THE EFFICACY OF CONTINUOUS ECG MONITORING
AMONG LOW, INTERMEDIATE, AND HIGH RISK
PHASE II CARDIAC REHABILITATION PATIENTS

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ABSTRACT

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Continuous electrocardiographic (CECG) monitoring is commonly used in Phase II cardiac rehabilitation programs to detect complications resulting from exercise. It has been suggested that high risk cardiac patients are more likely to experience a serious event during exercise sessions, and therefore should be monitored more closely. Stratifying risk implies that one can predict which patients are at an increased risk of experiencing complications during cardiac rehabilitation. To determine the usefulness of CECG and the application of risk stratification, a retrospective 5-year study of 241 Phase II patients was conducted. Risk stratification, based on AACVPR criteria resulted in 123 (51%) patients classified as low risk, 80 (33%) as intermediate risk, and 38 (16%) as high risk. The Phase II exercise records were examined to identify individuals who had a significant event during Phase II. All documented events which necessitated physician intervention or cessation of the exercise session were recorded. A total of 3,877 exercise sessions were reviewed. Ninety-nine significant events occurred in a total of 69 patients. Of the 99 total events, 57 (57%) were detected through the use of CECG. With regard to risk level, it was found that 29 (24%) low, 27 (34%) intermediate, and 13 (34%) high risk patients had at least one significant event. Chi-square analysis revealed no significant (p > .05) difference in the proportion of patients within each stratified subgroup who experienced events. Sixty-six events occurred within the first 3 weeks of program initiation, with 75% being detected through CECG. These results indicate that CECG may be efficacious for detecting abnormalities during Phase II cardiac rehabilitation, especially during the first 3 weeks of the program. Also, it appears that based on current risk stratification guidelines, it may be difficult to predict which patients will have complications during Phase II cardiac rehabilitation. The findings of this study may be helpful in formulating standardized monitoring guidelines for Phase II cardiac exercisers, and may also aid in revising current risk stratification procedures.
COLLEGE OF HEALTH, PHYSICAL EDUCATION, AND RECREATION
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THESIS FINAL DEFENSE FORM

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The candidate has successfully completed her final oral examination.

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CHAPTER I
INTRODUCTION

Cardiac rehabilitation is a multidimensional approach to restoring and maintaining the health of patients with known or suspected cardiac disease. The ultimate goal of cardiac rehabilitation is to enable patients to return to performing activities of daily living while achieving a state of optimal physical health. The rehabilitation process usually involves a program of multiphased, progressive activity beginning a few days postevent and ideally lasting a lifetime. Exercise training has become a widely accepted, central component in many cardiac rehabilitation programs, and can begin soon after a significant cardiac event (Greenland & Chu, 1988).

Phase II cardiac rehabilitation usually begins within 3 weeks of hospital discharge (Berra, et al., 1991). It is commonly administered on an out-patient basis within a hospital or clinic setting (Pate, et al., 1991). During this time, patients participate in supervised exercise training sessions two or three times per week for up to 36 visits. Most Phase II cardiac rehabilitation programs employ the use of continuous electrocardiographic (ECG) monitoring during at least some portion of the program.

The use of continuous ECG monitoring is a controversial issue in Phase II cardiac rehabilitation. There appears to be a lack of consensus among cardiac rehabilitation providers as to the extent to which ECG monitoring should be used. Some programs use continuous ECG monitoring during each session, while others use it on an intermittent basis. Those in favor of continuous ECG monitoring point to its potential benefit in detecting life threatening arrhythmias or inappropriate heart rate responses (Greenland & Pomilla, 1991). Those opposed to continuous ECG monitoring cite the low incidence of cardiovascular complications during Phase II exercise training (Van
Determining a patient's risk may be helpful in determining the amount of monitoring needed (Balady & Weiner, 1991). Clearly, some patients will require more intensive monitoring during exercise, especially those patients who would be at high risk for complications as a result of exercise. However, risk stratification of patients is not yet a universal practice.

In evaluating the efficacy of cardiac rehabilitation, the cost of long-term ECG monitoring has become a major issue. In an effort to curtail unnecessary medical expenses, insurance companies are revising reimbursement policies regarding the use of continuous ECG monitoring, as well as cardiac rehabilitation in general. Proposed guidelines center around a "risk stratification" model, in which only "high risk" patients would receive formal cardiac rehabilitation services with continuous ECG monitoring. Low and intermediate risk patients may not be candidates for cardiac rehabilitation.

Statement of the Problem

There is an inherent risk for cardiovascular complications among cardiac exercisers in a Phase II setting. These complications include, but are not limited to, cardiac arrest and myocardial infarction. While symptoms often precede these events, continuous ECG monitoring is widely used as a "screening" mechanism for the detection of rhythms that may lead to serious complications. It is not known whether patients of all levels of risk benefit from the application of continuous ECG monitoring. There are very limited data which examine the cardiovascular complication rate associated with Phase II exercise training among a risk stratified population.

Purpose of the Study

The purpose of this study was to retrospectively determine the efficacy of continuous ECG monitoring among low, intermediate, and high risk Phase II cardiac rehabilitation patients. By examining patient records, the questions to be answered were:
1. What percentage of patients were in each risk category?
2. What types of problems occurred during, or as a result of the exercise session(s)?
3. How were the problems detected?
4. What were the outcomes or interventions?
5. Were there differences among the risk groups in the frequency of problems?

Hypothesis

The following hypothesis was tested in this study:
1. There will be no significant difference in the extent to which continuous ECG monitoring benefits low, intermediate, and high risk Phase II cardiac rehabilitation participants.

Assumptions

The following assumptions were made in the context of this study:
1. Testing data, medical records, and progress reports were accurate and reliable.
2. Patients reported all problems to the staff.
3. Patients adhered to routine medical management (i.e. prescribed medications).

