

ABSTRACT

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(J.P. Porcari)

This study examined the cardiovascular (CV) responses to exercise while wearing a transdermal nicotine patch. Fifteen apparently healthy volunteers (6M,9F: \bar{x} age = 36.3 yrs, \bar{x} ht = 168.5 cm, \bar{x} wt = 75.5 kg) who wanted to quit smoking served as subjects. Each subject completed 3 symptom limited GXTs utilizing the Bruce protocol. The tests were completed on the initial quit day (PRE), 2 weeks later (2WK) while wearing the 21 mg Nicoderm patch, and 6 weeks after quitting (6WK) while still wearing the 21 mg Nicoderm patch. HR, SBP, and DBP were recorded at rest, at the end of each 3 minute stage, and at maximal exertion. No significant differences ($p > .05$) were found in the resting, submaximal, or maximal CV responses to exercise while wearing the Nicoderm patch. No adverse ECG changes were observed. There were significant increases ($p < .05$) in maximal ventilation, maximal tidal volume, and maximal oxygen consumption over the 6 week period. Thus it appears that exercising while wearing the 21 mg Nicoderm patch does not alter the CV responses to exercise in apparently healthy adults, and smoking cessation results in favorable changes in ventilatory function and aerobic capacity, independent of training.

THE EFFECTS OF TRANSDERMAL NICOTINE DELIVERY
ON THE CARDIOVASCULAR RESPONSES
TO EXERCISE

A THESIS PRESENTED
TO
THE GRADUATE FACULTY
UNIVERSITY OF WISCONSIN-LA CROSSE

IN PARTIAL FULFILLMENT
OF THE REQUIREMENTS FOR THE
MASTER OF SCIENCE DEGREE

BY
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COLLEGE OF HEALTH, PHYSICAL EDUCATION, AND RECREATION
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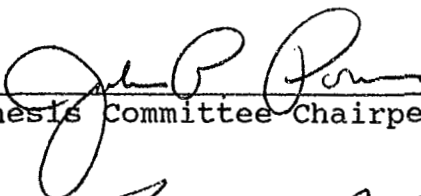
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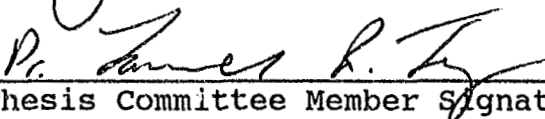
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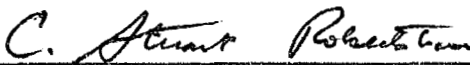
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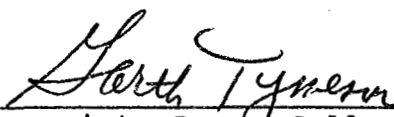


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This thesis is approved by the College of Health, Physical Education, and Recreation.



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DEDICATION

I want to dedicate my thesis to my dear husband, Frank. This thesis represents 2 years of my efforts and 2 years of his patience, support, understanding, and enduring love. The process is finally over! Thanks, love.

This is also dedicated to my family. To my mom, Colleen, for supporting me always. My roots were beautifully planted by my parents. I know my dad would be proud of me for challenging myself at this time in my life. And to Mike, who continued a standard of academic success which I chose to follow I love you all.

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I wish to express my gratitude and admiration to the 15 subjects who completed the study and took the challenge to quit smoking plus exercise for me in the early morning hours. I grew in understanding the difficult addiction of smoking.

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CHAPTER 1

INTRODUCTION

Cigarette smoking is the largest preventable cause of morbidity and premature mortality in the United States. In 1990, a total of 418,690 deaths in the United States were attributed to smoking according to the Morbidity and Mortality Weekly Report, August 27, 1993. This number is larger than all the combined deaths from World War I, World War II, and the Vietnam War (Pollin, 1984).

The estimated health care costs related to smoking in 1985 were \$65 billion, which would be equivalent to \$100 billion in 1994 dollars (MacKenzie, Bartecchi, & Schrier, 1994). With health care reform as a national priority, one can understand why antismoking coalitions are gaining momentum in accomplishing reform as the nation struggles to deal with this most important public health issue. Despite the concern and knowledge of the ill effects of smoking, 46.3 million people (25.7% of the population) continue to smoke (Bartecchi, MacKenzie, & Schrier, 1994). Smoking is a complex addiction with both behavioral and pharmacologic components (U.S. Department of Health and Human Services, 1988). Optimal treatment of this addiction requires addressing both aspects.

Nicotine is the addictive substance in tobacco products. Replacement therapies have been developed to assist people

in quitting smoking and have been shown to be effective in reducing nicotine withdrawal symptoms which include irritability, restlessness, tenseness, hunger, constipation, cigarette craving, and difficulty with concentration (Abelin, Muller, Buehler, Vesanen, & Imhoff, 1989; Fiore, Jorenby, Baker, & Kenford, 1992; Hurt et al., 1994; Kenford, Fiore, Jorenby, Smith, Wetter, & Baker, 1994; Rose, Herskovic, Trilling, & Jarvick, 1985; Rose, Levin, Behm, Adivi, & Schur, 1990).

Nicotine replacement delivery systems include nasal spray, chewing gum, and most recently, the transdermal nicotine patch. Since FDA approval in 1991, the transdermal nicotine patch has become the most frequently used form of nicotine replacement therapy. In 1992, 5 million people used the nicotine patch in their attempt to stop smoking (Fiore et al., 1992). Placebo-controlled trials investigating the use of "the patch" for smoking cessation support its effectiveness (Daughton et al., 1991; Hurt, Lauger, Offord, Kottke, & Dale, 1990; Tonneson, Norregaard, Simonsen, & Sawe, 1991). The 6 month cessation rate is 22% for the nicotine patch compared to 9% for the placebo patch. Cessation rates diminish over time. Tonneson et al. (1991) found the 1 year quit rate to be 17% for the nicotine patch and 4% for the placebo patch. In a study by Kenford et al. (1994), individual vs. group counseling did not seem to make a difference in cessation rates but remaining smoke free

during the first 2 weeks was a strong indicator for cessation success. Quit rates at 6 months were 59% vs 3% in comparing no smoking to smoking in the first 2 weeks of cessation.

The U.S. Food and Drug Administration approved the nicotine patch only for use with a comprehensive smoking cessation program. Behavior modification programs increase: cessation rates; adherence to prescribed dosing and weaning schedules; adherence to not smoking during patch therapy; and knowledge about relapse prevention skills for long term abstinence (Orleans et al., 1994).

Exercise is a commonly used component of comprehensive smoking cessation programs. It helps to reduce the weight gain commonly associated with smoking cessation and reduces emotional stress (Marks & Perkins, 1990). In developing an exercise prescription or determining the safety of an exercise program, many people undergo graded exercise testing. Currently, there has been little research on the effects of the nicotine patch on the cardiovascular responses to exercise or to exercise tolerance.

Statement of the Problem

According to the American College of Sports Medicine (1991), a person should not eat food, drink caffeinated beverages or alcohol, or partake of tobacco for at least 3 hours prior to performing an exercise test. These substances have all been shown to increase heart rate and

systolic blood pressure during exercise. Cigarette smoking, in particular, typically elevates the heart rate by an average of 6-8 bpm and systolic blood pressure by 6-10 mm Hg above baseline conditions (Benowitz, Kuyt, & Jacob, 1984). An important difference between smoking and wearing a transdermal nicotine patch is one of timing. During exercise, people usually do not smoke; but a person wearing a patch is exposed to continuous levels of nicotine at rest and during exercise. The effects of this constant level of nicotine coupled with the cardiovascular responses to exercise has not been investigated.

Because exercise prescription is often based on a target heart rate zone determined from the maximum heart rate obtained during a graded exercise test, data must be accurate. It would be of interest to see if there is a difference in the cardiovascular responses to exercise with or without the nicotine patch. If such differences do exist, they may result in inaccurate exercise prescription guidelines.

Purpose of the Study

To date, there are no published studies regarding the cardiovascular responses to exercise while wearing the transdermal nicotine patch. The purpose of the study was to evaluate the effect of the transdermal delivery of nicotine on the cardiovascular responses to exercise.

Hypothesis

1. The nicotine patch does not effect the heart rate or blood pressure responses to exercise.

Assumptions

Assumptions of this study were:

1. All subjects performed the symptom-limited exercise test to the best of their ability.
2. All subjects remained smoke-free for 6 hours prior to the initial graded exercise test.
3. All subjects took their medications at the same time of day.

