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[Intervention Review]

Methods for securing endotracheal tubes in newborn infants

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ABSTRACT

Background

Securing the endotracheal tube is a common procedure in the neonatal intensive care unit. Adequate fixation of the tube is essential to ensure effective ventilation of the infant whilst minimising potential complications secondary to the intervention. Methods used to secure the endotracheal tube often vary between units and sometimes even between healthcare providers in the same nursery.

Objectives

To compare the different methods of securing the endotracheal tube in the ventilated neonate and their effects on the risk of accidental extubation and other potential complications that can result from an unstable endotracheal tube.

Search methods

A literature search of MEDLINE (from 1966 to June 2013), CINAHL (from 1982 to June 2013) and CENTRAL in *The Cochrane Library* was conducted to identify relevant trials to be analysed.

Selection criteria

All randomised and quasi-randomised controlled trials of infants who were intubated for mechanical ventilation in a neonatal intensive care nursery where methods of stabilising the endotracheal tube were being compared.

Data collection and analysis

Data were collected from individual studies to determine the methods being compared, the methodology of the trial, and whether there were areas of bias that could significantly affect the results of the studies. In particular, studies were assessed for blinding of randomisation and allocation, blinding of the intervention, completeness of follow up, blinding of outcome assessments and selective reporting.

Main results

Five randomised controlled trials were identified and included for review. Accidental extubation was the most common outcome measured (five studies). None of the studies reported on the need for re-intubation or the rate of tube malposition, however one study did report on endotracheal tube slippage. A variety of other adverse effects were reported including mortality, incidence of perioral skin trauma and tube re-taping. All five studies were of poor methodological quality, small size, contained significant risks of bias and compared methods of securing the endotracheal tube that were too dissimilar for the data to be collated or included in a meta-analysis. We have not reported these further.

Authors' conclusions

This review highlighted the need for further well designed and completed studies to be conducted for this common neonatal procedure. Evidence is lacking to determine the most effective and safe method to stabilise the endotracheal tube in the ventilated neonate.

PLAIN LANGUAGE SUMMARY

Methods for securing endotracheal tubes in newborn infants

Review question

Over the years, there have been multiple different ways an endotracheal tube has been secured in the ventilated newborn. We reviewed the evidence for the most effective method to secure an endotracheal tube in infants requiring mechanical ventilation. We found five randomised controlled trials which compared different methods of securing an endotracheal tube and studied their effects on outcomes such as accidental extubation.

Background

As neonatal care and the survival rates of premature infants continues to improve, there will be an ongoing need for newborns to be intubated and ventilated. These are often the sickest babies in the nursery, so optimising practice in this area could impact outcomes. The aim of effectively securing an endotracheal tube is to provide continuous optimal ventilation whilst minimising the risk of developing complications from an unstable tube.

Search date

The evidence was current to June 2013.

Study characteristics

The five studies included in this review enrolled patients from a neonatal intensive care nursery who were intubated and ventilated. Trial durations ranged from the time required to enrol the small recruitment targets up to 10 months. Numbers of participants in the studies ranged from 30 to 203 ventilated infants.

Key results

Accidental extubation was the outcome measured in all five studies and was the outcome of interest in this review. Other secondary outcomes included skin trauma, tube slippage and rates of preventive re-taping. All five studies compared methods of securing the endotracheal tube that were too dissimilar for the data to be collated or included in a meta-analysis.

Quality of the evidence

The overall quality of the evidence was low. Limitations in design and implementation were evident to different degrees in all five studies. None of the studies indicated whether allocation was concealed. Due to the nature of the intervention the studies were unable to be blinded, however none of the studies indicated whether data were collected in a blinded fashion therefore conferring risks of bias. One study had a large group of neonates that were excluded from the analysis and publication bias. Conclusive results from well designed and conducted trials could help to optimise current practice.

BACKGROUND

Since the 1960s, mechanical ventilation via the endotracheal tube has significantly improved overall survival of the critically ill newborn infant and, in particular, the premature infant. For this intervention to function effectively it requires the endotracheal tube, the conduit for exchanging gases, to be sufficiently stabilised. The use of uncuffed endotracheal tubes in newborns necessitates meticulous attention to the process of securing the tube. The challenges faced by neonatal staff arise from the awkward configuration of the thin plastic tube and it being secured well enough to the skin so that its movement is minimal, but not so adherent as to cause skin trauma if the tube needs to be moved or re-secured.

Description of the condition

Poor fixation of the endotracheal tube has been reported to be the most common cause of accidental extubation (Veldman 2006). Re-intubation following unplanned extubation can expose the infant to additional pain and trauma. With each intubation attempt there is the potential risk for local trauma to the mouth and pharynx from the laryngoscope (Ahluwalia 2005) and the vocal cords and trachea from the endotracheal tube. Skin loss secondary to repeated removal of tape adhesive can lead to infection and further pain. Ideally, these complications can be avoided if the tube is well secured after the first successful intubation.

The optimal position for the lower end of the endotracheal tube in newborn infants is midway between the larynx and the carina. As this distance can be very short, there is minimal room for error. Apart from accidental extubation when the endotracheal tube is too high in the trachea, poor fixation can lead to the tube being positioned too low resulting in bronchial intubation and subsequent lung collapse or air leak.

