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(AMI) IN COMMUNITY HOSPITALS

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**DETERMINANTS ON THE USE OF ANGIOGRAPHY AND
REVASCULARIZATION PROCEDURES AFTER ACUTE
MYOCARDIAL INFARCTION (AMI)
IN COMMUNITY HOSPITALS**

By

Qin CHEN

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ABSTRACT

DETERMINANTS ON THE USE OF ANGIOGRAPHY AND REVASCULARIZATION PROCEDURES AFTER ACUTE MYOCARDIAL INFARCTION (AMI) IN COMMUNITY HOSPITALS

By

Qin CHEN

The rates of angiography and revascularization use have increased dramatically in the US in patients with acute myocardial infarction (AMI) over recent years. Observational studies have shown strong associations between demographic and some clinical characteristics and the use of coronary procedure. MICH study was a hospital-based study of the hospital care for AMI patients in five community hospitals in Michigan. This study is to analysis the differences in demographic and clinical characteristics among the 846 AMI patients. We found that increased age, female gender, no insurance were associated with less use of angiography after adjusting for other factors. Except for recurrent angina, patients developing complications of AMI such as cardiac arrest, cardiogenic shock and patients with prior CVD-related history such as prior AMI, prior CHF or prior cardiac arrest were less likely to have angiography. In contrast, we found that once the angiography was done, the severity of coronary disease was the strongest predictor of type of revascularization use. Patients with complications of AMI were more likely to have CABG. However, blacks were less likely to have both PTCA and CABG after adjusting for other factors.

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LIST OF SYMBOLS OR ABBREVIATIONS

ACC/AHA	American College Of Cardiology/American Heart Association
AMI	Acute Myocardial Infarction
ARIC	Atherosclerosis Risk In Communities
CA	Coronary Angiography
CABG	Coronary Artery Bypass Graft
CHD	Coronary Heart Disease
CHF	Congestive Heart Failure
CVD	Cardiovascular Disease
GUSTO	Global Utilization Of Streptokinase And Tissue Plasminogen Activator For Occluded Coronary Arteries
IAB	Intraaortic Balloon Counterpulsation
LAD	Left Anterior Descending Coronary Artery
LCX	Left Circumflex Coronary Artery
LVEF	Left Ventricular Ejection Fraction
PTCA	Percutaneous Transluminal Coronary Angioplasty
RA	Right Coronary Artery
SAVE	The Survival And Ventricular Enlargement Study
SWIFT	Should We Intervene Following Thrombolysis Study
TIMI	Thrombolysis In Myocardial Infarction Study
TPA	Recombinant Tissue-Type Plasminogen Activator
TT	Thrombolysis Therapy

Chapter 1

BACKGROUND

1.1 Overall burden and costs of Coronary Heart Disease (CHD)

Despite the decline of cardiovascular disease (CVD) mortality rate in the past 40 years, CVD remains the leading cause of death in the United States. Around 50% of CVD deaths are due to coronary heart disease (CHD). According to 1997 estimates, CHD claimed 466,101 deaths (50.9% were men). Age-adjusted CHD death rates (using the year 2000 age standard) were 236.3 for white males and 223.9 for black males, and 139.7 for white females and 160.1 for black females per 100,000 population¹. Among American adults age 20 and older, the estimated age-adjusted (2000 standard) prevalence of CHD was 6.9% for non-Hispanic white males and 5.4% for females; whereas for non-Hispanic black males it was 7.1% for males and 9.0% for females; and for Mexican-American males and females, it was 7.2% and 6.8%, respectively. It is estimated that 7.2 million Americans, aged 20 and older have a history of myocardial infarction (MI) (61.1% of whom are men)¹. Based on data collected, the incidence rate of new and recurrent MI in non-black men aged 65-74 was 26.3 per 1,000 population, 39.7 for aged 75-84, and 53.6 for aged 85 and older per 1,000. For non-black women in the same age groups, the rates were 7.8, 21.0 and 24.2, respectively. For black men, the rates were 16.3, 54.9 and 40.8, and for black women, the rates were 13.3, 18.3 and 14.1, respectively¹.

Because CHD may strike an individual during the most productive years, it can have profound deleterious psychosocial and economic ramifications. Besides causing death, CHD is the leading cause of premature, permanent disability in the U.S. labor force, accounting for 19% of disability allowances by the social security Administration¹. The estimated cost of CHD in the United States in 2000 was estimated at \$118.2 billion, while the cost of CVD was much higher -- \$ 328.8 billion. This figure includes health expenditures (direct costs, which include the cost of physicians and other professionals, hospital and nursing home services, the cost of medications, home health and other medical durable) and lost productivity resulting from morbidity and mortality (indirect costs). It was said as much as half of this cost is related to acute myocardial infarction (AMI) and its prevention and treatment (Figure 1).

1.2 Mortality trends of CHD and relative contributions of prevention and treatment

A steady decline in the age-adjusted death rates from AMI and CHD have been observed across several population groups²⁻⁸ since 1960s. Figure 2 shows the decline in mortality of heart disease in the US since the 1960. Reasons for the declines in CHD may vary by period and across regions or socioeconomic groups. Prevention efforts and improvement in early detection, treatment, and care have resulted in a number of beneficial outcomes⁴.

Studies suggested that primary prevention accounted for a greater proportion of the decline in CHD in the late 1960s and 1970s⁹. Goldman¹⁰ reviewed the literature regarding the effect of various potential explanations for the reduction in coronary mortality between 1968 and 1976. He found that 60% of the decline was related to

changes in lifestyle, specifically to reductions in serum cholesterol level and cigarette smoking. In comparison, about 40% of the decline was directly attribution to specific medical interventions, with Coronary Care Unit and the medical treatment of clinical ischemic heart disease and hypertension. However, improvement in the treatment of patients with CHD was thought to be the major factor in this decline in late 80s. According to a recent study looking at mortality data in the United States in the period 1980 to 1990, Hunink¹¹ found that the actual coronary heart disease mortality in 1990 was 34% lower than would be predicted if risk factor levels, case-fatality rates, and event rates in those with and without coronary disease remained the same as in 1980. One quarter of the decline was explained by primary prevention, 29% was explained by secondary prevention reduction in risk factors in patients with coronary disease, while 43% of the decline was explained by other improvements in treatment of patients with CHD.

1.3 Standard therapeutic regimes for patients with AMI

The primary goal of therapy in AMI is rapid, complete, and sustained restoration of infarction-artery blood flow¹². In the reperfusion era, a constellation of therapies for the management of patients with AMI were introduced, including treatments with thrombolytic agents such as streptokinase, tissue plasminogen activator (tPA) as well as procedures such as percutaneous transluminal coronary angioplasty (PTCA), and emergency coronary artery bypass graft (CABG) surgery in suitable patients. It also included the extensive use of aspirin, beta blockers, vasodilation therapy, and the common use of ACE inhibitors. In addition, this era has witnessed far more aggressive techniques such as intraaortic balloon counterpulsation (IAB) in patients with clinical

markers of poor prognoses (e.g., hypotension, congestive heart failure, and continuing ischemia). The combined use of all these therapies has resulted in an impressive reduction in short-term and 1-year mortality for patients with AMI¹³⁻¹⁵.

Physician practices have changed dramatically as newer approaches to the care of the AMI patient have become available. Invasive and/or noninvasive procedures such as angiography, stress echocardiography and radionuclide imaging to evaluate prognosis and the need for further therapy are now used in most post-MI patients, whereas only a small percentage of patients had such procedures performed 25 years ago¹⁶⁻¹⁸. The National Registry of Myocardial Infarction, an observational database¹⁹ of practice patterns reflecting treatment of 240,989 patients with AMI at 1073 hospitals between 1990 and 1993, reported the rates of invasive procedures in thrombolytic recipients were 70.7% for coronary angiography, 30.3% for angioplasty, and 13.3% for bypass surgery. Thrombolytic therapy and angioplasty are now the standard of care in appropriately selected patients¹⁹⁻²².

Two goals for the clinical cardiologists are to reduce the mortality and morbidity of AMI to their lowest possible rates and to do so in a cost-effective manner. Attaining these goals requires the development of the most effective immediate treatments, the most accurate risk stratification methods, and the selective use of revascularization procedures in those patients most likely to benefit. However, the precise role of diagnostic angiography and coronary angioplasty in reaching these goals is controversial²³. Specially, clinicians disagree on the appropriate use of diagnostic angiography versus noninvasive methods of post-infarction risk stratification, as well as

the extent to which primary angioplasty should be emphasized over thrombolytic therapy²⁴⁻²⁷. The controversies have far-reaching implications²⁸.

1.4 Utilization of coronary angiography and revascularization

The growth of interventional cardiovascular procedures has been staggering (Figure 4-6). In the United States, an estimated 1,194,000 inpatient CA procedures, 447,000 PTCA procedures and an estimated 607,000 CABG procedures were performed on 366,000 patients in 1997¹. From 1979 to 1997, the number of CAs performed in the US increased 3 folds; the number of PTCA increased 188% and the number of patients treated increased by almost 2 folds. The average cost of PTCA in 1995 was \$20,370. The number of CABG procedures increased 432%, and the number of patients increased 227%. The average cost of CABG in 1995 was \$44,820.

In the patients with AMI, the frequency of CA use has increased too. For example, from 1987 to 1990, the proportion of Medicare patients with MI who had CA increased from 24% to 33%¹⁸.

The growth in coronary procedures is also rapidly increasing worldwide too. For example, in Germany, between 1984 and 1996, the number of CA rose 10 folds from about 45,000 to more than 450,000, while the number of PTCA increased by a factor of about 50 to 125,000 procedures in 1996²⁹. In the UK, the total number of coronary procedures increased by 77% from 11,575 in 1992 to 20,511 in 1996³. No other country matched the procedure rate in the United States. For example, Germany, the country that performs the most coronary procedures per capita in Europe, has a CA rate that is only 75% as high as that in the U.S.³⁰. Great Britain performs only one-third as many

CA as the United States. Similarly, the rate of coronary revascularization is much lower outside of the U.S.

1.5 Variation in procedure use in patients with AMI and related outcomes

Geographic variation of coronary procedure use in AMI patients

There is considerable geographic variation in the use of coronary angiography and revascularization within the United States and internationally, both in general population with chest pain or angina and among patients who had AMI. In the U.S., there are substantial regional differences in the use of CA^{31, 32}. In the GUSTO-1 (Global Utilization of Streptokinase and Tissue Plasminogen Activator for Occluded Coronary Arteries) study of patients with AMI, Pilote³² compared the management of AMI among census regions across the United State and found the proportion undergoing CA varied substantially between the 7 regions evaluated. For example, angiography use varied from 52 to 81%; angioplasty, 22 to 35%; and CABG, 9 to 17%. The regional use of coronary procedures was closely related to their availability. Despite these regional variations in utilization of angiography, there was no apparent relationship between procedure rate and patient outcomes. For example, the incidence of recurrent infarction or death at 30-day or one-year follow-up did not vary from region to region.

In another study³³ that evaluated Medicare patients with AMI, the proportion of patients who received CA during their hospital stay or within 90 days of admission was 45% in patients in Texas but only 30% in patients in New York. Despite the increased use of coronary angioplasty as well as CABG in Texas, the adjusted mortality after two-

year follow-up was significantly lower in New York and patients in New York had fewer symptoms. Patients from Texas were more likely to report angina and more likely to say they could not perform activities requiring energy expenditure of 5 or more metabolic equivalents than patients from New York at the time of follow-up assessment. So mortality rates and measures of health-related quality of life were no better in Texas than in New York.

Selby found the percentage of patients who underwent angiography within three months after infarction ranged from 30 to 77% at 16 Kaiser Permanente hospitals³⁴. The author then selected a cohort of 1,109 patients from three hospitals with higher rates of angiography and four with lower rates to undergo a comprehensive record review to determine the severity of infarction, the number of coexisting conditions, treatments received, and the appropriateness and necessity of angiography, using established criteria. The rates of angiography were inversely related to the risk of death from heart disease ($P = 0.03$) and the risk of heart disease events ($P < 0.001$) among the 16 hospitals, after adjustment for age, sex, race, coexisting conditions, and the location of the infarction.

In addition to variation within the U.S., there are also international differences in use of angiography in AMI³⁵⁻³⁷. Rouleau³⁵ compared the treatment patterns for patients with AMI in 19 Canadian and 93 U.S. hospitals participating in the Survival and Ventricular Enlargement (SAVE) study, which tested the effectiveness of captopril after a MI. Despite the similar clinical characteristics of the 1573 U.S. patients and 658 Canadian patients participating in the Randomized Control Clinical Trial, CA was more commonly performed in the United States than in Canada (68% versus 35%, $P < 0.001$),

as were revascularization procedures (31% versus 12%, $P < 0.001$). During an average follow-up of 42 months, these coronary procedures were also performed more commonly in the United States than in Canada. However, these differences were not associated with any apparent difference in mortality (23% versus 22%) or rate of reinfarction (13% versus 14%), although there was a higher incidence of activity-limiting angina in Canada than in the United States (33% versus 27%, $P < 0.007$).

Mark compared 2,600 U.S. and 400 Canadian patients from the GUSTO trial with respect to their use of medical resources and their quality of life during the year after AMI³⁶. He found that the Canadian patients had a much lower rate of CA (25% versus 72%, $P < 0.001$), PTCA (11% versus 29%, $P < 0.001$), and CABG (3% versus 14%, $P < 0.001$) during their hospitalization as well as at one-year. They also underwent fewer invasive cardiac procedures and had fewer visits to specialist physicians. The Canadian patients however had more cardiac symptoms and worse functional status one year after AMI than the U.S. patients.

Tu³⁷ compared the use of coronary procedures and the mortality rates among 224,258 elderly Medicare beneficiaries in the United States and 9,444 elderly first MI patients in Canada. The U.S. patients were significantly more likely than the Canadian patients to undergo CA, PTCA and CABG during the first 30 days and 180 days of follow-up after index infarction. The 30-day mortality rates were slightly but significantly lower for the U.S (21.4% versus 22.3%, $p < 0.03$) patients than for the Canada patients. However, the one- year mortality rates were virtually identical (33.4% in American and 33.3% in Canada).

Gender variation of coronary procedure use in AMI patients

Variations in the use of procedures in AMI patients have also been observed between men and women. A retrospective cohort study in community-based tertiary teaching hospital conducted by Krumholz³⁸, found women underwent angiography during hospitalization for AMI much less frequently than men (OR 0.55, 95%CI 0.46-0.65), When adjustments were made for age, women had PTCA as often as men (OR 1.16, 95%CI 0.83-1.62) but had CABG significantly less frequently (OR 0.58, 95%CI 0.37-0.91). When adjustments were made for age and the severity of coronary artery disease, the difference in rates was large but of borderline significance (OR 0.65, 95%CI 0.41-1.01).

Myocardial Infarction Triage and Intervention Registry (MITIR) was a registry database for hospitalized AMI in 19 hospitals in the Seattle metropolitan area. From that database, Maynard³⁹ found that women were older and more often had histories of previous hypertension and congestive heart failure compared to men. Both CA and PTCA were used less frequently in women. For example, CA was performed in 40% of women and 58% of men during hospitalization ($P<0.001$). However, of patients who had CA, equal proportions of women and men received PTCA and/or CABG ($p=0.25$).

Race variation of procedure use in AMI patients

Giles used data from the National Hospital Discharge Survey to investigate race and sex differences in rates of CA, PTCA and CABG among 10,348 patients hospitalized for AMI⁴⁰. It was found that white men consistently had the highest procedure rates, followed by white women, black men, and black women. After matching for the hospital of admission and adjusting for age, in-hospital mortality,

health insurance, and hospital transfer rates, the odds ratio for CA were 0.67 (95% CI 0.51-0.87) for black men, 0.72 (95% CI 0.63-0.83) for white women, and 0.50 (95% CI 0.37-0.68) for black women, compared to white men. Similar race-sex differences were noted for use of PTCA and CABG.

