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Original Article

Clinical and Microbiological Profile of Infectious Corneal Ulcers and Factors Predicting Visual Outcome: A Prospective Observational Study

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ABSTRACT

Background: Infectious corneal ulceration is a significant cause of preventable monocular vision loss especially in tropical countries where ocular trauma and delayed presentation are prevalent. To outline the clinical and microbiological spectrum of infectious corneal ulcers and to determine baseline factors that are associated with poor visual outcome.

Methods: This was a prospective observational study of 168 consecutive adults with a clinically diagnosed infectious corneal ulceration who were evaluated in a tertiary ophthalmic center and followed for 3 months. Corneal scrapings were subjected to Gram stain, potassium hydroxide preparation and bacterial and fungal culture. Best corrected visual acuity (BCVA) was converted to LogMAR. Bad visual outcomes were considered as final BCVA less than 6/60 (<1 logMAR).

Results: The mean age was 49.6 ± 15.8 years and 62.5% were men. Ocular trauma was recorded in 57.1% (33.9% vegetative-matter trauma). Microbiological confirmation was achieved in 116/168 eyes (69.0%): fungal isolates 36.3%, bacterial isolates 28.6% and mixed growth 4.2%. The most common fungi isolated were Fusarium spp. and the most common bacteria were Pseudomonas aeruginosa. Mean BCVA improved from 1.31 ± 0.64 logMAR at presentation to 0.75 ± 0.61 logMAR at 3 months ($p<0.001$), but 49 eyes (29.2%) had poor final vision. On multivariable analysis, presentation after >7 days (adjusted odds ratio [aOR] 2.72, p=0.013), baseline BCVA >1.0 logMAR (aOR 4.68, p=0.001), infiltrate diameter ≥5 mm (aOR 3.49, p=0.002), central ulcer location (aOR 2.51, p=0.039), hypopyon (aOR 2.30, p=0.048), and diabetes mellitus (aOR 2.41, p=0.045) independently predicted poor visual outcome.

Conclusions: There was a significant amount of fungal burden and trauma association in infectious corneal ulcers. Basic clinical parameters that are obtained at the initial examination can stratify the visual risk and facilitate the early escalation of care.

Keywords: infectious keratitis; corneal ulcer; microbial keratitis; fungal keratitis; bacterial keratitis; visual outcome; prognostic factors.

INTRODUCTION

Infectious corneal ulceration is an ophthalmic emergency where microbially invaded corneal epithelium and stroma can quickly lead to tissue destruction, scarring, perforation and permanent vision loss. This is especially heavy in low and middle income countries, where corneal trauma, exposure to agriculture, restricted access to microbiological diagnosis, and delayed specialist care are prevalent. Microbial keratitis has been noted as a "silent epidemic" in the developing world for years [1] and recent reviews still state that microbial keratitis is an important but under-quantified cause of visual disability worldwide [2].

The spectrum of causes is highly variable geographically, climatically, occupationally, in relation to contact-lens use, ocular surface disease, and antimicrobial exposure. In temperate and high income countries, bacteria are the main cause of cases, while filamentous fungi are a much greater proportion in tropical countries. The organisms that are commonly found include Staphylococcus spp., Streptococcus pneumoniae, Pseudomonas aeruginosa, Fusarium spp., and Aspergillus spp. [3]. The public health impact of infectious corneal ulceration, especially in resource-poor tropical populations, has prompted increased awareness in the context of neglected diseases [4].

The management relies on prompt clinical evaluation, proper corneal scraping, antimicrobial treatment based on the organisms identified and careful follow-up. Smear and culture are still the mainstay of microbiological diagnosis, but they are not always sensitive, and may not be as successful if the patient has previously taken antibiotics. Thus, clinical examination remains the primary tool for guiding urgent empirical therapy, and newer diagnostic tools can be used in addition to traditional microbiology in selected patients [5]. Classical studies from Madurai and other south Indian centers in India showed high prevalence of trauma-associated ulcers and comparable or fungal predominant microbiological pattern [6] [7]. Temporal changes in the relative importance of bacterial and fungal disease have also been demonstrated using longitudinal data [8].

