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Is there a need for dedicated bifurcation devices?

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Introduction

Coronary bifurcation disease is one of the outstanding challenges of treatment with percutaneous coronary intervention (PCI), and may be present in up to 20 to 30% of patients with multivessel disease encountered in daily practice[1-5]. Compared with simple lesions, bifurcations have been associated with lower procedural success rates, higher adverse event rates, and poorer angiographic and clinical outcomes[1,6]. The less favourable outcomes associated with bifurcation compared with non-bifurcation lesions may in part result from the inability of current devices and techniques to scaffold adequately and preserve the side-branch (SB) ostium, which is a common site for restenosis[1,6]. Complex strategies are technically demanding and may compromise the main branch (MB) when not carried out properly[7,8] or when the final result is not optimal in terms of stent apposition and flow dynamic[8,9]. Furthermore, compromise of the SB during stent implantation is also common as many techniques do not allow the operator to maintain a usable wire in the SB[1,6,9,10]. The use of drug-eluting stents (DES) has resulted in significantly improved outcomes compared with bare metal stents (BMS)[11,12], with a single digit re-intervention rate in the majority of non-randomised real world studies[13] and also in randomised studies comparing the systematic use of two stents to the strategy of provisional SB stenting[14-19]. Meta-analyses of these randomised studies, which were performed in selected cases, did not show any advantages associated with the systematic use of two stents compared to the provisional approach. Indeed, the two-stent approach was associated with a higher rate of periprocedural myocardial infraction and a trend towards a higher rate of stent thrombosis[20-23]. Consequently, there is a common acceptance that provisional SB stenting should be the gold standard approach in the majority of bifurcation lesions and the main question is when we should use two stents to improve procedural safety and long-term efficacy. Although a large variety of dedicated bifurcation stents, both BMS and DES, have been studied none of them has become widely used[24-31].

An unmet need

In the DES era, the most significant independent predictor of clinical outcome is the angiographic success at the level of the main branch[13] and this is a very important point to keep in mind. The acute result achieved in the SB is not a predictive factor of late outcome and this is one of the key reasons why the provisional SB stenting approach is a successful strategy compared to a more complex approach with two stents or more. Dedicated stents are every interventionalist's dream because they simplify the procedure and make it easy for everybody, improving procedural success rate, decreasing the risk of stent thrombosis and decreasing the risk of SB restenosis. But many questions remain unanswered: How clinically important is it compared to the provisional approach? How cost-effective is it? What about the distal left main trunk?

What are the anatomical challenges?

The 3-diameter rule

Bifurcations follow the general law of flow conservation in nature and there is a very close relationship between the blood distribution function and vascularised myocardial mass. Consequently, in each bifurcation there is a close geometrical relation between mother-vessel diameter and the sum of the two daughter-vessel diameters. For this reason the diameter of each branch (MB proximal, MB distal and SB) follows the branching law described by Murray[32], recently simplified by Finet[33]: Dm=0.678* (Dd1+Dd2), and refined by Kassab[34]. This information is crucial to understanding that there are three diameters in a bifurcation, which should be taken into account when stenting a bifurcation.

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The shape and angle of the SB ostium

The shape of the SB ostium is complex and should be visualised in a three dimensional (3-D) perspective as well as the angle which varies from 20 to 120° and this should be taken into consideration. It is also submitted to cyclic changes which may increase the risk of stent fracture especially for true bifurcated stents. The impact of the angle and the asymmetry of bifurcation on flow dynamic are very important and may influence clinical outcome particularly for the left main bifurcation. Finally, the angle is also modified by the stent, which may also influence the outcome and increase the risk of stent fracture.

The carina

The carina is the flow divider at the level of the bifurcation. This area is submitted to high shear stress and is usually free of disease as atheroma formation is related to areas of low/oscillating shear stress which are located on the opposite side of the divider. As a result, there is no or minimal plaque shifting after stenting the MB of the bifurcation, but if the MB stent diameter is too large at this level, we may have a carina displacement. The fact that there is no plaque at the level of the carina in the majority of cases may reinforce the idea that no or little stent scaffolding is needed at this level.

What should be an ideal dedicated device for bifurcation lesions?

