Structured Abstract

Background: Electrocardiographic (ECG) monitored outpatient-cardiac rehabilitation (OP-CR) is routinely performed following a variety of cardiovascular procedures and conditions.

Objective: To determine if diagnostic-quality ECG monitoring in patients with coronary artery disease (CAD) during OP-CR is useful in identifying asymptomatic myocardial ischemia, resulting in change(s) in care or medical management.

Methods: A retrospective analysis of ECG-monitoring was done on all OP-CR patients diagnosed with CAD (n=1213) from January 2000 through June 2013.

Results: Nearly a quarter of the patients (24%; n=288) displayed at least 1mm of asymptomatic ST-segment depression at 80 milliseconds after the J-point during at least 1 session of OP-CR. Of these patients, 57% had medical management change(s) compared with 24% for those who did not show ECG changes suggesting ischemia ($p<0.0001$). In patients with asymptomatic ischemia having medical management change(s), 84% resulted directly from OP-CR staff detection. Fewer patients diagnosed with myocardial infarction (MI) and coronary artery bypass graft (CABG) surgery demonstrated ECG signs of ischemia while more patients diagnosed with stable angina and percutaneous coronary interventions (PCI) demonstrated ECG signs of ischemia.

Conclusion: This study demonstrates that most patients with CAD showing asymptomatic ECG signs suggesting ischemia undergo medical management change(s) as a result of the finding. Diagnostic-quality ECG monitoring during OP-CR appears warranted in this population.

Introduction and Statement of Purpose

Outpatient-cardiac rehabilitation (OP-CR) is a cost-effective Class I indication by the American Heart Association (AHA) for several patient populations including those diagnosed with coronary artery disease (CAD), post-operative valve surgery, and heart failure. The purpose of OP-CR is risk factor modification, including blood pressure (BP), diet therapy, stress management, lipid management, and monitored exercise to reduce cardiovascular morbidity and mortality[1-8].

ECG surveillance ranges from patients walking around a track stopping for "quick-look" defibrillator paddles on every round to diagnostic-quality 5-wire telemetry. Staff education ranges from basic ECG interpretation of arrhythmias to comprehensive 12-lead ECG interpretation. Patients are commonly monitored during exercise with simple ECG monitoring[3,5] for the detection of arrhythmias using 3-5 wire telemetry units, monitoring lead 2, and usually not diagnostic-quality.

ST-segment depression in V_5 during exercise indicates increased risk for cardiovascular death and asymptomatic (silent) ST-segment changes during exercise predict future coronary events in patients with CAD[3,9-12,19]. However, it is commonly believed that symptoms associated with ischemia may serve as a safety warning; the absence of symptoms allows the patient to continue exercise[5]. This is disconcerting because the majority of ischemic episodes in patients with CAD are asymptomatic[12]. Additionally, patients with type 2 diabetes mellitus (DM) and CAD with asymptomatic ischemia are at high risk for all-cause mortality and major cardiovascular events[14]. Identification and frequency of significant asymptomatic ST-segment depression during OP-CR exercise in patients with CAD has not been published. Moreover, the frequency of active change(s) of care of the patient (used herein as ACC including previously unscheduled physician consultation, change in medication and/or dosage, diagnostic testing, hospitalization) when there are ECG signs of ischemia during exercise in OP-CR is unknown. Residual ischemia is common in this patient population[15]. Given the established focus on the medical management of CAD as demonstrated in the COURAGE Trial[14], OP-CR may play a larger role in optimizing care[16].

