High-Frequency Ventilation Versus Conventional Ventilation for the Treatment of Acute Lung Injury and Acute Respiratory Distress Syndrome: A Systematic Review and Cochrane Analysis

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In this review, we examine outcomes from using high-frequency ventilation compared with conventional ventilation as therapy for acute lung injury and acute respiratory distress syndrome in children and adults. We conducted a systematic search of the literature based on the guidelines of the Cochrane Collaboration. Two trials met the inclusion criteria; one recruited children ($n = 58$), and the other recruited adults ($n = 148$). Both trials used a high-frequency oscillatory ventilator as the intervention and included variable use of lung-volume recruitment strategies. The intervention groups showed a trend toward less 30-day mortality (children: relative risk [RR], 0.83; 95% confidence interval [CI], 0.43–1.62; adults: RR, 0.72; 95% CI, 0.50–1.03), although neither study showed a statistically significant difference. Similarly, there was no statistically significant difference between the intervention and control groups for "total length of ventilator days." There was a statistically significant reduction in the risk of requiring supplemental oxygen among survivors at 30 days in the pediatric study (RR, 0.36; 95% CI, 0.14–0.93). Overall there is not enough evidence to conclude that high-frequency ventilation reduces mortality or long-term morbidity in patients with acute lung injury or acute respiratory distress syndrome. (This review is published as a Cochrane Review in *The Cochrane Library* 2004, Issue 3. Cochrane Reviews are regularly updated as new evidence emerges and in response to comments and criticisms, and The Cochrane Library should be consulted for the most recent version of the Review.)

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Acute lung injury (ALI) and acute respiratory distress syndrome (ARDS) are life-threatening conditions that affect many patients in intensive care. Although there is disagreement about the exact definitions, criteria that are often used were set forth by the North American-European Consensus Conference in 1994 (1). The criteria for ALI are acute onset of lung injury, diffuse bilateral infiltrates seen on chest radiography, Pao_2/fraction of inspired oxygen <300 mm Hg, pulmonary artery occlusion pressure <19 mm Hg, or no clinical evidence of congestive heart failure. ARDS is considered a more severe form of ALI, with Pao_2/fraction of inspired oxygen <200 mm Hg. Accurate estimation of the incidence of ALI or ARDS has been difficult, and the incidence has been placed at anywhere from 1.5 to 75 per 100,000 per year, although more recent studies suggest that a number closer to 75 per 100,000 is more accurate (2).

Patients with ARDS usually have a risk of mortality more than 30% (3,4). There is currently no method of prevention for ALI and ARDS, and mechanical ventilation is considered the primary treatment for these patients. Other treatments are used, such as fluid restriction, repositioning of the patient in the prone position, corticosteroids, and inhaled nitric oxide. However, none of these treatments has been convincingly shown to improve outcome (2).

Conventional ventilation (CV) strategies seek to maintain tidal volumes that approximate those seen during spontaneous ventilation or are larger volumes to achieve a normal partial pressure of arterial carbon dioxide and pH. Although CV can provide adequate gas exchange, it is associated with high airway pressures and pulmonary air leaks that are thought to induce further lung injury and to potentially harm patients.

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High-frequency ventilation (HFV) uses respiratory rates more than 4 times (and up to 250 times) the normal rate and delivers small tidal volumes. It was introduced for the treatment of ALI or ARDS to optimize gas exchange while preventing the further lung injury seen with CV. It has been implemented as a treatment in intensive care units (ICU) as both elective and rescue therapy. However, it is currently used without clear evidence as to whether it confers any benefit. Cochrane reviews examining the use of rescue and elective HFV for lung injury in term and preterm infants have concluded that there is insufficient evidence to recommend its use (5–7). The objective of this review was to examine the effect of HFV compared with CV as therapy for ALI or ARDS in children (1 to 17-yr-old) and adults to quantify its effect on patient outcome (mortality, morbidity, and other relevant outcomes).

