Stenting of Unprotected Left Main Coronary Artery Stenoses: Immediate and six months Outcomes

وضع دعامة لتضيق الشريان التاجي الرئيسي الأيسر : النتائج الفورية وبعد ستة أشهر

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الخلاصة:

الخلفية : تعتبر إعادة الوعائية بواسطة زراعة الشرايين القاعدة الذهبية لعلاج تضيق الشريان التاجي الرئيسي الأيسر. إن تحسن وتطور التداخل القسطاري باستعمال الدعامات يستدعي إعادة تقييم هذه الطريقة في العلاج

الهدف: لتقييم النتائج الفورية وبعد مضي ستة أشهر لوضع دعامة لتضيق الشريان التاجي الرئيسي الأيسر غير المحمي

المنهجية: دراسة مستقبلية في مركز ثلاثي للتداخل القسطاري وجراحة القلب حيث تم علاج ٦٤ مريضاً يعانون من تضيق الشريان التاجي الرئيسي الأيسر غير المحمي بواسطة الدعامات المعدنية المجردة، وتم إجراء المتابعة بواسطة التصوير الوعائي (قسطرة الشرايين التاجية) بعد مضي ٣ و ٦ أشهر من إجراء التداخل.

النتائج: كانت نسبة نجاح إجراء التداخل ١٠٠% مع عدم حدوث حالات تخثر داخل الدعامة الحاد و شبه الحاد. وظهر ان نسبة رجوع التضيق داخل الدعامة ١٥.٦% و ١٥.٩% في غضون الثلاثة والستة أشهر الأولى على التوالي ولم تحصل حالات وفاة خلال هذه المدة.

الاستنتاج: ان وضع دعامة لتضيق الشريان التاجي الرئيسي الأيسر يستحق أن يعتبر بديلاً أميناً وفعالاً لزراعة الشرايين لدى بعض المرضى الذين يتم اختيارهم بعناية.

التوصيات: سلسله اكبر من الدراسات يجب ان توضح فيما اذا كان وضع دعامه لتضيق الشريان التاجي الرئيسي الايسر له نفس النتائج الإيجابية لزراعة الشرايين التاجية.

ABSTRACT :

Background: Revascularization with coronary bypass grafting (CABG) has been the gold standard therapy for left main coronary artery (LMCA) stenosis. Improvements in angioplasty and coronary stent techniques and equipment warrant a reappraisal of angioplasty in LMCA stenosis.

Objectives: To assess in-hospital and six-month clinical outcomes after stenting of unprotected left main coronary artery (LMCA) stenosis.

Methods: Prospective study in a tertiary center of interventional cardiology and cardiac surgery *for* 64 patients with unprotected LMCA stenoses who were treated with bare-metal stents and underwent angiographic follow-up at 3 and months following the intervention.

Results: The procedural success rate was 100% with no episodes of acute or subacute stent thrombosis. in-stent restenosis rate was 15.6% and 15.9% in the first 3 and 6 months respectively. Six month mortality was nil.

Conclusion: Stenting of unprotected LMCA stenosis deserves to be considered a safe and effective alternative to CABG in carefully selected patients

Recommendation: Larger series should clarify whether unprotected LMCA stenting has the same favourable results as CABG .

Key word: left main coronary artery stenting

INTRODUCTION

Since the veterans administration cooperative study,[1] the treatment of choice recommended for patients with left main coronary artery (LMCA) stenosis is coronary artery bypass surgery (CABG)[2]. The initial experiences of balloon angioplasty for unprotected LM stenosis were disappointing, but the use of stents has ushered in a renewed interest in the practice of percutaneous coronary interventions (PCI) in selected patients[3]. However, in the revised ACC/AHA Guidelines recommendations; patients with significant LM coronary artery disease (CAD) who are candidate for CABG were recommended in class IIIB[4]. The new European Society of Cardiology ESC guidelines on PCI, indicate that surgery should remain the preferred approach, because the prognostic benefit of surgery has been demonstrated[5]. PCI for patients with angina and LM stenosis is in class IIbC recommendations[6]. The objective of the current study was to determine whether stenting of unprotected LMCA stenoses in selected patients with normal left ventricular (LV) function is safe, and thus may provide an alternative treatment to CABG.