The ideal stent for bifurcations[28,35,36] should be easy to use, intuitive and simplify the procedure by shortening the procedural time and x-ray exposure and decrease the amount of contrast media. It should be safe, allow permanent SB access and have a high rate of device success with predictable successful ostial SB stenting. It should also provide an optimal long-term outcome with a low rate of restenosis and stent thrombosis. Finally, the ideal dedicated device should be able to treat all kinds of bifurcation lesions.

General rules for using dedicated devices

The need for SB stenting should be relatively low when treating bifurcation lesions with dedicated devices designed for provisional SB stenting. An optimal view is crucial, in order to clearly see the bifurcation, especially the ostium of the SB. When two stents are used, final kissing balloon inflation is strongly recommended. The risk of wire wrap is high with some devices and should be prevented and identified as early as possible.

As the appropriate use of these devices requires a learning phase it is very important to follow the recommendations for use.

Classification of dedicated bifurcation devices

Many devices are already available or under clinical investigation. These devices may be divided into four groups: 1. Devices treating the MB with some degree of SB scaffolding, following a strategy of provisional SB stenting (Frontier, Pathfinder, Petal, SideKick, Trireme, Twin-Rail, Nile, Stentys). 2. Side branch stents (Sideguard, Tryton). 3. Proximal bifurcation stents (Devax). 4. Bifurcated stents (Medtronic stent)

Main branch stenting with provisional SB stenting approach

POTENTIAL GENERAL ADVANTAGES

This approach has already been validated as the “gold standard technique”. The priority is the MB, scaffolding of the SB ostium is more reliable compared to the classical provisional approach, and only one stent can be used in the majority of cases. One device is supposed to fit all types of bifurcation lesions except 001 lesions (branch ostial lesions). Because of their specific design it is probable that these devices may improve local drug delivery and decrease the risk of stent and polymer fracture.

DIFFERENT TYPES OF DEVICE

They can be divided into three subcategories: self-alignment devices, controlled alignment devices and devices which do not need alignment:

Self-alignment devices

These devices (Twin-Rail, Nile, Petal, Frontier and Abbott SB access) are shown in Figure 1[24,25,29,37,38]. They will be described in more detail in the next chapters. They are all drug-eluting stents except for the Twin-Rail and Frontier stent. The advantages are the relative simplicity and intuitive use of the devices. The main limitations are related to the risk of wire wrap because the devices are loaded on two wires (Figures 2 and 3). There is also a risk of miss alignment of the device especially when the bifurcation is located in a curve, with the SB originating in the internal part of the curve. Therefore a learning curve does exist and device success is about 85 to 92%. The profile and deliverability are not the same as those of a workhorse stent, and device failure increased when the vessel is calcified or tortuous.

There are several tips and tricks to decrease the risk of wire wrap. First and foremost, the problem may be prevented during manipulation of the second wire. For this reason, it is very important to wire the most difficult branch first, then the second branch with limited rotation of the wire (no more than a wrist rotation). Another useful and easy technique to avoid wire wrap is to keep the wires separate on the table in the same position from the beginning to the end of the procedure because wire wrap can start on the table and pushing the device will introduce the problem into the guiding catheter and the coronary arteries. The second important trick is to recognise wire wrap as soon as possible. With experience, it becomes relatively easy. A certain degree of resistance is felt when pushing the device into the coronary arteries and the wire wrap can be seen on the screen with magnification. Further pushing results in one of the two wires moving backwards. It is very important to avoid pushing the wire when resistance is felt, because this may cause deformation of the device and/or the wires(s). Therefore, when wire wrap is identified, the device should not be pushed forcefully, but one of the two wires should be simply pulled back (usually from the easiest branch to access) and rewiring should be subsequently performed with limited rotation. Sometimes, it can be useful to push the SB wire in the MB, push the device up to the bifurcation, then pull back the device and rewire the SB and finally push the device in the two branches of the bifurcation.

