CIGARETTE SMOKING AND THE EFFECT ON LENGTH OF STAY FOR LUMBAR DISCECTOMY/LAMINECTOMY PATIENTS IN PACU

by

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A clinical research project submitted in partial fulfillment of the requirements for the degree of MASTER OF NURSING

Intercollegiate Center for Nursing Education

WHITWORTH COLLEGE

May 1996
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The members of the Committee appointed to examine the clinical project of PATRICIA LEA HINES find it satisfactory and recommend that it be accepted.

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ABSTRACT
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Chair: Lorna Schumann, PhD

The purpose of this retrospective study was to examine the correlation between smoking and length of stay in the Post Anesthesia Care Unit for patients having lumbar discectomy and/or laminectomy surgery. This study used a descriptive comparative design with two groups of lumbar spinal surgery patients; those who smoke and those who do not smoke. The investigation compared the difference in time spent in the Post Anesthesia Care Unit by the two groups of patients. The study also compared the difference in oxygen therapy necessary to maintain oxygen saturation above 90% between smokers and nonsmokers.

To investigate the effect of smoking on length of stay in PACU, the charts of 87 patients having lumbar discectomy and/or laminectomy were reviewed. Patients with a history of smoking (n = 45) were compared to nonsmokers (n = 42) for length of stay in PACU, complications, and the need for oxygen therapy at discharge to maintain oxygen saturation above 90%. Although the
mean length of stay for patients in PACU was increased for smokers, the results were not statistically significant. Patients with a smoking history had increased frequency of oxygen therapy at discharge equaling 28% compared to 19% for nonsmokers. Future studies should broaden the population and increase the sample size to support and generalize findings.
TABLE OF CONTENTS

ACKNOWLEDGEMENTS .............................................................. ii
ABSTRACT ........................................................................ iii
LIST OF TABLES ................................................................. vii

Chapter 1

Introduction ................................................................. 1
Review of Relevant Clinical Research ......................... 2
Specific Aims ............................................................... 7
Background and Significance ........................................ 7
Clinical Literature Support .......................................... 9
Definition of Terms ...................................................... 15

Chapter 2

RESEARCH DESIGN AND METHODS OF DATA COLLECTION .... 17
Introduction ................................................................. 17
Design ........................................................................... 17
Setting .......................................................................... 17
Sample ........................................................................... 18
Instrumentation .......................................................... 18
Human Subjects .......................................................... 20
Data Analysis ............................................................. 21
References ................................................................. 23
Chapter 3

Manuscript Format

Title Page.........................................................28
Abstract.........................................................29
Introduction......................................................31
Review of Literature.................................32
Relavant Clinical Research..........................33
Research Design.............................................36
Results.........................................................38
Discussion and Implications......................41
Limitations....................................................43
Conclusions..................................................45
References....................................................47

List of Tables

Average PACU Stays for Smokers and Nonsmokers........6
Sample Characteristics.................................37
Length of Stay in PACU.................................39
Frequency of Complications Impacting Discharge......40
Frequency of Oxygen Therapy.........................41

Appendices

Appendix A - Data Collection Tool..................49
Appendix B - American Society of Anesthesiologists

  Physician Status Scale.................................52
Appendix C - SHMC Revised Aldrete Score ............. 54
Appendix D - Human Subject Review Summary Form ...... 56
Chapter One

Introduction to the Problem

Cigarette smoking has a devastating impact on the health of Americans. The number of smokers is decreasing in the United States however, "fifty-six million Americans still smoke," (Julian, 1992). Smoking is the most preventable cause of death in the United States, yet 390,000 deaths each year are directly attributable to smoking (Office on Smoking and Health, 1989). Pulmonary and cardiovascular diseases, birth defects, strokes, ulcers, dental caries, and a variety of other illnesses are associated with smoking. Cigarette smoking damages the health of Americans and drives medical costs up. The latest data on medical and lost productivity costs attributed to smoking is $65 billion each year (Office of Technology Assessment, 1985). Health care providers are well aware that treating illnesses related to smoking could reduce the expense. Interventions should be directed toward preventing complications and smoking cessation (United States Department of Health and Human Services, 1991).

Many hospitalized patients receive treatment for illnesses resulting directly from smoking. Cigarette smoking is a primary risk factor for development of complications in surgery patients in the post-anesthesia period (Shekleton and Litwack, 1991). The complications that occur can extend the time spent in the Post
Anesthesia Care Unit (PACU), time spent in the hospital, and significantly inflate medical costs. Identification of specific risk factors influencing length of stay in the PACU may be a first step toward decreasing the length of stay.

Length of anesthesia time and type of surgery are two main factors that impact length of stay in PACU (McConnell, 1987). Length of anesthesia time for lumbar laminectomy/discectomy surgery is midrange in the scope of surgeries. Respiratory problems, which extend PACU stay, are fewer with back surgery compared to abdominal surgery. Painful abdominal incisions cause patients to restrict chest expansion (Drain, 1994). Therefore, lumbar laminectomy/disectomy surgery represents an average surgical procedure without many complicating factors. The effect of cigarette smoking on length of stay in PACU for patients having lumbar laminectomy/discectomy surgery is the focus of this study.

Review of Relevant Clinical Research

Review of the literature on the effects of smoking on surgical patients in PACU includes summaries of studies that identify smoking as a risk factor for postoperative complications. Information regarding the physiological effects of smoking on the respiratory system, hypoxia, and other concepts specific to the post-anesthesia stay is provided.
Few studies published on the effects of smoking on surgical patients length of stay in the PACU were found. Two successive studies (Handlin and Baker, 1992) examined the effects of smoking on length of stay in PACU. Since only two research studies were found, the review of literature will expand to include studies that identify smoking as a risk for various surgical complications.

Garibaldi and Britt (1981) studied smoking in relation to perioperative time and risk factors for the development of pneumonia. In 500 surgery patients, smokers had twice the risk for developing pneumonia as did non-smokers.

Smoking is one of the risk factors for postoperative pulmonary morbidity in a 1982 study of 200 surgery patients (Mitchell, Garrahy, and Peake, 1982). Risk factors such as upper abdominal surgery, duration of anesthesia, smoking, preexisting bronchopulmonary disease, cardiovascular disease, and age were identified. Direct changes in pulmonary function related to anesthesia and surgery lead to atelectasis, pneumonia, acute respiratory failure, and embolism. These complications are the most frequent causes of postoperative morbidity (Bartlett, Brennan, Gazzaniga, and Hanson, 1973).

