Developed and established in Canadian neonatal intensive care units, EPIQ (Evidence-based Practice for Improving Quality) is a scientific method for continuous quality improvement that is evidence-based; targeted on key outcomes; collaborative, involving interprofessional teams of experts; and continuous, promoting a culture of change. Based on the International Liaison Committee on Resuscitation literature review template, the EPIQ review process addresses important clinical questions by summarizing relevant studies. They are intended as guides to best practices and do not represent unique or mandatory protocols. Full versions of these reviews are available at www.epiq.ca.

Khalid Aziz MD, Assistant Editor, *Paediatrics & Child Health*

Does the use of primary continuous positive airway pressure reduce the need for intubation and mechanical ventilation in infants ≤32 weeks' gestation?

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Evidence-based Practice for Improving Quality (EPIQ) Evidence Review Group

WH Yee, J Scotland, Y Pham, R Finch; Evidence-based Practice for Improving Quality (EPIQ) Evidence Review Group. Does the use of primary continuous positive airway pressure reduce the need for intubation and mechanical ventilation in infants ≤32 weeks' gestation? Paediatr Child Health 2011;16(10):633-637.

BACKGROUND: Ventilator-induced lung injury is a recognized risk factor for bronchopulmonary dysplasia.
OBJECTIVE: To determine whether primary continuous positive airway pressure (CPAP), defined as CPAP without previous endotracheal intubation for any indication, can reduce the need for intubation and mechanical ventilation in infants born at ≤32 weeks' gestational age.
METHODS: The literature was reviewed using the methodology for systematic reviews for the Consensus on Resuscitation Science adapted from the American Heart Association's International Liaison Committee on Resuscitation.
RESULTS: Fourteen studies were reviewed. Eleven studies provided varying degrees of supportive evidence (level of evidence 3 to 4) that the use of primary CPAP can reduce the need for intubation and mechanical ventilation.
CONCLUSION: The use of CPAP as a primary intervention and mode of respiratory support is an option for infants ≤32 weeks' gestation, but avoidance of intubation and mechanical ventilation is more likely in mature infants >27 weeks' gestation.

Key Words: *CPAP; Evidence review; Preterm infant*

L'utilisation de la pression positive continue primaire réduit-elle le recours à l'intubation et à la ventilation mécanique chez les nourrissons de 32 semaines d'âge gestationnel ou moins?

HISTORIQUE : Les lésions pulmonaires induites par les respirateurs constituent un facteur de risque connu de dysplasie bronchopulmonaire.
OBJECTIF : Déterminer si la pression positive continue (PPC) primaire, définie comme une PPC sans intubation trachéale antérieure pour quelque indication que ce soit, peut réduire la nécessité d'intuber et d'administrer une ventilation mécanique aux nourrissons nés à 32 semaines d'âge gestationnel ou moins.
MÉTHODOLOGIE : Les chercheurs ont analysé les publications au moyen de la méthodologie d'analyse systématique du *Consensus on Resuscitation Science* adapté de l'*International Liaison Committee on Resuscitation* de l'*American Heart Association*.
RÉSULTATS : Les chercheurs ont analysé 14 études. Onze ont fourni des degrés divers de données probantes (qualité des preuves 3 à 4), appuyant le fait que le recours à la PPC primaire peut réduire la nécessité de procéder à une intubation et à la ventilation mécanique.
CONCLUSION : Le recours à la PPC comme intervention primaire et mode de soutien respiratoire constitue une possibilité chez les nourrissons de 32 semaines d'âge gestationnel ou moins, mais il est davantage possible d'éviter l'intubation et la ventilation mécanique chez les nourrissons matures de plus de 27 semaines d'âge gestationnel.

BACKGROUND

Bronchopulmonary dysplasia (BPD) is a significant morbidity among surviving preterm infants (1). Rates of BPD vary widely across centres and range from 4.0% to 58.3% (2-4). The pathogenesis is multifactorial, with multiple risk factors such as early volutrauma, barotrauma and oxygen exposure superimposed on immature, developing lungs (1,5-7). Therefore, strategies to minimize these factors would be advantageous. One such strategy is the use of primary continuous positive airway pressure (pCPAP) after delivery to avoid ventilator-induced lung injury.

