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Incidence of Endophthalmitis after Cataract Surgery with Intracameral Moxifloxacin as Prophylaxis

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Abstract:

Cataract is the Opacification of the lens in the eye due to protein buildup in the ocular tissue. Postoperative topical antibiotic regimens are intended to reduce the bacterial burden during the time of the surgical incision to re-epithelialize and significantly reduce the rate endophthalmitis. As prophylaxis Intracameral antibiotic injection administered during the surgery is initiated as clinical benefits ensuring in decline of postoperative endophthalmitis rates. Therefore our study aims to investigate appropriate use of 0.5% Moxifloxacin as prophylactic agent for the endophthalmitis given in 280 patients. In our Observational study we have advised the patients to visit prior the surgery with no other use of antibiotics & the data collected in 2 follow-ups i.e. on the day of cataract surgery after Postoperative condition (followup-1) & following 1st day of Surgery (followup-2). On SLIT lamp examination of eye structures of those 280 patients we found no evidence of Endophthalmitis by using intracameral 0.5% moxifloxacin as prophylaxis after Cataract surgery.

Key-words:

Cataract, Endophthalmitis, Small Incision cataract Surgery (SICS), Phacoemulsification (Phaco), Intracameral, 0.5% Moxifloxacin (MFXL). European Society of Cornea and Retina Care (ESCRS).

Introduction

Cataract is the Opacification of the lens in the eye due to protein build-up in the ocular tissue because of the Aging, injury/trauma,any genetically acquired as a result there may be decrease in the vision leading to Blindness [5, 18, 19, 21, 32] and is reversible by the Cataract surgery [12, 27] by Phacoemulsification or Small incision Cataract surgery which 20-30 minutes procedure where the Opacified lens are removed and replaced by the Artificial Intraocular lens (IOLs) that helps to increase the clarity of vision in aseptic and sterile conditions [12, 15, 18]. Cataract extraction is one of the most successful operations performed, even the more risk of the complications are confined through the Cataract surgery where, the Endophthalmitis (Pus in the eye) is one of the devastating ocular complication that is very rare and serious complication of Cataract surgery that every ophthalmic Surgeon & Patient strives to avoid [24]. Endophthalmitis is the pan-intraocular inflammation involving both the anterior and posterior segments of the eye [28]. It can involve all coats of the eye, as well as adjacent structures [7]. Endophthalmitis may be a subtle as white nodules on the lens capsule, iris, retina or choroid. It can also be as ubiquitous as inflammation of all the ocular tissues, leading to a globe full of purulent exudates that can spread to involve the orbital soft tissue [7] It is typically defined (by Vivek P, et al) & Classified (by Rubens C. et al 2010) as Shown in table no.1 & Figure no.1 [3]. Detailed Explanation about Common signs & symptoms of endophthalmitis is given by the Taraprasad Das adoptive of EVS & ESCRS study on Endophthalmitis in Table no.2 [8, 11, 13, 23, 30]. Postoperative Endophthalmitis originate

(Etiology) from Environmental, Climatic, Surgical and Patient specific factors that are caused by the different Microbial spectrum of microorganisms in India was given (by Peter Barry et al 2013) in Table.no.3/25].

