

Clinical Evidence of the Efficacy of Balloon Angioplasty with Stenting vs. Angioplasty Alone,  
and Drug-eluting vs. Bare-metal Stenting in the Prevention of Re-stenosis in Patients with  
Coronary Artery Disease

A Research Project by

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of Master of Physician Assistant

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Wichita State University  
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We hereby certify that the research project prepared under our supervision by Andrew Rendoff entitled Clinical Evidence of the Efficacy of Balloon Angioplasty with Stenting vs. Angioplasty Alone, and Drug-eluting vs. Bare-metal Stenting in the Prevention of Re-stenosis in Patients with Coronary Artery Disease will be accepted as partial fulfillment for the degree of Master of Physician Assistant.

Approved:



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## ABSTRACT

Introduction: The risk of developing coronary artery disease for both men and women is increasing in society today. While previous cardiovascular research emphasized only hypertension and hyperlipidemia, the importance of treating the inflammation process is becoming understood. Over the past twenty-five years, the concepts of PTCA and stenting have become dominant modalities in the treatment of CAD. In the late 1970's and early 1980's, PTCA was seen as the best possible alternative to bypass surgery until repetitive treatments were required to reopen occluded arteries. Following the failure of PTCA, stenting and derivatives of stenting with drug-eluting compounds have been developed to examine the most effective revascularization technique to reduce the rate at which re-stenosis occurs. Methodology: The purpose of this study was to perform a systematic examination of the literature to evaluate these techniques. Articles included in the review involved randomized controlled clinical trials of adults from 50-75 years of age who had undergone either angioplasty or stenting from the years 1979 to 2006. Terms the research included were coronary artery disease, balloon angioplasty, stenting, atherosclerosis, drug-eluting stents, and re-stenosis. Results: Thirty-seven articles met inclusion criteria and were reviewed for accuracy and applicability. Following an analysis of the articles, the overwhelming consensus was that the use of balloon angioplasty with stenting is more effective than angioplasty alone, and insufficient evidence is available to determine whether drug-eluting stenting is more effective than bare-metal stenting in the prevention of re-stenosis in patients with CAD. Conclusion: The most effective treatment for patients with CAD is balloon angioplasty with stenting with insufficient evidence as to the type of stent most appropriate due to potential side-effects of both types of stents.

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## INTRODUCTION

The risk of developing coronary artery disease (CAD) and other heart conditions is increasing in society. Recent statistics illustrate that heart disease is considered the leading cause of death in the United States with approximately one death occurring every thirty-three seconds.<sup>1</sup> Current research also indicates that the development of heart disease is increased with factors including: older age, male gender, family history, smoking, hypertension, diabetes mellitus, hyperlipidemia, obesity, and living a sedentary lifestyle.<sup>1</sup> While previous cardiovascular research mostly emphasized the treatment of risk factors such as hypertension and high cholesterol, the importance of inflammation and its resultant damage to endothelial cells leading to CAD is now becoming understood as a major risk factor as well.<sup>2</sup>

As the role of inflammation is researched, its effect upon interventional treatment (angioplasty and/or stenting) of CAD is uncertain. Over the past 20 to 25 years, the revascularization techniques of percutaneous transluminal coronary angioplasty (PTCA) and transluminal stenting have been examined with inconclusive results.

## LITERATURE REVIEW

In the early to mid 1980's, as a result of the need to treat patients with CAD, clinical trials of balloon PTCA were found to be an effective technique for widening and dilating coronary and peripheral arteries.<sup>3</sup> Unfortunately, the results of balloon PTCA upon the prevention of re-stenosis and occlusion of arteries were not sufficient to suggest this technique as the treatment of choice.<sup>3</sup> Following the failure of balloon PTCA to provide a sufficient treatment plan for patients with CAD, transluminal stents were developed and are currently considered a dominant modality in the treatment of CAD.<sup>4</sup> The intervention of coronary artery stenting has been an effective method for reducing the rate at which re-stenosis occurs.<sup>5</sup>

Although research reveals that re-stenosis may be reduced, the repetition of stenting may fail as a viable revascularization technique.<sup>6</sup>

The combination of stenting with advanced coating of stents using anticoagulating substances is currently under review as a treatment for CAD. Preliminary results from studies beginning in 1994 indicate that the use of drug eluting stents over a period of time in arteries with small lesions can “significantly reduce the rate of reblockage that occurs where bare metal stents have been used.”<sup>7</sup> But while drug-eluting stents may be effective in the treatment of coronary vessel lesions, the evaluation of more complex lesions is yet to be determined.<sup>8</sup> Equal consideration of efficacy must also include examination of the incidence of thrombosis and aneurysms, risk factors rarely seen in patients who have received bare-metal stents.<sup>7,8</sup>

A superficial review of the literature suggests that stenting coronary arteries may be more effective than balloon PTCA alone, and drug-eluting stenting may be more effective than bare-metal stenting.

