PharmaSUG2011 - Paper HS04

COST-EFFECTIVENESS OF PRIMARY PCI AT HOSPITALS WITHOUT ONSITE CABG

Pedro Ramos, University of Louisville, Louisville, KY

ABSTRACT

A myocardial infarction (MI) occurs when blood supply to the heart is cut off by a blockage in one of the coronary arteries. Most hospitals treat a patient with thrombolysis or a percutaneous coronary intervention (PCI). The latter has been established as the preferred revascularization method. However, the American College of Cardiologists and the American Heart Association strongly recommend that a hospital performing PCI must also have coronary artery bypass graft capabilities (CABG). By following these recommendations, the state of Kentucky has limited the number of hospitals allowed to perform PCI and thereby limiting access to such a life-saving procedure.
Recently, the state of Kentucky evaluated if hospitals without such capabilities should be allowed to perform primary PCI, and the resulting data allowed the establishment of the medical soundness of allowing such hospitals to perform primary PCI. The current study aims to evaluate the financial feasibility of allowing these hospitals to do emergency PCI in addition to hospitals with onsite open-heart surgery capabilities.

Estimates have been derived from a systematic literature review of national studies based on PCI registries as well as our earlier study - *KENTUCKY PILOT PROJECT FOR PRIMARY PCI WITHOUT ONSITE CABG*. Costs estimates were derived from the National Inpatient Sample, which approximates a twenty percent sample of the U.S. community hospitals. In determining costs, the observations were extracted by filtering using ICD-9 codes. A deterministic model was developed so that more uncertainty would not be introduced. The economic evaluation focused on estimating the incremental cost effectiveness ratio (ICER) of allowing regional hospitals to perform primary PCI from a payer's perspective. Uncertainty about the model parameters was investigated through sensitivity analysis techniques.

The study found that there were no statistically significant differences in outcomes between hospitals with and without CABG capabilities. The only characteristic, which was significantly different between these two groups, was total charges. The alternative to allow *Regional Hospitals as well* to perform primary PCI dominated the other alternative of *Only Allowing Hospitals with Onsite CABG* to perform PCI. The study suggests that by allowing primary PCI to be performed at selected facilities without onsite CABG, the state of Kentucky can expand access to PCI and reduce geographical health disparities, one of its main healthcare initiatives.

INTRODUCTION

For individuals experiencing a myocardial infarction (MI), commonly referred to as a heart attack ((Association, 2010)), a trip to an emergency department to have the blocked artery quickly opened by inflating a small balloon and inserting a tiny metal structure called a stent that acts as permanent scaffolding is lifesaving. In these emergency situations, the above procedure is termed primary Percutaneous Coronary Intervention (PCI) ((Tcheng, 2002)). This is contrasted with elective PCI in which PCI is performed prior to a heart attack. Restoring blood flow to the heart muscle as quickly as possible is truly a benefit to the patient. The American College of Cardiology, the American Heart Association and the Society for Cardiovascular Angiography and Interventions strongly recommend that primary PCI should only be performed in facilities that have an experienced cardiovascular surgical team available as emergency backup for all procedures ((Antman, et al., 2004)).

Recently, the State of Kentucky has begun evaluating if hospitals without such capabilities should be allowed to perform primary PCI. As a result, data from this evaluation allowed us to establish the medical soundness of allowing such hospitals to perform primary PCI ((Myers, Brock, Appana, & Gray, 2009)); our results suggest that hospitals without surgical backup capabilities achieved similar outcomes as hospitals with surgical backup capabilities for all studied outcomes (mortality, door-to-balloon time, cardiac arrests and emergency surgeries as a result of the PCI). However, in order for health interventions to be incorporated effectively, both the effectiveness and the costs must be evaluated simultaneously. That is, to have the most comprehensive understanding of the effects of allowing hospitals without backup surgical capabilities performing primary PCI, the effects and costs must be evaluated simultaneously ((Drummond, 1997; Gold, Siegel, Russell, Weinstein, & Freemantle, 1997)). Myers et al.'s initial study failed to include costs in the analysis. Therefore, the current study investigates the costs associated with allowing hospitals without onsite Coronary Artery Bypass Graft surgery (CABG) capabilities to perform primary PCI in the State of Kentucky. As such, combing the current study with our earlier results allows us to calculate an incremental cost-effectiveness ratio to investigate the cost-effectiveness of this pilot program and established whether it is financially feasible to perform primary PCI at hospitals without backup surgical capabilities. A heart attack or myocardial infarction (MI) occurs when blood supply to the heart is disrupted by an occlusion in one or more of the coronary arteries. This deprivation of blood to the heart muscle causes damage or possibly death to the heart's tissues known as myocardium ((Association, 2008)). It is been well established that the longer the heart is deprived of blood, the more heart muscle is damaged and killed. The axiom cardiologists have is that time saved is heart saved; thus establishing the need to open the coronary arteries occluded as quickly as possible ((Tcheng, 2002)).

When an individual is experiencing a heart attack, the individual should visit an emergency department immediately. Once a patient is at the emergency department, emergency personnel will follow a well established and studied algorithm to determine if the individual is experiencing a MI. Nonetheless, emergency departments routinely begin treatment for an MI, believing a false-positive (treating a MI while the patient truly has, for example, heart burn) is a less severe mistake to make than a false-negative (treat for heart burn while the patient is experiencing an MI) ((Thygesen, et al., 2007)). A series of diagnostic tests will be conducted immediately upon arrival to the hospital: electrocardiogram, blood test, and echocardiogram. The electrocardiogram (ECG) and echocardiogram (ECHO) are usually performed in tandem. While an electrocardiogram assesses the electrical activity of the heart, an echocardiogram uses ultrasound to produce images of the heart structures. The benefits of these tests will be discussed below, but the results of these tests allow cardiologists to determine the exact type of MI a patient is experiencing (e.g., STEMI). The most definitive test to establish if a MI is occurring is the confirmatory blood tests. The human body only produces changes in the levels of the enzymes troponin and creatinine kinase if the heart muscle has recently been damaged. Therefore, if these enzymes show in the blood test, it is very definitive that a MI has occurred ((Thygesen, et al., 2007)). One of the least predictable and most severe heart attacks is classified as ST-elevated myocardial infarction (STEMI). It is caused by sudden clots, known as thrombotic occlusions, in the coronary arteries that had not experienced any narrowing previously ((DeGeare, Dangas, Stone, & Grines, 2001)). They are indicated by the electrocardiogram (ECG) that is performed upon admission to the emergency department when the ECG displays an abnormal elevation in the "ST segment" of the electrical heart wave. STEMI is considered the most severe type of heart attack because it is caused by a complete occlusion of one of the coronary arteries. The less blood flows into the heart and the longer the diminished flow lasts, the greater the damage to the heart muscle (myocardium) and the less likely the patient will recuperate. Currently, there are three options to treat patients experiencing a STEMI heart attack: (1) thrombolysis, (2) percutaneous coronary intervention (PCI), also known as balloon angioplasty, and (3) coronary artery bypass graft surgery (CABG) if three or more occlusions have occurred ((DeGeare, et al., 2001; King & Yeung, 2006; Manson, Ridker, Gaziano, & Hennekens, 1996)).

Thrombolysis consists of injecting the patient with clot-diluting drugs in order to open the blocked artery. However, thrombolysis has been considered a less effective and less efficacious reperfusion technique since it takes an extended amount of time to begin to work ((Antman, et al., 2004; King & Yeung, 2006)). By the time thrombolysis dilutes the clot, too much of the myocardium is dead or damaged severely. Thrombolysis was the first strategy developed to combat occlusions. However, more recently, PCI has been repeatedly shown in numerous differing populations to be more effective and efficacious when compared with thrombolysis in preserving more of a patient's myocardium. PCI has shown to have superior clinical outcomes such as lower mortality rates, lower rates of recurrence of thrombotic occlusion, lower rates of re-infarction, and shorter recovery times to a productive life ((DeGeare, et al., 2001; Nielsen, et al., 2010; Ribeiro, et al., 1993; Ribichini, et al., 1998; Zijlstra, et al., 1993)).

PCI (emergency angioplasty) is performed in a series of steps with slight variations for an individual case. Once the patient presents at the emergency facility, the patient's symptoms are assessed. Subsequently and immediately, an angiogram is performed. During an angiogram, a catheter is inserted into one of the femoral arteries (located in the groin/thigh) and guided to the coronary arteries. A contrasting substance is then injected into the vessel to make the area surrounding the heart clear in the X-ray images. It is this tool that allows the emergency personnel to determine what vessels are blocked. After the affected area has been determined, a balloon catheter is inserted and guided to the blocked vessel. Once in place, the balloon is inflated to open out the walls of the blood vessel and crush the clot. Also, it is recommended to place a tubular mesh, known as a stent, in the affected segment of the blood vessel to prevent the collapsing of the vessel's walls. Finally, the catheter is often removed and the entry-puncture sealed or the catheter may be left in place up to twelve hours depending on the length of time needed to thin the patient's blood. After successful angioplasty, most patients are discharged within 24 hours of the procedure. One key aspect for PCI to be successful is the door-to-balloon time (DTB) ((Blankenship, et al., 2009; Bohmer, Hoffmann, Abdelnoor, Arnesen, & Halvorsen, 2010; Fox, et al., 2002; Gibbons, et al., 1993; Grines, et al., 1993; Lotfi, Mackie, Dzavik, & Seidelin, 2004)). This is the length of time between the patient arriving at the emergency facility and the moment the balloon is inflated in the affected segment of a blood vessel. After many clinical studies, it has been determined that the DTB should be less than 90 minutes. The reason for this timeframe is that it provided, in multiple clinical trials, lower in-hospital death rates, reduced 30-day mortality rates, shorter average lengths of stay in the hospital, lower rates of re-infarction, and lower rates of re-occlusion ((Blankenship, et al., 2009; Gibbons, et al., 1993; Jamal, Shrive, Ghali, Knudtson, & Eisenberg, 2003; Lotfi, et al., 2004; Rathore, et al., 2009)).