The purpose of this study is to: 1) Report the frequency of ECG signs of ischemia in a large CAD cohort participating in OP-CR; and 2) determine if diagnostic quality ECG-monitoring during OP-CR is efficacious in the context of facilitating ACC. We hypothesize the frequency of ischemic ECG changes and resultant ACC supports continued monitoring during OP-CR in patients diagnosed with CAD, although some guidelines suggest decreasing ECG monitoring based on risk.[18,19]

Patients and Methods

This is a retrospective observational study using an existing database and includes patients who participated in OP-CR from January 2000 through June 2013 (n=1651). All patients signed an informed written consent prior to starting the program. Eliminated from this analysis were patients including those 1) without CAD; 2) with ventricular assist devices, and 3) who had a heart transplant. Also omitted were patients with CAD whose ST-segments were not interpretable according to ST-segment depression inclusion criteria: 1) left ventricular hypertrophy; 2) left bundle branch block; 3) prescribed digoxin; and 4) ventricular pacemakers. The final sample for this analysis was 1213 with mean age of 60 years, predominantly Caucasian male (**Tables** 1, 2, 3).

All patients were risk stratified according to the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), the AHA and American College of

Physicians (**Tables** 4, 5). All were ECG-monitored for each exercise session. ECG-monitoring consisted of diagnostic-quality tracings typically using a true V_1 lead and a bipolar substitute for V_5 (CM_5)[17,18] (**Figure** 1).

On the first session, an exercise test was performed by a qualified OP-CR staff member preceded by a physical examination and medical record review, including 12-lead ECG and most recent graded exercise test results (if available). For patients who had been diagnosed with myocardial infarction (MI), peak heart rate (HR) was limited to 70% age-predicted maximum HR for the first 6 weeks post infarct, or per physician's order. However, if the patient did not show adverse signs and the rating of perceived exertion was 12 or less (Borg 6-20 scale) on the first test, the physician would be notified and the exercise HR increased. For non-MI patients, peak HR was limited to 85% age-predicted maximum HR with the same guidelines for peak HR as described for MI patients. In addition to the peak HR, adverse signs and symptoms that would warrant HR restrictions included: 1) angina pectoris; 2) ST-segment depression or elevation; 3) significant arrhythmias (runs of ventricular tachycardia; new atrial fibrillation; type II, second or third degree atrio-ventricular block); 4) rating of perceived exertion of 14 or greater; 5) fall in systolic BP of >10mmHg with an increase in workload; and 6) high rate-pressure-product (RPP). Stress test protocol was based on the patient's functional level. BP was measured at the end of each stage with a mercury manometer. For patients who finished the OP-CR program, exercise testing was performed on the final session. The initial exercise prescription was based on initial testing. As patients increased workloads, the initial peak estimated metabolic equivalent level (MET) was typically exceeded by half-way through the program.

ECG criteria used to define ischemia was a minimum of 1 mm ST-segment depression at 80 milliseconds after the J-point in lead CM_5 for a minimum of 3 consecutive beats using diagnostic-quality (0.05–150 Hz, compliant with AAMI EC11-1991 for diagnostic electrocardiographic devices) ECG telemetry monitoring (Mortara Quinton Q-Tel RMS® Rehabilitation Management System). All patients were asymptomatic upon OP-CR enrollment. To be considered positive for the ECG criteria, patients had to demonstrate this pattern during at least 1 OP-CR session. When ST-segment depression was noted during exercise, it was documented and characterized (i.e., upsloping, flat, or downsloping), the BP measured, RPP determined, symptoms assessed, and the ECG rhythm strip was entered into the medical record. **Figure** 2 illustrates down-sloping ST-segment depression during exercise.

Up to 36 OP-CR sessions were commonly approved; those returning to work typically underwent fewer sessions. The mean number of sessions for all patients was 17.12 (range 1-72, SD 12.87, SEM 0.37). Mean duration of each ECG-monitored session was 36.4 minutes (range 4-54.4, SD 9.29, SEM 0.27) and included the shorter duration first and final tests. Following aerobic exercise, strength training was undertaken, during which ECG-monitoring continued but was not included in this study. Patient education classes preceded or followed exercise sessions.

All ACC occurring for patients were recorded and included: 1) medication change; 2) hospitalization; 3) cardiac catheterization or other diagnostic tests; and/or 4) clinic visit. Changes in exercise prescription were nearly universally made by the OP-CR staff and, therefore, not included in the analysis. If the managing physician chose to allow ST-segment depression to occur during exercise, the order was written as such. Whatever the ACC, the staff kept the physician informed of whether the ACC improved the situation.

