Use of R™ stent in the percutaneous coronary intervention of coronary bifurcation lesions

Mazhar M Khan, Vaikom S Mahadevan, Vincent P Moohan and Samuel W Webb

Regional Medical Cardiology Centre, Royal Victoria Hospital, Belfast, BT12 6BA Northern Ireland
Correspondence: Mazhar M Khan
Regional Medical Cardiology Centre
Royal Victoria Hospital
Belfast
BT12 6BA
Northern Ireland

Received 6 March 2001
Revised 5 October 2001
Accepted 15 February 2002

BACKGROUND: Percutaneous Coronary Intervention (PCI) of coronary bifurcation lesion is technically quite demanding. It has been associated with a lower procedural success, higher rates of complication and restenosis. Side-branch occlusion and plaque shifting or ‘snow plow’ effect are not uncommon. Stenting of the main vessel may cause ‘stent jail’ of the side-branch. Modern stent design may allow passage of a balloon or stent into the side-branch through the struts of the stent placed in the main vessel. A newly developed 316 stainless steel tubular stent, the R™ stent is uniquely designed to provide flexibility, radial strength on deployment and conformability. Its large cell size facilitates PCI of bifurcation lesion.

AIM: To assess the feasibility of R™ stent in the treatment of symptomatic patients with bifurcation coronary lesions. The main objective was to assess the ease of deployment, side-branch access and overall success of the R™ stent in this group of patients without any major adverse events.

METHODS: Between December 1998 and September 2000 the R™ stent was used as a main stent in 28 consecutive patients with coronary bifurcation lesions, 46% of which had unstable angina. The mean age was 59 ± 10 and 89% were male. Adjunctive medical therapy included clopidogrel, aspirin and intraprocedure heparin. Abciximab (Reopro) was given to 9 patients.

RESULTS: Successful stent deployment was achieved in all patients. Thirty-four R Stents and 16 other stents were used. Two patients had post-procedure rise in cardiac enzymes. There were no major adverse events at 30 days. LAD/D1 with LAD/diagonal was the target lesion in the majority of patients. Stenting of the side-branch was done in 18 and balloon dilation in 9 patients. At 3–23 months (mean 11.8) follow-up, repeat angiography was done in 18 patients with restenosis in 4, two of them had repeat PCI and one had coronary artery bypass graft (CABG).

CONCLUSION: Coronary bifurcation lesions are not uncommon. Current advances in stent technology offer a safe and effective revascularisation strategy for such complex lesions. The R™ stent appears to be a suitable device that provides good wall coverage, radial strength, conformability and easy side-branch access. (Int J Cardiovasc Intervent 2002; 4: 173–180)

Keywords: bifurcation stenting – R™ stent – percutaneous intervention of bifurcation lesion.

Introduction

Percutaneous intervention of coronary bifurcation lesion represents a technical challenge to the interventional cardiologist. It has been associated with lower procedural success, higher complication and restenosis rates. A bifurcation lesion is defined as the presence of significant (greater than 50%) stenosis involving a parent (main) vessel at the ostium of the side-branch with or without significant side-branch disease. Vessel bifurcation may be predisposed to atheromatous plaque formation because of turbulent flow and increased shear stress. Although true bifurcation lesions account for 4–11% of all PTCA procedures, the vast majority involves LAD/diagonal bifurcation.

Balloon angioplasty of such lesions is often associated with a significant risk of side-branch occlusion. Several techniques including debulking or stenting have been
developed to improve the outcome of intervention. Important considerations include the likelihood of immediate and future revascularisation of the side-branch, the size of the side-branch and the amount of myocardium supplied by the side-branch. Stenting of the parent vessel frequently leads to plaque shift or ‘stent jail’ of the side-branch.

Modern stent designs allow placement of the stent in the parent vessel across the side-branch and passage of a second balloon or stent through the struts of the first. The outcome of such a measure is often variable. It depends upon the type of stent and the size and angulation of the branch vessel. Stenting both vessels in a complex bifurcation lesion can be difficult. It is often associated with plaque shift, stent overlap and uncovered area at the carina of the bifurcation. With improvement in the implantation technique, stent and balloon technology and potent adjunctive pharmacological therapy, stenting of bifurcation lesion has become an accepted PCI procedure with acceptable risk. However, stent deformity following balloon dilatation of the side-branch is a known risk.

