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Original Research Article

COMPARISON OF CLINICAL EFFICACY OF TOPICAL FORTIFIED CEFAZOLIN-TOBRAMYCIN COMBINATION WITH TOPICAL MOXIFLOXACIN AS INITIAL THERAPY IN CLINICALLY SUSPECTED PATIENT OF BACTERIAL CORNEAL ULCER

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ABSTRACT

Background: Microbial keratitis is an ophthalmic emergency due to the often rapid progression with the threat of vision loss and potential corneal perforation. Bacterial keratitis accounts for significant proportion of infectious keratitis worldwide and may have diverse clinical presentation depending on the geographical location and climatic conditions. **Objective:** To compare clinical efficacy of topical fortified cefazolin-tobramycin combination with topical moxifloxacin as initial therapy in clinically suspected patient of bacterial corneal ulcer.

Materials and Methods: A total of 23 cases of clinically suspected bacterial corneal ulcer of all ages and either sex, who presented in Department of Ophthalmology, Dr Rajendra Prasad Govt Medical College, Kangra at Tanda (Himachal Pradesh) during a period of one year were included in this study. All patients met the inclusion criteria as per the protocol.10 patients were randomized to Group A (combined fortified cefazolin-tobramycin) and 13 patients were randomized to Group B (moxifloxacin monotherapy).

Results: Mean age of the patients was 57.09±18.46 years with a range between 3-80 years of age. Mean age of patients in group A (Combined Fortified cefazolin-tobramycin) was 53.0±22.6 years and in group B (Moxifloxacin monotherapy), it was 60.23±14.73years. Males (15,65.2%) outnumbered females (8,34.8%) in both the groups. The predominance of corneal ulceration in males was most pronounced in 51-80 years of age, There was no significant difference in ulcer size in both the groups at presentation before initiation of therapy. The difference in size of corneal ulcer between the two groups on day 3 (p=0.04) and day 7 (p=0.03) was statistically significant with group B being better. Overall, mean size of stromal infiltration 3.74±1.52mm. In group A, mean size of stromal infiltration was 4.51±1.48mm and in group B was 3.38±1.62mm. There was no significant difference between the two groups at presentation. On follow up, in Group A, there was initial increase in size of ulcer till day 7, whereas in Group B, reduction was seen from start of therapy moxifloxacin monotherapy showed better results than fortified Cefazolin-Tobramycin combination' in epithelium of ulcer initially.

Conclusion: Topical moxifloxacin monotherapy is equally efficacious as compared to topical combined fortified cefazolin-tobramycin group as initial treatment in clinically suspected bacterial corneal ulcer

Keywords: Topical moxifloxacin monotherapy, topical combined fortified cefazolin-tobramycin, bacterial corneal ulcer.

INTRODUCTION

Corneal blindness resulting from microbial keratitis has been recognised as an emerging cause of visual disability by World Health Organisation. Corneal ulceration is considered as a silent epidemic in developing countries, especially in South-east Asia region,[1] and requires urgent and meticulous management to prevent any sight threatening complications.[2]

Suppurative keratitis is defined as loss of corneal epithelium with underlying stromal infiltration associated with signs of inflammation with or without hypopyon.[4] Bacterial keratitis is considered a leading cause of monocular blindness in developing countries. In developed countries, the increasing popularity of contact lens wear has contributed to its rising incidence. Given the potential blinding complications of severe bacterial keratitis, these infections are a significant public health issue.[3]

Bacterial keratitis produces a wide spectrum of clinical signs and symptoms ranging from small peripheral superficial keratitis to deep corneal stromal ulceration.[4] Clinical features include symptoms of pain, photophobia, blurred vision, mucopurulent or purulent discharge, chemosis and eyelid swelling (in severe cases).[5]

Early diagnosis and prompt adequate therapy is essential to eradicate the infectious agents, to prevent tissue damage and to minimise scarring or melting.[4]

The prorocol for management or bacterial keratitis deally involves collection of corneal scraping material for smear and culture and Sensitivity, empirical intensive antimicrobial therapy that is either monothcrapy with a broad spectrum antibiotic or a combination of two fortified antibiotics to cover both gram negative and gram positive organisms.

This study is aimed at comparing the clinical efficacy of combined topical fortified cefazolin-tobramycin with topical moxifloxacin monotherapy as initial therapy in clinically suspected patients of bacterial corneal ulcer so as to find out an effective antibacterial regimen in the initial therapy of suppurative corneal ulceration in this rural referral and treating centre as earlier no such study has been conducted.

