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Original Article

Ophthalmology Section

# A Prospective Cohort Study Comparing Retinopathy of Prematurity between Small for Gestational Age and Appropriate for Gestational Age Babies at a Tertiary Care Centre in Western Maharashtra, India

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## ABSTRACT

**Introduction:** Retinopathy of Prematurity (ROP) is a leading cause of preventable blindness in premature infants. Differences in incidence and severity between Small for Gestational Age (SGA) and Appropriate for Gestational Age (AGA) infants have been variably reported.

**Aim:** To compare the incidence, risk factors, and clinical characteristics of ROP between SGA and AGA neonates admitted to a tertiary care hospital in Western Maharashtra.

**Materials and Methods:** A prospective cohort study was conducted at the Department of Ophthalmology at Rajiv Gandhi Medical College and Chhatrapati Shivaji Maharaj Hospital, Kalwa, Thane, Maharashtra, India, from May 2022 to May 2023. A total of 150 neonates ≤ 34 weeks GA and/or ≤ 2000 g birth weight were enrolled and classified as SGA (n=103) or AGA (n=47) using the Fenton growth chart. ROP screening was performed with the Forus Trinetra Neo fundus camera. Sample size was calculated using Cochran's formula, and data were analysed using Statistical Package for Social Sciences (SPSS), version 26.0, with the Chi-square test, considering p-value <0.05 as statistically significant.

**Results:** ROP was identified in 32 infants (21.33%), comprising 23 SGA (22.33%) and 9 AGA (19.14%) neonates (p-value=0.82). Prematurity, oxygen exposure, and low birth weight were the predominant neonatal contributors, while maternal hypertension and anaemia were more frequently noted among SGA pregnancies. Among infants diagnosed with ROP, 34.37% required treatment primarily intravitreal bevacizumab, whereas 65.63% demonstrated spontaneous regression. There were no statistically significant differences in ROP incidence or associated maternal and neonatal risk profiles between SGA and AGA infants, suggesting that SGA status did not independently influence ROP development in this population.

**Conclusion:** Early screening of preterm SGA neonates is crucial to prevent ROP-related blindness, and addressing modifiable risk factors can reduce ROP-associated morbidity and improve neonatal visual outcomes. There was no statistically significant difference between the groups for ROP incidence.


**Keywords:** Blindness prevention, Fundus photography, Infant, Low birth weight, Neonatal screening, Oxygen inhalation therapy, Visual acuity

## INTRODUCTION

Premature neonates with low birth weight and small gestational age are highly vulnerable to ROP, a proliferative retinal vascular disorder [1]. ROP remains a leading cause of lifelong visual impairment in children across both industrialised and developing nations, despite significant advancements in neonatal care [1]. It is also recognised as one of the major preventable causes of childhood blindness [2]. Among neonates with low birth weight, the incidence of ROP has been reported to range between 38 to 51.9% [3]. According to the 2017 Rashtriya Bal Swasthya Karyakram guidelines, recent evidence suggests that the risk of developing ROP is higher in infants classified as SGA compared to those categorised as AGA [4]. ROP is expected to occur to some extent in nearly 80% of infants weighing less than 1000 grams and approximately 65% of those weighing less than 1250 grams at birth [5]. With ongoing improvements in neonatal resuscitation and the increased survival of very low birth weight and extremely low birth weight infants [6], a rise in the incidence of ROP is anticipated. Early identification and intervention remain crucial in minimising vision-threatening complications associated with this condition.

Although current screening criteria result in many infants being evaluated despite not developing clinically serious ROP [7], standardised documentation remains essential. The International Classification of Retinopathy of Prematurity (ICROP) facilitates this by defining the location, severity, and extent of disease, dividing the retina into three concentric zones around the optic disc. Therefore, the present study compares the incidence, risk factors and clinical characteristics of ROP between SGA and AGA neonates admitted to a tertiary care hospital in Western Maharashtra.