Weitzman compared rates of cardiac procedure use in relation to gender, race, and geographic location in patients' hospitalization for AMI using data from the Atherosclerosis Risk in Communities (ARIC) data⁴¹. This study provided population data and standardized data collection methods, and found that women treated in these hospitals were less likely than men to have CA and CABG (CA: OR 0.7, 95% CI 0.5-1.0, CABG, OR 0.6 95% CI 0.4- 0.8), after controlling for age, race, severities of myocardial infarction, co-morbidity, and geographic area. Blacks in the biracial communities were significant less likely than whites to have CA, CABG and PTCA.

Maynard reported racial differences in the utilization of procedures in MITIR study from 1988 to 1994⁴². Similar proportions of black and white hospitalized AMI patients underwent CA. However, only 18% of black patients underwent PTCA compared with 26% of white patients ($p=0.0004$) and CABG was also used less frequently in black patients compared to whites (7% versus 12%, $p=0.002$). Despite the less intensive use of revascularization procedures in black patients, 2-year survival after AMI was similar in both groups.

In the study of 1,165 AMI patients from January 1990 to December 1992 at seven health maintenance organization hospitals⁴³, CA was highly indicated in 854 (73.3%) patients using the American College of Cardiology/American Heart Association (ACC/AHA) practice guidelines. Among these, women received

significantly fewer CA (hazard ratio (HR)=0.78) and revascularization (HR 0.62). Crude CVD mortality for women was higher than for men (HR 1.7), but after adjustment for age, Charlson Index, and congestive heart failure, the hazard ratio of CVD mortality was not significantly difference than for men (HR 1.19)

These differences in rates of procedure use among the races and genders⁴⁴ were conceivably due to differences in confounders as well as selection criteria. More complicated and detailed information was acquired by collecting data from individual medical records rather than from computerized databases or from secondary analyses of existing databases. Additionally, some studies reflected practice 10 to 25 years ago, whereas now advances in practice had made angioplasty a common therapeutic option for many patients with AMI.

Other studies have attempted to isolate additional factors that help to explain variation of procedure use. Infarction patients admitted to hospitals with angiography laboratories are about 3 times more likely to undergo angiography than patients admitted to hospitals without such facilities^{45, 46}. Patients treated for AMI by invasive cardiologists (defined as cardiologist who perform the procedures) have a similar likelihood of undergoing CA as patients treated by noninvasive cardiologists, but the likelihood of having PTCA or CABG is higher for patients treated by invasive cardiologists⁴⁷.

1.6 Coronary procedures use and AMI outcome

As discussed above, several studies have shown considerable variations in the use of CA after MI within regions of U.S., between the U.S. and Canada, between health maintenance organizations and fee-for service hospitals, between primary care

physicians and cardiologists, and between invasive and noninvasive cardiologists. These data do not show a consistent relationship between the increased use of CA or PTCA after MI and improved outcomes. Data on the impact of differences in cardiac procedure rates in patients with AMI on subsequent quality of life are also conflicting. The utilization of procedures has not been studied in typical, non-selected populations of patients admitted to hospital with AMI. Most study population are from veterans, or Medicare patients, or patients in Random Clinical Trial setting. In addition, the small number of outcome studies published have produced opposing conclusions concerning the impact of the high rates of these coronary procedures^{34, 36, 37}. These studies, based largely on administrative data, attributed geographic variation in the use of procedures to physician “practice style”.

Adjunctive angioplasty following thrombolysis

Several clinical scenarios have been described that represent different categories of use of PTCA when it is not selected as the primary reperfusion strategy⁴⁸ (Figure 3). The Thrombolysis in Myocardial Infarction (TIMI II-A) study^{49, 50} addressed the use of angiography after thrombolysis therapy (TT) in AMI patients. This study compared three treatment strategies: immediate invasive, delayed invasive, and conservative. With the immediate invasive strategy, angiography and angioplasty (if indicated) were done as early as possible after TT use, with the delayed invasive strategy, routine angiography was done between 18 and 48 hours after thrombolytic therapy, and with the conservative approach, angiography and angioplasty (if indicated) were done only if the patient developed spontaneous or exercise-induced ischemia. The 24-hour complication rate for patients who received the immediate invasive strategy was

significantly higher (8.5%) than that for patients who received the delayed invasive strategy (4.6%). No benefit for any of the major endpoints was shown. Patients who received the conservative strategy had outcomes equal to those for patients who received the delayed invasive strategy for major outcomes. For example, 6-week survival (95.3% in the conservative group compared with 94.5% in the delayed invasive group), absence of reinfarction (93.5% in the conservative groups compared with 93.1% in the delayed invasive group), and ejection fraction (EF) at discharge (49.9% in the conservative group compared with 50.5% in the delayed invasive group).

The SWIFT (Should We Intervene Following Thrombolysis) trial also compared an invasive strategy with a conservative approach after thrombolytic therapy⁵¹. The invasive strategy was early elective angioplasty (within 48 hours). AMI patients in the conservative group had angiography only if they had recurrent ischemic symptoms or positive results on exercise tests at 3 months. Mortality rates after 3 months were similar between the conservative group (3.2%) and the invasive group (4.8%); ejection fraction was also similar, thus confirmed those of the TIMI II-A study^{49, 50}.

In the TIMI IIB trial⁵² patients who received tPA were randomized to receive CA and PTCA within 18 to 48 hr of thrombolysis or conservative management. After six weeks, there was no difference in mortality, nonfatal recurrent MI, or left ventricular ejection fraction (LVEF) between two groups. Follow-up reports from this study showed no difference in survival, severity of angina or the frequency of bypass surgery between the two groups after one and three years. Thus, there was no evidence to support use of PTCA in patients without evidence of recurrent or provokable ischemia.

A summary of the design features and main findings of 16 randomized trials, which assessed the effect of both primary and adjunct PTCA in AMI on mortality and reinfarction rates, that collectively enrolled about 6200 patients had been published along with meta-analysis of the mortality results⁵³. Although none of the individual comparisons of strategies achieved conventional statistical significance, a consistent theme was observed--the routine empirical use of PTCA (either immediate or delayed) following thrombolysis was associated with a trend toward increased mortality^{15, 53, 54}. Conservative and invasive strategies did not differ in mortality rate or nonfatal reinfarction or mortality rate at either 6 weeks or 1 year. Therefore, at least as seen in these trials, the strategy of performing routine PTCA in a delayed fashion or immediate fashion following thrombolysis did not improve the mortality rate or improve left ventricular function.

Adjunctive angioplasty in specific subgroup AMI patients

While no benefit has been shown for immediate or routine PTCA in AMI patients without complication, angiography and angioplasty may be useful in specific subgroups that have such complications as angina and cardiogenic shock after MI.

Recurrent angina and persist chest pain

Patients who develop persistent chest pain after MI have a greater risk for extension of the infarction and death⁵⁵. The DANAMI (Danish Acute MI) investigators⁵⁶ reported that when patients with provokable ischemia after infarction were randomized to angiography and revascularization versus conservative medical therapy, they required less anti-angina medications, had less unstable angina, and experienced fewer nonfatal infarctions. There were 1,008 patients with first AMI treated

with TT who had subsequent ischemia were randomized to coronary angiography and revascularization versus medical management. In the invasive strategy, PTCA was performed in 266 (52.9%) and CABG in 147 (29.2%) from 2 to 10 weeks after the AMI. Of the 505 patients in the conservative treatment group, only 8 (1.6%) had been revascularized 2 months after the AMI. At 2.4-year follow-up (median), mortality was 3.6% in the invasive treatment group and 4.4% in the conservative treatment group (not significant). However, invasive treatment was associated with a lower incidence of recurrent AMI (5.6% versus 10.5%; $P < .0038$) and a lower incidence of admission for unstable angina (17.9% versus 29.5%; $P < .00001$). The percentages of patients with a primary endpoint were 15.4% and 29.5% at 1 year, 23.5% and 36.6% at 2 years, and 31.7% versus 44.0% at 4 years ($P < .00001$) in the invasive and conservative treatment groups, respectively. At 12 months, stable angina pectoris was present in 21% of patients in the invasive treatment group and 43% in the conservative treatment group.

In major randomized trials of thrombolysis therapy, patients with recurrent chest pain usually have angiography. Although no data from randomized trials have proven its efficacy, angiography is probably effective in this setting⁵⁷.

CHF group

AMI patients who develop clinical congest heart failure (CHF) or who have evidence of left ventricular dysfunction during the hospital management phase are important subgroups. Numerous studies have demonstrated that prognosis after AMI is largely dependent on residual left ventricular function, as determined by global ejection fraction^{58, 59}. Evidence from randomized trials comparing bypass surgery in patients with medical therapy shows improved survival with surgery in patients with depressed

left ventricular function who have three-vessels disease or two-vessel disease with involvement of the left anterior descending (LAD) coronary artery⁶⁰⁻⁶². Although these studies were performed in patients with chronic stable angina, the results are frequently extrapolated to patients with recent MI.

Cardiogenic shock

At the extreme of patients with left ventricular dysfunction are those who develop cardiogenic shock after MI. Data from the Worcester Heart Study⁶³ accumulated over a 13-year period show that around 7.5% of patients with MI developed cardiogenic shock after MI, and rates remained relatively constant from 1975 to 1988. Without any interventions, AMI patients with cardiogenic shock had a mortality rate between 74% and 82% compared to patients without this complication (13.5%). Because these patients often have poor outcomes^{49, 50, 64}, they have been excluded from many trials. A randomized study of PTCA versus medical therapy (SHOCK trial) provided important, definitive data on the relative benefit of PTCA for cardiogenic shock⁶⁵. It showed that in-hospital mortality was lower in early revascularization group (15% versus 67%, RR=0.74, 95% CI 0.54-1.02). After adjusting for difference in age, the difference in mortality was still significant. This is the largest multicenter prospective study of AMI patients diagnosed with cardiogenic shock. Nonrandomized observational data from the GUSTO trial supported the use of PTCA for management of shock both in patients who arrive in shock and in those who develop it during hospitalization too⁶⁶. Mortality rate in 30-day was 33 to 40% in PTCA-treated patients, compared with 75% in medically treated patients.

Prior MI

In TIMI-II, patients with a history of prior MI had a higher 42-day case-fatality rate (8.8% versus 4.3%; $p<0.001$), a higher prevalence of multivessel coronary artery disease (60% versus 28%; $p<0.001$) and a lower LVEF (42% versus 48%; $p<0.0001$) compared with patients presenting with a first MI. Among patients assigned to the conservative treatment after TT, those with a prior MI had a significantly higher 42-day mortality (11.5% versus 3.5%; $p<0.0001$), whereas with the invasive strategy, the mortality outcome was essentially the same in the two groups. This mortality benefit persisted up to 1 year⁶⁷ (10.3% versus 17.0%, $p=0.03$). Based on these observations, routine use of coronary angiography and coronary revascularization within 18 to 48 hours following intravenous thrombolytic therapy has been suggested for patients who have experienced a prior MI.

Diabetes

In TIMI-IIB, patients with diabetes mellitus had significantly higher 6 week (11.6% versus 4.7%), 1-year (18.0% versus 6.7%), and 3-year (21.6% versus 9.6%) mortality rates compared with non diabetic patients⁶⁸. In spite of these higher mortality rates, diabetic patients with a first MI who were randomly assigned to the invasive post thrombolytic strategy did worse than those managed conservatively in terms of 42-day mortality, (14.8% versus 4.2%, $p<0.001$). Contrary to clinical intuition, the expected benefits of an aggressive coronary angiography and coronary revascularization after thrombolysis appear to be offset in the presence of a first MI in diabetic patients.

Surgical reperfusion

About 10 to 20% of AMI patients are currently referred for CABG for one of the following indications: persistent or recurrent chest pain despite thrombolysis or PTCA⁶⁹, high-risk coronary anatomy (e.g., left main stenosis) discovered at angiography, or a complication of AMI such as ventricular septal rupture or severe mitral regurgitation due to papillary muscle dysfunction. Patients with AMI with continued severe ischemic and hemodynamic instability are likely to benefit from emergency revascularization. PTCA is the preferable technique when revascularization is needed in the first 48 to 72 hours following AMI. Surgery should be reserved for those in whom PTCA has been unsuccessful or whose anatomy dictates the need for coronary artery bypass grafting, such as patients with left main or extensive multivessel coronary artery disease⁷⁰.

1.7 Guidelines for coronary procedures use in AMI patients

Rigorous and expert analysis of the available data documenting relative benefit and risks of procedures have been used to produce guidelines designed to improve the effectiveness of care, optimize patients outcomes, and impact the overall cost of care favorably by focusing resources on the most effective strategies. Panels have developed criteria for the appropriateness and necessity of coronary angiography and revascularization. The American College of Cardiology (ACC) and American Heart Association (AHA) have published guidelines for the care of patients with AMI and guidelines for use of coronary procedures^{12, 71, 72}. These guidelines categorize indications for performing CA or revascularization as class I (usually indicated, always acceptable), class IIa (controversial, but favored owing to the weight of evidence and/or

opinion), class IIb (not well established by evidence, but probably not harmful) or class III (not indicated) (Table 1). The guidelines have been updated to include the most significant advances that have occurred in the management of patients with AMI as well as enable the medical profession play a significant role in critically evaluating the use of diagnostic procedures and therapies in the management and prevention of disease states.

1.8 Summary

Though studies showed there are variations in the rates of procedure use in the patients with AMI, it is less clear whether these variations result in important differences in patients' outcomes. Most of ecological or observational studies have not found significant differences in mortality between areas with high rates of use compared to those with low rates of use. The variations in use of angiography and revascularization and lack of clear benefit in general AMI patients have led many to question the appropriateness of angiography or angioplasty for patients with MI^{23, 36}. Because angiography and revascularization after AMI are not risk-free procedures, and the efficacy of routine CA and PTCA in improving prognosis has not yet been determined in all MI patients. Given the potential benefits, risks, and costs of these procedures, the marked variations in their utilization emphasize the difficulty in choosing the appropriate degree of intervention in the absence of data on definite outcomes, such as survival, recurrent cardiac events and quality of life.

The utilization of coronary angiography and revascularization procedures has important cost and resource implications in the provision of cardiologist services. Establishment of the appropriate role of coronary procedures in patients with AMI awaits demonstration of clear benefit, the definition of patients subsets most likely to

benefit, and better understanding of the cost effectiveness of such approaches. Therefore rates of use, determinants of use and resultant patient outcome require further study. However, it seems clear that coronary angiography and revascularization procedures should be used selectively rather than routinely in the post-myocardial infarction patient. Also the appropriate use of revascularization after AMI will be very much dependent on national priorities in health expenditure. Also, it is important to understand the sources of variation in procedure use from the standpoint of equity in the delivery of health care services and their impact on mortality and morbidity.

1.9 Thesis rationale

Thesis objectives

The purpose of the study is to analyze the differences in demographic and clinical characteristics among patients who receive invasive cardiac produces and those who do not. The main outcomes of the study are the use of coronary angiography and revascularization procedure in patients with AMI.

Specific questions

- Determine the rates of coronary angiography and revascularization (including angioplasty and bypass surgery) in patients who were hospitalized with AMI.
- Identify demographic and clinical features that were associated with coronary angiography and revascularization use

Chapter 2

METHODS

2.1 MICH Study

Purpose

The Michigan State University Inter-Institutional Collaborative Heart Study (MICH) was a hospital-based collaborative study of the hospital care for AMI patients in five community hospitals in Michigan. The area consisted of the counties of Genesee and Saginaw in the east-central region of the lower peninsular of Michigan. The project involved an organizing committee of the College of Human Medicine at three of MSU campuses: East Lansing, Saginaw and Flint. The study investigated the health care services in AMI and follow-up care in the first year following hospitalization. This study also investigated variations in care and costs by ethnicity, social class, age, gender, and payer type. In addition, the study examined how demographic characteristics, comorbid conditions, severity of illness and treatment affect patients' functional and mental states and impact upon family caregivers. The study included two cohorts of subjects. Phase I subjects were enrolled from January 1994 to April 1995. Phase II subjects were from February to September 1997. Observations on both cohorts continued for a minimum of one year after their hospitalization. This study is limited to Phase I patients because the data collection and diagnosis criteria were different in two phases.

