Evaluation Of Therapeutic Modalities And Outcome In Patients Of Infectious Keratitis: A Prospective Observational Study At A Tertiary Care Eye Hospital

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Abstract: Background: Among corneal diseases, microbial keratitis is a major blinding disease. Objectives: To study the disease pattern and aetiology, to evaluate drug use pattern and the therapeutic outcome in Infectious Keratitis patients. Material And Methods: Prospective observational follow up study was carried out for 16 weeks. IEC permission and Written Informed Consent from the patients were taken before hand. Patients above 18 years of age and of either gender presenting to Outpatient department of Ophthalmology and diagnosed with Infectious Keratitis were included in the study. Patient's demographic details, diagnosis and the complete prescription were recorded in a case record form. Result: A total of 150 patients were enrolled. Infectious Keratitis was prevalent in age group of 61–70 years (39.33%). Bacterial keratitis (52%) was the most common type followed by fungal (42%) and Viral keratitis (5%). A total of 17(11.33%) patients needed surgical intervention. At the last follow up 61(40.66%) patients had improved vision. There was a significant statistical difference found between age groups of <65 years and >65years for keratitis outcome. Improvement in vision (p=0.0264) & slit lamp findings (p=0.0148) were seen in younger age group. Conclusion: Bacterial keratitis was the most common cause of Infectious keratitis. Trauma was the commonest factor found majority of cases. Younger age group had better visual outcome. [Shah S Natl J Integr Res Med, 2021; 12(6): 32-39]

Key Words: Fluroquinolones, Infectious Keratitis, Therapeutic Modalities

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Introduction: Corneal opacity represents the 5th leading cause of blindness globally, accounting for ~3.2% of all cases. The recent World Health Organisation (WHO) report highlighted that ~6 million of the world population are affected by cornea-related blindness or moderate/severe visual impairment[1,2]. Corneal opacity is estimated to be responsible for 1.5–2.0 million cases of monocular blindness annually, highlighting an ongoing unchecked burden on human health[3,4].

The global burden of corneal blindness is concentrated in emerging and developing countries. Approximately 2 million people develop a corneal ulcer every year in India alone. Being a developing country with a predominantly rural population, India faces a significant challenge in eliminating corneal blindness[5,6].

Any significant insult to the cornea such as infection, trauma, inflammation, degeneration, or nutritional deficiency can result in corneal opacity with visual impairment. Among all, infectious keratitis (IK) has been shown to be the most common cause for corneal blindness. It is a common yet potentially vision threatening ophthalmic condition, characterised by acute ocular pain, decreased vision, corneal ulceration, and/or stromal infiltrates[7]. Previously, it has been recognised as a "silent epidemic" in the developing world,[8] and recently, a consortium-led proposal has suggested the designation of infectious keratitis as a "neglected tropical disease (NTD)", adding on to the list of NTDs in ophthalmology (i.e., trachoma and leprosy) [9]. The proposal to attain status of an NTD aims to draw concerted global effort to tackle IK in under-resourced tropical countries, to ameliorate its societal and humanistic burden[4]. Amongst corneal diseases, microbial keratitis is a major blinding disease. 5% of all blinding conditions are directly related to ocular trauma and subsequent infection[10].

Bacterial keratitis is controlled by the intensive local use of fortified antibiotic drugs. Monotherapy with Fluoroquinolones has also been recommended but is not a standard practice as resistance to Fluoroquinolones is high in some countries. Topical antifungal agents include Natamycin eyedrops, fortified Amphotericin B eyedrops and Nystatin eyedrops

while oral antifungal agents include Ketoconazole, Voriconazole and Fluconazole tablets. Treatment of viral keratitis is symptomatic with lubricants. Topical steroids have a marked suppressive effect but the lesions can recur on withdrawal of steroids therefore should be used with caution. Antivirals include 5% Idoxuridine, 5% Acyclovir eye ointment and oral Acyclovir 400 mg are used[11].

Study of corneal diseases is a relatively unexplored field. It is a first study of the kind in our set up. Herein we have conducted a study for the detailed evaluation of infectious keratitis, drug use pattern and the therapeutic outcome for the same.

Aims & Objectives: To study the disease pattern and aetiology of keratitis. To evaluate the drug use pattern & therapeutic outcome in patients diagnosed with Infectious keratitis.