Methods

The following criteria were used for considering studies for this review:

Types of studies: Randomized controlled trials (RCTs) that compared HFV with CV and included at least one of the outcomes of interest.

Types of participants: Children (1 to 17 yr old) and adults (≥18 yr old). Participants must have been diagnosed with ALI or ARDS according to the working definitions of the European-American Consensus Conference on ARDS or similar criteria (1).

Types of interventions: Use of a high-frequency ventilator (greater than 40 breaths/min) for any length of time as therapy after clinical diagnosis of ALI or ARDS.

Types of outcome measures:

Primary: mortality (ICU, hospital, 30 days, and ≥60 days).

Secondary: total length of mechanical ventilation (high-frequency and conventional combined), length of stay in the ICU, length of hospital stay, any long-term quality-of-life measurements, any long-term cognitive measurements, and cost-effectiveness.

Search strategy for identification of studies: Trials were identified by searching electronic bibliographic databases, the reference lists of all identified trials, and reference lists of relevant systematic reviews and by contacting an author of each included trial.

We searched the Cochrane Central Register of Controlled Trials (CENTRAL; The Cochrane Library, Issue 4, 2002), MEDLINE (1966 to October Week 5, 2002), EMBASE (1980 to Week 51, 2002), and the World Wide Web (http://www.controlled-trials.com; ARDS clinical network) and used the Cited Reference Search (Web of Science 1988 to 2002) for specific reference lists of articles.

Electronic bibliographic databases searched:

MEDLINE (1966 to March 2002)

Complaint (1 OR 2 OR 3 OR 4 OR 5 OR 6)
1. Respiratory distress syndrome
2. ARDS
3. Acute lung injury
4. ALI
5. Respiratory distress syndrome/
6. Respiratory distress syndrome, adult/

AND

Treatment (1 OR 2 OR 3 OR 4 OR 5)
1. High adj frequency adj3 ventilation
2. High adj frequency oscillat*
3. Jet adj3 ventilation
4. Oscillat* adj3 ventilation
5. High frequency ventilation (explode)/

AND

Study design (1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10)
1. Clin* adj3 trial*
2. Random*
3. Study
4. Control*
5. Randomized controlled trials/
6. Controlled clinical trials/
7. Random allocation/
8. Double-blind method/
9. Single-blind method/
10. Prospective studies/

*denotes that any letter or letters may follow
/denotes a MEDLINE Medical Subject Heading term.

Cochrane Controlled Trials Register (January 2002) as MEDLINE.

EMBASE (1980 to May 2002) as MEDLINE, exploding heading "respiratory distress syndrome" and using heading "jet ventilation" as well as "HFV," with an additional RCT filter (as presented by Lefebvre C, McDonald S, at the Fourth International Cochrane Colloquium, 1996).

ISI Science Citation Index Expanded (1981 to June 2002) for all included trials.

World Wide Web (http://www.controlled-trials.com; ARDS clinical network).

We contacted research departments at companies that make high-frequency ventilators for information on any unpublished industry trials.

No language restrictions were applied.

Methods of the Review

Identifying trials: Titles and abstracts of the electronic search results were screened by two reviewers. The two reviewers independently selected trials that

Table 1. Characteristics of Excluded Studies

Study	Reason for exclusion
Carlon (13)	Patient population had "acute respiratory failure" from a variety of reasons and included many patients requiring mechanical ventilation who would not necessarily fit modern criteria for ALI or ARDS
Dobyns (11)	Randomized on inhaled nitric oxide, not HFV
Hurst (12)	Patients served as their own controls. Total of only nine patients randomized
Hurst (14)	Patients in the study who received HFOV were only "at risk" of developing ALI/ARDS

ARDS = acute respiratory distress syndrome; ALI = acute lung injury; HFV = high-frequency ventilation; HFOV = high-frequency oscillatory ventilation.

met the specific inclusion criteria. Any disagreements were resolved through discussion.

