Five years of treatment for retinopathy of prematurity in Sweden: results from SWEDROP, a national quality register

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ABSTRACT

Background/aims Retinopathy of prematurity (ROP) is a sight-threatening disease, requiring efficient screening and treatment. The present study aims to describe various aspects on treatment for ROP in Sweden.

Methods Data on treatment for ROP in infants born in 2008–2012 were extracted from Swedish national register for retinopathy of prematurity, a web-based national register.

Results During 2008–2012, 3488 infants with a gestational age (GA) at birth of <31 weeks had been screened for ROP in Sweden. Altogether, 30.3% (1057/3488) of the infants developed ROP and 5.2% (181/3488) were treated. Type 1 ROP was found in at least one eye in 83.2% (149/179) of the treated infants. One third of the eyes (32.2% right, 29.9% left eyes) were treated more than once. Laser was the only treatment in 90% of the eyes. Mean number of laser spots at first laser session was 1177 and 1386 in right and left eyes, respectively. Number of laser spots correlated negatively with GA at birth (p=0.01). There was no change in frequency of treatment or number of laser spots during the 5-year period. Anti-vascular endothelial growth factor injections were performed in 28 eyes, encircling band was used in five eyes and vitrectomies were performed in seven eyes. Twenty-six retinal surgeons performed 9.4 (range 1–37) treatment sessions in the 181 infants.

Conclusions The present study reveals similar incidences of ROP and frequencies of treatment during the 5-year study period. Many surgeons were involved in treatment of a rather limited number of infants. The results call for national discussions on organisation of ROP treatment.

INTRODUCTION

Swedish national register for retinopathy of prematurity (SWEDROP) is a national Swedish quality register for retinopathy of prematurity (ROP), initiated in 2006. The main purpose of the register is to increase the knowledge of ROP and to optimise screening and treatment routines to improve outcome of this sight-threatening disease.

Two previous papers reported on incidence and frequency of treatment for ROP during two time periods, that is, 2008–2009 and 2010–2011, in Sweden.[1 2] Based on the first study, national screening criteria for ROP were changed to include only infants with a gestational age (GA) of <31 weeks in July 2012.[1] The second study confirmed that those guidelines were safe and applicable also during the following 2 years.[2]

The main purpose of the present study is to report on various aspects on treatment for ROP in Sweden during a 5-year period from 2008 to 2012.

MATERIAL AND METHODS

Data on infants screened and treated for ROP in Sweden during 2008–2012 were extracted from SWEDROP, a national web-based register. National screening criteria were changed from previously <32 weeks GA[3] to <31 weeks in July 2012.[1] The international classification for ROP is used for staging and typing of ROP[4] and treatment criteria in Sweden follow Early Treatment for Retinopathy Of Prematurity (ETROP) recommendations, that is, treating type 1 ROP.[5]

Laser treatment is the initial method of choice. Indication for surgery with encircling band and vitrectomy is based on the clinical decision of the retinal surgeon. Regarding injection with anti-vascular endothelial growth factor (VEGF), this was based on a joint clinical decision of the paediatric ophthalmologist, retinal surgeon and neonatologist. Ethical approval for studies of the national register for ROP, SWEDROP, was achieved in 2010 (Dnr 2010/117).

Statistical analyses were performed using SPSS V.21 and R V.3.1.1. Developments over the years are presented descriptively by quarters. Continuous variables are presented as mean and SDs and categorical as proportions (%). In addition, the risks of ROP and treated ROP are analysed using multivariate logistic models (three separate models), with the condition as dependent variable and calendar year, gestation age and birth weight (BW) as independent variables.

Linear regression analyses were used when evaluating mean GA and BW of the total cohort, of infants with ROP and of those with treated ROP, over time, that is, during the 5 years of the study period, using 2008 as a reference. Such analyses were also used for evaluation of postnatal age (PNA) and postmenstrual age (PMA) at first treatment, number of treatments and number of laser spots, over time.

Pearson correlation coefficients were calculated to evaluate the linear dependence between PMA at first treatment, number of treatment sessions, number of laser spots and GA at birth, as well as between number of laser spots at first treatment and the total number of treatment sessions. Correlation coefficients were also calculated between number of performed primary laser treatments and number of retreatments of the eyes performed by the 26 surgeons per se.