Geographic setting

Saginaw County has a population of 212,295 in 1995. The largest city is the city of Saginaw, which has a population of approximately 70,000. Genesee County has 436,381 residents in 1995, with its largest city of Flint having a population of 138,864. In Genesee County, 51% of who were females and 18% were African or other minority. Five hospitals participated in the study. Those hospitals were Hurley Medical Center and McLaren Hospital located in Flint and Saginaw General, St. Mary's and St. Luke's Hospitals located in Saginaw.

Methodology

Human Subjects and informed consent

The Institutional Review Boards of Michigan State University and of all five participating hospitals approved this study. The consent form was approved by the University Committee on Research in Human Subjects (UCRIHS) with IRB# 93-334 (see appendix C). At the time of the study, all five participating hospitals were certified to offer coronary angiography (CA), percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass graft (CABG). None of the hospitals offered primary angioplasty (direct angioplasty) as initial management of AMI.

Case definition

MICH study is a hospital-based case series of AMI hospitalization patients recruited from two counties of Genesee and Saginaw.

Diagnosis criteria of AMI

The World Health Organization (WHO) criteria for the diagnosis of AMI were used to identify all acute myocardial infarction cases. The criteria required at least two of the following three elements be present.

1. Symptoms – any of the following chest discomfort such as shortness of breath, nausea, diaphoresis, dizziness, severe discomfort in the anterior chest, back, epigastrium, jaw, neck, shoulders, elbow, forearm or wrist, arm.
2. Elevated creatinine kinase (CK) and creatine kinase-MB (CK-MB) fraction >1.2 times upper limit of normal within 48 hours of onset of symptoms or acute event, or elevation of aspartate amino-transferase (SGOT) or Lactate dehydrogenase (LDH) > 2 times the upper limit of normal within 72 hours of onset of symptoms or event.
3. Evolutionary changes on serially obtained electrocardiographic (ECG) tracing: Q waves ($\geq 0.04s$) or QS finding ($\geq 0.04s$) + 0.1mV ST segment elevation in contiguous leads or 0.1mV ST segment depression or define T wave inversion.

Inclusion criteria

All patients from the five participant hospitals meeting the criteria of symptom of chest pain, high enzymes, and/or positive EKG were eligible for the MICH study.

Exclusion criteria

1. Those who were transferred from a non-MICH hospital. This is because the information of presenting symptoms and treatment was not available in detail in AMI patients transferred from a non-MICH hospital.

2. Those whose MI occurred as a complication of coronary angiography, coronary angioplasty, coronary artery bypass graft surgery or any other surgical procedure

Recruitment

Recruitment occurred in two distinct phases. Phase 1 began January 1, 1994 and recruited patients through April 30, 1995. Phase 2 began additional patient recruitment on March 1, 1997 ending in September 30, 1997. Two trained nurses identified eligible patients while they were hospitalized and approached them to obtain study consent. For phase I ward logs and medical records in all units likely to manage AMI patients (intensive care units, coronary care units, and surgical intensive care units) were screened to identify potential eligible patients. In addition, each patient who was admitted to a general medical ward with an admission diagnosis of chest pain, rule out "AMI or congestive heart failure (CHF)" was screened for eligibility.

Each admission for AMI during the enrollment period was assigned a unique study record number. Multiple hospitalizations occurred in the some individuals during the study period. The first AMI that resulted in study enrollment (that is, occurred during the enrollment period and that resulted in identification of the patient by the research nurse) was designated the "index MI" and was used as the reference point for follow-up. Patients were interviewed during hospitalization only once during a specified enrollment period.

Follow-up

Phase I patients who were interviewed during hospitalization were contacted by mail at three, six, nine and twelve months after discharge and participated in a final closing phone interview 12-36 months after their discharge. Data regarding function

status, stress score, quality of life, behavior changes and medication use were collected during the follow-up.

Data collection from medical charts

Data regarding demographics, prior history related to cardiac disease, physical findings, laboratory test, symptoms, complications, treatments (medical and surgical), comorbidity, in-hospital mortality and morbidity, and discharge instructions were abstracted from the medical charts. The data were recorded on a standard chart abstract form developed for the study (See Appendix D). A manual describing coding rules for each item on the chart abstract form was developed and used by all chart abstractors.

The data entry was performed by the study nurses at the time of the chart review, with a laptop computer. Data were audited for accuracy by two cardiologists who reviewed the medical records, ECGs and coronary angiogram when necessary.

Quality control of the data

For data abstracted from medical records, data quality control was maintained by checking a random 5% sample of medical records to ensure >90% interrater reliability. After data entry, similar random checks and range checks were performed to ensure data accuracy.

2.2 Thesis study

Study population

From the MICH database, we included the patients only admitted directly to the 5 MICH study hospitals in Phase I. We did not included phase II patients because the way the data collected and diagnosis criteria for AMI were different in two phases.

Definition of variables

Demographic characteristics of study patients were grouped into categorical variables. For example, age was classified as under 45, 45 through 54, 55 through 64, 65 through 74, and 75 year and older. Race was categorized into three groups: white, black and other. There were four insurance types (commercial, Medicare, Medicaid, self-insurance). Prior history of coronary artery disease, the development of AMI complications, procedures and treatments received during hospitalization were expressed as dichotomous variables (present or absent).

Complications of AMI during hospitalization were defined according to the evidence in the hospital records of either cardiogenic shock, congestive heart failure, or arrhythmia (VT/VF) having occurred during hospitalization. Prior medical history was recorded based on the hospital discharge diagnosis (ICD-9 CM). Charts were also reviewed to gather the information on prior medical history. For example, the diagnosis of diabetes was also recorded if information on the patient requiring insulin, oral hypoglycemic drugs, or dietary sugar restriction in the chart.

The diagnosis of new onset congestive heart failure (CHF) was defined from the typed chest X-ray report on the chart which contained any or the following phrases: congestive heart failure, pulmonary edema, pulmonary vascular congestion, pulmonary venous cephalization, Kerly B lines.

Charlson comorbidity index was computed for each patient according to the weighted index of comorbidity at the time of enrollment into the study⁷³.

The extent of coronary artery disease was summarized using a traditional classification of one, two and three-vessel disease. In addition if left main disease was

presented it was noted⁷⁴. Significant coronary artery disease was defined as $\geq 50\%$ occlusion of the lumen diameter of either the left anterior descending (LAD), circumflex (LCX) or right coronary (RA) at diagnostic coronary angiography. Significant left main disease was defined $\geq 40\%$ of the lumen diameter of the left main coronary artery. All coronary angiograms were read by one of two cardiologists. Stenoses were measured by the use of hand-held calipers in multiple views and quantified in comparison to the closest nonstenotic arterial segment.

Endpoints

The primary endpoints of this study were utilization of coronary angiography (CA) and revascularization procedures. Coronary angiography was defined as dichotomized variables, yes or no. Revascularization had three categories: medical therapy, PTCA only and CABG only. We recoded 18 patients who underwent both PTCA and CABG according to their first procedure.

Statistical analysis

In our primary analysis we examined the use of coronary angiography during hospitalization after the index admission among each MI patient. We used logistic regression analysis with specified predictors variables to predict whether the variables were associated with CA use for the overall study sample. We calculated odds ratios and 95 percent confidence intervals by exponent of the regression coefficient^{75, 76}.

To investigate what factors in the use of coronary angiography, a multiple logistic regression analysis was performed. Race, gender, age, and insurance were set as priority variables or prior confounders, which means that they stay in the model regardless of significance. Other potential independent variables in the full model were

selected on the basis of their univariate associations with a coronary angiography use. Only the variables with significant level ≤ 0.25 for univariate analysis were considered as candidate variables. The following demographic and clinical predictors were tested in the full model: demographic (age, race, gender, insurance), prior medical history and procedure (MI, angina, CHF, previous PTCA, CABG), cardiac risk factors (diabetes, hypertension, hypercholesterolemia), characteristics of AMI (chest pain at presentation, infarction location), complication of AMI during hospitalization (recurrent angina, cardiac shock, new onset of CHF) hospital and type of doctor involved. All the variables were categorical variables. Non priority factors that were statistically insignificant (i.e. $P > 0.05$) in the multivariable model were removed in a hierarchical backward elimination. The odds ratio of the remaining factors and the associated 95% confidence intervals were reported to demonstrate the relative influence of each factor on angiography utilization. We also evaluated the effect of adjusting for additional comorbidity measures (Charlson Index) in the final model. All statistics analyses were performed with SAS 8.0 statistical package programs. PROC LOGISTIC was used (SAS Institute, Inc, Cary, N. C., USA.).

In our second analysis we examined the use of revascularization procedures (defined as medical therapy, PTCA only, or CABG only) during hospitalization for these 619 patients who underwent angiography. Polychotomous logistic regression analyses were performed to determine the associated with revascularization procedures for the 619 patients who underwent coronary angiography. We also examined if the information from the cardiac angiogram had an effect on the decision whether to revascularization the patient and which procedure was used. Polychotomous logistic

analysis were performed with STATA 6.0 statistic package programs (STATA Corporation, College Station, TX)

Chapter 3

RESULTS

In the period between January 1994 and April 1995, 849 hospitalized myocardial infarctions were identified among the 5 MICH study hospitals. We obtained medical records for 846 eligible patients (Figure 7)

3.1 Demographics and clinical characteristics in total population

Table 2 presents selected baseline characteristics and previous CVD-related history of the 846 study patients. The mean age of the study population was 64.0 years with standard deviation 13.7 (median age 65 years). Age was also categorized into five groups, with 26.6% patients were 75 years older and more. Two-thirds of study population was male (73.3%). The majority of the study population was white (83.6%) with 15.2% black and 1.3% other race. Most of the patients had some type of health insurance. This included 38.3% patients with commercial insurance, 54.4% with Medicare, and 3.1% with Medicaid. Only 4.2% had no insurance. A majority of the patients had a prior history of CVD-related disease or risk factor, including prior MI (27.3%), prior angina (26.1%), hypertension (56.0%), and prior CHF (15.5%) (Table 2). A substantial proportion of the study population had prior coronary procedures. For example, 22.0% had prior coronary angiography, 10.3% had prior PTCA and 13.1% had prior CABG.

3.2 Clinical characteristics and complications of AMI

Clinical characteristics on presentation of the AMI population are displayed in Table 3. The majority of the 846 patients reported chest pain on presentation (74.5%). Their median peak CK and CK-MB level was 760 and 72 IU/L, respectively. Almost one-third of the patients had anterior infarction (30.1%), while other one-third (36.9%) had inferior infarction. Complications after AMI were very common. For example, half of the patients experienced recurrent angina pectoris (50.0%), and more than one-third (31.6%) patients developed new onset congestive heart failure during hospitalization. Nearly 7% patients had experienced ventricular tachycardia (≥ 3 consecutive ventricular beats) at least once during hospitalization (Table 3).

3.3 Coronary procedures use during hospitalization

Seventy-three percent (619/846) of MI patients underwent angiography during hospitalization in our study population. Among these 619 patients, approximately 30% (168) of the patients underwent bypass surgery and 35.2% (218) underwent angioplasty. However, a few patients (18 patients) were treated with both CABG and PTCA. We recoded them into PTCA or CABG group according to their first procedure. Coronary anatomy information was recorded for 600 patients (96.9%) who underwent CA. Approximately 10% of patients had significant left main coronary artery disease; more than one-third of the patients had significant one-vessel disease (31.5%); one-fourth of the patients had significant two-vessel disease (27.1%), and one-fourth had significant three-vessel disease (25.2%) (Figure 8). However, approximately 4.0% of the patients had no significant coronary artery disease as determined by angiography. Overall, approximately one-third of the patients had severe coronary disease as defined by either

$\geq 50\%$ stenose of the left main coronary artery or $\geq 40\%$ stenose of the main other three coronary vessels.

Among total patients, approximately 45% of patients were treated with TT during hospitalization. This proportion was higher for the patients who underwent CA than for those patients who did not receive CA (53.5% versus 24.7%).

3.4 Determinants of coronary angiography

We first examined the use of coronary angiography (CA) among patients hospitalized for AMI, as coronary angiography is a necessary diagnostic prerequisite to use of PTCA or CABG. The univariate analysis showed that women were significantly less likely to receive CA compared to men during hospitalization (OR 0.61, 95% CI 0.45-0.94) and that increasing age was associated with decreased use of angiography. When those less than age 45 years were compared to those 75 years old or more, the percent of patients receiving CA decreased from 89.5% to 52.4% (OR 0.13, 95% CI 0.06-0.26). A higher proportion of patients with commercial insurance received CA than those with Medicare or Medicaid (Medicare 62.8%, Medicaid 68.2%, no insurance 71.4%, versus Commercial 89.7%, $P < 0.0001$). However, this findings was probably confounded by age. Patients admitted to hospitals B, D, E were more likely to have their angiography done during hospitalization compared to hospital A (Table 4).

In the univariate analysis, it was also found that most factors associated with a worse prognosis or greater severity were associated with a lower likelihood of undergoing CA (Table 5). For example, patients with prior AMI were significantly less likely to undergo CA (OR 0.39, 95% CI 0.28-0.54) as were a patient with a history of CHF (OR 0.22, 95% CI 0.15-0.32), a history of cardiac arrest (OR 0.13, 95% CI 0.04-

0.38). Patients with complication of cardiogenic shock were less likely to undergo CA (OR 0.36, 95% CI 0.263-0.498) (Table 5). Coronary angiography was used less frequently in patients who developed new CHF during their hospitalization (OR 0.45, 95% CI 0.32-0.61, $P < 0.0001$). Coronary angiography was also performed less often in the patients that developed VT/VF arrhythmia during hospitalization (OR 0.39, 95% CI 0.13-0.34) (Table 6). Patients who did not receive TT were less likely to receive CA compared to patients who did receive TT (OR 0.29, 95% CI 0.20-0.40). The only adverse prognostic factor associated with a greater use of CA was recurrent angina (OR 1.38, 95% CI 1.02-1.87).

Multiple logistic regression model was used to identify predictors of having coronary angiography performed in AMI patients during hospitalization. All variables with p value less than 0.25 in the univariate analysis were entered in a full model. Ten patients whose race was categorized as other race were eliminated in the multiple logistic analysis because of small number. Thus, a final sample size of 836 was used to develop the multiple logistic regression model.

Age, gender, race, insurance status, prior cardiac history (AMI, CHF, cardiac arrest) CVD-related risk factors (hypertension, hypercholesterolemia, diabetes), and prior CABG, clinical characteristics (such as peak CKMB, peak CK, location of AMI), complications of AMI (recurrent angina, cardiogenic shock, new CHF developed at hospital, VT/VF arrhythmia, cardiac arrest), and thrombolysis therapy, hospital, type of doctor involved, which were all significant in univariate analysis ($P < 0.25$). Four variables were set as priority variables: age, gender, race and insurance status. We use backwards elimination which sequentially deletes the non-significant variables to create

a final model. The stepwise model development is illustrated in Table 7. The final model included age, race, gender, insurance type, prior AMI, prior CHF, prior cardiac arrest, complications of AMI, (such as cardiac arrest, cardiogenic shock, recurrent angina) and absence of TT use in the model. The final model included 827 observations due to missing values for the response or explanatory variables and was overall statistical significant ($p < 0.0001$). The deviance of the final model was 576.084 with 16 degree of freedom. The Hosmer and Lemeshow goodness-of-fit test statistic has a value 0.7132 with 8 degree of freedom, overall, p value < 0.7132 , so indicating a good fit of the data.

