Original Research Article

A prospective study of drug utilization in patients undergoing cataract surgery

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Abstract

Background: Drug utilization studies are an important part of rational use of drugs. Assessment of drug use pattern especially in developing countries is becoming increasingly necessary to promote the rational use of drugs. This study was planned to prospectively assess the drug utilization pattern in patients undergoing cataract operation at KBN teaching and General hospital. **Methods:** This was a prospective observational study done at Department of Ophthalmology, KBN Institute of Medical Sciences, Gulbarga. It commenced after the approval from 'Institutional Ethics Committee' and after obtaining informed consent from the patient; prescriptions of 100 patients were analyzed using a predesigned form to record information from the eligible patients satisfying the inclusion and exclusion criteria. WHO drug use indicators and additional indices were analyzed. **Results:** A total of 513 drugs were prescribed for 100 patients (average 5.13) who underwent cataract surgery. Maximum were from 'age group of 45-65' and most of them were suffering from 'immature senile cataract'. Females had higher incidence and most of them presenting with 'blurring of vision'. 'Topical eye drops' are most commonly used route of drug administration. Drugs which were prescribed by 'brand names'were 80%. 'Fixed drug combination' includes 22% of prescribed drugs and drugs from essential drug list were 92%. Overall antimicrobials were the most commonly prescribed group followed by anti-inflammatory, steroid etc. **Conclusions:** Study reflects on lack of awareness so as to avoid polypharmacy. The prescription writing errors were less, however, there was very low generic prescribing and inadequate information about the duration of therapy in many prescriptions. It is essential that appropriate guidelines on the use of topical antimicrobials are required to ensure rational prescribing

Key Word: Drug utilization evaluation, Ophthalmology, Prospective study, Cataract, Eye drops.

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INTRODUCTION

In health care system, use of medicines is considered one of the most cost-effective medical interventions for treatment and prevention of disease and it is important to realize that inefficient use of medicines might affect the safety and quality of therapeutic care and waste resources. The drug utilization studies is defined as "the marketing, distribution, prescription, and use of drugs in a society, with special emphasis on the resulting medical, social, and economic consequences" (WHO).[1] In the past few decades, marketing of new drugs, variations in the pattern of drug prescribing, concerns about the delayed adverse effects of drugs and the increase in the cost of drugs has increased the importance of drug utilization studies.[2] Drug utilization studies are powerful exploratory tools to ascertain the role of drugs in the society.[3] WHO identifies cataract as one among the five major blinding eye conditions for immediate attention to achieve the goals of vision 2020. Cataract surgeries are commonly performed to prevent blindness. Vision 2020 aims to eliminate blindness due to cataract by performing cataract extraction with IOL implantation and also by increasing the number of cataract surgery rate.[4] Cataract surgery is one of the most frequently performed elective surgical procedure throughout the country.[5] Like other types of surgery, cataract surgery induces uncontrolled infection and inflammation which may leads to serious side effects such as hyphaema, iris prolapse, anterior uveitis, bacterial

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endopthalmitis and secondary glaucoma.[6] Prevention and management of infection and inflammation is thus a mainstay in modern cataract surgery. As the surgical procedure has become less invasive, the recovery after surgery is now easier and patients usually no longer require in-patient hospital care after the operation.[7] The modern minimally invasive cataracts surgery with phacoemulsification is considered as a minor procedure with an uneventful and pain-free recovery period.[8] However, little attention has been paid to pain and other post-operative ocular irritation symptoms, and the data on the incidence of these symptoms is conflicting. In some studies, rather few patients have reported many complaints after surgery.[9] Whereas in other studies some post-operative ocular irritation symptoms and pain have been experienced by the majority and even as many as 90% of patients.[10] So the present study was taken up prospectively to analyze the drugs utilized in post-operative cataract surgery patients.