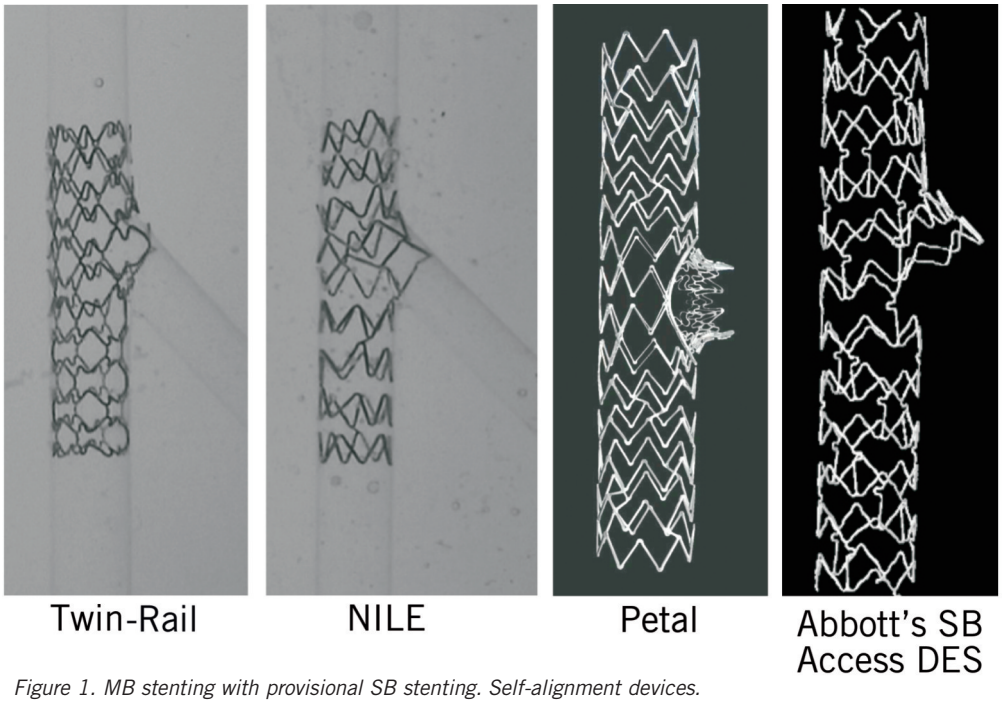

Figure 1. MB stenting with provisional SB stenting. Self-alignment devices.

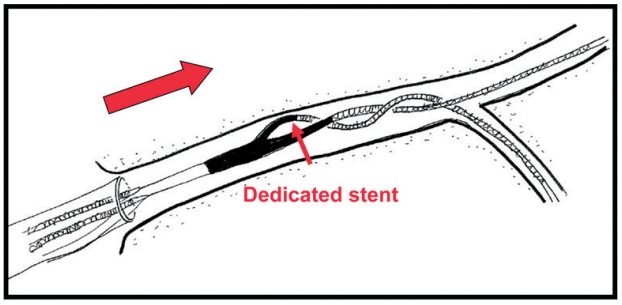

Figure 2. MB stenting with provisional SB stenting. Wire wrap.

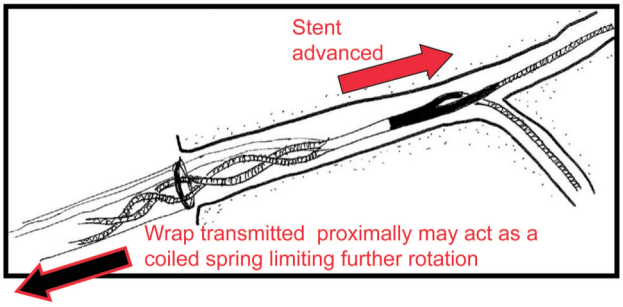

Figure 3. MB stenting with provisional SB stenting. Wire wrap.

The next generation of the Petal stent will probably solve the wire wrap issue with a new controlled alignment delivery system.

Controlled alignment devices

These devices are shown in Figure 4 (Trireme and SideKick), there are both bare metal stents[39,40]. The profile is better than self-alignment devices and the problem of wire wrap can be controlled by a controlled rotation of the device. Conversely, it is preferable, for safety reasons to use three wires. Limited data are available to date.

