

Pharmaco epidemiology of drugs used in post-cataract surgery patients in tertiary care hospital

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ABSTRACT

Background: In India cataract is the principal cause of blindness responsible for 62.6% as per national programme for control of blindness survey and as per our knowledge, very few systematically analysed data are available on the drug utilization study pattern of medical intervention for post cataract surgery in India. Hence, the present study was under taken to generate baseline drug use data and analyse various aspects of drug prescribing practices.

Methods: This study was conducted in department of ophthalmology BIMS Belagavi. A total of 449 patients' prescription was analysed prospectively. The data was analysed statistically, and results were expressed as numbers and percentage.

Results: A total of 2306 drugs were prescribed for 449 patients who underwent cataract surgery. All patients received topical eye drops includes bromfenac 0.1% eye drop and other one is a fixed drug combination of dexamethasone 0.1% plus ofloxacin 0.3% eye drop. Use of antibiotic in association with sex found to be significant (p- value <0.004). Average number of drugs per prescription was 5.1 and drugs which prescribed in generic name were 60.99% and overall percentage of drugs prescribed by brand name was 38.94% which includes 100% eye drops were prescribed by brand names. Fixed drug combination includes 19.50% and drugs from essential drug list used were 80.49%.

Conclusions: 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 to wellbeing of individual patient.

Keywords: Cataract, Drug utilization study, Eye drop, Pharmacoepidemiology

INTRODUCTION

Pharmaco-epidemiology is the application of epidemiological knowledge, methods, measurements, analysis and reasoning to study uses, cost effectiveness and adverse effect of drugs in defined population.¹ Cataract causes 33% of blindness worldwide. In India cataract is the principal cause of blindness responsible for 62.6% as per NPCB survey 2006-2007.

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.^{2,3}

Cataract surgery is one of the most frequently performed elective surgical procedure throughout the country. The surgical methods have improved significantly with the advent of microsurgery. And the quality of treatment has dramatically improved hence complications have reduced, thus raising patients and surgeons' expectations of a successful visual outcome.⁴

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 endophthalmitis and secondary glaucoma.⁵ 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.

The modern minimally invasive cataracts surgery with phacoemulsification is considered as a minor procedure with an uneventful and pain-free recovery period.

However, little attention has been paid to pain and other postoperative ocular irritation symptoms, and the data on the incidence of these symptoms is conflicting. In some studies, rather few patients have reported any complaints after surgery.^{6,7} Whereas in other studies some postoperative ocular irritation symptoms and pain have been experienced by the majority and even as many as 90% of patients.⁸⁻¹⁰ So this study was taken to analyse drugs used in post-operative cataract surgery patients prospectively.

METHODS

This prospective study was carried out in the department of pharmacology and ophthalmology BIMS Belagavi after obtaining approval and clearance from the institutional ethical committee for period of 6 month from 1st December 2015 to 30th May 2016.

Inclusion criteria

- Patients of either sex
- Age above 50 years operated for immature senile cataract.

Exclusion criteria

- Patients age below 50 years

- Cataract associated with diabetes, hypertension and other metabolic diseases.

The data was collected from the 449 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 analyse whether the drug is prescribed in generic or proprietary names.

Statistical analysis

Data were analysed using Microsoft Excel through statistical software: SPSS VERSION 22. All parameters were expressed in numbers and percentages. Chi-square test was used to see the association between different variables.

RESULTS

Out of 449 patients 287 (63.92%) were female and 162 (36.08%) were male, this shows female predominance in incidence of cataract and the most common symptom of patient was blurring of vision 357 (79.51 %) followed by patients who were accidentally diagnosed with cataract during their refraction testing 14.92% and rest 5% accounts for complaints like watering of eye 10 (2.22%), clouding of vision 13 (2.89%) and halo with diplopia 2 (0.44%). There was no much difference in incidence of cataract occurrence in both eyes i.e. Right eye constituting 247 (55.02%) and left eye is 202 (44.98%). Total 2306 drugs were prescribed post operatively in present study which were given in different dosage forms which are shown in table 6, includes eye drops 100% a fixed dose combination (FDC) of dexamethasone plus ofloxacin eye drops (100%) and bromfenac eye drops (100%).

