the prescription format for its appropriateness and basic drug-use indicators. The prescription format consists of information [4]. Patient demographics :(Name/age/sex/address/profession), patient medical history: (if any), sign and symptoms or complaints diagnosis, investigations or any other remark.

Following drug-use indicators (core-indicators) were used in the study [5].

- Distribution of prescriptions.
- Average number of FDCs per patient.
- Percentage of prescriptions contains FDCs.
- Percentage of prescribing frequency of FDCs.

For the study of drugs prescribing pattern, each drug was counted once per patient.

Prescribing indicators :(Core Indicators WHO 1993)[6] were calculated as follows:

1. Average number of FDCs per patient was calculated by dividing the total number of FDCs prescribed by the number of patient surveyed.
2. Percentage of prescriptions with FDCs was determined by dividing the number of prescriptions with FDCs by total number of prescription multiplies by 100.
3. Percentage of FDCs prescribed was determined by dividing the number of FDCs prescribed by the total number of drugs prescribed, multiply by 100.

To analyze the data statistically test of significance of difference of proportion was used: by the following formulas;

$SE=P1- P2/\sqrt{(P1XQ1/n1) + (P2XQ2/n2)}$

Where: SE- Standard error

P1 and P2 – Is % of prescription and drugs

Q1 and Q2 – Is 100-P1 or P2

n1 and n2 are total no. of prescriptions of drug category in the respective sectors.

To test the significance following criteria was used:

If $P1 – P2 \geq 2SE$ ($P<0.05$) – significant

If $P1 – P2 \geq 3SE$ ($P<0.01$) – highly significant

If $P1 – P2 \leq 3SE$ ($P>0.05$) – not significant

RESULTS

Most of the prescriptions in both the sectors were incomplete with respect to the prescribing format. The prescribing error was maximum in the various department of surgery followed by medicine. Patient medical history and sign/symptoms, histories of drug allergy, or drug interaction were hardly mentioned on the prescription in any department of both the sectors. Most of the prescriptions were mentioned with various types of investigation. Superscription was replaced by word ‘Adv’ indicating changing pattern in 8.2% of the prescriptions. While it was not mentioned on 4.3% of the prescription but symbol Rx was incorrectly mentioned on 6.4% of the prescription. Instructions regarding substitution of the drug, percussion or warning were not mentioned on any of the prescription. 16.2% of the prescriptions were not signed by the doctors in government sectors and 7.6% of prescriptions were not signed in private sector.

Average number of FDCs per prescription was found to be 0.67, &0.88 in government, & private sectors respectively (Table-2).Average number of FDCs prescribed was highest 1.54 and 1.87 in skin of both the sectors. (Table-2 and Fig.-1 &2)Average number of FDCs prescribed was lowest 0.13 and 0.21 in ophthalmology of both the sectors government and private sectors respectively. (Table-2 and Fig. 1 & 2)Percentage of prescriptions with FDCs were found to be 43.28, & 49.71 in government, & private sectors (Table-2) and these differences are statistically

significant (Table-3).Percentage of prescribed FDCs of the total drugs was 16.43 and 16.81 in government, and private respectively (Table-2) and the difference is statistically significant only in private sector in comparison to government sector (Table-3).

FDCs were one of the most frequently prescribed drugs 44.84 % and 54.45 in skin of both the sectors (Table-3), and Least 4.19 %& 5.17 in ophthalmology of both the sectors sector.(Table-3 and Fig. 3)

As the number of the drugs per prescription increased, the prescribing frequency of FDCs also increased. Among the different categories of FDCs analgesic-anti-inflammatory, antimicrobials, cold& cough remedies containing antihistaminic and Vitamins -tonics, followed by other were most commonly prescribed FDCs. A large number of unnecessary combination formulations were prescribed. The results of study call for interventional strategies to promote rational drug therapy.

Table -1: Prescription pattern of FDCs in government and private sectors (Specialty wise)

Departments	Total No. of prescriptions (G.S.)	Total No. of Drugs (G.S.)	No. of prescriptions with FDCs (G.S.)	Total no. of FDCs (G.S.)	Total No. of prescriptions (P.S.)	Total No. of Drugs (P.S.)	No. of prescriptions with FDCs(P.S.)	Total no. of FDCs (P.S.)
Cardiology	36	188	24	35	11	62	9	14
Gastroenterology	31	154	10	14	15	81	7	10
Resp. medicine	35	169	22	32	16	102	11	19
Endocrinology	31	82	17	28	0	0	0	……..
Paediatrics	34	161	23	37	25	131	17	33
Skin	48	165	35	74	16	66	13	30
Gen. Surgery	35	151	09	12	20	112	7	13
Ophthalmology	52	167	07	07	14	58	3	3
Otorhinolarygology	51	183	11	12	20	92	6	8
Orthopedics	61	266	28	39	20	113	10	17
Obs./Gyn	25	121	04	07	18	105	04	8
Total	439	1807	190	297	175	922	87	155

