Abstract

Background

Newborn infants who have delayed establishment of independent respiratory effort after birth may require transition support in the delivery room. Cochrane systematic reviews which summarise evidence for delivery room interventions are used to inform policy, practice and research. Our aim was to identify Cochrane reviews of delivery room transition support interventions, appraise their quality, and identify important gaps in the evidence.

Methods

We searched the Cochrane Database of Systematic Reviews (Issue 6, 2015) for reviews evaluating the effects of delivery room transition support for newborn infants. Review quality was assessed using the AMSTAR tool.

Results

Eighteen Cochrane reviews were identified. Broadly, these reviews assessed delivery room interventions for airway management, respiratory or circulatory support, supplemental oxygen or other drugs, and measures to prevent hypothermia or metabolic compromise. The overall quality of reviews was good, but the methodological quality of the included trials varied greatly. Most reviews assessed interventions to support the infant airway and breathing, and the strongest evidence of effect was for types and timing of surfactant replacement. Reviews of oxygen and other drug therapies identified few good quality trials to inform practice.

Conclusions

Existing Cochrane reviews provide good quality evidence to inform the airway and respiratory management of newborn infants in the delivery room. They also demonstrate gaps in the evidence with the need for further research, particularly with regard to circulatory support and pharmacological interventions.

Introduction

One-in-ten newborn infants has delayed establishment of independent respiratory effort after birth requiring delivery room resuscitation or transition support. Delivery room interventions to support newborn infants include airway, breathing and circulatory support, supplemental oxygen or other drugs, and measures to prevent hypothermia or metabolic compromise.[1-5] Increasingly consensus guidelines with recommendations for delivery room transition support are informed by evidence from Cochrane systematic reviews.[6, 7] The validity and utility of guidelines and policy recommendations are dependent on the quality of the included reviews. The methodological quality of Cochrane reviews in several areas of health care, including perinatal and neonatal, is variable.[8, 9] Low methodological quality introduces potential for bias. This work package aimed to describe the available Cochrane reviews evaluating delivery room interventions for newborn infants, assess their methodological quality and the validity of their findings, and identify important research gaps in the evidence. This chapter presents an overview (umbrella review) of systematic reviews evaluating immediate care and transitional support at birth for very preterm infants. The results supported guidance for initial neonatal care beside the mother, and also provided a context for determining how deferred cord clamping might be implemented in the Cord Pilot Trial reported in Chapter 11.

Methods

We undertook a systematic overview using the standard methods of the Cochrane Collaboration and the Centre for Reviews and Dissemination.[10, 11] We registered the overview on PROSPERO, the international prospective register of systematic reviews (registration number CRD42012003038).

Criteria for including reviews

We searched the Cochrane Database of Systematic Reviews Issue 6, 2015 for reviews examining any intervention for delivery room support of newborn infants. We did not include (i) reviews of interventions that are more usually or feasibly delivered following admission of the newborn infant to the neonatal unit, or (ii) reviews of delivery room interventions administered as part of routine practice to all infants. We did not apply any date limits. We searched the bibliographies of all relevant reviews for references to other related Cochrane Reviews. Two reviewers independently screened titles and abstracts of all records identified in the search, and assessed the full texts of any potentially relevant reports.

Data extraction

Two reviewers used piloted data extraction forms to collect information on quality characteristics, participants, treatment and control interventions, and outcomes.

Assessment of methodological quality of included reviews

Two authors assessed independently the methodological quality of included reviews across 11 domains used the AMSTAR tool (see box).[12, 13] If necessary, we requested additional information to clarify methodology and results from the review authors. We resolved disagreements in the assessments and data extraction by consensus.

Box 1: AMSTAR questions

1. Was an 'a priori' design provided?
2. Was there duplicate study selection and data extraction?
3. Was a comprehensive literature search performed?
4. Were published and unpublished studies eligible, irrespective of language of publication?
5. Was a list of studies (included and excluded) provided?
6. Were the characteristics of the included studies provided?
7. Was the scientific quality of the included studies assessed and documented?
8. Was the scientific quality of the included studies used appropriately in formulating conclusions?
9. Were the methods used to combine the findings of studies appropriate?
10. Was the likelihood of publication bias assessed?
11. Was the conflict of interest stated?

We rated each criterion as 'Yes' (definitely done), 'No' (definitely not done), 'Unclear' or 'Not applicable' (NA). Criteria rated as 'Not applicable' were removed from the denominator, with appropriate adjustment to the ranking.