The decision to allow hospitals without CABG capabilities to perform primary PCI rests on each state's regulatory body. While the American College of Cardiology/American Heart Association (ACC/AHA) guidelines give primary angioplasty without surgical backup a class 2b indication ("probably reasonable"), 30 states currently allow hospitals without surgical open heart surgery (SOS) capabilities to perform primary (emergency) PCI. A myriad of studies, mostly retrospective, have shown that no difference in clinical outcomes exists between hospitals with CABG capabilities and hospitals without surgical backup for primary PCI ((Brown, Mogelson, Harris, Kemp, & Massey, 2006; Hannan, et al., 2009; Jamal, et al., 2003; Myers, et al., 2009; Ong, et al., 2009; Paraschos, et al., 2005; Singh & Harrington, 2007; Thompson, et al., 2004; Wharton, et al., 2004)). Since, in the state of Kentucky, most cases of heart attack seem to originate in rural areas and the state of Kentucky does not permit the delivery of primary PCI in hospitals without surgical backup, a three-year pilot study to assess the soundness of allowing select facilities in Kentucky to perform primary PCI despite lacking onsite surgical backup was implemented in 2005 ((Myers, et al., 2009)). It involved two regional hospitals without onsite CABG capabilities: T.J Samson Community Hospital in Glasgow, Ky and Ephraim McDowell Regional Medical Center in Danville, Ky. This study concluded that there was no significant difference in any of the clinical outcomes between facilities with and without emergency backup capacity. Recommendations from this study included the revision of the ACC/AHA guidelines for primary PCI by allowing hospitals without backup open-heart surgical capabilities to perform emergency PCI with restrictions on surgeon's experience, catheterization lab team training, and facilities volume.

By incorporating the costs associated with the pilot program in addition to the effectiveness of the program, a Cost Effectiveness Analysis (CEA) can be executed to evaluate the cost-effectiveness of allowing hospitals without onsite CABG capabilities to perform primary PCI. Therefore, the current study alludes to the financial feasibility of allowing these hospitals to do emergency PCI in addition to hospitals with onsite open-heart surgery capabilities. Specifically, the current study focuses on the cost-effectiveness of allowing select facilities in Kentucky to perform primary PCI despite lacking onsite surgical backup capabilities when compared to only allowing hospitals with back-up surgical capabilities to perform primary PC. In addition, the current study discusses further potential savings in costs due to such effects as shorter hospital lengths of stay, transfer costs, readmission costs, and possibly the decrease in coronary heart failure (CHF) care that may materialize with a well-timed reperfusion.

METHODS

ST-elevation myocardial infarction (MI) is considered one the leading causes of acute cardiac syndromes. During the last decade, many technological and methodological developments have occurred in interventional cardiology that is aimed to assist with this type of MI. Such progress has made percutaneous coronary interventions (PCI's) safe and effective in the treatment of acute MI (AMI), in particular STEMI. During this time, many studies have shown that PCI produces significantly better outcomes compared to thrombolysis. Furthermore, these studies suggest that an aggressive treatment of STEMI is the more effective way to prevent deaths attributed to MI's. As a result, the national guidelines developed by the American Heart Association and the American College of Cardiology advocate primary PCI as the preferred treatment for patients with STEMI. However, a key aspect for the success of PCI is the door-to-balloon time. Studies have consistently demonstrated a negative association with the outcomes from a PCI and DTB time: the longer the DTB time, the less likely PCI will be successful. During the last decade, many interventional cardiologists and public health administrators have promoted the idea of allowing regional hospitals without open-heart surgery-on-site capabilities to perform primary PCI as one way to address this issue in rural areas.

It was the objective of this study to determine the cost-effectiveness of allowing selective regional hospitals without surgical backup for coronary artery bypass to perform primary PCI. The medical soundness of allowing selective regional hospitals without surgical backup for coronary artery bypass to perform primary PCI was established in our initial report from this pilot program. "Cost-effectiveness analysis is a method designed to assess the comparative impacts of expenditures on different health interventions… based on the premise that 'for any given level of resources available, society wishes to maximize the total aggregate health benefits conferred.' The central measure used in cost-effectiveness analysis is the cost-effectiveness ratio. Implicit in the cost-effectiveness ratio is a comparison between alternatives. The cost-effectiveness ratio for comparing the two alternatives is the difference in their costs divided by the difference in their effectiveness, or C/E."

The measurement of effectiveness for the current study is the number of deaths averted. The effectiveness estimates have been derived from a systematic literature review of national prospective studies based on PCI registries as well as our earlier study evaluating the KENTUCKY PILOT PROJECT FOR PRIMARY PCI WITHOUT ONSITE CABG ((Myers, et al., 2009)). Such studies have shown that differences in effectiveness of PCI between the two alternatives (allowing/not allowing these regional hospitals to perform primary PCI) were not statistically significant. Five studies from the literature review were considered to have relevance and deemed pertinent for the current study. They were selected by the author based on the study population, sample size, study design, outcome variables of interest, and follow-up time. Specifically of interest were studies that included mortality rates stratified by door to balloon time intervals, complication rates due to the differing physiology of the patients and due to catheterization, and the corresponding emergency surgery rates. The measures of clinical complications comprised several major adverse coronary cardiac events: stroke, bleeding, infarction size, and repeated PCI. Most studies favored a short door to balloon time. Also, many of the studies suggested that it is efficacious to allow regional hospitals without surgical backup to perform primary PCI. For example, the study "Safety In Numbers For Community Hospitals Performing Emergency Angioplasty" from Johns Hopkins University School of Medicine and its Heart and Vascular Institute found that the mortality rate in nonsurgical hospitals to be 2.2% and not significantly different from the mortality rate observed in hospitals equipped with open-heart surgical facilities. Also from this study, the proportion estimates for a door-to-balloon time less than or equal to 90 minutes was determined to be 44.8%. Similarly, the earlier report evaluating the KENTUCKY PILOT PROJECT FOR PRIMARY PCI WITHOUT ONSITE CABG found that there were no differences in mortality rates, emergency surgery as a result from PCI, and door-to-balloon time between regional non-surgical hospitals and national estimates from hospitals with open heart surgery capabilities.

INTERVENTION COSTS

The National Inpatient Sample (NIS) database contains all-payer data on hospital inpatient stays from states participating in the Healthcare Cost and Utilization Project (HCUP). The database consists of three tables with records from the year 2005: inpatient records, hospital characteristics, and severity index. One of the NIS main functions is to promote comparative studies on costs and the use of hospital services. The NIS contains information on nearly eight million hospital stays for the year 2005, which makes the NIS the largest database of all-payer inpatient observations. The inpatient records table contains one record per inpatient admission with information about primary and secondary diagnosis, primary and secondary procedures, patients' demographics, admission and discharge status, total charges, and length of stay. The charge information is collected on all patients regardless of payer; that is, it includes coverage information from patients covered by Medicare, Medicaid, and private insurance, as well as those who are uninsured. The hospital characteristics table has information on 1,056 hospitals that comprise the sample. This table contains information such as hospital ownership, size, teaching status, region, metropolitan area, and hospital ID that corresponds to records in the American Hospital Association database. The design of the sample is to approximate a twenty percent sample of the U.S. community hospitals, which encompasses specialty hospitals, public hospitals, and academic medical centers. The hospital universe is defined by all hospitals that were open during any part of each calendar year and were designated as community hospitals in the American Hospital Association Annual Survey Database. In determining costs, the inpatient table was first filtered to contain only observations corresponding to a principal diagnosis of STEMI. This was achieved by filtering using the ICD-9 code 410. Hospital information was added by linking this table to the hospital characteristic table using the hospital ID. Subsequently, only observations from the Midwest and South were retained to make cost more appropriate for the regional hospitals evaluated. From this subset, observations corresponding to primary PCI were identified using the procedure variables: the corresponding ICD-9 code used was 00.66, and all non-PCI records were dropped. Then, observations corresponding to emergency CABG were identified by using the ICD9 code 36.1X. Finally, cost estimates were obtained for primary PCI only for facilities without onsite backup and for facilities with surgery on site capabilities. Table 1 summarizes the codes used to obtain these costs.