The final model (Table 8) indicated that after adjusting for other factors, women were as equally likely to have angiography as men (OR 0.98, 95% CI 0.63-1.54). Blacks were equally likely to undergoing coronary angiography as whites (OR 0.84, 95% CI 0.46-1.56). However, insurance status had large effect on the receiving CA. For example, patients with no insurance were significant less likely to have CA compared to patients with commercial insurance (OR 0.19, 95% CI 0.07-0.53). Patients 75 years old or more were still significantly less likely to have coronary angiography performed during their hospitalization compared to patients under 45 years of age (OR 0.19, 95% CI 0.07-0.53).

The multiple logistic models confirmed that factors associated with worse prognoses or greater severities were associated with a lower likelihood of undergoing CA (Table 8). Coronary angiography was performed less frequently in the patients with prior cardiac-related history. For example, patients with prior MI, or prior CHF, or prior cardiac arrest were less likely to have CA done during hospitalization. Patients who

experienced severe complications of AMI during their hospitalization such as cardiac arrest, cardiogenic shock were also significantly less likely to have CA. Patients who did not receive TT use were almost half less likely to receive CA. The only factor that was associated with high CA use was recurrent angina (OR 1.70, 95% CI 0.34-0.81) (Table 8).

We also checked the final model excluding the patients who had terminal disease, such as patients with metastatic cancer, or patients with liver failure (15 patients were excluded). We found that the ORs for each of the predictors did not change.

We also evaluated the effect of adjusting for additional comorbidity measures (Charlson Index) in the final model. With the Charlson index in the model, which was categorized into four groups (1, 2, 3, 4+), the overall model was significant with $p < 0.0001$. The ORs for each predictor variable did not change much (Table 9).

3.5 Determinants of revascularization

Polychotomous logistic regression model was used to estimate the odds of having revascularization procedure (Medical therapy only, PTCA only, or CABG only) performed in AMI patients who underwent CA during hospitalization. A total of 619 patients were in the univariate analysis. We recoded 18 patients who underwent both PTCA and CABG according to their first procedure.

Univariate Analysis

Several factors were found related to the revascularization use in the univariate analysis. Older patients were much more likely to have CABG over medical therapy relative to patients under 45 years of age (OR 3.30, 95% CI 1.52-7.15 for age 65-74, OR 3.18, 95% CI 1.41-7.13 for age 75+), but they were equal likely to undergo PTCA

(OR 0.79 95% CI 0.42-1.50 for age 65-74, OR 1.07, 95% CI 0.56-2.06 for age 75+) (Table 10). Men and women were equal in receiving PTCA or CABG as a treatment of AMI compared to receive medical therapy (OR 1.01, 95% CI 0.69-1.48 for PTCA, OR 0.77, 95% CI 0.51-1.18 for CABG) (Table 10). However, blacks were less likely to have their PTCA or CABG performed during hospitalization compared to whites (OR 0.51, 95% CI 0.30-0.87 for PTCA, OR 0.53, 95% CI 0.30-0.96). Medicaid patients and no insurance patients were less likely to have CABG, however, here associations were not statistically significant (Table 10). Compared to hospital A, patients admitted to hospital B were more likely to have both PTCA and CABG procedure over medical therapy. However, none of the other hospitals (C to E) showed statistically significant difference.

The univariate analysis also found prior CHF had strong association with less use of both PTCA and CABG (OR 0.46, 95% CI 0.24-0.88 for PTCA, OR 0.44, 95% CI 0.21-0.90) compared to patients without history of CHF (Table 11). Patients who developed complications during hospitalization were more likely to have revascularization during hospitalization. For example, PTCA and CABG were used more frequently in patients with recurrent angina and in patients with cardiogenic shock complication (Table 12).

We found that once CA was done, the information on the number of diseased vessels was the strongest predictor of the type of revascularization procedure. As expected, among patients underwent PTCA procedures, 86.4% of those patients had one- or two-vessel disease. Among patients underwent CABG, 71.6% of those patients had high severity of coronary disease defined as three-vessel disease or left main

coronary disease (Table 13). Patients with left main coronary or three-vessel disease were almost 6 times as likely to receive CABG over medical therapy relative to patients with only one- or two-vessel disease (OR 5.82, 95% CI 3.73-9.08) in the univariate polychotomous logistic analysis (Table 12). On the other hand, they were less likely to received PTCA over medical therapy compared to patients who had only one- or two-vessel disease (OR 0.36, 95% CI 0.22-0.59).

Multiple polychotomous logistic analysis

Multiple polychotomous logistic regression model was used to identify predictors of having revascularization procedure performed in AMI patients who underwent CA during hospitalization. All variables with p value less than 0.25 in the univariate analysis were entered in a full model. Twenty-eight patients whose race was categorized as other race or whose angiography data were missing were eliminated in the multiple polychotomous logistic analysis. Thus, a final sample size of 591 was used to develop the multiple polychotomous logistic regression model.

Age, gender, race, insurance status, prior cardiac history (AMI, CHF, angina) CVD-related risk factors (hypertension, hypercholesterolemia, diabetes), and prior CABG, prior PTCA, clinical characteristics (such as peak CKMB, location of AMI), complications of AMI (recurrent angina, cardiogenic shock, new CHF developed at hospital, cardiac arrest), and thrombolysis therapy, hospital, type of doctor involved and severity of coronary disease, which were all significant in univariate analysis ($P < 0.25$). Four variables were set as priority variables: age, gender, race and insurance status. We use backwards elimination which sequentially deletes non-significant variables to create a final model. The final model included age, race, gender, insurance type, prior CHF,

prior CABG, hypercholesterolemia, complications of AMI, (such as onset of new heart failure, cardiogenic shock, recurrent angina), type of doctor involved and severity of coronary disease. The final model included 587 observations due to missing values for the response or explanatory variables and was overall statistical significant ($p < 0.0000$).

The multiple polychotomous logistic model found that severity of coronary disease and complications of AMI were much more important determinants of revascularization use, while the demographic characteristics and insurance status were less important to determine the revascularization use. It consistently found that the severity of the diseased coronary was the strongest predictor to receive the type of revascularization (OR 6.68, 95% CI 3.94-11.3 for CABG, OR 0.35, 95% CI 0.21-0.61 for PTCA) (Table 14). Presence of AMI complications, such as cardiogenic shock was associated with greater likelihood of undergoing PTCA (OR 2.20, 95% CI 1.31-3.70) and CABG (OR 2.30, 95% CI 1.30-4.07). The occurrence of recurrent angina was associated with higher utilization rates of PTCA (OR 1.88, 95% CI 1.23-2.84) and CABG (OR 1.51, 95% CI 0.91-2.49) too. However, the patients with prior CHF were still less likely to receive CABG over medical therapy, patients with new onset CHF during hospitalization although they were equally likely to have PTCA over medical therapy.

In contrast to CA use in older age groups, patients 75 years and older were more likely to undergo both PTCA and CABG compared to patients under 45 years of age. However, the relationship between age and revascularization were not statistical significant. There were no statistical significant relationships between gender, insurance type, prior CVD-related history and PTCA use. However, many non-clinical factors

were associated with CABG use. Females were less likely to have CABG compared to males. Patients who were cared by cardiologists were more likely to have CABG. Interesting, race was the only demographic variables associated with less use of both PTCA and CABG. After adjusted for other factors, blacks were significant less likely to have PTCA compared to whites (OR 0.36, 95% CI 0.20-0.67). Blacks were also less likely to have CABG either (OR 0.55, 95% CI 0.32-0.96).

We also evaluated the effect of adjusting for additional comorbidity measures (Charlson Index) in the use of revascularization for the patients who underwent angiography. The ORs for each predictor variables did not change much with Charlson Index in the model (Table not shown).

Chapter 4

DISCUSSION

4.1 Angiography and revascularization rates in hospitalized AMI patients

This study found that the majority of patients (two-thirds) with acute myocardial infarction hospitalized in one of five community hospitals in mid-Michigan area underwent coronary angiography during hospitalization. After angiography, 35.2% patients received PTCA, 29.6% received CABG and 37.6% received medication therapy. Our results are similar to the study of Pilote³² who evaluated the angiography and revascularization use in the AMI patients according to region of the United States. He found that there were region variations in coronary procedure use in AMI patients among the US. The CA rate was 72% in the west-north central, and rate of PTCA and CABG was 48% and 19% respectively. The rates of coronary procedures use were lower in the study of 4823 AMI survivors in the Myocardial Infarction Triage and Intervention Project⁷⁷. Only 47.2% underwent CA, 14.4% underwent PTCA and 10.4% underwent CABG. Other studies have shown that procedure use was much lower in Medicare patients with AMI. Udvarhelyi¹⁶ found during the first 90 days after AMI, that only 23% of all patients underwent angiography, 8% underwent CABG and 5% underwent PTCA. High procedure rates in our study are probably due to the availability of catheterization laboratory facilities in all five participating hospitals. Some studies have shown that the patients admitted to hospitals with catheterization laboratory were more likely to undergo coronary angiography or revascularization^{32, 78}.

4.2 Demographics and angiography and revascularization procedures use

Our study explored the relationship between demographic characteristics and the use of angiography and revascularization procedures in patients with AMI. We found that demographic factors (such as older age) were associated with a lower rate of coronary angiography (CA) use. For example, although overall rate of CA use was two-thirds in our study, patients 75 years and older were less likely to undergo CA, compared to patients under 45 years of age after adjusting for other factors. Krumholz⁷⁹ also found that the percentage of patients who were referred for coronary angiography decreased significantly with age, from 60% among the patients younger than 65 years, to 37% among the patients 65 to 79 years old, to 11% among the patients 80 years and older ($p=0.0001$). Our study indicated among the 591 patients who had coronary angiography, no statistical significant relationship between age and the likelihood of undergoing coronary revascularization (both PTCA and CABG) before hospital discharge after adjusted for other factors, but several 'large' ORs indicated a potentially strong age effect, but these had wide confidence intervals (Table 14).

Race, gender and cardiac procedure use

Numerous studies have reported racial differences in the use of angiography or revascularization use in CHD patients as well as in AMI patients. Some of the studies had consistently found that whites with CHD were more likely to undergo CA than blacks or Hispanic¹⁶, some studies of CA have found rates more than twice as high for whites than blacks^{42, 80-82}, while others have found that the rates to be similar in whites and blacks.

Several studies have found that men with CHD are more likely to undergo CA than women after adjusting for other factors^{43, 83}, while other found there were no difference in utilization of CA between men and women with CHD or AMI.^{38, 39, 84-86} Many of these studies, however, have significant limitations. For example, these studies often relied on medical-claims data or administrative data, however, which do not contain important clinical information needed to identify patients with CHD accurately and to adjust for differences in the severity of disease or comorbidity⁸⁷. For instance, if blacks or women had less extensive coronary disease, fewer symptoms, or fewer comorbidities, then low rates of coronary revascularization procedures would be expected.

To overcome the limitations of those studies, we examined the use of CA and revascularization among patients whose severity of coronary disease was angiographically defined. We also adjusted our results to reflect baseline differences in demographic variables, prior CVD history and risk factors, and CVD-related diseases. Our study found that after adjusting for these confounders, whites and blacks were equally likely to undergo CA. However, revascularization (both PTCA and CABG) was performed less frequently in blacks than in whites, women were less likely to have CABG over medical therapy compared to men. However, they were equally likely to have PTCA as men (Table 14). Our study results were consistent with those of Maynard⁴² who found among 4,891 AMI patients, similar proportions of black and white patients received coronary angiography during hospitalization, while only 18% of black patients underwent coronary angioplasty compared with 26% of white patients (p

= 0.0004); CABG was also used less frequently in black patients (7% vs 12%, $p = 0.002$).

Our data also showed on average, women with AMI were 7 years older than men. Women had more comorbidity, such as diabetes (39.2% vs 21.4%), hypertension (64.3% versus 51.0%). Women also developed more complications of AMI, such as congestive heart failure (36.7% vs 28.5%), cardiogenic shock (32.0% vs 29.0%) recurrent angina (56.7% vs 45.7%) than men during hospitalization. Those findings are consistent with other studies^{44, 88, 89}. Hendricks found women were on average 5 years older than men ($p < .01$). By univariate comparison, women were more likely to have underlying hypertension ($p < .01$), diabetes mellitus ($p < 0.05$), and congestive heart failure (CHF, $p < .05$)⁸⁸.

Explanations for these racial or gender differences in the use of revascularization are few. It is possible that the patient's preferences for particular cardiac revascularization may differ according to race or gender. The decision to undergo coronary procedures is a complex one and can be influenced by the patient's symptoms, the perceived risks and benefits of the procedures, and other factors, such as one's trust in medical approaches involving advanced forms of technology. Because these preferences can alter the final therapeutic decision in many instances, physician-patient interactions become key to understanding practice patterns of revascularization in races⁹⁰. In this regard, the Coronary Artery Surgery Study (CASS) found that blacks were slightly more likely to decline CABG when their physicians recommend to it^{91, 92}. Schechter and colleagues⁹³ found in a study of 272 patients that black patients were more likely than whites to disagree with physicians' recommendations that they

undergo coronary angiography. Unfortunately, no information has been available about decision making by patients and physicians concerning coronary procedures in our study.

Second, it remains possible that unmeasured differences in clinical factors account for the lower use of revascularization among blacks or women. Although we did control for the extent of coronary disease, our measure of coronary disease severity was relatively crude, we were unable to determine whether a given patient was "angiographically" suitable for CABG or PTCA. Third, race or gender may be only a surrogate marker for other socioeconomic factors (such as educational level, employment status, and family support structures) which were not available in our study that may affect decisions about care to an equal or greater extent. Further investigations must clearly be directed at determining how patients assess the risks and benefits of coronary procedures and how their interactions with physician may affect that assessment.

4.3 Clinical characteristics and cardiac procedure use

Coronary angiography use

Our study found that except for an association between recurrent angina and the subsequent use of angiography, unfavorable prognostic factors such as prior AMI, prior CHF, prior cardiac arrest, or developing AMI complications, were associated with a lower and not a higher rate of CA. These findings are in contrast to the published guidelines,^{12, 71, 72} which stated that all of these factors as major indications for angiography. While our data suggest that angiography is predominantly performed in patients with the least potential to obtain a survival advantage from revascularization. It

appeared that patients at high risk, the group most likely to benefit from intervention, had the least chance to undergo angiography and revascularization. The large proportion of patients undergoing coronary procedures and the clinical variables that predicted the use of CA in our study are not completely consistent with the criteria identified in published guidelines and clinical trials. These sources suggest that uncomplicated infarctions have an excellent prognosis regardless of whether efforts at revascularization are made, whereas patients with complications have the most to gain from the procedures⁵³.

In our study, patients who had cardiogenic shock or congest heart failure that developed during hospitalization as well as patients who had prior MI, CHF or cardiac arrest were less likelihood to undergo CA than that of patients without these complications or prior CVD-related history. Spertus and coworker came to a similar conclusion in an analysis of 4823 MI survival patients⁷⁷. In their study it was found that except for recurrent angina, factors predicting higher mortality were associated with a lower rather than a higher use of angiography, which suggests that many patients who needed angiography did not receive it.

Revascularization use

In contrast to the angiography, we found that once the angiography was performed, however, the coronary anatomy chiefly determined the use of revascularization and the choice of the procedures. The choice of angioplasty as compared with bypass surgery clearly followed the pattern of “angiography for one or two-vessel disease” and “bypass surgery for three-vessels or left main disease”, as is consistent with current guidelines^{12, 71, 72}. In our study population, coronary disease

was less extensive in the PTCA group and more extensive in the CABG and medical therapy groups. Majority of patients underwent PTCA are one or two-vessels disease (86.4%), while majority of patients underwent CABG are left main disease or three vessel disease (71.6%). All other clinical or demographic factors were much less important in determining PTCA use.