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T-test was used for evaluating difference in GA and BW between infants treated and not treated with anti-VEGF. p Values below 0.05 were considered as significant (but since no adjustment for multiplicity was performed the p values should be interpreted as exploratory).

RESULTS

The results of ROP screening and treatment during 2008–2011 in Sweden have previously been reported.[1 2] During 2012, there were 868 infants with a GA of <32 weeks who survived until full screening for ROP was completed. When comparing various aspects on treatment for ROP during the years between 2008 and 2012, because of the change of screening criteria in July 2012, we choose to include only infants with a GA of <31 weeks, giving a total study group of 3488 infants. Mean GA at birth of the total cohort was 27.7 weeks (range 22–30) and mean BW was 1132 g (range 307–2842). Linear regression analyses revealed similar GA and BW over the 5-year time period. Some stage of ROP was found in 30.3% (1057/3488) of the infants and 5.2% (181/3488) were treated for ROP. Proportions of infants with any ROP, severe ROP (stages 3–5) and treated ROP during each quarter of the study period of 2008–2012 are illustrated in figure 1. Multiple logistic regression analyses revealed no apparent time trend based on year of birth regarding the incidence of ROP (ORs for the years 2009–2012 vs 2008 were 1.37, 1.11, 1.12 and 1.23) or frequency of treatment (ORs for the years 2009–2012 vs 2008 were 0.98, 1.25, 0.71 and 0.68) during the 5-year period, even when adjusted for GA at birth or BW.

Treated infants

Mean GA at birth and BW of the 181 treated infants were 24.5 weeks (range 22–29) and 702 g (range 385–1230), and did not change during the 5-year period, according to linear regression analyses. The distribution of GA at birth in relation to treatment is illustrated in figure 2. Four infants were treated in only one eye. Maximal stages, zone, plus disease and type of ROP in the treated eyes are reported in table 1. Type 1 ROP was found in at least one of the eyes with available information in 83.4% (149/178) of the children who were treated for ROP. Aggressive posterior ROP (AP-ROP) was found in 15 infants (both eyes).

Information on number of treatment sessions was available in 177 right and left eyes. Mean number of treatments of the right and left eyes was 1.4 (range 1–5) and 1.38 (range 1–4), respectively. In 32.2% (57/177) of the right eyes and 29.9% (53/177) of the left eyes, treatment was performed more than once. There was no significant correlation between number of treatment sessions and GA at birth in either eye (r=−0.043 right eyes, −0.005 left eyes). Furthermore, linear regression analyses revealed no difference of number of treatments per infant and year of birth.

Mean PNA at first treatment was 12.8 and 12.7 weeks in the right and left eyes (range 7.3–24.4), respectively, and mean PMA of the right and left eyes was 37.2 weeks (range 32.1–51.4). Mean PNA and PMA at the different treatments in both eyes are illustrated in table 2. There was a significant correlation between PMA (weeks) at first treatment and GA (weeks) at birth (r=0.44/0.47, p=0.01 right and left eyes), that is, the higher the GA at birth, the higher the PMA at the first treatment. Linear regression analyses revealed no difference of PNA or PMA at first treatment and year of birth.

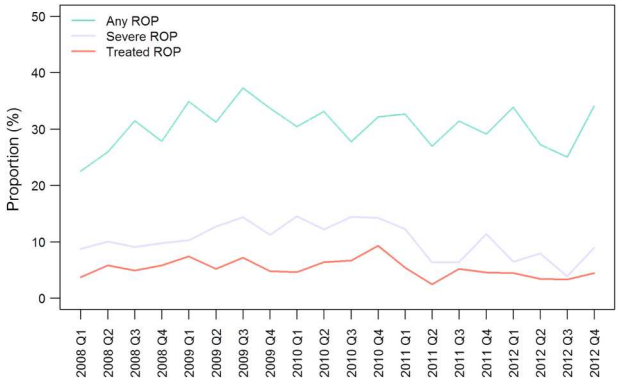

Figure 1 Proportion of infants with any retinopathy of prematurity (ROP), severe ROP and treated ROP. Proportion of infants with any ROP, severe ROP (stages 3–5) and treated ROP, during each quarter (Q) of the 5-year study period 2008–2012.

