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## Pharmacoepidemiology of drugs utilized in ophthalmic outpatient and inpatient department of a tertiary care hospital

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### ABSTRACT

Periodical auditing of drug utilization is vital for promotion of rational use of drugs. So for pharmacoepidemiological analysis of the drugs, utilized in eye OPD and IPD, a study was conducted prospectively for six months, in the Department of ophthalmology and pharmacology. Data were collected, from the prescription form of patients in OPD and from the bed head tickets of patients in IPD. Various parameters of utilization pattern were evaluated. The maximum number of patients belongs to age group of 46-60 years and lower middle class of socioeconomic status but there was no sex preponderance. Dosage, frequency and duration of therapy were recorded in more than 89% of prescriptions. An average number of drugs per prescription were 2.69 and 3.2; drugs prescribed by their generic names were 26.04% and 35.33%; fixed dose combinations prescribed were 36.98% and 67.29% and polypharmacy found were 23.3% and 11.47% of prescription in OPD and IPD respectively. The commonest dosage forms were eye drops in OPD and injections in IPD. More than 80% of the drugs were prescribed from hospital pharmacy. Average total cost per prescription was 87.40 INR in OPD and 135.80 INR in IPD but it was free of cost from hospital pharmacy.

**Keywords:** Pharmacoepidemiology, drug utilization, OPD, IPD

### INTRODUCTION

Pharmacoepidemiology refers to the epidemiological methods to study the clinical use and effects/side-effects of drugs in large numbers of people with the purpose of supporting the rational and cost-effective use of drugs in the population. It may be drug-oriented, emphasizing the safety and effectiveness of drugs as well as utilization-oriented aiming to improve the quality of drug therapy through educational interventions. So the drug utilization research or studies are the powerful exploratory tools to ascertain the role of drugs in the society which refers to the marketing, distribution, prescription, and use of drugs with special emphasis on the medical, social and economic consequences. That's why drug utilization research has become an essential part of pharmacoepidemiology and together both provide the insights into various aspects of drug prescribing and drug use like pattern of use, quality of use, determinants of use and outcomes of use (WHO, 2003). Hence periodical auditing of drug utilization pattern is vital for promotion of rational use of drugs, for increasing the therapeutic efficacy and the cost effectiveness, for decreasing the adverse effects and to provide feedback to the prescribers (Krishnaswamy et al, 1985). Therefore the principal aim of drug utilization research is to facilitate the rational use of drugs in population and generate hypotheses that set the agenda for further investigations and thus

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avoid prolonged irrational use of drugs. There are many studies done for the prescription or drug utilization pattern in various departments including the ophthalmology but most of them are restricted to outpatient department only. No data are available from the inpatient department. Keeping these facts in consideration, the present study was planned with the aim of pharmacoepidemiological analysis of the drugs to define the pattern of use, their availability in the hospital and to evaluate their cost analysis in each prescription of ophthalmic OPD and IPD of a tertiary care hospital attached to SRMS, IMS Bareilly.

## MATERIAL AND METHODS

The present study was conducted in the Department of ophthalmology in collaboration with department of pharmacology and the approval from Institutional Ethics Committee was taken before the initiation of the study. Data were collected in a specially designed form to record the required information.

Analysis of the prescriptions was done prospectively in outdoor patient department (OPD) visiting the OPD, twice a week for six months (July 2010 to December 2010) after taking the written informed consent from all the patients. Screening of the records and collection of the data from the inpatient department (IPD) was carried out during the same period, from the bed head tickets (BHTs) of admitted patients till their discharge, after obtaining the permission from department of ophthalmology.

The variables assessed from the prescriptions or BHTs included the demographic profile (male/female, age, socio economic status according to Kuppaswamy scale indications for which the drug were prescribed or surgery performed, drugs prescribed by generic or brand name, doses prescribed, dosage forms, frequency and routes of administration, duration of therapy, average number of drugs prescribed per prescription, number of fixed-dose combination versus single agents, average number of drugs prescribed from hospital pharmacy and cost analysis per prescription.

