Effects of non-invasive ventilation on reintubation rate: a systematic review and meta-analysis of randomised studies of patients undergoing cardiothoracic surgery

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ABSTRACT

Objective: To estimate the effect of non-invasive mechanical ventilation (NIV) on the rate of reintubation among patients undergoing cardiothoracic surgery.

Design: A meta-analysis of randomised trials.

Data sources: Medline, Embase, and the Cochrane Central Register of clinical trials were searched (April 2012) for pertinent studies by two trained investigators. International experts were contacted.

Data extraction: Articles were assessed by two trained investigators, with divergences resolved by consensus. Inclusion criterion was random allocation to NIV versus standard treatment without restrictions on duration or modalities of the treatment delivered.

Data synthesis: Fourteen studies enrolling 1211 patients were included in the meta-analysis. NIV reduced the reintubation rate (risk ratio [RR], 0.29; 95% CI, 0.16–0.53; P for efficacy < 0.0001; $I^2 = 0$), hospital length of stay and mortality. Subgroup analyses suggested that the benefits of NIV are more important in patients with ongoing acute respiratory failure (RR, 0.25; 95% CI, 0.07–0.89) and in those at high risk of developing postoperative pulmonary complications (RR, 0.19; 95% CI, 0.04–0.84). Analyses including prophylactic studies in patients at low risk did not show a significant effect of NIV on reintubation rate (RR = 0.42; 95% CI, 0.12–1.48) and on any of the outcomes considered except for oxygenation.

Conclusions: NIV seems to be effective in reducing reintubation rate after cardiothoracic surgery. The results of this meta-analysis should be confirmed by large randomised controlled studies.

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During cardiac and thoracic surgery, perioperative and postoperative factors contribute to the development of postoperative pulmonary complications (PPC).[1,2] The decrease of end-expiratory volume induced by general anaesthesia, pleural opening and supine posture contributes to atelectasis development. Atelectasis is a major cause of postoperative hypoxaemia and increases the risk of pneumonia occurring in 3%–6% of patients undergoing cardiac and lung resection surgery.[1,2] Cardiopulmonary bypass and one-lung ventilation can lead to acute lung injury and acute respiratory distress syndrome in 1%–2% of patients after cardiac[1] and thoracic surgery.[2] Cardiothoracic surgery may impair respiratory muscle strength by different mechanisms including phrenic nerve dysfunction, surgical incision of the chest or abdominal walls, anaesthetics and postoperative pain.

Risk factors that increase the incidence of PPC are older age, smoking, obesity and chronic obstructive pulmonary disease.[1,2] The risk of PPC also increases with the extent of surgery, the greatest risk being with major open procedures and thoracoabdominal surgery.[3]

Most of these postoperative modifications of respiratory function resolve within a few days through early mobilisation, but in some patients acute respiratory failure (ARF) may occur. Reported incidence of ARF is 12% in thoracic and 11% in cardiac surgery.[4,5] ARF may lead to endotracheal reintubation, thus increasing hospital length of stay and mortality.[5] One way to overcome alveolar collapse and respiratory muscle weakness is to raise lung volumes using non-invasive mechanical ventilation (NIV). NIV is a mechanical ventilation modality that does not require endotracheal intubation and, compared with invasive ventilation, improves patients' level of comfort and reduces the nosocomial infection rate.[6] NIV is a well recognised, effective treatment that reduces intubation and mortality among patients with ARF due to exacerbation of chronic obstructive pulmonary disease, patients with cardiogenic pulmonary oedema, and immunocompromised patients with acute lung injury.[7] In patients with hypoxaemic ARF due to pneumonia or severe acute respiratory distress syndrome, NIV is less recommended because of the high rate of failure observed.[7] In the past decades, the use of NIV to prevent and treat PPC and postoperative ARF has increased.[8] Recent reviews[9,10] concluded that the application of postoperative NIV could be considered a promising prophylactic and therapeutic tool to improve patient outcomes after major surgery. A meta-analysis reported that after abdominal surgery the use of

continuous positive airway pressure (CPAP) can reduce the risk of PPC, pneumonia and atelectasis.[11]

We recently reviewed randomised trials of the use of NIV in cardiothoracic surgery.[12] To determine whether use of NIV among patients undergoing cardiothoracic surgery is associated with a lower rate of reintubation compared with conventional respiratory care, we undertook the systematic review and meta-analysis of randomised trials described here.

