Author’s response to reviews

Title: Randomised controlled trial of weaning strategies for preterm infants on nasal continuous positive airway pressure

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Author’s response to reviews:

The Editor
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Dear Editor

Re: BPED-D-15-00075 Randomised controlled trial of weaning strategies for preterm infants on nasal continuous positive airway pressure

Thank you for allowing a revised manuscript to be considered. Our responses to the reviewers’ well considered comments are documented below. Changes are highlighted in the submitted revision.

Reviewer #1:

Study population and study design: page 4, line 8: Added ‘Mouth closure was achieved by use of a chin strap or a pacifier and targeted to the infant’s work of breathing. A ≥6 FG gastric tube was used to avoid gastric over distension with air.’

Study Devices: Added: ‘..’ and flow rate was set ≥1 L/minute above the ‘bubbling point’.

Results: The reviewer is confused about the ‘intention to treat’ analysis. Added to statistical analysis section: ‘The data for infants withdrawn from treatment is reported in group of assignment.’
Discussion: Page 8, line 32: Deleted word ‘the’.

Table 1: Grade 2 apnea is already defined in methods: ‘including grade 2 apnea (required positive pressure ventilation),’ Added ‘IPPV’ to definition and table.

Table 2: analysis is ‘intention to treat’ as documented in statistical analysis.

Reviewer #2:

Background: changed the aims are suggested: ‘This is a pilot study designed to inform the optimal comparisons for a larger trial. The primary aim of a larger trial will be to determine the optimal method for weaning infants born <30 weeks gestation from NCPAP to reduce duration of respiratory support and time to full suck feeds. The secondary aims are to determine the efficacy of abrupt versus gradual weaning from NCPAP; and the efficacy of use of HFNC versus no HFNC for weaning infants from NCPAP.’

The groups were similar at baseline: We have added this to results text: ‘They were aged 28 days (range 2 – 76) with mean postmenstrual age 31 weeks (27 – 37) and weight 1237g (662 – 1890) and were similar between groups. Infants were on median FiO2 0.21 (range 21 – 23), pressure 5 cmH20 (5 – 5), on NCPAP for 19 hours (5 – 24) and tolerated 5 hours (0 – 15) off NCPAP and were similar between groups.’ The weight groups are reported in table 1. The medians are identical with no statistically significant difference so reported in text to document the status of infants enrolled.

Outcomes: As the reviewer has pointed out, we have adjusted the p-value for secondary outcomes and have taken this into account in the discussion and conclusions. We consider that the duration in days of respiratory support from randomisation and the corrected gestational age at which infants cease interventions and achieve full enteral feeds will be of interest to readers. No changes made but will address if the request is still considered important.

We have stated in methods, statistical analysis: Sample size calculation was not performed as this was a pilot study.

Figure 1: deaths included in excluded infants. N=29. Figure changed.

Measures of illness severity are reported as above for baseline.

Discussion:
Corrected ‘lower’ to ‘higher’.

Deleted: ‘, and is associated with a reduced risk of nasal trauma. ’ as requested.

Added to discussion to address concerns regarding overstatement of findings: ‘Given this is a small pilot study caution is advised in interpreting the findings.’
Added into discussion ‘The reason for withdrawal of all infants was dissatisfaction with weaning method. Parents reported feeling their infant was ‘failing the weaning process’ when attempting to abruptly cease NCPAP. The analyses from our trial suggest a strategy of abrupt wean with use of HFNC may be the most efficient and acceptable to parents.’

Yours sincerely

A/Professor David Osborn on behalf of the author team.