Smoking is also linked to ischemic heart disease which puts surgery patients at risk for arrhythmias during the perioperative period. O'Kelly, Browner, Massie, Tubau, Ngo, and Mangano (1992) found "cigarette smokers are more likely to develop ventricular
arrhythmias during the preoperative and intraoperative periods" (p.220). However, postoperatively there was not a significant difference in the incidence of arrhythmias among smokers. This difference is attributed to decreasing nicotine levels in the patients.

Functional residual capacity refers to the amount of gas left in the lungs at the end of normal expiration. The remaining gas decreases when patients are supine or in respiratory failure and increases in emphysema (Ganong, 1993). Intrapulmonary shunt occurs when blood pumped by the right ventricle bypasses the pulmonary capillaries and does not participate in the gas exchange with the alveoli. The amount of shunted blood may increase in lung disease such as atelectasis and pulmonary edema. Breathing 100% oxygen does not increase the oxygenation of the shunted blood. Hypoxia and cyanosis result from intrapulmonary shunt (Ganong, 1993).

Dueck, Prutow, Davies, Clausen, and Davidson (1988) examined the relationship between functional residual capacity (FRC) and shunt development with halothane anesthesia in healthy male (n=18) surgical patients aged 21-34. The physical examination, chest radiograph, and a normal pulmonary history revealed a healthy history. "Inhalation anesthesia is associated with reduced functional residual capacity (FRC) and impaired pulmonary gas exchange due to increased intrapulmonary shunt and increased
ventilation-perfusion" (p. 854). Computerized assisted tomography (CT scan) reveals different sizes of lung densities that suggest the shunt is caused by atelectasis. Ten smokers in the group showed a significantly higher shunt (P < 0.001) compared to nonsmokers (Dueck, M., Prutow, R., Davies, M., Causen, J., and Davidson, T., 1988).

Handlin and Baker (1992) investigated the effects of smoking on the duration of time spent in the postoperative recovery room. The first study examined the effect of smoking on surgical patients (n = 327) and length of stay in PACU. Open-heart and obstetrical patients are excluded from the study. One hundred variables of preoperative, intraoperative, and postoperative factors that could affect the length of stay were tracked on each patient. The study found a positive smoking history as the independent variable in 105 patients. Patients' anesthesia time correlated closely to the duration of time spent in the PACU. Regardless of the type of surgery, the longer the anesthesia time, the longer the recovery time. However, smokers had longer length of stays in PACU that were independent of the anesthesia time (p < 0.05). The length of time in PACU is divided into three categories for smokers and nonsmokers as shown below:
Table 1

AVERAGE PACU STAYS FOR SMOKERS AND NONSMOKERS

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>PACU TIME</th>
<th>SMOKERS</th>
<th>NONSMOKERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>SHORT</td>
<td>&lt; 1 hour</td>
<td>23%</td>
<td>38%</td>
</tr>
<tr>
<td>AVERAGE</td>
<td>1-2 hours</td>
<td>58%</td>
<td>55%</td>
</tr>
<tr>
<td>LONG</td>
<td>&gt; 2 hours</td>
<td>19%</td>
<td>7%</td>
</tr>
</tbody>
</table>

Handlin and Baker (1992) examined (n = 359) the effects of light (< 1/2 pack/day) and heavy smoking (> 2 packs/day) on time spent in PACU. Smokers (n = 138) are divided into five groups according to the number of packs per day they smoked, starting at 1/2 pack and ending at ≥ 2 and 1/2 packs. The researchers determine that smoking significantly increased the length of stay in the PACU. Light and heavy smokers were at risk for extended stays. The cost of the increased length of stay for smokers is calculated at an extra 20% compared to nonsmokers (Handlin, 1992).

Preventive treatments initiated preoperative, intraoperative, and postoperative may hasten the recovery time from anesthesia and provide comfort for the patient (Wilmore, 1991). There is evidence that discontinuing smoking for even 48 hours prior to surgery increases available oxygen for the tissues. "The incidence of respiratory complications was 24% after surgery in those given preoperative pulmonary preparation compared with 43% of those in a control group" (Miller, 1986).
Preoperative incentive spirometry and chest physical therapy results in improved pulmonary status (Wilmore, 1991).

Specific Aims

The aim of this study was to describe the correlation between smoking and length of stay in PACU for patients having lumbar discectomy/laminectomy surgery. This study addressed the following questions:

1. What effect does smoking have on the length of stay in the PACU for patients having lumbar discectomy/laminectomy surgery?

2. What type of complications delay discharge from PACU for lumbar discectomy/laminectomy patients with a smoking history compared to nonsmokers.

3. What percentage of smokers compared to nonsmokers having lumbar discectomy/laminectomy surgery, require oxygen therapy to maintain oxygen saturation above 90% upon discharge from PACU?

Background and Significance

Respiratory complications are the most common problems in the PACU (McConnell, 1987; Odem, 1993). Patients who have a smoking history are more prone to respiratory complications after surgery (Shekleton and Litwack, 1991). Results of previous
research have been used to decide what preventive treatments will maximize health outcomes of surgical patients (Wells, 1987).

Although complications of any sort are likely to result in spending more time in the PACU, minimal research has been directed to correlating smoking and length of stay. As Hardin and Baker (1992) indicated, cigarette smokers spend more time in PACU than nonsmokers. Hardin and Baker, (1992) recommended greater detailed studies on the effects of smoking on the length of stay in PACU. Future studies could identify complications common to smokers in PACU. Initiating strategies to prevent complications can decrease the time spent in PACU. "The incidence of respiratory complications is 24% after surgery in patients given preoperative pulmonary preparation compared with 43% in a control group" (Miller, 1986, p. 1378).

