

5. PCI for Left Main Trunk Disease

c) bifurcation lesion

ii) Rota / Cutting balloon / Stent

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1) Introduction

Left Main Trunk (LMT) lesions directly affect patient survival and prognosis. A high-degree of skill is required in the decision making, strategy-selection and in the procedure itself. Since late restenosis may cause death in these patients, perfect procedural practice and detailed follow-up are required. Bifurcation lesions are technically the most challenging of all PCI procedures, and should only be attempted by experienced operators. Here, we will discuss PCI strategy and procedure for LMT bifurcation lesions, including reference to case presentations.

2) Preparation

If the procedure is elective, hospitalization will be for only one day, on the day of Intervention. A few days before PCI, oral ticlopidine and aspirin should be administered to all patients in preparation for stent implantation. Immediately before PCI, an intravenous bolus of 10000 U heparin should be administered. In principle, the femoral approach should be selected. In many cases, LMT bifurcation lesions are highly complicated, and require a flexible approach as strategy may need to be changed during the procedure. For flexibility, a large sheath is ideal because it facilitates the use of any device. In our hospital, where we allow for the possibility of DCA, a large burr rotablator or the simultaneous use of 2 or more balloons, a 10F or 8F sheath is usually inserted by the right femoral approach. When operating at 10F, a long sheath allows the best manipulation.

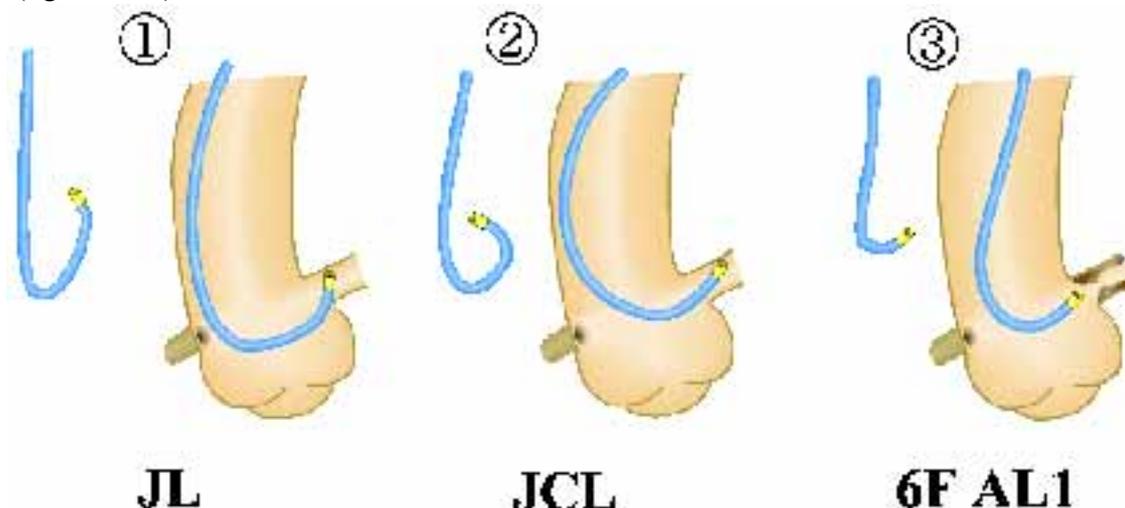
Hemostasis is thought to be complicated by the use of large sheaths but in our hospital, we leave the sheath in for 2 hours and withdraw it when the effect of heparin seems to have dissipated. Complete rest is maintained for 4 hours. In our experience, there is no difference in the risk of repeat bleeding between 7F and 8F sheaths.

An IABP should be used where possible to preserve the hemodynamics, since these procedures are often complex and may take a long time. Also, when necessary, temporary pacing should be available. If the lesion is in the RCA, if there is multivessel disease or an LVEF<40%, a pacing catheter should be inserted from the first as back up.

3) Your Guiding Catheter

a) Guiding Cath Selection: As stated above, a 10F guiding catheter will allow the use of any device. Even if we feel that DCA and large-burr rotablation are unlikely, we use a guiding catheter larger than 8F. With a 10F, we usually use a JCL, while for 8F, a JL or VL that has good support. Approaching via the brachial or radial artery is not ideal for PCI for LMT bifurcation lesions as these approaches limit the devices available to you, and in emergency situations, may present difficulties providing assisted circulation quickly and effectively.

(figure 1 1-3)

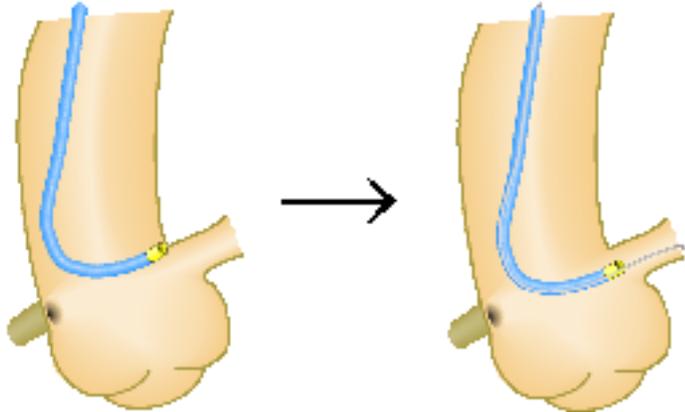


<Figure 1>

1. The standard guiding catheter for the LMT. It is universal and easy to manipulate, even if support is somewhat weak.
2. Compared to the JL, degree of support is strong and the catheter goes relatively deep into the ostium. The shape of the curve is sharper than that of the JL. This type is particularly suitable for bifurcation debulkings.
3. If there is severe stenosis at the LMT ostium, a 6F AL1 may be the best bet (picture 1).