Data extraction: Data extraction was performed independently by the two reviewers. Disagreements about the extracted data were resolved through discussion. Authors of trials were contacted for information needed for review that was not available in the published reports. In particular, both J. Arnold and S. Derdak were contacted to find out whether there were any other outcome measures that may have been collected but not included in the published articles. Both confirmed that there were no other outcomes from the trials.

Data extracted included the type of randomization used and allocation concealment, blinding, single or multicenter, size of the study, population (children, adults, or both), definition of ALI or ARDS used, specifics of respirator settings (including lung-volume recruitment strategies and the type of high-frequency ventilator used), outcomes of interest, loss to follow-up, and whether analysis was performed according to the intention-to-treat principle.

Methodological quality was evaluated according to the method described by Schultz et al. (8). Particular emphasis was placed on concealment of treatment allocation, generation of allocation sequences, and intention-to-treat analysis. No scoring or grading system was used.

Data Analysis

Trials were summarized individually. A decision was made not to pool results, because the two trials involved mutually exclusive groups of patients.

Description of Studies

Six RCTs were identified with the search methods described above. Two [Arnold et al. (9) and Derdak et al. (10)] were included in the systematic review. Both of the included studies used high-frequency oscillatory ventilation (HFOV) and involved variable lung-volume recruitment strategies. One was a pediatric trial (Arnold et al.), whereas the other enrolled only adults (Derdak et al.).

Of the four identified trials that were excluded, one was excluded because patients were not randomized on ventilator type [Dobyns et al. (11)], another was excluded because patients were used as their own controls [Hurst and DeHaven (12)], the third was excluded because the inclusion criteria for ALI or ARDS were too broad [Carlon et al. (13)], and the last was excluded because HFV was begun before patients had even developed ALI/ARDS [Hurst et al. (14)] (Table 1). Because of the limited number of studies eligible for inclusion in the review, reporting (publication) bias was not assessed with a funnel plot.

Methodological Quality of Included Studies

Details of the methodological quality of studies are listed in Table 2. Both trials used adequate allocation concealment and valid randomization techniques (Arnold et al. used a blinded balanced block design, and Derdak et al. used computer randomization). Treatment could not be blinded in any study because of the type of intervention. Post-randomization exclusions occurred in one trial (Arnold et al.; 12 of 70 randomized were then excluded). These were a combination of exclusion within 8 h of enrollment (6 patients), protocol violations (4 patients), and transfer to another institution (2 patients).

Neither study was designed as a crossover trial. However, both allowed crossover of patients to the alternative treatment if they "failed" the original treatment, according to certain physiological variables chosen at the time of study design. Derdak et al. also allowed treatment with the alternate form of ventilation if the attending physicians believed that additional therapies could be life-saving.

Results

Outcomes from the two included studies are summarized in Table 3.

30-Day Mortality

Arnold et al. and Derdak et al. both examined 30-day mortality. Neither study found a significant difference in 30-day mortality for patients treated with HFOV versus CV. Arnold et al. reported a 30-day mortality of 34% (10 of 29) for HFOV versus 41% (12 of 29) for CV (relative risk [RR], 0.83; 95% confidence interval [CI],

