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# The use of the manual resuscitation bag on mechanically ventilated patients and its effects on arterial oxygen tensions and lung compliance: a meta-analysis of the literature

**Barker, Michael**

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# CHAPTER 1

"History suggests that the road to a firm
research consensus is extraordinarily arduous."

(T.S. Kuhn, 1970)

## 1.1 INTRODUCTION

The normal development of a new science is much the same as the embryology of a human where the morula continues to divide in the first week of intra-uterine life. Every cell is considered equal, until each one divides and eventually differentiates into a recognizable human foetus at nine weeks of life. So too with a new science, the initial gathering of information is a random process with no particular form of information being sought. During this time all facts, like the cells of the morula, are evenly weighted and considered equal. The science only becomes recognizable when it universally accepts its first paradigm.

The concept of paradigms and how they function in the philosophy of science is described by Thomas Kuhn (1970) in "The structure of scientific revolutions".
A paradigm is defined in the Oxford dictionary as an 'example or pattern'. According to Kuhn, a paradigm is a unique philosophy or set of beliefs which a science adopts for problem-solving. The acceptance of these beliefs is based on the previous achievements made by the science. A paradigm has the following characteristics:

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## LIST OF ABBREVIATIONS

| | |
|---|---|
| MRB | - manual resuscitation bag |
| PaO2 | - arterial oxygen tension |
| $C_L$ | - lung compliance |
| $FDO_2$ | - fractional delivered oxygen concentration |
| $FiO_2$ | - fractional inspired oxygen concentration |
| MAP | - mean airway pressure |
| IPPV | - intermittent positive pressure ventilation |
| CPAP | - continuous positive airway pressure |
| SaO2 | - arterial oxygen saturations |
| ICU | - intensive care unit |
| $V_T$ | - delivered tidal volume |
| $\ell$ | - litres |
| $t_i$ | - inspiratory time |
| C.I. | - confidence interval |
| SD | - standard deviation |
| $\bar{x}_{fb}$ | - differences between mean values at final and baseline readings |
| S1 - S7 | - Study 1 - Study 7 |

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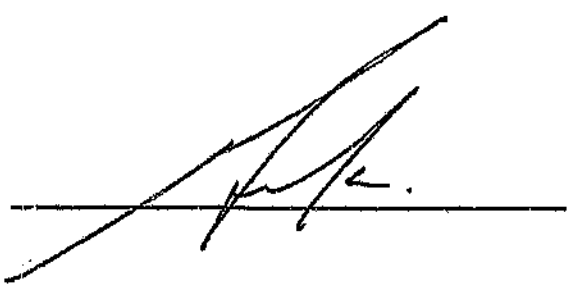
## DECLARATION

I declare that this research report is my own, unaided work. It is being submitted for the degree of Master of Science in Physiotherapy in the University of the Witwatersrand, Johannesburg. This work has not been previously submitted for any degree or examination in any other university, nor has it been prepared under the aegis of or with the assistance of any other person or organisation outside the University of the Witwatersrand except to the extent of those mentioned in the acknowledgements and references.



12TH day of SEPTEMBER, 1995

## ABSTRACT

The manual resuscitation bag 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 use and the literature is not in agreement as to the effects of manual hyperinflation. A meta-analysis of the current research has been conducted to investigate the effects of this modality on arterial oxygen tension and lung compliance. All 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. Twelve studies were identified between the time period 1968 - 1994. Seven of these studies fitted the inclusion criteria. The mean and standard error of the mean values for arterial oxygen tensions (PaO2) 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 PaO2 and $C_L$ values was demonstrated.Great discrepancies were identified in the designs of the seven studies.Since the seven studies included in this meta-analysis show an overall non-significant association, it is reasonable to assume that the manual resuscitation bag has limited capacity for increasing the PaO2 and $C_L$ values.It is unfortunate that in the studies where a positive outcome of bagging was demonstrated, inadequate data was presented in the trials.Therefore, these studies could not be included in this meta-analysis. The studies which have been included, however, presented such divergent designs that they do not offer conclusive evidence.Recommendations are presented for a standardised, multicentre study which hopefully will clarify the therapeutic value of this elusive modality.

# THE USE OF THE MANUAL RESUSCITATION BAG ON MECHANICALLY VENTILATED PATIENTS AND ITS EFFECTS ON ARTERIAL OXYGEN TENSIONS AND LUNG COMPLIANCE:

## A META-ANALYSIS OF THE LITERATURE

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Michael Barker

B.Sc. Physiotherapy (Witwatersrand)

A research report submitted in partial fulfilment of the requirements for the degree of Master in Science in Physiotherapy in the Faculty of Medicine of the University of the Witwatersrand, Johannesburg.

Johannesburg, 1994

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lung, while perfusion remains greatest in the dependent zones (Bergman, 1963; Klingstedt et al, 1990). Low $\dot{V}/\dot{Q}$ ratios are thus established in underventilated alveoli, which become unstable and may ultimately collapse after having their residual gas volume resorbed. The collapse of these peripheral lung units is associated with a decrease in the functional residual capacity (FRC) and a subsequent fall in pulmonary compliance. The pulmonary compliance of the spontaneously breathing individual is 200mℓ/cm$H_2O$, whereas that of a mechanically ventilated patient may drop to between 40 - 80 mℓ/cm$H_2O$ (Comroe,1974). $\dot{V}/\dot{Q}$ ratios may become further disturbed when smaller tidal volumes than required are delivered to the patient and in the case where high inspiratory pressures cause compression of the lung's microvasculature and thus interfere with perfusion.

Barotrauma, or pressure- induced damage to the lung parenchyma, has long since been realised as a complication associated with the clinical use of positive pressure ventilation (Kravath and Schonberg, 1968; Miller and Hamilton, 1969; Dolan et al, 1981; Hirschman and Kravath, 1982; Jumper et al, 1983). Patients who are particularly at risk of pressure-induced trauma are those with diseased lungs eg. emphysema sufferers with bullous formation or pre-term infants with immature lungs. Miller and Hamilton (1969) proposed that it was the size which the alveolus attained and not the absolute intraluminal pressure which would cause rupture. They claimed that the size was dictated by the magnitude of the transmural pressure i.e the pressure inside the alveolus minus the pressure outside the alveolus. Parker et al (1993), when reviewing studies investigating the mechanisms of pressure-induced lung injury, concluded that high peak inspiratory pressures and volumes were predisposing factors for lung injury and that this injury could take the form of "stress fractures" of vascular endothelium, respiratory epithelium and basement membranes, with

## 2.2 THE PHYSIOLOGICAL EFFECTS OF POSITIVE PRESSURE VENTILATION

It is important that all clinicians who deal with patients on mechanical ventilation and who operate MRB appreciate both the desired therapeutic effects of positive pressure ventilation as well as the undesirable consequences that it may have on their patients. The following discussion will deal specifically with the effects of positive pressure on the respiratory and cardiovascular systems. While it is recognised that mechanical ventilation in itself has other adverse effects viz., nosocomial respiratory infections and that of oxygen toxicity associated with high a fractional inspired oxygen concentration ($FiO_2$), these will not be dealt with as this review is primarily concerned with the effects of positive pressure ventilation as delivered by the MRB..

### 2.2.1 The respiratory system

During normal tidal breathing, there is preferential distribution of the inspired gas volume to the dependent regions of the lungs. In the erect position, there will be greater gas distribution ($\dot{V}$) to the bases and peripheral lung zones. This phenomenon is brought about as the diaphragm contracts to generate a greater increase in trans-pulmonary pressure[1] in the dependent zones. As perfusion ($\dot{Q}$) is also greatest in the dependent areas in this position, there is good physiological matching of ventilation and perfusion and this ensures good oxygenation of arterial blood (Scanlan, 1990; Yeaw,1992).

Optimal $\dot{V}/\dot{Q}$ matching is, however, not seen with positive pressure ventilation as the positive pressure is preferentially driven to non-dependent and more central areas of the

The need to determine the efficacy of bagging was to become a challenge to future researchers in this field. The challenge lay in closely examining the advantages of the technique despite its associated hazards. The 'how' of manually hyperinflating lungs had established, the 'why', however, remained controversial.

One of the earliest descriptions in the literature on how physiotherapists used the MRB was in 1968, when Clement and Hubsch presented the technique as used in the Cardio-thoracic unit of St. Thomas' hospital in London. The paper detailed the contemporary role of the anaesthetist, nurse and physiotherapist in the correct application of the "bag-squeezing" technique. Using a 4ℓ anaesthetic bag, the authors outlined their protocol of "bag-squeezing" patients twice daily and highlighted the possible dangers of the technique. They recommended that a plateau/hold at the end of inspiration be achieved. This allowed filling and recruitment of poorly ventilated lung units. The point was also strongly put forward that the physiotherapist should never be allowed to "bag-squeeze" a patient without an anaesthetist or physician in attendance. This opinion was to change in subsequent years, as it has become impractical to have three clinicians performing the technique.

Clement and Hubsch's article set a precedent in establishing the guidelines of the bagging technique, for useage by physiotherapists in many centres world-wide. Windsor et al (1972) depicted the Australian experience of "bag-squeezing" by merely echoing the protocol adopted by their English colleagues and indeed used Clement and Hubsch as their only reference.

Windsor et al (1972) proceeded to present three case studies in the paper of the effect of "bag-squeezing" on their patients showing the radiological changes which took place after the technique was applied. They offered some insight into the potential therapeutic benefits of using the MRB on mechanically ventilated patients.

Chest physiotherapy traditionally has two aims. The first being to aid in the clearance of excessive or retained pulmonary secretions and the second, to recruit collapsed distal lung units. This perception is currently being expanded into a more extensive concept (Dean, 1994). The new concept is based on the current thinking of cardiopulmonary function in terms of oxygen transport pathways. These pathways incorporate a series of steps referred to as "ventilatory-cardiovascular-metabolic coupling". Research to date, regarding the efficacy of bagging, was based on the old concept of lung clearance and recruitment of collapsed distal lung units which only forms part of the new philosophy.
Techniques such as postural drainage, percussion and chest wall vibrations were and still are used to mobilise and assist in removing secretions from the lungs, with subsequent recruitment of collapsed lung units.

Since Van Allen and Lindskog (1931) outlined the role of collateral ventilation in the prevention of atelectasis, it was agreed that intercommunicating channels had an important part to play in the even distribution of gas during normal breathing and in the re-expansion of atelectatic lung units. These intercommunicating channels were identified between adjacent alveoli (interalveolar pores of Kohn), between alveoli and terminal bronchioles (broncho-alveolar canals of Lambert) and between terminal bronchioles (inter-bronchiolar channels of Martin). Physiotherapists then began to reason that since patients receiving positive pressure ventilation were prone to decreased mucociliary activity and atelectasis, hyperinflating the lungs would utilise these intercommunication channels and facilitate the mobilisation of secretions and the recruitment of atelectatic lung units. The use of a MRB to deliver these hyperinflation volumes became a logical option.

was characterised by a high mortalities from respiratory failure. During this epidemic in Denmark, the literature details the shifts of students who were employed over a 24 hour period to manually ventilate patients. Mortalities from respiratory failure dropped significantly from 80% before the epidemic to 23% , by using manual ventilation (Young and Sykes, 1990). Although these figures were impressive, this labour intensive experience and the fear that the epidemic may happen again, lead to the design and development of automatic intermittent positive pressure ventilators.

By 1953 the concept of intermittent positive pressure ventilation had become recognised as an important modality in the management of acute respiratory failure (Phillips and Skowronski, 1986). Notwithstanding the acceptance of the mechanical ventilator, manual resuscitation still had a place in offering temporary ventilation to patients requiring artificial respiratory support when transporting such patients or in a resuscitation situation where the patient couldn't always get to a mechanical ventilator. By 1957 the first self-inflating manual resuscitation bag (the Ambu-bag) was pioneered.(Ruben and Ruben, 1957).

Before this time physiotherapists had been involved in the treatment of patients on negative pressure devices like the iron-lung. With the phasing out of negative pressure devices and the advent of positive pressure mechanical ventilators, artificial airways were used and the physiotherapist became more involved in the respiratory care of these patients as they needed assistance in airway clearance. This aspect of physiotherapy practice has since expanded to the extent of it becoming a speciality area of the profession today.

# CHAPTER 2

## LITERATURE REVIEW

### 2.1 A HISTORICAL PERSPECTIVE OF POSITIVE PRESSURE VENTILATION AND MANUAL RESUSCITATION BAGS

The first report of an asphyxiated adult victim given mouth-to-mouth resuscitation is dated back as early as 1744 (Fothergill, 1744). Fothergill relates an incident where a man, who appeared to be dead, was given air to distend his lungs and that "inflating the lungs [was]..... like giving the first vibration to a pendulum.....[enabling] this something to resume the government of the fabric, and actuate its organs afresh". Mouth-to-mouth resuscitation was replaced by the fireside bellows in the latter part of the 18th century. The bellows was in reality the first manual resuscitator which delivered air under positive pressure to the lungs. Reports then appeared citing barotrauma as a possible complication caused by the bellows. Thus the bellows lost favour as a resuscitation tool for the greater part of the 1800's. It was then reintroduced by Fell, in 1894, as a method of ventilating patients via artificial airways. Positive pressure then became recognised as a method of resuscitation even though it was used in a rather crude form (Phillips and Skowronski, 1986).

After the introduction of the first automatic resuscitator in 1907 and the development of the 'iron-lung' (a negative pressure device) in 1929, the greatest collective thinking about positive pressure ventilatory support came with the 1952 poliomyelitis epidemic which

on the value of this technique. The meta-analysis will offer more useful information to the practising physiotherapist as it considers the pooled result of all the trials. The meta-analysis will also aid in identifying methodological errors in the research of this technique and so help to guide future research projects in the field.

An analysis such as this brings physiotherapists closer to the truths about the techniques which they use. This report also presents the type of scientific achievement, referred to by Kuhn (1970), which could later allow the profession to construct a paradigm. It is hoped that this report will enable physiotherapists who deal with mechanically ventilated patients in the intensive care unit to start questioning the routine bagging of these patients. In this way both individual as well as professional development will be facilitated.

Before presenting the meta-analysis, it is worthwhile to first explore the origins of the MRB in physiotherapy practice. An overview of the effects of positive pressure ventilation, the physical properties of MRBs, the hazards associated with their use and the operator characteristics will outline concepts which aid in appreciating the clinical research which has been conducted on this modality.

## 1.2 THE AIMS OF THIS META-ANALYSIS

"Professionalism is embodied in . . . . . a critical attitude
to modes of treatment previously taken for granted."

