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Consensus from the 5th European Bifurcation Club meeting

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Introduction

A bifurcation coronary lesion is a lesion occurring at, or adjacent to, a significant division of a major epicardial coronary artery.¹ These lesions remain complex for the interventionist. During the last 12 months, several important trials have reported with the emphasis that “simpler is better”. This paper covers the consensus from the 5th European Bifurcation Club meeting in Berlin, October 2009.

Recent publications of note

During the year since the last EBC meeting, five publications of note regarding randomised analysis of stenting bifurcation coronary lesions have appeared.

The first was the NORDIC complex bifurcation stenting study.² In this study, 424 patients were randomly allocated to receive either crush or culotte sirolimus-eluting stents at coronary bifurcation lesions, 77% of which were “true” coronary bifurcation lesions (≥50% lesion in both branches). At six months clinical follow-up, there was no difference between the two groups in terms of death, post-procedure MI or revascularisation (crush 4.3% vs culotte 3.7%). However, the incidence of periprocedural MI was significantly higher in the crush group (crush 15.5% vs culotte

8.8%) as was the occurrence of in-stent restenosis (crush 10.5% vs culotte 4.5%).

The second was the BBC ONE study.³ In this trial, 500 patients were randomly allocated to either a simple strategy (minimalist provisional T) or a complex strategy (crush or culotte) using paclitaxel-eluting stents. At nine months clinical follow-up, there was a significant difference between the two groups in terms of death, MI or revascularisation (simple 8.0% vs complex 15.5%). This difference was largely driven by the higher incidence of myocardial infarction in the complex group (11.2% vs 3.6%, $p=0.001$).

The third trial of interest was the CACTUS trial. In this study, 350 patients were randomly allocated to either provisional T or crush stenting. A high proportion of patients (92%) had true bifurcations, and 31% in the provisional T group progressed to dual vessel stenting. The primary clinical outcome (death, MI, revascularisation) was equivalent in both groups (15.0% provisional vs 15.8% crush).⁴

In the fourth trial, Ferenc et al compared 202 patients randomly allocated to either provisional T stenting or routine T stenting. Re-intervention at one year was required in 10.9% vs 8.9% of cases ($p=ns$).⁵

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Finally, NORDIC III was presented at TCT 2009. In this study, patients with coronary bifurcation lesions (52% true) underwent a provisional T stent strategy and were randomised to a final kissing balloon inflation (FKB) or no FKB. In all, 477 patients were recruited, with a 6-month primary clinical endpoint of death, non-procedure-related MI, TLR or stent thrombosis. Of the patients allocated to FKB, 90% had the allocated treatment. The primary endpoint was similar in both groups at 2.9%; procedural CK elevation was seen equally at 18.9%. The conclusion was that routine use of kissing balloon inflations did not improve early clinical outcome, but neither was there a penalty for undertaking FKB where deemed appropriate.⁶

The consensus from the year's randomised trial data was therefore that routine two vessel stenting did not improve either angiographic or clinical outcomes for most patients with coronary bifurcation lesions. Depending on one's view of the importance of periprocedural CK elevation, it could also be argued that routine dual vessel stenting did not involve a significant penalty either. Equally, kissing balloon inflations appeared neither beneficial nor harmful, but could justifiably be undertaken at the operator's discretion.

The year was also marked by the appearance of a number of poor quality "meta-analyses" which used simply abstract or grouped patient data, but did not have access to patient level information. This kind of assessment can be misleading.⁷

The EBC consensus was that further studies were required. The first area concerns large calibre true bifurcations with significant ostial side branch length disease. These lesions are currently considered by most experts to require a systematic two-stent strategy, but evidence to support this approach is lacking. The second area is the perennial thorny issue of the O,O,1 lesion. An EBC Registry has been set up for the interventional management of such cases.

Specific areas of interest were discussed in detail during the two-day EBC meeting. A synopsis of these discussions is presented below.

Murray's law

Finet's adaptation of Murray's law calculates that the proximal main vessel diameter is the sum of the daughter vessel diameters (distal main plus side) multiplied by 0.67. This approximation holds good for most coronary vessel diameters. Murrays' law should be born in mind when undertaking coronary angioplasty in view of the fact that the proximal main and distal main vessels are not the same diameter.

– In single stent techniques, the primary stent should be sized according to the distal main vessel diameter.

– Postdilatation, or kissing balloon inflations, are required to optimise the proximal main vessel stent diameter.

