A Randomized Trial of Nasal Prong or Face Mask for Respiratory Support for Preterm Newborns

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KEY WORDS
delivery room, face mask, infant, newborn, preterm, positive pressure ventilation, randomized trial, respiratory support, resuscitation, nasal prong

ABBREVIATIONS
CPAP—continuous positive airway pressure
DR—delivery room
FM—face mask
HR—heart rate
NMH—National Maternity Hospital
PPV—positive pressure ventilation
SNP—single nasal prong

Dr McCarthy made substantial contributions to the conception and design of the study; acquired the data and made a substantial contribution to the analysis and interpretation of the data; and wrote the first draft of the manuscript; Dr O’Donnell conceived and designed the study; made substantial contribution to the analysis and interpretation of the data; and redrafted the manuscript and revised it for important intellectual content; Drs Twomey, Molloy, and Murphy made substantial contributions to the design of the study; they critically revised the manuscript for important intellectual content; and all authors approve this version of the manuscript.

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WHAT’S KNOWN ON THIS SUBJECT: Respiratory support is commonly given to newborn infants via a face mask in the delivery room. Respiratory support given to preterm infants via a single nasal prong may be more effective.

WHAT THIS STUDY ADDS: Compared with a face mask, using a single nasal prong to deliver respiratory support to preterm newborns did not result in less intubation and ventilation in the delivery room.

abstract

BACKGROUND AND OBJECTIVE: Resuscitation guidelines recommend that respiratory support should be given to newborns via a face mask (FM) in the delivery room (DR). Respiratory support given to preterm newborns via a single nasal prong (SNP; ie, short nasal tube, nasopharyngeal tube) may be more effective. We wished to determine whether giving respiratory support to preterm newborns with a SNP rather than a FM reduces the rate of intubation in the DR.

METHODS: Infants <31 weeks’ gestation were randomized just before delivery to SNP (endotracheal tube shortened to 5 cm) or FM. Randomization was stratified by gestation (<28 weeks, 28–30⁎⁎). Infants with apnea, respiratory distress, and/or heart rate <100 received positive pressure ventilation with a T-piece. The primary outcome was intubation and mechanical ventilation in the DR. Infants in both groups were intubated for heart rate <100 and/or apnea despite PPV and not solely for surfactant administration. All other aspects of treatment in the DR and NICU were the same. Relevant secondary outcomes were recorded and data were analyzed by using the intention-to-treat principle.

RESULTS: One hundred forty-four infants were enrolled. The rate of intubation in the DR was the same in both groups (11/72 [15%] vs 11/72 [15%], P = 1.000). Infants assigned to SNP had lower SpO₂ at 5 minutes and received a higher maximum concentration of oxygen in the DR. There were no significant differences in other secondary outcomes.

CONCLUSIONS: Giving respiratory support to newborn infants <31 weeks’ gestation via a SNP, compared with a FM, did not result in less intubation and ventilation in the DR. Pediatrics 2013;132:e389–e395.
The Neonatal Task Force of the International Liaison Committee on Resuscitation makes treatment recommendations for the care of newborn infants in the delivery room (DR). The committee identifies breathing support as the priority for newborns and recommends that infants who have inadequate breathing, are gasping, or have a heart rate (HR) <100 beats per minute after birth should be given respiratory support. Respiratory support is most commonly given to newborns via a soft cushioned face mask (FM) that fits over the infants’ nose and mouth. Up to 10% of all newborns require some assistance to establish effective breathing after birth. Most of these infants breathe well after tactile stimulation, airway opening maneuvers, supplemental oxygen, and/or a brief period of positive pressure ventilation (PPV) with a manual ventilation device (T-piece, self-inflating bag, or flow-inflating bag) via a face mask. However, a number of infants, many of whom are born premature, do not breathe independently or remain bradycardic despite mask PPV and are intubated and mechanically ventilated in the DR. Airway obstruction and gas leak from the FM occur frequently and can go unnoticed during mask PPV of preterm infants in the DR. Studies have suggested that giving respiratory support to newborns via the nasal route in the DR may be more effective. In a quasi-randomized trial, moderately asphyxiated term and preterm infants were less likely to require chest compressions or intubation in the DR when short binaural prongs were used to deliver PPV compared with an FM. In a retrospective cohort study, Lindner et al showed a reduction (from 84% to 40%) in the proportion of infants <1000 g intubated in the DR after the introduction of a series of measures including the use of a single nasal prong (SNP) instead of an FM to deliver PPV. In a randomized trial of a similar multifaceted intervention that included using a SNP rather than a FM for infants <33 weeks’ gestation, te Pas et al demonstrated reductions in the rate of DR intubation (from 36% to 17%), intubation within 72 hours (from 51% to 37%) and in moderate-severe bronchopulmonary dysplasia (from 19% to 9%).

