Drug Eluting Stents vs. Bare Metal Stents: An Analysis of Stent Restenosis and Mortality Rates

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Abstract

The purpose of this research project is to find clarity in the recent media publicity surrounding drug eluting stents. As a cardiac cath lab worker, I felt that it was imperative that I research this topic further due to the fact that I work with both bare metal and drug eluting stents on a day to day basis. I believe that knowing the findings of this study will make me better at my job and help me to feel more comfortable with my patients.

Researching the topic of drug eluting versus bare metal stents is something that I felt would be easy due to the recent media attention. There were, in fact, many articles online and in journals about this topic, however, it was hard to find unbiased information online. I did however find several unbiased articles and was able to conclude my study in a positive way.

Recent media hype has deemed drug-eluting stents dangerous. To research this topic, several studies were concluded with more than one thousand participants each. The results of these studies varied greatly. Several studies concluded that there was not a greater risk of using a drug eluting stent than using a bare metal stent. Others, however, disagreed. Restenosis rates were studied as well as mortality rates and acute myocardial infarction rates. A key factor that was shown to be a major contributing factor to in drug eluting stent restenosis was the compliance of the patient in using his/her post stent anticoagulant therapy. I will compare these studies, and hopefully shed light on the situation of controversy.

In my research findings, I will differentiate drug eluting stents and bare metal stents, explain restenosis, and hopefully shed some light on the negative attention that has been given to drug eluting stents over the past several months.

INTRODUCTION

A patient having an acute myocardial infarction, more commonly known as a heart attack, has few options where treatment is concerned. A myocardial infarction occurs when a plaque, or blockage, inside the vessel ruptures from the vessel wall and totally blocks blood flow from that artery to the heart muscle. It is imperative that this person receives immediate treatment due to myocardial death, which occurs when the heart muscle, or myocardium, goes without oxygen that is supplied by the blood flow that the cardiac arteries carry. When the patient arrives at the hospital, he/she is taken to the cardiac cath lab where x-ray images are made of the patient's coronary arteries to determine the area of blockage and treatment options. Treatment options for the myocardial infarction depend solely on the amount of artery blockage, the number of arteries with blockages, and the area of the artery that is blocked. There are four main arteries in the heart, the left main coronary artery, the left anterior descending coronary artery, the circumflex artery, and the right coronary artery. These arteries feed separate portions of the heart muscle and according to which of these vessels are blocked the decision is made as to whether stents can be utilized or coronary bypass grafting is required. Coronary artery stenting was the basis of my studies and from this point forward will be the focus.

A stent is a metal cage that pushes plaque to the sides of an artery and opens the vessel for blood flow. Stents can be drug eluting or bare metal. A drug eluting stent is one that contains a time-release drug, which is slowly released to keep the stent from restenosing, or clogging. A bare metal stent is just as it sounds a stent with no drug on it. Both stents serve a very critical purpose in the treatment of coronary artery disease.

REVIEW OF LITERATURE

Over the past several months, many reports of restenosed drug eluting stents have emerged into the media. For this reason, studies have been performed to give insight on the potential problem.

NORDMANN STUDY

Alain Joel Nordmann, Matthias Briel, and Heiner Claudins

Bucher conducted one such study. This study was done to compare mortality in randomized controlled trials comparing drug eluting versus bare metal stents in coronary artery disease. Seventeen trials including a total of eight thousand two hundred twenty one people were done (Nordmann, 2006). Trial data was reviewed and extracted independently by two investigators in an unblended standardized manner. This trail concluded that there was no difference in or for cardiac mortality among all trials. This trial showed that drug-eluting stents for the treatment of coronary artery disease don not reduce total mortality when compared with bare metal stents. Long term follow up and assessment of cause specific deaths in patients receiving drug-eluting stents is mandatory to determine the long-term safety of these devices (Nordmann, 2006).