### *Purpose of the Study*

Coronary artery disease has many treatment options with inconclusive ideas as to the most appropriate treatment plan for patients. Therefore, the purpose of this study was to evaluate the reduction in re-stenosis by balloon angioplasty with stenting versus balloon angioplasty alone and secondly, whether drug-eluting stenting is more effective than bare-metal stenting in the prevention of re-stenosis within coronary arteries.

## METHODOLOGY

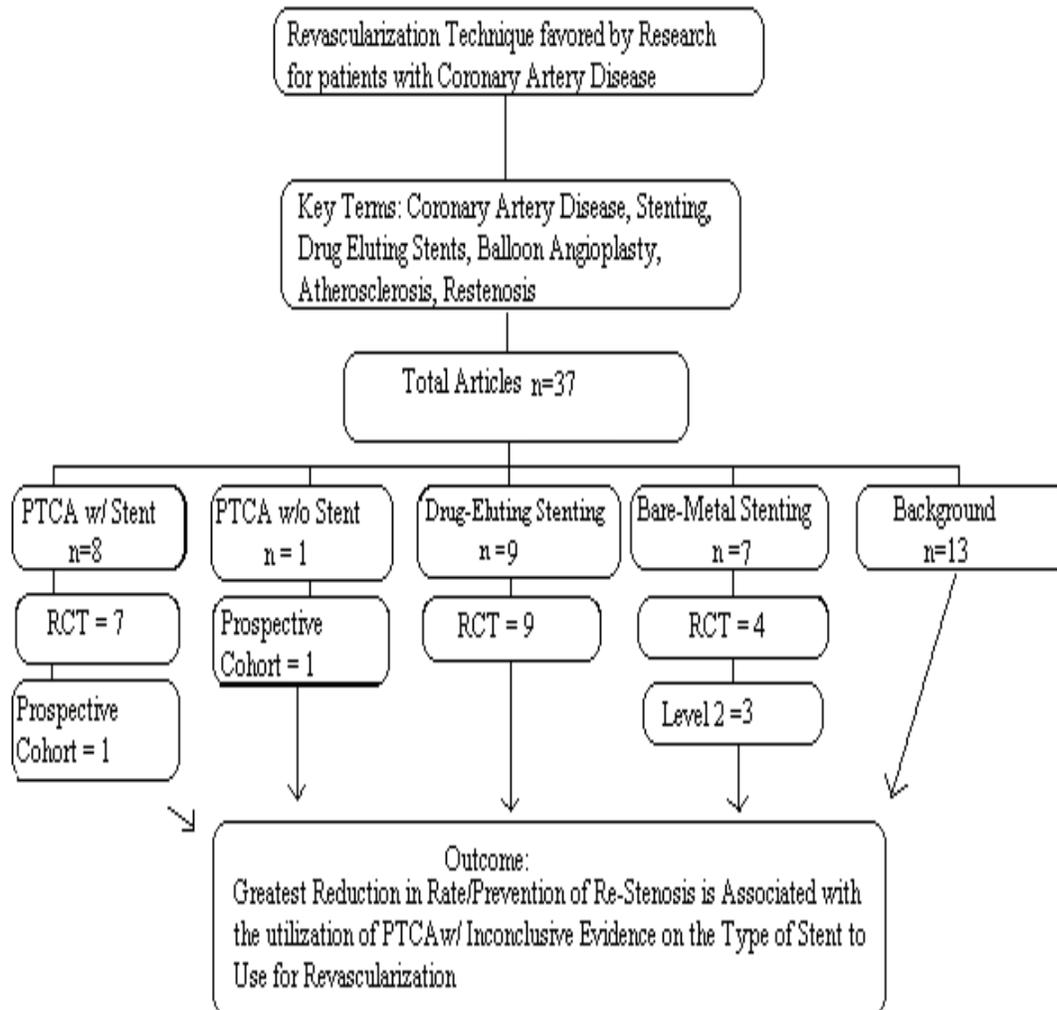
An evidenced based systematic review of the literature was completed pertaining to studies regarding angioplasty and stenting. Articles included in the study pertained to subjects evaluated for angioplasty and stenting ranging from 50 to 75 years of age. Medline was searched