This will help us in devising a standardised drug regimen for starting the appropriate initial treatment before getting the microbiological confirmation. It will also provide information to primary and secondary health care ophthalmologists in initiating therapy without delay, as many of these centres lack microbiology facilities.

On a wider perspective, this information will also guide us while formulating recommendations for preferred practice patterns and preventive measures of suppurative keratitis in the population at risk.

MATERIALS AND METHODS

This Restricted randomized trial with Allocation concealment was conducted among all Patients with clinically suspected bacterial corneal ulcer who visited Department of Ophthalmology and Department of Microbiology at Dr. RPGMC, Kangra at Tanda. A total of 23 patients of clinically suspected bacterial corneal ulcer during a period of one year that was from June 2015- June 2016 with following inclusion and exclusion criteria were included. This study was conducted after getting approval of Institutional ethics committee.

Inclusion Criterion

All cases of bacterial corneal ulcers of all ages and either gender diagnosed on clinical examination were included.

Exclusion Criterion

1. Patients suspected of fungal corneal ulcer or if culture report showed fungal growth.
2. Patients suspected of viral corneal ulcer
3. Neuroparalytic keratitis.
4. Interstitial keratitis.
5. Complications such as corneal perforation, descemetocoele at time of presentation.
6. Size of ulcer less than 2mm.
7. Patient's refusal

Methods

Patients were subjected to meticulous history taking, documenting socio-demographic information including duration of symptoms, previous treatment, predisposing ocular conditions and associated risk factors. A complete clinical evaluation of patients were done.

1. Assessment of visual acuity using Snellen's chart was done.
2. Anterior segment of each eye was examined using slit-lamp bio-microscope (Haag Streit BM 900).
3. Assessment of location of corneal ulcer was done.
4. Size of the epithelial defect in terms of horizontal and vertical size in its maximum dimension were measured using fluorescein stain. Cornea was anaesthetized with instillation of I drop of 4% xylocaine in affected eye. Fluorescein dye impregnated filter paper strips wetted with sterile normal saline were used to instill fluorescein dye in the conjunctival sac.
5. Margins of Ulcer (serrated or well defined) were noted.
6. Horizontal and vertical size of stromal infiltration in its maximum dimension were noted.
7. Depth of stromal infiltration was recorded.
8. Corneal sensations were noted
9. Anterior chamber reaction and height of hypopyon (if present) were recorded.
10. Details of iris regarding its colour, pattern and synechiae (anterior or posterior) were noted.

11. Pupillary reactions were assessed using a penlight. Direct and consensual reflexes were tested.
12. Detailed examination of lens was done.
13. The fundus was examined with direct ophthalmoscope (Heine beta 200 S) after dilatation of pupils with 1% tropicamide eye drop.

RESULTS

Mean age of the subjects was 57.09±18.46 years with a range between 3-80 years of age.
Mean age of subjects in Group A was 53.0±22.6 years and in Group B was 60.23±14.73years. Majority of subjects in each group were from 51-80 years of age.
In Group A, equal number of patients had right and left eye involvement whereas in
Group B, more number of patients had involvement of left eye than right eye.
Male subjects comprised 65.2%(15) of the study group. Females comprised 34.8%(8) in the study group ln Group A. 80% (8) of subjects wcre males and 20% (2) were females, In Group B.
males comprised 53.8% (7) and females compared 46.2% (6) of subjects.
Out of all the subjects, 91.3% (21) of subjects belonged to rural areas whereas 8.7%(2) of subjects belonged to urban areas. In Group A, 90% (9) were from rural areas and 10% (1) belonged to urban areas. In Group B, 92.3% (12) subjects belonged to rural area and 7.7%(1) subjects belonged to urban areas
Majority of subjects were from rural area in both the groups.
Most of the subjects in the study group were illiterate. Of total subject, 30% (7) of
subjects were literate and 70%(16) were illiterate. In Group A, 20% (2) of subjects were literate and 80%(8) were illiterate. In Group B, 38.5% (5) of subjects were literate and 61.5%(8) were illiterate.
Among all subjects in the study, majority were agriculturists (52.2%,12). In Group A, 60%(6) of subjects were agriculturists,20%(2) were labourers followed by homemakers and others which accounted for 10%(1) each. In Group B,46.2%(6) of subjects were agriculturists followed by 23%(3) homemakers, labourers and others accounted for 15,4%(2) each, In Group A,20%(2) of subjects had history of foreign body removal from local traditional healer and had instilled some plant juice/honey in the affected eye. In Group B, 23.1%(3) of subjects had similar history.
One subject had diabetes and other had pulmonary tuberculosis in Group A and leukemia (1) and anaphylaxis (1) was seen in Group B subjects.
Majority of patients in both the groups were on topical antibiotics and topical steroids before presentation.