One way to reduce medical cost is to decrease the length of stay in the hospital and special care units. "As much as 20 to 30% of the length of stay of the average patient is estimated to be unnecessary" (Wilmore, Brennan, Harken, Holcroft, and Meakins, 1991). Charges made to the patient and health care insurers for staying in PACU are calculated every fifteen minutes. Decreasing time spent in PACU significantly reduces the cost of hospitalization for a surgical procedure. Early transfer of surgical patients to less costly hospital units is an important cost containing strategy (Wilmore, 1991).
Significance to Nursing

Investigating the effects of smoking on duration of length of stay in the PACU and reporting the results will provide information to nurses involved in the care of surgical patients. The primary goal of the PACU nurse is to ensure the patient's safe recovery from anesthesia. By first identifying smoking as a risk factor for increased length of stay in PACU, further research can examine perioperative treatment measures for decreasing the length of stay for smokers. Patient care strategies can decrease complications and discomfort experienced during post-anesthesia recovery. Health care providers can potentiate a smooth recovery from anesthesia by being aware of possible problems and take prophylactic action rather than waiting to treat the problem (McConnell, 1987).

Primary health care providers can begin preparing patients for surgery through early health promotion planning. Patients can be educated regarding effects of smoking during the postanesthesia period and benefits of smoking cessation prior to having surgery.

Clinical Literature Support

Cigarette Smoking and Respiratory Tissue Changes

Cigarette smoking causes an inflammatory response in the respiratory system resulting in two main disease processes:
emphysema and chronic bronchitis. The tissue injury responsible for these diseases results from small airway narrowing, excess mucous secretion, and impaired ability of the tracheobronchial tree to clear the secretions (McCusker, 1992).

Not only does cigarette smoke contain oxidants, but inflammatory cells recruited to the area produce oxidized free radicals and halogens. The oxidants injure normal structures in the lower airways and result in narrowing of the small airways (McKusker, 1992; Pearce, 1984).

The excess mucous in smokers begins with an inflammatory response to the physical and chemical properties of cigarette smoke. Tar, carbon monoxide, and hydrocarbons are several of the components of cigarette smoke responsible for tissue changes in the pulmonary system. "Tar particles carry nicotine, carcinogens, and oxidants," (McCusker, 1992, p. 18). The tar is deposited in lung tissue and inflammatory cells invade the area causing edema, fibrosis, and epithelial hyperplasia. Excess mucous production and secretion is the result. The cilia of the respiratory tract are also impaired by cigarette components resulting in decreased airway clearance (McCusker, 1992; Pearce, 1984).

The impaired mucociliary transport system leads to respiratory complications such as bronchiolar obstruction, infection, and atelectasis. The respiratory effects of cigarette smoke result in increased postoperative respiratory morbidity six
times more frequent in patients who smoke more than 10 cigarettes each day compared to nonsmokers (Morton, 1944).

General Anesthesia

General anesthesia is drug-induced depression of the central nervous system causing loss of consciousness for the purpose of performing surgery. General anesthetics produce amnesia, analgesia, loss of consciousness, muscle relaxation, and suppression of reflexes (Wilmore, 1991). Inhalation agents and intravenous agents are the two divisions of general anesthetics. A combination of two or more drugs are utilized to produce the desired effect and selected for the individual needs of the patient. Respiratory and circulatory depression are two main disadvantages of general anesthetics (McConnell, 1987).

There are three desired stages of anesthesia: the stage of analgesia, the stage of delirium, and the stage of surgical anesthesia. Overdosage can result in medullary depression which begins with apnea and ends with circulatory collapse (Goodwin, 1991).

Emergence from general anesthesia occurs in the reverse order from the stages of anesthesia. Inhalation anesthetic agents are expelled through the alveoli of the lungs at a rapid rate. Anesthetic agents are stored in muscles and fat during long surgical cases. Fat releases the anesthetic slowly due to its lack of blood supply which delays the elimination of the agent and extends the recovery time. Other factors such as
length of time anesthetics are administered, type of surgery, obesity, certain disease processes, pain medications, muscle relaxants, drug and alcohol use, hypothermia, and individuals response to the medications can also affect the recovery time frame. Alcohol misuse is associated with increased tolerance for anesthetic drugs and post-operative complications such as infections, bleeding, and cardiopulmonary insufficiency (Tonnesen et al, 1992). Short-acting anesthetics are currently used resulting in average PACU stays of less than 2 hours (McConnell, 1987).

Hypoxia

The tissue injury from cigarette smoke increases the risk of hypoxia in smokers. Hypoxia occurs in response to impaired delivery or decreased utilization of oxygen at the cellular level (Ganong, 1993). Atelectasis and upper airway obstruction are causes of impaired oxygen delivery that result in post-operative hypoxia. Atelectasis results from hypoventilation secondary to anesthetic agents, opiate pain medications and sedatives, surgical pain, age, preexisting disease, and obesity. Upper airway obstruction can result from a relaxed tongue blocking the airway, secretions, and laryngeal spasm (McConnell, 1987; Vender, Spiess, 1992).

Patients having postoperative hypoxia are more at risk for complications such as myocardial ischemia, arrhythmias, cognitive deficits, decreased wound healing, and death. Hypoxia may occur
Cigarette smokers are more at risk for hypoxia than nonsmokers for several reasons. Smokers have increased levels of carboxyhemoglobin (COHb) up to 3-15 percent compared to 2.5 percent in nonsmokers. The main effects of COHb are a decrease in hemoglobin available to bind with oxygen and an increase in the affinity of hemoglobin for the oxygen molecule. The increase of affinity prevents easy release of oxygen at the tissue. Both effects decrease the amount of oxygen at the tissue level and increase the risk of smokers to hypoxia (Pearce and Jones, 1984).

Narcotics are frequently used in the PACU for postsurgical pain. Narcotics increase the risk of hypoxic episodes because they cause respiratory depression and decrease the hypoxic ventilatory drive (Vender, 1992). The amount and type of narcotics may result in extended PACU stays. Sedative antiemetics potentiate the effect of narcotics and also depress respiration (Shekleton and Litwack, 1991). Smokers may require an increased amount of narcotics for pain control due to anxiety of cigarette withdrawal and alteration in drug metabolism (Pearce, 1984).

