Review article

Dedicated bifurcation stents

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A B S T R A C T

Bifurcation percutaneous coronary intervention (PCI) is still a difficult call for the interventionist despite advancements in the instrumentation, technical skill and the imaging modalities. With major cardiac events relate to the side-branch (SB) compromise, the concept and practice of dedicated bifurcation stents seems exciting. Several designs of such dedicated stents are currently undergoing trials. This novel concept and pristine technology offers new hope notwithstanding the fact that we need to go a long way in widespread acceptance and practice of these gadgets. Some of these designs even though looks enterprising, the mere complex delivering technique and the demanding knowledge of the exact coronary anatomy makes their routine use challenging.

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Introduction

Coronary bifurcations vary not only in basal anatomy (plaque burden, plaque location, angle, branch diameter, and site) but also in dynamic anatomical changes during treatment (plaque shift, dissection, and carina modification). The search for an optimal approach to treat this subset of lesions has resulted in the introduction of different techniques (each with its own advantages and disadvantages). However, no two bifurcations are identical and no single strategy exists that can be applied to every bifurcation. In the past few years, significant advancements have occurred in our understanding and treatment of bifurcation lesions.¹ These may include:

1. Introduction of drug-eluting stents (DES).
2. Use of single stent strategy more often than double stents.
3. Acceptance of a suboptimal result in the side-branch (SB).
4. Performance of high pressure post dilation, kissing inflation, and use of intravascular ultrasound (IVUS).
5. Introduction of drug-eluting balloons especially for SB ostium.

Bifurcation percutaneous coronary intervention (PCI) has moved past an important milestone in accepting single stent strategy being the best for most of the bifurcations. The adoption of two stent strategy may be considered in the case of a large SB with ostial lesion, dissection of SB, significant

pinching with decreased flow, etc. The different stenting techniques have been boiled down to largely provisional T-stenting. Whatever may be the strategy, the outcomes of bifurcation have largely improved thanks to the above mentioned advancements.

Recent studies on bifurcation percutaneous coronary intervention

In the last few years the optimal stenting strategy has been an area of considerable debate in bifurcation PCI. In order to clarify the best bifurcation PCI approach between 'provisional' T-stenting of implanting only one-DES (1 DES) in the main-branch (MB) vs a two-DES approach with routine stenting of both bifurcation branches (MB and SB), a number of studies and randomised controlled trials (RCT) have been performed.^{1–3} The 'Randomised Study of the Crush Technique Versus Provisional Side-Branch Stenting in True Coronary Bifurcations (CACTUS Study)' was a prospective, randomised, multicentre study enrolling 350 patients was designed to assess whether elective stenting of both branches (by the use of Crush technique), which can be more technically demanding, provides greater benefits than the simple approach of stenting only the MB (provisional T-stenting) with additional stenting on the SB only in the case of unsatisfactory result at that site. Of the 350 patients, 177 were enrolled in the Crush arm while 173 in the provisional group. The true bifurcation

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lesions were 94% of which 75% were type 1,1,1 according to the Medina classification.⁴ The two groups were well matched for clinical characteristics and no differences were found in the distribution of true and non-true bifurcations. Of interest, is the fact that in the provisional group an additional stent implantation in 31% of cases was required for the following reasons: thrombolysis in myocardial infarction (TIMI) flow <3 (1.9%); significant residual stenosis (72%), and flow limiting dissection in the SB (39%). At 6-months follow-up no significant differences were found regarding the primary endpoint: cumulative major adverse cardiac event (MACE) rate was 15.8% in the Crush group vs 15% in the provisional group ($P=0.95$). Of interest the performance of final kissing balloon inflation (FKI) compared with no FKI was associated in both groups with: significantly lower incidence of in-hospital and follow-up myocardial infarction (MI) (7.5% FKI vs 29% no FKI, $P<0.001$) and angiographic restenosis in the MB (4.7% FKI vs 16% no FKI, $P=0.03$) and in the SB (11.9% vs 36%, $P<0.001$).

