THE EFFECTS OF MANUAL HYPERFLATION USING SELF-INFLATING MANUAL RESUSCITATION BAGS ON ARTERIAL OXYGEN TENSIONS AND LUNG COMPLIANCE - A META-ANALYSIS OF THE LITERATURE

This research was submitted to the University of the Witwatersrand in partial fulfillment of the degree MSc (Physiotherapy)

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ABSTRACT: *The self-inflating manual resuscitation bag (MRB) is a modality which is commonly used by physiotherapists to manually hyperinflate the lungs of mechanically ventilated patients. There is limited scientific evidence to support its therapeutic use and the literature is not in agreement as to the effects of manual hyperinflation. A meta-analysis of the current research on humans has been conducted to investigate the effects of this modality on arterial oxygen tensions and lung compliance. All published studies evaluating the effects of manual hyperinflation (or bagging) on arterial oxygen tensions and/or lung compliance on mechanically ventilated patients have been retrieved. Only studies which reported results in terms of mean values and standard deviation or standard error of the mean could be used in this analysis. Eleven studies were identified between the time period 1968 - 1995. Seven of these studies fitted the inclusion criteria. The mean and standard error of the mean values for arterial oxygen tensions (PaO_2) and lung compliance (C_L) have been used to calculate the 95% confidence intervals and these results were plotted on a graph. A comparative analysis has been performed on the results of the seven studies. A generally non-significant association between bagging and the PaO_2 and C_L values was demonstrated. Great discrepancies were identified in the designs of the seven included studies. Since the seven studies included in this meta-analysis show an overall non-significant association, it is reasonable to assume that the therapeutic value of the self-inflating manual resuscitation bag is questionable. The studies presented such divergent designs that they do not offer conclusive evidence. More standardized, multi-centre studies are required to clarify the therapeutic value of this modality. Other methods of recruiting the lungs of critically ill patients during and after physiotherapy intervention, need to be explored.*

KEYWORDS: META-ANALYSIS, MANUAL HYPERINFLATION, PHYSIOTHERAPY, MECHANICAL VENTILATION

INTRODUCTION

Manual hyperinflation is a technique traditionally used by physiotherapists in the treatment of mechanically ventilated patients. The use of this technique is based more on clinical experience than on scientific evidence. Few experimental trials have addressed the ability of manual resuscitators per se to achieve increased secretion clearance and recruitment of atelectatic lung units. Of this small number of published trials, a greater proportion have to do with self-inflating manual resuscitation bags (MRBs) and for this reason this analysis has focused on the self-inflating type of MRB.

The literature which is available presents conflicting evidence to the reader. This is particularly true when each of these studies are viewed in isolation and not as part of a whole. The results of the few experimental trials do not allow standard guidelines to be adopted on when the MRB should be used and when not (Reiterer, 1993). The literature has thus failed to provide a firm research consensus to support or refute the continued use of the self-inflating MRB in the treatment of mechanically ventilated patients in the intensive care unit.

The aim of this meta-analysis is to evaluate the available trials on the therapeutic value of the MRB quantitatively and qualitatively. The results will offer useful information to both the researcher and the practising physiotherapist. A meta-analysis will also aid in identifying methodological errors in the existing literature and so help to guide future research projects in the field. An analysis such as this can help to bring physiotherapists closer to the truths about the techniques which they use. This is especially important in today's need for evidence based practice.

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METHOD

This meta - analysis was conducted in the Department of Physiotherapy at the University of the Witwatersrand. An online computer search of the MEDLINE (National Library of Medicine, Bethesda, Md) database was performed to isolate all the relevant literature on self-inflating manual resuscitation bags. The following terms were used to search the titles and abstracts of indexed articles: Respiration, Artificial/Methods or Standards; Insufflation/Method or Instrumentation; Respiratory Therapy/Method; Respiratory Insufficiency/Therapy; Positive Pressure Respiration/Method.

The search dated back from 1995 to 1968. As MEDLINE may not have all the relevant articles indexed on its database and, therefore, has limitations as a retrieval system (Dickerson et al, 1985), the reference lists of those articles selected from the computer search were scanned for additional published reports. The reference lists of two recognised textbooks in the field (Mackenzie, 1989; Scanlan, 1990) were also scrutinised to identify any further literature. The authors have also recognised the existence of publication bias in retrieving "all" the current literature for a meta-analysis.

For inclusion into the meta-analysis, the studies had to fit all of the following criteria. They had to:

1. Be randomised controlled trials.
2. Be experimental, clinical trials using only human subjects who mechanically ventilated via either an endotracheal or tracheostomy tube.
3. Have made use of self-inflating manual resuscitation bags as method of achieving pulmonary hyperinflation.
4. Have measured either arterial oxygen tensions (PaO_2) and/or the lung compliance (C_L) as the end-points of effect of the MRB. If the research article reported other independent observations (e.g. Alveolar-arterial oxygen difference (A-aDO_2), cardiac output etc.) as well as PaO_2 and C_L these studies were still included but only the latter two parameters were used in the analysis.
5. Have presented their results as mean values and standard deviations or standard error of the mean values in order that the 95% confidence intervals (C.I.) could be recalculated.

If a study included other physiotherapy or nursing procedures in their methods in addition to manual hyperinflation, then only the results of the groups, which were manually hyperinflated, were included in the meta - analysis. Inclusion into the meta - analysis was thus based on methodology and not on the outcome of the trials.