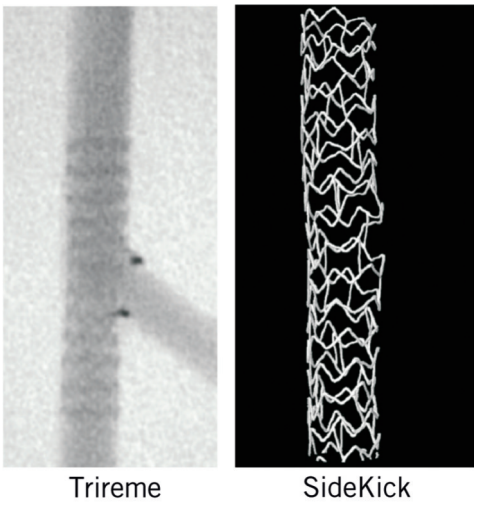

Figure 4. MB stenting with provisional SB stenting. Controlled alignment devices.

No need for alignment

This device is shown in Figure 5 (Stentys). It is an original concept associated with the strategy of provisional SB stenting[41,42]. This is a self-expandable stent (BMS or DES with paclitaxel) which can be deployed across the bifurcation. After accessing the SB through a distal strut, SB balloon dilatation will break a strut connection and push some metal in the SB. The advantages are related to the good profile of the stent and the fact that the device is delivered on only one guidewire. Therefore, there is no risk of wire wrap or miss-alignment. Limitations are related to the fact that it is necessary to open a distal strut in order to obtain an optimal SB ostial stenting. Limited data are available with this device in bifurcation lesions.

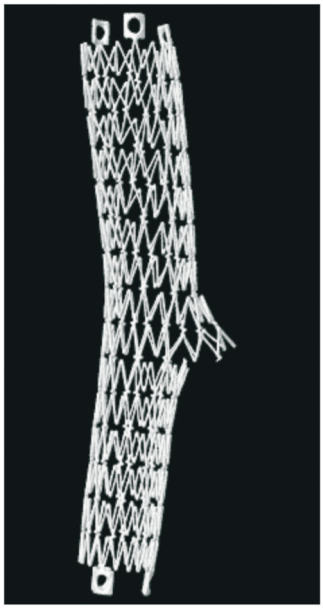

Figure 5. MB stenting with provisional SB stenting. No need for alignment.

SIDE BRANCH STENTS

Potential advantages

These devices (Figure 6) were specifically designed to secure the SB and facilitate the procedure. They should be used only for true bifurcation lesions (1,1,0; 1,0,0; or 0,1,0 according to the Medina classification). Deliverability is good; There is no risk of wire wrap, no need for stent rotation to conform to the configuration of the bifurcation lesion. Stent positioning is relatively easy and MB access is good if the recommended stent positioning and steps of the procedure are followed carefully. The Sideguard stent is self-expandable but easy to position because of its specific delivery system[30,43]. The Tryton stent[44] is balloon expandable. Both are bare metal stents. Few data are available with respect to the Capella stent. Conversely, there are substantial data from large European registries regarding the Tryton stents confirming the data obtained in the first-in-man study: high rate of success, good safety profile and good efficacy with a single digit SB restenosis rate.

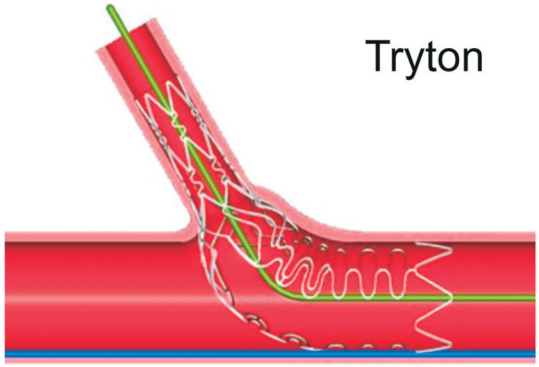

Figure 6. Side branch stents.

Limitations

Two stents are systematically used for treating bifurcation lesions with these devices, which may increase the risk of periprocedural myocardial infarction and late stent thrombosis. A large randomised study (900 patients) comparing provisional SB stenting to systematic SB stenting with the Tryton stent in true bifurcation lesions will start in January 2011. This study will be the first large randomised study comparing dedicated devices to a strategy of provisional SB stenting. It should provide important information not only about the use of the Tryton stent in the treatment of bifurcation lesions, but also about the procedural and clinical outcomes of provisional SB stenting which will serve as reference for future evaluations with other devices or techniques.

