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Sealy, Mary Louise

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COMPARISON OF SUSTAINED MAXIMAL INSPIRATION AND PURSE-LIPPED EXHALATION ON LUNG VOLUMES IN HEALTHY VOLUNTEERS

by

Mary Louise Sealy

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STATEMENT BY AUTHOR

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APPROVAL BY THESIS DIRECTOR

This thesis has been approved on the data shown below.

Gayle A. Traver
Gayle A. Traver
Associate Professor of Nursing

Dec. 19 1985
Date

DEDICATION

This thesis is most affectionately dedicated to my family; my husband Dick, whose support was most needed, my son Randy, whose own achievements were a constant inspiration; my brothers and their wives, whose belief in my efforts have bolstered my self esteem, and my extended family, Beth, Debbie and Isela, whose emotional support has given new meaning to the word support. This thesis is, of course, dedicated to all my instructors, who finally perhaps have taught me how to learn. Last but never least, this thesis is dedicated to my mother whose spirit and wisdom have pervaded all my life's work.

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ABSTRACT

The purpose of the study was to determine the effects of abdominal restriction on lung volumes as a simulation of post-operative pulmonary effects and further, to evaluate the effectiveness of the sustained maximal inspiration (SMI) maneuver as compared to the "purse-lipped" breathing (PLB) maneuver in improving lung volumes. A sample of ten healthy volunteers was studied on two occasions. Functional residual capacity (FRC), inspiratory capacity (IC), and vital capacity (VC) were measured at baseline, 15 minutes after application of an abdominal restrictive device and immediately following treatment with one or the other of the breathing maneuvers.

Results demonstrated that some lung volumes could be reduced, although not consistently, using abdominal restriction. By analysis of covariance (ANCOVA), significant variance was found in baseline and post-restriction measures. The VC demonstrated a significant treatment effect with PLB resulting in a greater increase than with the SMI.

CHAPTER 1

INTRODUCTION

Despite notable advances in surgical practice, one patient in every three or four undergoing a major operation sustains a significant complication. A postoperative complication may be defined as a specific abnormal condition related to an operation (Polk, 1978). Common postoperative complications include wound infections, neurological deficits, cardiac, and respiratory complications.

Pulmonary complications remain the single most frequent cause of morbidity and mortality following surgery and anesthesia (Alexander, Schreiner, Smiler, & Brown, 1981; Bartlett, Gazzaniga, & Geraghty, 1973; Hansen, Drablos, & Steinert, 1977). Pulmonary complications exhibit one or more features of tachypnea, tachycardia, decreased lung volume, transpulmonary shunting and atelectasis (Bartlett, et al., 1973). There is an increased incidence of postoperative pulmonary complications in abdominal procedures with the highest incidence reported in surgeries involving the upper abdomen (Hansen, et al., 1977; Wightman, 1968).

In order to study lung volumes under various circumstances, Caro, Butler, and DuBois (1960) simulated shallow breathing, as seen in postoperative patients, with the use of chest restriction and/or abdominal restrictive devices. The methods of strapping were either adhesive taping, rubber straps or a webbed corset. Caro et al. (1960)

noted altered mechanical properties of the lung following strapping. Following the release of restriction, these findings were reversed. Caro et al. (1960) concluded that the technique of strapping could be used to mimic the physiological changes occurring in the pulmonary dynamics of the individual with shallow breathing. For the purposes of this study, the technique was utilized to simulate the breathing pattern seen in the postoperative patient.

During actual surgery and anesthesia, altered lung mechanics compromise alveolar stability and predispose the lungs to small airway closure and collapse. Postoperative pulmonary pathologic changes often occur in otherwise normal patients without pre-existing pulmonary disease (Tisi, 1979).

Atelectasis is the most commonly recognized pulmonary complication and accounts for 90 percent of all pulmonary complications (Pierce & Robertson, 1977). Atelectasis (Greek <u>ateles</u>, incomplete; <u>ektasis</u>, distention) is defined as acquired de-aeration, or more correctly termed "collapse". It is associated with lowered lung volumes and small airway closure (Nunn, 1978).

The lower volume of air in the alveoli is demonstrated by a decrease in functional residual capacity (FRC) as well as decreased vital capacity (VC) and inspiratory capacity (IC). Functional residual capacity is the volume of gas in the lungs at the end of normal expiration. The maximum amount of air that a person can expel from the lung after first filling the lungs to their maximum extent and then expiring to the maximum extent is the vital capacity. Finally, IC is that amount of air that a person can inhale beginning at the normal expiratory level and distending his lungs to the maximum amount. With the use of an abdominal restrictive device, Caro et al. (1960) noted changes in certain lung volumes almost immediately following strapping. Over time, decreased lung volumes will lead to alveolar collapse or atelectasis.

Normally, adults breathe a tidal volume (V_T) of 400 to 500 milliliters (ml) (volume of air inspired or expired with each normal breath), alternating with spontaneous deep breaths to total lung capacity every five to ten minutes. Total lung capacity (TLC) is the total volume of gas in the lung following a maximal inspiration. If the normal pattern of ventilation is altered to a pattern of shallow, monotonous tidal ventilation with deep breaths, gradual loss of volume and alveolar collapse begins within one hour (Bartlett, et al. 1973). In the postoperative period, especially after upper abdominal surgery, this monotonous type of ventilation is common. After several hours of abnormal ventilation, gross atelectasis is present and those areas may be difficult to reinflate (Bartlett in Burton & Hodgkin, 1984). Without adequate respiratory maneuvers to enhance the FRC, IC and VC, pulmonary complications will result.

Several respiratory manuevers have been advocated to prevent alveolar collapse. Incentive spirometry utilizing the sustained maximal inspiration (SMI) has been recommended as a useful respiratory maneuver to enhance lung volumes in the postoperative period (Bartlett, et al., 1973). Bartlett (1984) has also suggested that in the postoperative period "quantitated maximal inspiration combined with positive expiratory pressure should provide the best means of assuring maximal alveolar inflation in the nonintubated patient" (p. 675). Further, Bartlett (1984) advised that respiratory maneuvers be carried out several times hourly to effectively re-establish the normal pattern of breathing and avoid atelectasis.

Statement of the Purpose

The purpose of this study was to describe the effects of the sustained maximal inspiration (SMI) maneuver and expiratory positive airway pressure ("purse-lipped" exhalation maneuver) on lung volumes in a preliminary study using healthy volunteers. Simulating, with an abdominal restrictive device, the shallow breathing seen in postoperative patients undergoing upper abdominal procedures, allows one to evaluate the effectiveness of breathing maneuvers prior to introducing the method on an uncomfortable postoperative surgical patient. Describing the most effective technique to prohibit the fall in FRC, IC and VC in otherwise healthy subjects will enable nurses to utilize the information to help prevent pulmonary complications in postoperative patients and improve patient care outcomes.

Hypotheses

Specific research hypotheses are:

1. Fifteen minutes after the application of the abdominal restriction device, FRC, IC, ERV, RV, VC and FEV_1 will be

significantly (.05 level) reduced compared to pre-abdominal restriction device application in healthy volunteers.

2. Compared to post restriction measurement, values for FRC, IC, ERV, RV, VC and FEV_1 will be significantly (.05 level) increased following treatment with sustained maximal inspiration in healthy volunteers.
3. Compared to post restriction, values for FRC, IC, ERV, RV, VC and FEV_1 will be significantly (.05 level) increased following treatment with "purse-lipped" exhalation in healthy volunteers.
4. Increases in values for FRC, IC, ERV, RV, VC and FEV_1 will be significantly (.05 level) greater after treatment with the "purse-lipped" exhalation compared to the sustained maximal inhalation maneuver.

Theoretical Framework

The theoretical framework for this study is based on the belief that nursing interventions which will increase lung volumes will decrease pulmonary complications postoperatively. A need still exists to evaluate suggested respiratory maneuvers to enhance lung volumes in the postoperative period. Despite the increased manufacture and utilization of various devices designed to motivate patients to take deep breaths after surgery, the incidence of postoperative pulmonary complications has not changed in many years and is still 18 to 25% for patients undergoing abdominal surgery (Alexander et al., 1981).

Model Illustrating the Theoretical Framework for Comparison of the SMI and PLB on Lung Function in Healthy Volunteers

Figure 1 illustrates how nursing interventions improve the pulmonary function of the patient in the postoperative period. Ordinarily the tidal volume in spontaneously breathing man is 400 to 500 ml with intermittent sighs to total lung capacity. This pattern of ventilation can be altered by pain, surgery, anesthesia and narcotics. For purposes of studying the effects of shallow breathing on lung volumes in healthy volunteers, simulation of shallow breathing (as seen in the postoperative period of those patients undergoing upper abdominal surgery) may be accomplished by utilizing an abdominal restrictive device. Altered monotonous, shallow respirations have been shown to be the cause of decreased lung volumes, progressive airway closure and atelectasis (Bartlett, 1984). Utilizing respiratory maneuvers which will increase lung volumes will reverse the sequence of events leading to atelectasis. By increasing lung volumes, transpulmonary pressures are increased, alveoli are opened and compliance is increased. Thus the identification and institution of individual nursing interventions that will enhance lung volumes may decrease the incidence of pulmonary complications.

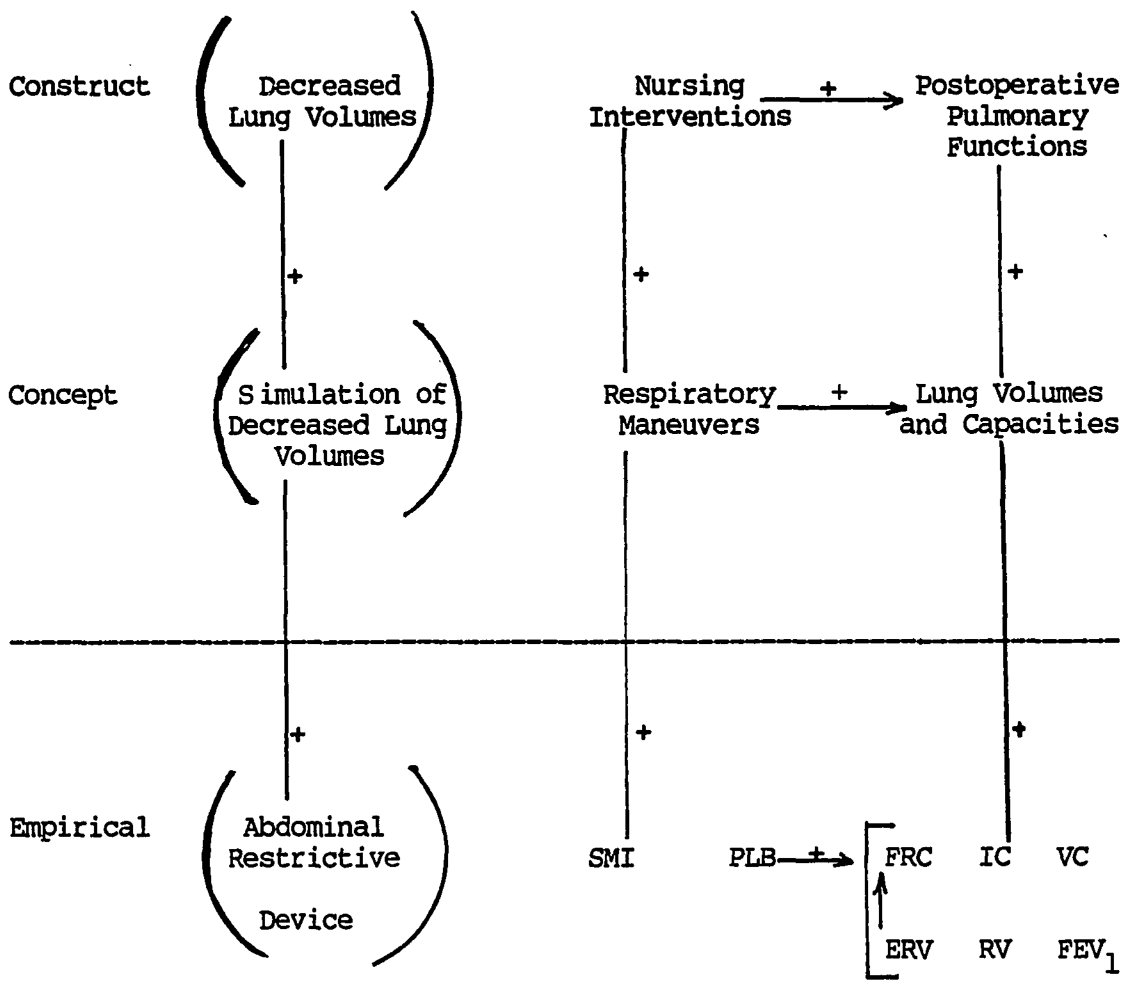

Figure 1. Theoretical Framework for Comparison of the Sustained Maximal Inspiration and Purse-Lipped Exhalation on Lung Function in Healthy Volunteers

Definitions

1. Sustained maximal inspiration: The sustained maximal inspiration is a respiratory maneuver in which the individual is encouraged to take a deep inspiration, and at the peak of the inspiration the individual is encouraged to hold the inspired air for a count of three and then the subject is instructed to exhale normally.
2. Purse-lipped breathing: The purse-lipped breathing exhalation maneuver is a respiratory maneuver in which the subject is encouraged to take a deep inspiration and upon exhalation the subject is instructed to "purse" the lips as though blowing out a candle, for a count of two, then to begin immediately the next inspiration.