This study has demonstrated that in most true bifurcations, a provisional strategy is effective with the necessity to implant a second stent in the SB in about one-third of cases. The Crush technique did not appear to be associated with higher incidence of adverse events despite the limited follow-up time of 6 months. Data from the CACTUS study and other randomised trials⁴ supports at present that the general recommended strategy in coronary bifurcation treatment is provisional SB stenting.^{5–8} However, a number of coronary bifurcation lesions need stent implantation in both the SB and MB. Many techniques are used during the everyday clinical practice of which the Crush⁷ and Culotte⁸ outcomes.⁹

More definitive data regarding the use of one stent or two stent strategy in bifurcation angioplasty with DESs has come from the prospective randomised NORDIC study. This was a landmark trial in which strategy of stenting both the main vessel (MV) and the SB was compared with a strategy of stenting the MV only, with optional stenting of the SB (MV), with sirolimus-eluting stents. In the MV group, the main treatment principles were (1) stenting of MV; (2) SB dilation if there was TIMI flow <3 in the SB; and (3) SB stenting if TIMI flow 0 in the SB after dilation. In the MV/SB group, the main treatment principles were stenting of both the MV and the SB by application of the Crush or Culotte technique. In all cases of SB stenting, the operator was required to attempt 'kissing balloon' dilation at the end of the procedure. A total of 413 patients with a bifurcation lesion were randomised. The primary end-point was a MACE: cardiac death, MI, target vessel revascularisation (TVR), or stent thrombosis after 6 months. At 6 months, there were no significant differences in rates of MACE between the groups (MV/SB 3.4%, MV 2.9%; $P=NS$). In the MV/SB group, there were significantly longer procedure and fluoroscopy times, higher contrast volumes, and higher rates of procedure-related increases in biomarkers of myocardial injury. A total of 307 patients had a quantitative coronary assessment at the index procedure and after 8 months. The combined angiographic end point of diameter stenosis >50% of MV and occlusion of the SB after 8 months was found in 5.3% in the MV group and 5.1% in the MV/SB group ($P=NS$). Independent of stenting strategy, excellent clinical and

angiographic results were obtained with percutaneous treatment of de novo coronary artery bifurcation lesions with sirolimus-eluting stents. The simple stenting strategy used in the MV group was associated with reduced procedure and fluoroscopy times and lower rates of procedure-related biomarker elevation. Therefore, this strategy can be recommended as the routine bifurcation stenting technique. The study again underscoring the fact that most of the bifurcations can be managed with a provisional stenting strategy with optional second stent. However, there are lesions with a large SB (like left main bifurcation) where a planned two stent strategy should be selected.

The study by Erglis et al. is the first randomised clinical and angiographic comparison of 2-DES bifurcation techniques: Crush vs the Culotte.⁹ A total of 424 patients were randomised to Crush ($n=209$) and Culotte ($n=215$) stenting. The 2 groups were well balanced regarding baseline clinical characteristics while there were more patients with 'true' bifurcation lesions (as type 1,1,1; 1,0,1; 0,1,1) in the Culotte group (82.3% vs 73.3%, $P=0.03$). No differences were found in procedure time, fluoroscopy time, and volume of contrast used while FKI was performed in significantly less patients in the Crush group (85% vs 92%, $P=0.03$). At 6-months follow-up there were no differences regarding cumulative MACE rate: 4.3% in Crush vs 3.7% in Culotte; $P=0.87$. There were no differences in the other clinical event rates either: cardiac death 1% vs 0.5%, MI 1.9% vs 1.4%, TVR 2.4% vs 2.8% and ST 1.4% vs 1.9%. Complete angiographic follow-up was available in 88% of patients and there was a trend to less in segment restenosis at 8-months follow-up because of significantly reduced SB in-stent restenosis in Culotte treated patients (9.8% Crush vs 3.8% Culotte, $P=0.04$). These results showed that both Culotte and Crush were associated with excellent clinical and angiographic results and even though Culotte tended to have lower angiographic restenosis rates, neither of the 2 techniques can be claimed to be absolutely superior to the other. Data from NORDIC II Stent Study have demonstrated that a 2-DES strategy (Crush or Culotte) is associated with excellent clinical and angiographic results and should be considered in the treatment of large SBs where suboptimal angiographic results could be associated with subsequent clinical problems.

