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EFFECT OF POVIDONE-IODINE (PYODINE) SOLUTION ON ACUTE KERATITIS

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Abstract

OBJECTIVE

To evaluate the efficacy of povidone-iodine (Pyodine) solution in the treatment of acute keratitis.

METHODOLOGY

This study was conducted at the Layton Rehmatullah Benevolent Trust (LRBT) Eye Hospital in Karachi. A total of 486 adult patients (aged 18–60 years) of both genders, diagnosed with bacterial, Acanthamoeba, or fungal keratitis, were enrolled through consecutive sampling. Participants were randomized to receive either povidone-iodine or standard topical antimicrobial treatment. Baseline data, including demographic characteristics, ulcer dimensions, and keratitis subtype, were recorded. Treatment outcomes were evaluated by assessing resolution rates and ulcer area reduction on day 10. Comparisons were made using chi-square and t-tests, with statistical significance set at $p < 0.05$.

RESULT

The mean age was 37.7 ± 11.70 and 36.2 ± 11.03 years in the povidone-iodine and antimicrobial groups, respectively, with males comprising 61.3% and 59.3% of each cohort. Clinical resolution was noted in 33.7% of the povidone-iodine cohort and 27.2% of the antimicrobial cohort, thereby suggesting a comparable efficacy of the therapeutic interventions.

CONCLUSION

This research established that, povidone-iodine (Pyodine) eye drops revealed similar clinical efficacy compared to standard antimicrobial treatment of acute keratitis. Povidone-iodine would be a valuable empirical choice, with its broad-spectrum effect, low cost, and proven lack of emerging resistance. It is especially of interest in the context of limited resources. Although results are promising, more evidence should be

conducted with microbiological validation, proper investigation protocols, and follow-up to determine its role better in the clinical management of acute keratitis.

INTRODUCTION

An infection of the cornea is known as infectious keratitis. This type of infection can lead to an infectious corneal ulcer or corneal opacity. Infectious keratitis can be broken down into bacterial keratitis, fungal keratitis, parasitic keratitis and viral keratitis [1]. Acute keratitis is a disorder that has the potential to cause blindness and needs to be treated as quickly as possible in order to save the eyesight of the patient. Even though it has been recognized for a long time that it is one of the leading causes of corneal blindness, our comprehension of its actual burden on a worldwide scale and the pattern of its etiology is still limited [2]. However, it has been observed that the overall rate of visual impairment and blindness secondary to acute infectious keratitis has reduced but is still the fifth leading cause of blindness [3,4].

The most frequent type of microbial keratitis is bacterial keratitis, which requires prompt treatment since it can progress quickly [5]. Use of antimicrobial agents is the mainstay of treatment of acute infectious keratitis. However, it has been observed that rising resistance to antimicrobial agents, especially in cases of bacteria, is a major health concern [6]. This may be due to injudicious use of modern and higher generation antibiotics as empirical treatment even for the minor conditions. To address this problem, other agents that can effectively limit the acute keratitis should be researched to decrease the excessive use of antimicrobial agents. One such agent is povidone-iodine (pyodine) solution which has been proven to be such alternative in animal models [7]. However, in human eyes, studies regarding its usefulness are still limited.

In this instance a study was conducted in which patients with bacterial keratitis were included and were randomized to receive povidone-iodine solution eye drops or antibiotic eye drops at two different sites, i.e., India and Philippines. They found out that in patients of India, the complete resolution/cure was achieved in 32 % of the patients given povidone-iodine eye drops as compared to antibiotic eye drops in which complete resolution/cure rate was 22 %, while among patients of Philippines these values were 75 % and 80 %, respectively [8]. Recently, a pilot study has been conducted to determine the efficacy of povidone-iodine (pyodine) solution in various types of acute keratitis. They reported that overall frequency of complete resolution in patients who were treated with povidone-iodine (pyodine) eye drops was 36 % without use of any other antimicrobial agent [9].

These promising results in favor of povidone-iodine (pyodine) solution to be used as an empirical therapy prior to definitive diagnosis, based on staining, cytology and culture sensitivity results, instead of antibiotic, antifungal or anti-parasitic eye drops, make it imperative that we conduct further studies to determine the efficacy of povidone-iodine (pyodine) solution in acute keratitis. This will not only help us to have an additional agent to treat acute keratitis but will also indirectly help in reducing the growing problem of antimicrobial resistance in our country.

