Retinopathy of Prematurity Malpractice Claims

The Ophthalmic Mutual Insurance Company Experience

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Objective: To examine the causes of retinopathy of prematurity (ROP) malpractice claims filed with the Ophthalmic Mutual Insurance Company.

Methods: All closed ROP malpractice claims were reviewed.

Results: Eight cases involved failure of transfer of care on patient discharge from the hospital, 3 cases demonstrated inappropriately long periods between follow-up examinations, 1 case was due to failure of outpatient referral from screening to the treating ophthalmologist, and 1 case concerned unsupervised resident provision of ROP care.

Conclusions: Many preventable factors can be addressed to improve ROP care. It is essential to ensure that ophthalmologists, neonatologists, pediatricians, and families are updated on current guidelines for ROP screening and treatment and to facilitate follow-up appointments before patient discharge from the hospital. Doing so can help avoid future malpractice claims and patient harm.


Retinopathy of Prematurity (ROP) is one of the leading causes of childhood blindness in industrialized countries.¹ The Cryotherapy for Retinopathy of Prematurity² and Early Treatment for Retinopathy of Prematurity³ studies demonstrated that visual loss from ROP can be significantly mitigated by timely screening and treatment. As a result, the ophthalmologist has an important role and responsibility. Perhaps more so than other aspects of ophthalmology, however, appropriate ROP care requires the cooperation of multiple different people, including the neonatologist, the pediatrician, members of the family, and the ophthalmologist. This factor has made the ensuring of appropriate ophthalmologic follow-up and treatment for the premature infant uniquely challenging. Malpractice cases involving ROP are uncommon, and data on factors that lead to malpractice claims are limited: only 2 published, peer-reviewed studies⁴,⁵ specifically analyze ROP malpractice claims or suits (N=17 cases). Given the severe and lifelong visual loss that can result from ROP, however, indemnity payments from ROP often total in the millions of dollars. The risk of medical liability for providing ROP services has diminished the number of ophthalmologists willing to care for premature infants and has increased the burden for those who continue to manage ROP. A recent survey by the American Academy of Ophthalmology found that only half of all pediatric and retinal specialists provide ROP services, and one-fifth of those surveyed were planning to stop providing ROP care.⁶ Of those who had stopped providing ROP care in the past 10 years, 67% cited medical liability as the primary reason for the discontinuation of these services.⁶

For editorial comment see page 803

Current ROP screening guidelines are based on the 2006 consensus statement by the Section on Ophthalmology of the American Academy of Pediatrics, the American Academy of Ophthalmology, and the American Association for Pediatric Ophthalmology and Strabismus; the statement is based on a review of peer-reviewed studies and articles on ROP management.⁷ This statement recommends the screening of infants with a birth weight of less than 1500 g or a gestational age of less than 30 weeks or selected infants with a birth weight of 1500 to 2000 g or a gestational age greater than 30 weeks who have had an unstable clinical course.⁷ The international classification of ROP disease and the suggested timing of follow-up are detailed in Table 1 and Table 2, respectively.⁸ Screening examinations can be discontinued when any 1 of the following criteria is met: (1) zone III retinal vascularization is attained without previous zone I or II ROP (if there is examiner doubt about the zone or if the postmenstrual age is <35 weeks, confirmatory examinations may be warranted), (2) full retinal vascularization,
METHODS

All 12 closed ROP malpractice claims filed with OMIC since 1987 were reviewed by 2 of us (S.D. and A.M.). The OMIC Professional Liability Policy defines a claim as a written notice or demand for money or services, including the institution of a lawsuit or arbitration proceeding that results from a professional services incident (eg, from an error or act of omission or commission during direct patient treatment). Open claims were excluded from this analysis. The demographics of each case were recorded, and each case was analyzed for medical care issues that led to the filing of a claim.