Table 1: Mean size of ucer stromal infltraton and hypopyon on day of Presentation

	Group A:(n=10)	Group B:(n=13)	P value	All patients(n=23)
Mean size of ulcer (±SD); (mm)	4.14±1.58mm	3.15±1.28mm	0.11	3.57±1.47mm
Mean size of stromal infiltration (±SD);(mm)	451±1.48mm	3.38±1.62mm	0.1	3.74±1.52mm
Mcan size of hypopyon (±SD):(mm)	0.92±0.99	0.86±0.99	0.91	0.83±1.00

Ulcer size: Overall, mean size of ulcer is 3.5741.47mm. Mean size of ulcer (1SD) on
day of presentation (Day l) i Group A was 4.14=1.58mm and in Group B. it was
3.15±1.28 mm
Stromal infltration: Mean size of stromal infiltration in Group A was 4.51=1.48mm
and in Group. B, it was 3.38=1.62mm. Overall, it was 374=1.52 mm.
Hypopyoп: Mean size of hypopyon in both the groups was comparable. lt was 0,9240.99 mm in Group A and in Group B, it was 0.8б-O.99mm,
There is no significant difference in size of ulcer, size ofstromal infiltration and size of hypopyon on day of presentation

Margins of ulcer:
Margins of ulcer i bot the groups were well defined.
Site of ulcer in Group A:
Majority (40%) of the subject had central and paracentral involvement of cornea.
Site of ulcer in Group B:
Six (46.2%) subject had both central and paracentral involvement of cornea followed by
central involvement of cornea in 5(38.5%) subjects. One (7.7%) had paracentral involvement and one (7.7%) subject had complete involvement of cornea.

Table 2: Mean percentage change in size of ulcer, mean percentage change in size of stromal infiltration and mean change in size of hypopyon of subjects in Group A

	Mean percentage change as compared to day one				
Variable	Day 3 (mean percentage), (P value)	Day 7 (mcan percentage) (P value)	Day 14 (mcan percentage) (P value)	Day 30 (mean percentage) (P value)	Day 60 (mean percentage) (P value)
Ulcer size	14.07% -0.07 [%decrease	13.81% -0.37 [%decrease]	23.61% -0.25 [%decrease]	47.40% -0.04 [%decrease]	68.83% 0 [%decrease]

Size of stromal infiltration	0.14% -0.95 [%decreasel	9.36% -0.25 [%decrease]	18.60% -0.08 [%decrease]	45.96% -0.01 [%decrease]	61.02% 0 [%decrease]
Size of hypopyon	3.40% -0.69 [%decrease	59.88% -0.05 [%decrease	68.00% (0,06) [%decrease]	50.00% -0.13 [%decrease]	100.00% -0.04 [%decrease]

ln Group B, reduction in size of ulcer was noted on subsequent days after initiation of Moxifloxacin therapy. Mean percentage reduction in size of ulcer on day 3, day 7, day14 and 30 and 60 was 14.07%, 13.81%, 23.61%, 47.40% and 68.83% respectively
Significant difference was found on day 30 and day 60 with values 0.04 and 0.00 on comparison with day of presentation.
ln Group B, there was reduction in size of stromal infiltration on subsequent days from baseline (day1). Mean percentage reduction in size of infiltration on day 3,7,14,30 and 60 was 0.14%, 9.36%, 18.60%, 45.96% and 61.02% respectively. Significant reduction was seen on day 30 and 60 with p values of 0.01 and 0.00 on comparison with day of presentation. ln Group B, percentage reduction in size of hypopyon on day 3.7, 14,30 and day 60 was 3.40%, 59.88%. 68,00%, 50.00% and 100% respectively. Significance with p value of 0.04 was noted on day 60 on comparison with day of presentation.

Table 4: Comparison of mean difference in ulcer size, stromal size and Hypopyon between two groups

	Mean difference in ulcer size	Mean difference in Stromal size	Mean difference in Hypopyon size
Between day one and	**P value**	**P value**	**P value**
3	0.14	0.74	0.77
7	0.24	0.48	0.38
14	0.82	0.31	0.86
30	0.81	0.37	0.54
Day 60	0,45	0.04	0.5

On comparison of two groups, significant difference in change (reduction) in mean size of stromal infiltration from day one to day 60 was observed with statistically significant p value of 0.04 with group B being better. Although, there were differences in terms of change in ulcer size and sire of hypopyon between the groups but were not statistically significant.

