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Contamination and Sensitivity of Eye Medications Used By Patients in A Teaching Hospital

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Abstract:
Background*: Eye drop instillation increases the chance of contamination. It is primarily because of the risk of such contamination that pharmaceutical companies assign a label of "Use the medication within a month after opening the container" on all eye medication containers. Among the commonly isolated microbes are coagulase-negative Staphylococcus, S.aureus, Bacillus, Pseudomonas, Proteus, Haemophilus, Enterobacter, Serratia, and Klebsiella. This study was planned to estimate the rate and type of microbial contamination of in-use eye drops among patients attending a rural tertiary care hospital.*
Objectives:
1. To estimate the prevalence and type of microbial contamination of in-use ophthalmic medication bottles by patients attending the ophthalmology department.
2. To assess the antimicrobial susceptibility of microbes isolated from any such contaminated bottles
Materials and Methods*: 60 patients with stroke were included. This prospective study was done in the Department of Ophthalmology at PSIMS, Kuppam, Andhra Pradesh, India on patients attending this tertiary care center.*
Results: *Mean age was 60.7 years. Majority were males, 28.3 % population had co-morbid conditions, out of which 13.3% had only Diabetes. Most of them were using single medications. Most of the patients in this group were post-operative cataract patients. Gross appearance was clean among 100% of patients. Staphylococcus aureus was sensitive to ciprofloxacin, gentamycin, linezolid, vancomycin, ampicillin and azithromycin.*
Conclusion: *A proper set of rules and correct storage, handling, and application of eye medications are important. Healthcare providers and patients should be trained and informed as to how to administer eye medications.*
Keywords*: Topical medications, Ocular diseases, infections, eye drops.*

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I. INTRODUCTION

Patients are subjected to various types of topical medications while undergoing treatment for ocular diseases. Ocular disorders such as infections, uveitic diseases, ocular hypertension, and glaucoma are treated with topical medicines. To treat disease processes, patients are frequently exposed to several classes of drugs, with treatment regimens ranging from short-term courses to long-term therapy.[1] Ophthalmic medications used to treat eye conditions frequently become contaminated with microbes as reported from some studies[2-7] and this contamination was shown to be associated with duration of use. Factors like increased frequency of instillation and touching of the bottle tip to the eyelids or surrounding area increase rate of contamination. Apart from contamination, it will also change the pH of the medication, reducing its efficacy. The use of contaminated topical drugs has been linked to serious eye infections such as bacterial keratitis and endophthalmitis. The majority of research revealed that a container's tip is more contaminated than the medication itself.[8] Many studies have shown that increasing the frequency of eye drop instillation increases the chance of contamination. [8] It is primarily because of the risk of such contamination that pharmaceutical companies assign a label of "Use the medication within a month after opening the container" on all eye medication containers. Albeit, such a guideline does not seem to have been formulated based on scientific evidence, and Wilson had rightly postulated that the assignment of expiry dates for in-use eye medications are "based on fear, not science".[9] In the published literature, microbial contamination of ophthalmic medication bottles varies from 0.07% to 70%.[2,3,5,6,10] Among the commonly isolated microbes are coagulase-negative Staphylococcus, S.aureus, Bacillus, Pseudomonas, Proteus, Haemophilus, Enterobacter, Serratia, and Klebsiella.

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II. MATERIALS AND METHODS

STUDY DESIGN: Prospective study
Source of study population: Topical ophthalmic medications used by in-patients and outpatients of the ophthalmology department of PESIMSR
STUDY PERIOD: 18 MONTHS -
SAMPLE SIZE: 60
Based on an Ethiopian study where the rate of contamination was reported as 11%, by using the formula n=4pq/d2 where d=8% n is calculated as 55, however, it was decided to take 60 sample size for this study.
Ethical approval: Ethical approval was taken before conducting the study.
Inclusion criteria:
1. Patients of the ophthalmology department who are prescribed eye drops to be instilled for at least one month and are willing to come for two follow-up visits, at two weeks and one month later.
2. Patients who are willing to give information on how the medication was stored and handled.
3. Patients above 18 years of age, irrespective of gender and co-morbid conditions.