The first attempt at treating bifurcation lesions was with the first generation Palmaz–Schatz 153 or Cook stent. Initial experience proved to be unpredictable and unsatisfactory as side-branches were sacrificed in a substantial proportion of cases. The other major problem is plaque shifting at side-branch ostium after stent implantation, particularly in patients without significant disease of the side-branch. This observation is not uncommon after stent implantation and can result in minor or major complications including non-Q-wave myocardial infarction or significant cardiac enzyme elevation.

The recent generation of stents has provided a new dimension in the management of such lesions, with the availability of low profile balloons and large internal lumen of guide catheters. It is now possible to treat such lesions with greater success. Intra-coronary stenting thus represents one of the most important advances in the practice of coronary intervention. Greater operator experience and improvement in stent design with greater tractability, flexibility and conformability have extended the indications of stenting.

**Classification of bifurcation lesions**

Several classifications have been proposed for bifurcation lesions. The likelihood of significant side-branch occlusion depends largely on the lesion location and the origin of the side-branch in relation to the primary lesion in the main vessel. We classified bifurcation lesions into four Types and Type 2 is further divided depending upon the side-branch involvement (Figure 1).

The classification adopted here is a modification of the classification proposed by Lefèvre et al except that it does not include ostial lesions of the individual branches.

**Subjects and methods**

Since December 1998, angioplasty and stenting utilizing the R™ stent (ORbus Medical Technologies, Fort Landale, FL, USA) as a primary stent for bifurcation lesion has been performed on 28 consecutive patients. Informed consent was obtained from all patients. The R™ coronary stent is designed to overcome major problems of first- and second-generation stents of the slotted tube, coil and modular designs. It is a balloon expandable stainless steel stent with a dual helical configuration, thus providing the radial strength of a slotted tube and the flexibility of coil design. Each cell is expandable to at least 4.5 mm in diameter and permits side-branch access. Initially unmounted stents of 9 and 16 mm in length crimped on a low profile balloon were used, later pre-mounted stents of 9, 13, 16 and 18 mm lengths were used.

Table 1 gives the clinical characteristics of the patients: 46% had unstable angina; 89% of patients were male with a mean age of 59 (±10) years. All patients received 6000–12,000 units of heparin for a target ACT of ≥250 seconds, 300 mg aspirin and clopidogrel 75 mg once daily. Those patients not on clopidogrel already were commenced on 300 mg loading dose followed by 75 mg daily. All patients had cardiac enzymes and electrocardiogram checked 6–8 hours after the procedure and the next day. Twenty-six out of 28 patients were discharged the follow-
ing day. The procedure was accomplished using 6 or 7 French Guide Catheter. Procedure details are shown in Table 2.

### Technique of stent deployment

LAD/Diagonal was the target lesion in the majority of patients (Table 3). Thirty-four R™ stents and 16 other stents were used. In our series, the majority of patients had either Type 1 or Type 2A/Type 2B lesions (Table 4). Stenting of the side-branch was done in 18 patients and 9 had balloon angioplasty. One other patient with a Type 3 lesion did not require kissing balloon for side-branch dilation. Double (kissing) balloon inflation (Figure 2) was carried out in 27 patients. Nine patients received abciximab (ReoPro, Eli Lilly & Co) for complex vessel morphology, intra-coronary thrombus, complex and difficult procedure or unstable symptoms.

Lesions involving a side-branch of greater than 2 mm in diameter by visual assessment were considered a bifurcation lesion requiring treatment. The angulation of the bifurcation was also taken into account as this is an important factor and may influence the final outcome of the procedure. The risk of ‘snow plowing’ seems to be higher in certain types of lesion especially T type lesions where a side-branch is arising perpendicular to the main vessel.

Our main strategy of stenting was to use double wire and dilatation of both branches and main vessel in Type 1 and Type 2 lesions. In the T-junction type of side-branch (5 patients), the side-branch was stented first, followed by the main vessel (Figure 3), while in other cases the main vessel was stented first. The side-branch was then entered through the struts of the main vessel stent and after balloon angioplasty, through the stent struts; a stent was placed if necessary. Side-branch stenting can be accomplished with any low profile stent. Our choice here is S 670™ stent (Medtronic AVE, Galway, Ireland), Carbo Medic™ stent (Sorin Biomedic, Italy). R™ stent mounted on a low profile balloon like Maxum™ (Boston Scientific/Sciomed, Galway, Ireland) or recently introduced Talos™ and Evolution™ (Orbis Technologies, Netherlands) stent delivery system.