Delimitations

Delimitations of this study are:

1. The three exercise tests for each subject were done at the same time of day.
2. The three exercise tests for each subject utilized the same protocol.
3. All subjects were regular smokers for at least 1 year prior to the study and smoking at least 15 cigarettes per day.
4. No subjects were on medications which effected heart rate or blood pressure.
5. None of the subjects had known cardiac, pulmonary, or metabolic disease.
6. Each subject had the same technician measure their blood pressure during all three tests.

Limitations

1. There was no randomization of the testing procedures. All subjects performed the quit/no patch trial first, followed by the 21 mg Nicoderm nicotine patch GXTs at 2 weeks and 6 weeks after smoking cessation.
2. All subjects were volunteers.
3. The only patch evaluated was the 21 mg Nicoderm nicotine patch.

Definition of Terms

Cardiovascular Responses - blood pressure and heart rate measurements obtained during the graded exercise test.

MET (Metabolic Equivalent) - the amount of oxygen required by the body per minute under seated resting conditions. One MET is equal to 3.5 milliliters of oxygen consumed per kilogram of body weight per minute (ml/kg/min) (ACSM 1991).

Nicotine Patch - an adhesive patch that is applied to nonhairy, intact skin on the upper torso or outer upper arm. While several brands and sizes are available, this study evaluated the 21 mg Nicoderm nicotine patch.

Rating of Perceived Exertion (RPE) - a subjective indicator or rating of physical strain during a physical activity. The overall rating integrates information including signals elicited from peripheral working muscles and joints, the central cardiovascular and respiratory function, and the central nervous system (Borg, 1982).

Target Heart Rate Zone - a range of heart rates consistent in achieving cardiorespiratory benefits determined by the Karvonen method.

CHAPTER II

REVIEW OF RELATED LITERATURE

Introduction

The first part of the literature review is a discussion of nicotine replacement therapies. The second part summarizes the pharmacodynamic aspects of nicotine with the third part addressing the cardiovascular responses to nicotine.

Nicotine Replacement Therapies

Nicotine replacement therapies first became available in 1984. The initial goal was to reduce the nicotine withdrawal symptoms in individuals trying to quit smoking. Replacement nicotine was tapered off after smoking cessation. Nicotine nasal spray and nicotine chewing gum were the early forms of replacement therapies. Nasal sprays were often abused due to the ease of self-overdosing and problems with nicotine chewing gum included bad taste, nausea, the need for frequent dosing, the requirement for a special chewing technique, hiccups, and nicotine overdosing.

Nicotine patches are the newest form of nicotine replacement therapy, receiving FDA approval in 1991. Presently, there are four FDA approved nicotine patches on the market. The names and manufacturers are: Habitrol by Ciba-Geigy, Nicoderm by Marion Merrell Dow, Prostep by

Lederle, and Nicotrol by Parke-Davis (Abramowicz, 1992).

Habitrol, Nicoderm, and Prostep systemically deliver nicotine over 24 hours following the application to intact skin. The 24 hour delivery systems have the advantage of eliminating a morning nicotine nadir, thus eliminating the initial craving for a cigarette in the morning. Nicotrol is worn only during the waking hours for 16 hours of nicotine delivery. The main advantage of Nicotrol is the elimination of the sleep disturbances experienced by some individuals, due to the constant levels of nicotine delivered by the other patches.

Possible advantages of the transdermal delivery system over older replacement systems include improved compliance with once a day application, constant blood levels of nicotine, fewer side effects, and reduced frequency of overdosing (Daughton et al., 1991; Ebert, McNabb, & Snow, 1984; Rose et al., 1990). The cost of a month supply of patches ranges from \$110 to \$120, depending on the brand and pharmacy (Brandstetter, 1992).

The patches themselves, are a multilayered system with the nicotine in a drug reservoir or gel matrix. Layers of a patch from outer to inner are: 1) a flesh colored occlusive lining, 2) a drug reservoir, 3) a rate controlling membrane, 4) a contact adhesive, and 5) a protective layer. The protective layer is removed before application.

The patches are used on a tapering schedule. Ciba-Geigy and Marion Merrell Dow products come in 21, 14, and 7 mg doses. Lederle and Parke-Davis products each come in two sizes, 22 and 11 mg for the former and 20 and 10 mg for the latter. For all brands, a person starts at the highest dosage if he/she weighs over 100 lbs, smokes more than 1/2 pack of cigarettes per day, and has no known cardiovascular disease. The first dosage is used for up to 6-8 weeks. The physician then prescribes the next dose for 2 to 4 weeks followed by the last dose for 2 to 4 weeks. If a person weighs less than 100 lbs, smokes less than 1/2 pack of cigarettes per day, or has cardiovascular disease, he/she would begin at the next lower dose of the nicotine patch.

Smoking cessation is essential at the beginning of the tapering system. If a person is still smoking 2 weeks after beginning the patch, it is not recommended that he/she continue to wear the patches. All drug manufacturers recommend that the patch system be used with a comprehensive behavioral smoking cessation program and recommend that individuals stop smoking when the patches are started.

The patches are applied once a day to a nonhairy, clean, dry, intact skin site on the upper body or upper arm. After 16 or 24 hours, the used nicotine patch is removed and a new patch is applied to a different site. Application sites should not be reused within a 7 day period. Skin irritation under the patch is a common side effect, occurring in 25-50%

of users (Abramowicz, 1992). Headache, nausea, vertigo, increased cough, insomnia, sweating, dry mouth, and diarrhea have all been described as side effects. These symptoms are typical of nicotine excess and/or withdrawal. If a person has symptoms of nicotine excess, the patch is removed and the site is rinsed with water. No soap is applied since this is felt to enhance the absorption of nicotine.

About 68% of the nicotine released from the patch is absorbed into the circulation. Plasma concentrations rise rapidly after the application of the patch following a lag time of 1 to 2 hours. Peak blood levels occur between 3 and 12 hours. The half-life of transdermal nicotine is longer than that of the nicotine delivered by inhalation or intravenous routes due to continued absorption from the skin depot. After intravenous or inhaled administration, the plasma half-life of nicotine is 1 to 2 hours. After removal of a transdermal patch, the half-life is 3 to 4 hours. The average plasma concentration from a 21 mg nicotine patch is 17 ng/ml (Mulligan, Masterson, Devane, & Kelly, 1990), which is equivalent to smoking one cigarette every half hour.

At least when used incorrectly, the nicotine patch may have serious adverse effects. A Massachusetts hospital reported that five people suffered myocardial infarctions while wearing the nicotine patch. However, all five individuals had continued to smoke while using the patch (USA Today, July 16, 1992). The U.S. Food and Drug

Administration approved the nicotine patch with the following guidelines: 1) don't smoke if wearing the patch, and 2) use the patch only as part of a behavior modification smoking cessation program.

Pharmacodynamics of Nicotine

Nicotine is the chief alkaloid in tobacco products. It is a tertiary amine composed of a pyridine and pyrrolidine ring. It is colorless to pale yellow in color, water soluble, strongly alkaline, and volatile. Nicotine has a characteristic odor and turns brown on exposure to air or light. Of the two stereoisomers, S(-) nicotine is the more active and the prevalent form in tobacco. It is rapidly absorbed through the skin, buccal membranes, and respiratory tract (Marion Merrell Dow, 1991) and the half life is 90 to 120 minutes (Benowitz, Kuyt, Jacob, Jones, & Osman, 1983). Nicotine can cause both excitatory and inhibitory effects, since it can stimulate the postganglionic neurons of both the sympathetic and parasympathetic nervous system in the same manner as acetylcholine (Guyton, 1991, p. 678). One difference between nicotine and acetylcholine is that the former is slowly broken down by cholinesterase (Guyton, 1991, p. 83). Sympathetic stimulation predominates at lower doses of nicotine with increases in heart rate, blood pressure, mental activity, muscle strength, and vasoconstriction of internal organs. At higher doses, the parasympathetic stimulation becomes dominant, with increased

gastrointestinal activity, dry mouth, blurred vision, bradycardia, and decreased blood pressure. Nicotine can also stimulate the adrenal medulla, the neuromuscular junction and the brain, all of which have the nicotinic type of acetylcholine receptors. Nicotine can cause release of both norepinephrine and epinephrine from the adrenal medulla (Cryer, Haymond, Santiago, & Shan, 1976). Nicotine causes vasoconstriction of blood vessels in the extremities, heart, placenta, and fetus. Nicotine is also felt to cause an acceleration in the process of atherosclerosis by increasing platelet aggregation (Mennies, 1983).