BHATT STUDY

Another study that gives insight into the drug eluting stent debate was done by dr. Deepak L. Bhatt, MD, Associate Director of the Cleveland Clinic Cardiovascular Coordinating Center, Cleveland Ohio. This study was the first drug eluting stent meta analysis and studied six thousand six hundred and seventy five total patients. It was a study of randomized clinical trials so it was representative of low or moderate risk patients with low or moderate risk lesions. This meta analysis was prompted by the fact that physicians were concerned that there might be an excess rate of late stent thrombosis with drug eluting stents versus bare metal stents (Bhatt, 2007)). What was found by this study was a small but real excess hazard. This trial concluded that 0.5 percent of patients who received drug eluting stents versus those who received bare metal stents may have suffered a late thrombotic event. This means that one in two hundred patients may have suffered a late restenosis of their drug eluting stent.

THE BASKET-LATE STUDY

The Basel Stent Cost-effectiveness trial-Late Thrombotic Events (BASKET-LATE) study was published in the 2006 Journal of the American College of Cardiology and presented data earlier that year at the American College of Cardiology meeting. It actually showed that with the discontinuation of anti-platelet therapy, that there was a higher rate of death or myocardial infarction in drug eluting stent patients (Bhatt, 2007)). Even a large study does not really address the mechanisms, but BASKET-LATE suggested that perhaps the reason for any sort of excess late thrombotic event is the discontinuation of anti-platelet therapy. A number of analyses, registry analyses and others, have shown that discontinuation of anti-platelet therapy is the most powerful predictor of stent thrombosis (Bhatt, 2007)).

THE WORLD CONGRESS OF CARDIOLOGY STUDY

In 2006, the World Congress of Cardiology presented evidence that patients treated with drug eluting stents may be more prone than bare metal stents to have late problems-namely late, sudden occlusion of the coronary artery (Foforos, 2006). In one study, researchers presented evidence that patients treated with drug eluting stents may have an increased long-term risk of poor outcomes, compared to patients who were treated with bare metal stents. This evidence came from long-term results from the clinical trials that originally gained approval for drug eluting stents (Foforos, 2006).

THE RAVEL TRIAL

In a study called the RAVEL trial, the original trial reporting a remarkable decrease in the rate of restenosis with drug eluting stents, the long-term incidence of death or heart attack was not significantly different between drug eluting stents and bare metal stents. Indeed, there was a non-significant trend toward better outcomes with the bare metal stents (Foforos, 2006).

According to articles posted by Shelley Wood on TheHeart.Org (a website for medical professionals), the presentation of this new evidence at the World Congress led to heated discussion among the cardiologists in attendance. The cardiology community has enthusiastically embraced drug eluting stents over the past five years, and this new evidence that drug eluting stents may not be superior to bare metal stents in producing favorable long-term outcomes - and may even be detrimental in some – strikes at some fundamental beliefs among heart specialists, who now realize that they may have to grapple with complications.

DRUG ELUTING VS. BARE METAL STINTS META ANALYSIS

In a separate meta analysis, the effects of drug eluting and bare metal stents for the treatment of coronary artery disease on overall, cardiac, and non-cardiac mortalities, have been assessed. This analysis concluded, “drug eluting stents for the treatment of coronary artery disease do not reduce total mortality when compared with bare metal stents.”(Yuet, 2006).

