Direct coronary artery … balloon predilatio…

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ABSTRACT

Objective: Direct stenting of coronary stenosis without balloon predilation has shown to reduce the cost, procedure duration and the radiation exposure associated with the stenting of coronary artery stenosis. We sought to study the feasibility, safety and immediate learning curve of direct stenting in a Cardiac center in the Kingdom of Saudi Arabia.

Methods: We prospectively studied 76 consecutive patients with coronary artery stenoses who underwent direct stenting without balloon predilation. This study was carried out at King Fahad Armed Forces Hospital, Jeddah, Kingdom of Saudi Arabia during the period January 2000 through to November 2001. Patients were selected by the operators based on reference vessel diameter ≥2.5 mm, absence of calcification, absence of vessel angulation and absence of total occlusion.

Results: Forty-six percent of the patients were diabetics, 34% had post infarction angina … stenting of the left anterior descen… 100% … 3.0 mm … size … success … patients and there … for urgent bypass surgery, … embolization. One patient deve… myocardial infarction.

Conclusion: Direct stenting wit… is safe and feasible with almos… interventionalist experienced in … stenting and can be used for sel… without prior experience in direct …

Keywords: Coronary artery disease, coronary angioplasty, stents.

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Multi-center randomized trials have demonstrated that the restenosis and repeat revascularization are reduced when elective coronary stent implantation is performed.[1] Acute complications associated with stents such as sub-acute stent thrombosis are reduced with the use of new anti-thrombotic regimens.[2] These developments have lead to stent implantation in over 80% of percutaneous coronary artery interventions. The standard stent implantation technique requires predilation of the lesion with a balloon catheter, followed by dilation with a high pressure balloon catheter. Predilating the lesion facilitates the passage of the stent, avoids stent disl… complete expansion of the s… stenting without balloon pr… theoretical advantage of reduc… dissection … radiation … contrast use and reduced co… Newer generation stents are no… crossing profile and are moun… balloons. Similar direct sten… results have bee… centers with experien… sought to study prospectivel… safety of direct stenting, the le…

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term outcome of introducing direct stenting to a cardiac center in the Kingdom of Saudi Arabia (KSA).

Methods.

Patients. Between January 2000 and November 2001, 76 patients underwent direct stenting (18% of all stent patients during this period). Direct stenting was considered for patients with 1. Reference vessel diameter >2.5 mm, 2. Absence of lesion calcification, 3. Absence of total occlusion, 4. Absence of vessel angulation >45°.

Stent procedure. All patients received aspirin (300mg) plus ticlopidine (250mg) or clopidogrel (75 mg) prior to the procedure and intravenous heparin (70-80U/kg) during the procedure. The target activated clotting time was >300 seconds unless the adjuvant abciximab was used then the target was >200 seconds. Using standard percutaneous techniques the lesion was crossed with a guidewire but not dilated with a balloon catheter. The stent was positioned across the lesion and the stent delivery balloon inflated. The deployment pressure and the use of further balloons to post-dilate the stent was at the discretion of the operator.

End points and follow-up. Successful stent deployment was defined as angiographic residual stenosis <20%, in the absence of major in-hospital adverse events of death, Q wave myocardial infarction, repeat intervention or coronary artery bypass surgery. All patients were followed up in the clinic after procedure or were contacted via telephone.

Statistical methods. Data was prospectively entered into a computerized database. Continuous variables are presented as mean ± standard deviation.

Results.

The baseline clinical and angiographic characteristics of the patients are shown in **Table 1**. The majority of patients were men, treated diabetes mellitus was present in 46% of patients, 34% had post infarction angina and 13% had reduced left ventricular ejection fraction (<40%). The procedural characteristics are shown in **Table 2** Ninety percent of stents were >3 mm in size, the mean stent length was 13 mm and the mean deployment pressure was 16 mmHg, reflecting current practice of using shorter stents at relatively high pressures. A 2nd stent was placed in 9 patients (12%) for complete lesion coverage and not for dissections. In 15 patients (20%) a 2nd balloon was used to post-dilate the stent and the operator used a bigger balloon than the original stent size in 9. Adjuvant abciximab was used in 15 patients (20%). Pre-mounted stents on high pressure balloons were used in all patients. Direct stenting was successful in all patients. There was no stent embolisation or failure of stent expansion. There was one patient with peri-procedural creatine kinase elevation without electrocardiogram changes. There were no deaths or need for emergency bypass surgery.

Table 1 - Baseline characteristics.

Characteristics	N (%)
N of patients	76
Age (years)	54 ± 10
Male gender	67 (88)
Recent myocardial infarction	26 (34)
Current smoker	29 (38)
Diabetes	35 (46)
Hyperlipidemia	37 (49)
Ejection fraction <40%	10 (13)
N of diseased vessels	
1	39 (51)
2	27 (36)
3	10 (13)
Coronary artery	
LAD	46 (60)
LCX	15 (20)
RCA	15 (20)
Proximal lesion	42 (55)
Denovo lesion	73 (96)

LAD - left anterior descending artery, LCX - left circumflex artery, RCA - right coronary artery, N - number

Table 2 - Procedural characteristics.

Characteristics	N (%)
Stent type	
Tetra or tiristar	59 (77)
Velocity	12 (16)
R stent	4 (3)
Express	1 (2)
Stent size	
2.5	1 (2)
2.75	6 (8)
3	42 (55)
3.5	23 (30)
4	4 (5)
Stent length (mm)	13 ± 4
Highest pressure (atm)	16 ± 2
2nd stent	9 (12)
Inflation with 2nd balloon	15 (20)
2nd balloon pressure (atm)	13 ± 4
Ajunct Reopro	15 (20)

N - number

Discussion. In this prospective study we report our experience of introducing direct stenting in a Cardiac center in KSA. Coronary stenting has replaced balloon angioplasty as the most frequent percutaneous coronary intervention due to better safety and efficacy but at a higher cost.[5] Studies from high volume centers have demonstrated safety and feasibility of direct stenting in 20% of the total stent volume.[6] A number of theoretical advantages to direct stenting have been reported. These advantages include decreased use of contrast agents, less radiation exposure and reduced procedure times.[4,8] Eliminating the balloon dilation reduced the cost of the procedure by US$900.[6] Two studies randomized patients to direct stenting versus conventional stenting and the results confirmed lower cost, contrast use and radiation with equal clinical outcomes.[9,10] Compared to these studies our study shows a similar pattern of feasibility and success in 20% of patients. The high success rate is mainly due to the careful selection of patients.

One limitation of our study is the relatively small number of patients but the aim of this study was to prospectively assess direct stenting in lower volume centers.

In conclusion, direct stenting without balloon predilation is safe and feasible with almost no learning curve for the experienced interventionalist and can be used in selected patients in centers without prior experience in direct stenting. This will help in reducing the high cost associated with coronary artery stenting. The high incidence of diabetes mellitus in the coronary artery disease population in KSA and its impact on long-term outcome needs further study.

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