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Nationwide inventory on retinopathy of prematurity screening in the Netherlands

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ABSTRACT

Purpose Provide up-to-date insight in incidence of retinopathy of prematurity (ROP), logistics of screening and treatment in the Netherlands and influence of the new national ROP guideline in which more stringent screening criteria were implemented and the early treatment for ROP criteria (ETROP) were emphasised.

Methods Multicentre prospective nationwide study including all preterm infants, born in the Netherlands in 2017, and considered eligible for ROP screening. Anonymised data from ophthalmologists and paediatricians were merged. Outcome data were compared with the first national ROP inventory (NEDROP-1, 2009).

Results In 2017, 1492 infants were live born with gestational age (GA) <32 weeks (2009: 1662); 1287 infants were eligible for screening (2009: 2033). Ophthalmologists screened 1085 infants, versus 1688 in 2009, corrected with factor 1.114 for the difference in number of live births, a 28.4% (479/1688) decrease in screened infants was seen. Among surviving infants with GA <32 week, ROP was found in 305/1492 babies, 20.4% (2009: 324/1662, 19.5%) of which 49/1492 stage ≥3, 3.3% (2009: 30/1662, 1.8%). In all infants, report on presence or absence of plus disease was provided, according to the ETROP criteria. Treatment was performed in 39 infants. Of infants with ROP stage ≥3, 3/49 (6.1%) progressed to retinal detachment (2009: 6/30, 20.0%).

Conclusion The overall ROP incidence expressed as a percentage, remained stable but the number of infants that developed severe ROP nearly doubled. A near one-third reduction in screened infants shows satisfactory implementation of the new screening criteria. A notable decrease in retinal detachment delineates improved treatment outcome.

INTRODUCTION

Retinopathy of prematurity (ROP) is a mostly self-limiting yet, potentially blinding disease in premature infants. While knowledge and experience on the pathological mechanisms progress, management success rates improve. However, advances in neonatal care lead to increasing survival of extremely premature infants, subsequently causing the group particularly at risk for ROP to grow.[1–3] Moreover, neonatal risk factors cannot always be fully controlled, therefore, timely screening and treatment remain the foundation for preventing irreversible vision loss due to progressive ROP.

The first Dutch nationwide ROP inventory, the NEDROP study (NEDROP 1, including infants completely screened for ROP and born between 1 January and 31 December 2009),[4] resulted in the implementation of a new ROP screening and treatment guideline in 2013.[5 6]

In 2009, ROP was found in 324/1688 (19.2%) screened infants (17.4% mild, 1.8% severe). Furthermore, critical aspects on the logistics and reporting of screening were revealed: (1) in 624/1688 (37.0%), first screening was not performed within the required period, (2) risk of loss to follow-up increased with hospital transfer and (3) nearly one-fourth of treated infants (23.5%) could not be classified according to the early treatment for ROP criteria (ETROP[7]), due to incomplete data reporting on plus disease.

On these findings, several measures were taken. First, quality indicators were added to the Dutch National Monitoring System for Quality in Health Care, in which documentation of the required time period of (follow-up) screening and defined ophthalmological findings in the transferal letter were made obligatory. Second, a parental information folder was developed, which is to be handed before first screening, in order to stress the importance of ROP screening. Third, a section about treatment was added to the guideline, in which the ETROP treatment criteria were emphasised and widely promoted through conferences, courses and so on.

Further, following detailed risk analyses, more stringent and risk factor-based screening inclusion criteria were introduced in 2013,[6] allowing a predicted 29.0% reduction of screened infants without missing severe ROP. Finally, to help achieve good implementation, a screening and follow-up NEDROP-app was developed for paediatricians and ophthalmologists.

Yet, since 2009, the risk for (severe) ROP increased, due to the lowering of gestational age (GA) limit for active treatment from 25.0 to 24.0 weeks in Dutch neonatal intensive care units (NICUs) (2010)[8 9] and implementation of higher oxygen saturation target limits (NeOProM, 2014[10]). As all these policy changes are likely to influence incidence, risk factors and logistics of screening and treatment since the first NEDROP, a second nationwide ROP inventory was performed: the NEDROP 2.