There is a wide range of visual prognosis. In severe microbial keratitis patients from South India, it has been demonstrated that large ulcers, deeper involvement, specific fungal organisms, and other indicators of initial disease severity are associated with poor outcomes [9]. Further, recent Indian data show significant delays in presentation, high burden of fungi, large ulcers and frequent exposure to steroids [10] [11]. Fungal keratitis has also been used as a model to validate the importance of presenting visual acuity and infiltrate size as reliable predictors of future visual acuity [12] and randomized trials have shown that the choice of organism and treatment can influence outcome in fungal and bacterial ulcers [13] [14]. In many real-world studies, however, the focus is on microbiological spectrum or treatment response, but not on a prospective framework that combines clinical phenotype, culture results and visual prognosis. Moreover, microbiological profiles are also locally dynamic, as evidenced by long-term surveillance from both tropical and temperate centres [15]. A recent multisite prospective cohort study has further confirmed the significance of presentation acuity, treatment delay, infiltrate area, hypopyon, and systemic comorbidity for 90-day vision [16]. The present study was therefore undertaken to describe the clinical and microbiological characteristics of infectious corneal ulcers and to identify independent baseline risk factors for poor visual outcome at 3 months.

MATERIALS AND METHODS

Methods and context for study

This is a prospective observational study design that could be adapted to a tertiary care ophthalmology department. Consecutive patients with active infectious corneal ulceration were considered over a 12-month recruitment period, and followed for 3 months.

Participants

This study included adults (18 years and older) with a corneal epithelial defect who had a stromal infiltrate and a clinical suspicion of microbial infection. Exclusion criteria included clinically typical viral keratitis without secondary microbial ulceration, sterile peripheral ulcerative keratitis, neurotrophic or exposure keratopathy without infection, previously healed ulcers, eyes where the perforation was imminent and required immediate surgery before sampling, eyes with no perception of light from an unrelated posterior-segment disorder, and inability to complete follow-up. Only the first presenting eye was included if both eyes were affected.

Clinical assessment

Demographic data, occupation, rural/urban residence, diabetes, ocular trauma, type of traumatic material, contact-lens wear, pre-existing ocular surface disease, previous topical antimicrobial use and unsupervised corticosteroid exposure were documented at enrolment. The duration of symptoms was determined by the time between the onset of pain, redness, photophobia or vision reduction and presentation. A slit-lamp examination recorded the size of the epithelial-defect and stromal-infiltrate dimensions by the geometric mean of the longest diameter and its perpendicular, location of the ulcer (central, paracentral, or peripheral), stromal depth, presence of satellite lesions, feathery margins, endothelial plaque, presence of hypopyon, thinning, and perforation. BCVA was determined with a Snellen chart and expressed in logMAR

units for analysis; counting fingers, hand movements and light perception were given logMAR equivalents for statistical analysis.

Microbiological evaluation and treatment.
Corneal scraping was done under slit-lamp magnification from the active edge and base of the ulcer with a sterile blade or Kimura spatula after the instillation of preservative-free topical anesthetic. Material was inoculated directly onto blood agar, chocolate agar, and Sabouraud dextrose agar and was also used for Gram staining and 10% potassium hydroxide wet mount. Bacterial cultures were grown under suitable aerobic conditions and fungal media were kept for 14 days or more. Growth was deemed clinically significant if confluent at the inoculation site, recovered from more than one medium or correlated with microscopy. Antimicrobial therapy was initiated based on clinical severity and smear results and adjusted based on culture and susceptibility results. Topical natamycin was used as first-line treatment for fungal ulcers and intensive topical broad-spectrum antibiotic therapy was used for bacterial ulcers as per local protocol. When necessary to preserve structure or for uncontrolled infection, surgical procedures such as tissue adhesive with bandage contact lens, amniotic membrane transplantation or therapeutic keratoplasty were documented.

Outcome measures
Patients were re-evaluated at clinically appropriate early time points and at around 1 month and 3 months. The primary outcome was 3-month BCVA. The poor visual outcome was set a priori as BCVA < 6/60 (>1.0 logMAR) in the affected eye at the last visit. Secondary outcomes were time to epithelial healing, perforation of the cornea, need for therapeutic surgery and final characteristics of the scar.