Delimitations

The delimitations of this study were:
1. Participants were enrolled in the Gundersen Clinic (La Crosse, WI) Phase II program between 1988-1991.
2. Participants had at least one cardiac event that required hospitalization.
3. Continuous ECG monitoring was used on all patients during all exercise training sessions.
4. Participants had a graded exercise test at discharge or prior to entrance into the Phase II program.
Limitations

The limitations of this study were:

1. The researcher had no control over Phase II data collection.

2. Since 1988-1991, cardiovascular procedures, treatments, and the medical management of cardiac patients may have changed, due to advances in technology and/or greater understanding of coronary artery disease.

Definition of Terms

The following terms were used in this study:

**Angina** - transient chest discomfort resulting from localized ischemia (Pollock, Wilmore, & Fox, 1984).

**Arrhythmia** - a disturbance in the heart's rhythm. A significant arrhythmia is one that requires a change in medical management (Greenland & Pomilla, 1989) or cessation of an exercise session.

**Coronary Artery Bypass Graft (CABG)** - the most common type of cardiac surgery performed, in which a narrowed or obstructed coronary artery is "bypassed" by attaching one end of a vein to the aorta and the other end to an area beyond the blockage (Guyton, 1991). Internal mammary arteries are also used to bypass blockages. This procedure is used to improve blood flow to the heart muscle.

**Ejection Fraction (EF)** - the amount of blood ejected from the left ventricle during systolic contraction. Normal EF is 55-70%.

**Electrocardiogram (ECG)** - a record of the heart's electrical activity, which can be visualized on an oscilloscope or recorded on paper (Dubin, 1985).

**Graded Exercise Test (GXT)** - a diagnostic tool that evaluates one's physiological, electrical, and clinical responses to exercise. A GXT is often required for cardiac patients upon hospital discharge or prior to entrance into a Phase II program. Training regimens are often formulated from GXT results.

**Heart Rate (HR)** - the number of ventricular contractions per minute. Heart rate is often "targeted" within a specific range the exercise training of cardiac patients.
Hypertension - a condition in which the blood pressure (BP) is chronically elevated above normal levels (Pollock et al., 1984). Ideal BP is considered to be 120 mm Hg systolic over 80 mm Hg diastolic.

Hypotension - an abnormal condition in which the blood pressure is not adequate for normal perfusion and oxygenation of the tissues (Urdang & Swallow, 1983).

Ischemia - decreased blood supply to a body organ or part (Urdang, 1983). In the heart, ischemia results from diminished coronary blood flow (Guyton, 1991).

METs - a weight-relative unit of measurement of oxygen uptake expressed in milliliters of oxygen per kilogram of body weight per minute. One MET is the equivalent of 3.5 ml/kg/min (Pate et al., 1991). METs are commonly used to quantify functional capacity and give a basis for exercise prescription.

Myocardial Infarction (MI) - the process in which a coronary artery becomes totally obstructed and blood flow beyond the obstruction ceases. The muscle area around the obstruction has either no flow or so little flow that it cannot sustain cardiac muscle function and is thereby infarcted (Guyton, 1991).

Phase I - in-patient cardiac rehabilitation, involving education, exercise therapy, and counseling (Berra et al., 1991).

Phase II - out-patient cardiac rehabilitation, usually within a medical center or clinic. It involves light to moderate endurance activities with approximately 3 supervised exercise sessions per week, for up to 3 months (Pollock et al., 1984).

Phase III - extended out-patient and exercise maintenance (Berra et al., 1991).

Risk Stratification - a means of categorizing levels of risk (low, intermediate, and high) among cardiac patients based on clinical variables.

ST Segment - the part of an ECG tracing that is used to diagnose myocardial ischemia or infarction (Blair, Painter, Pate, Smith, & Taylor, 1988)
CHAPTER II
REVIEW OF THE LITERATURE

Introduction

Electrocardiographic monitoring is a common practice in the Phase II cardiac rehabilitation setting. It has been used routinely to detect adverse responses to exercise and is thought to be helpful in the medical management of patients (Greenland & Pomilla, 1989). However, the universal use of continuous ECG monitoring among Phase II exercisers has been questioned. Past studies suggest that ECG monitoring may not be necessary for patients exercising in supervised settings (Hossack & Hartwig, 1982; Van Camp & Peterson, 1986). In addition, identifying the risk status of a patient appears to be helpful in determining who would benefit most from intensive monitoring. Continuous ECG monitoring also adds to the expense of a Phase II program, making cost another issue.

Types of Monitoring

The heart's electrical activity can be monitored in various ways. Most Phase II programs use a single-lead telemetry monitoring system. This allows the patient to wear a wireless monitor which transmits an ECG through the air to a receiver. The receiver, equipped with an oscilloscope, provides a visual representation of the heart's rate and rhythm. Electrocardiograms can also be obtained by using the paddles of certain monitor defibrillators (Blair et al., 1988). In this so-called "quick look" method, the paddles are used in place of electrodes. Again, a visual representation on a small screen allows the clinician to determine heart rate and rhythm at a given point in time. Telemetry monitors and defibrillators are usually equipped with "strip" paper recorders that enable the user to record (on paper) an ECG if desired. Both monitoring methods
are helpful in observing arrhythmias and ST-segment changes during Phase II cardiac rehabilitation (Pate et al., 1991).

Exercise activity can also be monitored through a transtelephonic system. Transtelephonic ECG monitoring allows a patient to exercise at home (or in another facility) while their ECG activity is monitored in a clinical setting via a telephone line. This method of monitoring is especially useful in assessing patients between discharge from the hospital and entrance into a formal Phase II program (Fardy, Yanowitz, & Wilson, 1988). Since Phase II participation is not always convenient or financially feasible, transtelephonic ECG monitoring is a viable alternative to formal cardiac rehabilitation services. In addition, Squires, Miller, Harn, Micheels, & Palma (1991) found transtelephonic monitoring to be safe in that the equipment is accurate and reliable (only one instance of system failure was observed in a total of 1,865 exercise sessions).