These findings point to a divergence between an ideal decision-making strategy and the reality of clinical practice. First, clinicians appear to see younger age as a key factor. Second, clinicians appear to be selecting the patients likely to have good procedural outcomes rather than those who would derive the most benefit from a procedure. Third, insurance type plays a role in the decision-making of angiography. In an ideal world, clinicians would develop an overall estimate of the likely outcome given one treatment as compared to another, and would preferentially allocate resources to patients with more potential for benefit. If this had occurred in the cases we studied, angiography would have been performed much more often in older patients, and the majority of revascularization procedures would have been done in patients who develop complications of AMI.

Given the observational nature of our study, our results are more likely to reflect true practice patterns seen in communities. The ACC/AHA quality indicators are practice guidelines based largely on evidence from randomized clinical trials and were widely accepted even by the time this study was conducted. Why then does this gap between the actual care provided and the guidelines exist? Physicians may be unaware of the guidelines or disagree with their content, or they may be resistant to guidelines⁹⁴,⁹⁵. Alternatively, changes in behavior lag behind knowledge.

Gaps between physician knowledge and practice have important consequences. AMI is a common and serious condition, and the evidence from clinical trials strongly suggests that adherence to these established guidelines will result in better patient outcomes. It is undoubtedly true that some AMI patients experience unnecessary morbidity or mortality because they receive substandard medical care.

Although it may be possible to maintain or enhance the quality of care for patients through lower rates of use of procedures, we need to suggest specific situations in which clinicians should consider changes in current practice. To understand this issue, we should focus on clinical strategies, studies of strategies that provided information that can guide clinicians in making decisions and indicate opportunities for improvement in the care of patients.

4.4 Study limitations

There are several limitations to this study that should be noted. First, the analyses were restricted to the influence of a relative small number of clinical factors and demographic factors. There was no method for evaluating the effects of other factors that may influence the decision to undergo invasive patients management such as fears of malpractice, types of patients employment, patient preferences, or physician reimbursement. No information on physician and/or patient decision-making. Second, we did not have the information on the time ordering of developing complications of AMI and cardiac procedure use.

A third potential limitation of this study is focus on procedures performed only during the hospitalization and which is a relative short time frame. It is possible that the

use of an expanded time window to include post discharge procedure utilization may have altered these findings.

The fourth potential limitation of this study is a single geographic location with all five hospitals licensed to perform coronary procedures. Several studies have demonstrated that the presence of an on-site coronary angiography laboratory at the admitting hospital is an important predictor of subsequent angiography. The presence of an angiography laboratory appears to be a more important predictor than the clinical characteristics of the patient, including whether he or she has postinfarction angina or shock. Every and coworkers found that patients with AMI who were admitted to hospitals with angiography facilities were about three times more likely to undergo angiography than patients admitted to hospital without such facilities⁹⁶.

In conclusion, the use of coronary procedures among patients with AMI is more prevalent in our MICH population. Instead of the presence of high-risk clinical characteristic, which is associated with a greater benefit from revascularization, younger age appears to be the primary predictors of the use of coronary angiography. Aside from age, the presence of complications of AMI negative prognosis factors and no insurance predominately determine the less likelihood of angiography use. However, once the angiography is performed, the coronary anatomy largely determines the use of revascularization and the choice of the procedure.

APPENDIX A

Table 1 Classification Recommended by ACC/AHA for Indications for a Diagnostic Procedure, a Particular Therapy, or an Intervention in Patients with AMI

Class I	Conditions for which there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.
Class II	Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficiency of a procedure or treatment
Class II a	Weight of evidence/opinion is in favor of usefulness/efficiency
Class II b	Usefulness/efficacy is less well established by evidence/opinion
Class III	Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective and in some cases may be harmful

Table 2 Baseline Characteristics and Prior CVD-Related Histories Among the Total Population

	Total (846) N (%)
Age group, year	
<45	86 (10.2)
45-54	142 (16.8)
55-64	188 (22.2)
65-74	205(24.3)
>75	225 (26.6)
Female Sex (% of patients)	319 (37.7)
Race	
White	707(83.6)
Black	128 (15.1)
Other	11 (1.3)
Insurance	
Commercial	321 (38.3)
Medicare	456 (54.4)
Medicaid	26 (3.1)
No-insurance	35 (4.2)
Hospital	
A	168 (19.9)
B	344 (40.7)
C	71 (8.4)
D	217 (25.7)
E	46 (5.4)
Cardiologist involved (yes)	774 (91.5)
CVD-related history (% of patients)	
Myocardial infarction	231 (27.3)
Angina	221 (26.1)
CHF	131 (15.5)
Cardiac arrest	15 (1.8)
Risk factors (% of patients)	
Hypertension	474 (56.0)
Diabetes	238 (28.1)
Hypercholesterolemia	186 (22.0)
Prior coronary procedures	
Prior Angiography (CA)	186 (22.0)
Prior Angioplasty (PTCA)	87 (10.3)
Prior Bypass surgery (CABG)	111 (13.1)

CHF: congestive heart failure, CVD: cardiovascular disease

Table 3 Clinical Characteristics of AMI Among the Total Population

	Total (N= 846)
Median of peak cardiac enzyme (IU/liter)	
CK	760
CKMB	72
LDH	293
Infarction location N (%)	
Anterior	255 (30.1)
Inferior	312 (36.9)
Other	140 (16.6)
Missing	139 (16.4)
In-hospital Complication of AMI N (%)	
Recurrent angina	422 (50.0)
Cardiogenic Shock	255 (30.1)
New onset CHF	267 (31.6)
VT/VF arrhythmia	60 (7.1)
Asystole or AV block	81 (10.0)

CK: creatine kinase; CK-MB: creatine kinase MB, LDH: Lactate dehydrogenase; SBP: systolic blood pressure; DBP: diastolic blood pressure; HR: heart rate; VT/VF arrhythmia: Ventricular tachycardia/ ventricular fibrillation arrhythmia

Table 4 Univariate Associations of Baseline Characteristic and the Likelihood of Undergoing Coronary Angiography

Variables	Total N	CA N (%)	OR	95% CI	P
Age group, year					<0.0001
<45	86	77 (89.53)	1.00		
45-54	142	121 (85.21)	0.65	0.28-1.51	
55-64	188	155 (82.5)	0.55	0.24-1.16	
65-74	205	148 (72.2)	0.30	0.13-0.62	
>75	225	118 (52.4)	0.13	0.06-0.26	
Gender					<0.002
Male	527	405 (76.9)	1.00		
Female	319	214 (67.1)	0.61	0.45-0.94	
Race					<0.2353
White	707	521 (73.7)	1.00		
Black	128	88 (68.8)	0.79	0.53-1.19	
Other	11	10 (90.9)	3.57	0.68-65.7	
Insurance					<0.0001
Commercial	321	288 (89.7)	1.00		
Medicare	456	284 (62.8)	0.19	0.17-0.28	
Medicaid	26	18 (69.2)	0.26	0.10-0.64	
No-insurance	35	25 (71.4)	0.29	0.13-0.65	
Hospital					0.0127
A	168	106 (63.1)	1.00		
B	344	257 (74.7)	1.73	1.16-2.57	
C	71	50 (70.4)	1.40	0.77-2.57	
D	217	170 (78.3)	2.11	1.35-3.30	
E	46	36 (78.3)	2.11	1.01-4.75	
Cardiologist involved					<0.1161
No	72	47 (65.3)	1.00		
Yes	774	572 (73.9)	1.51	0.89-2.49	

OR: Odds Ratio; CI: confidence interval; CA: coronary angiography

Table 5 Univariate Associations Between Prior CVD-Related Histories, Coronary procedures and Cardiac Risk Factors and the Likelihood of Undergoing Coronary Angiography

Variables	Total N	CA N (%)	OR	95% CI	P
Prior CVD-related history					
AMI					<0.0001
Absent	615	483 (78.5)	1.00		
Present	231	136 (58.9)	0.39	0.28-0.54	
Angina					<0.1249
Absent	625	466 (74.6)	1.00		
Present	221	153 (69.2)	0.77	0.55-1.08	
CHF					<0.0001
Absent	715	561 (78.5)	1.00		
Present	131	58 (44.3)	0.22	0.15-0.32	
Cardiac arrest					<0.0005
Absent	835	4 (26.7)	1.00		
Present	15	615 (74.0)	0.13	0.04-0.38	
Risk factor					
Hypertension					<0.2221
Absent	372	280 (75.3)	1.00		
Present	474	339 (71.5)	0.83	0.61-1.12	
Diabetes					<0.0366
Absent	608	457 (75.2)	1.00		
Present	238	162 (68.1)	0.70	0.51-0.98	
Hypercholesterolemia					<0.0001
Absent	660	457 (69.2)	1.00		
Present	186	162 (87.1)	3.00	1.93-4.85	
Prior cardiac procedure					
Prior Angiography					<0.4435
No	660	487 (73.8)	1.00		
Yes	186	132 (71.0)	0.87	0.61-1.25	
Prior Angioplasty					<0.3938
No	759	552 (72.7)	1.00		
Yes	87	67 (77.0)	1.26	0.76-2.17	
Prior Bypass surgery					<0.0001
No	735	555 (75.5)	1.00		
Yes	111	64 (57.7)	0.44	0.29-0.67	

OR: Odds Ratio; CI: confidence interval; CVD: cardiovascular disease; CA: coronary angiography

Table 6 Univariate Associations Between Infarction Characteristics and the Likelihood of Undergoing Coronary Angiography

Variables	N	CA N (%)	OR	95% CI	P
Infarction Characteristics					
Peak cardiac enzyme (IU/liter)					
CK					<0.0070
≤ 760	427	295 (69.1)	1.00		
>760	419	324 (77.3)	1.53	1.12-2.08	
CKMB					<0.0090
≤ 72	444	308 (69.4)	1.00		
>72	402	311 (77.4)	1.11	1.11-2.06	
Infarction location					
Anterior	255	179 (70.2)	1.00		<0.1637
Inferior	312	241 (77.2)	1.44	0.99-2.10	
Other	140	104 (74.3)	1.23	0.78-1.97	
In-hospital Complications of AMI					
Recurrent angina					<0.0404
Absent	424	297 (70.1)	1.00		
Present	422	322 (76.3)	1.38	1.02-1.87	
Cardiogenic Shock					<0.0001
Absent	591	470 (79.5)	1.00		
Present	255	149 (58.4)	0.36	0.26-0.50	
New onset CHF					<0.0001
Absent	579	454 (78.4)	1.00		
Present	267	165 (61.8)	0.45	0.32-0.61	
VT/VF arrhythmia					<0.0005
Absent	786	589 (74.7)	1.00		
Present	60	32 (53.3)	0.39	0.23-0.66	
Cardiac arrest					<0.0001
Absent	765	586 (76.6)	1.00		
Present	81	33 (40.7)	0.21	0.13-0.34	
TT use					
Yes	387	331 (85.5)	1.00		<0.0001
No	549	288 (62.8)	0.29	0.20-0.40	

CK; creatine kinase; CK-MB; creatine kinase MB; LDH: Lactate dehydrogenase; SBP: systolic blood pressure; DBP: diastolic blood pressure; HR: heart rate; TT: thrombolysis therapy; VT/VF arrhythmia: Ventricular tachycardia/ ventricular fibrillation arrhythmia; OR: Odds Ratio; CI: confidence interval; CA: coronary angiography

Table 7 Model Selection for Coronary Angiography among 836 patients: Hierarchical Backward Elimination Approach

	-2ln L	Df	ΔDeviance	ΔDf	P value	N in the odel
Intercept only	787.875					
Model A	558.822	31				690
Model B	568.708	19	9.886	12	0.6260	827
Model C	573.429	17	4.721	2	0.0943	827
Model D	576.084	16	2.655	1	0.1030	827

Df: degree of freedom; L: Likelihood value

Model A is the full model initially consisting of all variables which were significant in univariate analysis ($p < 0.25$).

Model B removed the variables that were not significant in model A. (Those variables were prior, history of hypertension, diabetes, hypercholesterolemia, new onset CHF, cardiac enzyme level, location of AMI, and type of doctor involved, hospital)

Model C moved variables that were not significant in model B. (Those variables were prior CABG, cardiac enzyme level, VT/VF arrhythmia)

Model D is the final model with 11 variables as listed in Table 8

Table 8 Final Multiple Logistic Regression Model Relating Demographic and Clinical Characteristics to the Likelihood of Receiving Coronary Angiography in 836* Patients Hospitalized With AMI

Variables	N	OR	95% CI	P value
Age				0.0016
<45 (reference)	82	1.00		
45-54	137	0.84	0.46-1.56	
55-64	181	0.63	0.29-1.37	
65-74	203	0.82	0.21-4.14	
>75	224	0.19	0.07-0.53	
Gender				0.9295
Male	516	1.00		
Female	311	0.98	0.63-1.54	
Race				0.5620
White	700	1.00		
Black	127	0.84	0.46-1.56	
Insurance				0.0131
Commercial (reference)	317	1.00		
Medicare	451	0.63	0.29-1.37	
Medicaid	25	0.82	0.21-4.14	
No-insurance	34	0.19	0.07-0.53	
Absence of TT				< 0.0038
Present	578	1.00		
Absent	249	0.52	0.34-0.81	

Table 8 Final Multiple Logistic Regression Model Relating Demographic and Clinical Characteristics to the Likelihood of Receiving Coronary Angiography in 836 + Patients Hospitalized With AMI (Cont'd)

Variables	N	OR	95% CI	P value
Prior CVD-related history				
Prior MI				
Absent	600	1.00		< 0.001
Present	227	0.39	0.25-0.62	
Prior CHF				
Absent	698	1.00		< 0.011
Present	129	0.31	0.18-0.51	
Prior cardiac arrest				
Absent	812	1.00		< 0.0038
Present	15	0.14	0.03-0.60	
Complications of AMI				
Cardiac arrest during hospitalization				
Absent	812	1.00		< 0.0001
Present	15	0.26	0.13-0.52	
Cardiogenic shock during hospitalization				
Absent	451	1.00		< 0.0011
Present	376	0.47	0.30-0.74	
Recurrent angina during hospitalization				
Absent	750	1.00		< 0.0164
Present	77	1.70	1.11-2.63	

[†]Ten patients whose race was categorized as other was eliminated in the model.

Overall model was significant with p value <0.0001. The deviance of the final model was 576.084 with 16 degree of freedom. The Hosmer and Lemeshow goodness-of-fit test statistic has a value 0.7132 with 8 degree of freedom, overall, p value < 0.7132, so indicating a good fit of the data.

AMI: acute myocardial infarction, CHF: congestive heart failure, TT: thrombolysis therapy, OR: Odds Ratio; CI: confidence interval

Table 9 Multiple Logistic Regression Model Relating Demographic and Clinical Characteristics to the Likelihood of Receiving Coronary Angiography in 836* Patients Hospitalized With AMI

Variables	N	OR	95% CI	P value
Age				0.0023
<45 (reference)	82	1.00		
45-54	137	0.80	0.25-0.34	
55-64	181	0.66	0.21-1.81	
65-74	203	0.49	0.14-1.48	
>75	224	0.19	0.06-0.60	
Gender				0.9224
Male	516	1.00		
Female	311	1.02	0.65-1.61	
Race				0.6847
White	700	1.00		
Black	127	0.88	0.48-1.67	
Insurance				0.0118
Commercial (reference)	317	1.00		
Medicare	451	0.67	0.30-1.46	
Medicaid	25	0.88	0.22-4.60	
No-insurance	34	0.19	0.07-0.52	
Absence of TT				< 0.0086
Present	578	1.00		
Absent	249	0.55	0.35-0.86	

Table 9 Multiple Logistic Regression Model Relating Demographic and Clinical Characteristics to the Likelihood of Receiving Coronary Angiography in 836[†] Patients Hospitalized With AMI (Cont'd)

Variables	N	OR	95% CI	P value
Prior CVD-related history				
Prior MI				
Absent	600	1.00		< 0.001
Present	227	0.38	0.24-0.61	
Prior CHF				
Absent	698	1.00		< 0.001
Present	129	0.33	0.19-0.57	
Prior cardiac arrest				
Absent	812	1.00		< 0.0091
Present	15	0.13	0.03-0.56	
Complications of AMI				
Cardiac arrest during hospitalization				
Absent	812	1.00		< 0.0001
Present	15	0.26	0.13-0.50	
Cardiogenic shock during hospitalization				
Absent	451	1.00		< 0.0023
Present	376	0.49	0.31-0.78	
Recurrent angina during hospitalization				
Absent	750	1.00		< 0.0129
Present	77	1.74	1.13-2.70	

[†]Ten patients whose race was categorized as other was eliminated in the model.