(J. Sim, 1985)

The place of the manual resuscitation bag (MRB) in the treatment of mechanically ventilated patients has been secured by tradition and anecdotal evidence rather than by scientific confirmation of its efficacy. The reason for this is that few experimental trials have addressed the effects of manual hyperinflation, in terms of increased secretion clearance and recruitment of atelectatic lung units and thus, its effects on arterial oxygen tensions and lung compliance. Furthermore, the literature which is available presents conflicting evidence to the reader. This is particularly evident when each of these studies is viewed in isolation and not as part of a whole. The results obtained in the few experimental trials do not allow standard guidelines to be adopted on when manual hyperinflation should be used (Reiterer, 1993). The literature thus far, seems to have failed to provide a sound argument to support or refute the continued use of bagging in the treatment of mechanically ventilated patients in the intensive care unit.

The reader is requested to note that from this point onward, the term "bagging" will be used to refer to the manual hyperinflation breaths delivered by a manual resuscitation bag as this is the commonly used clinical term.

The aim of this meta-analysis is to quantitatively and qualitatively evaluate the available trials which have investigated the effects of bagging on arterial oxygen tensions and/or lung compliance. The results of the meta-analysis will then allow conclusions to be drawn

health care system. Changing health needs of communities will place new demands on the profile of the profession and challenge it by posing questions to validate its practice. The answers to these questions will be sought by testing the paradigm and either adopting or rejecting the outcome. In this way a profession develops and matures.

The above proposal seems daunting considering the wide spectrum of physiotherapy practice today, ranging from the care of critically ill patients to the management of physiotherapy services in rural communities. Just as Kuhn identified that paradigms relate to a particular science, so too has Tornebohn (1986) described the existence of individual paradigms within a science. Such paradigms are the philosophies which belong to the individuals who practice that science. Therefore, the responsibility of establishing a paradigm for a profession rests with the members of that profession. They need to acquire an ability to think analytically about the patterns of their science and how these affect their scope of practice. Once individual paradigms have been adopted, interaction amongst the individuals of the profession then becomes important to ensure that the individual paradigms are similar and that a paradigm for the profession can be constructed.

If we are to accept physiotherapy as a science, the shift in professional thinking should incorporate less of "how" but rather "why" we practice.

1. It is forceful - i.e. it steers the scientific group away from competing forms of scientific activity and starts to dictate the science.
2. It is open-ended and as such can still pose enough unresolved problems to be tackled by that scientific group.

As the paradigm becomes functional it offers the science, or the profession, security and encourages subsequent scientific enquiry to be more precise. The paradigm governs the acceptable methods and instrumentation to be employed in the science's research activity. Research activity thus becomes 'paradigm-based'. The paradigm is then repeatedly tested by the questions which arise in the particular field of practice. As long as it functions well, the paradigm will continue to be used and with time it expands and becomes more elaborate.

A paradigm ceases to function when it is no longer successful in supplying a template for satisfactorily answering the questions posed by the scientific group. The paradigm is then revised, either entirely or in part and this process Kuhn refers to as a "scientific revolution" (Fig 1.1).

Physiotherapy is a new and developing science. As it is still in an evolutionary phase, it has not yet accepted its first paradigm (Richardson,1992). Richardson concentrates on the need of the physiotherapy profession to isolate its own set of beliefs and in so doing define an exclusive theory for physiotherapy practice. Only once this is done can the parameters of physiotherapy practice be set and the questions posed by the profession be answered in a 'paradigm-based' fashion. The parameters within which the physiotherapy profession practices are important in justifying the place of the profession in any multi-disciplinary

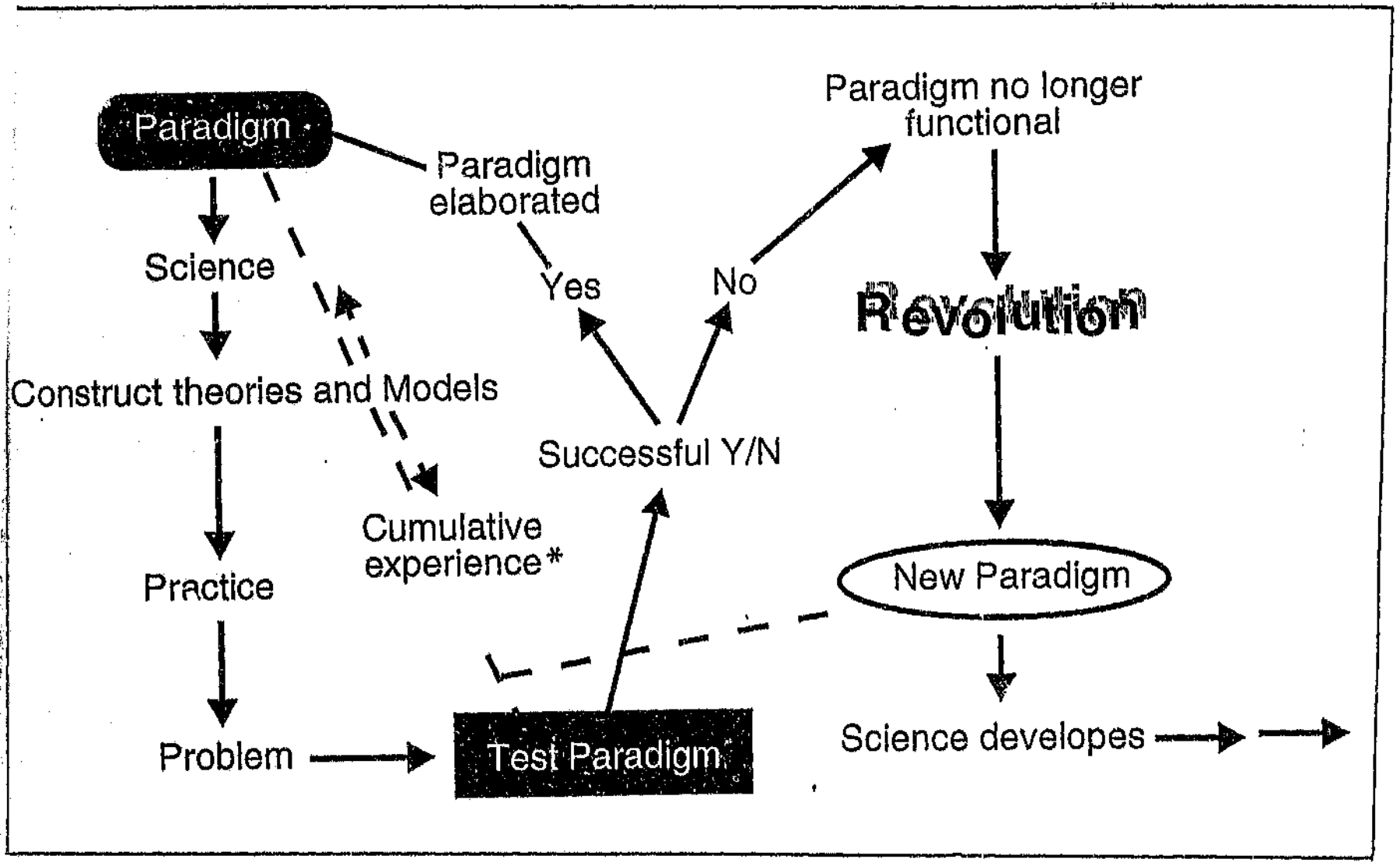


Fig 1.1 How a paradigm functions within a science

(* Van Gigch and Pipino, 1986)

The physical properties and performance characteristics of currently used MRBs have evolved over the last three decades. During this time, as newer bags arrived on the market, they required testing for appropriate oxygen delivery and valve function. Testing was also necessary to ascertain whether the bags would be capable of performing well in specific resuscitation situations i.e. where resistance was encountered during manual compression, in extremes of temperature and where operators of varying competencies were using them.

The following critique focuses on the oxygen delivery characteristics and valve systems of MRBs as they developed over time. Other factors such as the environmental influences and their effect on MRB performance will be discussed.

### 2.3.2 Oxygen Delivery and Valve Systems

Since the MRB was developed to offer hyperoxygenation to patients in respiratory failure, its capacity for optimal oxygen delivery has been the focus of much of the research done on performance characteristics. The early literature seemed to concentrate on how oxygen was delivered to the bag, the presence or absence of reservoirs and the flow rates which were necessary to achieve optimal fractional delivered oxygen concentrations ($FDO_2$s). It was also recognised that malfunction of the inflating valve could affect oxygen delivery.

Some of the initial work on establishing the $FDO_2$ of commercially available MRBs was done by Karl (1966) and Redick et al (1970). Both authors reported that the $FDO_2$ was related to the rate at which oxygen flowed into the bag. Karl measured a maximum $FDO_2$ of only 74% in the Ambu bag, with the flow meter opened to it full extent. If flow rate

**2.3.1 How a MRB functions.** (Fig 2.1)

The functioning of a MRB can best be described in terms of the events which take place during compression and re-inflation of the bag.

Compression

Tubing connects the bag to an oxygen supply source (oxygen flow rate set at 15ℓ/min) which enters the bag at the reservoir. It is uncommon for the oxygen source to enter directly into the bag itself. When the bag is compressed, two things happen. Firstly, the positive pressure generated by manually squeezing the bag forces the valves at the patient connection (inhalation/exhalation port) to open. This allows delivery of gas to the patient. The valves at the inhalation/exhalation port may be either of the fish mouth or spring loaded type. At this time the volume delivered flows unidirectionally to the patient because of the closure of another one - way valve at the reservoir end.

Re-inflation

The MRBs under consideration here are of the self-inflating type. This implies that at the end of the compression phase of the bag i.e. once the patient starts to exhale, the bag automatically re-inflates. This causes an air/oxygen mix to be drawn into the bag through the one-way valve at the reservoir. Once the bag is released, this valve becomes patent. The valve at the inhalation/exhalation port then closes to ensure that the gas delivered to the patient does not re-enter the bag-valve system i.e. no re-breathing of the patient's exhaled air takes place.

Once full re-inflation of the bag has taken place, the cycle is repeated by manually compressing the bag again.

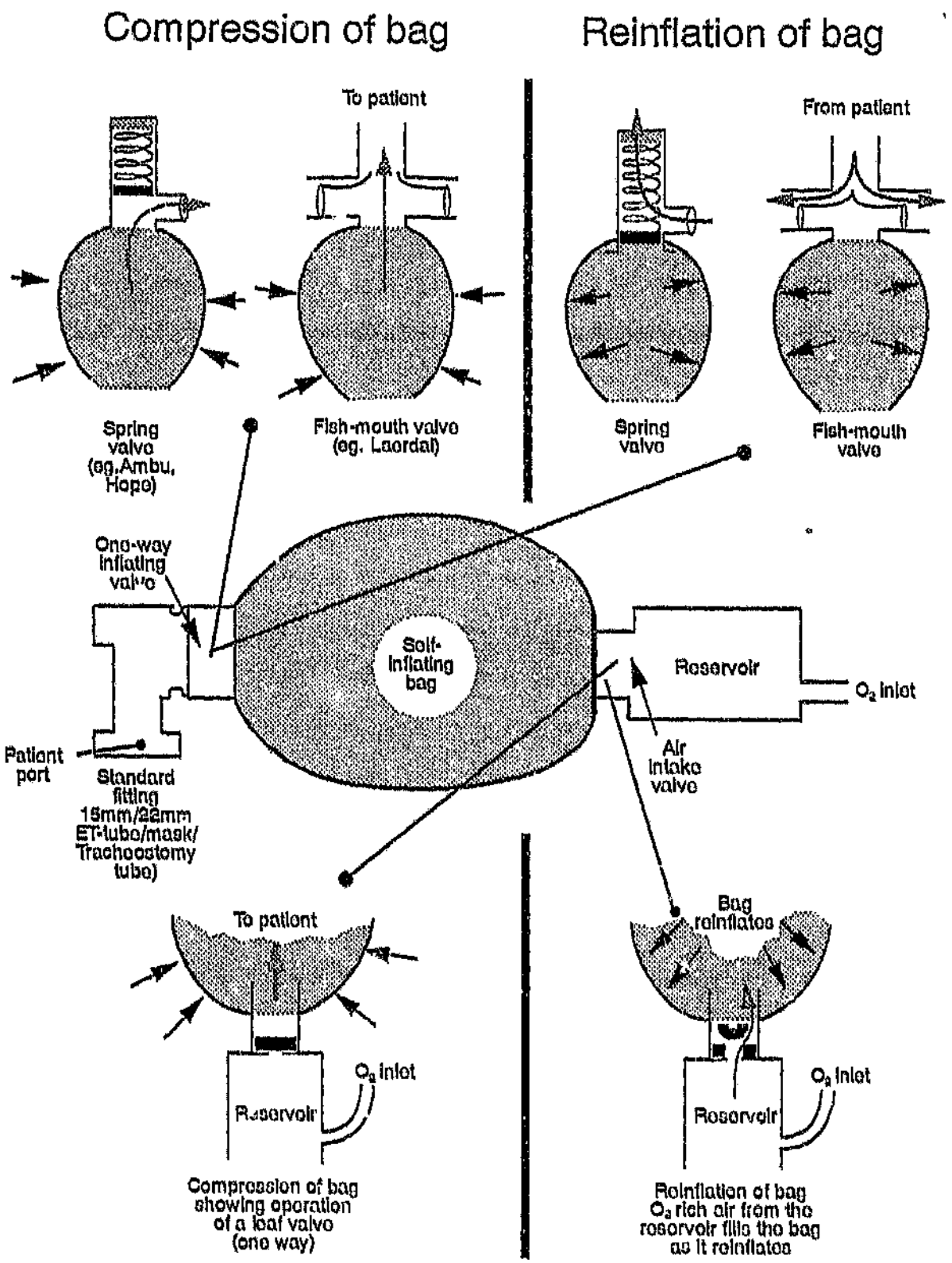


**Fig 2.1** An illustration of the mechanics of a typical self-inflating manual resuscitation bag. (mm = millimeters, ET = endotracheal, $O_2$ = oxygen). Adapted from Pfister, 1982.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Laerdal Infant | 240 ml | 205 | - | High oxygen flows will not affect proper function | Tube or oxygen reservoir assembly | Up to 100 | Spring-loaded valve set to open near 35 cm $H_2O$ bag pressure | No |
| PMR | 2000 ml | 950 | 1200 | Oxygen flows up to 20 l/min will not affect proper function; flows from 20 to 50 l/min may cause some resistance to patient's exhalation | None commercially available | Up to 80 | None | Yes |
| AIRbird | Adult, 2000 ml; paediatric, 500 ml | 700 | 800 | High oxygen flows will not affect proper function | Tube or tube with bag and safety one-way valve inlet | Up to 100 | Fixed orifice leak | Yes |
| Robertshaw bag | Adult, 1600 ml; child, 500 ml | 600 | 900 | With oxygen reservoir system, high flows will not affect proper function | Tube or tube with bag assembly may be added as modification; demand valve can also be attached | Up to 100 | None | Yes |