We performed a prospective randomized controlled trial in newborns <31 weeks’ gestation to determine whether giving respiratory support via a SNP compared with an FM resulted in less intubation and mechanical ventilation in the DR.

**METHODS**

We conducted this study at the National Maternity Hospital (NMH); Dublin, Ireland from July 2010 to August 2012. The NMH is a stand-alone university maternity hospital with >8500 deliveries annually and a level 3 NICU to which ~150 infants with birth weights <1500 g are admitted annually. Infants were eligible for inclusion if they were born at the NMH at <31 weeks’ gestation by best obstetric estimate and received respiratory support in the DR. Infants were excluded from the study if they had a known major congenital anomaly. The NMH Research Ethics Committee approved the study protocol, and written informed consent was obtained from a parent or guardian before delivery.

Infants were randomly assigned to receive respiratory support via a SNP or a FM in a 1:1 ratio. Randomization was stratified by gestational age (<28 weeks, 28–30 weeks, 30–32 weeks, 32–34 weeks, 34–36 weeks, and ≥36 weeks), and infants of multiple births were randomized separately. The treatment allocation schedule was generated in permuted blocks of 4 using a random number table. The treatment allocation for each enrolled infant was concealed in sequentially numbered sealed opaque envelopes. The next envelope in the sequence from the appropriate stratum was brought to the DR and opened just before delivery to allow adequate time to prepare the SNP for infants assigned to that group. Neither caregivers nor outcome assessors were blinded to treatment allocation.

**Delivery Room Care for All Infants**

Each delivery was attended by at least 2 doctors, either or both a specialist registrar/registrar (trainee with ≥2 years experience in pediatrics and ≥6 months experience in neonatology) and/or a consultant neonatologist (≥5 years experience in neonatology), a senior house officer (trainee with <6 months experience in neonatology) and at least 1 neonatal nurse. All staff attending deliveries had completed the Neonatal Resuscitation Program. After birth infants were transferred to a resuscitation cot (CosyCot Infant Warmer, Fisher and Paykel Healthcare, Auckland, New Zealand) where they were wrapped in polyethylene bags and placed under a radiant warmer. A pulse oximetry sensor was applied to the right wrist of each infant before connecting it to the pulse oximeter (Masimo SET Radical; Masimo Corporation, Irvine, CA; Nellcor OxiMax NP8-40 or N-595, Covidien, Mansfield, MA). All infants was assessed for signs of apnea and respiratory distress (gasping, tachypnea, chest retractions, grunting); had their heart rate HR measured clinically (by auscultation or palpation of the umbilical cord) and/or by pulse oximetry; had their airway positioned; and had their oropharynx and nares suctioned if judged necessary by the caregivers attending the delivery. Infants were given respiratory support with a T-piece device...
oxygen, the FiO2 was reduced aiming for the infant was receiving supplemental oxygen increased by 10% every minute or who were gasping were given PPV with a peak inflation pressure of 25 cm H2O and positive end-expiratory pressure of 5 cm H2O. For PPV, an inflation rate of 40 to 60 breaths per minute was recommended. Clinicians were permitted to adjust the pressures and frequency with which CPAP/PPV was delivered according to the infant’s response as determined by ongoing assessment of their breathing and HR. We commenced respiratory support with 30% oxygen as determined by a air/oxygen blender (Bird Low-Flow Air/O2Blender, VIASYS Healthcare, Plymouth-Whitemarsh, Pennsylvania).1,17 Infants with SpO2 <70% at 5 minutes of age (ie, <10th centile)18 had their oxygen increased by 10% every minute aiming for SpO2 ≥85% at 10 minutes. If an infant required chest compressions the oxygen concentration was increased more promptly to a maximum of 100%. If the SpO2 was >95% at any time and the infant was receiving supplemental oxygen, the FiO2 was reduced aiming to keep the SpO2 in the range of 85% to 95% in the DR.