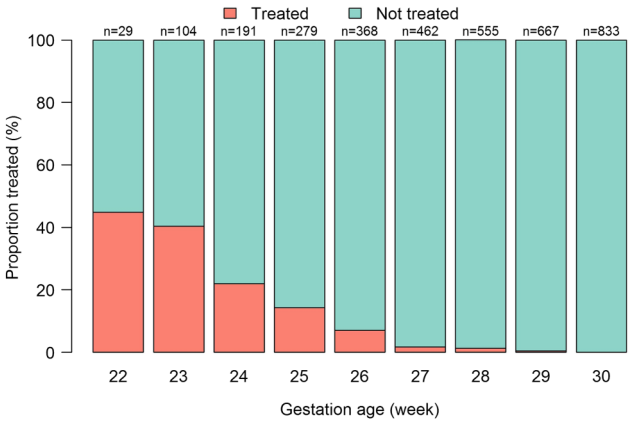

Figure 2 Treatment for retinopathy of prematurity (ROP) in relation to gestational week at birth. Proportion of infants treated for ROP in relation to gestational week at birth. N, number of infants screened for ROP in relation to gestational age (week) at birth.

Table 1 Maximal stage, zone, plus disease and type of ROP in treated right and left eyes

	Right eyes (n, %)	Left eyes (n, %)
Maximal ROP stage* (179 right, left eyes)		
Stage 1	0 (0)	0 (0)
Stage 2	3 (1.7)	6 (3.4)
Stage 3	169 (94.4)	163 (91.1)
Stage 4A	5 (2.8)	4 (2.2)
Stage 4B	0 (0)	2 (1.1)
Stage 5	2 (1.1)	4 (2.2)
Zone of ROP* (172 right, left eyes)		
Zone I	20 (11.6)	22 (12.8)
Zone II	147 (85.5)	146 (84.9)
Zone III	5 (2.9)	4 (2.3)
Plus disease* (179 right/178 left eyes)		
Yes	140 (78.2)	138 (77.5)
No	39 (21.8)	40 (22.5)
Type of ROP* (178 right, left eyes)		
Type 1	141 (79.2)	137 (77.0)
Type 2	37 (20.8)	41 (23.0)

*Available information on maximal stage, zone, plus disease and type of ROP in the right and left eyes is given in brackets.
ROP, retinopathy of prematurity.

Table 2 PNA and PMA age (weeks) (mean and range) at the different treatments of the right and left eyes (available information in 176 right and left eyes, respectively)

	Treatment number	Eyes (n)	PNA (weeks) Mean (range)	PMA (weeks) Mean (range)
Right eyes	1	176	12.8 (7.3–25.4)	37.2 (32.1– 51.4)
	2	57	14.7 (9.3–29.7)	39.2 (34.3–55.7)
	3	14	15.7 (10.0–21.6)	40.0 (36.1–45.6)
	4	2	16.4 (13.4–19.4)	40.9 (38.4–43.4)
	5	1	23.1	47.1
Left eyes	1	176	12.7 (7.3–25.4)	37.2 (32.1–51.4)
	2	52	14.7 (9.3–24.6)	39.1 (34.3–47.6)
	3	15	16.1 (10.0–29.7)	40.6 (36.1–53.7)
	4	1	13.4	38.4
	5	0		

PMA, postmenstrual age; PNA, postnatal age.

Information on type of treatment was available in 177 right and left eyes. Laser was the only treatment in 159 right eyes and 160 left eyes. Anti-VEGF injection (bevacizumab) was the only treatment in three right and two left eyes. The remaining eyes had a combination of treatments, including laser, cryotherapy, anti-VEGF injections, surgery with encircling band and vitrectomy.