Many methods of endotracheal tube fixation have been employed with different levels of success and risk of complications. Some of these methods include adhesive tapes (Emami 1981a), sutures (Cussel 1974), silk ties (Andrews 2007), endotracheal tube holders (Petros 1997), umbilical cord clamps (DeJonge 1998; Loughead 2008), head restraints (Bloch 1973) and bonnets (Grammatikopoulos 2003), or a combination of these techniques (Cussel 1974). The ease and success of each method can be affected by the level of skill of the nursing and medical staff.

Some infants only require a short period of ventilation, while others may need to remain intubated for many weeks. With the advent of plastic endotracheal tubes (Shann 2003), the capability for prolonged endotracheal intubation has contributed to a significant improvement in survival of newborns, especially in the preterm infant population. Reported complications of prolonged intubation include the development of pressure areas and cosmetic deformity, airway damage, subglottic stenosis, iatrogenic cleft palate (Ahluwalia 2005), palatal grooves (Macey-Dare 1999) and defective dentition (Angelos 1989).

Description of the intervention

Methods of tube stabilisation include but are not limited to adhesive tapes, sutures, silk ties, endotracheal tube holders, umbilical cord clamps or a combination of these techniques.

How the intervention might work

The ideal tube stabilisation method must be able to allow movement of the infant during care and minimise movement of the tube. It should also decrease the number of times the tube needs re-taping or adjustment as each episode of tube manipulation may increase the risk of tube dislodgement. The optimal method may also differ depending on whether the infant is nasally or orally intubated.

Why it is important to do this review

There is wide variation in the methods of endotracheal tube fixation in neonates. It would be helpful to determine the most effective way to stabilise the endotracheal tube in this population.

OBJECTIVES

To compare the different methods of securing the endotracheal tube in the ventilated neonate and their effects on the risk of accidental extubation and other potential complications that can result from an unstable endotracheal tube.

Data permitting, subgroup analyses were planned to determine whether the results differed by:

1. weight at time of randomisation (< 1000 g versus ≥ 1000 g);
2. nasal versus oral intubation.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials of any quality and some types of non-randomised trials (that is quasi-randomised trials) in intubated neonates.

Types of participants

Infants admitted to the neonatal intensive care unit who required intubation for mechanical ventilation.

Types of interventions

Studies which compared different methods of endotracheal tube fixation, which may include but not necessarily be limited to the use of adhesive tapes only, the use of sutures or ties alone or in combination with tapes, endotracheal tube holders, umbilical cord clamps, the use of head restraints, the use of bonnets that encompass the head, or any other method not included in the above.

Types of outcome measures

Primary outcomes

1. Accidental extubation (number of episodes per patient-days of intubation)
2. The need for re-intubation (number of episodes per patient-days of intubation)
3. Rate of tube malposition on x-ray (number of episodes per patient-days of intubation)

Secondary outcomes

1. Mortality (neonatal mortality and mortality during hospital admission)
2. Incidence of tube re-taping (number of episodes per patient-days of intubation)
3. Total or partial lung collapse (number of episodes per patient-days of intubation)
4. Incidence of air leak (e.g., pneumothorax, pulmonary interstitial emphysema)
5. Incidence of subglottic stenosis or post-extubation stridor
6. Incidence of perioral or facial pressure areas and skin trauma
7. Incidence of chronic lung disease (oxygen requirement at 28 postnatal days or oxygen requirement at 36 weeks postmenstrual age)
8. Duration of hospital stay (days)
9. Duration of ventilation (days and hours, or hours)
10. Duration of oxygen therapy (days and hours, or hours)
11. Incidence of an adverse neurodevelopmental outcome (e.g., cerebral palsy, sensorineural hearing loss, visual impairment, developmental delay) whenever measured in the primary studies
12. Incidence of long-term dentition problems (at 2, 5, 11 and 21 years of age)
13. Any other clinically relevant outcomes identified in individual studies

Search methods for identification of studies

Electronic searches

See: Cochrane Neonatal Review Group search strategy
The standard search strategy for the Cochrane Neonatal Review Group was used. A search of MEDLINE (from 1950 to present), CINAHL (from 1982 to present), Cochrane Central Register of Controlled Trials (CENTRAL) in *The Cochrane Library* was conducted using the following search strategy:
MeSH search terms "Infant, Newborn" OR the textwords "neonat$" or "infant$"
AND
MeSH search terms "Intubation, intratracheal" OR the textwords ("tracheal" OR "endotracheal" OR "endo-tracheal" OR "intratracheal" OR "intra-tracheal" OR "nasoendotracheal" OR "naso-endotracheal") AND ("tube" OR "intubat$")
AND
The textwords "fix$" or "tap$" or "secur$" or "stabili$"

Searching other resources

Previous reviews (including cross references) were searched. Searches were not restricted to publications in the English language or published data.

Data collection and analysis

Data were collected from the included studies and analysed where possible using the standard methods of the *Cochrane Handbook for Systematic Reviews of Interventions* (http://handbook.cochrane.org/).

Selection of studies

To assess the methodological quality of the trials we used the standard methods and criteria of the Cochrane Neonatal Review Group and the *Cochrane Handbook for Systematic Reviews of Interventions* (http://handbook.cochrane.org/).

Assessment of risk of bias in included studies

The standard method of the Cochrane Neonatal Review Group was used with authors independently assessing the risk of bias for each study using the criteria outlined in the *Cochrane Handbook*

for Systematic Reviews of Interventions (Higgins 2011). We resolved any disagreement by discussion.

The methodological quality of the studies was assessed using the following criteria.

