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Safety and Technical Success of Percutaneous Left Main Coronary Artery Stenting

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Abstract:
Background & Objective: Critical stenosis of left main coronary artery (LMCA) remains a challenge for interventional cardiologists and Coronary artery bypass grafting (CABG) remains first option. Recently, Percutaneous Coronary Intervention (PCI) is also being offered, but data is scarce in this regard. The aim of our study was to determine the safety and technical success rate of percutaneous left main coronary artery stenting.
Design: Quasi experimental study
Place & duration of study: The study was conducted at Cardiology department of Pakistan Institute of Medical Sciences (PIMS), Islamabad from 11th Jan 2011 to 10th Jan 2013.
Subjects & Methods: All symptomatic patients who underwent coronary angiogram at PIMS and were found to have either isolated LMCA disease or coexisting osteal Left Anterior Descending (LAD) artery disease were potentially eligible for the study. After counselling, those who opted for PCI were included in the study. All these patients were treated with percutaneous left main coronary artery stenting with or without osteal LAD stenting.
Results: 72 patients had LMCA disease, 15 opted for CABG, in addition to four who did not met the inclusion criteria. So, 53 patients were finally enrolled with mean age of 55.5$\pm$10.3 years. 29 patients had acute coronary syndrome and 22 presented with unstable angina. PCI with stenting was technically successful in all patients. One patient died 03 months after PCI, and there was no other mortality.
Conclusion: Our study showed that PCI to LMS has good technical success rate; the safety of the procedure is also acceptable.
Key words: Left main coronary artery; Percutaneous Coronary Intervention; coronary artery bypass graft;

Introduction:

Significant left main coronary artery (LMCA) disease has been found in 3% to 5% of all patients who suffer coronary angiography and in 10% to 30% of patients who undergo bypass surgery [1-4]. Critical LMCA stenosis places patients at high risk of cardiovascular events because of the extent of jeopardized myocardium and associated multi-vessel coronary artery disease and, therefore, it has been considered as the prognostically most important coronary lesion. Current practice guidelines suggest coronary artery bypass grafting (CABG) as the standard procedure for patients with unprotected LMCA disease [5-7], primarily because long-term outcomes of surgical revascularization are superior to those of medical treatment [8-10]. However, because of anatomic accessibility and other characteristics, percutaneous coronary intervention (PCI) for LMCA disease was attractive to the interventional cardiologist, and data from several archives showed its feasibility and short and midterm effectiveness. Nevertheless, PCI for LMCA disease has been limited to surgically high-risk patients and those with protected LMCA disease, or has been used as bailout procedures in patients with angioplasty complications.

Nonetheless, current improvements in interventional techniques and adjunctive pharmacology have challenged the orthodox wisdom that significant LMCA stenosis should be cured surgically [11-13]. The introduction of coronary artery stenting has led to a reassessment of the role of PCI as a practical treatment option for LMCA disease [14-17], and the widespread availability of drug-eluting stents (DES), together with enhanced stenting techniques, has lowered the threshold for use of PCI, instead of CABG, in patients with LMCA disease [18]. The clinical experience with PCI for LMCA disease involves a wide spectrum of clinical and angiographic subcategories of such patients. However, there has been little evaluation of the long-term safety and efficiency of PCI with stenting for LMCA disease, and no randomized trial has compared the 2 primary interventions (PCI versus CABG) in a large population [19]. We have therefore reviewed recent advances and the current status of percutaneous versus surgical treatment for LMCA disease, focusing on whether PCI is an alternative to or a possible replacement for CABG in these patients [20]. The rationale of the study was to recognize the success rate of percutaneous left main coronary artery along with determination of safety with 12 months of follow-up.

Subjects and Methods:

This non-randomized, prospective study was carried out from 11th Jan 2011 to 10th Jan 2013 after approval of institution review board/ethical committee at PIMS, Islamabad, Pakistan.