Nicotine is metabolized primarily in the liver, with a small percent processed in the lungs. The major metabolites are cotinine and nicotine-n-oxide. Cotinine, which is formed by the oxidation of the pyrrolidine ring, has a much longer half-life (from 16 to 20 hours) than nicotine-n-oxide. Cotinine is often used as a marker of nicotine use (Benowitz, et al., 1983).

Cardiovascular Responses to Nicotine

Norepinephrine excites predominantly alpha-adrenergic receptors, whereas epinephrine excites both alpha-receptors and beta₁ and beta₂ adrenergic receptors. Both produce sympathetic stimulation (Guyton, 1991, p. 671). The sympathetic stimulation is the cause of increased heart rate and systolic blood pressure typically seen with nicotine usage.

Chronic smoking has been shown to decrease the beta adrenergic receptors by 40% in the lymphocytes of smoking twins compared to their nonsmoking cotwins (Laustiola, Lassila, Kaprio, & Koskenvuo, 1988). This mechanism was used to explain why beta-blockers were less effective in treating hypertension and angina pectoris in smokers compared to nonsmokers. In 1993, Sidney et al., concluded that chronic smoking appeared to blunt the heart rate response to exercise, so that exercise time to submaximal heart rates was increased yet maximal heart rate was lower, based on the principle of the down regulation of the beta receptors.

The normal heart-rate response to exercise is a linear increase as a function of increasing oxygen demand. A plateau in heart rate is typically reached just prior to achievement of VO_{2max} . The normal intrinsic rate of the sino-atrial node is about 100 beats per minute. Parasympathetic tone reduces the actual resting heart rate to around 70 beats per minute. With exercise, the parasympathetic tone is withdrawn and sympathetic input is increased (ACSM, 1991), resulting in increased heart rate.

Normal systolic blood pressure response to exercise is a linear rise in relation to exercise intensity. Diastolic pressure normally stays the same or decreases slightly. The pulse pressure (systolic minus diastolic blood pressure) should rise with increasing exercise intensity (ACSM, 1991).

Several authors have studied the cardiovascular responses to nicotine while at rest. The short-term (15 minutes) effect of nicotine by smoking a cigarette produces a 10 to 12 mm Hg increase in systolic blood pressure and a 15 to 20 bpm increase in heart rate (Tachmes, Fernandez, & Sackner, 1978). In 1988, Benowitz, Porchet, Sheiner, and Jacob found significant increases in heart rate and blood pressure after the intake of cigarette smoke, oral snuff, chewing tobacco, and nicotine gum. The average increases in heart rate and blood pressure for the subjects were 20 bpm and 8/7 mm Hg after cigarette smoking, 19 bpm and 8/9 mm Hg after oral snuff, 21 bpm and 11/12 mm Hg after chewing tobacco, and 12 bpm and 8/7 mm Hg after nicotine gum. The measurements were taken within 10 minutes after administration of the four different forms of nicotine.

A linear dose-dependant increase in plasma nicotine and heart rate was demonstrated by Perkins, Epstein, Sexton, Stiller, and Jacob in 1991. Resting heart rate increased 3-4 bpm for each increase in nasally administered nicotine doses which were 7.5 ug/kg, 15 ug/kg, and 30 ug/kg. Marion Merrell Dow (1991) found a continuous 10 bpm and 5 mm Hg systolic blood pressure elevation from wearing a Nicoderm patch for 24 hours or smoking a cigarette every 30 minutes during waking hours compared to abstinence.

Others have evaluated the effects of nicotine on the heart rate during exercise. Perkins, Epstein, Marks,

Stiller, and Jacob (1989) found an 8 bpm increase at a 3 MET level of exertion following a 15 ug/kg dose of nasally administered nicotine. Van Duser and Raven (1992) found an average increase in heart rate of 11 beats per minute at 60% of VO_2 max and 6 beats per minute at 85% of VO_2 max when comparing oral smokeless tobacco to placebo. The measurements were taken 50 minutes after placement of the oral sample in the mouth. Perkins et al. (1991) showed that heart rate was significantly increased from baseline (rest, 30 WATTS or 60 WATTS) for different nicotine doses but not activity intensity. Morton and Holmick (1985) found that smoking 2 cigarettes within 15 minutes of exercise in both smokers and nonsmokers increased the resting heart by 15 bpm with no change in the exercise maximum heart rate. However, another study showed that exercising 15 minutes after smoking 1 cigarette produced a 20 bpm increase in heart rate at rest, and at 300 kg/min, 600 kg/min and 900 kg/min exercise stages (Goldbarg, Krone, & Resnekov, 1971).

Blood pressure responses to nicotine usage during exercise have also been observed. Perkins et al. (1989) observed a 5 mm Hg increase in systolic pressure at rest and at a 3 MET level following 15 ug/kg dose of nasally administered nicotine. Gapter and Noble (1986) showed that subjects had significantly higher systolic blood pressure at 80% of VO_2 max while chewing tobacco as compared to control periods. No significant changes in systolic blood pressure

were found after smoking one cigarette at the previously mentioned exercise workloads by Goldberg et al. (1971).

CHAPTER III
METHODS AND PROCEDURES

Introduction

The purpose of the study was to evaluate the effect of the transdermal delivery of nicotine on the cardiovascular responses to exercise.

Subject Selection

Twenty-two volunteers who wanted to quit smoking and wished to utilize the nicotine patch were used as subjects. The subjects were referred to the study by their primary care physician, who provided the written prescription for the nicotine patch. Physicians in the community had been informed of the study via an introductory letter (see Appendix A). Subjects had no known cardiac, pulmonary, or metabolic disease. Subjects learned more about the study from their physician via a flyer (see Appendix B) and called the primary investigator to obtain more details and arranged an initial meeting and practice session.

Testing Procedures

Overview

All testing took place in the Human Performance Laboratory in Mitchell Hall on the University of Wisconsin - LaCrosse campus. Each subject met with the principal investigator four times. The initial meeting was a practice

and information gathering session with the following three meetings used for exercise testing and data collection. The three exercise sessions were held on each of the subject's quit day, 2 weeks after smoking cessation and wearing the 21 mg Nicoderm nicotine patch, and 6 weeks after smoking cessation and still wearing the 21 mg Nicoderm nicotine patch.

Practice Session

About 1 week before the initial testing date, the subject met with the principal investigator. The study was explained and informed consent was obtained (see Appendix C). A health history form was also completed (see Appendix D). The subject practiced walking on the treadmill while wearing the mouthpiece and headgear used for the measurement of oxygen consumption in an attempt to help reduce anxiety and become familiar with the testing procedures. Explanations were given regarding the Borg rating of perceived exertion scale, walking on the treadmill, the sequencing of measurements during testing, and pretesting limitations (see Appendix E). No food, alcohol, or caffeinated beverages could be ingested for 3 hours prior to testing, and smoking would be abstained from for a minimum of 6 hours prior to testing. Each of the subject's quit day was discussed with the testing dates scheduled accordingly.

Initial Testing Session - (PRE)

On the initial testing day, height and weight were measured for each subject. Exhaled carbon monoxide was measured via a Vitalograph BreathCO monitor. The subject held his/her breath for 20 seconds and slowly exhaled into the mouthpiece of the hand-held monitor. The procedure was done twice, with an average of the two readings recorded as the subject's exhaled carbon monoxide level. The subject then had 10 electrodes applied for ECG monitoring using the Mason-Likar configuration. Resting heart rate and blood pressure were obtained after the subject was supine for 5 minutes. Standing blood pressure and ECG were measured followed by 20 seconds of hyperventilation with an EKG obtained immediately after the hyperventilation.

