

## ORIGINAL ARTICLE

# Respiratory outcomes after delivery room stabilisation with a new respiratory support system using nasal prongs

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## Funding information

Hjärt-Lungfonden; Region Stockholm; Sällskapet Barnavård; H.K.H. Kronprinsessan Lovisas Förening för Barnsjukvård

## Abstract

**Aim:** To study if stabilisation using a new respiratory support system with nasal prongs compared to T-piece with a face mask is associated with less need for mechanical ventilation and bronchopulmonary dysplasia.

**Methods:** A single-centre follow-up study of neonates born <28 weeks gestation at Karolinska University Hospital, Stockholm included in the multicentre Comparison of Respiratory Support after Delivery (CORSAD) trial and randomised to initial respiratory support with the new system versus T-piece. Data on respiratory support, neonatal morbidities and mortality were collected up to 36 weeks post-menstrual age.

**Results:** Ninety-four infants, 51 female, with a median (range) gestational age of 25 + 2 (23 + 0, 27 + 6) weeks and days, were included. Significantly fewer infants in the new system group received mechanical ventilation during the first 72 h, 24 (52.2%) compared with 35 (72.9%) ( $p = 0.034$ ) and during the first 7 days, 29 (63.0%) compared with 39 (81.3%) ( $p = 0.045$ ) in the T-piece group. At 36 weeks post-menstrual age, 13 (28.3%) in the new system and 13 (27.1%) in the T-piece group were diagnosed with bronchopulmonary dysplasia.

**Conclusion:** Stabilisation with the new system was associated with less need for mechanical ventilation during the first week of life. No significant difference was seen in the outcome of bronchopulmonary dysplasia.

## KEYWORDS

bronchopulmonary dysplasia, delivery room, nasal prongs, pre-term, stabilisation

## 1 | INTRODUCTION

The aim of modern neonatal stabilisation and respiratory support is to support the infants breathing with minimally invasive methods to reduce the risk of developing bronchopulmonary dysplasia (BPD).

International treatment recommendations and guidelines recommend continuous positive airway pressure (CPAP) for spontaneously breathing infants rather than intubation and intermittent positive pressure ventilation.<sup>1-3</sup> This approach is based on randomised controlled trials and meta-analyses showing a reduction in the combined

**Abbreviations:** BPD, bronchopulmonary dysplasia; CORSAD, comparison of respiratory support after delivery; CPAP, continuous positive airway pressure; HFNC, high-flow nasal cannula; IQR, interquartile range; PMA, post-menstrual age; SD, standard deviation.

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outcome of BPD and death when respiratory support was started with CPAP compared to intubation and mechanical ventilation in pre-term infants with respiratory distress after birth.<sup>4-8</sup>

A prerequisite to avoiding mechanical ventilation is establishing spontaneous breathing after birth. Studies have shown that despite their immaturity, the majority of extremely pre-term infants have breathing efforts after birth.<sup>9,10</sup> This can be either promoted or inhibited by different interventions during delivery room stabilisation.<sup>11</sup> For example, the use of a face mask may induce apnoea by triggering the trigeminocardiac reflex.<sup>12</sup> This has raised the question of whether other interfaces might be more appropriate for supporting infants breathing in the delivery room.

A new respiratory support system with low imposed work of breathing aimed for delivery room stabilisation has been developed.<sup>13</sup> The respiratory support system can be used with either a face mask or nasal prongs and is now marketed as the rPAP (Inspiration Healthcare, Leicester, UK) (Figure S1). The multicentre Comparison Of Respiratory Support After Delivery (CORSAD) randomised clinical trial found that initial respiratory support with the rPAP using nasal prongs compared with a standard T-piece system with a face mask reduced delivery room intubations in extremely pre-term infants.<sup>14</sup> The follow-up period of the multicentre CORSAD trial was 72 h after birth and it was not powered to assess later outcomes such as BPD.