Risk of bias in the included trials

For each included trial, we extracted data from the Cochrane reviews' "risk of bias" tables on the risk of selection bias, detection bias and attrition bias.[14]

Results

We included 18 Cochrane reviews in this overview,[15-32] and grouped them by type of intervention: airway or respiratory support interventions; surfactant replacement therapy for preterm infants with or at risk of respiratory distress syndrome; oxygen and other drugs for infants compromised at birth; strategies for timing of cord clamping at preterm birth.

Quality of included reviews

All of the reviews used methods consistent with those recommended in the Cochrane Handbook.[10] Four reviews did not have any included trials and therefore could not be assessed for the relevant domains.[16, 18, 25, 27] The overall quality of the other reviews assessed was high, based on the AMSTAR assessment (see Table 1). Most reviews failed to have a positive score in just one domain. The only common quality concern was that reviews did not explicitly assess the likelihood of publication bias, but most of these reviews did not include sufficient trials to allow assessment of funnel plot symmetry or statistical assessment with meta-regression.

Search strategy in the reviews

The reviews all searched the three major bibliographic databases (Medline, EMBASE, and The Cochrane Library), and they all described methods for identifying unpublished studies. The last search was after 2010 for seven reviews. Three reviews had last conducted searches in 2009, and the remainder had not had a search update since 2007 or earlier.

Primary outcomes in the reviews

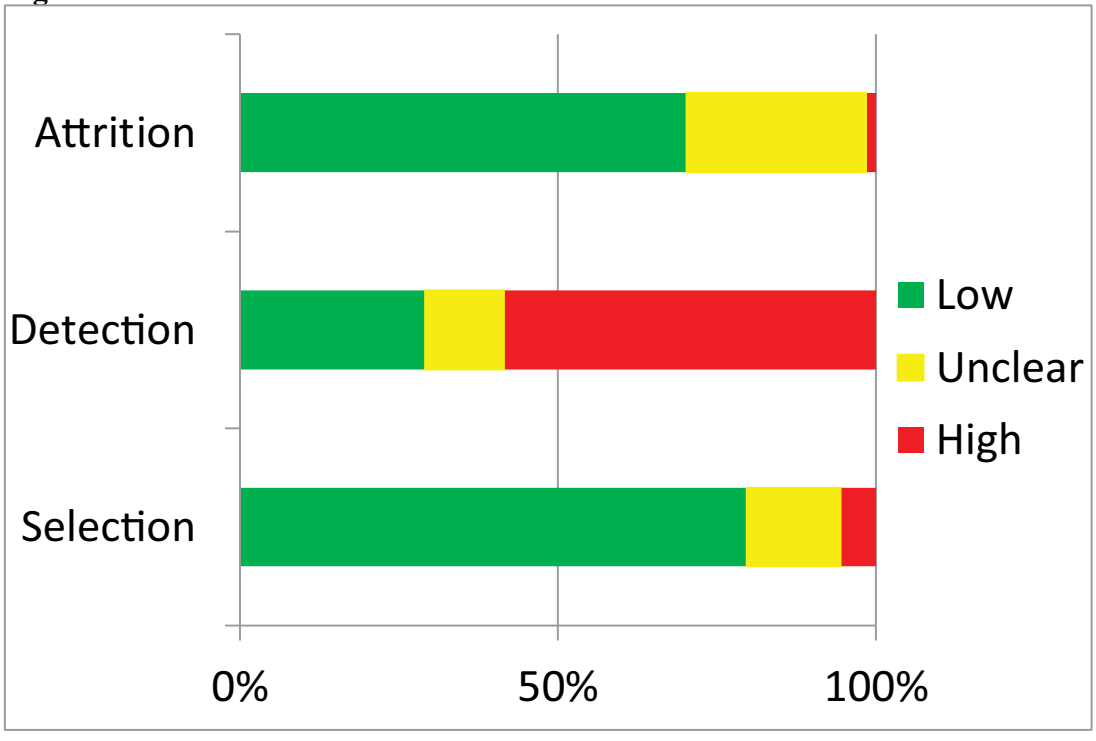
The most commonly pre-specified primary outcomes were death, incidence of chronic lung disease, and neuro-disability (18 of 20 reviews). Two reviews pre-specified surrogate outcomes such as physiological measures (heart rate, temperature) rather than infant-important primary outcomes. The available trial data provide limited evidence of the effects on other outcomes. There are few data on long term neuro-developmental outcomes.

Risk of bias in the included trials

All the reviews assessed the risk of bias for included trials by assessing the risk of selection bias (randomisation sequence and allocation concealment), detection bias (blinding of intervention and outcomes assessment), and attrition bias (complete or near-complete participant outcomes assessment). Of the 74 trials included in the reviews, 76% were

assessed as being at low risk of selection bias, 41% at low risk of detection bias, and 93% at low risk of attrition bias (Figure 1). The risk of detection bias and attrition bias was consistent across the types of interventions. The risk of selection bias varied; with 96% of surfactant replacement trials assessed to be at low risk of selection bias, compared with 45% of trials of circulatory, pharmacological or thermal support.