METHODS

This multicentre, prospective, population-based study was initiated and approved by the Leiden University Medical Center. In the Netherlands, neonatal data are recorded in a national perinatal

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register called Perined. Data are only recorded after parental approval.

All babies born between 1 January and 31 December of the year 2017 who were eligible for ROP screening were reported by neonatologists and paediatricians. They prospectively reported a coded dataset consisting of date of birth, four digits of the ZIP code, GA, birth weight (BW) and the index number in case of multiple birth (1/2, 2/2, 1/3 and so on). Through a separate notification form, ophthalmologists provided the same code of the infants they screened, together with the following ophthalmological findings: date of first examination, suggested and executed dates of follow-up examinations, ROP classification, reason for discontinuation of screening, hospital transfer and, if applicable, date and modality of treatment. Eventually, neonatal and ophthalmological data were merged.

According to the 2013 guideline,[11] screening applies to infants with GA <30.0 weeks and/or BW <1250 g and GA 30.0–32.0 weeks and/or BW 1250–1500 g with presence of one or more of the established risk factors: mechanical ventilation, sepsis, necrotising enterocolitis (NEC), postnatal glucocorticoids and hypotension treated with inotropic agents. If the presence of risk factors is uncertain, screening is recommended according to the old guideline, advising examination of all infants with GA <32.0 weeks and/or BW <1500 g.[6]

First screening examination should be scheduled in the 5th postnatal week (35–42 days), but not before 31.0 weeks of postmenstrual age (PMA). Screening examinations were considered timely if performed within 3 days of scheduled date.

ROP was categorised into type 1 and type 2 ROP. For the purpose of comparison to NEDROP 1, ROP was also classified into mild (stages 1 and 2) or severe (stage 3 or higher, including aggressive posterior ROP) according to the The International Classification of Retinopathy of Prematurityclassification (revisited 2005).[12]

For incidences, national live born premature infants were used as denominator, for which the same cut-off GA was used as in 2009 (<32.0 weeks). Birth rates were obtained from Perined and the Dutch Central Bureau of Statistics.[13 14]

Statistical analysis

Numerical values are reported as median (25%–75% IQR or range). Statistical analysis was performed with SAS Enterprise Guide 7.1 (SAS Institute) and R (V.3.6.1). Frequencies of events were compared using Pearson's χ^2 or Fisher's exact test when a cell count was smaller than 5. For the comparison of multiple groups, pairwise comparisons were calculated. Population parameters were treated as known and a binomial test was used to compare a frequency with a birth rate. Logistic regression was used, when correction for covariates was required.

RESULTS

Population

In 2017, 1492 babies with GA <32.0 weeks were live born (2009: 1662). Participation of all Dutch hospitals (80) involved in ROP screening was realised, including 10 NICUs, 16 high-care centres (HCs) and 54 regional centres (RCs).

Between 1 January and 31 December of 2017, neonatologists and paediatricians identified 1287 infants eligible for screening (table 1). Infants were born at an NICU (1171; 91.0%), an HC (61; 4.7%), RC (51; 4.0%) and in a foreign (3) or unknown (1) hospital (together 0.3%). Population characteristics are shown in table 2A.

Table 1 Data from first (2009) and second (2017) NEDROP studies

	2009	2017
Live born babies	1662	1492
GA 28.0–32.0	1303	1092
GA 25.0 to <28.0	313	331
GA <25.0	46	69
Eligible for screening*	2033	1287
Fully screened	1688 (83.0%)	1085 (84.3%)
Timely first screening	1064 (63%)	849 (78.2%)
GA†	30.1 (28.6–31.4)	29 (27.3–30.4)
BW†	1320 (1050–1560)	1150 (935–1350)
Infants transferred	822	906
Lost to follow-up after transfer	189/822 (23.0%)	22/902 (2.4%)‡
Number of screenings total	3891	3750
Number of screenings no ROP	2402	1981
Number of screenings with ROP	1489	1769
ROP total	324	305
Incidence among live births	19.5%	20.4%
Type 1 ROP§	21	38
Type 2 ROP§	10	15
Stage 3 or higher	30	49
Treatment	17	39
Retinal detachment	6	3

*According to Dutch paediatricians.
†Median (IQR) of screened infants.
‡This group includes only infants who survived and met the new screening criteria.
§Incomplete data on plus disease for 2009.
BW, birth weight (g); GA, gestational age (weeks); ROP, retinopathy of prematurity.