RESULTS

The demographics of the 12 OMIC closed ROP malpractice claims are given in Table 3. Cases of ROP represent 12 of 2442 OMIC total closed claims (0.49%) and 18 of 2898 OMIC total open claims (0.62%) between 1987 and November 24, 2008. Of the 12 cases reviewed, 9 progressed to litigation. Of the 5 cases in which an amount was awarded to the plaintiff (eg, indemnity payment), the amount of the award ranged from $26,667 to $3,757,000. The mean indemnity payment was $939,270, and the median indemnity payment was $400,000. Of the 12 claims, 3 involved retina specialists and 9 involved pediatric ophthalmologists. Two claims were against 2 different ophthalmologists who provided care for the same infant. Eight cases involved failure of transfer of care from the hospital to the outpatient ophthalmologist on patient discharge from the hospital, 3 cases demonstrated inappropriately long periods between follow-up examinations, 1 case was due to failure of outpatient referral from screening to the treating ophthalmologist, and 1 case concerned unsupervised resident provision of ROP care (Table 4). The OMIC cases previously reported by Demorest1 never proceeded to a lawsuit and was, therefore, never classified as a claim. The cases previously reported by Reynolds3 are the twins in claims 1 and 2 (listed together in the article by Reynolds as case 5) and claim 8 (listed in the article by Reynolds as case 1). Of the identifiable cases that had been previously reported, we concur with the previous authors regarding the relevant medical care issues.

In 8 cases involving failure of transfer of care between the neonatal intensive care unit (NICU) and the ophthalmologist in the outpatient setting, 1 child was never examined in the NICU and subsequently was seen 2 months later as an outpatient, 3 children had delays in outpatient follow-up visits (range, 1-3 months) after having been screened in the NICU, and 3 children were never seen as outpatients by the ophthalmologist who had screened them in the hospital setting. These failures occurred in 1 case because the follow-up date was recorded incorrectly by the hospital staff and in another case because the patient was transferred to another NICU and the admitting neonatologist did not realize the need for further ROP care. In 4 cases, the length of time between follow-up examinations was inappropriately long despite documentation by the screening ophthalmologist of a requested follow-up time and in another case despite the screening ophthalmologist hav-
ing directly contacted the family of the patient for follow-up appointments. For further details, please refer to cases 1 to 8 in Table 4.

In cases 9, 10, and 11, there was an inappropriately long period between follow-up examinations. One case occurred on August 14, 1984, before current standards of care for screening and follow-up were established. In that case, a child was seen at 37 weeks of age and was reported to have no ROP, but a follow-up visit was not recommended until 3 months later. In the second case, a child with rapidly progressive threshold disease was treated 3 times with a diode laser by a pediatric ophthalmologist who then requested follow-up with a retinal specialist within 2 weeks, at which point the child had developed bilateral retinal detachments. In the third case, a premature infant born at 26 weeks was seen once at age 32 weeks in the NICU with normal examination findings and no ROP, but the follow-up period recommended by the ophthalmologist was 6 months rather than 1 more examination before age 35 weeks as recommended by the 2006 American Academy of Ophthalmology/American Academy of Pediatrics/American Association for Pediatric Ophthalmology and Strabismus consensus statement.

Case 8 also involved unsupervised resident care of a premature infant. In fact, this premature infant, born at 26 weeks, was actually seen at ages 32 and 35 weeks by 2 different third-year residents but without the supervision of an attending physician during either examination. Subsequently, the child was transferred to another hospital with instructions for a 2-week follow-up ophthalmologic examination. However, the admitting neonatologist apparently missed these instructions in the discharge summary, and the next examination of the patient did not take place until 1 month after transfer.

Case 12 is notable for the failure of outpatient referral from a pediatric ophthalmologist to a retinal specialist. In this case, a child was noted to have stage 1 or 2 ROP in both eyes on May 9, 1989, by a pediatric ophthalmologist who recommended that the child undergo further evaluation by a retinal specialist within 1 week. The pediatric ophthalmologist claims he communicated this to the mother of the patient, although this was not documented. The child was not seen by a retinal specialist until July 28, 1989, at which point the child had developed stage 4 ROP.

