The effects of manual hyperflation using self-inflating manual resuscitation bags on arterial oxygen tensions and lung compliance: a meta-analysis of the literature

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Authors' objectives
To evaluate the available trials on the therapeutic value of the self-inflating manual resuscitation bag (MRB), both quantitatively and qualitatively.

Searching
MEDLINE was searched from 1968 to 1995 using the following search terms: 'respiration, artificial/methods or standards', 'insufflation/method or instrumentation', 'respiratory therapy/method', 'respiratory insufficiency/therapy', and 'positive pressure respiration/method'. The authors also examined the reference lists of the identified articles and two recognised textbooks in the field (see Other Publications of Related Interest nos.1-2) for additional published reports and literature.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials were included.

Specific interventions included in the review
Self-inflating MRBs used as a method of achieving pulmonary hyperinflation via either an endotracheal or tracheostomy tube. Studies were excluded if they made use of a ventilator to deliver hyperinflation volumes to their patients, or they applied the manual hyperinflation via a facemask rather than an endotracheal or tracheostomy tube. If a study included other physiotherapy or nursing procedures, only the results of groups of patients who were manually hyperinflated were included in the meta-analysis.

Participants included in the review
Patients who were mechanically ventilated via either an endotracheal or tracheostomy tube. The participants were adults in 6 of the 7 included studies, and neonates in the other. The position of the patients was supine in 2 studies; alternate side lying in one study; alternate side lying with head up (angle of 30 degrees) in another study; supine with head up (angle of 20 degrees) in a further study; and not stated for 2 studies. The disease status of the patients was not included in the study selection criteria. However, 2 studies included patients who had established respiratory failure, and who were paralysed and sedated for the duration of the trial; 3 studies included post-operative cardiac surgery patients; 1 study included patients who required mechanical ventilation for respiratory failure; and 1 study included neonates who were recovering from respiratory distress.

Outcomes assessed in the review
Arterial oxygen tension (PaO2) and/or lung compliance (CL) were assessed. Details of how these outcomes were measured were not given. The studies had to present the results as mean values with the standard deviation (SD) or standard error.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the reviewers performed the selection.

Assessment of study quality
The authors do not state that they assessed validity.
Data extraction
The authors do not state how the data were extracted for the review, or how many of the reviewers performed the data extraction. Data were extracted for the following:

- the sample, i.e. size, patient pathology, selection criteria, mean age and whether or not a control group was used;
- the patient's position during treatment and during monitoring;
- monitoring, in terms of the end points, length of monitoring, and stages of monitoring;
- the manual hyperinflation protocol, i.e. the type of MRB used, the number of compressions per session or treatment, and the fractional delivered oxygen concentration (FD02) pre-treatment, during treatment and post-treatment; and
- the results.

Methods of synthesis
How were the studies combined?
The mean difference PaO2 and/or CL was calculated for each study. The SD of the baseline and final values were pooled. From this value, the pooled standard error of the mean for PaO2 and/or CL was calculated for each study. The 95% confidence interval (CI) was then determined. The mean difference and 95% CI for PaO2 and CL for each study were then plotted on a graph, by ranking them in order of the time of the final measurement.

The authors stated that, due to the limited data supplied in the research reports, pooling the SDs of PaO2 and/or CL in each study was the only statistical method for calculating the upper and lower bounds of the means of the samples of the individual studies. However, the authors stated that this 'pooled' SD value artificially treats the baseline and final measurements on each patient as if two separate groups of patients were being compared; the values obtained from these calculations are generally overestimated. The correct SD to have used in the calculation of the 95% CI would have been the SD of the differences, i.e. Sdf-b. The Sdf-b was calculated from raw data, which were available for one study. The 'pooled' SD was then divided by the Sdf-b, to ascertain the factor by which the 'pooled' SD was greater than the Sdf-b; this factor was then applied to the data from the other trials to estimate their Sdf-b values.

The findings of the studies were compared narratively.

Publication bias was not assessed.