Figure 1: Risk of bias in the 74 trials included in the 18 reviews



Effects of the interventions

Airway or respiratory support interventions: Four reviews assessed devices and techniques for airway support in newborn infants with, or at risk of, respiratory compromise (table 1).[15-18] Of there, two reviews did not find any eligible trials and one included only a single small trial.[16-18] The fourth review assessed delivery room airway support for infants at risk of meconium aspiration, and included four trials with 2,884 participants.[15] This review provides evidence that routine endotracheal intubation does not reduce mortality or morbidity in vigorous term babies with meconium staining compared with standard resuscitation, including oro-pharyngeal suction.

Table 1: Characteristics of reviews of airway or respiratory support interventions at birth

Review	Last search	Population	Intervention	Comparison	Primary outcomes	N=Trials (participants)
Halliday[15]	2002	Non-asphyxiated term infants with meconium staining	Endotracheal intubation and airway aspiration at birth	Routine care determined by attending clinician	Death, meconium aspiration syndrome, air leak	4 (2884)
O'Donnell[16]	2004	Receiving positive pressure ventilation at birth	PEEP	No PEEP	Death, Apgar scores	0 (0)
Grein[17]	2004	Requiring intermittent positive pressure ventilation	Laryngeal mask airway for respiratory support	Bag-mask device or endotracheal tube for respiratory support	Time to heart rate >100/min or device inserted, placement attempts	1 (44)
Schmölzer[18]	2010	Newborn infants who need resuscitation	Respiratory function monitoring in addition to clinical assessment	Clinical assessment alone	Death	0 (0)

PEEP = Positive end expiratory pressure

Surfactant replacement therapy for preterm infants with or at risk of respiratory distress syndrome: Eight reviews assessed the effects of different types of surfactant, different routes of administration, and different timing and thresholds for administration in preterm infants with or at risk of respiratory distress syndrome (table 2).[19-26] Two early reviews, originally published in 1997, provide strong evidence that for very preterm infants surfactant replacement reduced the risk of death by about 40%.[19, 20] A related review provides evidence that natural surfactant is more effective than synthetic surfactant for reducing the risk of death.[21] These reviews are now regarded as "complete" as further trials would be unlikely to change their conclusions.

Subsequent reviews examined various modifications of the intervention in the context of evolving practice, particularly the use of antenatal corticosteroids to enhance fetal lung maturation and the adoption of non-invasive ventilation modalities. The reviews found evidence that early surfactant administration with brief ventilation reduces the need for mechanical ventilation and associated morbidity, but that prophylactic (delivery room) surfactant administration is not more effective than delayed, selective administration when infants have prophylactic nasal continuous positive airway pressure support.[24, 26] Uncertainty remains about the effects of newer synthetic surfactants that contain "surfactant protein mimics", and of novel non-invasive delivery routes.[22, 23]

Table 2: Characteristics of reviews of strategies for surfactant replacement therapy for infants with, or at risk of, respiratory distress syndrome

Review	Last search	Population	Intervention	Comparison	Primary outcomes	N=Trials (participants)
Soll[19]	2009	Preterm infants with or at risk of RDS	Prophylactic protein-free synthetic surfactant	Placebo or no surfactant	Death, chronic lung disease	7 (1500)
Soll[20]	2010	Infants <30 weeks gestation	Prophylactic natural surfactant	Placebo or no surfactant	Death, chronic lung disease	9 (1256)
Soll[21]	2000	Preterm infants with or at risk of RDS	Natural (animal derived) surfactant	Synthetic surfactant	Pneumothorax, patent ductus arteriosus, necrotising enterocolitis	11 (4657)
Pfister[22]	2007	Preterm infants with or at risk of RDS	Protein-containing synthetic surfactant	Natural surfactant	Death, chronic lung disease	2 (1037)
Pfister[23]	2009	Preterm infants with or at risk of RDS	Protein-containing synthetic surfactant	Synthetic surfactant (protein-free)	Death, chronic lung disease	1 (785)
Stevens[24]	2006	Preterm infants with or at risk of RDS	Prophylactic or early surfactant, followed by early extubation	"Conventional" treatment (surfactant administration and mechanical ventilation)	Death, need for mechanical ventilation, chronic lung disease	6 (1863)

