



Stabilisation of premature infants in the delivery room with nasal high flow

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Received 2 September 2015

Revised 25 November 2015

Accepted 5 December 2015

Published Online First

5 January 2016

ABSTRACT

Objective This was a pilot study to determine the feasibility of using nasal high flow (nHF) (also known as heated humidified high-flow nasal cannula) for stabilisation of babies born at <30 weeks gestation in the delivery room (DR) and transfer to the neonatal intensive care unit (NICU).

Design Observational study.

Setting Single-centre NICU.

Patients Infants born at <30 weeks gestation.

Interventions Stabilisation and transfer to NICU using nHF.

Main outcome measures Feasibility of stabilisation as defined by successful transfer and clinical measures of stability at admission to NICU including oxygen requirement, temperature, requirement for surfactant and inotrope use within 72 h of delivery.

Results Twenty-eight babies were enrolled after written parental consent had been obtained. 25/28 were successfully stabilised in the DR and transferred to the NICU on nHF. The average admission temperature for babies transferred on nHF was 36.9°C and the average inspired oxygen at admission was 29%. Less than half (48%) required surfactant and 60% were still on nHF 72 h after admission. 1 baby received inotropes.

Conclusions Our study suggests that using nHF for stabilisation of premature infants in the DR and subsequent transfer to NICU is feasible.

Clinical trial registration number NCT01991886.

INTRODUCTION

Stabilisation of preterm babies using nasal continuous positive airway pressure (NCPAP) in the delivery room (DR) is recommended by international guidelines,^{1,2} with evidence of improved outcomes compared with routine intubation and ventilation.^{3,4} Selective administration of surfactant after stabilisation is also associated with improved outcomes.⁵ The use of nasal high flow (nHF) is increasingly established for the postextubation management of preterm babies, with several large studies demonstrating that it is generally as effective as nasal CPAP for postextubation support^{6–8} and may offer further advantages such as ease of use, greater comfort and reduction in nasal trauma.⁹ In our neonatal intensive care unit (NICU) we have been using nHF (Vapotherm Precision Flow) for non-invasive ventilation, as a replacement for nCPAP for >8 years. Our experience led us to hypothesise that nHF might be suitable for DR stabilisation and respiratory support immediately after birth.² Given the paucity of literature on the use of nHF in the DR, it was not known if nHF would be straightforward to use in the DR setting, if it would be

What is already known on this topic?

- Delivery room stabilisation of preterm infants using nasal continuous positive airway pressure (NCPAP) improves outcomes.
- Nasal high flow (nHF) is not inferior to NCPAP for postextubation management of neonates.
- nHF has gained popularity due to ease of use, effectiveness and patient comfort.

What this study adds?

- It is feasible to stabilise premature babies in the delivery room (DR) using nasal high flow (nHF).
- Stabilisation on nHF may reduce rates of DR intubation and surfactant administration.
- The clinical stability of the well preterm infant may be evident soon after birth.

tolerated in the first few minutes after birth, nor if babies could be stabilised and moved to the NICU using nHF support. We, therefore, conducted a pilot study to establish the feasibility of using nHF in the DR to stabilise and transfer preterm infants born at 30 weeks gestation or less.

MATERIALS AND METHODS

Study design

This was an observational study to determine the feasibility (defined as 'The state or degree of being easily or conveniently done'¹⁰) of the use of nHF in the stabilisation and transfer of preterm infants. We used quantitative measures to determine feasibility including transfer to NICU on nHF, evidence of clinical stability on admission to NICU—temperature and oxygen requirement and need for further stabilisation (eg, intubation and ventilation, surfactant administration and use of inotropes). Staff comments were invited.

Setting

The study was carried out in the NICU at St. Peter's Hospital, Chertsey, Surrey, UK between January 2014 and March 2015. Prior to this study, our normal practice was that babies born at <26 weeks gestation were electively intubated in the DR and received prophylactic surfactant (Curosurf 100–200 mg/kg).² Above 26 weeks gestation intubation would be at the discretion of the attending clinician.



► <http://dx.doi.org/10.1136/archdischild-2015-310269>



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To cite: Reynolds P, Leontiadi S, Lawson T, et al. *Arch Dis Child Fetal Neonatal Ed* 2016;**101**:F284–F287.

Intubated babies would be transferred on intermittent positive pressure ventilation (IPPV), with early extubation to nHF if possible. Non-intubated babies would be stabilised and transferred to NICU on the resuscitaire using either CPAP or IPPV by face mask using the resuscitaire gas supply and nHF started when in the NICU. The majority of babies followed these pathways. Rescue surfactant would normally be given if the FiO_2 was persistently ≥ 0.4 although clinical judgement of work-of-breathing and rate of rise of FiO_2 would be taken into account. Dopamine would be started as the first line inotrope if the mean blood pressure was lower than 20 mm Hg, or was persistently lower than the gestational age with evidence (clinical or biochemical) of poor perfusion.