FM GROUP
For infants assigned to FM, we used a round silicone mask (Neonatal Resuscitation Mask, Fisher & Paykel Healthcare) of an appropriate size (42 mm for infants <28 weeks or ≤1 kg; 55 mm for infants 28–30 weeks or >1 kg; Fig 1). The person giving PPV held the FM in place over the chin, mouth, and nose of the infant using 1 hand. If CPAP was given during transport to the NICU, the FM was held in place by a caregiver.

SNP GROUP
For infants assigned to SNP, an endotracheal tube (Portex, Smiths Medical, Keene NH) of appropriate size for gestation and weight (internal diameter 2.5 mm for infants ≤28 weeks or ≤1 kg; 3.0 mm for infants 28–30 weeks or >1 kg) was cut obliquely at 5 cm, and the connector was reinserted in the DR just before delivery (Fig 1). The prong was then inserted into 1 nostril at right angles to the face and was secured at ∼4 cm using a Steri-Strip (3M, St Paul, MN). When giving PPV, the contralateral nostril was occluded with a finger and the mouth was kept shut by placing a thumb under the point of the infants’ chin. Infants given CPAP during transport to the NICU received it via the SNP.

OUTCOMES
The primary outcome was intubation and mechanical ventilation in the DR. We specified that, as per resuscitation guidelines, infants should be intubated if they had HR <100 beats per minute or if they had persistent apnea despite PPV via their allocated interface.1 Infants were not intubated in the DR solely for surfactant administration. After admission to the NICU, infants were given respiratory support in accordance with clinician preference. We recorded secondary outcomes in the DR and the NICU and followed infants until hospital discharge.

SAMPLE SIZE ESTIMATION
The rate of DR intubation among infants born at the NMH at ≤30 weeks’ gestation from 2003 through 2007 was 227 of 368 (62%). Lindner and te Pas showed >50% reduction in the rate of DR intubation with their approach to ventilation including the use of a SNP.13,14 To demonstrate a relative reduction of 40% in the rate of DR intubation (ie, to 37%) by using a SNP with a 2-tailed type I error rate of 0.05 and 80% power, we estimated that we would need to recruit 142 infants to this study. An external data and safety monitor analyzed data from the first 71 enrolled infants and recommended that we complete recruitment.

STATISTICS
Data were analyzed by using SPSS version 18.0 (IBM Corporation, Armonk, NY). Analyses were performed by using the intention-to-treat principle. The primary outcome data and other dichotomous secondary outcomes were expressed as numbers and percentages and were compared by using Pearson χ² test. Continuous variables with a normal distribution were expressed as mean (SD) and were compared by using a 2-tailed t test, whereas data with nonparametric distribution were expressed as median (interquartile range) and compared using 2-tailed Mann-Whitney U test.
We considered \textit{P} values <0.05 statistically significant.

**RESULTS**

One hundred eighty-four infants <31 weeks’ gestation were born at the NMH between July 2010 and August 2012. Forty infants were not enrolled in the study (Fig 2). Seventy-two infants were randomly assigned to each group. Two infants assigned to respiratory support via SNP did not require PPV or CPAP and were given facial oxygen. All infants randomized to FM received PPV and/or CPAP in the DR. The groups were well matched for gestational age, birth weight, gender, mode of delivery, multiple births, clinically suspected chorioamnionitis, preeclampsia, and the use of antenatal magnesium sulfate. All infants in both groups received at least 1 dose of antenatal steroids before delivery (Table 1).

