ORIGINAL ARTICLE

DIRECT STENTING VERSUS BALLOON PRE-DILATATION IN ELECTIVE PERCUTANEOUS CORONARY INTERVENTION

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Background: Stents are now deployed in almost 95% of all percutaneous coronary interventions (PCIs). Recent advances in balloon and stent technology has improved the technique of direct stent (DS) strategy, i.e., stent delivery without pre-dilatation instead of conventional stenting (CS), i.e., stent implantation after balloon pre-dilatation with multiple advantages. **Methods:** This randomized controlled trial was conducted at the Cardiology. Department, Punjab Institute of Cardiology, Lahore from April to September, 2017. One hundred patients who were being treated by percutaneous coronary intervention (PCI) were enrolled into two Groups e.g., Group I & group II. 50 patients undergoing direct stenting were enrolled in group I and 50 patients undergoing stenting after balloon pre-dilatation were enrolled in group II after randomization. All patients were treated by single type drug eluting or bare metal stents. Chi square test was used for association and t-test for mean difference between two groups in comparison to post dilatation, fluoroscopy time, procedure time, amount of contrast used, procedural success, side branch compromise, slow flow. The *p*-value of < 0.05 was significant. **Results** This study consisted of 76 males and 24 females out of a total count of 100, with the average age of 52.2±0.01 years. Overall, 43 (43%) patients were diabetic and overall, 44 (44%) were hypertensive. Most of the patients 55 (55%) had PCI to LAD. Average fluoroscopy time 4.l±2.5 minutes in Group I was significantly lesser as compared to 6.7±3.8 minute group II (*p*-value <0.05). The average procedure time was also marginally lesser in Group I, 23.4±11.6 in comparison to the second Group 33.7±14 (*p*-value <0.05). Side branch compromise was observed in 10 (20%) in the first group as compared to 8 (16%) the second group. **Conclusion:** In comparison to stenting preceded by balloon pre-dilatation, direct stenting is a safer and more feasible procedure with respect to radiation exposure, cost and time duration of the procedure.

Keywords: PCI; Coronary artery disease; Stenting directly; Balloon angioplasty

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INTRODUCTION

Stents are now used in up to 95% of all PCI procedures. Increases in stent and balloon applicative procedures have allowed the development of direct stent strategy DS (stent delivery without prior dilation) instead of conventional stenting (CS), which is the implantation of a stent after balloon pre-dilation. Several studies have shown that this technique is feasible and safe in selected cases, resulting in reduced procedure costs, duration and exposure to radiation.[1] However, in randomized trials, the DS technique showed results similar to the standard CS for long-term clinical outcome.[2–7]

Two recent studies showed a direct stent (DS) benefit compared to the stent after pre-dilation. Ormiston *et al*[8] observed that direct stenting with Taxus Liberte Paclitaxel-eluting stents (PES) in carefully selected lesions was associated with significantly reduced procedural complications and expected restenosis. In a small study, Cuisset *et al*[9] used guidewire with intracoronary pressure / sensor tip to measure microcirculatory resistance and observed that direct stent deployment in patients with stable angina reduced microcirculatory dysfunction as compared to conventional deployment. This technique is advantageous by saving the time of fluoroscopy and procedure, the amount of contrast agents and using fewer balloons.[10] A possible disadvantage of this approach is limited visualization due to the decrease in distal contrast leakage through the unilateral lesions that can hinder the stent positioning and the appropriate choice of its dimensions.[11]

Other drawbacks may be the incomplete deployment of the stent, the loss and displacement of the stent in the un-dilated lesion, and the impossibility of crossing the lesion. The aim of this randomized study was to compare the angiographic and short-term clinical results of direct stent implantation versus stenting after balloon pre-dilatation.

MATERIAL AND METHODS

This randomized controlled trial was initiated at the Cardiology Department of the Cardiology Institute of Punjab, Lahore, from April to September 2017. One hundred patients undergoing percutaneous coronary intervention were randomly split into two groups. Fifty patients undergoing direct stent were enrolled in Group I and 50 patients undergoing stenting after balloon dilatation were enrolled in group II after their written informed consent. Data was collected through structured proforma. It included the history, the general physical and systemic examination along with the information on the procedure of percutaneous coronary intervention. Baseline variables such as diabetes mellitus, hypertension, smoking, dyslipidaemia, family history of IC were observed. Acquisition of standard images was performed in the Department of Coronary Angiography and Interventional Cardiology, Punjab Cardiology Institute, Lahore, using 2 or more angiographic projections of the stenosis, intracoronary nitro-glycerine in order to receive a maximum coronary vasodilation and the repetition of similar angiographic projections. The lesion over time of follow-up angiography. Cineangiograms were sent to two observers who were blinded to the study protocol. The catheter opacified with filled contrast was used as a calibration source, a quantitative angiographic analysis was performed using a validated quantitative coronary angiographic algorithm (Cardiovascular Angiography Analysis System, CAAS II, Medical Imaging, Maastricht, The Netherlands). Angiographic projections demonstrating minimum degree of overlapping of vessel with sharper and tighter view of stenotic lesion were selected. All patients received 300 mg of clopidogrel and then 75 mg/d in addition to 150 mg/d of aspirin. The rest however were treated by the use of regularly applied techniques. Patients in Group I received a direct stent, while the predisposition of the balloon with a 2×15 mm mercury balloon was mandatory before stent placement in Group II. All patients were treated with a single eluting drug or bare metal stents. A subsequent dilatation was performed with the same stent balloon to optimize the angiographic deployment, especially in case of any insufficient deployment. During the procedure, boluses of intravenous heparin were administered. The PCI vessel was identified as LAD, LCx or RCA. The use of intravenous lIb / IIIa glycoprotein inhibitors was at the discretion of the operator and was observed if it was administered. The posterior dilation, the fluoroscopy time, the procedure time, the amount of contrast used, the success of the procedure, the involvement of the lateral branch, the slow flow were recorded in the *proforma*.