Inclusion criteria

1. Patients with less than 70 years of age
2. History of coronary heart disease or who presented with acute coronary syndrome
3. Angiographic evidenced of either isolated LMCA disease or Osteal LAD disease along with LMCA
4. Patients unwilling for CABG

Exclusion criteria

1. Patients who had previous surgical treatment for coronary artery disease
2. Extreme left-dominant coronary artery perfusion
3. Significant carotid stenosis requiring treatment
4. Renal dysfunction requiring dialysis
5. Severe left ventricular dysfunction

Data Collection Procedure

All patients who have history of coronary artery disease or who presented with acute coronary syndrome and were found to have either isolated LMCA disease or Osteal LAD disease along

with LMCA were potentially eligible for enrolment (Figure 01). Patients were counselled in detail regarding pros and cons of PCI versus CABG. High risk informed consent was taken from those who opted for PCI and were subsequently enrolled in the study. All procedures were performed by a single operator who has extensive experience of interventional cardiology Angiogram was performed in Cardiac Catheterization laboratory at PIMS. All these patients were treated with PCI along with DES. In all patients Xience – V (USA) stents were used. Post stenting, all patients were nursed in Coronary Care unit (CCU) where their hemodynamics along with continuous ECG monitoring was done. All patients were started on dual anti-platelet cover namely Aspirin and Clopidogrel. Those patients who had history of acute coronary syndrome were also treated with the anti-platelet agent tirofibane (Aggrastat). If patients remained stable for 24 hours they were moved to cardiology ward and discharged later on. All patients were followed up in cardiology outpatient department fortnightly for the first 2 months and then monthly for the next 12 months.

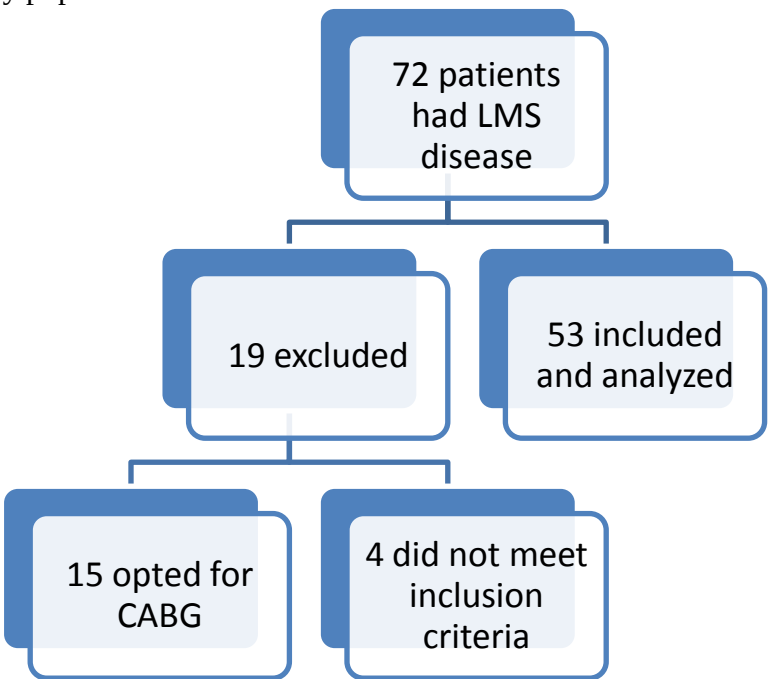
STATISTICAL ANALYSIS:

Data was recorded on predesigned proforma and analyzed on SPSS version 17.0. Mean and standard deviation was calculated for quantitative variables whereas frequency and percentages were calculated for qualitative variables.

Results:

72 patients initially screened to be included in the study that had LMS disease during coronary angiogram. 15 patients opted for CABG, whereas another 04 patients did not meet the inclusion/exclusion criteria. So, 53 patients were finally enrolled in the study (Graph 1).

Graph 01: Study population flow chart



Patient's ages ranged from 35 – 86 years with mean of 55.5+10.3 years. Male patients were 39 (76.5%) and female patients were 12 (23.5%). 29 (52.8%) patients presented with acute coronary syndrome and 22 (41.5%) patients were presented with unstable angina (Table 1).