- b) Manipulation: It is not so difficult to insert the guiding catheter as long as the lesion is not at the ostial LMT. Still, inserting 10F guiding catheters may require a degree of experience compared to smaller sized catheters, since torque transfer is delayed and the catheter can seem stiff. Just as for ordinary LCA guiding catheters, rotate the catheter anti-clockwise at the left Sinus of Valsalva and bring the catheter near to the ostium and co-axial to the LMT for engagement. If the diameter of the aorto-ostium is too small for the catheter to engage or so that it gets wedged, adjust the angle of the catheter tip, making it as co-axial as you can, and fix the catheter as near to the ostium as it will go.
(figure1-4)

④



4. If you are having trouble engaging your guiding catheter, position it near the ostium of the LMT. In most cases, the catheter will become co-axial when the guidewire is inserted.

4) Your Guidewire

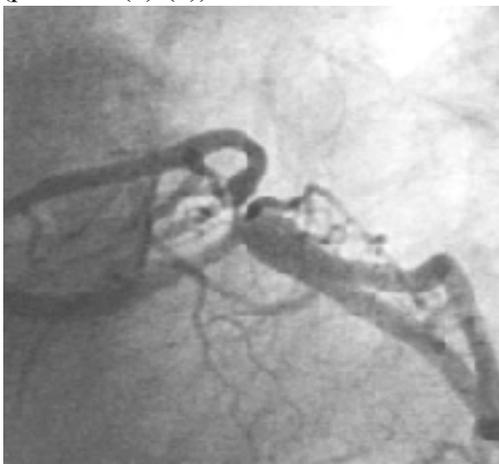
- a) Guidewire Selection: If there is any possibility of your using DCA, for example, go for a guidewire that gives strong support (such as the Grandslam), but otherwise, select your wire according to the distal shape of the artery. Change to a rotawire if and when you use a rotablator.
- b) Manipulation: Insert the wire using straight caudal imaging views until it passes from the LMT ostium to the bifurcation. Once the wire is in the LAD, change the view to RAO or straight cranial and advance the wire to a distal position. After inserting the wire, remember to check the overall image from the RAO view.
During the procedure, insertion of another guidewire to protect the side branch (LAD or LCX) may often be necessary. How to handle the wire in this situation will be set out in each relevant part of the procedure.

5) Intravascular Ultrasound (IVUS)

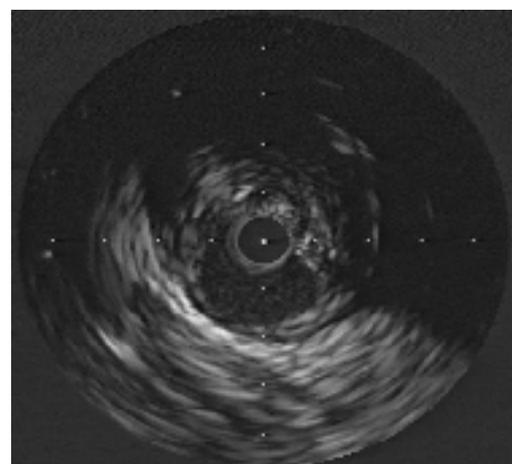
Being in possession of information about vessel diameter, lumen diameter, whether or not there's calcification, plaque volume and distribution is indispensable for determining the type and size of device you will need. IVUS should be used to the full, pre-, during and post-procedure.

6) Standard Strategy

(picture 1 (1)-(4))



(picture 1 (1))

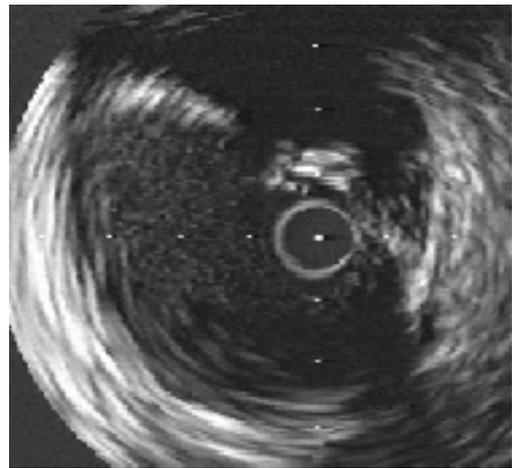


(picture 1 (2))

No or mild calcification (DCA,CB,POBA)-(STENT,KTB)



(picture 1 (3))



(picture 1 (4))

Moderate or severe calcification (Rota,POBA)-(STENT)

Our data shows that as acute post-procedural luminal cross sectional area (CSA) goes up, and % plaque area down (measured by IVUS), the TLR rates also fall (details will appear later). Strategy should be determined according to these two goals; 1) reducing plaque as much as possible 2) dilating the vessel as fully as possible.