## MATERIALS AND METHODS

A prospective cohort study was conducted at the Department of Ophthalmology, Rajiv Gandhi Medical College and Chhatrapati Shivaji Maharaj Hospital, Kalwa, Thane, Maharashtra, India, from May 2022 to May 2023, in collaboration with the ROP team from Khan Bahadur Haji Bachoo Ali Hospital, Parel, Mumbai. Ethical principles outlined in the Helsinki Declaration were strictly followed. Ethical approval was obtained on 12/04/2022(IEC No: RGMC/CSMH/IEC/Q/01/2022). Written informed consent was obtained from the parents of all participating neonates.

**Sample size calculation:** The sample size was calculated using the COCHRAN'S formula for estimating proportions in comparative studies:

$$n = \frac{(Z_{(1-\alpha/2)})^2 \times p \times (1-p)}{d^2}$$

Where,

n=required minimum sample size;

$Z_{1-\alpha/2}$= standard normal deviate at 95% confidence (1.96);

p=anticipated proportion of ROP among preterm infants from previous literature; and

d=allowable margin of error.

Based on a prior study by Raj R et al., (2017) from Kerala, the incidence of ROP among preterm neonates was approximately 20% [4]. Substituting these values:

$$n = \frac{(1.96)^2 \times 0.20 \times (1-0.20)}{(0.07)^2} = 125.4$$

Thus, the minimum sample required was 126 neonates. To improve statistical validity and account for potential attrition, a total of 150 neonates were enrolled, comprising 103 SGA and 47 AGA infants.

Based on the Fenton growth chart, the neonates were categorised into two groups [7]:

- SGA: Infants with birth weight below the 10th percentile for their gestational age.
- AGA: Infants with birth weight between the 10th and 90th percentiles for their gestational age. Demographic data, maternal (hypertension, diabetes, anaemia), and neonatal {$O_2$ exposure, Respiratory Distress Syndrome (RDS), sepsis} variables were recorded.

**Inclusion criteria:** All the babies who were <2000 gm at birth and/or <34 weeks of gestation as per revised ROP guidelines and babies who completed a minimum of two weeks postgestation age [8].

**Exclusion criteria:** Neonates who were lost to follow-up before complete vascularisation or resolution of ROP, with or without treatment, were excluded from the study. Infants classified as large for gestational age, those who died before completing four weeks of follow-up and those whose parents or guardians did not provide informed consent were also excluded. In addition, patients who were on ventilator support or were severely ill and for whom the attending paediatrician advised deferring ROP screening were excluded from the study.

### Study Procedure

**The diagnostic ROP screening:** Written informed consent was obtained from the parents of all neonates prior to screening. Pupillary dilation was performed 30 minutes before examination using 0.4% tropicamide and 1.25% phenylephrine eye drops. Each baby was well-clothed, wrapped, and positioned comfortably in a dedicated neonatal screening room within the Neonatal Intensive Care Unit (NICU).

Under strict sterile and aseptic conditions, serial fundus photographs were obtained using the Forus Trinetra Neo Fundus Camera by a trained ROP technician, in the presence of a standby paediatrician. The captured retinal images were transmitted to the Senior Paediatric Ophthalmologist at Khan Bahadur Haji Bachoo Ali Charitable Ophthalmic and ENT Hospital, Parel, for expert evaluation of ROP presence and staging based on standard ROP screening guidelines. The classification and staging of ROP were carried out in accordance with the International Classification of Retinopathy of Prematurity (ICROP), 3rd edition (2021) [8].

All findings were documented and summarised for each neonate and parents were provided with a written report, explicit follow-up instructions and educational brochures on ROP. Infants with early-stage or no ROP at the initial examination were closely monitored in subsequent follow-up visits for disease progression. Those diagnosed with advanced stages of ROP were treated as per established protocols, either with retinal laser photocoagulation or intravitreal Vascular Endothelial Growth Factor (VEGF) (Bevacizumab) injection, within 48 hours of diagnosis. Weekly follow-up examinations were conducted until retinal vascularisation matured completely. Neonates who achieved complete retinal maturity were subsequently re-evaluated after six months to confirm disease stability.

