Zeynep Kamil Med J 2023;54(4):209–215
DOI: 10.14744/zkmj.2023.26986

ORIGINAL ARTICLE

Retinopathy of prematurity malpractice cases: A medicolegal evaluation

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ABSTRACT

Objective: Retinopathy of prematurity (ROP) is a disease that is caused by abnormal proliferation of retinal vessels in pre-term infants. Difficulties and delays in diagnosing ROP are thought to bring along claims of medical malpractice. We aimed to provide an assessment of medical malpractice claims regarding the ROP cases, which were evaluated in the 7th Specialization Board of the Council of Forensic Science.

Material and Methods: This study is a retrospective descriptive study. The cases with ROP diagnose were included in the study which was evaluated in the 7th Specialization Board of the Council of Forensic Science within 3 years between 2017 and 2020.

Results: The number of cases included in the study was twenty-six cases. The mean gestational age was 30.26±2.12 weeks. While the mean birth weight was 1501±407.93 g. Medical malpractice was found in 16 (61.5%) cases. In 7 (26.9%) cases, malpractice was given because the pediatrician did not consult an ophthalmologist on time. In 9 (34.6%) cases, there was malpractice due to the diagnosis or follow-up fault of the ophthalmologist. Stage 4–5 ROP was found in all cases at the time of diagnosis.

Conclusion: Most problems of ROP cases evaluated for malpractice were associated with diagnosis and follow-up. It is essential that specialized pediatric ophthalmologists assess these cases. Multidisciplinary cooperation and standard management algorithms should be introduced. Delays in treatments were either due to failure of timely diagnosis and staging of ROP by ophthalmologists or incomplete documentation of patient files and consultation delays by pediatricians.

Keywords: Medical malpractice, ophthalmologist, pediatrician, retinopathy of prematurity.

Cite this article as: Silahlı NY, Özsütçü M, Aslıyüksek H, Celkan TT. Retinopathy of prematurity malpractice cases: A medicolegal evaluation. Zeynep Kamil Med J 2023;54(4):209–215.

Received: February 01, 2023 **Revised:** May 18, 2023 **Accepted:** May 24, 2023 **Online:** October 10, 2023
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Zeynep Kamil Medical Journal published by Kare Publishing. Zeynep Kamil Tıp Dergisi, Kare Yayıncılık tarafından basılmıştır.

INTRODUCTION

Retinopathy of prematurity (ROP) is a disease that is caused by abnormal proliferation of retinal vessels in pre-term infants.[1–3] ROP is the leading cause of preventable infant blindness in the world, yet the exact pathogenesis of the disease is unknown. While the survival of pre-mature babies increases with the development of newborn care standards, there is a significant increase in the rates of ROP, especially in developing countries.[1–3] By identifying possible risk factors, early screening and treatment reduce sequelae rates significantly.[4–6] Follow-up of newborns at risk for ROP is one of the critical diagnoses having the potential for causing very important medicolegal problems for pediatricians and ophthalmologists.[6–9] In studies, delivery method, number of births, birth weight, gestational age, APGAR score at 1-min, maternal race, the presence of maternal diabetes, pre-natal steroid use, first resuscitation (supplementary oxygen, positive airway pressure, intubation, chest compression, and epinephrine) may contribute to ROP and are identified as risk factors.[3–9]

ROP is one of the important and preventable causes of childhood visual impairment.[1,7] Visual impairment caused by retinopathy causes a dependent life as well as a decrease in quality of life.[2–5] Difficulties and delays in diagnosing ROP are thought to bring along claims of medical malpractice.