Material & Methods: Ethics committee approval was obtained prior to commencement of the study. Patients presenting to the Outpatient department of Ophthalmology and diagnosed with Infectious keratitis were included in our study during the period of 1st November 2019 to 28th February 2020.

Inclusion Criteria: Patients 18 years and above belonging to either gender, diagnosed with Keratitis and who are willing to give their written informed consent.

Exclusion Criteria: Patients with other ocular comorbidities and with poor general condition.

Clinical procedures:
Every patient was examined using the slit-lamp biomicroscope. After detailed ocular examination corneal scrapings were performed under aseptic conditions by an ophthalmologist to determine the type of keratitis.

Material from the corneal scraping was smeared on two separate glass slides: one for Gram stain and other for KOH wet mount. The data of every patient was recorded in a case record form.

The data of the patient enrolled was collected on subsequent follow up visit at 1 week, 15 days and 1 month.

Statistical Analysis: Data was entered in Microsoft Excel version 2019. The statistical evaluation was done with the help of SPSS version 21.0 manufactured by IBM (demo version) and Microsoft Excel 2019. Analysis was carried out using independent t-test and Fisher's exact test and $p<0.05$ considered statistically significant.

Results: Demographic Details: A total of 150 patients met the inclusion criteria of the study, of which 92(65.33%) were male and 52(34.67%) were female. Ratio of Male: Female = 1.88:1. Infectious keratitis was prevalent in age group of 61–70 years (39.33%). The mean age of patients was 60.51±SD 12.1 years. The occupation of the patients was as following, Farmer 48(32%), Profession 34(23%), Housewife 25(17%), Unemployed 23(15%), Labourer 18(12%) and Student 2(1%).

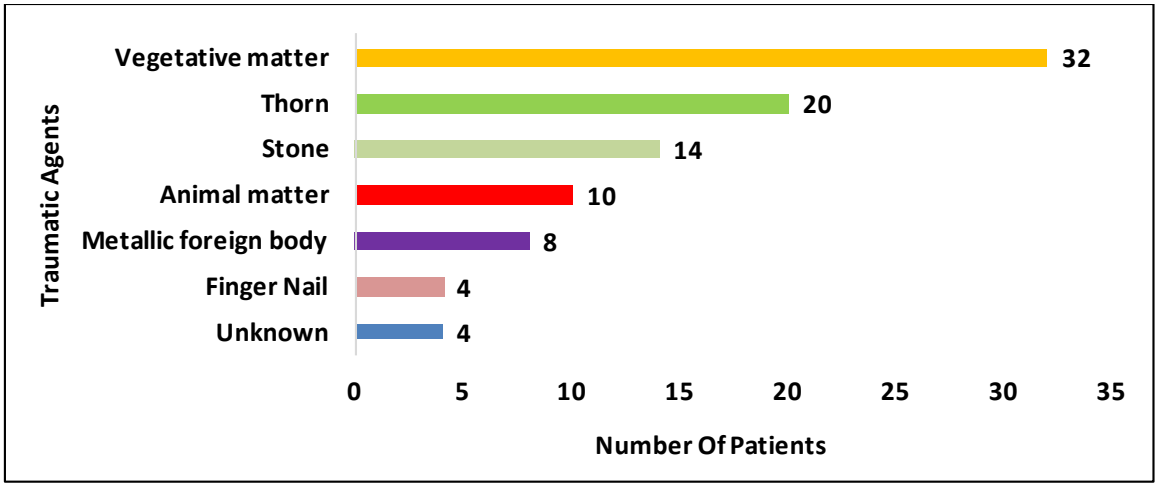
Clinical History: Almost all the patients were having diminished vision, pain, and redness and watering of eye with an average duration of 9.89±6.4 days. (Table 1) There were 87 left eyes and 63 right eyes involved. Microscopic findings showed 47(31.3%) slides Gram stain positive, 31(20.7%) slides Gram stain negative and 64(42.7%) smears positive for KOH mount.

