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The Netherlands retinopathy of prematurity study

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Chapter 2

The incidence of visual impairment due to retinopathy of prematurity (ROP) and concomitant disabilities in the Netherlands: a 30 year overview

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ABSTRACT

Aim To determine the incidence of visual impairment (VI) caused by retinopathy of prematurity (ROP) and concomitant disabilities in preterm neonates born between 2000 and 2009 in the Netherlands.

Methods Data were retrieved from the Dutch institutes for the visually impaired. They were compared with similar Dutch studies conducted in 1975-1987, 1986-1994 and 1994-2000.

Results Records of 42 infants with VI due to ROP were included. A gradual decrease of gestational age and birthweight but an increase of duration of artificial ventilation, supplemental oxygen administration, bronchopulmonary dysplasia, developmental delay and behavioural abnormalities was found. Compared with the previous study (1994-2000), significantly fewer children were visually impaired due to ROP (1.84 per 100,000 live births/year vs 3.93 per 100,000 live births/year, $p < 0.000$), the incidence of complete blindness decreased from 27.5% to 7.1% ($p < 0.05$) and more children were treated (66.7% vs 56.9%, NS). The incidence of concomitant disabilities was high and did not differ greatly from the previous study.

Conclusion This was a retrospective study showing a significant decrease in VI due to ROP in the Netherlands. Changes in neonatal care practices did not result in a decrease in the incidence of concomitant disabilities. More children were treated for ROP, but 33% were not treated.

INTRODUCTION

Retinopathy of prematurity (ROP) is still one of the most important causes of partial sight or blindness in premature infants. In developed countries, ROP accounts for 5.5% to 20% of childhood blindness.¹⁻⁴ The pathogenesis of ROP is multifactorial, but the most significant risk factors for ROP are low gestational age (GA) and low birthweight (BW).⁵⁻⁷ Changes in neonatal care over the past two decades have increased the survival rate of very small and very preterm infants. This was due to introduction of surfactant, increased use of antenatal steroids, resuscitation of infants with lower GA, improved nutrition and prophylactic use of indomethacin. Due to this increased survival rate, many very preterm infants are at risk not only of visual impairment (VI) caused by ROP but also of nonvisual disabilities.⁸⁻¹⁰ Apart from changes in neonatal care practices, there have been changes in management of ROP. To reduce the number of adverse outcomes, treatment in the pre-threshold phase was introduced, resulting in an increased number of infants treated for ROP.¹¹⁻¹³ From 1952 onwards, five surveys were carried out in the Netherlands to calculate the number of children visually disabled due to ROP per 100 000 live births per year: 3.24/100 000 from 1952 to 1964 (Schappert-Kimmijser; survey 1),¹⁴ 2.89/100 000 from 1961 to 1973 (van de Pol; survey 2),¹⁵ 4.22/100 000 from 1975 to 1987 (Cats and Tan; survey 3),¹⁶ 5.49/100 000 from 1986 to 1994 (Schalij-Delfos; survey 4)¹⁷ and 3.85/100 000 from 1994 to 2000 (Termote et al; survey 5).¹⁸ The last three surveys also included an inventory of concomitant disabilities, showing a marked increase in developmental and behavioural abnormalities. To monitor trends and to determine the incidence of VI caused by ROP, as well as the incidence of associated disabilities in these high-risk, vision-impaired children born between 2000 and 2009, a retrospective study was performed (survey 6). Data from the last three surveys were used for comparison, resulting in an overview of more than three decades.

PATIENTS AND METHODS

Due to privacy regulations and lack of an obligatory registry for children with VI in the Netherlands, access to patient data is limited. Therefore, data retrieval was only possible by collecting the records of all infants with a registered diagnosis of ROP who are known at one of the Dutch institutes for the partially sighted and blind. This information was obtained by one investigator (AJvS). For comparison, the same neonatal and ophthalmological data as in the previous surveys were collected: GA, BW, visual acuity, treatment for ROP, sex, multiple birth, incidence of bronchopulmonary dysplasia (BPD) and duration of supplementary oxygen administration, artificial ventilation (AV) and admission to the neonatal intensive care unit (NICU). With regard to concomitant disabilities the same



definitions and classifications as described by Termote et al were used.¹³ We considered children to have multiple disabilities when they had VI caused by ROP plus one or more of the concomitant disabilities that were listed, excluding BPD as pulmonary function usually improves through the years.