Perioperative and Postoperative antibiotic regimens are intended to reduce the bacterial burden during the time of the surgical incision and significantly reduce the rate of post-cataract surgery endophthalmitis [14]. Moxifloxacin is probably the most commonly used antibiotic for this, which is a Synthetic, Broad spectrum, Antibacterial agent belongs to 4th generation fluoroquinolone [29] that is active against both Gram-positive and Gram-negative bacteria. It functions by bacterial DNA from unwinding and duplicating or inhibiting DNA gyrase, a type II topoisomerase, and topoisomerase IV, enzymes necessary to separate bacterial DNA, thereby inhibiting cell replication (Jensen M K et al 2008) [16, 17, 20, 31]. As prophylaxis Intracamerally 0.5% Moxifloxacin injection administered during the cataract surgery has clinical benefits ensuring the safety and effectiveness in reducing of postoperative endophthalmitis rates also cost per patient almost negligible [4, 14, 29, 33]. Intracameral means within or into a chamber (Typically of the eye), such as the anterior or posterior chamber of the eye [1, 2, 6]. Therefore, our aim of the study is to investigate appropriate use of 0.5% Moxifloxacin as prophylactic agent for endophthalmitis, and the rate of endophthalmitis after initiation of intracameral moxifloxacin for endophthalmitis prophylaxis in patients undergoing Cataract surgery. The main Objective of our study is to study therapeutic effectiveness of 0.5% Moxifloxacin as prophylaxis against endophthalmitis; to study any possible drug related problems in patients on 0.5% Moxifloxacin; and To Study the Incidence of Endophthalmitis in postoperative Cataract surgery. Where from 0.5% Moxifloxacin single-use 1 cc vials the 0.8 cc injected into a small sterile cup on each scrub table, and approximately 0.6 cc of this mixture is aspirated into a 1 mL Tuberculin (TB) syringe (0.1 cc which contains 500 mcg or 4-Quin PFS 0.5% single-use prefilled syringes were Injected either of these 2 single-use Indian preparations achieves a concentration of 1 mg/mL.), a 27-gauge hockey stick blunt cannula is then attached to the Tuberculin syringe and approximately 0.1 mL expelled, flushing the anterior chamber with 2 to 3 mL of diluted solution use of a relatively small volume (0.05 to 0.4 mL) of highly concentrated solution (undiluted or diluted up to 10-fold) at the end of surgery.

Our experience of injecting 0.1 ml of a 5 mg/ml intracameral moxifloxacin solution (Vigimox, Auromox, Aurolab, India) as prophylaxis for endophthalmitis at the Santhiram Medical College & General Hospitals (SMGH) in, Nandyal, Andhra Pradesh, India. has been reported approximately 60% of cataract surgery is performed at little or no cost on charity patients using suture less, manual small incision cataract surgery (MSICS/SICS). Because of a historically higher rate of postoperative endophthalmitis & other ocular complications occurs with MSICS, routine intracameral 0.5% moxifloxacin prophylaxis was started for all the patients at SMGH. During a 6-month study period, in which 280 consecutive cases done randomly and the consecutive eyes that received intracameral 0.5% moxifloxacin, the endophthalmitis rate fell 4 fold from 0.078% to 0.012% Based on this convincing efficacy data, SMGH initiated routine intracameral moxifloxacin.

Material and Methods:

Our Prospective observational study was conducted with a Sample study population of Approximately 280 patients and the protocol of our study was approved by the institutional ethics committee of Santhiram medical college and general hospital, Nandyal, which is tertiary care teaching hospital with approximately 700 bedded capacity. The study was conducted in compliance with good clinical practice guidelines for a duration of 6 months. Patients are included in the study by taking prior permission from the patient by using patient informed consent form, we have designed the Data Collection forms, collected the Consent Form's from the subjective who are included in our study, Reviewed the Patient case sheets & their treatment chart and the selection of the sample was accordance with the Study Criteria taken as:

- a) Inclusion Criteria: Patients who accepted for the study by written Informed Consent, Patients with the age group of > 25 years, Patients who are undergoing for Cataract surgery & to be treated with intracameral moxifloxacin as prophylactic agent for Endopthalmitis following Cataract surgery.
- b) Exclusion Criteria: Patients with the age group of < 25 years, Patients who are unwilling for the study and the Pregnant women.

Patients who satisfy the study criteria were randomly selected were informed the study content and their risk consent were taken then undergone for the cataract surgery where all the study subjects are only given 0.5% Moxifloxacin with no added preservatives at the end step of the Cataract surgery without any prescription of topical Antibiotic drops and were requested to visit after cataract surgery and the drug efficacy was checked at 2 follow-ups visited by the Postoperative patients as scheduled for only on the day of followed cataract surgery [i.e. 1stday after the cataract surgery on the evening of the date of surgery (Followup-1)] and after the 1st followup the Patients starts their medication on the evening of the second eligibility visit i.e., 1st day of the Post cataract surgery [the following 1st day of the Surgery (Followup-2)] without the use of any other topical Antibiotic eye drops. At each of these eligibility visits, Slit lamp examination is followed, medical history was recorded and visual acuity assessment was performed. At the completion of the eligibility visits, qualified patients were also examined for clinical features of endophthalmitis for every following 1st week, 4th week and 6th week. If any sign & symptoms observed the patients were advised for the Fundoscopy, B-scan ultrasonography, Microbial culture test and hematological examination that are measured for the diagnosis of Endophthalmitis. Where the patients visual activity was assessed, Slit lamp examination is performed and any adverse event recorded.