**Factors assessed:** The study analysed demographic data, clinical and outcome-related parameters to compare SGA and AGA neonates. Factors included gender distribution, gestational age and birth weight categories. Clinical characteristics comprised the incidence and stages of ROP, retinal zone involvement and presence of Plus disease or aggressive posterior ROP. Additional neonatal risk factors such as prematurity, low birth weight, oxygen exposure, Respiratory Distress Syndrome (RDS) and mechanical ventilation were assessed. Maternal factors included diabetes, anaemia, low haemoglobin levels and hypertensive disorders of pregnancy. Fundus findings and treatment outcomes were also evaluated in terms of zone and stage at presentation, need for intervention, spontaneous regression and attainment of complete retinal maturity.

**Rationale for selection of risk factors:** The neonatal and maternal variables were chosen based on established literature demonstrating their influence on ROP development [9]. Prematurity, low birth weight and oxygen exposure are recognised as key postnatal predictors, while maternal conditions such as anaemia, hypertension and diabetes contribute to fetal growth restriction and altered retinal vascularisation. Inclusion of these parameters allowed for a balanced assessment of both intrauterine and postnatal determinants of ROP among preterm infants.

## STATISTICAL ANALYSIS

Data analysis was conducted using the Statistical Package for the Social Sciences (SPSS) version 26.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics, including mean, standard deviation and percentages, were used for data summarisation. The Chi-square test and Fisher's-exact test were applied for categorical variables, while Student's t-test was used for continuous data. A p-value <0.05 was considered statistically significant and a p-value <0.01 was regarded as highly significant.

## RESULTS

A total of 150 neonates were enrolled, with 103 classified as SGA and 47 as AGA. Female neonates predominated in both groups, but the gender distribution was statistically comparable (p-value=0.36). A significantly higher proportion of SGA neonates were born before 34 weeks of gestation compared to AGA neonates (p-value=0.001). Although the majority of both groups had birth weights between 1001-1500 g, extremely low birth weight (<1000 g) was observed exclusively in the SGA group. However, birth weight distribution differences were not statistically significant (p-value=0.13) [Table/Fig-1].

| Parameters | SGA (n=103) | AGA (n=47 ) | Total (N=150) | p-value |
|---|---|---|---|---|
| **Gender distribution** | | | | |
| Male | 47 (45.63%) | 17 (36.17%) | 64 (42.66%) | 0.36 |
| Female | 56 (54.36%) | 30 (63.82%) | 86 (57.33%) | |
| **Gestational age (weeks)** | | | | |
| <30 weeks | 23 (22.33%) | 4 (8.51%) | 27 (18%) | 0.001** |
| 30-34 weeks | 65 (63.10%) | 24 (51.06%) | 89 (59.33%) | |
| >34 weeks | 15 (14.56%) | 19 (40.42%) | 34 (22.66%) | |
| **Birth weight (gm)** | | | | |
| <1000 g | 7 (6.79%) | 0 | 7 (4.66%) | 0.13 |
| 1001-1250 g | 34 (33%) | 11 (23.4%) | 45 (30%) | |
| 1251-1500 g | 30 (29.12%) | 14 (29.78%) | 44 (29.33%) | |
| 1501-2000 g | 21 (20.38%) | 12 (25.53%) | 33 (22%) | |
| >2001 g | 11 (10.67%) | 10 (21.27%) | 21 (14%) | |

**[Table/Fig-1]:** Baseline demographic and clinical characteristics of SGA and AGA neonates.
Values are expressed as n (%). The p-values were calculated using the Chi-square test for categorical variables; p-value <0.05 was considered statistically significant; (p-value <0.01 marked as highly significant **)

