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Erdem Eriş

erdem-eris@hotmail.com

University of Health Sciences Türkiye

Sinan Bekmez

University of Health Sciences Türkiye

Diem Aydin

Izmir Bakircay University Cigli Training and Research Hospital

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Treatment-Requiring Retinopathy of Prematurity by Neonatal Intensive Care Unit Level: A Retrospective Cohort Study

Erdem Eriş[1]*, Sinan Bekmez[1], Diem Aydin[2]

[1] Department of Ophthalmology, University of Health Sciences, Izmir, Türkiye

[2]Department of Neonatology, Izmir Bakircay University Cigli Training and Research Hospital, Turkiye

***Corresponding author**: Erdem Eriş

E-mail: erdem-eris@hotmail.com

Abstract

Background: Retinopathy of prematurity (ROP) is a neovascular retinal disease. With the development of neonatal intensive care units (NICU), the rate of ROP has changed over the years. However, there is a lack of sufficient studies regarding the protocols of NICU and the frequency of ROP.

Purpose: Our objective is to compare the characteristics of infants who are monitored and treated for ROP in level II and Level ≥III neonatal intensive care units (NICUs).

Methods: From January 2018 to 2025, we collected data on gestational age (GA), birth weight (BW), ROP stages, duration of oxygen therapy, and risk factors associated with different levels of NICU from infants diagnosed with ROP.

Results: Out of a total of 2071 infants screened for ROP, 1640 (79.2%) were classified as level II, while 431 (20.8%) fell into the category of Level ≥III NICUs. Among these, 537 infants in level II and 92 infants in Level ≥III NICUs were diagnosed with ROP at any stage. Severe ROP was identified in 93 (5.7%) infants in level II and 17 (3.9%) infants in Level ≥III NICUs.

The mean gestational ages (GAs) of infants with severe ROP were 31.41 ± 2.67 weeks and 26.00 ± 1.70 weeks in level II and Level ≥III NICUs respectively (P < 0.001).

The mean birth weights (BWs) of infants with severe ROP were 1558 ± 409 grams and 823 ± 110 grams in level II and Level ≥III NICUs respectively (P < 0.001).

Conclusion: Although infants in Level ≥III NICUs were more premature and had lower birth weights, treatment-requiring ROP was more common in Level II NICUs. Even after adjustment for the main neonatal risk factors, care in a Level II NICU remained significantly associated with a higher risk of treatment-requiring ROP.

Keywords: Severe ROP; NICU level II; Level ≥III NICUs

What is known about this subject

- Throughout history, advancements in neonatal intensive care services have influenced the rate of retinopathy of prematurity, reflecting developments in intensive care units.
- Severe ROP is prevalent in younger premature infants in developed countries.

Contribution of the study

- In this study, severe retinopathy of prematurity cases were more prevalent in Level II neonatal intensive care units.

1. Introduction

Retinopathy of prematurity (ROP) is a neovascular retinal disease affecting prematurely born infants, and it stands as a leading cause of blindness during infancy in both developed and developing nations.[1,2] According to The Early Treatment for Retinopathy of Prematurity Cooperative Group (ETROP), type 1 ROP and aggressive posterior retinopathy of prematurity (APROP) require treatment.[3]

A comprehensive review of ROP epidemiological studies reveals three distinct epidemics. The first epidemic, documented in the 1940s, primarily affected premature infants in Europe and the United States due to unregulated oxygen supplementation.[4] The "2nd epidemic" emerged in the 1970s, driven by increased survival rates among small premature infants in developed countries.[5] The "3rd epidemic" of ROP emerged in the 2000s, spurred by improved survival rates among premature infants in middle-income countries such as Latin America, Eastern Europe, China, and India.[6,7]

Throughout history, advancements in neonatal intensive care services have influenced the incidence of ROP, reflecting developments in intensive care units (ICUs). Premature infants are typically monitored in secondary or higher-level NICUs, which are categorized based on personnel expertise and technological resources. Previous studies haven't adequately investigated the association between ROP incidence and the level of care provided in NICUs. Consequently, there is a paucity of literature on the frequency of ROP within different NICU settings. This study aims to compare NICUs based on the severity of ROP requiring treatment.