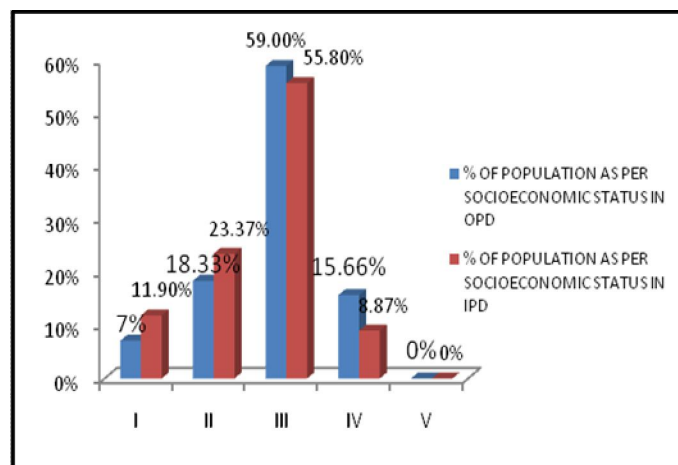
## RESULTS

After screening the six months prescriptions and BHTs of the patients, it was found that a total of 1200 prescriptions were analyzed in OPD, among them 676 were males and 524 were females. The demographic profile of the IPD showed that a total of 462 patients were admitted among them 245 were males and 217 were females. Distribution of patients in OPD and IPD according to age is shown in Table. 1 which shows that the maximum number of patients belongs to age group of 46-60 years both in OPD as well as in IPD.

The study population was also classified according to Kuppaswamy scale taking into account the education, type of profession and family income per month. In OPD, 59% of patients belonged to the lower middle class, 18.33% to upper middle class, 15.66% were of upper lower class and remaining 7.01% were of lower class. The same data in IPD was 55.8%, 23.37%, 8.87% and 11.9% (Kumar et al, 2007). (Figure.1).

**Table .1-** Demographic profile of the patients.

PATIENT CHARACTERISTICS	AGE GROUPS	OPD		IPD	
Age groups (years)	0-5	92	7.66%	22	4.76%
	6-15	70	5.80%	5	1.08%
	16-30	156	13.0%	9	1.95%
	31-45	193	16.08%	65	14.07%
	46-60	441	36.75%	238	51.50%
	61-75	248	20.66%	123	26.70%
Sex	Male	676	56.33%	245	53.03%
	female	524	43.66%	217	46.96%
	M : F		1.3:1		1.1:1



**Fig 1:** Classification of population according to socioeconomic status.

The common eye conditions encountered in the ophthalmology OPD were refractive errors (29.67%), cataract (21.17%), conjunctivitis/iridocyclitis (13.17%), corneal ulcer (10.08%), keratitis (9.08%), glaucoma (8.75%), dacryocystitis (2.08%), foreign body (1.08%), postherpetic neuralgia (1%), chalazion (0.92%) and others (3%) like diabetic retinopathy, external hordeolum, blepharitis, ptosis, squint, entropion etc. while in IPD, patients were admitted for cataract (65.37%), glaucoma (15.37%), corneal ulcer (6.93%), severe iridocyclitis (4.11%), chronic dacryocystitis (3.68%), entropion (1.73%), ptosis (1.52%), and squint correction (1.29%).

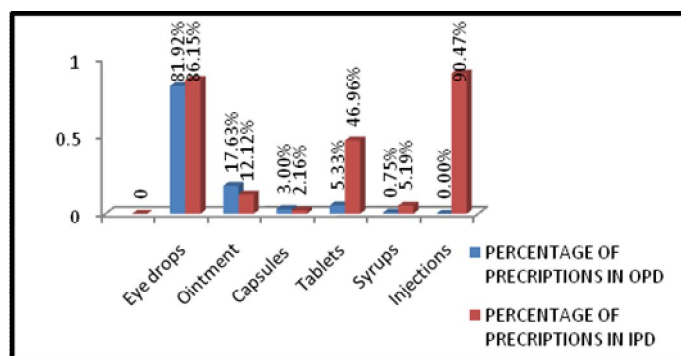
Table. 2 depicts the various parameters of pharmacoepidemiology which showed that dosage and frequency were recorded in more than 98% of prescriptions but the duration of therapy was recorded only in 89.4% of OPD and 93.7% of IPD prescriptions. The average numbers of drugs per prescription were 2.69 and 3.2 in OPD and IPD respectively. Similarly drugs prescribed by their generic names were 26.04% in OPD and 35.33% in IPD and more than 60% of the drugs were prescribed by their brand names. The percentage of drugs dispensed from the hospital pharmacy was more than 80% but the percentage of fixed dose combinations prescribed was 36.98% in OPD and only 67.29% in IPD. The polypharmacy found in the prescriptions were 23.3% and 11.47% in OPD and IPD respectively. Regarding the dosage forms (Figure.2), it was found that the most common dosage form of drug prescribed in OPD was eye drops (81.92%)

followed by ointment (17.63%) , capsules (3.00%), tablets (5.33%) and syrups (0.75%) while in IPD injections (90.47%) were the commonest dosage forms followed by eye drops (86.15%), tablets (46.96%), ointment (12.12%), syrups (5.19%) and capsules (2.16%).(Figure.2)