Eleven (15%) infants in both groups were intubated and ventilated in the DR (\textit{P} = 1.000; odds ratio 1.0; 95% confidence interval: 0.40–2.48; Table 2). The 95% confidence intervals for the difference in intubation rates are (−0.12 to 0.12). One infant assigned to SNP initially received PPV via a SNP before it was replaced with a FM at 6 minutes. This infant was intubated and ventilated in the DR at 8 minutes for persistent apnea and bradycardia despite PPV. One infant born at 24 weeks’ gestation assigned to FM was intubated in the DR for “prematurity” without meeting the specified criteria for intubation in the DR. Per-protocol analysis (ie, excluding the 2 infants in the SNP group who did not receive respiratory support; and counting the infant in the FM group who did not meet intubation criteria as not reaching the primary outcome) revealed no significant difference in the primary outcome between the groups (\textit{P} = .759). Of the 22 infants intubated in the DR, 12 were intubated for apnea and bradycardia despite PPV, 5 for bradycardia despite PPV, 4 for apnea despite PPV, and 1 for prematurity. There was no difference in the mean [SD] time from birth to intubation between the 2 groups (SNP 6.8 [4.3] vs FM 7.1 [3.4] minutes, \textit{P} = .871).

Of the 61 infants in the SNP group that were not intubated in the DR two received only supplemental oxygen, 12 received CPAP only and 47 received CPAP and IPPV. Similarly, in the FM group 24 received CPAP only while 37 received both IPPV and CPAP.

Secondary outcomes are shown in Table 2. There were no significant differences between the groups in HR or Apgar scores at 5 minutes, or in the number of infants given chest compressions, adrenaline, or fluid volume in the DR. All 144 infants had a pulse oximeter (Masimo SET: 19 SNP vs 16 FM, NPB-40: 53 SNP vs 55 FM, N-595: 1 infant FM) applied to the right wrist. Infants randomized to SNP had lower median (interquartile range) oxygen saturations at 5 minutes compared with infants in the mask group (76% [64%–88%] vs 85% [78%–90%], \textit{P} = .002) and received higher median concentrations of supplemental oxygen at 5 minutes (50% [30%–60%] vs 37% [30%–57%], \textit{P} = .033).

In addition to the 11 infants in each group that were intubated in the DR an additional 37 (51%) infants assigned to SNP and 34 (47%) infants assigned to FM were intubated in the NICU within 72 hours of birth. Overall the proportion of infants intubated during NICU admission was similar between the 2 groups (54 [75%] vs 47 [65%], \textit{P} = .202). Forty-nine (72%) infants allocated to SNP received at least 1 dose of surfactant during admission compared with 43 (60%) infants allocated to FM (\textit{P} = .298). Seven (10%) infants assigned to SNP had a pneumothorax compared with 3 (4%) infants in the FM group (\textit{P} = .190).
All but 1 infant in each group had their pneumothoraces drained by needle aspiration or by chest drain insertion. Three infants assigned to SNP and 7 to FM had pulmonary hemorrhage ($P = .190$). The total period (days) of mechanical ventilation and duration of oxygen therapy did not differ between groups. The proportion of infants with chronic lung disease (21/65 [32%] vs 18/65 [29%], $P = .646$) in surviving infants was not different between groups. Nine (13%) infants in both groups died before discharge home from the NICU. The median time of death for those allocated to SNP was 4 days (3–47) compared with 2 days (1–4) for infants allocated to FM ($P = .044$). Twenty-seven infants (38%) assigned to SNP were born at <28 weeks compared with 25 infants (35%) assigned to FM. Our study was not sufficiently powered to detect differences in subgroups; however, there was no significant difference in DR intubation rates between groups for infants <28 weeks’ gestation (8/27 [30%] vs 8/25 [32%], $P = .853$) or for infants 28 to 30 weeks’ gestation (3/45 [7%] vs. 3/47 [6%], $P = .956$).

### DISCUSSION

We found that giving respiratory support to preterm newborns via a SNP instead of a FM did not result in fewer infants being intubated in the DR. Our results differ, therefore, from previous studies that demonstrated less DR intubation and BPD in very preterm infants when a SNP was used instead of a FM.13,14 These studies simultaneously evaluated multiple aspects of DR care including interfaces, modes of ventilation, and ventilation devices. It is probable that the improvements in outcomes observed in these studies were attributable to aspects of DR care other than using a nasal interface.13,14

