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CLOPIDOGREL PROVISION FOR INDIGENT PATIENTS WITH ST-ELEVATION
MYOCARDIAL INFARCTION

by

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ABSTRACT

The Joint Commission in a joint effort with the Centers of Medicare and Medicaid Services (CMS) has established certain “core measures” by which hospital performance is measured. One of these is the measure for patients with ST-elevation myocardial infarction (STEMI) recommending percutaneous coronary intervention within 90 minutes of presentation to the Emergency Department in institutions that are able to provide this service. This recommendation does not take into account the long-term use of clopidogrel that is recommended by the American College of Cardiology and American Heart Association for patients that are treated with coronary stents.

The purpose of this study was to evaluate outcomes of providing a short course of clopidogrel versus a prescription alone for clopidogrel to uninsured patients experiencing STEMI who were treated with a bare metal stent.

After conducting a cost-benefit analysis, a policy was approved that provided uninsured STEMI patients with clopidogrel at discharge rather than a prescription. A social worker evaluated patients to determine if they met criteria and arranged for medication delivery to the patient’s bedside. A retrospective chart review for all patients who presented to the Emergency Department during two different time frames (before and after policy implementation) was conducted to evaluate if providing clopidogrel decreased readmissions. Data were collected on over a 15-month period of time before and after the clopidogrel policy implementation to allow for evaluation of 90-day readmissions with repeat STEMI. Data were analyzed using chi-square cross tabulation and T-test for independent samples.

A total of 201 charts were reviewed: 100 from the pre-intervention group and 101 from the post-intervention group. Demographic characteristics of age, gender and insurance status

were not statistically different between groups. The mean age for the control group was 59.1 (\pm 13.8) years and 58.9 (\pm 13.6) years for the intervention group. Twenty percent of the patients were uninsured. Five uninsured patients were readmitted with STEMI prior to the intervention compared to two patients in the intervention group ($p = .191$). The admissions for the pre-intervention patients occurred in the first 30 days after discharge compared to 31-60 days in the post-intervention group. All of the patients who were readmitted were assessed to be noncompliant with treatment. Additionally, a transition to increased use of bare metal stents in STEMI patients from 23.1% pre-intervention to 67.4% post-intervention was noted ($p < .001$).

Although no differences were found in readmission rates, fewer readmissions for STEMI were noted after the intervention. The small number of patients who were readmitted with STEMI likely accounted for this finding, and additional monitoring of readmission rates is warranted. Despite provision of the clopidogrel, adherence remains an issue and needs to be addressed. During the intervention, physicians were encouraged to consider the financial and social resources of individual STEMI patients presenting to the Emergency Department to help identify patients that would be less likely to adhere to antiplatelet therapy. In those believed to be at high risk for non-adherence, primarily due to inability to purchase the relatively expensive medication clopidogrel, many physicians chose to insert bare metal stents rather than drug-eluting stents to take advantage of the shorter course of clopidogrel required post procedure. Provision of a 30-day course of clopidogrel and aspirin was a major part of this effort to decrease recurrent myocardial infarction in this at-risk population. A few patients eligible for the clopidogrel were not provided the medication if they were admitted to a nursing unit where staff members were not familiar with the policy; revisions to the policy to ensure medication is provided to all eligible patients will be made. Providing clopidogrel to patients who experience

STEMI may improve adherence and thereby decrease readmissions as a result of repeat STEMI due to subacute thrombus formation. Patients who experience STEMI continue to be vulnerable after STEMI. Programs that provide medication to patients should be expanded within this facility and to other hospital systems to encompass all patients who are treated for STEMI. Multi-disciplinary collaboration is necessary in developing and implementing a program that will address care for this.

This paper is dedicated to my parents who fill me with their love and strength.

ACKNOWLEDGMENTS

This project was developed as a result of the passion for excellent patient care across the continuum exhibited by one physician. Robert P. Dalton, MD experienced a tragic outcome for one of his patients as a result of a breakdown in transition from inpatient to outpatient care. Based on this one patient he challenged me to find a solution and I hope that with this project I have met his expectations.

I also want to extend appreciation to Mary Lou Sole, PhD who was my advisor throughout this program. Dr. Sole never let me give up and for that I am always grateful.

Finally, I have to thank my Imagine South Lake Charter School family and especially Mrs. Christine Watson. They cared for my children and supported me at every turn, always encouraging me to continue and be successful. This project would never have been completed without the faculty and leadership at this wonderful charter school in Lake County, Florida.

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CHAPTER ONE: INTRODUCTION

In February 2006, a 581-bed tertiary care center in Central Florida initiated a Code STEMI process to provide timely interventional care to patients presenting to the Emergency Department (ED) with ST- segment elevation myocardial infarction (STEMI). In July 2006, after approximately 50 patients had been treated using the Code STEMI process, a 55-year old, female patient presented to the ED with signs and symptoms consistent with STEMI. She was treated in a very timely manner using the same process. In this particular case, the physician had determined that there was a potential for medication non-adherence and therefore treated her with a bare metal stent (BMS). The patient had a successful outcome and was discharged home after 2 days. Prior to discharge the patient was educated regarding the importance of medication adherence and she reassured the physician and nurses that she understood and that she would take her follow-up medications.

As was the hospital policy at the time, the patient was given a 7-day supply of clopidogrel through the Social Work department. She was also referred to the County Medical Clinic (CMC) for follow up. It was at this point that she 'fell through the cracks'. The earliest that the patient was able to schedule an appointment with the CMC was two weeks after the date of discharge (actually a timely appointment). She took her medication as she was instructed, but ran out of medication one week prior to her appointment and was unable to afford a refill. Once she was seen by the CMC, she received more clopidogrel and began taking her medication as prescribed. Unfortunately, in the one week that she did not take clopidogrel, she developed subacute thrombosis in the previously placed stent and she returned to the ED with an more serious STEMI the following evening. While she was again treated in a very timely manner, the second STEMI resulted in complete embarrassment of her cardiac function and she required a

prolonged stay in the coronary care unit (CCU). While in the CCU, she required treatment with balloon counterpulsation and nearly died. The second STEMI resulted in unnecessary suffering for the patient and likely shortened her life.

This patient event was the impetus for designing a project based on the available evidence for treating STEMI patients. The intent of this project is to help patients with clopidogrel adherence and decrease the occurrence of subacute thrombosis.

Background

Coronary heart disease (CHD) is the killer of more Americans than any other single disease. CHD includes acute myocardial infarction (AMI), acute coronary syndromes (ACS), and angina pectoris. The American Heart Association (AHA) estimates that 565,000 new AMI's occur annually while there are about 300,000 occurrences of repeat AMI each year. In 2004, 157,559 people in the United States died as a result of an AMI (American Heart Association, 2007). AMI is identified using electrocardiography (ECG) and cardiac enzymes (CPK-MB and troponins). STEMI is one type of AMI and is easily and quickly identified using ECG. This tends to be the more immediately lethal form of AMI and resources to expedite care of these patients presenting to healthcare facilities has been the focus of a world-wide initiative in recent years.

A large volume of data shows early recognition and treatment of patients with STEMI results in improved outcomes for these patients (Faxon, 2007). Options for treating patients with AMI that present to the hospital typically have included percutaneous coronary intervention (PCI), which includes balloon angioplasty and/or stent deployment, atherectomy, and

thrombectomy; or the use of fibrinolytics. Our facility's current practice is to facilitate emergent coronary thrombectomy and stent placement in most cases.

The Joint Commission, in conjunction with the Centers for Medicare and Medicaid Services (CMS), developed a set of measurable outcomes for certain disease states that each accredited hospital in the United States (US) must measure and report. These diseases were chosen based on prevalence and literature support that quality of care and outcomes could be improved with consistent delivery of treatment. AMI is included in these measures (The Joint Commission, Centers for Medicare and Medicaid Services, 2006).

The AMI core measure is made up of nine indicators. The two indicators that affect early intervention of STEMI are AMI-7 and AMI 7a, median time to fibrinolysis, and fibrinolytic therapy received within 30 minutes of arrival to hospital; and AMI-8 and AMI 8a, median time to primary PCI and primary PCI received within 90 minutes of arrival to hospital. Because the use of fibrinolytics has decreased due to the ease of access to interventional cardiac catheterization labs and data that shows PCI received within 90 minutes for patients presenting to the ED where primary PCI is performed or within 120 minutes for patients presenting to an ED of a facility that does not provide PCI and requires transfer results in decreased mortality and morbidity, this discussion focuses on indicators AMI 8 and AMI 8a.