- Sequence generation (checking for possible selection bias). For each included study, we categorized the method used to generate the allocation sequence as:

  i) low risk (any truly random process e.g., random number table, computer random number generator);
  ii) high risk (any non-random process e.g., odd or even date of birth, hospital or clinic record number);
  iii) unclear risk.

- Allocation concealment (checking for possible selection bias). For each included study, we categorized the method used to conceal the allocation sequence as:

  i) low risk (e.g., telephone or central randomisation, consecutively numbered sealed opaque envelopes);
  ii) high risk (e.g., open random allocation, unsealed or non-opaque envelopes, alternation, date of birth);
  iii) unclear risk.

- Blinding of participants and personnel (checking for performance bias). For each included study, we categorized the methods used to blind study participants and personnel from knowledge of which intervention a participant received. We categorized the methods as:

  i) low risk, high risk or unclear risk for participants;
  ii) low risk, high risk or unclear risk for personnel;
  iii) low risk, high risk or unclear risk for outcome assessors.

- Blinding of outcome assessment (checking for possible detection bias). For each included study, we categorized the methods used to blind study participants and personnel from knowledge of which intervention a participant received. Blinding was assessed separately for different outcomes or classes of outcomes. We categorized the methods as:

  i) low risk, high risk or unclear risk for participants;
  ii) low risk, high risk or unclear risk for personnel;
  iii) low risk, high risk or unclear risk for outcome assessors.

- Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations). For each included study and for each outcome, we described the completeness of the data including attrition and exclusions from the analysis. We noted whether attrition and exclusions were reported, the numbers included in the analysis at each stage (compared with the total number of randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported or supplied by the trial authors, we re-included missing data in the analyses. We categorized the methods as:

  i) low risk (< 20% missing data);
  ii) high risk (≥ 20% missing data);
  iii) unclear risk.

- Selective reporting bias. For each included study, we described how we investigated the possibility of selective outcome reporting bias and what we found. We assessed the methods as:

  i) low risk (where it was clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
  ii) high risk (where not all the study's pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest were reported incompletely and so cannot be used; study failed to include results of a key outcome that would have been expected to have been reported);
  iii) unclear risk.

- Other sources of bias. For each included study, we described any important concerns we had about other possible sources of bias (e.g., whether there was a potential source of bias related to the specific study design or whether the trial was stopped early due to some data-dependent process). We assessed whether each study was free of other problems that could put it at risk of bias, as:

  i) low risk, high risk or unclear risk.

We made explicit judgements regarding whether studies were at high risk of bias, according to the criteria given in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We assessed the likely magnitude and direction of the bias and whether we considered it likely to impact on the findings. If needed, we planned to explore the impact of the level of bias through undertaking sensitivity analyses (see 'Sensitivity analysis' below).

Measures of treatment effect

For continuous variables, weighted mean differences and 95% confidence intervals would be reported. For categorical outcomes, the relative risks and 95% confidence intervals would be reported. For significant findings, the risk difference and number needed to treat with 95% confidence intervals would be reported.

For outcomes such as counts or rates (such as the number of episodes of accidental extubation per patient-days of intubation) the data would be pooled as for continuous variables. If such methods were required, we would have used those in section 9.4.8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (http://handbook.cochrane.org/).

Dealing with missing data

We did not contact the authors of the studies for additional information or data.

Assessment of heterogeneity

The fixed-effect model would be used for meta-analysis. If there were sufficient included studies, heterogeneity would be assessed using the I^2 statistic.

Subgroup analysis and investigation of heterogeneity

If statistical heterogeneity was found, the authors looked for an explanation as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (http://handbook.cochrane.org/).

Sensitivity analysis

Data permitting, a sensitivity analysis would be used to see if results differed by quality of included studies that is, adequacy of randomisation (quasi-randomised versus randomised).

Unit of analysis

No unit of analysis issues arose. If they had arisen, we would have used the methods in section 9.3.1 of the *Cochrane Handbook for Systematic Reviews of Interventions* (http://handbook.cochrane.org/).

RESULTS

Description of studies

See: Characteristics of included studies

Performing a search through PubMed, CINAHL and CENTRAL, 342 references were identified. From the title and abstract 31 studies contained relevant material and of these four met the eligibility criteria (Brown 1988; McCann 1988; McLean 1992; Volsko 1998). The remaining studies were excluded because they were not randomised or they were retrospective or case studies. One unpublished study was found during an ad hoc, unplanned Google search (Conley 1989). A total of five studies which met the eligibility criteria were included in this review.

Brown 1988 was a prospective comparison of two taping methods with or without head restraint. There were four groups of care practices, "tape method 1 with or without head restraint and tape method 2 with or without head restraint". The tape method 1 used cloth tape over dried benzoin: "Two strips of one-inch cloth tape partially split in Y and taped to side of face, with one leg of each piece taped to tube and other leg taped to upper or lower lip". Tape method 2 used elastic tape over dried benzoin: "Elastic tape split into H, with one side taped to middle-upper lip and other side taped to tube. Next, half inch strip of pink tape was taped from skin over one zygoma down to tube, around, then back up to other side of face". The infants were also stratified by birth weight, < 1500 g or > 1500 g. Care practices were assigned randomly during the six month study. Of the 203 infants enrolled, 71 patients (35%) were not included in the analysis because of lack of head restraint, wrong taping method, nasal intubation or paralysis and sedation. After the fourth month of the study, analysis of the data showed that taping method 2 was significantly better, so only this method was used for the remaining two months and infants were randomised to receive head restraint or not. The rates of accidental extubation of the four randomised groups were calculated on a total of 142 patients.