ROP was observed in 21.33% of all neonates, with a comparable incidence among SGA (22.33%) and AGA (19.14%) groups (p-value=0.83). Common neonatal risk factors such as preterm birth (41.75% vs. 40.43%), low birth weight (31.07% vs. 36.17%), and high oxygen exposure (21.36% vs. 21.28%) were similarly distributed between SGA and AGA neonates (p-value>0.05 for all). RDS occurred exclusively in SGA infants (4.85%) but was not statistically significant (p-value=0.33), while other neonatal complications, including mechanical ventilation, convulsions, and endocrine disorders, were rare and comparable across both groups. Maternal factors such as diabetes, anaemia, and low haemoglobin were seen only among mothers of SGA neonates but showed no significant association (p-value=1.00). Overall, no statistically significant differences were found in the incidence of ROP or related neonatal and maternal risk factors between SGA and AGA groups, indicating that SGA status alone was not an independent predictor of ROP in the present study cohort [Table/Fig-2].

| Parameters | SGA (n=103) | AGA (n=47) | Total (N=150) | p-value |
|---|---|---|---|---|
| **ROP distribution** | | | | |
| With ROP | 23 (22.33%) | 9 (19.14%) | 32 (21.33%) | 0.82 |
| Without ROP | 80 (77.66%) | 38 (80.85%) | 118 (78.66%) | |
| **Neonatal risk factors** | | | | |
| Preterm | 43 (41.75%) | 19 (40.43%) | 62 (41.33%) | 1.00 |
| Low birth weight | 32 (31.07%) | 17 (36.17%) | 49 (32.67%) | 0.58 |
| High $O_2$ exposure | 22 (21.36%) | 10 (21.28%) | 32 (21.33%) | 1.00 |
| Respiratory Distress Syndrome (RDS) | 5 (4.85%) | 0 | 5 (3.33%) | 0.33 |
| **Mechanical ventilation** | **1 (0.97%)** | **1 (2.12%)** | **2 (1.33%)** | **0.53** |
| Convulsion | 0 | 0 | 0 | - |
| Hypokalemia/Endocrine | 0 | 0 | 0 | - |
| Maternal risk factors | SGA | AGA | Total | - |
| Diabetes | 1 (0.97%) | 0 | 1 (0.66%) | |
| Low haemoglobin | 2 (1.94%) | 0 | 2 (1.33%) | |
| Anaemia | 2 (1.94%) | 0 | 2 (1.33%) | |

**[Table/Fig-2]:** Incidence of ROP and associated neonatal and maternal risk factors.
Values are expressed as n (%). p-values were calculated using Fisher's-exact test (two-tailed) for SGA vs AGA comparisons; rows with all zeros are not applicable. Statistical significance set at p-value <0.05].

At the first ophthalmic screening, the majority of ROP cases in both SGA and AGA neonates were localised to Zone 2 and were predominantly in the early stages (Stages 1-2). Higher-stage disease (Stages 3-5), plus disease, and aggressive posterior ROP were uncommon, and no statistically significant differences were observed between the two groups (p-value >0.05 for all). During subsequent follow-up, most infants exhibited disease regression, with approximately two-thirds in each group achieving complete retinal maturation. Treatment requirements were similar across groups- about one-fourth of neonates required intravitreal bevacizumab, while fewer than 10% underwent laser photocoagulation. Around 60-65% of eyes resolved spontaneously without active intervention, demonstrating comparable regression and maturation patterns in both groups.

An additional observation in the follow-up cohort included one patient with regressing ROP, who was monitored longitudinally until complete retinal maturation was achieved, confirming favourable spontaneous resolution without the need for therapeutic intervention. Overall, the findings indicate similar disease progression, regression, and treatment outcomes among SGA and AGA neonates [Table/Fig-3a,b].