Problem

Prior to the implementation of the The Joint Commission / CMS AMI indicators, a patient was evaluated for PCI versus fibrinolytics based on financial status and ability and/or willingness to be compliant with long-term medications. As treatment has trended towards early PCI, it is important to recognize that when PCI involves stent deployment (which is common),

continued medical treatment with clopidogrel is necessary to decrease the risk of subacute thrombosis.

Subacute thrombosis is defined as partial or total stent occlusion in the initial stent as documented by angiography (Iakovou, 2005). Antiplatelet agents (i.e. clopidogrel and aspirin) decrease the risk of subacute thrombosis. The American College of Cardiology/American Heart Association (ACC/AHA) recommend varying lengths of antiplatelet therapy based on the type of stent that is placed. ACC/AHA recommends a minimum of 12 months of clopidogrel for patients who receive a drug-eluting stent (DES) and are not at high risk for bleeding. In patients that receive a bare metal stent (BMS), ACC/AHA recommends a minimum of one month of clopidogrel, but also notes that it would be ideal to continue clopidogrel for 12 months (Antman et al., 2008). Unfortunately, the cost for clopidogrel ranges from \$5.60 to \$6.10 per tablet at local pharmacies and no generic preparation available. Uninsured or underinsured patients without financial resources sufficient to purchase these medications easily are at particularly high risk for non-adherence.

In an effort to meet the CMS AMI indicators, a Central Florida tertiary care center implemented a Code STEMI process in February 2006. This process focuses on early recognition by the ED and rapid activation of and transport to the cardiac catheterization lab. This ensures that patients having a STEMI are receiving the same quality care on an inpatient basis regardless of financial status and ability to pay. While the intent of the core measures is to provide the best care to all STEMI patients presenting to the hospital, they do not take into consideration the ability of the patient to adhere to necessary follow up care. The component of medication adherence post procedurally has been neglected in considering the care of these patients.

Once the STEMI program was initiated at the facility, the number of Code STEMI's treated during the first year was obtained and noted to be 97 cases, an average of 8.1 cases per month. Of these STEMI's, 17 were identified as patients who were either uninsured or who might have some difficulty paying for the clopidogrel.

Four of the 17 patients that underwent PCI during this period of time were readmitted to the facility through the ED with subacute thrombosis in the recently implanted stent. All four of these patients returned within 1 months of discharge. In all four cases the physicians documented non-adherence with regards to clopidogrel. In other words, 23.5% of uninsured patients were readmitted with subacute thrombosis as a result of being non-adherent to their anti-platelet regimen.

Objective/Aim

The main objective of this project is to evaluate outcomes of providing clopidogrel (actual medication rather than a prescription that the patient will have to fill) to all uninsured patients presenting to the tertiary care center with STEMI who receive BMS or DES as their method of treatment. The assumption is that if the patient is provided with this very costly medication, he/she will be more likely to adhere to the prescribed medication regimen. Comparing three-month readmission rates for patients with STEMI will assess medication adherence. The time period reviewed for initial presentation with STEMI will be from February 2009 to February 2010. Readmissions (repeat STEMI) will be reviewed for the time period beginning February 2009 and ending May 2010 to ensure that 3-month readmission data are captured.

Research Questions

1. Is there a difference in readmission rates between uninsured STEMI patients who receive medication, actual “drug-in-hand”, and those who receive a prescription to fill?
2. Are uninsured patients who receive “drug-in-hand” less likely to be readmitted than insured patients who receive a prescription to fill?

Definitions

For this project, terms are defined as follows:

Table 1: Project Definitions

Term	Conceptual Definition	Operational Definition
Subacute thrombosis	A partial or total stent occlusion in the initial stent as documented by angiography (Iakovou, 2005).	Documentation in catheterization report by interventional cardiologist.
Adherence	Taking medications as prescribed.	No readmission within 3 months of initial AMI assumes adherence
Medication provision	Patient will have “drug in hand” (clopidogrel and aspirin only) prior to discharge.	Documentation by the Social Work Department that medication was provided to patient prior to discharge.
True uninsured	Patients for whom no evidence of insurance coverage can be found.	Business office verification.
Prescription	Paper prescription for clopidogrel that is given to the patient.	Patient discharge assessment form, absent documentation of medication provision.

Assumptions

For the purposes of this project, the following assumptions are made:

1. Patients will take medication if it is provided to them
2. Medication adherence is assumed when a patient is not readmitted with repeat STEMI within the study period.
3. Uninsured patients find it more difficult to afford medications.

Study Importance

The importance of this project revolves around patient outcomes. Patients that have a STEMI are in a position to receive the best interventional care available. Unfortunately, this care does not always ensure positive long-term outcomes. This is, in part, due to the cost of medication that is required to help ensure stent patency. If providing medication to patients promotes medication adherence, a catastrophic cost to the patient, in addition to the burden on the health care system and society, may be avoided.

CHAPTER TWO: LITERATURE REVIEW

An integrative review of the literature was conducted to evaluate the concept of adherence, specifically medication adherence. To begin the integrative review, the CINAHL and PubMed databases were searched. Key words that were searched were *adherence*, *medication*, *clopidogrel* and *cardiac*. The search of the electronic database was limited to English articles from 2004 to 2010. The year limitation was chosen to obtain the most recent research pertaining to medication adherence. Using the key words *adherence* and *medication*, 2,364 articles were returned. Combining *medication* with *adherence* or *compliance* returned 592 articles. When the terms *cardiac* and *clopidogrel* were added, 51 articles were returned. Of these 51 articles, 5 articles were an actual analysis of the concept of adherence. An additional 9 articles that pertained directly to medication adherence in patients with diagnosed cardiac disease, with one article specifically discussing adherence to clopidogrel, were included in the review (Figure 1). Medication compliance was used in the search because it is frequently used interchangeably with adherence. Antecedents that were identified in the search were compliance, concordance, and non-adherence.