Table 2. Characteristics of Included Studies

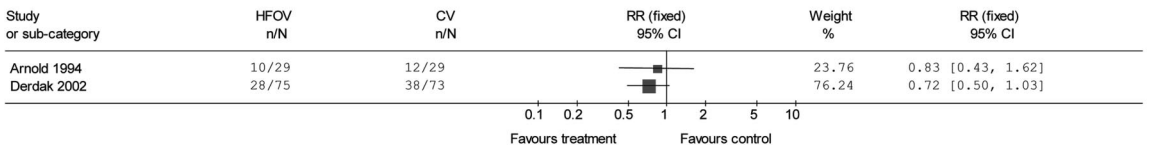
Study	Methods	Participants	Interventions	Outcomes	Notes	Allocation concealment
Arnold (9)	Multicenter (5 tertiary care pediatric units) Not analyzed by intention-to-treat	Body weight <35 kg. Acute diffuse lung injury with decreased oxygenation (see criteria in Methods) Excluded: if <40 weeks postconceptual age or former prematurity with residual chronic lung disease, obstructive airway disease, intractable septic or cardiogenic shock, nonpulmonary terminal diagnosis	3100 high-frequency oscillatory ventilator (SensorMedics). Initial settings of F_{IO_2}: 1.0, frequency of 5 to 10 Hz, mPaw of CV+(4 to 8) cm H_2O, pressure amplitude of oscillation set for "adequate chest wall movement," bias gas flow 18 L/min Controls were ventilated with CV (Servo 900C; Siemens; Veolar, Hamilton Medical). Target blood gas values were the same as for HFV Crossover to the alternate ventilator was required if the patient met certain treatment failure criteria (see article)	Duration of mechanical ventilation, 30-day survival, supplemental oxygen at 30 days, neurological events on study	12 patients excluded from the analysis because of exclusion from the study within 8 h of enrollment (n = 6); protocol violations (n = 4); transferred to other institution (n = 2) Open-lung approach to achieve oxygenation targets used. No specific use of lung-volume recruitment maneuvers	Adequate
Derdak (10)	Multicenter (13 university-affiliated medical centers) Analysis by intention-to-treat	Age 16+ years. ARDS diagnosed by American-European consensus criteria Excluded: weight <35 kg, severe COPD or asthma, intractable shock, severe air leak, nonpulmonary terminal diagnosis with an estimated 6-mo mortality >50%, F_{IO_2} >0.80 for more than 48 h, or participated in another trial for ARDS or septic shock within 30 d	3100B high-frequency oscillatory ventilator (SensorMedics). Initial settings of frequency of 5 Hz, mPaw of CV+5, pressure amplitude of oscillation set for "vibration down to level of mid-thigh." Switched back to CV when F_{IO_2} was 0.50 or less and mPaw was weaned to 24 cm H_2O or less with an Sao_2 of 88% or more Controls were ventilated with CV using the pressure control mode with an initial VT (mL/kg) of 6 to 10, RR adjusted for pH greater than 7.15, PEEP of 10, inspiratory time 33%	Survival without need for mechanical ventilation at 30 d from entry to study, 6-mo mortality, need for mechanical ventilation at 30 d and 6 mo	Designed as an equivalence trial 9% of the HFOV group and 16% of the CV group received other rescue therapies Used lung-volume recruitment maneuvers, although this was not protocolized	Adequate

Authors from both studies were contacted regarding other outcomes that may not have been published. Authors confirmed that no other outcomes were collected.

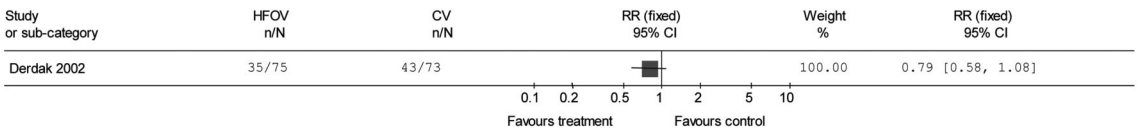
CV = conventional ventilation; HFV = high-frequency ventilation; ARDS = acute respiratory distress syndrome; ALI = acute lung injury; COPD = chronic obstructive pulmonary disease; VT = tidal volume; PEEP = positive end-expiratory pressure; HFOV = high-frequency oscillatory ventilation; F_{IO_2} = fraction of inspired oxygen; mPaw = mean airway pressure; RR = respiratory rate; Sao_2 = arterial oxygen saturation.

