



Short Term Outcome in a Severe Coronary Artery Disease with Different Therapeutic Strategies

Authors

Vidur Karnik¹, N. Pai², M. N. Bhat³, Yogesh Patil⁴, R. L. Kamath⁵, P. Kamath⁶,
Rajesh Bhat⁷

¹Assistant Professor, RCSM GMC Kolhapur, Maharashtra, India

²Associate Professor, KMC & H, Manglore, Karnataka, India

³Associate Professor, KMC & H, Manglore, Karnataka, India

⁴Assistant Professor, RCSM GMC Kolhapur, Maharashtra, India

⁵Professor & HOD, KMC & H, Manglore, Karnataka, India

⁶Additional Professor, KMC & H, Manglore, Karnataka, India

⁷Associate Professor, KMC & H, Manglore, Karnataka, India

*Corresponding Author

Dr N. Pai

KMC & H, Manglore, Karnataka, India

Address- 63- B, Vasantrya Jadhav Park, Ramanand Nagar, Kolhapur, Maharashtra, India Pin- 416007

Tel: 07022129345, Email: narasimhapai@yahoo.com

Abstract

Background: *The specific question of whether PCI or surgical treatment offers any advantage over medical treatment in patients with stable angina and multivessel disease remains unanswered.*

Objective: *To compare the major adverse cardiac event at the end of 1 year within different therapeutic modalities.*

Materials & Method: *Total 98 patients with angiographically documented severe CAD (SYNTAX SCORE >22) by visual assessment and documented ischemia. Patients were then randomized to continue with aggressive medical therapy alone or to undergo PCI or CABG concurrently with medical treatment. Clinical details of the studied cases was noted. Adverse and other clinical events were tracked from patients who were assessed with follow up visits every 3 months until one year.*

Results: *Out of total 98 patients 52.04 % patients suffered from major adverse cardiovascular events. Most common adverse event was non-fatal myocardial infarction (31.63%). proportion of patients with MACE was more among medical group followed by PTCA group and Least in CABG group (p<0.01). Deaths (5.10%) were more commonly observed in medical treatment.*

Conclusion: *Our study shows that there was a significant need for additional revascularization procedures in patients who underwent PCI and MT.*

Keywords: *Coronary artery disease, Percutaneous Coronary intervention (PCI), Coronary artery bypass graft, (CABG), major adverse cardiac event.*

Introduction

Medical therapy for patients with severe CAD has changed considerably in recent years. Current therapeutic strategies, including aggressive modification of risk factors and intermittent use of nitrates, beta-blockers, calcium channel blockers, angiotensin converting enzyme inhibitors, and more recently, 3-hydroxy-3-methylglutaryl-coenzyme A reductase inhibitors, have improved the outcomes of patients with CAD^(1,2). Nonetheless, the rate of major cardiovascular events is considerable in medically treated patients, particularly those with multivessel disease⁽³⁾.

The specific question of whether PCI or surgical treatment offers any advantage over MT in patients with stable angina and multivessel disease remains unanswered. Because PCI is unlikely to be more effective than CABG in reducing mortality or myocardial infarction (MI) in this patient population, its potential benefits are measured more readily in terms of symptomatic and functional outcomes. In this respect, several factors complicate the choices among patients who are appropriate candidates for all three therapies—namely, CABG, MT, or PCI. For example, the incidence of the most common adverse event—restenosis remains high despite the reduction observed after stent placement in PCI patients.^(4,5)

Objective

Objective of this study was to compare the major adverse cardiac event at the end of 1 year within different therapeutic modalities.

Materials and Method

Study place: KMC Hospital, Ambedkar Circle

Study Design: Observational follow up study

Study duration: 2 years (July 2014 to July 2016)

Study Population: after meeting the inclusion & exclusion criteria; patients admitted with acute or chronic coronary syndrome scheduled to undergo coronary angiogram was taken & underwent different treatment strategies.

Sample Size: A total of 98 subjects were followed up. It was calculated online

(<http://hedwig.mgh.harvard.edu>) with minimal detectable hazard ratio as 2, duration of follow up is 1 year, power of the study 90% and level of significance 5%.

The Sample size was verified using following formula

$$N = E (\alpha, \beta, \psi) / PE$$

Where

E = Number of events

α = Level of significance

β = Power of the study

ψ = hazard ratio

Inclusion Criteria

1. Patients with angiographically documented severe CAD (SYNTAX SCORE >22) by visual assessment and documented ischemia. Ischemia will be considered for inclusion either stress testing or electrocardiographic changes or typical stable angina assessment of Canadian cardiovascular society (CCS) class II/III
2. Age- 45-65 years
3. Patients who has been given written informed consent.