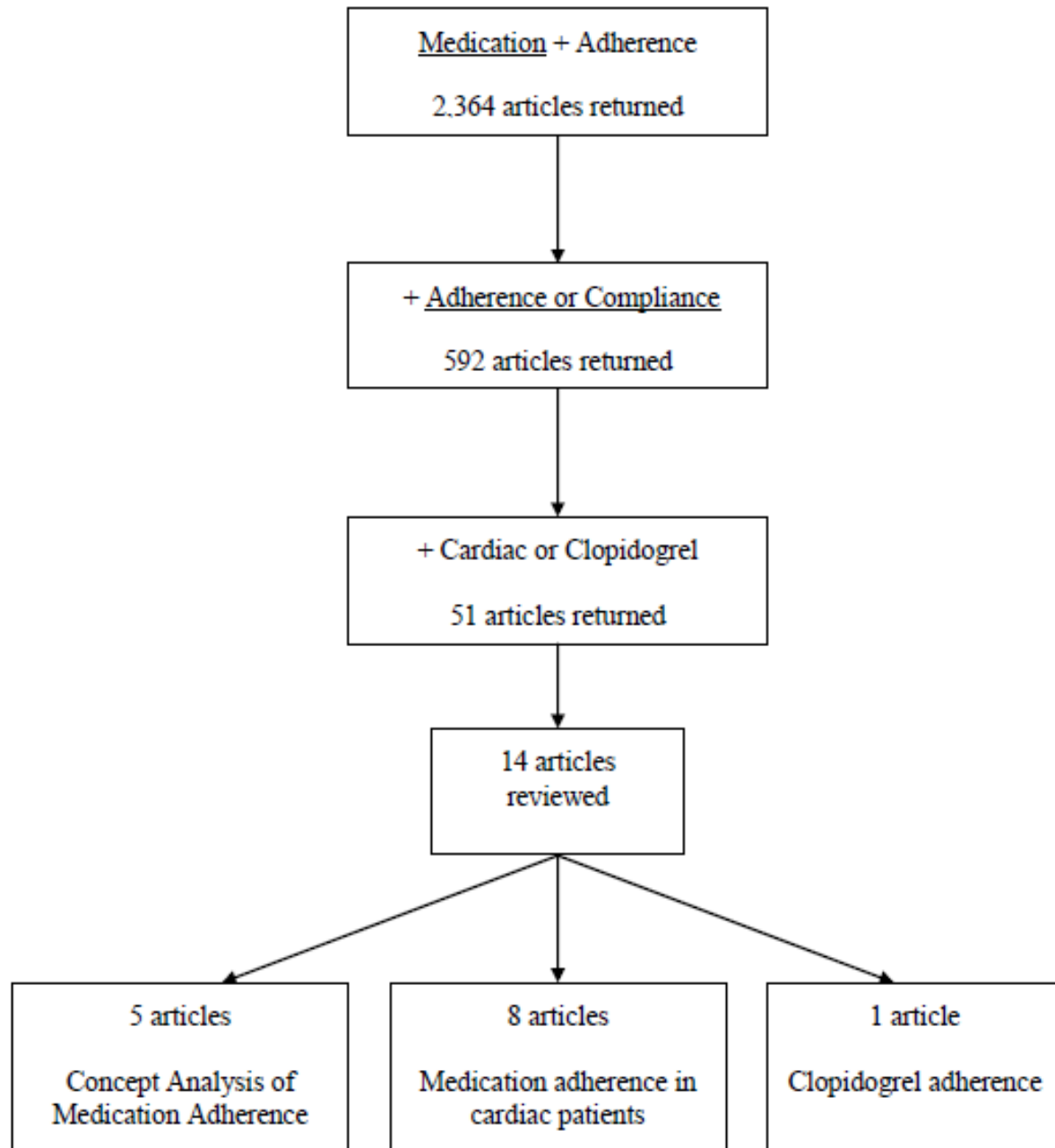


Figure 1: Literature Search Results

The World Health Organization (WHO) defines adherence as “the extent to which a person's behavior – taking medication, following a diet, and/or executing lifestyle changes,

corresponds with agreed recommendations from a health-care provider.” Terms that have been recognized as interchangeable with adherence include compliance and concordance (Rolley, et al, 2008).

Compliance is a term that is not frequently used due to the negative connotation that it carries (Shay, 2007, Bissonnette, 2008). The term compliance indicates an unequal relationship between provider and patient due to the paternal undertones it carries (Bissonnette, 2008).

Compliance also refers to obedience, which detracts from a collaborative relationship with a provider (Bissonnette, 2008). Different ways of viewing the term compliance within healthcare have been identified and it is the way that it is viewed that determines the connotation. The three ways of viewing compliance are evaluative, rationalization, and acceptance. When compliance is viewed in an evaluative manner, patients may be seen as difficult if they are not compliant in their therapies (Shay, 2007).

Adherence as a Concept

The WHO definition of adherence indicates a more collaborative relationship between patient and provider. Another very common definition of adherence is how well the patient follows a prescribed treatment regimen (Haynes, et al, 2005). Adherence is also considered to be non-judgmental and is the preferred term when discussing patients’ health behaviors in relation to prescribed medication therapies (Julius, et al, 2009). Poor adherence to prescribed medical therapies increases mortality and morbidity in certain diagnoses (Wu, et al, 2008).

From adherence, there has been a gradual movement towards the term concordance, which suggests a more participative relationship between patient and provider. Concordance also suggests that a negotiation between patient and provider has led to an agreement suitable to both

parties (Bissonnette, 2008, Lehane & McCarthy, 2009). However, there is currently limited research related to concordance as an individual concept (Bissonnette, 2008). There is an abundance of literature addressing concordance as a synonym for adherence.

Non-adherence is a concept that is used interchangeably with lack of, or poor adherence. Non-adherence is recognized as a serious health issue. Recommendations have been made to elevate the issue of non-adherence to a critical health care issue. Non-adherence leads to increases in hospitalization, mortality and morbidity (Lehane & McCarthy, 2009, Wu, et al, 2008).

Barriers to Adherence

Factors affecting medication adherence fall into four areas: patient-related, psychological, medication-related, and social/environmental. Patient related factors include age, gender, marital status and ethnicity. Of more interest are the psychological risk factors, which are denial of illness and negative attitudes about medications (Julius, et al, 2009). Negative attitudes about medications are attributed to patient concerns about necessity and safety of prescribed medications (Aikens & Piette, 2009).

Medication-related factors that contribute to non-adherence are side effects and dosing schedules. More complex dosing schedules are associated with decreased adherence (Julius, et al, 2009).

The other factors that influence medication adherence are social and environmental factors. A collaborative or therapeutic relationship with a provider improves medication adherence (Julius, et al, 2009). Socioeconomic status also contributes to adherence as demonstrated by decreased adherence to lipid lowering agents when co-pays are increased

(Doshi, et al, 2009). A predictive study by Choudry, et al (2007) suggested that post AMI patients that had no out-of-pocket costs for medications after hospitalizations would be more adherent to medication regimens. Through medication adherence, a resultant cost savings was predicted based on decreased rehospitalizations. Cost was also cited as a reason for not filling prescriptions for clopidogrel by patients who had received a coronary stent. This is an example of non-adherence that can lead to rehospitalization as discontinuation of clopidogrel by patients with stent placement puts them at risk for in-stent thrombus formation (Jackevicius, et al, 2007).

Barriers to Adherence in the Cardiovascular Patient

Medication adherence in cardiovascular disorders is well documented. Heart failure is an area where medication non-adherence has been shown to increase the risk of mortality and morbidity as well as increase health costs (Wu, et al, 2008). Medication adherence is also linked with self-efficacy. Schoenthaler, et al (2009) showed that self-efficacy mediates the relationship between depression and adherence. It was noted that depressive symptoms led to medication non-adherence. Depression in patients experiencing acute myocardial infarction (AMI) is prevalent as seen by the number of prescriptions for antidepressants prescribed at discharge for these patients (Jackevicius, et al, 2007).

Another area that contributes to decreased adherence in patients diagnosed with acute coronary syndrome (ACS) was partner stress defined as stress or conflict within a relationship (Molloy, et al, 2008). In this study, partner stress within six months prior to onset of ACS predicted medication non-adherence.

Discharge medication counseling by pharmacists has been shown to improve medication adherence and understanding. Interventions that occur at the time of an acute event have been

shown to increase adherence to prescribed treatment therapies; therefore, discharge medication counseling has the potential to improve long-term adherence. However, discussion of discharge medication counseling has been inconsistent (Jackevicius, et al, 2007).

The most recent article addressing adherence in the cardiac patient was specific to clopidogrel adherence. The focus of this article was prescription filling and delays associated with filling. The authors identified factors associated with delays to include advanced age, prior AMI, other comorbidities such as diabetes or renal failure, and in-hospital bleeding (Jackevicius, et al, 2010). Cost as a barrier was not addressed. In this article the authors emphasized the importance of transition care in patients that have DES implanted (see Table 2).

Table 2: Summary Table

Authors/ Year/ Country	Discipline	Methods	Sample/Setting	Findings
Aikens, J.E. & Piette, J.D. (2009)	Psychosocial	Face to face interviews, Bayer 2000 analyzer for HgbA1C, Omron automatic BP monitor with appropriately sized cuff for BP measurement	806 type II diabetics on antihyperglycemic and antihypertensive medications	Up to one half of patients underused their medications as a result of low health literacy, cost of medications, perceived need for medications, and fear of harmfulness of medications. Adherence was determined through self-reporting
Bissonnette, J.M. (2008)	Nursing	Evolutionary Method Antecedents/Consequences/Related Concepts: A prescribed medication regimen is the primary antecedent. Consequences fall into 3 categories – patient related, health care professional related and health care system related. Related concepts are therapeutic alliance, acceptance and agreement.	Papers identified = 114: Nursing – 27 Psychology – 39 Medicine – 33 Pharmacy – 15 Final sample: Pharmacy – 8 Psychology – 15 Medicine – 15 Nursing - 15	Findings by healthcare discipline: Nursing uses compliance and adherence. Psychology uses compliance and adherence interchangeably and considers these a key component of care. Medicine uses adherence and compliance synonymously. Pharmacy mirrors the approach of medicine.