While reviewing the literature, little data were found regarding the medicolegal aspects of ROP in Türkiye. We aimed to provide an as-

Table 1: Sociodemographic and clinical characteristics of cases

Case	Sex	Malpractice claims against	Gestational age (weeks)	DM	Birth weight	NICU hosp. (days)	ROP stages	Treat.	The board opinion about the case	Mal.	Reason malpractice
1	M	Ped.	32	C/S	1930	37	3	+	Malpractice was not detected.		
2	F	Ped.	29	C/S	1980	Unk.	Unk.	Unk.	Malpractice was not detected.		
3	M	Ped. Oph.	28	C/S	1420	Unk.	Unk.	Unk.	Malpractice was not detected.		
4	M	Ped. Oph.	34	C/S	1690	34	5	+	Malpractice was not detected.		
5	M	Ped. Oph.	31	C/S	1625	13	4	+	Mal.	Oph.	Late diagnosis
6	M	Ped.	30	C/S	1300	Unk.	5	+	Mal.	Ped.	Late consultation
7	M	Oph.	32	C/S	1870	Unk.	3-4	Unt.	Malpractice was not detected.		
8	M	Oph.	32	C/S	1380	26	0	Unt.	Malpractice was not detected.		
9	M	Ped.	29	C/S	Unk.	47	0	Unt.	Mal.	Ped.	Late consultation
10	M	Ped.	30	C/S	1410	37	5	Unt.	Mal.	Ped.	Late consultation
11	F	Ped.	32	C/S	1750	30	4	Unt.	Mal.	Ped.	Late consultation
12	F	Ped. Oph.	26	NVD	680	103	4	Unt.	Mal.	Oph.	Late diagnosis
13	M	Ped.	30	C/S	1710	38	Unk.	Unt.	Mal.	Ped.	Late consultation
14	M	Ped. Obs.	34	C/S	2400	11	5	Unt.	Malpractice was not detected.		
15	F	Ped.	34	C/S	2000	26	Unk.	+	Mal.	Ped.	Late consultation
16	M	Ped. Oph.	27	C/S	940	82	Unk.	Unt.	Mal.	Oph.	Late diagnosis
17	F	Ped.	29	C/S	935	75	Unk.	+	Malpractice was not detected.		
18	F	Ped.	29	Unk.	1300	58	5	+	Mal.	Oph.	Lack of follow-up
19	M	Oph.	32	C/S	1900	Unk.	5	+	Mal.	Oph.	Late diagnosis
20	F	Ped. Oph.	29	C/S	1180	52	5	+	Mal.	Oph.	Late diagnosis
21	F	Ped. Oph.	29	C/S	1130	Unk.	5	Unk.	Malpractice was not detected.		
22	F	Unk.	30	C/S	1350	61	0	None	Malpractice was not detected.		
23	M	Ped.	30+6	NVD	1600	92	Unk.	Unk.	Mal.	Oph.	Late diagnosis
24	F	Oph.	31+2	C/S	1670	35	Unk.	+	Mal.	Oph.	Late diagnosis
25	F	Oph.	27	C/S	910	69	3	+	Mal.	Oph.	Late diagnosis
26	M	Ped.	30	NVD	1480	Unk.	5	Unk.	Mal.	Ped.	Late consultation

M: Male; F: Female; DM: Delivery method; NICU: Neonatal intensive care unit; Hosp: Hospitalization; ROP: Retinopathy of prematurity; Treat: Treatment; Ped: Pediatrician; Oph: Ophthalmologist; Unk: Unknown; Mal: Malpractice; C/S: Cesarean section; NVD: Normal vaginal delivery.

Table 2: Recommended screening criteria for retinopathy of prematurity

Screening criteria for retinopathy of prematurity recommended by Turkish pre-mature retınopathy guide	Screening criteria for retinopathy of prematurity recommended by academy american of pediatrics
All infants with a gestational age of <34 weeks or a with a birth weight ≤1700 g Pre-term infants with a gestational age of ≥34 weeks or infants with a birth weight >1700 g who received cardiopulmonary support therapy or whom the follow-up clinician considered at risk for the development of ROP *The quality of care in neonatal intensive care units may vary from unit to unit. Units should determine upper limits for ROP screening according to birth weight and gestational age in the light of epidemiological data including their own patient group.*	All infants with a birth weight of ≤1500 g Gestational age of 30 weeks or less (as defined by the attending neonatologist) Selected infants with a birth weight between 1500 and 2000 g or a gestational age of >30 weeks who are believed by their attending pediatrician or neonatologist to be at risk for ROP • Infants with hypotension requiring inotropic support • Infants who received oxygen supplementation for more than a few days • Infants who received oxygen without saturation monitoring

From: Screening Examination of Premature Infants for Retinopathy of Prematurity Pediatrics. 2018;142(6). doi:10.1542/peds.2018-3061; From: Türk Neonatoloji ROP Rehberi; avable:https://www.neonatology.org.tr/storage/2021/09/Turkiye-Premature-Retinopatisi-Rehberi-2021-Guncellemesi.pdf; ROP: Retinopathy of prematurity.

sessment of medical malpractice claims regarding the ROP cases, which were evaluated in the 7th Specialization Board of the Council of Forensic Science.