The importance of FKI in reducing late loss and restenosis, especially at the SB, has been repeatedly demonstrated and has now become standard in the performance of all two stent techniques.^{9,10} However, whether FKI is mandatory with provisional stenting is still unsettled. The 'Nordic-Baltic Bifurcation III Study: A Prospective Randomised Trial of Side-Branch Dilatation Strategies in Patients with Coronary Bifurcation Lesions Undergoing Treatment with a Single Stent' was presented by Niemela at transcatheter cardiovascular therapeutics (TCT) 2009 conference. This study had the purpose of evaluate the outcome of two SB strategies (no-FKI vs FKI) in coronary bifurcation lesions treated with MB stenting using sirolimus-eluting stents (SES). A total of 477 patients were randomised to no-FKI ($n=239$) and FKI (238). The groups were well matched in terms of clinical and angiographic baseline characteristics. However, it should be noted that only about half of the bifurcations treated were true bifurcations (51.8% no-FKI group

vs 54.6% FKI group) and the SB stenosis was not severe ($39.4 \pm 34.4\%$ no-FKI vs $40.3 \pm 34.4\%$ FKI group). At 6-months follow-up, no differences were found in the primary endpoint of cumulative MACE (2.9% vs 2.9%) between the two groups (cardiac death: 0% vs 0.8%, index lesion MI: 2.2% vs 0%, target lesion revascularisation (TLR) 2.1% vs 1.3% and ST 0.4% vs 0.4%, in the no-FKI and FKI groups, respectively). These results showed that in bifurcation lesions, a strategy of routine FKI of the SB through the MB stent did not improve the 6-months clinical outcomes as compared to a strategy of no FKI. The recently published Korean CORBIS registry also has shown routine final kissing inflation with single stent technique do more harm than good.¹¹ 'TIMI Flow-Guided Concept to Treat Side-Branched in Bifurcation Lesions—A Prospective Randomised Clinical Study (Thueringer Bifurcation Study, The THUEBIUS as Pilot Trial)' was designed to assess whether treating the SB only when TIMI flow was 0 or 1 and/or the patient had angina was not inferior to routine FKI-PCI. One hundred and ten patients with bifurcation lesions undergoing provisional-T-stenting were randomly assigned to two arms: (A) stenting of the MB and FKI-PCI (simultaneous or sequential balloon angioplasty) in 56 patients; and (B) stenting of the MB and SB dilatation only if there was SB TIMI flow 0 or 1 or if the patient complained angina after deployment of the MB stent (54 patients). In both groups, inserting a guide wire in the SB was mandatory. The bifurcation site most often treated was left anterior descending artery-diagonal (81%) while most of patients had true bifurcation at visual assessment. According to the study protocol, PCI of the SB was performed in 82.1% in A group vs 16.7% in B group ($P < 0.05$). No difference in periprocedural MI were found (4.6% group A vs 2.9% group B, $P = 0.52$). At 6-months follow-up no significant differences were found in: TLR (primary endpoint) 17.9% vs 14.8% ($P = 0.67$); MACE 23.2% vs 24.1% ($P = 0.92$) and ST 3.6% vs 3.7% ($P = 0.97$), in groups A and B, respectively.

These results showed no differences between the two treatment approaches and suggested a simple strategy with only 'keep it open' of the SB if the final SB TIMI flow was 2 and the patient is asymptomatic.²¹ However, it must be acknowledged that this study was markedly underpowered for detecting differences in clinical endpoints. As we have seen SB ostium is still a central point in the debate of bifurcation lesions PCI while it is the most common restenotic site in this subset of lesion. The specific mechanism underlying restenosis at SB ostium is at the moment not completely clear and presumably many factors are involved.^{1,8,11–13}

The British Bifurcation Coronary study¹⁴ randomised 500 patients with coronary bifurcation lesion for simple or complex strategy using Paclitaxel DES. The simple group had provisional stenting where as the complex group had crush or Culotte technique with two DES. In the simple group ($n = 250$), 66 patients (26%) had kissing balloons in addition to MV stenting, and 7 (3%) had T stenting. In the complex group ($n = 250$), 89% of Culotte ($n = 75$) and 72% of Crush ($n = 169$) cases were completed successfully with final kissing balloon inflations. The primary end-point (a composite at 9 months of death, MI, and target vessel failure) occurred in 8% of the simple group versus 15.2% of the complex group (hazard ratio

2.02, 95% CI 1.17–3.47, $P = 0.009$). The MI occurred in 3.6% vs 11.2%, respectively ($P = 0.001$), and in-hospital major adverse cardiovascular events occurred in 2% vs 8% ($P = 0.002$), respectively. The study concluded with recommending provisional stenting for majority of bifurcations.