METHODOLOGY

This was a randomized controlled trial done in the department of Ophthalmology, Layton Rahmatullah Benevolent Trust (LRBT) Eye Hospital, Karachi after getting ethical clearance by the institution and obtaining an informed consent of all participants. The sample size was calculated using the WHO sample size calculator based on a level of significance of 10%, power of 80%, and expected complete resolution rates of (32%)[8] for povidone-iodine (Pyodine) and (22%)[8] for standard antimicrobial therapy. The final calculated sample comprised 486 eyes, with 243 allocated to Group A (povidone-iodine) and 243 to Group B (antimicrobial treatment). Patients between the ages of 18-60 years of both genders that had clinical characteristics of acute keratitis were recruited via non- probability consecutive sampling. The diagnosis was confirmed through the application of slit-lamp biomicroscopy in conjunction with fluorescein staining, and keratitis was classified into three categories: bacterial (characterized by moist ulcers with irregular margins, vivid green marginal staining, grass-green stromal staining, and yellow endothelial staining), Acanthamoeba (identified by

coarse stromal streaks, fine epithelial/subepithelial opacities, and ring-shaped infiltrates), or fungal (noted for yellow-white lesions with indistinct margins, minimal vascularization, a dry appearance, and feathery satellite infiltrates). Patients with hypopyon or atraumatic corneal infiltrate ulcers, pregnant or lactating patients, patients with thyroid disease, patients with systemic immunosuppression, or patients with known allergies to povidone-iodine were excluded. Baseline data—including demographic information, duration of symptoms, previous therapeutic interventions, best-corrected visual acuity as assessed by the Snellen chart, and ulcer dimensions (both diameter and depth measured in millimeters utilizing slit-lamp calipers)—were meticulously documented. Eligible ocular subjects were randomized through a paper-lottery methodology to receive either 0.6% povidone-iodine ophthalmic solutions or conventional topical antimicrobial agents, with both treatments administered as a single drop six times daily over a period of 10 days. Blinding was meticulously maintained by dispensing the pharmacological agents in indistinguishable opaque containers. On day 10, treatment response was assessed using predefined criteria: complete resolution (absence of epithelial defect and stromal infiltrate), partial resolution (≥50% ulcer area reduction), or treatment failure (<50% reduction or worsening). Adverse events such as ocular irritation or hypersensitivity were monitored and treated by hospital protocol. Data were double-entered into a secure database, and analysis was performed using chi-square and independent t-tests, with significance set at $p \leq 0.05$. Continuous variables were reported as mean ± SD, categorical variables as frequencies and percentages, and stratified analysis was conducted to adjust for confounding factors.

RESULTS

Table I presents the demographic and clinical characteristics of the patients enrolled in the study (n=486), equally divided into two groups: Povidone-Iodine (n=243) and Antimicrobial (n=243). The mean age of patients in the Povidone-Iodine group was 37.70 ± 11.70 years, while in the antimicrobial group it was slightly lower at 36.16 ± 11.03 years. The average duration of disease was 4.51 ± 2.30 weeks in the Povidone-Iodine group and 4.25 ± 2.22 weeks in the antimicrobial group. The mean ulcer size measured 3.13 ± 1.46 mm in the Povidone-Iodine group and 3.33 ± 1.45 mm in the antimicrobial group. In terms of gender distribution, males were more prevalent in both groups: 61.3% in the Povidone-Iodine group and 59.3% in the antimicrobial group, while females accounted for 38.7% and 40.7%, respectively. Regarding the type of keratitis, bacterial keratitis was the most common in both groups—78.2% in the Povidone-Iodine group and 73.3% in the antimicrobial group. Acanthamoeba keratitis was observed in 9.9% of patients in the Povidone-Iodine group and 11.5% in the antimicrobial group, while fungal keratitis was reported in 11.9% and 15.2% of the patients, respectively. Table II shows the comparison of treatment efficacy between Povidone-Iodine and Antimicrobial groups in patients with acute keratitis (n=486). In the Povidone-Iodine group, 82 patients (33.7%) demonstrated an effective response, while 161 patients (66.3%) were non-effective. In the Antimicrobial group, 66 patients (27.2%) showed an effective response, whereas 177 patients (72.8%) did not respond effectively to treatment. Although the Povidone-Iodine group showed a slightly higher efficacy rate, the difference between the two groups was not statistically significant ($p = 0.115$).