In this single-centre follow-up of the CORSAD trial, we describe respiratory outcomes and other neonatal morbidities up to 36 weeks of post-menstrual age (PMA) in infants who were enrolled at the Karolinska University Hospital in Stockholm. The aim was to investigate if stabilisation with the rPAP system compared to standard treatment was associated with the need for mechanical ventilation and later respiratory morbidities.

## 2 | METHODS

### 2.1 | Study design and intervention

This is a single-centre follow-up study of all infants who were enrolled in the CORSAD randomised clinical trial at the Karolinska University Hospital in Stockholm, Sweden.

The CORSAD randomised clinical trial enrolled 246 infants less than 28 weeks of gestational age in seven neonatal intensive care units in five countries (Iceland, Lithuania, Norway, Poland and Sweden) from 23 March 2016 to 14 May 2020 after antenatal parental consent.<sup>14</sup> The intervention was respiratory support with the randomised system, either the new respiratory support system rPAP with prongs or T-piece with a round face mask, for the first 10–30 min of life. Randomisation was stratified on centre, gestational age (less than 24, 24–25 and 25 weeks or more) and antenatal steroid treatment (none, partial and complete course). Post-intervention treatment followed local protocols and international guidelines.<sup>3,15</sup>

The study was approved by the Swedish Ethical Review Authority, Dnr: 2019-01122.

### Key Notes

- In the multicentre Comparison of Respiratory Support After Delivery (CORSAD) randomised clinical trial, stabilisation with a new respiratory support system using nasal prongs compared with a standard T-piece using a face mask reduced delivery room intubations.
- In our centre, infants stabilised with the new system received less mechanical ventilation during the first week of life.
- No statistically significant difference was seen in bronchopulmonary dysplasia depending on the system used for stabilisation.

### 2.2 | Clinical variables

Information on the mode and duration of respiratory support, surfactant administration, respiratory and other neonatal morbidities as well as mortality up to 36 weeks of PMA, was collected from medical records.

BPD was defined and graded by the mode of respiratory support administered at 36 weeks of PMA irrespective of oxygen use. According to this definition, reported by Jensen et al. to best predict early childhood morbidity, infants breathing in room air at 36 weeks of PMA do not have BPD. Infants supported with nasal cannula at flow rates  $\leq 2$  L/min are classified as having grade 1 BPD. Infants supported with nasal cannula with flow rates  $> 2$  L/min or non-invasive positive airway pressure having grade 2 BPD and infants supported with invasive mechanical ventilation as having grade 3 BPD.<sup>16</sup> The analysis of the outcome of BPD was post hoc and an oxygen reduction test was not performed as standard of care.

Data regarding mechanical ventilation during the first 3 and 7 days were gathered as a proxy for the severity of the respiratory disease. As mechanical ventilation has been linked to BPD but can occur for other reasons than primary pulmonary disease, data regarding mechanical ventilation at any time before 36 weeks of PMA was also collected.

The need for mechanical ventilation was also analysed after stratification on the gestational age group to explore if the treatment effect was associated with gestational age.

Surfactant administration was recorded as surfactant delivered by Intubate–Surfactant–Extubate (INSURE) or through endotracheal tube during mechanical ventilation.

### 2.3 | Statistical analysis

Continuous variables were presented as median (IQR) or mean ( $\pm$ SD) as appropriate, normally distributed continuous variables were analysed using the independent *t* test and skewed continuous variables

using the Mann–Whitney *U* test. Categorical variables were analysed using chi-square test or Fisher's exact test, as appropriate. A generalised linear model with an identity link was applied to calculate risk differences with 95% confidence intervals. All analyses were two-sided and based on the intention to treat. *p* values of <0.05 were considered statistically significant. Statistical analyses were performed with SPSS Statistics version 27 (IBM Corp) and STATA version 14.2 (Stata Corp).