In many cases, LMT vessel diameters are >4mm and at the lesion sites, there are large amounts of plaque or heavy calcification.

In our hospital, normal procedure is as follows.

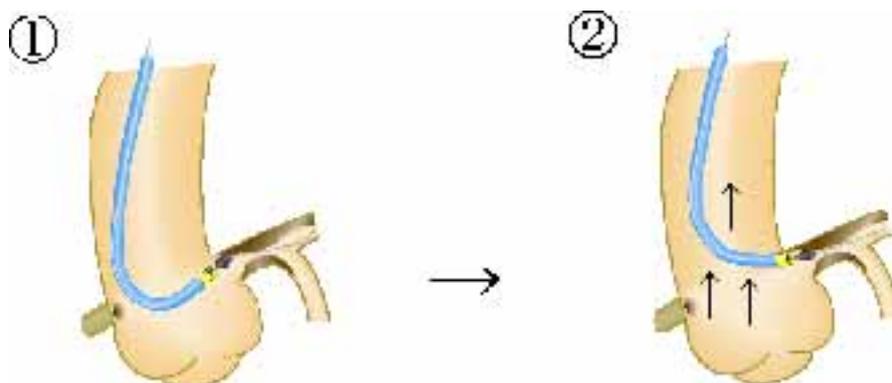
- 1 Reduce amount of plaque amount using DCA, rotablator and/or Cutting Balloon,.
- 2 If necessary, perform additional balloon dilation.
- 3 Implant stent.
- 4 Perform simultaneous balloon inflation at the LAD and LCX – kissing balloon technique, (KBT)

One or more of these steps will often be omitted in each case.

There follow procedural details for each modality. For DCA, refer to the preceding paragraph.

1-1) Rotablator

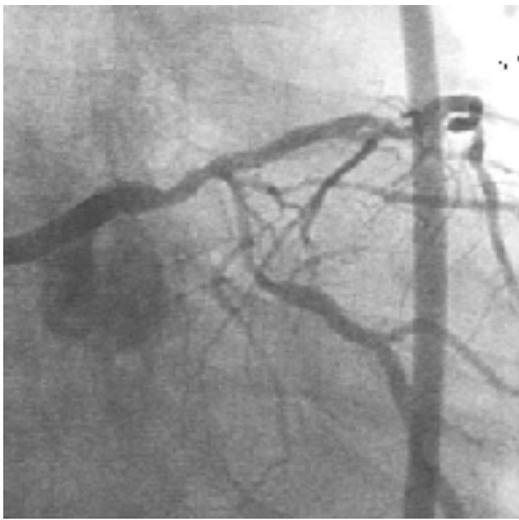
- The “rota-cocktail” is made in the usual way.
- A major indication for rotablator is heavy calcification, including in some cases ISR.
- When ablating with rotablator, the wire needs to be changed to a Rotawire using a wire exchange device.
- Unlike DCA, stand-alone rotablator results in insufficient dilation and sub-optimal long-term outcomes (TLR rate >50%!) as it can only be performed at burr sizes up to 2.5mm.
- If the burr and vessel are not co-axial, not only does ablation become difficult but also the fragile rotawire more easily gets bent and the burr becomes less incisive, or more likely to injure the vessel. Before introducing the burr into the artery, it is necessary to check whether the guiding catheter is co-axial with the artery. If engagement is difficult, pull the guiding catheter when maneuvering to make the catheter and artery horizontal. This may also help keep the two co-axial. (figure 2)



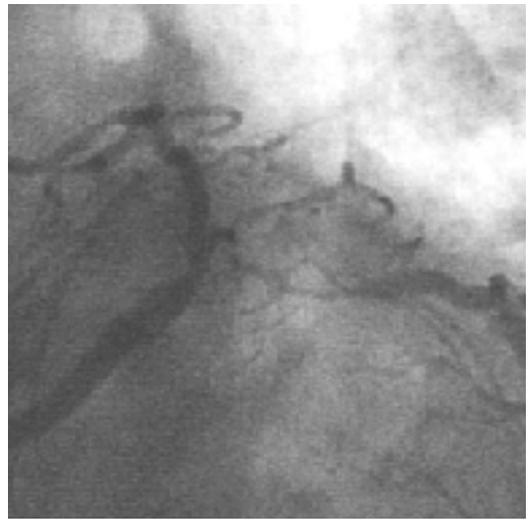
<Figure 2>

1. The rota burr has impacted on the upper wall of the LMT and can not easily be inserted.
- 2.A Sliding the guiding catheter up makes it co-axial and the burr can easily be manipulated.