Exclusion criteria:
1. Patients who are instilling medication from a bottle different to the one used from nthe first day of visit

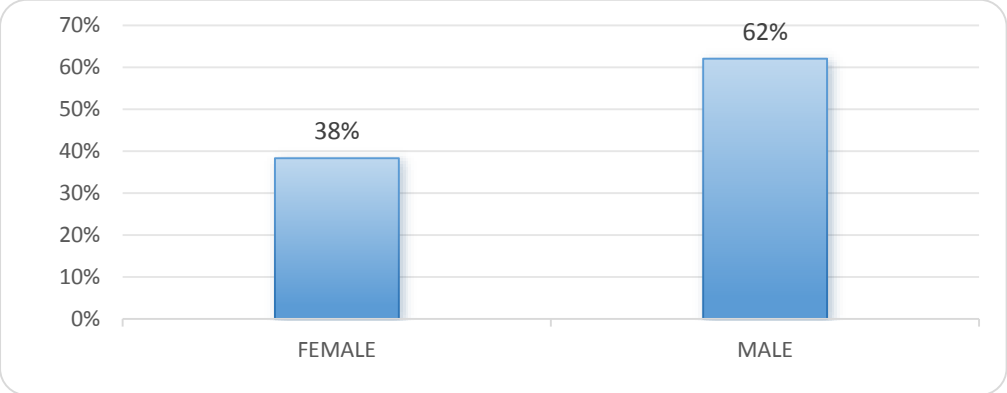
Tools used:
• In use eye medication bottles
• Sterile cotton swab
• Blood agar
• MacConkey agar
• Sabouraud's dextrose agar(SDA)
• Mueller – Hinton agar

Procedure for data collection:
Over one and half years, all eligible patients attending the ophthalmology department were counseled about this study. If willing to participate, relevant clinical information regarding age, gender, occupation, and clinical features were obtained from the patient. Patients who gave informed consent were educated on how to store and handle the medication and were asked to note if the bottle tip touches the finger or to the eye at anytime. They were advised to gently retract the lower eyelid and to instill a single eye drop as conjunctival sac volume is 10-30 microliter and anything instilled in excess will go waste and after instilling have to close the eye for a while. S/he were instructed to come for a follow-up visit at two weeks, at which time the patient was asked questions about how s/he stored & handled the medication, including information whether the bottle tip had been touched by the finger or to the eye. A microbiological evaluation of the medication bottle being used was performed. After conducting the appropriate tests, the bottle was handed back to the patient, and s/he was asked to continue instilling the medication from the same bottle. The patient was asked to make another visit to return the bottle, after one month of use or just before the container becomes empty, whichever is earlier. On both the visits, the status of the patient's eye for the presence of any infection was assessed. The in-use medication bottle was inspected under aseptic conditions for visible grime and possible microbial contamination, and findings were documented. Cotton bud was used to wipe the bottle tip and was streaked on blood agar. One drop from the residual solution in the bottle was inoculated onto blood agar; if no solution was remaining in the bottle, the same was noted and documented. An identical protocol was followed to streak MacConkey agar and Sabouraud's Dextrose Agar (SDA) similarly. All the inoculated media were incubated for 24 to 48 hours (SDA for up to one week). Microbes cultured from the bottles were tested for susceptibility to different antibacterial agents by the double-disc diffusion (Kirby-Bauer)method.

Statistical analysis: Analysis was done using Microsoft software. Mean, SD, percentages, and frequencies were used.

III. RESULTS

Age: Most of the patients were aged 45 years to 80 years, with a mean age of 60.7 + 8.5 years.
Gender: Most of the patients were males.



Graph 1: Gender of patients

Comorbidities: In this study group, 28.3 % population were having co-morbid conditions, out of which 13.3% were having only Diabetes, 3.3% were having only Hypertension whereas 11.7 % of people had both Diabetes and Hypertension.

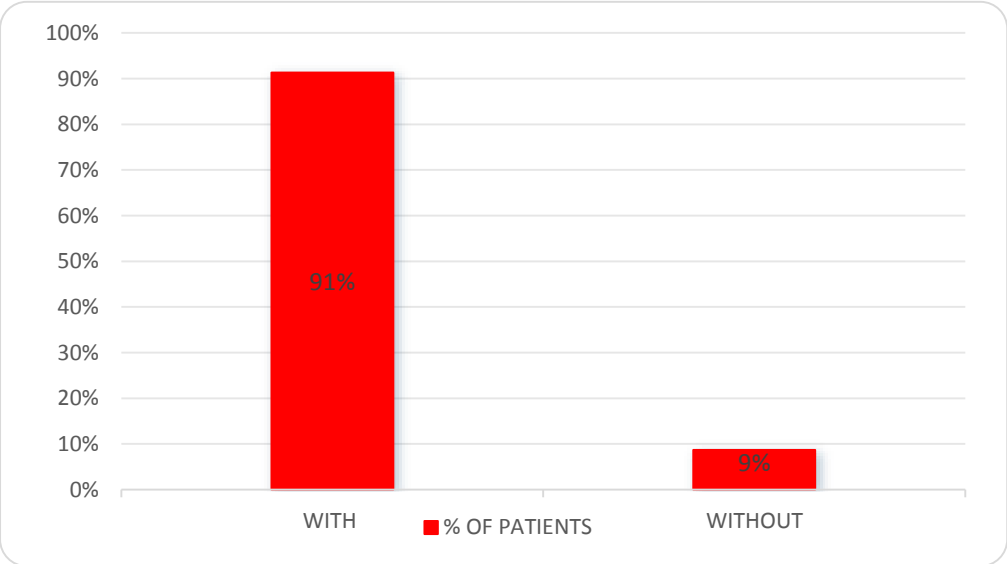
No of medications used:
Most of the patients were using single medication.