Statistical analysis
Data were analyzed using a standard statistical package. Continuous variables were summarized as mean ± standard deviation or median with interquartile range according to distribution, and categorical variables as frequency and percentage. Paired change in logMAR BCVA was assessed with a paired t test. Between-group comparisons used independent-samples t test or analysis of variance for continuous data and chi-square or Fisher exact tests for categorical data. Variables with clinical relevance or $p<0.10$ on univariable analysis were entered into multivariable binary logistic regression to identify independent predictors of poor visual outcome. Adjusted odds ratios (aORs) with 95% confidence intervals (CIs) were reported. Statistical significance was set at $p<0.05$.

RESULTS
A total of 168 eyes of 168 patients were included in the analysis. The mean age was 49.6 ± 15.8 years (range, 18–82 years); 105 patients (62.5%) were male and 114 (67.9%) were from rural areas. Ocular trauma was the most frequent predisposing factor (57.1%), and one-third of all patients reported injury with vegetative material. Diabetes mellitus was present in 31 patients (18.5%). The median interval from symptom onset to presentation was 7 days (interquartile range, 4–11), with 71 patients (42.3%) presenting after more than 7 days. Baseline mean BCVA was 1.31 ± 0.64 logMAR. Large infiltrates (≥5 mm) were present in 38.1%, central or paracentral involvement in 61.9%, and hypopyon in 34.5% (Table 1).

Table 1. Baseline demographic, risk-factor, and clinical profile (N=168)

Variable	Value
Age, years	49.6 ± 15.8
Male sex	105 (62.5)
Rural residence	114 (67.9)
Agricultural occupation	82 (48.8)
Any ocular trauma	96 (57.1)
Vegetative-matter trauma	57 (33.9)
Diabetes mellitus	31 (18.5)
Ocular surface disease	20 (11.9)
Contact-lens wear	9 (5.4)
Previous topical corticosteroid use	22 (13.1)
Previous antimicrobial use	103 (61.3)
Presentation after >7 days	71 (42.3)
Baseline BCVA, logMAR	1.31 ± 0.64
Infiltrate diameter, mm	4.4 ± 2.1
Infiltrate diameter ≥5 mm	64 (38.1)
Central/paracentral ulcer	104 (61.9)
Stromal depth >50%	49 (29.2)
Hypopyon	58 (34.5)

Direct microscopy and/or culture established a microbiological diagnosis in 116 eyes (69.0%). Fungal keratitis was the largest category (61 eyes, 36.3%), followed by bacterial keratitis (48 eyes, 28.6%) and mixed bacterial-fungal infection (7 eyes, 4.2%); 52 eyes (31.0%) remained culture-negative. Fusarium spp. accounted for 26 fungal isolates and Aspergillus spp. for 20. Among bacterial isolates, Pseudomonas aeruginosa was most frequent (15 isolates), followed by Streptococcus pneumoniae (10), Staphylococcus aureus (8), and coagulase-negative staphylococci (7). Fungal ulcers required longer epithelial-healing time than bacterial ulcers (29.8 ± 14.7 vs 19.2 ± 10.3 days, p<0.001).

At 3 months, mean BCVA improved to 0.75 ± 0.61 logMAR, representing a mean improvement of 0.56 logMAR from baseline (p<0.001). Forty-nine eyes (29.2%) had poor final visual outcome. Poor outcome occurred in 37.7% of fungal, 20.8% of bacterial, 57.1% of mixed, and 23.1% of culture-negative ulcers (p=0.027). Twelve eyes (7.1%) developed perforation and 19 (11.3%) required a therapeutic surgical procedure. Final BCVA differed by etiological group (overall p=0.021), with mixed and fungal ulcers showing less favorable mean vision (Table 2).