### 3 | RESULTS

In total, 94 infants, 54.3% female, with a median (IQR) GA of 25 + 2 (24 + 4, 26 + 3) weeks and days were included in the CORSAD trial at our centre, 46 in the rPAP group and 48 in the T-piece group (Figure S2). All infants received support with the allocated system, 2 infants in the rPAP group crossed over to T-piece during the intervention period before intubation. There were no differences in baseline

characteristics between the groups except for foetal growth restriction which was statistically significantly more common in the rPAP group (Table 1). Follow-up information up to 36 weeks of PMA was available for all infants.

The rate of delivery room intubation was 13/46 (28.3%) in the rPAP and 26/48 (54.2%) in the T-piece group (risk difference -25.9%, 95% CI -45.1 to -6.7, *p* = 0.008) and significantly fewer infants in the rPAP group received any mechanical ventilation during the first 72 h, 24 (52.2%) compared with 35 (72.9%) (risk difference -20.7%, 95% CI -39.9 to -1.6, *p* = 0.034) and during the first 7 days, 29 (63.0%) compared with 39 (81.3%) (risk difference -18.2%, 95% CI -36.0 to -0.42, *p* = 0.045) in the T-piece group. The difference was primarily seen in the subgroup of infants born at 24–25 weeks.

The majority of infants in both groups received any mechanical ventilation before 36 weeks of PMA, 35 (76.1%) in the rPAP and 43 (89.6%) in the T-piece group (risk difference -13.5%, 95% CI -28.5 to +1.5, *p* = 0.079) (Table 2).

TABLE 1 Background Information

	New system (n = 46)	T-Piece (n = 48)
Gestational age median (IQR) [min-max], w + d	25 + 4 (2 + 2) [23 + 0–27 + 6]	25 + 1 (2 + 0) [23 + 2–27 + 5]
Gestational age group, n(%)		
<24 weeks	6 (13.0)	5 (10.4)
24–25 weeks	23 (50.0)	29 (60.4)
>25 weeks	17 (37.0)	14 (29.2)
Multiple pregnancy, n(%)		
Singleton	40 (87.0)	43 (89.6)
Multiple	6 (13.0)	5 (10.4)
Female sex	25 (54.3)	26 (54.2)
Birth weight, g, median (IQR) [min-max]	730 (201) [485–1156]	727 (202) [411–1160]
Antenatal steroids, n(%)		
Complete course	40 (87.0)	43 (89.6)
Incomplete	6 (13.0)	5 (10.4)
No	0	0
Delivery C-section, n(%)	31 (67.4)	31 (64.6)
General anaesthesia, n(%)	2 (4.3)	4 (8.3)
C-section for fetal concern, n(%)	23 (50.0)	28 (58.3)
Mother in active labour, n(%)	31 (67.4)	39 (81.3)
Fetal growth restriction <sup>a,*</sup> , n(%)	15 (32.6)	6 (12.5)
Tocolytic therapy, n(%)	23 (50.0)	28 (58.3)
Mother received antibiotics, n(%)	36 (78.3)	37 (77.1)
Clinical chorioamnionitis, n(%)	15 (32.6)	18 (37.5)
Preeclampsia or eclampsia, n(%)	10 (21.7)	4 (8.3)
PROM, n(%)	18 (39.1)	17 (35.4)
Ablatio, n(%)	6 (13.0)	13 (27.1)

Abbreviation: PROM, premature rupture of membranes.

<sup>a</sup>Estimated foetal weight < 10th centile.

\*Statistically significant difference between groups, *p* value 0.019.