MATERIAL AND METHODS

Study Design

This study is a retrospective descriptive study evaluating cases submitted to the 7th Specialization Board of the Council of Forensic Science within 3 years between 2017 and 2020. In total, 16,697 malpractice cases were evaluated on the board. The board is responsible for medical malpractice cases that do not result in death on trial. In our study, 26 cases were included with ROP diagnosis. These were the cases claimed as physician malpractice. Case summaries that were considered included the judicial authority sent, the date of the report, the question asked, the allegations made, pre-natal and natal history, gestational week, delivery type, birth weight, whether resuscitation was performed, 1st and 5th min APGAR score, diagnosis and duration of hospitalization in the neonatal intensive care unit (NICU), whether he received respiratory support, duration and type of respiratory support, the presence of concomitant anomaly, whether ROP examination was performed, date of ROP examination and examination findings, age at first diagnosis, whether treatment was applied, type of treatment applied, follow-up recommendations, and medical records. Board opinions and observations were also recorded and evaluated retrospectively.

Compliance with Ethical Standards

Permission to ethical approval undergo this study was taken from the Scientific Research Committee of the Council of Forensic Science on September 10, 2020, and the number 2020/856.

The informed consent form was not signed by participants as the study was designed as a retrospective study. The study complies with the Declaration of Helsinki.

RESULTS

Sociodemographics

The number of cases included in the study was twenty-six cases. The mean gestational age was 30.26±2.12 (min: 26; max: 34; median: 30) weeks. While the mean birth weight was 1501±407.93 (min: 680 g; max: 2400 g; median: 1480 g) g. Twenty-two cases (84.6%) were born with cesarean section, and 3 (11.5%) cases were delivered by normal vaginal delivery. The birth type of one case could not be reached. The mean hospitalization period of 18 cases in the NICU was 48±25.98 (min: 11; max: 103; median: 38) days. While NICU hospitalization diagnoses were prematurity and respiratory distress, it was found that the additional diagnoses of sepsis (n=3), congenital pneumonia (n=2), and hyperbilirubinemia (n=5) were added in the follow-up. Twenty-three cases received respiratory support. All of the allegations were that "the ROP examination was not performed in exact time, and vision loss was caused by inadequate diagnosis." Although, the question posed by the judicial authorities was whether the ROP examination was performed at the appropriate time and whether there was a medical practice error in the occurrence of vision loss. Medical malpractice was found in 16 (61.5%) cases. Diagnosis, treatment, and follow-up processes of 10 (38.4%) cases were carried out in accordance with current medical knowledge. Malpractice claims were attributable to pediatricians in 11 (42.3%) cases, both pediatricians and ophthalmologists in 7 (26.9%) cases, ophthalmologists in 5 (19.2%) cases, and both pediatricians and obstetricians in 1 case. In one case, the branch of the physician against whom the lawsuit was filed was not registered. In the cases with medical malpractice, there were problems with the appropriate first examination time, diagnosis, and follow-up process (Table 1). In 7 (26.9%) cases, malpractice was given because the pediatrician did not consult an ophthalmologist on time. It was determined that 9 (34.6%) cases of ophthalmologist malpractices given; whereas the diagnosis was erroneous in 8 (30.7%) cases, the follow-up planning of 1 case was faulty. On the other hand,