Table 1: Demographics of the study subjects

Age mean ± Sd (Years)	**55.45±10.275**
Male/Female	**40/13**
Acute coronary syndrome	**29(52.8%)**
Unstable Angina	**22(41.5%)**
Stable angina	**2(3.7%)**

On coronary angiograms 45 patients had LMCA stenosis along with Osteal LAD stenosis while the rest had isolated LMCA disease. 05 patients developed Ventricular Tachycardia during PCI that was successfully reverted by Cardioversion. PCI with stenting was technically successful in all patients. On follow up at 1 month, none of the patients had any symptoms of coronary artery disease. Their ECG did not show any new change. One of our patients died during follow up. He presented after 03 months of PCI, to the emergency department of PIMS with acute chest pain and his ECG showed ST elevation. In spite of appropriate measure, patient died soon thereafter. There was no other mortality at 12 months (Table 2)

Table 2: Procedure findings in study population

VARIABLES	**N (%)**
Isolated LMCA disease	8 (15%)
Osteal LAD involvement	45 (84%)
Ventricular Tachycardia during procedure	05 (9.4%)
Death	01 (1.8%)
Technical success	53 (100%)

Discussion:

Significant LMCA disease is a high-risk lesion that compromises blood flow to approximately 75% of the heart. Its prevalence in patients undergoing coronary angiography is estimated to be 2.5% to 10%, and typically it coexists with other significant narrowing of the coronary tree. Medical treatment of LM disease has unacceptably high mortality rates [7,21]. Early observational studies demonstrated that long-term prognoses of patients with medically treated LMCA disease were poor, with 3-year survival rates of 50% [11]. Traditionally the main mode of treatment for LMCA has been CABG with PCI being reserved only for surgically poor candidates. But with the advent of improvement in techniques and drug eluting metallic stents the interested in treating LMS stenosis with PCI has emerged.

In our study, the patients affected with LMCA which were later treated with PCI have mean ages of 55.5±10.3, where as in other studies majority of patients presented at an advanced age [22]. This highlights the fact that Coronary artery disease presents more early in this part of the world. In our study the frequency and percentage of patients suffered from unstable angina were 22 (43.1%) with all normal base line investigations. Similarly, the percentage of unstable angina was 46% in the study conducted by Lee et al [22].

In our study, there was no early death and we had only one late mortality at 03 months after PCI, which is in fact a very good result, keeping in mind the risks involved with PCI for LMCA disease. One of the reasons may be that we selected patients who underwent either stenting of isolated LMCA or the stents extend to adjacent associated LAD (single vessel stenting) as opposed to some of the prior studies in which both the adjacent LAD and Left circumflex are stented along with LMCA (Bifurcation stenting). This has also clearly been shown that bifurcation stenting as opposed to single vessel stenting has been associated with more adverse cardiac events, and increased incidence of in-stent thrombosis and Myocardial Infarction [23].

An interesting finding in our study was that a considerable number of patients presented with acute coronary syndrome with leakage of cardiac enzymes, whereas most of the other studies in the West have included cohort in which non-emergent PCI was done [23]. Nevertheless, the ejection fraction of our patients was well preserved. And this may be one of the reasons for low incidence of adverse cardiovascular events in our study population. Other studies also reported a very low incidence of adverse effects post PCI [24].

The limitation of this study is that we do not have a long term follow up beyond 12 months to document long term safety. More large multicenter trials with long term follow up needs to be done from this region in order to assess the long term safety and the need to revascularize these patients. Secondly this was not a randomized controlled trial to compare the two techniques namely PCI versus CABG. Nevertheless this is one of the initial studies of its kind from this region clearly showing good technical success as well as short term safety of PCI in LMCA.

Conclusion:

Our study showed that PCI to LMCA has good technical success rate and the short term safety of the procedure is also acceptable. The result suggests potential need for a large, multicenter, randomized study with long-term follow up to provide a basis for re-evaluation of treatment guidelines for the treatment of left main coronary artery disease.

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