Electrocardiographic monitoring of cardiac patients during exercise is recommended by many cardiovascular specialists who believe it is helpful in detecting arrhythmias that are not detected during exercise testing (Mitchell, Franklin, Johnson, & Rubenfire, 1984). However, the length of monitoring varies among Phase II programs. Some programs use continuous ECG monitoring for all patients, during every exercise session. Some programs use ECG monitoring on an intermittent basis. Other programs use a graduated approach to ECG monitoring--that is, the patient is monitored continuously for the first few weeks and then intermittently or as needed for the remainder of the program. In order to formulate sound guidelines, data need to be gathered which indicate what type of monitoring is most advantageous in the Phase II environment, and what types of patients would benefit most from it.

Safety Issues

The safety of cardiac rehabilitation programs has been studied extensively in the last 15 years. Exercise ECG monitoring is one factor that contributes to the safe
Continuous ECG monitoring allows the detection of arrhythmias, ST-segment changes, and determination of exercise heart rate (Greenland & Chu, 1988). In a 1987 survey by Cole (Diagnostic and Therapeutic Technology Assessment), 87% of a panel of physicians supported the use of telemetry ECG as an essential component of a safe and effective exercise regimen. In addition, the utilization of cardiac telemetry has been thought to minimize the complication rate among cardiac exercisers.

One of the earliest studies (Haskell, 1978) examined the complication rate among 30 cardiac rehabilitation programs in North America between 1960-1977. Complications were reported as fatal or nonfatal, and included MI, cardiac arrest, and other. Information was collected for a total of 1,629,634 patient hours of supervised exercise. It was found that complication rates were lower in programs that used continuous ECG monitoring during exercise (1 event per 117,333 patient hours, for a total of 3 events) as compared to programs that did not use continuous ECG monitoring (1 major complication every 22,028 patient hours).

A more recent and comprehensive study by Van Camp and Peterson (1986) examined the safety of 167 randomly selected cardiac rehabilitation programs between the years 1980-1984. They found no significant difference in the complication rate among programs that used various degrees of continuous ECG monitoring. For an estimated 2,251,916 patient hours, cardiac arrests occurred at a rate of 8.9 per million patient hours of exercise. Myocardial infarction (in this study all were nonfatal) occurred at a rate of 3.4 per million patient hours of exercise. The authors concluded that there is a low risk for cardiovascular complication in current cardiac rehabilitation programs regardless of the extent of ECG monitoring.

Greenland and Pomilla (1989) investigated the data of Haskell as well as that of Van Camp and Peterson. Despite differences between the two investigations, Greenland and Pomilla cite a lack of empirical evidence that substantiates the worth of continuous ECG monitoring. They agree that medical supervision enhances the
safety of cardiac exercisers, but believe that continuous ECG monitoring has not proven to be the element that provides the additional safety. Based on their own observations, they found that cardiac events that occur during rehabilitation and require medical intervention are usually detected by changes in heart rate, blood pressure, or by signs and symptoms (and not ECG monitoring). Therefore, they estimate that fewer than 5% of patients benefit from continuous ECG monitoring with regard to medical management.

Hossack and Hartwig (1982) collected data from close to 2,500 patients (over a 13 year period) who participated in the CAPRI rehabilitation program. They reported 25 episodes of cardiac arrest associated with exercise training. Even though all persons were resuscitated, the authors suggest a significant element of risk for cardiac arrest in patients participating in an exercise program. The authors imply that after 1976, greater emphasis has been placed on the use of ECG monitoring and supervision during exercise training. These two factors are thought to have contributed to a lower cardiac arrest rate in recent years.

Fardy, Doll, Taylor, & Williams (1982) analyzed progress reports of 100 patients who completed a 12 week program of Phase II cardiac rehabilitation. In total, it was found that 54% of the sample studied exhibited arrhythmias at some point during the 12 week program. They found that an average of 16 patients per week experienced a serious untoward event (more than 5 premature ventricular contractions per minute, ventricular bigeminy or trigeminy, ventricular coupling, chest pain, or syncope) during the first 7 weeks. During the remaining 5 weeks, an average of 13 patients per week experienced a serious event. The authors considered the rates of serious events high enough to warrant monitoring all patients for at least 7 weeks, preferably 12.

Mitchell et al. (1984) agree that ECG monitoring during exercise training of cardiac patients is helpful for detecting arrhythmias that were not present during a single monitoring session, as in the case of exercise testing. But they question the need for continuous monitoring throughout a 12-week program. In their study of 177 patients,
12 individuals developed arrhythmias that were not present during initial exercise testing. Eleven (91%) exhibited abnormalities during the first 3 weeks of the program with only one patient developing an arrhythmia after 3 weeks. Therefore, the authors imply that only a very small percentage of patients would actually benefit from continuous ECG monitoring after the first 6 weeks of a rehabilitation program.

The safety of cardiac rehabilitation services was reviewed by Greenland and Chu (1988). Based on the information from the above studies, they concluded that supervised programs "appear to be safe for the average patient...". In discussing the role of continuous ECG monitoring, they concluded that the longer one performs ECG monitoring, the more likely abnormal rhythms or ischemic changes will be detected. They acknowledged the need for further study with regard to what type of patients would require longer, intensive ECG monitoring.

**Determining Risk**

Cardiac rehabilitation can be a safe and effective method of improving the functional status of persons with cardiac disease. It must be applied to patients with the goal of optimal health benefit and minimal risk (Balady & Weiner, 1991). To facilitate proper medical management of cardiac patients, risk should be assessed prior to entrance into an exercise program. Risk assessment or risk stratification involves a detailed and thorough examination of a patient's medical history, clinical diagnosis, and current health status. It is helpful in determining 1) the appropriateness of an individual for exercise training, 2) the effectiveness of the patient's current medical management, and 3) the degree of monitoring and supervision necessary during exercise sessions (Balady & Weiner, 1991).