Studies were excluded from the meta - analysis if they:

1. Were laboratory studies conducted on mannequins, test-lungs or animals.
2. Made use of a ventilator to deliver hyperinflation volumes to their subjects.
3. Applied the manual hyperinflation via a facemask and not an endotracheal or tracheostomy tube.
4. Did not measure PaO_2 and/or C_L.
5. Presented their results graphically or as a percentage increase/decrease in the measured parameters, without tabulating mean values and standard deviations or standard error of the mean values.

The following data were extracted from the studies, which fitted the inclusion criteria:

i) sample (size, patient pathology, selection criteria, mean age and whether or not a control group was used)
ii) patient position (during treatment and during monitoring)
iii) monitoring (end-points, length of monitoring and stages of monitoring)
iv) manual hyperinflation protocol (type of MRB used and the number of compressions per session/treatment and the fractional delivered oxygen concentration ($FD0_2$s) pre-treatment, during treatment and post-treatment).

A number was assigned to each study for ease of reference eg. Study 1 (S1) and Study 2 (S2).

Funding for this research was granted by the Medical Faculty Research Endowment Fund of the University of the Witwatersrand, Johannesburg, South Africa.

STATISTICAL ANALYSES

The following statistical methods were applied to the PaO_2 and/or C_L measurements in the studies which fitted all of the above stated inclusion criteria. The mean values (x) and standard deviations (SD) of PaO_2 and/or C_L values before commencement of the intervention i.e. the baseline measurement (x_b ; SD_b) and the mean and standard deviation values at the end of the observed period of the intervention i.e. the final measurement (x_f ; SD_f) were identified in each study. Where standard error of the mean (SEM) values were given instead of SD, the SD was calculated using the formula:

$$SD = SEM \cdot \sqrt{n}$$

where n = sample size.

For each study, the x_f - x_b (or $x_{f\text{-}b}$) was determined to give the difference of the means between the final and baseline readings for PaO_2 and/or C_L. The SD_f and SD_b were pooled by applying the formula:

$$\text{Pooled SD} = \sqrt{[(SD_f)^2 + (SD_b)^2]/2}$$

From this value the pooled SEM for PaO_2 and /or C_L for each study was calculated. The 95% C.I. were then determined using the following relationship:

$$95\%\ C.I. = x_{f\text{-}b} \pm (1.96 \cdot SEM)$$

The $x_{f\text{-}b}$ and C.I. for PaO_2 (Fig 1) and C_L (Fig 2) for each study were then plotted on a graph. Studies were plotted by ranking them in order of time of final measurement. This was done to assess any effect of the time period over which monitoring was conducted on the outcome of the two measured end-points. A separate plot (Fig 3) was done using the values obtained from calculations of the 'old' and 'new' C.I.'s done on Study 3. A comparative analysis of the studies was then carried out.

Note on 'pooled' SD vs. $SD_{f\text{-}b}$ and 'new' C.I. calculations for Study 3

Given the data supplied in the research reports, pooling the SDs of PaO_2 and/or C_L 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. The 'pooled' SD value, however, artificially treats the baseline and final measurements on each patient as if two separate groups of patients were being compared i.e. as if between patient differences/

FIGURE 1: $\bar{X}_{f\text{-}b}$ and C.I. and C.I of PaO_2 values S1, S2, S3, S4, S5 and S6