Adapted from Scanlan, C.L.; Spearman, C.B.; Sheldon, R.L. (eds). Egan's Fundamentals of Respiratory Care, 5th Edition, C. V. Mosby Company, St Louis, 1990

* Le Bouef, 1980

+ Phillips and Skowronski (1986)

where: MRB = Manual Resuscitator bag

: PMR = Puritan (Bennett) Manual Resuscitator

TABLE Physical Properties of Commonly Used Manual Resuscitator Bags

| MRB | Volume of the MRB when full | Achievable Tidal Volumes (in ml) | | Maximum (Safe) Oxygen flow rate | Type of Oxygen Reservoir | Maximum Oxygen Percentage Expected with Optimum Conditions (%) | Type of Pressure Relief | Spontaneous breathing opens valve for oxygen |
|---|---|---|---|---|---|---|---|---|
| | | One Hand | Two Hand | | | | | |
| Air Viva-2* | 1700 ml | Achievable tidal volume (1200 ml) | | 10 to 15 l/min may cause jamming of valve | Bag | 98% | Pressure limit = 70 | No |
| Hope II* | Adult, 2000 ml; paediatric, 750 ml | 1211 | 452 | High oxygen flows will not affect proper function | "Elephant" bore tube | Up to 100 | Optical magnetic ball set to open at 40 cm $H_2O$ | No |
| AMBU Mark II | Adult Mark II, 1300 ml; infant 400 ml | 952 | 999 | High flows may be used when unit is equipped with valve without affecting proper function (AMBU (early models) - <10-15 l/min to avoid jamming the valves) | Tube or bag with inlet one-way valve such as Laerdal's reservoir assembly | Up to 100 | Adult bag stretches at 70 cm $H_2O$; Infant at 50 cm $H_2O$ | No |
| Laerdal RPB-II, Adult | RPB-II, 1000 ml; Adult 1600 ml | 1000 | 1200 | High oxygen flows will not affect proper function | Tube or oxygen reservoir assembly | Up to 100 | None | No |
| Laerdal Child | 500 ml | * | * | High oxygen flows will not affect proper function | Tube or oxygen reservoir assembly | Up to 100 | Spring-loaded valve set to open near 35 cm $H_2O$ bag pressure | No |

- the valve assembly should ideally be in a transparent casing to have full view of the valve mechanism, should this become dysfunctional.
- a positive end expiratory pressure (PEEP) valve should accompany the bag-valve assembly so that pre-set PEEP levels can be maintained during manual hyperinflation.
- the unit should be able to function in any position eg. offering a trapped victim temporary ventilation until such time as they are extricated.
- the bag ought to consist of a minimum number of parts to facilitate easy reassembly, with connections fitting only a specific bag in one specific way.
- the entire bag-valve unit should have low expiratory resistance (less than 5 cmH2O at 60 ℓ/min air flow) and low dead space.

Table 2.1 summarises the physical properties of some commonly used MRBs. This information is useful to the physiotherapist in selecting an appropriate MRB to fit the needs of the patient.

1. Self refilling bag, easily cleaned and sterilized.
2. A non-jam valve system allowing an inlet flow of 15 ℓ/min of oxygen.
3. A no-pop-off valve.
4. Standard fittings of 15 mm/22 mm.
5. A system to allow high $FDO_2$* by either a reservoir or an ancillary oxygen inlet at the back of the bag.
6. A non-rebreathing valve
7. Should perform well (in terms of maximum cycling rates and valve function) in all common environmental conditions, notably extremes of temperature.
8. Obtainable in adult and paediatric sizes.

* Fractional Delivered Oxygen Concentration

**Text Box 2.3** Criteria for adequate bag-valve units - Standards and Guidelines Conference, 1992

Although the above are the minimum standards, additional features of bag-valve units are desirable: (Pfister, 1980; Eaton, 1984; Phillips and Skowronski, 1985):

- if a face mask is used, this mask should be transparent to be able to assess cyanosis and the presence of vomitus. The mask should also have a air-filled, contoured cuff.
- the material from which the bag is made should be durable and not deteriorate with time and break up into fine particles which may be blown into the patient's lungs.

## 2.3 PHYSICAL PROPERTIES OF MANUAL RESUSCITATION BAGS

This section deals with the physical properties of current manual resuscitation bags, their performance characteristics and the structural modifications which became necessary to satisfy minimum standards for their use.

Manual resuscitators can be broadly divided into two groups :

1. those which are self - inflating eg. Laerdal and Ambu bags
2. those which are dependant on an oxygen supply source in order to re- inflate eg. Mapleson B system (Phillips and Skowronski, 1986).

This review will only concentrate on manual resuscitators with self - inflating bags and non-rebreathing valve systems which are currently in use today.

These portable, operator powered manual resuscitation bags (MRBs) may be used via a face mask to assist the ventilation of spontaneously breathing patients as well as via artificial airways to manually ventilate intubated patients. The MRB is commonly employed in the following clinical settings:

- cardiopulmonary resuscitation
- transport of patients requiring ventilatory assistance
- temporary ventilation of patients who need to be removed from a mechanical ventilator and to offer hyperinflation and hyperoxygenation and
- to assist in mobilising secretions for endotracheal suction.

Currently accepted standards of an 'adequate' bag - valve unit as described in the proceedings of the most recent Standards and Guidelines Conference (1992) are summarized in Text Box 2.3

ventilatory settings secured a constant MAP for all patients, the specific ventilatory mode used was not important.

From the literature it seems that the mechanisms of lung-induced injury from positive pressure ventilation are better understood than the absolute effects of positive pressure ventilation on the intricacies of haemodynamics. This has been illustrated in two studies which considered the effects of pulmonary hyperinflation as it is used in standard endotracheal suction protocols (Goodnough, 1985; Stone et al, 1991). Goodnough reported observed swings in arterial blood pressure above and below baseline values, while Stone et al recorded increases in the mean arterial pressure in their subjects during and after treatment. The explanation for these alterations was not clearly elucidated in either of the two studies and recommendations were made by both authors that the adverse effects of pulmonary hyperinflation on haemodynamics be more carefully investigated.

amount of MAP which is generated depends to a large extent on the mechanics of the lung and thorax. If lung compliance is increased there will be increased transmission of the positive pressure to the pleural space and so an increase in MAP. Conversely, if lung compliance is decreased, less pressure is transmitted through to the pleural space. Thus, haemodynamic compromise is more likely in patients with high lung compliance (eg emphysema) receiving positive pressure ventilation than in patients with low lung compliance, the latter often tolerating high levels of PEEP with minimal cardiovascular side-effects. A reduced thoracic compliance on the other hand (obesity, kyphoscoliosis) will cause higher MAPs to be generated. Other factors which may influence the magnitude of MAP (Text Box 2.2) relate to the amount of pressure used and the time constants which determine the exhalation phase. All of the above factors will thus dictate the total amount of positive pressure which the lungs 'see' at any one time (Scanlan, 1990).

**Text Box 2.2** Factors which may influence MAP

- Amount of positive pressure applied
- Type of inspiratory wave form
- Duration of positive pressure
- Duration of the expiratory phase
- Nature of the expiratory phase
- Properties of the lungs and thorax

The levels of MAP that will disturb haemodynamics vary between patients i.e a patient with pre-existing cardiovascular disease or hypovolemic shock will suffer greater adverse effects from the positive pressure. Goertz et al (1991) examined the effects of varying ventilatory patterns on the haemodynamics of 15 post-abdominal surgery patients without any cardiorespiratory disease. They concluded that the major determinant of haemodynamic upset was indeed the magnitude of the MAP and that as long as the

Positive pressure is thus associated with uneven distribution of gas in the lung resulting in atelectasis and altered V/Q ratios, the potential for pulmonary barotrauma, air-trapping and the possibility of an increase in the work of breathing of the patient (Scanlan, 1990). These effects are summarised in Text Box 2.1.

**Text Box 2.1** The effects of positive pressure on the respiratory system.

- uneven gas distribution
- altered V/Q ratios
- atelectasis
- pulmonary barotrauma
- air-trapping
- increased work of breathing

### 2.2.2 The cardiovascular system

Normal tidal breathing is characterised by the development of a negative intra-thoracic pressure which not only creates a concentration gradient down which air will flow into the lungs but also a force which facilitates a greater venous return to the heart and hence a greater cardiac output.

The effects of positive intra-thoracic pressure on the cardiovascular system are characterised by a decrease in the output from the left ventricle following a generalised decrease in blood flow to and from the heart (Scanlan, 1990).

The impact which positive pressure ventilation has on a patient's haemodynamics is directly related to the magnitude of the mean airway pressure (MAP). MAP is the average pressure 'seen' by the lungs during a respiratory cycle (Malinowski, 1990). The transmission of positive pressure from the alveolus to the pleural space and thus the

eventual lung rupture. The induced trauma would then be followed by air leaks into adjacent tissues and an inflammatory response with leaking of exudate [illegible] pulmonary interstitium, increases in the alveolar surface tension and a decrease in the pulmonary compliance.

Another consideration in the effects of positive pressure on the respiratory system is the inspiration to expiration (I:E) ratio. Normal I:E ratios of 1:2 ensure that enough time is allowed for an inhaled volume of gas to be expelled from the lung. If exhalation time is shortened, the lungs cannot be fully emptied at the end of expiration and this may cause air- trapping. Air-trapping may either be due to an intrinsic pulmonary disease eg asthma, where there is physical obstruction to air flow out of the lungs or due to adjusted I:E ratios with positive pressure ventilation by means of a mechanical ventilator or a MRB. The cumulative stacking of the trapped air will lead to an increase in the intra-alveolar pressure by the formation of "intrinsic" PEEP and, therefore, a higher risk of pulmonary barotrauma and haemodynamic disturbances (Schuster, 1990).

Positive pressure ventilation is also associated with an increase in the work of breathing if the patient is ventilated on a mode which allows spontaneous efforts between mechanical breaths eg. synchronised intermittent mandatory ventilation (SIMV). This increase in the work of breathing may be brought on by resistances imposed by the inspiratory and/or expiratory valves in the positive pressure equipment, which must be overcome by the patient (Scanlan, 1990).

Greater work of breathing can therfore also occur if the patient's attempt at breathing is out of phase with the fixed pattern of the ventilator (mechanical or manual).

## 2.6 ABOUT META-ANALYSES

"..far better an approximate answer to the right question, which is often vague, than an exact answer to the wrong question, which can always be made precise"

(Tukey J, 1962)

The Concise Oxford dictionary defines 'meta' as "after/of a higher or second-order". A meta-analysis of the literature is, therefore, a more highly organised or specialised form of the conventional narrative literature review (Glass,1976).

A meta-analysis may also be described as a structured and systematic integration of the results of similar independent, randomised controlled trials. This technique of reviewing the literature by pooling results is relatively new. The earliest recorded meta-analysis was conducted by Beecher (1955) on the powerful effects of the placebo. Meta - analyses mostly began to appear in the medical literature in the early 1980's (Felson, 1990).

Meta-analyses are particularly applicable to randomised controlled trials as these trials typically have small sample sizes and, therefore, a statistical disadvantage in being able to detect significant difference. By pooling the results of randomised controlled trials, the statistical power of the individual studies can be increased. Sackett and Cook (1993) observe that when small trials are individually inconclusive, a meta-analysis carries greater credibility than a repeat of any one of these trials using greater numbers. Meta-analyses may also be used to discern relationships between study characteristics (i.e populations tested, methods used etc.) and study outcome. There is often disagreement amongst authors with regard to the outcome of individual trials. By performing a meta-analysis, the meta-analyst is able to identify the sources of interstudy variation. Often poorly conducted

to pick up these changes irrespective of their level of training. Letters were then written to disagree with this finding and reaffirm the "educated hand" of the paediatric anaesthesiologist (Heneghan, 1992; Fisher and Zwass, 1992). They explained that the disposable MRBs used by Spears et al had large compressible volumes and that small changes in compliance would therefore be difficult to assess. The "not-so-educated hand" was then described by Steward (1991) with a recommendation that neonates rather be placed back on ventilators intra-operatively, as the modern ventilators of today would probably be more sensitive in exacting changes in pulmonary dynamics.

In a study where 74 hospital personnel including respiratory therapists, intensive care nurses, emergency room nurses and physicians were investigated (Augustine et al, 1987), occupation was also not found to be related to delivered $V_T$ . Interestingly though, it was the respiratory therapists who were found to have produced the most appropriate volumes at the most acceptable peak pressures.

With regard to airway pressures generated by operators using the MRB, both Zmora and Merritt (1982) and Douglas and McKelvey (1991) agreed that these peak pressures could be sufficiently matched only when some form of feedback mechanism was present for the operator eg. a manometer attached to the bag. The monitoring of peak pressures becomes particularly critical in manually ventilating neonates, as high peak pressures are known to be associated with the development of intra-ventricular haemorrhage, pneumothoraces and bronchopulmonary dysplasia.

(Carden and Hughes, 1975; LeBouef, 1980; Hess and Goff, 1987; Eaton, 1984; Augustine et al, 1987; Kissoon et al, 1990; Glass et al, 1993). Gender differences - male greater than female - also seem to be a factor in how much tidal volume is delivered when compressing a MRB (LeBouef, 1980).

Hess and Goff (1987), for example, found that a two-handed technique produced tidal volumes of 250 mℓ greater than a one-handed technique, even when compliance was increased and resistance was decreased in the lung model used for the experiment. Similarly, Glass et al (1993) established that the patient's lung compliance correlated well with the delivered $V_T$ i.e larger $V_T$s could be delivered to a patient with high lung compliance and vice versa. An alternative 'hand-against-forearm' technique was described by these authors after they observed that this mode of compressing the MRB was associated with a higher delivered $V_T$. Thomas et al (1992) also related an alternative to the one-handed system. They observed that when the bag was compressed between the operator's body and the open palm, larger volumes were delivered.

It would be reasonable to assume that the operator's level of experience would significantly affect the delivered $V_T$s, the peak airway pressures generated and the ability to assess any changes in compliance while manually ventilating patients. Three studies, however, found no correlation between levels of experience and the performance parameters which were measured in the studies (Spears et al, 1991; Douglas and McKelvey, 1991; Glass et al, 1993). Spears et al (1991), in particular, provoked much debate about whether paediatric anaesthetists could assess subtle changes in compliance while manually ventilating test lungs (which simulated the intra-operative bagging of neonates). They referred to the "educated hand" and stated that their subjects were unable

## 2.5 OPERATOR CHARACTERISTICS

There are certain factors which can vary between operators viz. hand-size, technique of bagging in terms of delivered tidal volume ($V_T$), respiratory rate achieved and the level of experience of the operator.