To define VI, the recommendations of the International Association for Prevention of Blindness (IAPB) were used (World Health Organization, 1984).¹⁹ Due to limitations in data collection, information on stages of ROP was unreliable and therefore again excluded. As the number of infants with cerebral VI increased over the last decade and became the most important cause of VI in prematurely born infants,²⁰ data on cerebral VI were collected for this survey. However, they could not be compared with the previous studies. Data on the Dutch birth rate were obtained from the Central Bureau of Statistics (CBS). Survival rates of premature infants according to GA were collected from the Netherlands Perinatal Registry (PRN).

Data collected for this study (2000-2009) were compared with data from the previous study (1994-2000). In addition, data from the four surveys conducted from 1975 onwards were compared to identify and evaluate trends in treatments and outcomes.

Statistical analysis

Clinical data from the four surveys (presented in table 1) were evaluated using the independent samples t test. The Poisson regression was used to perform calculations on data on VI caused by ROP in relation to Dutch birth rates, and the c2 test was used for all other data. Differences with a p value of <0.05 were considered significant. As all children with

Table 1 Neonatal data of infants with visual impairment caused by ROP in four consecutive periods in the Netherlands.

Period / survey #	1975-1987 / 3	1986-1994 / 4	1994-2000 / 5	2000-2009 / 6
No. Infants	76	87	51	42
Male (%)	47	58	59	74
Mean gestational age (wks) ¹	28.7 ± 2.7	27.5 ± 2.5	27.7 ± 2.4	27.4 ± 2.0
Mean birth weight (gr) ²	1128 ± 331	1071 ± 385	942 ± 306	912 ± 385
Multiple birth (%)	18.9	20.7	31.4	31.0
Supplemental O ₂ administration (days) ³	43.2 ± 40.7	78.6 ± 88.8	83.2 ± 81.6	81.8 ± 78.4
Artificial ventilation (days) ⁴	13.3 ± 22.0	27.6 ± 27.7	24.6 ± 16.6	25.3 ± 17.5
Admission to NICU (days) ⁵	-	-	92.1 ± 58.2	97.2 ± 71.1

¹ column 1 vs column 2 p=0.004, 1 vs 4 p=0.004, 2 vs 3, 3 vs 4 and 2 vs 4 ns

² column 1 vs 2 ns, 1 vs 3 p=0.001, 1 vs 4 p=0.003, 2 vs 3 p=0.032, 3 vs 4 ns, 2 vs 4 p=0.03

³ column 1 vs 2 p=0.003, 1 vs 3 p=0.005, 1 vs 4 p=0.004, 2 vs 3, 3 vs 4 and 2 vs 4 ns

⁴ column 1 vs 2 p=0.0009, 1 vs 3 p=0.004, 1 vs 4 p=0.004, 2 vs 3, 3 vs 4 and 2 vs 4 ns

⁵ column 3 vs 4 ns

VI due to ROP were studied in the subsequent periods, trends could be determined even though the separate values failed to reach significance.

RESULTS

Records of 43 children with VI caused by ROP were found. Informed consent was obtained from 42 parents. No additional infants born between 1994 and 2000 (survey 5) registered with the diagnosis of ROP were found during survey 6.

General data and neonatal data from infants diagnosed with ROP in four consecutive periods in the Netherlands are presented in table 1.

Compared with the previous study (1994-2000) no significant differences were found. However, a gradual decrease of mean GA and BW over the years was seen. For supplemental oxygen and AV a significant increase was found between surveys 3 and 4, but there were no significant changes after the mid 1980s. Not all infants from surveys 3 and 4 were admitted to a NICU, so admission days to a NICU were only analysed for the fifth and sixth survey periods, for which there was no significant difference. Although no significant differences were found in clinical data of children from the present study compared with the previous study, the proportion of infants with VI caused by ROP in relation to Dutch birth rates decreased significantly (table 2).

The average incidence of VI due to ROP is presented column 3 is the result of the fraction of the absolute number of individuals with ROP sequelae (column 1) and the absolute number of individuals born during the study period (column 2). The average incidence of VI due to ROP shows a decrease from the early 1990s.

A decline can be seen starting in the mid 1990s. The incidence of VI due to ROP decreased in the period 1994-2000, but failed to reach significance when compared with the period 1986-1994 ($p=0.07$). Comparing our study to surveys 4 and 5 a significant

Table 2 Visual impairment caused by ROP in relation to Dutch birth rates.