OBJECTIVE

We reviewed the literature to determine whether pCPAP, defined as CPAP without previous endotracheal intubation for any indication, as a mode of respiratory support after delivery reduces the need for intubation and mechanical ventilation in infants ≤32 weeks' gestational age.

METHOD

Key words selected with synonyms were "continuous positive airway pressure" OR "CPAP" OR "nasal CPAP" OR "early CPAP"; "preterm" OR "premature infant" OR "neonate" OR "newborn"; "resuscitation" OR "delivery room". These concepts were combined with the Boolean operator "AND". Exclusion criteria were nonhuman subjects; non-English language; abstract only; review articles; CPAP as nonprimary intervention; children/adult subjects; late preterm or term infants; >32 weeks' gestation; extubation to CPAP; and surfactant administration with CPAP.

Databases searched were Ovid Medline (1950 to 2009), Scopus (1997 to 2009), Web of Science (1997 to 2009), Embase (1987 to 2008), PubMed (1975 to 2009), CINAHL (1996 to 2008), Cochrane Central Register of Controlled Trials (first quarter of 2009) and Cochrane Database of Systematic Reviews (first quarter of 2009). The abstracts of all available reports and studies were reviewed including single-centre case series, observational studies with

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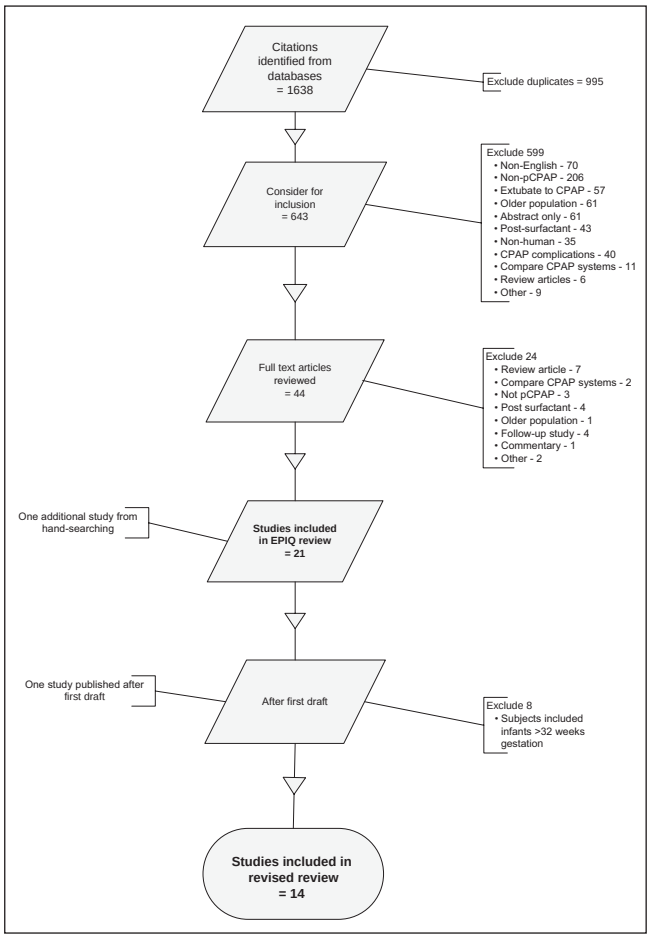

Figure 1) *Flow diagram for study selection. CPAP Continuous positive airway pressure; EPIQ Evidence-based Practice for Improving Quality; pCPAP Primary CPAP*

historical and other centre controls, and randomized controlled trials (RCTs). The bibliographies of all selected articles and several review articles were manually searched for additional studies.

From an initial review of 1638 citations and 46 full-text articles (Figure 1), 14 studies were eligible for inclusion in the present review. They were scored using the Evidence Evaluation Worksheet adapted from the American Heart Association's International Liaison Committee on Resuscitation (<www.americanheart.org/presenter.jhtml?identifier=3052119>) (8). Four reviewers independently assigned level of evidence (LOE), direction of support and quality (<www.cebm.net/index.aspx?o=1157>) (9). Inconsistencies were resolved by consensus.