| Category | SGA (n=23) | AGA (n=9) | Total (n=32) | p-value |
|---|---|---|---|---|
| **Zone** | | | | |
| Zone 1 | 3 (13.0%) | 0 | 3 (9.4%) | 0.541 |
| Zone 2 | 12 (52.2%) | 4 (44.4%) | 16 (50.0%) | 1.00 |
| Zone 3 | 8 (34.8%) | 5 (55.6%) | 13 (40.6%) | 0.427 |
| **Stage** | | | | |
| Stage 1 | 12 (52.2%) | 5 (55.6%) | 17 (53.1%) | 1.00 |
| Stage 2 | 6 (26.1%) | 3 (33.3%) | 9 (28.1%) | 0.685 |
| Stage 3 | 3 (13.0%) | 1 (11.1%) | 6 (18.8%) | 1.00 |
| Stage 4 | 1 (4.3%) | 0 | 1 (4.3%) | 1.00 |
| Stage 5 | 1 (4.3%) | 0 | 1 (4.3%) | 1.00 |
| Plus disease (present) | 4 (17.4%) | 1 (11.1%) | 5 (15.6%) | 1.00 |
| Aggressive posterior ROP | 2 (8.7%) | 1 (11.1%) | 3 (9.4%) | 1.00 |

**[Table/Fig-3a]:** Fundus findings at first visit among neonates with ROP SGA (n=23) vs AGA (n=9). Values are expressed as n (%).

| Category | SGA (n=23) | AGA (n=9) | Total (n=32) | p-value |
|---|---|---|---|---|
| **Follow-up findings** | | | | |
| Zone 2 involvement | 3 (13.0%) | 1 (11.1%) | 4 (12.5%) | 1 |
| Stage 1 | 2 (8.7%) | 1 (11.1%) | 3 (9.4%) | 1 |
| Plus disease | 1 (4.3%) | 0 | 1 (3.1%) | 1 |
| Regressing ROP | 1 (4.3%) | 0 | 1 (3.1%) | |
| Both-eye mature retina | 15 (65.22%) | 6 (66.7%) | 21 (68.8%) | 1 |
| **Treatment outcome** | | | | |
| Intravitreal bevacizumab | 7 (30.4%) | 2 (22.2%) | 9 (28.1%) | 1 |
| Laser photocoagulation | 2 (8.7%) | 1 (11.1%) | 3 (9.4%) | 1 |
| Both treatments | 0 | 0 | 0 | – |
| Resolved without treatment | 14 (60.9%) | 6 (66.7%) | 20 (62.5%) | 1 |

**[Table/Fig-3b]:** Follow-up findings and treatment outcomes among neonates with ROP SGA (n=23) vs AGA (n=9).
Values are expressed as n (%). Classification of zones, stages plus disease follows the International Classification of Retinopathy of Prematurity (ICROP, 3rd Edition, 2021) criteria.

## DISCUSSION

The ROP continues to represent a significant cause of neonatal morbidity, particularly among preterm and low birth weight infants. The present observational study compared the incidence, associated risk factors, and clinical profile of ROP between SGA and AGA neonates.

Out of 150 neonates enrolled, 103 (68.6%) were SGA and 47 (31.4%) were AGA. Female neonates predominated overall (57.33%) in both groups, and the gender distribution was statistically comparable (p-value=0.36), consistent with demographic patterns observed in previous neonatal ROP cohorts [10]. A significantly higher proportion of SGA neonates were born before 34 weeks of gestation (85.43% vs. 59.57%, p-value=0.001), emphasising prematurity as a critical risk factor within this subset. Although the majority of both SGA and AGA neonates weighed between 1001-1500 g, extremely low birth weight (<1000 g) occurred exclusively among SGA infants (6.79%), though without statistical significance (p-value=0.13).

The overall incidence of ROP in the present study was 21.33%. ROP was detected in 22.33% of SGA and 19.14% of AGA neonates (p-value=0.82), confirming the absence of a statistically significant difference. These findings are in close agreement with Arora P et al., who reported similar incidences of ROP between SGA and AGA neonates, suggesting that growth restriction alone is not an independent determinant of ROP [8]. Conversely, Dhaliwal CA et al., (2021) reported a higher rate and severity of ROP in SGA neonates, underscoring that the clinical heterogeneity and neonatal care protocols across regions may influence these outcomes [11]. Similar trends have been observed in larger multicentric analyses, which emphasise that ROP risk is primarily driven by gestational age, birth

weight, and systemic instability rather than SGA status alone [12]. Collectively, this reinforces that ROP pathogenesis is multifactorial and not solely dependent on intrauterine growth parameters.