This review of 12 OMIC closed ROP claims illustrates the multiple medical and logistical issues involved in the care of premature infants. Perhaps most striking is that two-thirds of these claims demonstrated a failure of transfer of care from the NICU, an issue that was also noted by Reynolds in 4 of the 13 ROP malpractice cases he reviewed. Reynolds found that 8 of 13 cases involved a “failure to refer/missed window of opportunity” on the part of the neonatologist or pediatrician (with 4 of these cases specifically involving a failure during the transfer of care from the NICU to the outpatient setting), 6 cases involved a failure to follow up on the part of the ophthalmologist, and 2 cases involved unsupervised examinations performed by a resident. A 2005 retrospective study of 74 NICU infants designated as needing ROP follow-up care found that only 49% received a follow-up appointment within 1 month of the requested time, and a 2000 study of 126 NICU infants thought to be at risk for ROP found that only 49% received timely outpatient evaluation. This particular weakness in the chain of care of premature infants may be due to the multiple parties involved, including the neonatologist, the hospital staff, the pediatrician, the ophthalmologist, and the family of the patient. Responsibility for the arrangement of follow-up care for these infants does not fall solely on the ophthalmologist, especially because the ophthalmologist plays a consulting role while the child is in the hospital. One of the first steps in remedying this problem is to ensure that neonatologists and ophthalmologists are operating from a common understanding of the standard of care for ROP screening. A survey of 300 randomly selected neonatologists (with a 62% response rate) found that 98% of respondents used gestational age to identify infants who need ROP screening, with 19% using the currently recommended gestational age of 30 weeks; 6% using a lower, less restrictive criterion; and 74% using a higher, more inclusive criterion. Fewer respondents (77%) used birth weight as a criterion to determine which infants to screen. More than one-third of respondents noted that they had been unable to transfer a child to an inpatient facility of lower acuity or have had to delay dis-

Table 3. Demographics of OMIC Closed ROP Malpractice Claims

<table>
<thead>
<tr>
<th>Claim No.</th>
<th>Year of Incident</th>
<th>Gestational Age of Patient, wk</th>
<th>Birth Weight of Patient, g</th>
<th>Award Paid on Behalf of Ophthalmologist, $</th>
<th>Additional Parties Sued</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1997</td>
<td>30</td>
<td>1162</td>
<td>0</td>
<td>Neonatologist, pediatrician, hospital</td>
</tr>
<tr>
<td>2</td>
<td>1997</td>
<td>30</td>
<td>1389</td>
<td>0</td>
<td>Neonatologist, pediatrician, hospital</td>
</tr>
<tr>
<td>3</td>
<td>1994</td>
<td>28</td>
<td>950</td>
<td>0</td>
<td>Obstetrician, hospital</td>
</tr>
<tr>
<td>4</td>
<td>1994</td>
<td>28</td>
<td>950</td>
<td>0</td>
<td>Obstetrician, hospital</td>
</tr>
<tr>
<td>5</td>
<td>1997</td>
<td>29</td>
<td>1200</td>
<td>319 681</td>
<td>Neonatologist, pediatrician, hospital</td>
</tr>
<tr>
<td>6</td>
<td>1991</td>
<td>28</td>
<td>949</td>
<td>575 000</td>
<td>Neonatologist</td>
</tr>
<tr>
<td>7</td>
<td>1989</td>
<td>24</td>
<td>733</td>
<td>400 000</td>
<td>Hospital</td>
</tr>
<tr>
<td>8</td>
<td>1997</td>
<td>26</td>
<td>890</td>
<td>0</td>
<td>Obstetrician, pediatrician, hospital</td>
</tr>
<tr>
<td>9</td>
<td>1985</td>
<td>26</td>
<td>850</td>
<td>26 667</td>
<td>Obstetrician, hospital</td>
</tr>
<tr>
<td>10</td>
<td>2001</td>
<td>22</td>
<td>460</td>
<td>0</td>
<td>None</td>
</tr>
<tr>
<td>11</td>
<td>2003</td>
<td>26</td>
<td>960</td>
<td>3 375 000</td>
<td>Obstetrician, hospital</td>
</tr>
<tr>
<td>12</td>
<td>1989</td>
<td>27</td>
<td>1247</td>
<td>0</td>
<td>Neonatologist, hospital</td>
</tr>
</tbody>
</table>