The principal investigator then reviewed getting on and off the treadmill and the Borg scale with the subject. Heart sounds and breath sounds were auscultated and recorded by the principal investigator and reported to the supervising physician. The subject was fitted with his/her headgear, nose clip, and mouth piece. The subject then performed a 3 to 4 minute warm-up at 2 mph, 0% grade prior to the start of the test. The test conducted was a symptom-limited maximal test using the Bruce protocol. Blood pressure, RPE, and ECG were measured during each 3 minute stage and at maximal exertion. Expired gases were continuously measured during the exercise test via the

Quinton Q-Plex metabolic cart which was calibrated according to protocol prior to each testing session. Blood pressures were taken in the left arm using a stethoscope and mercury sphygmomanometer. The systolic and diastolic blood pressures were determined according to the appearance and disappearance of Korotkoff sounds, respectively. Heart rate was determined from ECG recordings and RPE from the Borg scale. Once the test was completed, the subject was assisted with the removal of the headgear and mouthpiece and the treadmill was returned to 2.0 mph and 0% grade. Subjects continued walking until their heart rate was below 100 beats per minute and the systolic blood pressure had returned to within 15 mm Hg of preexercise values. Recovery measurements were taken every 2 minutes.

After completing the test, the subject was instructed on the proper use of the nicotine patch, signs and symptoms to watch for, and how to apply the patch (see Appendix F). The subject then received a 2 week supply of 21 mg Nicoderm nicotine patches, plus a handout on behavior modification to assist the subject in the quitting process (see Appendix G). The next testing date was scheduled in 2 weeks and a written reminder was given to the subject.

Second Testing Session - (2 WK)

The subject returned to the Human Performance Laboratory for the second testing session 2 weeks after smoking cessation while wearing the 21 mg Nicoderm patch. The exact

testing and data collection procedures were followed as during the initial testing session. After the completion of the symptom-limited maximal test, the subject received a 4 week supply of 21 mg Nicoderm nicotine patches. The final testing date (6 WK) was scheduled and a written reminder was given to the subject.

Third Testing Session - (6 WK)

The third and final exercise test was completed 6 weeks after quitting smoking while still wearing the 21 mg Nicoderm patch. The exact same testing and data collection procedures were followed as for the PRE and 2 WK tests. Once the third exercise test was completed, the subject had completed the testing required for the study and received the taper Nicoderm patches of 14 mg, which were to be worn for 2 weeks, and 7 mg Nicoderm patches, also to be worn for 2 weeks. Each subject was to continue on the nicotine patches with follow-up with his/her primary care physician. Individualized exercise guidelines were shared with each subject based on the results of their maximal heart rates obtained from their exercise tests (see Appendix H).

Statistical Analysis

Mean and standard deviations were calculated on demographic data to describe the subject population. Repeated measures ANOVA and Tukey's post-hoc tests were used for statistical analysis to determine whether significant changes occurred between the initial exercise test and the 2

and 6 week follow-up tests. Analysis was conducted on the resting, submaximal, and maximal values. Variables analyzed were body weight, exhaled carbon monoxide, heart rate, systolic blood pressure, diastolic blood pressure, RPE, oxygen consumption, ventilation, tidal volume, and RER.

CHAPTER IV
RESULTS AND DISCUSSION

Introduction

The purpose of the study was to evaluate the cardiovascular responses to exercise while wearing the transdermal nicotine patch. Presented in this chapter are descriptive characteristics of the subjects, results of the study, and a discussion of the results.

Subjects

Twenty-two subjects initially agreed to participate in the study. However, four subjects decided not to participate in the study prior to the initial exercise test because they were not ready to quit smoking. Three other subjects dropped out of the study after the first exercise test because they had continued to smoke. The descriptive statistics of the 15 subjects (6 males and 9 females) who completed the study are in Table 1.

Results of the Study

There were no significant differences in the responses between males and females over the course of the study, therefore data were combined for all subsequent discussion.

Baseline Measurements

Table 2 presents the baseline data for body weight, carbon monoxide levels, resting heart rate, resting systolic

blood pressure, and resting diastolic blood pressure. There was a significant ($p < .05$) increase in body weight over the course of the study period. On average, body weight increased 1.4 kg from pretesting to the 6 week testing period. There were no significant ($p > .05$) differences in resting heart rate, systolic blood pressure, or diastolic blood pressure, although there was a tendency for resting systolic blood pressure to be approximately 6 mm Hg higher at the 2 and 6 week test dates.

Table 1. Descriptive characteristics of subjects (N = 15) at the beginning of the study.

Variable	Age $\bar{x} \pm SD$ (range)	Height $\bar{x} \pm SD$ (range)	Weight $\bar{x} \pm SD$ (range)
Males	36 \pm 7.6 (29 - 52)	70.5 \pm 2.1 (67 - 74)	84.6 \pm 8.9 (71.4 - 95.5)
Females	36.4 \pm 9.3 (25 - 58)	63.9 \pm 1.5 (61.5 - 66.5)	69.4 \pm 12.3 (53.6 - 88.2)
Overall	36.3 \pm 9.0 (25 - 58)	66.6 \pm 3.9 (61.5 - 74)	75.5 \pm 13.8 (53.6 - 95.5)

Table 2. Preexercise baseline data of subjects.

Variable	PRE $(\bar{x} \pm SD)$	2 WK $(\bar{x} \pm SD)$	6 WK $(\bar{x} \pm SD)$
Weight (kg)	75.5 \pm 13.8	76.1 \pm 14.1	76.9 \pm 14.1*
CO (ppm)	19.7 \pm 6.7	2.8 \pm 2.13*	2.8 \pm 2.8*
RHR	74 \pm 12.1	70 \pm 12.0	74 \pm 12.5
RSBP	110 \pm 10.4	115 \pm 14.5	116 \pm 12.5
RDBP	69 \pm 7.3	71 \pm 6.8	71 \pm 8.5

* Significantly different from PRE ($p < .05$)

Mean expired carbon monoxide level of the subjects pretesting value was 19.7 ppm. The mean expired carbon monoxide levels obtained at the 2 week and 6 week tests were 2.8 ppm and 2.8 ppm which supports that the subjects remained smoke free during the study.

Submaximal Cardiovascular Responses

Submaximal heart rate, systolic blood pressure, and diastolic blood pressure responses are presented in Table 3. There were no significant ($p > .05$) differences across the submaximal stages between the three tests. Cardiovascular responses did increase as expected as work load increased during the progressive stages of the Bruce protocol.

Table 3. Submaximal cardiovascular responses during the first three stages of the Bruce protocol.

Variable	PRE ($\bar{X} \pm SD$)	2 WK ($\bar{X} \pm SD$)	6 WK ($\bar{X} \pm SD$)
Stage I			
HR	118 \pm 11.9	113 \pm 12.2	116 \pm 14.8
SBP	128 \pm 17.4	126 \pm 19.9	130 \pm 14.0
DBP	70 \pm 10.5	72 \pm 10.5	70 \pm 7.6
Stage II			
HR	141 \pm 13.3	137 \pm 9.4	138 \pm 17.5
SBP	143 \pm 21	141 \pm 19.2	143 \pm 16.4
DBP	70 \pm 10.9	69 \pm 8.0	67 \pm 9.0
Stage III			
HR	169 \pm 11.3	167 \pm 10.0	167 \pm 13.1
SBP	158 \pm 16.7	160 \pm 15.2	161 \pm 17.1
DBP	72 \pm 11.6	72 \pm 9.2	68 \pm 10.7

* Significantly different from PRE ($p < .05$)

Maximal Responses

Maximal values obtained during the tests are presented in Table 4. There were no significant differences ($p > .05$) in the maximal heart rate, systolic blood pressure, diastolic blood pressure, RER, RPE, and VO_{2max} when expressed in ml/kg/min. There were significant improvements ($p < .05$) in VO_{2max} when expressed as L/min, maximal ventilation (VE), and maximal tidal volume (TV). For TV, the 2 and 6 week values were 12 and 11% higher when compared to the pretesting value. The significant improvements for VO_2 (L/min) and VE were observed between the pretesting value and the 2 week test value only. The magnitude of the improvement was approximately 13.5% for VE and 7% for VO_2 (L/min).