In General Ophthalmological evaluations include visual acuity, examining the both eyes in slit lamp Biomicroscopy, IOP, dilated Fundoscopy, ultrasonography and Microbial culture test (Daniel J Egan 2018) [9]. Differential elements for the diagnosis of

Endophthalmitis that looks similar with Endophthalmitis includes Corneal Abrasion, Globe rupture, Iritis, Uveitis, Post-operative inflammation (Daniel J Egan 2018) [10]. Here we want to check for any Presenting clinical characteristics of Endophthalmitis illustrated by ESCRS & EVS Study group (Adoptative of Barry P, et al) given (Table.no. 4 & 5) [26].

Our study is used to check these follow-up patients for any clinical characteristics of Endophthalmitis in Postoperative condition of the eye structures by Visual acuity & SLIT lamp Examination in the department of Ophthalmology.

Results:

In our observational study totally 280 patients were participated out of 118 (42.14%) were males and 162 (57.85%) were Females as shown in table no. 6 & Figure no. 2 & 3. The preparation and use of Vigamox for intracameral prophylactic moxifloxacin administration done by mixing an entire bottle (3 cc) of Vigamox with 7 cc of a balanced salt solution in a 12 cc syringe, yielding a concentration of 150 mg/0.1 cc. Then injected 0.8 cc into a small sterile cup on each scrub table, and approximately 0.6 cc are aspirated into a 1.0 mL Tuberculin (TB) syringe. A 27-gauge hockey stick blunt cannula is then attached to the Tuberculin syringe and approximately 0.1 mL expelled to make sure all air has been cleared then flushed into the anterior chamber with 2 to 3 mL of diluted solution or the use of a relatively small volume (0.05 to 0.4 mL containing 450 to 600 mg moxifloxacin) of highly concentrated solution (undiluted or diluted up to 10-fold) at the end of surgery. The consecutive eyes that received intracameral moxifloxacin, the endophthalmitis rate fell from 0.079% to 0.016% based on this convincing efficacy data, SMGH initiated routine intracameral moxifloxacin.

On the very 1st day of the Post Cataract Surgery condition on routine visits of the patients follow-up we have observed only 3 patients with Clinical features of Red Eye, inflammation, Eye pain, SLIT lamp examination revealed Hypopyon at Anterior Chamber, Hazy retina, Corneal edema. From the Table no 7 the Slit lamp examination obtained some of the Clinical characteristics of the Endophthalmitis in 3 Patients for the confirmatory diagnosis Microbial culture test for the 3 suspected patients was obtained as Negative for which the Opacification, Hypopyon of the cornea & Fundus showing cupping, optic edema & Blots are the resultant of the Toxic anterior segment syndrome (TASS) and Compromised ocular barriers (Immune privilege) that may not accept the Artificial IOLs replaced for the opacified lens in the capsular region. The overall drug wise distribution of 0.5% Moxifloxacin was done in all the patients and the every patient undergone for the SLIT lamp examination for the detection of the sign & symptoms of the eye structures exhibit if any cause of Endophthalmitis.

Hence the Intracameral Moxifloxacin 0.5% given prophylaxis at the end of the Cataract surgery has shown the Endophthalmitis prevention for which we have not observed any Endophthalmitis Condition in our study.

Discussion:

Endophthalmitis is a rare and serious complication that occurs after the Cataract surgery. The reduction and control of the Endophthalmitis occurs after the Cataract surgery is typically managed by administration of the Antibiotics especially 0.5% of Moxifloxacin administered intracamerally during cataract surgery which is a fourth generation fluoroquinolone a class of drugs that is capable of effectively reducing Endophthalmitis and other ocular infections [22]. Overall 280 patients were involved in the study were required to undergo for cataract surgery for which they are given Moxifloxacin 0.5% intracamerally administered by the surgeons as the Prophylaxis of the ocular infection especially Endophthalmitis as the process of the final procedure of the cataract surgery and we have to follow-up the Patients to evaluate any Clinical characteristics of Endophthalmitis that may occur if any during the two eligibility visits on the day of the Cataract surgery and the very following 1st day of the cataract surgery. The same eligible subjects were advised to attend for the Follow up - I and Follow up-II without taking any supportive topical eye drops of antibiotics and checked their visual acuity & eye structures by the SLIT lamp examination if needed Fundoscopy also collected for the evaluation of any Clinical characteristics of Endophthalmitis.