Reports on the size of the operator's hand have been presented by Law (1982), Augustine et al (1987), Thomas et al (1992) and Glass et al (1993). There is disagreement amongst these authors about how influential hand size is. Law concluded that hand size did affect the $V_T$ and minute volume delivered, having divided the sample into small, medium and large hand size groups. Using only one hand to compress the bag, the average $V_T$ delivered by the 'small' group and 'large' group was 691 mℓ and 902 mℓ , respectively. Thomas et al (1992) found results in accord ance with Law with resect to hand size and its influence on $V_T$. Neither Augustine et al (1987) nor Glass et al (1993), however, found any association between $V_T$ and the hand-size of the operator. The sample sizes of these two studies were 74 and 100 subjects, respectively, whereas Law only examined 15 subjects. Law's method for classing 'hand-size' was also more crude in that small, medium and large was classified on the basis of the fit of rubber examination gloves. This and the modest sample size may explain the difference in outcome.

Although there is some dispute about the importance of hand-size on $V_T$, there is consensus in the literature regarding the compression of a MRB with a one- handed versus a two- handed technique. All the reports which have considered this factor have consistently stated that delivered $V_T$s are lower when one hand is used to squeeze the bag

hose into the reservoir became kinked as the patient's position was changed from sitting to supine (Tucker et al,1992).

MRBs have also been pinpointed as potential sources of nosocomial bacterial infections. Cartwright and Hargrave (1969) and Hartstein et al (1988) documented findings where Pseudomonas Aeruginosa and Acinetobacter Anitratus, respectively, were cultured from the same MRBs which were used to manually ventilate the patients in their trials. Later, in 1990, Weber et al similarly established correlations between bacterial pathogens cultured from 14 ventilated patients and those cultured from the interior and exterior of the MRB. It has been advocated that these bags be cleaned at least once daily with all visible loose material being removed (Weber et al, 1990) and then disinfected by using ethylene-oxide (Hartstein et al,1988). Most of the currently used MRBs can also be autoclaved.

Regardless of the reported hazards of MRBs, complications of their use will still appear. In spite of the design adaptations made by the manufacturers of the bag, one is lead to conclude that the operators of the equipment determine the safety of these bags to a large extent. This may be particularly hazardous if the operator lacks knowledge about the mechanics of the MRB and is unskilled in its use.
Phillips and Skowronski (1986) state that no matter what the design of the bag, the operator's competence in ventilating the patient's lungs is still the most influential element in the appropriate use of the manual resuscitator bag.

evaluation of eight paediatric MRBs where four could not deliver adequate tidal volumes, especially in cases where pulmonary compliance was low.

After a trial which considered the variability of bag compliancies in some commonly used paediatric MRBs, Stone and Graves (1980) suggested that the peak pressures attained when the bag is maximally inflated appear on the bag itself. In this way, controlling the incidence of high airway pressure generation with MRBs would be facilitated. Such measures are necessary in light of the variety of MRB's available on the market and the constant upgrading and modification which is carried out on this equipment.

The potential for incorrect reassembly of commonly used bag-valve units after cleaning has been considered by many authors (Lebouef, 1980; Eaton, 1984; Phillips and Skowronski, 1985; Kissoon et al 1991). These reports state that personnel involved in the cleaning and reassembly of the bags should be thorough in reassembling the parts and checking that the bag functions well before it is put into use. Checking may be accomplished by using a test lung or in being unable to compress the bag when the exhalation port is occluded. Manufacturers were again challenged to design MRBs with parts which could only fit in one specific way. In 1987, Arellano gave an account of a disposable positive end expiratory pressure( PEEP) valve which was incorrectly reattached to a Pulmonex Ventilation bag. Since the inflow and outflow ports of this PEEP valve had similar diameters, the valve was connected in the reversed position during a resuscitation, despite labels on these ports. As a result of this, there was total obstruction to exhalation with undesirable sequelae for the patient.

Another case in which exhalation became obstructed occurred when the oxygen supply

causing a tension pneumothorax in their case. Kravath's suggestion to the producers of the Hope Infant MRB of a "bleed hole" on the oxygen inlet nipple to preclude such a problem was then incorporated into newer models. Ten years later, Klick et al (1978) reported two cases where a fault in the assembly of the Adult Hope MRB caused morbidity. This bag came with the same modifications as suggested by Kravath except that in the cleaning and reassembly of the bag, an oxygen nipple of another MRB model, which did not possess a venting hole, could be and was erroneously fitted to the Adult Hope bag. The producers of the bag were then encouraged to redesign the nipple such that only the correct one could be attached.

Carden and Hughes (1975) also described the malfunctioning of inflating valves in MRBs where oxygen was delivered directly into the bag at flow rates of greater than 5ℓ/min. Where oxygen was first delivered to a reservoir, the jamming of these valves was not as commonly observed and so higher flow rates could be used with safety when a reservoir was utilized. These researchers also identified that if slightly moistened, valves of the sliding type were more prone to sticking than hinged flap or silicone disc valves. Their laboratory findings were unfortunately recounted in the clinical setting ( Klick et al, 1978).

Problems associated with pop-off valves were also reported by Hirschman and Kravath (1982) and Zmora and Merritt (1982) who observed that the pop-off valve threshold pressures were far in excess of the normal pressures used when mechanically ventilating neonates. Moreover, inadequate volume ventilation of the patient could result in situations where low pulmonary compliance would require higher ventilating pressures above the threshold of the pop-off valve. This was also found by Kissoon et al (1992) in an

## 2.4 HAZARDS ASSOCIATED WITH THE USE OF THE MRB

Most of the reports in the literature regarding the hazards of MRBs focused on the complications of high pressures generated while ventilating patients leading to pulmonary barotrauma ( Kravath and Schonberg,1968; Miller and Hamilton, 1969; Jumper et al, 1983; Hirschman and Kravath, 1982; Dolan et al, 1981; Arellano et al, 1987). Rupture of the stomach was also reported in one case (Matikainen, 1978). According to Jumper et al (1983), barotrauma should be high on the list of differential diagnoses when complications arise from the use of MRBs.

Since the MRB's efficiency relies on the proper functioning of its valve systems, it is not surprising that these valve mechanisms have been the most common cause of malfunction of the MRB and thus the origin of high pulmonary pressures. Many case reports have cited a similar sequence of events which take place when the valves fail to open and close in a normal fashion viz obstruction to exhalation, inadequate ventilation of the patient and clinical respiratory distress.

Typically, an inlet valve jamming in the inspiratory position, a "pop-off" valve failing to vent excess pressure or incorrect assembly of the valve mechanisms, after cleaning, will lead to increases in the pressure of the bag-valve-patient system by not allowing full expiration.

Manufacturers of the MRB's were initially held accountable for these problems. Kravath , in 1968, focused on the design of the Hope Infant resuscitator which did not have any venting port to allow excess pressure to be released from within the bag thus

resuscitations. Most of the comparative studies on MRBs have, in fact, bee' conducted in the U.S.A, with only a few emanating from the U.K and Australia.

While the above factors are interesting to note, it is unlikely that temperature would have a significant effect on the performance of MRBs when they are used in a critical care settings, since room temperatures are maintained.

Additional factors which are important for adequate bag performance such as the influences of a one- hand versus a two- hand compression technique and the effects of the patient's lung compliance, relate to the volumes which can be delivered from the bag. Since delivering adequate tidal volumes with a MRB is closely related to the technique which the operator uses to squeeze the bag, these factors are discussed in the section on Operator Characteristics (section 2.5).

which were awkward to use, as their function was position dependent. Spring loaded PEEP valves, which could function well in any position, were then introduced. These valves have also since become recommended accessories to the bag-valve unit (Perel et al, 1975).

Many reviews on the MRBs' abilities to deliver adequate $FDO_2$s continued to be conducted through the 1980's and up to the present day, as newer designs (both adult and paediatric models) were introduced and older designs were reconsidered (LeBouef, 1980; Pfister, 1982; Eaton, 1984; Preusser, 1985; Phillips, 1986; Kissoon et al, 1991; Kissoon et al, 1992; Hermansen and Prior, 1993; Corley et al, 1993).
Considering all the factors which can influence oxygen delivery, $FDO_2$s are still highly variable in currently used MRBs (Corley et al, 1993; Glass et al, 1993).

### 2.3.3 Other Factors

The performance of MRBs may also be influenced by temperature. The thermo-lability of commonly used MRBs and how this affected the rate at which the bags could be compressed i.e the cycling rate, has been evaluated by many researchers (Carden and Hughes, 1975; LeBouef, 1980; Kissoon et al, 1991; Kissoon et al, 1992). Carden and Hughes (1975) stored the bags in a deep freeze at $0^{o}$ F and then compressed them. Most of the bags froze solid. More thorough investigations of the effects of cold on bag function were to follow in studies by LeBouef (1980) and Kissoon et al (1991,1992). It is not surprising that most of the studies which investigated the effects of cold on bag performance were conducted in Canada or in the U.S.A, where outside temperatures are often sub-zero and could alter the function of a MRB when it is used in pre-hospital

100%. As for the inflating valves, the silicone shutter inspiratory- valve mechanisms were better options than the sliding valve types which malfunctioned when damp.

Another factor was identified by Prie[illegible]o and Ham (1978) which was important in achieving high $FDO_2$s without a reservoir. This being the time allowed for refilling of the bag. Although none of the four MRBs evaluated in their study could achieve a 100% oxygen delivery without a reservoir, a significant increase in $FDO_2$ was noted when the refill time was four seconds, as opposed to one second. LeBouef (1980) found the same effect on $FDO_2$ with slower refill times, but $FDO_2$ did not drop to the same extent as the previous authors had reported.

The problem of how to increase the $FDO_2$s of the bags to deliver of up to 100% oxygen was resolved, in part, by the addition of a reservoir (also known as an accumulator) to the bag's structure and by the suggestion to the operators of a slower refill time. Reservoirs (or any ancillary device which allows oxygen enrichment of inspired air) have since become minimum requirements in MRBs and may take the form of an extra bag or a piece of large bore tubing attached to the back of the MRB.

Patients requiring mechanical ventilation have a decreased capacity for oxygenation and are thus given positive end expiratory pressure (PEEP) to maintain small airway stability and enhance oxygenation. Since these patients may at some stage require manual ventilation with an MRB, the MRB had to have the ability to maintain the PEEP levels. This was achieved by means of a PEEP valve system at the exhalation port of the bag. Previously, PEEP valves took the form of under-water or weight operated valve systems

decreased it was accompanied by a concomitant decrease in the delivery of oxygen. Carden and Bernstein (1970) assessed the $FDO_2$ and valve mechanisms in nine commonly used MRBs. Maintaining a fixed tidal volume and minute volume and a flow rate of 15ℓ/min, the authors reported that none of the bags delivered 100% oxygen without a reservoir. The Ambu bag attained the highest $FDO_2$ (87%) at 15ℓ/min. When the Laerdal and Aga MRBs were then assessed with reservoirs, both these bags achieved oxygen deliveries of 100%. Although this was found to be the case, the reservoirs were seen to make the bag more clumsy and less portable.

A similar study was later conducted by Carden and Hughes in 1975 to rate the improvements made by the manufacturers on five of the models which had previously been tested. An attempt was made to match this laboratory study to the clinical use of the MRB. The researchers employed four different ventilatory patterns and three oxygen flow rate settings (5, 10 and 15ℓ/min) to assess the effects that these factors would have on the $FDO_2$. The authors reported similar findings to their previous study regarding the $FDO_2$s with and without reservoirs. They did, however, stress that the method in which oxygen was entrained influenced the bag's performance in delivering optimal $FDO_2$s. If the oxygen was delivered directly into the bag itself, the $FDO_2$ would be high although the inflating valve would be prone to sticking in the inspiratory position. This would cause high pressures in the system and a risk of barotrauma to the patient. The optimal oxygen enrichment route was shown to be into the reservoir tubing.

Since this study and a subsequent trial in 1977 (Carden and Friedman), it was accepted that a reservoir was an important addition to the bag structure to achieve $FDO_2$ s of

**Table 4.2 Table summarising methods used in 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 | Trendellen - burg position | (A-a)$DO_2$ from ABG | MHI 3-4 times to TLC at 30cmH2O pressure |
| Okken et al (1978) | 15 preterm infants | Intubated - on nasal CPAP | Not stated | TcPO2 | 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 $C_L$ + SaO2 | Not clearly stated |

(Abd. = abdominal, CPAP = continuous positive airway pressure, ASL = alternate side lying, (A-a)$DO_2$ = alveolar-arterial oxygen difference, ABG = arterial blood gas, TcPO2 = transcutaneous oxygen tensions measured continuously by a transcutaneous oxygen electrode, $C_L$ = lung compliance, SaO2 = arterial oxygen saturations, MHI = manual hyperinflation, TLC = total lung capacity, min = minutes)

TABLE 4.1: Summary table of methods employed in study 1 through study 7 (S1 - S7)

| STUDY | SAMPLE SIZE | PATIENT TYPE | PATIENT POSITION | MRB and SETTINGS | MEASURED INDICES | TIME FINAL* |
|---|---|---|---|---|---|---|
| S1 Chulay 1988 | 52 | Adults - within 24 hrs post-CABG | Supine | PMR-2 15ℓ min | $PaO_2$ | 4 min |
| S2 Cubberley 1994 | 11 | Adults - Trauma post 24 hrs IPPV | ASL - 30° Head up | Ambubag 15ℓ min | $PaO_2$ and $C_L$ | 60 min |
| S3 Eales *et al.* 1994 | 11 | Adults - post-op CABG + MVR post 24 hrs | Supine - 20° head up | Ambubag 15ℓ/min | $PaO_2$ and $C_L$ | 60 min |
| S4 Novak *et al.* 1987 | 16 | Adults - Resp. failure | ASL | Laerdal 3 ($FDO_2$ = 0.8) | $PaO_2$ and $C_L$ | 30 min |
| S5 Eales 1989 | 18 | Adults - General | Supine | Ambubag 8ℓ/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).

# CHAPTER 4

## RESULTS

Having conducted the literature search, 11 reports were identified which documented the effects of manual ventilation, using a manual resuscitation bag (MRB), on either arterial oxygen tensions (PaO2) 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 4.1. Three of the seven measured PaO2 only, one study measured $C_l$ only and three measured both PaO2 and $C_l$. The descriptive statistics for the PaO2 and $C_l$ values of the included trials are presented in Table 4.3.

Three studies were excluded from the meta - analysis as they did not present their results in a form which was amenable to re-analysis. All three presented their results graphically with no description of mean values or standard deviations in table form nor 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 4.2.

### 4.1 General Observations

Of the seven studies included in the meta-analysis only three demonstrated any statistically significant results. S2 and S5 showed significantly negative effects of bagging on PaO2, while S7 showed a significantly negative result on $C_l$.