The principal limitation of our study is that neither the caregivers nor the outcome assessors were masked to the intervention. Another major limitation of our study is that our estimate of the rate of the primary outcome (DR intubation) in the control (FM) group when we designed the study (62%) was much greater than the rate we measured in the study (15%). Consequently, the study was not adequately powered to detect a significant difference in primary outcome between the 2 groups and, although we found no difference in outcome between the groups, we cannot definitively conclude from our results that the interfaces are equally effective. However, given the lack of difference between the groups that we found, we think it most unlikely that we would have found any difference in the primary outcome between the

### TABLE 1 Patient Demographics

<table>
<thead>
<tr>
<th>Outcome</th>
<th>SNP n = 72</th>
<th>FM n = 72</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gestational age (wks)$^a$</td>
<td>28 (2)</td>
<td>28 (2)</td>
<td>.280</td>
</tr>
<tr>
<td>Birth wt (g)$^a$</td>
<td>1112 (407)</td>
<td>1122 (358)</td>
<td>.883</td>
</tr>
<tr>
<td>Male gender$^b$</td>
<td>42 (58)</td>
<td>41 (57)</td>
<td>.866</td>
</tr>
<tr>
<td>Antenatal steroid exposure ($≥1$ dose)$^b$</td>
<td>72 (100)</td>
<td>72 (100)</td>
<td>1.000</td>
</tr>
<tr>
<td>Multiple birth$^b$</td>
<td>24 (33)</td>
<td>21 (29)</td>
<td>.590</td>
</tr>
<tr>
<td>Cesarean delivery$^b$</td>
<td>45 (63)</td>
<td>46 (64)</td>
<td>.863</td>
</tr>
<tr>
<td>Suspected clinical chorioamnionitis$^b$</td>
<td>13 (18)</td>
<td>6 (8)</td>
<td>.085</td>
</tr>
<tr>
<td>Antenatal magnesium sulfate$^b$</td>
<td>8 (11)</td>
<td>9 (13)</td>
<td>.796</td>
</tr>
</tbody>
</table>

$^a$ mean (SD).

$^b$ n (%).

### TABLE 2 Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>SNP n = 72</th>
<th>FM n = 72</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary outcome: intubation in DR$^a$</td>
<td>11 (15)</td>
<td>11 (15)</td>
<td>1.000</td>
</tr>
<tr>
<td>DR outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HR at 5 min (beats/min)$^b$</td>
<td>140 (120 151)</td>
<td>137 (125 154)</td>
<td>.649</td>
</tr>
<tr>
<td>Oxygen saturation at 5 min (%)$^b$</td>
<td>76 (64.88)</td>
<td>85 (78.80)</td>
<td>.002</td>
</tr>
<tr>
<td>Apgar score at 5 min$^c$</td>
<td>8 (2)</td>
<td>8 (2)</td>
<td>.689</td>
</tr>
<tr>
<td>Max supplemental oxygen in DR (%)$^b$</td>
<td>50 (30.60)</td>
<td>37 (30.57)</td>
<td>.033</td>
</tr>
<tr>
<td>Surfactant given in DR$^a$</td>
<td>4 (6)</td>
<td>2 (3)</td>
<td>.404</td>
</tr>
<tr>
<td>Chest compressions in DR$^a$</td>
<td>1 (1)</td>
<td>5 (7)</td>
<td>.085</td>
</tr>
<tr>
<td>Adrenaline or vol in DR$^a$</td>
<td>0 (0)</td>
<td>2 (3)</td>
<td>.154</td>
</tr>
<tr>
<td>NICU outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intubation &lt;72 h$^a$</td>
<td>48 (67)</td>
<td>45 (63)</td>
<td>.601</td>
</tr>
<tr>
<td>Intubation during admission$^a$</td>
<td>54 (75)</td>
<td>47 (65)</td>
<td>.202</td>
</tr>
<tr>
<td>Surfactant ≥1 dose$^a$</td>
<td>48 (67)</td>
<td>44 (61)</td>
<td>.488</td>
</tr>
<tr>
<td>Air leak$^a$</td>
<td>7 (10)</td>
<td>5 (4)</td>
<td>.190</td>
</tr>
<tr>
<td>Pulmonary hemorrhage$^a$</td>
<td>3 (4)</td>
<td>7 (10)</td>
<td>.190</td>
</tr>
<tr>
<td>Total period of mechanical ventilation (d)$^b$</td>
<td>2 (0-6)</td>
<td>1 (0-5)</td>
<td>.726</td>
</tr>
<tr>
<td>Total period of oxygen therapy (d)$^b$</td>
<td>10 (3–50)</td>
<td>9 (1–41)</td>
<td>.194</td>
</tr>
<tr>
<td>Chronic lung disease$^a$</td>
<td>21 (32)$^a$</td>
<td>18 (29)$^a$</td>
<td>.646</td>
</tr>
<tr>
<td>PDA treated medically$^a$</td>
<td>17 (24)</td>
<td>19 (26)</td>
<td>.700</td>
</tr>
<tr>
<td>Surgical treatment of PDA$^a$</td>
<td>3 (4)</td>
<td>4 (6)</td>
<td>.684</td>
</tr>
<tr>
<td>Necrotizing enterocolitis stage ≥2$^a$</td>
<td>2 (3)</td>
<td>3 (4)</td>
<td>.665</td>
</tr>
<tr>
<td>Retinopathy of prematurity stage ≥3$^a$</td>
<td>1 (1)</td>
<td>1 (1)</td>
<td>1.000</td>
</tr>
<tr>
<td>Abnormal cranial ultrasound$^a$</td>
<td>9 (13)</td>
<td>6 (8)</td>
<td>.482</td>
</tr>
<tr>
<td>Death before discharge$^a$</td>
<td>9 (13)</td>
<td>9 (13)</td>
<td>1.000</td>
</tr>
</tbody>
</table>