Prestudy practice on our NICU

Our routine practice for the DR management of babies born at <30 weeks gestation during the year preceding this study was noted for comparison. Of 52 babies born in 2013, 73% were intubated in the DR (100% if born at <26 weeks), with all intubated babies receiving surfactant in the DR. One planned and three unplanned extubations occurred prior to transfer to NICU, and 15/34 (44%) were then electively extubated within 24 h on NICU. We have a long-standing policy of early extubation and non-invasive ventilation to nHF. 5/52 babies were still ventilated at 72 h with only two babies receiving inotropes. There were three deaths. We do not use nCPAP routinely on our NICU for stabilisation or postextubation management and thus nCPAP was not a rescue option in the protocol for this study.

Participants

Babies were enrolled if they delivered between 23+0 and 29+6 weeks gestation and written parental consent had been obtained prior to delivery. For twin pregnancies, parents were counselled that, as there was only one mobile nHF device, we would apply nHF to the first twin initially if appropriate, with the option to apply nHF to the second twin depending on the progress of twin one and time permitting.

Delivery room nHF

In order to carry out this study, a mobile apparatus to deliver nHF was designed and constructed. VapoTherm constructed a prototype to our specifications, based on their Precision Flow high-flow device, which could be taken to each delivery and then moved with the baby to NICU, and could be operated with and without mains electricity and piped oxygen and air supplies. A gas manifold was essential to ensure that gas supplies could be smoothly switched over to cylinders and an uninterruptible power supply device was also included. In testing, the Precision Flow continued to function normally during gas and power switchover. The device is shown in figure 1.

Procedure

We followed a standardised clinical protocol for stabilisation (figure 2). The mobile apparatus could normally be set up and started within 2 min, requiring a further 2–3 min to reach the desired temperature of 37°C. During this time routine checks on the resuscitation equipment were carried out. Babies were placed into a plastic bag on a resuscitaire under a radiant warmer and assessed for the presence of breathing, heart rate and activity. Nasal prongs ('premature' size, VapoTherm) were applied and a flow of 6–7 L/min was commenced (not a step-wise increase, but clinician preference for initial flows varied). Flows up to 8 L/min were permitted by our standard guidelines. Preductal pulse and oxygen saturation monitoring was also



Figure 1 Mobile nasal high flow.

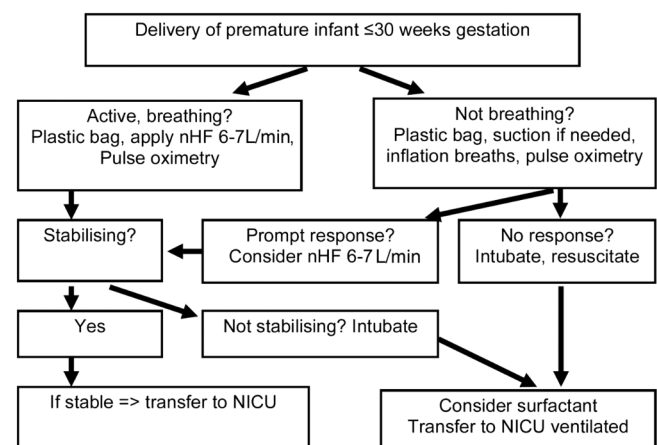


Figure 2 Protocol for stabilisation. nHF, nasal high flow; NICU, neonatal intensive care unit.

commenced using a Masimo pulse oximeter Rad-5V with values obtained after about 1 min, and oxygen given at the clinician's discretion. Acceptable initial values were heart rate >100 bpm and $\text{SaO}_2 >40\%$, with spontaneous respirations present (no rate defined). No other airway interventions such as suction or inflation breaths were applied. A steady increase in SaO_2 was expected (approximately 10% per minute over the next 5 min)

with SaO₂ targeted to 90%–95% after 10 min if requiring supplemental oxygen.^{11 12} If the baby was apnoeic, five normal inflation breaths were applied according to standard guidance.¹³ If the baby responded promptly to initial resuscitation measures, then stabilisation on nHF could be attempted at the discretion of the senior clinician present. Babies who were persistently apnoeic and/or with low heart rate (<100/min) were managed conventionally, with suction, further inflation breaths, intubation with an appropriate-sized endotracheal tube and further resuscitation as determined by the attending clinician. The decision to administer surfactant in the DR was at the discretion of the clinician.

When stable, babies were transferred to the NICU (a short corridor journey which normally takes about a minute). On arrival in the NICU, the admission temperature was checked, pulse and oxygen saturations and FiO₂ were noted and the baby was transferred to a humidified incubator. For babies on nHF the patient circuit was transferred from the mobile to the cotside nHF device which took about 20 s.

