RESEARCH ARTICLE

Assessment of drug rationality by World Health Organization/International Network of Rational Use of Drugs indicators in the department of ophthalmology – A descriptive study in North India

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ABSTRACT

Background: Pertinent use of drug is seen to be one of crucial parameter for maintaining standard medical health care in society leading to better life expectancy. Aims and Objectives: The aim of the study was to assess the drug rationality by World Health Organization (WHO)/International Network of Rational Use of Drug (INRUD) indicators in the Department of Ophthalmology at Medical College level in North India. Materials and Methods: This descriptive cross-sectional and observational study was conducted in eye and pharmacology department from May 2018 to August 2018. A total of 612 prescriptions were evaluated. The demographic details of participants and the drug prescription analysis were calculated. WHO/INRUD Drug Prescribing Indicators were used for comparison of data with the help of Index values. Results: Prescribing indicators non-polypharmacy index (1.19) and injection safety index (6.89) were within the range of the optimal value but generic name index, rational antibiotic index, and essential drugs list (EDL) index showed deviation. Only dispensing time index (0.27) was not up to the mark among patients care indicators. Every doctor had essential medicines list whereas 86% key medicines were available. The most common disease diagnosed was refractive error in 35.13% patients followed by allergic conjunctivitis (17.97%). Most commonly prescribed drug dosage form was eye drops 70.42%, followed by ointment/gel 19.98%, tablets/capsules 8.15%, and injections 1.45%. The maximum prescriptions (33.85%) had 3 drugs and total numbers of drugs were 1031. No drug was prescribed for 165 (26.96%) patients. Conclusions: The deviation of some observed values of WHO/INRUD indicators draw attention to the health care team for better understanding, planning, and making robust strategies toward rational prescribing. A positive attitude should be inculcated in the ophthalmologist for prescribing non-proprietary drugs preferentially from EDL. KEY WORDS: Drug Prescribing; Ophthalmology; Drug Utilization; India

INTRODUCTION

Pertinent use of drug is seen to be one of crucial parameter in society for achievement of human health care and rights, leading to attainment of health associated targets. Globally, nearly half of the drugs prescribed or dispensed are irrational and half of patient took it incorrectly. Approximately 33% of population worldwide do not get a reach to priority health care needs in context to essential medicines. Impact of irrational prescribing may lead to delay in affording relief and cure of patient, more adverse effect, emergence of antimicrobial drug resistance, economical burden for patient and community, prolongation of hospitalization, and increased morbidity and mortality. This ultimately leads to loss of faith and trust in the medical healthcare facilities. There are...
two strategies for minimizing it, firstly, monitoring the types and amount of irrational use of drugs in the prescriptions, secondly to find out the reasons behind this.\[1\]

Drug utilization studies are one of the robust instrument to establish drug’s irrationality.\[8\] The drug utilization research has been defined by World Health Organization (WHO): It includes marketing and dissemination of medicine with written instruction of drugs and its use by patients, with taking care of ultimate health and cost consequences in a community.\[7\] Discrepancies in the prescriptions, issues over side effects and increased drug cost have led to better outlook toward drug utilization studies.\[8\] A frequent drug audit is a need of hour for increasing the cost-effectiveness while decreasing risk benefit ratio of prescribed medicines.

WHO and the International Network for the rational use of drugs (INRUD) have innovated indicators for rational prescribing of drugs. These indicators are matter of more significance for developing countries like India and it has been already implemented in nearly 30 of them. They are categorized into: Prescribing, patient care and facility-specific.\[9,10\] As far as essential drug list (EDL) is concerned, latest revised essential medicines list issued by India in 2015 titled “National List of Essential Medicine.” It includes 376 medicines.\[5\]

In recent past, Pharmaceutical Industries have conducted many significant research and developments for ocular therapeutic agents.\[11,12\] There are many factors involved for enhancing efficacy and safety of ophthalmology drugs in the patient, firstly, accuracy of dose administration which relies on directives by the ophthalmologist, secondly rational prescription, and thirdly, appropriate understanding and communication to the patient.\[13\] Injudicious administration of non-steroidal anti-inflammatory drugs (NSAIDs) and antimicrobial drugs can result in many adverse drug reactions.\[14,15\]

Clinicians always try to do rational use of a drug but data suggested that irrational prescribing practice is more prevalent in developing countries like India. Periodic prescriptions monitoring and conducting drug utilization studies can fill the lacunae and give a ground for constructive solutions. Since there are limited healthcare resources and supply of drugs in developing countries, judicious prescription of drugs is necessary to avail resources at optimum level. Therefore, this research work was planned to not only acquire the current prescribing pattern of ophthalmologist at a tertiary healthcare center but also educate them about the prescribing indices for better health outcome.