Table 1: Duration Of Symptoms Of 150 Patients With Infectious Keratitis

Duration Of Symptoms	Number Of Patients	Percentage (%)
1-5 Days	44	29.3
6-10 Days	47	31.3
11-15 Days	22	14.7
16-20 Days	20	13.4
21-30 Days	12	8.0
1-2 Months	5	3.3
Total	150	100.0

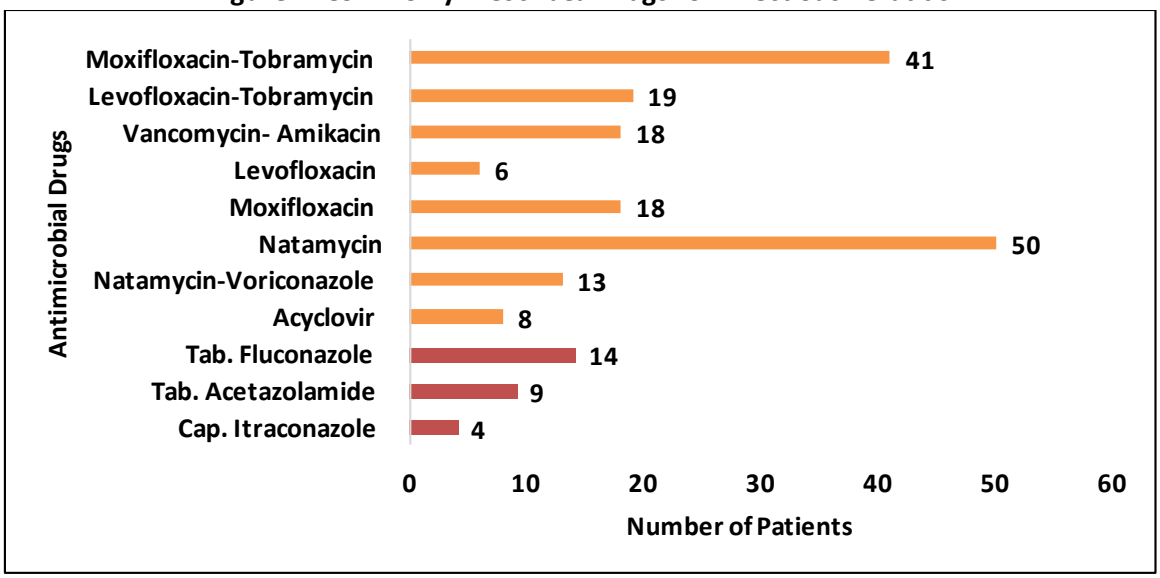
Aetiology: Bacterial keratitis 78(52%) was the most common type followed by fungal 64(43%) and Viral keratitis 8(5%). Patients' medical history showed a total of 20(13.3%) patients had ocular disease (Glaucoma, 17 and Dry eye, 3), patients with previous ocular surgery were 29(19.3%) (Bilateral Cataract surgery, 18; Cataract Surgery in same eye, 8 and Pterygium excision, 3) and 34(22.7%) were diabetic. Trauma was the commonest aetiology found in total 92(61.33%) patients. The various traumatic agents depicted in figure 1.

Figure 1: Traumatic Agents In Patients With Infectious Keratitis (N=92)



Therapeutic Modalities And Outcome: Total number of drugs prescribed were 688 (mean=4.52±0.82). Commonly prescribed antimicrobial drugs are depicted figure 2.

Figure 2: Commonly Prescribed Drugs For Infectious Keratitis



A total of 17(11.33%) patients needed surgical intervention including 10 Therapeutic Penetrating Keratoplasty (TPK), 4 Triple TPK, 3 Tenoplasty with TPK.

At the last follow up 61(46.67%) patients had improved vision. Therapeutic outcome and optical result at the last follow up is depicted in figure 3 and 4 respectively.