The "new" C.I. were then plotted on a third graph together with the "old" C.I. for the PaO2 and $C_L$ measurements in S3.

Knowing that the $SD_{fb}$ is often less than the "pooled" SD, the "pooled" SD was then divided by the $SD_{fb}$ to ascertain the factor by which the "pooled" SD was greater than the $SD_{fb}$. It was then hypothesized that this factor by which the "pooled" SD was greater than the $SD_{fb}$ (for both PaO2 and $C_L$) could be used in the other trials to estimate their $SD_{fb}$ values. This would facilitate a better look at the data of the other trials.

a graph. Studies were ranked in order of time of final measurement. This was to assess any effect of the time period over which monitoring was conducted on the outcome of the two outcome measures. A separate plot (Fig 4.3) was done using the values obtained from calculations of the "old" and "new" C.I. done on S3. A comparative analysis of the studies was then carried out. Common odds ratios were not calculated due to the heterogeneity which existed in the included trials.

### 3.3.1 Note on 'pooled' SD vs $SD_{f-b}$[1] and 'new' C.I. calculations for S3

Given the data supplied in the research reports, pooling the SDs of PaO2 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/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 $SD_{f-b}$. 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. S3 (Hales et al, 1994), the $SD_{f-b}$ was calculated for PaO2 and for $C_L$. The 95% C.I. for S3 were then recalculated using the $SD_{f-b}$ to derive a "new" SEM .

[1] $Sd_{f-b}$ - the standard deviation of the differences between the final and the baseline measurements.

A summary of the methods employed in the included trials is presented in Table 4.1 (Chapter 4). A number was assigned to each study for ease of reference eg. study 1 (S1) and study 2 (S2) etc.

### 3.3 Statistical Analysis

The following statistical methods were only applied to the PaO2 and/or $C_t$ measurements in the studies which fitted all of the above stated inclusion criteria. The mean values ($\bar{x}$) and standard deviations (SD) of PaO2 and/or $C_t$ before commencement of the intervention i.e the baseline measurement ($\bar{x}_b$ ; $SD_b$) and the mean and standard deviation values at the end of the observed period of the intervention i.e the final measurement ($\bar{x}_f$ ; $SD_f$) 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 $\bar{x}_f - \bar{x}_b$ (or $\bar{x}_{f-b}$) was determined to give the difference of the means between the final and baseline readings of PaO2 and/or $C_t$. The $SD_f$ and $SD_b$ were pooled by applying the formula:

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

From this value the pooled SEM for PaO2 and /or $C_t$ for each study was derived. The 95% confidence intervals (C.I.s) were then calculated by the following relationship:

$$95\%\ \text{C.I.} = \bar{x}_{f-b} \pm (1.96 \cdot \text{SEM}) \quad (p < 0.05)$$

The $\bar{x}_{f-b}$ and C.I. for PaO2 (Fig 4.1) and $C_t$ (Fig 4.2) for each study were then plotted on

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 as these trials often have limited clinical applicability (Jones et al, 1991).
2. made use of a ventilator to deliver hyperoxygenation/hyperinflation volumes to their subjects.
3. bagged subjects via a face mask.
4. did not measure PaO2 and/or $C_1$.
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.

### 3.2 Data Extraction

Data from the studies which fitted the inclusion criteria were then extracted. One researcher extracted the following data from the included trials:

(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: outcome measures monitored, length of monitoring and stages of monitoring

(iv) bagging protocol: type of MRB used and the number of compressions per session/treatment; the $FDO_2$s pre-treatment, during treatment and post-treatment.

libraries by means of an inter-library loan system. One unpublished trial was identified. This trial was conducted through the Department of Physiotherapy at the University of the Witwatersrand and was awarded a Master's degree.

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

1. be randomised controlled trials. Randomisation refers to the selection process which ensures that each individual of the population has an equal chance of being selected as a subject. Controlling the trial refers to keeping all possible influences constant throughout the study.
2. be experimental, clinical trials using only human subjects who were mechanically ventilated via either an endotracheal or tracheostomy tube.
3. have made use of self-inflating manual resuscitation bags as the method of achieving hyperinflation breaths.
4. have measured either arterial oxygen tensions (PaO2) and/or the lung compliance ($C_L$) in the trial. If the research article reported other independent observations (eg. Alveolar-arterial oxygen difference (A-a$DO_2$), cardiac output etc.) as well as PaO2 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 incorporated other physiotherapy or nursing procedures in its methods, in addition to the use of the MRB, then only the results of the groups which were bagged were included in the meta-analysis.

# CHAPTER 3

## METHODS

### 3.1 Literature Search

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 t . isolate all the relevant literature pertaining to manual ventilation and to manual resuscitation bags (MRBs). The following search 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 was dated back from the present 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 c .nputer 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 latter procedure was also described by Detrano et al (1989).

Once the above search strategy had been carried out and the appropriate articles had been identified, these articles were retrieved from the Witwatersrand Medical Library and when articles were not directly available from this library they were obtained from other

ratios or relative risk. Achieving a pooled or common p-value for the independent studies is another recognised end point of a meta-analysis. Presenting the pooled effect of several studies can sometimes be misleading, particularly if the studies which were combined had diverse methodologies. The impact which these diverse methods could have on study outcome and indeed on the outcome of the meta-analysis would then be masked. The meta-analysis should, in a such a case, address the underlying problems with the studies and should suggest ideas for further scientific enquiry. Indeed, Dickersin and Berlin (1992) state that a "legitimate result of meta-analysis could be a set of guidelines for future research." These authors also advocate the use of a meta-analysis as a standard tool before any research project is undertaken so that any new research trials can be more directed.

When the outcome of a meta-analysis is applied to the clinical situation, it becomes more useful to the practising clinician than the separate results of individual studies. Therefore, the meta-analysis should rather set out to answer a broader question than one which is too specific. This is because of the heterogeneity of studies which may be included in the analysis. Taking a strictly homogeneous sample may limit the number of studies available for meta-analysis and also offer a result which has little general applicability across various populations.

Meta-analyses have a role in establishing efficacy and safety of therapeutic modalities. Information obtained from meta-analyses becomes useful to the practising clinician and it thus likely that meta-analyses will continue to be conducted in the future to gather data from individual trials for use in the clinical setting.

certain degree of freedom in establishing criteria for studies to be included or excluded (selection bias) and this can contribute to publication bias. Selection bias will only become better controlled when more meta-analyses are performed in the medical sciences and minimum standards for judging these studies become established .

The meta-analyst cannot expect to retrieve all the relevant articles in a certain field of interest. This is firstly because a large proportion of studies conducted are not published and thus remain irretrievable sources of data which may or may not influence the final outcome of the analysis. Sacks et al (1987), Yach (1990) and Felson (1990) all observe that unpublished material may also contribute to publication bias. Secondly, inborn errors exist in the indexing of articles on databases (indexing bias). This makes it very difficult to search databases for all the relevant literature in a specific field (Dickersin et al, 1985).

There is also a tendency towards preferentially publishing studies which show a positive association over those that show a negative association and this may augment the bias in the selected sample for the meta-analysis.
Yach (1990) states quite categorically that the only way to minimise publication bias is to prevent it. A recommendation is also made by this author that a register be established for specific fields of interest in which all research in the field (published or unpublished) is documented and housed.

The results of meta-analyses can be presented in different forms. Meta- analyses of epidemiological studies, for example, display whether or not there was statistical significance between a treatment protocol and the outcome of disease by way of odds

studies warrant inclusion to the analysis to demonstrate the above mentioned relationship, especially when there is little research available on a particular topic. The fact that studies of poor quality are published is not within the control of the meta-analyst. These studies are useful though in being able to design better protocols for future research trials, taking into account the short-comings of all the existing trials at that time.

Sacks et al (1987) delineate what they regard as the six main components of a meta-analysis viz., the design of the analysis, the combinability of the articles, the control of bias, statistical techniques, sensitivity analysis and the application of the outcome of the analysis. The meta-analysis thus incorporates both a quantitative (statistical techniques) and a qualitative approach to arrive at a common end-point.

A meta-analysis requires planning and precision in its execution just as much as any randomised controlled trial would. The objectivity of the meta-analysis lies in the rigor applied to its methods of establishing inclusion and exclusion criteria and the control of bias in the sample. Despite these measures, there is still ambivalence amongst the members of the medical profession regarding the acceptance of a meta-analyses as research. Meta-analysis has been criticised for its reliability. The reliability of meta-analyses, however, cannot as yet be demonstrated as not enough data exist on repeats of any analyses in a specific field (Dickersin and Berlin, 1992).

Arguments against the formal acceptance of meta-analysis also point out that this procedure is subject to bias in the retrieving of the articles, the selection of articles for inclusion and in the extraction of data from these articles (Felson, 1990). Such bias is often referred to collectively as publication bias. Individual meta-analysts also have a

Stone (1990) noted that when ventilators are used to deliver hyperoxygenation breaths before endotracheal suction, higher or equivalent PaO2 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 the best method of hyperoxygenating patients before endotracheal suction.

All the studies which were included in this meta-analysis, except for S5 (Bales, 1980), used flow rates of 15ℓ/min. Despite this, none of the studies demonstrated a positive outcome on PaO2 [illegible] in any of the patient samples which were exposed to treatments using a MRB. Realising that oxygen flow rate is not the only factor influencing adequate oxygen delivery by the MRB, the PaO2 values obtained in these studies are therefore not easily explained in terms of incorrect oxygen flow settings but rather in terms of operator variability in the technique used for manual hyperinflation.

The time allowed for refilling of the bag once it has been compressed has also been shown to influence the $FDO_2$ (Priano and Ham, 1978; LeBouef, 1980). Slower refill times (+ 4 seconds) allow more time for oxygen enriched air to move from the reservoir into the bag and are thus associated with higher $FDO_2$s. Operators should consequently be made aware that the technique of compressing and releasing the bag has a great influence on the delivered oxygen concentrations.

Technique remains a most important variable in being able to attain desired therapeutic effects with the MRB. This is particularly true when regarding the ability to hyperinflate a patient's lungs with a MRB.

From previous studies conducted on the fractional delivered oxygen concentration ($FDO_2$) attained when using a MRB, it has been shown that $FDO_2$ is still highly variable (Phillips and Skowronski, 1986; Corley et al, 1993; Glass et al, 1993). This variability in $FDO_2$ is despite the minimum standards which have been specified to ensure high $FDO_2$s (Standards and Guidelines Conference, 1992) and is mostly operator dependent. One of the minimum standards states that the minimum oxygen flow rate setting should be at 15 ℓ/min to achieve high $FDO_2$s of between 0.8 and 1.0. Glass et al (1993) found that critical care nurses were not able to deliver hyperoxygenation to patients because of their variability in setting the oxygen flow rate. Flow rates ranged from 8 - 15 ℓ/min and resulted in a mean $FDO_2$ of 0.71. This did not, however, affect the patient's heart rate or mean arterial blood pressure. Eales (1980) in S5 used a low flow rate of 8ℓ/min and also achieved low $FDO_2$s of only 0.64. The significantly negative result on PaO2 observed in the S5 is thus not surprising considering these methods. Glass et al (1993) state that the oxygen flow rate is the most easily maintained factor by operators using a MRB and certainly the most important determinant of oxygen delivery.

Future studies in this field should guard against the possibility of setting the oxygen flows at less than 15ℓ/min. As mentioned before in the section dealing with the physical properties of MRBs, the valve mechanisms of some of these commonly used bags will not operate efficiently when a threshold flow rate of oxygen has been overridden (Table 2.1). If this is the case and effective oxygen delivery is not possible then this MRB should not be used and some other modality should be sought to achieve the desired hyper-oxygenation effect.

attained. Hyper- oxygenation and hyperinflation breaths given before, during and after endotracheal suction form part of a series of techniques which are used in order to achieve the objectives. Hyperoxygenation is given to prevent drastic falls in the PaO2 during suctioning and 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 ($V_T$) greater than the patient's baseline volume. The MRB has traditionally been used to produce these hyperoxygenation and hyperinflation breaths. An analysis of the literature, however, suggests that this is not being accomplished.

### 5.1.1 Hyperoxygenation

The adverse effects of endotracheal suction have been described by many authors (Nicholson, 1960; Urban and Weitzner, 1969; Adikofer and Powaser, 1978; Fox et al, 1978, Bodai, 1982; Shorten et al 1991). These include atelectasis, the induction of hypoxaemia, increases in the arterial blood pressure and the potential for cardiac dysrhythmias. Patients who do not receive any form of hyperoxygenation prior to endotracheal suction are particularly at risk for these complications. The degree of hypoxaemia created and thus the magnitude of the sequelae is related to the size of the catheter used, the power of the wall suction applied, the number of hyperoxygenation breaths given and the tidal volumes of these breaths (Fox et al, 1978). The optimal number and volumes of the breaths administered before suctioning has not been shown in the literature. It has been suggested though that three hyperoxygenation (at an $FiO_2$ of 1.0) and hyperinflation breaths (at 150% $V_T$ ) given before suctioning are sufficient to minimise the induced hypoxaemia (Stone, 1990)

# CHAPTER 5

## DISCUSSION AND RECOMMENDATIONS

### 5.1 DISCUSSION

The value of the MRB in the resuscitation situation, or in the case where temporary ventilation of an intubated patient is required, is not to be disregarded. It is important to note that the thrust of this review is to question the use of the MRB by physiotherapists, as a respiratory technique, in the treatment of patients requiring mechanical ventilation. The literature reviewed in this meta-analysis does not provide convincing evidence to support the use of the MRB by physiotherapists for attaining therapeutic goals. It is also potentially hazardous when used on critically ill patients. It is questionable whether the 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 delivering hyperinflation breaths by means of a MRB. These objectives, as stated previously, are the prevention of hypoxaemia induced by endotracheal suction, the mobilising and removal of retained pulmonary secretions and the recruitment of collapsed peripheral lung units. Alterations in commonly measured parameters such as the arterial oxygen tensions (PaO2) and/or the lung compliance ($C_L$) are then observed to assess whether these objectives have been

only study which investigated the changes in $C_l$ in post-operative cardiac surgery patients. The differences in the compliance values obtained in S3 and S2 are quite marked. These two studies, as mentioned above, followed a similar protocol, the only difference being the conditions of the patients used in the study (Table 4.1).

Fig 4.3 shows the 'old' and 'new' C.I. for $C_l$ measurements in S3. 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 $SD_{t_0}$ for $C_l$ was 2.64. Diving this factor into the 'old' SEM values for S4, S7 and S2 did not significantly alter the results of any of these studies.