Table 3. Outcomes from Included Reviews

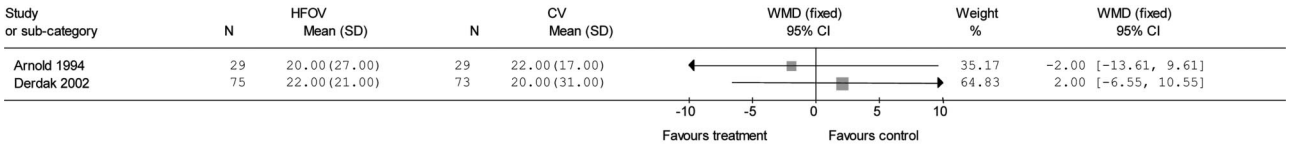
Outcome: 30 day mortality



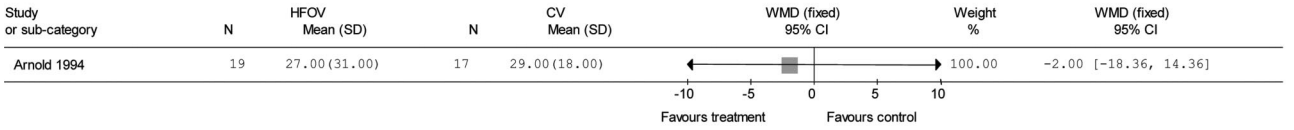
Outcome: 6 month mortality



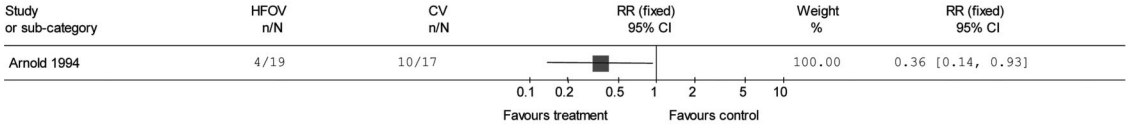
Outcome: Length of mechanical ventilation



Outcome: Length of mechanical ventilation for survivors



Outcome: Survivors requiring supplemental oxygen at 30 days



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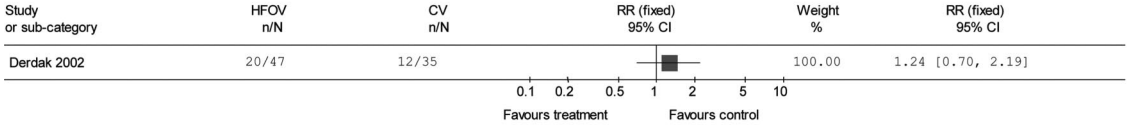
Outcome: Survivors requiring mechanical ventilation at 30 days



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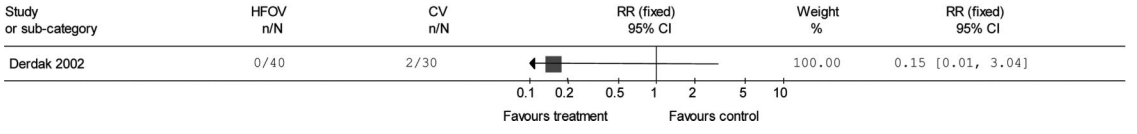
Outcome: survivors requiring mechanical ventilation at six months



0.43–1.62). Derdak et al. had a 30-day mortality of 37% (28 of 75) for HFOV versus 52% (38 of 73) for CV (RR, 0.72; 95% CI, 0.50–1.03).

Six-Month Mortality

Only Derdak et al. examined 6-mo mortality. This study reported a mortality of 47% (35 of 75) for HFOV versus 59% (43 of 73) for CV. There was no significant difference between groups (RR, 0.79; 95% CI, 0.58–1.08).

Total Ventilator Days

Both studies measured the total number of days on a ventilator. Neither study found a significant difference in number of ventilator days between the HFOV and CV groups (Arnold et al.'s weighted mean difference [WMD], −2.00; 95% CI, −13.61 to 9.61; Derdak et al.'s WMD, 2.00; 95% CI, −6.55 to 10.55). Arnold et al. also included a comparison of total ventilator days for survivors at 30 days (WMD, −2.00; 95% CI, −18.36 to 14.36).