Staff comments were invited, including on the ease of use of the protocol, the comfort of the baby if transferred on nHF and for documentation of parental comments.

Study size

The study was approved by the Research and Development Committee of Ashford and St. Peter's Hospitals NHS Foundation Trust and by the London–Surrey Borders Research Ethics Committee (REC). Written parental consent was obtained prior to delivery. The study was terminated after 28 babies had been enrolled in agreement with the R and D department and the REC as feasibility with successful completion of protocol in all cases had been established.

RESULTS

Participants

A total of 74 eligible babies were born during the study period and 33 consents were obtained. We enrolled 28 babies between 23+4 and 29+6 weeks gestation. The requirement for written informed consent prior to delivery meant that the majority of eligible babies could not be enrolled due to the unpredictable onset of premature delivery. Consent was obtained from five parents who did not subsequently deliver before 30 weeks. Mean birth weight was 876 g (range 456–1430 g). Twenty-two (79%) were from singleton pregnancies. Ten patients were male (36%) and 28 (100%) had received at least one dose of antenatal steroids. Further characteristics of the study participants are shown in [table 1](#).

Outcomes

Three babies born at 23 or 24 weeks were intubated and transferred to NICU ventilated as per protocol. Two of these (born at

23 and 24 weeks) subsequently died from necrotising enterocolitis (NEC) at days 13 and 30, respectively). [Table 2](#) shows the outcome measures for all study babies. For the 25 babies stabilised and transferred on nHF, the average admission temperature was 36.9°C (range 36.3°C–38.2°C) and the mean FiO₂ on admission to NICU was 0.29 (range 0.21–0.60), with nine babies (36%) in room air on admission. Twelve babies (48%) stabilised and transferred on nHF received rescue administration of surfactant, but only 5 (42%) were still on nHF at 72 h. They ranged from 23+4 to 29+6 weeks gestation. Of the 13 babies (24+1 to 29+5 weeks gestation) who did not require surfactant, 11 (85%) were still maintained on nHF at 72 h. One baby (4%) received inotropes in the first 72 h due to a pulmonary haemorrhage after 48 h.

The smallest baby stabilised successfully weighed 498 g, was still on nHF after 72 h, and was eventually transferred back to their local hospital. Two babies developed grade 3 or 4 intraventricular haemorrhages (8%). There was one pneumothorax after 24 h, which occurred after the baby had been intubated and received IPPV before and after administration of surfactant (Curosurf). The air leak was drained without complications.

There were two documented technical issues with inadequate flow from the nHF device, both quickly resolved. The first was caused by pooled water in the chamber preventing the internal impeller from spinning, and once wiped dry the flow was normal. The second was due to a poor connection between the patient circuit and the humidification unit; again this was recognised and corrected.

In every case, the use of the mobile high flow according to the protocol was described by staff as being straightforward, even if the baby required conventional resuscitation and ventilation. Several staff commented that transfers of babies on nHF were 'easy' and, in 21/25 that the comfort of the babies was good (not recorded in 4/25). They also recorded positive comments from some parents about being able to see their baby's face and head movements.

DISCUSSION

In this study, we have demonstrated that it is feasible to use nHF for the stabilisation of premature babies without the need for routine intubation and/or surfactant prior to and during transfer to NICU in the majority of cases.

Staff followed the clinical protocol easily. The nHF could be set up and started quickly, delivering warmed and humidified gas within a couple of minutes. The nasal prongs were simple and quick to fit. We found the prongs could be effectively secured for transfer using the plastic clasp at the back of the head. Unlike nCPAP, there was no need to size and fit a hat to hold the nasal prongs.

Table 1 Characteristics of study participants (n=28)

| GA at delivery | N (% total) | Vaginal/caesarean delivery | PPROM >24 h (%) | Intubated for transfer to NICU | Surfactant in DR |
|----------------|-------------|----------------------------|-----------------|--------------------------------|------------------|
| 23+0 to 23+6 | 1 (4) | 1/0 | 0 (0) | 1 | 1 |
| 24+0 to 24+6 | 3 (11) | 2/1 | 1 (33) | 2 | 2 |
| 25+0 to 25+6 | 6 (18.5) | 2/4 | 0 (0) | 0 | 1 |
| 26+0 to 26+6 | 5 (18.5) | 2/3 | 2 (40) | 0 | 0 |
| 27+0 to 27+6 | 5 (18.5) | 2/3 | 0 (0) | 0 | 0 |
| 28+0 to 28+6 | 5 (18.5) | 1/4 | 1 (20) | 0 | 0 |
| 29+0 to 29+6 | 3 (11) | 1/2 | 1 (33) | 0 | 0 |
| Mean GA 26+5 | 28 (100) | 11 (39%)/17 (61%) | 5 (18) | 3 (11%) | 4 (14%) |

DR, delivery room; GA, gestational age; NICU, neonatal intensive care unit; PPRM, preterm prelabour rupture of membranes.