TABLE 2 Delivery room intubation and mechanical ventilation

	New system (n = 46)	T-piece (n = 48)	Risk difference, % (95% CI)	p value
Intubated in the delivery room, n(%)	13 (28.3)	26 (54.2)	-25.9 (-45.1 to -6.7)	<b>0.008</b>
<24 weeks GA	3 (50.0)	3 (60.0)	-10.0 (-68.7 to +48.7)	0.74
24-25 weeks GA	7 (30.4)	19 (65.5)	-35.1 (-60.6 to -9.5)	<b>0.007</b>
>25 weeks GA	3 (17.6)	4 (28.6)	-10.9 (-40.7 to +18.9)	0.47
Surfactant, n(%)	29 (63.0)	35 (72.9)	-9.9 (-28.7 to +8.9)	0.31
First dose in the delivery room	13 (28.3)	25 (52.1)	-23.8 (-43.0 to -4.6)	<b>0.022</b>
First dose in NICU	16 (34.8)	10 (20.8)	+13.9 (-4.0 to +31.9)	0.15
Age at a first dose in minutes, median (IQR)	120 (9-325)	10(6-120)		<b>0.045</b>
Any MV during the first 3 days, n(%)	24 (52.2)	35 (72.9)	-20.7 (-39.9 to -1.6)	<b>0.034</b>
<24 weeks GA	6 (100)	3 (60.0)	*	
24-25 weeks GA	13 (56.5)	26 (89.7)	-33.1(-56.2 to -10.0)	<b>0.005</b>
>25 weeks GA	5 (29.4)	6 (42.9)	-13.4 (-47.2 to +20.3)	0.44
Any MV during the first 7 days, n(%)	29 (63.0)	39 (81.3)	-18.2 (-36.0 to -0.42)	<b>0.045</b>
<24 weeks GA	6 (100)	4 (80.0)	*	
24-25 weeks GA	17 (73.9)	27 (93.1)	-19.2 (-39.4 to +0.98)	0.062
>25 weeks GA	6 (35.3)	8 (57.1)	-21.8 (-56.3 to +12.6)	0.21
Any MV before 36 w PMA, n(%)	35 (76.1)	43 (89.6)	-13.5 (-28.5 to +1.5)	0.079
<24 weeks GA	6 (100)	5 (100)	*	
24-25 weeks GA	19 (82.6)	27 (93.1)	-10.5 (-28.5 to +7.5)	0.25
>25 weeks GA	10 (58.8)	11 (78.6)	-19.7 (-51.5 to +12.0)	0.22

Note: Risk differences, 95% CI and p values were calculated with a generalised linear model with identity link. p values indicating statistically significant difference between groups are shown in bold.

Abbreviations: GA, gestational age; IQR, interquartile range; MV, mechanical ventilation; NICU, neonatal intensive care unit; PMA, post-menstrual age.

\*Unable to calculate because of too few observations.

The number of infants receiving surfactant was similar in both groups, 29 (63.0%) in the rPAP and 35 (72.9%) in the T-piece group (risk difference -9.9%, 95% CI -28.7 to +8.9,  $p = 0.31$ ). Since more infants in the T-piece group were intubated and received the first dose of surfactant in the delivery room the timing of surfactant differed. The median age (IQR) at first surfactant administration was 120 (9-325) min in the rPAP and 10 (6-120) min in the T-piece group ( $p = 0.045$ ) (Table 2).

There was no difference in the rate of BPD or death at 36 weeks of PMA for infants that received initial respiratory support with the rPAP vs T-piece. At 36 weeks, 9 infants (19.6%) had died and 13 (28.3%) received respiratory support in the rPAP group compared with 11 (22.9%) and 13 (27.1%), respectively, in the T-piece group (Table 3). In the rPAP group, three infants had grade 1, nine infants had grade 2 and one had grade 3 BPD. In the T-piece group, seven infants had grade 1 and six had grade 2 BPD. A comparison of BPD

grades between the rPAP and T-piece groups did not show a statistically significant difference ( $p = 0.23$ ). Of infants who were receiving respiratory support at 36 weeks of PMA only one infant in the rPAP group was still on mechanical ventilation after failed extubation due to subglottic stenosis and one was on CPAP. The other infants were on high- or low-flow nasal cannula.

