

History

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Reliability of a novel method to assess acute bacterial conjunctivitis by photographs with a smartphone: a more reliable patient-centered care

Medical imaging is the technique and process of creating visual representations of parts of the body for clinical analysis and medical intervention. In this regard, photography is a form of imaging that can be used to precisely document patients' clinical presentation. Medical photography offers a unique opportunity to document the patient at the initial presentation and also ascertain the condition's progress throughout and after treatment. Photographs, taken over some time or at specific endpoints, represent a medical record that enables clear communication regarding patients' clinical improvement or deterioration. Mobile Health (mHealth) offers the possibility to perform a fast diagnosis, provide a feedback system to monitor health status, and provide easy access to treatment and rehabilitation.

The present study aimed to investigate the inter-method reliability between inspective assessment and a new clinical evaluation method through photographs of the affected eye in acute bacterial conjunctivitis (ABC) patients using a smartphone. The clinical evaluation method investigated in this study takes advantage of a patient's caregiver taking photographs of the eye of interest through a mobile study-specific App. This new method, namely, could be proved reliable for the clinical evaluation of ABC. Therefore, it may allow monitoring of the patient remotely in a non-clinical setting, such as at home, set by forwarding the pictures of the affected eye to the physician for his/her clinical assessment. Thus, this may represent a significant breakthrough toward more reliable patient-centered care.¹ Furthermore,

taking photographs using a smartphone could enable a person assisting the patient to capture suitable pictures of the affected eye at home after being instructed by the Investigator during the first visit without being required to return to the physician to be closely monitored. Thus, mobile applications incorporating clinical photography might offer the potential to increase access to patient-centered care and, therefore, to improve outcomes.^{2,3}

This study was an observational, prospective, inter-method reliability study conducted in three sites in Italy (Figure 1). Detailed methodology is reported as Supplementary Digital Material 1 (Supplementary Text File 1, Supplementary Table I and II).

Twenty-one patients were enrolled. The median age was 52 years (interquartile range: 41-67 years). Patients were mostly females (57.12%) and all whites (100%).

The study eye was the right one for most patients (71.43%). Eleven (52.38%) patients reported at least one previous disease or surgery. The most common medical history findings were metabolism and nutrition disorders (N.=4, 19.05%, including three patients with type 2 diabetes mellitus), hypertension (N.=4, 19.05%), and hypothyroidism (N.=3, 14.29%).

The ocular diseases and surgeries of enrolled patients are shown in Table I. Six (6, 28.57%) patients reported at least one disease to the study eye, five (23.81%) to the fellow eye, and four (19.05%) to both eyes. The most common ocular disease was glaucoma, reported by two patients in both eyes (9.52% as concomitant (*i.e.*, event flagged as 'ongoing')). Other diseases were angle closure glaucoma, cataract, and keratoconus, reported by one patient in both eyes, and retinal vein occlusion, reported by one patient in the study eye only. Among ocular surgical and medical procedures, the most frequent was cataract surgery, reported by three patients (14.29%). In addition, glaucoma surgery and iridotomy were reported by one patient each in both eyes.

Of the 21 patients enrolled in this study, 20 (95.24%) completed baseline and follow-up visits. One patient discontinued the study due to withdrawal of consent.

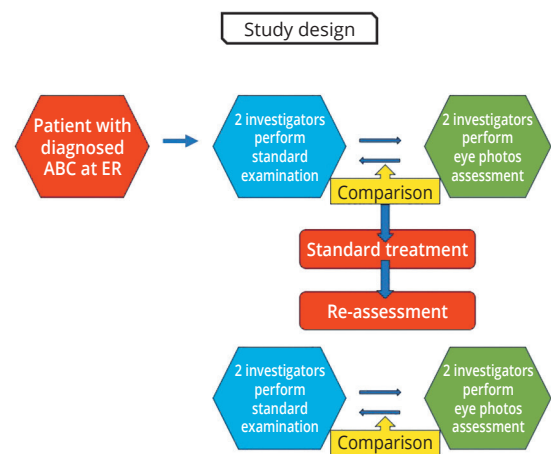


Figure 1.—Study design.

TABLE I.—Ocular diseases and surgeries of enrolled patients (N.=21).

MedDRA System organ class / Preferred term / Ongoing status	Study eye 6 (28.57%)	Fellow eye 5 (23.81%)	Both eyes 4 (19.05%)	Total 6 (28.57%)
Eye disorders	5 (23.81%)	4 (19.05%)	4 (19.05%)	5 (23.81%)
Angle closure glaucoma	1 (4.76%)	1 (4.76%)	1 (4.76%)	1 (4.76%)
Ongoing	1 (4.76%)	1 (4.76%)	1 (4.76%)	1 (4.76%)
Cataract	1 (4.76%)	1 (4.76%)	1 (4.76%)	1 (4.76%)
Not ongoing	1 (4.76%)	1 (4.76%)	1 (4.76%)	1 (4.76%)
Glaucoma	2 (9.52%)	2 (9.52%)	2 (9.52%)	2 (9.52%)
Ongoing	2 (9.52%)	2 (9.52%)	2 (9.52%)	2 (9.52%)
Keratoconus	1 (4.76%)	1 (4.76%)	1 (4.76%)	1 (4.76%)
Ongoing	1 (4.76%)	1 (4.76%)	1 (4.76%)	1 (4.76%)
Retinal vein occlusion	1 (4.76%)	0 (0.00%)	0 (0.00%)	1 (4.76%)
Ongoing	1 (4.76%)	0 (0.00%)	0 (0.00%)	1 (4.76%)
Surgical and medical procedures	4 (19.05%)	4 (19.05%)	3 (14.29%)	4 (19.05%)
Cataract operation	3 (14.29%)	3 (14.29%)	2 (9.52%)	3 (14.29%)
Not ongoing	3 (14.29%)	3 (14.29%)	2 (9.52%)	3 (14.29%)
Glaucoma surgery	1 (4.76%)	1 (4.76%)	1 (4.76%)	1 (4.76%)
Not ongoing	1 (4.76%)	1 (4.76%)	1 (4.76%)	1 (4.76%)
Iridotomy	1 (4.76%)	1 (4.76%)	1 (4.76%)	1 (4.76%)
Not ongoing	1 (4.76%)	1 (4.76%)	1 (4.76%)	1 (4.76%)