RESULTS

The process for selection of the studies is outlined in Figure 1. With the exception of one, all studies included were published between 1999 and 2010. Included studies reported data that described the need for intubation and mechanical ventilation in infants ≤32 weeks' gestation who were treated with pCPAP.

Characteristics of studies

In 1987, Han et al (10) reported an RCT with a population of infants (n=82) managed in the preantenatal corticosteroid and presurfactant era, using a nasopharyngeal continuous distending pressure device compared with headbox oxygen. They concluded that this mode of respiratory support was not beneficial and "may worsen the severity of RDS [respiratory distress syndrome]". Only one other RCT addressed the question of our review. In 2004, Sandri et al (11) randomly assigned 230 infants, 28 to 31 weeks' gestation, to early CPAP in the delivery room or delayed/rescue CPAP provided at 30 min of age. They concluded that the incidence of subsequent intubation in both groups was the same. Subramaniam et al (12) reviewed these two RCTs in a Cochrane systematic review and concluded that there was "insufficient information to evaluate the effectiveness of CPAP to reduce the need for IPPV [intermittent positive pressure ventilation]". The remaining studies (n=2824 subjects) included six observational studies (13-18) in centres using historical controls 'before-and-after' implementing routine use of early CPAP (LOE 3), one study (19) reporting a national cohort's experience with increasing use of CPAP over time and a parallel decrease in the use of intubation and mechanical ventilation (LOE 4), and one study (20) reporting a comparison between two centres with different resuscitation and ventilation practices (LOE 4). Additional observational data were identified from two RCTs (21,22). These studies were designed to address the primary outcome of death and/or BPD in patients treated with pCPAP compared with intubation and surfactant, rather than our primary question of pCPAP versus no prophylactic intervention. The group of infants (n=965) from the 'CPAP arm' of these studies (LOE 4) provided additional data regarding the effect of pCPAP. Another RCT (23) designed to address the feasibility of using a T-piece resuscitator in the delivery room before implementing CPAP as a mode of primary respiratory support also provided observational data (n=104) regarding the outcome of patients treated with pCPAP (LOE 4). These studies are presented in Table 1.

Quality of the studies

The majority of studies were observational, using historical controls or no controls in the context of observational data within a subset of subjects from an RCT designed to address a different primary outcome. The quality of the studies was generally good to fair, but was variable based on a clear definition of the comparison groups, outcomes measured objectively, known confounders identified and controlled for, and sufficient follow-up.

DISCUSSION

The overall observed rate of avoiding intubation and mechanical ventilation by using pCPAP in these studies ranged from 12% to 92.6%. This broad range reflects the heterogeneity of the observational studies along with the temporal changes in neonatal care that likely occurred over the reported time periods.

Some studies attempted to determine whether the use of pCPAP was associated with a decrease in the incidence of BPD. With the exception of the study by Aly et al (13), none of the studies identified a statistically significant decrease in the incidence of BPD, or differences in other neonatal morbidities including air leak and necrotizing enterocolitis. Aly et al reported avoiding intubation in 92.6% of patients and a decrease in BPD, but this was the result of a single centre's experience at the end of four successive time periods, after implementing a policy for use of early nasal CPAP in extremely low birth weight infants, and incorporating an education and training program. They specifically assigned experienced nurses to provide care in the first week with a 'minimal handling' strategy. It is of note that the outcomes were actually worse in the first time period than at baseline, suggesting that there was a 'learning curve', with sequential improvement over the three time periods after the change in practice. Only the data from the 'CPAP arm' of one RCT (22) reported a higher

TABLE 1
Studies of primary continuous positive airway pressure (pCPAP) in infants ≤32 weeks' gestation