METHODS

This study was carried out prospectively in Ophthalmology Department of KBN teaching and General Hospital from January 2016 to December 2016. Permission was obtained from the Institutional Ethics Committee. This was an open label, cross sectional, prospective, non-interventional, observational study conducted by 'Department of Pharmacology' in association with 'Department of Ophthalmology', KBN Institute of Medical Sciences.

INCLUSION CRITERIA

- Patients of either sex and any age diagnosed as having any form of cataract.
- Patients who were operated for the presenting cataract.

EXCLUSION CRITERIA

- Cataract associated with diabetes, hypertension and other metabolic diseases.
- Patients not operated due to any underlying cause/refused operation.

After obtaining informed consent, the data was collected from the 100 inpatients who underwent cataract surgery in ophthalmology department and recorded in a proforma containing relevant demographic details like including their average number of drugs per prescription, number of encounters with antibiotics, analgesics, anti-inflammatory and other drugs, dosage form, route of administration, frequency and duration of therapy. These forms are used to analyze whether the drug is prescribed in generic or proprietary names. All drugs prescribed were noted including dose, route, dosage form, frequency of administration, indications for prescription and duration of therapy, numbers of drugs prescribed from Essential Drug list were also noted as per WHO/International Network of Rational Use of Drugs (INRUD) drug use indicators.[11] Essential medicines as defined by the WHO are those drugs that satisfy the health-care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford.[12] Central Drugs Standard Control Organization, the regulatory body in India, has recently formulated the National list of essential medicines in 2015. A total of 100 prescriptions were analyzed following WHO recommendation.[11]

Ethical approval: The study was approved by the Institutional Ethics Committee of KBNIMS, Gulbarga, India vide letter No.: KBNIMS/IEC/2015-16/16 dated 13/11/2015.

STATISTICAL ANALYSIS

Data was coded and entered with the help of a statistician to minimize the data entry errors. Data was analyzed on EPI INFO version 7.2 and MS EXCEL**.** The different variables were expressed as frequencies and percentages.

RESULTS

A total of 100 prescriptions were analyzed. The total number of drugs in these prescriptions were 513. The number of drugs per prescription varied from four to seven, with an average of 5.1 per prescription. The various WHO prescribing drug indicators are as shown in table 1.

Table 1: WHO prescribing drug indicators.

Drug indicators	No. of patients	%
Total drugs prescribed	513	-
Average number of drugs per prescription	5.13	-
Drugs prescribed by brand names	410	80
Drugs prescribed by generic names	103	20
Fixed drug combination	113	22
Drugs from NLEM	472	92

*NLEM: National List of Essential Medicines.

WHO prescribing drug indicators includes 'average number of drugs per prescription' which was 5.1 Study also revealed that drugs which were prescribed by 'generic name' were 20% and overall percentage of drugs prescribed by 'brand name' were 80% which includes 100% eye drops prescribed by brand names. Fixed drug combination includes 22% and drugs from essential drug list were 92% as shown in table 1. Out of the 100 prescriptions maximum number of prescriptions (n=62) belonged to the age group of 45-65 years, followed by n=36 in the age group of >65 years, as shown in the figure 1.

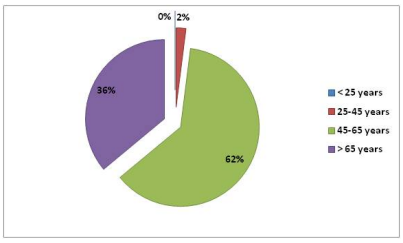

Figure 1: Showing the age wise distribution of the patients.

Out of the 100 patients 63 were female and 37 were males, this shows female predominance in incidence of cataract as shown in Figure 2.