How were differences between studies investigated?
No formal statistical test of heterogeneity was conducted. One study was excluded from the meta-analysis due to its complex research design, which did not render it comparable to the rest of the trials. Between-study variation was discussed in the results section of the paper.

Results of the review
Seven randomised controlled trials with a total of 136 participants were included in the review.

Six studies measured PaO2. Two studies showed significantly negative associations between the use of the MRBs and the effect on PaO2: the mean differences were -9.99 (95% CI: -16, -3.98) and -11.87 (95% CI: -21.18, -2.56). Three studies showed no significant difference: the mean differences were 14 (study 1; 95% CI: -3.35, +31.35), 1.61 (95% CI: -6.92, +10.14) and -9 (95% CI: -25.13, +7.13). One study showed a significantly positive association between the use of the MRBs and the effect on PaO2 (mean difference 9, 95% CI: -14.83, +32.83). When the 'new' CIs were calculated, one study (study 1) also showed a significantly positive association between the use of the MRBs and the effect on PaO2 (95% CI: 3.93, 24.07).

LC was measured in 4 of the studies. Only one of these studies demonstrated a statistically-significant result (mean difference -0.51, 95% CI: -0.57, -0.35); this result was no longer statistically significant when the 'new' CIs were calculated (95% CI: 0.57, -0.45).
Authors' conclusions
The authors concluded that their meta-analysis has demonstrated a trend, which suggests that the MRB has limited effect on the measured PaO2 and CL values of mechanically-ventilated patients. Hence, the self-inflating MRB may not achieve the desired therapeutic objectives.

CRD commentary
The review question was well defined with the inclusion criteria explicitly stated.

A very narrow search strategy was used; this may have missed relevant studies, allowing the introduction of publication bias. It was not stated whether any language restrictions were applied, but MEDLINE comprises predominantly English language publications. The authors recognised the existence of publication bias in their limited search strategy, but did not assess this statistically or discuss the implications of this with respect to their findings.

The validity of the individual studies was not assessed, although the included studies were restricted to randomised controlled trials. However, details of the control groups were not reported. In addition, it was unclear whether the trials did actually include a control group and, if so, whether the randomisation was adequate.

The authors did not report details relating to the decision-making process for selecting the studies and extracting the data; for example, how many reviewers were involved, whether studies were examined independently, whether reviewers were blinded to the source, and how disagreements were resolved.

The results from the individual studies were synthesised narratively but not statistically. Differences between the studies, in terms of their methodology and participant characteristics, rendered the meta-analysis inappropriate. These differences may have interacted with the intervention, e.g. positioning of the patient, compliance of the patient's lungs and thorax, and the technique used to compress the MRB. No formal statistical test of heterogeneity was conducted. The methods used to pool the data were complicated, and relied on assumptions that may not have been appropriate. The studies were not weighted for the analysis; there was no identification of the better quality studies. Although the studies were too heterogeneous to pool, these differences were not discussed in the narrative.

The authors' final conclusion, that self-inflating MRB may not be achieving the desired therapeutic objectives, appears to follow from the results. However their other conclusion is misleading as no significant effect was found in the majority of studies. This study was also open to potential selection bias and publication bias, and there was heterogeneity in the study methodology and participant characteristics. The authors' recommendation that more controlled, similar multicentre trials are needed appears appropriate given their findings and the uncertainty that still remains.

Implications of the review for practice and research
Practice: The authors state that until such time as the results of the suggested studies become known, and a meta-analysis is once again performed, physiotherapists working in those intensive care units that use self-inflating bags should consider alternative ways of achieving hyperoxygenation and hyperinflation in the treatment of their patients.

Research: The authors state that more controlled, similar multicentre trials are needed to resolve the uncertainty regarding the therapeutic value of self-inflating MRB alone, especially across a wide range of pathologies. These should be followed by a meta-analysis.

Bibliographic details

Other publications of related interest

**Indexing Status**
Subject indexing assigned by CRD

**MeSH**
Cardiac Output; Lung Compliance; Meta-Analysis; Physical Therapy Modalities; Respiration, Artificial; Respiratory Mechanics; Respiratory Therapy

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**Record Status**
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.