Table 1: Prescription summery.

Class of drugs	Major therapeutic agent	No. of cases prescribed (%)	Route and dosage form	Frequency and duration
Antibiotics*	Ofloxacin	449(100)	Eye drop 0.3% solution	1 drop × every 2hrs for× 3wk. 1 drop × every 4hrs/ 4 th , 5 th , and 6 th week
	Ciprofloxacin	374(83.29)	Tab 500mg P.O	Twice daily ×5days. 1 day pre-op and 4 days post-op
Analgesics	Diclofenac	374(83.29)	Tab 25mg P.O	Twice daily×5days
	Bromfenac	449 (100)	Eye drop 0.1% solution	1 drop × every 4hrs for× 3wk
Antacids	Ranitidine	374(83.29)	Tab 150 P.O	Twice daily ×5days. 1 day pre-op and 4 days post-op
Steroids	Dexamethasone in combination with ofloxacin	449(100)	Eye drop 0.1% solution	1 drop × every 2hrs for× 3wk. 1 drop × every 4hrs/ 4 th , 5 th , and 6 th wk.
	Dexamethasone	283(63.80)	Inj 8mg IM	Stat

*Use of antibiotic in association with sex found to be significant (p value <0.004)

These two eye drops were found to be the most frequently prescribed drugs followed by oral tablets 83.29% which include one antibiotic (ciprofloxacin), analgesic (diclofenac) and ranitidine. Injections dexamethasone constitute 63.80% was the least prescribed drug in the present study and is shown in the Tables (Table 1 and Table 2).

Table 2: Association of antibiotic usage with sex.

	Female	Male
Antibiotic use	287	162
Chi-square test	8.490	8.472
p- value	<0.004	<0.002

Table 3: Distribution based on chief complaints.

Chief complaints	No. of patients	Percentage (%)
Blurring of vision	357	79.51
Refraction testing	67	14.92
Clouding of vision	13	2.89
Watering of eye	10	2.22
Halo with diplopia	2	0.44

Table 4: WHO prescribing drug indicators.

Drug indicators	No. of patients	%
Total drugs prescribed	2302	-
Average number of drugs per prescription	5.12	-
Drugs prescribed by brand names	898	38.94
Drugs prescribed by generic name	1404	60.99
Fixed drug combination	449	19.50
Drugs from essential drug list	1853	80.49
No of drugs which are available in hospital	1404	60.99
Drugs which are prescribed from outside	898	38.94

WHO prescribing drug indicators shown in table 6 include, average number of drugs per prescription which was 5.1 and the range of drugs per prescription varied from 2 to 6. Study also revealed that drugs which prescribed in generic name were 60.99% and overall percentage of drugs prescribed by brand name is 38.94% which includes 100% eye drops prescribed by brand names. Fixed drug combination includes 19.50% and drugs from essential drug list used were 80.49%. Most of the drugs procured were from the hospital pharmacy and only few drugs are prescribed from outside (Table 3).

DISCUSSION

Authors analysed drug utilization of 449 patients prospectively who underwent cataract surgery. It was found that numbers of females (63.92%) were more than

males (36.08%) showing female sex predominance. Present study is in contrast with study done by Prajwal P et al, where males (56.01%) were more than females (43.99%).

Cataract can occur in all age group, but it is a disease of older age group. The maximum number of patients in present study belongs to age group of 60-69 years (51%), these findings show were similar to study done by Kumar et al, where maximum patients belonged to age group above 60 years (55.93%).