Table 3: Timing of first eye examination based on gestational age at birth

Gestational age at birth (week)	Age at initial examination (week)	
	Post-menstrual	Chronologic
Recommendation of the Academy American of Pediatrics		
22[a]	31	9
23[a]	31	8
24	31	7
25	31	6
26	31	5
27	31	4
28	32	4
29	33	4
30	34	4
Older gestational age, high-risk factors[b]	–	4
Recomendation of Turkish premature retinopathy guide		
22[c]	31	9
23[c]	31	8
24[c]	31	7
25	31	6
26	31	5
27	31	4
28	32	4
29	33	4
30	34	4
31	35	4
32[d]	36	4

Shown is a schedule for detecting prethreshold ROP with 99% confidence, usually before any required treatment. —, not applicable. a: This guideline should be considered tentative rather than evidence-based for infants with a gestational age of 22–23 weeks because of the small number of survivors in these post-menstrual age categories; b: Consider timing on the basis of the severity of comorbidities; From: Screening Examination of Premature Infants for Retinopathy of Prematurity Pediatrics. 2018;142(6). doi:10.1542/peds.2018-3061; c: The babies under 25 weeks of gestational age, the first examination can be performed when post-natal 6 weeks are completed without waiting for post-menstrual 31 weeks; d: In babies over 32 weeks of gestational age, the first examination is done when post-natal 4 weeks are completed; From: Türk Neonatoloji ROP Rehberi; avable:https://www.neonatology.org.tr/storage/2021/09/Turkiye-Premature-Retinopatisi-Rehberi-2021-Guncellemesi.pdf.

in the other 10 (38.4%) cases, medical malpractice was not detected. Stage 4–5 ROP was found in all cases at the time of diagnosis. Delays in treatments were either due to failure of timely diagnosis and staging of ROP by ophthalmologists or incomplete documentation of patient files and consultation delays by pediatricians.

Case Summaries

Table 1 shows a summary of the cases included in this study.

DISCUSSION

This study summarized the medical malpractice claims regarding ROP cases which were evaluated in the 7th Specialization Board of the Council of Forensic Science. It was found ophthalmologist's late and/or improper management and delays in consultation by pediatricians were the main reasons for ROP malpractice cases.

Statistics from a national study screening all pre-term infants in 69 NICUs across Türkiye showed that out of 6115 infants, 27% had any stage of ROP and 6.7% had severe ROP.[8,10] Although the prevalence of premature retinopathies among malpractice cases in our country is not known, it is reported to have a significant majority among malpractice cases filed in the United States and it was stated that in the vast majority of the cases in question, compensation was paid due to ROP.[11–13] The Board reviewed 16,697 malpractice cases during the study period. Among these cases, only 26 (0.15%) included a diagnosis of ROP and subsequent malpractice claims. In a study of 68 cases of ophthalmology malpractice involving plaintiffs younger than 18 years of age, 12 (17.6%) cases were found to be associated with ROP.[12] In our study, malpractice titles of ophthalmologists were also not evaluated.

Although the guidelines used in the detection and follow-up of ROP have high sensitivity, their specificity is low. In the vast majority of screened cases, ROP that requires intervention does not develop.[12–15] Although the diagnosis, follow-up, and treatment of cases diagnosed with ROP are improving day by day, ROP screening, follow-up, and treatment differ from unit to unit according to NICU standards.[16–19] Serial binocular indirect ophthalmoscopy is frequently used to detect signs of ROP. However, since this method requires individual experience, it can lead to misleading results.[17–20] According to the section on ophthalmology, American Academy of Pediatrics; the American Academy of Ophthalmology; and the American Association for Pediatric Ophthalmology and Strabismus ROP screening, along with timing and treatment recommendations; all infants with a birth weight of ≤1500 g or a gestational age of ≤30 weeks to be screened for ROP and selected screening for infants with an unstable clinical course with a birth weight between 1500 and 2000 g or a gestational age of >30 weeks.[17] Infants with a birth weight between 1500 and 2000 g or infants with a gestational age of >30 weeks with risk factors such as hypotension requiring inotropic support, received oxygen supplementation for more than a few days, and received oxygen without saturation monitoring should be screened for ROP.[21] There are similar recommendations in the Turkish Neonatology Association and Turkish Ophthalmology Association ROP follow-up guide (Table 2, 3).[8,9,21] Current ROP algorithms for screening, follow-up, and follow-up termination are given (Tables 2–6). It is reported that while ophthalmologists intervene early in cases with suspected ROP due to medicolegal problems that may occur in the future, pediatricians consult all possible cases with