In our study we have initially used SLIT lamp examination for the detection of eye structure that shows any Endophthalmitis features, if any case exhibits the Clinical Characteristics of the Endophthalmitis through Slit lamp examination it was then send to the microbial culturing of the vitreous sample or the aqueous humour; and haematological tests as these entire process is time consuming, cost burden to the every patient, hence only the Patients who are detected with Clinical characteristics of Endophthalmitis in SLIT lamp examination was only sent to the further tests.

Hence no untoward effects were observed after intracameral injection of moxifloxacin 0.5% ophthalmic solution diluted to a 0.1% concentration at the conclusion of routine cataract surgery. It is Effective in Treating Endophthalmitis given intracamerally as Prophylactic during Cataract surgery.

Conclusion:

Intracameral 0.5% moxifloxacin was given prophylactically is studied in 280 patients who are undergoing for the cataract surgery. It is effective based on its potency, penetration and safety profiles. Though 0.5% moxifloxacin is given as intracameral antibiotic during cataract surgery as prophylaxis and with perioperative & postoperative aseptic measures and the maintenance of patient eye hygiene & the cause of endophthalmitis was reduced. This medication is cost effective and cost saving than previously used cefuroxime and

other topical perioperative. In our observational study with 280 patients we have no single evidence of endophthalmitis with the use of intracameral 0.5% moxifloxacin given routinely at the end step of cataract surgery.

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Tables & Figures:

Table. no. 1 Definition of Endophthalmitis					
Category	Name	Comments			
Time	Acute	Endophthalmitis presenting within 6 weeks of surgery			
	Chronic	Endophthalmitis presenting after 6 weeks of surgery			
Signs & Symptoms	Early	An infection with relatively well preserved media clarity allowing good red reflex, occasionally even observing retinal details			
	Delayed	An infection with severe opacity in the anterior media, typically accompanied by severe vitreous infiltration or true abscess			
Microorganisms	Bacterial	Gram-positive & Gram-negative organisms cause infection			
	Fungal	Nonfilamentous or filamentous fungi cause infection			
Mode of Entry	Exogenous	The infectious agent reaches the vitreous cavity through external injury, either after intraocular surgery or trauma			
	Endogenous	The infectious agents reach vitreous cavity by Hematogenous spread			
	Adopted from Taraprasad Das et al 2018				

	Effects		
	Lid Edema		
	Corneal edema		
Signs	Hypopyon, anterior chamber fibrin		
	Vitreous cells		
	Perivascular exudates		
	Decrease vision, Red eye		
Symptoms	Pain		
	Lid edema		

Table 3; Etiology of postoperative Endophtha	almitis in India as per Jambulingam et al 2010	
Gram P <mark>ositive</mark>	53.1 %	
Gram Negative	42 %	
CNS	18.6 %	
S. Aureus	11.4 %	
Streptococcus SPP	2.9 %	
Enterococcus SPP	1.4 %	
Fungal	7.1 %	
Other Gram Positive	10 %	

Table 4 Time of Presentation of Postoperative Endophthalmitis					
Day of Onset	EVS	ESCRS			
1 - 3	24%	31%			
4 – 7	37%	31%			
8 – 14	17%	24%			
> 14	22%	14%			
By Wisniewski 2000					

Table 5. Clinical Characteristics of Postoperative Endophthalmitis				
Clinical Characteristics EVS ESCRS				

Blurred vision	94%	92.2%
Pain	74%	79%
Swollen eyelids	34%	46.25%
Hypopyon	75-85%	72%
Red eye	82%	-
Media haze	79%	63%