Among eyes treated with laser only, 27% (43/159) of the right and 24.4% (39/160) of the left eyes were treated more than once. Mean number of laser spots at the first treatment were 1177 in the right eyes (range 186–3480, SD 578) and 1124 (range 167–2895, SD 492) in the left eyes. In total, the right eyes had 1386 laser spots (range 227–3920, SD 749) and the left eyes 1280 laser spots (range 167–4681, SD 687). There was no significant correlation between number of laser spots at the first treatment and the total number of treatment sessions in either eye (r=−0.017 right eyes/−0.034 left eyes). There were significant correlations between number of laser spots at the first treatment and GA at birth in both eyes (r=−0.305/−0.242, p=0.01), as well as between the total number of laser spots, and GA at birth in the two eyes (r=−0.280/−0.165, p=0.01/0.05), that is, the lower the GA at birth, the higher the number of laser spots at first treatment and in total. Linear regression analyses revealed no differences in initial or total number of laser spots in either eye during the 5-year study period, see figure 3A,B for illustration of the results of the right eyes.

Encircling band was used in two right and three left eyes. Vitrectomies were performed in seven eyes of five infants, four boys and one girl. GAs of the infants varied between 22 and

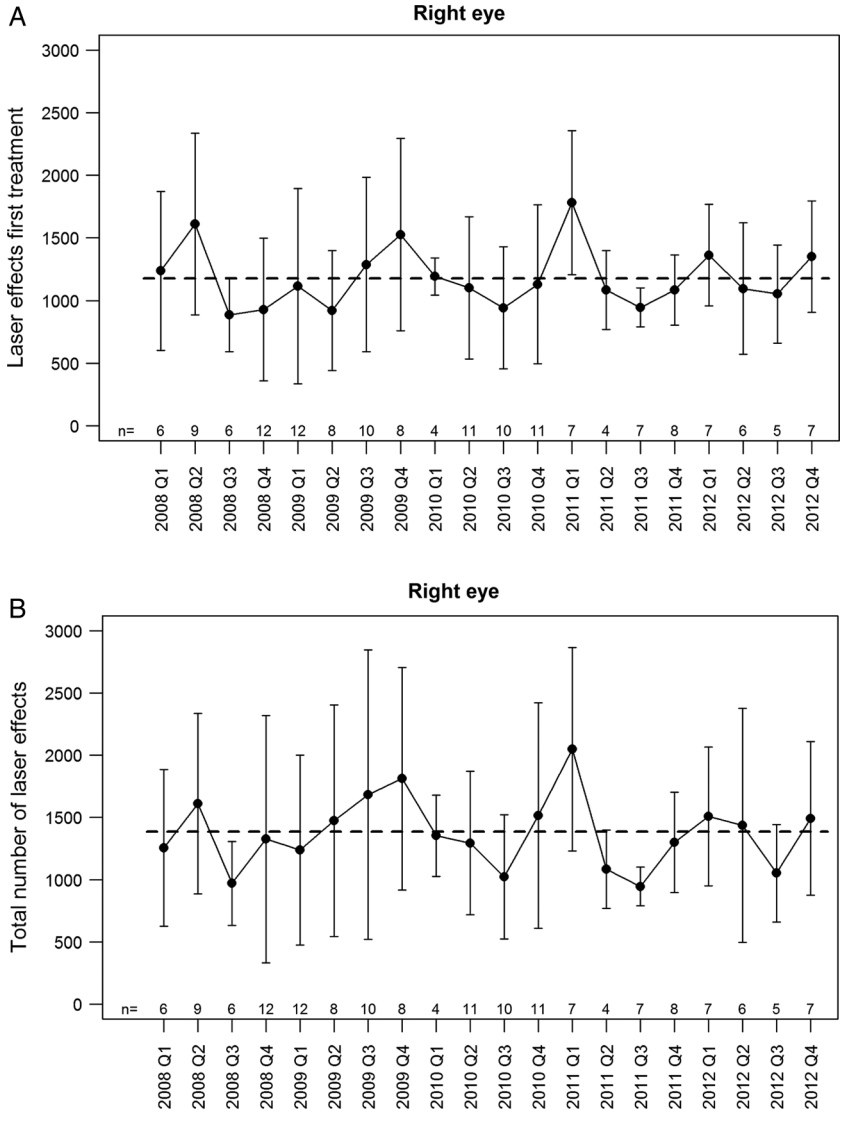

Figure 3 (A) Laser spots at first treatment, right eyes. Number of laser spots at first treatment in the right eyes (n=159) during each quarter (Q) of the 5-year study period 2008–2012. (B) Total number of laser spots, right eyes. Total number of laser spots in the right eyes (n=159) during each quarter (Q) of the 5-year study period 2008–2012.