Table 5: Percentage of ulcers healed at 14 days, 30 days and 60 days

	Group A(%	Group B(%)	P value
Day 14	0	1(8.33)	
Day 30	0	4(33.3)	
After one month	3(37.5)	4(44.4)	0.77

Healing started after one month in Group A and on 14th day in Group B. There were 37.5% healed ulcers on 60th day of follow up in Group A. The percentage of healed ulcers increased from 8.33% to 44.44% from day 14 to day60 of follow up respectively in group B. There was no significant difference in both groups on final follow up.
Worsening of the ulcer was similar in both groups with no significant difference. One Patient in each group was needed to be started on 2 % saline regimen (topical fortified Vancomycin 5% and Ceftazidime 5%) and referred for therapeutic keratoplasty to higher centre.

DISCUSSIONS

Mean age of the patients was 57.09±18.46 years with a range between 3-80 years of age. Mean age of patients in group A (Combined Fortified cefazolin-tobramycin) was 53.0±22.6 years and in group B (Moxifloxacin monotherapy), it was 60.23±14.73years. In our study, corneal ulcer was seen in all age groups, in accordance with studies reported by Sharma et al.[6]

Males (15,65.2%) outnumbered females (8,34.8%)in both the groups. In group A, 80% (8) patients were males and 20% (2) were females. In group B, 53.8% (7) were males and 46.2% (6) were females. The predominance of corneal ulceration in males was most pronounced in 51-80 years of age, with an overall ratio of male to female patients 2:1. Similar results were observed by Basak et al,[7] Panda et al.[8] This can be correlated to the fact that males were more involved in outdoor activities than females, thus more prone to ocular trauma.
Educational status of the patients played a pivotal role as illiterate patients had poor knowledge and awareness regarding preventive measures and eye care. Literacy, as defined in Census operations, is the ability to read and write with understanding in any language. A person who can merely read but cannot write is not classified as literate. Most of the subjects in both the groups were illiterate (16,70%). Similar results were noted by Gupta et al.[9]
Majority of patients were agriculturists (52.2%,12). Similar occupational predilection was seen by Basak et al.[7] Whereas, in study by Srinivasan et al10,

labourers /farmers contributed ranging from 54-70% and housewives/homemakers 11-13%.

Seasonal variation was quite evident in this study. A significant number of cases of bacterial corneal ulcer were observed during harvesting season of October-November (30.4%). Verma et al,[11] in their study observed increased incidence during harvesting seasons of March-April (35.4%) and November-December (25.8%).

According to description given by patients, attempts were made to remove foreign bodies with application of some herbal preparations in the affected eye. In one patient's eye, honey was instilled. Similar findings were corroborated by Verma et al,[11] and Srinivasan et al,[11] who reported that patients consulted village healers and had used different alternative topical traditional medicines which included breast milk, oil, plant juice and honey.

In present study, out of 23 patients, 8 patients were on topical antibiotic drops (5 in group A and 3 in group B); 5 on topical corticosteroids [2 in group A, and 3 in group B (taken from local chemists)] and 2 on topical antivirals in group A. There was history of over-the-counter use of steroids taken from the local chemists. Basak et al,[7] reported use of steroids inadvertently as one of the implicating factors for corneal ulceration.

None of the patients used contact lens in our study. In contrast, Sharma et al6 and Panda et al8 noted it as one of the commonly associated predisposing factor.

Systemic disease has led to delayed healing of ulcer in a diabetic patient in group A, and in patient with CLL in group B. Chhangte et al,[12] also report similar findings in diabetics.

Two patients were lost to follow up, one in each group. In both the groups, patients were lost to follow up after day 30.

Site of Ulcer: Majority of patients had ulcer involving central and paracentral zone in both the groups followed by central involvement. Observations are comparable to study done by Gangopadhyay et al,[13] and Srinivasan et al.[10]

Size of ulcer: Overall, mean size of ulcer was 3.57±1.47mm. Mean ulcer size on day of presentation in group A were 4.14±1.58mm (maximum diameter) and in group B were 3.15±1.28mm (maximum diameter). There was no significant difference in ulcer size in both the groups at presentation before initiation of therapy. Sharma et al6 in their study, found similar mean ulcer size without any significant p value. However, mean size of ulcer size varied in other studies done by Panda et al,[9] and Prajna et al.[7] On follow up, there was decrease in mean size of ulcer in both the groups on subsequent days. In group A, initially there was no reduction in size of ulcer till day 7 whereas in group B, reduction was seen from start of therapy. But statistically significant reduction in both the groups were noted on day 30 and day 60 (with significant p values of 0.01 and 0.00 in group A and p values 0.04 and 0.00 in group B).