MATERIALS AND METHODS

Type of Study and Study Design

This was a descriptive cross-sectional and observational study. It was carried out in Department of Pharmacology and Ophthalmology in a Tertiary Healthcare Center, situated in Western Uttar Pradesh, India, from 25 May 2018 to 25 August 2018.

Data Collection and Management

Data were collected from the eye outpatients department (OPD) for 4 months duration. Pre-validated case record form (CRF) was used for capturing the data of OPD patients. All the newly registered patients of both the gender from any age group were enrolled in the study. The post-surgical first prescription follow-ups in OPD were also included in the study. A total of 612 prescriptions were randomly collected as per WHO recommendation.\[9\] Patient characteristics, such as age, sex, place of residence, and diagnosis were noted. Drug’s name, dose, drug dosage form, routes of administration, frequency of administration, indications, and duration of therapy were documented in CRF. We also captured the doctor-patient communication in form of proper instruction to patients about the drugs and time-consultation of each patient.

Data Analysis

WHO/INRUD Drug Indicators is used for comparison of our data with the optimal value. The optimal value of each indicator has been mentioned in Table 1. For the comprehensive evaluation of rationality of healthcare system of Ophthalmology Department of Tertiary Care Hospital, we used the index system which was developed by Zhang and Zhi\[16,17\] [Table 1].

Statistical Analysis

Tabulation and statistical analysis of data were carried out by Microsoft excel-2020. Values were represented as actual numbers, mean and percentage and ratio.

Ethical Consideration

Ethical approval was taken from the Institutional Ethics Committee (IEC) of the studied tertiary care center (Ethics Committee Registration [ECR] Number: ECR/1082/Inst/UP/2018). The approval number of this study is GSMCH/2018/IEC/Approval/002, dated 24/05/2018. Voluntarily willingness in the form of informed consent process was conducted for each person before enrollment in the study.

RESULTS

Table 2 shows the demographic profile of our study in which total number of patient were 612. Out of which, 254 (41.50%) were male and 358 (58.50%) were female. The range of age was from 3 months to 87 years. The mean age of the study participants was 40.4 years, they were classified into different age groups, that is, vary from 0 to 5 years to...
>61 years. Maximum were from age group between 19 and 45 years (39.05%), whereas minimum from 0 to 5 years (6.37%).

A total of 612 prescriptions were collected and evaluated. Table 3 is showing patients with various ocular diseases in OPD, most common was refractive error in 215 patients (35.13%) followed by allergic conjunctivitis 110 (17.97%).

The total numbers of drugs prescribed were 1031. The average number of drugs per prescription was 1.68. The maximum prescription 201 (33.85%) had 3 drugs as given in Figure 1. No drug was prescribed for 165 (26.96%) patients.

The drug dosage forms were mentioned in all the prescriptions which are expressed in Figure 2. Most commonly prescribed drug dosage form was eye drops 70.42%, followed by ointment/gel 19.98%, tablets/capsules 8.15%, and injections 1.45%. Put only one drop of the drug was clearly written in all prescriptions of our study.

Table 1 shows the drug utilization parameters as per standard indicators. It also depicts the index value which is comparison of observed value to optimal value. The value of non-polypharmacy index and injection safety index were >1. In patients care indicators, the mean time taken by ophthalmologist for patients was 2.7 min and mean time taken by pharmacist was 210 s. The facility-specific indicators were up to the mark. About 25.35% drugs were prescribed by non-proprietary name and 1.45% drugs were administered by parenteral route.

The antimicrobials were the most frequently written drugs by the ophthalmologist on prescriptions 44.91%, then anti-allergic (steroids and anti-histamines) 18.43%, NSAIDs 15.81%, artificial tears 7.78%, multivitamins 7.37%, mydratic and cycloplegics 3.88%, and others 1.84% [Figure 3]. Antibiotics were prescribed either alone or in fixed-dose combinations (FDCs) with NSAIDs or with the steroids. Majority of prescriptions contain fluoroquinolones as an antimicrobial class, from which moxifloxacin was most preferred. Anti-histaminic class of drug mainly was olopatadine, whereas fluorometholone was preferred in corticosteroids. Flurbiprofen was preferred NSAID. Most commonly used anti-glaucoma drugs was beta blocker named timolol. For refraction testing, tropicamide plus phenylephrine FDCs in adults and atropine ointment in children were used most frequently.

