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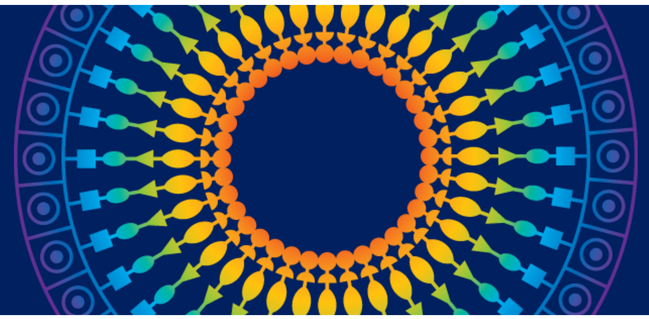
Reducing Adenoviral Patient Infected Days (RAPID) Study: Association of Clinical Signs and Symptoms with qPCR confirmed Adenoviral Conjunctivitis

Shorter, Ellen[1]; Migneco, Mary[2]; Harthan, Jennifer S.[3]; Whiteside, Meredith[4]; Morettin, Christina[3]; Than, Tammy[5]; Johnson, Spencer[6]; Olson, Christian K.[7]; Huecker, Julia[2]; Hartwick, Andrew T.[8]; Gordon, Mae O.[2]

1. Ophthalmology and Visual Sciences, University of Illinois at Chicago, Chicago, IL, United States. 2. Washington University in St. Louis, St. Louis, MO, United States. 3. Illinois College of Optometry, Chicago, IL, United States. 4. University of California School of Optometry, Berkeley, CA, United States. 5. University of Alabama, Birmingham, Birmingham, AL, United States. 6. Northeastern State University, Tahlequah, OK, United States. 7. Brooke Army Medical Center, San Antonio, TX, United States. 8. Ohio State University, Columbus, OH, United States.



PURPOSE

- There is no FDA-approved treatment for adenoviral conjunctivitis (Ad-Cs), a highly contagious eye infection.
- The RAPID pilot study is a multi-centered randomized clinical trial enrolling patients with suspected Ad-Cs to test the effectiveness of 5% ophthalmic Betadine treatment.
- We compare clinical signs and symptoms of patients who tested qPCR positive/negative for Ad-Cs at screening.

METHODS

- Eligibility included:
  - Informed consent, age 18 or older
  - Red eye symptoms ≤4 days in the first affected eye
- Patients rated ocular symptoms on 10 point scale – 0 (not bothersome) to 10 (very bothersome).
- Clinicians evaluated clinical signs on a scale of 1 (absent) to 5 (severe) and recorded the presence of subconjunctival hemorrhage and palpable lymph nodes.
- qPCR assay of conjunctival swabs performed using adenovirus 3' and 5' hexon primers and Integrated Cycler (DiaSorin Molecular)

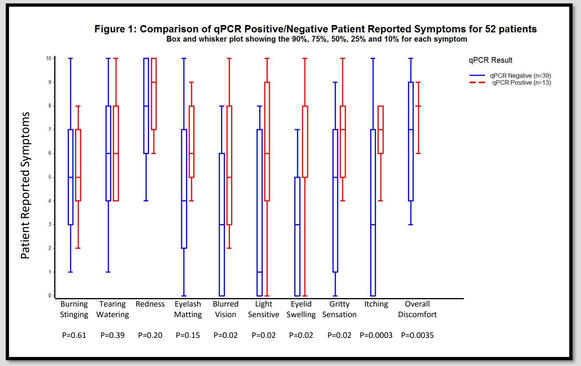
RESULTS

At the screening visit, conjunctival swabs were collected from the first affected eye of 52 patients. 25% (13/52 eyes) were deemed positive for Ad-Cs based on qPCR assay. Demographic characteristics are presented in Table 1.

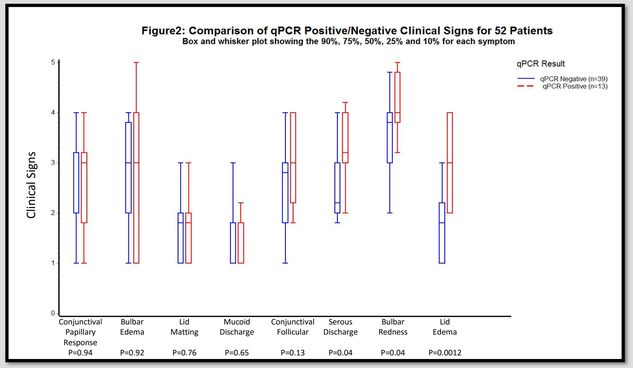
TABLE 1: Demographic characteristics (n=52)

	qPCR					
	Negative (n=39)		Positive (n=13)		All	
	N	%	N	%	N	%
Sex						
Male	10	58.8	7	41.2	17	100
Female	29	82.9	6	17.1	35	100
Race						
American Indian / Alaska Native	3	50	3	50	6	100
Asian	3	100	0	0	3	100
Black or African American	8	66.7	4	33.3	12	100
White	22	78.6	6	21.4	28	100
More than one race	1	100	0	0	1	100
Unknown or Unreported	2	100	0	0	2	100
Age (Mean ± Standard deviation)	34.5 ± 11.6		39.7 ± 13.1		35.8 ± 12.1	

Statistically significant differences were found between qPCR positive/negative patients for 6 of the 10 symptoms (itching, eyelid swelling, blurred vision, light sensitivity, gritty/sandy sensation and overall discomfort).

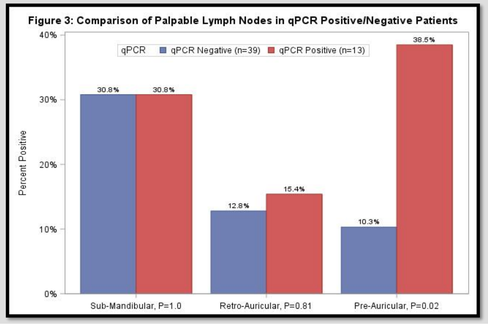


Statistically significant differences were found between qPCR positive/negative patients for 3 of the 8 clinical signs (lid edema, clear serous discharge and bulbar redness).



No difference was detected between qPCR positive/negative subjects for subconjunctival hemorrhage.

A statistically significant difference was found between qPCR positive/negative patients for presence of palpable pre-auricular node - 38.5% (5/13) in qPCR positive patients and 10% (4/39) in qPCR negative patients.



CONCLUSION

No single sign or symptom clearly distinguished qPCR positive patients from other patients who presented with red eye. This considerable overlap may highlight why it is difficult to diagnose Ad-Cs clinically. Patients with confirmed Ad-Cs had more serous discharge, greater bulbar redness and had a higher incidence of palpable pre-auricular nodes. Interestingly, no difference was detected in conjunctival follicular response, which is often emphasized in the textbook diagnosis of Ad-Cs.

This is one of the first reports of patient symptoms, clinical signs and qPCR confirmed Ad-Cs. We are continuing to enroll patients with a goal of screening 200 patients. We will attempt to identify a cluster of signs and symptoms that differentiates qPCR positive Ad-Cs from other causes of red eye.

SUPPORT

- DiaSorin Molecular LLC (Cypress, CA) for loaning the study a Liaison MDX instrument for qPCR analysis.
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- Clinical Trial Registration: https://clinicaltrials.gov/ct2/show/NCT02472223