

DRUG UTILIZATION STUDY IN OPHTHALMOLOGY OUTPATIENT DEPARTMENT IN A GOVERNMENT TERTIARY CARE HOSPITAL IN MAHARASHTRA

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ABSTRACT

Objective: Drug utilization research is an essential part of pharmacoepidemiology as it describes the extent, nature, and determinants of drug exposure. Indiscriminate use of topical antibiotics, steroids, and nonsteroidal anti-inflammatory drugs causes histological and structural changes in the conjunctiva. The present study was proposed to investigate prescription and drug utilization practices in ophthalmology outpatient department (OPD) in a government tertiary care hospital in Maharashtra.

Method: An observational, cross-sectional study was conducted in a tertiary care teaching hospital of rural Maharashtra, India, from January 2015 to June 2016 after approval of the institutional ethics committee. Patients of all age group and of either gender attending ophthalmology OPD in a tertiary care hospital were included in the study. Patients not willing to consent as well as follow-up patients were excluded from the study. Data collection was done in a predesigned pro forma. Prescriptions were evaluated for demographic data, World Health Organization (WHO) core drug prescription indicators. Statistical analysis was performed using Microsoft Office Excel® 2007.

Results: In a total of 600 patients, females outnumbered males. A bit less than a half of patients belonged to the age group of 19–45 years. An average number of drugs per encounter was (1080/600), i.e. 1.8. Of 1080 total drugs prescribed, 678 drugs (62.78%) were prescribed by their generic name. 1027/1080 (95.09%) drugs were prescribed from the National List of Essential Medicines and 671/1080 (62.13%) drugs prescribed were from the WHO- Essential medicines List. Total encounters having antibiotics and injectable formulations were 274 (45.66%) and 4 (0.66%), respectively.

Discussion: Drug utilization studies (DUS) are a tool for assessing the prescribing, dispensing, and distribution of drugs. The main aim of DUS is to facilitate rational use of medicines. Overall findings of the study suggest that ophthalmologists' drug prescribing habits were appropriate to a larger extent in the current setting.

Keywords: Drug prescription indicators, Drug prescription monitoring, Ophthalmology outpatient setting, Rural setup.

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INTRODUCTION

Preventable blindness is an important issue in public health for developing nations around the world, especially in India [1]. Estimates of blindness in India by the World Health Organization (WHO) show 11.2% of the population suffering from preventable blindness with more than 2 million new cases expected each year [2].

Drug utilization research was defined by the WHO in 1977 as marketing, distribution, prescription, and use of drugs in society, with special emphasis on the resulting medical, social, and economic consequences [3]. Drug utilization research is thus an essential part of pharmacoepidemiology as it describes the extent, nature, and determinants of drug exposure.

Access to standardized and validated information on drug use is essential for assessing patterns of drug utilization, identification of problems, accessing educational or other interventions, and monitoring the outcomes of interventions for the rational use of drugs [4,5]. Drug utilization research studies are important for policymaking at the national level as well as for individual patient management. However, in most of the developing countries, the availability of information on drug consumption is inadequate.

Indiscriminate use of topical antibiotics, steroids, and nonsteroidal anti-inflammatory drugs causes histological and structural changes in conjunctiva [2]. Recently, it has been noted that topical medications, in spite of good tolerance and apparent safety, induce ocular surface

changes which can cause damage to conjunctival and corneal cells. Adverse effects of prolonged topical therapy are partly attributed to preservative in the formulation [6]. This can be avoided by the judicious use of drugs.

A few drug utilization studies (DUS) carried out in ophthalmology outpatient department (OPD) are suggestive of irrational drug use. A study carried out by Dutta *et al.* point out 35.29% use of fixed-dose combinations (FDCs) of antimicrobials and steroids, where either of the two drugs was justified [7]. Most of them were combinations of antimicrobial and steroids. Bharti *et al.* found antibiotic use in more than 60% patients which was not justified in all cases [8]. Still, very scanty data are available regarding drug utilization pattern in ophthalmology OPD. In the given circumstances, the present study was proposed to investigate prescription and drug utilization practices in ophthalmology OPD in a government tertiary care hospital in Maharashtra.