for articles meeting the defined inclusion criteria from 1979 to 2006. Peer reviewed articles were used for background purposes including epidemiology data and information on clinical presentation, along with foreground articles, including systematic reviews of data and randomized control studies. The following key terms were used: coronary artery disease, balloon angioplasty, stenting, atherosclerosis, drug-eluting stents, and re-stenosis. From the selected articles, data was examined, extracted, and compared with one another regarding the selected treatments and their efficacy in treating CAD, including their relationships to bare metal and drug eluting stents.

## RESULTS

From 1979 to 2006, thirty-seven articles met the inclusion criteria as described previously in the methodology. The results can be visualized in Figure 1 and in Appendix A. It should be noted that because some articles addressed different outcomes, there was some overlap in the results section. Thirteen of the articles contained background information regarding PTCA or stenting.<sup>1-3, 9-19</sup> These articles included information regarding stent type and description, balloon angioplasty, coronary artery disease, and atherosclerosis.

Figure 1: Literature Review Flow Sheet



Of the thirty-seven studies that were found in the literature search, nine directly addressed the reduction in the rate and prevention of re-stenosis based upon the usage of PTCA with a combination of stenting. Of these, eight studies supported the efficacy of angioplasty combined with stenting instead of angioplasty alone.<sup>4-6, 20-24</sup> One other study addressed the issue and found no significant reduction in the rate or prevention of re-stenosis over time.<sup>6</sup>

Sixteen studies were found that directly addressed the reduction in rate or prevention of re-stenosis with the use of drug-eluting stents instead of bare-metal stents. Of the sixteen, nine

studies supported the efficacy of drug-eluting stenting instead of the use of bare-metal stenting to treat atherosclerosis.<sup>4, 8, 25-26, 27-31</sup> The other seven studies found no significant difference in the reduction in rate or the prevention of re-stenosis, and often times more side effects, when using drug-eluting stents instead of bare-metal stents for patients with coronary artery disease.<sup>7, 32-37</sup>

## DISCUSSION

### *Evidence in Literature*

The issue of the proper revascularization technique for every patient is an extremely important decision in the management of patients with coronary artery disease. And while many articles have substantiated the efficacy of a specific revascularization technique for every patient population, many others disagree, leaving us with an unclear picture as to the proper technique necessary for all patients. Therefore the purpose of this study was to gather studies and organize them into an effective and interpretable presentation.

After evaluation of the articles in this study an overwhelming consensus exists for the use of PTCA with the combination of stenting as opposed to angioplasty alone in the prevention of re-stenosis in CAD. Secondly, insufficient evidence is currently available to state that the use of a drug-eluting stent is more efficacious than a bare-metal stent in the reduction in rate and prevention of re-stenosis for patients with CAD due to the increased side-effect panel often associated with drug-eluting stents.

In making the determination that PTCA with stenting is a more efficacious revascularization technique than PTCA alone, six key studies helped to evaluate the problem. First, in 1994 Fischman et al published a study of 410 patients with coronary artery disease who had undergone either balloon angioplasty or stenting. The results of this study indicated that the elective use of stenting instead of angioplasty will decrease the need for repeat revascularization

due to lower rates of re-stenosis.<sup>5</sup> These results were also confirmed in 1994 by Serruys et al., 1996 by Macaya et al., and 1998 by Erbel et al. who found that stent implantation is associated with lower rates of re-stenosis.<sup>21-23</sup> Further substantiation of these findings can be found in the systematic review by Suwaidi et al. in 2000, and the meta-analysis by Moreno et al. in 2004.<sup>4,10</sup>