Table 4: Pre-mature Retinopathy follow-up recommendations

Recommendation of Academy American of Pediatrics			
1-week-or-less follow-up	**1–2-week follow-up**	**2-week follow-up**	**2–3-week follow-up**
Zone I immature vascularization, no ROP; Zone I stage 1 or stage 2 ROP; Immature retina extending into posterior zone II, near the boundary of zone I–zone II; Suspected presence of AP-ROP; and Stage 3 ROP, zone I requires treatment, not observation.	Posterior zone II immature vascularization; Zone II stage 2 ROP; and Zone I unequivocally regressing ROP	Zone II: stage 1 ROP; Zone II: No ROP, immature vascularization; and Zone II: unequivocally regressing ROP.	Zone III: stage 1 or 2 ROP; and Zone III: regressing ROP
Recommendation of Turkish Premature Retinopathy Guide			
3-4 days or more follow-up	**1-week follow-up**	**2-week follow-up**	**2-3 week follow-up**
Zone I stage 1–2 ROP Zone II stage 3 ROP Zone I avascular retina (none ROP) Suspected ROP	Zone II stage 2 ROP Posterior Zone II avascular retina (none ROP) Zone I regressing ROP	Zone II stage 1 ROP Zone II regressing ROP Zone II immature vascularization (none ROP)	Zone III stage 1-2 ROP Zone III regressing ROP

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ophthalmologists for the same reason, whether or not they are specialized ophthalmologists in the field of ROP.[11–15,20–22] In our study, the lack of evaluation by ophthalmologists who were qualified in this field, caused misdiagnosis, while it was observed that pediatricians often had medicolegal problems due to delays in consultation.

In our cohort, it was determined that pediatricians did not write clear data on electronic medical records hindering ROP treatment and controls. On the other hand, it was noted that there were delays in treatment due to staging errors, especially in stage 2–3 ROP cases, which ophthalmologists have difficulty diagnosing. Our documentation of malpractice cases once more emphasized the importance of interdisciplinary cooperation and experience in the follow-up of ROP. The main problem in ROP cases is the lack of experience parallel with the literature.[11–15,20–22]

As reflected in the literature and as proven in our study, malpractice in ROP cases results from not being screened at the appropriate time, poor documentation, failure in treatment, and/or not being referred to the appropriate center on time.[21–25] Preventative measures to face these issues need to be introduced as timely detection of risky cases, multidisciplinary cooperation, and standard management algorithms reduce the number of ROP-related malpractice cases.[11–13,23–25] Recommendations include regular morbidity and mortality meetings, and teaching sessions directed to pediatric and ophthalmology trainees focusing on local management guidelines and proper documentation from a medicolegal perspective.[11–13,23–25] Another important point is providing families with full disclosure and discussing all possible complications of prematurity.[11–13,22–25]

The main strength of our study was; it being one of the few studies documenting ROP cases from a medicolegal perspective. However, analyzing documents retrospectively, the limitations of our study included incomplete data and poorly documented case reports, which may have led to discrepancy when reporting our findings.

Limitation

The retrospective nature of our study caused some limitations. First, the fact that the data set was obtained from the reports caused deficiencies in some medical information. Since only the cases with a diagnosis of ROP were included in the study, the evaluation of malpractice claims separately for ophthalmologists and pediatricians did not given in the study. However, our study will guide future studies to be planned on these issues.

CONCLUSION

The most important issue for ROP malpractice cases was delays in diagnosis and treatment. It is essential that specialized pediatrics ophthalmologists assess these cases. Multidisciplinary cooperation and standard management algorithms should be introduced. Moreover, families must be informed about all possible complications of prematurity, especially ROP and its morbidity.