The proximal optimisation technique

The proximal optimisation technique (POT) was devised by Darremont, and relates to a method of expanding the stent at the carina, using a short oversized balloon. This produces curved expansion of the stent into the bifurcation point and facilitates

recrossing, distal recrossing, kissing inflations and ostial stent coverage of the side branch. Opinion remains divided as to whether this should be a part of the standard approach to bifurcation lesions, but certainly there was agreement that this should be used in any case of difficulty recrossing into the side branch with either wire or balloon. A dedicated balloon for this purpose is expected soon.

– The POT technique should be used in any case of difficulty recrossing into a side branch with either a wire or balloon.

Side branch diameter and length

These factors are often used as surrogates for muscle mass subtended. Data from swine heart models was presented, indicating that there is indeed a quantitative relationship between both side branch diameter and length and the size of any resulting infarction.

– Side branch diameter and length can both be used visually as surrogates for volume of muscle at risk.

Stent balloon inflation duration

There is evidence that short duration stent balloon inflation times limit complete stent expansion and allow greater immediate recoil. Serial IVUS images with variable duration stent inflation have shown a significant increase in minimal luminal area with increase in inflation time from 10 to 60 seconds.⁸ If a stent appears angiographically undersized, maintaining high pressure inflation for 60 seconds will increase stent expansion by up to 10%.

– Stent balloon inflation duration of 30 seconds minimum is encouraged.

Value of kissing inflations in simple stenting

Nordic III has established that there is no systematic clinical advantage to a routine kissing strategy when a single stent treatment is used. However, there are a number of theoretical reasons why kissing balloon inflations may remain important, not least because of Murray's law and the fact that the distal and proximal main vessel are not the same diameter.

There was significant debate regarding the use of routine kissing inflations, with the club split. There was agreement that in the absence of an angiographically tight lesion at the ostium of the side branch after main vessel stenting, kissing balloon inflations may not be routinely required (with the above proviso). When a tight lesion (>75%) is present in the side branch after main vessel stenting, it is known that a kissing balloon inflation will reduce the physiologically significant proportion from 30% to 5%.⁹ Therefore, two appropriate strategies are either to use a pressure wire to interrogate the significance of the side branch lesion and treat or not accordingly, or, simply to do kissing balloon inflations on all angiographically significant ostial side branch lesions in the knowledge that this reduces the proportion that remain physiologically significant, coupled with the information from NORDIC III that there appears to be no penalty for doing so.

– When using a single stent technique, in the absence of kissing balloon inflations, the proximal main vessel stent should be postdilated to an appropriate diameter.

–Kissing balloon inflations, or pressure wire interrogation, should be used when an angiographically significant (>75%) side branch lesion remains after main vessel stenting.

Stent distortion after kissing balloons in single stent techniques

A stent inevitably becomes distorted after side branch balloon inflation, and this is not fully corrected by kissing balloon inflation.^{10,11} The degree of distortion, and particularly the degree of metal overhang into the main vessel, is dictated mainly by the side branch crossing point, such that distal crossing promotes good ostial side branch coverage but proximal crossing offers little side branch ostial stent coverage and causes metal overhang into the main vessel.¹²

– When rewiring a side branch, efforts should be made to cross the main vessel stent distally, thereby ensuring stent coverage of the ostium of the side branch.

Stent distortion after kissing balloons in two stent techniques

The same principles of distal rewiring of the side branch apply to the use of two stents techniques. However, the reconstruction of the carina by the use of kissing balloon inflation in two stent techniques often results in distortion of the proximal part of the stents. This effect is most pronounced when there are differences in the diameter between the side branch and the main branch. Experience from OCT guided post dilatation in two stent techniques suggest that final proximal high pressure balloon inflation can correct proximal distortion.

–Kissing balloon inflation for carina reconstruction is mandatory in two stent techniques.

–High pressure proximal stent inflation using a short noncompliant balloon should be considered for correction of possible proximal stent distortion after kissing balloon inflation.

Use of non-compliant balloons for kissing

Non-compliant balloons allow high pressure individual and, if necessary, kissing inflations following bifurcation stenting. In the case of single vessel stenting, high pressure ostial side branch dilatation is not usually required and may risk side vessel dissection, but higher pressures can be achieved with a non-compliant balloon without over-dilatation. In the case of dual vessel stenting however, high pressure ostial and main vessel dilatation is mandatory to achieve full stent expansion at the relevant “ostia”, followed by a final lower pressure kissing inflation. New balloon technology means that this can now be achieved simply using two balloons in a 6 Fr guide catheter (e.g., Hiryu, Terumo Corp., Tokyo, Japan).