The most frequently prescribed class of drugs in OPD were antibiotics, mydriatics, antibiotics+steroids followed by anti-inflammatory drugs alone or combined with antibiotics. Others were antiallergics, steroids, lubricants, antiglaucoma drugs, antifungals and antivirals drugs. Similarly in IPD local anesthetics, mydriatics antibiotics+steroids and anti-inflammatory were the most frequently prescribed drugs(Figure.3). Pharmaco economic data of the prescriptions in OPD and IPD are presented in Table. 3.

**Table. 2** Analysis of prescriptions of patients with respect to different parameters.

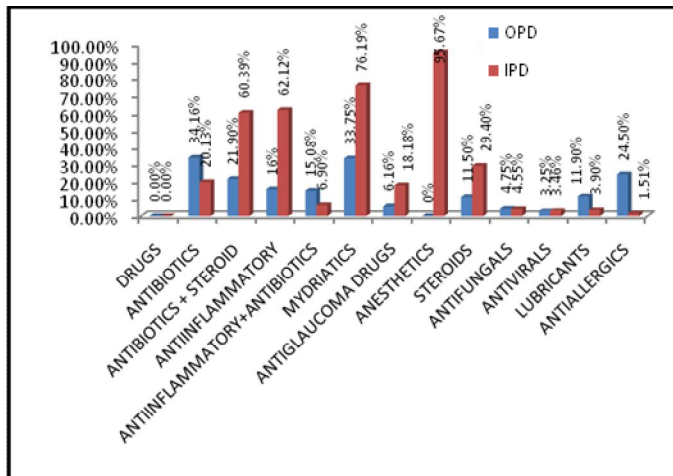
Sr. No	Drug use Indicators	Results	
		OPD	IPD
1	Total number of prescriptions	1200	462
2	Average number of drugs per prescription	2.69 (3233/1200)	3.2 (1483/462)
3	Percentage of dosage forms recorded	99.25% (1191/1200)	98.7% (456/462)
4	Percentage of frequency of therapy recorded	98% (1176/1200)	100% (462/462)
5	Percentage of duration of therapy recorded	89.4% (1073/1200)	93.7% (433/462)
6	Percentage of drugs prescribed by generic name	26.04% (842/3233)	35.33% (524/1483)
7	Percentage of drugs prescribed by Brand name	73.95% (2391/3233)	64.66% (959/1483)
8	Percentage of scheduled drugs actually dispensed from the hospital pharmacy	83.24% (2691/3233)	93.66% (1389/1483)
9	Percentage of fixed dose combination	36.98% (444/1200)	67.29% (311/462)
10.	Percentage of polypharmacy in prescription	23.3% (280/1200)	11.47% (53/462)



**Fig. 2.** Percentage of different prescribed dosage forms.

**Table .3** Pharmacoeconomic data of the prescriptions.

Sr. No	Parameter	Cost in INR	
		OPD	IPD
1	Average total cost per prescription	87.40	135.80
2	Average hospital pharmacy cost per prescription	0.00	0.00
3	Average outside pharmacy cost per prescription	87.40	135.80



**Fig.3.** Percentage of different classes of drugs prescribed.

**DISCUSSION**

Drug prescriptions form a very important point of contact between the health care provider and the user (Nehru et al, 2005). It provides an insight into the nature of health care delivery system and is a reflection of physicians’ attitude towards the disease and the role of drug in its treatment (Shankar et al, 2010). Historically the pharmaceutical and medical professions have devoted considerable time and efforts to the development and rational utilization of safe and effective drugs for the treatment and prevention of illness. There has been development of many new therapeutic agents which have made it possible to cure or provide the symptomatic control of many clinical disorders. However in many circumstances drugs are not used rationally for optimal benefits and safety (Hussar, 1995).

Therefore pharmacoepidemiology can be a powerful tool that can benefit patient and public health but only if used appropriately by providing the insights into various aspects of drug prescribing and drug uses. WHO organizes many drug utilization researches with the goal of rational prescription by various methods of auditing. The study was also a part of prescription audit.