Table 4. Maximal values recorded during the treadmill tests

Variable	PRE ($\bar{x} \pm SD$)	2 WK ($\bar{x} \pm SD$)	6 WK ($\bar{x} \pm SD$)
Max HR	175 \pm 12.5	177 \pm 11.1	177 \pm 12.4
Max SBP	166 \pm 17.9	165 \pm 14.2	168 \pm 16.2
Max DBP	71 \pm 10.9	68 \pm 11.8	68 \pm 16.2
Max VE	80.2 \pm 23.9	91.1 \pm 25.4*	86.2 \pm 27.6
Max LO_2	2.38 \pm 0.64	2.54 \pm 0.72*	2.51 \pm 0.73
Max O_2 /kg/min	31.5 \pm 5.8	33.3 \pm 6.4	32.7 \pm 7.1
Max RER	1.15 \pm 0.096	1.21 \pm 0.09	1.18 \pm 0.08
Max VT	2.25 \pm 0.64	2.53 \pm 0.69*	2.51 \pm 0.75*
Max RPE	17.2 \pm 1.8	16.4 \pm 1.53	16.7 \pm 1.76

* Significantly different than PRE ($p < .05$)

No arrhythmias or ST depression were observed during the submaximal exercise stages or at maximal exertion as determined via the continuous ECG recordings. Two subjects complained of skin irritation and three of active dreams while wearing the patch.

Test of the Hypothesis

Based on the results of this study, the null hypothesis was accepted because there were no significant differences in submaximal or maximal heart rate and blood pressure responses to exercise while wearing the transdermal nicotine patch.

Discussion

The major focus of the study showed there were no significant differences in submaximal or maximal heart rate or blood pressure responses between the three GXTs. Limited data are available for comparison because to this author's knowledge, no studies have been conducted investigating the responses to exercise while wearing the nicotine patch. However, other studies have investigated cardiovascular responses to exercise utilizing other forms of nicotine. A study done by Perkins et al. (1989) found a 8 bpm increase in heart rate at a 3 MET level of exercise following a 15 ug/kg dose of nasal nicotine spray. Van Duser and Raven (1992) found an average increase in heart rate of 11 bpm at 60% VO_2 max and 6 bpm at 85% VO_2 max in comparing 2.5 g of 1.5% nicotine oral smokeless tobacco versus placebo. The

measurements were taken 50 minutes after placement of the oral sample in the mouth. Morton and Holmick (1985) found a 15 bpm increase in resting heart rate but no change in maximum heart rate when smoking 2 cigarettes 15 minutes before exercising. This was true for both smokers and nonsmokers. Goldbarg et al. (1971) found a 20 bpm increase in heart rate after smoking 1 cigarette and exercising 15 minutes later at workloads of 300 kg/min, 600 kg/min, and 900 kg/min.

Blood pressure responses to nicotine and exercise have also been investigated. Perkins et al. (1989) observed a 5 mm Hg increase in systolic pressure at rest and at a 3 MET exertion level following a 15 ug/kg dose of nasally administered nicotine. Gapter and Noble (1986) found that subjects had significantly higher systolic blood pressure measurements at 80% VO_{2max} while chewing tobacco as compared to control studies. Goldbarg et al. (1971) found no significant changes in systolic blood pressure after smoking 1 cigarette and exercising 15 minutes later at workloads of 300 kg/min, 600 kg/min, and 900 kg/min.

In contrast to the above studies, this study found no significant differences in heart rate and blood pressure responses while wearing the 21 mg Nicoderm nicotine patch. It was felt three areas need to be addressed as possible explanations for the present findings.

First, anxiety may have played a dual role in elevating the pretesting values. The anxiety felt in anticipation of quitting smoking plus experiencing some withdrawal symptoms, since all subjects were at least 6 hours out from their last cigarette, may have given higher than normal readings on their quit day prepatch GXT. Also, anxiety may have been provoked in the subjects due to the testing environment. The practice session was intended to help relieve this type of pretest anxiety. It was possibly not adequate.

Secondly, the nicotine level could have possibly been higher than what was assumed for the prepatch GXT since blood nicotine levels were not measured in the study. The only objective data used in the present study were the exhaled carbon monoxide level measured on the morning of the prepatch GXT which had a mean value of 19.7 ppm and the subjective self-report of abstinence for at least 6 hours. All testing took place at 6:00 a.m. which supports the 6 hour abstinence because most likely the subjects had slept the prior 6 hours. Benowitz (1988) reported an overnight smoking abstinence blood nicotine level of 5 ng/ml is equivalent to a 4% carboxyhemoglobin concentration. Jarvis, Russell and Saloojee (1980) reported a direct linear relationship between carboxyhemoglobin concentrations and expired carbon monoxide levels. For every 1% increase in carboxyhemoglobin, the expired CO level increases 5 ppm. Thus, the pre-expired CO level of 19.7 ppm reflects a

carboxyhemoglobin level of approximately 4% which is consistent with a blood nicotine level of 5 ng/ml which reflects overnight abstinence from smoking. The exhaled carbon monoxide levels at the 2 and 6 week tests (2.8 ppm and 2.8 ppm) was also supportive of the subjects expressed nonsmoking behavior. According to Nett (1993) if the exhaled CO level is below 10 ppm, one can be fairly certain the subject is not smoking. A person who smokes a pack of cigarettes per day has an exhaled CO levels of 30 to 35 ppm which is reflective of a carboxyhemoglobin level of 6 to 7% (Jarvis et al. 1980).

Third and last, the previously reported studies evaluating the effects of nicotine and the cardiovascular responses with exercise were all measuring the heart rate and blood pressure within minutes to an hour of nicotine delivery, thus measuring the acute effect of the nicotine. This study measured the effects of nicotine after a 2 week and 6 week constant delivery via the 21 mg Nicoderm nicotine patch. Acute and chronic tolerance to nicotine is a known response. An example of acute tolerance was demonstrated by Benowitz, Jacob, Jones, and Rosenberg in 1982 when injecting intravenous nicotine. The heart rate reached a maximum rate in 5 to 10 minutes despite increasing blood nicotine levels. Benowitz (1988) reported tolerance developed within a day in regular smokers to the acceleration of the heart rate.

Thus, the subjects in this study were used to the level of nicotine which was delivered by the 21 mg Nicoderm nicotine patch.

The subjects in the study gained an average of 1.4 kg (3 lbs) over the course of the 6 week study. The significant weight gain is in agreement with most studies showing 5 to 12 pounds (2.2 to 5.4 kg) is a common weight gain seen with smoking cessation during the subsequent year (Mennies, 1983). Nervous energy, a substitution for the hand to mouth habit, and an increase in the taste and smell sensations are reasons sighted for weight gain with smoking cessation. Some studies state the weight gain is due to a decrease in the basal metabolic rate due to the withdrawal of the nicotine (Perkins et al., 1991). However, the subjects in this study continued to have a constant delivery of nicotine over their first 6 weeks of smoking cessation and still gained weight. One has to wonder if the nicotine patch effects the weight gain associated with smoking cessation. No clear answer has been found as reported by the following studies. Abelin et al. (1989) reported no change in weight for subjects wearing the nicotine patch compared to a 4.4 kg weight gain in subjects wearing placebo patches. These measurements were over a 12 week time period. In contrast, Tonnesen et al. (1992) reported the median weight gain after 12 weeks among patients who abstained from smoking was 2.7 kg with the patch and 3 kg with placebo.

An interesting finding was the significant increase in the maximal VE and maximal TV as a consequence of smoking cessation. These improvements were seen in just 2 weeks of smoking cessation and were independent of any formal exercise program. The absolute VO_{2max} (L/min) improved by 7% at 2 weeks and 5% at 6 weeks from pretest values. The improvements were probably mediated by the increases in the ventilatory parameters. When represented as a relative VO_{2max} measurement (ml/kg/min), there were no significant differences due to the increase in body weight by the subjects.

Even though a maximal effort was given by all subjects based on RER and HR criteria, it was felt that the subjects didn't push themselves quite as hard for the third and final test. Possibly a desire to just complete the study and receive the final taper doses of the nicotine patches (14 mg and 7 mg) was the motivating force and not one of giving an all out effort. RPE values decreased by .8 and .5 for the 2 and 6 week tests respectively. This is in agreement with Gapter and Noble's 1986 findings that subjects who chewed oral smokeless tobacco while exercising had significantly lower RPEs compared to nonchewers.

No adverse EKG changes (i.e., ST segment depression or dysrhythmia) were observed during the testing procedures. This has significant value when considering the safety of the nicotine patch while exercising. Three subjects

complained of "active" dreams during the first 5 days of initially wearing the 21 mg Nicoderm patch. Two different subjects complained of redness and itching at the nicotine patch application sites. The side effects reported by the subjects were minimal and below the reported side effect occurrences according to Orleans et al. (1994).