Pulse Oximetry

Pulse oximetry is a method of assessing tissue oxygenation in patients by a monitor that is safe and simple to use. Use of the pulse oximeter began in the anesthesia setting to recognize
hypoxemic events. Pulse oximetry determines the functional saturation of hemoglobin in arterial blood through light absorbance technology to reproduce waveforms produced by pulsatile blood. It compares hemoglobin molecules that are bound with oxygen, with molecules that are capable of binding with oxygen. Carbon monoxide (CO) has 200-250 times greater affinity for binding with hemoglobin compared to oxygen (Mihm and Halperin, 1985). Since Carboxyhemoglobin (COHb) levels of smokers are significantly higher than nonsmokers, there is increased risk for hypoxia (Pearce and Jones, 1884). Pulse oximetry is used on all patients during the recovery period as a standard of practice in PACUs (Fairchild, 1993; Vender, 1992). Acceptable oxygen saturation for discharge from PACU is > 90% by oximeter (SHMC Post Anesthesia Routine Orders, 1994). This level allows adequate oxygen delivery to the tissues. Supplemental oxygen therapy is essential if oxygen saturation falls below this level (Grossbach, 1994).

Cigarette smoking is a major risk factor associated with post-operative pulmonary complications. The physiological changes resulting from smoking, coupled with the effects of anesthesia and narcotics for pain control, create potential for hypoxia. Pulse oximetry alerts health care providers to hypoxic events so interventions can be initiated early in order to deter pulmonary complications.
Definition of Terms

**Length of stay** - The amount of time in minutes required for a patient to safely emerge from the effects of anesthesia and return to the receiving surgical floor.

**Lumbar Discectomy/Laminectomy Surgery** - Lumbar spinal surgery is done to relieve unrelenting pain, remove a tumor or meningocele, release pressure on a vertebral disc from trauma, or remove the disc completely. Laminotomy is the creation of an opening in the lamina to expose the spinal cord and/or disc. A laminectomy is when the lamina and bony process is removed to gain access to the disc during surgery. The removal of the disc is called discectomy (Schwartz, Shires, Spencer, and Husser, 1991).

**Nonsmoker** - Patient with a history of not smoking or tobacco smoking less than 1/4 package per day for less than a year.

**Post Anesthesia Care Unit Stay** - A nurse anesthetist or anesthesiologist and a surgical team member transport the surgery patient to the PACU. The team members give report to the receiving nurse of the patient's history and intraoperative course. These team members remain with the patient until adequate ventilation and circulatory status is established. If the patient is not transported with oxygen, oxygen therapy is initiated immediately on all patients on arrival to the PACU (McConnell, 1987).
Smoker - Patient with a history of tobacco smoking 1/4 package or more per day for over 1 year.
Chapter Two
Research Design and Methods of Data Collection

Introduction

This retrospective study compared the length of stay in PACU between lumbar laminectomy/discectomy patients who are smokers and those who are nonsmokers. The time in minutes patients spent in the PACU served as the direct measure to determine the outcome of the length of stay.

Design

This study was a comparative, descriptive design examining the difference in amount of time spent in the PACU between lumbar laminectomy/discectomy patients who smoke and those who do not smoke. The study variables were a history of smoking and length of PACU stay in minutes.

Setting

The site for the study was a PACU of a 640 bed tertiary care center in eastern Washington. The PACU staff delivers postoperative care to 750 surgery patients (average) per month. Lumbar laminectomy/discectomy surgeries average 5-10 per week. The nurse/patient ratio is 1 nurse for 2 patients.
Sample

The sample for this study was 87 postoperative lumbar laminectomy/discectomy patients cared for in the PACU. Subjects were selected from a convenience sample of an accessible population of patients 18 to 60 years of age. The patients were identified from the PACU log book. This study reviewed patient records of a nonprobability convenience sample selected from the PACU log book. Data were collected on all lumbar discectomy/laminectomy surgery patients over a period of three months until a total of 87 records were reviewed. The subjects were divided into groups of nonsmokers and smokers.

Instrumentation

Data Collection Instrument

Demographic and physiologic data were obtained from each subject’s chart. Demographic data such as gender, age, height, weight, tobacco consumption, and patient history were collected. Physiological data such as oxygen saturation on discharge, postoperative complications, and narcotic use were also collected. The information was recorded on the Data Collection Instrument (see Appendix A).

The American Society of Anesthesiologists (ASA) scale (Appendix B) and Aldrete score (Appendix C) are standard instruments used by health care providers during the operative
period. The ASA scale and admission Aldrete score were recorded on the Data Collection Instrument.

The researcher identified primary reasons for the extended stay as recorded in the patient chart to rule out extraneous variables. A pilot test of the instrument was done on five subjects' charts to identify problem areas of inconsistent data collection. The Data Collection Instrument was modified based on the pilot study.

Aldrete Score

Many PACU's use the Aldrete scoring system or a variation of it as standard practice (Aldrete, Krovlit, 1970; Fairchild, 1993). The Aldrete Scoring System measures respiration, circulation, skin color, activity, and level of consciousness. The patient was assessed according to a revised Aldrete score system (Appendix C) at admission, designated intervals during the stay, and discharge from the unit. A score of a 9 or above was required for discharge unless a specific order was received from the anesthesiologist.

Pulse Oximeter

Marquette (model 7010) pulse oximeter readings was used to document oxygen saturations throughout the PACU stay and verify the need for oxygen therapy at discharge. A pulse oximeter uses wavelength technology to determine functional oxygen saturation. Low perfusion and increased motion at the sensor site may cause
inaccurate readings (Mihm and Halperin, 1985). The Marquette monitor has an alternative ear probe to verify accuracy of oximeter readings if questions arise in response to low saturation readings.

Discharge Criteria from PACU

Discharge criteria varies with the institution. Patients may be discharged in 30 minutes if vital signs are stable and the modified Aldrete score is 9 or more (Sacred Heart Medical Center PACU Policy Manual, 1994). The Post Anesthesia Routine Orders include a standing discharge order for oxygen at "2L per nasal cannula for 24 hours to maintain oxygen saturation above 90%" (SHMC Post Anesthesia Routine Orders, 1994).

Procedures

1. Permission was obtained from the hospital to conduct the research.
2. Subjects were identified from the PACU log book.
3. Data from the patient chart was obtained and recorded on the Data Collection Instrument by the principal investigator.

Human Rights Protection

This research proposal was submitted for approval from the 1. Intercollegiate Center for Nursing Education, Spokane, Washington.
2. Research Committee, Sacred Heart Medical Center, Spokane, Washington.