Review	Last search	Population	Intervention	Comparison	Primary outcomes	N=Trials (participants)
Abdel-Latif[25]	2010	Infants < 32 weeks gestation	Pharyngeal instillation of surfactant before the first breath	Placebo, no treatment or intra-tracheal instilled surfactant	Death, chronic lung disease, neuro-disability	0 (0)
Rojas-Reyes[26]	2011	Very preterm infants	Prophylactic surfactant	Delayed (selective) surfactant treatment of RDS	Death, chronic lung disease	11 (4756)

RDS = respiratory distress syndrome

Oxygen and other drugs for infants compromised at birth: One review compared using air versus 100% oxygen for resuscitation of newborn infants at birth (table 3).[30] This review identified five trials (three of which were quasi-randomised), but concluded that insufficient evidence existed to support a recommendation for using either room air or 100% oxygen for resuscitation of newborn infants.

Three reviews assessed other drug interventions.[27-29] Reviews of using adrenaline or sodium bicarbonate during resuscitation found insufficient trial data to determine effects.[27,28] The review of naloxone for infants exposed transplacentally to opiate found nine trials but these did not assess the pre-specified, infant-important outcomes for the review.[29] One review examined interventions to prevent hypothermia in newborn very preterm infants.[31] This review found evidence that various measures including plastic wraps or bags and warming mattresses reduce the risk of delivery room hypothermia in preterm infants, but found insufficient data to assess effects on infant morbidity and mortality.

Table 3: Characteristics of reviews of delivery room oxygen and other drugs for infants compromised at birth

Review	Last search	Population	Intervention	Comparison	Primary outcomes	N=Trials (participants)
Ziino[27])	2010	Newborn with extreme bradycardia or apparent stillbirth	Epinephrine (adrenaline)	1. Placebo or no drug 2. Different doses or routes	Death or severe disability	0 (0)
Beveridge[28]	2006	Infants resuscitated at birth	Sodium bicarbonate	1. Placebo or no drug 2. Another alkalising agent	Death in the delivery room	1 (55)
Moe-Byrne[29]	2013	Newborn with opiate exposure *in utero*	Naloxone	Placebo or no drug	Neonatal unit admission, breastfeeding not established	9 (316)
Tan[30]	2005	Infants receiving IPPV at birth	Respiratory support using room air initially	Respiratory support using 100% oxygen initially	Death or severe disability	5 (1302)
McCall[31])	2009	Newborn preterm or low birth weight infants	Heat loss barriers, heated mattresses or skin-to-skin care	Routine thermal care (includes drying, wrapping, radiant heater or incubator)	Temperature on admission to neonatal unit	7 (400)

IPPV = intermittent positive pressure ventilation

***Strategies for timing of cord clamping at preterm birth*:** One review assessed alternative strategies for timing of cord clamping for preterm births (Table 4).[32] This review found evidence that deferring cord clamping for 30 to 120 seconds, rather than clamping before 30 seconds, reduced the need for blood transfusion or circulatory support and reduced the risk of intraventricular haemorrhage. Data from 13 of the 15 included trials did not identify a statistically significant effect on risk of death. Long-term neurodevelopmental outcomes were not reported.

Discussion

We identified 18 Cochrane reviews evaluating delivery room interventions for infants born very preterm: these included strategies for airway or respiratory support, surfactant replacement therapy, oxygen and other drugs for infants compromised at birth, and timing of cord clamping. Several effective interventions have been identified, particularly surfactant administration for preterm infants with or at risk of developing respiratory distress syndrome. However, many reviews highlight the paucity of trial data supporting even commonly used interventions.

Strengths and limitations of this overview

In general, the quality of these Cochrane reviews was high, as expected as the editorial process includes a published peer-reviewed protocol and a requirement to list all study characteristics and assessments. A potential concern is that many had not been updated within the past two years, as per Cochrane Collaboration guidelines. Of the 18 reviews, eight had not been updated within the past five years. The Cochrane Neonatal Group recognizes the challenges in keeping reviews up-to-date, and determines priorities for updating based on expert opinion and focused searches. Also, some reviews may be considered as "complete" or "dormant", and no longer be updated as new or modified interventions become established.[33]

Table 4: Characteristics of reviews of strategies for timing of cord clamping for preterm births

Review	Last search	Population	Intervention	Comparison	Primary outcomes	N=Trials (participants)
Rabe[32]	2011	Newborn preterm infants	Early cord clamping (< 30 seconds after birth)	Later (delayed) cord clamping	Death or severe disability (maternal postpartum haemorrhage)	15 (738)