On completion of the program, data were entered for each patient on a JMP (version 8

SAS® Institute) database. The center's Institutional Review Board considered this study exempt as a de-identified JMP database does not meet the regulatory definition of research involving human subjects.

Statistical Analysis

The following characteristics and measures were assessed: 1) presence of ischemia; 2) ACC during Phase II OP-CR; 3) if ACC was a direct result of Phase II OP-CR professional staff intervention; 4) diagnoses, of which there may have been overlaps, including MI, percutaneous coronary intervention(s) (PCI), coronary artery bypass graft (CABG) surgery, and stable angina (stable angina as a diagnosis was used only if that was the sole diagnosis) (**Table** 3); 5) days post-acute event; 6) ejection fraction if less than 55%; 7) whether the OP-CR program was completed; 8) AACVPR risk stratification (**Table** 5); 9) complications during exercise sessions; 10) functional capacity; 11) smoking status; and 12) presence of DM (type I or II). JMP (version 8 SAS® Institute) and Excel (version 4.5.2) software packages were used for all comparisons. The statistical tests included comparisons and determination of significant differences. All statistical tests with a p-value <0.05 were considered significant.

Results

Ischemia. 24% (n=288) of patients displayed at least 1mm of asymptomatic ST-segment depression at 80 msec after the J-point in CM_5 during at least 1 session of OP-CR, including two patients who displayed asymptomatic deep T-wave inversion during exercise.

Sessions. The total number of sessions during which ischemia was documented in these 288 patients was 1,608 (of 6,866 total sessions) with 4 patients displaying ST-segment depression during all 36 sessions. The first session at which ischemia was noted was on the first exercise test for 30.6% of patients (n=88) and for 16% (n=14) of these 88 patients, the first session test was the only session at which ischemia was detected; 2 of these patients attended only one OP-CR session. For the other patients, the first incidence of ischemia occurred during sessions 2-36.

First and Final Test METs. Mean peak METs during the first exercise test was 6.11 (n=282), SD 2.22, SEM 0.132; and 9.53 (n=223), SD 3.21, SEM 0.21 during the final test. (A minimal number of patients were unable to perform an exercise test for either the first or final session.) When first and final tests were analyzed (n=221), a significant difference was found between peak METs ($p < .0001$).

Ischemia at First and Final Tests. Comparing the first and final OP-CR tests, 87 patients displayed ischemia on the first test with only 48% (n=42) of those patients displaying ischemia on the final test, despite utilizing exercise intensities to patient tolerance.

ACC. Of these 288 patients showing myocardial ischemia, more than twice as many, 57%, had ACC, compared with only 24% of patients who did not show ischemia who had ACC ($p < 0.0001$). Of those patients with asymptomatic ischemia having ACC, 84% were a direct result of OP-CR staff detection and intervention. Only 16% of patients had ACC that were not a direct result of the OP-CR staff reporting abnormal responses during exercise. Specific ACC are delineated in **Figure** 3.

Diagnoses. Analysis of the 288 patients meeting the ST-segment change criteria defined in this study by diagnosis revealed that fewer patients diagnosed with MI and CABG surgery were in the group displaying ischemia: 1) MI patients: 38% (no ischemia) vs. 27% (with ischemia), p=0.0005; and 2) CABG surgery patients: 25% (no ischemia) vs. 16% (with ischemia), p=0.0012. However, significantly more patients with stable angina (as the only diagnosis) met the ST-segment change criteria defined in this study: 11% (no ischemia) vs. 16% (with ischemia), p=0.007. In addition, significantly more patients with PCI met this criterion: 46% (no ischemia) vs. 55% (with ischemia), p=0.006.

Risk Categories. The distribution of patients in AACVPR risk categories (**Table** 5) was significantly different in those not meeting the ST-segment change criteria compared to those who did (p=0.0037), with those meeting the ST-segment depression criteria tending to fall into lower risk categories. In this data set, patients with the diagnosis PCI were categorized as follows: 43% low-risk, 39% moderate-risk, and 18% high-risk.