Table 1. ICD-9 codes used to obtain relevant costs from the NIS dataset

ICD - 9	Description
410	Acute Myocardial Infarction
0.66	Percutaneous transluminal coronary angioplasty
0.4	Procedure on single vessel
0.41	Procedure on two vessels
0.42	Procedure on three vessels
0.43	Procedure on four or more vessels
36.11	(Aorto) coronary bypass of one coronary artery
36.12	(Aorto) coronary bypass of two coronary arteries
36.13	Aorto) coronary bypass of three coronary arteries
36.14	(Aorto) coronary bypass of four or more coronary arteries
36.06	Insertion of non-drug-eluting coronary artery stent(s)
0.45	Insertion of one vascular stents
0.46	Insertion of two vascular stents
0.47	Insertion of three vascular stents
0.48	Insertion of four or more vascular stents

ANALYSIS

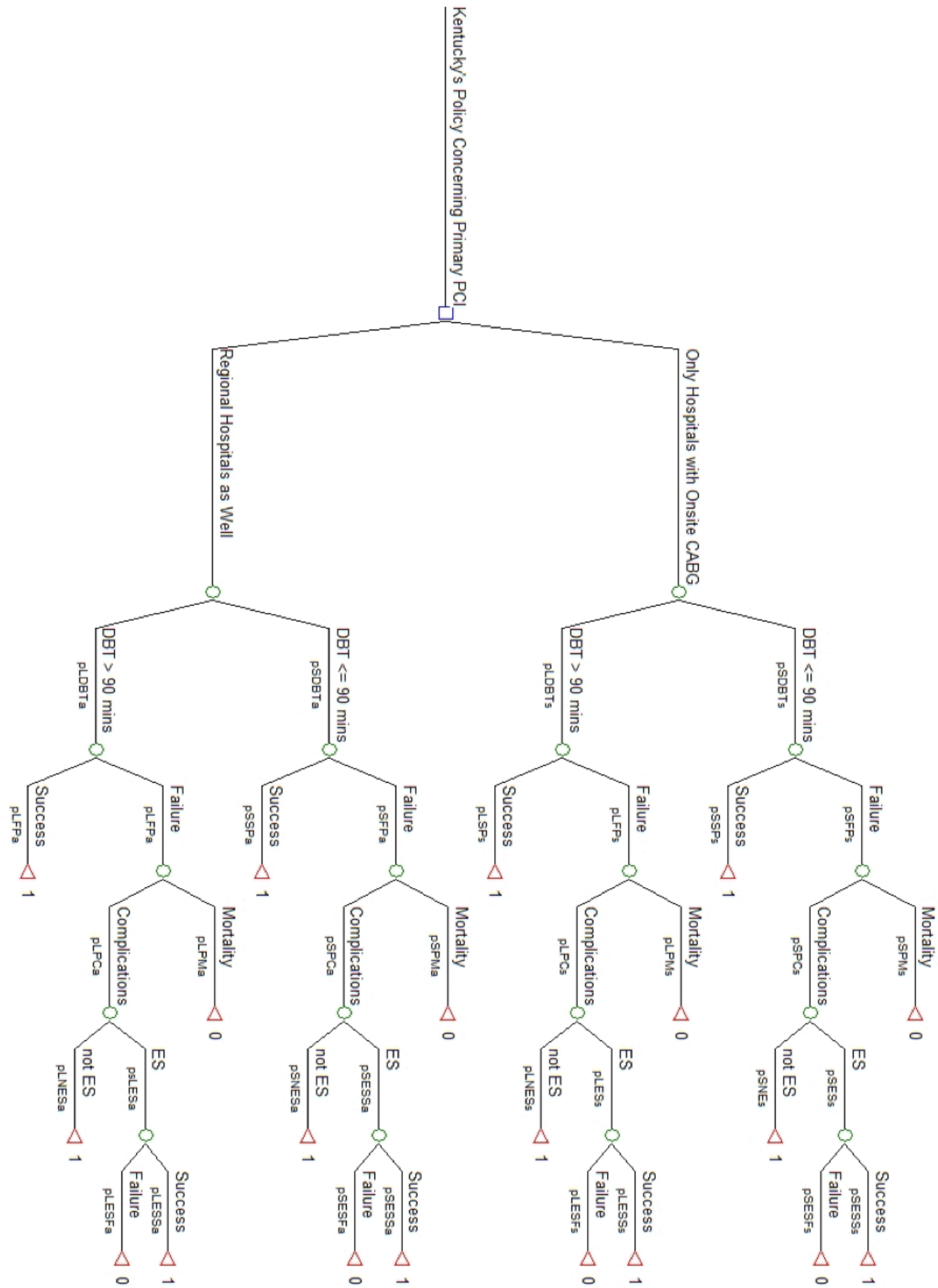
The current study was focused on Kentucky's policy on primary PCI. The question of interest is "Is allowing hospitals without open heart surgical backup to perform primary PCI cost effective?" The evaluation developed for this assessment is based on a 30-day decision-analytical model, which examines the benefits and costs of two strategies: (1) performing primary PCI only in hospitals with backup surgery and (2) performing primary PCI in both hospitals with and without CABG capabilities (that meet the recommendations in Myers et al.). The model displays the likelihood a patient having an acute myocardial infarction experiences all plausible and relevant c events (See figure 1 and table 3). The structure of the model, presented in figure 1, was developed using evidence from a systematic literature review of clinical effectiveness of primary PCI. The model represents the pivotal states that would determine both the costs and effectiveness of the alternative treatment options for people experiencing an acute myocardial infarction. The economic evaluation focused on estimating the incremental cost effectiveness ratio (ICER) of allowing the regional hospitals to perform primary PCI. The perspective of the study is from the payer. As a consequence, capital costs, training costs, and overhead costs were not included in this study. Uncertainty about the model parameters was investigated through employing sensitivity analysis techniques, which tested how the assumptions affected the outcomes and sensitivity of each variable. As a result, the model for this study includes two main pathways in the analysis tree for treatment of acute myocardial infarction (AMI). It shows that patients suffering from an acute myocardial infarction have two options: (1) only allowed to receive a primary PCI in a hospital with open-heart surgery backup or (2) (for those in rural areas) allowed to receive a primary PCI in a hospital without CABG capabilities. When an individual experiences an AMI, they will usually be transported to nearest hospital. This primary center may be equipped with surgical-on-site capabilities or, if in a rural area, may be a hospital without surgical backup. A key aspect in the treatment of AMI, in particular of STEMI, is the response time of the medical facility. In particular, the door-to-balloon time (DBT) is critical in the effectiveness of primary PCI with respect to mortality and morbidity. DBT refers to the time from the moment the individual arrives to the hospital to the moment when the catheter crosses the culprit lesion and a balloon is inflated to open up the artery's blockage. Based on many studies, the American Heart Association and the American College of Cardiology have established as a guideline that DBT is not to exceed 90 minutes. This means that the proportion of patients with a door-to-balloon time greater than ninety minutes is associated with a higher rate of mortality and unsuccessful PCI. Clearly, requiring that a person suffering from an AMI be transported to a facility with surgical backup capabilities increases the DBT. Thus, allowing individuals in more remote areas to receive a PCI at a regional facility may be beneficial. It is well established that medical interventions, even those successfully performed, do not guarantee a successful outcome. Primary PCI can have two direct outcomes regardless of door to balloon time: mortality and intervention survival. Having survived primary PCI occurs in two health states: successful PCI and complications. Patients who survive the intervention may have complications requiring emergency open-heart surgery or minor complications related to their physiology. Those patients who do not require emergency surgery are considered as lives saved with a utility value of 1. Alternatively, the complications that lead to emergency coronary by-pass surgery have with resulting outcomes of mortality or success as a saved life.

The cost-effectiveness ratios are computed by taking the difference in costs from the two clinical facilities for primary PCI while the denominator is obtained by the difference in the number of deaths prevented on each branch. Sensitivity analysis was conducted for the estimated proportions of door to balloon time and complications with respect to the hospital categories. In addition, estimated costs for primary PCI and emergency coronary bypass surgery are analyzed up to a two-fold increase for both branches.

Table 2. Model's probabilities

Probabilities	Definitions
pSDBTs	Short Door to Balloon Time for surgical hospitals (<=90 min)
pLDBTs	Long Door to Balloon Time for surgical hospitals (>90 min)
pSDBTa	Short Door to Balloon Time for all hospitals (<=90 min)
pLDBTa	Long Door to Balloon Time for all hospitals (>90 min)
pM_SDBTs	Mortality and Short Door to Balloon Time for surgical hospitals
pM_LDBTs	Mortality and Long Door to Balloon Time for surgical hospitals
pM_SDBTa	Mortality and Short Door to Balloon Time for all hospitals
pM_LDBTa	Mortality and Long Door to Balloon Time for all hospitals
pCPCIs	Complications after PCI for surgical hospitals
pCPCIa	Complications after PCI for all hospitals
pSFPs	Failed PCI given SDBT for surgical hospitals
pSSPs	Successful PCI given SDBT for surgical hospitals
pSPCs	PCI complications given SDBT for surgical hospitals
pSPMs	PCI mortality given SDBT for surgical hospitals
pLFPs	Failed PCI given LDBT for surgical hospitals
pLSPs	Successful PCI given LDBT for surgical hospitals
pLPCs	PCI complications given LDBT for surgical hospitals
pLPMs	PCI mortality given LDBT for surgical hospitals
pSFPa	Failed PCI given SDBT for all hospitals
pSSPa	Successful PCI given SDBT for all hospitals
pSPCa	PCI complications given SDBT for all hospitals
pSPMa	PCI mortality given SDBT for all hosptitals
pLFPa	Failed PCI given LDBT for all hospitals
pLSPa	Successful PCI given LDBT for all hospitals
pLPCa	PCI complications given LDBT for all hospitals
pLPMa	PCI mortality given LDBT for all hospitals
pSESs	Emergency Surgery given SDBT for surgical hospitals
pSNEs	Not Emergency Surgery given SDBT for surgical hospitals
pLESs	Emergency Surgery given LDBT for surgical hospitals
pLNESs	Not Emergency Surgery given LDBT for surgical hospitals
pSESSa	Emergency Surgery given SDBT for all hospitals
pSNESa	Not Emergency Surgery given SDBT for all hospitals
psLESa	Emergency Surgery given LDBT for all hospitals
pLNESa	Not Emergency Surgery given LDBT for all hospitals
pSESSs	Emergency Surgery Success given SDBT for surgical hospitals
pSESFs	Emergency Surgery Failure given SDBT for surgical hospitals
pLESSs	Emergency Surgery Success given LDBT for surgical hospitals
pLESFs	Emergency Surgery Failure given LDBT for surgical hospitals
pSESSa	Emergency Surgery Success given SDBT for all hospitals