Authors/ Year/ Country	Discipline	Methods	Sample/Setting	Findings
Choudhry, N. K., Avorn, J., Antman, E. M., Schneeweiss, S., & Shrank, W. H. (2007)	Medicine	A Markov Model was created by the authors to evaluate cost and quality-adjusted life expectancy to post MI Medicare patients without any out of pocket costs. This was compared with current Medicare part D coverage.	No actual patients were involved in this study. It was a predictive study.	Results predicted that Medicare patients that were under the partial coverage plan would live an average of 8.21 QALY and incur costs of \$114,000. Cost savings was attributed to decreased rehospitalizations and decreased non-drug expenditures.
Doshi, J. A., Zhu, J., Lee, B. Y., Kimmel, S. E., & Volpp, K. G. (2009)	Medicine	Quasiexperimental study utilizing administrative data and electronic medical record information to compare changes in lipid lowering medication use over time for veterans who experienced increases in prescription copayments vs. veterans who did not.	5,604 patients receiving care at the Philadelphia VAMC and filled at least one rx for lipid lowering agent within a 24 month period prior to increase in copayments.	Increase in co-payments adversely affects adherence to lipid lowering agents among veterans. This was true even among veterans that were at high risk for coronary artery disease.
Fernandez, R., Davidson, P., Griffiths, R., Juergens, C., & Salamonson, Y. (2007)	Nursing	Cross-sectional study utilizing a self-administered questionnaire that was mailed to participants. Subjects were followed up to 12-24 months following PCI.	270 subjects who underwent PCI between April 2003 and March 2004 and met inclusion criteria.	The authors found that patients report high rates of adherence to medication after PCI. Patients considered themselves to be adherent despite missing medication dosages.

Authors/ Year/ Country	Discipline	Methods	Sample/Setting	Findings
Jackevicius, C. A., Li, P., & Tu, J. V. (2008)	Medicine	Up to 125 charts from 104 hospitals in Ontario were abstracted. Charts were identified through the EFFECT Registry. The Registry was linked to prescription claims, demographics, physician service and hospital discharge. Non-Ontario residents were excluded because the investigators did not have access to their prescription filling information. Patients admitted to long-term care facilities were excluded.	4,591 post MI patients with 12,832 discharge prescriptions written	Of discharge Rx, 92.3% were for cardiac medications. 59.5% had ≤ 10 prescriptions filled within the 120 days. Only 74% of patients filled all of their prescriptions within 120 days. Aspirin was not considered a prescription and data regarding taking aspirin were not collected. 10% of patients did not fill any prescriptions.
Julius, R. J., Novitsky, M., J., & Dubin, W. R. (2009)	Psych	Literature Review	Search using key words “medication adherence” and “compliance” = 2,000 references After initial search articles were limited regarding psychiatric medications and specific medication classes. Also limited to articles involving clinical focus.	Factors affecting medication adherence were broken into four areas: patient related, psychological, medication-related and social/environmental. Interventional strategies: psychoeducational, cognitive-behavioral therapy, and motivational interviewing.

Authors/ Year/ Country	Discipline	Methods	Sample/Setting	Findings
Lehane, E., & McCarthy, G. (2009)	Nursing	Literature Review surrounding medication adherence.	A critical synthesis of the literature to determine key attributes for adherence, compliance, and concordance. 26 papers were reviewed	The definition of adherence is allocated into 5 categories – coincidence of patient behavior with professional advice, relationship as part of the process of care, outcome and process targets, taking medications as prescribed, and other factors influencing behavior.
Molloy, G. J., Perkins-Porras, L., Strike, P. C., & Steptoe, A. (2008)	Psychology	Prospective study design with follow-up data collected for 12 months after hospital admission.	Acute Coronary Syndrome (ACS) patients – N = 193 Setting: 4 local London hospitals	The authors found that partner stress predicted <i>nonadherence</i> . Just under 30% of patients were deemed to have poor adherence, but the authors felt that this is and underestimate because of the influence of social desirability biases. Patients with large social networks were more likely to attend rehab. Partner stress and small social networks were associated with poorer quality of life.

Authors/ Year/ Country	Discipline	Methods	Sample/Setting	Findings
Rolley, J.X., Davidson, P.M., Dennison, C.R., Ong, A., Everett, B., & Salamanson, Y. (2008)	Nursing	Integrative Literature Review	Search of electronic databases – CINAHL, Medline, Blackwell Synergy, Pubmed, Google Scholar using key words medication, adherence or compliance, self-report, and questionnaires/tools/surveys.	Medication adherence depends on a range of physical, social, economic and psychological considerations. Methods of assessing medication adherence require further investigation.
Schoenthaler, A., Ogedegbe, G., & Allegrante, J. P. (2009)	Psych	Cross-sectional study using Kenny and Baron analytic framework of mediation	167 hypertensive African American patients in a primary care practice.	Self-efficacy mediates the relationship between depressive symptoms and medication adherence, with the correlation that depressive symptoms lead the patient to be nonadherent with medications.
Shay, L.E. (2008)	Nursing	Walker and Avant Framework	Sample: Literature review with evaluation of the concept of compliance as an antecedent. Non-adherence is also reviewed, along with associated concepts to include self-efficacy, motivation, and environment Setting: Maintenance of Long-Term Weight Management	The author discusses compliance as an antecedent to adherence. Through literature review, identifies compliance as having a negative connotation. Identifies the importance of associated antecedents in meeting the concept of adherence. Identifies that more research is needed in the area of weight loss and adherence.

Authors/ Year/ Country	Discipline	Methods	Sample/Setting	Findings
Wu, J., Moser, D. K., Lennie, T. A., & Burkhart, P. V. (2008)	Nursing	Longitudinal Study	135 patients with HF. Medication Adherence measured using the Medication Event Monitoring System. Percentage of doses taken and percentage of days appropriate doses taken.	Adherence rates above 88% were more sensitive and specific to predicting better event free survival (decreased number of ED visits with increased adherence to prescribed medication regimen.

Summary

Adherence is the most commonly used term in healthcare to describe a patient's participation in their healthcare. Originally, compliance was the term that indicated a patient's participation in their healthcare, but due to the paternalistic tone of the term, healthcare has adopted the term adherence. There are many factors that affect adherence including but not limited to socioeconomic status, belief in the healthcare system and provider, depression, self-efficacy, and partner stress. Medication adherence has been shown to be imperative in decreasing risk of mortality and morbidity, and preventing rehospitalization. The reviewed studies demonstrate that medication adherence (adherence is assumed based on prescription fills and refills) is critical to positive outcomes post stent placement.

Current studies have reviewed medication adherence and its relationship to mortality and morbidity for the medications supported through evidence for treatment of MI. Many studies have been conducted to explore the relationship between clopidogrel and stent patency. No studies were found that explored the relationship of medication compliance and insurance status. Cost as a factor in medication adherence must be considered and is the premise for this project.

CHAPTER THREE: METHODS

Implementation of Project

As part of a quality improvement initiative, pre-test data were collected for the 15-month time period between February 2006 and February 2007 for all patients with STEMI that presented to the ED at ORMC. Readmission data were collected until May 2007 to provide 3-month readmission statistics after the STEMI. A cost-benefit analysis (CBA) was performed using these data and a policy was developed to provide clopidogrel to all patients with STEMI that had received a BMS and were uninsured.

The CBA reviewed admissions and 3-month readmissions of uninsured STEMI patients who had been treated with BMS. During this 15-month period of time 17 uninsured patients were admitted with STEMI and treated with BMS. Of these, 4, or 23.5% were readmitted within 3 months of initial presentation. A fifth uninsured patient was readmitted during this time frame, but was listed as “Medicaid pending” and was therefore excluded from analysis. The cause of readmission for this was also repeat STEMI. The repeat STEMI cost the patient in terms of health, and cost the organization in terms of finances. Neither the initial hospitalizations for the 17 patients, nor the rehospitalizations for the 4 patients were reimbursed. The direct cost of readmissions was approximately \$36,700 or an average of \$9,175 per patient.

The cost of providing clopidogrel for future uninsured STEMI patients was calculated by projecting a 15% increase in number of uninsured STEMI’s presenting to the ER for the next year. The projected cost of providing the additional 21-days of clopidogrel (Social Work Department was already providing 7-days of clopidogrel) to the projected 20 patients was calculated to be \$720.

Assuming a 23% readmission rate for the projected STEMI patients if no clopidogrel is provided, a 50% reduction in readmissions (2.5 less readmissions) with clopidogrel provision would save the organization about \$22,937.