Reference	Year	Study population	Study	Reported outcome	Comment	LOE*
Aly et al (13)	2004	Single centre n=101 infants <1000 g	Observational study over three time periods from 1997–2002 (n=34, n=34, n=33) compared with a historical cohort of n=45 infants in baseline period 1995–1997 Unit adopted a policy for use of ENCPAP in the delivery room	Increasing use of CPAP (17.6%, 61.8% and 66.7%) associated with progressive decrease in intubation and use of surfactant. Intubation increasingly avoided in first week (61.5%, 86.2% and 92.6%) over the three time periods Described trend to increase necrotizing enterocolitis, P=0.72 Decrease in BPD over the three time periods (definition of BPD not stated)	Implemented policy for use of ENCPAP with education and training program. Assigned experienced nurses to provide care in first week with 'minimal handling' strategy. Small number of infants in each time period Criteria for CPAP failure not well defined	3 (S) Q: fair
Finer et al (23)	2004	Five-centre RCT n=104 infants GA 23–28 weeks	Study to address feasibility of randomization to use of the T-piece resuscitator (Neopuff†) in the delivery room to deliver CPAP/PEEP (n=55) during resuscitation compared with standard mask positive pressure ventilation without PEEP (n=49)	One-half of patients <28 weeks intubated in delivery room for resuscitation indication. Overall, 20% of infants <28 weeks avoided intubation within the first 7 days, regardless of mode of initial resuscitation. Infants >27 weeks were less likely to require intubation. All infants at 23 weeks were intubated in the delivery room	Criteria for CPAP failure, PCO_2>55–60 mmHg, pH<7.25, apnea or FiO_2>0.30 for surfactant administration Both groups treated with CPAP in NICU after initial resuscitation, if not intubated in delivery room	4 (S) Q: good
Han et al (10)	1987	Single-centre RCT n=82 infants GA <32 weeks	Nasopharyngeal CDP (n=43) use compared with headbox oxygen with possible 'rescue' CDP (n=39)	Unable to demonstrate advantage to early CDP in reducing RDS. Higher FiO_2, lower a/A ratio in CDP early treated group, "worsen severity of RDS"	Predates current NICU care and use of antenatal corticosteroids	1 (O) Q: good
Jegatheesan et al (14)	2006	Single centre n=171 infants ≤1000 g GA 23–32 weeks	Observational study of two periods, before (2000–2004, n=96) and after (2002–2004, n=75) implementing a policy of early nCPAP in the delivery room with Infant Flow‡ nCPAP system	Using nCPAP in second period, 24% of infants were not intubated in delivery room and, overall, 12% were never intubated, proportions decrease to 15% and 3%, respectively for infants at GA <26 weeks No difference in CLD at 36 weeks	Criteria for CPAP failure: PCO_2>65 mmHg, pH<7.25, FiO_2>0.60, apnea	3 (S) Q: fair
Lindner et al (15)	1999	Single centre n=123 infants <1000 g GA ≥24 weeks	Observational study of two periods before (1994, n=56) and after (1996, n=67) implementation of lung recruitment with positive pressure via NPT followed by NPT CPAP delivered by mechanical ventilator	Greater proportion of infants avoided intubation and mechanical ventilation in the second time period: 25% in second period and 7% in first period	Increase in dosage of antenatal betamethasone in second time period Criteria for CPAP failure not detailed	3 (S) Q: fair
Morley et al (22); COIN trial	2008	Multicentre RCT n=610 infants GA 25–28 weeks (33% GA 25–26 weeks) CPAP group n=307	Randomized to use of CPAP versus endotracheal intubation in the delivery room at 5 min of age. Study conducted 1999–2006	Overall, 54% of infants in the CPAP group avoided intubation and ventilation; 45% in 25 to 26-week infants and 60% in 27 to 28-week infants. Use of surfactant halved in the CPAP group. No difference in primary outcome of death or BPD at 36 weeks	Criteria for CPAP failure: PCO_2>60 mmHg, pH<7.25, FiO_2>0.60, apnea despite caffeine. Higher incidence of pneumothorax in the CPAP group, NNH 16. NNT 2.5 to avoid surfactant use. Observational data from one arm of RCT	4 (S) Q: good
Narendran et al (16)	2003	Single centre n=171 infants <1000 g	Comparing two periods before (1998–1999, n=929) and after (2000–2001, n=79) use of ENCPAP	Decreased intubation in the delivery room and reduced need for mechanical ventilation; mechanical ventilation avoided in 17.4% in the first period compared with 27.8% in the second period No difference in CLD at 36 weeks	Criteria for CPAP failure: PCO_2>65 mmHg, pH<7.15, FiO_2>0.60	3 (S) Q: fair
Pelligra et al (17)	2008	Single centre n=1526 infants GA <32 weeks	Observational study of two sequential time periods before (1996–2000, n=675) and after (2000–2004, n=851) the centre adopted practice of using nCPAP (underwater 'bubble' CPAP) as a delivery room intervention	Reduction in use of surfactant and need for mechanical ventilation in second period. In the second period, 19% of infants avoided intubation compared with 9% of infants in the first period No difference in BPD at 36 weeks	Criteria for CPAP failure: PCO_2>60 mmHg, pH<7.25, FiO_2>0.50, apnea	3 (S) Q: good