2. Methods

2.1: Population and Study design

Infants who underwent ROP screening between January 2018 and January 2025 were included in this retrospective study.

Approval for this report was obtained from the Research Ethics Committee (protocol number: 373), and adhered to the principles outlined in the Declaration of Helsinki.

2.2: Outcomes

The primary outcome of the study was the proportion of infants requiring treatment for ROP according to NICU level (Level II vs. Level ≥III).

Secondary outcomes included the frequency and severity of ROP in the two NICU groups. Gestational age, birth weight, duration of oxygen therapy, and other clinical risk factors associated with ROP were also compared between the groups, particularly among infants who required treatment.

2.3: Variables

ROP examinations were conducted following the guidelines outlined in the Turkey ROP Guide: for infants with Gestational Age (GA) ≤34 weeks or Birth Weight (BW) ≤1750 grams, and for those with GA >34 weeks or BW >1750 grams recommended by attending clinicians for screening if deemed at risk for ROP development. ROP staging for treatment was assessed according to the criteria set by the International Committee for the Classification of ROP (ICROP).[8] Severe ROP was defined as ROP requiring treatment.

2.4: Examination and Treatment procedure

Newborn fundoscopic examinations were conducted using a binocular indirect ophthalmoscope and a 28 D Lens following adequate mydriasis to ensure clear visualization of the retina and vitreous details. Pupil dilation was achieved one hour prior to the examination by administering 2.5% phenylephrine and 0.5% tropicamide drops, repeated three times at 10-minute intervals. Premature infants were ready for examination with optimal pupil dilation within 45-60 minutes after the last drop administration. These examinations were conducted by experienced pediatric ophthalmologists specialized in ROP diagnosis and treatment. All infants included in the study were followed until retinal vascularization was complete.

Laser treatment was administered for type 1 ROP, while intravitreal anti-vascular endothelial growth factor (anti-VEGF) therapy was provided for infants diagnosed with aggressive posterior ROP (APROP). ROP treatment decisions were made according to the ETROP and ICROP criteria. Data on infants were collected from medical records and parental reports, encompassing birth information such as gestational age (GA), birth weight (BW), and multiple pregnancies, as well as postnatal details including ROP presence at examination, ROP staging, rate of sepsis, necrotizing enterocolitis (NEC), respiratory distress syndrome (RDS), treatment protocols, number of treatments administered, and recurrence rates.

2.5: Categorization of Neonatal Intensive Care Units (NICU)

In Turkey, Level II NICUs primarily provide care for newborns and offer medical treatment for conditions requiring Intermediate-level neonatal care. These NICU units also accommodate infants facing challenges such as maintaining body temperature, experiencing hypoglycemia, oral nutritional deficiencies, respiratory distress, or requiring oxygen therapy exceeding 24 hours. Additionally, minor surgical interventions such as central venous catheter placements are managed in these units. Equipment utilized in Level II NICUs includes tools for intravenous infusion, gavage feeding, phototherapy, and transfusion.[9]

In contrast, Level ≥III NICUs offer more advanced neonatal intensive care services than Level II NICUs. They provide continuous life support as needed and handle cases requiring major surgical interventions. Typically, infants may require invasive or non-invasive mechanical ventilation. These units are staffed with experienced nurses and neonatologists, and they are equipped with essential medical devices such as oxygen supply, infusion pumps, vital sign monitors, subcutaneous monitors, and ventilators.[10]

All ROP examinations were performed by the same experienced ophthalmologists (Dr. EE and Dr. SB). Infants were referred from the NICUs where they had received neonatal care. Accordingly, NICU level was determined based on the referring unit, and infants were classified as being referred from either a Level II or a Level ≥III NICU.