Based on the results of the CBA, a policy was developed to provide 28-days of clopidogrel to uninsured STEMI patients who are treated with BMS. This policy has slowly been adapted to include uninsured STEMI patients who are treated with DES, and any STEMI patient who does not have prescription insurance.

Design

The design for this study was a retrospective chart review in a pre and post-test type format. The phenomenon being studied is readmission post-stent placement for STEMI with subacute thrombosis to the initial stented artery. This is not a case-control design, but is to study project outcomes (Polit & Beck, 2008).

The major strength of this study design was that all patients were included. One limitation of the study was that discharge education may vary by provider and since data will be reviewed retrospectively with no exclusion criteria patient understanding of the importance of taking clopidogrel post stent placement was unknown. Another limitation was that patients with prescription insurance were not reviewed for compliance. An assumption was made that these patients were filling their prescriptions. This was considered a limitation because the amount of a patient's co-pay may have been too high for the patient to afford and still prevented the patients from acquiring the needed medication. There is new literature that demonstrates that some patients are non-responders to clopidogrel. The testing that can identify these patients was not being used at this organization, therefore this was another limitation of this study.

Variables

The independent variable (IV) was the method provision of 28 days of clopidogrel prior to discharge or provision of prescription prior to discharge with the expectation that the patient will fill the prescription. Level of measurement for these variables was nominal. Demographic data included gender (nominal), insurance status (nominal), type of insurance (nominal), patient age (ratio/scale), and type of stent (nominal).

The dependent variable (DV) was rehospitalization for AMI resultant of subacute thrombosis in the previously stented culprit vessel. This variable was also nominal level data.

Setting/Subjects/Sampling

This project was conducted at a tertiary care center in Central Florida. Subjects for the pre-test data collection were all patients with STEMI that presented to the center's ED from February 2006, prior to the implementation of the clopidogrel provision policy, until February 2007, and for the three months following or until May 2007. Subjects for post-test data collection were all patients with STEMI that presented to the center's ED from February 2009, the time the clopidogrel provision policy was initiated, until February 2010, and for the three months following or until May 2010. No patients were excluded from the data collection process, although the focus was on patients who are uninsured and therefore have a more difficult time obtaining prescriptions (an assumption of the project). An exclusion criteria for the project was insurance. If patients had insurance, they did not receive medication at discharge, only a prescription.

Based on preliminary assessment, it was estimated that 200 subjects or records will meet inclusion criteria for the two periods. Computing chi-square statistics, this sample size will

detect an effect size of .20, alpha of .05, at a power of .80. A sample size of 220 was requested from the IRB to ensure that data from all eligible subjects during the two time periods was retrieved for analysis.

Patient charts are coded after discharge by the Coding and Billing Department at the Center. Coding identifies all patients that had an STEMI. The Quality Department reviews all patient charts for those patients who had STEMI to determine whether or not the core measures were met. Quality is able to query all medical record (MR) numbers for patients with STEMI during a specified period of time. Since MR numbers are unique to each patient, they can also be used to access readmission information. MR numbers provided access to charts. Physician documentation and cardiac catheterization results were reviewed, as well as discharge instructions.

Human Subjects

The benefits of clopidogrel post-stenting are well documented throughout the research, and the ACC/AHA recommendation are that all patients receiving coronary stents should take clopidogrel for time periods determined by the type of stent they received (Faxon, 2007). Since all patients treated with stents for STEMI receive a prescription for clopidogrel at discharge, there was minimal risk to the patient in this project. The difference in treatment for subjects included in the study was that these patients received actual medication rather than a prescription.

Approval was requested from the Institutional Review Boards (IRB) at the University of Central Florida (UCF) and at the Center (Appendix B). The potential risk to the subjects was the possibility of a breach of confidentiality. Health Insurance Portability and Accountability Act

(HIPAA) guidelines were followed to prevent a breach of confidentiality. Each chart reviewed was assigned a unique identification number that did not have any association with the medical record number. The log with these numbers was kept by the primary researcher in a locked file cabinet. At the completion of the study, this information was destroyed by shredding. This information was not shared or reused by anyone except as required by law or the IRB's.

A waiver of consent was requested and a HIPAA Waiver Authorization Form was submitted to the IRB's. Additionally, the HIPAA De-identification form was also submitted.

Instruments/Data Collection Tool

An Excel spreadsheet was used to collect data (Appendix B). This tool was constructed for the purposes of this study. Data included gender, age, insurance, type of stent, vessel stented, whether or not the patient was readmitted, if readmitted for AMI which vessel was the cause, clopidogrel prescription or medication provided, and physician documentation of non-adherence. Sovera, a system which houses all patient permanent records for Center was used to obtain the data. Patients were identified by the Quality Department at the Center.

The current policy to provide clopidogrel to all uninsured STEMI patients who receive stents will continue. The data from the first time period was compared to the time period of 15 months after the clopidogrel provision policy began.

In addition to other documentation (physician documentation and cardiac catheterization results) reviewed, the Social Work note was included in the second data set to determine if eligible patients received their 28-days of clopidogrel prior to discharge. Excel was chosen for the ease of export to SPSS. Direct export also decreased the chance of transcription errors.

Procedures

Medication adherence was evaluated based on 3-month readmission rates and physician documentation. The conceptual definition for adherence is taken from Jackevicius, et al who defined adherence as filling and refilling prescriptions. (Jackevicius, Li, & Tu, 2008) Prescription fills and refills were not measured in this project because the patients of primary interest were those without insurance and there was no way to track fills and refills.

This project involved data collection prior to implementation of the clopidogrel provision policy (Appendix A) and for the time period of fifteen months (so that readmissions may be tracked for 3 months after stent placement) after implementation of the policy. Readmissions for the 3 months after stent placement for STEMI were reviewed.

All charts for patients admitted with STEMI were reviewed. Data collected included age, gender, insurance status, vessel stented, type of stent placed, and if patient was readmitted. Readmitted patient charts were reviewed to determine if the readmission was as a result of an AMI caused by subacute thrombosis. Physician documentation was reviewed for documentation of clopidogrel non-adherence and Social Work documentation was reviewed to ensure that clopidogrel was provided to patient prior to previous discharge. These results were compared to the data collected for the 15 month time period prior to implementation of the clopidogrel provision policy.

Once all data were collected, data were imported into the SPSS 16.0 statistical package (Chicago, IL) for data analysis.

Data Collection Tool

In addition to other documentation (physician documentation and cardiac catheterization results) reviewed, the Social Work note was included in the second data set to determine if eligible patients received their 28-days of clopidogrel prior to discharge. Excel was chosen for the ease of export to SPSS. Direct export also decreased the chance of transcription errors. The data collection tool used was developed to be specific to this study and to capture the required variables, therefore there was no reliability or validity data for this tool. (Appendix B)

Data Analysis

Since all data with the exception of age are nominal, non-parametric tests were conducted (Munro, 2005). For this project, chi-square/crosstabs analysis will be done. Another reason for choosing non-parametric tests was because the assumption of normal distribution is not required for these tests. The assumptions of independent categories, levels of measurement, and theoretical reasons for categories were made (Munro, 2005). The data to be collected was predetermined. Chi-square/crosstabs was used to compare readmissions by those insured versus those uninsured. It was also used to compare readmissions prior to implementation of the clopidogrel provision policy with readmissions occurring after the policy was in place. Readmissions were also compared by age group and insurance status, as well as gender and insurance status.

The primary research questions and data analyses were as follows:

1. Is there a difference in readmission rates between uninsured STEMI patients who receive medication, actual “drug-in-hand”, and those who receive a prescription to fill? – chi square/crosstabs analysis

2. Are uninsured patients who receive “drug-in-hand” less likely to be readmitted than insured patients who receive a prescription to fill? – chi square/crosstabs analysis

The a priori alpha level testing for the research questions is .05.

Limitations

A major limitation of this project was the inability to identify patients readmitted outside of this hospital system. Another limitation of the study was that discharge education may vary by provider. Since data was reviewed retrospectively with no exclusion criteria, patient understanding of the importance of taking clopidogrel post-stent placement may not have been consistent.