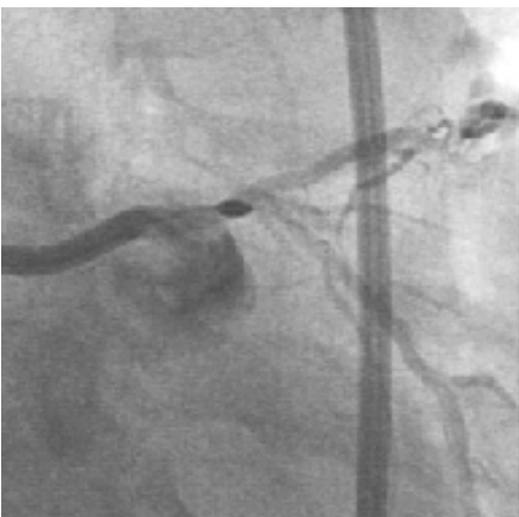
- Needless to say, quick and confident handling is a prerequisite in these procedures. As we have already explained in Section 5. b)-1) (Left Main Ostial Lesions), we set the burr's speed between lesion and platform at 100-200 times per minute (the "pecking motion"). This allows only a very short contact time for the burr and lesion at a time, which maintains the rotational frequency and makes reduces the risk of causing slow flow.
- With rotablation, one run lasts about 10 seconds and if one of the following occurs, we stop the procedure and assess the situation: evident ST change on ECG, the patient reporting more than mild chest pain, any hemodynamic changes (i.e. systolic blood pressure falling $<10\text{mmHg}$ in comparison with baseline or auto-systolic blood pressure falls 100mmHg), or the rotational frequency of the burr fall $>2000\text{bpm}$.
- During ablation with the rotablator, debris may pool distally which may cause slow flow. Especially in low EF patients or multivessel cases, try not to ablate all at once but take your time and ablate gradually over a period of time.
- Special manipulation of the rotablator: cases with heavy calcification and bending at the ostium of the side-branch: heavily-calcified stenosis and bending were seen extending from the LMT bifurcation to the LCX. A conventional balloon and a rotablator were the only devices that could be inserted. When inserting the rotawire, wire-bias was seen and the burr tended to move towards the opposite side of the LAD, so we carefully ablated that site. Lumen CSA was widened and good lumen area obtained.
(picture 2 (1)-(7)) (picture 4 (1)-(4))



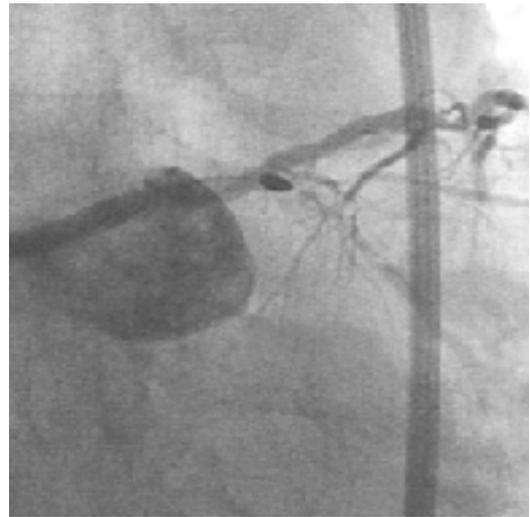
(picture 2 (1))



(picture 2 (2))



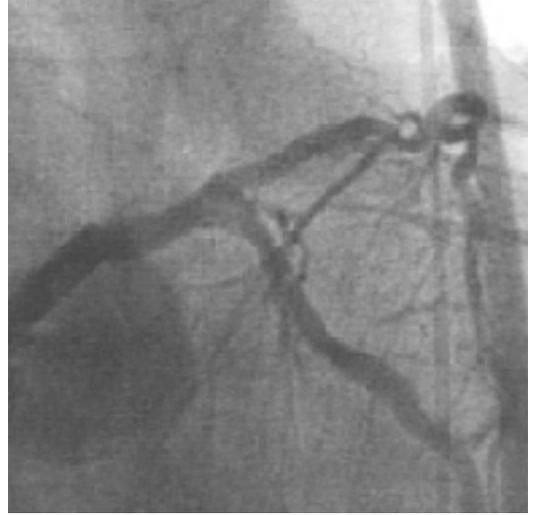
(picture 2 (3))



(picture 2 (4))



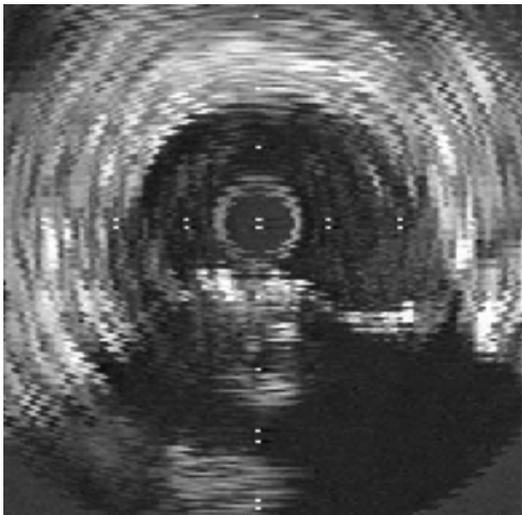
(picture 2 (5))