Infants who were transferred from one NICU level to another were excluded from the study to ensure that each infant could be assigned to a single NICU level.

2.6: Statistical analysis

Data were analyzed with IBM SPSS (Version 20, SPSS, IBM, Chicago, IL) statistical software. Mean / standard deviation (SD) was used as the distribution criterion. p <0.05 was considered statistically significant. Initially, all numerical and categorical data were evaluated using descriptive statistical methods. The normality of continuous variables was evaluated using

histograms, Q-Q plots and the Shapiro-Wilk test. The independent-samples t-test was used for normally distributed variables, while the Mann-Whitney U test was used for variables that did not follow a normal distribution.

2.7: Ethics

The study was approved by the Ethics Committee of Dr. Behçet Uz Children's Diseases and Surgery Training and Research Hospital (approval no. 373). As this was a retrospective study, the Ethics Committee waived the requirement for informed consent to participate. The study was conducted in accordance with the Declaration of Helsinki.

Results

Between January 2018 and 2025, a total of 2071 infants underwent ROP screening. Among them, 1640 (79.2%) were admitted to Level II neonatal intensive care units (NICUs), while 431 (20.8%) were in Level ≥III NICUs. The mean Gestational Ages (GAs) and Birth Weights (BWs) of infants in Level II NICUs were 31.67 ± 1.88 weeks and 1790 ± 1080 g, respectively. For infants in Level ≥III NICUs, the mean GAs and BWs were 30.56 ± 2.82 weeks and 1514 ± 470 g, respectively. Demographic data, including the presence of ROP at the initial examination and the distribution of ROP stages, are summarized in Table 1.

Treatment decisions were made for 220 eyes of 110 infants due to ROP. Of these treated infants, 93 (5.7%) were followed up in Level II NICUs, and 17 (3.9%) in Level ≥III NICUs. In Level II NICUs, 83 infants with type I ROP and 10 with APROP received treatment, while in Level ≥III NICUs, 15 infants with type I ROP and 2 with APROP were treated (p=0.155). There were no instances of recurrence among the patients treated for ROP. The mean GAs, BW, and duration of oxygen therapy are presented according to the level of NICU care and the need for

ROP treatment in Figure 1. Furthermore, Table 2 displays the mean GAs, BW, duration of oxygen intake, and risk factors for ROP in both Level II and Level ≥III NICUs.

After adjusting for gestational age, birth weight, duration of oxygen therapy, sepsis, necrotizing enterocolitis, respiratory distress syndrome, multiple pregnancy, and year of birth, NICU level was still significantly associated with severe ROP . Infants followed in Level II NICUs had approximately twice the odds of requiring ROP treatment compared with those in Level ≥III NICUs (adjusted OR: 2.08; 95% CI: 1.14–3.79; P = 0.017).

Discussion

According to the evolution of neonatal intensive care levels, three peaks in history due to ROP have been observed.[11] The first ROP epidemic occurred in the US and Western Europe between 1940 and 1950 due to unmonitored and uncontrolled high oxygen use, resulting in vision loss in approximately 10,000 infants.[12,13] The second ROP epidemic (acute ROP) emerged in the US and Europe between 1960 and 1970, driven by advancements in neonatal care and increased survival rates.[5,14] The third epidemic was witnessed in developing countries (Eastern Europe, Asia, Latin America) in the 2000s due to factors such as premature births, multiple pregnancies, and insufficient neonatal intensive care units.[7,15,16] Despite variations in ROP frequency across countries, it remains a significant cause of childhood blindness.[17,18] Severe ROP is prevalent in younger premature infants in developed countries, while older premature infants are more affected in developing countries, possibly due to the availability of advanced intensive care services in developed nations.

Currently, there is a paucity of studies in the literature comparing severe ROP development based on neonatal unit levels. Therefore, our study aimed to assess severe ROP frequencies according to the levels of neonatal intensive care.