METHODS

This was an observational, cross-sectional study conducted in a tertiary care teaching hospital of rural Maharashtra, India. The study was conducted over a 18 months from January 2015 to June 2016 after approval of the institutional ethics committee.

Inclusion criteria

Patients of all age group and either gender attending ophthalmology OPD in a tertiary care hospital were included in the study.

Exclusion criteria

The following criteria were excluded from the study:

1. Patients not willing to consent.
2. The same patient attending the OPD next time for follow-up.

The diagnosis and line of treatment to be given were decided by the physician. No additional drugs or investigations were advised by us during the study period. Data of patients matching inclusion criteria were recorded. Before including in the study, patients were explained about the research work. Written informed consent was taken from each patient before including him or her into the study.

Data collection was done by attending ophthalmology OPD. Data were collected in predesigned pro forma for this study. Prescriptions were evaluated for demographic data, WHO core drug prescription indicators such as average number of drugs prescribed per prescription, percentage of drugs prescribed by generic name, percentage of drugs prescribed from essential drug list, and percentage of antibiotics prescribed out of total drugs prescribed and category wise distribution of drugs. Furthermore, data were analyzed for different drug formulations, fixed drug combinations (FDCs), and different therapeutic classes of drugs.

Statistical analysis was done using Microsoft Office Excel® 2007.

RESULTS

A total of 600 patients were enrolled in the study. The demographic data are shown in Table 1.

A total of 1080 drugs were prescribed to 600 patients. The number of drugs was ranged from 1 to 8 per patient. Maximum patients (55.83%) received single drug only. An average number of drugs per encounter was 1080/600, i.e., 1.8. Of 1080 total drugs prescribed, 678 drugs (62.78%) were prescribed by their generic name. Of a total of 1080 drugs, 1027 (95.09%) drugs were prescribed from the National List of Essential Medicines (NLEM) and 671 (62.13%) drugs prescribed were from the WHO-essential medicines List (WHO-EML). Hospital dispensary provided 469 (43.42%) drugs out of all the drugs prescribed for ophthalmology outpatient department. Total encounters having antibiotics and injectable formulations were 274 (45.66%) and 4 (0.66%), respectively (Table 2).

Of a total number of drugs prescribed, 469 (43.42%) were dispensed from hospital dispensary. 903 (83.61%) drugs were adequately labeled. 53% of patients, out of total 600 patients, had correct knowledge of dosage.

Maximum drugs were prescribed in the form of eye drops (67.03%), followed by oral tablets (21.48%) and eye ointments (10%). (Fig. 1) Maximum drugs were prescribed for topical (77.40%) use. FDCs attributed 6.67% of total drugs prescribed. Topical FDCs used were mostly a combination of antibiotics and steroids (Fig. 2)

DISCUSSION

Drugs are an integral part of the health care, and modern health care is impossible without the availability of necessary drugs. They not only save lives and promote health but also prevent epidemics and diseases too. Accessibility of medicines is the fundamental right of every person [9]. However, to bring optimal benefit, they should be safe, efficacious, cost-effective, and rational.

DUSs are a tool for assessing the prescribing, dispensing, and distribution of drugs. The main aim of DUS is to facilitate rational use of medicines (RUM). Prescription monitoring studies provide a bridge between areas such as rational use of drugs, pharmacovigilance, evidence-based medicine, pharmacoconomics, pharmacogenetics, and ecopharmacovigilance [10].