Final kissing balloon dilatation is an important step in the treatment of bifurcation lesions. Stent conformability is maintained with simultaneous dilatation of both vessels. Other approaches that have recently been described include the Y technique, a T technique, the ‘culotte’ technique and double or triple wire technique. In the last technique, two guide wires are placed in the main vessel and the side-branch and kissing balloon dilatation is performed first. The stent is then placed in the main vessel with entrapment of the side-branch wire. The main vessel wire is then withdrawn and reintroduced through the stent into the side-branch or a third wire is used to enter the side-branch while keeping the entrapped wire in place and once the third wire is in the side-branch, the trapped wire is removed. The struts are dilated with the dilatation of the side-branch and if necessary a stent is placed in the side-branch. The modification of this technique that we use, is to keep a balloon in the main vessel so that the struts of the side-branch stent do not protrude into the main branch during deployment of the stent in the side-branch. This technique was used in the majority of patients. With the greater ease of reintroducing the wire through the struts of the R™ stent, leaving the wire trapped outside the stent is not necessary in every case. T stenting was carried out in 5 patients and consisted of side-branch stenting first, followed by main vessel stenting. Three patients had inverted V stenting for Type 4 lesions. Nine
other patients had stenting of the parent vessel followed by side-branch stenting through the first stent. Final kissing balloon dilatation was done in 27 of the 28 patients (Figure 4). Foreshortening of the stent was noted in two cases following high-pressure balloon dilatation, requiring further short stent deployment to optimize the angiographic result.

Results

The results are summarised in Table 5. The procedure was successful in all patients with TIMI grade 3 flow. Success was defined as angiographic evidence of successful dilatation with \( <50\% \) residual stenosis without death, acute closure, Q-wave MI or need for CABG during hospital stay. Two patients had a non-Q-wave myocardial infarction as suggested by greater than three times the cardiac enzymes. There were no major cardiac events at 30 days. All patients completed a minimum of 3 months follow up.

During the follow-up of 3–23 months (mean 11.8) angiographic restenosis was noted in four patients. Eighteen patients had repeat angiography either for other vessel PCI, recurrence of symptoms, or positive Exercise Stress Test.

Two patients had repeat percutaneous intervention. One had bypass graft surgery. The other patient had reocclusion of the diagonal branch, which previously had balloon dilatation. There was no mortality during the follow-up period.

Discussion

Intra-coronary stent implantation across side-branch is associated with the increased risk of side-branch occlusion or loss and restriction of future access to the side-branch. These considerations have therefore limited their use in bifurcation lesions. Previous studies of stenting across bifurcation lesions are limited to a few case reports. The choice of stent for bifurcation lesions depends upon good lesion and wall coverage and easy access to the side-branch. It is important to maintain the shape of the stent during side-branch dilatation. The R\textsuperscript{®} stent is a new 316 stainless steel tubular coronary stent uniquely designed to provide maximum flexibility, tractability and radial

<table>
<thead>
<tr>
<th>Follow-up 3–23 months (11.8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Success</td>
</tr>
<tr>
<td>Non-Q-wave MI</td>
</tr>
<tr>
<td>Re-angiogram</td>
</tr>
<tr>
<td>Target lesion restenosis</td>
</tr>
<tr>
<td>Repeat PTCA</td>
</tr>
<tr>
<td>Bypass surgery</td>
</tr>
</tbody>
</table>

Table 5

Results/Outcome.
strength on deployment.\textsuperscript{20,21} It also facilitates PCI of bifurcation lesion by virtue of large cell size for side-branch access. No ‘fish scaling’ or plaque prolapse is observed after deployment over tortuous curving vessels. It has been observed that tubular stents behave better than non-tubular stents for bifurcation lesions, particularly if balloon dilatation is needed for side-branch lesion (Figure 4).