According to Adaptive Wisniewski 2000

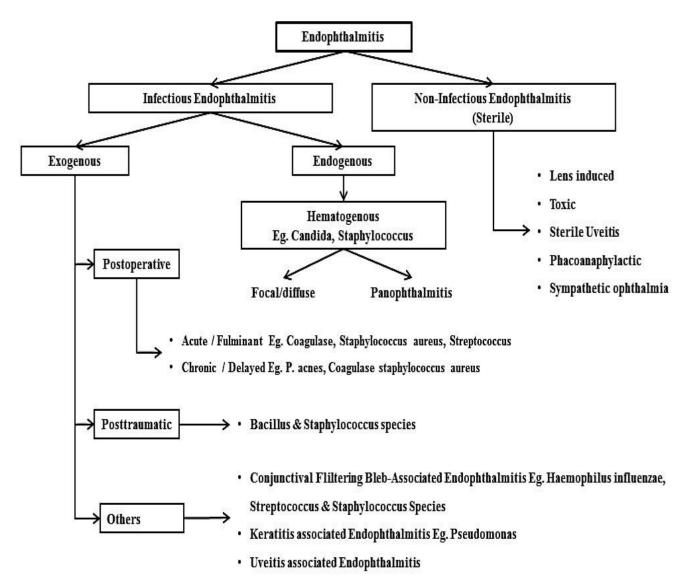
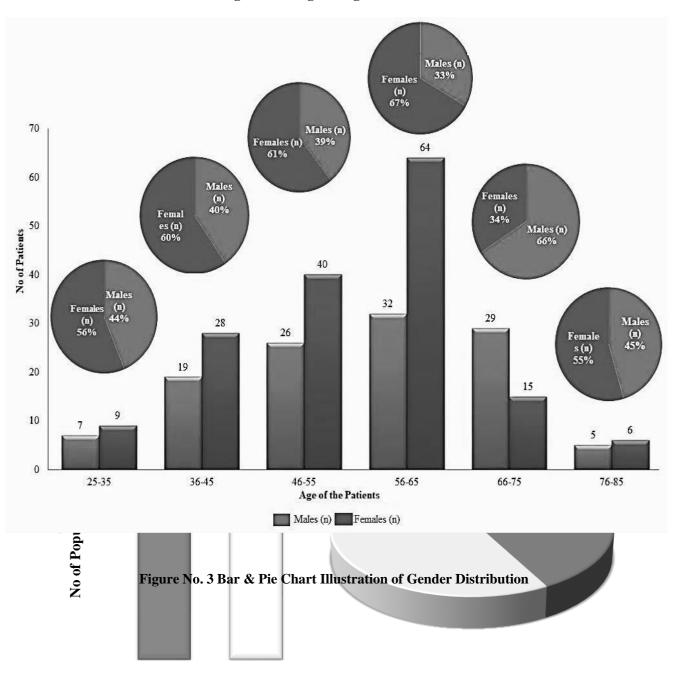


Figure no. 1 Classification of Endophthalmitis with causative organism

Table no. 6 Age wise Gender Distribution						
	Males		Females		Grand value	
Age (in years)	(n ₁)	(%)	(n ₂)	(%)	Total (N=n ₁ +n ₂)	Percentage (%)

25-35	7	2.5	9	3.21	16	5.714
36-45	19	6.78	28	10	47	16.785
46-55	26	9.28	40	14.28	66	23.571
56-65	32	11.42	64	22.85	96	34.285
66-75	29	10.35	15	5.35	44	15.714
76-85	5	1.78	6	2.14	11	3.928
Total (N)	118	42.14	162	57.85	280	100

Figure no. 2 Age wise gender distribution



180 160 140

120			
100			
80			Females 58%
60			
40			
20			
0			
	Males	Females	
	Gen	der	

Table no 7. Results of SLIT Lamp examination							
Examination of Eye	Results						
Structure	Findings	After surgery	1st day of Post op				
Vision acuity	6/6-9 (fts) 6/12 (fts) 6/24 (fts) 6/36 (fts)	111+83=194 42 33 11	111+83=194 42 33 11				
Wound	Normal	280	280				
Conjunctiva	Congested	240	3				
Conjunctiva	Normal	40	277				
Cornea	Clear	277	277				
Cornea	Hazy/Edema	3	3				
<i>-</i>	Quite	210	277				
Anterior chamber	Normal depth	280	280				
Anterior chamber	Reaction Cells & Flare	7	0				
	Hypopyon	3	3				
Iris	Normal	280	280				
Pupil	RRL	221	221				
1 upii	Irregular RL	59	59				
	Vitritis	3	3				
Fundoscopy	Optic Disc edema	0	0				
	Hemorrhage	0	0				
	Periphlebitis	0	0				
	Loss of Red Reflex	0	0				
	Normal	277	277				

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