The proposed study encompassed a review of records. No treatment was involved. Provision to protect the privacy of subjects and to maintain the confidentiality of data was by using a code number rather than the patient's name or hospital number. All data were maintained in a securely locked file for reference during the investigation. Only the researcher had access to this data. At the completion of the project all data were destroyed. Data will be published in aggregate form only.

Data Analysis

Demographic data were compiled on each subject from the patient record. Data were analyzed using Systat 5.0X computer program for statistics. Statistical analysis of each question for research was addressed separately.

Outline for data analysis

Question 1: What effect does smoking have on the length of stay in the PACU for patients having lumbar discectomy/laminectomy surgery?

This question is one of associations. The type of data is the
time in minutes (ratio data level) and demographic data of smoker versus nonsmoker (nominal data level). This data association requires the Pearson's Product Moment Correlation Coefficient or Simple Linear Regression Analysis (Burns and Grove, 1993).

Question 2: What type of complications delay discharge from PACU for lumbar discectomy/laminectomy patients with a smoking history compared to nonsmokers?

This question is one of descriptive statistics requiring a list of the types and frequencies of complications in smokers and nonsmokers.

Question 3: What percentage of smokers compared to nonsmokers having lumbar discectomy/laminectomy surgery require oxygen therapy to maintain oxygen saturation above 90% upon discharge from PACU?

Percentage differences (ratio data level) of oxygen requirements at discharge (nominal data level) will be compared. The percentage difference in a two-group design requires a paired t-Test (Burns and Grove, 1993).
References


Chapter Three

Chapter three is in manuscript form prepared for submission to the Journal of Post Anesthesia Nursing. The format is set according to the requirements of the journal.
CIGARETTE SMOKING AND THE EFFECT ON LENGTH OF STAY

FOR LUMBAR DISCECTOMY/LAMINECTOMY PATIENTS IN PACU

by

Trish Hines
ABSTRACT

by Patricia Lea Hines
Intercollegiate Center for Nursing

This retrospective study examined the correlation between smoking and length of stay in the Post Anesthesia Care Unit (PACU) for patients having lumbar discectomy and/or laminectomy surgery. This study used a descriptive comparative design with two groups of lumbar spinal surgery patients, those who smoke and those who do not smoke. The investigation compared the difference in time spent in the Post Anesthesia Care Unit by the two groups of patients. The study examined the type and frequency of complications recorded in the PACU medical as well as the difference in oxygen therapy necessary to maintain oxygen saturation above 90% between smokers and nonsmokers.

To investigate the effect of smoking on length of stay in PACU, the charts of 87 patients having lumbar discectomy and/or laminectomy were reviewed. Patients with a history of smoking (n = 45) were compared to nonsmokers (n = 42) for length of stay in PACU, complications, and the need for oxygen therapy at discharge to maintain oxygen saturation above 90%. Although the mean length of stay for patients in PACU was increased for smokers, the results were not statistically significant. Patients with a smoking history had increased frequency of oxygen therapy at discharge equaling 28% compared to 19% for nonsmokers.
Future studies should broaden the population and increase the sample size to support and generalize findings.
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Cigarette smoking has a devastating impact on the health of Americans. The number of smokers is decreasing in the United States however, "fifty-six million Americans still smoke," (Julian, 1992). Smoking is the most preventable cause of death in the United States, yet 390,000 deaths each year are directly attributable to smoking (Office on Smoking and Health, 1989). Cigarette smoking damages the health of Americans and drives medical costs up. The latest data on medical and lost productivity costs attributed to smoking is $65 billion each year (Office of Technology Assessment, 1985). Interventions should be directed toward preventing complications and smoking cessation (United States Department of Health and Human Services, 1991).

Many hospitalized patients receive treatment for illnesses resulting directly from smoking. Cigarette smoking is a primary risk factor for development of complications in surgery patients in the post-anesthesia period (Shekleton and Litwack, 1991). The complications that occur can extend the time spent in the Post Anesthesia Care Unit (PACU), time spent in the hospital, and significantly inflate medical costs. Identification of specific risk factors influencing length of stay in the PACU may be a first step toward decreasing the length of stay and improving patient care.

Length of anesthesia time and type of surgery are two main factors that impact length of stay in PACU (McConnell, 1987).
Length of anesthesia time for lumbar laminectomy/discectomy surgery is midrange in the scope of surgeries. Respiratory problems, which extend PACU stay, are fewer with back surgery compared to abdominal surgery. Painful abdominal incisions cause patients to restrict chest expansion (Drain, 1994). Therefore, lumbar laminectomy/disectomy surgery represents an average surgical procedure without many complicating factors. The effect of cigarette smoking on length of stay in PACU for patients having lumbar laminectomy/disectomy surgery is the focus of this study.

Review of Literature

Cigarette Smoking and Respiratory Tissue Changes

Cigarette smoking causes an inflammatory response in the respiratory system resulting in two main disease processes: emphysema and chronic bronchitis. The tissue injury responsible for these diseases results from small airway narrowing, excess mucous secretion, and impaired ability of the tracheobronchial tree to clear the secretions (McCusker, 1992).

Not only does cigarette smoke contain oxidants, but inflammatory cells recruited to the area produce oxygen free radicals and halogens. The oxidants injure normal structures in the lower airways and result in narrowing of the small airways (McKusker, 1992; Pearce, 1984).

Excess mucous production begins with an inflammatory response
to the physical and chemical properties of cigarette smoke. Tar, carbon monoxide, and hydrocarbons are several of the components of cigarette smoke responsible for tissue changes in the pulmonary system. "Tar particles carry nicotine, carcinogens, and oxidants," (McCusker, 1992, p. 18). The tar is deposited in lung tissue and inflammatory cells invade the area causing edema, fibrosis, and epithelial hyperplasia. Excess mucous production and secretion is the result. The cilia of the respiratory tract are also impaired by cigarette components resulting in decreased airway clearance (McCusker, 1992; Pearce, 1984).

The impaired mucociliary transport system leads to respiratory complications such as bronchiolar obstruction, infection, and atelectasis. The respiratory effects of cigarette smoke result in increased postoperative respiratory morbidity six times more frequent in patients who smoke more than 10 cigarettes each day compared to nonsmokers (Morton, 1944).