Table 1: Details of drug utilization based on WHO/INRUD* indicators

<table>
<thead>
<tr>
<th>Sr. no.</th>
<th>Indicators assessed</th>
<th>Observed value (%)</th>
<th>Optimal value</th>
<th>Index name</th>
<th>Index value***</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Prescribing indicators</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Average number of drugs per encounter</td>
<td>1.68</td>
<td>&lt;2</td>
<td>Non-polypharmacy index*</td>
<td>1.19</td>
</tr>
<tr>
<td>2</td>
<td>Percentage of drugs prescribed by generic name</td>
<td>25.35</td>
<td>Close to 100</td>
<td>Generic name index $</td>
<td>0.25</td>
</tr>
<tr>
<td>3</td>
<td>Percentage of encounters with an antibiotic prescribed</td>
<td>58.83</td>
<td>&lt;30</td>
<td>Rational antibiotic index*</td>
<td>0.51</td>
</tr>
<tr>
<td>4</td>
<td>Percentage of encounters with an injection prescribed</td>
<td>1.45</td>
<td>&lt;10</td>
<td>Injection safety index$</td>
<td>6.89</td>
</tr>
<tr>
<td>5</td>
<td>Percentage of drugs prescribed from NLEM** 2015</td>
<td>52.48</td>
<td>Close to 100</td>
<td>Essential drugs list index $</td>
<td>0.52</td>
</tr>
<tr>
<td>B. Patients care indicator</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Patients knowledge of correct dosage</td>
<td>98.03</td>
<td>100</td>
<td>Consultation time index $</td>
<td>0.98</td>
</tr>
<tr>
<td>7</td>
<td>Average consultation time (min)</td>
<td>2.7</td>
<td>≥10</td>
<td>Dispensing time index $</td>
<td>0.27</td>
</tr>
<tr>
<td>8</td>
<td>Average dispensing time (s)</td>
<td>210</td>
<td>≥90</td>
<td>Dispensed drugs index $</td>
<td>2.33</td>
</tr>
<tr>
<td>9</td>
<td>Percent medicines actually dispensed</td>
<td>90</td>
<td>100</td>
<td>Labeled drugs index $</td>
<td>0.90</td>
</tr>
<tr>
<td>10</td>
<td>Percent medicines adequately labeled</td>
<td>100</td>
<td>100</td>
<td>Patients’ knowledge index $</td>
<td>1</td>
</tr>
<tr>
<td>C. Facility specific indicators</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Availability of essential medicines list or formulary to practitioners</td>
<td>100</td>
<td>100</td>
<td>Index of EDL $</td>
<td>1</td>
</tr>
<tr>
<td>12</td>
<td>Percent key medicines available</td>
<td>86</td>
<td>100</td>
<td>Index of key drugs in stock $</td>
<td>0.86</td>
</tr>
</tbody>
</table>

*WHO: World Health Organization, INRUD: International Network for the rational use of drugs, **NLEM: National list of essential medicine, ***The value of optimal index for all indicators was set as one (01). The values nearer to one indicate rational drug use. #For the calculation of given indices, formula used: Optimum value divided by observed value. $For the calculation of given indices, formula used: Observed value divided by optimum value

Table 2: Distribution of patients according to demographic variable

<table>
<thead>
<tr>
<th>Demographic variable</th>
<th>Division</th>
<th>No. of patients (total patients – 612)</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>Female</td>
<td>358</td>
<td>58.50</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>254</td>
<td>41.50</td>
</tr>
<tr>
<td>Age group (years)</td>
<td>0–5</td>
<td>39</td>
<td>6.37</td>
</tr>
<tr>
<td></td>
<td>6–18</td>
<td>82</td>
<td>13.40</td>
</tr>
<tr>
<td></td>
<td>19–45</td>
<td>239</td>
<td>39.05</td>
</tr>
<tr>
<td></td>
<td>46–60</td>
<td>144</td>
<td>23.53</td>
</tr>
<tr>
<td></td>
<td>&gt;61</td>
<td>108</td>
<td>17.65</td>
</tr>
<tr>
<td>Residence</td>
<td>Rural</td>
<td>461</td>
<td>75.33</td>
</tr>
<tr>
<td></td>
<td>Urban</td>
<td>151</td>
<td>24.67</td>
</tr>
</tbody>
</table>

The antimicrobials were the most frequently written drugs by the ophthalmologist on prescriptions 44.91%, then anti-allergic (steroids and anti-histamines) 18.43%, NSAIDs 15.81%, artificial tears 7.78%, multivitamins 7.37%, mydratic and cycloplegics 3.88%, and others 1.84% [Figure 3]. Antibiotics were prescribed either alone or in fixed-dose combinations (FDCs) with NSAIDs or with the steroids. Majority of prescriptions contain fluoroquinolones as an antimicrobial class, from which moxifloxacin was most preferred. Anti-histaminic class of drug mainly was olopatadine, whereas fluorometholone was preferred in corticosteroids. Flurbiprofen was preferred NSAID. Most commonly used anti-glaucoma drugs was beta blocker named timolol. For refraction testing, tropicamide plus phenylephrine FDCs in adults and atropine ointment in children were used most frequently.
DISCUSSION

In our study, maximum number of the patients belongs to the age group of 19–45 (39.05%) and least was from 0 to 5 years with female preponderance (58.50%). As far as gender ratio is concerned, Jain et al. has shown the similar pattern while other studies indicated male preponderance.[18-22]

The most common disorders diagnosed in our study were refractive errors then conjunctivitis which is parallel to the study done by Banerjee et al. but some previous studies reported different pattern as eyelid disease (34%) by Vaniya et al. and conjunctivitis (61.1% and 34%, 28%) by Jain et al., Shakuntala et al., and Chetan et al., respectively.[18,19,23-25] The reason behind this might be taking refractive error patients in our study. We also found that no drug was prescribed for 165 (26.96%) patients and these patients were related to refractive error.