The rationale for dedicated bifurcation stents

The conventional approach to bifurcation PCI (with either single or double stents) still has a number of limitations such as the following^{15–20}:

1. Maintaining access to SB throughout the procedure.
2. MB stent struts jailing SB resulting in difficulty in re-wiring SB or passing balloon/stent into SB through the stent struts.^{21,22}
3. Distortion of MB stent by SB dilatation; inability to fully cover and scaffold ostium of SB.
4. Inability of stent structure to withstand SB balloon dilatation and deformation.
5. Operator skills and technical experience.

Clearly bifurcation PCI is technically challenging and time-consuming especially in order to achieve an optimal long-term result.²³ As a result, several stents have been specifically designed for bifurcations with the intention of addressing these shortcomings. However, the first generation of these dedicated bifurcation stents were difficult to deploy as they were stiff and accurate positioning of the stent at the SB ostium was tricky. Many also had larger crossing profiles and less flexibility compared with conventional stents, so that they were difficult to deliver in tortuous or calcified arteries. It is hoped that the newer generation of bifurcation stents will overcome these drawbacks.

The design and technique

The currently available (or under investigation) dedicated bifurcation stents can be broadly divided into:

1. Stents for provisional SB stenting that facilitate or maintain access to the SB after MB stenting and do not require re-crossing of MB stent struts—Petal (Boston Scientific, Natick, MA, USA); Invatec (Invatec S.r.l., Brescia, Italy); Antares (Trireme Medical Inc, CA, USA); Y-med Sidekick (Y-med Inc, San Diego, CA, 142 USA); Nile Croco (Minvasys, Genevilliers, France); Multilink Frontier (Abbott Vascular Devices, Redwood City, CA/Guidant Corporation, Santa Clara, CA, USA). These stents allow the placement of a second stent on the SB if needed.
2. Side-branch stenting and then MB stent implanted in the bifurcation and requires re-crossing—Sideguard (Cappella Inc, MA, USA); Tryton (Tryton Medical, MA, USA); Axxess Plus (Devax, Irvine, California). The Tryton and Sideguard are designed to treat the SB first and require re-crossing into the SB after MB stenting for FKI. The Axxess Plus is the exception as it is planted in the proximal MB at the level of the carina and does not require re-crossing into the SB but may require the additional implantation of two further

stents to completely treat some types of bifurcation lesions.

The stent delivery systems (SDS) of these dedicated bifurcation systems have a number of design features in common, which explains both their strengths and weaknesses:

- a. Double balloons SDS has to be tracked over two wires and thus, wire wrap (twisting) is a common problem but the stent is implanted by simultaneous kissing inflation possibly resulting in shorter procedure times. However, these devices still tend to be bulkier than single balloon SDS requiring guide catheters larger than the standard 6F and limiting their use in calcified lesions and tortuous vessels.
- b. Stents with a preformed SB aperture maintain access to the SB during MB stenting but successful implantation is dependent on accurate positioning with very little tolerance for incorrect placement.
- c. The SDS with a side hole has axial and rotational self-positioning properties, i.e.
  - Axial: SDS has a 'stopper' to position the side cell at the SB level, closest to the carina.
  - Rotational: SDS automatically turns the side hole exactly towards SB.
- d. The Nile, Frontier, Twin-Rail, Sidekick, and Stentys SDS have struts that only partially cover the ostium and thus, leave the potential for a gap and ostial restenosis.
- e. Stents that have struts that can be expanded into SB ostium (Petal, Ariste) may be clinically advantageous as they provide complete coverage of the SB orifice and offer the possibility of delivering drug to the SB ostium.
- f. Side-branch specific stents commit the operator to stenting both branches.
- g. Unfortunately, most are still bare-metal stents (BMS) but with DES currently under development in the majority.

In this review, we will describe each of these devices in detail, including their unique design features, implantation technique, and available clinical results regarding their implantation in humans.