Relevant Clinical Research

Respiratory complications are the most common problems in the PACU (McConnell, 1987; Odem, 1993). Patients who have a smoking history are more prone to respiratory complications after surgery (Shekleton and Litwack, 1991). Although complications of any sort are likely to result in spending more time in the PACU, minimal research has been directed to correlating smoking and length of stay. Review of the literature on the effects of
smoking on surgical patients in PACU includes summaries of studies that identify smoking as a risk factor for postoperative complications.

Few studies on the effects of smoking on surgical patients' length of stay in the PACU were found. Two successive studies (Handlin and Baker, 1992) examined the effects of smoking on length of stay in PACU.

Handlin and Baker (1992) investigated the effects of smoking on the duration of time spent in the postoperative recovery room. The first study examined the effect of smoking on surgical patients (n = 327) and length of stay in PACU. Open-heart and obstetrical patients are excluded from the study. One hundred variables of preoperative, intraoperative, and postoperative factors that could affect the length of stay were tracked on each patient. The study found a positive smoking history as the independent variable in 105 patients. Patients' anesthesia time correlated closely to the duration of time spent in the PACU. Regardless of the type of surgery, the longer the anesthesia time, the longer the recovery time. However, smokers had longer length of stays in PACU that were independent of the anesthesia time (p < 0.05).

Handlin and Baker (1992) examined (n = 359) the effects of light (< 1/2 pack/day) and heavy smoking (> 2 packs/day) on time spent in PACU. Smokers (n = 138) are divided into five groups according to the number of packs per day they smoked, starting at
1/2 pack and ending at ≥ 2 and 1/2 packs. The researchers determine that smoking significantly increased the length of stay in the PACU. Light and heavy smokers were at risk for extended stays. The cost of the increased length of stay in PACU for smokers is calculated at an extra 20% compared to nonsmokers (Handlin, 1992).

Smoking is one of the risk factors for postoperative pulmonary morbidity in a 1982 study of 200 surgery patients (Mitchell, Garrahy, and Peake, 1982). Risk factors such as upper abdominal surgery, duration of anesthesia, smoking, preexisting bronchopulmonary disease, cardiovascular disease, and age were identified. Direct changes in pulmonary function related to anesthesia and surgery lead to atelectasis, pneumonia, acute respiratory failure, and embolism. These complications are the most frequent causes of postoperative morbidity (Bartlett, Brennan, Gazzaniga, and Hanson, 1973).

Dueck, Prutow, Davies, Clausen, and Davidson (1988) examined the relationship between functional residual capacity (FRC) and shunt development with halothane anesthesia in healthy male (n = 18) surgical patients aged 21-34. The physical examination, chest radiograph, and "normal" pulmonary history revealed a history of good health. "Inhalation anesthesia is associated with reduced functional residual capacity (FRC) and impaired pulmonary gas exchange due to increased intrapulmonary shunt and increased ventilation-perfusion inequality" (p. 854).
Computerized assisted tomography (CT scan) reveals different sizes of lung densities that suggest the shunt is caused by atelectasis. Ten smokers in the group showed a significantly higher shunt ($p < 0.001$) compared to nonsmokers (Dueck, M., Prutow, R., Davies, M., Causen, J., and Davidson, T., 1988).

Preventive treatments initiated preoperative, intraoperative, and postoperative may hasten the recovery time from anesthesia and provide comfort for the patient (Wilmore, 1991). There is evidence that discontinuing smoking for even 48 hours prior to surgery increases available oxygen for the tissues. "The incidence of respiratory complications was 24% after surgery in those given preoperative pulmonary preparation compared with 43% of those in a control group" (Miller, 1986).

Research Design

This retrospective study was a comparative, descriptive design examining the effects of smoking on the length of stay in PACU for patients having lumbar discectomy/laminectomy surgery. The study variables were a history of smoking and length of PACU stay in minutes.

Setting

The site for the study was a PACU of a 640 bed tertiary care center in eastern Washington. The PACU staff delivers postoperative care to 750 surgery patients (average) per month.
Lumbar discectomy/laminectomy surgeries average 5-10 per week. The nurse/patient ratio was 1 nurse for 2 patients.

Sample

The subjects for this study were selected from a convenience sample of an accessible population of patients over a three-month period. The patients were identified from the PACU log book. Of the 134 patient medical records reviewed, 87 met the study criteria for ages 18 to 60 years. One patient having spinal anesthesia and one having an additional surgical procedure were excluded from the sample. The subjects were divided into one of two groups: nonsmokers (n = 42) and smokers (n = 45).

Table 2

<table>
<thead>
<tr>
<th>Sample Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Years)</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Smokers</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
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<td></td>
</tr>
<tr>
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<td></td>
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<tr>
<td></td>
</tr>
</tbody>
</table>

Instrumentation

Demographic and physiologic data were obtained from each subject's chart. Demographic data such as gender, age, height,
weight, tobacco consumption, and patient history were collected. Physiological data such as oxygen saturation on discharge, post-operative complications, and narcotic use were also collected. The researcher identified primary reasons for the extended stay as recorded in the patient chart to rule out extraneous variables. The information was recorded on the Data Collection Instrument (see Appendix A).

The American Society of Anesthesiologists (ASA) scale (Appendix B) and Aldrete score (Appendix C) are standard instruments used by health care providers during the operative period. The ASA scale and admission Aldrete score were recorded on the Data Collection Instrument.

Results

The aim of this study was to describe the correlation between smoking and length of stay in PACU for patients having lumbar discectomy/laminectomy surgery. This study addressed the following questions:

1. What effect does smoking have on the length of stay in the PACU for patients having lumbar discectomy/laminectomy surgery?

The mean length of stay in PACU for smokers ($\bar{x} = 72.06$, $SD = 18.98$) in minutes was compared to nonsmokers ($\bar{x} = 68.26$, $SD = 17.08$) as shown in Table 3 below. Statistical analysis did not
show a significant difference between the two groups in respect to the length of stay for patients having lumbar laminectomy surgery. No statistical differences were found between smokers and nonsmokers regarding sex, age, weight, Aldrete and ASA scores, narcotics, alcohol consumption, medical history, and complications. Anesthesia time did correlate with length of stay in PACU, consistent with Hardin and Baker's (1992) findings.

