

Extended Methods Section

Committee Composition

This guideline committee was composed of clinicians and experts in the field of non-invasive ventilation. Members (17 total) were either physicians (pulmonologists or intensivists, 15) or respiratory therapists (2). The committee was co-chaired by LB, NH, SN & PN. Committee members represented the ATS and ERS.

Also part of the committee were two methodologists with expertise in evidence synthesis and the guideline development process (BR & JB). Both methodologists were also clinicians, one an internist/allergist and the other an internist/intensivist. The methodologists conducted the systematic reviews and prepared the systematic evidence summaries following the GRADE approach, as described below [1, 2]. The executive committee for this guideline composed the chairs, methodologists as well as two other committee members (ME, DH).

Confidentiality agreement and Conflict of Interest Management

Committee members signed a confidentiality agreement and disclosed all potential conflicts of interest according to the ATS and ERS policies. The co-chairs were responsible for reviewing all potential conflicts of interest of committee members with the staff of the ATS. After review, no significant COI was disclosed by any member and therefore there was no limitation of committee members involvement in the recommendation formulation process. The methodologists participated in discussions, but were non-voting participants.

Meetings

A face-to-face planning meeting was held during the 2012 ERS International Conference in Vienna (Austria) at which the committee discussed the scope and objectives of the project. Additional planning meetings were held regularly over telephone between NH, SN, PN, LB, BR & JB. Conference calls and email correspondence were used to discuss specific issues requiring input from others.

Further face-to-face meetings occurred during the 2014 ATS International Conference in San Diego (USA) and the 2014 ERS Conference in Munich (Germany). During these meetings, evidence summaries were presented, discussed and recommendations were formulated. Members who were unable to be present had the option of participation through teleconference and webinar. The methodologists took notes of all matters and points discussed, and documented all the recommendations and proceedings.

Two follow-up teleconference-webinars were held on July 24th 2015 and November 16th, 2015 during which evidence was presented, discussed and recommendations formulated for the remaining questions. Only a smaller executive group of panel members participated in these follow-up teleconferences. However all members were given an opportunity to provide feedback and discussion via emails. The views and interests of the ATS, ERS, JRS (explain) and ALAT (explain) as well as of any commercial entity that provided external funding for professional societies had no influence on the topics and recommendations.

Formulating Clinical Questions

The committee chose the clinical questions based on perceived clinical importance and prioritization based on sampling of the committee members. Eleven specific questions pertinent and relevant to current clinical practice were selected. Some questions were not amenable to actionable recommendations were included as technical summaries or narrative descriptions without formal recommendations (these can be found in the guideline supplemental material).

The committee selected outcomes of interest for each question and these were explicitly rated for their relative importance (from the perspective of a patient with respiratory failure) from 'not important' to 'critical' [3]. Ranking outcomes by their relative clinical importance helps to focus on those that are most relevant to patients and may lead to improved clarification during potential disagreements in decision making. Rankings of all outcomes were agreed upon through consensus of the committee.

Literature search

The methodologists (BR & JB) designed a search strategy for each question using medical subject heading keywords and text words limited to human studies or non-indexed citations and articles in English or in any language with English abstracts. The Ovid platform was used to search MEDLINE and the Cochrane Registry of Controlled Trials. The last update of the search was performed in November 2016. All searches were pragmatic and more in keeping with rapid reviews[4, 5]. If a previous meta-analysis of high quality was identified which addressed one of the eleven questions then it was updated and used to formulate the evidence summary. One specific meta-analysis that looked at the role of

NIV in acute respiratory failure of any etiology on the outcome of mortality was especially useful in facilitating the search for most questions [6]. Search and screening results were provided to the committee of experts to ensure no important trials were missed or erroneously included.

Evidence Review

One of the methodologists (BR) screened titles and abstracts to identify articles for full review and evaluated the full text of articles deemed potentially relevant. In addition to clinical data, individual study risk of bias was assessed using the Cochrane Risk of Bias tool [7] for RCTs and the Ottawa-Newcastle tool [8] for observational studies.

Evidence summaries (online supplementary material) for each question were prepared following the GRADE approach [1] and reviewed by all committee members. We based the evidence summaries on existing up-to-date well-executed systematic reviews, and if necessary these were supplemented with additional recent RCTs. When there was no recent valid systematic review available we performed systematic reviews of RCTs and observational studies, when necessary, following the methods of the Cochrane Collaboration [9].

Results from identified studies with the same treatment agent were pooled and meta-analysis using the Cochrane Collaboration Review Manager 5.2 [9]. Pooling and meta-analyses of study data were independently performed by the methodologist specifically for this guideline document. Subsequently, the overall certainty in effect estimates (also

known as confidence in effect estimate) for each outcome of interest was assessed following the GRADE approach [10] based on the following criteria: risk of bias, precision, consistency, directness of the evidence, risk of publication bias, presence of dose-effect relationship, magnitude of effect and an assessment of the effect of plausible residual confounding or bias. The certainty in effect estimates for each outcome was categorized into one of four levels which included high, moderate, low or very low.

Evidence to Decision

This approach also ensures each of the following factors are considered in recommendation development: the quality of the evidence, the balance of desirable and undesirable consequences of compared management options, the assumptions about the values and preferences associated with the decision, the implications for resource use and health equity, the acceptability of intervention to stakeholders and the feasibility of implementation.

How to use these guidelines

These ERS/ATS evidence-based guidelines for the use of non-invasive ventilation in critically ill patients provide the basis for stakeholders to make rational, informed decisions. Clinicians, patients, third-party payers, institutional review committees, other stakeholders, or the courts should never view these recommendations as dictates. No recommendation can take into account all of the often-compelling unique individual clinical circumstances. Therefore, no one charged with evaluating a healthcare professional's actions should view these recommendations as absolute.

Note: statements regarding the underlying values and preferences as well as qualifying remarks accompanying each recommendation are integral to the recommendations and serve to facilitate more accurate interpretation; they should never be omitted when quoting recommendations from these guidelines.

Manuscript Preparation

The committee was divided into pairs or groups of three who were then responsible for composing individual components of the manuscript (organized by recommendation). These manuscript components were then collated by the executive to ensure cohesiveness and distributed to the entire committee for review. Feedback was provided by electronic communication. The final approved version was submitted to each co-sponsoring professional society for peer review.

References:

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