McCann et al (McCann 1988) was a two phase study designed to compare three methods of endotracheal tube stabilization. Phase 1 randomly selected participants for one of three taping methods. Method 1 involved "HSC Tapes" (HSCT), the name given for the existing taping method of adhesive tape with string supports. Method 2 involved "HSCT plus suture", which meant a sutured strip of adhesive bandage was applied to the neonate's upper lip in a moustache fashion, then the suture was inserted vertically through both sides of the endotracheal tube and secured with HSCT. Method 3 involved "waterproof tapes plus suture", which meant the adhesive bandage was applied as described in method 2, and two pieces of waterproof tape cut in a trouser leg pattern were applied to secure the endotracheal tube. Phase 2 selected participants for two taping methods. The taping methods were method 2 and method 3 as described in Phase 1. One hundred and twenty-five patients were collected over a 10 month period, each phase lasting five months.

McLean et al (McLean 1992) conducted a study to test whether a pectin-based barrier layer used to secure endotracheal tube taping could reduce the frequency of changing tapes and skin trauma. Infants who required oral endotracheal intubation were randomly assigned to one of three groups: a control group of 27 infants for whom transparent tape (Dermiclear®) was used as a base layer to secure the endotracheal tube, an experimental group of 27 infants for whom a skin barrier (Hollihesive®) was used as a base layer, and an experimental group of 29 infants for whom a hydrocolloid dressing (Duoderm®) was used as a base layer.

Volsko et al (Volsko 1998) conducted a pilot study comparing two methods of securing an endotracheal tube with infants requiring intubation and ventilation. Infants were randomised to either a facial scaffold device (Neobar® (Neotech Products Inc.)) or conventional tape. The facial scaffold device (Neobar®) is a small plastic arch with adhesive cheek pads. The endotracheal tube was taped to the arch rather than to the patient's upper lip. No additional fixatives were used under the cheek pads. The conventional taping method required the administration of tincture of benzoin to the

area of the upper lip prior to the application of a piece of adhesive bandage (Elastoplast®). A piece of cloth tape was wrapped around the tube twice and anchored to the opposite side of the face, over the adhesive bandage (Elastoplast®). This was repeated with a second piece of tape which started at the opposite side of the face. Thirty-two infants were randomised to the facial scaffold device (Neobar®) (14) or tape (18). This study was only available in abstract form. A complete published version was not located.

Conley 1989 conducted a prospective study of infants who required mechanical ventilation. Infants were randomly assigned (by coin toss) to the experimental and control groups. The sample consisted of 30 preterm infants aged at least 27 weeks gestation (born or corrected) who required mechanical ventilation. Infants who were less than 27 weeks, paralysed, or who were intubated for less than six days were excluded from the study. The experimental group used an endotracheal tube holder, a product of Respiratory Support Products, Inc. of California, which consists of a slip lock, a cylinder and a holder. The endotracheal tube was held in position within the cylinder by the slip lock which secured it. The holder has an adhesive surface which is applied to the patient's face. The control group had their endotracheal tubes secured with Dermiclear tape as a base layer and two strips of cloth tape split in a Y. The inferior arm of the Y of the first cloth tape was wrapped clockwise around the tube and the second was wrapped counterclockwise around the tube.

Risk of bias in included studies

All of the included studies randomised the individual patient. It was not stated how the random sequence lists were generated and whether randomisation lists were concealed in all studies except one (Conley 1989). Treatment could not be blinded due to the nature of the study. All patients were accounted for in two studies (McCann 1988; McLean 1992). Brown 1988 had a large exclusion list (after randomisation, due to various reasons including inconsistency in intervention methods provided). Conley 1989 reported that nine additional participants were enrolled in the traditional taping group but were extubated early and analysis was not by intention to treat. It was not stated in any of the five studies whether the groups were treated equally apart from the interventions. The treatment groups appeared similar at the start of the trial in McLean 1992 and Conley 1989, but it was unclear whether this was the case in Brown 1988, McCann 1988 or Volsko 1998. The methodological quality of McCann et al (McCann 1988), Volsko et al (Volsko 1998), McLean et al (McLean 1992) and Conley (Conley 1989) was average. The methodological quality of Brown (Brown 1988) was poor.

Effects of interventions

The results of the five included studies in this review could not be meta-analysed because the studies were too heterogeneous and the methods of securing the endotracheal tube were different between studies. The following are the results of individual studies.

Primary outcomes

Accidental extubation

Brown (Brown 1988) reported an overall accidental extubation rate of 4.4 per 100 days of intubation, and 4.2 per 100 days when results were calculated excluding patients with poor compliance to the protocol. Two different taping methods were compared, with and without head restraint. Tape method 1 used cloth tape over dried benzoin: "Two strips of one-inch cloth tape partially split in Y and taped to side of face, with one leg of each piece taped to tube and other leg taped to upper or lower lip". Tape method 2 used elastic tape over dried benzoin: "Elastic tape split into H, with one side taped to middle-upper lip and other side taped to tube. Next, half inch strip of pink tape was taped from skin over one zygoma down to tube, around, then back up to other side of face". Taping method 1 had a rate of 6.4 and 6.7 extubation episodes per 100 intubation days with or without head restraint, respectively. In comparison, taping method 2 had a rate of 2.6 and 2.5 extubation episodes per 100 intubation days with or without head restraint, respectively. There was no difference in extubation rate between infants with a head restraint and those without. A statistically significant difference ($P < 0.001$) was found between taping method 1 versus 2 with no head restraint, and for taping method 1 versus 2 with head restraint ($P < 0.03$).