In evaluating the efficacy of drug-eluting and bare-metal stenting in the prevention of restenosis, 12 key studies helped to evaluate this issue. First, in 2002 Morice et al evaluated 238 patients in a randomized double-blind study and determined that the technique of drug-eluting stenting shows a considerable reduction in vessel proliferation and subsequent re-stenosis.<sup>31</sup>

In a study published by Grube et al. in 2004, referred to as the SCORE trial, the randomized treatment of 266 patients with either a drug-eluting or bare-metal stent resulted in the reduction of re-stenosis for those who received the drug-eluting stent.<sup>32</sup> Unfortunately with the benefit of a reduction in re-stenosis, came the major cardiac side effect of stent thrombosis, resulting in the premature discontinuation of the study due to this adverse side-effect.<sup>32</sup> The results of this study made the researchers wonder if the benefit of this technique was worth the risk of future use.

For many cardiologists, the fear of a side effect did not reduce the value of the drug-eluting stent and according to studies in 2004 by Lemos et al., Holmes et al., and Ardissino et al., the benefit of reduced re-stenosis is worth the risk.<sup>25-26, 30</sup> And like the researchers before them, Stone et al in 2005 performed a randomized, double-blind, multi-center trial, and found that 664 patients had significantly reduced angiographic restenosis when compared to patients treated with bare-metal stents.<sup>8</sup>

While the majority of the articles show significant results, the results of the meta-analysis by Roiron et al in 2006 reveals substantial clinical significance. In this review, Roiron and

colleagues evaluated the treatment trials of patients with a Sirolimus, Paclitaxel, or a derivative of the two in comparison with a bare-metal stent.<sup>27</sup> The analysis revealed that drug-eluting stents showed a significant reduction in the need for repeat coronary interventions when compared to bare-metal stents. Additionally in this analysis it was determined that there was essentially no difference in the occurrence of side effects such as stent thrombosis and myocardial infarction between drug-eluting and bare-metal stents.

While prior research had negated the side-effect panel that many researchers were concerned about, five key studies were published in March 2007 with much different results. The first article by Spaulding et al, found that prior research showing efficacy in utilizing drug-eluting stents was incorrect.<sup>33</sup> Additionally, the researchers pointed to the increased association with stent thrombosis when using drug-eluting stents compared to the use of bare-metal stents.<sup>33</sup>

The second key study by Lagerqvist et al, was an evaluation of 13,738 patients in Sweden comparing long-term outcomes of drug-eluting and bare-metal stents.<sup>34</sup> The study found that not only did the incidence of adverse side effects significantly increased (12.7 more per 1000 patients), but the incidence of death was increased by a relative risk of 1.18 in the drug-eluting group versus 1.04 in the bare-metal stent group.

The third and fourth studies by Mauri et al and Stone et al, evaluated the incidence of stent-thrombosis between drug-eluting and bare-metal stents.<sup>35, 37</sup> Mauri's study was composed of 4,545 patients in randomized clinical trials which illustrated no significant difference in the adverse side effects. Stone's study, composed of 5,261 patients, additionally found no statistically significant difference in the risk profile of drug-eluting stents versus bare-metal stents. But instead, Stone noted that while statistical significance could not be compiled, it should be noted that more stent thrombosis occurred with drug-eluting stents versus bare-metal

(14:2). While no significance was found, researchers pointed to the fact that no distinct advantage was present for using the more expensive drug-eluting stent over the bare-metal stent.

The fifth study by Kastrati et al, evaluated 14 clinical trials of sirolimus-eluting stents and bare-metal stents.<sup>36</sup> Four-thousand nine-hundred fifty-eight patients took part in a randomized clinical trials and illustrated that the risk of “stent thrombosis is at least as great as that seen with bare-metal stents.” Like the studies published in March 2007, this article illustrates that there is still insufficient evidence to either condone or negate the use of bare-metal or drug-eluting stents at this time.

Of even more significance than prior studies, an article published by Boden et al in March 2007 provides further evaluation into the management of cardiac patients in general. Boden and his colleagues evaluated the medical management of patients utilizing medicinal therapy versus coronary intervention (i.e. angioplasty or stenting).<sup>19</sup> Two-thousand two-hundred eighty-seven patients with coronary artery disease at fifty clinical research sites, were evaluated to determine if stenting/angioplasty would have a resultant effect upon the outcome and risk of myocardial infarction and death. Boden found that the use of stenting/angioplasty in patients with stable angina had no significant change in their outcome than management of their angina with medicine alone.<sup>19</sup> While the study is fairly small and only evaluates patients with stable angina, the significance of this finding forces the healthcare provider to evaluate the cost-effectiveness and general management of their patients with stable angina.