Y-med Sidekick (Y-med Inc, San Diego, CA, USA)

The Sidekick (Figure 1) is a low-profile 6F guide compatible SDS that integrates a MB fixed-wire platform with a rapid-exchange steerable SB guide wire designed to preserve SB access during bifurcation stenting. There are three models with different exit ports (proximal, mid, and distal) that are selected depending on the location of the disease in the bifurcation; e.g. proximal exit port for lesion distal to bifurcation or ostial lesion. When the device is close to the carina, a guide wire is passed through the SB exit port and MB stent struts into the SB, thus avoiding re-crossing into the SB. Various BMS designs and even a DES platform are currently under investigation. A first-in-man (FIM) clinical study has been performed by Dr. T. Ischinger and Dr. E. Grube has in 17 patients with 20 lesions.²⁴ The device success rate was 80% and an additional stent was required in 40% of cases. During the short follow-up period (68–32 days), there was 1 MACE due to a subacute stent thrombosis.

Figure 1 Y-med Sidekick stent.

Figure 2 Multilink Frontier stent.

Multilink Frontier (Abbott Vascular Devices, CA/Guidant Corporation, Santa Clara, CA, USA)

The Multilink (ML) Frontier coronary stent system (Figure 2) is a balloon expandable stainless steel stent premounted on a dedicated delivery system with two balloons (monorail for MB and over-the-wire inner lumen for SB) and two guide wire lumens. To assist tracking and avoid guide wire crossing, the ML Frontier has an integrated-tip design that allows single tip delivery—the MB balloon tip includes a pocket on the distal sleeve for joining the MB and SB balloon tips with a mandrel. The ML Frontier is advanced into MB over a conventional wire. The joining mandrel is retracted, releasing the over-the-wire SB tip and a 300-cm wire is inserted into the SB balloon lumen and into the SB. The system is advanced to the carina and simultaneous kissing inflation of the two balloons is performed, using a single inflator, to expand the stent into the MB and SB. The Frontier stent multicentre registry evaluated the safety and performance of this device in 105 patients.²⁵ Device success was 91% and procedural success 93%. Two patients suffered an in-hospital MI secondary to SB occlusion. The late loss for the ML Frontier was 0.84–0.55 mm and the overall bifurcation restenosis rate (44.8%) was high (MB: 29.9%, SB: 29.1%). At 6-months follow-up, the TLR and MACE rates were 13.3% and 17.1%, respectively. The next-generation

Figure 3 Inverted Twin-rail stent.

of the ML Frontier will be a chromium cobalt stent with the Xience V drug-eluting stent platform (i.e. Everolimus on a non-erodible acrylic and fluoro polymer).

The Inverted Twin-Rail (Invatec S.r.l., Brescia, Italy)

The Inverted Twin-Rail (Figure 3) is a slotted tube, 316L stainless steel stent premounted on double balloons in its proximal portion, and only on the MB balloon in its distal portion. The stent has a closed cell type design with variable stent geometry. This 6F-compatible system consists of a single dual lumen catheter splitting into two distal balloons with a central stopper that prevents further advancement of the SDS when the carina is reached. The stent is deployed by simultaneous kissing inflation with a single inflator. The Twin-Rail is similar to the ML Frontier double balloon system except that in the latter the SB balloon is a short tapered balloon while in the Twin-Rail there is a full dilatation balloon. In the DESIRE Trial, presented by Dr. Lefevre at TCT 2005, the Twin-Rail double balloon SDS was compared to a single balloon SDS in 20 patients.²⁶ Although angiographic success was high, device success was only 75% with the Twin-Rail and there was a high rate of guide wire criss-cross with both devices. The TLR rate for the Twin-Rail was 14.3% at 7 months. In this small pilot study, there was also a trend for higher device success and better safety profile with the Twin-Rail compared to a single balloon SDS.

Nile Croco (Minvasys, Genevilliers, France)

The Nile Croco (Figure 4) is a double balloon SDS similar to the ML Frontier and Twin-Rail but unlike these latter SDS's that are a single catheter with single inflation port, the Nile Croco has two independent yet joined catheters that require independent manipulation and pressure monitoring. The two parallel rapid-exchange catheters are premounted with a chromium cobalt stent crimped on the MB balloon and the tip of the SB balloon. The MB balloon has three markers with the central marker indicating the position of the SB aperture. After the stent is deployed into the MB, the SB balloon is advanced into the SB and a final kissing inflation is performed.