Figure 3: Therapeutic Outcome Of 145 Patients At The Last Follow Up (Slit Lamp Examination)

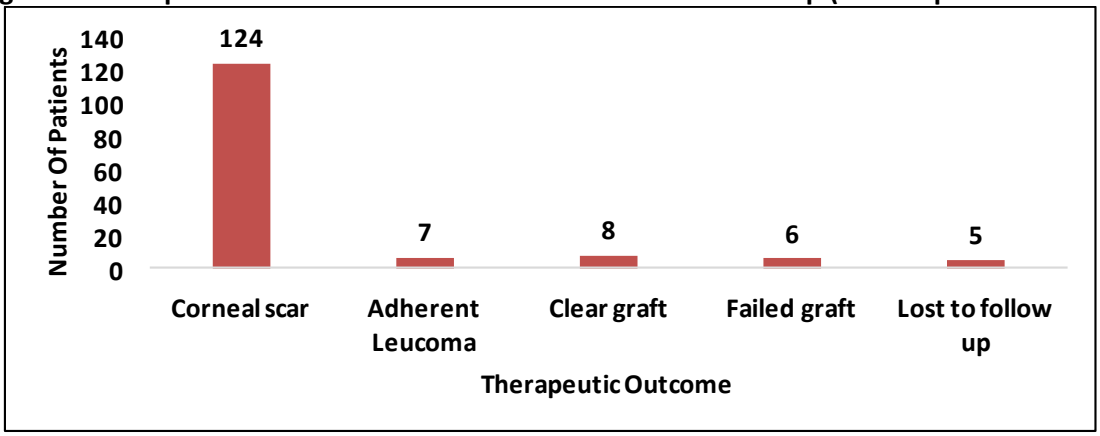
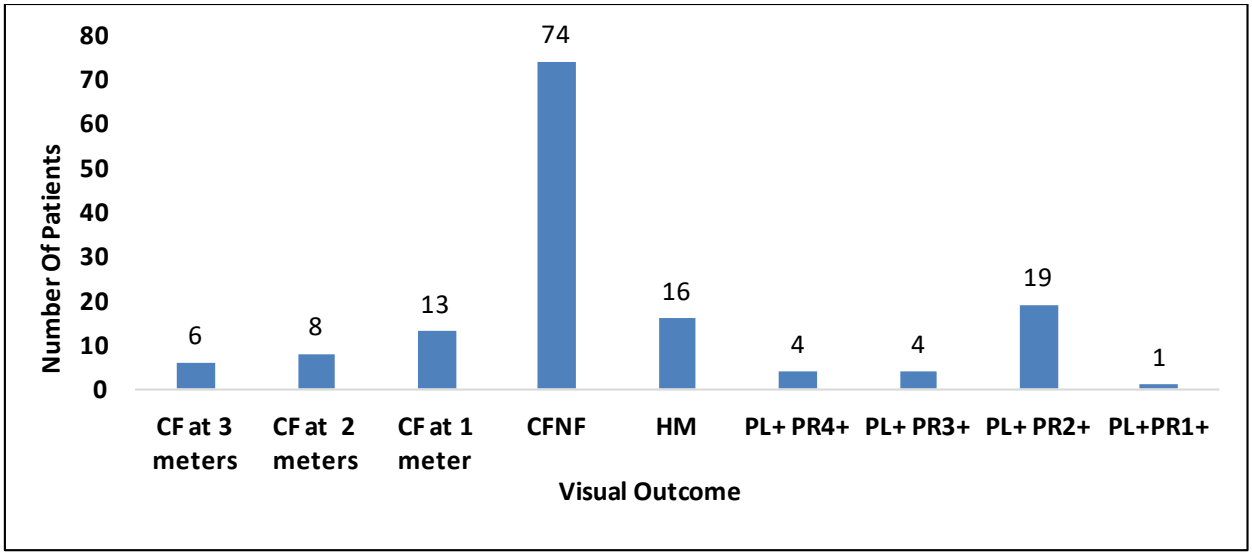


Figure 4: Optical Result Of 145 Patients At The Last Follow Up



There was a significant statistical difference found between age groups of <65 years and >65 years for keratitis outcome. Improvement in vision (p=0.0264) & slit lamp findings (p=0.0148) were seen more in younger age group patients.

No significant difference in gender (p=0.374) for keratitis outcome. Diabetic patients had poor visual outcome compared to nondiabetic patients (p=0.0036).

No statistical difference found between two drug groups Moxifloxacin-Tobramycin and Vancomycin - Amikacin for Bacterial keratitis outcome, including vision improvement (p=0.784) and slit lamp results (p=1).

Discussion: To date, there are limited studies available in the literature about the Infectious keratitis. A substantially higher rate has been reported in under-resourced countries such as South India (113 per 100,000 population-year) [12].