– Non-compliant balloons are recommended for kissing inflations.

– Individual non-compliant high pressure “ostial” post-inflations are mandatory in complex stenting techniques to achieve full stent expansion.

Importance of CK leaks

Controversy remains about the threshold at which CK release at the time of PCI become prognositically important. There is clear data that high levels of CK release (e.g., >5xULN) are important,^{13,14} but no consensus was reached as to the clinical significance of lower levels of CK release (e.g., CK 3xULN). Clinical data to date do not suggest a significant adverse effect of CK release at this level in the bifurcation lesions studied but long-term data are awaited.

– Periprocedure CK release of >5xULN is prognositically significant.

Atheroma and the carina

At the second EBC meeting, the concept of “plaque shift” was challenged on the basis that plaque is not seen at the carina. The concept of “carina shift” was born. However, data presented by Wentzel et al threw new light on the subject through CT angiography and suggested that the carina does, after all, have some atheroma present in 30% of bifurcations requiring intervention, though the volume of that plaque remains small¹⁵ and plaque only exists at the carina if there is significant volume of plaque at the contralateral walls. The theory was postulated that plaque “grows” circumferentially around a bifurcation from areas of low shear stress to areas of high shear stress.

– Low volume plaque does exist at the carina of a bifurcation lesion in 30% of cases, particularly where overall plaque volume is high.

When to use two stents

Controversy continues to surround this most basic and yet most complex of issues regarding bifurcation vessel stenting. Opinions vary from “Always start with a provisional technique” to “If you need two stents, use two stents, there is no penalty for doing so”. There was consensus however on the basic technique of choice for most simple bifurcations and the situations in which a two-stent technique was likely to be preferred.

– Provisional T stenting remains the gold standard technique for most bifurcations.

– Large side branches with ostial disease extending >5mm from the carina are likely to require a two-stent strategy.

– Side branches whose access is particularly challenging should be secured by stenting once accessed.

Crush technique

Crush stenting has been replaced by mini-crush stenting in the majority of centres. Even so, the unpredictable location of recrossing has a major effect on acute results of crush stenting, with a possible “dead zone” of unstented side branch ostial tissue if recrossing is too proximal. Even in the most experienced centres, rates of complete success with side branch kissing balloon inflations in crush stenting are ~90%, and are lower than for culotte stenting.

– Where two stents are required, the culotte technique, where appropriate, offers some advantages over crush stenting.

Is stent thrombosis more common in two-stent techniques?

Initial studies of two-stent techniques had high rates of stent thrombosis¹⁶ but once the technique was refined to include high pressure postdilatation and final kissing balloon inflations, the evidence from randomised studies did not demonstrate any clear increase in stent thrombosis with two-stent strategies.^{3-5,17} Registry data however consistently suggest that one of the risk factors for stent thrombosis (early, late and very late) is a bifurcation lesion.¹⁸

– Current evidence suggests that an optimal two-stent technique does not predict a significantly higher rate of stent thrombosis.

Angle of bifurcations and outcome

Wider angle bifurcations are unfavourable for two-stent strategies because of the relative inability of stents to conform uniformly to the vessel wall in regions of acute angulation, even with optimal techniques. This applies equally to the left main stem, which commonly has a wide angle bifurcation, as well as to standard bifurcation lesions.

– Bifurcations with angulation of > 60 degrees between the daughter vessels should be approached with single stent strategies where possible.

Dedicated bifurcation stent systems

These remain important areas for development. Neither the provisional T strategy, nor the culotte technique are likely to remain the “gold standard” for bifurcation stenting in the long term and therefore efforts to produce dedicated bifurcation stent delivery systems should be encouraged and research fostered. None of the currently available systems can at the moment challenge the excellent results offered by the provisional T stent strategy in the majority of bifurcation lesions.

– Dedicated bifurcation stent systems remain limited but are likely ultimately to prevail.

Conclusion

The EBC annual meeting remains compact and dedicated to a single topic. As such, it is able to bring together clinicians, engineers and physicists for detailed discussions. The consensus statements from the 5th EBC meeting reflect that unique opportunity.

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