Quality of the trials included in the reviews was variable. The potential contribution of methodological weaknesses to bias in trials and systematic reviews is well-described.[34] In particular, quasi-randomised trials and randomised trials with inadequate concealment of allocation tend to over-estimate effect size estimates compared with randomised trials with adequately concealed allocation.[35,36] For example, the Cochrane review of lower versus higher oxygen concentrations for delivery room transition support found evidence that high oxygen (up to 100%) conferred important harms, including a higher risk of death.[30] These effects were no longer statistically significant when the three trials with inadequate sequence generation and concealment of allocation were excluded. For emergency trials, use of quasi-random methods may not increase selection bias, as assessed by baseline characteristics.[37]

Trials that report a statistically significant effect are more likely to be submitted and accepted for publication than studies that do not.[38] Few reviews assessed the potential for publication bias, but most did not have enough trials for meaningful funnel plot asymmetry or regression testing. Prospective registration of trials aims to reduce publication bias and improve the quality of the conduct, analysis, and reporting of trials and systematic reviews.

For several reviews, it was unclear how the scientific quality of the included trials had informed the conclusions. No reviews used the GRADE approach to define the quality of the evidence with respect to risk of bias, directness of evidence, heterogeneity, precision of effect estimates and risk of publication bias.[39] This may change as the Cochrane Collaboration has endorsed use of GRADE.

Implications for future research

Some reviews identified key "evidence-gaps". These were mainly related to pharmacological intervention for transition support or resuscitation of newborn infants, and the effectiveness of new, less-invasive forms of airway management (and related issues regarding surfactant delivery).

Although the Cochrane reviews included in this overview in general focussed on clinically important primary outcomes such as death or chronic lung disease, few trials reported data for longer-term outcomes. Future trials should therefore assess the potential effects on disability and impairment. This is particularly important as delivery room interventions for newborn infants have the potential to have competing effects, that is, they may reduce mortality but with a consequent increase in the risk of disability.

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Table 1: AMSTAR quality assessment of reviews included in the overview

Review	*A priori* design provided	Duplicate study selection + data extraction	Compreh-ensive literature search	Published + unpublished studies included	List of included + excluded studies	Characteristics of included studies provided	Scientific quality of included studies assessed	Quality of included studies applied to conclusions	Appropriate methods for combining studies	Likelihood of publication bias	Conflict of interest stated	*Score*
Airway or respiratory support interventions at birth												
Halliday[14]	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	NA	Yes	***9/10***
O'Donnell[15]	Yes	Yes	Yes	Yes	Yes	NA	NA	NA	NA	NA	Yes	***6/6***
Grein[16]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	NA	Yes	***10/10***
Schmölzer[17]	Yes	Yes	Yes	Yes	Yes	NA	NA	NA	NA	NA	Yes	***6/6***
Surfactant replacement therapy for infants with, or at risk of, respiratory distress syndrome												
Soll[18]	Yes	Yes	Yes	Yes*	Yes	Yes	Yes	Yes	Yes	No	Yes	***10/11***
Soll[19]	Yes	Yes	Yes	Yes*	Yes	Yes	Yes	Yes	Yes	Yes	Yes	***11/11***
Soll[20]	Yes	Yes	Yes	Yes*	Yes	Yes	Yes	Yes	Yes	No	Yes	***10/11***
Pfister[21]	Yes	Yes	Yes	Yes*	Yes	Yes	Yes	Yes	Yes	No	Yes	***10/11***
Pfister[22]	Yes	Yes	Yes	Yes*	Yes	Yes	Yes	Yes	Yes	No	Yes	***10/11***
Stevens[23]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	***10/11***
Abdel-Latif[24]	Yes	Yes	Yes	Yes	Yes	NA	NA	NA	NA	NA	Yes	***6/6***
Rojas-Reyes[25]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	***10/11***

Review	*A priori* design provided	Duplicate study selection + data extraction	Compreh-ensive literature search	Published + unpublished studies included	List of included + excluded studies	Characteristics of included studies provided	Scientific quality of included studies assessed	Quality of included studies applied to conclusions	Appropriate methods for combining studies	Likelihood of publication bias	Conflict of interest stated	*Score*
Oxygen and other drugs for infants compromised at birth												
Ziino[26]	Yes	Yes*	Yes	Yes	Yes	NA	NA	NA	NA	NA	Yes	***6/6***
Beveridge[27]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	NA	No	Yes	***7/10***
Moe-Byrne[28]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	***10/11***
Tan[30]	Yes	Yes	Yes	Yes*	Yes	Yes	Yes	Yes	Yes	No	Yes	***10/11***
McCall[31]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	***9/11***
Strategies for timing of cord clamping at preterm birth												
Rabe[32]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	***11/11***

NA= not applicable