McCann (McCann 1988) reported, in Phase 1 of the study, the accidental extubation rates for the three methods: method 1 had 11 accidental extubations per 100 tube days, whereas method 2 and method 3 both had four accidental extubations per 100 tube days. The overall rate of accidental extubation decreased during the study period when compared to accidental extubation rates prior to the study. In Phase 1, the overall rate of accidental extubation decreased by 15%. In Phase 2, the overall rate of accidental extubation decreased by 50%.

Volsko et al (Volsko 1998) reported an extubation rate of 4.8 per 100 ventilation days for the facial scaffold device (Neobar®) method compared with 15.6 per 100 ventilation days for the tape method. There was no significant difference in extubations per 100 ventilator days between the two interventions.

McLean et al (McLean 1992) reported no statistically significant difference in the number of self-extubations among the intervention groups. It was unclear whether the rate was calculated per 100 ventilation days.

Conley (Conley 1989) observed the number of accidental extubations in a six day study period. There were 12 accidental extubations in the traditional taping method group compared to one

accidental extubation in the endotracheal tube holder group, a statistically significant difference (P = 0.0082). Thus the extubation rate for the traditional taping group was 200 extubations per 100 ventilation days compared to the 16.7 accidental extubations per 100 ventilation days in the tube holder group.

The need for re-intubation

No study reported this.

Rate of tube malposition on x-ray

No study reported this.

Secondary outcomes

Mortality

Brown et al (Brown 1988) reported a 16.3% mortality rate in those intubated and randomised, however there was a 35% exclusion rate and it was unclear how many of those who died were in this group.
Conley 1989 reported that one infant died in each group, one from peritoneal perforation in the tube holder group and the other from cardiorespiratory failure in the traditional taping group. It was not reported if these deaths were related to an accidental extubation.
No other studies in this review reported on mortality.

Degree of tube slippage (added post hoc)

Conley 1989 reported significantly more endotracheal tube slippage in the traditional taping method compared to the endotracheal tube holder (P = 0.044).

Incidence of tube re-taping

Conley 1989 reported no significant differences between groups regarding the frequency of re-stabilization of the endotracheal tube.
McCann 1988 reported a prophylactic re-taping rate < 1% for all three methods described.
McLean 1992 reported that the rate of stabilization layer changes in the hydrocolloid dressing (Duoderm®) group of 9.79/29 was statistically significantly less than the skin barrier (Hollihesive®) group's rate of 13.67/27 and the transparent tape (Dermiclear®) group's rate of 11.7/27.

Total or partial lung collapse

No study reported this.

Incidence of air leak

No study reported this.

Incidence of subglottic stenosis or post-extubation stridor

No study reported this.

Incidence of perioral or facial pressure areas and skin trauma

Brown (Brown 1988) reported no difference in skin abrasion between the two different taping methods.
Volsko et al (Volsko 1998) reported that the facial scaffold device (Neobar®) was superior to tape in the categories of skin condition.
McLean et al (McLean 1992) reported no difference in lip intactness and lip colour for the different base layers.

Incidence of chronic lung disease

No study reported this.

Duration of hospital stay

No study reported this.

Duration of ventilation

No study reported this.

Duration of oxygen therapy

No study reported this.

Incidence of an adverse neurodevelopmental outcome

No study reported this.

Incidence of long-term dentition problems

No study reported this.

Other clinically relevant outcomes identified in individual studies

Volsko et al (Volsko 1998) reported that the facial scaffold device (Neobar®) was superior to tape in the ease of verifying endotracheal placement.

Subgroups

Weight at time of randomisation (< 1000 g versus ≥ 1000 g)

No studies stratified for < 1000 g versus ≥ 1000 g. However, Brown 1988 stratified the infants by birthweight < 1500 g and > 1500 g and care was assigned randomly for each of the two weight groups. Twenty-eight (23%) of the 122 infants with a birthweight > 1500 g had accidental extubations, while 34 (42%) of the 81 infants with a birthweight < 1500 g had accidental extubations.

Nasal versus oral intubation

No study analysed this.

DISCUSSION

Summary of main results

The diversity in endotracheal stabilizing techniques that were compared in the five included studies precluded collation of the data for meta-analysis. Three out of the five studies included in this review appeared to be significantly underpowered, however this is not surprising given each of the three studies did not have a sample size calculation. McCann 1988 recruited a larger number of participants but it was unclear as to whether the decrease in accidental extubations between fixation methods was statistically significant due to poor reporting. Brown 1988 recruited a larger number of participants and did show a statistically significant difference between taping method 1 versus method 2 ($P < 0.001$) without head restraint and with head restraint ($P < 0.03$). However, the large group (35%) excluded from the results and lack of intention-to-treat analysis confers a serious analytical and reporting bias, rendering the results questionable. Conley 1989 found a statistically significant difference in accidental extubation between the control and tube holder groups ($P = 0.0082$); the extubation rate for the traditional taping group is 200 extubations per 100 ventilation days compared to the 16.7 accidental extubations per 100 ventilation in the tube holder group. However, as reported in the methodology, nine enrolled participants were excluded from the analysis because they were extubated prior to completing the six days required for study inclusion, decidedly raising questions about the study validity.