Figure 4 Nile Croco stent.

Figure 5 Advanced stent technologies SLK stent.

The feasibility, safety and efficacy of bifurcation stenting using the Nile stent is currently being evaluated in the multicentre (10 European centres) Nile Registry. Preliminary results of the first 75 patients showed a procedural success rate of 94.7% and a MACE rate of 10.7% in the 45 patients in whom follow-up was available at 7 months.

Advanced Stent Technologies SLK-view (AST, Pleasanton, CA)

The SLK-view (Figure 5) is a stainless steel flexible slotted tube stent with a side aperture located between the proximal and distal section to facilitate access to the SB after deployment of the stent in the MB. The delivery system has a dual over-the-wire design with a proximal dual lumen shaft that separates into two catheters (a balloon and a side-sheath) at its distal segment. The stent is premounted in the distal segment of delivery system with the side-sheath running under the proximal segment of the stent and exiting through the side hole. There are total of three radio-opaque markers on the balloon, located at the centre, proximal and distal edges. The SLK-view system is placed over two wires simultaneously and advanced to the bifurcation until the centre marker band is aligned to the branch vessel and the side-sheath marker separates from the centre marker. The SLK-view stent is then deployed in the MB leaving the pre-formed side hole positioned at the ostium. Unlike the petal or Antares stents,

Figure 6 Petal stent.

there are no stent struts protruding into and scaffolding the ostium. In a multicentre non-randomised study, Ikeno et al. report the 'Acute and Long-Term Outcomes of the Novel Side Access (SLK-view) Stent for Bifurcation Coronary Lesions' in 81 patients with 84 de novo bifurcation lesions.²⁷ The study proved the feasibility of this stent with high procedural success rates (97.6%) while maintaining SB access in all treated lesions. However, the SLK-view bare-metal stent was associated with a high restenosis rate (MB: 28.3%, SB: 37.7%) and TLR rate (21%) at 6 months follow-up.

Petal (Boston Scientific, Natick, MA, USA)

The petal stent (Figure 6), with a side aperture located mid-stent and deployable struts (a 'sleeve') may be an attractive solution to prevent SB occlusion after MB stenting. A guide wire is placed in the MB and another in the SB. The dual side-exchange (double balloon) delivery system has a main lumen that guides the catheter to the primary lesion over-the MB guide wire. The secondary lumen (side-sheath) facilitates proper alignment of the aperture to the SB ostium as it tracks over-the SB guide wire. In addition to a conventional cylindrical-shaped balloon, there is a secondary elliptical balloon adjacent to the main balloon and connected to the same inflation lumen so that a single inflation device is needed. The petal stent is crimped over both balloons such that the elliptical balloon is under the side aperture and petal elements. Upon inflation, the main balloon deploys the stent into the MB, while the elliptical balloon deploys the petal elements into the SB ostium. The purpose of the 'petal' aperture is to retain access to the SB during and after deployment and to scaffold the SB ostium with outwardly-deploying strut elements that extend up to 2 mm into the branch during deployment. This unique feature has potential for delivery of anti-proliferative drug to the most common site of bifurcation restenosis. The 1st generation of this stent, called AST petal, developed by Advanced Stent Technologies was a 316L stainless steel slotted tube design. The FIM experience with the AST petal dedicated bifurcation stent has been reported by Ormiston et al.²⁸ In this pilot study, the AST petal was successfully implanted in 12 of 13 patients. In nine patients,

Figure 7 Antares side-branch adaptive stent.

an additional stent was required in the bifurcation and the TLR rate was 15% at 6 months. The petal stent was acquired by Boston Scientific in 2004 and modified into the Taxus petal stent. This 2nd generation petal stent is a platinum chromium alloy stent which is coated with Paclitaxel on a Translate polymer [poly(styrene-*b*-isobutylene-*b*-styrene)]. The platinum chromium is superior to its stainless steel predecessor in that the new alloy allows even thinner stent struts with increased flexibility and radiopacity. In July 2007, the TAXUS PETAL I First Human Use (FHU) trial commenced with the successful implantation of the stent into the first patient by Dr. John Ormiston in Auckland, New Zealand. The TAXUS PETAL I FHU non-randomised trial will enrol a total of 45 patients in New Zealand, France and Germany to assess the acute performance and safety (death, MI, TVR) at 30 days and 6 months, as well as continued annual follow-up for 5 years.