Risk stratification is not an entirely new concept in cardiac rehabilitation. However, it has not been until recently that guidelines for determining risk have been established. The American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) recommends determining risk levels based on clinical variables as seen in Table 1 (Berra, et al., 1991). These clinical determinants of risk
coincide with the recommendations of the American College of Cardiology (ACC) and the American Heart Association (AHA). The rationale for monitoring and supervision should then be guided according to a patient's risk characteristics. Supervision involves both the observation of the patient's general appearance and the monitoring of heart rate and rhythm (Van Camp, 1991).

Table 1. AACVPR's guidelines for risk stratification

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<th>Risk Level</th>
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| Low          | Uncomplicated clinical course in hospital  
No evidence of myocardial ischemia  
Functional capacity > 7 METs  
Normal left ventricular function (EF > 50%)  
Absence of significant ventricular ectopy |
| Intermediate | ST-segment depression > 2mm flat or downsloping  
Reversible thallium defects  
Moderate to good left ventricular function (EF > 35%)  
Changing pattern of or new development of angina |
| High         | Prior MI or infarct involving > 35% of left ventricle  
EF < 35% at rest  
Fall in exercise systolic BP or failure of systolic BP to rise more than 10 mm Hg on GXT  
Persistent or recurrent ischemic pain 24 hours or more after hospital admission  
Functional capacity < 5 METs with hypotensive BP response or > 1 mm ST-segment depression  
Congestive heart failure syndrome in hospital  
> 2mm ST-segment depression at peak heart rate < 135 beats per minute  
High-grade ventricular ectopy |

Based on the above guidelines, many cardiovascular specialists advocate the use of exercise telemetry for patients who are considered high risk (Berra et al., 1991;
Greenland & Chu, 1988; Greenland & Pomilla, 1989; Parmley, 1988). These patients are considered to be at greatest risk for complications resulting from exercise.

It has been suggested that intermediate risk cardiac exercisers may benefit from short-term continuous ECG monitoring (Buchal, Franklin, & Gordon, 1991). An 8-year retrospective study was done to assess the value of continuous ECG monitoring in a single center's Phase II program. Of 570 patients, 14% (n = 80) met "intermediate risk" criteria. Of the 80 patients, 6% (n = 5) demonstrated significant arrhythmias that were not present during the entry GXT. Two of the patients required changes in their medical management; three patients were symptomatic; and two had their exercise sessions discontinued due to the arrhythmias. The authors conclude that short-term ECG monitoring is useful for detecting abnormalities that may lead to a change in medical management or cessation of exercise.

Medically monitored and supervised programs may not be necessary for low risk patients. Patients with uncomplicated Ml's or CABG's whose functional capacity 3 weeks post event is 8 METs or more, or those who are asymptomatic at rest and can exercise to peak workloads equivalent to most recreational and vocational activities (approximately 7 METs) are considered to be at lowest risk for complications during exercise (Greenland & Chu, 1988). These patients may benefit from supervised exercise sessions, but more than likely do not need intensive ECG monitoring.

In determining risk, the GXT is a powerful diagnostic tool. Because of its potential for detecting abnormal responses to exercise, a GXT is often required prior to entrance into a cardiac rehabilitation program. It can detect three important high risk characteristics: myocardial ischemia, left ventricular dysfunction, and arrhythmias (Weld, King-Lee, Bigger, & Rolnitzky, 1981). Significant cardiac abnormalities during the GXT indicate the need for further evaluation and treatment as well as for supervision and ECG monitoring during exercise training sessions (Leon et al., 1990). In addition, GXT's help identify low risk patients who can be spared additional medical interventions and physical restrictions (Nielsen, Mickley, Damsgaard, & Froland, 1990).
Exercise testing is also useful in estimating functional capacity or the exercise MET level of patients. These measurements in turn aid the clinician in prescribing a safe and appropriate exercise prescription.

Cost Considerations

Those individuals who are critical of the use of continuous ECG monitoring for Phase II programs cite its expense (Byl, Reed, Franklin & Gordon, 1988; Greenland & Pomilla, 1989). According to Parmley (1986), ECG monitoring is the most costly of the services provided by a cardiac rehabilitation program. The equipment used for continuous ECG monitoring is generally costly and involves continuous maintenance. In addition to equipment expenses, staff supervision is said to contribute to the cost of continuously monitored programs (Greenland & Pomilla, 1989).

Byl et al. (1988) examined the impact of ECG monitoring on the cost of Phase II programs. In a survey of 1,100 centers, they found that the average cost of a 10-12 week monitored program to be approximately $1,300 per patient. They also cite apparent "abuses" of excessive monitoring, which subsequently leads to excessive costs.

Greenland and Pomilla (1989) estimated the cost of ECG monitoring in a 12 week Phase II program (3 sessions per week) to be approximately $1,620, based on a calculated average of $45 per session. If a center accommodated 100 patients per year, the cost of ECG monitoring would exceed $125,000. In an 8 year period, the administrators of that program would spend over $1 million for indiscriminately monitoring all patients. They conclude that in light of the documented low risk of death among cardiac exercisers, continuous ECG monitoring of all patients cannot be justified.

Criticisms of costly ECG monitoring may be unfounded. Cardiac rehabilitation in general is expensive, independent of the use of continuous ECG monitoring. Initially, equipment costs will be significant. However, the maintenance and supplies involved with continuous telemetry monitoring are minimal, from an operational standpoint.
Staff supervision of exercising cardiac patients is a necessity, and constitutes the major cost of a cardiac rehabilitation program.

The cost/benefit issue is also being addressed by insurance providers. Payment for services such as cardiac rehabilitation differs from state to state, and policies are constantly changing (Blair et al., 1988). Due to the current controversy involving the role of continuous ECG monitoring, it is likely that insurance providers will be further investigating its use. Thus, for budgetary reasons and reimbursement practices, it seems imperative to use discretion when considering the application of continuous ECG monitoring.