Long-Term Quality-of-Life Measurements

Neither study used any validated questionnaires to evaluate long-term quality of life. Both studies measured proxies for long-term quality of life; Derdak et al. examined the percentage of patients alive on mechanical ventilation at 30 days and 6 mo. Derdak et al. reported patients alive on mechanical ventilation as a percentage of the total number in that arm of the study (those who survived and died), but we have chosen to present them here as a percentage of the survivors only, which is in line with the presentation of data in the Arnold et al. study. There was no significant difference between the HFOV and CV groups (30 day RR, 1.24; 95% CI, 0.70–2.19; 6-mo RR, 0.15; 95% CI, 0.01–3.04). Arnold et al. examined the number of survivors who required supplemental oxygen at 30 days. The study found that survivors who had received HFOV were statistically less likely to require supplemental oxygen (RR, 0.36; 95% CI, 0.14–0.93).

Discussion

Two RCTs were identified for inclusion in this systematic review of HFV versus CV for treatment of ALI and ARDS in children and adults. Neither Derdak et al. nor Arnold et al. showed a statistically significant difference in mortality with HFOV, although both showed a trend toward a decrease in 30-day mortality.

The effect of HFOV on 6-month mortality, length of mechanical ventilation, and need for continued ventilatory support at 30 days and 6 months all showed trends toward reduction in one or both studies, but the trends were not statistically significant. Regarding other outcomes examined in this review, the only difference found in any of the individual analyses was in the pediatric study (Arnold et al.). There was a statistically significant decreased need for supplementary oxygen among survivors at 30 days in the group randomized to HFOV versus CV, suggesting that there might be some quality-of-life benefit to using HFOV. However, no other measures of quality of life were examined.

Patients in the control arm of the study by Derdak et al. had a 30-day mortality of 51%. This is in contrast to a recent trial (15) of small tidal volumes for treatment of ARDS in which the reported mortality in controls was 39.8% (at 180 days) and is also in contrast to other reports of mortality from ARDS (3,16,17). The more frequent mortality in the study by Derdak et al. suggests that the patients enrolled in this trial may have been more severely ill than most ARDS patients.

On a number of key areas of design, the two studies are similar: both trials used the same type of high-frequency ventilator (oscillatory), they both used an open lung approach, and both were designed with the option for patients to receive the alternate therapy. However, we chose to report the findings from these trials separately, because the two studies included mutually exclusive groups of patients: one involved only children <35 kg, and one involved only adults more than 35 kg. Of note, Arnold et al. reported in a comment on the article that age was significantly associated with outcome (patients older than five years had significantly increased mortality compared with patients younger than five years) (18).

Although there are many types of high-frequency ventilators, both studies included in this review used HFOV. This is important to note, because the results reported may not necessarily be extrapolated to use with other types of high-frequency ventilators. The oscillatory ventilator uses reciprocating pumps or diaphragms and in this respect differs from other types of high-frequency ventilators because it provides active expiration (as well as active inspiration) (19).

We included the trial by Arnold et al. even though it randomized some infants (21 of 62; 34%). Our exclusion criteria were chosen because the review was not set up to examine HFV as a treatment for neonatal lung injury (this has been reviewed elsewhere) (5–7). The aim of the Arnold et al. study was to examine the use of HFOV in children (not neonates with lung injury); given that most participants were not infants (the mean age was 3.1 years and 2.5 years for the intervention and control groups, respectively) and that the authors specifically stated that they excluded any infants with former prematurity and with residual chronic lung disease, we believed that this study should still be used, because it otherwise met our inclusion criteria and had a strong trial design.

Also of concern in the results of Arnold et al. is the exclusion of 12 of 70 patients after randomization. This exclusion means that the analysis was not performed

with an intention-to-treat method. We performed a sensitivity analysis by using 30-day mortality to address this concern. Because the 12 dropouts were equally split between the 2 treatment groups, the best case favoring HFV would be the survival of all 6 HFV dropouts and the death of all 6 CV dropouts; this yields a mortality of 10 of 35 (HFV) versus 18 of 35 (CV), with a nonsignificant RR (0.56; 95% CI, 0.30–1.03). Similarly, the worst-case assumptions for HFV are a tally of 16 of 35 (HFV) versus 12 of 35 (CV), with a nonsignificant RR (1.33; 95% CI, 0.74–2.39). This reinforces the statement by Arnold et al. that the principle findings of the study were not altered when follow-up data from these excluded patients were included in the analysis (18).