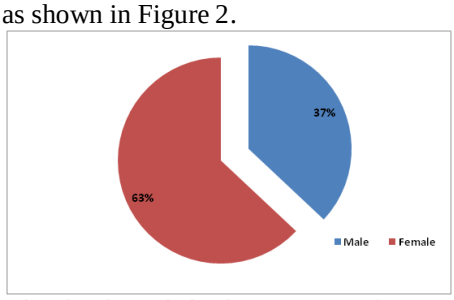

Figure 2: Showing the variation in occurrence of cataract among either sex

The most common symptom of patients was blurring of vision (n=87) followed by patients who were accidently diagnosed with cataract during their refraction testing (n=8) and rest accounts for complaints like watering of eye (n=3), clouding of vision (n=1) and halo with diplopia (n=1), as shown in Table 2.

Table 2: Showing the variations in occurrence of symptoms.

Symptom	Number of patients (n=100)
Blurring of vision	87
Accidentally diagnosed with cataract during refraction testing	8
Complaints with watering eye	3
Clouding of vision	1
Halo with diplopia	1

There was no much difference in incidence of cataract occurrence in either eyes i.e. Right eye constituting (n=52) and left eye n=48, as shown in Figure 3.

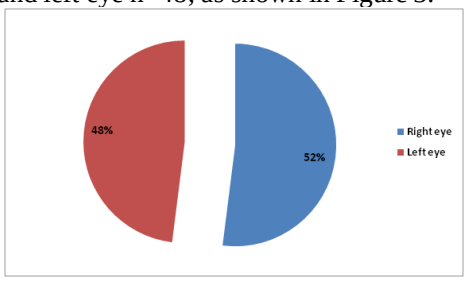

Figure 3: Showing the variation in occurrence of cataract in either eye

Around 55% (n=55) of cases were suffering from '*senile immature cataract*', followed by '*senile mature cataract*' in 35 cases, and with '*hyper-mature cataract*' in 6 cases, as shown in figure 4.

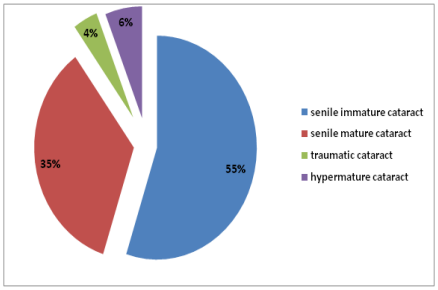

Figure 4: Showing the types of cataract

Table 3: List of all drugs employed in patients undergoing cataract surgery

Topical eye drop	Oral	Parenteral
Commonly used drugs		
Flubiprofen	Ofloxacin	Diclofenac
Gatifloxacin	Ciprofloxacin	Dexamethasone
Moxifloxacin	Alprazolam	
Gatifloxacin-dexamethasone/ Difluprednate/prednisolone	Antioxidant	
Moxifloxacin-dexamethasone/ Difluprednate		
Tropicamide/cyclopentolate		
Lubricant (CMC)		
Prednisolone		
Sodium chloride solution		

Miscellaneous drugs	
Drugs	**No. of drugs (%)**
Amoxicillin/Paracetamol/Rabeprazole or Antacid gel	3.5% (each drug)
Tobramycin/Timolol/Atropine/Botroxobin	1.5 % (each drug)

List of commonly used drugs in patients undergoing cataract surgery is listed in Table 3. Our study stated that Gatifloxacin eye drop is the most frequently prescribed anti-microbial followed by oral ciprofloxacin pre-operatively for cataract surgery. Flubiprofen eye drop was prescribed as an anti-inflammatory almost in 90% cases while 60% cases were prescribed Alprazolam to relieve anxiety, as shown in table 4.

Table 4: Pre-operative drugs employed in patients undergoing cataract surgery.

Oral drugs	Number of patients
Alprazolam	60
Ciprofloxacin	66
Ofloxacin	45
Botroxobin	2
Amoxyclav	10
Prednisolone	3
Eye drops	**Number of patients**
Flubiprofen	90
Gatifloxacin	60
Moxifloxacin	40
Atropine	4
Tobramycin	2
Timolol	2

Also oral ciprofloxacin is the most frequently prescribed anti-microbial followed by oral ofloxacin post-operatively for cataract surgery. Injection diclofenac was the most commonly used medication postoperatively and is given in 90 cases. Parenteral dexamethasone was the preferred glucocorticoid and was employed as an anti-inflammatory agent in nearly 30 cases, as shown in table 5.