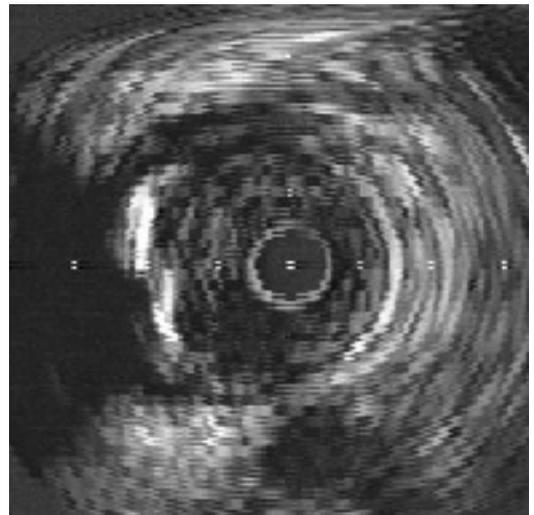
(picture 2 (6))



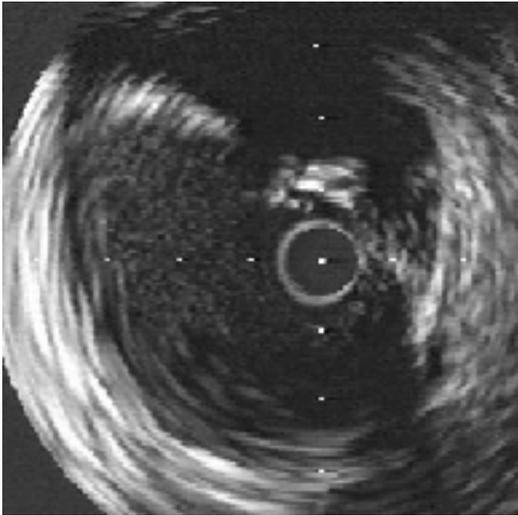
(picture 2 (7))



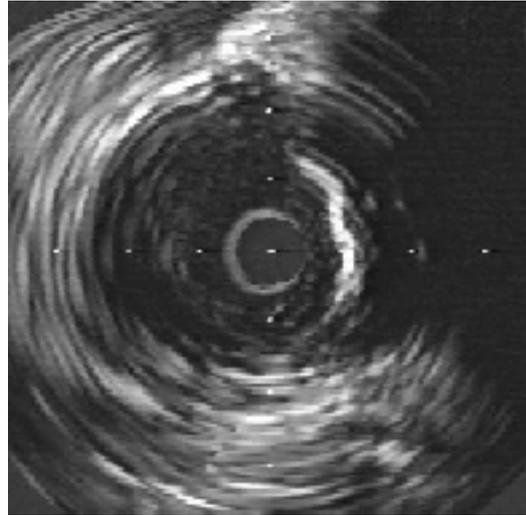
(picture 4 (1))
Pre-procedure LMT bifurcation



(picture 4 (2))
Pre-procedure LCX ostium



(picture 4 (3))
Post-procedure LMT bifurcation



(picture 4 (4))
Post-procedure LCX ostium

1-2) Cutting Balloon

Major indications are for cases with a large plaque volume but where debulking is unavailable because of heavy calcification or difficulty inserting the device. By making small incisions in the plaque, a “debulking” effect can be expected.

Since the diameter of the LMT is large, 4*10mm is often used for stand-alone CBA. The procedure is similar to that for a conventional balloon. Depending on hemodynamics, patient symptoms and changes on ECG, multiple inflations (approx. 30 secs. per inflation) may be performed. Since the Cutting Balloon is not a high-pressure device, post-dilation with another high-pressure balloon or stent should be performed. Also, if KBT is envisaged, a conventional balloon should be selected from the beginning since the Cutting Balloon is not compatible with this technique, in normal circumstances.

2 Plain Old PTCA

After DCA, rotablation or CBA, post-dilation with a conventional balloon may be performed in some cases. Direct PTCA using only one balloon is performed only in rare cases, but is limited to those contra-indicated for other devices. Stand-alone PTCA results in sub-optimal dilation in many cases and adjunctive KBT will usually be required. As for conventional PTCA, balloon type and size are determined by taking into account the information from both angiogram and IVUS regarding vessel diameter, lumen diameter, plaque burden and the presence of calcification. Careful sizing is necessary for stenting or for KBT. For stenting, the balloon used for post-dilation should be sized to match the stent exactly, and for KBT, a smaller balloon selected according to the size of the side-branch.

3 Stenting

In bifurcation lesions, the stent should be implanted from the body of the LMT to the LAD or LCX positioned so that the minimal lumen diameter is at the center. Stents are more usually inserted going towards the LAD. Accurate positioning of the stent is very important and should be done in conjunction with LAO caudal or straight caudal views. Extreme care should be taken not to locate the proximal stent edge at the LAD or LCX ostium as this is associated with high rates of restenosis.

Since side-branch access is relatively easy when you are stenting LMT bifurcations, we normally use Multilink stents. We size our stent to the side-branch.

When post-dilating with single balloon, we use a balloon sized to the stent body and apply high pressure (15-20atm). As avoiding restenosis is especially important in LMT lesions, make sure you get adequate stent expansion at this point and that you obtain a good lumen.

There is no specific balloon that we would recommend for post-dilation, but a semi-compliant balloon is recommended as these allow application of high pressure. To avoid problems with stent apposition, appropriate pre-debulking or pre-dilation are recommended. Direct stenting is not recommended.