Summary

Many factors must be taken into account when considering the role and application of continuous ECG monitoring in the Phase II setting. While it is clear that ECG monitoring is an essential component of a cardiac rehabilitation program, there is a lack of consensus as to what degree of monitoring is needed. The safety of the cardiac exercisers is of utmost importance. However, it is questionable whether continuous ECG monitoring enhances the safety element. Risk stratification is important in delineating levels of risk among cardiac exercisers. Once a patient's risk is known, guidelines for monitoring requirements may be better formulated. Lastly, cost is a major consideration. Continuous ECG monitoring contributes to the expense of a program. With escalating medical care costs, insurance providers can be expected to more closely scrutinize unnecessary procedures, ultimately revising reimbursement practices.
CHAPTER III
METHODOLOGY

Introduction

This study was done in cooperation with the Gundersen/Lutheran Medical Center's (La Crosse, WI) Wisconsin Heart Institute and Medical Records Departments. Data were collected from the records of patients who participated in the Phase II program from January 1988 through January 1992. Collected data included information that was pertinent to the question of the need for continuous ECG monitoring. Of particular interest was the incidence of cardiac events that were detected through ECG monitoring and/or supervision during exercise sessions.

This study attempted to identify the types of cardiac events that occurred, the frequency and severity of these events, and the medical intervention (if any) that occurred as a result of the event (i.e. changes in medications, termination of the exercise program, surgery, etc.).

Patients were stratified into risk categories according to AACVPR guidelines. The frequency of significant events among the different risk levels were analyzed to determine if any differences existed and to determine the efficacy of continuous ECG monitoring.

Hospital Approval

This study was done with permission from the Gundersen/Lutheran Medical Center. A proposal was submitted to the Institutional Review Board (IRB) of the Gundersen Medical Foundation LTD. Data collection commenced upon approval of this proposal and acceptance of the methods and procedures of this study.

Sample Population

The population studied included patients between the ages of 25 and 85 who
participated in the on-site Cardiac Rehabilitation Phase II program between 1988-1992. The Clinic's Phase II program is a multistation program involving treadmill walking, stationary cycling, stair-climbing, and upper body exercises such as rowing, shoulder wheel, and arm ergometry. Continuous ECG monitoring was used for all patients during exercise sessions.

**Data Collection**

The medical records of patients who participated in the Phase II program were reviewed by the investigator on hospital premises and recorded on a data sheet (see Appendix A). All information was kept confidential. Basic demographic information was gathered for the purpose of identifying the study population. Exact information taken from each patient's medical record included patient identification, age, and sex. Other information gathered from the medical records included:

1. Diagnosis (reason for referral to Phase II)

2. GXT results, including MET level, ECG, and/or BP abnormalities

3. LV function, including EF (from ventriculogram or echocardiogram)

4. Medical history, especially previous cardiac events

5. Number of sessions completed in Phase II

6. Medications taken while participating in Phase II

7. HR and BP ranges during exercise sessions

8. Ratings of Perceived Exertion (RPE) during exercise sessions

9. Significant events/problems occurring during or as a result of Phase II exercise session(s)

10. Method of detection of events (i.e. monitoring, signs and symptoms, etc.)

11. Medical interventions resulting from events during Phase II
Risk Stratification

Based on the information taken from medical records, the risk level of each patient was determined according to the clinical variables outlined by the AACVPR (see Table 1).

Statistical Analysis

Descriptive statistics were used to define the subject population. A chi-square analysis was used to detect differences in the occurrence of events during Phase II among the different risk groups. Alpha was set at .05 to achieve statistical significance.
CHAPTER IV
RESULTS AND DISCUSSION

Introduction

The purpose of this study was to retrospectively determine the efficacy of continuous ECG monitoring among low, intermediate, and high risk Phase II cardiac rehabilitation patients. This chapter provides a statistical analysis of the data and a discussion of the results in relation to current clinical practices involving risk stratification and the application of ECG monitoring. The chapter is divided into three major sections. The first will provide a description of the subject population. Secondly the important findings of the study are presented. Finally, a discussion of the results will conclude this chapter.

Subjects

The study was a 5-year retrospective examination of 241 patients who participated in Gundersen Clinic's (La Crosse, WI) outpatient Phase II program. Data were gathered from both male and female patient records. The descriptive characteristics of the 192 male and 49 female subjects are presented in Table 2.

All patients had an entry diagnosis of PTCA, CABG, and/or MI, or other (including valve surgery or valve/bypass procedure). A summary of patient diagnoses is presented in Table 3. The majority of patients were post CABG, or MI, with the percentages similar between males and females.

A total of 3,877 exercise sessions were reviewed. Each patient participated in an average of 16.2 sessions. The exercise program was multistationed, involving treadmill walking, rowing, arm ergometry, shoulder wheel, stair-climbing, and cycle ergometry. Typically, the program met three times weekly, for 40-60 minutes per session.
Table 2. Descriptive characteristics of subjects (N = 241)

<table>
<thead>
<tr>
<th></th>
<th>Age (yrs)</th>
<th>Height (cm)</th>
<th>Weight (kg)</th>
<th>EF (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male (n = 192)</td>
<td>58 ± 10</td>
<td>179 ± 45</td>
<td>86 ± 14</td>
<td>58 ± 13</td>
</tr>
<tr>
<td>Female (n = 49)</td>
<td>62 ± 10</td>
<td>167 ± 45</td>
<td>72 ± 18</td>
<td>60 ± 15</td>
</tr>
</tbody>
</table>

Note: All values represent mean ± standard deviation.