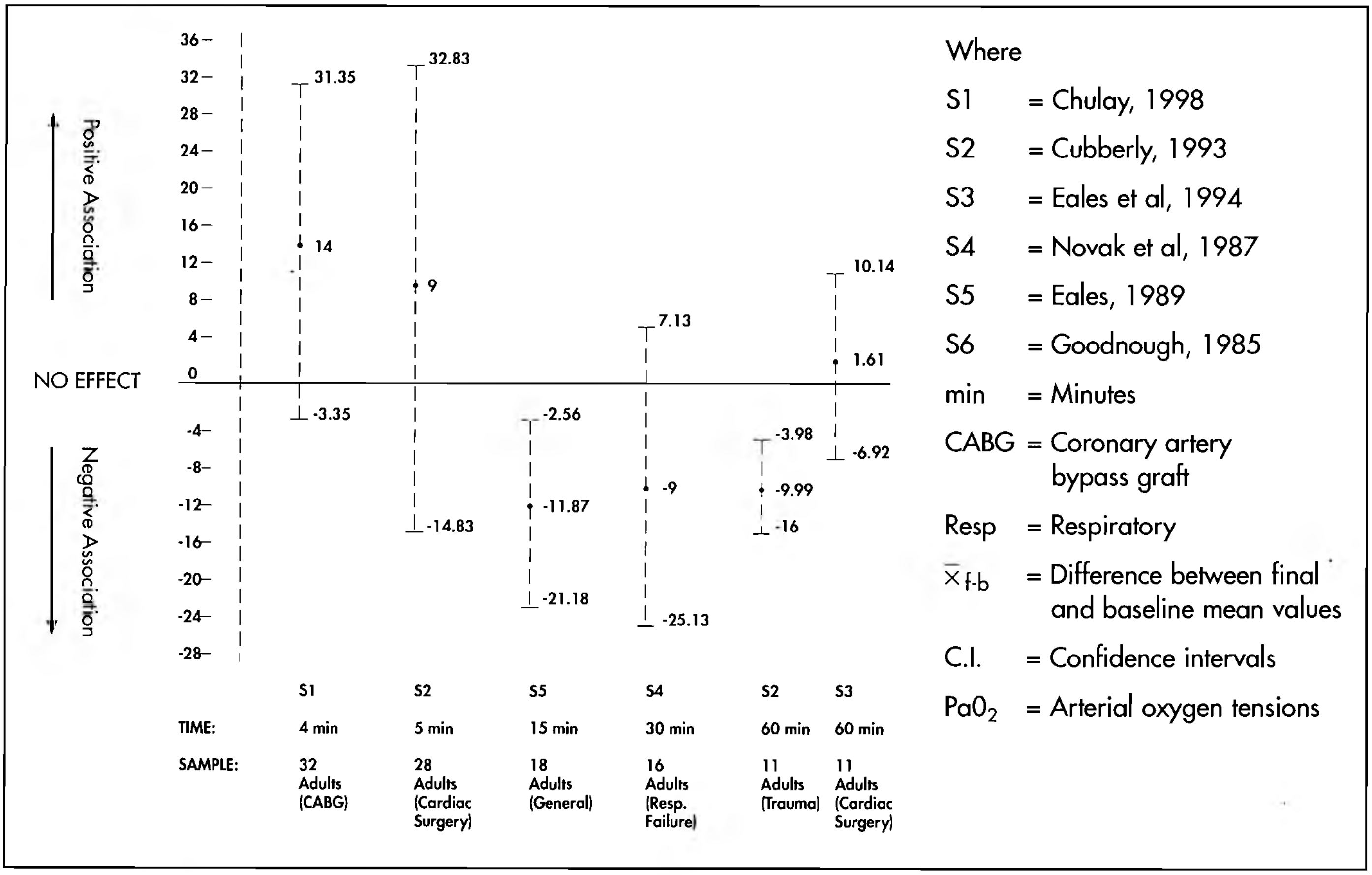


FIGURE 2: $\bar{X}_{f\text{-}b}$ and C.I. and C_L of PAO_2 values for S2, S3, S4 and S7

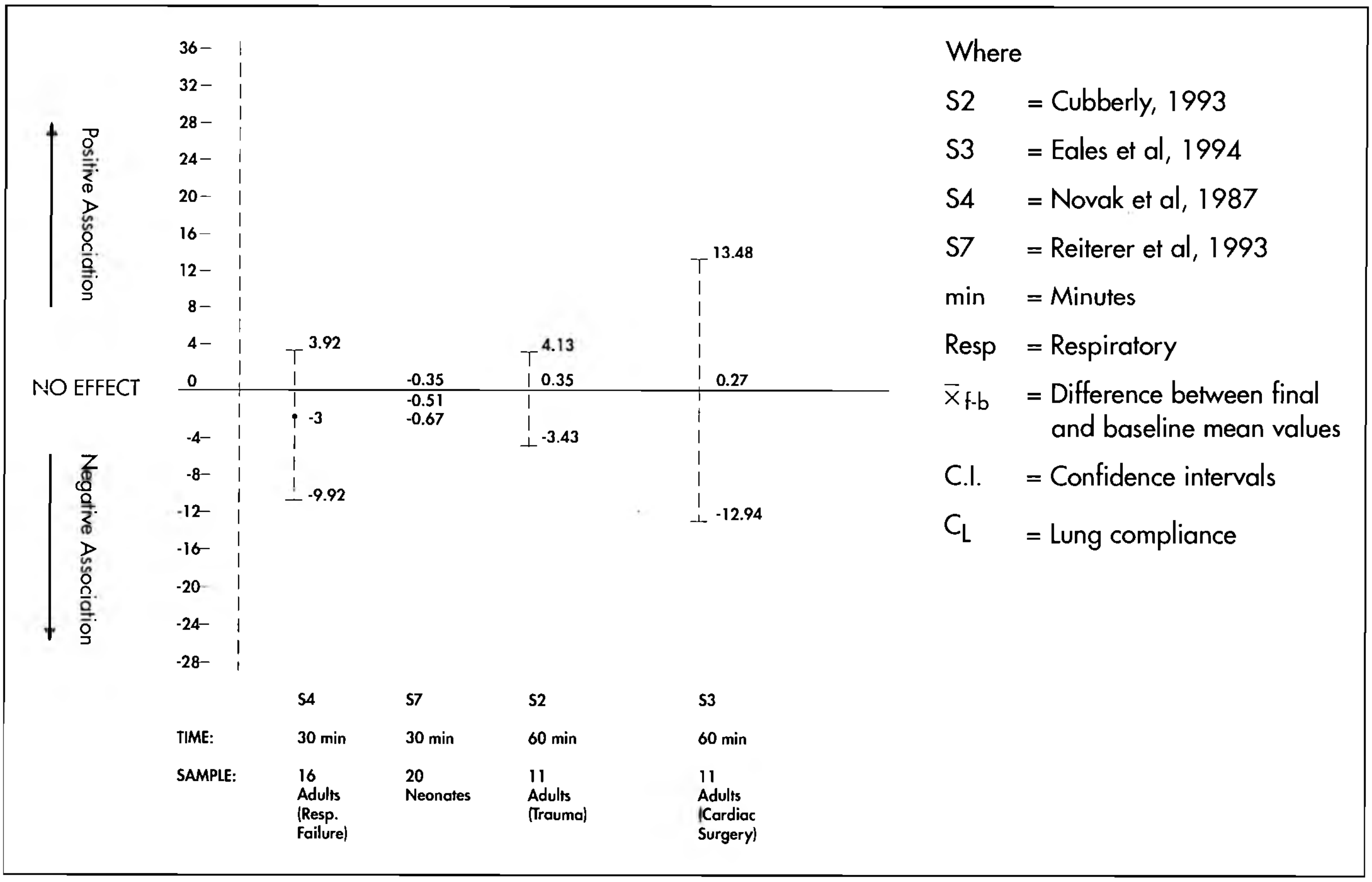
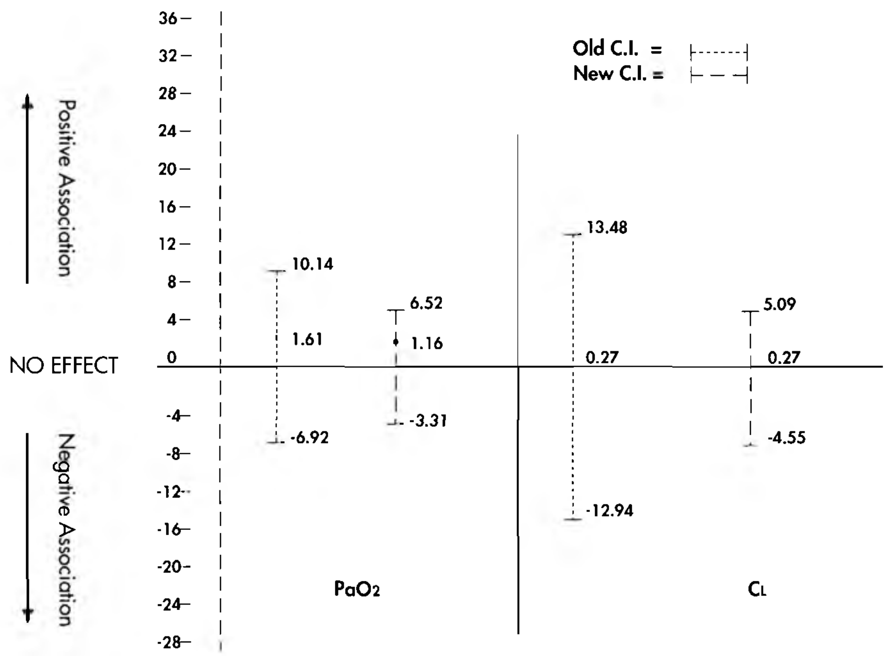