CHAPTER V

SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

Summary

The purpose of the study was to evaluate the cardiovascular responses to exercise while subjects wore the 21 mg Nicoderm nicotine patch. Fifteen apparently healthy adults (9 females and 6 males) who wanted to quit smoking and use the nicotine patch served as subjects. Each subject completed three symptom limited graded exercise tests over a 6 week period utilizing the standard Bruce protocol.

The tests were completed on the initial quit day after being smoke free for at least 6 hours, 2 weeks later while wearing the 21 mg Nicoderm nicotine patch, and 6 weeks after quitting while still wearing the 21 mg Nicoderm nicotine patch. Heart rate, systolic blood pressure, and diastolic blood pressure were measured at rest, during each submaximal stage, and at maximal effort. A 12-lead ECG was monitored continuously throughout all tests. Expired gases were analyzed throughout the tests using a Quinton Q-plex metabolic cart. The results indicate no significant differences in the resting, submaximal, or maximal cardiovascular responses to exercise while wearing the 21 mg Nicoderm nicotine patch. Additionally, no adverse ECG changes were observed. There were significant increases in

maximal VE, maximal TV, and maximal oxygen consumption (L/min) over the 6 week period. A significant increase occurred in the mean subject weight after the 6 weeks.

Conclusions

Based on the results of this study, the following conclusions were reached:

1. The subjects remained smoke free during the study based on the expired carbon monoxide levels measured.
2. Exercising while wearing the 21 mg Nicoderm nicotine patch does not alter the cardiovascular responses to exercise in apparently healthy adults.
3. An exercise prescription can be accurately calculated from a GXT performed while wearing a 21 mg Nicoderm nicotine patch.
4. Smoking cessation results in favorable changes in ventilatory function and aerobic capacity, independent of training.
5. Weight gain is a common finding with smoking cessation despite an unclear reason of why this occurs.

Recommendations

Based on the results of this study, it is recommended that future studies:

1. Investigate the cardiovascular response to exercise while wearing the transdermal nicotine patch in the cardiac population.

2. Investigate the acute cardiovascular response to exercise while wearing the transdermal nicotine patch (i.e., 1-2 days postcessation).
3. Investigate the cardiovascular responses to exercise while wearing the different doses of nicotine patches.

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APPENDIX A
PHYSICIAN LETTER

Dear Physician,

We need your help in recruiting patients for a study evaluating "The Effects of the Transdermal Nicotine Delivery on the Cardiovascular Responses to Exercise". We would like your referral of smokers who wish to quit, plan on using transdermal nicotine patches, and are in otherwise good health. They must be free of known cardiac or pulmonary disease.

The study involves the performance of three symptom-limited graded exercise tests--one before initiating the patch, then two more at two and six weeks with the patch. Oxygen consumption and standard hemodynamic parameters would be measured. Dr. Ward Brown will supervise all GXTs.

From participating in this study, your patients would get three free GXTs, an exercise prescription with heart rate guidelines, and free nicotine patches for ten weeks. You would get a full report from the testing.

This is a thesis study for a Master of Science degree in Adult Fitness and Cardiac Rehabilitation through the University of Wisconsin-LaCrosse. It has been approved by the UW-LaCrosse Internal Review Board. Gundersen/Lutheran IRB has given approval for subject recruitment. Partial funding and Nicoderm brand nicotine patches will be provided by Marion-Merrell Dow.

If you have patients who might be interested in participating in this study, please give them a flyer or have them call Kristi Cadwell RN at 781-8218 or Kathryn Bauer RN at 782-7300 ext.2461. We will also need you to sign a referral form and provide your patient with a prescription for the nicotine patch.

Thank you for your assistance!

Sincerely,

Kristi Cadwell BSN

Ward Brown MD
Cardiology
Gundersen Clinic

John Porcari PhD
Executive Director
Lacrosse Exercise and Health Program

APPENDIX B
SUBJECT FLYER

CONGRATULATIONS ON DECIDING TO STOP SMOKING!

MY NAME IS KRISTI CADWELL. I AM A MASTER'S DEGREE STUDENT
IN ADULT FITNESS AND CARDIAC REHAB AT UW-LACROSSE.
I WOULD LIKE TO INVITE YOU TO PARTICIPATE IN MY THESIS STUDY
WHICH IS EVALUATING THE EFFECTS OF THE NICOTINE PATCH AND
EXERCISE ON HEART RATE AND BLOOD PRESSURE

WHAT DO YOU GAIN BY PARTICIPATING?

THREE FREE PHYSICIAN EVALUATED EXERCISE STRESS TESTS
AN EXERCISE PRESCRIPTION WITH HEART RATE GUIDELINES
FREE NICOTINE PATCHES FOR TEN WEEKS

WHAT IS REQUIRED FROM YOU?

COMPLETING THREE EXERCISE TESTS
A TIME COMMITMENT OF FOUR 1 HOUR MEETINGS
REFRAINING FROM SMOKING FOR 6 HOURS PRIOR TO STARTING ON
"THE PATCH" AND THROUGHOUT THE TESTING PERIOD

IF YOU WISH TO PARTICIPATE OR HAVE QUESTIONS

PLEASE CALL KRISTI CADWELL R.N.

HOME:781-8218

PLEASE LEAVE A MESSAGE IF I AM NOT THERE

OR CALL

GREG HAGEN R.N. EDUCATION DEPARTMENT

SKEMP CLINIC:782-9760

APPENDIX C
INFORMED CONSENT

INFORMED CONSENT

Project Title: The Effects of Transdermal Nicotine Delivery on the Cardiovascular Responses to Exercise

Principle Investigators: Kristi Cadwell R.N.
Ward Brown MD
John Porcari PhD

Purpose

You are being asked to participate in a research study to define the cardiovascular responses to exercise while wearing the Nicoderm nicotine patch.

Explanation of the Exercise Test

You will perform three exercise tests on a motor-driven treadmill. The first test will be on the day you stop smoking, the second will be two weeks after you stop smoking and have worn the 21 mg Nicoderm nicotine patch, and the final test will be completed six weeks after you have quit smoking and have worn the 21 mg Nicoderm nicotine patch. Prior to each exercise test, you will have your carbon monoxide level checked by breathing into a machine and your lung volume capacities measured. The exercise intensity will begin at a level which you can easily accomplish and will be advanced in stages depending on your fitness level. Throughout all tests, your EKG will be monitored continuously with your blood pressure monitored at each stage. Additionally, you will breath through a mouthpiece which will analyze your oxygen consumption continuously. We may stop the tests at any time because of signs of fatigue, abnormal heart rate or blood pressure responses, or EKG abnormalities. Also, you may stop the tests at any time because of personal feelings of fatigue of discomfort.

Risks and Discomforts

There exists the possibility of certain abnormal changes occurring during the tests. They include atypical blood pressure and heart rate responses, fainting, disorders in heart beat, and in rare instances, heart attack, stroke, or death. Every effort will be made to minimize these risks by evaluation of preliminary information relating to your health and fitness and by observations during testing. A cardiologist will be present for all tests. Emergency equipment is available to deal with unusual situations that may arise. In the event of adverse reactions to the Nicoderm nicotine patch, you may wish to exit the research study and pursue other smoking cessation methods.

Responsibilities of the Participant

Information you possess about your health status or previous experiences of unusual feelings with physical effort may effect the safety or value of your exercise tests. Your prompt reporting of feelings with effort during the exercise tests are also of great importance. It is your responsibility to disclose such information from your past or if it occurs during testing. You are responsible to complete three exercise tests and to be honest with your smoking history for this study. Please inform me of the exact time you last smoked a cigarette before the tests. This is important for the validity of this study.

Benefits to be Expected

The results obtained from this study may be useful to the population in general by providing information in regards to the exercise response while wearing the Nicoderm nicotine patch. To you, individually, the tests will help determine your fitness level and an exercise prescription most appropriate for you. As a participant in the study, you will be provided, free of charge, a full ten-week supply of Nicoderm nicotine patches.

Confidentiality of Records

Your identity as a participant in this study will remain confidential. Authorized representatives of the Food and Drug Administration may review your medical records and the information collected during this study to assess compliance with the study protocol and all regulations. You will not be identified personally in any presentations or reports dealing with this research.