CHAPTER 2

REVIEW OF THE LITERATURE

A summary of the literature regarding the use of restriction devices in the study of pulmonary mechanics, factors contributing to pulmonary complications after abdominal surgery, and the effects of sustained maximal inspiration and expiratory positive airway pressures, is presented in this chapter.

The Use of Restriction Devices in the Study of Pulmonary Mechanics

Historically, Haldane, Meakins, and Priestley (1919) were some of the first investigators to study the effects of shallow breathing and the relationship between respiration and the metabolism of the body. They attempted to imitate the condition of shallow breathing by using a device which restricted the volume of air per breath available to normal individuals. The apparatus used was essentially a collapsible bellows that provided a constant but limited quantity of fresh air available to each individual. Experiments were carried out with the subjects in the sitting and lying positions. The findings related to development of uneven ventilation in the lungs were profound; but the experiments had to be discontinued when subjects' respirations increased to 100 per minute in an effort to eliminate carbon dioxide generated. Having found that shallow breathing had such striking consequences on the distribution of ventilation, Haldane et al. (1919)

were led subsequently to study the effects of abdominal and thoracic constriction on respirations. Haldane et al (1919) utilized ordinary corsets to restrict any abdominal movement leaving the thorax free. Respiratory tracings indicated periodic breathing and a restriction of the even expansion of the lungs. Chest restriction results were not satisfactory due to inabilty of the device to maintain constriction.

Forty years later, Caro et al. (1960) experimented with chest and abdominal strapping to study their effects on pulmonary mechanics. Twenty-five normal subjects were studied. Twenty-two individuals had their thoracic cage tightly strapped with either adhesive tape or rubber tubing. Three subjects had their abdomen alone restricted using the rubber strip. All measurements of lung function were made in the sitting position. The VC and its subdivisions were measured with a recording spirometer and the FRC was determined by means of a body plethysmograph. Caro et al. (1960) found that although there were mean reductions in all lung volumes, within the abdominal restrictive device group, two individuals had increases in absolute values for both inspiratory capacity and residual volume. A nitrogen gas analyzer was used to detect uneven alveolar ventilation following a single breath of oxygen. They found that during periods of restriction, the distribution of gas was unchanged and concluded that the accessible portions of the lung were evenly ventilated. With deep inspiration, however, nitrogen was released which gave investigators reason to believe that the gas had been present in nonventilated regions. The finding of a reduction in lung compliance also supported the theory that there was loss of lung volume (ventilated areas) during restriction.

<u>Pulmonary Complications After Abdominal Surgery</u>

The primary contributing factor in the development of postoperative pulmonary complications is the consistent decrease in lung volumes. The most commonly measured lung volumes and capacities that are reduced postoperatively are the VC, V_T, IC and FRC. Residual volume (RV), the volume of air still remaining in the lungs after the most forceful expiration, and total lung capacity also show a similar decline. The FRC appears to reflect most accurately alterations in alveolar inflation or collapse. A decline in FRC to 70% of preoperative values is typical on the first postoperative day following upper abdominal surgery (Alexander, Spence, Parikh & Stuart, 1973; Ali, Weisel, Layug, Kripke & Hechtman, 1974; Meyers, Lembeck, O'Kane, & Baue, 1975).

The major underlying factor which contributes to low lung volumes in the postoperative patient is shallow, monotonous breathing without spontaneous deep breaths. Circumstances leading to this ventilatory pattern include the surgical site (Williams & Brenowitz, 1975), pain, administration of narcotics for pain relief (Egbert & Bendixen, 1964), anesthesia and the supine position (Meyers et al., 1975).

Normal awake adults breathe at a tidal volume of 400 to 500 cc interrupted every five to ten minutes by sighs, yawns, or breaths to

TLC (Mead & Collier, 1959). With shallow and monotonous breathing, without the normal periodic sigh, instability of peripheral lung units results, leading to alveolar collapse (Bartlett et al., 1973; Craig, 1981).

A clinically significant factor in the decrease of lung volumes, specifically the FRC, is patient position. FRC declines approximately 30 percent in moving from the upright to the supine position (Marini, 1984). For this reason, if not otherwise contraindicated, patients are placed in semi-Fowler's in the immediate postoperative period.

Another factor with consequences for pulmonary mechanisms is the site of the operation. The incidence of clinically important atelectasis increases as the incision approaches the diaphragm. Upper abdominal incisions pose the greatest risk following by cardiothoracic procedures, lower abdominal procesures and extremity surgery (Ali et al., 1974).

Normally there is a gradient in pleural pressure between the top and bottom of the lung in upright man. The factors that contribute to the pressure gradient include the effects of lung weight, gravity and the anatomical structures of lung support. The higher distending pressure at the top compared with that of the bottom causes the alveoli to expand differently on inspiration. At lung volumes above FRC alveoli at the bottom of the lung expand considerably more than those at the top. As the lung is progressively inflated, and reaches TLC, alveoli at the top and bottom are equal in size. Contributing to the differential in ventilation is a positive pleural pressure which can develop in dependent areas. The positive pressure is a compressing force that tends to close small airways. If blood flow continues to the terminal respiratory units distal to the site of airway closure, gas exchange is impaired (Murray, 1976).

Postoperatively as lung volumes decrease, transpulmonary pressures at resting volumes also decrease. If one breathes at a reduced FRC, higher than atmospheric pleural pressures may exist in gravity-dependent areas of the lung. "Pleural pressure greater than atmospheric pressure results in a negative transpulmonary pressure causing small airways to be narrowed or closed" (Craig, 1981, p. 47). The lung volume where airways begin to close is termed the closing volume (Lewis, 1980).

Postoperatively the FRC is reduced. The causative factor may be the shallow, monotonous ventilatory pattern that occurs due to pain, anesthesia, surgical incision site, narcotics and position. The importance of a reduced FRC has become more apparent through an understanding of the physiology underlying airway closure. After the small airways close, gas is trapped distally in the alveoli. As gas is reabsorbed, atelectasis results. A net result is reduction in ventilation to affected lung regions, producing low ventilation/profusion relationships and impaired gas exchange leading to hypoxemia (Craig, 1981).

A further factor predisposing to atelectasis is the loss of pulmonary surfactant as a result of surgery or anesthesia. Surfactant normally lining the alveoli is essential for the reduction of surface tension and the maintenance of normal volume. Once atelectasis has occurred, surfactant levels decrease further within hours. This loss makes reexpansion more difficult as time passes (Lewis, 1980).

The incidence of postoperative pulmonary complications was investigated by Wightman (1968) in Great Britain over a period of seven months. During that period, 785 operative procedures were analyzed, of which 455 were abdominal and 330 were non-abdominal. All procedures had been performed under general anesthesia. A postoperative pulmonary complication was considered to have occurred if the patient developed a productive cough, a fever of 99 degrees Fahrenheit or above, and physical signs on examination of the chest which were not present preoperatively. The data from the study indicated a higher incidence of postoperative pulmonary complications following abdominal versus non-abdominal operations.

Hansen et al. (1977) studied forced vital capacity (FVC), forced expired volume in one second (FEV_1), arterial blood gases, and physical examination by auscultation preoperatively and on the first, second, third and sixth days after elective cholecystectomy on 40 patients to determine the incidence of postoperative pulmonary complications. All patients had chest roentgenograms preoperatively and on the second, and sixth or seventh postoperative days. Postoperative pulmonary complications were defined as the presence of basal crackles, absent breath sounds or tubular breathing by auscultation, and/or temperature elevation to 38 degrees Centigrade or above for more than three days and a productive cough, and/or atelectasis, consolidation or pleural effusion seen on roentgenographic examination. Using the above criteria, 75 percent of the subjects were found to have postoperative pulmonary complications. Sixty percent of those found to have pulmonary complications by auscultation also showed pathological changes on chest roentgenograms. Postoperatively the FVC and FEV_1 were reduced by 50% of the preoperative level. Sixty percent of those patients with evidence of postoperative complications demonstrated significant hypoxemia.

Meyers et al. (1975) studied 28 patients undergoing elective upper abdominal surgery under general anesthesia. Pulmonary function studies were obtained on all patients preoperatively and daily for five days following operation. All measurements were taken while the patient was in either the sitting or semi-Fowler's position. The measurements obtained included FRC, RV, VC, and FEV_1. In all patients there was a decrease in FRC in the postoperative period with a maximum reduction occurring on the first postoperative day. Eighteen percent of the patients developed severe reductions in FRC to 58% or less of predicted on the first postoperative day and all of these had clinical manifestations of pulmonary dysfunction as characterized by temperature elevations, decreased breath sounds and abnormal findings on chest roentgenogram. Patients with 40% or less decrese in FRC after operation did not develop pulmonary complications. The other pulmonary measurements obtained postoperatively, the VC, FEV_1 and RV demonstrated decreases following surgery with the greatest changes occurring on the first and second postoperative days.

Alexander et al. (1973) studied the FRC, closing volume (CV), VC and arterial blood gases in 173 patients before and after elective surgery. Functional residual capacity was reduced in all patients after abdominal surgery with a concomitant increase in alveolar/arterial oxygen tension difference. The increase in the alveolar/arterial oxygen difference was related to closing volume and a reduction of the FRC. The author's interpretation of the data was that an increase in CV and a decrease in FRC lead to a narrowing of the smaller airways which may lead to hypoxemia.

Ali et al. (1974) studied 58 patients scheduled for elective surgery. Tidal volume, respiratory frequency, VC, and FRC were examined preoperatively and several times postoperatively: at four hours after surgery and on the first, third, fifth, and seventh postoperative days. Patients were divided into five groups according to site of incision: upper abdominal (n=19), lower abdominal (n=9), superficial (n=20), thoracotomy (n=7), and posterior (n=3). The VC was significantly reduced in the immediate postoperative period, and remained decreased throughout the study period in all groups except the group with superficial incisions. The tidal volume was reduced while the respirtory frequency was elevated in the upper abdominal group. The FRC was significantly reduced from day one through day five in patients who had upper abdominal surgery, with the greatest decline occurring 16 hours after cessation of surgery. Diagnosis of postoperative pulmonary complication was made if all of the following criteria were met: temperature elevation above 38 degrees Centigrade, productive cough, and x-ray evidence of consolidation or atelectasis. Pulmonary complications were observed in 26% (five of nineteen) of the patients in the upper abdominal group, and in three persons in the thoracotomy group (43%).