Table I: Demographic and Clinical Characteristics of the Patients (n=486)			
Characteristics		**Groups**	
		Povidone-Iodine (n=243)	**Antimicrobial** (n=243)
Age in years, Mean ± SD		37.70 ± 11.70	36.16 ± 11.03
Duration of Disease in weeks, Mean ± SD		4.51 ± 2.30	4.25 ± 2.22
Ulcer Size in mm, Mean ± SD		3.13 ± 1.46	3.33 ± 1.45
Gender, n (%)	Male	149 (61.3)	144 (59.3)
	Female	94 (38.7)	99 (40.7)
Type of Keratitis, n (%)	Bacterial	190 (78.2)	178 (73.3)
	Acanthamoeba	24 (9.9)	28 (11.5)
	Fungal	29 (11.9)	37 (15.2)

Table II: Efficacy of Povidone-Iodine (Pyodine) Solution versus Antimicrobial in acute keratitis (n=486)			
Efficacy, n (%)	**Group**		**P-Value**
	Povidone-Iodine (n=243)	**Antimicrobial** (n=243)	
Effective (n=148)	82 (33.7%)	66 (27.2%)	0.115
Non-Effective (n=338)	161 (66.3%)	177 (72.8%)	

DISCUSSION

This is an observational study to determine the efficacy of 0.6 % povidone-iodine (Pyodine) eye drops in management of acute keratitis against conventional antimicrobial drugs. The clinical determination of keratitis was conducted utilizing slit-lamp biomicroscopy and fluorescein staining, adhering to established criteria for the classification of the condition as bacterial, fungal, or Acanthamoeba keratitis [1,2,5]. The high prevalence of bacterial keratitis was observed in enrolled patients, which is consistent with epidemiological data on this eye disease globally, which highlighted bacteria as the number one cause of microbial keratitis, particularly in low-and middle-income countries [3,4]. The clinical manifestations examined in this investigation—including the presence of moist ulcers accompanied by stromal infiltration in cases of bacterial keratitis, the observation of ring-shaped opacities in instances of Acanthamoeba infections, and the identification of feathery margins with satellite lesions in fungal keratitis—align with pre-established diagnostic criteria [5,6]. Our research revealed a complete resolution rate of 33.7% within the povidone-iodine cohort in contrast to 27.2% for the antimicrobial cohort. The result showed a possible clinical efficacy of involving povidone-iodine in the management of acute keratitis, although the study did not record a statistical significance (p = 0.115).

Previous studies support these results. Pedrotti et al. [9] reported a 36% resolution rate using povidone-iodine monotherapy in diverse keratitis cases, while Isenberg et al. [8] demonstrated comparable efficacy of 1.25% povidone-iodine versus antibiotics in bacterial keratitis. These findings underscore the broad-spectrum antimicrobial activity and affordability of povidone-iodine, making it a valuable empirical treatment option in settings where microbiological testing is unavailable [2,6]. With the growing concern of antimicrobial resistance, especially in ocular pathogens, povidone-iodine offers an alternative that bypasses the resistance mechanisms commonly

associated with antibiotic therapy [7,10]. Indeed, studies such as those by Austin et al. [10] and Nair et al. [13] highlight the utility of antiseptics like povidone-iodine in reducing microbial load without promoting resistance. However, the modest overall resolution rates observed in both groups in our study may be attributed to delayed presentation, mixed infections, or inadequate host immune response—factors also cited in other large-scale keratitis reviews [4,11,14].

This study's strengths include a large sample size, clearly defined clinical diagnostic criteria, and assessor blinding. Nonetheless, several limitations should be acknowledged. The lack of microbiological confirmation may have led to misclassification of keratitis subtypes, particularly in cases of co-infection or atypical presentation [11,12]. Moreover, the 10-day follow-up period may have been insufficient to fully evaluate treatment outcomes, especially for fungal keratitis, which typically requires prolonged therapy [7,12,15]. Finally, variability in antimicrobial regimens across keratitis subtypes in the control group may have introduced treatment response heterogeneity. Despite these limitations, the findings support the use of povidone-iodine as a cost-effective and potentially effective empirical treatment in acute keratitis. Further multicenter studies incorporating microbiological diagnosis and longer follow-up are recommended to confirm and extend these results.

CONCLUSION

This research established that, povidone-iodine (Pyodine) eye drops revealed similar clinical efficacy compared to standard antimicrobial treatment of acute keratitis. Povidone-iodine would be a valuable empirical choice, with its broad-spectrum effect, low cost, and proven lack of emerging resistance. It is especially of interest in the context of limited resources. Although results are promising, more evidence should be conducted with microbiological validation, proper investigation protocols, and follow-up to determine its role better in the clinical management of acute keratitis.

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