Methods

Search strategy

Medline, Embase and the Cochrane Central Register of clinical trials (CENTRAL) were independently searched by two trained investigators. All searches were updated to April 2012. The full search strategy is available in the Appendix; we aimed to include any randomised study ever performed with NIV in any cardiothoracic surgery setting.

In addition, we employed backward snowballing (scanning of references of retrieved articles and pertinent reviews) and contacted international experts for further studies. No language restriction was enforced.

Study selection

References obtained from database and literature searches were first independently examined at the title and abstract level by two investigators, with divergences resolved by consensus, and then, if potentially pertinent, complete articles were retrieved. The following inclusion criteria were used for potentially relevant studies: randomised controlled trials (RCTs); cardiac or thoracic surgery (including all thoracotomies for non-cardiac surgery, for example, oesophagectomy); allocation to NIV versus conventional respiratory care (oxygen, medications, chest physiotherapy, early mobilisation) without restrictions on duration or modalities of the treatment delivered.

NIV commonly includes the administration of CPAP or pressure support ventilation to support the inspiratory phase. The exclusion criteria were: duplicate publication, non-adult studies, lack of data. Two investigators independently assessed compliance to selection criteria and selected studies for the final analysis, and divergences were finally resolved by consensus.

Data abstraction and study characteristics

Baseline, procedural and outcome data were independently abstracted by two trained investigators, and divergences were resolved by consensus. Potential sources of significant clinical heterogeneity have been specified, such as study design, characteristics of patients, sample size, clinical setting, duration of NIV treatment as well as primary study end points and other key outcomes. If a trial reported multiple comparisons, the control group was considered as a whole. Corresponding authors were contacted at least twice to request missing data.

We divided the studies into three categories: a) prophylactic treatment in patients at low risk of developing PPC (studies including patients without reported risk factors such as preoperative pulmonary disease, obesity and older age);[1,2] b) prophylactic treatment in patients at high risk of developing PPC (studies including patients with reported risk factors and/or who had undergone major open procedures[3]); c) curative treatment in patients with ongoing ARF (patients with altered gas exchanges and tachypnoea, as defined by the authors).

The primary end point of our review was reintubation rate. The secondary outcomes were hospital length of stay, mortality rate, prevalence of pneumonia and atelectasis, and oxygenation (PaO_2/FiO_2; difference between post-extubation and post-treatment values).

Internal validity and risk of bias assessment

The internal validity and risk of bias of included trials was appraised by two independent reviewers according to Cochrane Collaboration methods[13] with divergences resolved by consensus.

Statistical analysis

Computations were performed with RevMan 5.1 (freeware available from The Cochrane Collaboration).[14] The hypothesis of statistical heterogeneity was tested by means of the Cochran Q test, with statistical significance set at the two-tailed 0.10 level, whereas extent of statistical consistency was measured with I^2, defined as $100\% \times (Q - df)/Q$, where Q is Cochran's heterogeneity statistic and df the degrees of freedom. Binary outcomes from individual studies were analysed to calculate individual and pooled risk ratios (RR, with equivalence set at 1, $RR < 1$ favouring the NIV treatment, and $RR > 1$ favouring standard care) with 95% confidence intervals, by means of the inverse variance method and using a fixed-effects model in case of low statistical inconsistency ($I^2 \leqslant 25\%$) or a random-effects model (which better accommodates clinical and statistical variations) in case of moderate or high statistical inconsistency ($I^2 > 25\%$). To explore the utility of NIV as a prophylactic or therapeutic tool we also analysed data according to the following subgroups: studies delivering NIV as a prophylactic tool in patients at low risk of developing PPC, studies delivering NIV as a prophylactic tool in patients at high risk of developing PPC, studies delivering NIV as a curative tool in patients with ongoing ARF.