Peters (1979) conducted a pilot study of 30 patients undergoing cardiac surgery and measured the mean postoperative changes in functional residual capacity (FRC). Data demonstrated a decrease in FRC from a mean preoperative value of 2800 ml $\pm$ 900 ml to a postoperative value of 1500 ml $\pm$ 500 ml. These declines in FRC were accompanied by roentgenographic evidence of atelectasis.

Sustained Maximal Inspiration and Expiratory Airway Pressure Breathing

Postoperatively, a primary focus for nursing care is the prevention of atelectasis. If not reversed, atelectasis will lead to ineffective airway clearance and impaired gas exchange. Ordinarily atelectasis occurs gradually and progressively and may involve small groups of alveoli or whole lung segments. Sequelae associated with atelectasis are a further decrease in FRC, an increased alveolar-arterial oxygen gradient, and hypoxemia.

Data are inclusive as to the efficacy of various maneuvers to prevent postoperative pulmonary complications. A recent survey indicated that Incentive Spirometry was utilized in over 95 percent of the hospitals surveyed, while Intermittent Positive Pressure Breathing

(IPPB) was prescribed 33 percent of the time as a prophylactic lung expansion maneuver. The incidence of atelectasis was reported to be between 19 and 22 percent for the hospitals surveyed (O'Donohue, 1985).

Maximal alveolar inflating pressures and preferably negative intrathoracic pressures are desirable in attaining a high transpulmonary pressure gradient with subsequent increases in lung volumes to re-expand atelectatic areas of the lung. The sustained maximal inspiration achieves this goal. Expiratory positive pressure (EPAP) is considered to be the equivalent of "pursed-lipped" breathing and differs from Positive End Expirtory Pressure (PEEP) and Continuous Positive Airway Pressure (CPAP) in that EPAP has the advantage of allowing negative intrathoracic pressures during inspriation (Gerrard & Shah, 1978). Pursing the lips is proposed to cause an expiratory retard producing positive pressure in the intrathoracic air passage which decreases the possibility of airway closure and a subsequent decrease in FRC (Miller, 1981). Increased FRC has been positively correlated with decreased closing volume and increased arterial oxygenation which has been considered to be an indication of opened atelectatic areas (Alexander et al., 1973). "Purse-lipped" breathing utilized as an expiratory retard differs from the pursed-lip maneuver taught to the emphysematous patient. In the presence of chronic obstructive pulmonary disease, the patient is instructed to purse the lips and prolong expiration which aids in removing more air from overexpanded alveoli. When used as an expiratory retard during normal or shortened expiratory time, it is used to "splint alveoli" in their position of function. The maintenance of more positive pressure in the airways during expiration makes them less likely to be collapsed by low or positive pleural pressures.

In 1973 Bartlett et al. investigated various respiratory maneuvers including rebreathing carbon dioxide, expiratory maneuvers excluding pursed lip (except as simulated by blow bottles), IPPB and SMI maneuvers to determine the most effective respiratory maneuver to prevent postoperative pulmonary complications. In the first phase of the study, the respirtory maneuvers were evaluated in five normal volunteers and the SMI was determined to be the most desirable maneuver to achieve maximum alveolar ventilation. Phase II involved the evaluation of the SMI maneuver in ten postoperative patients with normal pulmonary function studies preoperatively. There was a uniform reversal of postoperative hypoxemia when the SMI was utilized repeatedly. The incidence of postoperative pulmonary complications in patients undergoing laparotomy was studied in Phase III. Criteria for significant pulmonary complications was defined as the simultaneous occurrence of abnormal roentgenogram of the chest showing atelectasis or consolidation or both, temperature over 100 degrees Fahrenheit, abnormal physical findings of the chest, and significant sputum production. The incidence of pulmonary complications in the SMI treated group was seven of 75 patients, while in the control group the incidence of pulmonary complications was 19 of 75 patients. The difference between the two groups was statistically significant ($p<.02$).

Dohi and Gold (1978) studied 64 patients for five days postoperatively. The investigation evaluated spirometric measurements, radiologic findings as well as clinical pathological abnormalities on patients receiving either episodic IPPB therapy or incentive spirometry (TRIFLO II)^{R} which produced an SMI. Fifty-seven percent of the patients treated with IPPB developed pneumonia, atelectasis, or bronchitis while only 29% of those treated with the incentive spirometric device developed pulmonary complications. Data reflected a close relationship between radiologic and clinical signs (elevation of temperature, auscultatory abnormalities and increased production of sputum). While not statistically significant, the trend toward recovery of preoperative pulmonary function favored the incentive spirometric device. Dohi et al (1978) concluded that the SMI maneuver was equal to the IPPB therapy and that IPPB may not be "cost-effective" when compared to the cost of the incentive spirometer (TRIFLO II)^{R}.

Iverson, Ecker, Forx, and May (1978) investigated the incidence of atelectasis in 145 post cardiac surgery patients treated with either IPPB, blow bottles or incentive spirometry. Of the group receiving IPPB 30% experienced pulmonary complications while 20% experienced gastrointestinal side effects. In the group treated with incentive spirometry only 15% developed pulmonary complications and eight percent of those using blow bottles experienced pulmonary complications. Gastrointestinal side effects were rare in the latter two groups. The investigators concluded that IPPB was not necessary in the treatment and prevention of postoperative pulmonary complications.

Alexander et al. (1981) investigated the incidence of pulmonary complications in 377 subjects using either incentive spirometry, IPPB, a combination of the two, or "routine" care by the nursing and surgical staff. Determination of pulmonary complications was made on the basis of radiologic findings of atelectasis, infiltrates or pneumonia. For all groups, those patients who achieved 80% of the preoperative inspiratory volume, the complication rate was 16.5% as compared to a complication rate of 53.1% in those patients who achieved less than 70% of their preopertive inspiratory volume. Although the incidence of pulmonary complications was not significantly different between the treatment groups, the investigators concluded that the SMI was superior to IPPB on the bsis of economics, safety and incentive to the patient.

Lederer, Van de Water, and Indech (1980) investigated pulmonary function, vital signs, white blood cell count, length of hospital stay and the presence of pulmonary complications in 79 patients undergoing upper abdominal surgery when treated with one of three types of deep breathing devices which produce an SMI. The incidence of pulmonary complications as defined by atelectasis or pneumonia by chest roentgenogram during the first five postoperative days was only 3%. The investigators concluded that all three incentive spirometry devices were equally effective, and therefore, any device or respiratory maneuver which achieved maximal inspiratory effort would be of benefit to the patient.

Stock, Downs, Gauer, Alster and Imrey (1985) investigated 65 patients preoperatively and at four, 24, 48 and 72 hours postoperatively to evaluate pulmonary function, clinical status and postoperative pulmonary complications. Treatments were either continuous positive airway pressure with a mask, incentive spirometry using the SMI, or conservative therapy which included coughing and deep breathing. Functional residual capacity was increased from 70% to 85% of preoperative predicted values with both CPAP and incentive spirometry by 48 hours postoperatively. The overall incidence of pneumonia was only 3% for all groups. Pneumonia was defined by two of three criteria; a change in the color or quantity of sputum, an oral temperature greater than 38.5 degrees Centigrade for at least two days and an infiltrate on chest roentgenograms. The investigators concluded that the low incidence of pulmonary complications postoperatively may have been due to the early, supervised, frequent mobilization with coaching to take deep breaths with or without the devices under study.

Drain (1984) studied lung volumes in 14 postoperative upper abdominal surgical patients to compare the sustained maximal inspiration to the deep breathing maneuver. Measurements were obtained preoperatively and at one and two hours postoperatively. Drain (1984) demonstrated that in the immediate postoperative period the decrease in FRC was significantly less in those subjects utilizing the SMI maneuver compared to the subjects using the deep breathing maneuver. Drain (1984) also demonsrated that although not statistically significant, there was a trend for increase or stabilization of other lung volumes and capacities in the subjects utilizing the SMI maneuver contrasted to a continuing decrease in flow and volume measurements in subjects using the deep breathing maneuver.

Paul and Downs (1981) studied and compared the effects on end-expiratory transpulmonary pressure of intermittent positive pressure breathing (IPPB), incentive spirometry and 5-cm H_2O positive end-expiratory pressure (PEEP) applied with a face mask in eight patients 24 to 24 hours after aortocoronary bypass graft insertion. All patients were weaned from mechanical ventilation at 12 hours post operatively. Transpulmonary pressures were obtained using a fluid-filled catheter placed percutaneously into the right intrapleural space and connected to pressure transducers and strip chart recordings. Expiratory transpulmonary pressure was calculated by subtracting end-expiratory pulmonary airway pressure from end-expiratory pleural pressure. Expiratory transpulmonary pressure increased significantly with PEEP, less with IPPB, and incentive spirometry did not significantly affect expiratory transpulmonary pressure at any time. Investigtors concluded that PEEP as an expiratory maneuver was more effective in increasing FRC, an expiratory lung volume as reflected by changes indicating an increase in transpulmonary pressure recording.

O'Connor (1975) studied 23 male patients all of whom had undergone laparotomy, and compared blow bottles and a dead space-expiratory pressure device. Both devices have a resistive component. The blow bottles require the transfer of as much water as possible from one bottle to another. The dead space expiratory pressure device has a liter volume of dead space and a system of one way valves with the expiratory valve closing at 20 cms of water pressure. The average vital capacity increase of the dead space-expiratory pressure group measured over four days was 86% compared to 41% increase in the blow bottle group. The author concluded that since vital capacity was increased more using the dead space-expiratory pressure device, that use of the device should result in a decreased incidence of postoperative pulmonary complications.

Gerrard and Shah (1978) studied the effects of expiratory positive airway pressure on functional residual capacity in seven normal volunteers. Six of the seven subjects showed significant increases in FRC at one or more levels of expiratory airway pressure. Data were expressed as a percentage of the initial FRC and correlated with the level of expiratory airway pressure used. A slope indicted a 6.3% increase in FRC for each 5 cm H_2O rise in expiratory airway pressure. The largest increase in FRC was observed in a subject whose initial FRC was 85% of predicted. The authors concluded that patients with reduced FRC may demonstrate greater increases in FRC with the use of expiratory airway pressure than had been recorded in their normal subjects. Gerrard and Shah further concluded that expiratory positive airway pressure may offer advantages over positive end expiratory pressure (PEEP) and CPAP in the postoperative patient because it allows negative intrathoracic pressures during inspirtion, increasing venous return to the heart.

Schmidt, Parulkar, Brennan, and Feder (1977) described the use of expiratory positive airway pressure in three spontaneously breathing adult patients postoperatively. In all patients respirtory rate was decreased to an acceptable level and arterial PO_2 was improved postoperatiely. The investigators offered the use of expiratory positive airway pressure as a valuable adjunct to either chest physical therapy or incentive breathing exercises in the treatment of postoperative complications such as atelectasis or pneumonia.

No studies were found which specifically investigated intrathoracic airway pressures during the "purse-lipped" exhalation maneuver, the effects of the maneuver on FRC postoperatively, or relationship of use of the maneuver with numbers of pulmonary complications.

CHAPTER 3

METHODOLOGY

The research design, sample, instruments, method of data collection and analysis of data are presented in this chapter.

Research Design

A quasi-experimental research design was used to study the effects of the sustained maximal inspiration maneuver compared to the "purse-lipped" exhalation breathing maneuver on FRC, IC, VC, FEV_1 and expiratory reserve volume (ERV) during simulated shallow breathing in healthy volunteers. Treatment order was randomized using a random number table. Control measurements were taken prior to the simulation of shallow breathing. Measurements were repeated 15 minutes following the application of the abdominal restriction device and again following treatment with either the sustained maximal inspiration or the "purse-lipped" exhalation maneuver. A second session within seven days, included the same protocol utilizing the breathing maneuver which had not been performed during the first session.

