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The Reducing Adenoviral Patient-Infected Days (RAPID) Study: Safety and Tolerability of One-Time, In-Office Application of 5% Povidone-Iodine in the Treatment of Adenoviral Conjunctivitis

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Introduction

Adenoviral conjunctivitis (Ad-Cs) is a highly contagious disease that can quickly spread through clinics, homes, schools and work places with significant morbidity.

There is no FDA-approved treatment for Ad-Cs; however, the use of several off-label treatments have been reported, including a one-time administration of ophthalmic 5% povidone-iodine (PVP-I) [1-4]. In a 2013 survey of eye care practitioners, one-third of respondents reported using off-label ophthalmic 5% PVP-I in the treatment of Ad-Cs[5].

The safety and tolerability of 5% ophthalmic PVP-I has not been systematically evaluated in eyes with AdCs. Therefore, it is important to evaluate the safety and tolerability of PVP-I in a double-masked randomized clinical trial with placebo control.

The Reducing Adenoviral Patient Infected Days (RAPID) study is a double-masked, randomized planning trial to estimate parameters for designing a definitive clinical trial of the safety and efficacy of 5% PVP-I in the treatment of Ad-Cs.

Methods

Of 212 participants screened, 56 eligible participants with red eye symptoms ≤4 days and a positive adenoviral rapid immunoassay were randomized to a one-time administration of ophthalmic 5% PVP-I or preservative free artificial tears (AT).

- Safety was assessed by corneal fluorescein staining (baseline, immediate post-administration and Day 1) and visual acuity (VA) (baseline and Day 1).
- Tolerability was assessed using participant-rated overall ocular discomfort (baseline, immediate post- administration and on Day 1) and clinician-rated participant discomfort (immediately post-administration).

Results

- In the 5% PVP-I group, corneal staining increased immediately post- administration but returned to baseline levels by Day 1 (Figure 1).
- There was no change in VA between baseline and Day 1 in either 5% PVP-I or AT groups (p=0.87).
- In the 5% PVP-I group, there was no change in participant-rated overall discomfort immediately post-administration (p=0.78) or on day 1 (p=0.10), compared to baseline (Figure 2).
- In the AT group, participant-reported overall discomfort was lower immediately post- administration but returned to baseline levels by Day 1 (Figure 2).
- One adverse event was reported in the 5% PVP-I group on Day 1 that was classified as not related to treatment.
- The unmasked clinician-rated overall patient discomfort was higher in the 5% PVP-I group (5.6 ± 2.9) compared to the AT group (2.5 ± 2.7, p=0.0002).

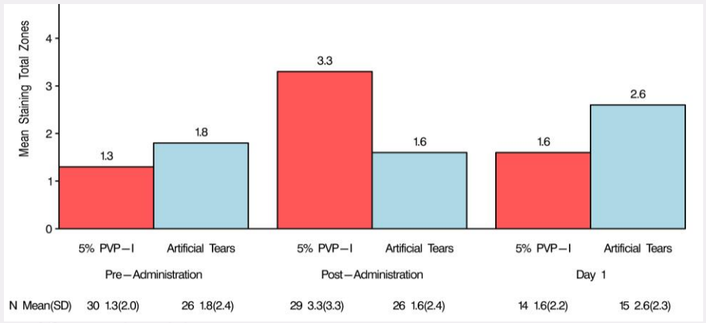

Figure 1. Total corneal fluorescein staining.
Mean corneal staining was significantly increased immediately post-administration in the 5% PVP-I group. There was no difference in mean staining in the AT group.

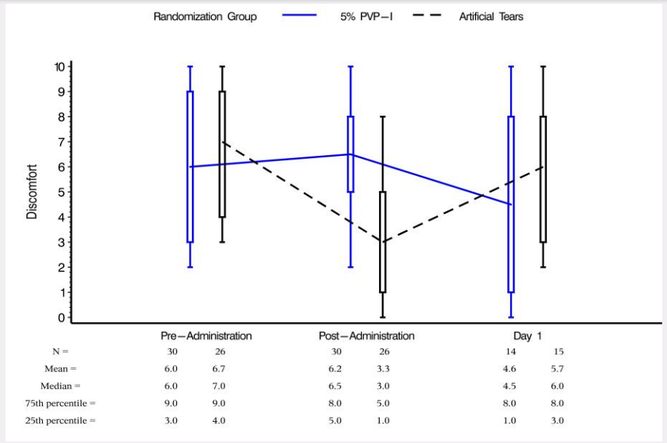

Figure 2. Participant-rated overall ocular discomfort
There was no difference in baseline and immediate post-administration overall discomfort in the 5% PVP-I group. In the AT group, overall discomfort immediately post-administration was lower than baseline rating. On Day 1, there was no difference in participant-rated overall discomfort compared to baseline levels.

Discussion

For decades, PVP-I has been used as an ophthalmic surgical antiseptic; however, there are limited in vivo studies assessing patient tolerability to exposure in the context of Ad-Cs.

In this study, by Day 1, corneal staining was minimal and was comparable to levels previously reported in successful daily wear and extended wear contact lens patients[6]. Participants had stable VA and were minimally symptomatic, providing evidence that supports the treatment with 5% PVP-I was safe in individuals with presumed Ad-Cs.

The results of this study demonstrate that although there is statistically significant corneal staining post-administration of 5% PVP-I, by day 1, corneal staining is equivalent to treatment with artificial tears alone.

References

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Clinical Trial Registration: https://clinicaltrials.gov/ct2/show/NCT02472223