In total, 1085 babies were fully screened versus 1688 in 2009. Corrected with factor 1.114 for the difference in number of live births between 2017 and 2009 (which gives a hypothetical number of 1209 screened infants), this was a 28.4% (479/1688) reduction of screened infants (table 1).

Two hundred and two infants were not (fully) screened. Of them, 120 died before screening was completed. Fifty-seven infants were wrongly included as did not fit the screening inclusion criteria. The remaining 25 (1.9% of the infants eligible for screening) were not screened or lost to follow-up because of: transfer abroad (1), no show at follow-up appointment (4) or unknown reason (20).

Screening

A total of 1085 infants was screened in 3750 screening examinations. Infants who developed ROP were screened 1769 times, those with no ROP, 1981 times (table 1). The number of examinations increased with the severity of ROP (tables 2B and 3).

Data about initial screening and first detection of ROP are shown in table 2B,C. At first screening, 924 infants had no ROP, ROP stage 1 was reported in 125, stage 2 in 34 and stage 3 in 2 infants. In 236 (21.8%) first screening was performed after the recommended date. At first screening, 40 infants that were screened too late already developed mild (stage 1: 28, stage 2: 12) and two stage 3 ROP. Follow-up examinations were carried out timely in 97.1%. In the remaining group, follow-up was performed outside this interval (range 4–67 days), without consequences for the outcome.

Retinopathy of prematurity

Of the 1085 screened infants, 305 (28.1%) developed ROP. Among 1492 live births with GA <32.0 weeks, the overall ROP incidence was 20.4%, assuming no ROP occurred in the unscreened population (table 1). Median GA and BW were lower

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Table 2 NEDROP 2 population characteristics

	Screened for ROP	No ROP	Overall ROP	Mild ROP	Severe ROP
A. The NEDROP 2 study population	1085	780	305	256	49
GA*	29.0 (27.3–30.4)	29.6 (28.3–30.9)	27.1 (26.0–28.7)	27.6 (26.3–28.9)	25.7 (24.9–26.6)
BW*	1150 (935–1350)	1213 (1029–1414)	938 (760–1150)	975 (800–1178)	750 (319-865)
Multiple pregnancy, n (%)	278 (25.6)	192 (24.6)	86 (28.1)	78 (30.5)	8 (16.3)
B. Screening					
Examinations per patient	3 (2–4)	2 (1–3)	5 (3–7)	4 (3–6)	9 (8–11)
First exam PMA	34.4 (32.9–36.0)	35.0 (33.6–36.4)	32.6 (31.7–34.1)	33.0 (31.9–34.3)	31.9 (31.2–33.1)
First exam PNA	5.4 (5.0–6.0)	5.3 (5.0–5.9)	5.6 (5.0–6.1)	5.4 (5.0–6.0)	6.1 (5.6–6.9)
Timely, n (%)	849 (78.2)	599 (76.8)	250 (82.0)	211 (82.4)	39 (79.6)
Too late, n (%)	236 (21.8)	181 (23.2)	55 (18.0)	45 (17.6)	10 (20.4)
C. ROP, median (IQR)					
First detection PMA	NA	NA	34.1 (33.0–35.7)	34.3 (33.0–35.9)	33.6 (32.1–34.6)
First detection PNA	NA	NA	6.7 (5.4–8.3)	6.6 (5.3–8.0)	7.3 (6.5–9.1)

Mild ROP: stages 1–2, severe ROP: stages ≥3.
*t-test no ROP versus overall ROP, p<0.001.
BW, birth weight; GA, gestational age; NA, not applicable; PMA, postmenstrual age; PNA, postnatal age; ROP, retinopathy of prematurity.

in babies developing ROP compared with those that did not (both p<0.001, table 2). The severity of ROP stages increased with decreasing GA (p<0.001, figure 1).