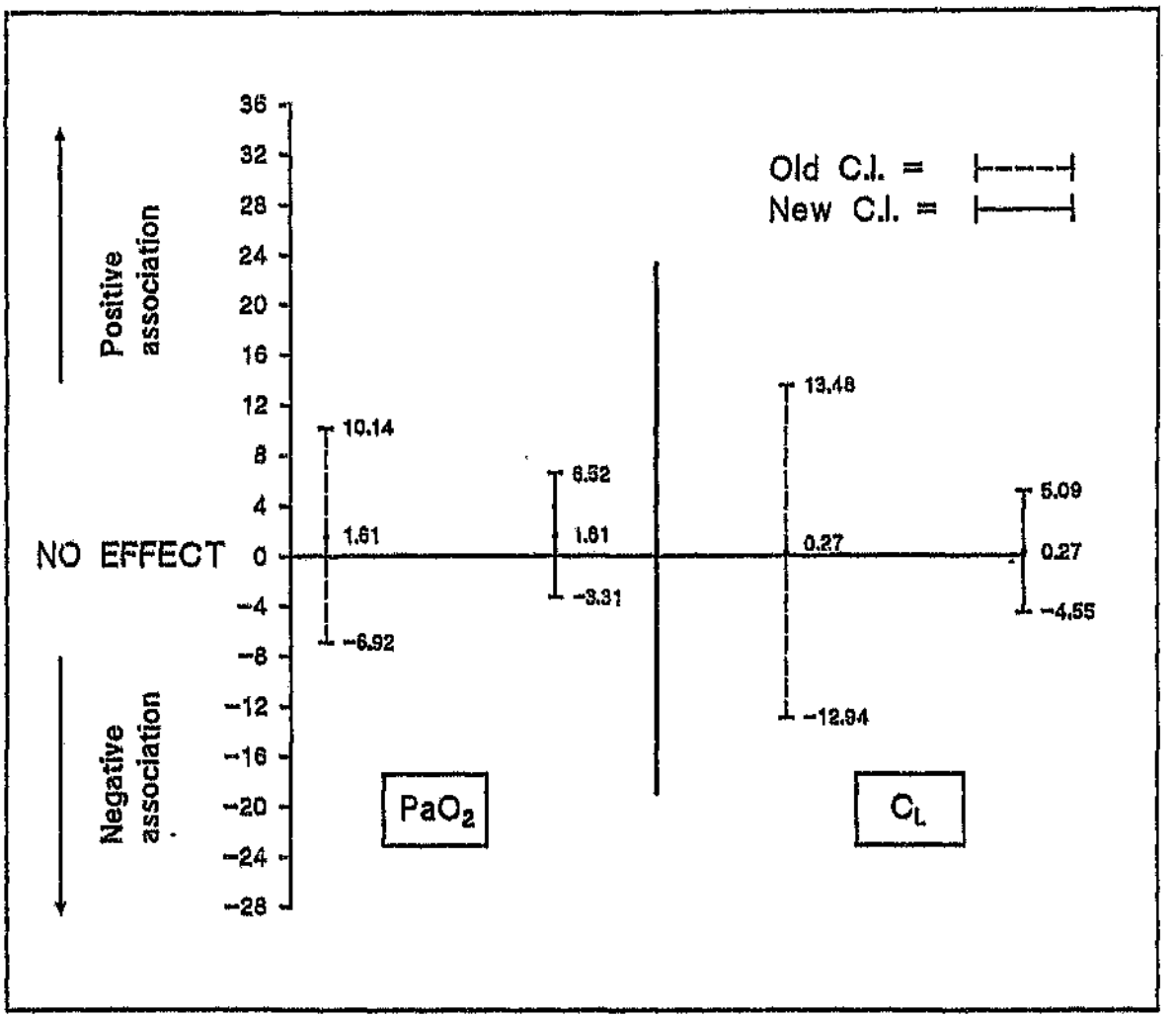


Figure 4.3 $\bar{X}_{f-b}$ and old and new C.I. for S3 for $PaO_2$ and $C_L$

where S3=Eales et all, 1994; $\bar{X}_{f-b}$=difference between final and baseline mean values; CI=confidence intervals; $PaO_2$=arterial oxygen tensions; $C_L$=lung compliance

used. S2 used trauma patients after 48 hours of mechanical ventilation, while S3 used patients after 18 hours of mechanical ventilation who had undergone cardiac surgery.

As expected from the recalculation of the 95 % C.I. for PaO2 in S3 using the $SD_{f-b}$ (Table 4.3), the range became much smaller. The factor by which 'pooled' SD was greater than $SD_{f-b}$ for PaO2 in S3 was 1.72. The 'new' C.I. reflects the true within patient differences between the baseline and final measurements. The new values did not alter the significance of S3 in any way (Fig 4.3). The same was not true for S1 where the original C.I. calculated from the data supplied in the report suggested no significant difference. Calculation of the new C.I., however, revealed a positively significant C.I. for S1 of [3.92; 24.07].

**4.3 Results of LungCompliance ($C_l$) values - Fig 4.2**

Lung compliance was measured in four of the studies which met the inclusion criteria of the meta-analysis (Fig 4.2). Of the four studies, only S7 demonstrated a statistically significant result. Although this was a negative result ($\bar{x}_{f-b}$ = -0.51 and a C.I. of [-0.67; -0.35] ) , S7 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 (S4, S2 and S3). S7 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 S3. Where as S2, S3 and S7 included patients with established respiratory failure, S3 was the

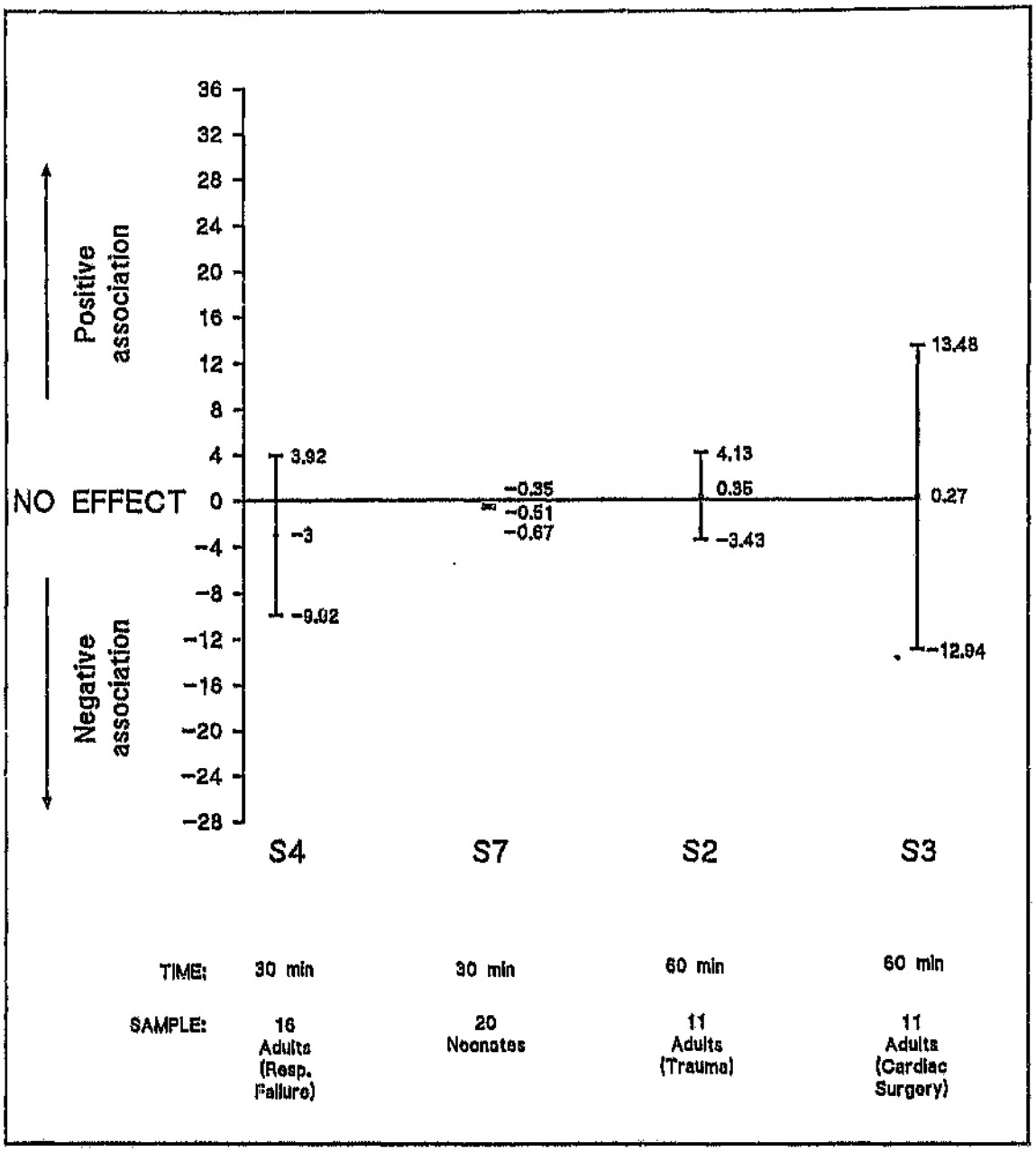


Figure 4.2 $\bar{X}_{f-b}$ and C.I. of $C_L$ values for S2, S3, S4, and S7

where S2=Cubberley, 1993; S3=Eales et al, 1994; S4=Novak et al, 1987; S7=Reiterer et al,1993; min=minutes; Resp=respiratory; $\bar{X}_{f-b}$=difference between final and baseline mean values; C.I.=confidence intervals; $C_L$=lung compliance in mℓ/cmH2O

(C I values based on the pooled SD and not on the estimated corrected SD values)

S1, S4 and S6 displayed the widest C.I.s for PaO2 across all the studies. S1 and S6 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 S1 and five minutes for S6. There is, however, little evidence from the data to suggest much similarity between these two trials and S4. Differences are apparent in the study design of S4 in terms of the condition of the patients used, the time of monitoring and the sample number. S4 had a population consisting of patients who required mechanical ventilation for respiratory failure, reports that patients were monitored for 30 minutes and had the smallest sample size of the three studies (n = 16). This is exactly half that of S1 (n = 32) and just over half that of S6 (n = 28). S1 and S6 displayed positive $\bar{x}_{r.b}$ values for PaO2 of 14 and 9, respectively, while the $\bar{x}_{r.b}$ for PaO2 in S4 was -9.

S1 and S2 were the only two studies which were significantly different from each other with regard to the measurements of PaO2 (upper bound on the C.I. for S2 is -3.98, the lower bound on the C.I. for S1 is -3.35). The extent to which these two studies were significantly different from each other became more marked when the "new" C.I.s were calculated, resulting in a significantly positive outcome for S1 (Table 4.3). The time of final measurement and the condition of the patients used in S1 and S2 were the salient features which distinguished these two trials (Table 4.1).

A comparison between S2 and S3 reveals a significantly negative outcome in S2 and no statistically significant outcome in S3 (Fig 4.1). 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 S2 and S3 was the study sample

The remaining four studies showed no statistically significant differences between the baseline and final measurements for PaO2 and/or $C_L$.

The time at which the final measurements were taken in S1 - S7 ranged from four minutes to 60 minutes (Table 4.1). From the graph depicting PaO2 results (Fig 4.1) it was observed that as the time of final measurement increased in the studies, there was a tendency for the confidence intervals (C.I.s) for PaO2 to become narrower. The tendency for the C.I.s of $C_L$ values to do the same was not observed (Fig 4.2). The C.I.s calculated for $C_L$ were generally not as wide as those calculated for PaO2, except in S3.

**4.2 Results of Arterial Oxygen Tension (PaO2) values - Fig 4.1**

S2 and S5 showed significantly negative associations between the use of the MRB and the effect on PaO2. A comparison between the methods used in S2 and S5 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. S2 used an oxygen flow rate of 15 ℓ/min achieving a fractional delivered oxygen concentration ($FDO_2$) of $\geq 0.8$, while S5 reports a flow rate of 8 ℓ/min and a $FDO_2$ of 0.64. S2 also describes positioning of their subjects in alternate side lying, whereas S5 maintained their subjects in the supine position throughout the trial.

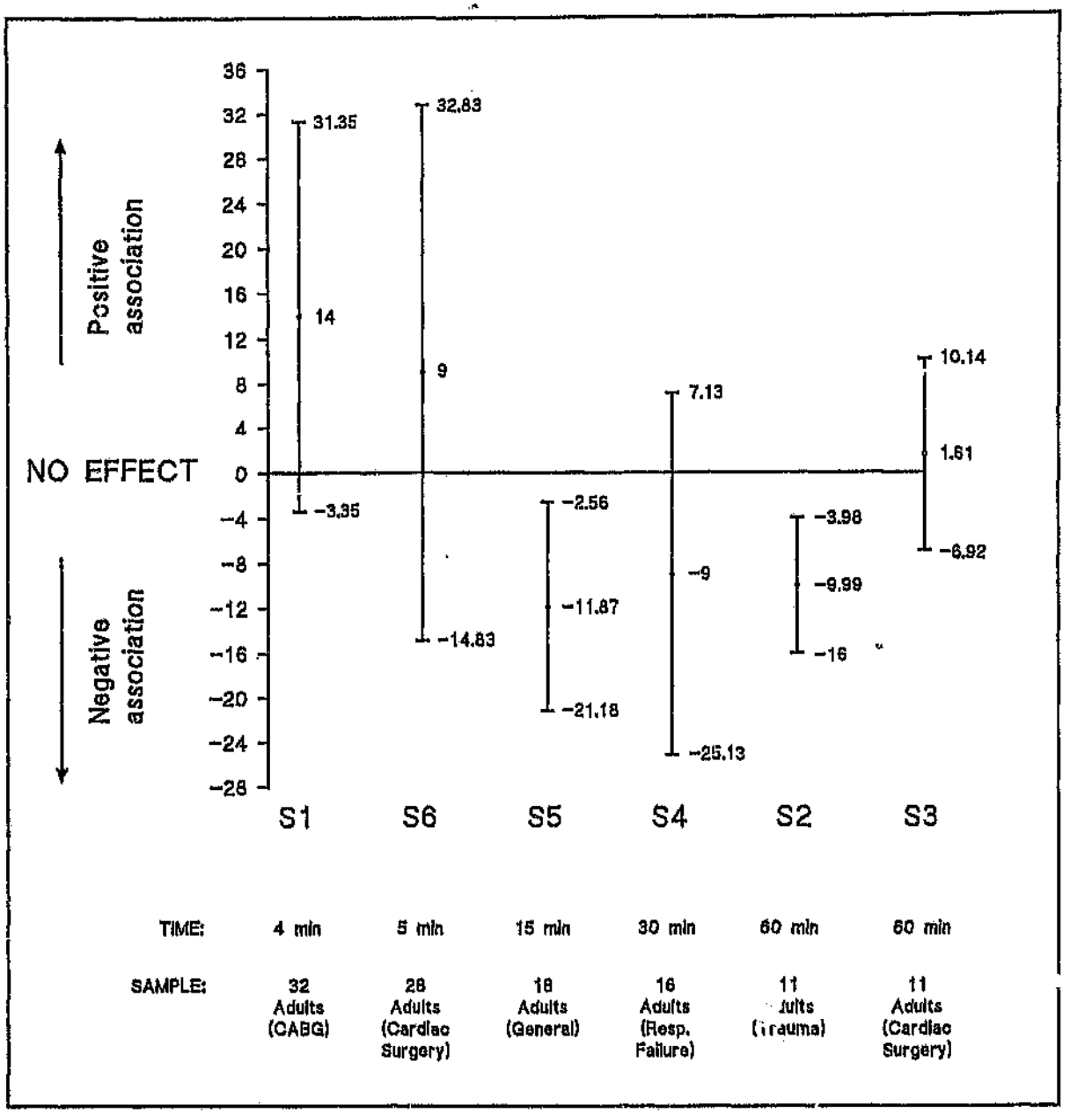


Figure 4.1 $\bar{X}_{f-b}$ and C.I. of $PaO_2$ values for S1, S2, S3, S4, S5 and S6

where S1=Chulay,1988; S2=Cubberley,1993; S3=Eales et al, 1994; S4=Novak et al, 1987; S5=Eales, 1989; S6=Goodnough, 1985; min=minutes; CABG=coronary artery bypass graft; Resp=respiratory; $\bar{X}_{f-b}$=difference between final and baseline mean values; C.I.=confidence intervals; $PaO_2$=arterial oxygen tensions in mmHg (C.I values based on the pooled SD and not the estimated corrected SD values)