Table 3. Diagnoses of males (n = 192) and females (n = 49)

<table>
<thead>
<tr>
<th></th>
<th>Males</th>
<th>Females</th>
</tr>
</thead>
<tbody>
<tr>
<td>CABG</td>
<td>111 (58%)</td>
<td>23 (47%)</td>
</tr>
<tr>
<td>MI</td>
<td>50 (26%)</td>
<td>14 (29%)</td>
</tr>
<tr>
<td>Both</td>
<td>12 (6%)</td>
<td>5 (10%)</td>
</tr>
<tr>
<td>PTCA</td>
<td>3 (2%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Other</td>
<td>16 (8%)</td>
<td>6 (12%)</td>
</tr>
<tr>
<td></td>
<td>192</td>
<td>49</td>
</tr>
</tbody>
</table>

Determination of Risk

Patients were stratified into risk categories according to AACVPR guidelines. These results are presented in Table 4. Overall, 51% of patients were classified as low risk, 33% as intermediate risk, and 16% as high risk, with the percentages being similar for males and females.
Table 4. Risk categories of male and female subjects

<table>
<thead>
<tr>
<th></th>
<th>Low</th>
<th>Intermediate</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>97 (51%)</td>
<td>67 (35%)</td>
<td>28 (14%)</td>
</tr>
<tr>
<td>Female</td>
<td>26 (53%)</td>
<td>13 (27%)</td>
<td>10 (20%)</td>
</tr>
<tr>
<td></td>
<td>123 (51%)</td>
<td>80 (33%)</td>
<td>38 (16%)</td>
</tr>
</tbody>
</table>

Documentation of Events

Subjects in the study were telemetry-monitored during all exercise sessions. A total of 3,877 exercise sessions were reviewed with each subject participating in an average of 16.2 sessions. Events which necessitated physician intervention and/or cessation of the exercise session were recorded. These included episodes of chest/arm/shoulder discomfort, shortness of breath, dizziness, new arrhythmias or arrhythmias increasing with exercise, and inappropriate BP and/or HR responses. A total of 99 significant events were recorded (see Table 5). Of the 99 events, 57 (57%) were detected through the use of continuous ECG monitoring. The remainder (43%) were detected through BP monitoring, abnormal symptoms, or patient complaints.

Of the 99 events, 66 (66%) occurred within the first 3 weeks of program initiation, with 75% of those events being detected through continuous ECG monitoring. The remaining 33 events occurred during weeks 4-12, with 55% being detected via continuous ECG monitoring.
Table 5. Description of events necessitating intervention

<table>
<thead>
<tr>
<th>Event (total #)</th>
<th>Type of Abnormality</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>New atrial arrhythmia</td>
<td>ER, change in meds</td>
</tr>
<tr>
<td>17</td>
<td>Ventricular tach</td>
<td>Admit, change in meds Holter monitor, echo</td>
</tr>
<tr>
<td>17</td>
<td>New or increasing ventricular ectopy</td>
<td>Holter monitor, change in meds, lab work</td>
</tr>
<tr>
<td>11</td>
<td>Inappropriate HR response</td>
<td>Change in meds, lab work</td>
</tr>
<tr>
<td>17</td>
<td>Symptomatic (anginal in nature)</td>
<td>Change in meds, admit, CABG, angiogram</td>
</tr>
<tr>
<td>11</td>
<td>Hypertension</td>
<td>Change in meds, GXT</td>
</tr>
<tr>
<td>3</td>
<td>Symptomatic (&quot;palpitations&quot;)</td>
<td>Admit, change in meds, Holter monitor</td>
</tr>
<tr>
<td>1</td>
<td>ST segment elevation</td>
<td>Further evaluation</td>
</tr>
<tr>
<td>1</td>
<td>ST segment depression</td>
<td>GXT</td>
</tr>
<tr>
<td>5</td>
<td>Dizziness</td>
<td>Change in meds, Holter monitor</td>
</tr>
<tr>
<td>3</td>
<td>Nausea</td>
<td>Lab work, change in meds, X-ray</td>
</tr>
<tr>
<td>2</td>
<td>Shortness of breath</td>
<td>Pulmonary studies</td>
</tr>
<tr>
<td>1</td>
<td>Hypotension</td>
<td>Change in meds</td>
</tr>
<tr>
<td>1</td>
<td>Episode of blindness</td>
<td>Further evaluation</td>
</tr>
</tbody>
</table>
Frequency of Events Among Risk Groups

Risk stratification is a method of determining a cardiac exerciser's likelihood of experiencing an untoward event during cardiac rehabilitation exercise sessions. It implies that one can predict which patients are at greater risk for an event. Using AACVPR's 1991 guidelines, patients were stratified into risk categories. As previously mentioned, 99 significant events occurred. These occurred in 69 different patients.

It was found that 29 (24%) low, 27 (34%) intermediate, and 13 (34%) high risk patients had at least one significant event. Chi-square analysis revealed no significant \( p > .05 \) difference in the proportion of patients within each stratified subgroup who experienced significant events during the Phase II program.

Twenty one of 69 patients had multiple events during the course of the Phase II program. There was no significant \( p > .05 \) difference in the proportion of patients within each stratified subgroup who had multiple events; 9 (31%) were low risk, 8 (30%) were intermediate risk, and 4 (31%) were high risk.

ECG Detection of Events Among Risk Groups

Of the 99 significant events which were reviewed in the present study, 39 events were experienced by low risk patients, 41 by intermediate risk, and 19 by high risk. Continuous ECG monitoring detected 25 (64%) of the 39 events in low risk patients, 24 (59%) of the 41 in the intermediate risk patients, and 8 (42%) of the 19 events in the high risk group. Chi-square analysis identified no significant \( p > .05 \) difference among the risk categories in how the event was detected.

Hypothesis

The hypothesis of this study stated that there would be no significant difference in the extent to which continuous ECG monitoring benefits low, intermediate, and high risk Phase II cardiac rehabilitation participants. The results of the study found that the percentage of events documented within each category were similar, thus failing to reject the null hypothesis.
Discussion

This section discusses the significance of the findings in relation to related literature. Areas to be discussed include the application of ECG monitoring in general, and with regard to risk stratification. The limitations of risk stratification will also be discussed.