Information on presence or absence of plus disease was provided in 304/305 (99.7%) of the overall ROP population (present in 41, absent in 263 and not noted in 1 infant with stage 1 ROP), and in 100% of treated infants. Thirty-eight infants could be categorised into type 1 and 15 into type 2 ROP. For unknown reasons, six babies with type 1 ROP were not treated (ROP3+ in zone II (3) and ROP2+ in zone II (3)). Eventually, in all six, ROP regressed spontaneously. Maximum ROP stage 1 was found in 159, stage 2 in 97 and stage ≥3 in 49 cases (table 3). At time of first detection, ROP was located in zone I in 22, posterior zone II in 4, zone II in 189 and zone III in 90 cases. Treatment was performed in 39 infants. At treatment decision, 33 had type 1 ROP, 3 had type 2 ROP and 3 could not be categorised because they did not fit the ETROP criteria: two with ROP in zone III and one with stage 2 without plus. Eventually, despite treatment, three babies with ROP stage 3+ at treatment decision progressed into retinal detachment (tables 1 and 3). Two babies with GA 30.0 weeks—one infant with BW 1415 g, NEC, sepsis and need for inotropic agents for hypotension and one with BW 1360 g, prolonged mechanical ventilation and inhaled nitric oxide—developed stage 3 ROP, illustrating the need for risk-based inclusion criteria to detect outliers in our population.

Transfer

Overall, 381/1287 (29.6%) babies were not transferred from the hospital of birth. Other infants were transferred up to six times. In the non-transferred group, the proportion of not screened infants was 126/381, 33.1%, however, the majority of them died before first screening (116/126, 92.1%). After excluding the deceased infants and those that were referred according to the old criteria (7), only 3/265 (1.1%) were not screened. In the transferred group, 76 infants were not screened of which 4 died and 50 were wrongly referred. After exclusion of these, the number of not screened infants was 22/902, 2.4%, p<0.2. Logistic regression showed no relation between the number of transfers and number of babies lost to follow-up (OR 1.2, p=0.195).

DISCUSSION

The NEDROP 2 study is a prospective, population-based inventory, based on data of all infants born in 2017 and referred for ROP screening in the Netherlands. It is the second national inventory to study the natural course of ROP and adherence to the adapted screening and treatment guideline following the NEDROP 1 (2009).[4] The then calculated reduction of 29%[6] for infants needing ROP screening was found to be 28.4% in our 2017 study population. However, the number of screening examinations did not decrease as much as the number of screened children (from 3891 in 2009 to 3750 in 2017, a reduction of only 3.6%). We attribute this to an increase in infants with lower GA (+18 with GA <28.0 weeks and +23 with GA <25.0 weeks), who require relatively more screening examinations. Thus, the implementation of new inclusion criteria for screening in 2013 relieved the burden of screening of the overall population, did not substantially reduce the overall workload

Table 3 Characteristics of infants with ROP specified per stage

	n	GA	BW	Screenings	Plus disease (n)	Treated (n)	Type 1 (n)
No ROP	780	29.6 (24.0–34.9)	1210 (500–2900)	2 (1–10)	NA	NA	NA
ROP 1	159	28.1 (24.4–32.1)	1020 (450–2350)	4 (1–10)	1	0	0
ROP 2	97	26.7 (24.0–31.4)	898 (520–1530)	6 (1–17)	9	8	8
ROP 3	44	25.7 (24.0–30.9)	750 (410–1415)	10 (2–19)	26	26	25
ROP 4	2	26.0 (25.6–26.4)	621 (578–665)	14 (9–19)	2	2	2
ROP 5	1	26.1	520	27	1	1	1
APROP	2	25.9 (25.1–26.6)	893 (785–1000)	7 (5–8)	2	2	2

Number of screenings shown as median (minimum–maximum range).
APROP, aggressive posterior ROP; BW, birth weight (g); GA, gestational age (weeks); ROP, retinopathy of prematurity.