PROXIMAL BIFURCATION STENTING

The Devax stent is a self-expandable drug-eluting stent (Biolimus A9) made of nitinol. The polymer is bioabsorbable. The design is ideal for 1,0,0 lesions because it allows the scaffolding of the MB proximal to the bifurcation up to the carina (Figure 7). For other lesions types two or three stents should be necessary in about 80% of cases. The stent has been carefully studied and data have shown good safety and efficacy profile[26,27,31,45]. Deliverability seems to be acceptable, self-rotation is not needed and wire wrap is not an issue because the device is loaded on a single wire. However, the need for a very accurate positioning could be a limitation.

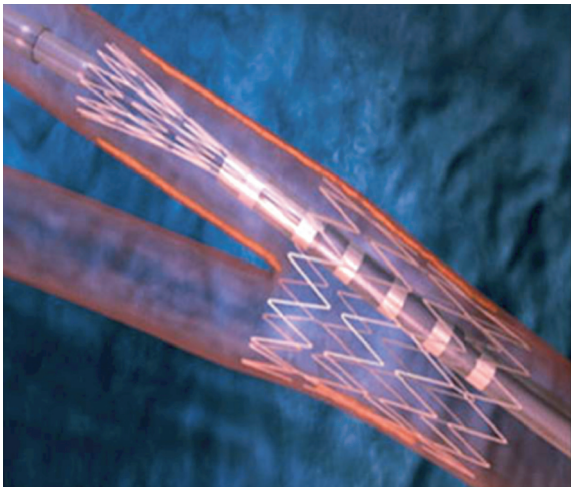

Figure 7. Proximal bifurcation stenting. DEVAX stent.

Bifurcated stents

This kind of device has always been every interventionalist's dream[46-49] because of its potential to solve the problems encountered in the majority of bifurcation lesions. However, because a device with two branches is less flexible than a single stent (Figure 8) and because it needs to be loaded on two wires, the risk of wire wrap and misalignment is high. Data with the new Medtronic bifurcated stent have shown a disappointing rate of device success. Like for the DBS stent[50], there is a potential for left main use which should be assessed.

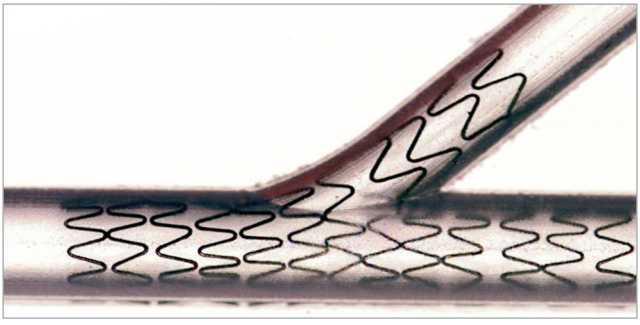

Figure 8. Bifurcated stents. Medtronic Y stent.

What are the dedicated stent-related issues?

Multiple-step approaches are required for all devices. Positioning of the stent is not so easy in the longitudinal and axial axis. Conformation to complex and various anatomies is not optimal and there are still many unanswered questions about the ideal stent (self or balloon expandable, dynamic or static conformability). Validation is still a major issue and randomised studies comparing dedicated devices to provisional SB stenting are needed. Regarding this last question, the ideal primary endpoint still needs to be defined (superiority in terms of procedural outcomes and non-inferiority in terms of clinical outcomes). New ideas and paradigms are emerging and the industry should perhaps increase its focus on left main disease because the vessel is large, access is very clause and there is more extension of the disease in a large SB.

Conclusion

There are many dedicated devices for the treatment of bifurcation lesions. All have interesting approaches which may improve a particular aspect without solving all technical problems. The availability of a dedicated stent customised for every type of bifurcation lesion is still a dream. The provisional SB stenting approach remains the gold standard strategy. In order to be routinely used, dedicated stents must improve procedural outcome by simplifying the intervention and enhancing its safety. These criteria must be fulfilled for these dedicated devices to gain wider acceptance.

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