Furthermore, to explore the effect of study quality and dose response on the overall estimate of treatment effect, we performed sensitivity analyses according to the reporting or

not of randomisation, allocation concealment, blinding and duration of NIV treatment (less v more than 5 hours per day).

Weighted mean differences and 95% CIs were computed for continuous variables as previously described.[13]

Funnel plots were drawn to investigate any relationship between effect size and study precision (closely related to sample size).[15,16]

Statistical significance was set at the two-tailed 0.05 level for hypothesis testing. Unadjusted *P* values are reported throughout. The reporting of this review is according to the PRISMA statement.[17]

Results

Twenty-three studies were initially retrieved (Figure 1); among these, nine studies did not meet the inclusion criteria.[18-26] A total of 14 studies were finally identified for inclusion in the review.[27-40] No unpublished studies were found.

Characteristics of included studies

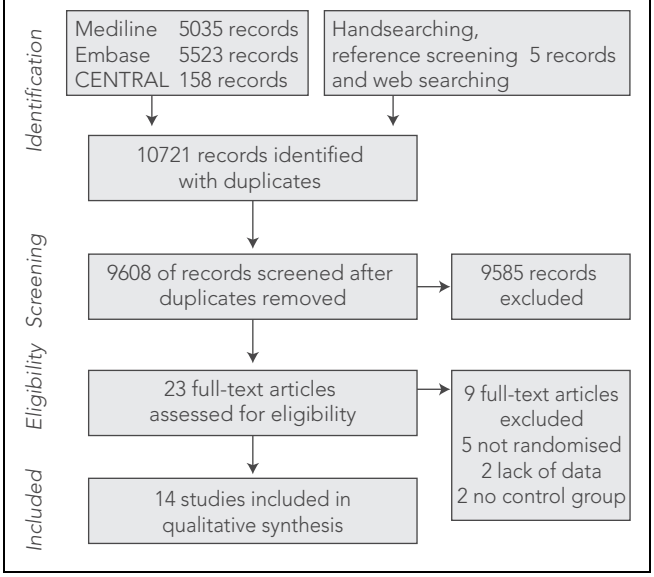
The included studies involved 1211 participants (614 allocated at random to receive NIV and 597 to control groups) (Table 1). There was no multicentre study. Six studies used only CPAP,[27-29,33,34,39] seven studies used only pressure support ventilation[30,32,35-38,40] and one study used both.[31]

In the included studies, the interfaces used for application of NIV were nasal as well as oro-nasal masks. Two studies[32,35] out of 14 used NIV as a treatment for ARF, whereas others used NIV as a preventive tool. Three studies[33,34,36] enrolled patients at high risk of developing PPC: Fagevick-Olsen et al[33] and Kindgen-Milles et al[34] evaluated NIV efficacy after thoracoabdominal surgery, Perrin et al[36] included patients with preoperative pulmonary function impairment (FEV1 < 70% of predicted). The remaining studies employed prophylactic NIV in low-risk patients. Eleven studies took place in an ICU, while two studies[27,40] did not clearly state the setting. In one study, NIV was started 7 days before surgery[34] and continued in the ICU after surgery. Nine studies out of 14 applied NIV only during the first postoperative day. Two studies, investigating only oxygenation, had an extremely short duration of NIV treatment (no more than 1 hour)[30,38] while all the others had an NIV duration of at least 4 hours a day.

Risk of bias

On average, the quality of trials was moderate to low. Only half reported an appropriate method of randomisation, and a minority reported allocation concealment. Most trials included blinding of data collectors. Only a few trials followed up patients adequately and reported and analysed data according to the intention-to-treat principle (Table 2). The funnel plot of the primary outcome (Figure 2) was not suggestive of publication bias.

Figure 1. Flow diagram showing selection of articles



Quantitative data synthesis

Reintubation rate was available for eight trials that included 854 patients. In the pooled analysis, NIV was associated with a significantly reduced reintubation rate (RR, 0.29; 95% CI, 0.16–0.53; *P* for efficacy, < 0.0001; $I^2 = 0$) (Figure 3).

NIV was also shown to be effective in reducing hospital length of stay and mortality, and in improving oxygenation (Table 3).