FIGURE 3: $\bar{x}_{f\text{-}b}$ and old and new C.I. for S3, PaO_2 and C_L



Where

S3 = Eales et al, 1994

$\bar{x}_{f\text{-}b}$ = Difference between final and baseline mean values

C.I. = Confidence intervals

PaO_2 = Arterial oxygen tensions

C_L = Lung compliance

deviations were being considered. The values obtained from these calculations are generally overestimated. Similarly, SD_f - SD_b considers the baseline and final measurements as two separate groups and when determining this value negative standard deviations (statistical non-entities) are likely. The correct SD to have used in the calculation of the 95% C.I. would have been the standard deviation of the differences i.e $SD_{f\text{-}b}$. This value considers within patient differences/deviations (Galpin, 1994).

Having the raw data available for only one of the studies included in the meta - analysis viz. Study 3 (Eales et al, 1994), the $SD_{f\text{-}b}$ was calculated for PaO_2 and for C_L. The 95% C.I. for Study 3 were then recalculated using the $SD_{f\text{-}b}$ to derive a "new" SEM. The "new" C.I. were then plotted on a third graph together with the "old" C.I. for the PaO_2 and C_L measurements in Study 3. Knowing that the $SD_{f\text{-}b}$ is often less than the "pooled" SD, the "pooled" SD was then divided by the $SD_{f\text{-}b}$ to ascertain the factor by which the "pooled" SD was greater than the $SD_{f\text{-}b}$. It was then hypothesised that this factor by which the "pooled" SD was greater than the $SD_{f\text{-}b}$ (for both PaO_2 and C_L) could be used in the other trials to estimate their $SD_{f\text{-}b}$ values. This would facilitate a better look at the data of the other trials.

RESULTS

Having conducted the literature search, 11 reports were identified which documented the effects of self-inflating manual resuscitation bags (MRBs), on either arterial oxygen tensions (PaO_2) and/or lung compliance (C_L). Of the 11 studies, only seven fitted all the inclusion criteria. The studies that fitted the criteria are listed in Table 1 and the descriptive statistics for each of these studies are presented in Table 3. Three of the seven measured PaO_2 only, one study measured C_L only and three measured both PaO_2 and C_L. Three studies were excluded from the meta - analysis as they presented their results graphically with no description of mean values or standard deviations in table form or in the text. One study (Tweed et al, 1991) was excluded based on a complex research design which did not render it comparable to the rest of the trials. A synopsis of the studies which were excluded from the meta-analysis is given in Table 2.