Summary

The goal of this project was to determine the effectiveness of providing clopidogrel to STEMI patients treated with stents in decreasing readmissions with repeat AMI. AMIs result in cardiac compromise and increased mortality and morbidity in patients with cardiac disease. If readmissions can be reduced, the financial impact will be examined. This data will be presented to the Department of Cardiology, Interventional Cardiology Collaborative Practice Team and Administration to determine if the policy to provide clopidogrel is beneficial and should be continued.

CHAPTER FOUR: RESULTS

Study results are discussed in this chapter. Data are organized by demographics followed by the research questions. Additional findings are also summarized.

Demographics

Demographics and statistical results of the retrospective chart review are discussed in this chapter. Statistical analyses were performed using the SPSS 16.0 statistical computer program. Data were analyzed using Chi square cross tabulation and T-test for independent samples. The study sample for the pre-test group for this project included all patients presenting with STEMI from February 2006 to February 2007, and for the 3 months following to assess for readmission. The post-test group included all patients presenting with STEMI from February 2008 to February 2009, and for the 3 months following to assess for readmission.

Two hundred and one patients (n=201) were eligible for inclusion. One patient in the post-test group was excluded because the medical record number could not be found in either of the electronic medical records. A total of 200 charts were reviewed; 100 from the pre-test group and 101 from the post test group. A summary of demographic characteristics is provided in Table 3. Demographic characteristics of age, gender and insurance status were not statistically different between groups. The mean age for the control group was 59.1 (\pm 13.8) and the mean age for the post-intervention group was 58.9 (\pm 13.6).

Although no significant differences were noted in the vessel stented between groups, a significant difference in type of stent placed was noted. In the pre-test group, 19% of patients admitted with STEMI were treated with (bare metal stents) BMS. In the post test group, 61.4% were treated with BMS ($p < .001$).

Table 3: Demographics

Variable	Group			
	Before Clopidogrel (Control)	After Clopidogrel (Intervention)	All	p-value
	N (%)	N (%)	N (%)	
Gender				.558
Male	74 (74.0%)	71 (70.3%)	145 (72.1%)	
Female	26 (46.4%)	30 (53.6%)	56 (27.9%)	
Insurance Status				.343
Uninsured	21 (21.0%)	20 (19.8%)	41 (20.4%)	
Medicare/ Medicaid	30 (30.0%)	37 (36.6%)	67 (33.3%)	
Commercial	39 (39.0%)	40 (39.6%)	79 (39.3%)	
Medicare + Commercial	10 (10.0%)	4 (4.0%)	14 (7.0%)	
Type of Stent				< .001
Bare Metal	19 (21.3%)	62 (67.4%)	81 (44.8%)	
Variable	Group			
	Before Clopidogrel (Control)	After Clopidogrel (Intervention)	All	p-value
	N (%)	N (%)	N (%)	
Type of stent				
Drug-eluting	70 (78.7%)	30 (32.6%)	100 (55.2%)	
Vessel Stented				.414
LAD	39 (43.8%)	35 (37.6%)	74 (40.7%)	
RCA	34 (38.2%)	44 (47.3%)	78 (42.9%)	
Cx	10 (11.2%)	7 (7.5%)	17 (9.3%)	
PDA	0 (0.0%)	2 (2.2%)	2 (1.1%)	
OM1	1 (1.1%)	3 (3.2%)	4 (2.2%)	
OM2	1 (1.1%)	0 (0.0%)	1 (0.5%)	
SVG	3 (3.4%)	2 (2.2%)	5 (2.7%)	
LIMA	1 (1.1%)	0 (0.0%)	1 (0.5%)	

Legend vessel: LAD – left anterior descending, RCA – right coronary artery, Cx – circumflex, PDA – posterior descending artery (a branch of the RCA), OM1 – obtuse marginal 1, OM2 – obtuse marginal 2, SVG – saphenous vein graft, LIMA – left internal mammary artery

Readmissions

The first objective of this project was to examine readmission rates in uninsured patients who experienced and were treated for STEMI, to determine if those who receive medication in hand were less likely to be readmitted than those who simply received a prescription.

The number of readmissions was not statistically different between groups ($n = 5$, 23.8% control and $n = 2$, 9.1% intervention). However, the number of patients admitted with STEMI was more than double during the control period versus the intervention. The goal of this project was to reduce STEMI readmissions, particularly in the uninsured population. Five uninsured patients (23.8% of readmissions) in the control group were readmitted with STEMI. In the post intervention group 2 uninsured patients (9.1% of readmissions) were admitted with STEMI. This was not statistically significant ($p = .191$) most likely due to the small sample size ($N = 43$). Additionally, all readmissions for STEMI patients in the control group occurred within 30 days while both readmissions in the post intervention group occurred within 31-60 days. This was a statistically significant finding ($p = .008$). Findings are summarized in Table 4.

Table 4: Readmission of Patients (n = 43)

Readmit	Group			
	Before Clopidogrel (Control)	After Clopidogrel (Intervention)	All	p-value
	N (%)	N (%)	N (%)	
Cause				.191
STEMI	5 (23.8%)	2 (9.1%)	7 (16.3%)	
Other	16 (76.2%)	20 (90.9%)	36 (83.7%)	
Time to Readmission				.008
≤ 30 days	5 (100.0%)	0 (0.0%)	5 (71.4%)	
31-60 days	0 (0.0%)	2 (100.0%)	2 (28.6%)	

Legend: STEMI – ST-elevation myocardial infarction

The second objective of this project was to determine if patients that received drug in hand were less likely to be readmitted with STEMI than patients who received a prescription. All STEMI readmissions from both groups were uninsured patients (N = 7). There were no STEMI readmissions in insured patients during the study time frame.

Additional Findings

STEMI readmissions were analyzed by adherence to prescribed medication regimen, specific to clopidogrel because readmission as a result of subacute thrombus formation occurs with non-adherence to prescribed antiplatelet agents. Uninsured patients in the pre-test group were provided with a prescription for clopidogrel. Uninsured patients in the post-test group were to be provided with clopidogrel rather than a prescription. Therefore, adherence to clopidogrel and provision of clopidogrel in the post-test group (n = 13) and were analyzed using cross tabs Chi-square. All patients (n = 7) that were readmitted with STEMI had physician documentation of clopidogrel non-adherence. Thirteen (13) patients met criteria for clopidogrel provision. Of these, 8 patients (61.5%) received clopidogrel and 5 (38.5%) did not. This was a clinically

significant but not statistically significant finding. Reasons for not getting the clopidogrel included being transferred to a telemetry unit other than the existing post interventional unit, leaving against medical advice and having an existing prescription for clopidogrel with documented medication adherence.

Table 5: Medication Adherence by MD Documentation

Variable	Group			
	Before Clopidogrel (Control)	After Clopidogrel (Intervention)	All	p-value
	N (%)	N (%)	N (%)	
Adherent				
No	5 (100.0%)	2 (100.0%)	7 (100%)	
Yes	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Clopidogrel Provided				
Yes	N/A	8 (61.5%)	8 (61.5%)	
No	N/A	5 (38.5%)	5 (38.5%)	

Findings were presented in this chapter. The last chapter discusses interpretation of findings.

CHAPTER FIVE: CONCLUSION

This chapter discusses findings, limitations, conclusions and implications for nursing practice of the study as related to the study questions. Recommendations for future research related to the outcomes of this study are also discussed.

Discussion

The main objective of this study was to evaluate outcomes of providing clopidogrel to uninsured patients presenting with STEMI who were treated with intervention utilizing BMS or DES. The first research question posed to evaluate these outcomes was “Is there a difference in readmission rates between uninsured STEMI patients who receive medication, actual ‘drug-in-hand’, and those who receive a prescription to fill?” To answer this question, readmission rates were compared between STEMI patients before and after implementation of a program that provided clopidogrel to uninsured patients.

All-cause readmission rates were similar between groups with 21.9% of STEMI patients being readmitted in the pre-test group and 23.0% being readmitted in the post-test group ($p = 0.85$). However, a reduction in readmission rates due to subacute thrombus formation leading to STEMI was noted between groups, with 5 uninsured patients being readmitted in the pre-test group and only 2 uninsured patients in the post-test group. However, this was not a statistically significant finding ($p = 0.191$), most likely related to the small sample size ($n = 43$). The finding is clinically significant (23.8% of readmissions in the pre-test group vs. 9.1% in the post-test group).