ECG Monitoring

The debate continues as to the role of ECG monitoring in cardiac exercise programs. The optimal amount of monitoring is uncertain (Fardy et al., 1982). Also, the universal application of monitoring cardiac exercisers is questionable. It has been estimated that 5% or fewer patients benefit from continuous ECG monitoring during cardiac rehabilitation (Greenland & Pomilla, 1989). The present study found that 41 (17%) of the 241 participants benefitted from continuous ECG monitoring. It was also found that continuous ECG monitoring was most useful for detecting abnormal responses to exercise during the initial 3 weeks of the program. Similarly, Fardy et al. (1982) reported an arrhythmia rate of 16% per week for the first 7 weeks of an exercise program, decreasing to 13% during the final 5 weeks (i.e. 13% had the initial arrhythmia during the last 5 weeks of the program). In a study by Mitchell et al. (1984), 12 of 177 cardiac patients developed abnormal arrhythmias which were not evident during initial exercise testing. Eleven of the 12 (91%) abnormalities were detected during the first 3 weeks of the program. Conflicting findings were found by Dolatowski and co-workers (1983). They documented the prevalence of significant arrhythmias during a 12-week cardiac rehabilitation program. Of 30 patients, 88% experienced significant arrhythmias. In this study, a greater number of events occurred during the second 6 weeks of the program as compared to the first 6 weeks of the program. These events were documented using a combination of ambulatory 24-hour monitoring, GXT’s, and monitored exercise training. Thus, the results are not truly comparable to the present study, in which only exercise electrocardiography was used to detect events.
The present study's results imply that continuous ECG monitoring may be efficacious for detecting abnormalities especially during the first 3 weeks of a Phase II program. Despite Dolatowski's results, the present study and previous research indicates that only a small percentage of patients may benefit from continuous ECG monitoring during the latter portion of a 12-week cardiac rehabilitation program.

**Risk Stratification**

Risk stratification is a process used to determine a patient's risk for adverse responses to exercise. Clinical variables and the patient's medical history can be used to describe low, intermediate, or high risk categories. It has been suggested that risk stratification can aid in determining the amount of monitoring a cardiac exerciser will need (Balady & Weiner, 1991). Risk stratification also implies that one can predict which type of patient is more predisposed to experiencing an untoward event during cardiac rehabilitation sessions.

Currently, risk stratification guidelines have been proposed by the American College of Cardiology (ACC), American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), and the American College of Sports Medicine (ASCM). The clinical variables that are used to delineate each risk subgroup are similar for all three groups. The first step in risk stratification involves a thorough review of the patient's medical history, clinical course, physiological variables, and test results. The patient's risk level is then determined and ideally should assist the clinician in providing the appropriate supervision and monitoring during exercise training.

Accurately stratifying risk according to current guidelines is difficult, as many of the determinants are dependent on standard, universal tests, particularly maximal GXT's, measurements of left ventricular function, and quantification of myocardial injury. The limitations of risk stratification are evident when potentially significant patient information is not known or is nonexistent. In the present study, several problems were encountered when determining risk using AACVPR guidelines. Many of the clinical variables can only be met under certain circumstances. For instance, a
patient's functional capacity is considered when determining risk. A patient's functional capacity can only be accurately measured during a maximal exercise test. At this time, it is not routinely done prior to entrance into a Phase II program. In the present study, patients were sub-maximally tested upon hospital discharge to a predetermined 4-6 MET level. Therefore, MET levels (which quantify maximal functional capacity) as denoted in the guidelines were not applicable. Another variable related to GXT results involves a drop in systolic BP or failure of systolic BP to rise more than 10 mm Hg during the exercise test. Many patients may have had flat BP responses because the discharge GXT was submaximal, or because they were on antihypertensive medicine. In addition, ST-segment depression of 1-2 mm is used as a determinant of risk. Considering the fact that many postevent medicines preclude accurate interpretation of the ST segments, this variable was not applicable in many cases.

Left ventricular function is another important clinical variable. Left ventricular function was known for the majority of the patient's in the present study, however 29 patients did not have documented left ventricular ejection fractions. Another criteria which delineates high risk is a quantification of left ventricular damage. A myocardial infarction involving 35% or more of the left ventricle would place a patient in the high risk category. Left ventricular damage was not quantified on test results or in the patient's history in any of the subjects in the present study.

Significant ventricular ectopy is another risk determinant. However, it is not clear when this variable is of value in delineating risk. The present guidelines do not indicate whether a history or a single episode of high grade ventricular ectopy during hospitalization and/or discharge GXT translates into more risk.

Events Among Risk Groups

The present study found no significant differences in the percentages of low, intermediate, and high risk cardiac exercisers who experienced a significant event in the Phase II setting. At this time, there are very limited data that examine the
complication rate associated with Phase II exercise training among the different risk groups. Most of the literature endorses the use of continuous ECG monitoring for high risk exercisers primarily as a "safety net" (Cole, 1987; Greenland & Chu, 1988). However, the present study did not demonstrate a significant difference in the percentage of events that continuous ECG monitoring detected among the risk subgroups. It appears that based on current risk stratification guidelines, it may be difficult to predict which patients will experience events during Phase II cardiac rehabilitation.

**ECG Monitoring Among Risk Groups**

Intuitively, it would seem likely that the use of telemetry monitoring would allow early detection of rhythm disturbances associated with the cardiac patient's exercise training. Continuous ECG monitoring is commonly thought to be necessary only for high risk cardiac exercisers (Greenland & Chu, 1988). Again, there are limited data to support this notion. The question remains as to whether continuous ECG monitoring benefits high risk cardiac exercisers more than low or intermediate risk cardiac exercisers. The present study did not find a significant difference in the extent to which continuous ECG monitoring detects abnormalities among the risk subgroups during Phase II exercise sessions. It was found that patients in the low risk category had 64% of total events detected through continuous ECG monitoring versus 59% of intermediate risk events and 42% of high risk events. Thus, it seems unlikely that risk stratification is an accurate predictor of who will benefit from monitored exercise sessions.