RESULTS OF ARTERIAL OXYGEN TENSION (PAO2) VALUES - FIG 1

Study 2 and Study 5 showed significantly negative associations between the use of the MRBs and the effect on PaO_2. A comparison between the methods used in Study 2 and Study 5 shows similarities in that both studies used the Ambu-Ruben MRB. Patients were bagged in both studies until they were clinically clear of secretions. Both studies investigated the effects of bagging on patients with established respiratory failure and who were paralysed and sedated for the duration of the trial. The differences between these studies, however, include the times of final measurement and the inconsistencies in the flow rate settings of the MRBs used. Study 2 used an oxygen flow rate of 15 L/min achieving a FDO_2 of ≥0.8, while Study 5 reports a flow rate of 8 L/min and a

TABLE 1: Summarizing the Methods used in the Studies Included in the Meta-Analysis ie Study 1 Through Study 7

Study	Sample Size	Patient Type	Patient Position	MRB and Settings	Measured Indices	Time Final*
S1 - Chulay 1988	32	Adults - within 24 hrs post CABG	Supine	PMR 2 at 15L/min	PaO_2	4 min
S2 - Cubberley 1994	11	Adults - Trauma post 48 hrs IPPV	ASL - 30° head up	Ambubag at 15L/min	PaO_2 and C_L	60 min
S3 - Eales et al 1995	11	Adults - 24hrs post CABG and MVR	Supine - 20° head up	Ambubag at 15L/min	PaO_2 and C_L	60 min
S4 - Novak et al 1987	16	Adults - Respiratory failure	ASL	Laerdal 3 (FDO_2 = 0.8)	PaO_2 and C_L	30 min
S5 - Eales 1989	18	Adults - General	Supine	Ambubag at 8 L/min (FDO_2 = 0.64)	PaO_2	15 min
S6 - Goodnough 1985	28	Adults - within 4 - 6 hrs post cardiac surgery	Not stated	Test bag system (FDO_2 = 1.0)	PaO_2	5 min
S7 - Reiterer et al 1993	20	Neonates	Not stated	Marquest system 6 - 8L/min	C_L	30 min

(MRB = manual resuscitation bag, * = time of final measurement in each trial , hrs. = hours, CABG = coronary artery bypass graft, PMR = Puritan Manual Resuscitator, min = minutes, IPPV = intermittent positive pressure ventilation, PaO_2 = arterial oxygen tensions, C_L = lung compliance, ASL = alternate side lying, MVR = mitral valve replacement, FDO_2 = fractional delivered oxygen percentage).

TABLE 2: Summarizing the Methods Used in the Studies Excluded from the Meta-Analysis

Study	Sample Size	Patients Studied	Position	Indices Measured	MRB Protocol
Tweed et al (1991)	24 Adults	Lower abd. surgery - intra operatively	Trendellenburg position	$(A\text{-}a)DO_2$ from ABG	MHI 3 - 4 times to TLC at 30 cmH_2O
Okken et al (1987)	15 Pre-term infants	Intubated - on nasal CPAP	Not stated	$TcPO_2$	MHI for 5 min every 20 - 30 min
Fox et al (1978)	13 Neonates	Intubated - Spontaneous breathing	Supine	Dynamic C_L + ABG	MHI with 10 breaths
Jones et al (1992)	20 Adults	Fully ventilated	ASL	Static C_L + SaO_2	Not clearly stated

(Abd. = abdominal, CPAP = continuos positive airway pressure, ASL = alternate side lying, $(A\text{-}a)DO_2$ = alveolar-arterial oxygen difference, ABG = arterial blood gas, $TcPO_2$ = trancutaneuos oxygen tensions measured continuously by a trancutaneuos oxygen electrode, C_L = lung compliance, SaO_2 = arterial oxygen saturations, MHI = manual hyperinflation, TLC = total lung capacity, min = minutes)

$FD0_2$ of 0.64. Study 2 also describes positioning of their subjects in alternate side lying, whereas Study 5 maintained their subjects in the supine position throughout the trial.

Study 1, Study 4 and Study 6 displayed the widest C.I.s for PaO_2 across all the studies. Study 1 and Study 6 were similar in their study designs in that they both used post-operative cardiac surgery patients and monitored their subjects for short periods of time (four minutes for Study 1 and five minutes for Study 6). There is, however, little evidence from the data to suggest much similarity between these two trials and Study 4. On the contrary, differences are apparent in the study design of Study 4 in terms of the condition of the patients used, the time of monitoring and the sample number. Study 4 had a population consisting of patients who required mechanical ventilation for respiratory failure and had the smallest sample size (n=16) of the three studies. This is exactly half that of Study 1 (n = 32) and just over half that of Study 6 (n = 28). Study 1 and Study 6 displayed positive $x_{f\text{-}b}$ values for PaO_2 of 14 and 9, respectively, while the $x_{f\text{-}b}$ for PaO_2 in Study 4 was -9.

Study 1 and Study 2 were the only two studies, which were significantly different from each other with regard to the measurements of PaO_2. Considering the original C.I values which were calculated from the data given in the reports,

TABLE 3: Table Showing Calculated Statistics for PaO_2 and C_L Values of Study 1 Through Study 7

Study	$\bar{x}_{f\text{-}b}$	Pooled SD	Pooled SEM	95% C.I.	Estimated SEM*	Estimated 95% C.i
			PaO_2			
S1	14	50.07	8.85	[-3.35; 31.35]	5.14	[3.93; 24.07]
S2	-9.99	10.64	3.07	[-16; -3.98]	1.78	[-13.47; -6.59]
S3	1.61	16.87	4.35	[-6.92; 10.14]	3.46	[-3.31; 6.52]
S4	-9	32.90	8.23	[-25.13; 7.13]	4.78	[-18.36; 0.36]
S5	-11.87	20.15	4.75	[-21.18; -2.56]	2.76	[-17.30; -6.46]
S6	9	64.34	12.15	[14.83; 32.83]	7.07	[4.85; 24.85]
			C_L			
S2	0.35	6.70	1.93	[-3.43; 4.13]	0.73	[-1.08; 1.78]
S3	0.27	26.13	6.74	[-12.94; 13.48]	2.46	[-4.55; 5.10]
S4	-3	14.14	3.53	[-9.92; 3.92]	1.33	[-2.34; 2.88]
S7	-0.51	0.38	0.08	[-0.57; -0.35]	0.03	[0.57; -0.45]