Table 3

<table>
<thead>
<tr>
<th>Minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
</tr>
<tr>
<td>10</td>
</tr>
<tr>
<td>20</td>
</tr>
<tr>
<td>30</td>
</tr>
<tr>
<td>40</td>
</tr>
<tr>
<td>50</td>
</tr>
<tr>
<td>60</td>
</tr>
<tr>
<td>70</td>
</tr>
<tr>
<td>80</td>
</tr>
</tbody>
</table>

Smokers 72.06 Nonamokers 68.26

2. What type of complications delay discharge from PACU for lumbar discectomy/laminectomy patients with a smoking history compared to nonsmokers?

Discharge criteria vary with the institution. Patients may be discharged in 30 minutes if vital signs are stable and the
modified Aldrete score is 9 or more (Sacred Heart Medical Center PACU Policy Manual, 1994). The Post Anesthesia Routine Orders include a standing discharge order for oxygen at 2L via nasal cannula for 24 hours to maintain oxygen saturation above 90% (SHMC Post Anesthesia Routine Orders, 1994).

Primary reasons for extended stay were identified in the patient chart through the nurses’ PACU notes. Pain was the most frequent factor found to delay discharge as recorded for both smokers and nonsmokers. Difficulty weaning oxygen and low saturations were recorded as respiratory complications. No reports of bronchospasm or laryngospasm were recorded in either group. Thirteen patient records had more then one problem as listed below (see Table 4) and each problem was recorded separately. One patient’s discharge was delayed while waiting for the chart to be processed and one was delayed waiting for a physician to return a phone call.

Table 4

FREQUENCY OF COMPLICATIONS IMPACTING DISCHARGE

<table>
<thead>
<tr>
<th></th>
<th>SMOKERS</th>
<th>NONSMokers</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAIN</td>
<td>16</td>
<td>5</td>
</tr>
<tr>
<td>RESPIRATORY</td>
<td>13</td>
<td>6</td>
</tr>
<tr>
<td>NAUSEA/VOMITING</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>BLOOD PRESSURE</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>CARDIAC</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
3. What percentage of smokers compared to nonsmokers having lumbar discectomy/laminectomy surgery, require oxygen therapy to maintain oxygen saturation above 90% upon discharge from PACU?

Percentage differences of oxygen requirements at discharge from PACU were compared between smokers and nonsmokers. Twenty eight percent of smokers were discharged with oxygen therapy two liters per nasal cannula compared to nineteen percent of nonsmokers. There was no statistical difference between the groups with respect to oxygen therapy (Fisher Exact Test, \( p = 0.324 \)). The mean oxygen saturation upon discharge for smokers (\( \bar{x} = 95.2\% \), SD = 1.86) was insignificant compared to nonsmokers (\( \bar{x} = 95.4\% \), SD = 2.12).

Table 5

<table>
<thead>
<tr>
<th></th>
<th>No Oxygen Therapy</th>
<th>Oxygen Therapy</th>
<th>Percentage With Oxygen Therapy</th>
<th>Oxygen Therapy Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>SMOKERS</td>
<td>32</td>
<td>13</td>
<td>28.8%</td>
<td>.57</td>
</tr>
<tr>
<td>NONSMOKERS</td>
<td>34</td>
<td>8</td>
<td>19%</td>
<td>.38</td>
</tr>
</tbody>
</table>

Discussion and Implications

The results of this study differed from the previous research in regards to a statistical difference in length of stay
in PACU between smokers and nonsmokers. No statistical
difference was found in length of stay for smokers and nonsmokers
having lumbar laminectomy/discectomy surgery in this study.
However, anesthesia time did correlate with length of stay in
PACU, consistent with Hardin and Baker's (1992) findings. The
narrow population and small sample of surgery patients may
explain the difference in study results. Further research should
focus on a broader population having different surgeries and
larger sample to support generalization of the findings.

Increased length of stay in PACU has clinical and economic
implications. Frequent delays in the PACU can influence the
number of surgeries that can be done at an institution in a day.
Increased length of stay is costly. The slight difference in the
mean length of stay, complications, and need for oxygen therapy
between groups in this study add to medical cost incrementally
over time. Therefore, efforts toward smoking cessation should be
encouraged prior to surgery.

One way to reduce medical cost is to decrease the length of
stay in the hospital and special care units. "As much as 20 to
30% of the length of stay of the average patient is estimated to
be unnecessary" (Wilmore, Brennan, Harken, Holcroft, and
Meakins, 1991). Charges made to the patient and health care
insurers for staying in PACU are calculated every fifteen
minutes. Decreasing time spent in PACU significantly reduces the
cost of hospitalization for a surgical procedure. Early transfer
of surgical patients to less costly hospital units is an important cost containing strategy (Wilmore, 1991). Future studies could further examine complications common to smokers in PACU which may indirectly increase length of stay.

*Guide to Preventive Services*, (1995) states that one-third of adults in the United States continue to smoke. An interesting detail in this study is the ratio of smokers (n = 45) to nonsmokers (n = 42) in this sample. The difference of this ratio compared to the national average should be examined further for consistency and influencing determinants.

Complications in surgery patients who smoke are often not seen during their hospital stay. Weeks after discharge smokers may experience impaired wound healing, infection, and increased pain (Lesmes, 1992). Further research in preventing complications in smokers will improve comfort and decrease health care costs.

Limitations

Limitations of this study are as follows:

1. Nurses may be inconsistent or inaccurate in recording data in patient charts.
2. Decisions of when to discharge a patient from the PACU varies with each nurse. Personality and personal values impact the decision-making process.
3. Generalizing the findings to patients with other types of surgery is limited.

4. Disease processes may influence the rate anesthesia is eliminated from the body which may result in increased length of stay in PACU.

5. Pulse oximetry may not reflect the oxygen requirements of the body since it measures hemoglobin saturation and not tissue oxygenation.

6. Complications in the hospital system of care may cause extended length of stay in the PACU. The extended PACU stay may falsely be attributed to smoking.

7. The sample size was limited because of time restriction for the study.

8. Disease processes that interfere with the length of stay may result in mortality of subjects.

9. Patients may give inaccurate or incomplete information regarding their medical or smoking history.

10. Patients with significant respiratory disease may receive preoperative respiratory treatment which may reduce complications in the postanesthesia time period.