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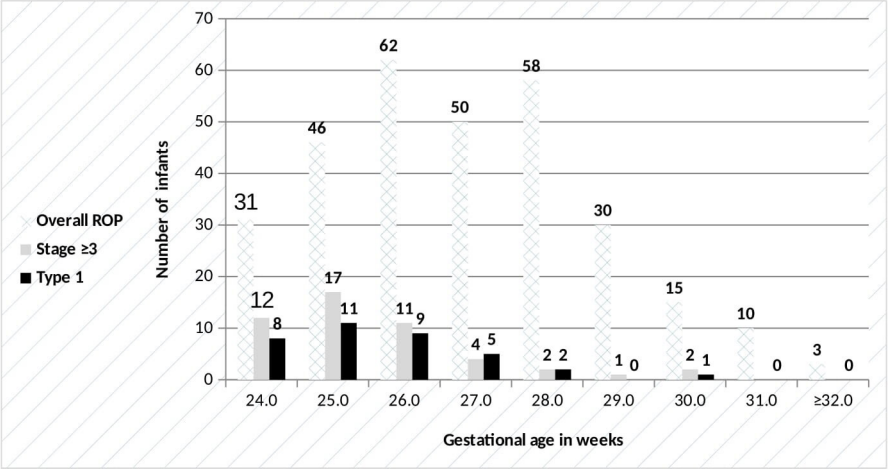

Figure 1 Number of infants with overall, stage >3 and type 1 retinopathy of prematurity (ROP) and their distribution of gestational age in weeks. The severity of ROP significantly increased with decreasing GA (p<0.001). GA, gestational age.

for ophthalmologists but enabled them to focus on babies with the highest risk.

The overall ROP incidence within the screened population increased from 19.2% in 2009 to 28.1% in 2017. However, among all live born babies with GA <32.0 weeks, this was 19.5% in 2009 and 20.4% in 2017, and thus, relatively stable assuming there was no ROP in the unscreened population (table 1). The increase within the screened population can be therefore attributed to the implementation of risk factor criteria focusing on high risk babies for ROP.

The occurrence of ROP is largely dependent on GA, BW, survival and the presence of ROP associated risk factors during the neonatal period.[15] Therefore, comparing incidences to other countries is challenging as neonatal policies, survival and screening criteria may differ. Survival for infants born at 24 weeks (as % of live borns) was 34.4% in the Netherlands in the period 2011–2017[16]. Other similar national population-based cohorts report however survival rates varying from 31% to 67% in 24-week infants.[17] This may be reflected in ROP incidence. Even among cohorts with similar mean population GA and BW, varying ROP incidences can be observed: that is, Sweden (2012: overall 24.0% of which 8.7% severe[18]; 2015: 24.1% overall, 8.5% severe[19]), Switzerland (6472 infants between 2006 and 2015: overall 9.2%, severe 1.8%[20]) and a large cohort from 29 Canadian and US hospitals (7483 infants between 2006 and 2011: 43.1% overall, 6.1% severe).[21]

We observed an increase in severe ROP (stage ≥3) among live born neonates with GA <32.0 weeks, from (30/1662) 1.8% in 2009 to (49/1492) 3.3% in 2017 (table 1). Additionally, the absolute number of ROP treatments has more than doubled from 17 (2009) to 39 (2017). This is supported by previous findings, that is, two times as many infants requiring ROP treatment in the Netherlands between 2010 and 2016, found in an earlier retrospective inventory,[22 23] and findings from countries such as Denmark,[24] the UK[2 25] and Sweden.[3] We hypothesise that several essential changes in Dutch neonatal care contributed to this increase.