Figure 1. Model for economic evaluation



RESULTS

This study was designed to extend previous findings from our earlier report, the Kentucky Pilot Project for Primary PCI without Onsite CABG, which demonstrated that there were no statistical differences in outcomes between facilities with onsite emergency backup capabilities and those that lacked such capabilities when compared to established values with the exception that TJSCH had a higher proportion of individuals who received their CABG in less than 90 minutes. Tables 3 and 4 show the results from the original study, which suggests that there is no significant difference in any of the outcome variables studied between facilities with and without onsite emergency open heart surgery capabilities. Since costs estimates were obtained from the 2005 National Inpatient Sample (NIS), the NIS data set was statistically investigated for many of the variables that were evaluated in the Kentucky Pilot Project for Primary PCI without Onsite CABG report. To allow for a more direct comparison with the earlier report, the NIS was initially filtered to include only observations in the Midwest and Southeast. This resulted in a sample of 7,586 subjects who received an emergency PCI. A majority of the cases were obtained from facilities with emergency backup capabilities (n=7,248) while only 338 of the observations came from individuals seen at facilities without open-heart surgery capabilities. Table 3 shows the main demographic characteristics stratified by facility type. In the NIS population, the mortality rate was 2.8% for individuals seen at hospitals with onsite CABG capabilities, while the mortality rate was 3.5% for individuals seen at hospitals that did not have onsite CABG capabilities.

About thirty-three percent of the patients were female in the hospitals with open-heart surgery capabilities, while in the hospitals without open-heart capabilities, the proportion of female patients was about thirty-seven percent. The mean age for PCI patients in emergency-surgery capable hospitals was 62.48 years, compared to a mean age of 63.08 patients in non-emergency-surgery capable hospitals. The proportion of patients needing emergent CABG after unsuccessful PCI was 2.47% in open-heart-surgery capable facilities while it was only 0.8% in facilities without open-heart-surgery capabilities. In addition, the mean length of stay was very similar for facilities with and without CABG capabilities: 4.36 days and 4.41 days respectively. None of these characteristics were statistically significantly different between individuals seen at these two types of facilities.

To provide a more comprehensive evaluation of the NIS data set, patients not requiring emergency CABG following emergent PCI were compared between the two types of facilities (Table 3). For hospital with open-heart-surgery capabilities, the mortality rate was 2.69%, the proportion of female patients was 33.56%, the mean age was 62.42 years, the mean length of stay was 4.1 days, and the mean total charges were $54,675. For hospitals without open-heart-surgery capabilities, the mortality rate was 3.58%, the proportion of female patients was 37.31%, the mean age was 63.11 years, the mean length of stay was 4.23 days, and the mean total charges were $48,234. The only characteristic that was significantly different between these two groups was total charges.

Table 3. NIS Outcome Measures by Primary Hospital Open Heart Surgery Capabilities

Outcome	W/ onsite CABG	W/O onsite CABG	p - value
Mortality	2.8% (2.4 – 3.2)	3.5% (1.6 – 5.5)	0.4370
Female	33.34% (32.3 – 34.4)	36.96% (31.8 – 42.1)	0.1653
Age	62.48 ± 13.22	63.08 ± 13.46	0.3600
Emergency CABG	2.47% (2.1 – 2.8)	0.8% (0 – 1.9)	0.0632
Length of Stay	4.36 ± 4.12	4.41 ± 4.15	0.8400

Similarly, patients requiring emergency CABG following emergent PCI were compared between the two types of facilities (Table 4). For a hospital with onsite CABG capabilities, the mortality rate was 8.38%, the proportion of female patients was 25%, the mean age was 62.73 years, the mean length of stay was 11 days, and the mean total charges were $134,498. For hospitals without onsite CABG capabilities, the proportion of mortality was 0%, the proportion of female patients was 0%, the mean age was 64.66 years, the mean length of stay was 10 days, and the mean total charges were $107,915. The mortality rate and the proportion of females were significantly different between hospitals with and without onsite CABG capabilities. Furthermore, kernel density estimation was used to estimate the probability density curve (pdf) for age, length of stay and total charges. For patients who did not require emergent CABG following PCI, the probability density function for age tends to be uniform between the ages of 45 and 85 years old for both types of facilities. For patients requiring emergent CABG after PCI, the *pdf* for facilities without onsite CABG capabilities is lightly skewed to the left with a peak at about 69 years while the curve for facilities with onsite CABG capabilities has less kurtosis and is less skewed. These results would support normality and allow us to use parametric methods.

Table 4. Patients who did not have emergency CABG

Outcome	W/ onsite CABG	W/O onsite CABG	p - value
Mortality	2.69% (2.3 – 3.1)	3.58 (1.6 – 5.6)	0.3027
Female	33.56% (32.4 – 34.6)	37.31 (32.1 – 42.5)	0.1561
Age	62.42 ± 13.27	63.11 ± 13.57	0.3691
Length of Stay	4.10 ± 3.39	4.23 ± 3.07	0.4393
Total Charges	$ 54,675 ± 29,987	$ 48,234 ± 26.359	< 0.0001*
# Stents			
0	1,093	63	
1	3,740	188	
2	1,503	57	
3	500	23	
4	233	4	

Table 5. Patients who had emergency CABG

Outcome	W/ onsite CABG	W/O onsite CABG	p - value
Mortality	8.38% (4.3 – 12.4)	0%	< 0.0001
Female	25% (18.1 – 31.5)	0%	< 0.0001
Age	62.73 ± 11.82	64.66 ± 8.74	0.7780
Length of Stay	11 ± 6.3	10 ± 3.22	0.554
Total Charges	$ 134,498 ± 69,791	$ 107,915 ± 34,099	0.3110
# Stents			
0	145	3	
1	25	0	
2	4	0	
3	5	0	
4	0	0	

The estimated curve for length of stay is skewed to the right, which was expected as this type of data tends to follow a lognormal or a gamma distribution. For patients who did not have emergency open heart surgery, the curve peaks at about 3 days. However, the curve corresponding to facilities without onsite CABG capabilities has less kurtosis than that corresponding to facilities with onsite CABG capabilities. As expected from the resulting statistics, the curves for those patients who had emergent CABG peak much more to the right. For hospitals with onsite open heart-surgery capabilities, the curve peaks near nine days and is severely skewed to the right. On the other hand, the curve for hospitals without onsite CABG peaks near twelve days and is slightly skewed to the left.