“Subacute thrombus” is the term to describe stent thrombosis which occurs in the first 30 days after stent implantation. (Grines et al., 2007) By providing the first 30-days worth of clopidogrel to uninsured patients, the likelihood of adherence was increased by removing barriers to obtain medication and therefore may be related to the decrease in readmissions as a result of subacute thrombus formation. This finding is supported by Rolley, et al (2008) who found that medication adherence depends on many factors, including social and economic considerations. By providing uninsured patients with medication economic status was taken into consideration and removed as a barrier. Additionally, increased education to STEMI patients regarding the importance of taking their clopidogrel as prescribed may have increased adherence, at least in the first month after discharge. A limitation is that factors related to adherence were not directly assessed.

In addition to a reduction in readmission rates, length of time to STEMI readmission was evaluated. In the pre-test group, all STEMI readmissions occurred within 30 days of discharge. In the post-test group, STEMI readmissions did not occur within the first 30 days, but in days 31-60. This was a both a statistical ($p = .008$) and clinically significant finding. Patients in the post-test group who were treated with BMS and met criteria were provided with 28-days of clopidogrel at the time of discharge therefore the patients would have completed their course of clopidogrel by the time of their readmission. This finding is supported by Ho, et al (2008) who found an increase in adverse events in the first 90 days after discontinuation of clopidogrel in patients who had been treated with PCI (Ho et al., 2008), since the two readmissions in the intervention group occurred within 31 to 60 days which began the time period after completing their 30-day course of clopidogrel.

The second research question was “Are uninsured patients who receive ‘drug-in-hand’ less likely to be readmitted with repeat STEMI than insured patients who receive a prescription to fill?” To answer this question readmissions were compared by insurance status and by reason for readmission. Both patients who were readmitted with STEMI were uninsured. Insured patients were readmitted for other reasons to include elective surgery, elective staged PCI, congestive heart failure, etc. It should be noted that more uninsured than insured patients were readmitted with STEMI from both groups. This was a statistically significant finding ($p = .012$). This may be due to the lower cost of clopidogrel for patients with insurance, thereby allowing them to continue clopidogrel for a longer period as recommended by the guidelines. It is ideal for patients treated with BMS to take clopidogrel for at least 6 months after stent implantation (Antman et al., 2008) and uninsured patients may not be able to afford clopidogrel after the first month’s supply.

Patients who met criteria for clopidogrel provision were evaluated to determine if all eligible patients received the medication. It was found that only 8 of 13 (61.5%) received medication. Five (38.5%) patients did not receive their medication at discharge. This was not a statistically significant finding, but is clearly clinically significant as five patients who were supposed to receive the clopidogrel per protocol did not receive their medication. Upon analysis, this finding can be attributed to patient location (unit) at time of discharge. The tertiary center where this study was conducted has a designated unit for post-PCI patients, both elective and those treated for STEMI. Some STEMI patients are admitted to the Coronary Care Unit (CCU) immediately following their intervention and then transferred to a telemetry unit. Bed availability occasionally causes these patients to be transferred to monitored units other than the designated post-PCI unit. Of the patients that did not receive their clopidogrel, one was already

taking it, one left against medical advice and the other three were discharged from telemetry units other than the post-intervention unit. Therefore, they did not receive the same evaluation by Social Work as those patients on the post-intervention unit. Additional systems/procedures are needed to ensure that all eligible patients receive the medication as indicated.

Answering the second question assumes that patients who receive medication will be adherent. Therefore, every STEMI readmission was evaluated for adherence to medication based on physician documentation. All STEMI readmissions, both pre-test and post-test, had physician documentation of non-adherence to clopidogrel.

Additional Findings

The intervention to provide 28 days of clopidogrel to uninsured STEMI patients (patients received 2 days of clopidogrel while hospitalized) was based on the ACC/AHA guidelines which recommend a minimum of 30 days of clopidogrel to prevent subacute thrombus formation with BMS.(Antman et al., 2008) At the time of project implementation interventional cardiologists involved with the Code STEMI process were educated to the criteria for clopidogrel provision and to consult Social Work for any patients that met the criteria.

It is believed that as a result of this project and related physician education (all interventional cardiologists taking STEMI call were individually educated by the principal investigator), a change in practices for treatment of STEMI occurred. Prior to the intervention, 19 (21.3%) of patients were treated with a BMS. After the intervention, 62 (76.5%) patients were treated with a BMS, ($p = < .001$). This practice change occurred despite insurance status. The STEMI process in place at the Center allows 25 minutes from time of presentation to the ED to transfer to cardiac catheterization laboratory. This time constraint and the urgency of the

situation decreases the opportunity to accurately assess for ability to be adherent. It was not sufficient to identify whether or not a patient had insurance, as insurance co-pays and limitations with Medicare prescription coverage can lead to barriers with adherence. Since the ACC/AHA guidelines for clopidogrel therapy with BMS recommend a minimum of 30 days, (Antman et al., 2008) socioeconomic barriers to adherence (Rolley et al., 2008) were decreased for insured patients treated with a BMS with this change in practice. It's important to note that while the ACC/AHA guidelines for clopidogrel therapy with a BMS recommend a minimum of 30 days, the guidelines also state it would be ideal if clopidogrel therapy could be continued for up to 12 months. While the socioeconomic barriers to obtaining the initial 28-days of clopidogrel were decreased, these barriers were not removed and patients were not able to continue the recommended ideal therapy.

Limitations

The major limitation of this study was the inability to identify patients that may have been readmitted with STEMI to a hospital not within the study site's healthcare system. Another limitation of the study is the small sample size, particularly in the evaluation of STEMI readmissions.

Lack of utilization of the dedicated unit for post-PCI patients was another limitation. This resulted in some patients that met criteria for clopidogrel provision not receiving their medication. This may have contributed to the two STEMI readmissions. However, is also identified the need to modify procedures to ensure that all eligible patients receive the medication. Additionally, the nursing staff and nurse practitioner on the dedicated unit provided uniform education on the importance of medication adherence, specific to clopidogrel, to all

patients. Patients admitted to other units may or may not have received the same education, resulting in varying understanding of the importance of medication adherence.

Implications for Nursing Practice

This study evaluated a process improvement project implemented to reduce readmissions as a result of subacute thrombus formation in STEMI patients by meeting the ACC/AHA guidelines (Antman et al., 2008) for anti-platelet regimens in patients being treated with stents for STEMI. This project was a collaborative effort between the coordinating nurse practitioner, interventional cardiologists, Social Work Department, outpatient pharmacy and nursing staff, with each department having a specific role. The goal of the project was to improve medication adherence in the uninsured STEMI population by providing clopidogrel “drug-in-hand” and thereby eliminate barriers to obtaining the medication. However, patient evaluation for type of stent and education regarding the importance of adherence to clopidogrel were imperative to the success of the program. These points could not have been addressed without collaboration from all departments. As a result of this project, the outpatient pharmacy has added a pharmacy tech to deliver the medications to the bedside, eliminating the need for the Social Worker to travel to the pharmacy to obtain the medication.

The education regarding medication adherence provided by the nursing staff was consistent for all PCI patients on the designated unit. Nursing was also instrumental in identifying patients that met criteria for clopidogrel provision when a Social Work consult had not been entered. The study also made the nurses more aware of the socioeconomic needs of patients.

For the purposes of this project, the coordinating nurse practitioner also collaborated with Sanofi-Aventis and Bristol Myers Squibb, the pharmaceutical agencies that co-market clopidogrel. As part of their marketing program, both companies provide vouchers for 14 free days of clopidogrel for patients receiving new prescriptions for the medication. Through this collaboration, the acute care hospital in Central Florida received more of these vouchers than any other site in the country. The redemption rate for these vouchers, as tracked by these companies, is higher in the Central Florida area than in any other area in the country (approximately 80% redemption versus approximately 14%). These vouchers were used in conjunction with the Social Work department's resources to provide medication for these patients. Since the completion of this project the policy has been revised to provide 30 days of clopidogrel to any patient presenting to the Emergency Department at the facility who is treated with a BMS, and has no insurance, no prescription coverage, or whose Medicare prescription benefits have expired.

Resources exist that would allow this policy to be adapted in other facilities. Multi-disciplinary collaboration that is physician and advanced practice nurse led is integral to implementing this type of project. Increased utilization of electronic medical records requires that information technology be included in the planning stages to assist in identifying these patients prior to discharge.