Table 5: Post-operative drugs employed in patients undergoing cataract surgery.

Parenteral drugs	Number of patients
Diclofenac	90
Dexamethasone	30
Botropase	2
Oral drugs	**Number of patients**
Ciprofloxacin	45
Ofloxacin	40
Amoxyclav	6
Paracetamol	25
Ibuprofen	18
Prednisolone	3
Rabeprazole/antacid gel	63

Antimicrobials are the commonly employed drugs followed by anti-inflammatory, lubricants, antioxidants multivitamins, Mydriatics and steroid eye drops. Out of antimicrobials, oral ofloxacin followed by gatifloxacin-dexamethasone eye drop were prescribed, as shown in table 6.

Table 6: Showing the drugs prescribed after discharge in patients who underwent cataract surgery.

Eye drops	Number of patients
Gatifloxacin-dexamethasone	37
Moxifloxacin-difluprednate	22
Gatifloxacin-prednisolone	14
Gatifloxacin	12
Moxifloxacin-dexamethasone	10
Moxifloxacin	4
Gatifloxacine-difluprednate	2
Lubricant	30
Cyclopentolate	15
Tropicamide	6
Prednisolone	10
Sodium chloride solution	8
Oral drugs	**Number of patients**
Ofloxacin	48
Ciprofloxacin	44
Antioxidant-multivitamin	27
Prednisolone	4
Pantoprazole/Antacid gel	2
Atropine	2

DISCUSSION

The indicators of prescribing practices measure the performance of health care providers in several key dimensions related to the appropriate use of drugs.[13] WHO drug use indicators were used in the present studies. Of the 100 prescriptions containing 513 drugs, number of drugs per prescription ranged from four to seven. In this study, most commonly five drugs were noted per prescription. Average number of drugs per prescription is an important index as it tends to measure the degree of polypharmacy.[14] It is preferable to keep the number of drugs per prescription as low as possible since higher figurers lead to increased risk of drug interactions, adverse effects, development of bacterial resistance and increased cost to the patient.[15] In this study, most of the drugs were prescribed with both topical and oral antibiotics. These were prescribed pre, post-operatively and after discharge. Overall most common group of drugs used preoperative, postoperative and on discharge are the antibiotics followed by anti-inflammatory, anxiolytics, steroids, lubricants, Mydriatics etc. Most of them were in the form of eye drops. dministering the drugs topically for eye diseases minimized their systemic adverse effects.[15] Generic drug use in India is yet to gain widespread popularity; the economic benefits of generic drug use are however well-known and undisputed.[16] Recently, regulatory authorities of different countries are advocating generic prescribing to cut total health-care cost.[17] In this regards, the percentage of drugs prescribed by generic names in this study was only 20%, inadequate sensitization of the clinicians to generic prescribing and the frequent visit of the medical representatives in health facilities may be the probable cause of under prescribing the drugs by generic name. The percentage of drugs prescribed from the National List of Essential Medicines (NLEM) 2015 was 92% which is higher compared to studies conducted in India.[18] The results of our study indicated that the maximum number of patients were in the age group of 45-65 years. This shows that cataract occurs commonly in the elderly age group. Females had high incidence of cataract than males. The most common form was senile immature cataract which was commonly associated with other conditions like hypertension and chronic dacryocystitis. The most commonly preferred route of administration was topical eye drops to prevent systemic side effects. Gatifloxacin eyedrop was the most frequently prescribed antibiotic followed by oral ciprofloxacin pre-operatively. Topically applied antibiotics are routinely used for the prophylaxis of postoperative bacterial ocular infections such as endophthalmitis. Fluoroquinolones have good efficacy against the causative organism of endophthalmitis.[19] In present study ofloxacin is being effective and it was the prescribed antibiotic in post-operative patients. This is similar to study done by Biswas *et al*, [20] where ofloxacin was commonly prescribed. Whereas Kumar *et al*,[21] has mentioned that newer fourth generation FQs Moxifloxacin is more potent and with broad spectrum of activity to prevent endophthalmitis. Rational drug