Figure 2

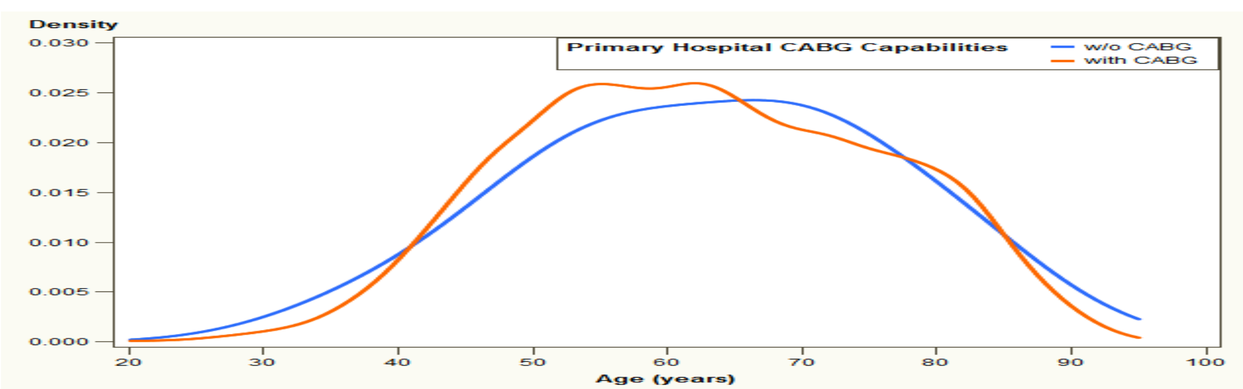


Figure 3

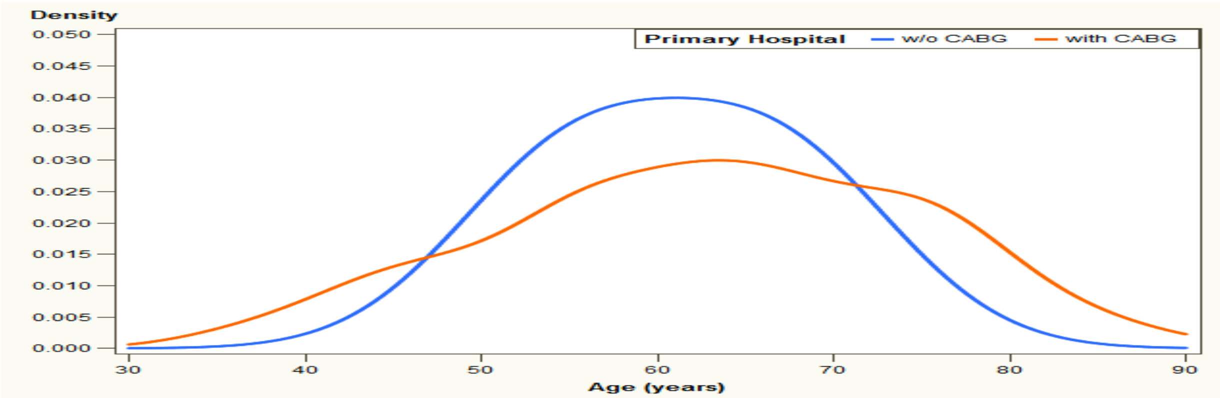


Figure 4

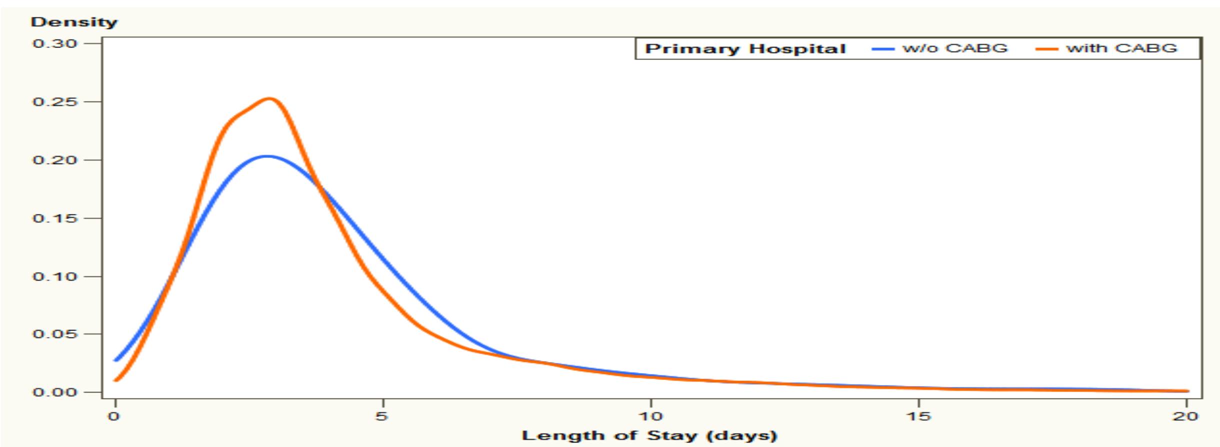
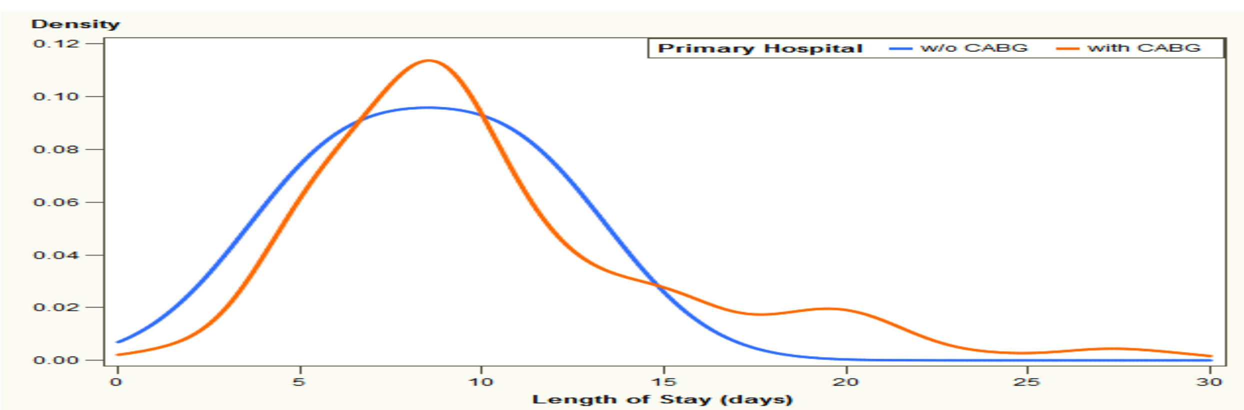


Figure 5



Cost Estimates

The main parameter obtained from the NIS data set for the current analysis is total charges for the two approaches, PCI and PCI+CABG. The estimated curves for those patients receiving only emergent PCI are both lightly skewed to the right, with the curve for facilities without onsite CABG capabilities peaking near $33,000 with a kurtosis of 1.6, while the curve for facilities with onsite CABG capabilities peak further to the right at about $42,000 with a kurtosis of 3. For patients with both emergent

PCI and emergent CABG, the curve for total charges in facilities without onsite CABG capabilities was heavily concentrated near $93,000, while the curve for hospitals with onsite CABG is more evenly dispersed with a peak at about $98,000.

Figure 6

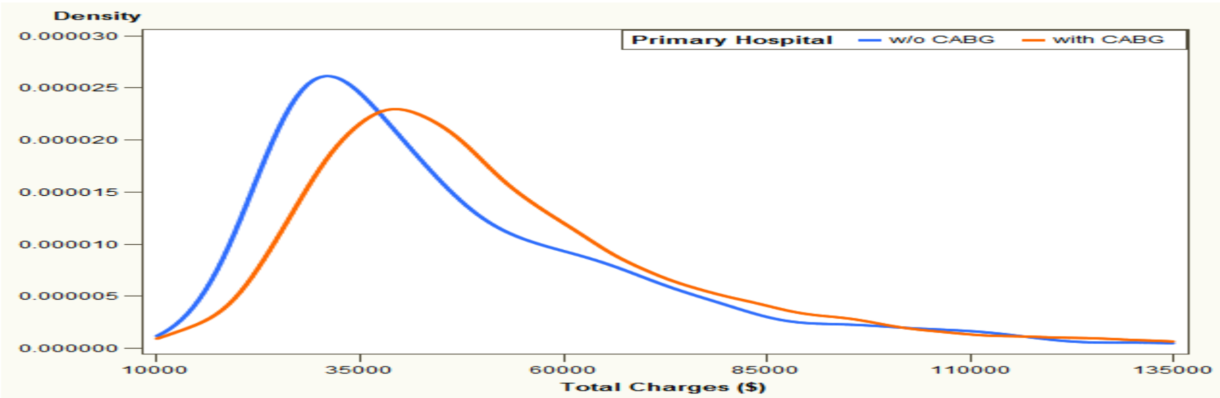
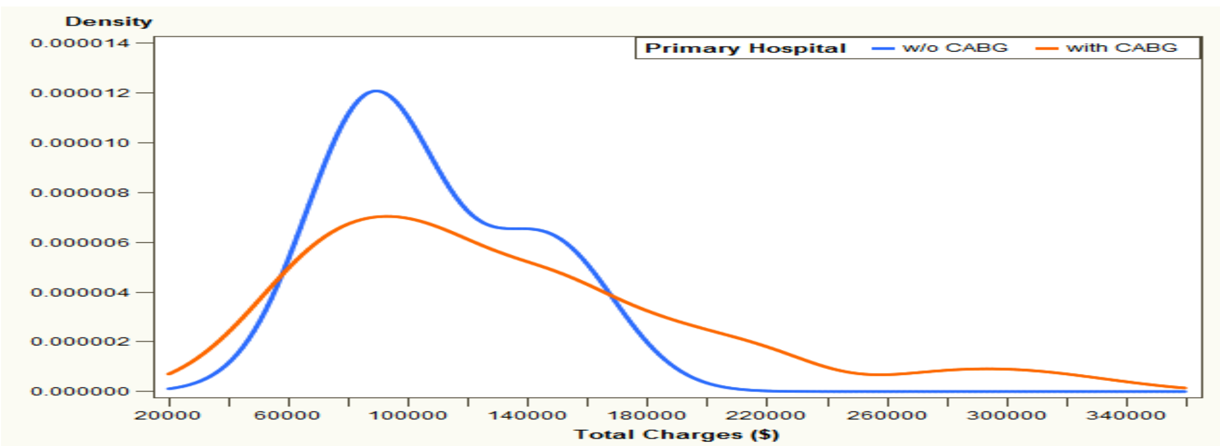


Figure 7



Probability Estimates

Probabilities were estimated from studies that evaluated the relevant outcomes of interest. In addition, the sample size and study design of the reports were evaluated as well to determine their usefulness. To provide precise estimates of these probabilities, traditional meta-analysis techniques were used. That is, the sample sizes for each study were aggregated (N), the numbers of cases were aggregated (n), and then the ratio was computed (n/N). Table 5 displays the estimated probabilities for the outcomes of interest for hospitals with onsite CABG capabilities. These estimates are listed along with the study from which they are derived along with the estimated 95% confidence interval. Similarly, table 6 shows the corresponding estimated probabilities for facilities without onsite CABG capabilities. The estimate for a door-to-balloon time less than ninety minutes for hospitals without open-heart-surgery capabilities is 0.551 and a 95% confidence interval of (0.485 - 0.618), while the corresponding estimate for facilities with onsite CABG capabilities is 0.448. Table 7 displays the variables that were incorporated in the model. Figure 1 shows the model along with its corresponding components. From the literature review, a key variable for successful PCI outcomes is a door-to-balloon time less than 90 minutes. The estimated proportion was estimated to be 55.2% for hospitals with onsite CABG and 50.0% when both types of facilities were considered. The probability of PCI failure for each door-to-balloon cut-off value was constituted by the probability of death corresponding to the specific cut-off value as well as the probability of complications, which was clearly dependent on the door-to-balloon time. This is contrasted with the probabilities for emergency CABG; these values did not depend on door-to-balloon time, but rather on the individual characteristics of the patient.