Exclusion Criteria

1. Congenital heart disease
2. Valvular heart disease
3. Cardiomyopathies
4. Age < 45 & >65 years

Methodology

Approval from institutional ethics committee was taken. Patients underwent coronary angiogram for evaluation of CAD. Based on coronary interventions patients were subsequently grouped into,

1. Those who underwent angioplasty
2. Those who underwent coronary artery bypass graft
3. Those who were medically managed.

In this study all patients were placed on an optimal regimen consisting of a stepped care approach using nitrates, aspirin, beta blockers, CCBs, ACE inhibitors, or combinations of these drugs, unless contraindicated. Hydroxymethylglutaryl coenzyme A reductase inhibitors, along with a low fat diet on

an individual basis. Patients were then randomized to continue with aggressive medical therapy alone or to undergo PCI or CABG concurrently with medical treatment.

Clinical details of the studied cases was noted. Adverse and other clinical events were tracked from patients who were assessed with follow up visits every 3 months until one year. All patients were also systematically followed up by telephone interviews for 12 months which showed good reliability and validated against face to face interviews or during general clinical follow up. Patients underwent a symptom limited treadmill exercise test, according to a modified Bruce protocol, at baseline and by the end of one year, unless contraindicated. Exercise test result were considered as positive when exertional angina developed or an ST- segment was observed with an abnormal depression (horizontal or down sloping of 1 mm for men 2 mm for women) 0.8 s after the J point. Routine examinations including ECG, 2 d echo and other relevant blood examinations.

Statistical Analysis

A p value <0.05 will be considered statistically significant. Chi square test was used as test of significance. Statistical analysis will be performed using IBM SPSS version 20.0. Results were presented in the form of tables and graphs.

Results

A total 98 patients who had a presumptive diagnosis of CAD and who underwent coronary angiography and labelled severe CAD were added in this analysis. These patients assigned to one of three groups CABG (n= 42;43%), PCI (n=31;32%), or MT (n=25;25%) in which single vessel disease (n=3;3%), double vessel disease (n=27;28%), triple vessel disease (n =68;68%) with SYNTAX score >22.

Table 1: Demographic characteristics of study population (N = 98).

Variable	Number (%)
Males	54 (55.1%)
Females	44 (44.9%)
Total	97 (100)

In this study 45 to 65 year group is included. The mean age of an overall study population was found to be 57.80 ± 4.65. Mean follow up of study was 8.2+_{3.06} months. In table 1 out of total 98 patients 55.1% were males and 44.9 % were females.

Figure 1: Treatment modality profile of the study participants

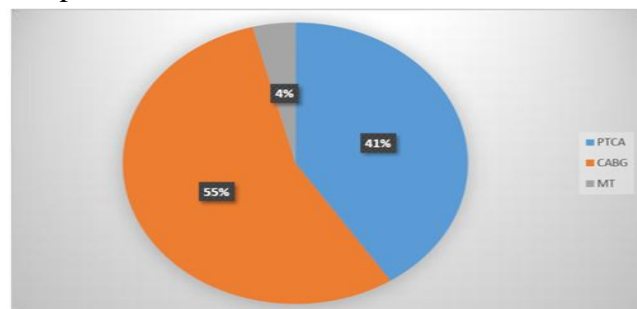


Figure 1 shows that patients were assigned to one of three groups CABG (n= 42;43%), PCI (n=31;32%), or MT (n=25;25%).

Figure 2 Major cardiovascular events at end of one year

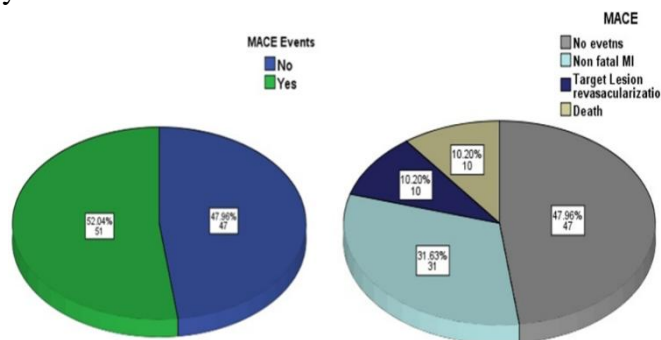


Figure 2 explains major adverse cardiovascular events at end of one year. Out of total 98 patients 52.04 % patients suffered from major adverse cardiovascular events. Most common adverse event was non-fatal myocardial infarction (31.63%). This followed by target lesion revascularization & death (10.20%).