Subgroup analyses suggested that the benefit of the therapy in reducing reintubation is mostly attributable to including patients at high risk of developing PPC (RR, 0.19; 95% CI, 0.04–0.84) and patients with ongoing ARF (RR, 0.25; 95% CI, 0.07–0.89). Analyses including prophylactic studies in patients at low risk did not show a significant effect of NIV on reintubation rate (RR, 0.42; 95% CI, 0.12–1.48) and on any of the outcomes considered except for oxygenation.

Sensitivity analyses showed that study quality and amount of treatment did not change the overall estimation of the effect of NIV on reintubation rates.

Discussion

Our comprehensive search identified 14 RCTs including 1211 participants in total. Most importantly, our meta-analysis suggested that NIV after cardiothoracic surgery was associated with a reduction in the primary end point — reintubation rate — and the funnel plot for reintubation rate excluded small publication bias. NIV was also associated with reduced hospital length of stay and mortality, and an improvement in oxygenation.

Severe PPC such as large atelectasis, pneumonia, acute respiratory distress syndrome and diaphragmatic paralysis

Table 1. Characteristics of studies

Study (first author, year)	Type of surgery	Sample size: NIV patients	Sample size: Control	Type of Intervention	Characteristics of treatment: Type of NIV, pressure (cmH_2O): CPAP	Characteristics of treatment: Type of NIV, pressure (cmH_2O): PS (PEEP+PS)	Mean hours per day	Cycles	No. of days	Characteristics of CRC
Stock 1984[27]	Cardiac	13	25	CPAP v CRC	7, 5		3	1 h cycles	3	Cough, DB, IS
Pinilla 1990[28]	Cardiac	32	26	CPAP v CRC	5–7, 5		12	1 cycle	1	nr
Jousela 1994[29]	Cardiac	15	15	CPAP v CRC	10		8	1 cycle	1	nr
Aguiló 1997[30]	Pulmonary	10	9	PS v CRC		5 + 10	1	1 cycle	1	None
Matte 2000[31]	Cardiac	62	28	CPAP + CRC v PS + CRC v CRC	5	5 + 7	6	1 h cycles	1	Cough, mobilisation, IS, aerosol therapy
Auriant 2001[32]	Pulmonary	24	24	PS v CRC		4 + 12	14	2 h cycles	2	Oxygen, aerosol therapy
Fagevick Olsén 2002[33]	Thoraco-abdominal	34	36	CPAP v CRC	5–10		4, 5	30 min cycles	3	Cough, IR-PEP
Kindgen-Milles 2005[34]	Thoraco-abdominal	25	25	CPAP v CRC	10		12–24	1 cycle	1	Manual vibration, mobilisation, oxygen, aerosol therapy
Chen 2007[35]	Cardiac	30	28	PS v CRC		3-8 + NR	8	8 on Day 1	unclear	Oxygen
Perrin 2007[36]	Pulmonary	14	18	PS v CRC		5 + 10	5	1 h cycles	10*	Cough, DB, IS, aerosol therapy
Celebi 2008a[37†]	Cardiac	25	25	PS + CRC v CRC		5 + 10	4	1 h cycles	1	Cough, mobilisation, IS
Celebi 2008b[37†]	Cardiac	25	25	PS + RM + CRC v CRC + RM		5 + 10	4	1 h cycles	1	Cough, mobilisation, IS
Lopes 2008[38]	Cardiac	50	50	PS v oxygen		5 + 8–12	0, 5	1 cycle	1	Oxygen
Zarbock 2009[39]	Cardiac	232	236	CPAP v CRC + intermittent CPAP	10		9	1 cycle	1	Manual vibration, mobilisation, oxygen, intermittent nasal CPAP
Liao 2010[40]	Pulmonary	23	27	PS v CRC		4 + 13	4	nr	3	nr

CPAP = continuous positive airway pressure. CRC = conventional respiratory care (oxygen therapy, medications, chest physiotherapy, early mobilisation). DB = deep breathing. IR PEP = inspiratory resistance positive expiratory pressure. IS = incentive spirometer. NIV = non-invasive mechanical ventilation. nr = not reported. PEEP = positive end-expiratory pressure. PS = pressure support. RM = recruitment manoeuvre. * 7 days before and 3 days after surgery. † a and b are different arms of the same trial.

