HIPPA and Malpractice Pitfalls in Providing Care to Infants at Risk for Retinopathy of Prematurity (ROP) for Physicians Employing Digital Imaging Technologies

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OBJECTIVE To present practical information to minimize risk of HIPPA violation penalties and malpractice litigation vulnerability for those using digital images and providing evaluation and management (E/M) services to infants at risk for developing ROP.

PURPOSE To review the current medical malpractice issues and pertinent digital imaging-related HIPPA vulnerabilities relevant to provision of ROP E/M services.

METHODS Current practices related to transfer and interpretation of digital fundus images are reviewed, with special emphasis on penalties levied for noncompliance with HIPPA regulations by the U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR). Retrospective review of the literature and a series of ROP malpractice cases the authors were involved in will be presented.

RESULTS HIPAA and FDA compliant image handling and storage of images are detailed, with special emphasis on common current practices which render practitioners at risk for HIPPA violation, including: non-secure image acquisition, non-secure image transmission, vulnerabilities associated with receiving/storing personal health information (PHI) on non-secure devices (smartphones and other personal digital/data assistant devices, laptops, home computers), and non-secure transmission of interpretative findings. Ophthalmologic aspects of ROP care delivery most commonly cited in malpractice litigation include failure to diagnose, failure to follow up and failure

to treat in a timely fashion. Improper/inadequate treatment is an uncommon malpractice litigation focus.

CONCLUSION Provision of ROP E/M services render ophthalmologic care-providers vulnerable to HIPPA violation penalties pertinent to digital image acquisition, transfer and interpretation and malpractice litigation vulnerability. A small number of care-provision vulnerabilities lead to the majority of ROP-related malpractice claims.

TAKE HOME MESSAGE Use of digital imaging for ROP care may expose providers to a variety of HIPPA vulnerabilities. Failure to diagnose/treat are the primary ROP malpractice vulnerabilities.

Longitudinal Changes of Peripapillary Pigmentation and Optic Nerve Area in the SUNDROP Preterm Infants: The Influence of Treatment Warranted ROP

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OBJECTIVE To describe changes in peripapillary pigmentation and optic nerve size over time in patients matched for development of treatment-warranted ROP (TW-ROP) and those not requiring treatment.

PURPOSE To determine the following in a preterm population screened for ROP in the SUNDROP telemedicine program: 1) is there post-natal development of peripapillary pigmentation on longitudinal follow-up; 2) is there post-natal change in the dimensions of the optic nerve on longitudinal follow-up; and, 3) do these differences track with need for treatment of ROP or are intrinsic to normal development.

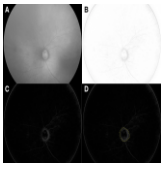
METHODS Matched case-control study. Preterm infants with bilateral Treatment Warranted ROP (TW-ROP) vs non-TW-ROP preterm infants. Peripapillary pigmentation and optic disc area were assessed on the first and last telemedicine screening exam. They were matched by gestational age at first and last telemedicine screening exam. Images were analyzed using ImageJ: converted to black and white, background noise was subtracted with rolling ball algorithm (radius 50 pixels), black

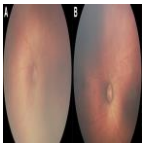
and white inversion, peripapillary region was delimited, area, mean gray value, and integrated density were measured. Optic disc area was determined by outlining the boundary of the optic disc and converting the pixels to area.

RESULTS Images of 148 eyes at baseline and last telemedicine screening were examined using ImageJ without exclusion. Average gestational age at baseline was 31.8 weeks (SD 1.65 weeks) for cases and 32.0 weeks (SD 1.09 weeks) for controls (paired t-test, 0.3433). Average gestational age at last exam was 41.8 weeks (SD 4.90 weeks) for cases and 40.8 weeks (SD 3.22 weeks) for controls (paired t-test, 0.0683). There was significant difference in the peripapillary pigmentation of each eye on the first and last telemedicine screening exam in cases (paired t-test for integrated density, $p<0.0001$) and controls ($p<0.0001$), with no significant mean difference between cases and controls (paired t-test, $p=0.6545$). Optic disc area was significantly different between the baseline and last exam for the cases (paired t-test, $p=0.0314$; mean difference cases minus controls 256.61 pixels, 95% CI 23.53 to 489.68) but not controls (paired t-test, $p=0.6887$).

CONCLUSION Telemedicine screening for ROP has allowed us to chart all aspects of retinal development in preterm infants. This current study demonstrates that peripapillary pigmentation changes over time, which is not intuitive, and that optic nerve area changes were recorded in TW-ROP over time, but not in controls. These two findings have anatomic correlates which might explain functional outcomes in ROP.

TAKE HOME MESSAGE Longitudinal follow-up of infants in the SUNDROP cohort indicate postnatal increases in peripapillary pigmentation in both TW-ROP and non-TW-ROP cases, with decreasing optic nerve area in TW-ROP.





HUMAN RESEARCH This study involves human research.
IRB Approval Status: Approved by institutional review board

Bilateral Simultaneous Vitrectomy in Stage 4-5 ROP

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OBJECTIVE The aim is to identify the advantages and disadvantages of bilateral simultaneous surgery in bilateral stage 4-5 ROP cases.

PURPOSE ROP surgery is usually urgent and some of the cases need surgery bilaterally. The aim is to identify the advantages and disadvantages of bilateral simultaneous surgery in those bilateral cases.

METHODS This is a retrospective case series of babies who underwent simultaneous bilateral vitrectomy for stage 4 or 5 ROP. ROP status including stage and presence or absence of plus disease, postoperative results including anatomical results, complications (vitreous hemorrhages, iatrogenic break, lensectomy need), and follow-up time were recorded.

RESULTS 44 eyes of 22 babies were included in the study. Patients were followed-up for a mean of 11.8 months. Plus disease was apparent in 18 eyes (40.9%). 91% of the eyes received laser treatment and 2 eyes (4.5%) received anti-VEGF treatment elsewhere before being referred to our hospital. Lensectomy was done in 18.2% of the eyes due to extensive anterior fibrovascular proliferation. The rate of lensectomy was 6.3% in stage 4a, 42.9% in stage 4b, and 60% in stage 5. 40.9% had postoperative vitreous hemorrhage of some degree, 38.9% of which needed additional surgery for hemorrhage. The anatomical success rate was 88.9% overall which was 100% for stage 4a. None of the patients had endophthalmitis during follow-up.

CONCLUSION VRS for ROP is usually an urgent intervention and when it is needed bilaterally, the waiting period between 2 eyes may cause progression. Secondly a 2nd general anesthesia may be dangerous sometimes necessitating intensive care postoperatively. Bilateral simultaneous surgery avoids these problems. Risk of endophthalmitis and surgeon's fatigue are other issues to be taken into account.

TAKE HOME MESSAGE Bilateral simultaneous VRS for ROP looks safe and effective. The risk of endophthalmitis should be weighed over the risks of second general anesthesia and disease progression with separated sessions surgery in bilateral stage 4-5 ROP cases.