METHODS

From June 2003 to February 2005, 64 consecutive patients with greater than 50% stenosis of unprotected LMCA stenosis who declined CABG were treated with stent implantation at Iraqi Center for Cardiac Diseases in Baghdad. The inclusion criteria were 1) Clinical symptoms or subjective evidence of myocardial ischemia; and2) angiographic evidence of $\geq$50% diameter stenosis of the LMCA. The criteria for exclusion were 1) Contraindication to aspirin or platelet adenosine diphosphate (ADP) receptor antagonist;2) Reduced left ventricualr function LVEF<40%; 3) Heavily calcified lesion;4) *Bifurcating* or trifurcating lesions;and 5) Short LMS (<8 mm) with normal ostial LAD and LCx.

Stent implantation was performed electively in 63 patients and in bailout situation in one patient only. Various types of bare metal stents were used . Stent implantation was done either directly with or without extradilation by balloon (for <30sec) or in patients with severe stenosis >80%, brief predilation (for 10-15 sec) with slightly undersized balloon was done before stent deployment. All patients, besides the meticulous clinical follow up, they regularly underwent angiographic follow up at 3 and 6 months following the procedure. Procedural success was defined as $\leq$0% residual diameter stenosis, without major procedural or in-hospital complications such as death, Q-wave MI, or emergent bypass surgery. A major adverse cardiac event (MACE) was defined as the occurrence of cardiac death, non-fatal myocardial infarction (MI) and target lesion revascularization (TLR) during the follow up period. Angiographic restenosis was defined as a diameter stenosis $\geq$50% at follow up.

Statistical analysis:

Data were expressed as mean ± standard deviation paired, t-test, independent t-test and chi-square test were used to analyze the results. Statistical significance was defined as $p \leq 0.05$

RESULTS

In-hospital outcome. Baseline clinical characteristics of the 64 patients are summarized in Table1. Mean age was 54.4+_ 11.3 9 years and 82.8% of patients presented with unstable angina. (table 1)

Table 1. Baseline clinical characteristics

Characteristics	N=64	(%)
Age (yrs)	53.4±11.3	(71.8)
Male gender	46	
Risk factors:		
Hypertçnsion	25	(39)
Diabetes mellitus	23	(35.9)
Smoking	24	(37.5)
Hypercholesterolemia	16	(25)
Presentation:		
Unstable angina	54	(84.3)
Stable angina	9	(14)
Acute MI	1	(1.5)
Canadian class III	64	(100)
Previous MI	46	(71.8)
LVEF (%)	61.8±6.8	

The site of the LMCA lesion was the ostium in 57.8%, the mid portion of the artery in 62% and the distal portion in 36% .

The characteristics of stents utilized in the procedure are shown in (table 3). Various types of bare metal stents were used:. Direct stenting was done in 78% of cases while predilation and stenting was performed in 22% of cases.

Table2. Stents characteristics

Characteristics	N=64
Size (mm)	4.0±2.9

Length (mm)	12.3±4.2
Maximal inflation pressure (mm)	16.6±3.9 (range 12-20)
Direct stenting	50 (78%)
Predilation plus stenting	14 (22%)
postdilation	30 (46.8%)

Stent placement was checked by angiography without intravascular ultrasound (IVUS) in 40 patients (62.5%) while IVUS was used in 24 patients (37.5%).

Immediate results:The results of quantitative angiographic analysis are displayed in (table 3). The mean reference vessel diameter was 4.1±0.5mn. The diameter stenosis (DS) decreased from 70.7% before the intervention to <0% after the intervention. The minimal lumen diameter (MLD) increased from 1.1±0.4 before the intervention to 4.2±0.4 after the intervention.

Table 3. Results of quantitative angiographic analysis.

Parameters	Results	p-value
Reference vessel diameter (mm)	4.1±0.5	
Diameter stenosis (%) Baseline Final	 70.7±8.7 -4±4	< 0.05
Minimal lumen diameter (mm) Baseline Final	 1.1±0.4 4.2±0.4	< 0.05

In-hospital outcome: The procedural success rate was 100%, there was no death, acute MI, emergency CABG or subacute stent thrombosis during hospital stay.