#### *Weaknesses in the Literature*

One major area of weakness found in the literature is the inability of the researchers to select participants who were all at the same clinical position when they started the study. For example, while one participant may have had a 45% occluded artery, another participant could

have had a 32% occlusion. While it may be questioned as to the merit of this discussion, the participants may still be experiencing clinical symptoms at these different levels of occlusion. The question remains how consistently a person with a 35% occlusion will come through the treatment with stenting versus a person with a 45% occlusion, for example.

A second area of weakness found in the literature is the limited amount of articles focusing on the subject of stenting/alone versus medical therapy alone. The study by Boden et al provides a small glimpse into the management of patients with angina and forces the healthcare provider to question their management plan in patients with stable angina. Perhaps further research would allow for a better evaluation and treatment plan for all patients with angina.

#### *Gaps in the Literature*

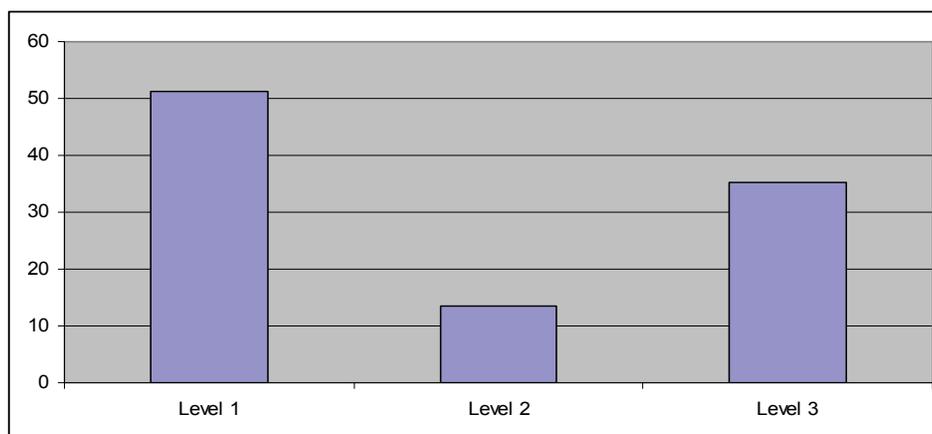
An area that is not addressed sufficiently throughout the literature and could be addressed by future research is the issue of which type of drug-eluting stent is best. Throughout the literature, the common major cardiac side effects of the stents are discussed, but never is the drug-eluting stent of choice ever mentioned.

A second area that is not addressed sufficiently in the literature and deserves further examination is the treatment of choice for patients who fail these methods of revascularization. For patients who fail angioplasty, the treatment of choice is a stent, but as some research points out, the failure of stenting to reproduce successful results in repetitive situations is a major concern. The failure of stenting in a repetitive setting would most likely result in an invasive surgery (i.e. Coronary Artery Bypass Graft) with a much longer recovery and more substantial cost.

### *Validity of the Review*

The process of selecting articles was performed in a systematic manner with emphasis placed upon the usage of Medline searching for the keywords which were mentioned previously. After all articles had been collected, the strict inclusion criteria as set forth by the methodology, was utilized to verify that all studies met the standard requirements for inclusion. Following this evaluation, all articles were examined and evaluated by the research advisor to ensure accuracy, and then placed for viewing in Figure 1. Upon evaluation for accuracy, the articles were then divided into the evidence levels of one, two, and three and the percentage of each type of evidence can be seen in Figure 2.

Figure 2: Levels of Evidence by Percentage



The breakdown in Figure 2 illustrates that 51.4% of the articles were level one, 13.5% were level two, and 35.1% were level three. Based upon this information, the overall grade of evidence that can be applied to this review is B.<sup>18</sup> In addition to the thirty-seven articles included in the study, there were nine articles which did not meet inclusion criteria and therefore were excluded from the study. A complete listing of these articles can be seen in Appendix B.