Compensation Clause

In the event that you experience any adverse reaction to the Nicoderm patch during the course of the study, you should immediately contact Kristi Cadwell R.N. at 781-8218. In the event of a medical emergency during the testing procedures, immediate medical care will be available at the testing site in the Human Performance Lab via the supervising R.N. and M.D. All other medical care is the responsibility of you, the participant in the study.

Inquires

Any questions about the research study, your rights as a research subject, the testing procedures, or the exercise prescription guidelines are encouraged. If you have any doubts or questions, please ask Kristi Cadwell R.N. or call her at 781-8218.

Freedom of Consent

Your permission to perform these tests is voluntary. You are free to deny consent or stop the tests at any point, if you so desire. However, if you withdraw from the study before all three tests are completed, you will not receive the final 4 to 8 week supply of Nicoderm nicotine patches.

I have read this information, understand the testing procedures that I will undergo and have received a copy of the informed consent. I voluntarily consent to participate in this study.

Signature of Subject

Witness

Date

APPENDIX D
HEALTH HISTORY

HEALTH HISTORY QUESTIONNAIRE

IDENTIFICATION DATA: Please fill in the following information.

Name _____ Date _____

Address _____

City _____ State _____ Zip _____

Date of Birth _____ Age _____

Home phone: _____ Work phone: _____

Physician _____ Clinic _____

Date of last check up _____ Height _____ Weight _____

How many years of formal education have you completed?

No high school High school diploma

College degree Some college

Graduate school

What is your usual occupation?

MEDICATIONS:

What prescribed medicines do you presently take? Why do you take them?

What non-prescription medicines (over the counter) do you take and why?

ALLERGIES: Are you allergic to or have you had a bad reaction to a medication? _____

What is the name of the medication? _____

PERSONAL HISTORY: Have you ever had	Yes	No
Heart attack	[]	[]
Open heart surgery (CABG, valve, other) . . .	[]	[]
Angioplasty	[]	[]
Congenital heart problems	[]	[]
Congestive heart failure (fluid in the lungs) .	[]	[]
Angina/chest pain, pressure or discomfort . . .	[]	[]
Abnormal heart beats (palpitation)	[]	[]
Heart murmurs	[]	[]
Stroke	[]	[]
Rheumatic fever	[]	[]
Thyroid problems	[]	[]
Diabetes (IDDM, NIDDM)	[]	[]
High blood pressure	[]	[]
Swelling of the feet or ankles	[]	[]
Cramping in the lower legs with exertion . . .	[]	[]
Blackouts/fainting spells	[]	[]
Shortness of breath at rest or with exertion .	[]	[]
COPD	[]	[]
Asthma	[]	[]
Bronchitis	[]	[]
Emphysema	[]	[]
Arthritis	[]	[]
Low back pain	[]	[]
Joint pain or swelling	[]	[]
Other orthopedic problems (bad knees/hips, etc.)	[]	[]

If you answered yes to any of the above questions, please elaborate:

HOSPITALIZATIONS: List all your hospitalizations as best as you can.

Type of illness/surgery (please be specific) Year

1. _____
2. _____
3. _____
4. _____

FAMILY HISTORY: Has any BLOOD RELATIVE had any of the following?

	<u>Yes</u>	<u>No</u>	<u>Relation</u>	<u>Age of occurrence?</u>
Diabetes (IDDM, NIDDM)	[]	[]	_____	_____
High cholesterol	[]	[]	_____	_____
High blood pressure	[]	[]	_____	_____
Heart attack	[]	[]	_____	_____
Open heart surgery	[]	[]	_____	_____
Stroke	[]	[]	_____	_____
Lung problems	[]	[]	_____	_____
Cancer	[]	[]	_____	_____
Obesity	[]	[]	_____	_____

HEALTH HABITS:

Do you currently smoke cigarettes? Yes [] No []

How many packs per day? _____

For how many years? _____

Have you ever tried to quit smoking before?

If yes, when and what helped you quit?

What motivated you to try to quit?

Are you bothered with a smoker's cough?

PHYSICAL ACTIVITY HISTORY:

Have you ever had an exercise test? [] Yes [] No

If yes, please answer the following questions:

Location of test: _____

Date of test: _____

If the test was abnormal, please explain.

Are you aware of any physical limitation that would prevent you from exercising regularly? [] Yes [] No

If yes, please specify: _____

Do you currently exercise on a regular basis? [] Yes []

No

If yes, please answer the following questions:

How many times per week do you exercise? _____

How long do you exercise per session? _____

What types of exercise do you perform? _____

If no, what types of exercise are you interested in?

I here by certify all statements provided by me in this questionnaire are complete and true to the best of my knowledge.

Signature _____

Date _____

APPENDIX E
TESTING INSTRUCTIONS

TESTING INSTRUCTIONS

Your treadmill tests have been scheduled for the following times: _____ at _____.
 _____ at _____.
 _____ at _____.

Please do not smoke for at least 6 hours prior to this time. This is very important! (This is your agreed upon quitting time.)

Please do not eat or drink beverages containing alcohol or caffeine for at least 3 hours prior to your test.

Wear loose clothing and comfortable shoes.

Do not engage in heavy physical exercise for 24 hours prior to your test.

Testing Location: Human Performance Laboratory
 Rm.225 Mitchell Hall

If you cannot keep this appointment, please call Kristi Cadwell at 781-8218 (home) or 785-8681 (lab). If I'm not there, please leave a message.

Review quit date.

Review treadmill walking procedure.

Review rating of perceived exertion.

Review nicotine patch application.

Review time commitments.

Review testing instruction.

APPENDIX F
NICOTINE PATCH GUIDELINES

Generic:

Nicotine Transdermal System

Trade Names: Prostep, Habitrol, Nicoderm, Nicotrol

A nicotine patch is a skin patch coated with nicotine. This patch is used to treat nicotine addiction and withdrawal. While wearing the patch, it releases nicotine through the skin into the bloodstream. To get the most success from the patch:

1. It is important that you really want to quit smoking or give up chewing tobacco.
2. Put the patch on a clean, non-hairy, dry area of the skin. The best places are above the elbows on your upper, outer arms or above the waist. Do not use on skin with bruises, cuts, rashes, or sunburn.
3. After 24 hours, remove the patch. Reapply a patch at about the same time each day at a new skin site. Do not return to an "old" skin site for at least one week.
4. Wash you hands after putting on the patch.
5. Some side effects to watch for may be:
 - A. Skin rash. Call your doctor.
 - B. Itching. Place a small amount of an over-the-counter steroid cream under the patch at the next application.
 - C. Headaches, dizziness, upset stomach. Contact your

doctor.

D. Vivid dreams. Try removing the patch at bedtime.

E. Dry mouth. Drink plenty of water. Avoid caffeine.

F. Possible sensitivity to the sun. Wear a sunscreen.

6. DO NOT SMOKE while using the patch. You may get too much nicotine in your body. Smoking while using the patch can cause chest pain, heart attacks, difficulty breathing, and maybe even death.
7. Water will not harm the patch. You can swim, take a bath, use a hot tub, or shower while wearing the patch. If your patch falls off, put on a new one.
8. Fold the used patch in half with the silver sides together, place it inside the opened pouch. Throw the pouch in the trash away from children and pets.
9. Cravings for nicotine begin to disappear within 1-3 hours of putting on the patch.

IF YOU HAVE ANY QUESTIONS ABOUT THE USE OF THIS MEDICATION
PLEASE CONTACT YOUR DOCTOR.

APPENDIX G
BEHAVIOR MODIFICATION

AMERICAN CANCER SOCIETY

QUIT SMOKING

TIP SHEET

The following are the different ways smokers have actually used in retraining themselves to live without cigarettes. Any one or several of these methods in combination might be helpful to you. Check the ones you like and from these develop your own retraining program.

1. Before you quit smoking, try wrapping your cigarettes with a sheet of paper like a Christmas present. Every time you want a cigarette, unwrap the pack and write down what you are doing, how you feel and how important this cigarette is to you. Do this for two weeks and you'll have cut down as well as developed new insights into your smoking.
2. If cigarettes give you an energy boost, try gum, modest exercise, a brisk walk or a new hobby. Avoid eating new foods that are high in calories.
3. If cigarettes help you relax, try eating, drinking new beverages, or social activities within reasonable bounds.
4. When you crave cigarettes, you must quit suddenly. Try

smoking an excess of cigarettes for a day or two before you quit so that the taste of cigarettes is spoiled. Or, an opportune time to quit is when you are ill with a cold or influenza, and have lost your taste for cigarettes.