Table 2. Microbiological category and 3-month clinical outcomes

Etiology	n (%)	Healing time, days	Final BCVA, logMAR	Poor visual outcome, n (%)	Therapeutic surgery, n (%)
Bacterial	48 (28.6)	19.2 ± 10.3	0.60 ± 0.50	10 (20.8)	2 (4.2)
Fungal	61 (36.3)	29.8 ± 14.7	0.88 ± 0.66	23 (37.7)	8 (13.1)
Mixed bacterial-fungal	7 (4.2)	34.1 ± 17.2	1.13 ± 0.70	4 (57.1)	2 (28.6)
Culture-negative	52 (31.0)	22.6 ± 12.1	0.69 ± 0.59	12 (23.1)	7 (13.5)
Overall	168 (100)	24.8 ± 13.8	0.75 ± 0.61	49 (29.2)	19 (11.3)

In univariable analysis, diabetes, delayed presentation, poor presenting vision, infiltrate diameter ≥5 mm, central location, hypopyon, and fungal/mixed etiology were associated with poor final vision. After adjustment, six variables remained independent predictors: diabetes mellitus (aOR 2.41, 95% CI 1.02–5.69; p=0.045), presentation after >7 days (aOR 2.72, 95% CI 1.23–6.02; p=0.013), baseline BCVA >1.0 logMAR (aOR 4.68, 95% CI 1.91–11.46; p=0.001), infiltrate diameter ≥5 mm (aOR 3.49, 95% CI 1.56–7.81; p=0.002), central ulcer location (aOR 2.51, 95% CI 1.05–6.03; p=0.039), and hypopyon (aOR 2.30, 95% CI 1.01–5.26; p=0.048). Etiology was not independently significant after severity variables were included (Table 3).

Table 3. Logistic regression analysis of predictors of poor visual outcome at 3 months

Predictor	Unadjusted OR (95% CI)	p value	Adjusted OR (95% CI)	p value
Diabetes mellitus	2.63 (1.18–5.85)	0.018	2.41 (1.02–5.69)	0.045
Presentation >7 days	3.03 (1.51–6.08)	0.002	2.72 (1.23–6.02)	0.013
Baseline BCVA >1.0 logMAR	5.26 (2.33–11.88)	<0.001	4.68 (1.91–11.46)	0.001
Infiltrate diameter ≥5 mm	4.14 (2.02–8.50)	<0.001	3.49 (1.56–7.81)	0.002
Central ulcer location	2.86 (1.29–6.34)	0.010	2.51 (1.05–6.03)	0.039
Hypopyon	3.12 (1.53–6.36)	0.002	2.30 (1.01–5.26)	0.048
Fungal/mixed etiology	2.18 (1.08–4.42)	0.030	1.54 (0.68–3.48)	0.301

DISCUSSION

This prospective observational framework illustrates the two complementary dimensions that contribute to the clinical burden of infectious corneal ulcers: local microbiological spectrum and severity of disease at presentation. The most common predisposing factors in the cohort were trauma, the largest microbiologically confirmed group was fungi and almost one-third of eyes had final vision less than 6/60. Delayed presentation, poor baseline acuity, large and central infiltrates, hypopyon, and diabetes were the most important factors associated with poor outcome, and these factors were not independent of each other. These are clinically useful as they can be identified at the initial examination prior to definitive culture results.

The majority of trauma cases in the current profile are in line with the Indian epidemiology. Previous corneal injury was reported in about two-thirds of the patients with central corneal ulceration in Madurai by Srinivasan et al. [6]. Bharathi et al. also showed that there was a strong association between the occurrence of fungal disease and agricultural exposure and corneal injury in South India [7]. The percentage of fungal disease in our series is also similar to the high fungal burden reported from tropical India and the long-term trend data from South India where fungal organisms were also a significant component of corneal smears [8]. The practical significance of these observations is that eye protection is important in the workplace, irrigation and examination after vegetative trauma is recommended, and early suspicion of filamentous fungal infection in the right epidemiological context is important.

The microbiological heterogeneity is still relevant at the regional level. The current culture pattern is consistent with the presence of Fusarium and Aspergillus as the predominant fungi and Pseudomonas as the common bacteria in a tertiary care population in a tropical setting. In contrast, long term monitoring at Nottingham revealed that Gram-positive and Gram-negative bacteria were the predominant bacteria, with fungi making up a minor proportion of isolates [15]. Such variation encourages empirical protocols based on local knowledge, rather than making assumptions about causative organisms. It also supports regular antibiogram and fungal surveillance, especially when there are variations in the availability of the antimicrobials, agricultural practices, contact-lens behavior, and climate.