One-month follow up: No major cardiac events were recorded within the first month after the intervention.

Three to six-month follow-up data: After the first 3 months after the intervention, only 10 patients (15.6%) had instent restenosis (ISR), 5 of them underwent repeat PCI and the other 5 patients were sent for surgery. The patency rate was 84.4%. The fourty-four patients who had follow-up angiography after 6 months, 37 of them (84.1%) were found to have patent stents, whereas only 7 patients (15.9%) had TSR, two of them underwent repeat PCI and five were sent for surgery (table 4).

Table 4. Late outcome.

Duration	No. of patients	Patent stent	ISR	PCI	CABG
3 months	64	54 (84.4%)	10 (15.6%)	5 (50%)	5 (50%)
6months	44	37 (84.1%)	7 (15.9%)	2 (28.6%)	5 (71.4%)

p-value > 0.05

No death, acute MI, stent thrombosis occurred in those patients who were followed-up for 3 to 6 months. The clinical manifestation was angina in all patients with restenosis.

Correlates of target lesion revascularization (TLR): No factors significantly predictive of restenosis were identified (table 5).

Table 5. Factors predictive of TLR within 6 months

Factor	No. of patients	TLR N47	No TLR N=47	P-value
		53.0±12	53.4±11	NS
Male gender	46	15 (32.6%)	31 (67.4%)	NS
Diabetes	23	7 (30.4%)	16 (69.6%)	NS
Final minimal lumen diameter (mm)		4.1±0.7	4.3±0.7	NS
Reference vessel size (mm)		4.0±0.5	4.1±0.5	NS
Lesion site Ostial Distal Mid	 37 23 4	 8 (2 1.6%) 9 (39%) 0	 29(78.4%) 14 (61%) 4(100%)	NS

NS → not significant

DISCUSSION

Many recent studies of LMCA stenting in patients with low risk group presented excellent results.[7] In this study, direct stenting without predilation used more frequently (i.e. 78.1%) to avoid arterial trauma outside the stented segment and also to avoid additional period of ischemia[8]. The use of high pressure stent deployment and extradilating balloon guided by IVUS help to minimize the risk of subacute stent thrombosis after stent deployment[9],

The procedure was successful in all patients and there were no intraprocedural or immediate post-procedural complications, nor acute or subacute stent thrombosis. These results were comparable with other studies((Silverstri et al.[10], and Black et al.[11]). Stent thrombosis is a real danger and the major limitation of LMCA stenting as it can be responsible for fatal myocardial infarction[10,12]. The large size of LMCA, optimal deployment of stent, perfect compliance of antiplatelet therapy and early detection of patients at high risk of thrombosis (inflammatory syndrome ... etc.), ensure the lowest possible thrombosis rate[10]**.** No intra-aortic balloon pump (IABP) was used during the procedure, this is because stenting reduces the need for haernodynamic assistance, and the rapid stent delivery ensures an optimal result without prolonged ischemia.[10]

Coronary angiography was performed after 3 and 6 months because it has been found that the majority of the reported events are occurring during the first 6 months after the index procedure[12].

In this study, in-stent restenosis rate was 15.6% and 15.9% in the first 3 and 6 months respectively after the intervention. This result was comparable with the published results that found the restenosis rate was between 9.5 and 34% [13]. This difference in results was due to heterogeneous group of patients (i.e. different patient subsets) and also due to different lesion characteristics [12] . The advent of drug-eluting stent (DES) technology has the potential promise of significantly reducing in-stent restenosis[14].

In this study, no factor significantly predictive of TLR was identified in particular diabetes mellitus, final minimal lumen diameter and distal lesion site, had no influence on the restenosis rate. Silvestri et al reported no relation between distal location of the lesion and restenosis[10]. On the contrary, Delezo et al reported that the predictors of restenosis at a mean of 9 months were small reference MLD (mean <3.6mm), lesion location at the LM bifurcation and the use of long stents for longer lesions[15].

CONCLUSION

Stenting of unprotected LMCA stenoses deserves to be considered a safe and effective alternative to CABG in carefully selected patients.

RECOMMENDATION

Larger series should clarify whether unprotected LMCA stenting has the same favourable results as CABG.

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