Table -2: Distribution of prescription & prescribing frequency of FDCs in various Departments of Government sectors (GS) & Pvt. Sectors (PS)

Departments	Average no. of FDCs /prescription (GS)	Prescription (GS)	Prescribing frequency(GS)	Average no. of FDCs /prescription (PS)	Prescription (PS)	Prescribing frequency (PS)
Cardiology	0.97	66.6	18.61	1.27	81.8	22.58
Gastroenterology	0.45	32.2	9.09	0.66	46.66	12.34
Resp. medicine	0.91	62.85	18.93	1.18	68.75	18.62
Endocrinology	0.90	54.83	34.14	00	00	00
Pediatrics	1.08	67.6	22.98	1.32	68	25.19
Skin	1.54	72.9	44.84	1.87	75	45.45
Gen. Surgery	0.34	25.7	7.94	0.65	35	11.6
Ophthalmology	0.13	13.46	4.19	0.21	21.42	5.17
Otorhinolarygology	0.23	21.56	6.55	0.40	30	8.69
Orthopedics	0.63	45.9	14.66	0.85	50	15.04
Obs./Gynae	0.28	16	5.78	0.44	22.2	7.61
Total	0.67	43.28	16.43	0.88	49.71	16.81

Table-3: Statistical Significance of % of prescriptions & prescribing frequency of FDCs in Govt. & Private Sectors

Sectors	Prescriptions	Prescribing frequency
Govt.	43.28	16.43
Private	49.71**	16.81*

