Telemedicine for ROP: An Update

A remote screening program can leverage the efforts of a single skilled screener.

BY DARIUS M. MOSHFEGHI, MD

There is a classic mythology regarding retinopathy of prematurity (ROP). One story line in this mythology is that, if we could only develop new therapies for this blinding disease, we could save many infants from a lifetime of blindness. The reality, however, is that most of these babies go blind not for lack of treatment, but because they were not examined in a timely fashion, for a variety of reasons. When infants are screened, and those needing treatment are identified and treated in a timely manner, intervention is highly effective in preserving vision.1

Telemedicine offers a unique opportunity to eliminate or greatly reduce blindness from ROP. We know whom to screen for ROP, and we know when to screen. We also know that, with the care of experienced specialists, blindness from ROP is preventable in up to 99% of babies receiving treatment for ROP.2 This suggests that we must change our paradigm, our goal, from seeking new treatments to ensuring all eligible babies are in fact being screened, so that they can be offered appropriate and timely treatment. Telemedicine is poised to help us do that.

Screening for ROP is currently performed in most situations with binocular indirect ophthalmoscopy (BIO). Among the advantages of BIO, it is a familiar modality that provides a 3-D view, and it is easy to manipulate the patient to improve the view. However, BIO also has significant disadvantages that are not often highlighted: It lacks reproducibility and precision, does not facilitate longitudinal tracking, provides no hard copy, requires interpretation (zone, stage, and presence of plus disease), and is not useful for education or conducive to use in studies. In addition, there can be gaps in continuity in the event an experienced screener is unavailable.

SCREENING CRUNCH

Currently in the United States there is an ROP screening crunch due to the confluence of several factors. In 2006 there was a major revision of recommendations for screening,3 which led to increased eligibility for screening, increased frequency of screening, and more intensive exams per patient. In the same year, a survey by the American Academy of Ophthalmology of members who provided ROP screening (www.aao.org) found that only 77% of those currently providing the service intended to continue doing so, for the most part due to financial issues.

Taken together, these changes meant that the number of infants to be screened increased by a third, with each infant needing more examinations, but at the same time there was a decrease in the number of ophthalmologists with sufficient knowledge, experience, and willingness to provide the screening.

PROMISE OF TELEMEDICINE

With an increase in the demands of screening and a reduction in the workforce to carry it out, the pool of existing talented, experienced ROP screeners must be better leveraged to accomplish the job. Telemedicine allows the opportunity to achieve this.

The Photo-ROP trial,4,5 the design of which included a direct comparison of telemedicine with bedside BIO, found the 2 technologies to be essentially equivalent. The Photo-ROP results highlighted the fact that BIO provides interpretations, and, while in practice these interpretations are always assumed to be correct, this was not always the case in the study.

An ongoing multicenter trial, Telemedicine Approaches to Evaluating Acute-phase ROP, or e-ROP (http://clinicaltrials.gov/ct2/show/NCT01264276), is also comparing remote evaluations to the so-called “gold standard” of BIO. The choice of comparator is unfortunate, because another storyline in the mythology of ROP is that all screeners are equivalent, but this...
Screening program identified clinically significant eye diseases in a significant percentage of healthy babies.  
By Li Li-Hong, MD

Screening for ocular pathology in newborn children may lead to early detection and treatment of eye diseases, which may in turn help to preserve visual function and prevent blindness in these children. We performed a study to establish the effectiveness of an eye-screening program to detect ocular pathology in healthy, full-term neonates in our facility.

The Maternal and Children’s Hospital is located in Kunming, the capital of Yunnan province in China. In a 27-month period beginning in May 2010 we screened 8439 healthy neonates; 7863 were gestational age 37 weeks or more at birth, and 576 were less than 37 weeks. On average, not including preterm infants, screening took place 2.89 days after birth. The screening rate was high, capturing 88.29% of all babies born in the hospital. Excluded from screening were those with systemic disease or whose mothers had a sexually transmitted disease.