Common neonatal risk factors such as preterm birth (41.33%), low birth weight (32.67%), and high oxygen exposure (21.33%) were nearly identical between SGA and AGA groups (p-value>0.05 for all). Interestingly, RDS occurred exclusively among SGA infants (4.85%) but did not reach statistical significance (p-value=0.33). This trend supports Lin CY et al., (2020), who suggested that SGA neonates, despite similar gestational age, exhibit heightened susceptibility to neonatal morbidities, including RDS due to intrauterine growth restriction and compromised pulmonary maturation [8,13]. Similar findings have been documented in other cohorts evaluating morbidity patterns in growth-restricted preterm infants [14].

Maternal conditions such as diabetes (0.97%), anaemia (1.94%), and low haemoglobin (1.94%) were observed only among mothers of SGA neonates, mirroring the findings of Raj R et al., (2017) and Dhaliwal CA et al., (2021), who highlighted that maternal co-morbidities may indirectly influence foetal retinal vascular development by impairing uteroplacental blood flow and oxygenation [4,11]. While these variables did not attain statistical significance, their exclusive occurrence in the SGA group emphasises the interplay between maternal health, placental insufficiency, and neonatal vulnerability.

At the initial ophthalmic examination, the majority of ROP cases in both SGA and AGA neonates were confined to Zone 2 (50%) and early stages (Stages 1-2; 81.2%), indicating mild disease presentation. Advanced stages (Stage 3-5) plus disease were uncommon (≤18.8%), and aggressive posterior ROP (AP-ROP) was rare (9.4%), with no intergroup difference (p-value >0.05). These patterns closely parallel those documented by Lin CY et al., (2020) and Arora P et al., (2022), who noted that early-stage, Zone-2 involvement predominates in screened preterm populations [8,13].

Follow-up evaluation revealed complete retinal maturation in 68.8% of all ROP-affected neonates, including 65.22% of SGA and 66.7% of AGA infants (p-value=1.00). Treatment requirements were also similar; intravitreal Bevacizumab was administered to 28.1%, and laser photocoagulation to 9.4% of neonates, while 62.5% showed spontaneous resolution without active intervention. These figures align with global practice trends emphasising Anti–Vascular Endothelial Growth Factor (anti-VEGF) therapy for posteriorly located or rapidly progressing ROP lesions [15,16]. Notably, one SGA infant exhibited spontaneous regression after serial monitoring, highlighting the self-limiting nature of mild ROP under vigilant surveillance.

The use of the Forus Trinetra Neo Fundus camera in the present study represents a modern tele-ophthalmology-enabled screening tool, facilitating high-resolution retinal imaging and early diagnosis, particularly valuable in resource-constrained neonatal units. This approach has the potential to expand screening coverage and reduce diagnostic delays.

Overall, despite SGA neonates demonstrating greater prematurity and higher morbidity rates, the incidence and clinical course of ROP were comparable between both groups. This reinforces the understanding that SGA status alone is not an independent predictor of ROP when gestational age and postnatal risk factors are accounted for. The findings underscore the necessity of universal, timely ROP screening among all preterm and low birth weight infants, regardless of growth classification, to ensure early detection and prompt management aimed at preventing irreversible visual impairment.

## Limitation(s)

This single-centre study with a modest sample size and short follow-up duration may limit generalisability. Detailed quantification of oxygen exposure, nutritional status, and neonatal sepsis was not feasible, and minor interobserver variation in fundus assessment may have occurred.

## CONCLUSION(S)

The present study demonstrated a comparable incidence of ROP (SGA: 22.33% vs AGA: 19.14%, p-value=0.82), indicating that intrauterine growth restriction was not an independent determinant of ROP occurrence. Most cases were limited to zone 2 and early stages, with high rates of spontaneous regression (62.5%) and favourable outcomes following anti-VEGF therapy when indicated. Neonatal and maternal risk factors were similar across groups. These findings highlight the importance of standardised, timely ROP screening and follow-up for all preterm and low-birth weight infants, irrespective of growth category, to minimise the risk of long-term visual morbidity.

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