Table 5: The termination of acute retinal screening examinations

Turkish pre-mature retinopathy guide	Academy American of Pediatrics
• Complete retinal vascularization (This criterion is especially important in patients receiving anti-VEGF agents.)	• Full retinal vascularization in close proximity to the ora serrata for 360°, that is, the normal distance found in the mature retina between the end of vascularization and the ora serrata. This criterion should also be used for all cases treated for ROP solely with anti-vascular endothelial growth factor (VEGF) injectable medications.
• Zone I or II ROP was not detected in previous screening examinations and retinal vascularization has reached zone III (If the ophthalmologist is suspicious about the zone or if the baby is younger than PM 35 weeks, repeat examinations are recommended.)	• Zone III retinal vascularization attained without previous zone I or II ROP (if there is examiner doubt about the zone or if the post-menstrual age is less than 35 weeks, confirmatory examinations may be warranted).
• Infants who have reached PM 45 weeks and have no pre-threshold or worse ROP at previous screening examinations	• Post-menstrual age of 45 weeks and no type 1 ROP (previously called "prethreshold") disease (defined as stage 3 ROP in zone II, any ROP in zone I) or worse ROP is present.
• Regressed ROP; the absence of abnormal vascular tissue that may be at risk of reactivation or progression • PM 44-55 with the highest reactivation in patients who received anti-VEGF therapy. Close follow-up should be done between weeks.	• If anti-VEGF injectable medications were used to cause regression of the ROP, post-menstrual age of at least 65 weeks, because this treatment alters the natural history of this disease. Very late recurrences of proliferative ROP have been reported, 19–21 so caution and clinical judgment are required to determine when surveillance can be safely terminated in individual cases. Infants treated with anti-VEGF medications need particularly close follow-up during the time of highest risk for disease reactivation, between postmenstrual age 45–55 weeks.
• In patients who have received anti-VEGF therapy, follow-up should not be terminated until at least the PM 60th week. • Very late proliferative recurrences of ROP have been reported in these patients.	• Regression of ROP 22 (care must be taken to be sure that there is no abnormal vascular tissue present that is capable of reactivation and progression in zone II or III). The termination of acute retinal screening examinations should be based on age and retinal ophthalmoscopic findings

From: Screening Examination of Premature Infants for Retinopathy of Prematurity Pediatrics. 2018;142(6); From:Türk Neonatoloji ROP Rehberi; avable:https://www.neonatology.org.tr/storage/2021/09/Turkiye-Premature-Retinopatisi-Rehberi-2021-Guncellemesi.pdf; ROP: Retinopathy of prematurity; VEGF: vasculer endothelial growth factor.

Table 6: Turkish pre-mature retinopathy guide recommendations

• Parents should be informed verbally and in writing about the ROP examination and follow-up.
• Before the first examination, consent/consent should be obtained from the parents.
• In families who do not give consent, permission should be obtained from the court for medical examination and procedure on the basis that the right to life of the baby is the highest right.
• If the parents request is not in accordance with the medical approach and practices in terms of the baby's health and right to life, the consent is invalid.
• The date requested for consultation for the ROP examination should be stated on the consultation paper.
• The name of the ophthalmologist performing the ROP examination and the date of the examination should be included in the documents.
• In the examination notes, the ophthalmologist should write down the pupil status, zone, stage, extent, and the presence of "plus" disease in detail, specify the treatment plan, and the date of the next examination.

From: Türk Neonatoloji ROP Rehberi; avable:https://www.neonatology.org.tr/storage/2021/09/Turkiye-Premature-Retinopatisi-Rehberi-2021-Guncellemesi.pdf; ROP: Retinopathy of prematurity.

Statement

Ethics Committee Approval: Permission to undergo this study was taken from the Scientific Research committee of the Institute of Forensic Medicine (date: 10.09.2020, number: 2020/856).

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – NYS, MÖ, HA, TTC; Design – NYS, MÖ, HA, TTC; Supervision – NYS, MÖ, HA, TTC; Resource – NYS, HA, TTC; Materials – NYS, HA, TTC; Data Collection and/or Processing – NYS, TTC; Analysis and/or Interpretation – NYS, TTC; Literature Search – NYS, TTC; Writing – NYS, TTC; Critical Reviews – NYS, HA, TTC.

Conflict of Interest: The authors have no conflict of interest to declare.

Financial Disclosure: The authors declared that this study has received no financial support.

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