Sample and Setting

A convenience sample was used for subject selection. Ten subjects from a healthy population in a southwestern city who met the criteria for selection were recruited.

Initial screening criteria for inclusion in the study included the following. The subject would be:

1. A healthy volunteer with no current pulmonary pathology.
2. Able to read and speak using the English language.
3. At least 18 years of age but less than 75.
4. Able to perform the maneuvers required for the lung volume measurements.

Subjects who met the above criteria were approached. The purpose and nature of the study was explained to each subject and further, each participant was assured that withdrawal from the study would not incur any ill will. Prior approval was obtained from the Human Subjects Committee at the College of Nursing to recruit and utilize graduate students as possible volunteers. Subjects who consented to participate in the study signed the Subject's Consent Form (See Appendix A). Approval from the Human Subjects Committee at the University of Arizona College of Nursing and the Human Subjects Committee from the University of Arizona was also obtained before the commencement of data collection (See Appendices B, C, and D).

Protocol Instruction for the Independent Variables

Sustained Maximal Inspiration (SMI) Maneuver

The SMI was done with verbal and manual assistance from the investigator. With the subject in the sitting position in a chair, and the abdominal binder in place, the investigator was positioned in front of the subject. The investigator's hands were placed on the lateral chest wall and instructions were given to the subject to inspire deeply, pushing the investigator's hands outward, and to hold the inspiration for a count of three and then exhale normally. The investigator's hands remained in place throughout the entire procedure. The subject was instructed to complete five repetitions.

Purse-Lipped Exhalation (PLB) Maneuver

The PLB was done with verbal and manual assistance from the investigator. The subject was in the sitting position with the abdominal binder in place. The investigator's hands were placed on the lateral chest wall to encourage deep breathing. The subject was instructed to take a deep inspiration pushing the investigator's hands outward and upon exhalation to "purse" the lips for a count of two, and then to begin immediately the next inspiration. The subject was instructed to complete five repetitions under the investigator's supervision.

Protocol for Measurement of Dependent Variables

The FRC was determined using the multiple breath helium dilution method using a Collins Modular Lung Analyzer[R]. The equipment included a spirometer with a closed blower system, a carbon dioxide absorber, and a helium analyzer which permitted constant analysis of helium inside the spirometer. Obtaining an FRC involved having the subject breathe a mixture of helium (10-13%) and air for up to 12 minutes.

The system was purged of any residual helium by turning on the blower and opening the system to room air for several minutes. The helium analyzer was zeroed indicating no residual amount of helium. A helium concentration of 10-13% was then obtained by adding approximately 600 milliliters of helium to the system after closing the spirometer to room air. The percentage obtained was then recorded and designated as the C1 helium concentration. Approximately two liters of air was then added to the system by opening the free breathing valve while pulling up on the bell chain to prevent helium loss. After running the blower for a minute, the helium percentage was recorded as the C2 helium concentration. At this time, the subject was instructed to tightly seal his/her mouth around the mouthpiece and a noseclip was applied and the subject breathed normally. At the end of a normal breath, the free breathing valve was opened and the subject began breathing the helium gas mixture. Oxygen was added to keep the volume of gas in the spirometer constant. A carbon dioxide absorber within the system allowed patient rebreathing without a buildup of carbon dioxide. While the subject was breathing normally, percentages of helium concentration were recorded at thirty second intervals until duplicate readings were obtained, indicating equilibration between subject's lungs and the spirometer. When equilibration occurred, the helium concentration was recorded and designated as the C3 concentration. Approximately three minutes are required for mixing to occur in a normal subject. An increase in equilibration time indicates an uneven distribution of ventilation.

The measurement of FRC was obtained by having the subject begin breathing on the spirometer at the end of a normal breath at FRC and then continue to breathe normally without ever taking a full inspiration. The FRC was then calcualted from the three helium concentrations obtained. This calcualtion was obtained by the formula shown in Figure 2. Measurement of inspiratory capacity (IC), expiratory reserve volume (ERV), vital capacity (VC), and forced expiratory volume in one second (FEV_1) was obtained after equilibration. The subject was instructed to inhale as deeply as possible to total lung capacity and then to exhale as much air as possible to residual volume. As the subject exhaled, he/she was encouraged to exhale as much air as quickly as possible. The IC, ERV, VC, and FEV_1 were measured and calculated from the reading obtained from the kymograph paper.

Method of Data Collection

Demographic data collected during the study were age, weight, height, and smoking history to include present use. The protocol outlined below was followed for each subject. During the first of two sessions, measurements of the FRC, IC, ERV, VC, and FEV_1 were obtained with the Collins Modular Lung Analyzer using the multiple breath helium dilution method with the subject in the sitting position. Upon completion of the baseline control data collection, either the SMI or the "purse-lipped" breathing maneuver was taught to the subject. The subject then applied either the male or female size rubberized abdominal binder (Pacific Assets^R). The abdominal restrictive device was applied to a level no higher than the xiphoid process of the

$$FRC = \frac{C1\ (C2 - C3)}{C3\ (C1 - C2)} \times \left[(VO_2 - 25)\ corr.\right] - 100\ ml \pm S.E.$$

The helium ratio $\frac{C1\ (C2 - C3)}{C3\ (C1 - C2)}$ is discussed in the text.

The term $\left[(VO_2 - 25)\ corr.\right]$ represents the volume of oxygen added to the system: 25 ml, the mouthpiece deadspace, was subtracted from the absolute volume (VO_2) added and then the obtained figure was corrected to BTPS according to temperture recorded. The amount of helium uptake is 100 ml. The S.E. represents the correction for measured switching error, to ensure that recording of the helium concentration began at FRC (Manual for operation of Collins Modular Lung Analyzer, E.P. Beeler, Arizona Medical Center).

Figure 2. Formula for Calculation of Functional Residual Capacity at Body Temperature Pressure Saturated (BTPS) Using the Multiple Breath Helium Dilution Method

sternum to produce a simulation of shallow breathing as seen in postoperative patients who have undergone upper abdominal surgery. Following 15 minutes of breathing with the abdomiinal binder in place (simulating shallow breathing), a second measurement was made of the FRC, IC, ERV, VC, and FEV_1. The subject was then assisted with one of the two breathing maneuvers, either the SMI or the "purse-lipped" exhalation. After completing five repetitions of the breathing maneuver, final measurements of FRC were obtained using the multiple breath helium dilution method. Inspiratory capacity, ERV, VC, and FEV_1 were obtained following equilibration. The second of the two sessions followed the identical protocol as the first session. The specific respiratory maneuver utilized however, was the maneuver that had not been performed during the first session. The subject was then informed that data collection was terminated.

Data Analysis

Demographic data were used to describe characteristics of the sample using general measures and central tendencies.

Absolute values of lung volumes and capabilities were converted to percent predicted values to correct for variations between individuals for age and height. These percent predicted values were used to compare measurements obtained pre and post breathing maneuvers in the postoperative period.

Hypothesis 1. To determine the effect of the abdominal binder, measurements obtained at baseline and those obtained 15 minutes after application of the abdominal restrictive device were subjected to a paired t-test. Since the same subjects participated in both treatment groups, the SMI and PLB were analyzed separately.

Hypotheses 2 and 3: The hypotheses relating to changes in lung volume from post binder to post treatment for each treatment group were tested using paired t-test for differences.

Hypothesis 4: To test differences between the two treatments, the data were subjected to analysis of covariance (ANCOVA) so that differences in baseline and post binder measures (the covariates) were considered in evaluating the actual treatment effect.

CHAPTER 4

PRESENTATION AND RESULTS OF ANALYSIS OF DATA

This chapter presents the characteristics of the sample in the study. The lung volume measurements at baseline, 15 minutes post application of the abdominal restrictive device, and post intervention are described and the statistical analyses of the hypotheses are presented.

Characteristics of the Sample

The sample consisted of ten subjects, who participated in two separate sessions and received both randomly assigned interventions. All of the subjects were healthy volunteers who gave no history of current pulmonary pathology and who met the established criteria for selection. The total group consisted of seven females and three males whose ages ranged from 21 to 60 years of age with a mean age of 37.60. The mean age for males was 47.10 while the mean age for females was 33.40.

Four of the ten subjects had a positive smoking history. Three of the four subjects were current smokers at the time of the study; pack years ranged from two to 40 years. The fourth subject had ceased smoking three months prior to the study with a history of two pack years.

Flow and Volume Measurements

Measurements of FRC, IC, ERV, VC, and FEV_1 were taken on all subjects in this study during each of two sessions at baseline, 15 minutes after application of the abdominal restrictive device, and immediately after treatment with either the SMI or the PLB breathing maneuver. The second of the two sessions included the breathing maneuver not performed during the initial session. Forced expiratory volume data is available on only nine subjects. Subject #1 was unable to perform the FEV_1 maneuver due to a misunderstanding in instruction. All other data were obtained from ten subjects. Data obtained at baseline, at 15 minutes after application of the restriction device and immediately following treatment with either the SMI or the PLB breathing maneuver were reported in percent predicted based on the predicted normals for each subject in accordance with his/her age, sex, and height (Knudson, Lebowitz, Holberg & Burrows, 1983). All subjects were within normal range of ideal weight for height according to Recommended Dietary Allowances (1980). All individual data expressed are absolute volume, and percent predicted values can be found in Appendices F, G, H, I, J, and K.

The mean baseline measurements of FRC, IC, ERV, RV, VC, and FEV_1 were all within 15 percent of predicted (see Table 1). These values were within the accepted range of normal variation. To assure no differences between baseline data obtained at the beginning of the two treatment sessions, data were subjected to a paired t-test for differences (Pagano, 1981). The analysis demonstrated that there were no

Table 1. Mean and Standard Deviation of Percent Predicted Values for Lung Volumes at Baseline and 15 Minutes Following Application of an Abdominal Restrictive Device (n = 10)

	Baseline		15 min Post Binder	
	Mean	Standard Deviation	Mean	Standard Deviation
SMI Session				
FRC	99.1	23.5	89.8*	23.1
IC	100.1	21.3	95.3	29.4
ERV	89.5	24.8	77.6*	23.7
RV	107	27.7	99.4	34.9
VC	95.8	16.6	88.5**	19.7
FEV_1 [a]	86.8	10.9	84.7	11.6
PLB Session				
FRC	96.4	14.8	86.8	22.5
IC	91.7	17.9	107.2*	23.4
ERV	91.7	25.8	74.9**	21.8
RV	100.7	17.0	96.4	37.0
VC	94.2	17.0	92.7	18.8
FEV_1 [a]	88.4	9.2	84.3	13.8

[a] n = 9

* Significant difference from baseline measurement (p<.05)

** Significant difference from baseline measurement (p<.025) significant differences for FRC, ERV, RV, VC, or FEV_1. There was a significant difference for percent predicted IC ($p<.05$) between the SMI session and the PLB session, with the baseline IC being larger at the SMI session.

Effects on Lung Volumes Following Application of an Abdominal Restrictive Device

The effect of the binder on lung volume was examined separately for each treatment session. Baseline measurements were compared to those obtained at 15 minutes after the restrictive device was applied. Prior to use of the SMI maneuver, application of the binder produced a decrease in all volumes measured. The changes ranged from a decrease of 2.1% for FEV_1 to an 11.9% decrease for ERV. The changes were statistically significant for FRC (99.1 to 89.8%), ERV (89.5 to 77.6%), and VC (95.8 to 88.5%) using a paired t-test (see Table 1).