Only 9% (n=124) of the patients with CAD complained of chest discomfort but did not meet the ST-segment depression criteria. Of those, 65% had a diagnosis of PCI, 7% CABG surgery, 32% MI, and 24% stable angina (as the only diagnosis); 41% of these patients had a ACC, of which 70% were a direct result of OP-CR staff reporting.

Other Signs.

Arrhythmias. In terms of arrhythmias detected in the population of all CAD patients, 16% of patients displayed new supraventricular tachycardia (typically, atrial fibrillation); 8% displayed nonsustained ventricular tachycardia; 0.08% (1 patient) exhibited sustained ventricular tachycardia; and 75% (n=904) displayed ventricular ectopic beats during at least 1 session. There were no cardiac arrests or MIs during OP-CR sessions. All arrhythmias were documented and the physician notified, with the exception of ventricular ectopic beats, which were documented but the physician was not notified unless the patient was symptomatic and/or the ventricular ectopy represented a marked change from previous sessions (**Table** 6).

Fall in Systolic BP. 18% (n=259) of patients with CAD had a fall in systolic BP of 10mmHg or more with an increase in workload. These patients were evaluated for of exercise intolerance, the physician was notified and the exercise prescription was altered if necessary.

Discussion

To our knowledge, the present study is the first to describe comprehensive findings of ECG-monitoring in OP-CR. Effective monitoring should not be labor-intensive and should be as low-cost as possible while still maintaining high quality and diagnostic validity/reliability. Features that help enable this include: 1) Full-disclosure (1-hour ECG monitoring on one page, one line per minute) allowing clinicians to attend to patients rather than monitors; 2) remote split-screen displays allow clinicians to see all patients' ECGs wherever staff is located; 3) lead choices most advantageous for select patients; 4) diagnostic quality (0.05 – 150 Hz) to prevent errors in interpretation; 5) good electrode application; and 6) staff members able to accurately interpret the ECG.

Two leads were monitored simultaneously during exercise (**Figure** 1). All patients who are ECG-monitored require detection of arrhythmias[22,23], which can typically be diagnosed in leads V_1 and CM_5. Other leads can be selected or configured depending on the arrhythmia being analyzed. A single lead is not enough and no single lead is ideal for every patient[24].

Of the patients assessed in the current study, 24% displayed ECG signs of myocardial ischemia during at least 1 OP-CR session. Despite the fact that the majority of these 288 patients displayed ST-segment depression during more than 1 session (n=199), each patient was counted only once. Providing the rating of perceived exertion was at least 13 ("somewhat hard") and the MET level achieved by the patient was the same or higher, patients were encouraged to exceed previous workloads, hence the likely explanation for the fact that many patients continued to exhibit ECG signs of ischemia. The OP-CR staff members understood the significance of ECG changes and were able to relay to the physician whether the ST-segment depression was upsloping (least serious), flat, or downsloping (more serious).

More than twice as many patients who displayed ischemia (57%) underwent an ACC compared with patients without ischemia who had ACC. The majority (84%) of ACC were a direct result of OP-CR staff detection and reporting. Patients most frequently displaying this sign were the patients who had undergone PCI and tended to fall into the "low-risk" category. Despite evidence that OP-CR is associated with lower mortality, rates of referral following PCI have been historically low, ≈40-60%[25,26].

Without the intervention by OP-CR staff, such ACC may have occurred as a result of an unscheduled physician office visit or an emergency-treatment-center visit[27] due to escalation of symptoms, both more costly options compared to the outcomes presented herein. The ACC described herein were typically not associated with any charges for the telephone consult, emergency physician consultation, and order(s) received for medication changes and diagnostic procedures, etc. Thus, considerable cost savings undoubtedly occurred. However, the costs of continuous ECG monitoring must be considered for large programs that currently do not use diagnostic-quality ECG monitoring. Moreover, the cost savings of using well-qualified OP-CR staff during testing is another area for future analysis[16].