Abbreviations: OMIC, Ophthalmic Mutual Insurance Company; ROP, retinopathy of prematurity.
The role is to designate an ROP coordinator, commonly an NICU nurse in charge of discharge planning, whose task is to generate a list of babies who need screening.12

A systematic process or checklist activated when the screening process begins, with the goal of eliminating human error as much as possible. Such a process was recommended by OMIC, which has provided a sample protocol on its Web site that includes checklists, current clinical guidelines, letters to parents, and consent forms.13 One possibility for ensuring that this process takes place is to designate an ROP coordinator, commonly an NICU nurse in charge of discharge planning, whose role is to generate a list of babies who need screen-
ing examinations based on the consensus statement criteria and who ensures that appropriate follow-up takes place, with particular attention given to the time of discharge. The 2000 study\(^\text{11}\) that looked at 126 NICU infants who required ROP follow-up found that, when instructions for follow-up were given orally and in writing to the parents, follow-up appointments were made only 39% of the time. However, when the hospital staff made the appointment before patient discharge, 71% of follow-up appointments were completed.\(^{12}\) The only situation in which a child should leave the hospital without an ophthalmology appointment is if he or she has met 1 of the criteria for the discontinuation of screening examinations (see the beginning of the article).

The second most common medical issue raised in this review was an inappropriate length of time between follow-up examinations. As mentioned previously herein, 1 of these cases took place in 1984, before the current standard of care established by the Cryotherapy for Retinopathy of Prematurity Early Treatment for Retinopathy of Prematurity studies. In the other 2 cases, however, the responsibility for the request of appropriately timed follow-up appointments falls to the ophthalmologist. This raises the issue of ensuring that practitioners who take care of premature infants are aware of the newest guidelines, perhaps through the continuation of medical education. This may place an additional burden on already overextended ophthalmologists who provide ROP care but should ultimately result in better care of these infants and, hopefully, less litigation.

One of the cases involved unsupervised resident provision of ROP care, a factor that can be remedied by the requirement that an attending physician be involved at every point of ROP care. This remedy is difficult when the overall demand for ophthalmologist screening examinations exceeds the number of ophthalmologists willing or able to provide this service, but unsupervised resident examinations in a high-risk population are even harder to defend in a court of law. The Joint Statement makes it clear that at-risk infants should "receive carefully timed retinal examinations by an ophthalmologist who is experienced in the examination of preterm infants for ROP."\(^{13}\)

Last, 1 of the cases presented in this series involved the failure of referral from a pediatric ophthalmologist to a retinal specialist in which 1-week follow-up was requested but the child was not seen until 2.5 months later. This case highlights the importance of communication between the ophthalmologist and the parents of the child, and between the different ophthalmic specialists. For children who are out of the ICU setting, the ophthalmologist assumes primary responsibility for their eye care, and the office of the ophthalmologist should have a system in place to make sure that referrals are completed in a timely manner. The following is a final summary of recommendations for ensuring appropriate ROP screening and treatment for inpatients and outpatients:

1. Update and review current ROP screening and treatment guidelines with all parties involved in the care of premature infants (neonatologists, ophthalmologists, pediatricians, and parents).
2. Activate a hospital ROP tracking system on the birth of infants who meet the age and weight requirements for ROP screening.
3. Designate an ROP coordinator who will follow up patients identified by the tracking system, ensure appropriate timing of screening examinations while patients are in the hospital, and coordinate initial follow-up appointments once patients leave the hospital.
4. Make written follow-up appointments before discharge for any patient who has not met the criteria for the conclusion of ROP screening.
5. Attending physicians must supervise residents who participate in ROP examinations.
6. Assume primary responsibility for ensuring further follow-up and transfer of care between different ophthalmic specialists once the patient is discharged from the hospital.
7. Implement an office-based ROP tracking system for outpatients. Institute a follow-up protocol for all changed or missed appointments.

For more detailed guidelines and forms, please refer to “ROP: Creating a Safety Net” by Menke AM, available on the OMIC Web site.\(^{12}\)

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REFERENCES