*P>0.05, in comparison to govt. Sector
**P<0.01, in comparison to govt. Sector

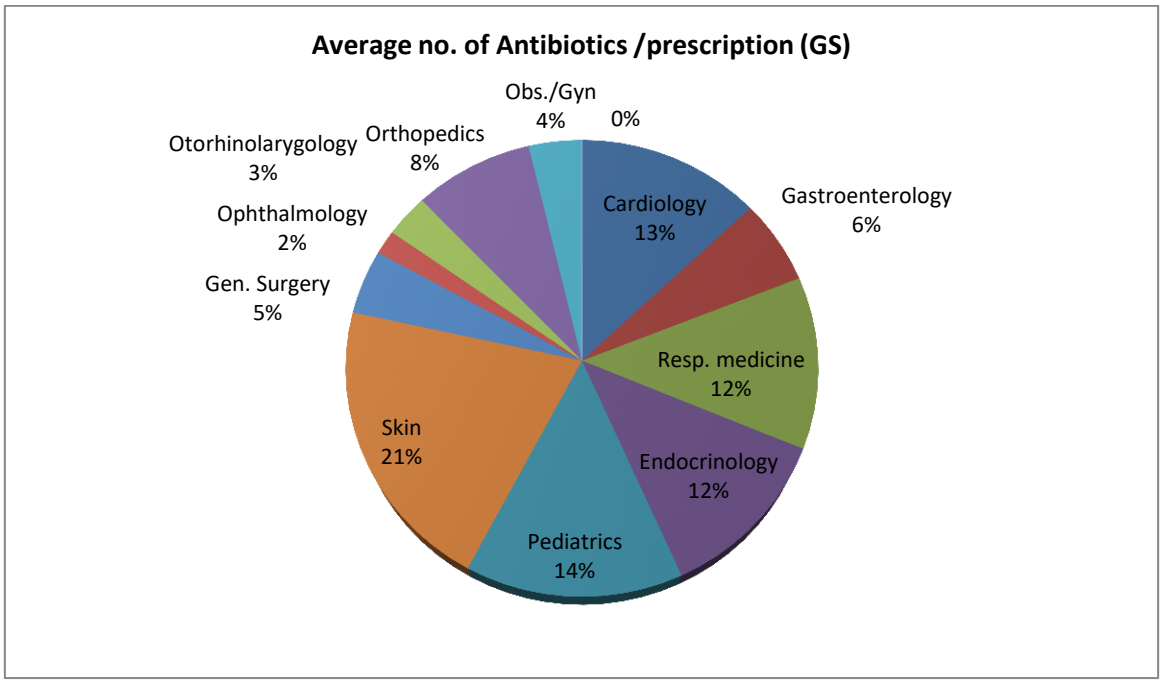

Fig-1: Distribution of Average Number of FDCs/Prescription in Govt. Sector

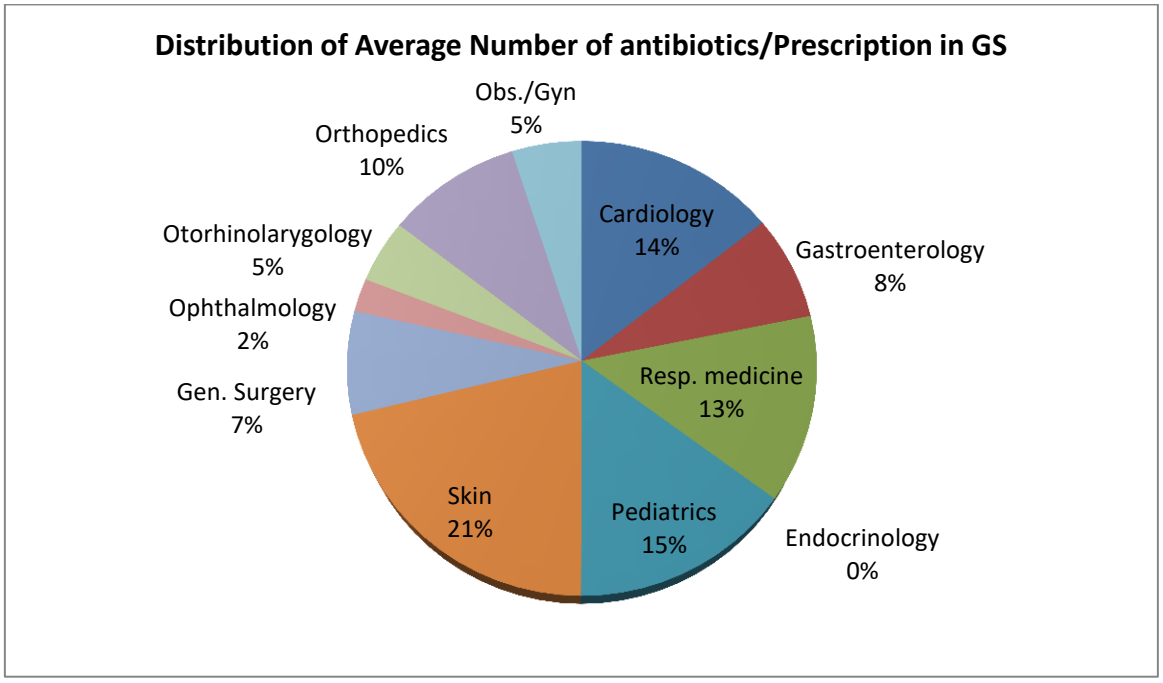

Fig 2: Distribution of Average Number of FDCs/Prescription in Private Sector

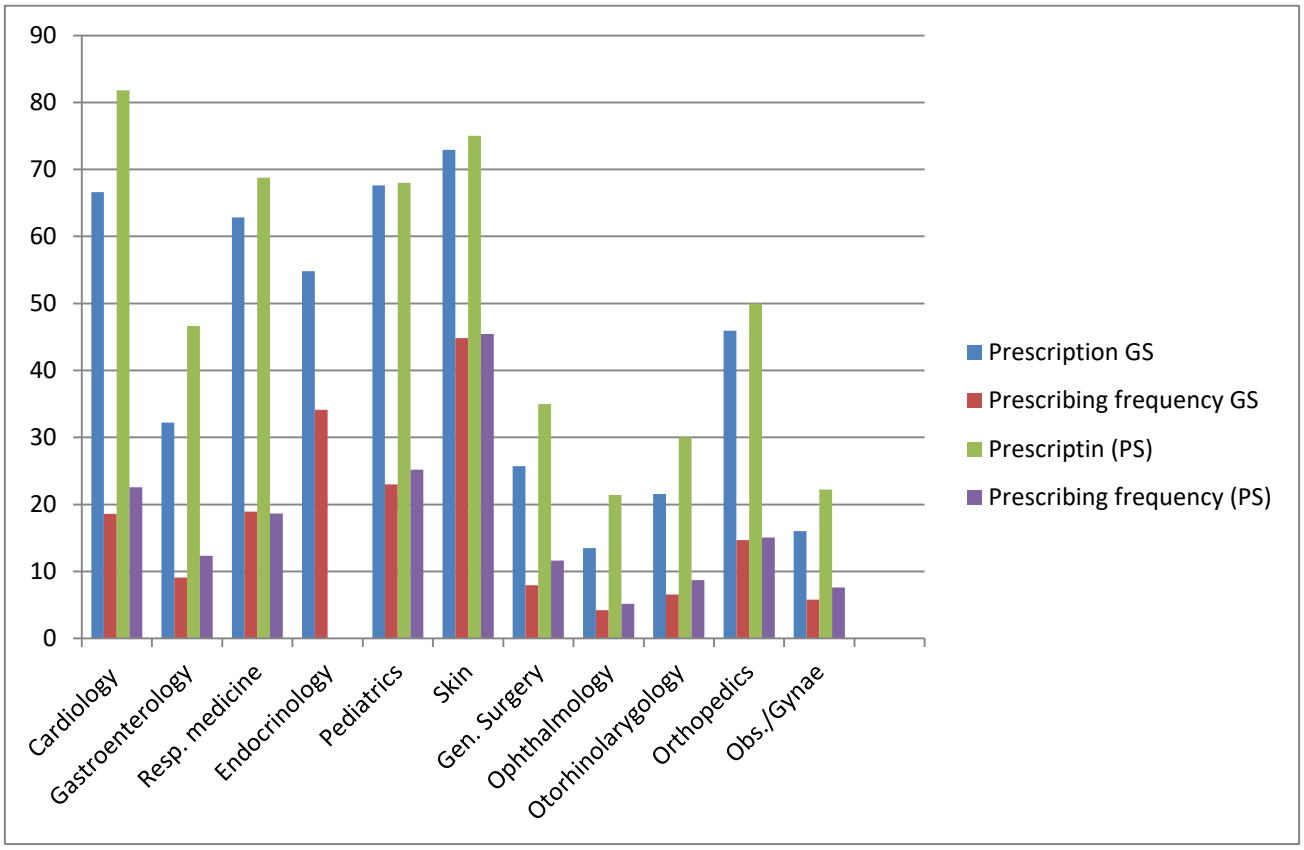

Fig 3: Distribution of prescription & prescribing frequency of FDCs in various Departments of Government sectors (GS) & Pvt. Sectors (PS)

DISCUSSION

A prescription provides an insight into a prescriber's attitude towards the disease being treated and the nature of health care delivery system in the community [7]. The average number of drug per prescription is an important index of a prescription audit. It is preferable to keep the number of drugs per prescription as low as possible to minimize the risk**.**

The result obtained in the present study indicates the majority of the prescribers do not adhere to the ideal pattern of prescription writing as has earlier been reported by Puthawala K, Mansuri S.M, [8] and Budhiraja R.D [9] and these prescriptions are not explicit to their contents. Replacement of Rx sign with the word 'Advise' in a large number of prescriptions is indicative of the changing pattern of the prescription.

Over prescription indicates the increasing tendency towards Polypharmacy. This tendency is more prevalent in the private sector as compared to Govt. sector is evident from greater number of medications per prescription (Table-2). The trend of polypharmacy may be due to the patient's expectation and demand for quick relief, incorrect diagnosis and the influence of lucrative promotional programmes of the drug companies. The concomitant use of two or more drugs adds to the complexity of individualization of drug therapy [10]. The dose of each drug should be adjusted to achieve the optimal benefit otherwise patient compliance is difficult to achieve. To obviate the latter problem, many fixed dose combinations (FDCs) are marketed. There are only 18 FDCs that are in accordance with the WHO recommended list of FDCs. Potential advantages [11] of FDCs include reduced side effects (levodopa with carbidopa), increased patient compliance (anti tubercular drug combination), synergy and increased efficacy (combination of estrogen and progesterone in oral contraceptives; combination ofsulfamethoxazole and trimethoprim; pyrimethamine and sulfadoxine for the treatment and prophylaxis offalciparam malaria [12] and reduced cost. Potential disadvantages [11] include inflexible fixed dose ratio, incompatible pharmacokinetics, increased toxicity and physician and pharmacist's ignorance of contents.