Prior to use of the PLB maneuver, application of the binder did not produce a consistent decrease in all volumes. The IC increased from 95.7% predicted to 107.2% predicted. Seven of the ten subjects demonstrated an increase while the other demonstrated a decrease in inspiratory capacity. The mean increase was statistically significant ($p<.05$). The other measured volumes demonstrated decreases ranging from 1.5 to 16.8% predicted. Only the decrease in ERV was significant ($p<.025$) by paired t-test with a fall from 91.7% predicted to 74.9% predicted (see Table 1). Although there was a 9.6% predicted decrease in FRC, the finding was not significant.

Sustained Maximal Inspiration Session

Lung volume measurements were obtained immediately following the SMI maneuver and were compared to post abdominal restriction values. Percent predicted FRC increased to 95.2% predicted after the intervention using the Sustained Maximal Inhalation from 89.8% predicted post application of the abdominal restrictive device. The percent predicted IC increased to 101.6% predicted after the SMI maneuver from 95.3% predicted following the restrictive device application. Percent predicted RV increased to 113.7% predicted from a post restrictive device RV of 99.4% predicted. Measurements of ERV continued to decrease to 71.2% predicted from a baseline percent predicted of 89.5% and a 15 minute post restrictive device application of 77.6% predicted. Percent predicted measurements of VC and FEV_1 remained essentially unchanged at 90.3% and 84.8% predicted from a 15 minute post restrictive device application of 88.5% and 84.7% respectively (see Table 2).

Using the paired t-test (Pagano, 1981), there was a significant increase ($p<.05$) in percent predicted FRC between 15 minutes post restrictive device application and post intervention using the SMI maneuver in measurements of percent predicted FRC. There were no significant differences for percent predicted IC, ERV, RV, VC, or FEV_1 between 15 minutes post restrictive device application and post intervention with the SMI maneuver.

Table 2. Mean and Standard Deviation for Percent Predicted Values for Lung Volumes 15 Minutes after Application of the Abdominal Restrictive Device and Immediately Following Treatment with the Sustained Maximal Inspiration Maneuver (n = 10)

	Post Binder		Post SMI	
	Mean	Standard Deviation	Mean	Standard Deviation
FRC	89.8	23.1	95.2*	24.9
IC	95.3	29.4	101.6	25.3
ERV	77.6	23.7	71.2	21.2
RV	99.4	34.9	113.7	29.8
VC	88.5	19.7	90.3	16.2
FEV_1 [a]	84.7	11.6	84.8	12.1

[a] n = 9

* Significant difference from Post Binder Measurement (p<.05)

"Purse-Lipped" Exhalation Session

Lung volume measurements were obtained immediately following the PLB maneuver and were compared to post restrictive device measurements. The percent predicted FRC was essentially unchanged after the PLB maneuver (86.8% predicted post restriction compared to 87.6% predicted after the PLB maneuver). Percent predicted IC increased to 113.5% predicted from a 15 minute post restrictive device measurement of 98.1% predicted. Vital capacity measurements increased to 100.8% predicted from a 15 minute post restrictive device application of 92.7% predicted. Percent predicted ERV demonstrated only a slight change from 74.9% post restriction to 76.9% post PLB maneuver. Percent predicted RV increased slightly from 96.4% predicted 15 minutes post restrictive device application to 100.8% predicted. Percent predicted FEV_1 increased less than 1% from 84.3% predicted to 84.4% predicted (see Table 3).

Using the paired t-test, there was a significant increase between post restrictive device and the PLB maneuver in percent predicted VC ($p<.05$). There were no significant differences between post restrictive device and post PLB maneuver for percent predicted FRC, IC, ERV, RV, VC or FEV_1.

Comparison of Flow and Volume Measurements Between the Treatment Sessions

To determine if there were differences between the two treatments, it was necessary to control for the changes from baseline to post binder. As previously presented in Table 1, the changes between

Table 3. Mean and Standard Deviation of Percent Predicted Values for Lung Volumes 15 Minutes after Application of the Abdominal Restrictive Device and Immediately Following Treatment with the Purse-Lipped Breathing Maneuver (n = 10)

	Post Binder		Post PLB	
	Mean	Standard Deviation	Mean	Standard Deviation
FRC	86.8	22.5	87.6	23.5
IC	98.1	38.7	113.5	30.4
ERV	74.9	21.8	76.9	20.3
RV	96.4	37.0	100.8	24.8
VC	92.7	18.8	100.8*	24.8
FEV_1 [a]	84.3	13.8	84.4	15.4

[a] n = 9

* Significant difference from Post Binder measurement (p<.05)

baseline and post binder were not always consistent between the two treatment sessions. Similarly, the treatments demonstrated different effects. In addition, there were inconsistent individual changes within the groups. To control for these variations, an analysis of covariance was used. This technique was used to detect significant differences between the effects of treatments while controlling for the baseline and post binder measures (covariates).

The ANCOVA results are reported for VC and FRC as these two lung volumes were those that demonstrated significance by paired t-tests done for the individual breathing maneuver. The other volume data were subjected to ANCOVA but none demonstrated a significant treatment effect.

The percent predicted FRC was significantly increased using the paired t-test folowing the SMI maneuver. There was no significant increase in percent predicted FRC following the PLB maneuver leading one to expect to see a difference between treatments. This finding was not verified by the ANCOVA however. The analysis of covariance indicated that a significant amount of variance was explained by the post binder covariate. Once accounting for this variance, there was no treatment effect. The analysis of covariance for VC demonstrated that the covariates accounted for a significant amount of the variance, both baseline and post binder ($p<.05$). After accounting for this variance, there was still a significant treatment effect ($p=.04$). Therefore, the PLB maneuver resulted in a significantly greater increase in VC than did the SMI maneuver. The percent predicted VC significantly increased

($p<.05$) following the PLB maneuver by paired t-test. The analysis of covariance demonstrated that the PLB treatment was significantly different ($p=.04$) from the SMI treatment after accounting for baseline and post binder measure (covariates) (see Table 4).

Summary of Findings Related to the Hypotheses

First, it was hypothesized that there would be a significant decrease (.05 level) from baseline measurements to 15 minutes post application of the abdominal restrictive device measurements of FRC, VC and IC in healthy volunteers. The findings demonstrated a significant decrease ($p<.05$) in the percent predicted FRC and VC during the session utilizing the SMI maneuver. The findings also indicated a decrease in percent predicted FRC and VC following use of the abdominal restrictive device during the session utilizing the PLB maneuver though the decrease was not significant. The percent predicted IC did not significantly decrease during the SMI session and significantly increased ($p<.05$) following application of the abdominal restrictive device during the PLB session. Therefore, the hypotheses relating to the FRC and VC were partially accepted and the hypothesis relating to the percent predicted IC was rejected.

Secondly, after performance of either of the two respiratory maneuvers, it was hypothesized that there would be a significant increase at the .05 level in the FRC, VC, and IC from measurements obtained 15 minutes following application of the abdominal restrictive device. The findings demonstrated a significant increase ($p<.05$) in percent predicted measurements for FRC following treatment with the SMI

Table 4. ANCOVA Results for Functional Residual Capacity and Vital Capacity Between Treatments with Baseline and Post-Binder Values Controlled

	Baseline	Post-Binder	Post Treatment	F	p
Functional Residual Capacity					
SMI	99.1	89.8	95.2		
	SD (23.5)	(23.1)	(24.9)		
				.50	.50
PLB	96.4	86.8	87.6		
	SD (14.8)	(22.5)	(23.5)		
Vital Capacity					
SMI	95.8	88.5	90.3		
	SD (16.6)	(19.7)	(16.2)		
				4.79	.04
PLB	94.2	92.7	100.8		
	SD (17.0)	(18.8)	(24.8)		

maneuver and an increase in VC and IC, though not significant, following the SMI. Percent predicted measurement for VC following the PLB maneuver was significantly increased ($p<.05$) and the percent predicted FRC and IC were increased though not significantly. Therefore the hypothesis relating to the FRC following the SMI was accepted while the hypotheses relating to the IC and VC following the SMI were rejected. The hypothesis relating to the VC following the PLB was accepted while the hypotheses relating to the FRC and IC following the PLB were rejected.

Lastly, it was hypothesized that the PLB maneuver would increase values for FRC, IC, and VC significantly more than the SMI maneuver. Percent predicted measurements for VC were significantly increased ($p=.04$) following treatment with the PLB maneuver compared to the SMI maneuver. No differences between treatments following the PLB for the other lung volumes could be demonstrated. Therefore the hypothesis that PLB would have a greater effect on VC than SMI was accepted while the hypotheses relating to the FRC and IC were rejected.

CHAPTER 5

DISCUSSION AND CONCLUSIONS

The findings of this study are compared and contrasted with those of other investigators and the mechanisms which may have contributed to the findings will be suggested. The implications for health professionals responsible for the postoperative care of the patient will be discussed. Finally, recommendations are made for further study.

Effects of Abdominal Restriction on Lung Volumes

The primary contributing factor in the development of postoperative pulmonary complications is the consistent decrease in lung volumes. The most commonly measured lung volumes and capacities that are reduced postoperatively are the VC, V_T, IC and FRC.

In the present study, simulation of shallow monotonous breathing, as seen in the postoperative period, was attempted with the use of an abdominal restrictive device. Caro et al. (1960) experimented with chest and abdominal strapping to study their effects on pulmonary mechanics and found that essentially all lung volumes were reduced following restriction of the chest with similar although less dramatic changes occurring following abdominal strapping using rubber straps. Post restriction measurements obtained on three subjects who had their abdomen restricted, demonstrated mean decreases in FRC (950 cc), IC (180 cc), ERV (780 cc), VC (970 cc), and RV (160 cc).

In the present study, decreases in the percent predicted lung olumes were observed for all lung volumes except IC, however, only the ERV demonstrated statistically significant decreases in both treatment groups. The mean decreases in absolute values were lower than Caro et al.'s (1960) and ranged from 67 cc mean decrease in ERV to 300 cc mean decrease in FRC. It is possible that the difference between Caro et al.'s (1960) study and the present study was related to the type of abdominal binder utilized.

It was interesting to note that in the Caro et al. (1960) study, there was a consistent decrease in VC, ERV, and FRC between the three subjects while the findings for IC and RV demonstrated variable changes between subjects. Data obtained on individuals in the study by Caro indicate that one of the subjects in the abdominal strapping group had increases in both IC and RV after abdominal restriction; one had a slight increase in IC while there was no change in RV, and the third had a decrease in IC and no change in RV. In the present study, individuals within groups demonstrated a similar variation with some individual increases in IC, ERV, and RV. Caro offered no explanation for this phenomenon, nor could one be identified in the present study since in the present study the same group of subjects demonstrated different responses on two occasions. The findings may be related to placement of the binder.

Consequences of Altered Pulmonary Mechanics in the Postoperative Period

In the present study, the abdominal binder was used to simulate the effects of shallow breathing seen in the postoperative period. The following presents a comparison of the findings of the present study to data in the literature derived from actual postoperative patients.

Previous investigators (Alexander et al., 1973; Ali et al., 1974; Myers et al., 1975) found that lung volume measurements of FRC and VC were reduced in the postoperative period up to seven days postoperatively. Ali et al. (1974) demonstrated a fall in FRC and VC in subjects who had upper abdominal surgical procedures. The VC was significantly reduced from one to seven days postoperatively. The FRC was significantly reduced from day one through day five in patients who had upper abdominal surgery.

Myers et al. (1975) found that in addition to the decrease in FRC and VC, postoperative values for the FEV_1 and RV were also reduced following surgery on the upper abdomen as compared to preoperative values. The change in RV was less than the change observed for the other measures. Alexander et al. (1973) found that the FRC 24 hours after upper abdominal surgery was reduced as compared to preoperative values. Twenty-four hours postoperatively the FRC measured 70% of the preoperative value.