can evolve into ARF. Respiratory physiotherapy involving deep-breathing exercises to re-expand collapsed alveoli has been proposed over the past decades as a means of preventing PPC. So far this kind of active exercise has not been shown to be effective in preventing or treating PPC after cardiac[41] and thoracic surgery.[42] Postoperative pain and respiratory muscle weakness caused by anaesthetics can make it difficult for patients to increase their lung volume in the postoperative period. In this setting, NIV can be used to increase lung volume without requiring the patient to make an effort.

NIV seems to also be a promising tool for treating postoperative ARF. In the two studies included in this meta-analysis that used NIV to treat postoperative ARF,[32,35] the success rates were 94% after cardiac and 80% after lung surgery. This is consistent with data reported by two prospective observational studies that showed similar rates of success for NIV in treating postoperative ARF after cardiothoracic surgery.[4,20] Furthermore they showed that pneumonia and no initial response to treatment are independent predictors of NIV failure.

The use of NIV as a preventive tool seems to be effective in reduction of reintubation rate only when applied in patients considered at risk of developing PPC. Two out of three studies involving high-risk patients[33,34] showed reduced reintubation rates, whereas analyses including

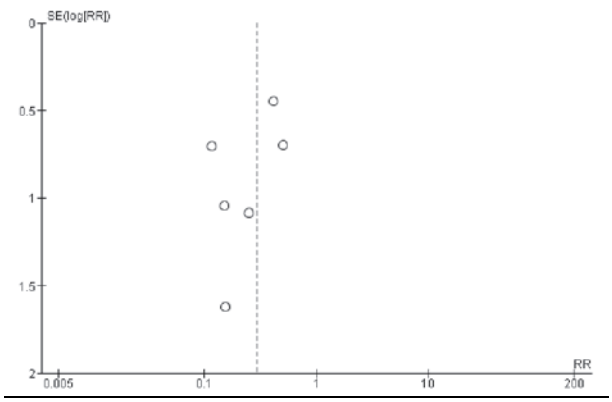
Table 2. Methodological quality of included studies

Study (first author, year)	Sample size	Description of randomisation	Allocation concealment*	Blinded assessor†	Withdrawals	Analysis‡
Stock 1984[27]	38	Yes	Unclear	Yes	nr	nr
Pinilla 1990[28]	77	nr	Unclear	No	25%	P
Jousela 1994[29]	30	nr	Adequate	No	nr	nr
Aguiló 1997[30]	20	nr	Unclear	No	5%	P
Matte 2000[31]	96	nr	Unclear	Yes	16%	P
Auriant 2001[32]	48	nr	Unclear	No	2%	I
Fagevick Olsen 2002[33]	70	Yes	Unclear	No	10%	nr
Kindgen-Milles 2005[34]	50	Yes	Unclear	Yes	4%	I
Chen 2007[35]	58	nr	Unclear	No	nr	nr
Perrin 2007[36]	39	Yes	Adequate	Yes	18%	P
Celebi 2008[37]	100	Yes	Adequate	Yes	nr	nr
Lopes 2008[38]	100	Yes	Unclear	No	nr	nr
Zarbock 2009[39]	468	Yes	Adequate	Yes	6%	I
Liao 2010[40]	50	nr	Unclear	No	nr	nr

nr = not reported.* Adequate indicates that the method of allocation is clearly described; "unclear" indicates the authors did not report any allocation concealment approach. † Yes indicates blinding of assessor to at least one outcome (generally atelectasis). ‡ P indicates analysis per protocol; I indicates analysis by intention-to-treat.