### *Weaknesses in the Review*

Upon completion of the review of literature, the importance of evaluating the weaknesses is necessitated. In retrospect, the validity of the review could have been improved in a number of ways. First, the review could have been improved by blinding the names and authors of the journals in order to avoid the potential for bias that too often is present in reviews. In addition, the strength of the review could have been improved upon by including more databases than Medline to broaden the spectrum of articles that could be attained. Third, the review could have been improved upon by attending to issues of internal validity of the included articles. By paying attention to the methodologies of the articles, the reviewer would have eliminated the risk of accepting the interpretation of the author without just cause.

A final area of weakness in the review was the broad range of stent types used in all the studies. The review could be improved upon by including in the inclusion criteria all articles that used a specific type of stent instead of a wide range of stents. By narrowing the criteria to only one type and showing the efficacy of that type in clinical trials, the decision for a medical professional to make the proper choice for their patient would be made much easier.

### *Conclusion*

As a health care provider in society today, the ability to make the best possible decisions for patients is highly dependent upon the understanding of new technologies. As medicine is a practice, and not always pure science, taking the time to evaluate the literature and new techniques on the market is extremely important. For patients with coronary artery disease, the importance for cardiologists and their physician assistants to know the best techniques from the literature is of utmost significance. As was illustrated in this review, the most effective treatment for patients with coronary artery disease is percutaneous transluminal coronary angioplasty with

insufficient evidence to decide which type of stenting of atherosclerotic lesions is most efficacious.

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APPENDIX A  
Raw Data

Study Year	Research Addresses 1.PTCA v s stenting 2.DE vs. bare-metal stents 3.background	Level of Evidence 1.random control 2.cohort/ level-2-reviews 3.background	Demographics Main data	Findings	Research Supports Use of 1. PTCA w/ stenting 2. PTCA w/o stenting 3. Drug-eluting Stenting 4. Bare-metal Stenting 5. Background
<b>1. Centers for Disease Control</b> 2005	3	3	n/a	*background: intro, risk factors, epidemiology	5
<b>2. Hansson</b> 2005	3	3	n/a	*risks for CAD & inflammation	5
<b>3. Sigwart et al</b> 1987	3	3	*19 patients with coronary stenosis	*PTCA with stenting a more viable technique than PTCA alone	5
<b>4. Moreno et al</b> 2004	1	1	*meta-analysis of 11 randomized trials	*Stenting significantly reduces need for further revascularization *DE stenting dramatically reduces restenosis rate	1 & 3
<b>5. Fischman et al</b> 1994	1	1	*410 patients with symptomatic CAD	*stenting has higher success rate than PTCA alone	1
<b>6. Mehran et al</b> 2001	1	2	*401 patients with focal in-stent restenosis	*repetitive stenting may fail as a viable revascularization technique	1 & 2
<b>7. Saljoughian</b> 2004	2	2	n/a	*DE stents reduce rate of restenosis compared to bare-metal stents *risk of thrombotic events high with DE stents	4
<b>8. Stone et al</b> 2005	2	1	*1156 patients with single coronary artery stenosis	*DE stents reduced the 9 month revascularization from 15.7 to 8.6% when compared to bare metal stents *long-term success undetermined	3
<b>9. Bittl</b> 1996	3	3	n/a	*stenting reduces restenosis in patients previously treated with PTCA alone	5
<b>10. Suwaidi et al</b> 2000	3	3	*meta-analysis of 12 RCT's	*stenting more effective than PTCA alone	5
<b>11. Kastrati et al</b> 2000	3	3	n/a	*Review of clinical trials to evaluate angiographic restenosis at one year post revascularization	5
<b>12. Faxon et al</b> 1990	3	3	*meta-analysis of RCT's	*PTCA of single lesion versus multi-lesions: long-term outcomes better for single lesions, requiring	5