In the present study, application of the abdominal restrictive device simulated some but not all of the changes seen in postoperative patients for values of FRC, ERV, and VC. On ten of the 20 occasions the measurement was made, the post binder FRC ranged between 51.7 to 87% predicted in both treatment groups with mean FRC remaining at levels above 87% predicted for the remaining occasions. Data are similar to Ali et al.'s (1974) and Alexander et al.'s (1973) studies which found that within 24 hours of surgery, the FRC had fallen to 57 to 94% predicted FRC.

Ali et al. (1974) and Hansen et al. (1977) also found decreases in VC to 37% of the preoperative value in patients who had upper abdominal surgery. In the present study, the fall in post binder VC is much less than Ali et al.'s (1974) findings in the postoperative patient. The post binder VC ranged from 64 to 79% predicted in five of the ten subjects in both treatment groups and was essentially unchanged in the remaining subjects. One explanation may be that inspiration against a painful incision is more difficult than inspiration against a rubberized restrictive binder. Logically inspiration for a healthy subject would continue beyond that of an individual having had a recent upper abdominal incision.

Myers et al. (1975) and Hansen et al. (1977) noted marked reductions in FEV_1 indicating abnormalities in pulmonary air flow. In the present study, FEV_1 remained essentially unchanged throughout the study period. Differences may be explained on the basis of an actual postoperative patient's lack of ability to forcefully expire which requires contraction of the abdominal muscles resulting in a painful experience. In the present study, no such painful experience occurred.

Drain (1984) found significant decreases in all lung volumes two hours post operatively with the greatest decreases in percent predicted IC and VC and ERV. In the present study, the greatest decreases were noted in FRC and ERV, with a mean increase in IC.

The smaller percent decreases found in the present study indicate that although the binder effectively lowered lung volumes (except inspiratory capacity) in an effort to simulate the shallow breathing of the postoperative patient, the binder could not simulate the postoperative scenario in full. The variables of pain and the administration of narcotics may have significant effect on an individual's ability to take deep inspirations.

Effects of Breathing Maneuvers on Lung Volumes

The incentive spirometer developed and described by Bartlett et al. (1973) and the deep breathing exercisor (ping-pong ball, hand-held) type currently in use in many institutions are both comparable to the sustained maximal inspiration described in Chapter One. The incentive spirometer is designed so that an individual must take a prolonged inspiration of such duration as to trigger a battery-operated light. The light provides the incentive for the patient to maintain a maximal inspiration creating an increased transpulmonary pressure. The deep breathing exerciser, although a flow-quantitated device, also uses positive feedback to encourage a maximal inspiration.

Previous investigators (Dohi & Gold, 1978; Drain, 1984; Stock et al., 1985) have reported success with the use of the sustained maximal inspiration compared with other methods of postoperative respiratory care. Dohi and Gold (19789 and Stock et al. (1985) found greater increases in VC following therapy with the sustained maximal inspiration as compared to IPPB. Dohi and Gold (1978) further evaluated the increased effectiveness of the SMI on the basis of pulmonary complications. In the Dohi and Gold (1978) study, no measurements were made of the FRC. In the present study, the VC remained essentially unchanged following treatment with the SMI although there was a significant increase in FRC followiqng the SMI maneuver from 89.9% predicted to 95.2% predicted. Differences between Dohi and Gold's (1978) study and the present study for measurement of VC may be due to the fact that IC and ERV are combined to make up VC and in the present study IC was not significantly decreased, and in fact increased in some individuals after application of the binder.

Drain (1984) found that during the immediate postoperative period, FRC was diminished less in those patients using the SMI maneuver as compared to those utilizing the cough and deep breath regimen. In the present study, the FRC was increased following treatment with the SMI maneuver giving support for the SMI as a useful postoperative respiratory maneuver.

In the present study, "purse-lipped" exhalation was studied to see if effects could be measured which would indicate that lung volumes were increased significantly. Expiratory Positive Airway Pressure (EPAP), similar to "purse-lipped" breathing, is comparable to Continuous Positive Airway Pressure or CPAP; although CPAP is achieved by a threshold resistance and purse-lipped breathing by creating a resistive or nonelastic resistance, both maneuvers have the effect of raising airway pressure during expiration.

Other investigators (Garrard & Shah, 1978; O'Connor, 1975; Paul & Downs, 1981) have evaluated the use of expiratory resistance methods to include blow bottles, dead space-expiratory pressure devices, expiratory airway pressure and face-mask positive end-expiratory pressure. Purse-lipped breathing per se has not been studied for its effects on lung volumes.

Garrard and Shah (1978) found increases in FRC almost immediately following the use of EPAP in six of seven normal subjects. Other lung volumes were apparently not measured. This FRC finding differs from the present study in that FRC was essentially unchanged following the PLB maneuver while IC increased 15% above post binder values. During the PLB maneuver, however, only two of the ten subjects demonstrated a decrease in IC after application of the binder, while half of the subjects had a decrease in IC prior to the SMI maneuver. An explanation may be that the binder, which was still in place during these measurements, may have had the effect of "splinting" the diaphragmatic area aiding the subject in their inspiratory effort. These findings would demonstrate a possible combined effect of the binder and the PLB maneuver on the inspiratory capacity.

O'Connor (1975) found greater increases in VC (86%) following use of the dead space-expiratory pressure device compared to 46% increase on the day of surgery noted in those patients using blow bottles, another expiratory device. The dead space-expiratory device most closely resembles the PLB in theory in that expiration does ont return to FRC or end-expiratory volume. Findings in the present study (VC increased to 100.8% predicted) are similar to O'Connor's (1975).

In the present study, the FRC was significantly increased following the SMI maneuver. However, when the differences between the two treatment sessions were analyzed, the variance between groups demonstrated that the SMI was not better than the PLB in increasing FRC. Other lung volumes which increased after the SMI treatment were IC and RV, though not significantly. Lung volumes which were essentially unchanged during the SMI session were the VC and the FEV_1. Expiratory reserve volume continued to decrease to 71.2% predicted. The decrease in ERV percent predicted found in the group using the SMI maneuver may be a reflection of increases in RV. As ERV decreases, the RV may increase.

During the session utilizing the PLB maneuver, VC was increased significantly. All other lung volumes increased, though not significantly and FEV_1 remained unchanged. When differences between the SMI and PLB session were analyzed, there was a significant increase in VC percent predicted following the PLB maneuver which was due to the treatment effect. It may be that the deep inspiration necessary prior to the "purse-lipped" exhalation breathing maneuver affected lung volumes as much as pursing of the lips. Increased vital capacity may be an early indicator of returning pulmonary function, and consequently it may be said that the PLB maneuver is more effective in increasing VC and therefore pulmonary function. The trend for an increase in FRC following the SMI maneuver may be of significance in patients following upper abdominal surgery; since increased FRC is a reflection of increased transpulmonary pressures necessary for improved lung volumes and hence decreased pulmonary complications.

Limitations of the Study

This study was limited by the factor that healthy subjects were utilized so that extrapolations were necessary when comparing present findings to those of other investigators. Simulations of events are ultimately only simulations, and can render less than exact comparisons. The abdominal binder utilized, one size for men and one size for women, did not appear to have exactly the same effect on each individual. Therefore, the reliabilty of results between individuals could not be determined. The sample size was small (n=10), and the same subjects performed both respiratory maneuvers. The findings following the breathing maneuver used during any given subject's second session had the potential for the learning phenomena. The subject, during their second session, would be more familiar with surroundings and with the methods used, and it is unknown how much of a variable anxiety might have had in this situation. Only one measurement of all lung volumes was made at each time during the study. There is a reported five to six percent variability between successive FRC measurements at any given time (Meyers et al., 1975). Therefore the reliability of individual data could not be determined.

Clinical Implications

The purpose of this study was two fold: first, to evaluate the effectiveness of an abdominal restrictive device to simulate the shallow breathing seen in the postoperative period, and secondly, to describe the effects of the sustained maximal inspiration maneuver and expiratory positive airway pressure on lung volumes in a preliminary study using healthy volunteers. It was demonstrated that it is possible to lower lung volumes, except inspiratory capacity, using the abdominal restrictive device thereby simulating some of the effects of shallow breathing such as is observed postoperatively. Knowing that decreased lung volumes can be simulated may allow for the clinical investigation of various respiratory maneuvers prior to their use in actual patient situations. The decreases were significant on at least one occasion for FRC, ERV, and VC, and decreased for RV though not significantly. The lung volumes were not however, decreased to the extent that other invetigators (Alexander, et al., 1973; Ali et al., 1974; Myers et al., 1975) have found in postoperative patients. Other significant findings in this study include the increase in percent predicted FRC following the SMI maneuver and the significantly increased VC following the PLB maneuver as compared to the increase following the SMI maneuver.

Based on the statistically significant data and the trends observed from the present study, the clinical research nurse could possibly develop other respiratory maneuvers and test them for their effectiveness prior to instituting the maneuvers on actual postoperative patients. Based on data developed during the evaluation of each of the respiratory maneuvers, the post anesthesia recovery nurses, who are the primary caregivers during the immediate postoperative period, should encourage their patients to use the SMI perhaps in conjunction with the PLB. Combined, the respiratory maneuvers as described in this study could possibly reinflate atelectatic areas and then hold them open in their position of function. By reinflating areas of collapse, redistribution between perfusion and ventilation could occur, improved oxygenation could take place, and finally pulmonary complications may be reduced.

Suggestions for Further Study

Further studies comparing respiratory maneuver to be used in the postoperative period are important for progress and improvement in patient care. Simulation of shallow breathing as observed during the postoperative period could possibly be improved by using a more restrictive, though more adjustable, device than the binder used in the present study. Taking several measures during each time period of the study would decrease the variability of measurements in individual subjects between the sessions. It may be helpful to design a study in which each subject performed only one respiratory maneuver and have a larger sample size, to demonstrate more clearly any measures in the effectiveness of a given respiratory maneuver. When experimentally using postoperative patients, the investigator's assessment of oxygenation using pulse oximetry both preoperatively and postoperatively, and before, during and after a respiratory maneuver, would be helpful and informative in evaluating the effectiveness of certain respiratory maneuvers.

CHAPTER 6

SUMMARY

Despite notable advances in surgical practice, pulmonary complications remain the single most frequent cause of morbidity and mortality following surgery and anesthesia (Bartlett et al., 1973). There is an increased incidence of postoperative pulmonary complications in abdominal procedures with the highest incidence reported in surgeries involving the upper abdomen (Hansen et al., 1977). Atelectasis is the most commonly recognized pulmonary complication and accounts for 90 percent of all pulmonary complications (Pierce et al., 1977). Atelectasis is associated with lowered lung volumes and small airway closure (Nunn, 1978). In order to study lung volumes under various circumstances, simulation of the shallow breathing as seen in the postoperative period may be approximated with the use of an abdominal restrictive device such as the one used in an early study by Caro et al. (1960).

The purpose of the present study was to describe the effects of the sustained maximal inspiration and expiratory positive airway pressure ("purse-lipped" exhalation maneuver) on lung volumes using healthy volunteers following the use of an abdominal restrictive device to simulate the shallow breathing seen in the postoperative period. The measurements of FRC, IC and VC were selected to assess the effectiveness of the sustained maximal inspiration maneuver and the purse-lipped breathing maneuver on increasing lung volumes following the use of an abdominal restriction device. In the study, these measurements were reported in percent predicted for each subject according to their age, sex and height (Knudson et al., 1983).

The sample consisted of 10 healthy volunteers who fulfilled the criteria for selection. Each subject participated in two sessions. During the first session, measurements were obtained for FRC, IC, ERV, RV, VC and FEV_1 at baseline, 15 minutes after application of an abdominal restrictive device and immediately following treatment with either the sustained maximal inspiration or the purse-lipped breathing maneuver. During the second session, the same protocol was followed except that the breathing maneuver chosen was the one that had not been performed during the first session.