The optimal management strategy for bifurcation lesions has remained unresolved. Few recent studies describe larger experience.\textsuperscript{12,22–24} With increasing experience of treating side-brances within stented segment, there has been an enhanced interest in developing a practical approach for stenting both the main vessel and a large side-branch of a true bifurcation lesion. Colombo et al reported a ‘kissing stent’ technique, but contact of the two stents impeded full endothelialisation of struts proximal to the bifurcation at its carena with a possibility of stent thrombosis in this segment.\textsuperscript{16} One approach to this problem is to position a stent in the ostium of the side-branch followed by placement of a second stent in the main vessel spanning the origin of the
side-branch. Placement of such T stent may need dilatation into the side-branch to improve the strut orientation overlaying the ostium and thus minimizing subsequent difficulties in treating late restenosis of the bifurcation. This technique may also leave an unstented gap within the bifurcation or cause protrusion of the stent into the main vessel. The potential risk is the inability to cross the first stent. The other simple approach is to stent the main vessel only, spanning the ostium of the side-branch and dilating the side-branch through the struts of the stent. In our study, an attempt was made to stent both vessels if there was any compromise to the flow. In one third of our patients stenting of the side-branch was not done and the follow-up of these patients did not show any worse prognosis. Others have also suggested that the treatment of true bifurcation lesion with stents in both vessels may not offer

Figure 4
(A) Severe disease of RCA Type 2A lesion (B) Double wire to enter both branches (C) Final double balloon after stent placement in PDA (D) Final result.
an advantage over stenting of one vessel and balloon angioplasty/ atherectomy of the other. The stenting for both parent vessel and side-branch was done only if there was dissection resulting in reduced or compromised blood flow in the side-branch or inadequate dilatation of side-branch lesion. Direct stenting without predilatation is possible but results in significant plaque shift; we therefore, used predilatation of main vessel, side-branch or both before stent placement.

Carrie et al\textsuperscript{22} reported their experience of stenting bifurcation lesions in 54 patients using either T or reverse Y stenting technique with Wiktor\textsuperscript{TM} stents (Medtronic Inc., USA). They demonstrated that the procedure success rate was high, regardless, of which approach was used. Our study also demonstrates that endoluminal reconstruction of coronary bifurcation with appropriate stents can be achieved with a high success rate and with very low complications. It is thus an important therapeutic option. Final kissing balloon dilatation, however, is essential. One further modification of our technique was to keep the balloon in the main vessel during stent deployment in the side-branch as this prevents the protrusion of the struts into the main vessel and allows subsequent stent placement in the main vessel without any difficulty.

\section*{Study limitations}

The major limitation of this study is its retrospective and observational nature. This study is further limited by the lack of routine angiographic follow-up. Since the ultimate goal of the percutaneous revascularisation is relief of angina and avoidance of additional procedure and cardiac events, our patients were all monitored closely for this and only patients who had symptomatic recurrence were restudied or those who required further intervention. This demonstrated a very low rate of restenosis or reocclusion of the target lesion. Furthermore, the primary objective of this study was to assess the feasibility of stenting, utilizing the R\textsuperscript{TM} stent for bifurcation lesions and this was adequately demonstrated in this experience.

\section*{Summary}

This study demonstrates that especially designed stents can be deployed with high success and low complication rates in coronary bifurcation lesions. Technical approach depending on the anatomy and final use of double kissing balloon dilatation maintains the conformability of the stent and is thus an important part of the strategy for bifurcation lesions to prevent undue distortion of the stent and plaque shift.\textsuperscript{10–12} It ensures immediate and medium term success. Routine stenting of the side-branch is not necessary if good patency and dilatation is obtained by placement of the stent in the main vessel and balloon dilatation of the side-branch.

Our results, though preliminary, are excellent for immediate and medium term outcome with target lesion stenosis of 22%. The incidence of death, myocardial infarction and need for CABG are lower than average for this cohort at a mean follow-up of 11.8 months. They also show that the R\textsuperscript{TM} stent, because of its unique design and remarkable ability to adapt to the shape and complex coronary artery morphology appears to be a suitable stent for bifurcation lesion. The availability of delivery system with pre-mounted stent has made it a very acceptable device and offers an efficient alternative revascularisation strategy for such lesions.

\section*{References}