29 weeks and BWs between 533 and 1200 g. Altogether, anti-VEGF injections (Bevacizumab) were used in 17 infants (16 right and 12 left eyes), 11 of which had AP-ROP. Five of the eyes were treated with anti-VEGF as monotherapy, as mentioned above. Doses varied between 0.3 and 0.65 mg. There was no difference in GA and BW between infants treated and not treated with anti-VEGF. Ten infants had necrotising enterocolitis, all of which had an onset before treatment with anti-VEGF injections. For detailed information on infants and eyes treated with anti-VEGF, see table 3.

Information on treatment and surgeon was available in 175 right and left eyes of the 181 infants. Altogether, 249 and 247 treatment sessions, mainly laser treatments, were undertaken in the eyes, respectively. There were 26 different retinal surgeons who were involved in the treatment. Each surgeon performed a mean number of 9.8 treatment sessions (range 1–37 sessions right eyes and 1–36 left eyes). Fifteen surgeons treated 1–10 right or left eyes, six surgeons treated 11–20 eyes and three surgeons performed >20 treatments, see figure 4 for illustration of treatment of the right eyes. Frequency of retreatments of the different surgeons varied between 3% and 100%. There was no significant correlation between number of treatment sessions and number of retreatments of any of the eyes performed by the 26 surgeons per se (r=0.358 right eyes, r=0.239 left eyes). Vitrectomies were performed in altogether seven eyes (three right and four left eyes) by three different retinal surgeons. Anti-VEGF injections were given by nine surgeons, of whom only three injected more than two eyes.

Table 3 Infants (17) treated with bevacizumab alone or in combination with other methods, in 16 right and 12 left eyes

		Right			Left			Right		Left	
GA (weeks)	BW (g)	Stage	Zone	AP-ROP	Stage	Zone	AP-ROP	Treatment (dose, mg)	PMA (weeks)	Treatment (dose, mg)	PMA (weeks)
22	533	4A	II	–	4A	II	–	1. Laser 2. Vitrectomy 3. Anti-VEGF (NA)	32.6 38.3 40.3	1. Laser	32.6
22	555	3	I	+	3	I	+	1. Anti-VEGF (0.625) 2. Anti-VEGF (0.625) 3. Laser	33.3 35.3 37.3	1. Anti-VEGF (0.625) 2. Anti-VEGF (0.625) 3. Laser	33.3 35.3 37.3
22	580	3	II	–	3	II	–	1. Laser	33.3	1. Laser 2. Anti-VEGF (NA)	33.3 36.1
23	495	3	I	+	3	I	+	1. Anti-VEGF (0.4)	34.1	1. Anti-VEGF (0.4)	34.1
23	585	3	I	+	3	I	+	1. Anti-VEGF (0.4)	34.4	1. Anti-VEGF (0.4)	34.4
24	470	3	I	+	4A	I	+	1. Laser 2. Cryo 3. Anti-VEGF (0.3)	32.4 34.4 39.1	1. Laser 2. Cryo 3. Anti-VEGF (0.3)	32.4 34.4 39.1
24	623	4A	I	+	3	I	+	1. Laser 2. Laser 3. Laser 4. Anti-VEGF (0.625) 5. Encircling band	34.4 35.6 37.6 43.4 47.1	1. Laser 2. Laser 3. Anti-VEGF (0.625)	34.4 35.6 37.6
24	668	3	I	+	3	I	+	1. Anti-VEGF (0.625) 2. Anti-VEGF (0.625) 3. Laser	32.6 36.1 43.6	1. Anti-VEGF (0.625) 2. Anti-VEGF (0.625) 3. Laser	32.6 36.1 43.6
24	675	3	II	–	3	II	–	1. Laser 2. Anti-VEGF (0.625) 3. Laser	34.6 35.4 38.3	1. Laser 2. Anti-VEGF (0.625) 3. Laser	34.6 35.4 38.3
24	716	3	I	+	3	I	+	1. Laser 2. Laser 3. Anti-VEGF (0.625)	32.1 34.3 36.1	1. Laser 2. Laser 3. Anti-VEGF (0.625)	32.1 34.3 36.1
25	648	3	I	+	3	I	+	1. Cryo 2. Laser 3. Anti-VEGF (0.5) 4. Cryo	35.6 36.6 37.6 38.4	1. Cryo 2. Laser 3. Cryo+anti-VEGF (0.5) 4. Cryo+anti-VEGF (0.625)	35.6 36.6 37.6 38.4
25	731	3	II	–	3	II	–	1. Laser 2. Laser+anti-VEGF (0.625)	34.0 35.3	1. Laser 2. Laser	34.0 35.3
25	972	3	I	+	3	I	+	1. Anti-VEGF (0.625)	35.7	1. Laser	32.7
26	514	3	I	+	3	I	+	1. Laser 2. Laser+anti-VEGF (0.5)	36.6 37.6	1. Cryo 2. Laser+anti-VEGF (0.5)	36.6 37.6
26	876	3	II	–	3	II	–	1. Laser 2. Anti-VEGF (0.625)	37.3 38.3	1. Laser 2. Laser 3. Laser	37.3 41.1 43.3
26	956	3	II	–	3	II	–	1. Laser 2. Anti-VEGF (0.625)	37.9 41.7	1. Laser 2. Laser	39.9 41.7
29	1200	5	I	+	5	I	+	1. Laser 2. Anti-VEGF (0.3) 3. Vitrectomy	36.9 38.4 39.0	1. Cryo 2. Anti-VEGF (0.3) 3. Vitrectomy	36.9 38.4 39.0