Table 2 Distribution of major adverse cardiac events (MACE) according to treatment intervention

Presence of MACE	Modality of treatment			Total N (%)
	PTCA n (%)	CABG n (%)	Medial n (%)	
Yes	22 (70.96)	8 (18.60)	21 (84)	51 (52.04)
No	9 (29.04)	34 (81.40)	4 (16)	47 (47.96)
Total	31(100)	43 (100)	25 (100)	98 (100)

X²=33, P Value= <0.01

*PTCA- Percutaneous transluminal coronary angioplasty
*CABG- Coronary artery bypass graft

In table 2 proportion of patients with MACE was more among medical group followed by PTCA group and Least in CABG group. This difference in proportion of patients with MACE among various modalities of treatment was statistically significant ($p < 0.01$).

Figure 3 Distribution of major adverse cardiac events according to treatment intervention

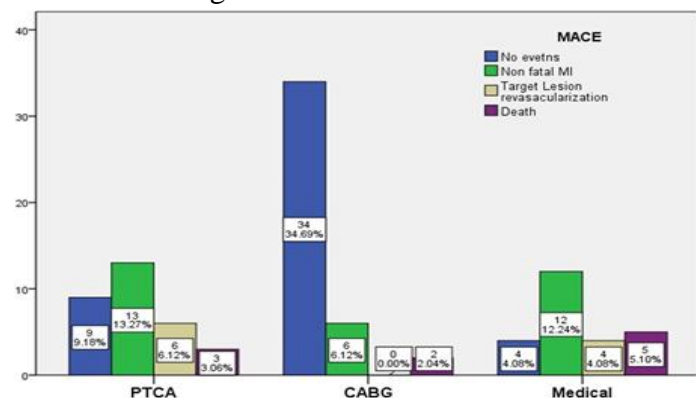


Figure 3 shows that non-fatal myocardial infarctions (13.27%) & target lesion revascularization (6.12%) were more common in percutaneous transluminal coronary angioplasty (PTCA). Deaths (5.10%) were more commonly observed in medical treatment.

Discussion

Most of the meta-analysis of the contemporary era shows that in patients with multivessel CAD, CABG reduces long-term mortality by 27% compared with PCI, regardless of whether the study population is limited to patients with diabetes or not. Regarding major morbidity, a 42% risk reduction in MI was observed in patients randomized to CABG. There was a trend for excess strokes with CABG, probably related to an increase in periprocedural strokes. However, the absolute risk increase in stroke was small compared with the absolute risk reduction in mortality and MI, as demonstrated by the numbers needed to treat.

In our study we found no significant difference between the CABG, PCI, and MT groups with regard to death during one-year follow-up. However, angina requiring new revascularization was higher in the PCI and medical management group compared with CABG group. The CABG-treated patients had better symptomatic relief than patients who underwent the PCI or MT strategy.

Our results are different with the Coronary Artery Surgery Study (CASS) trial, in which no difference was seen between patients in the surgical and medical groups in terms of mortality, Q-wave MI, or event-free survival rates after five years of follow-up. In the CASS trial, a subgroup of patients with preserved ventricular function and mild stable angina was more likely to experience event free survival with MT alone, even in the presence of three-vessel CAD.

After one-year follow-up study in the Asymptomatic Cardiac Ischemia Pilot (ACIP)⁽⁶⁾ trial, better outcomes were observed in patients treated with surgical revascularization, even though this trial had different inclusion criteria, Mortality and morbidity, as well as MI, were less common in patients assigned to the revascularization treatment strategy than in patients in the angina-guided group, but not less common than in patients in the ischemia-guided group.

More recently, in the Arterial Revascularization Therapy Study (ARTS), data were analyzed from one year of follow-up of 1,205 patients who were randomly assigned to undergo stent implantation or CABG⁽⁷⁾. In ARTS, there was no statistically significant difference between the two groups regarding the rates of death, stroke, or MI. However, the stent group was associated with a greater need for repeat revascularization. Similarly, in our study, not a single patient in the CABG group required further revascularization, and 19% (6 pts) of those in the PCI group underwent a second revascularization. The need for repeat revascularization was the greatest difference among our groups. MASS II at 1 year has same results.

In major trials⁽⁸⁻¹³⁾ that enrolled about 4,130 patients with stable multi vessel CAD who were followed up from one to five years, data showed no differences in mortality between patients in the PCI group and those in the CABG group. These trials were similar to our study, except that a third randomized arm—MT alone—was not included as a treatment strategy. In contrast, in the RITA-2 trial⁽¹²⁾, among patients with CAD considered suitable for either PCI or MT, and especially among patients with more severe

angina, early intervention with PCI was associated with greater symptomatic improvement.

Conclusion

This study showed no significant difference in cardiac death in the CABG, PCI or MT group.(0% vs 3% vs 5% respectively.) However, it did show a significant need for additional revascularization procedures in patients who underwent PCI and MT. Our findings of comparable mortality and morbidity for patients who underwent CABG or MT suggests that MT is may reasonable alternative for patients with severe CAD who refuse surgical therapy. But patient must be made aware of the possibility that further revascularization may be required during the follow up period.

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