The values indicated by the asterisk (*) were estimated by dividing the factor of 1.72 and 2.64 for PaO2 and C_L, respectively into the pooled SEM and calculating new 95% C.I. Grey shaded areas = the actual values recalculated from the raw data of S3. ($\bar{x}_{f\text{-}b}$ = the difference between final and baseline mean values, SD = standard deviation, SEM = standard error of the mean, C.I. = confidence interval, PaO_2 = arterial oxygen tension values, C_L = lung compliance).

the upper bound on the C.I for Study 2 (-3.98) did not overlap with the lower bound on the C.I for Study 1 (-3.35). The extent to which these two studies were significantly different from each other was enhanced when the "new" C.I.s were calculated, resulting in a significantly positive outcome for Study 1 (Table 3). The time of final measurement and the condition of the patients were the salient features which distinguished Study 1 from Study 2 (Table 1).

A comparison between Study 2 and Study 3 revealed a significantly negative outcome in Study 2 and no statistically significant outcome in Study 3 (Fig 1). This result is despite a similar protocol adopted in both studies. The positions in which the subjects were treated in these two trials differed, however the most notable feature separating Study 2 and Study 3 was the study sample used. Study 2 used trauma patients after 48 hours of mechanical ventilation, while Study 3 used patients after 18 hours of mechanical ventilation who had undergone cardiac surgery.

As expected from the recalculation of the 95 % C.I for PaO_2 in Study 3 using the $SD_{f\text{-}b}$ (Table 3), the range became much smaller. The factor by which 'pooled' SD was greater than $SD_{f\text{-}b}$ for PaO_2 in Study 3 was 1.72. The 'new' C.I reflects the true within patient differences between the baseline and final measurements. The new values only altered the significance of Study 1. Where the original C.I calculated from the data supplied in the report suggested no significant difference, calculation of the new C.I revealed a positively significant C.I for Study 1 [3.92; 24.07].

RESULTS OF LUNG COMPLIANCE (CL) VALUES - FIG 2

Lung compliance was measured in four of the studies, which met the inclusion criteria of the meta-analysis (Fig 2). Of the four studies, only Study 7 demonstrated a statistically significant result (Fig 2). Although this was a negative result, Study 7 showed the smallest variance in the C.I's values and also reflected the largest sample size (n=20) when compared to the other studies which measured changes in pulmonary compliance (Study 4, Study 2 and Study 3). Study 7 was the only study which examined neonates prior to extubation and who were recovering from respiratory distress. The other three studies all considered adult populations.

The study showing the widest variance with regard to compliance measurements was Study 3. Whereas Study 2 , Study 4 and Study 7 included patients with established respiratory failure, Study 3 was the only study, which investigated the changes in C_L in post-operative cardiac surgery patients. The differences in the compliance values obtained in Study 3 and Study 2 are quite marked. These two studies, as mentioned above, followed a similar protocol, the only difference being the pathologies of the patients used in the study (Table 1).

Fig 3 shows the 'old' and 'new' C.I. for C_L measurements in Study 3. The range of the 'new' C.I. is expectedly less than that of the 'old' C.I. The factor by which the 'pooled' SD was greater than the $SD_{f\text{-}b}$ for C_L was 2.64. Dividing this factor into the 'old' SEM values for Study 2, Study 4 and Study 7 did not significantly alter the results of any of these studies.

DISCUSSION

The thrust of this analysis is to question the use of the self-inflating manual resuscitation bag (MRB) by physiotherapists in the treatment of patients requiring mechanical ventilation. The value of the

MRB in the resuscitation situation, or in the case where temporary ventilation of an intubated patient is required is not being questioned.

The literature reviewed in this meta-analysis does not provide convincing evidence to support the use of the self-inflating MRB by physiotherapists for attaining therapeutic goals. Furthermore, it has been described as being potentially hazardous when used on critically ill patients (Miller and Hamilton, 1969; Jumper et al, 1983; Arellano et al, 1987). It is questionable whether the self-inflating MRB should continue to be recognised as an efficacious modality in intensive care respiratory therapy.

When treating patients in the intensive care unit (ICU) the physiotherapist needs to ask if the objectives of the respiratory therapy can best be met by using a MRB. These objectives include the prevention of hypoxaemia induced by endotracheal (ET) suction, the mobilising and removal of retained pulmonary secretions and the recruitment of collapsed peripheral lung units. Alterations in measured parameters such as the arterial oxygen tensions (PaO_2) and/or the lung compliance (C_L) are usually observed to assess whether these objectives have been attained. Hyperoxygenation and hyperinflation breaths before, during and after ET suction form part of a series of techniques which are used in order to achieve the above stated objectives. Hyperoxygenation implies that the patient is offered a fractional inspired oxygen concentration (FiO_2) above the baseline FiO_2. Similarly, hyperinflation refers to delivering a tidal volume (V_T) 1.5 times greater than the patient's baseline volume. The MRB has traditionally been used to produce these hyperoxygenation and hyperinflation breaths. The literature, however, suggests that this has not been accomplished successfully.