Recommendations for Further Research

One of the issues that was identified with this study was providing medication to all uninsured STEMI patients that met criteria. This occurred due to patients being transferred to telemetry units other than the designated post-PCI unit. A prospective study that identified

patients at time of STEMI admission and enrolled them would allow for a more controlled study and ensure that all eligible patients receive medication prior to discharge.

Prescription co-pays and restrictions with Medicare coverage have proven to be barriers in obtaining medication. The program should be expanded to evaluate the socioeconomic needs of any STEMI patient regardless of insurance status to determine if the patient can reasonably afford his/her medication, providing medication to those whose socioeconomic status creates a barrier to acquiring clopidogrel. Further research could then be conducted to determine if supplying the initial month of clopidogrel improves adherence and decreases readmissions.

Since the inception of this study a new anti-platelet agent, prasugrel, has been approved for use. Future studies might compare readmission rates between patients prescribed clopidogrel versus those prescribed prasugrel. Consistent education and identification of patients would be necessary for both groups.

Conclusions

This study evaluated the benefit of providing clopidogrel to uninsured STEMI patients who were treated with a BMS. The pre-test group showed a 23.8% readmission rate with uninsured STEMI patients. The post-test group showed a 9.1% readmission rate. The cost of providing the clopidogrel to the 8 patients that received it was \$297.92, compared to average direct cost of one STEMI readmission which was \$9,175.00, demonstrating a cost savings just under \$27,000.00. The medication in addition to the focused education each patient received may have contributed to this reduction in readmissions.

Additionally, a transition to increased use of BMS (21.3% vs. 67.4%) in STEMI patients was noted in the post-test group. This was most likely a result of increased physician awareness of barriers to adherence.

This program should be continued with increased focus on ensuring that patients are placed on the appropriate unit. Additionally, other vulnerable populations should be considered for inclusion in the program.

**APPENDIX A: PLAVIX PROVISION FOR INDIGENT CODE STEMI STENT
RECIPIENTS**

There are three criteria a patient must meet in order to qualify for 28 days of Plavix. The patient must be a Code STEMI, uninsured and the recipient of a stent. The stent can be either Bare Metal (BMS) or Drug Eluting (DES). In addition, a patient will qualify if they have insurance without prescription coverage. They must still be a Code STEMI and the recipient of a stent.

The process is as follows:

- 1) Social Work/Case Management Tech identifies the Code STEMI patients who have received a stent and is self pay status or without prescription coverage.
- 2) Two scripts are needed, both for 14 days. The ARNP may be able to assist with writing the scripts if the doctor is not available.
- 3) SW/CMT must complete the Walgreens referral process for fourteen days of Plavix then take the referral, a fourteen day trial card and the two scripts to OHScripts to be processed. The trial card can be obtained from ARNP Sita Price on 5B/Cang or Carolyn La Londe. SW/CMT later delivers the medication to the patient at bedside.
- 4) The unit pharmacist needs to be informed that one of these patients has been identified so that they can provide a bottle of aspirin. A copy of the script will need to be provided to the pharmacist.
- 5) SW/CMT should also provide the patient with a patient assistance program packet which can be obtained through the Needymeds website.
- 6) If an uninsured patient is going to be on Plavix for any length of time this is a good indication that an OCMC referral would be appropriate.

- 7) **Weekends/Holidays: The patient will have to take the Walgreens referral, 14 day trial card and scripts to Walgreens for processing. A 14 day trial card will be kept in Team Leader's (Dari) mailbox.

If you should have any questions about the process please contact:

Sita Price, ARNP 321-841-5168

Carolyn La Londe, MSW 321-841-5168 or 407-980-6037

APPENDIX B: DATA COLLECTION TOOL

Variables	Codes							
ID								
Age								
Gender	1 = Male	2 = Female						
Insurance	1 = Uninsured	2 = Medicare/ Medicaid	3 = Commercial Insurance	4 = Medicare + Commercial	5 = Not Available			
Type of Intervention	0 = N/A	1 = Stent	2 = PCI/No Stent	3 = CABG				
Vessel_Stent	1 = LAD	2 = RCA	3 = Circ	4 = OM1	5 = OM2	6 = PDA	7 = SVG	8 = LIMA
Type_Stent	1 = BMS	2 = DES	3 = Not Available					
Readmit_STEMI	0 = No	1 = Yes	2 = Not Available					
Cause of Readmission	0 = N/A	1 = STEMI/MI	2 = Other					
Time to Readmit	0 = N/A	1 = Within 30 Days	2 = Within 90 days	3 = Not Available				
Thrombus	0 = No	1 = Yes	2 = Not Available					
MD Documentation of Non-adherence	0 = No	1 = Yes	3 = Not Documented					
Plavix Provided	0 = No	1 = Yes	2 = N/A (insured)	3 = Not Documented				
Adherence, if Readmitted	0 = No	1 = Yes	2 = N/A	3 = Not Available				
LOS if Readmitted	# of Days	0 = N/A						
Discharge Disposition	1 = Home	2 = SNF	3 = ALF	4 = Expired	5 = Not Available			

APPENDIX C: UCF IRB



University of Central Florida Institutional Review Board
Office of Research & Commercialization
12201 Research Parkway, Suite 501
Orlando, Florida 32826-3246
Telephone: 407-823-2901 or 407-882-2276
www.research.ucf.edu/compliance/irb.html

Approval of Human Research

From: UCF Institutional Review Board #1
FWA00000351, IRB00001138

To: Sita S. Price

Date: October 20, 2010

Dear Researcher:

On October 20, 2010, the IRB approved the following human participant research until 10/19/2011 inclusive:

Type of Review: UCF Initial Review Submission Form
Project Title: Outcomes of Providing Clopidogrel (Plavix®) for Indigent Patients
Investigator: Sita S. Price
IRB Number: SBE-10-07136
Funding Agency: None

The Continuing Review Application must be submitted 30 days prior to the expiration date for studies that were previously expedited, and 60 days prior to the expiration date for research that was previously reviewed at a convened meeting. Do not make changes to the study (i.e., protocol, methodology, consent form, personnel, site, etc.) before obtaining IRB approval. A Modification Form cannot be used to extend the approval period of a study. All forms may be completed and submitted online at <https://iris.research.ucf.edu>.

If continuing review approval is not granted before the expiration date of 10/19/2011, approval of this research expires on that date. When you have completed your research, please submit a Study Closure request in iRIS so that IRB records will be accurate.

In the conduct of this research, you are responsible to follow the requirements of the Investigator Manual.

On behalf of Joseph Bielitzki, DVM, UCF IRB Chair, this letter is signed by:

Signature applied by Janice Turchin on 10/20/2010 03:29:02 PM EDT

IRB Coordinator

APPENDIX D: ORMC IRB



1414 Kuhl Ave.
Orlando, FL 32806
321.843.7000
orlandohealth.com

September 16, 2010

Sita Price ARNP
1414 Kuhl Ave
MP 143
Orlando, FL 32806

Dear Ms. Price:


Concerning the following Study:

Our Study # 1009709

Protocol Title: Outcomes of Providing Clopidogrel (Plavix) for Indigent Patients

Under federal guidelines for expedited review, I have reviewed and approved the fact sheet received by the IRB office on 9/13/10, protocol dated 8/31/10, version 2 for your project stated above. The study is approved under 21CFR 56.110 (b) (1) for this project since it presents no more than minimal risk. The waiver of informed consent is approved under 45 CFR 46.116 (d) and 45CFR 46.117(C)(2) for this project since it presents no more than minimal risk and protected health information will be de-identified. The Chair has approved this study at all Orlando Health, Inc. facilities and your office. The Institutional Review Board review process is in compliance with GCP's and included review of potential risks to subjects, risk benefit ratio, subject selection criteria and safety, content of the informed consent, confidentiality and appropriate safeguards. The project was reviewed in detail on 9/16/2010. It will be sent to the 10/7/2010 Institutional Review Board meeting and be reviewed by a majority of membership with quorum present.

Subjects may be enrolled in your project from the date of this letter through 9/15/2011. For approval to be extended after that date, a continuing review report must be submitted to the Institutional Review Board meeting prior to the deadline date. A form for continuing review is available on the IRB website (click "For Medical Professionals") at www.orlandohealth.com. If you wish to terminate your project before the expiration date, please notify the IRB office at 321-841-5895.



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