## TABLE 4.3: Table showing calculated statistics of $PaO_2$ and $C_L$ values for S1 and S7

| | | | $[PaO_2]$ in mmHg | | | |
|---|---|---|---|---|---|---|
| STUDY | $\bar{X}_{db}$ | POOLED SD | POOLED SEM | 95% C.I | ESTIMATED SEM* | ESTIMATED 95% C.I* |
| 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; -6.50] |
| 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 | 6 | 64.34 | 12.15 | [-14.83; 32.83] | 7.07 | [4.85; 24.85] |

| | | | $[C_L]$ in ml/cmH2O | | | |
|---|---|---|---|---|---|---|
| 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 | [-12.94; 13.48] |
| S4 | -3 | 14.14 | 3.53 | [-9.92; 3.92] | 1.33 | [-2.34; 2.88] |
| S7 | -0.51 | 0.38 | 0.08 | [-0.67; -0.35] | 0.03 | [-0.57; -0.45] |

*These values were estimated by dividing the factor of 1.72 for $PaO_2$ and 2.64 for $C_L$ into the pooled SEM values and calculating new 95% C.I.
(Grey shaded area = the actual values recalculated from raw data of S3).
$\bar{X}_{db}$ = the difference between the 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).

patients, mixed groups of adult patients in general intensive care units and on intubated neonates (both awake and sedated).

Although only one significantly positive result was displayed amongst the studies included in the meta-analysis, the magnitude of effect of the MRB (as shown by the confidence intervals in Fig 4.1 and Fig 4.2) seemed to vary between the individual studies. 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, for example, who have a greater risk of adverse effects from manual hyperinflation because of their highly compliant, immature lungs was shown in S7 (Reiterer et al, 1993). This study presented the only significantly negative outcome on $C_L$ with hyperinflation. Reiterer et al (1993) proposed that the observed drop in lung compliance was from over-distention of distal lung units with the manual hyperinflation. The over-distention seemed to stem from differences which were noted in the time constants of inhalation between hyperinflation breaths and spontaneous breathing. Hyperinflation breaths were identified as having greater inspiratory times ($t_I$) than spontaneous breathing. The increased $t_I$ with hyperinflation breaths and the typically high respiratory rates of neonates resulted in insufficient exhalation time and consequently overdistention of the lungs. The over-distention may then cause alveolar damage, leaking of exudate into the pulmonary interstitium and a drop in the pulmonary compliance. This same sequence of events has previously been described by Parker et al (1993). Reiterer et al (1993) also stated that the overdistention may create a greater build up of intrinsic PEEP which can likewise lower pulmonary compliance.

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 PaO2 and $C_L$ has not been elucidated. It may, though, 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 MHI and then the patients on which it is used that accounts for the nett effect of positioning on pulmonary performance. Herein lies a need for further 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).

The confounding influences of positioning were not addressed in a recent meta-analysis on the role of incentive spirometry, intermittent positive pressure breathing and deep breathing exercises in the prevention of pulmonary complications after upper abdominal surgery (Thomas and McIntosh, 1994). The authors pooled the studies to the extent of displaying common odds ratios for the outcome of each modality. This cannot be regarded as sound research methodology when the consequences of positioning and mobilisation of patients is ignored. When a meta-analysis reaches the point of identifying methodological inconsistencies in the included studies, it can go no further. At this stage the meta-analysis has reached a legitimate end-point (Dickersin and Berlin, 1992).

### 5.1.5 Patient Populations

The variability in patient populations used in the analyzed trials presents another inconsistency in methods and one which may explain many of the results. Clinical research on MRBs has been performed on post-operative cardiac surgery cases, trauma

### 5.1.4 Positioning

As has been stated previously, positioning of patients receiving positive pressure ventilation influences the distribution of gas in such a way that the non-dependent lung is preferentially ventilated. Treating patients in the correct postural drainage position would thus facilitate moving secretions in distal airways to more proximal airways, following which a recruitment of more functional lung units would be achieved. This would certainly be more effective than maintaining the patient in a supine position. Positioning is used in many other areas of physiotherapy practice but is somewhat underutilised in respiratory therapy. Paratz (1993) 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. S2 (Cubberley, 1992) and S4 (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. The following studies viz., S1 (Chulay, 1988), S5 (Eales, 1989) , S6 (Goodnough, 1985) and S7(Reiterer et al, 1993), 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 positioning in their methods their findings may have been altered.

treatment of bagging, positioning and chest wall vibrations had a positive outcome on static pulmonary compliance for two hours.

Understanding the implications of the research done by Jones et al (1992) requires a comparison to be made between this study and two studies by Mackenzie and colleagues (1980 and 1985). These studies also revealed an increase in static pulmonary compliance for two hours after chest physiotherapy in patients requiring mechanical ventilation for acute respiratory failure. The chest physiotherapy protocol included percussion, postural drainage, chest wall vibrations and endotracheal suction. Neither of these two studies included bagging or any mechanical hyperinflation in their methodologies. Based on the radiological findings of involved broncho-pulmonary segments, patients were positioned in the appropriate postural drainage position. The patients were then treated until clinically clear of secretions on auscultation.

This protocol is comparable to the one adopted by Jones et al (1992). Mackenzie nonetheless showed the same outcome on static pulmonary compliance without the use of any hyperinflation technique. One may infer from this that bagging may not have been the modality which brought about the observed increases in static pulmonary compliance in the study by Jones et al (1992). The findings of these two studies, therefore, indicate the value of proper positioning in the treatment of mechanically ventilated patients. The benefits to be gained from positioning were similarly shown by Wagaman et al (1979) who reported that prone positions were associated with significantly higher PaO2 and dynamic lung compliance values in intubated neonates.

The findings of the above studies show that there is no added advantage of either hyperoxygenating or hyperinflating patients by using a MRB versus a mechanical ventilator. Further studies need to be designed to distinguish if the hyperinflation or the hyperoxygenation component of a breath has a greater part to play in sustaining PaO2 levels with endotracheal suction.

The fourth study to be excluded, by Jones et al (1992), similarly displayed a return of arterial oxygen saturations (SaO2) to baseline with no significant improvement from pre-suction values after bagging. This study also measured the effects of bagging on static pulmonary compliance. Their sample comprised 20 mechanically ventilated adult patients in a general ICU. The presence or absence of "lung problems" in this sample was made on the basis of radiological evidence. Only half of the sample of 20 were found to have lung pathology. The most notable result obtained from this trial was a sustained increase in static pulmonary compliance both in patients with and without lung pathology, for up to two hours after bagging. This increase was shown to a greater extent, however, in patients who did not have "lung problems" (a 19% increase) when compared to those with "lung problems" (a 12% increase).

Positioning of some patients in alternate side lying and some in the head down position was included in the research protocol. The number of patients who were tipped in the head down position in this trial, is not stated. The authors also report that chest wall vibrations were employed with the endotracheal suction. 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 but rather showed that a component

drop in PaO2 levels was observed with suctioning (43 mmHg recorded). The study revealed a significant improvement in PaO2 with hyperinflations, to a level of 78 mmHg. These post-hyperinflation values may have been significantly different from those obtained immediately after endotracheal suction, but they were not significantly different from the pre-suction values. Having documented no changes in either the FRC or the pulmonary compliance indicates that no notable atelectasis had developed as a result of the suctioning. The return of the PaO2 to baseline (pre-suction) values was, therefore rely a function of the hyperoxygenation and not the hyperinflation offered by the MRB. Arterial oxygen tensions can be expected to rise during the time of the hyperoxygenation and then conversely be expected to fall once the patient is returned to the pre-set $FiO_2$.

The observation of PaO2 values returning to baseline after hyperoxygenation and endotracheal suction was paralleled in S3 (Eales et al, 1994). S3, however, had no hyperinflation delivered to their patients at this stage and used the ventilator to achieve the hyperoxygenation at an $FiO_2$ of 1.0. Moreover, S1 (Chulay, 1988) demonstrated a significant increase in PaO2 values after suctioning, when using a two-handed bagging technique on stable patient having undergone coronary artery bypass surgery. Having measured mean $FDO_2$s of only 0.78 from the MRB, the explanation for the increased PaO2 levels lies in the appropriately delivered hyperinflation breaths. When hyperoxygenation is therefore required before endotracheal suction, this can be achieved just as effectively by using the ventilator and in so doing the patient's circuit need not be disconnected.

The decreases in the TcPO2 in the "restless" infants should alert physiotherapists to the fact that using a MRB on restless patients who are inclined to breath out of phase with the bag, may result in notable declines in arterial oxygen tensions. It is often the patient who is already hypoxic who is also very restless.

There is, therefore, potential for increasing the work of breathing of a patient who is bagged, by either not bagging synchronously with the patients' efforts or by allowing the patient to breath spontaneously through the bag and so encounter resistance to inhalation/exhalation caused by demand valves in the system..

The fact that the MRB may augment the spontaneous respiratory efforts of intubated patients may support its use in the following situation. When long term mechanically ventilated patients begin to show signs of improvement in their pulmonary status such that they can start to be weaned from the artificial support, they often struggle to generate adequate tidal volumes when breathing spontaneously. This may be due to respiratory muscle atrophy or even a loss of the kinaesthetic sense of a good tidal breath. In the above situation it may be clinically valuable to use the MRB as a "respiratory system exerciser/ re-educator". The patient is asked to mimic the larger tidal volume delivered by the MRB with their own efforts. During the treatment, the physiotherapist can control and encourage the patient's efforts and establish an efficient respiratory pattern that would be required for successful weaning and extubation (Barker and Eales, 1994).

The third study which was excluded was carried out by Fox et al (1978) on 13 neonates recovering from respiratory failure and also receiving CPAP. The study aimed to investigate the alterations which took place in PaO2 values with endotracheal suction, with hyperinflation immediately post-suction and then at two hours post-suction. An expected

The hyperinflation was performed in a very controlled experimental setting. This, however, is not the case when hyperinflation is used by a physiotherapist. In such a case, total lung capacity volumes are seldom achieved as the MRBs which are commonly used do not have the capacity to deliver these volumes (Table 2.1). Pressure manometers are also not standardly available to assess the peak pressures at which the volumes are being delivered. Owing to the complex manner in which these researchers administered the hyperinflation breaths and that they probably did not use a standard MRB, this study could not be included in the meta-analysis.

Endotracheal suction was also not a standard feature in the methodology employed by Tweed et al (1991). Comparatively, respiratory therapy treatments require frequent passes of the suction catheter until the patient is clinically clear of secretions. Future research could perhaps separately consider the sole effects of periodic hyperinflation on mechanically ventilated patients without the addition of endotracheal suction and its known sequelae.

The second of the studies to be excluded was by Okken et al (1978). Their trial was conducted in order to assess what outcome manual hyperinflation would have on transcutaneous oxygen tensions (TcPO2). The study used preterm infants who were receiving nasal continuous positive airway pressure (CPAP). Not surprisingly, they found that infants who were restless while bagging had significant decreases in their TcPO2 values, while those that were breathing in phase with the bag demonstrated significant increases in TcPO2. In the "quite" infants, the manual hyperinflation breaths were undoubtedly greater than the infants' spontaneous ventilatory efforts on the nasal CPAP and thus augmented the use of peripheral lung units for oxygenation.

### 5.1.3 The excluded studies

The first of the studies which showed positive results was conducted by Tweed et al (1991). These researchers examined the effects of periodic hyperinflation on 24 adult patients undergoing lower abdominal gynaecological surgery. These patients were placed in the Trendellenberg position intra-operatively and owing to the above factors were considered at high risk of intra-pulmonary shunting. Since the induction of anaesthesia is associated with dependent atelectasis, a reduction in functional residual capacity (FRC) by as much as 20% and a lowering of pulmonary compliance (Nunn et al, 1965), these effects can be interpreted by changes in the alveolar-arterial oxygen difference [$(A\text{-}a)D0_2$ ] values which are seen to increase on induction of anaesthesia. The study aimed to determine if there was any additional advantage of hyperinflation when compared to conventional tidal volume ventilation and high tidal volume ventilation. The periodic hyperinflation was administered either before or after conventional tidal volume ventilation and high tidal volume ventilation, but not on its own. Arterial blood gases were taken after 30 minutes of each of the three modalities were applied and the $(A\text{-}a)D0_2$ was calculated. Control values of $(A\text{-}a)DO_2$ were determined on induction of anaesthesia. The $(A\text{-}a)DO_2$ was significantly less when hyperinflation was used compared to conventional tidal volume ventilation, but no different when hyperinflation was compared to high tidal volume ventilation. These results indicate that stepping up the volume on the ventilator was as effective as HI in improving the patients' $(A\text{-}a)DO_2$.

The authors state that when the lungs were periodically hyperinflated, this was done to total lung capacity at 30 $cmH_20$ peak pressure. As the exact equipment used to achieve the hyperinflation is not stated, it may be reasonable to presume that a large volume anaesthetic bag was used, considering that the research was conducted intra-operatively.

experienced operators who are familiar with the ventilatory dynamics and physiological principles of this technique. Few studies have concentrated on the specific abilities of respiratory therapists or physiotherapists to achieve optimal $FDO_2$s and $V_T$s. 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 by means of a MRB.