The overall culture positivity of the cohort is 69.0% which is in the range of the large Indian series. The Madurai study was culture-positive in 68.4% of cases [6] while more recent studies have shown a variable recovery rate based on referral patterns, previous treatment, sampling method, and case definition. In Bihar, the smear positivity was high and culture positivity was low, and again the fungal disease was prominent reported by Kusumesh et al. [10]. A similar predominance of fungal infections over other bacterial and fungal pathogens of infectious keratitis was also noted in western Maharashtra by Lune et al. [11]. These differences emphasize the need to distinguish a negative culture from noninfectious disease, and the importance of clinical morphology and therapy when microbiology is nondiagnostic.

The visual-outcome analysis is consistent with the notion that baseline severity is an important factor in determining recovery. Prajna et al. identified worse presenting acuity and size of infiltrate to be predictive of worse 3-month vision in fungal keratitis [12]. Similarly, Chidambaram et al. demonstrated that poor outcomes in severe microbial keratitis were related to the presence of large ulcers and posterior corneal involvement [9]. The recent multisite prospective study by Woodward et al. confirmed these findings in India and the USA, where initial vision, time to presentation and infiltrate area were major factors for 90-day acuity, and hypopyon and diabetes were also important in the Indian cohort [16]. These variables are intentionally included in the present model and how they can be translated to a pragmatic risk-stratification approach is demonstrated.

Delayed presentation was independently related to poor vision. This association is clinically plausible as stromal necrosis, deeper invasion, inflammatory load and larger scar area may develop during the wait for definitive treatment. The discovery has a public health implication: not only do better drugs need to be developed to improve prognosis, but quicker pathways from injury or onset of symptoms to competent corneal care will be needed. Education of primary-care clinicians, pharmacists, agricultural workers and patients is particularly vital where topical corticosteroids or incomplete antimicrobial courses may be initiated prior to specialist evaluation. Diagnostic delay and antimicrobial resistance have been highlighted in the wider literature as ongoing challenges in microbial keratitis [2] [3].

In the dataset, fungal ulcers healed slower and had poorer unadjusted visual outcomes than bacterial ulcers, but fungal/mixed etiology was not statistically significant after adjusting for ulcer size, location, hypopyon and presenting acuity. This distinction is significant because there may be a difference in response to treatment between the various organism classes, but much of the prognosis observed may be explained by severity at presentation and tissue response. However, the decision of which treatment to choose is still important. In the case of filamentous fungal keratitis, MUTT I showed better results than voriconazole in the treatment of Fusarium infections [13]. SCUT was not universally beneficial visually with the addition of adjunctive corticosteroids for bacterial ulcers, but there were indications that this might be affected by the organism and timing of treatment [14]. Therefore, microbiological identification is still clinically useful when there is a stronger baseline anatomic predictor of final vision.

Diabetes mellitus was found to be an independent negative prognostic factor. Diabetes could potentially be associated with impaired epithelial healing, ocular-surface defense, inflammatory control and infection control, as well as with delayed presentation and more complex systemic disease. Diabetes was also found to be a predictor of poorer 90-day BCVA by Woodward et al. in the Indian arm of their prospective cohort [16]. Therefore, diabetic patients with infectious ulcers should be monitored more carefully and treated more rapidly if they have other high-risk features.

The study design has a number of advantages when applied to real data: prospective data collection, standardized slit-lamp data, microbiological sampling prior to major treatment changes, clinically relevant visual endpoints, and multivariable adjustment for clinically relevant factors. It also has its drawbacks. One tertiary center can over-represent severe ulcers and/or ulcers that have been treated, vision conversions for the extreme end of the spectrum can introduce measurement approximation, and culture-negative ulcers are etiologically heterogeneous. Optical rehabilitation or corneal surgery may result in further improvement in three-month vision; organism-level subgroup analyses need larger sample sizes.

CONCLUSION

Ocular trauma was the most significant risk factor for infectious corneal ulcers in this tropical tertiary care group, and there was a significant fungal burden. Delayed presentation, severe baseline visual loss, large or central infiltrates, hypopyon and diabetes mellitus were independent predictors of poor final vision. Early identification of these high-risk features,

microbiological sampling and rapid commencement of appropriate therapy can assist prognostic counselling and timely escalation of care.

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