Data were analyzed in terms of changes in the percent predicted FRC, IC, ERV, RV, VC, and FEV_1 from baseline to 15 minutes following abdominal restriction, and from post restriction to immediately following treatment with one of the breathing maneuvers. There was a statistically significant decrease in measurements of FRC, ERV and VC following application of the abdominal restrictive device during the session in which the SMI was used. There was a statistically significant decrease in measurements of ERV following application of the abdominal restrictive device during the session in which the PLB was utilized. Other lung volumes decreased though not significantly following abdominal restriction except for the inspiratory capacity.

Following the performance of the SMI maneuver, there was a statistically significant increase in FRC by paired t-test. Although the FRC increased after the PLB, the change was not significant by paired t-test. However after subjecting the data for both treatment sessions to an ANCOVA, it could not be demonstrated that the SMI was significantly more effective than the PLB in increasing the FRC. The ANCOVA for VC demonstrated that there was a significant treatment effect with the PLB resulting in a greater increase in VC than with the SMI. Therefore in the present study, the sustained maximal inspiration may be effective in preventing a decline in lung volumes seen in the postoperative period; and further, the purse-lipped breathing may be as effective in increasing some lung volumes either alone or perhaps in combination with the sustained maximal inspiration.

This study demonstrated that shallow breathing, as seen in the postoperative period, can possibly be simulated with the use of an abdominal restrictive device, and thus this procedure may be useful in the evalution of respiratory maneuvers prior to the institution in patients postoperatively. Further, this study indicates that use of the sustained maximal inspiration and purse-lipped breathing may be of value in the postoperative period in increasing lung volumes thereby preventing possible pulmonary complications. The responsibility for the selection and institution of respiratory maneuvers to assist the patient during the critical period following anesthesia and surgery remains in the hands of the nurse caring for the patient in the postoperative period. Available data do not permit the selection of a single maneuver which would be effective in all patients. Therefore until further studies provide more conclusive results, the nurse must individualize the method used for each patient. Regardless of the technique instituted, the aim is to return lung volumes to pre-operative levels as soon as possible. Increasing lung volumes as soon as possible following upper abdominal surgery may reduce the incidence of postoperative pulmonary complications.

APPENDIX A

SUBJECT'S CONSENT

SUBJECT'S CONSENT

Project Title: Comparison of Sustained Maximal Inspiration and Purse-Lipped Exhalation on Lung Volumes in Healthy Volunteers

I, Mary L. Sealy, CRNA, am conducting a study of two techniques used to help patients expand their lungs after surgery. The study will investigate the effect of the two techniques on healthy volunteers in whom a shallow breathing pattern (as seen in postoperative patients) is simulated by the use of a rubberized abdominal binder. The effects of the binder and the two treatments on lung expansion will be evaluated by having you breathe into a recording and measuring device.

If you decide to participate in this study, you will be asked to participate in two study sessions. Session one will evaluate one breathing method and session two will evaluate the other technique. The methods of breathing are described as follows:

1. Sustained Maximal Inspiration. I will verbally and manually assist you in taking a deep breath. I will place my hands on either side of your lower chest to help you move your chest in this area as you breathe. With my hands in place, you will be instructed to take a deep enough breath to move my hands outward. As you you breathe in, I will count slowly to three and ask you to hold this breath for a count of three, then exhale normally.

2. Pursed-Lipped Exhalation. You will be instructed to take in a deep breath and as you begin to exhale, to "purse" your lips as if blowing out a candle, for a count of two. You will then be instructed to begin the next breath in exactly the same manner as the first.

Each of the two sessions will take place in the pulmonary function laboratory. You will be asked to wear loose-fitting clothing and slacks. The total time will require about two hours of your time. Before applying the abdominal restriction device, I will measure how much air you can get into and out of your lungs. This measurement will be done two times. I will then demonstrate one of the two breathing methods (described above) that you will be performing during the test period. The binder will then be applied. After breathing for a period of 15 minutes with the abdominal device in place, I will measure again how much air you can get into and out of your lungs. Then I will assist you in performing the breathing method. You will be asked to perform the breathing technique five times, always with my assistance. At the end of this procedure, I will measure for the last time how much air goes into and out of your lungs. In order to measure the amount of air in your lungs, you will be asked to breathe a mixture of helium and oxygen from a device called a Collins Modular Lung Analyzer. You will have a padded noseclip applied during the breathing period. After breathing normally, you will be asked to breathe in as deeply as possible and then breathe out as much air as quickly as you can. This breathing test is a clinically accepted and approved method for measuring the amount of air in a person's lungs. Within one week, the second of the two sessions will be scheduled. During the second session the other described breathing technique will be evaluated in exactly the same fashion.

Any information obtained in this study will be confidential. Your name will not be used. The information will be recorded and analyzed by a computer. Your participation includes allowing your investigator to obtain and record pertinent information, such as your height, weight, smoking history and any history of previous pulmonary disease. This information will also be used in analyzing the results obtained in this study. The data obtained from this study may be combined with data in later studies. You will, however, remain anonymous.

There are no known medical, social or psychological risks involved in participating in this study and there is no added cost to you for your participation. You may experience a temporary discomfort while the abdominal restrictive device is in place. A feeling of lightheadedness may also follow taking deep breaths. These symptoms are temporary and will pass quickly. A physician will be available should any of these symptoms continue. You may also have a temporary voice change after breathing the helium/oxygen mixture from the lung analyzer, but this will also quickly return to normal.

The benefits of this study include:

1. Providing information on how much air is in the subject's lungs after simulation of shallow postoperative breathing.

2. Providing information which may help nurses give more comprehensive postoperative respiratory care to patients.

I will answer any questions you may have about the study at any time. I can be reached during the day at 626-6154. You may withdraw from this study at any time. A copy of this consent form is available to subjects upon request.

If you understand what is involved and you consent to participate in this study, please sign your name below.

The nature, demands, risks, and benefits of the project have been fully explained to me and I fully understand what my participation involves. I understand that I may ask questions and that I am free to withdraw from the study at any time without incurring ill will. I understand that in the event of physical injury resulting from the research procedures, financial compensation for wages and time lost and the cost of medical care is not available and must be borne by the subject. I grant permission to use the data obtained for projects other than the one explained to me at this time.

I also understand that this consent form will be filed in an area designated by the Human Subjects Committee with access restricted to the principal investigator or authorized representatives of the particular department.

Subject's Signature Date

Witness' Signature Date

I have carefully explained to the subject the nature of the above project. I hereby certify that to the best of my knowledge the subject signing this consent form understands clearly the nature, demands, benefits, and risks involved in participating in this study. A medical problem or language or educational barrier has not precluded a clear understanding of his/her involvement in this subject.

Investigator's Signature Date

APPENDIX B

APPROVAL FORM,
COMMITTEE ON RESEARCH ON HUMAN SUBJECTS

THE UNIVERSITY OF ARIZONA
HEALTH SCIENCES CENTER
TUCSON, ARIZONA 85724

HUMAN SUBJECTS COMMITTEE
1609 N. WARREN (BUILDING 220), ROOM 112

TELEPHONE: (602) 626-6721 or 626-7575

20 September 1985

Mary L. Sealy, B.S.N., C.R.N.A.
College of Nursing
Arizona Health Sciences Center

Dear Ms. Sealy:

We are in receipt of your project, "Effects of Sustained Maximal Inspiration and Purse-Lipped Exhalation on Postoperative Lung Volumes", which was submitted to this Committee for review. The procedures to be followed in this study pose no more than minimal risk to the participating subjects. Regulations issued by the U.S. Department of Health and Human Services [45 CFR Part 46.110(b)] authorize approval of this type project through the expedited review procedures, with the condition(s) that subjects' anonymity be maintained. Although full Committee review is not required, a brief summary of the project procedures is submitted to the Committee for their information and comment, if any, after administrative approval is granted. This project is approved effective 20 September 1985.

Approval is granted with the understanding that no changes or additions will be made to either the procedures followed or the consent form(s) used (copies of which we have on file) without the knowledge and approval of the Human Subjects Committee and your College or Departmental Review Committee. Any physical or psychological harm to any subject must also be reported to each committee.

A university policy requires that all signed subject consent forms be kept in a permanent file in an area designated for that purpose by the Department Head or comparable authority. This will assure their accessibility in the event that university officials require the information and the principal investigator is unavailable for some reason.

Sincerely yours,

Milan Novak

Milan Novak, M.D., Ph.D.
Chairman
Human Subjects Committee

MN/jm

cc: Ada Sue Hinshaw, R.N., Ph.D.
College Review Committee

APPENDIX C

APPROVAL FORM FOR CHANGES, COMMITTEE ON RESEARCH ON HUMAN SUBJECTS

THE UNIVERSITY OF ARIZONA
HEALTH SCIENCES CENTER
TUCSON, ARIZONA 85724

HUMAN SUBJECTS COMMITTEE
1609 N. WARREN (BUILDING 220), ROOM 112

TELEPHONE: (602) 626-6721 or 626-7575

10 October 1985

Mary L. Sealy, B.S.N., C.R.N.A.
College of Nursing
Arizona Health Sciences Center

Dear Ms. Sealy:

We are in receipt of your 9 October 1985 letter and the accompanying revised consent form for your project, "Effects of Sustained Maximal Inspiration and Purse-Lipped Exhalation on Postoperative Lung Volumes". The changes reflected in this revision are minor and do not alter the risks inherent in this research study. Therefore, approval for these changes is granted effective 10 October 1985.

The changes approved are:

1. Substitution of normal volunteers for the post-operative patients originally approved, and a concomitant change in title and study site.

2. Addition of a rubberized abdominal binder to simulate shallow breathing in this healthy population.

Approval is granted with the understanding that no further changes or additions will be made either to the procedures followed or the consent form(s) used (copies of which we have on file) without the knowledge and approval of the Human Subjects Committee and your College or Departmental Review Committee. Any physical or psychological harm to any subject must also be reported to each committee.

A university policy requires that all signed subject consent forms be kept in a permanent file in an area designated for that purpose by the Department Head or comparable authority. This will assure their accessibility in the event that university officials require the information and the principal investigator is unavailable for some reason.

Sincerely yours,

Milan Novak

Milan Novak, M.D., Ph.D.
Chairman
Human Subjects Committee

MN/jm

cc: Ada Sue Hinshaw, R.N., Ph.D.
College of Nursing

APPENDIX D

LETTER GRANTING APPROVAL FOR CHANGES
FOR RESEARCH

THE UNIVERSITY OF ARIZONA
TUCSON, ARIZONA 85721

COLLEGE OF NURSING

MEMORANDUM

TO: Mary L. Sealy
Graduate Student
College of Nursing

ASH

FROM: Ada Sue Hinshaw, PhD, RN — Director of Research
Merle Mishel, PhD, RN — Chairman, Research Committee

DATE: October 30, 1985

RE: Access to Conduct Research in the College of Nursing

It is a pleasure to approve your request to access College of Nursing graduate students as part of the sample population for your study entitled, "Comparison of Sustained Maximal Inspiration and Purse-Lipped Exhalation on Lung Volumes in Healthy Volunteers." If you have any questions about this access approval, please donn't hesitate to contact me. Otherwise, arrange to post requests for subjects either on the bulletin board or to announce your project in the graduate courses.

ASH/fp

APPENDIX E

DATA COLLECTION SHEET

DATA COLLECTION SHEET

SUBJECT PROFILE DATA

Name______________________________ Sex_____ Age_____ ID___________

Height___________ Weight___________ Group Order_____SMI _____PL

Smoking Hx _____Pack Years _____Present _____If not, how long since?