The difference in size of corneal ulcer between the two groups on day 3 (p=0.04) and day 7 (p=0.03) was statistically significant with group B being better.

This implied that Moxifloxacin monotherapy showed better results than fortified group in epithelisation of ulcer initially. This can be attributed to the fact that combination therapy may enhance ocular toxicity and may prevent re-epitheliasation. However, the difference was not significant on day 60 i.e. final follow up. Sharma et al,[6] have corroborated similar reduction in ulcer size in their study.

Size of stromal infiltrate

Overall, mean size of stromal infiltration 3.74±1.52mm. In group A, mean size of stromal infiltration was 4.51±1.48mm and in group B was 3.38±1.62mm. There was no significant difference between the two groups at presentation. On follow up, in group A, there was initial increase in size of infiltration till day 7, then, there was decrease in mean size of stromal infiltration on subsequent days whereas in group B, reduction in stromal infiltration was seen from day 3 onwards.

There was significant difference between the two groups on final follow up (day 60) (p value=0.04) in mean size of infiltration.

We found that, initial resolution in stromal infiltration was better with monotherapy than with fortified medication. This may be due to the fact that risk of first drug being washed away is seen more frequently with fortified drugs as they are used simultaneously. Moreover, difference was also statistically significant on final follow up (day 60). It can thus safely be concurred that resolution of stromal infiltration was better with moxifloxacin monotherapy.

Size of hypopyon: Mean size of hypopyon in group A was 0.86 ±0.98mm and in group B was 0.81 ±1.07mm. Resolution of hypopyon was similar in both fortified group and moxifloxacin group. Early resolution of hypopyon was seen in patients in group A compared to group B but results were not significant on final follow up day.

Mean duration of hospital stay was similar in both the groups. This is because most of the patients in both the study groups refused to come for frequent follow ups so they were treated as inpatients. As opposed to this, study done by Gangopadhyay et al13, stated that monotherapy with fluoroquinolone eye drops led to shorter duration of intensive therapy and a shorter hospital stay compared with combined fortified therapy (tobramycin and cefazolin).

In the present study, outcome was compared in terms of epitheliasation and healing of the ulcer. Epithelialization started earlier in fortified group; however, it was completed earlier in moxifloxacin group. Healing started after one month in fortified group; on 14th day in moxifloxacin group.

Although, more number of patients had healed in group B (44.4%) than group A (37.5%) at final follow up (day 60) but on comparison, data was not statistically significant. In study done by Sharma et al,[6] healing of ulcer was similar in both the groups as seen in our study but there were few differences between these two studies. Duration of their study was of 3 months (90days) with 81.8% and 81.4% healed ulcers in group A and B respectively.

We conclude that topical moxifloxacin monotherapy is equally efficacious as compared to topical combined fortified cefazolin-tobramycin group as initial treatment in clinically suspected bacterial corneal ulcer. Although, initial healing of ulcer was greater with Moxifloxacin group than Fortified group, but, duration of treatment was not shortened with moxifloxacin monotherapy. Compliance of the patients was also more in moxifloxacin group with minimal adverse effects.

Treatment either with conventional combined fortified cefazolin-tobramycin or moxifloxacin monotherapy is found to be equally efficacious. Most of the pathogenic bacterias isolated in our region, respond well to either regimens. Regular follow up is mandatory. Patients should be managed as inpatients in active stage of the disease so that daily assessment is possible and especially in hilly terrains like ours, where patients can not comply for regular and longer follow up.

Response to the therapy should be assessed after 48-72 hours after initiation of therapy. Patients non responsive to the treatment must be started on second line regimen according to antibiotic sensitivity patterns. In present study patient were started on combined fortified vancomycin-ceftazidime topical therapy which was observed as beneficial therapy.

Moxifloxacin monotherapy has been found to be a better alternative for patients who are not willing for admission and do not comply for regular follow up because fortified eye drops need to be timely prepared owing to its variable and short shelf life.

CONCLUSION

We conclude that topical moxifloxacin monotherapy is equally efficacious as compared to topical combined fortified cefazolin-tobramycin group as initial treatment in clinically suspected bacterial corneal ulcer. Although, initial healing of ulcer was greater with Moxifloxacin group than Fortified group, but, duration of treatment was not shortened with moxifloxacin monotherapy. Compliance of the patients was also more in moxifloxacin group with minimal adverse effects.

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