All 17 infants had plus disease and type 1 ROP in both eyes. Stage of ROP and aggressive posterior ROP (AP-ROP) in either eye is presented in the table.
AP-ROP, aggressive posterior ROP; BW, birth weight; GA, gestational age; NA, not available; PMA, postmenstrual age; ROP, retinopathy of prematurity.

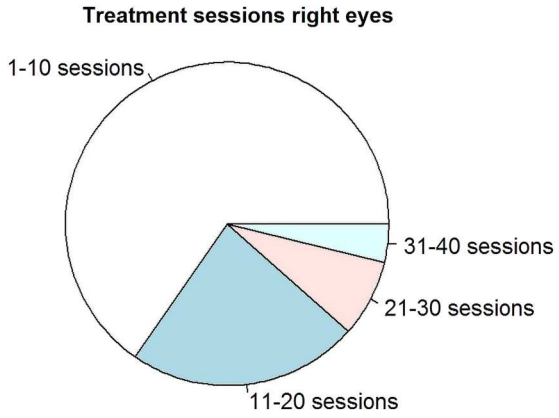

Figure 4 Treatment sessions per doctor, right eyes. Number of treatment sessions per doctor (n=26) of the right eyes (totally 249 treatment sessions of these eyes) during the 5-year period (2008–2012).

DISCUSSION

SWEDROP is a Swedish quality register for ROP and makes it possible to continuously follow the frequency of treatments as well as various aspects of the treatment per se in the country over time.

The incidence of ROP and frequency of treatment remained similar during the 5-year period between 2008 and 2012, as did mean GA at birth and BW. Furthermore, comparison with a previous national Swedish study of extremely preterm infants with GA <27 weeks (EXPRESS) and born in 2004–2007 revealed similar results at similar GAs as in the present study, pointing to a rather stationary neonatal care in Sweden during the last decade.[6 7] Surprisingly, a Danish study reported an increased frequency of treatment during the past half-decade, when compared with a previous period, and suggested that changes in neonatal care might be an explanation.[8]

Mean GA at birth and BW of the treated infants were similar during the whole study period. Furthermore, and reassuringly, no infant born after 30 gestational weeks was treated for ROP. Hence, the new Swedish guidelines for ROP screening, including only infants with a GA at birth of <31 weeks, still seem to be safe and applicable.[1]