Rates of air leak, pulmonary haemorrhage, culture-positive sepsis, intraventricular haemorrhage, necrotizing enterocolitis, retinopathy of prematurity and patent ductus arteriosus treatment did not differ between groups (Table S1).

## 4 | DISCUSSION

In this single-centre follow-up of extremely pre-term infants included in the CORSAD trial in Stockholm, initial stabilisation with the

TABLE 3 BPD or death

	New system (n = 46) n(%)	T-piece (n = 48) n(%)	Risk difference, % (95% CI)	p value
BPD or death	22 (47.8)	24 (50.0)	-2.2 (-22.4 to +18.0)	0.83
Death	9 (19.6)	11 (22.9)	-3.4 (-19.9 to +13.2)	0.69
BPD	13 (28.3)	13 (27.1)	+1.1 (-16.9 to +19.3)	0.90
BPD, grade 1	3 (6.5)	7 (14.6)		
BPD, grade 2	9 (19.6)	6 (12.5)		
BPD, grade 3	1 (2.2)	0		

Note: Risk differences, 95% CI and p values were calculated with a generalised linear model with identity link.

Abbreviation: BPD, bronchopulmonary dysplasia.

rPAP versus standard treatment was associated with less mechanical ventilation during the first week of life. However, no statistically significant difference was seen in the outcome of BPD or the combined outcome of BPD or death.

BPD development has been linked to the duration and number of mechanical ventilation courses.<sup>17</sup> In our cohort, significantly fewer infants in the rPAP group needed invasive respiratory support during their first week of life. However, at 36 weeks of PMA, most infants had received any mechanical ventilation and the difference between the groups was no longer statistically significant. This was perhaps not unexpected as the need for mechanical ventilation during the first week of life is most often respiratory related. Later, non-respiratory causes such as gastrointestinal events, haemodynamically significant PDA, infections and surgery start playing a larger role in the need for mechanical ventilation.<sup>18</sup> So, even if BPD is strongly linked to mechanical ventilation use, it is multifactorial and may be affected by both co-morbidities and pulmonary physiologic parameters that come into play beyond the initial acute respiratory phase.<sup>19</sup> Thus, with a post hoc analysis with a lack of power for BPD as an endpoint, we can only offer a descriptive scenario for the relationship between mechanical ventilation and the BPD outcome. Even though the risk of requiring intubation during the first days of life can be reduced by optimising initial stabilisation in the delivery room, there is room for improvement in the continued treatment in the neonatal intensive care unit.

The rate of BPD was 27.6% in our centre. The low BPD rate indicates an overall good respiratory outcome for our infants who had a median gestational age of 25 weeks. In 2018, a study using the same BPD definition on infants born between 22 and 29 weeks gestation at 715 US hospitals, reported an overall BPD rate of 40.7%. For those born before 28 weeks gestation, the rate was 51.7%.<sup>20</sup>

Of all infants categorised as having grade 2 BPD in our study, only one was on CPAP and the other were on high-flow nasal cannula (HFNC). After a long tradition of using CPAP, HFNC has been increasingly used for weaning CPAP during the last years. So far, we lack robust guidelines on how to wean off HFNC and the decision is made by the treating physician. Studies have shown associations between the use of HFNC and longer duration of respiratory support and oxygen supplementation as well as higher rates of BPD.<sup>21-23</sup> This change in practice may have affected our BPD rates, however, both groups should have been affected equally.