If a protective guidewire is in place in the side-branch prior to stent-implantation, expand the stent with the guidewire as it is. If ballooning is necessary in the side branch, withdraw the side branch guidewire, re-insert it into the stent lumen, re-cross it through into the side branch-through the stent struts and inflate.

We are not great fans of side-branch stenting after main-branch stenting, or “T-stenting”. The reasons for this are that, in our experience, when the proximal edge of the stent covers the ostium of the side branch, the restenosis rate goes up, and also because, if a new lesions appears distal to the two stents, you have a very complicated procedure on your hands. This may not apply to cases with heavy residual stenosis at the ostium of the side branch or cases where the ostial lumen of the side-branch is insufficient due to plaque shift.

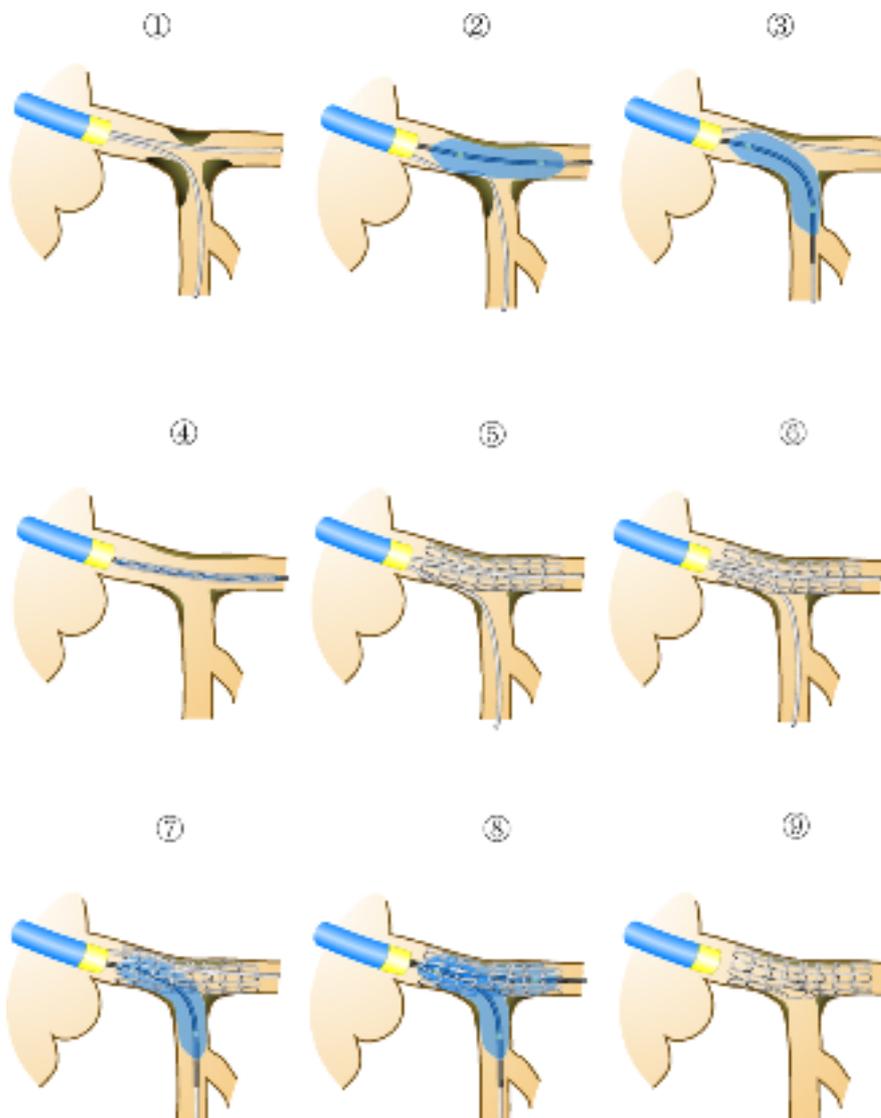
4 Kissing Balloon Technique (KBT)

KBT is indicated when 1) the lesion extends to the ostium of both the LAD and LCX, 2) when the plaque has shifted into the side-branch, 3) LMT dilatation was insufficient with due to LAD or LCX dilation alone. In general, KBT is especially effective in lesions with a large amount of plaque or angiographical concentricity. In contrast, KBT is generally not necessary in lesions with a small amount of plaque or which are eccentric on angiogram, and where there is plaque only on the other side of the side-branch and which could be treated by debulking, ballooning or stenting.

The picture shows a KBT procedure post-stenting.

With guidewires having crossed to both LAD and LCX, first, implant the stent from the LMT to the LAD. Next, withdraw the guidewire from the LCX, reinsert it into the stent lumen and re-cross it into the LCX through the stent struts. Deploy balloons on each guidewire, attach a three-way connector to the balloons, and connect an Indeflator to them in parallel. Dilate the balloons simultaneously with the MLD site at their center.