Percentages were computed on patients belonging to the Enrolled Set.

Patients with more than one ocular medical condition or multiple occurrences of the same ocular condition were counted only once for each condition/row.

Patients with ocular medical condition reported in both eyes were counted both for the 'study eye' category and for the 'fellow eye' category.

The Concordance Results are reported in the Supplementary Digital Material 2 (Supplementary Text File 2, Supplementary Table III, IV, V, VI).

Nowadays, photography is widely used in several areas of clinical practice and research, including ophthalmology. Gebresilliasie *et al.* investigated the trachoma grading of 269 children by three independent graders in field conditions compared with a photographic review, showing a very high agreement between the consensus photographic grade and the consensus in-field grade. Conjunctival photography through mobile applications may offer several benefits over direct clinical observation. Medical photography provides a unique opportunity to monitor patients longitudinally and assess the therapeutic responses quantitatively and qualitatively. Mobile applications are scalable and low-cost resources that can improve the quality of care and capture patient-reported outcomes (PROs).⁴ Smartphones come with a digital camera, coaxial light source, video capturing software, and the innate ability to share information in real-time required for proper imaging. Moreover, the connectivity of smartphones and their password protection and encryption make them a robust and secure tool for patient care.⁵ Mobile health is the new edge of healthcare innovation; its services and applications propose healthcare delivery anytime and anywhere with low and affordable costs, increasing remote monitoring of patients.⁴

The present study aimed to investigate the inter-method reliability between inspective assessment and a new clinical evaluation method through photographs of the affected eye in patients with bacterial conjunctivitis using a smartphone. The inter-method reliability,

estimated through the ICC, was very elevated, equal to 0.96 (95% CI: 0.916, 0.988) for the total score, indicating an excellent concordance between the two methods. When considering the three cardinal signs separately, all the ICCs also revealed excellent concordance, ranging from 0.92 to 0.96. The exploratory analyses conducted separately for the baseline and the follow-up visits also found elevated ICC point estimates, thought affected by high variability.

The assessment through photographs showed a 100% (95% CI: 88%, 100%) sensitivity, indicating an excellent ability of the method to identify ill eyes correctly. The specificity, *i.e.*, the ability to correctly identify 'healthy' eyes, was also elevated, equal to 82%. However, this estimate was affected by a high variability due to the low number of 'healthy' eyes included. The positive and negative predicted values were also very elevated, 94% and 100%, respectively, suggesting a good ability of the photographic assessment to correctly identify ill and healthy eyes, respectively, in a population characterized by a quite high prevalence of the disease.

In conclusion, the photographic method's inter-method reliabilities, sensitivity, and specificity were excellent. Therefore, the photographic evaluation of patients suffering from acute bacterial conjunctivitis can allow an accurate follow-up of the evolution of the pathology, which needs to be carried out in clinical practice due to the difficulty of re-evaluating the patient in a clinical setting within a short timeframe. Furthermore, the photographic method could also be usefully employed in clinical trials requiring continuous patient monitoring to compare the speed at which different therapeutic approaches achieve control of disease signs.

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References

1. Rose PW, Harnden A, Brueggemann AB, Perera R, Sheikh A, Crook D, *et al.* Chloramphenicol treatment for acute infective conjunctivitis in children in primary care: a randomised double-blind placebo-controlled trial. *Lancet* 2005;366:37–43.
2. Broman KK, Poulouse B, Evans H, Fernandes-Taylor S.

Apps incorporating clinical photography offer the potential to improve care. *Bull Am Coll Surg* 2016;101:44.

3. Cicchetti DV. Guidelines, Criteria, and Rules of Thumb for Evaluating Normed and Standardized Assessment Instruments in Psychology. *Psychol Assess* 2014;6:284–90.

4. Silva BM, Rodrigues JJ, de la Torre Díez I, López-Coronado M, Saleem K. Mobile-health: A review of current state in 2015. *J Biomed Inform* 2015;56:265–72.

5. Bifolck E, Fink A, Pedersen D, Gregory T. Smartphone imaging for the ophthalmic examination in primary care. *JAAPA* 2018;31:34–8.

Conflicts of interest

The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Authors' contributions

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Marino Carnovali. Michele Figus, Luca Mario Rossetti, Chiara Posarelli, Dario Romano, Niccolò Castellino, and Teresio Avitabile. The first draft of the manuscript was written by Giorgio Ciprandi. All authors commented the draft. All authors read and approved the final version of the manuscript.

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Supplementary data

For supplementary materials, please see the HTML version of this article at www.minervamedica.it

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