The higher incidence observed in these regions was primarily attributable to the poorer environmental and personal hygiene, lower level of education, agricultural industry, increased risk to work related corneal trauma and poorer access to sanitation and healthcare facility.

The epidemiological patterns and risk factors have been found to vary with demographic factors such as age, gender and socioeconomic status[4]. Infectious keratitis is significantly higher (79.33%) among those aged >50 years in our study and in elderly patients (>65 years) visual outcome was poor compared to younger age group. Some studies have demonstrated that elderly patients affected by Infectious keratitis were associated with poor visual outcome and higher rate of complications such as corneal melting, perforation and loss of eye[13,14]. This might be related to the higher rate of ocular co-morbidities and the delay in presentation and/or diagnosis as elderly patients are usually dependent on spouse or family when seeking medical care and they may relate their condition to "normal" age-related changes[15,16].

Male preponderance (65.33%) in our study was not different from the study done in south India (males 61.3%, females 38.7%). The incidence of microbial keratitis in this series was significantly higher in males than females (p = <0.0001). Males in their sixth decade of life are particularly at risk. Overall, the ratio of male to female patients with corneal ulceration is 1.6 to 1[17].

Some studies in the literature also have shown female preponderance[18]. By the nature of their work, men are more exposed to outdoor activities, hence increasing their vulnerability to the disease.

Corneal trauma is the leading cause of microbial keratitis[17,19] which was also found in the present study (61.33%). Study done by Chidambaram et al. had shown trauma related Infectious keratitis is associated with a male predominance.

Based on the studies reported in the literature, farmers (54–70%) and manual labour workers (11–17%) constituted the main occupations in Asia.

These groups of workers were at a high risk of developing the disease due to the increased occupational exposure to plant materials and foreign bodies, which was frequently compounded by the lack of eye protection[20].

Diabetes mellitus serves as one of the most important systemic risk factors. Hyperglycaemia has been shown to facilitate microbial growth and alter the microbiota of ocular surface, affect the homeostasis, corneal sensation and wound healing of the corneal epithelium, thereby increasing the risk of Infectious keratitis[21].

In this study visual outcome was poor in diabetic patients compared to non-diabetics. Sub-basal corneal nerve plexus of patients with diabetic neuropathy is often affected and can lead to neuropathic keratopathy with complications such as corneal melt and Infectious keratitis[22].

It is of interest that 64(42.7%) patients in the study presented for examination during the first week of their illness and 41(27.3%) reported in the second week, is similar with findings of study done by Kumar et al.[19] Majority of the patients from rural areas don't present to tertiary eye care institute at the initiation of the disease, instead they consult a local healthcare provider or visit the village healer. Courtright et al. described the use of traditional eye medicines among patients with corneal diseases in rural Malawi[23].

In this study microscopic findings showed Gram stain positivity (31.3%), Gram stain negativity (20.7%) and smear positivity for KOH mount was (42.7%), suggestive of bacterial keratitis (52%) was the commonest form followed by fungal (43%) and viral keratitis. In a study done by Gopinathan et al. high prevalence of bacterial keratitis was reported. Staphylococcus spp. 33(47.4%) was the predominant bacterial species[19,24]. Some studies have also reported predominance of Pseudomonas aeruginosa[25] and Streptococcus pneumonia[17] bacterial species. These findings show that there is distinct pattern of geographical variation in aetiology.

Topical antibiotics remain the first-line treatment for bacterial keratitis. Clinicians weigh many factors when choosing an antibiotic regimen, including broad-spectrum coverage, toxicity, availability and cost, and region-specific epidemiology of pathogens and resistance patterns[5]. In the present study out of 78 patients having bacterial keratitis, majority of the patients 60(77%) were prescribed fluoroquinolones-aminoglycoside combination and rest 18(23%) were prescribed Vancomycin-aminoglycoside combination. There was no difference in the therapeutic outcome of these two groups.

McDonald et al. found no significant difference in comparative effectiveness between fluoroquinolones and Aminoglycoside–Cephalosporin treatment options in the management of bacterial keratitis but found the differences in safety profile[26]. Vancomycin, a highly active antibiotic agent against gram-positive bacteria, is a first-line treatment for staphylococcal keratitis resistant to other antibiotic agents. Jhanji et al. reported a case who was resistant to Moxifloxacin and was treated with Vancomycin-tobramycin eyedrops giving good results[27].