Previous pulmonary Hx___________________

Helium Dilution_____________

Date #1_______________ Group _____SMI _____PL

Pretreatment Measurements
C1 _________ FRC _______ IC _________
C2 _________ ERV _______ VC _________
C3 _________ RV ________ FEV_1 _______

15 minutes post abdominal binder
C1 _________ FRC _______ IC _________
C2 _________ ERV _______ VC _________
C3 _________ RV ________ FEV_1 _______

Post-treatment measurements
C1 _________ FRC _______ IC _________
C2 _________ ERV _______ VC _________
C3 _________ RV ________ FEV_1 _______

Date #2_______________ Group _____SMI _____PL

Pretreatment Measurements
C1 _________ FRC _______ IC _________
C2 _________ ERV _______ VC _________
C3 _________ RV ________ FEV_1 _______

15 minutes post abdominal binder
C1 _________ FRC _______ IC _________
C2 _________ ERV _______ VC _________
C3 _________ RV ________ FEV_1 _______

Post-treatment measurements
C1 _________ FRC _______ IC _________
C2 _________ ERV _______ VC _________
C3 _________ RV ________ FEV_1 _______

APPENDIX F

ABSOLUTE AND PERCENT PREDICTED MEASUREMENTS OF FUNCTIONAL RESIDUAL CAPACITY FOR EACH SUBJECT AT BASELINE, 15 MINUTES AFTER BINDER APPLICATION AND IMMEDIATELY FOLLOWING TREATMENT WITH THE SUSTAINED MAXIMAL INSPIRATION AND "PURSE LIPPED" BREATHING MANEUVER

Absolute and Percent Predicted Measurements of Functional Residual Capacity For Each Subject at Baseline, 15 Minutes After Binder Aplication and Immediately Following Treatment with the Sustained Maximal Inspiration and "Purse Lipped" Breathing Maneuver

Subject	Baseline Liters	% Predicted	15 minutes after Binder Liters	% Predicted	Post SMI Rx Liters	% Predicted
SMI Maneuvers						
1	3.3	103	3.0	93.8	3.5	107
2	2.4	69.3	2.2	63.3	2.6	75.9
3	4.4	139	3.2	102	3.3	105
4	2.5	66.2	1.9	51.7	1.9	51.6
5	2.8	105	2.2	82.6	1.9	72.7
6	2.7	103	2.3	87.0	2.7	100
7	1.7	70.9	1.8	74.1	1.9	77.2
8	2.3	106	2.4	109	2.7	124
9	3.7	110	4.4	130	4.4	130
10	3.2	119	2.8	104	2.9	108
PLB Manuevers						
1	3.7	115	2.6	79.1	3.4	104
2	3.2	91.7	2.0	57.3	2.1	60.6
3	3.6	114	3.7	118	2.3	72.4
4	2.7	73.2	2.5	66	1.7	45.5
5	2.5	93.6	1.7	62.2	2.2	80.8
6	2.6	95.8	2.4	90.6	2.9	108
7	1.8	74.1	1.8	74.4	1.9	76.7
8	2.0	91.8	2.2	100	2.3	103
9	3.6	108	3.9	119	3.9	117
10	2.8	105	2.7	102	2.8	106

APPENDIX G

ABSOLUTE AND PERCENT PREDICTED MEASUREMENTS OF INSPIRATORY CAPACITY FOR EACH SUBJECT AT BASELINE, 15 MINUTES AFTER BINDER APPLICATION AND IMMEDIATELY FOLLOWING TREATMENT WITH THE SUSTAINED MAXIMAL INSPIRATION AND "PURSE LIPPED" BREATHING MANEUVER

Absolute and Percent Predicted Measurements of Inspiratory Capacity for Each Subject at Baseline, 15 Minutes After Binder Application and Immediately Following Treatment with the Sustained Maximal Inspiration and "Pursed Lipped" Breathing Maneuver

Subject	Baseline Liters	% Predicted	15 minutes after Binder Liters	% Predicted	Post SMI Rx Liters	% Predicted
SMI Maneuvers						
1	3.3	136	3.2	130	3.5	140
2	2.9	97	1.4	47	3.2	103
3	2.2	106	2.5	119	2.4	113
4	2.9	107	2.8	103	2.9	107
5	2.6	113	2.8	125	2.5	129
6	2.3	104	2.4	111	2.0	92
7	2.3	111	1.8	84	2.3	112
8	2.1	68	2.1	68	2.0	66
9	1.7	63	1.5	57	1.5	58
10	2.1	96	2.4	109	2.1	96
PLB Maneuver						
1	3.0	122	3.7	149	4.5	182
2	2.9	93	3.2	104	3.4	97
3	2.0	96	2.5	120	2.5	117
4	3.0	109	2.9	107	2.8	104
5	2.6	113	2.9	131	3.0	132
6	2.1	94	2.3	106	2.5	114
7	2.2	105	1.8	88	2.3	111
8	2.0	67	2.1	104	2.1	104
9	1.8	68	1.6	62	1.5	60
10	1.9	90	2.2	101	3.2	148

APPENDIX H

ABSOLUTE AND PERCENT PREDICTED MEASUREMENTS OF EXPIRATORY RESERVE VOLUME FOR EACH SUBJECT AT BASELINE, 15 MINUTES AFTER BINDER APPLICATION AND IMMEDIATELY FOLLOWING TREATMENT WITH THE SUSTAINED MAXIMAL INSPIRATION AND "PURSE LIPPED" BREATHING MANEUVER

Absolute and Percent Predicted measurements of Expiratory Reserve Volume For Each Subject at Baseline, 15 Minutes After Binder Application and Immediately Following Treatment with the Sustained Maximal Inspiration and "Purse Lipped" Breathing Maneuver

Subject	Baseline Liters	% Predicted	15 minutes after Binder Liters	% Predicted	Post SMI Rx Liters	% Predicted
SMI Maneuvers						
1	1.6	118	1.1	82.5	1.1	79.2
2	1.0	58.6	1.6	96.0	.72	41.0
3	1.3	102	1.1	91	1.0	86.
4	.79	46	.27	16	.56	33
5	1.4	109	1.1	86	.90	69
6	1.2	94	.97	77	.90	71
7	.79	63	.77	62	.76	62
8	1.1	108	1.0	95	1.1	102
9	1.6	105	1.2	82	1.2	81
10	1.3	90	1.2	88	1.2	88
PLB Maneuver						
1	1.9	140	1.2	91	1.2	91
2	1.0	59	1.6	89	1.3	77
3	1.4	115	1.1	88	1.1	89
4	.94	55	.36	21	.45	26
5	1.3	104	.90	69	.97	74
6	1.2	94	.97	77	.90	71
7	.90	72	.72	58	.85	69
8	1.0	95	.99	93	1.0	95
9	1.2	82	1.1	78	1.2	82
10	1.4	101	1.2	85	1.3	95

APPENDIX I

ABSOLUTE AND PERCENT PREDICTED MEASUREMENTS OF RESIDUAL VOLUME FOR EACH SUBJECT AT BASELINE, 15 MINUTES AFTER BINDER APPLICATION AND IMMEDIATELY FOLLOWING TREATMENT WITH THE SUSTAINED MAXIMAL INSPIRATION AND "PURSE LIPPED" BREATHING MANEUVER

Absoute and Percent Predicted Measurements of Residual Volume for Each Subject at Baseline, 15 minutes after Binder Application and Immediately Following Treatment with the Sustained Maximal Inspiration and the "Purse Lipped" Breathing Maneuver

Subject	Baseline Liters	% Predicted	15 minutes after Binder Liters	% Predicted	Post SMI Rx Liters	% Predicted
SMI Maneuvers						
1	1.7	92	1.9	102	2.4	127
2	1.4	80	.52	30	1.9	112
3	3.1	163	2.1	110	2.0	107
4	1.7	84	1.7	82	1.4	68
5	1.4	101	1.1	82	1.0	79
6	1.6	110	1.4	96	1.6	112
7	.94	79	1.0	87	1.1	94
8	1.2	104	1.4	122	1.7	146
9	2.1	112	3.2	166	3.2	168
10	1.9	145	1.5	117	1.6	124
PLB Maneuver						
1	1.8	97	1.3	71	2.1	113
2	2.2	126	.43	75	.76	44
3	2.2	114	2.6	138	1.2	62
4	1.8	89	2.1	104	1.3	62
5	1.2	87	.76	58	1.2	91
6	1.4	97	1.5	103	1.9	140
7	.91	76	1.1	92	1.0	85
8	1.0	89	1.2	107	1.3	111
9	2.4	127	2.8	149	2.7	143
10	1.4	105	1.5	117	1.5	114

APPENDIX J

ABSOLUTE AND PERCENT PREDICTED MEASUREMENTS OF VITAL CAPACITY FOR EACH SUBJECT AT BASELINE, 15 MINUTES AFTER BINDER APPLICATION AND IMMEDIATELY FOLLOWING TREATMENT WITH THE SUSTAINED MAXIMAL INSPIRATION AND "PURSE LIPPED" BREATHING MANEUVER

Absolute and Percent Predicted measurements of Vital Capacity for Each Subject at Baseline, 15 Minutes After Binder Application and Immediately Following Treatment with the Sustained Maximal Inspiration and the "Purse Lipped" Breathing Maneuver

Subject	Baseline Liters	% Predicted	15 minutes after Binder Liters	% Predicted	Post SMI Rx Liters	% Predicted
SMI Maneuvers						
1	4.9	130	4.3	113	4.5	119
2	4.0	83	3.1	64	3.9	80
3	3.5	105	3.6	109	3.4	103
4	3.7	83	3.1	70	3.5	79
5	3.9	112	3.9	111	3.8	107
6	3.5	100	3.4	98	2.9	85
7	3.1	96	2.5	78	3.1	96
8	3.2	78	3.1	75	3.1	75
9	3.2	78	2.7	66	2.7	66
10	3.3	93	3.6	101	3.3	93
PLB Maneuver						
1	4.9	129	4.8	128	5.7	150
2	3.9	81	4.7	99	4.7	97
3	3.4	103	3.6	108	3.5	107
4	3.9	88	3.3	74	3.3	74
5	3.9	110	3.8	108	3.9	111
6	3.2	94	3.2	95	3.3	98
7	3.1	96	2.5	79	3.1	98
8	3.0	74	3.1	76	3.1	76
9	3.0	73	2.8	68	2.8	70
10	3.3	94	3.3	92	4.5	127

APPENDIX K

ABSOLUTE AND PERCENT PREDICTED MEASUREMENTS OF FORCED EXPIRATORY VOLUME FOR EACH SUBJECT AT BASELINE, 15 MINUTES AFTER BINDER APPLICATION AND IMMEDIATELY FOLLOWING TREATMENT WITH THE SUSTAINED MAXIMAL INSPIRATION AND "PURSE LIPPED" BREATHING MANEUVER

Absolute and Percent Predicted Measurements of Forced Expiratory Volume at One Second For Each Subject at Baseline, 15 Minutes After Binder Application and Immediately Following Treatment with the Sustained Maximal Inspiration and the "Purse Lipped" Breathing Maneuver

Subject	Baseline Liters	% Predicted	15 minutes after Binder Liters	% Predicted	Post SMI Rx Liters	% Predicted
SMI Maneuvers						
1	No data obtained					
2	2.9	73	3.2	81	2.9	74
3	2.3	88	2.3	88	2.2	82
4	2.6	72	2.3	65	2.4	68
5	3.1	102	3.2	104	3.2	104
6	2.8	97	2.8	98	2.9	101
7	2.8	99	2.4	84	2.8	99
8	2.8	81	2.7	80	2.7	80
9	2.8	82	2.5	73	2.6	78
10	2.7	88	2.9	94	2.5	81
PLB Maneuver						
1	No data obtained					
2	3.2	80	2.9	74	2.6	66
3	2.3	86	2.4	89	2.4	89
4	2.7	75	2.1	60	2.2	61
5	3.1	103	3.2	106	3.2	106
6	2.8	96	2.7	94	2.9	99
7	2.7	97	2.4	86	2.8	99
8	2.8	83	2.7	78	2.8	81
9	3.1	93	-	-	2.5	74
10	2.5	83	2.7	88	2.6	85

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