The most widely prescribed FDCs without rational basis were those of analgesics, multivitamin combinations and cold and cough mixtures. The analgesics combinations are extremely popular. There is little evidence that any analgesic combination is better than its individual components alone [13]. However, many patients are benefited by the use of combinations probably because individual component may not have

complete anti-inflammatory, analgesic and antipyretic activities. The high incidence use of drugs for acid peptic diseases may be because of high frequency of use of nonsteroidal anti-inflammatory drugs. WHO has deleted the combination of vitamins from its list of recommended FDCs with the comment that vitamins are considered part of nutrition and vitamin combinations should not be used indiscriminately. Most of the vitamine and tonics were prescribed in gynecology, pediatrics and gen. surgery. The practice of prescribing fixed dose combinations need to be discouraged.

CIMS lists more than 100 irrational combinations which are not approved in any developed country but are being marketed in India [14]. This fact has to be taught to undergraduate medical students in their formative years of learning so that they are more logical in selecting appropriate drug combinations and are not swayed by marketing tricks or false claims made by the pharmaceutical industry. The pharmacological basis of choosing each ingredient in the formulation should be clarified. The basis of many fixed dose drug combinations being taught to the undergraduate medical students and also being prescribed popularly appears to be irrational to pharmacologists.

CONCLUSIONS

The result of the study indicates a considerable scope for improving the prescribing pattern of FDCs and minimizing the use of irrational FDCs. This would be facilitated by providing feedback by educators, prescribers and other interventions like introduction of hospital formulary or control by institutional regularly authorities.

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