Despite good tolerance and apparent safety, topical medications have been noted to induce long-term ocular surface changes which may often cause damage to conjunctival and corneal cells. Toxic immune-

Table 1: Demographic data

| | n (%) |
|----------------------|-------------|
| Age group (in years) | |
| 0-12 | 63 (10.50) |
| 13-18 | 47 (07.83) |
| 19-45 | 276 (46.00) |
| 46-60 | 104 (17.33) |
| >60 | 110 (18.33) |
| Gender | |
| Female | 345 (57.50) |
| Male | 255 (42.50) |

Table 2: The WHO Drug prescribing indicators

| | |
|---|---------------|
| Prescribing indicators | |
| Average number of drugs per prescription | 1.8 |
| Drugs prescribed by generic name | 678 (62.78%) |
| Drugs from WHO-ELM | 671 (62.13%) |
| Drugs from NLEM 2015-2016 | 1027 (95.09%) |
| Percentage encounters with injections | 4 (0.66%) |
| Percentage encounters with antibiotics | 274 (45.66%) |
| Patient care indicators | |
| Percentage of drugs actually dispensed | 469 (43.42%) |
| Percentage of drugs adequately labeled | 903 (83.61%) |
| Patient's knowledge of correct dosage (%) | 53% |

WHO-ELM: World Health Organization-Essential medicines List

pathological changes in the ocular surface are noted with long-term use of topical drugs. Long-term topical medical therapy has a deleterious effect on surgical outcome due to chronic inflammation. Several adverse drug events are reported of prolonged topical therapy, partly due to the active ingredient and partly due to preservative associated with the formulations [6].

In the current study, female patients (57.50%) outnumbered male patients (42.50%) and maximum patients were of age group 19-45 years (46%). These are similar findings to the study of Vaniya *et al.* where female patients (53.16%) were more with the mean age of study sample being 40.1±22.2 years [11]. Prajapati and Yadav *et al.*, Prajwal *et al.*, and Suman *et al.* were having a male preponderance in their respective studies [12-14]. These differences can be attributed to the fact that demographic data depend and differ on the basis of geographic conditions, social, and cultural practices of specific regions.

In this study, average number of drugs per prescription was 1.8. It is comparable to the average number of drugs prescribed in the studies of Nehru *et al.* (1.87), Maniyar *et al.* (2), and Suman *et al.* (2.01) [14-16]. It is much less as compared to the findings of Mondal *et al.* (4.03±1.5) [17]. This difference can be attributed to the fact that prescription analysis in the latter study was carried out in inpatient setting. It is essential to keep the number of drugs per prescription to the minimum. Otherwise, it leads to increase in adverse drug reactions and drug interactions, increase in treatment cost, and increase in prescribing errors. It is also found to be important in the causation of the development of bacterial resistance and decreased compliance of patients with the treatment.

In the current study, the prescription analysis showed that 678 (62.78%) drugs were prescribed by their generic names. This is in complete contrast with the findings of studies of Prajapati and Yadav (1.04%), Maniyar *et al.* (1%), and Jain *et al.* (1.19%) [12,16,18]. In a similar study of Rathnakar *et al.* [19], no drug was prescribed with generic name. Prescription with generic names helps in reducing the cost of treatment for the patients. Furthermore, it helps in avoiding prescription writing errors and confusion in dispensing of different brand names which sound alike and/or spell similar.

In the present study, of a total of 1080 drugs, 1027 (95.09%) were prescribed from the NLEM and 671 (62.13%) were prescribed from the WHO-EML. Hospital dispensary provided 469 (43.42%) drugs out of all

the drugs prescribed for ophthalmology outpatient department. Other similar studies cited in the literature, i.e., Suman *et al.* [14] 64% and 62% drugs were prescribed from NLEM, while other studies cited in the literature by Vaniya *et al.* [11] and Jadhav *et al.* [20] show a mere 24% and 19.48% of the drugs respectively were prescribed from NLEM. Percentage of drugs prescribed from NLEM depicts the degree to which drug prescribing adheres to the national drug policy. Adherence to NLEM for drug prescription not only promotes the RUM but also optimizes the available health resources of a country.

In the present study, injections were prescribed only in 4 (0.66%) encounters among all encounters. In a similar study of Vaniya *et al.*, 0.7% of encounters were injections. These findings are in contrast with those of studies of Suman *et al.* and Rathnakar *et al.* where no encounters were noted with injections [14,19]. Overall low usage of injections can be because of the fact that studies were focused on the prescription pattern of ophthalmic OPD where most of the ophthalmic drugs are used topically.