In our study, 93 infants (5.7% of all screened infants in level II neonatal intensive care) required ROP treatment within follow-up in level II units. However, only 17 infants (3.9% of all screened infants in level ≥III neonatal intensive care) received treatment in level ≥III units.

Zin et al.[19], in their evaluation of ROP development in seven level III intensive care units in Brazil, reported that 124 infants (3.6%) were treated for severe ROP. While their findings align with our results for level ≥III intensive care, Zin et al. did not consider level II intensive care in their studies. Our study indicates that ROP infants requiring treatment were predominantly followed in level II intensive care units. Furthermore, our study evaluates the characteristics of severe ROPs developed in two different levels of intensive care.

Isaza et al.[20] screened patients in level III intensive care units in Canada between August 2010 and 2016, finding the incidence of severe ROP to be 14.3%. Their study population's gestational ages ranged from 23 to 37 weeks, similar to our study. However, unlike our findings, they observed a mean gestational age of 26 weeks for infants with severe ROP. In our study, the mean gestational age of infants with severe ROP in level III intensive care units was 26 ± 1.70 weeks and 31.41 ± 2.67 weeks in level II intensive care units. While the rates of severe ROP in Canadian intensive care units were high, the average gestational ages were lower, indicating that infants with lower gestational ages are primarily hospitalized in level III intensive care units in industrial countries compared to less developed nations.

Hungi et al.[21] screened infants with gestational ages ≤34 weeks and birth weights ≤2000 g in level III neonatal intensive care in India, finding severe ROP in 10.2% of these infants. In our study, 3.9% of all screened infants in level ≥III neonatal intensive care had severe ROP. The higher percentage found by Hungi may be attributed to screening only small infants. Conversely, in Canadian and our study, infants considered at risk of ROP included those between 34 and 37 weeks of gestational age.

ROP is a retinovascular disease with significant risk factors including gestational age, birth weight, and oxygen treatment.[22,23] In our study, severe ROP was observed in 93 infants (5.7%) in level II intensive care units and 17 infants (3.9%) in level ≥III. It was noted that infants with severe ROP in level ≥III had lower gestational ages and birth weights compared to those in level II (mean gestational age 26.00 ± 1.70 weeks and 31.41 ± 2.67 weeks, mean birth weight 823 ± 110 g and 1558 ± 409 g, respectively). Despite these results, severe ROP was more frequently observed in infants hospitalized in level II facilities.

While infants in level ≥III intensive care units typically have higher risks for ROP such as low gestational ages and birth weights, our study observed fewer infants requiring ROP treatment in level ≥III compared to level II intensive care units. This suggests that differences in neonatal care practices may play a crucial role in the severe ROP process.

In severe ROP infants, although the mean duration of oxygen intake in level ≥III intensive care units was longer than in level II, there was no statistically significant difference between these results ($p = 0.628$). The way oxygen delivery may be more important than the duration of oxygen therapy. Colaizy et al.[24] also reported that a standardized protocol for providing targeted supplemental oxygen effectively reduces the progression of active ROP, supporting our study's findings.

Importantly, the higher rate of severe ROP in Level II NICUs remained significant after adjustment for the main neonatal risk factors. This suggests that differences in gestational age, birth weight, and neonatal morbidities alone may not fully explain our findings. Differences in neonatal care practices, such as oxygen management, respiratory support, and clinical monitoring, may also have played a role. However, other factors that were not available in our data may have influenced the results. Therefore, due to the retrospective design of the study, these findings should be interpreted with caution and do not establish a causal relationship

between NICU level and severe ROP. Further prospective studies may help clarify the reasons for this difference.