Quality of the evidence

Overall, the studies were of poor quality, underpowered, poorly reported or contained serious risks of bias. More well designed randomised controlled trials with a larger number of participants are required.

Potential biases in the review process

There were no potential biases in the review process.

Future studies

Given the lack of reliable evidence to support the use of one particular method over any other it would seem prudent for individual neonatal units to use the quality improvement cycle for clinical problem solving through evidence generation, synthesis, implementation, and evaluation (Henderson-Smart 2003). This would aid the identification and clarification of the best technique for use in their own unit. There would then be potential for comparing this method to any new proposed methods in a randomised controlled trial.

AUTHORS' CONCLUSIONS

Implications for practice

There is insufficient evidence to indicate that one particular method of securing endotracheal tubes compared to other methods results in fewer accidental extubations in intubated infants. The authors chose not to combine the results of the individual trials because of the heterogeneity of the interventions and the poor quality of the studies. In the absence of evidence from randomised controlled trials, individual units could apply the methods of quality improvement to identify the best technique for their own setting.

Implications for research

Relevant studies performed to date are few. One of the reasons that the practice for tube fixation is so variable from site to site is because randomised controlled trials of good quality have not been done. Therefore, more randomised controlled trials that are of adequate power and better quality, using comparable methods of securing the endotracheal tube (where one method is perceived to be advantageous to the other) in intubated neonates, are required for study results to be integrated and clinically useful.

ACKNOWLEDGEMENTS

Those who assisted in locating some the studies from document delivery.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Brown 1988

Methods	Prospective comparison. Taping methods were "assigned randomly on admission" for 2 weight groups (<1500g or >1500g) and continued until intentional extubation, death or 28 days postnatal age. Patients were excluded if (for over half the time they were intubated): (1) the incorrect protocol was being used, (2) they were nasally intubated, (3) they were paralysed or (3) they were sedated. 35% were excluded from analysis for these reasons. After 4 months, data analysis revealed that taping method 2 was better, so for the remaining two months only taping method 2 was used and infants were randomised to receive either head restraint or not
Participants	Infants who were admitted to the centre and required oral endotracheal intubation during a 6 month period
Interventions	Four groups of care practices. Two interventions using different taping methods and tape material. Group separated into 2, depending on whether head restraint was added or not. Tape method 1, with (n=22) or without head restraint (n=36) and tape method 2 with (n=31) or without head restraint (n=53)
Outcomes	Accidental extubation rates per 100 patient days of intubation Accidental extubation rates as affected by the length of intubation by Poisson regression analysis Pre-extubation activities most likely to cause accidental extubation
Notes	Infants were stratified by birthweight (<1500g or >1500g)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not stated how the random sequence was generated. Taping methods were "assigned randomly on admission"
Allocation concealment (selection bias)	Unclear risk	Not stated in the methods whether allocation was concealed
Blinding of participants and personnel (performance bias) All outcomes	High risk	Treatment could not be blinded due to the nature of the study
Blinding of outcome assessment (detection bias) All outcomes	High risk	Accidental extubations were picked up from the bedside chart and/or extubation logs. The nurse entering the events into the charts or logs could not be blinded due to the nature of the study. Not stated in the

Brown 1988 (*Continued*)

		methods whether outcome assessment of the charts or logs were blinded
Incomplete outcome data (attrition bias) All outcomes	High risk	Analysis was not intention to treat. There was a large exclusion rate which affected the overall results
Selective reporting (reporting bias)	High risk	The tables included in the study summarising the results excluded 35% of infants' results because the research protocol was not followed correctly in these infants
Other bias	Unclear risk	35% of infants randomised were excluded due to various reasons including inconsistency in care methods provided. It was not stated whether the treatment group was similar at the start of the trial. It was not stated whether treatment groups were treated equally apart from the intervention. The study was interrupted early because method 2 was thought to be a better method and for the last two months of the study, only method 2 was used to tape the endotracheal tubes. The results included data to suggest there was a large variation in gestational ages and weights

Conley 1989

Methods	Subjects were randomly assigned (coin toss) to experimental and control groups. A stabilization method was implemented in the experimental group and the more traditional method of stabilizing an endotracheal tube was performed on the control group
Participants	Thirty preterm infants at least 27 weeks gestation who required mechanical ventilation. Exclusion criteria used included infants medicated with pancuronium bromide (or similar paralysing drugs), infants less than 27 weeks gestation and infants intubated for less than 6 days
Interventions	The intervention was the stabilization method employed for subjects in the experimental group. The stabilization device consisted of a slip lock, a cylinder and a holder. The endotracheal tube was held in position within the cylinder by the slip lock which secured it. The holder had a sticky surface that adhered to the baby's face
Outcomes	The rate of accidental extubation, the number of re-stabilizations required to maintain endotracheal tube stability and the amount of endotracheal tube slippage
Notes	The groups were similar at the start of the trial

Conley 1989 (*Continued*)

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	The random sequence was generated by the toss of a coin
Allocation concealment (selection bias)	Unclear risk	It was not stated whether allocation was concealed
Blinding of participants and personnel (performance bias) All outcomes	High risk	Treatment could not be blinded due to the nature of the study
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessments could not be blinded due to the nature of the study. Data were collected and recorded by the subject's bedside nurse. This included the number of re-stabilizations required to maintain endotracheal tube stability, the reason each re-stabilization was necessary, the approximate time required to reapply the method of stabilization, the number of extubations exhibited and the cause of extubation
Incomplete outcome data (attrition bias) All outcomes	High risk	It was stated in the methods that an additional 9 subjects "were enrolled in the study but were subsequently dropped when each extubated prior to the completion of the 6 day study period. One female subject was dropped from the study as a result of mortality prior to the completion of the 6 day study period"
Selective reporting (reporting bias)	Unclear risk	See above "incomplete outcome data entry"
Other bias	Unclear risk	It was not stated whether the groups were treated equally apart from the intervention