In our centre, a traditional T-piece system has been used for delivery room stabilisation for decades and intubation rates have been relatively low. The baseline delivery room intubation rate in extremely pre-term infants born in Sweden prior to the CORSAD trial, on which power calculations were based, was 60%.<sup>14,24</sup> Others have reported rates of 72-75%.<sup>25,26</sup>

As in the original CORSAD trial cohort, initial respiratory support with the rPAP compared to standard treatment reduced the need for delivery room intubation with statistical significance in our centre with intubation rates of 28.3% versus 54.2% respectively. In the analysis of delivery room intubations and mechanical ventilation stratified by gestational age, the largest benefit was found in infants with a gestational age of 24-25 weeks. The need for intubation and invasive respiratory support was high in the most immature infants born before 24 weeks irrespective of the system used, while most infants born at 26 weeks or later could be stabilised with non-invasive respiratory support. As described in a recent review, data from the Swedish National Quality Registry show, that in the years before the CORSAD trial more than two-thirds of all infants born at 25 weeks or less were intubated in the delivery room and during the CORSAD trial period the intubation rates for infants born alive at 22-23 weeks remained high. For infants born at 24 and 25 weeks, intubation rates declined nationally though still remaining at a significantly higher level compared to infants in the rPAP group in the present study cohort.<sup>27</sup> This indicates that the rPAP system may facilitate the continuing trend towards successful non-invasive delivery room stabilisation in this group of immature infants who were previously intubated in the delivery room.

Although the number of infants receiving surfactant was similar between groups, infants in the T-piece group received the first dose at an earlier time point, as more were intubated and therefore received the first dose in the delivery room. The treatment beyond the first 30 min after birth was not regulated by the CORSAD study protocol and information on the exact oxygen needed prior to surfactant administration was not available for all infants. As previously recognised, the timing of surfactant administration may be of importance for the later respiratory outcomes and early selective administration is recommended for the treatment of RDS.<sup>3,28,29</sup> We propose, that being able to stabilise extremely pre-term infants in the delivery room with non-invasive respiratory support provides an opportunity to administer early selective surfactant with less invasive methods under controlled circumstances and should not be further delayed.

This study had several limitations. First, it was a follow-up of only one of the centres from the CORSAD multicenter trial, however, this was the centre that included the most patients and had complete follow-up data on all subjects. Second, the intervention in the original CORSAD trial was not blinded, inducing risk for bias. Furthermore, BPD was not a predefined outcome in the CORSAD trial and it was not powered to detect a statistically significant difference between groups in the bigger sample. However, we believe that this information is of value in the context of evaluating the rPAP system and giving a rough indication of the effect on BPD incidence. We acknowledge that the results might be different in a larger cohort with other baseline intubation and BPD rates.

A key strength of the study was that data on mortality and respiratory support at 36 weeks of PMA were available for all infants included in the CORSAD trial at our centre.

## 5 | CONCLUSION

In our centre, stabilisation of extremely pre-term infants with the rPAP system was associated with less need for mechanical ventilation during the first week of life. However, at 36 weeks of PMA, the majority of infants had received any mechanical ventilation irrespective of the system used for initial stabilisation and there was no statistically significant difference in rates of BPD or death.

### AUTHOR CONTRIBUTIONS

SB: study design, data collection, data and statistical analysis, manuscript writing and review. SD: study design, data collection, data analysis, manuscript writing and review. EP: study design, data and statistical analysis, manuscript writing and review. TD: data analysis, manuscript writing and review. BJ: study design, data analysis, manuscript writing and review.

### FUNDING INFORMATION

The study was funded by H.K.H. Kronprinsessan Lovisas Förening för Barnsjukvård, Sällskapet Barnavård Research Fund, Region Stockholm and the Swedish Heart-Lung Fund.

### CONFLICT OF INTEREST

Dr Drevhammar has received royalties from Inspiration Healthcare for designing the new respiratory support system tested in the CORSAD trial.

### DATA AVAILABILITY STATEMENT

Deidentified data are available from the corresponding author on reasonable request.

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## SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

**How to cite this article:** Baldursdottir S, Donaldsson S, Palleri E, Drevhammar T, Jonsson B. Respiratory outcomes after delivery room stabilisation with a new respiratory support system using nasal prongs. *Acta Paediatr*. 2023;00:1-7. <https://doi.org/10.1111/apa.16665>