Current guidelines advise that ECG-monitoring be done on OP-CR patients as appropriate[18]. For patients deemed at lowest risk for exercise-related events, continuous ECG monitoring is recommended initially with a subsequent decrease in ECG-monitoring, for example, beginning at sessions 6-12. For patients at moderate risk, ECG-monitoring is recommended to decrease to intermittent or no monitoring at 12-18 sessions. For patients at highest risk, ECG-monitoring should be decreased to intermittent monitoring as appropriate[28]. Recommendations for ECG-monitoring of OP-CR patients have traditionally focused only on "hard" cardiovascular events, such as death, MI, heart failure, and stroke[29-31]. However, these complications are rare[3,32,33]. The fact that the patients showing ST-segment depression tended to fall into lower risk categories suggests that the recommendations for ECG-monitoring may need to be re-evaluated and determine whether intermediate outcomes, such as ACC, contribute to cost-effective management in patients with CAD, including those with microvascular angina[34], and may prevent future cardiac events[12]. Following patients post OP-CR to determine if ACC had long-term positive effects and the nature of such effects would be a topic of future research.

Study Strengths and Limitations

This was a retrospective analysis of a large group in a single center. Exercise session size was typically 4-12 patients per session, unlike larger centers who see considerably more patients per session. Similar assessments in multi-center locations would enable establishment of predictive models to identify those with characteristics at greatest risk for ECG changes and determination if detection reduces cost of care and further reduces readmissions[2].

Conclusions

The purposes of this study were met: 1) Report the frequency of ECG signs of ischemia in CAD patients participating in OP-CR; and 2) determine if diagnostic quality ECG-monitoring is efficacious in facilitating ACC. ACC are useful and cost-effective aspects of disease management. The current recommendation is to decrease ECG-monitoring, especially for low-risk patients.[18] Yet, these patients were the group who benefitted most from ECG-monitoring in detecting ST-segment depression. These results suggest ECG-monitoring, using appropriate procedures and leads as well as appropriately trained staff, is useful and warranted.

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Figure Titles and Legends

Figure 1. Two leads are monitored simultaneously during exercise. When a 5-wire cable is used, a "true" V lead (chest lead) is available. Since differential diagnosis of wide QRS complexes is often necessary in OP-CR, the chest lead is used for monitoring V_1, considered the best lead, along with V_6, for this purpose and is more accurate than a bipolar substitute for V_1, most commonly MCL_1. The other lead, to diagnose ST-segment depression, is V_4 or V_5. V_5 serves the additional purpose of assisting with the diagnosis of wide QRS complexes due to its proximity to V_6. Since the "true" V lead is already in use, a good bipolar substitute for V_5, CM_5, is obtained by placement of the right arm and left arm electrodes in their designated locations (beneath the distal right and left clavicles) and placing the left leg electrode in the V_5 position (same horizontal line as V_4, anterior axillary line) and choosing aVF on the lead selector. Therefore, the negative pole is equidistant between the right and left arm electrodes, or the manubrium, which is where the negative pole for CM_5 is located. This electrode placement also has the advantage of allowing quick checking of axis if and when necessary by checking lead 1. The chest lead is placed in the V_1 position (4th intercostal space, right sternal border). The right leg electrode (ground) can be placed anywhere.

Figure 2. Definition of terms: The J-point is located at the end of the QRS complex and beginning of the ST-segment (first arrow). A typical example of ST-segment depression during exercise (note motion artifact) illustrating leads CM_5 (top) and V_1 (bottom), typical leads that are ECG-monitored. The first arrow illustrates the J-point in CM_5 (2mm depressed). The second arrow illustrates 80 milliseconds (2 small squares) after the J-point (3mm depressed).

Figure 3. Active Changes in Care for the 288 patients showing myocardial ischemia, 16% underwent cardiac catheterization, 8% were admitted to the hospital, 70% had a change in medication, and 19% had a clinic visit and/or additional diagnostic testing.