McCann 1988

Methods	A 2 phase study design. Three methods of endotracheal tube stabilization were compared. Phase 1 randomly selected subjects for one of 3 taping methods. Method 1 involved "HSC Tapes" (HSCT = Hospital for Sick Children Tapes), the name given for the existing taping method of adhesive tape with string supports. Method 2 involved "HSCT plus suture" which meant a sutured strip of adhesive bandage was applied to the neonates upper lip in a moustache fashion, then the suture was inserted vertically through both sides of the endotracheal tube and secured with HSCT. Method 3 involved "waterproof tapes plus suture" which meant the adhesive bandage was applied as described in method 2, and 2 pieces of waterproof tape cut in a trouser leg pattern were applied to secure the endotracheal tube. Phase 2 selected subjects for 2 taping methods. The taping methods were Method 2 and Method 3 as described in Phase 1. Patients were recruited over a 10 month period, each phase lasting 5 months each
Participants	"The convenience sample of one hundred and twenty-five patients represented a characteristic population in a sixty bed tertiary referral NICU"
Interventions	All 3 methods used naso-endotracheal tubes. Waterproof tapes with suture method consisted of tincture of benzoin on the infants upper lip and cheeks, and applying pre-sutured adhesive dressing in moustache fashion. Silk suture was inserted vertically through both sides of the endotracheal tube (ETT) and some length was left. A knot was tied proximal to nares and distal to nares. Waterproof tape in trouser leg pattern was used with the bottom leg of waterproof tape on top of moustache adhesive dressing. The upper leg was wrapped around the ETT in clockwise fashion. A second piece of waterproof tape was used and the upper leg was wrapped around the ETT in counter-clockwise fashion
Outcomes	Rates of accidental extubation of the 3 methods Difference in rates of accidental extubation over the different study phases Nursing perception of factors which contributed to accidental extubations
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not stated how the random sequence was generated
Allocation concealment (selection bias)	Unclear risk	Not stated whether the allocation list was sealed
Blinding of participants and personnel (performance bias) All outcomes	High risk	Treatment could not be blinded due to the nature of the study
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated whether the assessment of the outcomes were blinded

McCann 1988 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Data were collected on all intubated neonates
Selective reporting (reporting bias)	Unclear risk	Not stated whether all results were reported
Other bias	Unclear risk	Not stated whether the groups were similar at the start of the trial. Not stated whether the groups were treated equally apart from the intervention

McLean 1992

Methods	"The 83 infants who participated in the study were randomly assigned to one of three groups". One control group and 2 experimental groups. Iniital demographic data were collected on each infant upon entry into the study. Information included date of birth, gestational age, birth weight and present weight, diagnosis and overall skin condition. The nursing staff kept a record of the date, time and reasons for each tape change, whether base and/or stabilisation layers were changed, and the condition and colour of the skin under the base layer. This information was recorded on a tape change record at the bedside
Participants	Infants requiring initial oral endotracheal intubation following admission to the NICU were eligible. Infants remained in the study until extubation or death. Infants with a primary diagnosis of respiratory distress regardless of etiology were included. Infants with primary or subsequent diagnoses of congenital anomalies or genetic defects were excluded to avoid difficulties with facial assessment
Interventions	Control group used transparent tape (Dermiclear®) as a base layer (layers on the infant's skin upon which stabilization tapes are placed) and 2 experimental groups were a skin barrier (Hollihesive®) and a hydrocolloid dressing (Duoderm®). The transparent tape (Dermiclear®) was cut into moustache-shaped strips to fit the infant's upper lip and cheek. The two pectin-based barriers (Hollihesive® and Duoderm®) were cut into moustache-shaped strips and sized according to the infant's weight
Outcomes	Episodes of stabilization layer changes, self extubation and lip trauma
Notes	"The validity of prior informed consent of parent(s) undergoing the stress and crisis of premature birth has been questioned. For this reason, informed parental consent to enrol the infant was waived in favour of consent of a patient advocate or ombudsman (in this case the chief resident in the NICU or the NICU charge nurse). The University of Utah Health Sciences Institutional Review Board approved the study and the modification of the consent procedure. Parents were advised of their infant's participation in the study along with any additional appropriate information at the earliest opportunity. Parents were able to withdraw the infant at any time if they desired; one infant was withdrawn."