**Timing of Events**

Results from the present study indicate that significant events during Phase II cardiac rehabilitation are more likely to occur within the first 3 weeks of program initiation. Therefore, closer supervision including the use of continuous ECG monitoring is justifiable and recommended for the first 3 weeks of a Phase II program.
Implications for Cardiac Rehabilitation Programs

The results of the present study have several important implications for present day cardiac rehabilitation programs. First, accurately stratifying risk using current guidelines is difficult. Delineating risk for cardiac rehabilitation purposes will be a challenge until discharge (or entry) GXT's are standardized and clinical variables are more clearly defined. Secondly, it seems imperative that monitoring guidelines be established. It appears that the process of risk stratification may assist in determining risk of subsequent cardiac mortality, but may not be useful in determining the degree of monitoring a cardiac exerciser needs. The present study found that the majority of events that occurred in the Phase II setting happened within the first 3 weeks, without regard to risk classification. In other words, the present study strongly supports the necessity of continuous ECG monitoring of all Phase II patients for the first 3 weeks. This suggestion has strong implications for third-party reimbursers, who have recently proposed cost-cutting policy revisions which would limit reimbursement for monitored cardiac rehabilitation sessions in low or intermediate risk patients.

Summary

The purpose of this study was to determine the efficacy of continuous ECG monitoring among low, intermediate, and high risk Phase II cardiac rehabilitation patients. The results indicate that continuous ECG monitoring is useful in detecting abnormalities, especially during the first 3 weeks of the program. In addition risk stratification based on current guidelines may not accurately predict which patients will have significant events during Phase II. Finally, the results did not indicate that any one risk subgroup will yield a greater benefit from using continuous ECG monitoring to detect potential problems associated with Phase II exercise sessions.
CHAPTER V
SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

Summary

The purpose of this study was to determine the efficacy of continuous ECG monitoring among low, intermediate, and high risk Phase II cardiac rehabilitation patients. A retrospective chart review of 241 Phase II patients constituted data collection. All patients were stratified into risk categories according to AACVPR guidelines. In total, 3,877 exercise sessions were reviewed. All significant events which necessitated physician intervention or cessation of the exercise session were reviewed. A total of 99 events were recorded, with method of detection determined as well as risk subgroup and diagnoses.

The results of the study were that continuous ECG monitoring is useful for detecting abnormal responses to exercise in the Phase II setting, especially during the first 3 weeks of the program. There were no significant differences among the risk categories as to which subgroup was more prone to experiencing an untoward event during exercise sessions. The third important finding of the study was that there was no significant difference in the extent to which ECG monitoring detects abnormal responses to exercise between low, intermediate, and high risk Phase II cardiac exercisers.

Conclusions

The following conclusions are made based on the present study:

1. Continuous ECG monitoring is useful for detecting abnormal responses to exercise.

2. Abnormal responses to exercise are more likely to occur and be detected by continuous ECG monitoring during the first 3 weeks of the program.
3. There was no significant difference in the frequency of significant events between low, intermediate, and high risk Phase II patients.

4. There was no significant difference in the extent to which continuous ECG monitoring detected abnormalities between the risk categories.

5. Current risk stratification procedures may preclude accurate prediction of which risk subgroup is more likely to experience complications associated with exercise training.

Recommendations for Further Study

The following recommendations are made for future studies:

1. Conduct a study involving a larger sample size to validate the results of the present study.

2. A prospective, multicenter study should be conducted to provide valuable information which may influence current monitoring practices, and form the basis for standardized monitoring guidelines.

3. A national survey of current monitoring and risk stratification practices should be conducted to determine current trends.
REFERENCES


APPENDIX A
DATA SHEET
DATA SHEET (pg. 1)

PATIENT IDENTIFICATION

D.O.B. ___________ SEX _______ HT _______ ADMIT WT ___________

CARDIAC DIAGNOSIS & DATE ____________________________

MEDICAL HISTORY ____________________________

RISK FACTORS ___________________________

LV FUNCTION ___________ EF (%) _______ DATE _______ TYPE OF TEST _______

GXT RESULTS __________________________

DATE: ___________ TYPE: ___________ MAX HR: ___________ MAX BP: ___________ MAX RPE: ___________
S/SX: ___________ Reason for stop: ___________ METs: ___________ ECG: ___________

PHASE II __________________________

NUMBER OF SESSIONS ___________ DATES __________________

MEDICATIONS __________________________

EX HR RANGE ___________ EX BP RANGE ___________ RPE RANGE ___________

RHYTHM __________________________

EVENTS __________________________

DATE _______ HOW DETECTED ___________ HR _______ BP _______ RPE _______
SESSION# _______ DESCRIPTION __________________________
INTERVENTION __________________________ OUTCOME __________________

DATE _______ HOW DETECTED ___________ HR _______ BP _______ RPE _______
SESSION# _______ DESCRIPTION __________________________
INTERVENTION __________________________ OUTCOME __________________
### RISK STRATIFICATION

(ACCORDING TO AACVPR GUIDELINES)

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LOW</strong></td>
<td>Complicated clinical course</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Evidence of myocardial ischemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Functional capacity &gt; 7 METs</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Normal LV function (EF &gt; 50%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Significant ventricular ectopy</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ST-seg depression &gt; 2 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reversible thallium defects</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>INTERM.</strong></td>
<td>Moderate LV function (EF &gt; 35%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Changing or new devel. of angina</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Prior MI involving &gt; 35% of LV</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EF &lt; 35% at rest</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fall in ex. SBP or failure of SBP</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>HIGH</strong></td>
<td>to rise 10 mm Hg with ex.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Persistant or recurrent ischemic pain 24 hrs after admission</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Functional capacity &lt; 5 METs with hypotensive BP or 1mm ST depress.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Congestive heart failure syndrome</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; 2mm ST-seg depression at peak HR</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt; 135 beats per minute</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>High grade ventricular ectopy</td>
<td></td>
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</table>