The main limitation of this review is the very small number of trials eligible for inclusion. There may be other trials that have not been published which we did not identify during our search and which, therefore, were not included. These exclusions remain a potential source of bias. The fact that both of the included trials also involved small numbers of participants makes it almost impossible to reach any conclusions regarding the efficacy of the intervention. Even if it had been possible to pool the trial data to increase power, the numbers would still be too small to reach meaningful conclusions. This lack of information is in itself an important conclusion of this systematic review, because clinicians need to be aware of the quality and quantity of evidence when deciding whether to treat a patient with HFOV. Although 30-day mortality is certainly an important outcome, the utility of measuring the length of mechanical ventilation as a useful clinical outcome is also questionable.

HFV has come in and out of favor over the last 20 years as a treatment for ALI/ARDS. During this time, definitions for ALI and ARDS have changed. The American-European Consensus Conference on ARDS (1,20) has provided some guidance to standardize case definitions, but even now not every study chooses to use these definitions, and comparisons with earlier studies remain problematic. Moreover, identifying clinically the point at which these criteria have been met is always subjective.

A recent trial demonstrated a marked improvement in mortality from ALI/ARDS by using CV with smaller tidal volumes as compared with traditional tidal volumes, although the Cochrane Review of the topic found no clear evidence of a difference in mortality (15,21). Both trials examined in this review compared HFOV with more traditional tidal volume ventilation, which was considered the standard of care at the time the studies were designed. What constitutes CV for ARDS is now complicated by the recent emphasis on smaller tidal volume ventilation, and this issue would need to be addressed in any future trial.

Cochrane reviews of HFOV in neonates found either no mortality benefit (elective therapy) or not enough data to support any conclusion (rescue therapy) (6,7). Initial studies in adults completed when HFV was first introduced showed little evidence that HFOV improved outcome, despite the reasoning that the small lung volumes delivered would decrease further damage to the lungs (12,13,22,23). A systematic review in 1998 (24) that included nonrandomized studies found that there was too much heterogeneity in study design and that current clinical trials were underpowered. However, the review also suggested that a potential reason why many of the early studies had failed to demonstrate an improvement with HFV was that they did not include a lung-volume recruitment strategy, which could help to keep alveoli open and further minimize damage to the lung. Instead, these early studies tended to focus on minimizing airway pressures. The more recent trials included in this review do incorporate lung-volume recruitment strategies, although debate continues as to how best to achieve this goal.

A review of HFV for ALI and ARDS (19) concluded that the treatment should be considered "promising but experimental" because of a lack of evidence that it improved important clinical outcomes. The authors of a *New England Journal of Medicine* review article on ARDS [Ware and Matthay (2)] chose to refer to treatment with HFV only in a list of references of many approaches to ventilation that have not been shown to be beneficial (the reviews were published before the Derdak et al. study). Our review provides a rigorous analysis of the best available data to allow clinicians to fully understand the known risks and benefits of choosing to place a patient on an HFOV. Having access to all of the relevant data (or knowledge of the lack of data) regarding this therapy is essential for clinicians faced with making treatment decisions for patients with such severe illness.

Conclusion

Very few quality data are available to assess HFV as a treatment for ALI and ARDS. The few data that exist suggest that there may be some clinical benefit to HFOV; larger trials that incorporate current standard practice for CV and that are powered to detect clinically significant differences in outcome are still needed before any conclusions can be drawn regarding its relative merits as a treatment option. As well as focusing on hard outcomes, future trials should assess both quality of life for survivors and cost-effectiveness.

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