Model adjusting for all the variables listed in the table and Charlson Index. Overall model was significant with p value <0.0001. The deviance of the final model was 572.697 with 19 degree of freedom. The Hosmer and Lemeshow goodness-of-fit test statistic has a value 0.6054 with 8 degree of freedom, overall, p value < 0.6054, so indicating a good fit of the data.

AMI: acute myocardial infarction, CHF: congestive heart failure, TT: thrombolysis therapy, OR: Odds Ratio; CI: confidence interval

Table 10 Univariate Polychotomous Logistic Model Estimating the Associations of Demographic Characteristics and Initial Type of Cardiac Revascularization Procedure Received During Hospitalization, Among 619 Patients with AMI Who Received Coronary angiography

Variables	Total N	Nothing N (%)	PTCA N (%)	CABG N (%)	PTCA OR [95%CI]*	CABG OR [95% CI]§	P
Age group, y							0.0196
<45	77	35 (45.5)	31 (40.3)	11 (14.3)	1.00	1.00	
45-54	121	47 (38.8)	52 (43.0)	22 (18.2)	1.25 [0.67-2.33]	1.49 [0.64-3.47]	
55-64	155	57 (36.8)	59 (38.1)	39 (25.2)	1.16 [0.64-2.14]	2.17 [0.98-4.80]	
65-74	148	54 (36.5)	38 (25.7)	56 (37.8)	0.79 [0.42-1.50]	3.30 [1.52-7.15]	
>75	118	40 (17.2)	38 (32.2)	40 (33.9)	1.07 [0.56-2.06]	3.18 [1.41-7.13]	
Gender							0.3991
Male	405	149 (36.8)	139 (34.3)	117 (28.9)	1.00	1.00	
Female	214	84 (39.3)	79 (36.9)	51 (23.8)	1.01 [0.69-1.48]	0.77 [0.51-1.18]	
Race							0.0568
White	521	184 (35.3)	192 (36.9)	145 (27.8)	1.00	1.00	
Black	88	45 (51.1)	24 (27.3)	19 (21.6)	0.51 [0.30-0.87]	0.53 [0.30-0.96]	
Other	10	4 (40.0)	2 (20.0)	4 (40.0)	0.48 [0.09-2.64]	1.27 [0.31-5.16]	
Insurance							0.0049
Commercial	288	108 (37.5)	112 (38.9)	68 (23.6)	1.00	1.00	
Medicare	284	104 (36.6)	84 (29.6)	96 (33.8)	0.78 [0.53-1.15]	1.46 [0.97-2.21]	
Medicaid	18	7 (38.9)	9 (50.)	2 (11.1)	1.23 [0.45-3.46]	0.45 [0.09-2.24]	
Self-insurance	25	12 (48.0)	11 (44.0)	2 (8.0)	0.88 [0.37-2.08]	0.26 [0.06-1.21]	

Table 10 Univariate Polychotomous Logistic Model Estimating the Associations of Demographic Characteristics and Initial Type of Cardiac Revascularization Procedure Received During Hospitalization, Among 619 Patients with AMI Who Received Coronary angiography (Cont'd)

Variables	Total N	Nothing N (%)	PTCA N (%)	CABG N (%)	PTCA OR [95%CI]*	CABG OR [95% CI] [§]	P
Cardiologist involved							0.1955
No	47	22 (46.8)	17 (36.2)	8 (17.0)	1.00	1.00	
Yes	572	211 (36.9)	201 (35.1)	160 (28.0)	1.23 [0.63-2.39]	2.08 [0.90-1.81]	
Hospital							0.0196
A	106	52 (49.1)	31 (29.3)	23 (21.7)	1.00	1.00	
B	257	77 (30.0)	110(40.8)	70 (27.2)	2.40 [1.41-4.08]	2.06 [1.14-3.70]	
C	50	33 (66.0)	13 (26.0)	4 (8.0)	0.66 0.30-1.44]	0.27 [0.09-0.86]	
D	170	58 (34.1)	53 (31.2)	59 (34.7)	1.53 [0.86-2.74]	2.30 [1.24-4.23]	
E	36	13 (36.1)	11 (30.6)	12 (33.3)	1.42 [0.57-3.55]	2.09 [0.82-5.27]	

* OR compare PTCA vs with no procedure [§] OR compare CABG with no procedure

PTCA: percutaneous transluminal coronary angiography; CABG: coronary artery bypass graft

Table 11 Univariate Polychotomous Logistic Models Estimating the Associations of Prior Medical History and Initial Type of Cardiac Revascularization Procedure Received During Hospitalization, Among 619 Patients with AMI Who Received Coronary angiography

Variables	Total N	Medical N (%)	PTCA N (%)	CABG N (%)	PTCA OR [95%CI]*	CABG OR [95% CI] §	P
Prior CVD-related history							
MI							
Absent	483	172 (35.6)	184 (38.1)	127 (26.3)	1.00	1.00	0.0145
Present	136	61 (44.9)	34 (25.0)	41 (30.2)	0.52 [0.32-0.83]	0.91 [0.58-1.43]	
Angina							
Absent	466	167 (35.8)	177 (38.0)	122 (26.2)	1.00	1.00	0.0377
Present	153	66 (43.1)	41 (26.8)	46 (30.1)	0.59 [0.38-0.91]	0.95[0.61-1.49]	
CHF							
Absent	561	201 (35.8)	203 (36.2)	157 (28.0)	1.00	1.00	0.0173
Present	58	32 (55.2)	32 (25.9)	11 (19.0)	0.46 [0.24-0.88]	0.44 [0.21-0.90]	
Cardiac arrest							
Absent	615	231 (37.6)	217 (35.3)	167 (27.2)	1.00	1.00	0.8659
Present	4	2 (50.0)	1 (25.0)	1 (25.0)	0.53 [0.04-5.9]	0.69[0.06-7.69]	
Risk factor							
Hypertension							
Absent	280	107 (38.2)	101 (36.1)	72 (25.7)	1.00	1.00	0.7654
Present	339	126 (37.2)	117 (34.5)	96 (28.3)	0.98 [0.68-1.42]	1.13 [0.76-1.69]	
Diabetes							
Absent	457	174 (38.1)	174 (38.1)	109 (23.9)	1.00	1.00	0.0043
Present	162	59 (36.4)	44 (27.2)	59 (36.4)	0.75 [0.48-1.16]	1.59 [1.03-2.46]	

Table 11 Univariate Polychotomous Logistic Models Estimating the Associations of Prior Medical History and Initial Type of Cardiac Revascularization Procedure Received During Hospitalization, Among 619 Patients with AMI Who Received Coronary angiography (Cont'd)

Variables	Total N	Medical N (%)	PTCA N (%)	CABG N (%)	OR [95%CI]*	PTCA OR [95%CI] §	CABG OR [95%CI] §	P
Hypercholesterolemia								0.0555
Absent	457	183 (40.0)	160 (35.1)	114 (25.0)	1.00		1.00	
Present	162	50 (30.9)	58 (35.8)	54 (33.3)	1.32 [0.85-2.04]		1.73 [1.10-2.71]	
Prior cardiac procedure								
Prior								0.3369
Angiography								
No	487	176 (36.1)	176 (36.1)	135 (27.7)	1.00		1.00	
Yes	132	57 (43.2)	42 (31.8)	33 (25.0)	0.74 [0.47-1.16]		0.75 [0.47-1.22]	
Prior								0.1522
Angioplasty								
No	552	212 (38.4)	197 (35.7)	143 (25.9)	1.00		1.00	
Yes	67	21 (31.3)	21 (31.3)	25 (37.3)	1.08 [0.57-2.03]		1.76 [0.95-3.27]	
Prior Bypass surgery								0.0805
No	555	201 (36.2)	198 (35.7)	156 (28.1)	1.00		1.00	
Yes	64	32 (50.0)	20 (31.3)	12 (18.8)	0.63 [0.35-1.15]		0.48 [0.24-0.97]	

* OR compare PTCA vs with no procedure § OR compare CABG with no procedure

PTCA: percutaneous transluminal coronary angiography; CABG: coronary artery bypass graft

Table 12 Univariate Polychotomous Logistic Models Estimating the Associations of Infarction Characteristics and Initial Type of Cardiac Revascularization Procedure Received During Hospitalization, Among 619 Patients with AMI Who Received Coronary angiography

Variables	Total N	Nothing N (%)	PTCA N (%)	CABG N (%)	PTCA OR [95%CI]*	CABG OR [95% CI] §	
Infarction Characteristics							
CK							0.2629
≤ 760	295	113 (38.3)	95 (32.2)	87 (29.5)	1.00	1.00	
>760	324	120 (37.0)	123 (38.0)	81 (25.0)	1.21 [0.84-1.76]	0.87 [0.59-1.30]	
CKMB							0.0131
≤ 72	308	126 (40.9)	91 (30.0)	91 (30.0)	1.00	1.00	
>72	311	107 (34.4)	127 (40.8)	77 (24.8)	1.64 [1.13-2.38]	0.99 [0.67-1.48]	
LDH							0.3480
≤ 293	339	132 (38.9)	123 (36.3)	84 (24.8)	1.00	1.00	
>293	280	101 (36.1)	95 (33.9)	84 (30.0)	1.00 [0.70-1.47]	1.31 [0.88-1.95]	
Infarction location							
Anterior	179	66 (36.87)	68 (38.0)	45 (25.1)	1.00	1.00	0.0699
Inferior	241	78 (32.4)	96 (39.8)	67 (27.8)	1.19 [0.76-1.87]	1.25 [0.76-2.07]	
Other	104	50 (48.1)	28 (26.9)	26 (25.0)	0.54 [0.51-0.96]	0.76 [0.42-1.40]	
Severe							0.0000
Low	387	157 (40.6)	184 (47.6)	46 (11.9)	1.00	1.00	
High	213	68 (31.9)	29 (13.6)	116 (54.5)	0.36 [0.22-0.59]	5.82 [3.73-9.08]	

Table 12 Univariate Polychotomous Logistic Models Estimating the Associations of Infarction Characteristics and Initial Type of Cardiac Revascularization Procedure Received During Hospitalization, Among 619 Patients with AMI Who Received Coronary angiography (Cont'd)

Variables	Total N	Medical N (%)	PTCA N (%)	CABG N (%)	PTCA OR [95%CI]*	CABG OR [95% CI] §
Complications of AMI						
Recurrent angina						0.0207
Absent	297	128 (43.1)	92 (31.0)	77 (25.9)	1.00	1.00
Present	322	105 (32.6)	126 (39.1)	91 (28.3)	1.67 [1.15-2.42]	1.44 [0.96-2.14]
Cardiogenic Shock						0.0002
Absent	470	195 (41.5)	164 (34.9)	111 (23.6)	1.00	1.00
Present	149	38 (25.5)	54 (36.2)	57 (38.3)	1.69 [1.06-2.69]	2.64 [1.64-4.22]
New onset CHF						0.0000
Absent	454	18 (94.0)	184 (40.5)	90 (19.8)	1.00	1.00
Present	165	53 (32.1)	34 (20.6)	78 (42.3)	0.62 [0.39-1.01]	2.94 [1.91-4.53]
VT/VF arrhythmia						0.6075
Absent	587	223 (38.0)	207 (35.3)	157 (26.8)	1.00	1.00
Present	32	10 (31.3)	11 (34.4)	11 (34.4)	1.18 [0.50-2.85]	1.56 [0.64-3.77]
Cardiac arrest						0.1049
Absent	586	225 (38.4)	207 (35.3)	154 (26.3)	1.00	1.00
Present	33	8 (24.2)	11 (33.3)	14 (42.4)	1.50 [0.59-3.79]	2.56 [1.04-6.24]
TT use						0.0001
Yes	331	108 (32.6)	142 (42.9)	81 (24.5)	1.00	1.00
No	288	125 (43.4)	76 (26.4)	87 (30.2)	0.83 [0.75-0.91]	1.00 [0.88-1.09]

CK creatine kinase, CK-MB creatine kinase MB, LDH: Lactate dehydrogenase, SBP: systolic blood pressure, DBP: diastolic blood pressure, HR: heart rate, TT: thrombolysis therapy; VT/VF arrhythmia: Ventricular tachycardia/ ventricular fibrillation arrhythmia, OR: Odds Ratio; CI: confidence interval

PTCA: percutaneous transluminal coronary angiography; CABG: coronary artery bypass graft

* OR compare PTCA vs with no procedure § OR compare CABG with no procedure

Table 13 Number of Diseased Coronary for Patients Who Underwent Angiography (N=619) by Revascularization Procedures

	Total N=619	Medical therapy N=233	PTCA group N=218	CABG group N=168
No. of diseased coronary vessels				
None	24 (3.9)	22 (9.4)	2 (0.9)	0
One	195 (31.5)	76 (32.6)	115 (52.8)	4 (2.4)
Two	168 (27.1)	59 (25.3)	67 (30.7)	42 (25.0)
Three	156 (25.2)	52 (22.3)	25 (11.5)	79 (47.0)
Left main	57 (9.2)	16 (6.9)	4 (1.8)	37 (22.0)
Missing	19 (3.1)	8 (3.4)	5 (2.3)	6 (3.6)
Severity of vessel disease*				
Low	387 (64.5)	157 (69.8)	184 (86.4)	46 (28.4)
High	213 (35.5)	68 (30.2)	29 (13.6)	116 (71.6)

*Severity of vessels was defined as either left main stenosed greater equal 40% or three vessels stenosed greater than 50% if left main artery stenosed was less than 40%.