All patients received two eye drops. Analgesic, bromfenac eye drop 0.1% and combination of anti-inflammatory with antibiotic fluroquinolone that is a fixed drug combination of dexamethasone 0.1% plus ofloxacin 0.3% eye drops. 83.29% patients received oral therapy for 5 days post operatively with one antibiotic ciprofloxacin, one anti-inflammatory and analgesic diclofenac given along with ranitidine.

Topically applied antibiotics are routinely used for the prophylaxis for postoperative bacterial ocular infections such as endophthalmitis. Fluroquinolones have good efficacy against the causative organism of endophthalmitis. 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, where ofloxacin was commonly prescribed.¹¹ Whereas Kumar et al, has mentioned that newer fourth generation FQs moxifloxacin is more potent and with broad spectrum of activity to prevent endophthalmitis.¹²

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.¹³ In the present study, the average number of drugs per prescription was 5.1. WHO has recommended that average number of drugs per prescription should be two.¹⁴ In present study, the result reflects polypharmacy, Recommendation by WHO is not applicable as the patients included were in-patients who underwent surgery. In present study, the average length of stay was longer, there by more medication was prescribed. In such cases polypharmacy can be justifiable. Other hospital-based studies in India reported 3-5 drugs per prescription almost in the same range as present study.¹⁵⁻¹⁷ Polypharmacy is often associated with increased risk of drug interactions and adverse effects, higher cost and decreased compliance to patient.^{18,19} Hence, it is essential to keep the number of drugs per prescription as low as possible.

In present study, systemic antibiotic ciprofloxacin was prescribed orally twice daily for 5 days, but the benefit of systemic antibiotic therapy to prevent endophthalmitis remains controversial. Optimum antibiotic concentration in aqueous humor can be achieved by topical application.^{20,21} Authentic Indian document Vision 2020: The Right to sight publication - guideline for management of cataract in India (Vision 2020) clearly denies the need of systemic

antibiotics on routine basis after post cataract surgery.²² High use of antibiotics reflects the condition of poor sanitation, nutrition, prevalence of various infections and certain acute infective conditions which needs conservative treatment.

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 cystoid macular edema and reducing different intra-and extra-ocular inflammation.²³ 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.²⁴

A study done by Flach AJ et al, conclude that advantage of NSAIDs over corticosteroids include a reduction in post-operative pain and photophobia, decreased itching in allergic conjunctivitis, decrease in ocular pressure and reduction of intra-operative miosis.²⁵ Depending on severity of inflammation and prolonged surgery, 63.02% patients received Inj dexamethasone intramuscularly apart from topical application.

Fixed dose combination of drugs prescribed were 19.50% which was less compared to the other studies done by Kshirasagaretal.²⁶ where 36.9% FDC were prescribed.

The percentage of drugs dispensed from the hospital pharmacy was 60.99% as there were more drugs available which was in contrast to the study Narwane et al, 36.78% drugs were not available in hospital pharmacy.²⁷

In present study, authors found that written instructions regarding dose, dosing interval and duration of therapy were clearly mentioned in all the prescriptions. Whereas earlier study of drug use pattern in ophthalmology from India shows 30% incomplete prescriptions.²⁸ Instructions regarding drug instillation is important aspect of ocular therapy.²⁹ Patients were asked to put only one drop of the drug which was clearly written in all prescriptions but patients usually have the habit of applying 2-3 drops in the eye resulting into the wastage, increased cost and poor compliance, About the same was informed to all patients in present study.³⁰

FDC Dexamethasone plus ofloxacin treatment strategy was found to be the cheapest among another drug therapy and bromfenac eye drop was costlier. These were prescribed for all 449 patients in present study. Average total cost per patient was 115.00 INR. The results were similar to the earlier studies done by Goyal et al, and Narwane et al, where the cost paid by the patient was significantly higher than that paid by the Hospital pharmacy ($p < 0.0001$).³¹

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 for convenience 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 to 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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Ethical approval: The study was approved by the Institutional Ethics Committee

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