prescribing is defined as the use of the least number of drugs to obtain the best possible results in the shortest period and at a reasonable cost.[22] In the present study, the average number of drugs per prescription was 5.1, the result reflects polypharmacy, Recommendation by WHO is not applicable as the patients included were in-patients who underwent surgery. Other hospital-based studies in India reported 3-5 drugs per prescription almost in the same range as present study.[23-25] Polypharmacy is often associated with increased risk of drug interactions and adverse effects, higher cost and decreased compliance to patient.[26-27] The other most commonly prescribed agent was NSAIDs and corticosteroid along with an antibiotic mainly a fixed dose combination. Corticosteroids were the main anti-inflammatory drugs prescribed post operatively before the advent of NSAIDs. NSAIDs as anti-inflammatory drugs in postoperative cataract patients have some advantages producing analgesia and sustained pupillary dilatation during intra-operative preventing postoperative cystoids macular edema and reducing different intra and extra-ocular inflammation.[28] Several trials have established that topical NSAIDs have a number of important roles in the treatment of inflammation following ophthalmic cataract surgery and some were more advantageous over steroids.[29] A study done by Flach A.J.,[30]conclude that advantage of NSAIDs over corticosteroids include a reduction in postoperative pain and photophobia, decreased itching in allergic conjunctivitis, decrease in ocular pressure and reduction of intra-operative miosis. Depending on severity of inflammation and prolonged surgery few patients received Inj. dexamethasone intramuscularly apart from topical application. Fixed dose combination of drugs were prescribed such as gatifloxacin-dexamethasone/prednisolone, Moxifloxacin-dexamethasone/ Difluprednate. These FDC's were comparable to the other studies done by Kshirasagar *et al*.[31] where 36.9% FDC were prescribed. In present study, authors found that written instructions regarding dose, dosing interval and duration of therapy were not clearly mentioned in all the prescriptions. Whereas earlier study of drug use pattern in ophthalmology from India shows 30% incomplete prescriptions.[32] Instructions regarding drug instillation is important aspect of ocular therapy.[33] This study showed a need for improvement in prescription writing, as the duration of therapy was missing in most of the prescriptions. The present study revealed certain lacunae in the prescribing practices of the Ophthalmologists in this institute evident by the low generic prescribing, inadequate information about duration of therapy in many prescriptions. There is margin for betterment. Ophthalmologists should be encouraged to prescribe by generic name and opt for essential drugs from National List of Essential Medicines. The study suggests educational initiative, development of drug policy, and National Essential drug list based hospital formulary to reduce the drug cost and ensure rational use of medicines.

CONCLUSION

To conclude, Fluoroquinolones and corticosteroids were the most frequently prescribed drug groups in post cataract surgery patients. The other most commonly prescribed agent was NSAIDs as anti-inflammatory and analgesic, the advent of NSAIDs in management of post cataract surgery patients over and above the steroids was proven with many studies and was included accordingly in the present study. Rational prescribing is an important criterion forconvenience of a patient in terms of disease, adverse events and treatment cost. Study data may be helpful to understand the need of writing generic name in prescriptions, adherence with the National essential drugs list policy and availability of chief alternative medicines in hospital pharmacy. Health care providers have to take initiative for rational prescribing keeping in mind that it is not only a matter of national policy but also the wellbeing of individual patient. Dosing intervals and duration of therapy of combined topical antibiotic and steroid treatment postoperatively matched with Indian document Vision 2020. This is a positive phenomenon towards rationalization and homogeneity in the treatment part. It also increases the quality management of cataract in India.

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