No of medications	% of patients
1	91.7%
2	1.7%
3	6.7%

Table 1: No of medications used

Type of medication used: In this study group, patients who used Dexoren S eye drops were 86.7% and those who used Predforte, Moxicip, and Nevanac were 6.7% and Predforte, Moxicip and
Refresh Tears were 1.7% and Predforte and Moxicip were 1.7% and Timolol was 3.3%

Preservatives: 8.7% of the patients used medication bottles without preservatives.



Graph 2: Presence of preservatives in medication bottles

Diagnosis: Post operative Right eye SICS was seen among 53.4% of patients

Diagnosis	Frequency	Percentage of patients
BE POAG	2	3.4%
Post op Left eye SICS	25	41.7%
Post-pterygium excision	1	1.7%
Post Op right eye SICS	32	53.4%

Table 2: Diagnosis among patients

Most of the patients in this group were post-operative cataract patients (95.1%) rest were glaucoma and post-operative pterygium excision cases

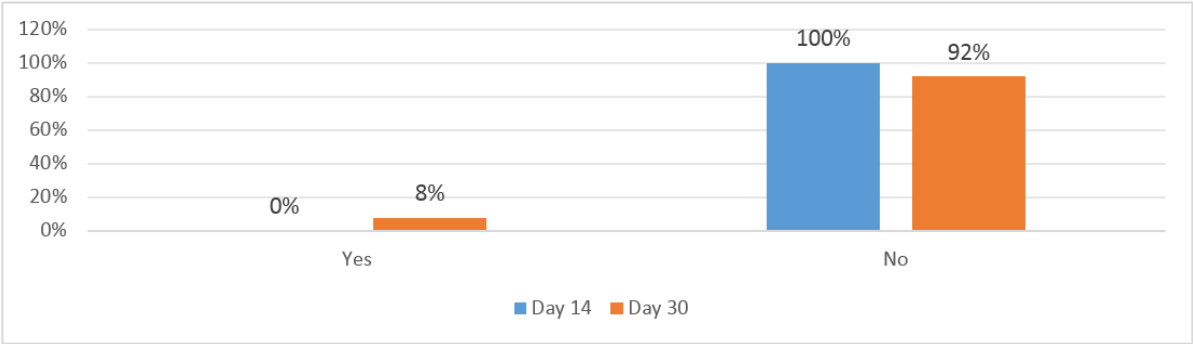
Culture of the Tip and Drop of the medications on Day 14: Gross appearance was clean among 100% of patients.

Antibiotic sensitivity pattern: Staphylococcus aureus was sensitive to ciprofloxacin, gentamycin, linezolid, vancomycin, ampicillin and azithromycin.

Antibiotic	**Staph aureus**	**Staph epidermidis**	**pseudomonas**
Ciprofloxacin	Sensitive	Sensitive	Sensitive
Gentamycin	Sensitive	Sensitive	Sensitive
Linezolid	Sensitive	Sensitive	Sensitive
Vancomycin	Sensitive	Sensitive	_
Ampicillin	Sensitive	Resistant	_
Azithromycin	Sensitive	Sensitive	_
Piperacillin/Tazobactam	_	_	Sensitive
Ceftazidime	_	_	Sensitive

Table 3: Sensitivity pattern of microbes to antibiotics

Presence of empty bottles during follow up on 14th and 30th day: On day 30, empty bottles were seen among 8% of patients.