HYPEROXYGENATION

Stone (1990) noted that when ventilators are used to deliver hyperoxygenation breaths before ET suction, higher or equivalent PaO_2 levels were attained when compared to those attained by using a MRB. Such findings ought to break the mindset amongst physiotherapists and nurses who work in the ICU that the MRB is always the most appropriate or the only method of hyperoxygenating patients before ET suction.

HYPERINFLATION

The inspiratory volumes, which are delivered from a MRB, depend on factors such as the compliance of the patient's lungs and thorax, the actual volume of the bag and the technique used to compress the bag viz. a one-handed, a two-handed technique or any alternative technique such as hand-against forearm. Compressing a MRB with two hands has consistently been shown to be associated with higher tidal volumes (V_Ts) when compared to a one handed technique (Carden and Hughes, 1975; Lebouef, 1980; Eaton, 1984; Hess and Goff, 1987; Augustine et al, 1987; Kissoon et al, 1992; Glass et al; 1993). Glass et al (1993) showed that when using one hand to compress the bag, critical care nurses delivered a mean V_T of 17% less than the pre-set volume on the ventilator. Hypoinflation, rather than hyperinflation is therefore likely to occur when the MRB is compressed with one hand.

Authors of trials conducted on the therapeutic effects of MRBs seldom state the technique which was used to compress the bag. This was certainly the case in the studies included in the meta-analysis. This information becomes important to the reader and the meta-analyst so that factors which govern the outcome of the trial can be discerned.

The level of experience or occupation of the operator of the MRB has not been shown to be a statistically significant determinant of the V_T which is delivered (Spears et al, 1991; Glass et al, 1993). Augustine et al (1987) found that of a wide variety of hospital personnel, respiratory therapists delivered the most appropriate tidal volumes at acceptable peak inspiratory pressures. Douglas and McKelvey (1991) similarly demonstrated the ability of respiratory therapists to match a pre-set ventilator rate when using the MRB on two animal models. Although occupation has not been shown to be a statistically significant factor, it may be clinically significant factor in safely delivering hyperoxygenation and hyperinflation breaths to patients in situations when the MRB is indicated. Subtle changes in the patient's respiratory rate or compliance may be better accommodated by experienced operators who are familiar with the ventilatory dynamics and physiological principles associated with bagging. Few studies have concentrated on the specific abilities of respiratory therapists or physiotherapists to achieve optimal FDO_2s and V_Ts. Perhaps once this data becomes available, further conclusions can be drawn from the trends already demonstrated about the importance of familiarity with the bagging technique and hence the role of occupation and experience in achieving desired therapeutic effects.

The capacity for delivering hyperoxygenation and hyperinflation breaths by means of a MRB therefore seems to be inconsistent. This inconsistency was mostly demonstrated in controlled, laboratory settings. When the focus is shifted to the clinical setting, however, it can be seen that the ability to improve the PaO_2 and C_L values of mechanically ventilated patients by using a MRB, may be limited. Six of the seven studies included in this meta-analysis reflect that hyperoxygenation and hyperinflation breaths delivered during ET suctioning were not accompanied by a positive outcome on PaO_2 and/or C_L measurements.

Interestingly, the four studies which were excluded from the meta-analysis, mostly because their data were presented in a way which did not allow them to be critically appraised, all showed positive relationships between the use of a MRB and the outcome on the measured parameters. The results of these four studies may reassure clinicians who intuitively believe in the value of the self-inflating MRB. However, when these studies are closely scrutinised, the research becomes questionable and the results are less encouraging.

One of the excluded studies (Jones et al, 1992) is particularly relevant to the latter point. These researchers showed a sustained increase in static pulmonary compliance after bagging. The authors also report that positioning as well as chest wall vibrations formed part of the treatment. The addition of the chest wall vibrations and the positioning may have been confounding variables in this trial. This study could not separate the effects of bagging *alone*. It showed, rather, that a component treatment of bagging, positioning and chest wall vibrations had a positive outcome on static pulmonary compliance for two hours.

The research conducted by Mackenzie and colleagues (1980 and 1985) presents the same increase in static pulmonary compliance *without* the addition of bagging in the treatment. The chest physiotherapy performed on these patients included percussion, appropriate postural drainage, chest wall vibrations and ET suction. The findings of these studies, therefore, indicate the value of proper positioning in the treatment of mechanically ventilated patients. From the inclusion of positioning in the study by Jones et al (1992), one may infer that bagging may not have been the modality which brought about the observed increases in static pulmonary compliance in their study.

POSITIONING

Positioning is used in many other areas of physiotherapy practice but is somewhat under-utilised in respiratory therapy. Paratz (1992) maintains that "appropriate" positioning is a most useful technique for achieving the desired effects of respiratory therapy, performed within the constraints of haemodynamic stability and parameters such as raised intracranial pressures in head injured or neurosurgical cases. Perhaps it is these constraints that have not been fully appreciated and as such have made many respiratory physiotherapists anxious to adequately position intubated patients eg. in the head down position.

The discouraging results demonstrated in two of the studies included in the meta-analysis which did use positioning viz. Study 2 (Cubberley, 1992) and Study 4 (Novak et al, 1987), may cloud the issue of whether or not positioning per se is all that important. When the methodologies of these two studies are examined, it can be seen that inappropriate positioning or other variables may have influenced the final outcome of these trials. Study 1 (Chulay, 1988), Study 5 (Eales, 1989), Study 6 (Goodnough, 1985) and Study 7 (Reiterer et al, 1993), on the other hand, did not employ a change in the position of their subjects from the supine position. One might then argue that if these studies had incorporated appropriate positioning in their methods their findings may well have been altered.