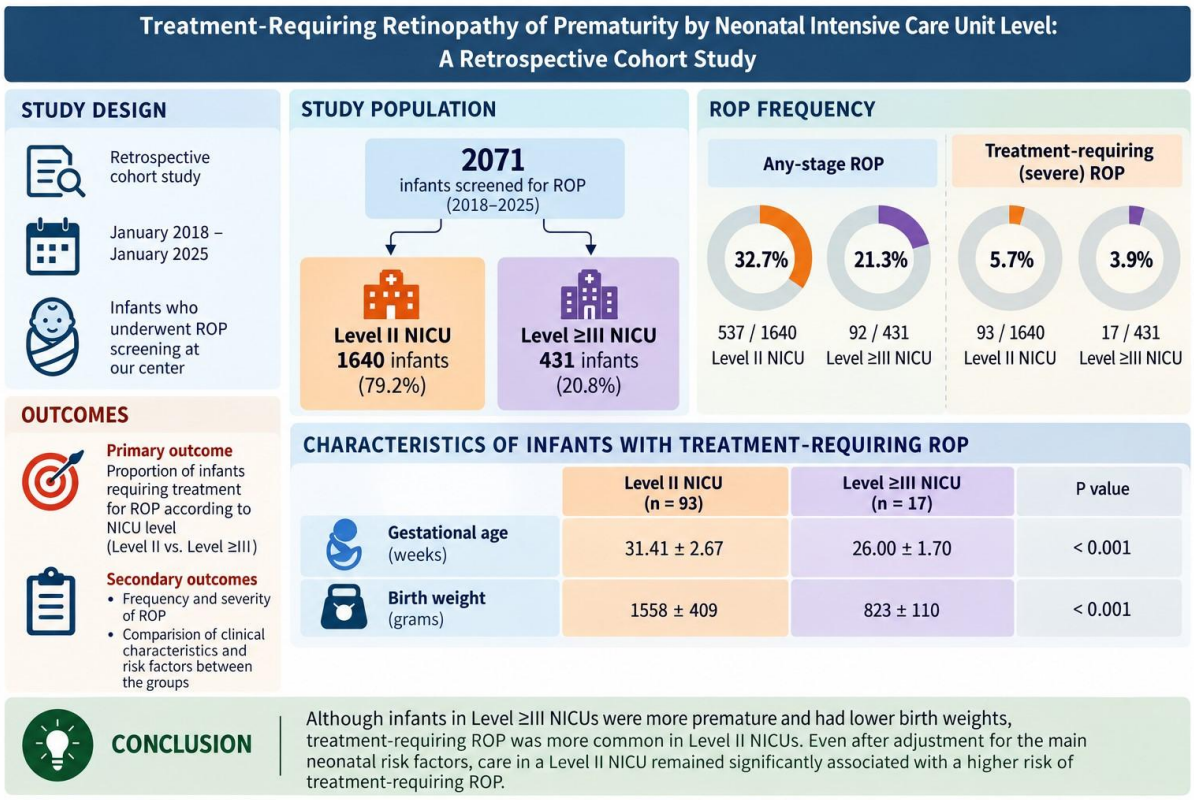
Limitations and future directions

The retrospective design is the main limitation of our study. Although several known neonatal risk factors were included in the adjusted analysis, we cannot rule out the influence of other factors that were not available in our data. In particular, detailed information on oxygen targets, respiratory support strategies, and specific care practices in each NICU was not available. For this reason, the association between NICU level and treatment-requiring ROP should be interpreted with caution and cannot be considered causal. On the other hand, the relatively large number of infants and the comparison of different NICU levels are important strengths of our study. Prospective studies with more detailed information on neonatal care practices may provide a better understanding of the differences observed between NICU levels.

Conclusion

Despite their lower gestational ages and birth weights, infants cared for in Level ≥III NICUs were less likely to require ROP treatment than those cared for in Level II NICUs. This difference remained significant even after adjustment for major neonatal risk factors, suggesting that baseline differences between the groups may not fully explain this finding. Differences in neonatal care practices between NICU levels may have contributed to the observed difference. However, because of the retrospective design of the study and the possibility of unmeasured confounding factors, these results should be interpreted with caution. Further prospective studies are needed to better understand the factors underlying the higher rate of severe ROP observed in Level II NICUs.