APPLEGATE STUDY

RJ Applegate, MT Sacrinity, MA Kutcher, TT Baki, SK Gandhi, RM Santos, and WC Little did another study. In this study, clinical trials of highly selected patients revealed that drug eluting stents decreased restenosis rates but not the rate of acute myocardial infarction or death (Applegate, 2007). Whether drug eluting stent use has an affect on the rate of acute myocardial infarction or death in unselected patients is uncertain. Bare metal stents were placed in one thousand one hundred sixty four consecutive patients in the year before the introduction of drug eluting stents. Drug eluting stents were subsequently placed in one thousand two hundred eighty five consecutive comparable patients at Wake Forest Baptist Medical Center. Propensity score analysis was used to adjust outcomes for baseline differences (Applegate, 2007). Patient and procedural characteristics of the two groups were similar, with an overall incidence of seventy two percent for acute coronary syndromes. At nine months, target vessel revascularization, acute myocardial infarction, and death were lower in the drug eluting stent group versus the bare metal stent group (Applegate, 2007). This single center observational study showed that the use of drug eluting stents in consecutive unselected patients, most of whom would not have been eligible for inclusion in the randomized trials of drug eluting stent versus bare metal stent, were associated with lower acute myocardial infarction rates and death rates than in a comparable group of patients treated with bare metal stents at nine month follow up (Applegate, 2007).

By reviewing the literature and reading the studies, it is still unclear the risks and benefits of drug eluting stents versus bare metal stenting. It seems that with the many negative studies which are published that there are just as many positive studies.

CONCLUSION

After researching the clinical trials which are readily available online and in medial journals, there is still significant concern about the debate regarding drug eluting stents. The data suggest that truly that the brunt of the problem correlates directly with patient compliance. As mentioned in the BASKET-LATE SUDY, anti platelet therapy plays a major role in the restenosis of stents, both drug eluting and bare metal. The significance of this finding, in my opinion, may be more useful to cardiologists, health care workers, and especially patients than any of the other findings mentioned. If resolving the problem lies in the hands of the patients, then the issue could be dramatically reduced by more pronounced patient education. By educating the patient on the risks of discontinuing their antiplatelet therapy, physicians and health care workers could feel less responsible for in stent restenosis. On the other hand, if using a drug eluting stent bares no greater long term health benefit than bare metal stenting, as suggested in some studies, the cost effectiveness of only implanting bare metal stents could be overwhelming. Patients usually spend ten thousand dollars per stent if receiving a drug eluting stent. Compared to the five thousand dollars per stent spent on a bare metal stent, this extra amount of money could really add up across the United States for patients as well as insurance companies and hospitals that often get stuck with the bill for non paying patients. When this is considered, it seems to me that it is almost worth not using drug-eluting stents at all. The topic of drug eluting stents versus bare metal stents is one that will probably continue to attract great amounts of controversy over the coming months and years. I often wonder if this is just another advancement in health care that appeared to be great in the beginning but fell by the wayside as time and clinical trials were utilized. Given the information gathered by these studies, I still feel comfortable implanting drug eluting stents into patients. I do, however, feel just as comfortable implanting bare metal stents. It seems that over the past four years, I have listened to cardiologists “preach” about how much better drug eluting stents are and what a significant difference that they have made in the restenosis rates of patients. By studying these findings, however, I realize that bare metal stents could be just as effective in patient treatment and much more cost effective to patients, insurance companies, and hospitals.

References

r-0. Applegate, RJ (2007). Entrez Pub Med. Retrieved March 1, 2007, from ncbi.nlm.nih.gov Web site: http://www.ncbi.nlm.nih.gov/entrez/query
r-1. Bhatt, D (2007). Cath Lab Digest Online. Retrieved March 12, 2007, from Cathlabdigest.com Web http://www.cathlabdigest.com/article/6700
r-2. Foforos, R (2006). Heart Disease. Retrieved March 12, 2007, from heartdisease.about.com Web site: http://heartdisease.about.com/angiopalstystents/a/DESproblems.htm
r-3. Nordmann, A (2006). oxford journals. Retrieved March 1, 2007, from euroheartj.oxfordjournals.org Web site: http://eurheartj.oxfordjournals.org/cgi/content/abstract/27/23/2784
r-4. Yuet, Wan (2006). Drug-Eluting vs. bare metal stents in coronary artery disease: a meta analysis. European Heart Journal, Retrieved March 9, 2007, from http://www.nelm.nhs.uk

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