prophylactic studies in patients at low risk didn't show efficacy of NIV in any considered outcome except for the improvement in oxygenation. Notably, one of the studies with positive results of applying NIV as a preventive tool involved oesophageal surgery.[33] No complications were observed in this study, despite NIV being commonly considered to be contraindicated after upper gastrointestinal surgery[7] for safety reasons. The authors underlined the importance of maintaining a nasogastric tube during the entire period of CPAP treatment to avoid the distension of the oesophageal conduit. Similar highly positive findings regarding the use of CPAP after upper abdominal surgery were reported by Squadrone et al.[43] In this study, one case of anastomic leakage was observed in the CPAP group (105 patients), versus six cases among the 104 patients treated with standard oxygen therapy by mask. The largest study included in our meta-analysis, involving 468 low-risk patients,[39] reported a reduction of PPC incidence (defined as the sum of reintubation, pneumonia and hypoxaemic ARF) without a difference between the groups in length of stay in hospital or the ICU. A recent consensus conference on mortality reduction in cardiac anaesthesia and intensive care concluded that NIV early after extubation has potential value, despite a lack of evidence.[44]

Figure 2. Funnel plot for reintubation rate



SE = standard error. RR = risk ratio.

Sensitivity analyses showed that the results were not affected by the quality of the included studies and the amount of treatment. It is notable that one study of prophylactic use of NIV showed that treatment of a few hours resulted in a reduction of reintubation.[33] As patient compliance is an issue with NIV treatment, it would be interesting to confirm these findings with future studies. It should also be remembered that NIV is a complex and time-consuming procedure.[45,46] Although the studies included didn't observe major complications associated with the use of NIV, several minor side effects may occur, such as facial skin necrosis, nasal congestion, mask intolerance, claustrophobia and gastric distension.[47]

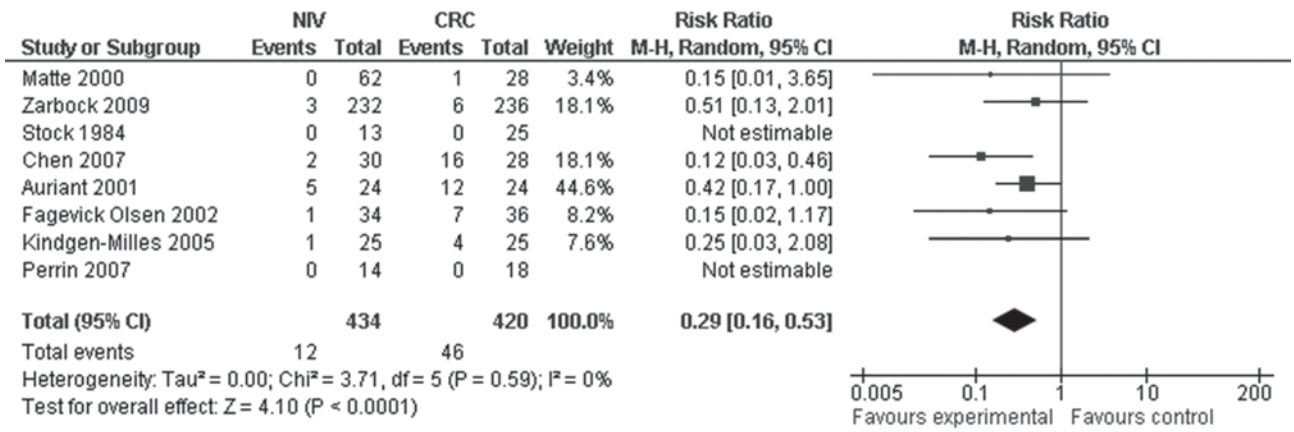
The limitations of meta-analyses are well known.[48] In particular, the most important limitation of this meta-analysis is the possibility of biases because the methodolog-