The screening exam included external eye examination, pupillary light reflex, red reflex, opacity of refractive media, and anterior and posterior segment examination. Equipment used included flashlight, retinoscope, hand-held slit-lamp biomicroscope, and a wide-angle digital retinal image acquisition system (RetCam II, Clarity Medical Systems). Five retinal images were taken at different angles in each eye to provide a complete picture of retinal status.

RESULTS

Among the babies screened, 76.81% were (thankfully) normal. Identified as abnormal were 23.19%, including 20.96% with retinal hemorrhage and 2.28% with other pathologies. There was a long list of other abnormalities, each seen in small percentages of patients, including subconjunctival hemorrhage, familial exudative vitreoretinopathy, abnormal fundus pigmen, ocular dysplasia, lacrimal duct obstruction, retinal venous tortuosity, congenital cataract, retinoblastoma, optic nerve coloboma, and microphthalmos. No differences in incidence of abnormalities were seen between male and female patients.

Some screening results were compiled separately for the entire infant population (n = 8439) and for term infants (n = 7863) to allow comparisons. There were no differences between the 2 populations in the incidence of retinal hemorrhage (20.96%) or significant retinal hemorrhage (grade 3 or greater; 6.1%). For macular hemorrhage, however, the incidence was 2.7% in the total population and 1.87% in the term babies. There was also a difference in the rate of other abnormalities between the total population (2.22%) and the term babies (2.99%).

As noted, the rate of retinal hemorrhage was high, at more than 20% in both populations. Among the infants with retinal hemorrhage, the incidence of macular hemorrhage was 8.27%, and 8 eyes had foveal hemorrhage.

Within 20 days, 85% of hemorrhages were absorbed. For macular hemorrhages, however, it took longer—3 weeks to 3 months—for the hemorrhages to absorb.

Interestingly, the incidence of hemorrhage was higher in natural-birth babies (33.7%) than in those delivered by cesarean section (4.76%). Also, the incidence of hemorrhage was higher when the infant had a shorter birth process as opposed to a longer birth process.

IMPLICATIONS

Identification of certain pathologies allowed treatment to be performed in a timely fashion. For example, in 2 children in whom retinoblastoma was identified by screening at 3 days after birth (in 1 case, bilateral retinoblastoma), surgery was successfully performed. These children are now 2 and 3 years old and healthy with good vision.

With the program now in place for less than 3 years, we cannot yet say what the long-term results of universal ocular screening of neonates will be. We hope to be able to continue this neonatal screening program and to follow these children for 5 to 10 years to track the results.

We can say that universal newborn eye screening has revealed clinically significant eye diseases in a significant percentage of healthy babies. The incidence of eye diseases is 2 to 3 times greater than the incidence of hearing defects identified in screening of healthy newborns. Evaluation of the natural history of these diseases and the impact of early intervention is ongoing. We hope this program will lead to opportunities for improvements in public health.

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is not the case. In reviewing medicolegal literature, one can identify cases in which, on the same day, the referring physician identifies zone III, stage 1 disease, and the treating physician calls it a zone I, stage 3 eye. Both interpretations are presumed to be correct, but obviously one is wrong.

The advantages of photographic telemedicine screening are the exact inverse of the disadvantages of BIO. Remote photographic assessment offers reproducibility, precision, the ability to track patients longitudinally, the ability to produce hard copy for the medicolegal record, and amenability to educational purposes and studies. Photographic telemedicine leverages screeners and allows continuity of screening. It allows one to characterize zone, stage, and plus disease based on the optics of the camera rather than a drawing.

There are disadvantages to photoscreening. The cameras require a significant investment by each neonatal intensive care unit (NICU) involved in a remote screening program, and use of the camera requires training. The medium provides only 2-D images. And there is a bias in the community toward the more traditional bedside BIO. Fortunately, the new joint statement screening guidelines support the use of photoscreening with the proviso that all babies have 1 binocular indirect ophthalmoscopy examination prior to termination of screening.

**SUNDROP NETWORK**

The Stanford University Network for Diagnosis of ROP (SUNDROP) is a hub-and-spoke, store-and-forward telemedicine screening program. The central hub at the university is a single remote screener who reads images generated by cameras (RetCam; Clarity Medical Systems) at each of 6 peripheral NICUs. The protocol for photographs, based on the Photo-ROP trial, includes an iris view and 5 views of the fundus in each eye, a total of 12 standard photographs for a patient’s 2 eyes.