(figure 3)



<Figure 3>

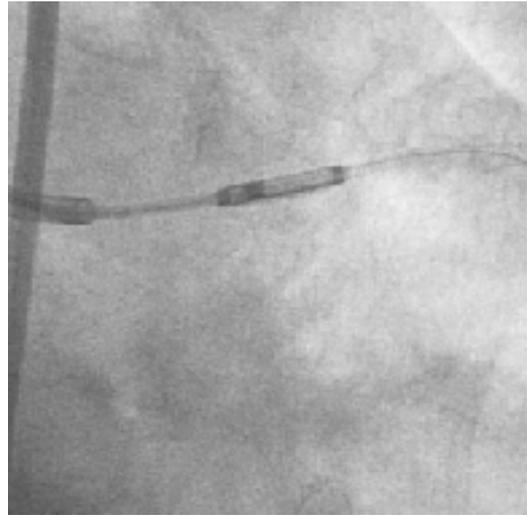
Procedure

1. Insert guidewires to both LAD and LCX.
2. Inflate the balloon at LMT-LAD.
3. Inflate the balloon at LMT-LCX.
4. Determine the position of the stent at LMT-LAD.
5. Stent deployment at LMT-LAD.
6. Withdraw the guidewire at LCX and recross through the stent struts.
7. Inflate the balloon at LMT-LCX through stent struts.
8. Inflate the balloon at LMT-LAD and LMT-LCX simultaneously (KBT).
9. Final result.

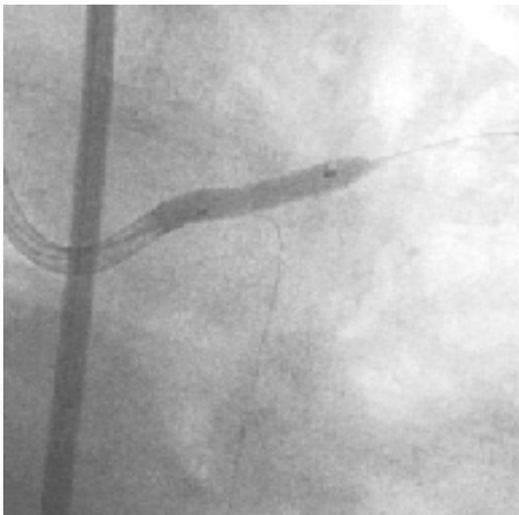
The following shows a typical case: 1 to 4. (picture 3 1-5)



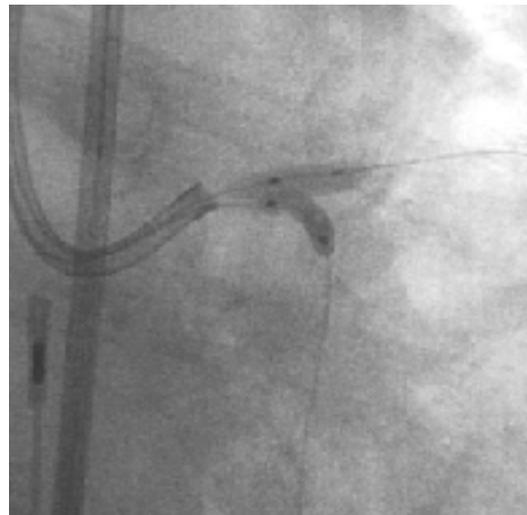
(picture 3 (1)) Pre-procedure



(picture 3 (2)) DCA



(picture 3 (3)) Stent deployment



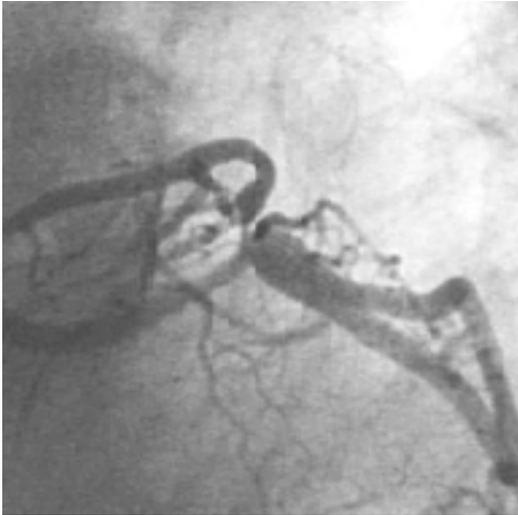
(picture 3 (4)) Kissing balloon technique



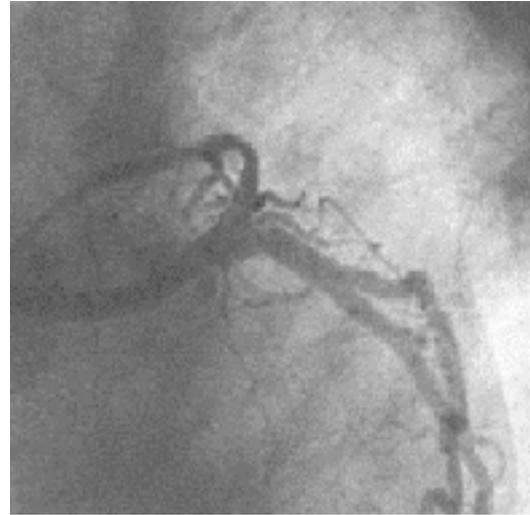
(picture 3 (5)) Post-procedure

When dilating in this way, the lumen CSA may look oval or like an “8” on IVUS. When this happens, our data suggests lumen area is significantly enlarged (10-13mm²) and residual plaque suppressed to <50% of vessel CSA. As a result, optimal long-term outcomes can be expected, with TLR rates of around 10% (see below).