First, in 2010 the age limit for active neonatal treatment was lowered from 25.0 to 24.0 weeks of gestation.[8 9] As anticipated, this has indeed led to a higher number of infants who, based on GA, are at particular risk for severe ROP. While the overall number of preterm infants with GA <32.0 weeks decreased from 1662 (2009) to 1492 (2017), the subgroup born GA <25.0 weeks increased by 50% (table 1). Although survival of extremely premature infants in the Netherlands is still in the lower range compared with other high income countries, with continuously improving survival of these neonates, awareness of concomitant conditions such as (severe) ROP remains crucial.[16] Second, surprisingly the NEDROP 1 revealed that the ETROP criteria,[7] which apply since their publication in 2004, were not yet fully implemented in the Netherlands.[4] The former guideline dating from 1997 did not include a directive on ROP treatment, therefore possibly, utilisation into practice stayed behind. Subsequently, the criteria were emphasised in the 2013 guideline, which might lead to treatment decision in earlier (less advanced) stages and therefore, might increase the number of infants requiring treatment. The present study shows a notable improvement of report on plus disease in both overall population and treated group (from 83.0% to 99.7% and 76.5% to 100%, respectively), delineating the need for periodic monitoring of screening and treatment outcomes in order to improve national guidelines and their implementation. Although the proportion of infants with end stage ROP decreased, ROP stages at treatment decision were comparable in both studies and thus truly earlier treatment was not observed. So more awareness for signs of disease progression remains important.

Third, following the NeOProM meta-analysis, higher oxygen saturation targets are now globally advised,[10 26] because of better survival and lower risk of NEC. Simultaneously however, an increased risk for severe ROP is expected. Since in the Netherlands higher SaO2 target limits were accepted in most NICUs, we hypothesise that when applied during the first weeks of life, the oxygen regime could have contributed to the increase in severe ROP.

ROP is predominantly self-limiting. However, undiagnosed and untreated progressive stages can lead to devastating and life-long consequences. Our inventory demonstrates the benefits of measures taken to promote timely screening, as this number notably decreased from 624/1688, 37.0% in 2009[4] to 236/1085, 21.8% (p<0.001). Still, over one-fifth is not screened within the required period. Moreover, two infants already had stage 3 ROP at first screening, performed at 6 and 10 weeks PMA. Therefore, as ROP has a narrow window of opportunity for treatment, the importance of well-timed screening must be stressed continuously.

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The well-known obstacle in ROP screening of loss to follow-up due to hospital transfer[27 28] was addressed in the 2013 ROP guideline and our results illustrate the positive effect of the increased awareness of both physicians and parents: within the transferred group, the number of not screened infants decreased from 189/822, 23.0% (2009)[4] to 22/902, 2.4% (2017). Still, the absolute number of loss to follow-up is two times as high in transferred infants compared to the non-transferred group. Considering a higher number of transferred infants compared to NEDROP 1, marked by the fact that in 2017 only 29.6% of all infants were fully screened in hospital of birth (vs 59.6% in 2009), we underline this issue of concern in future hospital transfers.

The main strength of this study is its design which gives insight in annual incidence, screening and treatment of ROP in the Netherlands. Data were provided by both ophthalmologists and paediatricians, therefore apart from nationwide insight in ROP, screening referral and guideline adherence could also be monitored. The identical study design allowed comparison with NEDROP 1 and thus, to evaluate the influence of policy changes in ROP care. Still, due to the new screening inclusion criteria, many infants with a low ROP risk were no longer included in the present study, thus, the two study populations were not entirely comparable. To correct for this difference, the number of surviving infants was used as denominator instead of the screened population. Finally, all data were collected anonymously. For this reason, in infants who were not screened, it was impossible to determine if they eventually developed ROP.

To conclude, the overall ROP incidence in the Netherlands was comparable to 2009, but the number of infants with treatment requiring ROP nearly doubled. A 28.4% reduction in infants screened for ROP was accomplished since the implementation of new, risk-based screening inclusion criteria, shifting the focus of ROP screening to babies with the highest risk. The number of infants lost to follow-up due to hospital transfer has decreased, but the risk for not being screened remains. Although the general opinion might be that the screening programme functions properly, this study shows that periodic evaluation is valuable and should be mandatory.

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