PTCA: percutaneous transluminal coronary angiography; CABG: coronary artery bypass graft

Table 14 Multiple Polychotomous Logistic Regression Model Estimating the Association between Predictors and Type of Cardiac Revascularization Procedure Received During Hospitalization compared to Medical Therapy, Among 591⁺ AMI Patients Who Received Coronary Angiography

Variables	N	PTCA OR [95%CI]*	CABG OR [95% CI] ‡	P value
Age				0.0466
<45 (reference)	72	1.00	1.00	
45-54	111	1.85 [0.92-3.70]	0.78 [0.29-2.16]	
55-64	146	1.71 [0.87-3.37]	1.13 [0.44-2.89]	
65-74	143	1.30 [0.50-3.35]	2.42 [0.72-8.12]	
>75	115	1.57 [0.58-4.23]	2.25 [0.63-8.05]	
Gender				0.0184
Male	388	1.00	1.00	
Female	199	1.05 [0.68-1.64]	0.55 [0.32-0.96]	
Race				0.000
White	505	1.00	1.00	
Black	82	0.36 [0.20-0.67]	0.47 [0.22-0.97]	
Insurance				0.3286
Commercial (reference)	274	1.00	1.00	
Medicare	275	1.03 [0.48-2.20]	0.73 [0.28-1.86]	
Medicaid	16	2.38 [0.71-8.03]	0.84 [0.14-5.08]	
No-insurance	22	1.16 [0.44-3.10]	0.53 [0.09-2.98]	
Severity of coronary disease				0.0000
Low	379	1.00	1.00	
High	208	0.35 [0.20-0.61]	6.67 [3.94-11.3]	
Cardiologist involved				0.017
No	43	1.00	1.00	
Yes	544	1.11 [0.53-2.31]	3.42 [1.14-10.26]	

Table 14 Multiple Polychotomous Logistic Regression Model Estimating the Association between Predictors and Type of Cardiac Revascularization Procedure Received During Hospitalization compared to Medical Therapy, Among 591[†] AMI Patients Who Received Coronary Angiography (Cont'd)

Variables	N	PTCA OR [95%CI]*	CABG OR [95% CI] [§]	P value
Prior CVD-related history				
Hypercholesterolemia				
Absent	435	1.00	1.00	0.0082
Present	152	1.20 [0.74-1.94]	2.12 [1.21-3.73]	
Prior CHF				0.019
Absent	532	1.00	1.00	
Present	55	0.60 [0.29-1.21]	0.34 [0.14-0.85]	
Prior CABG				0.0000
No	524	1.00	1.00	
Yes	63	0.92 [0.46-1.85]	0.15 [0.06-0.34]	
Complication of AMI during hospitalization				
Cardiogenic shock				0.0004
Absent	443	1.00	1.00	
Present	144	2.20 [1.30-3.70]	2.30 [1.29-4.07]	
Recurrent angina				0.0023
Absent	280	1.00	1.00	
Present	307	1.88 [1.24-2.85]	1.51 [0.91-2.49]	
New onset of CHF				0.0000
Absent	432	1.00	1.00	
Present	155	0.54 [0.31-0.93]	2.67 [1.53-4.64]	

[†] Twenty-eight patients were excluded in the model due to in other race group or missing angiogram.

Total observation in the model was 587 due to missing in explanatory or response variables. The model was significant with p value < 0.0000. MI: myocardial infarction, CHF: congestive heart failure, TT: thrombolysis therapy, PTCA: percutaneous transluminal coronary angiography; CABG: coronary artery bypass graft

* OR compare PTCA vs with no procedure[§] OR compare CABG with no procedure; OR: Odds Ratio; CI: confidence interval

APPENDIX B

Estimate Direct and Indirect Costs of Cardiovascular Diseases and Stroke, United States 2000

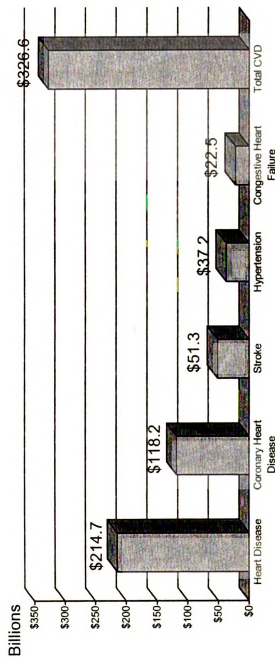


Figure 1 Estimate Direct And Indirect Costs of Cardiovascular Diseases and Stroke, United State 2000

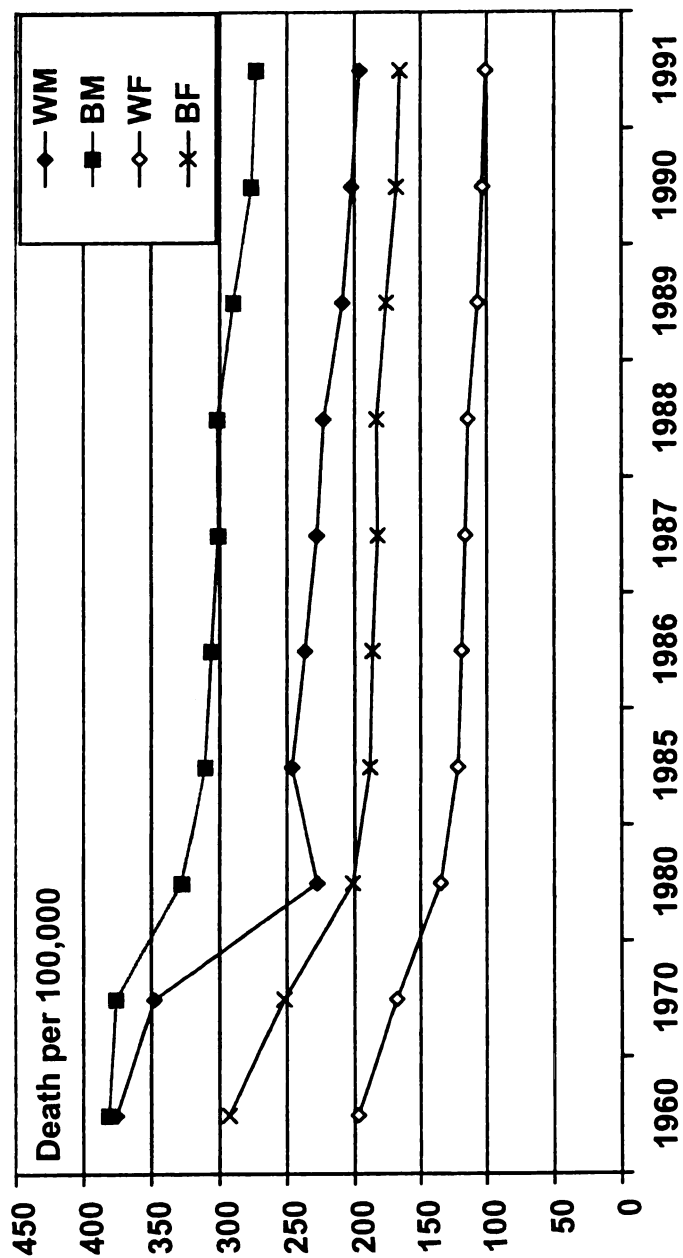


Figure 2 Age-Adjusted Death Rates for Disease of Heart by Race And Sex, 1960-91
Source: National Center for Health Statistics: Vital statistics of the United States, Vol. II, Mortality, Part A, 1960-91
Public health Service. Washington. U. S.

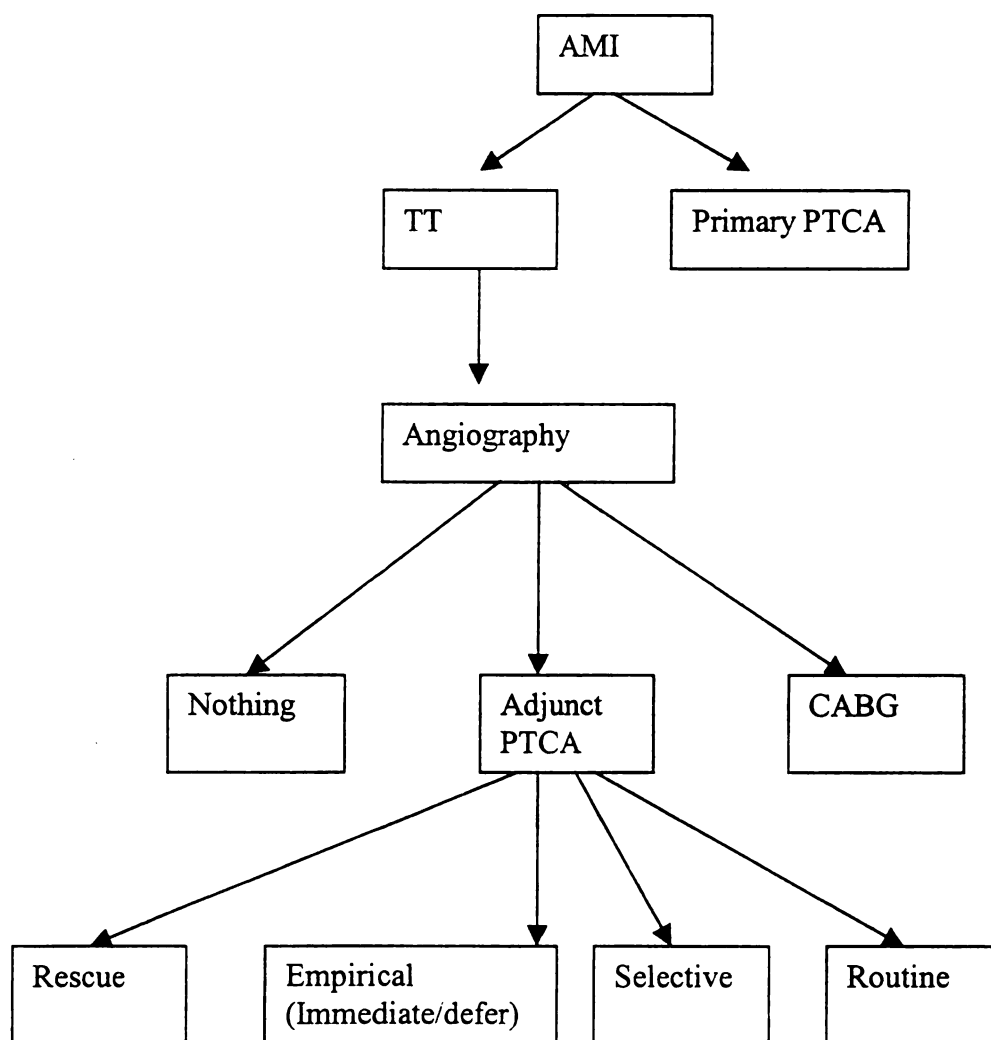


Figure 3 Flow of AMI Patients Undergoing Coronary Procedures

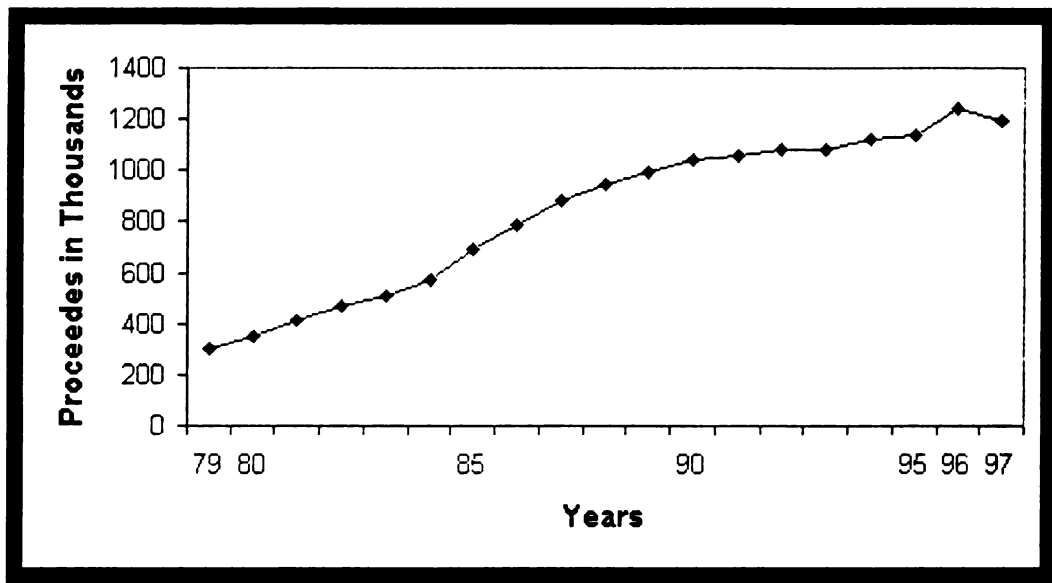


Figure 4 Diagnostic Coronary Angiography (CA) United States: 1979–97

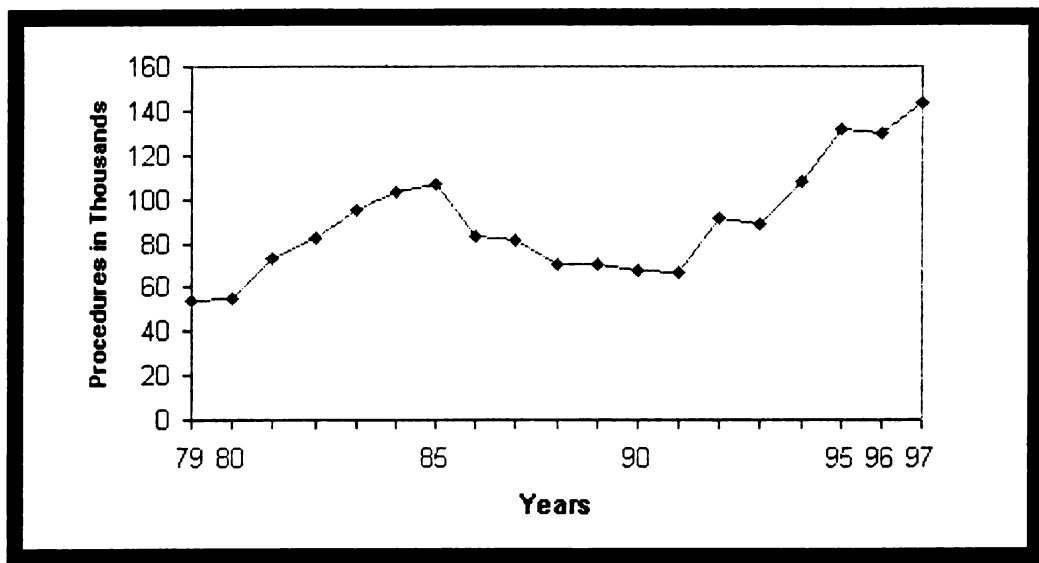


Figure 5 Percutaneous Transluminal Coronary Angioplasty Procedures (PTCA) United States: 1986–97

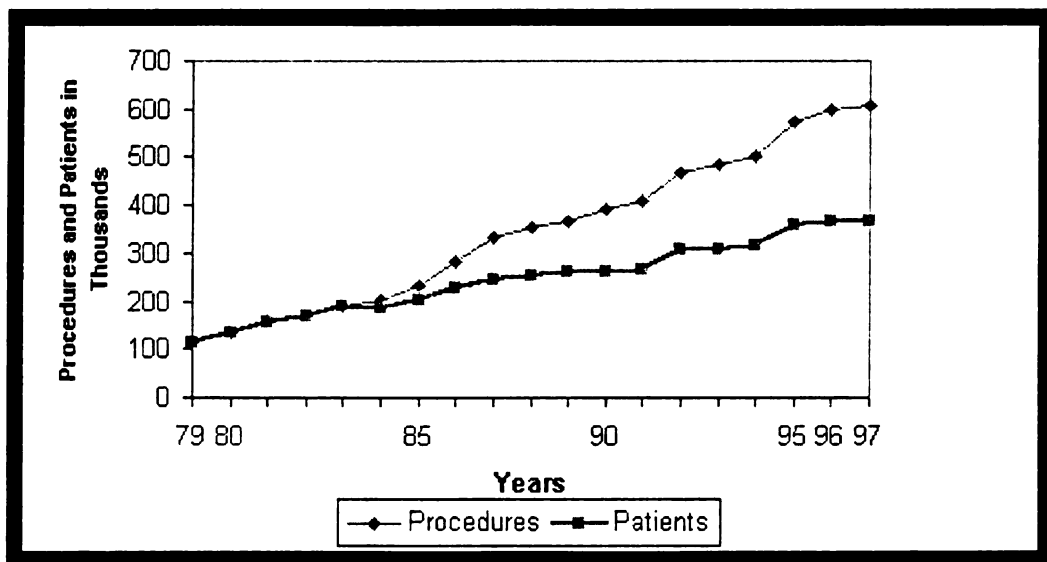


Figure 6 Corneary Artery Bypass Graft Procedures and Patients United States: 1979-97