11. PACU nurses may vary in the technique and number of times they have patients deep breath and cough.

12. Problems of incomplete or difficult to interpret data in a retrospective chart review may effect validity or cause faulty study results.
Conclusions

Hardin and Baker (1992) indicated that cigarette smokers spend more time in PACU than nonsmokers. Hardin and Baker (1992) recommended further investigation on the effects of smoking on the length of stay in PACU. Although this study did not reflect a statistical increase in length of stay for smokers having lumbar discectomy/laminectomy, there was an increase in the mean PACU time and more frequent postoperative complications of all types were recorded. Smoking may indirectly influence PACU length of stay by contributing to the onset of other pathological processes as a patient ages. Initiating strategies to prevent complications can decrease the time spent in PACU.

Results of previous research have been used to decide what preventive treatments will maximize health outcomes of surgical patients (Wells, 1987). Cigarette smoking is a significant preventable health risk. Smoking cessation will reduce the risk associated with surgery. Health care providers should direct care toward smoking cessation and preoperative treatments to maximize better outcomes for their patients.
References


APPENDIX A

Data Collection Tool
APPENDIX A

Data Collection Tool

ANESTHESIA TIME: Start____ Finish____
PACU TIME: Start____ Finish____
ASA CLASSIFICATION___ALDRETI SCORE: admit___ discharge___
SEX____AGE____HEIGHT____WEIGHT____
SMOKER: Yes__No__ AMOUNT PER DAY ____ NUMBER OF YEARS SMOKED____
ALCOHOL USE: Yes__No__ Data Unavailable____
AMOUNT/DAY IF SPECIFIED____
1 drink = 1 oz (shot) whiskey = 1 glass wine = 1 bottle beer)
TYPE AND AMOUNT OF PAIN MEDICATION USED DURING RECOVERY STAY:
Demerol _____ Morphine ______ Fentanyl ______ Other _____
TYPE AND AMOUNT ANTIEMETIC MEDICATION:________
OXYGEN L/MIN ON DISCHARGE____ OXYGEN SATURATION ON DISCHARGE____
COMPLICATIONS EXTENDING PACU STAY:

RESPIRATORY____
Circle: Bronchospasm, Laryngospasm, Hypoventilation
   Hypoxemia (Difficulty weaning oxygen)
CARDIAC____
Circle: Hypotension, Hypertension, Arrhythmias,
   Chest pain
PAIN_____ NAUSEA &or VOMITING____ HYPOTHERMIA____
OVERSEDATION____
SYSTEMS COMPLICATIONS:
Second patient's needs interfere with discharge____
Transport unavailable _____
Floor unable to accept patient _____
Waiting for physician consult _____
OTHER______.

MEDICAL HISTORY:

PULMONARY_____
CARDIAC______
BP____
ENDOCRINE_____
RENAL____
GASTROINTESTINAL____
OTHER_____
APPENDIX B

American Society of Anesthesiologists

Physical Status Scale
# APPENDIX B

American Society of Anesthesiologists

Physical Status Scale

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A normally healthy individual</td>
</tr>
<tr>
<td>2</td>
<td>A patient with mild systemic disease</td>
</tr>
<tr>
<td>3</td>
<td>A patient with severe systemic disease that is not incapacitating</td>
</tr>
<tr>
<td>4</td>
<td>A patient with incapacitating systemic disease that is a constant threat to life</td>
</tr>
<tr>
<td>5</td>
<td>A moribund patient who is not expected to survive with or without operation</td>
</tr>
<tr>
<td>E</td>
<td>Added for emergency procedures</td>
</tr>
</tbody>
</table>

(Wilmore, 1991)
APPENDIX C

SHMC Revised Aldrete Score System
APPENDIX C

SHMC Revised Aldrete Score System

<table>
<thead>
<tr>
<th>Recovery Score</th>
<th>Admit</th>
<th>30&quot;</th>
<th>Dis ch</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CONSCIOUSNESS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No response</td>
<td>0.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Responds to physical stimuli</td>
<td>0.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drowsy, responds to touch</td>
<td>1.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Responds to verbal stimuli</td>
<td>1.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Awake</td>
<td>2.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ACTIVITY</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moves 0 extremities</td>
<td>0.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moves 1 extremity</td>
<td>0.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moves 2 extremities</td>
<td>1.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moves 3 extremities</td>
<td>1.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moves 4 extremities</td>
<td>2.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>VENTILATION</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No spontaneous breaths</td>
<td>0.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Limited breathing</td>
<td>0.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Airway support, spon. breaths</td>
<td>1.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Min. airway support, spon. breaths</td>
<td>1.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adequate ventilations</td>
<td>2.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CIRCULATION</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B/P +/- 51% of baseline</td>
<td>1.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B/P +/- 20-50% baseline</td>
<td>1.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B/P +/- 20% baseline</td>
<td>2.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>COLOR</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cyanotic</td>
<td>1.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pale, dusky, jaundiced</td>
<td>1.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal skin tone</td>
<td>2.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>TOTALS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


APPENDIX D

Washington State University

Human Subject Review Summary Form
MEMORANDUM

TO: Patricia Hines, Department of ICNE (5291)
FROM: Paul Whitney, Chair, WSU IRB
SUBJECT: Review of Human Subjects Protocol

Your Human Subject Review Summary Form and additional information provided for the proposal entitled "Cigarette Smoking and the Effect on Length of Stay for Lumber Discectomy/Laminectomy Patients in Post-Anaesthesia Care Unit (PACU)," OGRD #NF was reviewed for the protection of the subjects participating in the study. Based on the information received from you, the IRB has approved your human subjects protocol on October 9, 1995.

The IRB approval indicates the IRB's belief that the Human Subjects protocol as presented in the Human Subjects Review Summary Form by the investigator, is designed to adequately protect the subjects participating in the study. This approval does not relieve the investigator from the responsibility of providing continuing attention to ethical considerations involved in the utilization of human subjects participating in the protocol. This approval is valid for one year from approval date. If any significant changes are anticipated in the study please notify the IRB before implementation.

In accordance with federal regulations, this approval must be kept by the researcher for THREE years after completion of the research.