After screening of 1200 OPD prescriptions and 462 IPD BHTs, it was found that there was no sex preponderance [M : F = 1.3:1 and 1.1:1 in OPD and IPD] among the patients and the maximum number of patients belong to age group of 46-60 years in OPD as well as in IPD. These findings showed that the eye diseases are usually not sex linked but may be age related.

The economic status of the patients revealed that most of the patients (59% in OPD and 55.8% in IPD) belonged to the lower middle class (Figure 4) which was in contrast with the results of the study conducted in psychiatry, in which the most common class was upper lower class (Goyal et al , 2008). This high magnitude of lower middle class may be because of high prevalence of that community nearby hospital or may be because of low registration and admission fees of the hospital.

Regarding the indications, we found the refractive errors (29.67%) and cataract (21.17%) as common disorders in OPD

while cataract (65.37%) and glaucoma (15.37%) were the common indications for admission in IPD.

Empirical treatment in eye conditions is based on the likely etiology, the available medical treatment and the surgical treatment. In the OPD, patients were treated by the various drugs in different dosage forms and ongoing medical treatment was modified according to clinical response and the most common drugs prescribed in OPD were antibiotics (Moxifloxacin), mydriatics (Tropicamide+Phenylephrine) antibiotics+steroids (Tobramycin + Dexamethasone) and anti-inflammatory (Nepafenac). In IPD, most of the patients needed surgical interventions but still they required drugs in form of preoperative or postoperative medications. In IPD the most common drugs prescribed were local anesthetics followed by anti-inflammatory (Paracetamol) and antibiotics + steroids (Tobramycin + Dexamethasone). The high use of antibiotics in OPD reflect the condition of poor sanitation, nutrition and prevalence of various infections in our region while their use in IPD was mainly to prevent post operative infection and for some other acute infective conditions (iridocyclitis) which needs conservative management. Similar anti-inflammatory drugs were used for relief of pain and swelling and mydriatics were used for fundus examination and surgery and for conservative management of particular disease. Other drugs used were antivirals (acyclovir) for viral infection like herpes, antifungal drugs (natamycin) for fungal infection like aspergillus, antiallergics, lubricants and multivitamins.

The average number of drugs per prescription is an important criterion of the prescription audit. It has been recommended that the limit of number of drugs prescribed per prescription should be two and that justification for prescribing more than two drugs would be required because of the increased risk of drug interactions (Nies, 1990). In this study, the average number of drugs per prescription was 2.69 in OPD and 3.2 in IPD which is more than the current recommendation. Other hospital based studies in India reported 3-5 drugs per prescription almost in the same range or a little higher than our study (Maini et al, 2002, Kutty et al, 2002, Sharma et al, 1990). Therefore it is advisable to keep the number of drugs per prescription as low as possible since higher figures lead to increased risk of drug interactions, increased hospital cost and errors of prescribing (Nies, 1990, Atanasova and Terziivanov, 1995, Pradhan et al, 1990).

The frequency, dosage and duration of drug therapy are the three important parameters, if not clearly recorded, can result in indiscriminate and injudicious use of drugs. The present study showed that the dosage and frequency were recorded in more than 98% of prescriptions but the duration of therapy was recorded only in 89.4% of OPD and 93.7% of IPD prescriptions. The same parameters were also noted in a study in which the frequency of application was recorded in 93% and the duration of treatment was mentioned in 75% of all the prescriptions audited (Sharma et al, 1990). But some contrast results were also found in which the duration of therapy was not recorded for 73.26% of the drugs prescribed (Biswas et al, 2001).

When the various dosage forms were compared it was found that eye drops were commonly prescribed in OPD followed by ointments tablets, capsules and injections while in IPD injections were the commonest prescribed drugs in form of local anesthetics followed by eye drops, tablets, ointments, syrups and capsules. The results of OPD were similar to other studies in which the maximum number of drugs prescribed were in the form of eye drops (topical form), followed by tablets (Biswas et al, 2001). This finding supports the use of topical preparation for treating eye disease as they have site specific action, less systemic absorption resulting in fewer side effects and convenient for patient use.