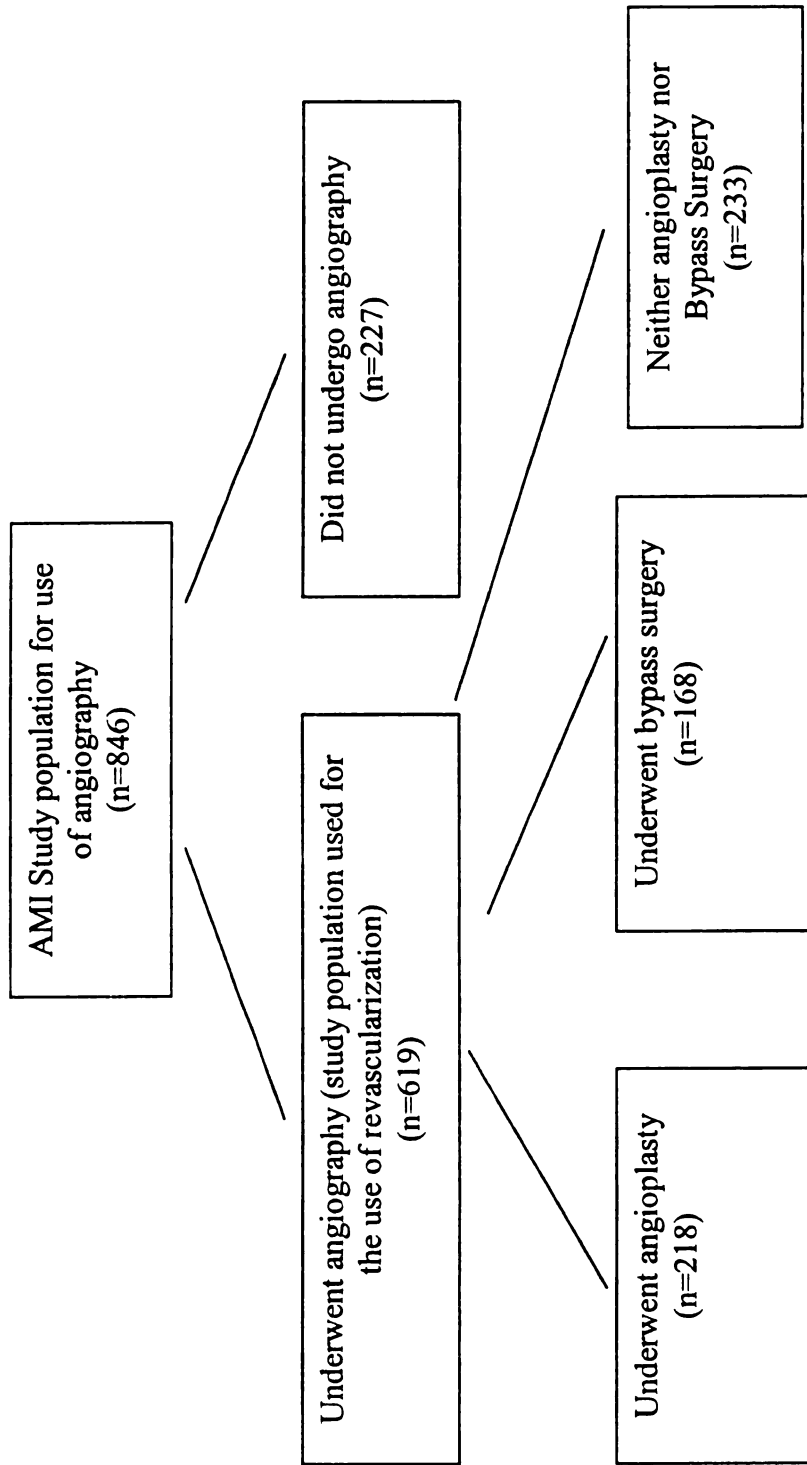


Figure 7 Outline of Study Samples Used for Each Analysis

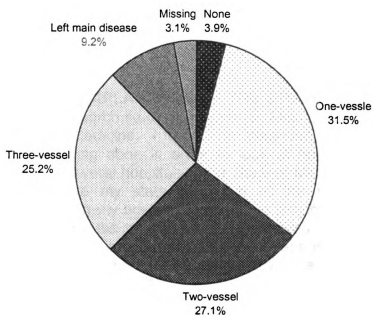


Figure 8 Coronary Anatomy Characteristics for Patients Who Underwent Coronary Angiography (N=619)

APPENDIX C

MICHIGAN STATE UNIVERSITY INTER-INSTITUTIONAL COLLABORATIVE HEART STUDY (MICH Study)

Consent Form

1. **SUMMARY EXPLANATION OF THE STUDY:** I am being asked to take part in a research study sponsored by Michigan State University College of Human Medicine. I have been diagnosed with a heart attack. This study is being done in order to look at how heart attacks are being treated in several hospitals in the State of Michigan. I will be interviewed to determine my state of health at the time of my heart attack. Information in my hospital chart will be studied to determine my medical condition and the treatments that I received while I was in the hospital. Also, I will be interviewed over the telephone at three, six, nine and twelve months after I am discharged from the hospital to determine how I am doing.
2. **ESTIMATE OF THE SUBJECT'S TIME:** The interview in the hospital will take about thirty minutes. The telephone interviews after I leave the hospital will take ten to fifteen minutes.
3. **VOLUNTARY PARTICIPATION** I freely consent to participate in this study. I may choose not to answer any of the questions during the interview at any time. I understand that I may stop the interview at any time if I choose to do so. I understand that I may also choose not to answer any of the questions during the telephone interviews after my discharge from the hospital. My participation in all aspects of this study is voluntary. If I refuse to participate in this study, it will not make any difference in the quality of any treatment that I may receive at this hospital. If I agree to participate in this study, I may change my mind and withdraw my participation at any time. If I later refuse to continue participating, it will not make any difference in the quality of any treatment I receive at this hospital.
4. **CONFIDENTIALITY AND ANONYMITY:** The investigators will keep all of the information obtained in this study confidential. No information obtained from this study that can be associated with me or my identity will be given to anyone without my permission within the limits of the law. I understand that the information obtained in this study may be published for scientific purposes provided that my identity is not revealed.

5. **PAYMENT FOR BEING IN THE STUDY:** I understand that I will not be given any payment for participation in this study.
6. **POTENTIAL RISK:** The interviews should cause no significant risk to me. I realize that I may refuse to answer any question that makes me nervous or uncomfortable.
7. **POTENTIAL BENEFITS:** The benefits that I will receive personally from participating in this study are minimal. If, during the interview, I think of any questions that I want answered about my medical care during this hospitalization, I will be encouraged to discuss this with my physician. This could possibly improve communication between me and my physician. Investigators hope that this study will be of very significant benefit to society in general. It is hoped that this information will help doctors better understand what tests and what treatments are most effective for people who have heart attacks.
8. **CONTACT PERSON:** If I have any questions later, Dr. Susan Smith at (313) 762-2063 or Dr. Ralph Watson at (517) 336-2404, will be happy to answer them.
9. **CONSENT:** I have read, or had read to me, the above information before signing this consent form. I have been given plenty of opportunity to ask questions and have received answers that fully satisfy those questions. If I do not participate, or if I discontinue my participation in this study, it will not affect my treatment in this hospital and I will not give up any of my legal rights. I volunteer to take part in this study.

I have received a signed, dated, and witnessed copy of this Informed Consent Agreement.

Patient's Signature

Date

Witness

Date

Signature of Investigator

Date

APPENDIX D

Study Record Number: _____

Hosp. of Initial Arrival _____

Arrival date _____ / _____ / _____
mm dd yy

Transfer from Hospital _____

Arrival date _____ / _____ / _____
mm dd yy

Transfer to Hospital (after identification) _____

Arrival Date _____ / _____ / _____
mm dd yy

Final Discharge Date..... _____ / _____ / _____
mm dd yy

Primary Insurance NIC(99)..... _____

Secondary Insurance NIC(99) _____

Date of Birth: _____ / _____ / _____
mm dd yy

Sex: Male (1) / Female (2) _____

Race (1)Aleut, Eskimo or American Indian/ _____
(2)Asian/Pacific Islander, (3)Black, (4)White, (5)Other, (9)NIC

Hispanic origin No(1)/Yes(5)/NIC(9) _____

Marital status..... _____
(1)Married, (2)Divorced, (3)Widowed, (4)Separated, (5) Never married, (6)Single, (9)NIC

Date of MI _____ / _____ / _____
mm dd yy

Did MI occur in hospital? _____
No (1) / Yes-In-patient (5) / Yes Out-patient (8)

Onset of chest pain:

Date: / /
mm dd yy

Calculated(1) or Explicit(2)

Time: :
hh mm

Calculated(1) or Explicit(2)

Arrival of EMS:

Date: / /
mm dd yy

Time: :
hh mm

Arrival in first ED:

Date: / /
 mm dd yy

Time: :
 hh mm

Cardiologist:
Not involved(1)/ Admitting(5)/ Consulted(7)

ENZYMES (NIC=9's)	Initial	Peak Value	Upper Limit of Normal
CK	_____	_____	_____
CKMB (amt)	_____	_____	_____
CKMB (%) or Index	_____	_____	_____

Symptoms during present event:

Severe discomfort in the:

No(1), Yes or non-specific(5), Right(2), Left(3), Both (4), NIC (9)

anterior chest.....
back.....
epigastrium.....
jaw.....
neck.....
shoulders.....
elbow.....
forearm or wrist.....
arm.....

No(1), Yes(5), NIC (9)

Shortness of breath.....
Nausea.....
Diaphoresis.....
Dizziness.....

Past Medical History

Smoke tobacco Never(1), quit(3), Current(5), NIC(9) _____

If quit, number of years since quit.....

Type of tobacco No(1), Yes(5), NIC (9)

cigarettes.....
cigars.....
pipe.....
other.....

[Specify] ..

Years smoked.....__ __

cigarettes smoked per day__ __

(1 pack = 20 cigarettes)

N(1)/Y(5)/NIC(9) Duration (yrs)

History of DKA__

Currently on diabetic diet.....__ __

Hypertension.....__ __

High cholesterol *Unknown(7)*__ __

Angina__ __

Previous cardiac interventions

N(1)/Y(5)/NIC(9) Year

CABG__ __

Angioplasty__ __

Thrombolysis__ __

of episodes__ __

Type of most recent TT before this admission *None(1)/ tPA(2)/SK(3)/ UK(4)/ APSAC(5)/ not specified(6)/ NIC(9)*.....__

Catheterization.....__ __

Perm. Cardiac Pacemaker.....__ __

Prosthetic valve__ __

**Implantable Cardiac
Defibrillator**.....__ __

Cardiac arrest *(suspected =7)*.....__ __

History of disease/Comorbidity at admission

	<i>Never (1) Suspected(3) Current (5) In past (7) Both (8) NIC (9)</i>	Notes
Myocardial infarct		
Congestive heart failure		
Peripheral vascular disease		
Cerebrovascular disease		
Dementia		
Chronic pulmonary disease		

Connective tissue disease		
Ulcer disease		
Diabetes Evidence of end organ damage? ____ (1)No/(5)Yes/ (9)NIC (non-diabetic enter 9)		Duration of diabetes in years: ____ (non-diabetic enter 0) Treated by diet alone? N(1)/Y(5)/NIC(9) ____ (non-diabetic enter 1)
Hemiplegia		
Moderate or severe renal disease		
Any tumor		
Metastatic solid tumor		
Leukemia		
Lymphoma		
Mild liver disease		
Moderate or severe liver disease		
AIDS		
Other[specify in notes]		
Other[specify in notes]		

Hospital Course

N(1)/Y(5)/NIC(9)

Recurrence of angina or ischemic symptoms..... __

Date: ____ / ____ / ____

Time: ____ : ____

Hypotension requiring intervention..... __

Diagnosed during hospital course

N(1)/Y(5)/NIC(9)

*confirmed
by X-ray*

Pulmonary Vascular

Congestion _____

Pulmonary Venous

Cephalization..... _____

Pulmonary Edema _____

Kerley B-Lines..... _____

Congestive Heart Failure _____

Arrhythmias *N(1)/Y(5)/NIC(9)* _____

Date: / /

Time: :

Type..... _____

Type: (1)sinus tachycardia, (2)sinus bradycardia, (3)sinus dysrhythmia, (4)atrial premature contractions/APC/PAC, (5)supraventricular tachycardia/SVT, (6)atrial flutter, (7)atrial fibrillation, (8)Junctional escape rhythm(nodal), (10)premature junctional contractions, (11)premature ventricular contractions/PVC, (12)ventricular tachycardia, (13)torsades de pointes, (14)ventricular fibrillation, (15)first degree AV heart block, (16)second degree AV heart block/Mobitz type I/Wenckebach, (17)seconddegree AV heart bloc/Mobitz type II, (18)third degree AV block/complete, (99)NIC

Tachycardia

Supraventricular tachycardia *N(1)/Y(5)/NIC(9)* _____
enter YES if either A. flutter or A. fib. present

Atrial flutter *N(1)/Y(5)/NIC(9)* _____

Atrial fibrillation *N(1)/Y(5)/NIC(9)* _____

Nonsustained ventricular tach. *N(1)/Y(5)/NIC(9)* .. _____

Sustained ventricular tach.(>30 sec) *N(1)/Y(5)/NIC(9)*..... _____

Ventricular fibrillation *N(1)/Y(5)/NIC(9)* _____

AV block _____
I(1) II(2) III(3) not specified(4) No(7) NIC(9)

Electrical defibrillation or cardioversion

None(1)/ During Transport(3)/ In Hosp.(5)/ Both(7)/ NIC(9) _____

Conduction Defects *N(1)/Y(5)/NIC(9)*

Atrioventricular dissociation..... _____

Asystole (*sinus arrest*)..... _____

Complete heart block..... _____

Pacemaker use *None(1)/ Temporary(5)/ Permanent(8)*..... _____

Complications during hospitalization

Date of procedure or NIC(9's)

Pleuritis (x-ray,ECHO) ___ / ___ / ___

Pleurocarditis(x-ray,ECHO) ___ / ___ / ___

Pleural effusion(x-ray, ECHO) ___ / ___ / ___

Pericardial effusion
(x-ray or ECHO) ___ / ___ / ___

Tamponade(ECHO) ___ / ___ / ___

Cardiac arrest ___ / ___ / ___

**Ruptured Papillary muscle
or chordae tendinae**..... ___ / ___ / ___

Ventricular septal rupture..... ___ / ___ / ___

Ventricular wall rupture ___ / ___ / ___

Thrombus (ECHO) ___ / ___ / ___

Death ___ / ___ / ___
[complete mortality form]

Pneumonia N(1)/Y(5)/NIC(9) ___

Sepsis N(1)/Y(5)/NIC(9)..... ___

Acute Renal Failure N(1)/Y(5)/NIC(9) ___

Stroke N(1)/Y(5)/NIC(9) ___

Hemorrhage N(1)/Y(5)/NIC(9) ___

Hematuria N(1)/Y(5)/NIC(9)..... ___

Other N(1)/Y(5)/NIC(9)..... ___

[Specify] _____

Procedures / treatments

N(1)/Y(5)

Date

Cardiac Catheterization #1 ___

Cardiac Catheterization #2 ___

Cardiac Surgery/ CABG..... ___

PTCA..... ___

Endotracheal Intubation ___

Date ___ / ___ / ___

Intra-Aortic Balloon Pump..... ___

Date ___ / ___ / ___

Echocardiogram ___

Radionuclide Ventriculogram (RVG)/MUGA.. ____

Date ____ / ____ / ____

LVEF % ____

RVEF % ____

Exercise tolerance test (ETT) (Rate Limited)..... ____

ETT (Rate Limited) with radionuclide

SPECT scan..... ____

Dipyridamole or Adenosine SPECT scan..... ____

Stress Echo ____

Other procedure..... ____

Date ____ / ____ / ____

[Specify] _____

Abstractor's Signature

personnel code

____ / ____ / ____

Date Completed

Reviewer's Signature

personnel code

____ / ____ / ____

Date Passed

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