$^a$ n (%).

$^b$ Median (interquartile range).

$^c$ Mean (SD).

$^d$ Oxygen therapy at 36 weeks’ corrected gestational age.

$^e$ Of surviving infants.

$^f$ Abnormal cranial ultrasound = intraventricular hemorrhage grade ≥3, periventricular leukomalacia, or postrhemorrhagic hydrocephalus.

PDA, patent ductus arteriosus.

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2 groups had we enrolled many more infants. Before this study commenced, many infants born <28 weeks’ gestation were intubated in the DR for prophylactic surfactant administration. We find it interesting that requesting that caregivers only intubate infants in the DR for bradycardia or apnea despite PPV had a larger treatment effect (76% relative reduction regardless of the interface used) than we hypothesized that using a SNP might have. This demonstrates that very preterm infants can be managed and transferred to the NICU without being routinely intubated and ventilated in the DR. Once admitted to the NICU, infants were intubated according to the treating clinicians preference for a variety reasons, including for prophylactic or early surfactant treatment without a trial of nasal CPAP. Because there were no criteria as to when enrolled infants should be intubated after NICU admission, any differences detected between the groups should be interpreted with caution.

Our study was not powered to detect differences in secondary outcomes. However, infants in the SNP group had significantly lower median SpO2 at 5 minutes of age and, perhaps as a consequence, received higher concentrations of supplemental oxygen in the DR. The clinical relevance of this finding is debatable. The same model of pulse oximeter was not used for every baby, and it appears that different machines give different readings at lower SpO2. Moreover, all other DR outcomes including HR and Apgar score at 5 minutes, respiratory support, chest compressions, adrenaline, and fluid volume resuscitation were comparable between groups.

We used an SNP because we were aware of the results of te Pas and Lindner’s studies and had previous experience of using them in the DR. Short binasal prongs have been demonstrated to be superior to a SNP for giving nasal CPAP to preterm infants in the NICU. It is possible that binasal prongs could be more effective than a SNP in the DR; however, in our limited experience of using binasal prongs, we had difficulty maintaining their position during resuscitation and transport to the NICU. Although complications of using a SNP to deliver respiratory support have been reported, we found no difficulties with its use, and the general consensus from staff was that it was more convenient and stable than the FM for NCPAP delivery during transfer to the NICU.

CONCLUSIONS

Compared with an FM, using an SNP to deliver respiratory support to newborn infants <31 weeks’ gestation did not result in less intubation and ventilation in the DR.

ACKNOWLEDGMENT

We thank Professor Peter Davis for his interim analysis of our data.

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