Figure 1. Graphical abstract comparing treatment-requiring ROP between Level II and Level ≥III NICUs.



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No external funding was received for this study.

Declarations

Abbreviations

ROP: Retinopathy of prematurity; TR-ROP: Treatment-requiring retinopathy of prematurity; NICU: Neonatal intensive care unit; GA: Gestational age; BW: Birth weight; RDS: Respiratory distress syndrome; NEC: Necrotizing enterocolitis.

Ethics approval and consent to participate

Ethical approval for this study was obtained from the Ethics Committee of Dr. Behçet Uz Children's Diseases and Surgery Training and Research Hospital (approval no. 373). Given the

retrospective design of the study, the requirement for informed consent was waived by the Ethics Committee. The study was carried out in accordance with the Declaration of Helsinki.

Consent for publication

Not applicable.

Availability of data and materials

The data used in this study are not publicly available because of patient confidentiality. They may be obtained from the corresponding author upon reasonable request.

Competing interests

The authors have no competing interests to declare.

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Author contributions

E.E. conceived and designed the study, interpreted the data, and drafted the manuscript. S.B. and D.A. contributed to data collection and ophthalmologic examinations. E.E. and S.B. were involved in the collection and evaluation of clinical data. E.E., S.B., and D.A. performed the statistical analysis and interpreted the results. All authors critically reviewed the manuscript and approved the final version.

Acknowledgements

Not applicable.

Availability of data and materials

The study data are not publicly available because of patient confidentiality. However, they can be obtained from the corresponding author upon reasonable request.

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Table 1. Demographic and retinopathy characteristics of premature infants by intensive care levels

		Level II intensive care units (n=1640)	**Level ≥III intensive care units (n=431)**
	ROP (+)	31.16 ± 2.11	29.17 ± 3.14

Gestational age (week), mean ± SD	ROP (-)	32.17 ± 1.43	30.90 ± 2.62
Birth weight (g), mean ± SD	ROP (+)	1615 ± 407	1389 ± 552
	ROP (-)	1963 ± 1445	1545 ± 444
ROP (+) n (%)		537 (32.8)	92 (21.3)
ROP (-) n (%)		1103 (67.8)	339 (78.7)
Severe ROP n (%)		93 (5.7)	17 (3.9)

*SD: standard deviation, ROP: Retinopathy of prematurity, ROP (+): baby with any stage of retinopathy of prematurity, ROP (-): baby without any stage of retinopathy of prematurity

Table 2. Demographic characteristics and risk factors of all premature infants by intensive care levels

	All Prematures		**Premature with severe ROPs**		**Premature without severe ROPs**	
	Level II intensive care units (n=1640)	**Level ≥III intensive care units**	**Level II intensive care units (n=93)**	**Level ≥III intensive care units**	**Level II intensive care units (n=1547)**	**Level ≥III intensive care units**

		(n=431)		**(n=17)**		**(n=414)**
Oxygen intake (day), mean ± SD	11.8 ± 10.7	12.2 ± 11.3	17.9 ± 13.1	19.9 ± 15.2	11.5 ± 10.4	11.9 ± 11.1
Sepsis, n (%)	23 (1.4)	20 (4.62)	3 (3.2)	1 (5.9)	20 (1.3)	19 (4,56)
NEC, n (%)	46 (2.8)	6 (1.4)	2 (2.2)	1 (5.9)	44 (2.8)	5 (1.2)
RDS, n (%)	609 (37.1)	185 (42.9)	35 (37.6)	6 (35.3)	574 (37.1)	179 (43.2)
Multiple pregnancies, n (%)	30 (1.8)	26 (6.04)	25 (26.9)	6 (35.29)	5 (0.3)	20 (4,83)

*SD: standard deviation, NEC: Necrotizing enterocolitis, RDS: Respiratory distress syndrome