Fungal ulcers often have worse outcomes than bacterial ulcers. In this study majority of patients were treated with Natamycin eye drops and rest were prescribed Natamycin-Voriconazole combination. Effective treatment with topical natamycin 5% is limited by its poor penetration into the corneal stroma[28]. Topical amphotericin B is an alternative, but its use requires access to a compounding pharmacy and is limited by toxicity.

Voriconazole, a newer-generation triazole, has gained popularity in the treatment of fungal keratitis because of its excellent ocular penetration[29]. The randomized controlled Mycotic Ulcer Treatment Trial (MUTT) I showed a benefit of topical natamycin over topical voriconazole for fungal ulcers, particularly among those caused by Fusarium keratitis[30]. These results have been confirmed by a second randomized clinical trial[31] and a recent Cochrane review[32]. Also, Natamycin eye drops are comparatively cheaper and easily available than Voriconazole, hence more economical and sustainable option in a developing country like India.

Antimicrobial resistance (AMR) has been recognised as a major public health crisis in the past two decades, with many infectious organisms developing resistance against previously effective antimicrobial agents. Broad-spectrum topical antibiotic therapy is the gold

standard treatment for Infectious keratitis. A few recent studies have highlighted the emergence of AMR in ocular infections[4]. It is likely to be multifactorial, including the injudicious wide spread use of antibiotics in both ocular and systemic infections, incorrect dosing regimen, and representations of the community prevalence of drug resistance, with consequent colonisation of ocular surface by drug resistant pathogens[4,33].

Broad spectrum antibiotics are prescribed on empirical bases overlooking the culture sensitivity details which could lead to AMR hence timely shift to targeted antimicrobial therapy can help in curbing AMR to certain extent.

Corneal graft surgery is one of the most successful forms of human solid-tissue transplantation, and nowadays, there is a worldwide expansion of the surgical volume of corneal grafts. This surgery is continuously evolving, with new surgical techniques and postoperative treatments that have considerably increased the chance of survival for the grafts. Despite the high rate of success, corneal transplantation is still complicated by a relevant risk of graft failure. The graft failure can be of primary graft failure (PGF), immunological rejection and late endothelial failure[34]. In the present study 17 patients underwent TPK, of which 6(35.3%) patients presented with a failed graft.

There are no clearly defined risk factors in the majority of cases, but postulated aetiologies which have been associated with PGF include donor factors such as unhealthy tissue (endothelial damage during donor retrieval or storage, prolonged death-to-preservation time or prolonged donor storage time) and unhealthy recipient circumstances (blood, interface foreign bodies for lamellar techniques)[35]. Surgeon experience is a predictor of iatrogenic PGF, with higher rates of failure among surgeons who had performed less than 15 procedures[36].

Strength, Limitations & Future Prospects: It was the first study of the kind in our set up on such a difficult topic like Cornea as visual outcome is often poor in patients with corneal diseases.

As it was a follow up study it evaluated the common treatments used in different aetiologies of Infectious keratitis which can guide prescribers optimizing the treatments and achieving better patient care.

Despite the strengths, there are few limitations associated with the present study. Sample size was less and due to lack of data regarding Bacterial culture the treatment prescribed was not specific against offending organism.

Further studies are required for longer periods with large sample size. More studies comparing long term effectiveness of medical and surgical treatment are required.

Economic burden on patients can be analysed to further modify the prescribing habits.

Future research should focus on qualitative research to comprehend patient's experience with the disease, which will be better for effectiveness of the care and treatment provided.

In addition to the introduction of new treatments, a need for the development of novel tools to help diagnose, monitor and quantify the severity of the disorder is desirable.

Conclusion: Bacterial keratitis was the most common cause of Infectious keratitis. Trauma was the commonest factor found majority of cases. Younger age group had better visual outcome. Majority of patients with bacterial keratitis were prescribed Fluroquinolones and aminoglycoside combination.

Despite having appropriate antimicrobial treatments for most of the pathogens implicated in Infectious keratitis, clinical outcomes often are poor.

Patients with Infectious keratitis should be followed carefully, and adequate modification of antimicrobial therapy may be required according to the patient's compliance and to prevent antimicrobial resistance.

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