Reviewer's report

Title: Pain and Stress Assessment After Retinopathy of Prematurity Screening Examination: Indirect Ophthalmoscopy vs. Digital Retinal Imaging

Version: 2 Date: 3 April 2012

Reviewer: Eugene Dempsey

Reviewer's report:

The authors present the results of a comparative study, evaluating pain responses obtained from babies undergoing ROP screening with BIO and WFDRI.

The manuscript is generally well presented. However I would have the following concerns which need to be addressed. Many of these relate to the methodology of the study.

1. This is described as a comparative evaluation. Whilst it is not a crossover trial in the conventional sense, it is still prone to both period effects and carryover effects, none of which are alluded to or addressed in the manuscript. These potential effects need to be addressed.

2. ‘A neonatologist (MMP or SCC) performed and reported the pain measurements. Prior to commencing the study, both neonatologists were trained specifically on assessment of pain scales until a good inter observer agreement was attained”. What does this mean? How many assessments were performed prior to the study. What was the inter and intra rater variability?

3. The scoring of the pain scores seems to have been performed at the time of the assessment by a single assessor per assessment. However there were two assessors as mentioned previously. Was there any difference in individuals scores from assessments performed by each assessor? The only way this could be assessed was if the two performed the assessment at the same time or if video recording was performed and these scores were evaluated afterwards.

4. Why not evaluate at predefined times during the examination. Whilst 30 secs afterwards is not unreasonable there may have been significantly higher scores during the examination which will therefore be missed.

5. ‘The number of paired examinations required to estimate a difference between techniques of 1 point in the pain scales with a confidence level of 95% and a power of 80% was 30’. There were two pain scales used. Which one was chosen to determine the sample size from this study? Why a one point difference? Is this 1-point difference likely to be clinically significant? Please elaborate.

Minor issues.

Abstract

1. ‘Median PIPP score (interquartile interval) at baseline was 4 (3-5), and
respectively 8 (6-9) for BIO and 6 (5-7) for WFDRI'. Please clarify.
2. ‘Infants examined for screening of ROP with digital retinal imaging present less pain/stress compared to binocular indirect ophthalmoscopy’. To be exact they present less pain/stress 30 secs following completion of the exam.

Introduction
1. Line 52. Reference 8 is not consistent with this sentence.
2. Line 57. Oral sucrose

Results
1. It appears 16 infants had both studies performed and 8 others had a number of studies performed. A breakdown of these groups would be interesting.

Discussion
1. ‘The results of this study reveal that there is less immediate pain/stress in premature children when screening for ROP is performed with Retcam compared to examination with BIO’. This statement is incorrect. Less immediate implies during the examination whereas the authors found less immediate following completion of the exam. For example some exams were 11-12mins in duration.
2. Line 212 -214 is repetition and should be included in the introduction
3. There are many typographical and grammatical errors, which need to be addressed.

I have no competing interests to declare.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

I declare that I have no competing interests.

Eugene Dempsey