5. On a 3" x 5" card, make a list of what you like and dislike about smoking. Add to it and read it daily.
6. Make a short list of luxuries you have wanted or items you would like to purchase for a loved one. Next to each item write down the cost. Now convert the cost to "packs of cigarettes". If you save the money each day from packs of cigarettes, you will be able to purchase these items. Use a special "piggy" bank for saving your money or start a "Christmas Club" account at your bank.
7. Never smoke after you get a craving for a cigarette until three minutes have passed since you got the urge. During that three minutes change your thinking or activity. Telephone an ex-smoker or somebody you can talk to until the craving subsides.
8. Plan a memorable date for stopping. You might choose your vacation, New Year's Day, your birthday, a holiday,

the birthday of your child, your anniversary. But, don't make the date so distant that you lose momentum.

9. If you smoke under stress at work, pick a date for stopping when you will be away from your work.
10. Decide whether you are going to stop suddenly or gradually. If it is to be gradual, work out a tapering system so that you have intermediate goals on your way to an "I.Q." day.
11. Don't store up on cigarettes. Never buy by the carton. Wait until one pack is finished before you buy another.
12. Never carry cigarettes about with you at home. Keep cigarettes as far from you as possible. Leave them with someone or lock them up.
13. Until you quit, make yourself a "smoking corner" that is far from anything interesting. If you like to smoke with others, always smoke alone. If you like to smoke alone, always smoke with others, preferably if they are non-smokers. Never smoke while watching television.
14. Never carry matches or a lighter with you.

15. Put away your ashtrays or fill them with objects so they cannot be used for ashes. Plant flowers in them or fill with walnuts. The latter will give you something to do with your hands.
16. Change your brand of cigarettes weekly so you are always smoking a brand of lower tar and nicotine content than the week before.
17. Never say "I quit smoking" because your resolution is broken if you have a cigarette. Better to say "I don't want to smoke". This way, you maintain your resolution even if you accidentally have a cigarette.
18. Try to help someone else quit smoking, particularly your spouse.
19. Always ask yourself, "Do I need this cigarette or is this just a reflex?"
20. Each day try to put off lighting your first cigarette.
21. Decide arbitrarily that you will smoke only on even or odd-numbered hours of the clock.

22. Try going to bed early and rising a half-hour earlier than usual to avoid hurrying through breakfast and rushing to work.
23. Keep your hands occupied. Try playing a musical instrument, knitting or fiddling with hand puzzles.
24. Take a shower. You cannot smoke in the shower.
25. Brush your teeth frequently to get rid of the tobacco taste and stains.
26. If you have a sudden craving for a cigarette, take ten deep breaths, holding the last breath while you strike a match. Exhale slowly, blowing out the match. Pretend the match was a cigarette by crushing it out in an ashtray. Now immediately get busy on some work or activity.
27. Only smoke half a cigarette.
28. After you quit, start using your lungs. Increase your activities and indulge in moderate exercise, such as short walks before or after a meal.

29. Bet with someone that you can quit. Put the cigarette money in a jar each morning and forfeit it if you smoke. You keep the money if you don't smoke by the end of the week. Try to extend this period to a month.
30. If you gain weight because you are not smoking, wait until you get over the craving before you diet. Dieting is easier then.
31. If you are depressed or have physical symptoms that might be related to your smoking, relieve your mind by discussing this with your physician. It is easier to quit when you know your health status.
32. Visit your dentist after you quit and have your teeth cleaned to get rid of the tobacco stain.
33. If the cost of cigarettes is your motivation for quitting, try purchasing a money order equivalent to a year's supply of cigarettes. Give it to a friend. If you smoke in the next year, he cashes the money order and keeps the money. If you don't smoke, he gives back the money order at the end of the year.
34. After you have quit, never face the confusion of "craving a cigarette" alone. Find someone you can call

or visit at this critical time.

35. When you feel irritable or tense, shut your eyes and count backwards from ten to zero as you imagine yourself descending a flight of stairs or imagine you are looking at the horizon as the sun sets in the west.
36. Get out of your old habits. Seek new activities or perform old activities in new ways. Don't rely on old ways of solving problems. Do things differently.
37. If you are a "kitchen smoker" in the morning, volunteer your services to schools or non-profit organizations to get you out of the house.
38. Stock up on light reading materials, crossword puzzles and vacation brochures you can read during your coffee breaks.
39. Frequent places you can't smoke, such as libraries, buses, theaters, swimming pools, department stores or just going to bed during the first weeks you are off cigarettes.
40. Give yourself time to think and get fit by walking 1/2

hour each day. If you have a dog, take him for a walk with you.

DO YOU HAVE A TECHNIQUE TO SHARE WITH OTHER SMOKERS? WE WOULD LIKE TO HEAR FROM YOU AND MAKE THIS INFORMATION AVAILABLE TO OTHERS. SEND IDEAS TO:

Public Education Department
American Cancer Society
Wisconsin Division, Inc.
P.O. box 8370
Madison, WI 53708

APPENDIX H
EXERCISE PRESCRIPTION

Three Phases of Your Exercise Program

1. Warm up (5-10 minutes)

It is very important to warm-up gradually for at least five minutes prior to exercising. This allows for your body to adjust to the increased demands of exercise. You should try to stretch before and after the work out. The stretch should be very gradual. As you are holding the stretch in a comfortable position, the tension should subside. Breathe slowly and deeply in a normal rhythmic pattern. If you have problems with warm-up or specific stretches feel free to ask a student or the Unit Director.

2. Aerobic Phase (15-60 minutes)

This phase will challenge the body's oxygen delivery system. It is important to check your pulse often during exercise to be sure you are working in the proper heart rate range.

Your target heart rate range is _____ to _____/10 seconds

If you are exercising above your target rate you need to slow down. If you are not reaching your target heart rate you will need to work harder. Ideally, you will work up to 30-60 minutes in this heart rate range.

3. Cool-down (5-10 minutes)

After exercise a slow cool-down is necessary. Stopping abruptly may cause blood to "pool" in your legs, thus not returning to the heart, which is still beating

rapidly. This may cause faintness or dizziness. It is best to walk slowly, checking your heart rate periodically until its back to your starting pulse rate.

How to Take Your Pulse

1. Wrist - lightly place the first two fingers of your hand on the thumb side of your other wrist. You will feel the pulsations between the tendons in the center of your wrist and the wrist bone directly down from your thumb. Count for 10 seconds.
2. Neck - Find your Adam's apple with your first two fingers. Move 1-1/2 inches to the right or left side to feel your carotid pulse. Press lightly on only one side of your neck at a time. Count for 10 seconds.

WHY EXERCISE?

What are the benefits of exercise?

Feeling Better

- *gives you more energy
- *helps in coping with stress
- *increases resistance to fatigue
- *helps counter anxiety and depression
- *helps you to relax and feel less tension
- *improves the ability to fall asleep quickly

Looking Better

- *tones your muscles
- *burns off calories to help lose weight
- *helps maintain ideal body weight
- *helps control your appetite

Working Better

- *often contributes to more productivity at work
- *increases your capacity for physical work
- *builds stamina for other physical activities
- *helps increase muscle strength
- *helps your heart and lungs work more efficiently

Exercise Effects on Risk Factors

- *regular exercise is associated with lower blood pressure
- *people who exercise are more likely to cut down or stop smoking
- *people at their ideal weight are less likely to develop diabetes
- *exercise may also decrease insulin requirements
- *research has proven that regular exercise significantly increases the levels of HDL ("good cholesterol") in the blood

Five Common Myths about Exercise

1. Exercise makes you tired.

As their bodies get more in shape, most people feel exercising gives them even more energy than before. Regular, brisk exercise can also help you resist fatigue and stress.

2. Exercise takes too much time.

Regular exercise does not have to take more than 30-40 minutes, three times a week.

3. All exercises give you the same benefit.

All physical activity can give you enjoyment. But, only regular, brisk and sustained exercises such as brisk walking improve the efficiency of the heart and lungs, and burn off calories.

4. The older you are the less exercise you need.

With age we tend to become less physically active, and therefore need to make sure we are getting enough exercise. The benefits from exercise are the same for both young and old.

5. You have to be athletic to exercise.

Most brisk activities do not require any special athletic abilities. In fact, many people have found these activities to be fun and enjoyable.