In the current study, hospital dispensary actually dispensed 469 (43.42%) drugs. Along with correct diagnosis and drug prescription, correct dispensing of prescribed drugs is equally important for RUM. The use of brand names for prescribing and inadequate supply of drugs to dispensary as compared to the patient load can be possible reasons for the lower percentage of actually dispensed drugs. Consideration of changing disease burden, political willingness, and prompt response from administration can help in changing the scenario.

In the present study, of 1080 prescribed drugs, 903 (83.61%) were adequately labeled. Adequate labeling of drugs is a crucial component of dispensing, and it reflects the quality of patient care. Inadequate labeling can mislead patients about the use of drugs and can increase chances of adverse drug reactions.

In this study, patients' understanding of drug usage was assessed by interviewing the patients. It was found that only 21% of patients possessed well understanding of the drug usage; 32% of the patients could be attributed to understood category, while 47% of patients had a poor understanding of the drug usage. Hence, in total, 52% of patients had correct knowledge of dosage. It is much less as compared to the findings from studies of Jain *et al.* (95%) and Jadhav *et al.* (93.83%) [18,20]. This difference may be attributed to the lower literacy rate of the patients in the current setting. Patient's knowledge of correct dosage schedule is a good indicator of compliance. It ensures adherence to the treatment and may help it succeed.

In this study, of a total number of drugs prescribed, maximum drugs were prescribed for topical (77.40%) use followed by oral (22.31%) use. The prescribed drugs were commonly in the dosage forms such as eye drops (67.03%), followed by oral tablets (21.48%) and eye ointments (10%). In the studies of Nehru *et al.* [15] (66.18%), Maniyar *et al.* [16] (65.81%), and Vaniya *et al.* [11] (66.8%), drugs were prescribed most commonly in the form of eye drops. The use of topical drug formulations, wherever possible, ensures higher local bioavailability and lowers systemic adverse effects.

In the current study, a total of 1080 drugs were prescribed, of which 73 (6.67%) were fixed drug combinations (FDCs). It is less as compared to those used in the study of Prajapati and Yadav [12] (43.27%) and Jain *et al.* [18] (25.4%). In a similar study of Vaniya *et al.* [11] 12.46%, FDCs were used. Lesser use of FDCs may be suggestive of more rational prescribing. In FDC, a dose cannot be individualized for the drug used in the combination and drugs with different pharmacokinetic properties cannot be combined. Inappropriate use of the FDCs can lead to increased adverse drug reactions and financial burden on the patients. Furthermore, many FDCs available in market may not be rational.

The most commonly prescribed therapeutic class of drugs in the current study was antibiotics (47.77%), followed by lubricants (24.53) and anti-inflammatory drugs (7.03). In various studies reported in literature, antimicrobial drugs were most commonly prescribed such as those by Vaniya *et al.* (45%) and Prajapati and Yadav (59.50%) [11,12]. Dry environment, poor education, less awareness, and low and/or poor quality of sanitation in the region leads to more infective conditions which entail the higher use of antimicrobials.

CONCLUSION

Overall findings of the study suggest that ophthalmologists' drug prescribing habits were appropriate to a larger extent in the current setting. Adverse environmental factors such as lack of sanitation, pollution, and dry hot weather had a significant impact on disease pattern observed which justify the use of antimicrobials. However, judicious use of antimicrobial drugs should be promoted. Level of literacy had an impact on prescribing trend with lower percentage of patients having correct knowledge of dosage.

There is a need for proper sensitization of clinicians in the context of rational prescribing, which can be achieved by conducting short-term training sessions and continuous medical education. Such studies should be followed by education of prescribers on rational drug therapy for benefit and safety of the patients.

Limitations

The present study was conducted in a single institute. Multicentric studies in similar context would shade more light on the subject. We have collected data from only one institute; therefore, population is relatively homogenous. Hence, results cannot be extrapolated to general population.

CONFLICTS OF INTEREST

The authors have no conflict of interest to report.

AUTHORS' CONTRIBUTION

All authors have contributed equally in developing the concept of the study, data collection, data analysis, and drafting the manuscript.

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