Period / Number	No. ROP sequelae	No. live births x 10 ⁵ *	ROP sequelae / 100.000 live births
1952 – 1964 ¹⁴ (survey 1)	100	30.9	3.24
1961 – 1973 ¹⁵ (survey 2)	89	30.8	2.89
1975 – 1987 ¹⁶ (survey 3)	97	23.0	4.22
1986 – 1994 ¹⁷ (survey 4)	79	14.4	5.49
1994 – 2000 ¹⁸ (survey 5)	46	11.7	3.93
2000 – 2009 (survey 6)	32	17.4	1.84

*Central Bureau of Statistics for the Netherlands

The average incidence of VI due to ROP is presented column 3 is the result of the fraction of the absolute number of individuals with ROP sequelae (column 1) and the absolute number of individuals born during the study period (column 2). The average incidence of VI due to ROP shows a decrease since the early 1990s.



Table 3 Visual acuity in children with ROP in four consecutive periods

Period	1975 – 1987 survey 3	1986 – 1994 survey 4	1994 – 2000 survey 5	2000 – 2009 survey 6
No. Infants	76	87	51	42
Visual acuity unspecified	5.1%			
Not partially sighted or blind (VA>0.3) ¹	2%	10.3%	9.8%	23.8%
Partially sighted (VA 0.1 – 0.3)	34.3%	31.0%	25.5%	38.1%
Socially blind (VA < 0.1 - ≥ 1/60)	12.1%	10.3%	11.8%	14.3%
Practically blind (VA < 1/60 – LP)	8.1%	21.8%	25.5%	16.7%
Completely blind (VA = 0) ²	38.4%	26.4%	27.5%	7.1%
Treatment of acute ROP ³	24.6%	43.9%	56.9%	66.7%

⁺ = infants with unilateral blindness and infants whose vision is expected to deteriorate in the future

LP= light perception

VA= visual acuity

¹ column 1 vs 4 p= 0.000, 2 vs 4 p= 0.043

² column 1 vs 4 p=0.000, 2 vs 4 p=0.010 and 3 vs 4 p=0.012

³ column 1 vs 2 p=0.013, 1 vs 3 p=0.000, 1 vs 4 p=0.000, 2 vs 4 p=0.014

decrease in the incidence of VI caused by ROP was found (p=0.000 for both surveys). More specific data on visual acuity are presented in table 3.

In the current study there were 32 of 42 infants (76.2%) with VI, compared with 46 of 51 children (90.2%) in survey 5, representing a non-significant decrease. In more detail, our survey shows a significant decrease in the number of completely

blind children due to ROP compared with the previous period (7.1% vs 27.5%; p=0.012), as well as a significant increase in children who did not fulfill the WHO criteria for VI at the time of inclusion in this study (23.8% vs 9.8%; p=0.043). Eight children (19%) were diagnosed with cerebral VI: two not partially sighted or blind, four partially sighted, one socially blind and one practically blind. The number of children who were treated for ROP increased significantly since survey 3, but there was no significant increase between surveys 5 and 6. Infants were treated with laser (n=16), cryotherapy (n=1), laser + cryotherapy (n=2), cerclage (n=1), cerclage + laser (n=1), cerclage + cryotherapy (n=1), vitrectomy + lensectomy (n=2), vitrectomy + laser (n=2), vitrectomy + laser + lensectomy (n=1) or bevacizumab (n=1). The most commonly used therapy was laser treatment (79%). Fourteen infants (33.3%) in the present study had not been treated versus 22 (43.1%) in the previous study. Four of the untreated children in this study had a final visual acuity >0.3 in at least one eye.

Comparing the incidence of concomitant disabilities in infants with ROP, no significant changes were found except for epilepsy (p=0.007) (table 4).

In the previous study a significant increase in behavioural abnormalities was seen, but this tendency did not extend to the current study. A gradual increase of children with BPD, developmental delay and hearing deficit were observed, but differences did not

Table 4 Concomitant disabilities in infants with visual impairment caused by ROP in four consecutive periods in the Netherlands (%).

