Board # 75

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

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

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

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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 presumed Ad-Cs to test the effectiveness of 5% ophthalmic Betadine treatment.
- We compare clinical signs and symptoms for those with and without molecularly-confirmed (qPCR) Ad-Cs.

METHODS

- Eligibility included:
  - informed consent
  - age 18 or older
  - red eye symptoms ≤4 days in the first affected eye
- Patients rated their ocular symptoms on a 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.

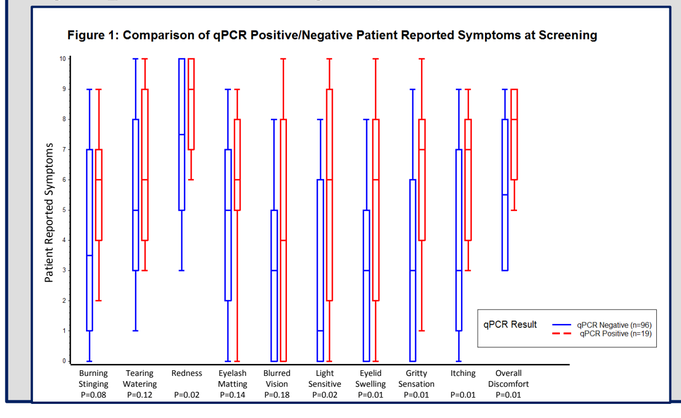
RESULTS

At the screening visit, conjunctival swabs were collected from the first affected eye of 115 patients of which 16.5% (19/115 eyes) were confirmed Ad-Cs by qPCR. Demographic characteristics are presented in Table 1.

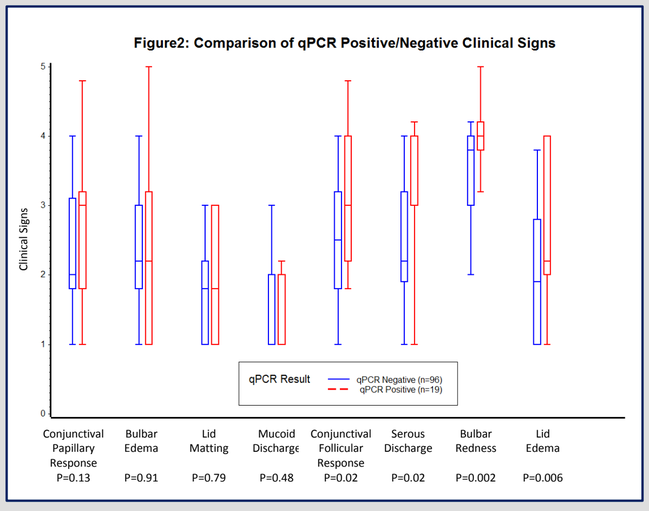
Table 1: Demographic Characteristics of Patients Screened (n=115)

	qPCR					
	Negative (n=96)		Positive (n=19)		All	
	N	%	N	%	N	%
SEX						
Male	42	81	10	19	52	100
Female	54	86	9	14	63	100
RACE						
American Indian / Alaska Native	5	50	5	50	10	100
Asian	12	100	0	0	12	100
Native Hawaiian or Other Pacific Islander	2	100	0	0	2	100
Black or African American	19	79	5	21	24	100
White	49	86	8	14	57	100
More than one race	3	100	0	0	3	100
Unknown or Unreported	6	86	1	14	7	100
AGE (Mean ± Standard deviation)	32.6 ± 14.5		36.9 ± 15.4		33.3 ± 14.7	

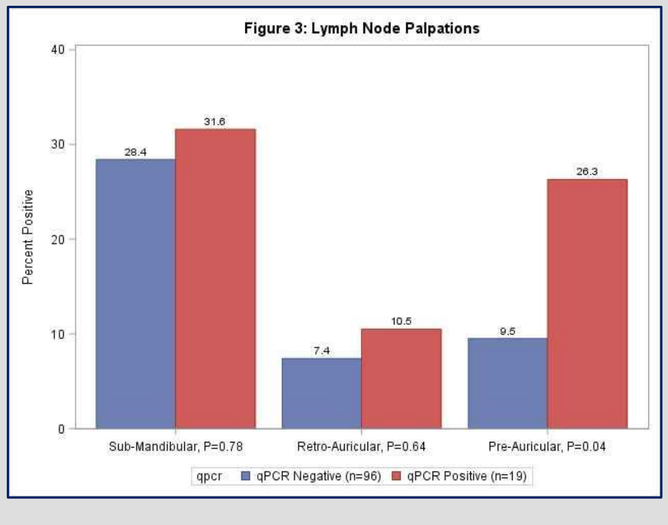
Patients with confirmed Ad-Cs reported statistically significant greater itching, lid swelling, redness, light sensitivity, gritty sensation and overall discomfort (6 of the 10 symptoms surveyed).



Clinicians reported statistically significant greater lid edema, serous discharge, bulbar redness and conjunctival follicular response in patients with confirmed Ad-Cs. No statistically significant difference between the two groups was found for lid crusting, mucoid discharge, bulbar conjunctival edema or conjunctival papillary response.



A palpable pre-auricular node was present in 26.3% (5/19) of qPCR positive patients and in 9.5% (9/96) of 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 were more likely to have lid edema, serous discharge, bulbar redness, conjunctival follicles and had a higher incidence of palpable pre-auricular nodes.

This is one of the first reports correlating patient symptoms and clinical signs with 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