Antares side-branch adaptive stent (Tireme Medical Inc, CA, USA)

The Antares side-branch adaptive stent (SAS) (Figure 7) with automatic SB support deployment consists of a single balloon expandable stainless steel stent. It has a SB support structure in the centre of the stent provided with four radio-opaque tantalum markers for positioning and orienting at the bifurcation site. Stent deployment is achieved using a single rapid-exchange balloon catheter and a SB stabilising wire encased in a peel away lumen to minimise wire crossing. As the stent approaches the targeted bifurcation, the catheter is torqued to align the stent central opening with the SB ostium. The SB wire is advanced into the ostium thus assisting with accurate placement and facilitating access after MB stent deployment. Upon expansion of the main stent body, the ostial crown is automatically deployed with elements protruding approximately 2 mm into the SB to scaffold the ostium. The Antares is very similar to the petal stent but has the advantage of tracking over a single wire and unlike the petal that uses a balloon to expand the SB elements,

Figure 8 Sideguard stent.

they expand automatically with this stent. A FIM study conducted by Dr. Alexander Abizaid is currently underway.

Sideguard (Cappella Inc, MA, USA)

The Sideguard (Figure 8) ostium protection device is a self-expanding trumpet shaped nitinol stent that is deployed using a special balloon release sheath system. It is currently a bare-metal stent but the next-generation will be drug-eluting with a biodegradable polymer. The Sideguard's trumpet shaped design helps the stent conform to the ostium allowing for complete stent-to-wall apposition, optimizing scaffolding, and drug delivery. Its short length, self-expandable nitinol system, low-profile (<3.5 Fr) delivery system allows greater navigability even in very tortuous anatomy. Radio-opaque markers located at the distal and proximal ends of the Sideguard delivery system facilitate positioning of the stent at the SB ostium. The stent is deployed using a nominal pressure balloon, which helps tear a protective sheath that keeps the Sideguard in place until deployment. Once released, the Sideguard self-expands into place. The delivery system and the guide wire are then removed from the SB. A conventional stent is then placed in the MB, the SB is re-accessed with a guide wire and the procedure is completed with a standard FKI. At TCT 2007, Dr. Grube presented the 6 months follow-up data from the first 16 patients enrolled in Cappella's FIM multicentre clinical trial (SG-1). In 14 patients, the Sideguard was successfully implanted in the SB and a Cypher was implanted in the MB. At 6-months, the TLR rate was 12.5% (2/16) and there were no cases of stent thrombosis.²⁹

Tryton (Tryton Medical, MA, USA)

The Tryton SB stent (Figure 9) is a slotted tube, cobalt chromium balloon expandable stent designed to be implanted in the SB of a bifurcation. The stent consists of three zones: a distal SB zone (that treats the disease in the SB); a transition zone (positioned at the SB ostium); and a MB zone. The central transition zone has a specific geometry, which contains

Figure 9 Tryton stent.

three panels, each of which can be deformed in an independent fashion. The proximal MV zone is composed of three fronds that are connected proximally to the transitional panel and terminate in a circumferential band and the distal zone has the design characteristics of a standard slotted tube workhorse stent. Treatment of a bifurcation with the Tryton stent generally commits the operator to implanting two stents in the bifurcation and the technique is identical to the approach when performing the Culotte technique. The Tryton stent is deployed across the SB ostium first. The initial FIM experience has shown that predilatation of the Tryton is essential to allow a MB stent to be advanced through the Tryton struts.³⁰ A standard MV stent is then tracked through the proximal MV zone of the Tryton into the distal MV and deployed. The MB stent struts then have to be re-crossed in order to perform a FKI. In the 'Tryton I, FIM Study: acute and 30 day outcome', Kaplan et al. report the results of the first 30 patients treated with the Tryton SB stent in conjunction with a standard DES.³⁰ The Tryton was successfully implanted in all but one patient (96.7% angiographic success) and at 30 days follow-up two patients had experienced a MACE.