The screener looks for all referral-warranted (RW) and/or treatment-warranted (TW) disease. The camera provides adequate visualization of zone II, and it is good at highlighting plus disease (Figures 1 and 2).

To date, with more than 7 years of data, the SUNDROP telemedicine program has achieved 100% capture of more than 600 premature infants born at 6 centers over 7. Screening sensitivity was 100%, and specificity was in excess of 99.5%, with high negative and positive predictive values.

The current technology has limitations: Because the camera cannot reliably and reproducibly photograph zone III, it is not possible to discharge infants from acute phase screening of ROP based on the joint statement screening guidelines. Additionally, it is difficult to routinely screen babies using the camera upon discharge from the NICU because the babies have grown in size and strength.

In the future we hope to automate the system so that the camera automatically syncs with the remote server. We would also like to institute a tracking system similar to what is used with hearing tests.

Another exciting possibility is to expand beyond ROP and do universal screening of newborns, which is currently occurring in Brazil and China. (See *Universal Eye Screening in Healthy Neonates.*) The institutional review board at Stanford recently approved our evaluation of the efficacy of such an effort in our community. A single screening could lead to early identification of cataract, vitreous hemorrhage, congenital glaucoma, coloboma, hamartoma, retinoblastoma, and nerve anomalies, possibly resulting in improved functional outcomes.

**CONCLUSION**

Screening is vital for the prevention of blindness from ROP. Telemedicine is potentially a highly effective screening tool that allows the leveraging of skilled ROP screeners. We look forward to expanded use of remote screening in other centers, modeled on the successful SUNDROP program.
Cover Story

INSURER PERSPECTIVE ON TELEMEDICINE SCREENING FOR ROP

By Arthur W. Allen Jr, MD

When a new medical technology is introduced, medical liability insurers must come to an understanding of its risks and benefits in order to formulate underwriting guidelines. Telemedicine screening for retinopathy of prematurity (ROP), in which experienced screeners at a remote location evaluate photos sent over the Internet and make treatment recommendations, is an example of a new diagnostic modality for which guidelines are still emerging.

Screening for ROP from a distant site via telemedicine raises certain concerns from a medicolegal standpoint. Unfortunately, current laws governing medical liability vary from state to state and were enacted at a time when the patient and physician were almost always in the same state. With remote screening, this may no longer be the case. Issues of concern can include state licensure, credentialing, privileging, confidentiality, physician-patient relationships, informed consent for real-time patient encounters, jurisdiction in the event of a lawsuit, storage and quality of images, and training of readers.

When images cross state lines, obtaining licensure in both states is advisable because of the risk of being sued for practicing without a license. Similarly, credentialing and privileging issues should be resolved. Centers for Medicare and Medicaid Services (CMS) regulations state that credentialing and privileging must be done at both the originating and interpretation sites. The credentialing of remote readers should be documented in case questions arise in the event of a misdiagnosis.

Transferring images over the Internet raises concerns regarding security and confidentiality of potentially sensitive information. Images should be transferred and stored securely.

Attention should also be paid to image quality. Hazy media or small palpebral fissures in very premature infants could make image interpretation difficult, in comparison with a bedside retinal drawing. This could prompt scrutiny by subsequent expert examiners regarding the findings.

When doctors at a remote location give opinions on treatment, the definition of the physician-patient relationship is less than clear. The relationship should be spelled out in informed consent documents to afford some relief to the distant site.

Telemedicine can potentially improve the care of premature infants in remote areas. However, if a suit is filed, the plaintiff will likely want the trial to be in the most favorable jurisdiction for litigation awards. This often will be the urban areas where most reading centers are located and where indemnity awards tend to be higher.

Standard-of-care definitions also vary state by state, and this could be an incentive to favor a certain location for litigation.

The Ophthalmic Mutual Insurance Company (OMIC) has established underwriting guidelines that physicians must satisfy before the can be insured to practice telemedicine. These include such issues as who provides backup grading, how many images are taken per eye per screening, and 24-hour turnaround.

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