Continued on next page

TABLE 1 – CONTINUED
Studies of primary continuous positive airway pressure (pCPAP) in infants ≤32 weeks' gestation

Reference	Year	Study population	Study	Reported outcome	Comment	LOE*
Sandri et al (11)	2004	Multicentre RCT n=230 infants GA 28–31 weeks	Randomized infants to nCPAP within 30 min of age (n=115) or rescue nCPAP if FiO_2>0.40 beyond 30 min of age (n=115), using the Infant Flow‡ Driver system. Study conducted 1999–2000	No difference in the need for intubation or surfactant use in the two groups Practice of routine prophylactic surfactant in infants at GA <28 weeks	Criteria for CPAP failure: PCO_2>70 mmHg, pH<7.2, apnea or FiO_2>0.80 in first 30 min	1 (N) Q: good
Subramaniam et al (12)	2005	Meta-analysis 2 studies (n=312) GA <32 weeks	Analysis of two RCTs conducted in 1987 and 1999, respectively	Concluded that there was "insufficient information to evaluate the effectiveness of CPAP to reduce need for IPPV"	Different population, time period and NICU practices in two studies	2 (N) Q: fair
Finer et al (21) (SUPPORT Trial Group)	2010	Multicentre RCT n=1316 GA 24–28 weeks (43% GA 24–25 weeks) CPAP group: n=663	Randomized to CPAP or intubation in delivery room and surfactant treatment (within 1 h after birth). Also randomized to one of two target ranges of oxygen saturation. Study conducted 2005–2009	Within the CPAP group, 65.6% avoided intubation in the delivery room, 32.9% avoided treatment with surfactant and intubation was avoided in 16.9% overall No difference in the primary outcome of death or BPD at 36 weeks	Criteria for CPAP failure: PCO_2>65 mmHg, FiO_2>0.50, hemodynamic instability Observational data from one arm of RCT	4 (S) Q: good
Swietlinski et al (19)	2007	National cohort 2003 to 2005 Subset of infants ≤30 weeks' GA, n=236	Observational study after implementing use of the Infant Flow† Advance Driver CPAP within a national program across 57 secondary and tertiary care NICUs	In a subset of infants ≤30 weeks' gestation, able to avoid intubation in 157 of 236 (66.5%) Incidence of nasal and facial complications noted to be higher in lower birth weight infants	Multicentre, three modes of CPAP used: standard, bi-level and triggered bi-level. Criteria for CPAP failure: PCO_2>65 mmHg, pH<7.25, FiO_2>0.60, apnea	4 (S) Q: poor
Vanpee et al (20)	2007	Two centres n=172 infants GA <28 weeks	Comparison over two years at a European centre (n=102) and a United States centre (n=70) to evaluate differences in resuscitation and ventilation practices	nCPAP (Infant Flow‡ Driver system) was used initially in 56% of infants in the first centre; overall, 22% avoided intubation during the first week of life. Routine intubation and surfactant use in the second centre	Infants in first centre had higher SNAPPE-II scores, and antenatal steroids used less frequently in second centre	4 (S) Q: poor
Zecca et al (18)	2006	Single centre n=324 infants GA 24–28 weeks	Observational study of two periods before (1992–1997, n=161) and after (1998–2003, n=163) implementation of practice change from immediate intubation to use of nCPAP initiated in delivery room with T-piece resuscitator (NeoPuff†)	Overall, intubation avoided in 14% of infants in the second period compared with 3% in the first period. Infants 27–28 weeks' GA, 21.3% avoided intubation in the second period compared with 2.8% in the first period. Infants 24–26 weeks' GA, >95% intubated in both periods	Greater use of antenatal steroids in the second period Prophylactic ibuprofen used in the second period Criteria for CPAP failure: PCO_2>60 mmHg, pH<7.25	3 (S) Q: fair