Period	1975 – 1987 survey 3	1986 – 1994 survey 4	1994 – 2000 survey 5	2000 – 2009 survey 6
No. Infants	76	87	51	42
BPD ¹	26.3	45.9	60.4	78.3
Behavioral abnormalities and problems ²	9.2	21.8	46.9	40.0
Epilepsy ³	5.3	6.9	16.3	0
Hearing deficit ⁴	5.3	2.3	8.2	12.5
Developmental delay ⁵	35.5	47.1	52.9	65.0
Neurological handicaps ⁶	30.3	49.4	45.1	42.5
Multiple disabled ⁷	39.5	58.6	68.2	66.7

¹ column 1 vs 2 p=0.009, 1 vs 3 p=0.000, 3 vs 4 p= 0.016

² column 1 vs 2 p= 0.028, 1 vs 3 p= 0.000, 1 vs 4 p= 0.000, 2 vs 3 p= 0.000, 2vs 4 p= 0.027, 3 vs 4 ns

³ column 1 vs 3 p= 0.049 and 3 vs 4 p=0.007

⁴ column 2 vs 4 p=0.024

⁵ column 1 vs 4 p=0.003

⁶ column 1 vs 2 p=0.013

⁷ column 1 vs 2 p=0.015, 1 vs 3 p=0.0011 vs 4 p=0.001

reach statistical significance. The number of infants with neurological impairment and a multiple disability increased significantly between surveys 3 and 4 but was stable after this. When the population was subdivided for GA, the incidence of VI caused by ROP based on the estimated number of survivors, as well as the incidence of concomitant disabilities in surveys 5 and 6, was highest in children born under 30 weeks; the incidence of VI increased as GA decreased (table 5). The five infants with unilateral blindness (n=1) or visual acuity >0.3 (n=4) were also included in this analysis because this was also done in the previous studies.

The percentage of children with concomitant disabilities was again high in this survey, but did not differ greatly from survey 5. In survey 5 there were 35 children with concomitant disabilities (68.6%) versus 31 (73.8%) in our survey.

Table 5 Visual impairment caused by ROP in relation to estimated number of survivors and concomitant disabilities.

GA (wks)	% VI caused by ROP (n) related to estimated survivors*				% Concomitant disabilities (n)	
	'75 – '87 survey 3	'86 – '94 survey 4	'94 – '00 survey 5	'00 – '09 survey 6	'94 – '00 survey 5	'00 – '09 survey 6
24 – 25	10.4 (11)	12.5 (11)	3.1 (9)	2.4(10)	67 (6)	70 (7)
26 – 27	3.3 (40)	4.3 (36)	1.3 (23)	0.9(19)	65 (15)	79 (15)
28 – 29	0.8 (26)	0.4 (10)	0.3 (10)	0.2(9)	80 (8)	78 (7)
30 – 31	0.2 (13)	0.2 (8)	0.1 (6)	0.03(2)	66 (4)	50 (1)
>32 - <37	0.01 (12)	0.01 (7)	<0.001 (2)	<0.002 (2)	100 (2)	50 (1)

* Numbers of estimated survivors were derived from the Netherlands Perinatal Registry



DISCUSSION

We performed a retrospective study on the incidence of VI due to ROP in preterm infants born between 2000 and 2009 in the Netherlands. The incidence presented in this study must be considered as a minimum incidence because there is no obligatory national registry for VI, children may be missed and there is always a possibility that children born in the study period will become visually impaired at a later age. However, the same caveats apply to earlier studies and no additional infants from the previous periods were found during our current search. Data were compared with three earlier Dutch studies starting in 1975 (surveys 3, 4 and 5), thus providing an overview of more than 30 years. Over the years there has been an increase in the survival rate of smaller and more immature infants due to changes in neonatal care practices.²¹ From 1975 until the present time mean GA and BW of infants with VI due to ROP in the Netherlands has gradually decreased. Although we found no significant changes in neonatal data in infants with VI in the present study compared with the previous study of Termote et al¹⁸, we found a decrease in VI due to ROP. It seems reasonable to assume that improvement in neonatal care might contribute to a better visual outcome in these preterm neonates. An important limitation is that we were unable to gain detailed information about the neonatal period. From other Dutch studies covering approximately the same period we can learn more about general changes that have taken place. Two Dutch cohort studies from Hoogerwerf et al²² and Groenendaal et al²³ demonstrated an improvement in outcome. Groenendaal et al analysed two cohorts of inborn preterm neonates (1997-2001) and (2002-2006) with a GA of 25-29.9 weeks and found an improved survival rate but no increase in the number of infants treated for severe ROP. The study from Hoogerwerf et al focused on changes in the incidence and risk factors responsible for the development of ROP and compared two cohorts of premature infants born in the time periods of 1991-1995 and 2001-2005.