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 from this meta-analysis that the ability to improve the PaO2 and $C_L$ values of mechanically ventilated patients by using a MRB, is limited. Six of the seven studies included in this meta-analysis reflect that hyperoxygenation and hyperinflation breaths delivered during endotracheal suctioning, were not accompanied by a positive outcome on PaO2 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 MRB. When the methodologies of these studies are closely scrutinized, however, their results are more fully appreciated. A summary of the methodologies of these studies is presented in Table 4.2.

The one-handed technique is more the rule than the exception in the clinical use of the MRB by nurses and physiotherapists. It is not often practical to have a separate clinician at every treatment who just takes care of the manual hyperinflation. This being the case, the nurse often bags the patients with the non-sterile hand or if the physiotherapist does the bagging then only one hand is usually removed from the patient's chest to compress the bag. Clinicians who use the MRB in this way may not always be aware of the potential for hypoinflating their patient's and thus possibly jeopardising the patient's haemodynamics by inducing hypoxaemia rather than preventing it.

Authors of trials conducted on the therapeutic effects of MRBs seldom state the technique which was used to compress the bag. This type of information becomes important to the reader and indeed the meta-analyst in being able to discern the factors which governed the outcome of the trial.

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 preset 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 important 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

### 5.1.2 Hyperinflation

The "bag-squeezing" technique, as presented by Clement and Hubsch in 1968 and then echoed by Paratz in 1992, incorporates a long inspiration, an inflation hold for one or two seconds then a rapid release of the bag to generate high expiratory flow rates in order to facilitate the mobilisation and removal of secretions. This procedure has been the gold-standard used by physiotherapists for manually ventilating intubated patients. Such ventilatory dynamics, however, have been described as being contributory to the generation of high mean airway pressures ([illegible]) consequently a greater chance of haemodynamic upset (Scanlan, 1990).

The inspiratory volumes which are delivered from a manual resuscitator bag 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 been shown to be associated with higher $V_T$s 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, 1990; Glass et al; 1993). Glass et al showed that when using one hand to compress the bag, critical care nurses delivered a mean $V_T$ of 17% less than the preset volume on the ventilator. Hypoinflation, rather than hyperinflation is likely to occur when the MRB is compressed with one hand. Interestingly, those nurses who chose to compress the MRB with one hand (58%) also bagged at a faster rate.

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studies which were included in the meta-analysis. This prohibited the pooling of these studies to the extent of arriving at a common end-point for all the studies. Although this meta-analysis could not provide conclusive evidence, it did show trends which suggest that bagging has little therapeutic value in the treatment of mechanically ventilated patients. It also highlighted the factors which could explain the disagreement amongst the authors and which could be controlled in further trials.

In conclusion, more controlled, similar, multicentre trials are needed to resolve the uncertainty regarding the therapeutic value of the MRB, as it is used by physiotherapists. Until such time as the results of these studies become known and a meta-analysis is once again performed, physiotherapists working in the ICUs may need to consider alternative ways of achieving hyperoxygenation and hyperinflation in the treatment of their patients.

It is hoped that this meta-analysis could pave some of the road towards a firm research consensus, which Kuhn refers to as being "extraordinarily arduous". Continuing research on intensive care respiratory therapy can then lead us closer to scientific truths regarding the management of patients who are critically ill.

# CHAPTER 6

## CONCLUSION

The meta-analysis revealed that bagging may not be achieving the desired therapeutic objectives of improvements in PaO2 and/or $C_L$ values in mechanically ventilated patients. It is questionable whether the 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 hazards associated with the use of MRBs such as nosocomial infections and barotrauma should be acknowledged together with what the literature suggests regarding the efficacy of bagging. There is an indication that clinicians may want to steer away from this technique towards alternative modalities which best suit the needs of their patients. The mechanical ventilator has been shown to be a suitable alternative in delivering the hyperoxygenation and hyperinflation breaths in a controlled, reliable manner.

Although there have been studies which have shown a positive outcome on patients who have been bagged, these studies could not be pooled with the other studies in this meta-analysis. This was mostly because the results of these studies were presented in a form which did not allow them to be critically analyzed. There was also heterogeneity in the

sheet and the establish the interobserver variability.

13. Confidence intervals are a more useful means of presenting the reader with the results of a meta-analysis (Sacks et al,1987). Future meta-analyses on the therapeutic effects of manual hyperinflation could adopt this approach to facilitate the interpretation of the outcome of the analysis.

9. New trials should monitor heir patients for at least two hours. Shorter monitoring times may not as valuable in showing significant carry over effects of the hyperinflation/ hyperoxygenation breaths delivered by the MRB.

10. When results of the trials are written up, they should be presented as mean values and standard deviation or standard error of the mean values to facilitate the pooling of these results in a future meta-analysis. Graphically presented data are visually easy to read but are of little use to the meta-analyst. It would also be useful to present the standard deviations of within patient differences between the final and baseline measurements i.e the $SD_{f-b}$. The relevance of displaying these values was demonstrated in the results obtained from S1 in this met-analysis. Having calculated the confidence intervals for PaO2 in S1 using the data presented in the report, a non-significant outcome was demonstrated despite positive outcome described in the report. However, having subsequently divided the old C.I. by the factor of 1.72 (Table 4.3), the new result demonstrated a positive outcome on PaO2 values.

11. Having very similar protocols, the results of the multicentre trials could be pooled to a greater extent than that done in the present meta-analysis. The outcome of another meta-analysis could then provide more conclusive evidence regarding the value of the MRB in the treatment of mechanically ventilated patients.

12. Future meta-analyses should use a system for data extraction form the included trials which allows two extractors to independently score trials on an extraction

(Eales et al, 1994), it may be more valuable to examine the responses of patients who are at high risk of physiological shunting or those with established respiratory failure.

7. The role of appropriate positioning should be investigated in the new trials. A control group who are positioned appropriately and treated on the ventilator should be compared to an experimental group who are treated in the same way except with the addition of manually ventilating the experimental group.

8. The choice of measuring tools in these trials is another important factor to be considered in designing new protocols. In view of what the literature has shown regarding the value of lung compliance measurements, future randomised controlled trials should continue to use pulmonary compliance as one of the parameters to evaluate the effects of the manual ventilation. The use of arterial oxygen saturations, measured by noninvasive oximetry, can also serve as an easy and reliable way to measure changes in pulmonary function (Tobin, 1988). Arterial blood gas measurements can still be of value, provided they are taken in a controlled and accurate manner. Other indices such as the $PaO2/FIO_2$ and the $(A\text{-}a)DO_2$ can be calculated from these well controlled arterial blood gas measurements. These indices may be more worthwhile in interpreting the degree of intra-pulmonary shunting. The monitoring of haemodynamic indices should also be included in the methods of the new trials as there is uncertainty regarding the range of effects which manual ventilation has on haemodynamics.

significant therapeutic effect, recommendations could then be made in these trials of viable alternatives which would achieve the objectives of respiratory therapy.

2. Future studies should evaluate the use of commonly used MRBs, state which MRB was used and how this bag was compressed eg. with one hand or two hands. The operators of the bag should be assessed for the tidal volumes which they were able to deliver and these volumes should be reported.

3. Experienced ICU physiotherapists should be used to operate the MRBs to gain more insight into these clinician's abilities to perform the technique safely and appropriately.

4. The $FDO_2$ delivered by the bag should be assessed by means of an oxygen analyzer attached to the bag-valve unit. The $FDO_2$s of the individual operators should also be measured and reported. The oxygen flow rate should be set to deliver 15 ℓ/min to the reservoir of the MRB.

5. It may be valuable to perform sample size calculations before conducting the new trials, to ascertain the sample number needed to detect a significant change.

6. Patient populations chosen for the research will be determined to a large extent by the availability of patients and the decisions made by local ethics committees. As post-operative cardiac surgery patients have been extensively used and there is little evidence to support the MRBs role in the management of these patients

## 5.2 RECOMMENDATIONS

Dickersin and Berlin (1992) point out that emphasis should be placed on the methodologies and accurate, comprehensive reporting of scientific trials. Moreover, a fundamental reason for conducting scientific enquiry is to investigate relationships between independent and dependent variables by strictly controlling the influences which independent variables can have on the dependent variables i.e. the outcome measures of a trial (Currier, 1984). Considering the paucity of literature available on the therapeutic value of the MRB and the divergence which exists in the methodologies employed in these trials, there is a lot of scope for further work to be done in this field.
Well controlled multi -centre randomised controlled trials with comparable methodologies need be conducted and the results of these studies pooled, by way of a meta-analysis, in order to conclusively resolve the uncertainty surrounding the use of the MRB on intubated patients.

This meta-analysis has been able been able to identify factors which contributed to divergence in the existing research and which should be controlled in future studies. Accordingly the following points would need to be taken into account by prospective researchers in designing new protocols to standardise the methods across these multicentre trials. Recommendations are also made for future meta-analyses.

1. Future on the therapeutic value of the MRB should simulate the clinical setting i.e studies should be designed to assess the efficacy of the MRB as it is used clinically and not in an artificial, experimental way. If this modality is not found to have any

ventilator and the patient has made no effort during that breath (Suter et al, 1978; Tobin, 1988).

Conversely, for a number of reasons, arterial oxygen tensions may yield less reliable data. The variations seen in the PaO2 data may be explained by the manner in which the arterial blood gas (ABG) is taken, transported to the laboratory and then interpreted. For example, excess heparin in the syringe may influence the pH of the ABG and hence the whole analysis of the sample. The distance from the patient's bedside to the laboratory or blood gas analyzer may influence the quality of the ABG sample by the time it is analyzed and this may give spurious results. Finally the calibration of the blood - gas analyzer and the functioning of the oxygen electrode may also alter the interpretation of the ABG. Tweed et al (1991) were the only authors who described their method of drawing the ABG sample and its analysis. They state that the sample was drawn anaerobically, placed on ice and analyzed within three minutes in a blood gas analyzer at $37^0$ C. The blood gas analyzer underwent a two-point calibration every two hours and a one-point calibration before each sample was analyzed.

Although ABG analysis is a universally used technique for assessing respiratory function, there is the potential for these values to artificially represent changes when non exist or vice versa.

haemodynamic status and may be inconsistent in their responses to interventions such as manual hyperinflation, having not had sufficient time to "settle-down" after the surgery. According to the data available it would appear that the more controlled the patients were the more controlled the results of the studies were. This could indicate that considering an immediate effect may be premature and that the therapeutic value of the MRB may only be evident, and thus assessed within one or two hours of it being used.

Although it seems likely that time had an influence on the data, it was again one of many components which differed in the methodologies of the trials and one which ought to be more standardised in future research if we are to isolate those factors which most affect the outcome of manual ventilation on intubated patients.

### 5.1.7 Outcome measures

The observation that PaO2 values displayed more discordance than the data obtained for $C_L$ may indicate that $C_L$ is a perhaps a better measuring tool for assessing changes in pulmonary function brought about by manual ventilation. Mackenzie et al (1979) state that measuring $C_L$ has great applicability in the ICU and have shown that measuring this parameter need not be an ordeal. The calculation of pulmonary compliance can easily be performed at the bedside by reading values such as tidal volume ($V_T$) , plateau airway pressure and positive end expiratory pressure (PEEP) from the ventilator and applying the formula: $C_L = V_T$/ Plateau Pressure - PEEP. Plateau pressure is read after the expiratory port has been occluded for 1-2 seconds to allow airway pressure to reach a constant value. Compliance measurements are remarkably reproducible, provided the above readings are taken when the entire inspired gas volume has been generated by the

the studies which used post-operative cardiac surgery cases ( S1, S6 and S3) suggests that the manual hyperinflation may have augmented the patients' ability to match ventilation and perfusion, but to no significant degree. The more negative mean values for PaO2 seen in S5, S4 and S2, which used patients with evidence of established intra-pulmonary shunting, suggests that the MRB was ineffective in achieving suitable PaO2 levels in this subgroup. Another result that illustrates the impact which varying pathologies can have on the outcome of the study is that between S1 and S2. The confidence intervals for these two studies did not overlap making them significantly different from each other. The extent to which these studies differed from one another was enhanced when the new confidence intervals were calculated, resulting in a significantly positive outcome for S1 (Table 4.3).

S1 and S2 were also situated on either end of the time spectrum (Fig 4.1) and so the time of final measurement may also have influenced the outcome of the two trials.

### 5.1.6 Time of Final Measurement

Discrepancies in the methodologies of the trials are again demonstrated in the contrasting times of final measurement. Factors such as the [illegible] final measurement and at what stage i.e. how early in the course of the mechanical ventilation the experiment was started on the patients may have governed the "look" of the data obtained in these trials The data appeared erratic for trials which monitored their patients for short periods and which started the study early after commencement of mechanical ventilation. This is illustrated in S6 which showed the greatest variance in the C.I. for PaO2, having studied patients within 4 - 6 hours after surgery and then monitoring their responses for 5 minutes. In this immediate post-operative period these patients are labile in both their respiratory and

When pathologies vary amongst patients who receive hyperinflation breaths, the magnitude of effect can be expected to differ. This was illustrated in S2 (Cubberley, 199[illegible]) and S3 (Eales et al, 1994) which used the same protocol on two very different patient su[illegible] and achieved very different results. S2 examined trauma patients who were mechanically ventilated for 48 hours, while S3 considered uncomplicated post-operative cardiac surgery patients prior to extubation. S2 displayed a significantly negative effect on PaO2 while S3 showed that the bagging had no effect on the PaO2 values (Fig 4.1). Lung compliance results in both studies were not significantly altered (Fig 4.2). The comparison between these two studies serves as an example of how different pathologies alone can have an impact on the outcome of a treatment procedure. One might expect that patients in S2, with pulmonary disease states of traumatic origin (neurogenic pulmonary oedema, pulmonary contusions and aspiration pneumonias) may present with marked V/Q imbalances and hypoxaemia, causing them to be intolerant of swings in the FiO2 brought about by constant disconnections from the ventilator as well as the potential inconsistencies associated with the use of the MRB (Selsby and Jones, 1990)

The significant drops in PaO2 values observed in S2 should serve as a warning to the physiotherapist to exercise more caution when next considering the use of the MRB on patients in the trauma unit.

Conversely, the post-operative cardiac surgery patient (S3) generally receives mechanical ventilation to correct the type II respiratory failure induced by narcotic anaesthetics until such time as these drugs are metabolised and eliminated. The need for artificial assistance is ,therefore, not because of intrinsic pulmonary disease. Since the use of the MRB did not significantly improve the measured parameters in S3, its use in this patient subgroup does not seem to be indicated. The trend towards more positive mean values for PaO2 in

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**Author: Barker M**
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