**Letters in parentheses under level of evidence (LOE): N Neutral to intervention; O Oppose intervention; S Support intervention; †Fisher & Paykel Healthcare Limited, Canada; ‡CareFusion, USA. BPD Bronchopulmonary dysplasia; CDP Continuous distending pressure; CLD Chronic lung disease; COIN Nasal CPAP or Intubation at Birth; CPAP continuous positive airway pressure; ENCPAP Early 'bubble' nasal CPAP; FiO_2 Fraction of inspired O_2; GA Gestational age; IPPV Intermittent positive pressure ventilation; nCPAP Nasal CPAP; NICU Neonatal intensive care unit; NNH Number needed to harm; NNT Number needed to treat; NPT Nasopharyngeal tube; PCO_2 Partial pressure of CO_2; PEEP Positive end expiratory pressure; Q Quality; RCT Randomized controlled trial; RDS Respiratory distress syndrome; SNAPPE Score for Neonatal Acute Physiology Perinatal Extension; SUPPORT Surfactant, Positive Pressure, and Oxygenation Randomized Trial*

incidence of air leak in the CPAP group compared with the group managed with intubation.

The set criteria for 'CPAP failure' resulting in intubation and mechanical ventilation were all very similar in the studies (Table 1), with the exception of the delivery room feasibility study of the T-piece resuscitator (23). Infants requiring a fraction of inspired O_2 >0.30 could be intubated to receive surfactant, so in the present study, 80% of infants <28 weeks' gestation placed on CPAP were subsequently intubated.

Despite its observational nature, data from the 'CPAP arms' of the large RCTs represent a large sample of similar, extremely premature infants exposed to pCPAP. The lower intubation rate in the Nasal CPAP or Intubation at Birth (COIN) trial (22), in contrast to the Surfactant, Positive Pressure, and Oxygenation Randomized Trial (SUPPORT) (21), likely reflects the lower gestational age of the patients in the SUPPORT trial. This is congruent with observations made in other studies (14,18,23). Collectively, the studies suggest that use of pCPAP is more likely to be successful in infants >27 weeks' gestation.

The success of surfactant in treating respiratory distress in preterm infants led to the strategy of prophylactic surfactant (24). More recently, centres have adopted the practice of intubation for surfactant administration followed by extubation to early CPAP, in efforts to avoid the presumed deleterious effects of positive pressure ventilation (25). These practice strategies have made it difficult to conduct RCTs comparing pCPAP with a true noninterventional control group. With good prenatal care, including administration of antenatal corticosteroids, some extremely premature infants are observed to experience minimal clinical symptoms of respiratory distress, and the chest radiographs do not have the classical reticular granular pattern of RDS. It is in this group of infants that it may be possible to provide respiratory support with pCPAP, and avoid intubation and

mechanical ventilation. The present review suggests that intubation may be avoided in some of these infants, but the success rate described is as low as 12% or as high as 92.6%. Most of the observational data report success rates ranging from 12% to 54%, with higher success rates identified in more mature infants >27 weeks' gestation. The observational nature of these studies is confounded by biases that include, but are not limited to, the different types of CPAP systems used, different pressure used and other concurrent practices such as the changing use of antenatal corticosteroids because some of these 'before-and-after' studies spanned several years.

Successful use of pCPAP could circumvent the need for endotracheal intubation. The appeal of this strategy is that it could avoid the deleterious effects of mechanical ventilation and the occurrence of ventilator-induced lung injury.

CONSENSUS ON SCIENCE

There is good to fair-quality supportive evidence from 11 studies (LOE 3 to LOE 4) that the use of pCPAP can reduce the need for intubation and mechanical ventilation in infants ≤32 weeks' gestation.

RECOMMENDATION

The use of CPAP as a primary intervention and mode of respiratory support is an option for infants ≤32 weeks' gestation, but avoidance of intubation and mechanical ventilation is more likely in mature infants >27 weeks' gestation.

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