PMA and PNA at treatment remained similar during the study period, pointing to a stable natural course of the ROP disease as well as estimation of ETROP criteria in our country. Type 1 ROP was found in at least one of the eyes in only 83% (83.2) of the 181 treated infants of this 5-year cohort. This finding accords with a recent Australian study in which plus disease was present in only 77% of treated infants.[9] Various practical reasons, such as long distance transports, may contribute to the occasional lack of adherence of treatment criteria, as suggested by Slidsborg *et al*[8] in the Danish study. Furthermore, it should be mentioned that plus disease, which is a major criterion for type 1 ROP, is a very subjective diagnosis and discrepancies between ophthalmologists in the judgement of plus disease is a well known phenomenon.[10]

The vast majority (90%) of treated eyes in the present study had laser therapy only, emphasising the good effect of this treatment. Around 25% of the infants, however, were treated more than once. During the last two decades, several studies have supported a more confluent laser treatment, leading to a more prompt regression of the ROP disease and to a reduced number of retreatments.[11 12] In a recent, retrospective, hospital-based study from Australia, Gunn *et al*[9] showed an increase in the number of laser spots and regression rate of ROP during an 18-year study period, and a decrease in the frequency of retreatments from 42% to 19% of the eyes. In the present study, the number of laser spots and treatment sessions remained similar throughout the 5-year period. The positive development in the Australian study was probably facilitated by the fact that all treatments were performed by one surgeon.

In 2008, the first infant was treated with anti-VEGF injections for ROP in Sweden. In the present cohort including infants born up to 2012, 17 infants had been treated with anti-VEGF injections. Indications for the anti-VEGF treatment in these infants were AP-ROP (n=11), type 1 zone I disease (n=1) and type 1 posterior zone II disease (n=5). There was no difference in GA at birth or BW of infants treated with or without anti-VEGF. The majority of the infants treated with anti-VEGF were generally very ill and 10 of the 17 infants had necrotising enterocolitis, all of which had an onset before treatment with anti-VEGF injections. Although SWEDROP does not yet include long-term follow-up, all infants who were treated with anti-VEGF injections are closely monitored up to at least school age.

Of the treated infants, 6% (11/181) progressed into ROP stages 4 and 5 in at least one of their eyes. Eight of these infants were operated with encircling band and/or vitrectomies. Repka *et al* reported disappointing functional results after surgery for ROP stages 4 and 5 in a 6-year follow-up of the ETROP study.[13] Unfortunately, we cannot report on the visual outcome of infants with ROP stages 4 and 5 after surgery in the present study, since follow-up information is lacking for the time being.

In the present study, many surgeons were involved in treatment of the rather limited number of infants. Only a small number of surgeons performed a large number of treatments, including the few vitrectomies, while 15 of the surgeons performed 10 or less treatments during the 5-year study period. A relationship between surgical volume in general and positive outcome is well-known[14] and is applicable also in ophthalmology, as illustrated by Bell *et al*,[15] who found a strong relationship between annual surgeon volume of cataract procedures and outcome, also regarding very high-volume surgeons. Furthermore, it is reported that there is a significant learning curve for laser treatment in prematurely born children.[16] In the present study, the number of retreatments was high. Although we did not find any correlations between number of laser spots at first treatment and the total number of treatment sessions, or between number of performed treatments per surgeon and number of retreatments in this limited number of eyes, as stated above, it is assumed that more confluent laser treatment would reduce the number of retreatments. Experienced surgeons, however, are important, and the whole team of competent paediatric ophthalmologists, neonatologists and paediatric anaesthetists is important for the outcome of the infant. This issue poses great demands on subspecialist education in a small country like Sweden. No outcome measures are available in the present study, and therefore the consequences of the small number of treatments of some surgeons are not possible to evaluate.

To conclude, the present study shows similar incidences of ROP and frequencies of treatment in Sweden during a 5-year period. However, detailed analyses of various aspects of treatment for ROP reveal some possible areas of improvements, such as more confluent laser treatment leading to a reduced number of treatments in each infant.

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Contributors All authors substantially contributed to design, acquisition and interpretation of the work, revised it critically, approved the final version and agreed to be accountable for all aspects of the work.

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Competing interests None declared.

Ethics approval Faculty of Medicine, Uppsala University, Sweden.

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Data sharing statement Raw data could be made available on request and discussion with the authors.

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