Percentage of drugs prescribed by their generic names in our study were 26.04% in OPD and 35.33% in IPD which was almost similar to one study (23%) as well as contrast (just over half i.e. 53.6% ) to some other studies (Ghosh et al, 2003, Joshi et al, 1997). Few earlier studies have also reported to only 29.3% and 19% of drugs prescribed by generic name (Rehana et al, 1998, Minocha et al, 2000). It suggests the popularity of brand names amongst the medical practitioners of the institute and the influence of pharmaceutical companies. Prescriptions by brand names could possibly result in prescribing (writing as well as reading) errors because the brand names of many pharmacologically different drugs sound alike and spell similar. It may also lead to increase in side effects in turn increasing the cost of the treatment (Rataboli and Garg, 2005). In general, generic drugs are less expensive as compared to the brands that contain the same active ingredient (Brady, 2003). So the prescriptions of generic drugs should be emphasized to facilitate cheaper and better treatment for the patient.

The percentage of drugs dispensed from the hospital pharmacy was more than 80% (83.24% in OPD and 93.66% in IPD) which was in contrast to another study (Narwane et al, 2011). There were only few drugs which were not available in hospital pharmacy. Hence the hospital authorities should also make provisions for making these drugs available in the hospital pharmacy.

The fixed dose combinations (FDCs) prescribed were 36.98% in OPD and 67.29% in IPD which were higher as compared to the percentage of FDCs prescribed in other studies (Kshirsagar et al, 1998, Narwane et al, 2011). However use of FDCs was less in OPD, because the commonest condition in OPD was refractive error where only correction by glasses are required not the drug treatment and another common condition was cataract in both OPD and IPD where the main treatment is surgery and the drugs are required mainly in postoperative period.

Rational drug prescribing is defined as the use of the least number of drugs to obtain the best possible effect in the shortest period and at a reasonable cost (Shankar et al, 2010). Since, WHO has recommended that average number of drug per prescription should be two, result of our study reflects polypharmacy (Gross, 1981). It was 14.0% and 22.94% in OPD and IPD respectively. The recommendation by WHO is not applicable to inpatient, since majority of patients of IPD in our study have undergone surgery,

and average length of stay was also higher which means more medication prescribed and administered. In such cases polypharmacy can be justifiable. The practice of polypharmacy should be restricted to conditions, as many a times they are unnecessary, increasing the morbidity by pharmacokinetic and pharmacodynamic drug interactions and increasing the cost of treatment.

In our study, average total cost per prescription was 87.40 INR in OPD and 135.80 INR in IPD. The average hospital pharmacy cost per prescription was 0.00 INR, because of free distribution of drugs in hospital pharmacy. Therefore, the average cost borne by patients was always more as compared to cost borne by hospital pharmacy. The results were similar to the earlier studies where the cost paid by the patient was significantly higher than that paid by the Hospital pharmacy ( $p < 0.0001$ ) (Goyal et al, 2008 and Narwane et al, 2011). The limitation of our study was that it was one time cross sectional study and while calculating cost of treatment, we did not measure the actual direct costs and indirect costs. Direct costs involve cost of the drugs, cost of traveling, taking time off from work for the patient (Sharma and Das, 2006). Among the direct costs, hospital and outpatient expenses form the bulk (Swaminath, 2008).

## CONCLUSION

The study concludes with overall impression of rational prescription at maximum places. However it needs few improvements as duration of therapy were missing in some cases. This was also coupled with low generic prescribing and less numbers of fixed dose combinations in OPD that can result in less safe and more expensive prescribing. It is thus necessary to make doctors aware about the use of drugs, importance of prescribing drugs with generic names and for patients point of view, the factor of costeffectiveness. Also, there is a need for the development of prescribing guidelines and educational initiatives to encourage the rational and appropriate use of drugs. Improvement through continuous education is desired on the part of prescribers to ensure a good standard of care. Drug information services including side effects and drug interactions for professionals and consumers at the hospital are highly desirable. The hospital administration should look into issues of the hospital by continuous monitoring of the prescriptions and making the essential drugs available. The actual direct costs and indirect costs were not included in the study, which is the limitation of this study. Therefore it is advised to conduct many such studies in other departments as well, to audit large number of prescriptions and educate the prescribers by means of short-term training sessions on rational drug therapy for benefits and safety to the patient. The prescriptions can then be re-audited to measure the impact of intervention. This will not also help in rationalizing the prescription practices based on the feedback from these studies but also we can compare these practices between different institutions, regions and countries.

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## CONFLICT OF INTERESTS

The authors declare that there is no conflict of interest to disclose.

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