The estimated costs are calculated from a third-party payer point of view from public *total charges* records rather than *net payments*. Since the latter payment is not a public record and considered proprietary information, they are not available for analysis. For hospitals without onsite CABG capabilities, the estimated cost for emergency PCI is $48,244 with a standard deviation of $26,359. In contrast, facilities with onsite CABG capabilities had a mean total cost for emergent PCI of $54,675 and a standard deviation of $29,987.

Cost-Effectiveness

To evaluate the cost-effectiveness of allowing regional hospitals to perform primary PCI, the decision model (Figure 1) had to be rolled back. That is, the joint probability of each outcome (e.g., DBT < 90 minutes with no adverse effects) was multiplied by the utility of the outcome (probability of death) and summed over all outcomes; these values were then stratified by alternatives. The incremental cost-effectiveness, then, was evaluated by dividing the incremental costs by the incremental effectiveness.

When the cost-effectiveness model was rolled back, the alternative to allow *Regional Hospitals as well* to perform primary PCI dominated the other alternative of *Only Allowing Hospitals with Onsite CABG* to perform PCI. That is, allowing regional hospitals to perform primary PCI incur fewer costs while also averting more deaths (Table 14). Therefore, it "dominates" the other alternative since it performs better on all attributes studied. The incremental cost-effectiveness ratio of allowing regional hospitals to perform PCI was -$41K per death averted, when compared to the option of *Only Hospitals with Onsite CABG* (Table 14). That is, allowing regional hospitals to perform PCI will save $41K per death averted. Therefore, establishing this alternative as a cost-effectiveness way in which to provide primary PCI in the State of Kentucky and providing further evidence to allow regional hospitals (that meet the recommendations outlined in Myers et al) to perform primary PCI.

Sensitivity Analysis

The decision to allow regional hospitals to perform PCI was only sensitive to one variable in the model (the cost of PCI at Regional hospitals, cPa). As this cost increases, the cost per death averted associated with allowing regional hospitals to perform primary PCI also increases, making this alternative less attractive. The decision is sensitive within the plausible range of values for this variable. If the cost of PCI in regional hospitals increases by $5000 (representing a 9.2% increase from baseline, from $54,300 to $59,300), allowing regional hospitals to perform primary PCI would not be cost effective.

Table 12. Estimates for Hospitals with onsite CABG

Outcome	n	N
DTB < 90 min		
Thom et al. ((Thom, et al., 2006))	N/A	N/A
Proportion of DBT < 90 min and 95% CI	44.8%	
Mortality when DTB < 90 min		
McNamara et al. ((McNamara, et al., 2006))	876	29222
Rathore et al. ((Rathore, et al., 2009))	909	25359
Yang et al. (4)	7	479
Total	1792	55060
Mortality Rate and 95% CI	3.25%	3.10%-3.40%
Complications after PCI		
Mattichak et al. ((Mattichak, Dixon, Shannon, Boura,	357	7426
Rate of Complications and 95% CI	4.80%	4.30%-5.30%
Emergency CABG		
Darwaza et al. (1)	31	1200
Haan at al. (2)	3352	1042864
Moscucci et al. (3)	49	2303
Yang et al. (4)	20	6577
Mattichak et al. ((Mattichak, et al., 2008))	20	7426
Total	3472	1060370
Rate of Emergency CABG and 95% CI	0.33%	0.31%-0.34%
Mortality after E. CABG		
Darwaza AK et al. (1)	155	1200
Haan at al. (2)	536	3352
Moscucci et al. (3)	10	49

Yang et al. (4)	2	20
Seshadri et al. (7)	6	29
Total	709	4650
Mortality Rate and 95% CI	15.2%	14.2%-16.3%

Table 13. Estimates for Hospitals w/o onsite CABG

Outcome	n	N
DBT < 90 min		
Myers et al.	118	214
proportion and 95% CI	55.1%	48.5% - 61.8%
Mortality and DBT < 90 min		
Myers et al.	1	235
K.J. Mishra (1)	0	778
Total	1	1013
proportion and 95% CI	0.1%	0.0 - 0.5%
Complications after PCI		
Myers et al.	60	235
proportion and 95% CI	25.5%	19.9% - 31.1%
Emergency CABG		
K.J. Mishra (1)	0	778
Sea Hing Ong et al. (2)	0	259
Myers et al.	1	235
Total	1	1272
proportion and 95% CI	0.08%	0.0% - 0.23%
Mortality after E. CABG		
Myers et al.	1	235
proportion and 95% CI	0.4%	0.0% - 1.2%

Table 14. Cost Effectiveness Analysis

Strategy	Data		Incremental Comparison		
	Cost / 1000	Lives Saved	Cost	Deaths	C/E Ratio
Only Hospitals with onsite CABG	$54,687.38 K	954			
All PCI equipped Hospitals	$54,401.25 K	961	-$286.19 K	7	-$41,164.25

Table 15. Model specifications in summary

Variable	Value	Variable	Value
pSDBTs	0.448	pLFPa	0.094
pLDBTs	0.552	pLSPa	0.906
pSDBTa	0.50	pLPCa	0.574
pLDBTa	0.50	pLPMa	0.426
pM_SDBTs	0.030	pSESs	0.003
pM_LDBTs	0.058	pSNEs	0.997
pM_SDBTa	0.032	pLESs	0.003
pM_LDBTa	0.040	pLNESs	0.997
pCPCIs	0.048	pSESa	0.003
pCPCIa	0.054	pSNESa	0.997
pSFPs	0.078	pLESa	0.003
pSSPs	0.922	pLNESa	0.997
pSPCs	0.615	pSESSs	0.848
pSPMs	0.385	pSESFs	0.152
pLFPs	0.106	pLESSs	0.848
pLSPs	0.894	pLESFs	0.152
pLPCs	0.453	pSESSa	0.855
pLPMs	0.547	pSESFa	0.145
pSFPa	0.086	pLESSa	0.855
pSSPa	0.914	pLESFa	0.145
pSPCa	0.628	CPs	$54,675
pSPMa	0.372	CPa	$54,389

Table 16. Sensitivity Analysis of PCI cost at hospitals with onsite CABG

CPs	Strategy	Cost	Eff	C/E	ICER
54675	Regional Hospitals as Well	$54,410	1	$56,450	
	Only Hospitals with Onsite CABG	$54,686	1	$57,292	(Dominated)
59645.45	Regional Hospitals as Well	$54,543	1	$56,588	
	Only Hospitals with Onsite CABG	$59,656	1	$62,499	(Dominated)
64615.91	Regional Hospitals as Well	$54,677	1	$56,727	
	Only Hospitals with Onsite CABG	$64,626	1	$67,705	(Dominated)
69586.36	Regional Hospitals as Well	$54,811	1	$56,866	
	Only Hospitals with Onsite CABG	$69,596	1	$72,912	(Dominated)
74556.82	Regional Hospitals as Well	$54,945	1	$57,005	
	Only Hospitals with Onsite CABG	$74,565	1	$78,118	(Dominated)
79527.27	Regional Hospitals as Well	$55,079	1	$57,144	
	Only Hospitals with Onsite CABG	$79,535	1	$83,325	(Dominated)
84497.73	Regional Hospitals as Well	$55,212	1	$57,283	
	Only Hospitals with Onsite CABG	$84,505	1	$88,531	(Dominated)
89468.18	Regional Hospitals as Well	$55,346	1	$57,421	
	Only Hospitals with Onsite CABG	$89,475	1	$93,738	(Dominated)

94438.64	Regional Hospitals as Well	$55,480	1	$57,560	
	Only Hospitals with Onsite CABG	$94,444	1	$98,944	(Dominated)
99409.09	Regional Hospitals as Well	$55,614	1	$57,699	
	Only Hospitals with Onsite CABG	$99,414	1	$104,151	(Dominated)
104379.5	Regional Hospitals as Well	$55,748	1	$57,838	
	Only Hospitals with Onsite CABG	$104,384	1	$109,357	(Dominated)
109350	Regional Hospitals as Well	$55,881	1	$57,977	
	Only Hospitals with Onsite CABG	$109,354	1	$114,564	(Dominated)