Table 2 Outcomes in first 72 h after delivery (n=28)

| | Stabilised and transferred on nHF | Intubated in DR |
|--|-----------------------------------|------------------------|
| Number of babies | 25 | 3 |
| Admission temperature (mean, range) | 36.9°C (36.3°C–38.2°C) | 37.3°C (36.3°C–38.4°C) |
| Admission FiO ₂ (mean, range) | 0.29 (0.21–0.60) | 0.37 (0.3–0.5) |
| Surfactant | 12 (48%) | 3 (100%) |
| Inotropes | 1 (4%) | 0 (0%) |
| HF sustained for 72 h | 15 (60%) | Not applicable |
| Pneumothorax | 1 (4%) | 0 (0%) |
| Pulmonary haemorrhage | 2 (8%) | 1 (33%) |
| IVH (grade 3 or 4) | 2 (8%) | 2 (55%) |

DR, delivery room; nHF, nasal high flow; IVH, intraventricular haemorrhage.

Transfer to NICU was straightforward, especially as staff did not have to hold masks or tubes in place on the baby's face. Babies were invariably stable on arrival in NICU; although one baby arrived requiring 60% oxygen, the mode FiO₂ (nine babies) was 0.21 and the median was 0.27. Our observations on the admission temperature (mean 36.9°C, range 36.3°C–38.2°C) appears to confirm that administration of humidified nasal gas at 37°C helps to maintain thermal stability.¹⁴ We believe that humidification is a key part of successful non-invasive respiratory management, and that the stabilisation or resuscitation of babies using cold, dry gases from wall or cylinder supplies does not constitute optimal management and should be routinely available.

Staff commented positively on the comfort of the babies, who sometimes opened their eyes and even lifted their heads. Showing parents their baby prior to transfer was also easy and some parents commented that they liked seeing their baby breathing by themselves after delivery.

In this pilot study, the majority of babies were transferred on nHF, and less than half subsequently required surfactant. This compared favourably with our prestudy rate of 73% for DR intubation and surfactant administration. We noted that the need for surfactant appeared to predict a greater chance of intubation within 72 h.

The group was clinically stable, with low requirements overall for early intubation/ventilation. The low incidence of hypotension requiring inotropes is consistent with our normal practice of early extubation to nHF, and we suggest that the use of HF facilitates cardiovascular stability. The absence of nCPAP in our protocol reflects our long-standing use of nHF as a replacement for nCPAP in the postextubation management of preterm babies.

There are several limitations of this study. This was a small pilot study designed to generate the hypothesis that using nHF for DR stabilisation would be feasible. It was conducted in a single centre with considerable expertise in using nHF in premature babies, potentially limiting its current generalisability. Deliveries were always attended by either an experienced neonatal registrar and/or a consultant, which may have contributed to the successful outcomes for the majority of babies. The strengths of the study are that it demonstrated that the use of nHF is feasible as measured by short-term outcomes, and the clinical protocol is easy to follow.

We have described a cohort of premature babies in whom the use of intubation, ventilation, surfactant and inotropes is low, and the clinical outcomes describe a 'well' preterm population which helps us to understand how stable some babies can be from 25 weeks upwards.

We think that the use of nHF at birth contributed to this clinical stability. We recognise that the use of nHF as a primary therapy in preterm babies still has limited data to support it. Larger studies to determine either superiority or non-inferiority to other non-invasive methods for DR stabilisation of premature babies are now needed.

CONCLUSIONS

This was a pilot study designed to establish if it was possible to use nHF for DR stabilisation of preterm infants, and we believe it to be the first of its kind. The least 'successful' group for stabilisation were those born at 23–24 weeks gestation (as expected) and from 25 weeks upwards the stabilisation was, in this study, always successful. Our findings may be generalisable to other nHF devices provided that the humidification and flow can be rapidly delivered. In summary, preterm babies <30 weeks gestation can often be stabilised in the DR and transferred, in stable condition, to the NICU using nHF. Further work is ongoing to establish optimal flow rates and we continue to use this protocol in our day-to-day practice.

Contributors PR conceived and acted as main investigator for the study, analysing and interpreting data and drafting and revising the manuscript. He acts as the principal guarantor and corresponding author for the manuscript. SL, TL, TO and OE all helped to conduct the study including training nursing staff, collection of data and made critical revisions to the final manuscript. NH provided clinical support and training for the nursing staff, designed the data collection forms, collected and analysed data and contributed to the final manuscript. All authors have agreed to be accountable for all aspects of the work.

Competing interests None declared.

Ethics approval NRES Committee London—Surrey Borders.

Provenance and peer review Not commissioned; externally peer reviewed.

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