SHORT REPORT

Effect of light reduction on the incidence of retinopathy of prematurity

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The effect of ocular protection on the incidence of retinopathy of prematurity was tested in 188 newborns weighing less than 1600 g in a randomised controlled trial. No effect of ambient light reduction on the incidence of retinopathy of prematurity was shown.

Clinical studies conducted to date have yielded conflicting results on the effects of light on retinopathy of prematurity (ROP).[1–4] Phelps and Watts[5] performed a Cochrane Review and meta-analysis, reviewing all papers published to date (and included the present study as ''in progress''). They concluded that it is unlikely that the ambient luminosity affects the incidence of ROP, but stressed the large confidence intervals in the combined data, which were due to the small number of threshold or pre-threshold diseases.[5]

This study concurs with the final outcomes of the previous studies and yields additional evidence that exposure to light does not affect the incidence of ROP.

METHODS

All infants born at a gestational age of less than 32 weeks and or a birth weight less than 1600 g at two neonatal intensive care units were included. They were randomised to two groups, trial and control, and stratified by birth weight (>1000 g or <1000 g). Infants in the trial group received ocular protection against the ambient light on both eyes, from birth until 35 weeks of corrected gestational age. Infants in the control group did not receive ocular protection and were kept under the regular light conditions.

Indirect ophthalmoscopy was performed within four to six weeks of birth and thereafter every one or two weeks. The diagnosis of ROP was confirmed at at least two examinations according to the criteria of the CRYO-ROP study.[6] The ambient light was measured using an ICEL digital light meter, model LD-500 (Parana, Brazil).

Statistical analysis was performed using the χ^2 test, Student's *t* test, and logistic regression.

The study protocol was approved by the institution review board for ethical conduct in humans, and written informed consent was obtained from the parents.

RESULTS

A total of 226 newborns met the requirements for admission to the study and were randomly allocated to the trial or control group. During this period, two parents refused to participate in the study, 33 babies died, two infants were transferred, and one infant did not complete the allocation procedure properly. The final breakdown was 95 newborns in the trial group and 93 in the control group.

The mean luminosity was 383 lux (range 188–540).

There were no significant differences between the groups with regard to body weight, gestational age, and the main maternal and neonatal morbidities (table 1).

There were no significant differences with regard to respiratory assistance between the groups. Mechanical ventilation was administered for 293 (509) hours to the trial group compared with 259 (103) hours to the control group (median 90 *v* 103 hours), continuous positive airway pressure for 140 (20) *v* 161 (18) hours (median 48 *v* 84 hours), and oxygen 23 (33) *v* 23 (29) days (median 6 *v* 12 days).

A total of 368 ophthalmological examinations were performed during the period of the study with a mean (SD) of 1.96 (1.24) per baby.

Table 2 shows the frequency of confirmed retinopathy, grade 3 and 3+ (pre-threshold disease).

To control for possible confounding variables, we conducted a logistic regression analysis adjusting for the time of exposure to oxygen, sex, gestational age, birth weight, and suspected or confirmed sepsis. The odds ratio and confidence intervals for eye protection were 1.24 (0.61 to 2.48) ($p = 0.55$).

DISCUSSION

It is difficult to compare the results of this study with those reported by initial clinical studies that investigated the role of ambient light on the development of ROP such as those conducted by Glass *et al*,[1] Ackerman *et al*,[2] and Seiberth *et al*[3] because of the differences in methodology, population, and study design. Our results are very similar to those of Reynolds *et al*,[4] differing only in the population of newborns admitted (<1600 g *v* <1250 g). For this reason, the incidence of ROP in our study was lower: 46% *v* 58%. If we stratify the data using the same birthweight bracket (<1250 g), our ROP incidence was 63% in the trial group and 60% in the control group, which is very close to the values found by Reynolds *et al*.

Table 1 Characteristics of the study groups

	Control (n = 93)	Trial (n = 95)	p Value
Birth weight	1137 (324)	1194 (273)	>0.05
Gestational age	29.7 (2.3)	30.2 (2.3)	>0.05
Male infants	61	48	>0.05
Maternal steroids	42	37	>0.05
Normal delivery	34	33	>0.05
HMD	50.5	42	>0.05
PDA	26	27	>0.05
Suspected sepsis	59	55	>0.05
Confirmed sepsis	29	23	>0.05
Apnoea	77.4	72	>0.05

Values are mean (SD) or percentages.
HMD, Hyaline membrane disease; PDA, patent ductus arteriosus.

Table 2 Incidence of retinopathy of prematurity

	Control group	Trial group	p Value
Absent	50/93 (54)	51/95 (54)	>0.05
Grades 1 & 2	36/93 (39)	37/95 (39)	>0.05
Grades 3 & 3+	7/93 (7)	7/95 (7)	>0.05
Cryo/Laser	6 (6)	5 (5)	>0.05
Total	43/93 (46)	44/95 (46)	>0.05

Values in parentheses are percentages.
Cryo/Laser, cryotherapy or laser therapy for retinopathy.

What is already known on this topic

- Known risk factors for retinopathy of prematurity are low birth weight and oxygen exposure
- Light exposure has been studied as a possible risk factor

What this study adds

- Further evidence is provided that light reduction does not decrease the incidence of retinopathy of prematurity

The results of this study combined with published data provide strong evidence that reduction of ambient light does not have any effect on the incidence of retinopathy in infants with very low birth weight.

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