Table 17. Sensitivity Analysis of PCI cost at all hospitals

CPa	Strategy	Cost	Eff	C/E	ICER
54389	Regional Hospitals as Well	$54K	0.96	$56,450	
	Only Hospitals with Onsite CABG	$55K	0.95	$57,292	(Dominated)
59333.45	Only Hospitals with Onsite CABG	$55K	0.95	$57,292	
	Regional Hospitals as Well	$59K	0.96	$61,441	$485,435
64277.90	Only Hospitals with Onsite CABG	$55K	0.95	$57,292	
	Regional Hospitals as Well	$64K	0.96	$66,431	$1,000,518
69222.36	Only Hospitals with Onsite CABG	$55K	0.95	$57,292	
	Regional Hospitals as Well	$69K	0.96	$71,422	$1,515,601
74166.81	Only Hospitals with Onsite CABG	$55K	0.95	$57,292	
	Regional Hospitals as Well	$74K	0.96	$76,413	$2,030,684
79111.27	Only Hospitals with Onsite CABG	$55K	0.95	$57,292	
	Regional Hospitals as Well	$78K	0.96	$81,404	$2,545,767
84055.72	Only Hospitals with Onsite CABG	$55K	0.95	$57,292	
	Regional Hospitals as Well	$83K	0.96	$86,395	$3,060,849
89000.18	Only Hospitals with Onsite CABG	$55K	0.95	$57,292	
	Regional Hospitals as Well	$88K	0.96	$91,386	$3,575,932
93944.63	Only Hospitals with Onsite CABG	$55K	0.95	$57,292	
	Regional Hospitals as Well	$93K	0.96	$96,377	$4,091,015
98889.09	Only Hospitals with Onsite CABG	$55K	0.95	$57,292	
	Regional Hospitals as Well	$98K	0.96	$101,368	$4,606,098
103833.54	Only Hospitals with Onsite CABG	$55K	0.95	$57,292	
	Regional Hospitals as Well	$103K	0.96	$106,359	$5,121,181
108778	Only Hospitals with Onsite CABG	$55K	0.95	$57,292	
	Regional Hospitals as Well	$107K	0.96	$111,350	$5,636,264

Table 18. Sensibility Analysis of proportion of DBT<90 min. at hospitals with onsite CABG

pSDBTs	Strategy	Cost	Eff	C/E	ICER
0.298	Regional Hospitals as Well	$54.4K	0.96	$56,450	
	Only Hospitals with Onsite CABG	$54.7K	0.95	$57,545	(Dominated)
0.3478333	Regional Hospitals as Well	$54.4K	0.96	$56,450	
	Only Hospitals with Onsite CABG	$54.7K	0.95	$57,461	(Dominated)
0.3976666	Regional Hospitals as Well	$54.4K	0.96	$56,450	
	Only Hospitals with Onsite CABG	$54.7K	0.95	$57,377	(Dominated)
0.4475	Regional Hospitals as Well	$54.4K	0.96	$56,450	
	Only Hospitals with Onsite CABG	$54.7K	0.95	$57,293	(Dominated)
0.4973333	Regional Hospitals as Well	$54.4K	0.96	$56,450	
	Only Hospitals with Onsite CABG	$54.7K	0.96	$57,209	(Dominated)
0.5471666	Regional Hospitals as Well	$54.4K	0.96	$56,450	
	Only Hospitals with Onsite CABG	$54.7K	0.96	$57,126	(Dominated)
0.597	Regional Hospitals as Well	$54.4K	0.96	$56,450	
	Only Hospitals with Onsite CABG	$54.7K	0.96	$57,043	(Dominated)

Table 19. Sensibility Analysis of proportion of DBT<90 min. at all hospitals

pSDBTa	**Strategy**	**Cost**	**Eff**	**C/E**	**ICER**
0.33	Regional Hospitals as Well	$54.4K	0.96	$56,527	
	Only Hospitals with Onsite CABG	$54.7K	0.95	$57,292	(Dominated)
0.385	Regional Hospitals as Well	$54.4K	0.96	$56,502	
	Only Hospitals with Onsite CABG	$54.7K	0.95	$57,292	(Dominated)
0.44	Regional Hospitals as Well	$54.4K	0.96	$56,477	
	Only Hospitals with Onsite CABG	$54.7K	0.95	$57,292	(Dominated)
0.495	Regional Hospitals as Well	$54.4K	0.96	$56,452	
	Only Hospitals with Onsite CABG	$54.7K	0.95	$57,292	(Dominated)
0.55	Regional Hospitals as Well	$54.4K	0.96	$56,427	
	Only Hospitals with Onsite CABG	$54.7K	0.95	$57,292	(Dominated)
0.605	Regional Hospitals as Well	$54.4K	0.96	$56,402	
	Only Hospitals with Onsite CABG	$54.7K	0.95	$57,292	(Dominated)
0.66	Regional Hospitals as Well	$54.4K	0.97	$56,377	
	Only Hospitals with Onsite CABG	$54.7K	0.95	$57,292	(Dominated)

CONCLUSION

The current study was based on the results obtained by Myers and his colleagues in their report, *Kentucky Pilot Project for Primary PCI without Onsite CABG,* with a purpose to investigate whether it was medically sound to allow select facilities in Kentucky to perform primary PCI even when lacking onsite emergency CABG capabilities. Because the former report established no statistical difference in outcomes between facilities with and without open-heart surgery backup, this study extended the former report by investigating how cost-effective it is to allow the latter hospitals to perform emergency PCI given that these facilities meet recommendations concerning screening criteria, surgeons' experience, and facility's volume (table 1).

A careful literature review and meta-analysis resulted in robust estimates for event rates used in the model. However, the pilot study on which the previous report was based did not collect data concerning costs and expenditures or information related to the quality of life of the patients. For this reason, a dataset from the National Inpatient Sample 2005 was used to obtain cost estimates. To verify that the costs estimated from this data set were relevant, the dataset was explored for demographic characteristics using classical numerical and graphical statistical methods. The resulting sample from this data set was similar in characteristics and outcomes; variables such as age, number of stents used, length of stay, and mortality rate were similar to samples used in the literature review studies, meta-analysis, and Kentucky pilot study on primary PCI.

Since the pilot study from which the efficacy data was obtained was devoid of cost information, the National Inpatient Sample from 2005 was used to obtain estimates of costs from total charges to patients. The reason to use total charges as a surrogate to costs is that the latter are considered proprietary information to insurance companies; hence, they are not readily available in the United States. In addition, costs related to expenditures incurred for transportation or incurred by the patient's personal care-giver (e.g. relative or spouse) during the hospitalization were not estimated and therefore not included in the cost-effectiveness analysis. The time lag between the records of the cost data and the clinical trial data is lightly lengthy, and no cost adjustment (i.e., discounting) was made to evaluate the 2005 currency in 2009 dollars. More sophisticated analyses in the future may require a cost-adjustment to estimates to 2009 or 2010 dollars, or they may collect cost data and all other variables concurrently. Hence, this limitation may undermine the internal validity of the results from the cost effectiveness analysis and its associated results.

The *Kentucky Pilot Project for Primary PCI without Onsite CABG* did not collect quality of life data from patients or patients' care-giver(s). For this reason, the current study was based on cost per death adverted instead. Quality of life data from patients such as preference on proximity of the facility providing PCI, reduction on door-to-balloon time, and access to primary care provider could have increased the cost-effectiveness of allowing facilities without onsite CABG capabilities to perform emergent PCI. Also, measurements were not available on preference of outcomes such as the presence or lack of post-procedure complications, speedier recovery given a shorter door-to-balloon time, or even the need of a quick delivery emergent CABG. Furthermore, determining whether delivery of emergent PCI in a regional hospital rather than transfer to a distant urban facility would facilitate access to a loved one, and this in turn could affect the quality of life of the patient.

Another issue at hand when implementing the delivery of emergent PCI at a regional hospital is the use and allocation of resources in these facilities. This study did not measure how this implementation could have affected the allocation of resources such as the need to hire more medical staff or the reallocation of current medical staff from one unit to another. If the delivery of emergent PCI by regional hospitals incurs in the hiring of more medical staff, this could bring about economical development to the region surrounding the hospital; however, this could also mean an increase in costs of emergent PCI and a possible change in the results of this study. Because the recommendations about the quality of care include the need of an interventional cardiologist in charge of emergent PCI requires a relatively high volume of procedures per year, the chief cardiologist in a regional hospital may have to commute several times a month to an urban hospital in order to meet the volume recommendations. Another byproduct of these recommendations is the possible need to extend PCI delivery to non-emergent cases in order to meet a facility's volume recommended to keep a highly competent medical staff.

Sensitivity to the cost of PCI at regional hospitals was observed in the model. A mere increase of 9.2% or $5,000 from baseline in this variable increased the cost per death adverted. This means that the decision is sensitive within the plausible range of values for this variable. Consequently, allowing regional hospitals to perform primary PCI could become non-cost-effective easily. A heart attack or myocardial infarction (MI) is a serious detrimental event because deprivation of blood to the heart muscle causes damage or possibly death to the heart's tissues known as myocardium, which carry long-term negative health conditions. It is been well established that the longer the heart is deprived of blood, the more heart muscle is damaged and killed. The maxim cardiologists follow is that time saved is heart saved; thus establishing the need to open the coronary arteries occluded as quickly as possible. For this reason, a short door-to-balloon time is a key aspect for PCI to be successful. Allowing regional hospitals to perform emergent PCI is a means to achieve the goal of a door-to-balloon time less than ninety minutes for everyone suffering a heart attack. Many clinical studies have shown that shorter door-to-balloon time leads to shorter average lengths of stay in the hospital, lower rates of re-infarction, and lower rates of re-occlusion.