				fewer revascularization attempts	
<b>13. Peck</b> 2005	3	3	n/a	*current recommendations suggest use of DE instead of bare-metal stents	5
<b>14. Gershlick and Baron</b> 1998	3	3	n/a	*Due to restenosis rate of 15% and failure of redilatation, further research is required for cost-effective stenting	5
<b>15. Peck</b> 2006	3	3	n/a	*No statistical significance between DE & BM stents in adverse side effects at one year	5
<b>16. Chieffo et al</b> 2006	3	2	n/a	*No degree of protection against death between DES and CABG	5
<b>17. Peck</b> 2006	3	3	n/a	*Cypher DES increases rate of MI and death	5
<b>18. Sackett et al</b> 2000	3	3	n/a	*EBM review	5
<b>19. Boden et al</b> 2007	3	3	n/a	*PCI vs. Medication for Stable CAD	5
<b>20. Hong et al</b> 1997	1	1	*97 acute MI patients	*total occlusion at follow-up reduced from 26% with PTCA alone to 0% with stenting	1
<b>21. Macaya et al</b> 1996	1	1	*515 patients at one year follow-up of Benestent Trial	*One-year outcome shows stenting decreases need for revascularizations	1
<b>22. Erbel et al</b> 1998	1	1	*RCT of 383 patients undergoing PTCA w/ stenting	*Revascularization at 6 months = 27% w/ angioplasty alone versus 10% with stenting	1
<b>23. Serruys et al</b> 1994	1	1	*RCT of 520 patients with CAD	*Stent implantation associated with lower rates of restenosis	1
<b>24. Savage et al</b> 1998	1	1	*RCT of 331 patients with coronary stenosis	*Stenting provides greater outcomes than angioplasty alone	1
<b>25. Ong et al</b> 2005	2	1	*inception cohort of 369 patients	*DE stents efficacious in decreasing the need for revascularization	3
<b>26. Ardissino et al</b> 2004	2	1	*257 ischemic heart disease patients	*Sirolimus-eluting stents reduce the rate of restenosis in comparison with uncoated stents (53% : 9%)	3
<b>27. Roiron et al</b> 2006	2	1	*meta-analysis of RCT's	*DES decrease risk of MACE from 19.9% to 10.1% and restenosis from 31.7% to 10.5%	3
<b>28. Van Hout et al</b> 2004	2	1	*Double blind RCT of 238 patients with stable or unstable angina	*DES decrease need for revascularization, but no substantial decrease in cardiac deaths *Further examination of complex lesions still	3

				needed	
<b>29. Morice et al</b> 2006	2	1	*RCT of 1386 patients with angina pectoris and lesions in native coronary arteries	*DES show considerable decrease in angiographic restenosis compared to bare-metal stents *Still no standard for which DES to use	3
<b>30. Holmes et al</b> 2004	2	1	*RCT of 1058 patients with coronary stenosis	*70-80% relative reduction in restenosis compared to bare-metal stenting	3
<b>31. Morice et al</b> 2002	2	1	*Randomized double-blind trial of 238 patients at 19 medical centers	*DES shows considerable decrease in neointimal proliferation and restenosis	3
<b>32. Grube et al</b> 2004	2	1	*RCT of 266 patients *--stopped prematurely due to safety concerns	*DE stents present outstanding anti-restenotic benefit But *DE stents present an unacceptable safety profile	4
<b>33. Spaulding et al</b> 2007	2	1	*Analysis of 1748 patients requiring revascularization	*No significant difference in DES vs BMS	4
<b>34. Lagerqvist et al</b> 2007	2	2	*Cohort of 19,771 patients in Sweden	*DE stents associated with increased risk of death by 30%	4
<b>35. Mauri et al</b> 2007	2	2	*Analysis of 4,545 patients requiring revascularization	*No significant difference between DES vs BMS	4
<b>36. Kastrati et al</b> 2007	2	1	*Analysis of 4958 patients in RCTs of DE stenting vs BMS	*Slightly significant risk of stent thrombosis with DE stenting	4
<b>37. Stone et al</b> 2007	2	1	*Analysis of 5261 patients requiring revascularization	*Stent thrombosis increased with DE stenting	4

## DISCARDED ARTICLES

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5. Butany J, Carmichael K, Leong S, Collins M. Coronary artery stents: identification and evaluation. *Journal of Clinical Pathology*. 2005 ; 58: 795-804.
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7. Moscucci M, Mansour K, Kent K, Kuntz R, Senerchia C, Bairn D, Carrozza J. Peripheral Vascular Complications of Directional Coronary Atherectomy and Stenting: Predictors, Management, and Outcome. *The American Journal of Cardiology*. 1994 September; 74: 448-453.
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9. Lally C, Dolan F, Prendergrast P. Cardiovascular stent design and vessel stresses: a finite element analysis. *Journal of Biomechanics*. 2005: 34: 1574-1581.

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