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

McLean 1992 (*Continued*)

Random sequence generation (selection bias)	Unclear risk	Not stated how the random sequence was generated
Allocation concealment (selection bias)	Unclear risk	Not stated whether the allocation list was concealed
Blinding of participants and personnel (performance bias) All outcomes	High risk	Treatment could not be blinded due to the nature of the study
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated whether the outcome assessor was blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	All patients were accounted for
Selective reporting (reporting bias)	Unclear risk	Not stated whether all results were reported
Other bias	Unclear risk	Not stated whether the groups were treated equally apart from the intervention. The groups were similar at the start of the trial

Volsko 1998

Methods	Pilot study, randomised. Compared the facial scaffold device (Neobar® (Neotech Products Inc.)), a small device with a plastic arch and adhesive cheek pads, to a conventional taping method using tincture of benzoin, adhesive bandage (Elastoplast®) and cloth tape
Participants	Infants from a Level III NICU requiring intubation and mechanical ventilation. Infants with limb restraints, sedation or paralytic drugs that inhibited activity, along with those who had neurological impairment that prevented purposeful movement, and/or those whose positive pressure ventilation requirements were less than one day (24 ± 1 hours) or greater than 30 days were excluded from the study
Interventions	Facial scaffold device (Neobar®) versus conventional taping. The hydrogel adhesive on the cheek pads of the facial scaffold device (Neobar®) was applied to dry skin without additional fixatives. A piece of adhesive tape was used to secure the endotracheal tube to a vertical bar on the arch. The conventional taping method required the application of tincture of benzoin to the area of the upper lip prior to the application of a piece of adhesive bandage (Elastoplast®). One piece of cloth tape, approximately five inches long was applied to the endotracheal tube by wrapping it around the tube twice and anchoring it to the opposite side of the face, over the adhesive bandage (Elastoplast®). This procedure was repeated with a second piece of tape, which started at the opposite side of the face

Volsko 1998 (*Continued*)

Outcomes	Accidental extubations per 100 ventilator days Survey of skin condition Ease of verifying endotracheal tube placement
Notes	The study information was in abstract form only. No full version of the study was identified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not stated how the random sequence was generated
Allocation concealment (selection bias)	Unclear risk	Not stated whether randomisation list was concealed
Blinding of participants and personnel (performance bias) All outcomes	High risk	Treatment could not be blinded due to the nature of the study
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated whether the outcome assessor was blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not stated whether all enrolled in the study were accounted for at the end of the trial
Selective reporting (reporting bias)	Unclear risk	Not stated whether all results were reported at the end of the trial
Other bias	Unclear risk	Unclear as to whether the groups were similar at the start of the trial

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Agarwal 2005	A description of a method used to stabilize the endotracheal tube during taping. Not a randomised controlled trial
Andrews 2007	A review of different methods of securing an endotracheal tube. Not randomised
Ash 1987	The study investigated the effect of prolonged orotracheal intubation with and without the presence of a protective appliance to the palate. Non-intubated babies formed the control group. By random selection, half of the babies who required orotracheal intubation were fitted with appliances throughout

(*Continued*)

	the intubation period. The appliance supported the orotracheal tube
Brinsmead 2010	Retrospective study which compared two cohorts of intubated neonates. Each cohort used a different taping method which allowed comparison of endotracheal tube tip position on chest x-ray
Conner 1977	Retrospective study of endotracheal intubation of neonates in the newborn intensive care unit
DeJonge 1998	Retrospective study comparing two cohorts which used 2 different methods of securing the endotracheal tube
Dynott 1999	A letter to the editor
Emami 1981b	Retrospective comparison of 2 different taping methods
Epstein 1970	A description of a method used to secure a nasotracheal tube
Fadavi 1990	The study primarily looked at a palatal stabilizing device to prevent palatal grooves in premature infants who required orotracheal intubation. This stabilizing device supported or was secured to the endotracheal tube. Infants were randomised to control and experimental groups. The degree of palatal groove depth was measured
Gagnon 1996	A letter to the editor
Grammatikopoulos 2003	Case reports of iatrogenic ear deformities as a result of endotracheal tube fixation
Hemingway 1997	A description of a method used to secure endotracheal tubes
Heyman 2009	A letter to the editor
Infantino 2011	Retrospective review comparing 2 different methods of securing an endotracheal tube
Loughead 2008	Retrospective study of infants requiring endotracheal intubation for mechanical ventilation. Two different methods were more closely analysed
Molho 1975	A description of a method used to secure an endotracheal tube
Pai 2003	A postscript comment about endotracheal tube fixation
Petros 1997	A description of a new disposable system for tracheal tube fixation in children
Seaver 1984	A description of a method to secure endotracheal tubes
Srivatsa 1991	A description of a method to secure endotracheal tubes
Testa 2012	A retrospective study on palatal stabilizing devices and their effect on accidental extubation
Toomey 2011	A comparison of three methods of endotracheal tube stabilization. Not randomised

(*Continued*)

Van Deventer 1995	A description of a method used to secure endotracheal tubes
Volsko 1997	Comparison of two methods for securing the endotracheal tube. Not randomised

DATA AND ANALYSES

This review has no analyses.

CONTRIBUTIONS OF AUTHORS

Preparation of protocol - GDTI and MML

Revision of protocol - GDTI, MWD, KH and LAJ

Revision of review - GDTI and MWD

Preparation of review - MML

DECLARATIONS OF INTEREST

None

SOURCES OF SUPPORT

Internal sources

- Grantley Stable Neonatal Unit, Royal Brisbane and Women's Hospital, Brisbane, Australia.
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External sources

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The outcome "Degree of tube slippage" was added post hoc to the secondary outcomes as there was a significant difference in this parameter in one study.

The methods of assessment of risk bias were updated according to the Cochrane Collaboration guidelines.

No attempt was made to contact authors for additional information or data.

NOTES

None

INDEX TERMS

Medical Subject Headings (MeSH)

Equipment Safety; Infant, Premature; Intensive Care, Neonatal [methods]; Intubation, Intratracheal [adverse effects; *instrumentation; methods]; Randomized Controlled Trials as Topic; Respiration, Artificial [instrumentation; methods]

MeSH check words

Humans; Infant, Newborn