As detailed before in this study, it is well established that PCI is considered the superior management strategy for AMI patients, especially those experiencing a STEMI. It is also well established that PCI is cost-effective when compared to thrombolysis and that it is medically sound to allow hospitals without backup surgical capabilities to perform primary PCI. This study had filled the gap in the knowledge about the cost-effectiveness of allowing hospitals without surgical backup capabilities to perform PCI, when compared to only allowing hospitals with backup capabilities to perform PCI in the state of Kentucky. Therefore, the results of this thesis have pushed forward the knowledge concerning primary PCI.

References

Antman, E. M., Anbe, D. T., Armstrong, P. W., Bates, E. R., Green, L. A., Hand, M., et al. (2004). ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction--Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 1999 Guidelines for the Management of Patients With Acute Myocardial Infarction). [doi: DOI: 10.1016/j.jacc.2004.07.002]. *Journal of the American College of Cardiology, 44*(3), 671-719.

Association, A. H. (2008, November 24). Myocardial Ischemai, Injury and Infarction. from http://www.americanheart.org/presenter.jhtml?identifier=251

Association, A. H. (2010). Heart Attack.

Blankenship, J. C., Skelding, K. A., Scott, T. D., Buckley, J., Zimmerman, D. K., Temple, A., et al. (2009). ST-elevation myocardial infarction patients can be enrolled in randomized trials before emergent coronary intervention without sacrificing door-to-balloon time. *Am Heart J., 158*(3), 400-407.

Bohmer, E., Hoffmann, P., Abdelnoor, M., Arnesen, H., & Halvorsen, S. (2010). Efficacy and safety of immediate angioplasty versus ischemia-guided management after thrombolysis in acute myocardial infarction in areas with very long transfer distances results of the NORDISTEMI (NORwegian study on DIstrict treatment of ST-elevation myocardial infarction). *J Am Coll Cardiol., 55*(2), 102-110. Epub 2009 Sep 2010.

Brown, D. C., Mogelson, S., Harris, R., Kemp, D., & Massey, M. (2006). Percutaneous coronary interventions in a rural hospital without surgical backup: report of one year of experience. *Clin Cardiol., 29*(8), 337-340.

DeGeare, V. S. M. D. F. a., Dangas, G. M. D. P. F. b., Stone, G. W. M. D. F. b., & Grines, C. L. M. D. F. c. (2001). Interventional procedures in acute myocardial infarction. [Miscellaneous Article]. *American Heart Journal January, 141*(1), 15-25.

Drummond, M. F. (1997). *Methods for the economic evaluation of health care programmes*. Oxford; New York: Oxford University Press.

Fox, K. A., Goodman, S. G., Klein, W., Brieger, D., Steg, P. G., Dabbous, O., et al. (2002). Management of acute coronary syndromes. Variations in practice and outcome; findings from the Global Registry of Acute Coronary Events (GRACE). *Eur Heart J., 23*(15), 1177-1189.

Gibbons, R. J., Holmes, D. R., Reeder, G. S., Bailey, K. R., Hopfenspirger, M. R., & Gersh, B. J. (1993). Immediate angioplasty compared with the administration of a thrombolytic agent followed by conservative treatment for myocardial infarction. The Mayo Coronary Care Unit and Catheterization Laboratory Groups. *N Engl J Med., 328*(10), 685-691.

Gold, M. R., Siegel, J. E., Russell, L. B., Weinstein, M. C., & Freemantle, N. (1997). Cost-Effectiveness in Health and Medicine. *BMJ : British medical journal /, 315*(7109), 689.

Grines, C. L., Browne, K. F., Marco, J., Rothbaum, D., Stone, G. W., O'Keefe, J., et al. (1993). A comparison of immediate angioplasty with thrombolytic therapy for acute myocardial infarction. The Primary Angioplasty in Myocardial Infarction Study Group. *N Engl J Med., 328*(10), 673-679.

Hannan, E. L., Zhong, Y., Racz, M., Jacobs, A. K., Walford, G., Cozzens, K., et al. (2009). Outcomes for Patients With ST-Elevation Myocardial Infarction in Hospitals With and Without Onsite Coronary Artery Bypass Graft Surgery: The New York State Experience. *Circ Cardiovasc Interv, 2*(6), 519-527.

Jamal, S. M., Shrive, F. M., Ghali, W. A., Knudtson, M. L., & Eisenberg, M. J. (2003). In-hospital outcomes after percutaneous coronary intervention in Canada: 1992/93 to 2000/01. *Can J Cardiol., 19*(7), 782-789.

King, S., & Yeung, A. (2006). *Interventional Cardiology* (1 ed.): McGraw-Hill Professional.

Lotfi, M., Mackie, K., Dzavik, V., & Seidelin, P. H. (2004). Impact of delays to cardiac surgery after failed angioplasty and stenting. [doi: DOI: 10.1016/j.jacc.2003.08.045]. *Journal of the American College of Cardiology, 43*(3), 337-342.

Manson, J., Ridker, P., Gaziano, M., & Hennekens, C. (1996). *Prevention of myocardial infarction* (1 ed.). New York: Oxford University Press.

Mattichak, S. J., Dixon, S. R., Shannon, F., Boura, J. A., & Safian, R. D. (2008). Failed percutaneous coronary intervention: a decade of experience in 21,000 patients. *Catheter Cardiovasc Interv., 71*(2), 131-137.

McNamara, R. L., Wang, Y., Herrin, J., Curtis, J. P., Bradley, E. H., Magid, D. J., et al. (2006). Effect of door-to-balloon time on mortality in patients with ST-segment elevation myocardial infarction. *J Am Coll Cardiol., 47*(11), 2180-2186. Epub 2006 May 2115.

Myers, J., Brock, G., Appana, S., & Gray, L. (2009). Kentucky pilot project for primary PCI without onsite CABG. *J Ky Med Assoc., 107*(11), 451-458.

Nielsen, P. H., Maeng, M., Busk, M., Mortensen, L. S., Kristensen, S. D., Nielsen, T. T., et al. (2010). Primary Angioplasty Versus Fibrinolysis in Acute Myocardial Infarction. Long-Term Follow-Up in the Danish Acute Myocardial Infarction 2 Trial. *Circulation, 22*, 22.

Ong, S. H., Lim, V. Y., Chang, B. C., Lingamanaicker, J., Tan, C. H., Goh, Y. S., et al. (2009). Three-year experience of primary percutaneous coronary intervention for acute ST-segment elevation myocardial infarction in a hospital without on-site cardiac surgery. *Ann Acad Med Singapore., 38*(12), 1085-1089.

Paraschos, A., Callwood, D., Wightman, M. B., Tcheng, J. E., Phillips, H. R., Stiles, G. L., et al. (2005). Outcomes following elective percutaneous coronary intervention without on-site surgical backup in a community hospital. *Am J Cardiol., 95*(9), 1091-1093.

Rathore, S. S., Curtis, J. P., Chen, J., Wang, Y., Nallamothu, B. K., Epstein, A. J., et al. (2009). Association of door-to-balloon time and mortality in patients admitted to hospital with ST elevation myocardial infarction: national cohort study. *BMJ, 338*(may19_1), b1807-.

Ribeiro, E. E., Silva, L. A., Carneiro, R., D'Oliveira, L. G., Gasquez, A., Amino, J. G., et al. (1993). Randomized trial of direct coronary angioplasty versus intravenous streptokinase in acute myocardial infarction. *J Am Coll Cardiol., 22*(2), 376-380.

Ribichini, F., Steffenino, G., Dellavalle, A., Ferrero, V., Vado, A., Feola, M., et al. (1998). Comparison of thrombolytic therapy and primary coronary angioplasty with liberal stenting for inferior myocardial infarction with precordial ST-segment depression: immediate and long-term results of a randomized study. *J Am Coll Cardiol., 32*(6), 1687-1694.

Singh, K. P., & Harrington, R. A. (2007). Primary percutaneous coronary intervention in acute myocardial infarction. *Med Clin North Am., 91*(4), 639-655; x-xi.

Tcheng, J. (2002). *Primary Angioplasty in Acute Myocardial Infarction* (1 ed.). Totowa: Humana Press.

Thom, T., Haase, N., Rosamond, W., Howard, V. J., Rumsfeld, J., Manolio, T., et al. (2006). Heart disease and stroke statistics--2006 update: a report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. *Circulation., 113*(6), e85-151. Epub 2006 Jan 2011.

Thompson, C. R., Humphries, K. H., Gao, M., Galbraith, P. D., Norris, C., Carere, R. G., et al. (2004). Revascularization use and survival outcomes after cardiac catheterization in British Columbia and Alberta. *Can J Cardiol., 20*(14), 1417-1423.

Thygesen, K., Alpert, J. S., White, H. D., Jaffe, A. S., Apple, F. S., Galvani, M., et al. (2007). Universal definition of myocardial infarction. *Circulation., 116*(22), 2634-2653. Epub 2007 Oct 2619.

Wharton, T. P., Jr., Grines, L. L., Turco, M. A., Johnston, J. D., Souther, J., Lew, D. C., et al. (2004). Primary angioplasty in acute myocardial infarction at hospitals with no surgery on-site (the PAMI-No SOS study) versus transfer to surgical centers for primary angioplasty. *J Am Coll Cardiol., 43*(11), 1943-1950.

Zijlstra, F., de Boer, M. J., Hoorntje, J. C., Reiffers, S., Reiber, J. H., & Suryapranata, H. (1993). A comparison of immediate coronary angioplasty with intravenous streptokinase in acute myocardial infarction. *N Engl J Med., 328*(10), 680-684.