Stentys (Stentys SAS, Clichy, France)

The Stentys (Figure 10) bifurcated drug-eluting stent reported by Dr. Laborde and associates in the 'Stentys coronary bifurcation stent' the first of the next-generation bifurcation stents developed by Jacques Soguin the founder of the Devax Axxess stent. The Stentys is a self-expanding nitinol stent made of Z-shaped mesh linked by small interconnections.³¹ The stent is coated on the abluminal side with Paclitaxel on a durable polymer matrix (PESU), a polysulphone that permits controlled drug-elution.²⁸ The unique feature of this stent is the ability to disconnect the stent struts with an angioplasty balloon. Thus, an opening for the SB can be created anywhere in the stent after it is implanted in the vessel while at the same time the disconnected struts scaffold the SB ostium. Thus, in comparison to the implantation of some of the other bifurcation stents such as the petal and the Antares, the procedural success is not dependant on accurate positioning of the stent and there is significant placement tolerance with

the Stentys. However, it would appear from the design that the disconnected struts only partially scaffold the ostium. The implantation procedure is performed in three steps: (1) Stentys is implanted in the MV with an approximate positioning, like a standard stent; (2) optimal location for the SB opening is chosen by inserting a balloon through the stent mesh; and (3) the balloon inflation disconnects the mesh and creates the opening. It is hoped that the self-expanding property of the stent will allow in situ modelling of the stent to fit the patient's unique arterial anatomy. However, it is not known if the Stentys is more prone to stent fracture due to its disconnectable strut design. The FIM study with the Stentys bifurcation stent was initiated in September 2007 with the successful implantation of the Stentys by Dr. Eberhard Grube in a 56-year-old male patient at the HELIOS Heart Centre in Siegburg, Germany.³²

Figure 10 Stentys stent.

Axxess Plus (Devax, Irvine, California, USA)

The Axxess Plus stent (Figure 11) is the first of these dedicated bifurcation stents designed to elute an *anti-restenotic drug*. It delivers *Biolimus-A9*, a sirolimus derivative via a bio-erodable polylactic acid polymer carrier. The Axxess Plus is a self-expanding, nickel-titanium, and conically shaped stent that is placed at the level of the carina. It has a rapid-exchange delivery system with hydrophilic coating with controlled deployment upon withdrawal of a cover sheath using the actuator. In the study, Six-Month Clinical and Angiographic Results of a Dedicated Drug-Eluting Stent for the Treatment of Coronary Bifurcation Narrowings, Grube et al. report the results of the prospective multicentre single-arm Axxess Plus trial that enrolled 139 patients.³³ The Axxess stent was successfully implanted in the MB in 93.5% of cases with 80% of the patients receiving an additional stent to the MB or SB. At 6-months follow-up, the in-stent late loss was 0.09–0.56 mm and the overall TLR was 7.5% confirming the feasibility and efficacy of a dedicated bifurcation stent. In the multicentre AXXENT Trial,³² the safety and efficacy of the Axxess Plus stent in the left main coronary artery was evaluated in 33 patients using a 3 stent technique of implanting the Axxess in the distal left main and 2 Cypher stents in the left anterior descending and circumflex arteries. At 6-months follow-up, there was minimal late loss (0.043–0.32 mm) and no restenosis in the Axxess stent, whereas there the restenosis rate was 6.9% for the left anterior descending artery and 16.1% for the circumflex artery. The overall TLR rate was 9.1% and there were no cases of stent thrombosis in this small pilot study. Currently, the Axxess Plus stent is being analysed in the DIVERGE Trial, a 600-patient study at 40 centres in the US,

Figure 11 Axxess plus stent.

Europe, Australia, and New Zealand. However, the Axxess stent is limited by the fact that it needs to be precisely nested at the carina to be effective and in majority cases will need another stent to fully treat the bifurcation.

Conclusion

The dedicated bifurcation stents opens out a new array of highly innovative technology in to catheterisation laboratory, which requires skilful expertise to handle given the complexities in the design and technique. It is definitively a step forwards, but long-term large volume clinical trials are warranted before reaching a solid conclusion. Given the dynamicity and the individual variations in the coronary bifurcation anatomy, it is logical to think whether the dedicated stents do really dedicate themselves to all patients.

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