

Introduction

As the incidence of premature births rises and the rates of survival improve as a result of advancements in neonatal healthcare, there remains a significant global population of infants who are susceptible to the development of retinopathy of prematurity (ROP), particularly in middle-income nations. Risk of ROP differs according to economic situation, in developed countries, infants born with gestational age (GA) less than 28 weeks and birth weight (BW) less than 1 kg are at high risk of ROP, but in developing countries, these parameters differ as infants born with GA of 37 weeks or less and with BW of 2000 gm. or less are at high risk of ROP. There is ongoing debate on the use of topical anesthetics with premature neonates during ROP examination. A seven-indicator composite metric called the preterm infant pain profile (PIPP) is used to gauge newborns' acute pain. Gestational age, oxygen saturation, heart rate, behavioral state, eyelid squeeze, nasolabial furrow and brow bulging are the indicators.

Aim of the work

The aim of the study was to evaluate the role of benoxinate in reducing pain score in patients with ROP.

Patients and Methods

This was a prospective randomized double masked cross-over study conducted for infants undergoing routine ROP screening exams after signing a written informed consent by the parents following explaining all the examination procedures. Randomization done with closed envelops technique. The current study included a total of 77 neonates who underwent screening for ROP twice, of which 44 neonates were examined with tears substitutes eye drops in first examination and benoxinate eye drops in second examination, and other 33 neonates were examined with benoxinate eye drops in first examination and tears substitutes eye drops in second examination.



Figure:
(A) Camera fixed in front of the pulse oximetry monitor (Drager monitor) to record heart rate and oxygen saturation.
(B) PIPP score calculated at indirect ophthalmoscopy.
(C) PIPP score calculated at scleral indentation.

Results

Table 1: Comparison between benoxinate eye drops and tears substitutes eye drops (regardless order of examination) according to PIPP score at six stages and average PIPP

PIPP score	Benoxinate drops	Tears substitutes drops	P value
Baseline	3 (1 – 7)	3 (1 – 5)	0.2
Speculum	7 (3 – 13)	7 (3 – 12)	0.6
Indirect ophthalmoscopy	9 (4 – 15)	9 (4 – 14)	0.3
Scleral indentation	12 (6 – 18)	12 (5 – 16)	0.5
1 minute post Examination	3 (1 – 9)	3 (1 – 6)	0.6
5 minutes post Examination	3 (1 – 7)	3 (1 – 5)	0.2
Average PIPP	7.1 ± 1.5	6.8 ± 1.3	0.2

Non parametric data were expressed as median (min-max), analyzed by Mann-Whitney test; Parametric data are expressed as Mean (±) SD, analyzed by T-test.

Table 2: Comparison between benoxinate eye drops and tears substitutes eye drops (regardless order of examination) according to difference of average PIPP from baseline PIPP and average PIPP category

	Benoxinate drops	Tears substitutes drops	P value
Difference of average PIPP from baseline PIPP ≥4 (No., %)	46 (59.7%)	43 (55.8%)	0.6
Average PIPP < 7 (No., %)	41 (53.2%)	46 (59.7%)	0.4
Average PIPP 7-12 (No., %)	36 (46.8%)	31 (40.3%)	
Average PIPP > 12 (No., %)	0	0	

Qualitative data were expressed as frequency (percentage), analyzed by chi-square test

Conclusion

In the context of preterm infants undergoing screening for ROP, benoxinate topical anesthetic eye drops have no additional advantage over placebo (tears substitutes). They cannot be relied on as a sole factor to control infant stress and additional measures should be considered during examination.