They found an increase in the use of antenatal steroids and surfactant and a decrease in the duration of AV, supplemental oxygen administration and NICU admission, as well as a decrease in incidence of ROP. Most of these changes were not reproducible in our study. However, we included only those infants that were referred to one of the Dutch institutes for the visually impaired and were supposedly the most critically ill neonates. We speculate that more subtle improvements in neonatal care are responsible for the decrease in the incidence of VI caused by ROP and of completely blind children. Furthermore, there was an increase in infants treated for ROP (from 56.9% to 66.7%). The Early Treatment of Retinopathy of Prematurity criteria (ETROP) were introduced in the early phase of this survey resulting in a larger number to treat and an expected reduction of adverse outcomes.^{3,11,12} In addition, the study of Termote et al¹⁸ resulted in a campaign for more awareness of necessity to treat timely and for potential visual problems on the

long term. Earlier referral to the Dutch institutes for partially sighted and blind together with changed treatment criteria could be an additional explanation for the significantly higher number of infants with a visual acuity >0.3 found in the current study and the significant decrease in VI due to ROP. Although more infants received treatment in the current study, 33% ($n=14$) did not, of which 10 had a visual acuity of <0.3 . Haines et al²⁴ also described that, even after implementation of screening guidelines, some children developed VI because of non-adherence to the screening protocol.

Studies from the UK on VI due to ROP as a proportion of childhood VI, covering the same period,^{4,25} show a tendency that compares favourably with our surveys. A study by Schiariti et al¹ demonstrated an increase in ROP as well as severe ROP without changes in the incidence of VI when comparing neonates born in 1992-1996 and 1997-2001. Slidsborg et al⁵ found a more than twofold increase in the incidence of treated ROP cases born in Denmark from 2001 to 2005 compared with 1996-2000. This increase was most pronounced for the smallest infants. The number of infants with VI or blindness caused by ROP was stable. These studies also attribute the decline of VI due to ROP to a more complete ophthalmic surveillance, earlier treatment and improvement in neonatal care. Similarly to the earlier Dutch surveys, most children with VI caused by ROP were surviving preterm neonates <30 weeks of gestation. This group of infants also showed the highest incidence of concomitant disabilities. Although a substantial number of infants had one or more concomitant disabilities (73.8%), no significant changes were found compared with the study of Termote et al. Inexplicably, no children with epilepsy were registered in the present study. The incidence of BPD, developmental delay and hearing deficit gradually increased whereas behavioural abnormalities, multiple disabilities and neurological impairment decreased minimally. A Dutch study by van Baar et al²⁶ showed a clear association between preterm birth and multiple disabilities at 5.5 years of age in 157 children born before 30 weeks GA. One or more disabilities were found in 75% of the children. Several other studies have concluded that the survival rate for extremely preterm born infants has improved over the past decade, but that the overall prevalence of neurodisability after preterm birth has not fallen, thus supporting the findings in our study.⁸⁻¹⁰ This overview of more than 30 years shows a decrease in GA and BW and a gradual increase in AV and supplemental oxygen administration, with a turning point in the early 1990s when novel treatments such as surfactant treatment, high frequency oscillation (HFO), postnatal steroids and inhaled NO were introduced. The incidence of VI caused by ROP has decreased over the past 30 years with the most obvious change seen in the last survey period. Additional changes in neonatal care practices such as treatment with antenatal steroids and antenatal antibiotics together with earlier treatment for ROP could be an explanation. However, these changes did not result in a decrease of concomitant as well as multiple disabilities. Although more children were treated, 33% were not treated.



Therefore, it can not be emphasised enough that timely screening, follow-up and treatment, as well as close collaboration by all professionals involved in the care of these at-risk neonates should be our aim to enable a further decrease the number of children with VI caused by ROP. While the GA and BW of survivors continue to decrease, it seems a more difficult task to diminish the number of children with multiple disabilities.

Competing interests

None. Patient consent Children were included in the study when informed consent was obtained from their parents.

Ethics approval

This study was conducted with the approval of the medical ethics committees of all participating institutes for the partially sighted and blind.

Provenance and peer review Not commissioned; externally peer reviewed.

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