The numbers of drugs prescribed were 1031 in the study. The maximum number of drug prescribed in one prescription was three which is supported by Chetan et al.[25] In contrast to this, two drugs were in maximum prescription in previous studies done by many researchers.[19,23,24] This might be due to the difference in disease pattern of studied patients.

Topical route (90.40%) was preferred by ophthalmologist in present study. Almost same results were shown in the study by Prajawal et al., Nehru et al., and by Prajapati et al.[26-28] which strengthen the rationality of topical routes which has minimal systemic side effect with better therapeutic efficacy in eye disease.

Put only one drop of the drug was written in all prescriptions of our study. The results are parallel to study conducted by Neeraj et al. The education regarding drug administration is crucial aspect of therapy as usually patients have tendency to apply excess of drops in eye causing drug wastage, economical burden, and low adherence to the therapy.[29]

Prescribing Indicators

The conducted study revealed that the average number of drugs per prescription is 1.68%. It is similar to the study conducted by other investigators.[18,19,30] This number should be minimized for decreasing the occurrence of drug-drug interactions and side effects. It also decreases the economic burden and chance of errors of prescribing.

The % of drugs prescribed by non-proprietary names in present study was 25.35%. In a majority of studies done in India, this value was <40% as shown in the previous studies.[18,19,23] The countries such as Ethiopia, Cambodia, and some other have showed the value near normal.[31,33] Discrepancies may be due to factors related to firm belief of doctors on innovators, robust marketing strategies of
pharma industries affecting prescriber’s outlook, deficiency of regulatory pressure to prescribe generic medicines, and lack of sensitization of the clinicians for generics. Variability in potency and fluctuation in clinical response may be some major factors for ophthalmologists to prescribe medicines by branded name. WHO has given strong recommendation for generic prescription.\cite{34} In developing country like India, prescription by non-proprietary name might lower the economic burden of therapy which may lead to easy availability of health facility to all.

About 58.83% of prescriptions contain antibiotic which is almost similar finding observed in study done by Vaniya \textit{et al}. 62.2%, whereas other studies depicted 19.48% by Jadhav \textit{et al}. 81.96% by Jai \textit{et al}. and 70.6% Shakuntala \textit{et al}.\cite{18,19,24,30} The reason of over-prescription of antimicrobials might be due to lack of sensitization of doctors and firm mindset of society.

The % of prescription with an injection was 1.45% which is good for healthcare system. Less prescribing of injection might be due to ophthalmic diseases where topical route is preferred. Only 52.48% of antibiotics belong to national essential medicines list 2015 list which is parallel to Bhat \textit{et al}. (53.26%)\cite{35} Contrary to this, study done by Suman \textit{et al}.\cite{21} has shown more value 96%. There is a need of hour to sensitize about the essential medicines list and its sustainable use.

Patients Care Indicators

About 93.83% of patients were aware of correct drug dosage schedule. It increases the therapeutic efficacy, decreases the side effect and poor compliance. The time taken by ophthalmologist was low (2.7 min) in our study, might be due to more number of patients per doctor. It shows correspondence with the values measured in India 2.3 min\cite{36} and other developing countries ranging from 1 to 3 min, whereas in developed countries, it showed higher side, that is, from 9.5 to 22.5 min.\cite{19-43}

One important limitation of study that it has been conducted in new private medical college and hospital where complete picture of ophthalmic OPD might be lacking. However, our strength of study is to capture whole prescriptions in a day during study period and first study in ophthalmology department where index value of prescribing indicator were calculated and evaluated.

CONCLUSIONS

Both rational and irrational drug prescribing practices were prevalent in ophthalmology department. The observed values of our study draw attention to the health care stakeholders for meticulous planning toward rational prescribing and making robust strategies for promoting it. A positive attitude should be inculcated in the ophthalmologist for prescribing non-proprietary drugs preferentially from EDL. For increasing the consultation time, the competent authority must take the initiative toward deficiency of doctors and increasing recruitments in health care centers. Our entire study focused on not only assessing prescribing indicators but also gave insight to indexing by which health care team understand the need of better prescribing and dispensing the medicines for the rural patients.

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