Table 3. Secondary outcomes

Outcome or subgroup	No. of studies	No. of participants	Overall effect (95% CI)	*P*	I^2
Hospital length of stay	8	798	WMD –2.25 (–4.21 to –1.10)	0.0008	97%
Preventive low risk	4	598	WMD –0.08 (–1.09 to 0.93)	0.88	94%
Preventive high risk	3	152	WMD –7.40 (–11.90 to –2.91)	0.001	91%
Curative	1	48	WMD 4.30 (–4.60 to 13.20)	0.34	ne
Mortality	3	176	RR 0.26 (0.11 to 0.66)	0.005	0
Preventive low risk	0	0	ne	ne	ne
Preventive high risk	1	70	RR 0.26 (0.03 to 2.25)	0.22	ne
Curative	2	106	RR 0.26 (0.10 to 0.73)	0.01	0
Pneumonia	8	816	RR 0.39 (0.12 to 1.26)	0.11	1%
Preventive low risk	6	734	RR 0.48 (0.12 to 1.96)	0.31	14%
Preventive high risk	2	82	RR 0.14 (0.01 to 2.63)	0.19	ne
Curative	0	0	ne	ne	ne
Atelectasis	9	448	RR 0.75 (0.53 to 1.06)	0.11	65%
Preventive low risk	7	366	RR 0.80 (0.57 to 1.13)	0.22	68%
Preventive high risk	2	82	RR 0.38 (0.13 to 1.08)	0.07	0
Curative	0	0	ne	ne	ne
Gas exchange	8	367	WMD 17.93 (10.91 to 24.94)	< 0.00001	0
Preventive low risk	7	335	WMD 13.01 (0.89 to 25.13)	0.04	0
Preventive high risk	1	32	WMD 20.40 (11.80 to 29.00)	< 0.00001	ne
Curative	0	0	ne	ne	ne

RR = risk ratio. WMD = weighted mean difference. ne = not estimable.

Figure 3. Forest plot for reintubation rate



CRC = conventional respiratory care (oxygen therapy, medications, chest physiotherapy, early mobilisation). M–H = Mantel–Haenszel. NIV = non-invasive mechanical ventilation.

ical quality of the included studies was moderate to low. Nonetheless, it should be highlighted that reintubation rate is a clinically relevant end point. Another important limitation of this analysis is the heterogeneous mix of comparators (comprehensively described in Table 1).

Conclusions

The results of this meta-analysis suggest that NIV reduced reintubation rate after cardiothoracic surgery especially in patients with ARF and in patients at high risk of developing PPC. Hospital length of stay and mortality were also

reduced in the NIV group. Large randomised controlled studies are needed to confirm these promising results; in particular, the controversial practice of using NIV after upper gastrointestinal surgery and the appropriate dose of treatment urgently require research.

Competing interests

None declared.

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Appendix

1. Thoracotomy OR thoracic Surgical Procedures OR Pneumonectomy OR Pulmonary Surgical Procedures OR Aortic Aneurysm, Thoracic OR Blood Vessel Prosthesis Implantation OR Vascular Surgical Procedures OR Myocardial Reperfusion OR Coronary Artery Bypass OR Myocardial Revascularization OR Heart Valve Prosthesis Implantation OR Heart Bypass, Right OR Cardiovascular Surgical Procedures OR Circulatory Arrest, Deep Hypothermia Induced OR Heart Transplantation OR Pericardiectomy
2. CABG OR "cardiac surgery" OR "cardiopulmonary bypass" OR "open heart surgery" OR "aortic valve" OR "mitral valve" OR "tricuspid valve" OR "pulmonary valve" OR "pulmonary surgery" OR "thoracic surgery" OR "aortic surgery" OR "thoracic aortic surgery" OR "coronary artery bypass graft*" OR "aortocoronary bypass surgery" OR "Coronary surgery" OR "Heart Valve Prosthesis" OR "heart surgery" OR "cardiac surgery"
3. Esophagus/surgery OR Stomach/surgery OR stomach OR esophagus
4. #1 OR #2 OR #3
5. High-Frequency Ventilation OR Positive-Pressure Respiration OR Respiration, Artificial OR Oxygen Inhalation Therapy OR Mechanical Ventilation OR Recruitment maneuver OR NIV OR CPAP OR PEEP OR "Mechanical Ventilation" OR "non-invasive mechanical ventilation" OR "Recruitment maneuver*" OR "Vital Capacity Maneuver*"
6. Postoperative Complications OR Respiratory Insufficiency OR Hospitalization OR Pulmonary Atelectasis OR Blood Gas Analysis OR Oximetry OR "post-operative pulmonary complications" OR "pulmonary complications" OR "atelectasis" OR length of stay
7. #4 AND #5 AND #6