Positioning is one of the many inconsistencies seen in the methodologies of trials which considered the therapeutic value of the MRB. The influence which positioning alone has on PaO_2 and C_L is still an issue which needs to be fully explored. It may be the degree to which positioning is used i.e. alternate side lying versus a head down tilt position, its use in combination with other techniques such as chest wall vibrations, percussions and manual hyperinflation and then also the patients on which it is used that accounts for the nett effect of positioning on the final outcome of treatment. Herein lies a desperate need for further respiratory therapy research. When positioning of patients is included in the methods of a clinical study, it should be suitably controlled as changes in body position have direct effects on cardiopulmonary performance (Dean, 1992).

PATIENT POPULATIONS

The variability in patient populations used in the analysed trials presents another inconsistency in methods and one which may explain some of the variation seen in the results. When pathologies vary amongst patients on whom the MRB is tested, the magnitude of effect can be expected to differ.

This observation can be explained in terms of the state of the patient's lungs and the type of pathology for which the patients required mechanical ventilation. The responses seen in neonates who have a greater risk of adverse effects from manual hyperinflation because of their highly compliant, immature lungs were shown in Study 7 (Reiterer et al, 1993). This study presented a significantly negative outcome on C_L with manual hyperinflation. Reiterer et al (1993) proposed that the observed drop in compliance was from over-distension of distal lung units. Over-distension may result in alveolar damage and thus leaking of exudate into the pulmonary interstitium (Parker et al, 1993). Within twenty minutes of the application of high volume ventilation wide spread alveolar flooding and epithelial damage has also been noted in animal studies (Dreyfuss et al, 1988 a). Low volume ventilation protocols have since been shown to markedly improve the lung function in patients with the adult respiratory distress syndrome (ARDS), thus facilitating weaning from mechanical ventilation (Amato et al, 1995). Hickling et al (1994) have also observed that peak inspiratory pressures should be limited through low tidal volumes, with permissive hypercapnia, to minimise iatrogenic lung injury in patients with ARDS. Physiotherapists should thus align themselves with the current thinking on low volume ventilation and permissive hypercapnoea in patients with acute lung injury and ARDS and should carefully consider whether or not hyperinflation of the patient's lungs is indeed what is indicated. Furthermore, the protective effects of PEEP ventilation are now well recognised (Dreyfuss et al, 1988 b; Muscredere et al,1994) and may become jeopardised when the patient is bagged.

Perhaps the MRB has been offered too much attention by physiotherapists, to the detriment of other techniques such as movement and position. Controlled clinical trials on the therapeutic value of other manual resuscitators e.g. the Mapleson C Bag need to be conducted. Since this type of bag relies on an oxygen source for its inflation and is not self-inflating, an 'inflation hold' as well as a PEEP can be achieved. Although these claims may be clinically real, they have not been demonstrated scientifically. The authors are aware that since this meta-analysis was conducted, other reports on manual hyperinflation have been published. Many of these studies were conducted on experimental lung models (Rusterholz and Ellis, 1998; Cheah et al, 1998; McCarren and Chow, 1996;) while others report the results of audits on manual hyperinflation (Clapham et al, 1995) or present subjective reviews of the literature (Maxwell and Ellis, 1998; Robson, 1998).

Two of the most recently published trials were conducted on adult, mechanically ventilated patients (Patman et al, 1998; McCarren and Chow, 1998). Patman and colleagues (1998) considered the cardiovascular effects of manual hyperinflation in early, stable, post-operative coronary artery surgery patients, while McCarren and Chow (1998) present a simple, descriptive study on the tidal volumes and airways pressures generated by the technique in patients with atelectasis. None of these published reports meet the inclusion criteria of this meta-analysis. Furthermore, no other reports have arisen that could have been included. We, therefore argue that despite delays in publication, the results of this meta-analysis and its recommendations remain relevant.

CONCLUSION

This meta-analysis has demonstrated a trend which suggests that the MRB has limited effect on the measured PaO_2 and C_L values of mechanically ventilated patients. Hence, the self-inflating MRB may not be achieving the desired therapeutic objectives. It is questionable whether using a self-inflating MRB can consistently and reliably deliver hyperoxygenation and hyperinflation breaths to patients requiring mechanical ventilation. Much of this inconsistency is related to the operators of the MRB. Variability in how the operator compresses and releases the MRB and the ability to make careful, clinical judgements may influence the efficiency and safety with which the MRB is used. The meta-analysis also highlighted the great divergence in the research and the factors, such as positioning, which could be controlled in further trials.

Considering the above, it becomes clear that more controlled, similar, multicentre trials are needed to resolve the uncertainty regarding the therapeutic value of the self-inflating MRB alone, especially across a wide range of pathologies. Until such time as the results of these studies become known and a meta-analysis is once again performed, physiotherapists working in the intensive care units which use self-inflating bags, should consider alternative ways of achieving hyperoxygenation and hyperinflation in the treatment of their patients. This is supposing that hyperinflation is indeed indicated, considering the current thinking on low volume and PEEP ventilation. It is hoped that this report will enable physiotherapists who deal with mechanically ventilated patients in the intensive care unit to start asking "why" before routinely making use of the self-inflating MRB.

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