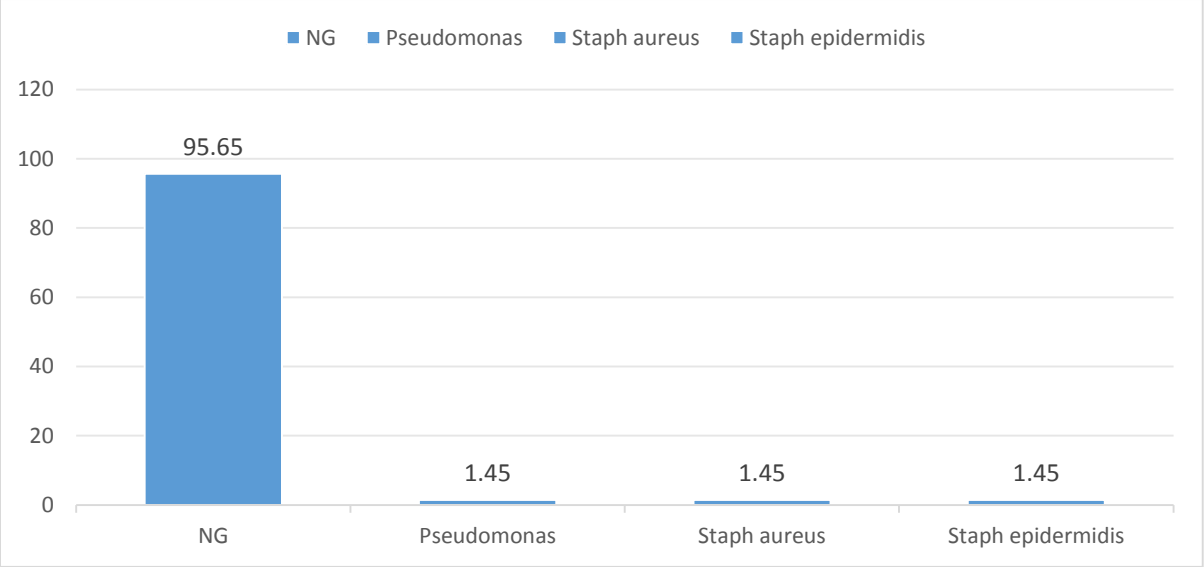
Graph 3: Presence of empty bottles during follow up

Culture of the Tip and Drop of the medications on Day 30:

On day 30 there were no signs of infection in all the 60 patients' gross appearance of two containers was dirty rest were clean and there was a growth of organisms from the tip of three containers over Blood agar and McConkey agar, there is no growth of fungal organisms on SDA.

Distribution of medication bottles by Growth on culture media:

Out of the three containers which got contaminated the organisms isolated were Pseudomonas, Staph aureus, and Staph epidermidis, and no organism was isolatedfrom sixty-six containers.



Graph 4: Medication bottles and growth of organism

IV. DISCUSSION

In the current study, 60 patients were included and 69 bottles were assessed. Out of 5 types of medications that contained preservatives Benzalkonium chloride is present in 3 medications. In this study out of 69 medication bottles, 6 bottles were preservative-free rest 63 bottles contained preservatives. Figuriedo Lucas et al[11] in their study mentioned that Benzalkonium chloride is the very often used preservative. On day 30 we identified that the gross appearance of the two containers was dirty and organisms were isolated from the tip of three containers. Out of 69 medication bottles collected from 60 patients, 3 bottles showed contamination i.e 4.34%.This is low compared to other studies example in a study done by LemlemTamratet al[12] in southwest Ethiopia reported the rate of contamination as 72.8% and in a study done by M MNentwich et al[5], the contamination rate is 6%.

The low contamination rate could be explained due to good handling and storage of medications and increased hand hygiene practice due to fear of COVID. As far present study is concerned rate of contamination will be low if medications are stored and handled properly. From different types of medications used in this study tip of Dexoren-s is contaminated this might be because of old age, self- administration, and increased frequency of instillation. All three containers which got contaminated were used by patients aged above 65 years. This could be another reason that older patients will have decreased fine grasping and they may have tremors and they might have touched the tip with fingers or to the surrounding area while instilling the drops. In this study, there was no growth from residual solution irrespective of the presence or absence of preservatives. The antibacterial activity of preservatives or the solution itself in antibiotic drops is one reason for this. But, because contact time is minimal, such antibacterial effects may not be sufficient on the tip.

Contamination from ocular structures and hands is spread out over a broad surface area at the tip. On occasion, dry crusts may be detected on the bottle tips. Using a sterile wipe to remove such residues could help to limit infection even more contamination of the eye drop solution, on the other hand, must be considered clinically more important because it comes into direct contact with the patient's eye. Lem et al reported rate of contamination as 72.8%.[12] Chua[13] reported it as 30%. And the present study showed it as 4.34%. Raghad et al[14] reported that Staph aureus, Micrococcus, Neisseria, Catarrhalis, Gram-negative rods, Candida albicans, Staph epidermidis as isolated organisms, while in the present study, Staph aureus, Staph epidermidis, Pseudomonas aeruginosa are isolated.

V. CONCLUSION

In this study there is a low rate of contamination of eye drops. Organisms contaminate tip of container rather than the drop. Chances of contamination after one month of opening the vial are less if handled properly. A proper set of rules and correct storage, handling, and application of eye medications are important. Healthcare providers and patients should be trained and informed as to how to administer eye medications. Patients who cant use eye drops in an aseptic way should be assisted by their caretakers.

The study is self-sponsored.

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