SPSS Version 21 was used for analysis. Quantitative variable were e.g Age, Fluoroscopy Time, Procedure Time, Amount of Contrast Used were expressed with Mean±SD (Standard Deviation), while qualitative variables like diabetes mellitus, hypertension, smoking, dyslipidaemia, family history of IHD, PCI Vessel, GP IIb/IIIa used, DES, BMS, post dilatation were expressed with frequency and percentages. Chi square test was used for association between two groups for variables involved in quality and student t test was used for mean difference between quantitative variables. p value <0.05 was taken as significant.

RESULTS

The baseline characteristics are presented in Table-1. There was only significant difference between genders in both groups (p <0.05) but there was no significant difference regarding mean age, diabetic mellitus, hypertension, smoking, dyslipidaemia, and family history of ischemic heart disease between two groups (Table-1).

There was no significant difference in treatment of vessels and different type of stents (Table-2). Fluoroscopic time was significantly lower in group I as compared to group II (6.7±3.8 vs 4.1±2.5; p-value <0.05). Procedure was also significantly lower in group I as compared to group II (33.7±14 vs 23.4±11.6; p-value <0.05) (Table-2).

Table-1: Baseline profile of study population.

Characteristics	Group I	Group II	Total	*p* value
Age mean years	51.2±10.1	53.06±10.2	52.2±10.1	
Gender				<0.05
Male	42 (84%)	34 (68%)	76 (76%)	
Female	8 (16%)	16 (32%)	24 (24%)	
Diabetes Mellitus	18 (36%)	25 (50%)	43 (43%)	<0.157
Hypertension	24 (48%)	20 (40%)	44 (44%)	<0.42
Smoking	18 (36%)	19 (38%)	37 (37%)	<0.836
Dyslipidaemia	3(6%)	2 (4%)	5 (5%)	<0.64
Family History of IHD	22 (22%)	8 (16%)	1 9(19%)	<0.44

IHD= Ischemic heart disease

Table-2: Procedural variables of the study population

Characteristics		Group I	Group II	Total	*p* value
PCI Vessel					
	LAD	30 (60%)	25 (50%)	55 (55%)	<0.336
	LCx	9 (18%)	13 (26%)	22 (22%)	
	RCA	**11** (22%)	13 (26%)	24 (24%)	
GP IIb/IIIa **blockers used**		30 (60%)	36 (72%)	66 (66%)	<0.205
DES		34 (68%)	34 (68%)	68 (68%)	-
BMS		16 (32%)	16 (32%)	32 (32%)	-
Post dilatation		2 (4%)	3(6%)	5 (5%)	<0.646
Fluoroscopy Time		4.1±2.5	6.7±3.8	5.4±3.5	<0.002
Procedure Time		23.4±11.6	33.7±14	28.5±13.8	<0.007
Amount of Contrast Used		90±32.6	119.3±51.9	104.6±45.5	<0.158

LAD=Left antenor descending artery; LCx=Left circumflex; RCA=Right coronary artery; GP IIbIIIIa=Glycoprotein IIb/IIIa; DES=Drug elutind stent; BMS=Bare metal stent.

DISCUSSION

Direct stent technique (DS) has been emerged as another option along the conventional stent with a balloon predilection.[13] The regular stent use in the treatment of CAD helped the procedure by putting forth the concept of DS. This study authenticated the feasibility of the safety of coronary stenting without balloon pre-dilation with similar success rate of the procedure in both groups, which agrees with previous studies.[2,14,15] This study showed that the similar complication profiles such as lateral branch involvement, slow flow, dissection that is comparable with previous studies.[16,17]

In a study by Martínez-Elbai *et al* comparing these techniques concluded that in selected coronary cases, the DS is as safe and composite outcome as midterm clinical outcome, In the current study, only hospital events were recorded that were similar in both groups.[3]

Another study conducted by Miketic *et al* CAD compared both techniques and revealed that there was reduced fluoroscopy and procedural time, number of guiding catheters and contrast quantity used in DS group.[18]

In study by Stys and colleagues with 128 patients revealed the success rate was 99% with direct stent technique without major procedural complications. Six-month follow-up also showed statistically insignificant main the main general adverse cardiovascular events concluding better long-term outcome comprising low complication and better success rate.[19]

Piscione *et al* presented a meta-analysis recently that the DS technique resulted in reduced myocardial infarction and composite death at six months post procedure.[13] Several studies showed that there was significant reduction in procedure duration, use of contrast amount and fluoroscopy.[3,20] The same results were achieved in our present study. The reduced fluoroscopy exposure duration is safe for both the patient and operating team. As operator is very close to the radiation source so is vulnerable to errors and adverse effects.[21] The lower amount of radio contrast use provides multiple positive effects especially those with compromised renal function. Anaphylaxis and nephropathy are the main adverse effects of radio-contrast.

The direct stent is also cost-effective, compared to stenting with pre-dilation showing the similar cost savings documented by same studies with the use of a direct stent.[1]

CONCLUSION

Direct stenting is safe and feasible in percutaneous treatment of CAD as compared to balloon dilation. It can reduce the radiation exposure, procedural cost and time thus improvising outcome for both the patient and operating team.

AUTHORS' CONTRIBUTION

KS: Data collection, conducted the study and wrote the article. NHM: Helped in conducting the study and gave frequent advices. SA: Helped in the analysis of data. SA: Helped in collecting and reanalysing the data and proof reading. HU: Helped in proof reading and compiling the results.

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