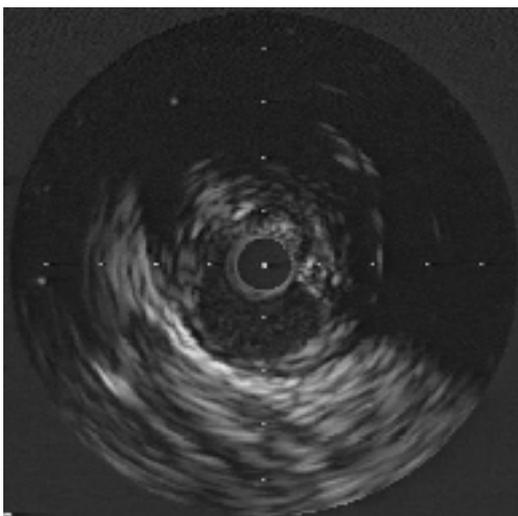
(picture 5 1-4)



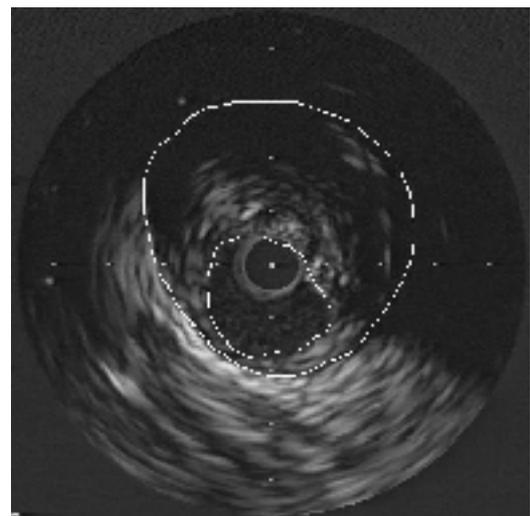
(picture 5 (1)) Pre-procedure CAG



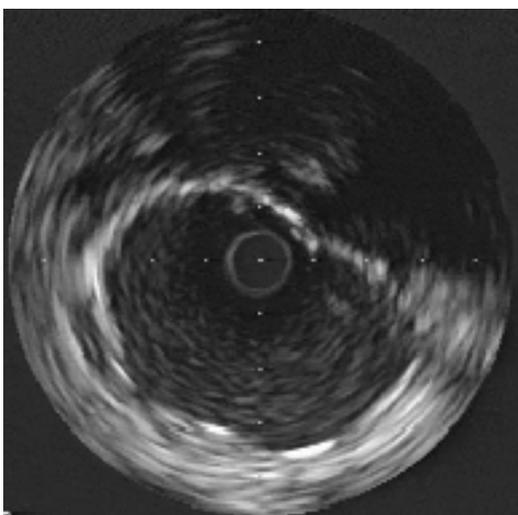
(picture 5 (2)) Post-procedure CAG



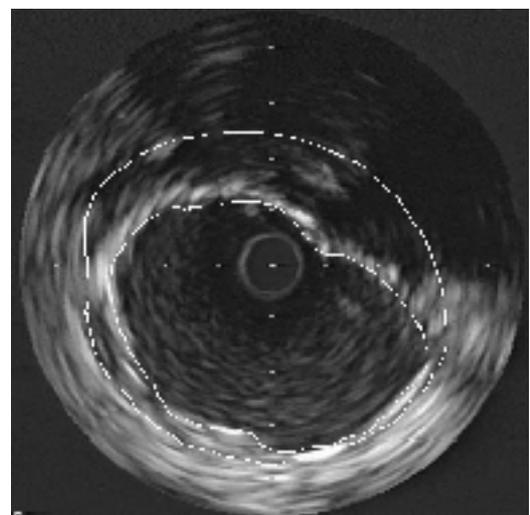
(picture 5 (3)) Pre-procedure IVUS



(picture 5 (4)) Pre-procedure IVUS



(picture 5 (5)) Post-procedure IVUS



(picture 5 (6)) Post-procedure IVUS

7) Post-procedural Care

In our hospital, patients with stable cardiac function and hemodynamics, undergo elective PCI with good success rates and without any major complications, in a similar way, with the sheath withdrawn 2 hours after the procedure and with IABP being discontinued at the same time. Patients are kept at complete rest for the following 4 hours and movement then permitted allowed in the absence of any complications, and with discharge from the hospital the next day. No adverse effects for short hospitalization have been seen at present.

Follow-up CAG is performed at 2-3 months, 4-6 months and 1 year post-procedure.

8) Clinical Results

Excluding AMI cases, procedural success is 100%, MACE including in-hospital death 0%, long-term death 0% and our TLR rate 22%. Most patients stayed in hospital for 2 days and leave without complications. These patients are at no disadvantage to patients undergoing PCI at other lesion sites.

9) Predictors Determining the Prognosis

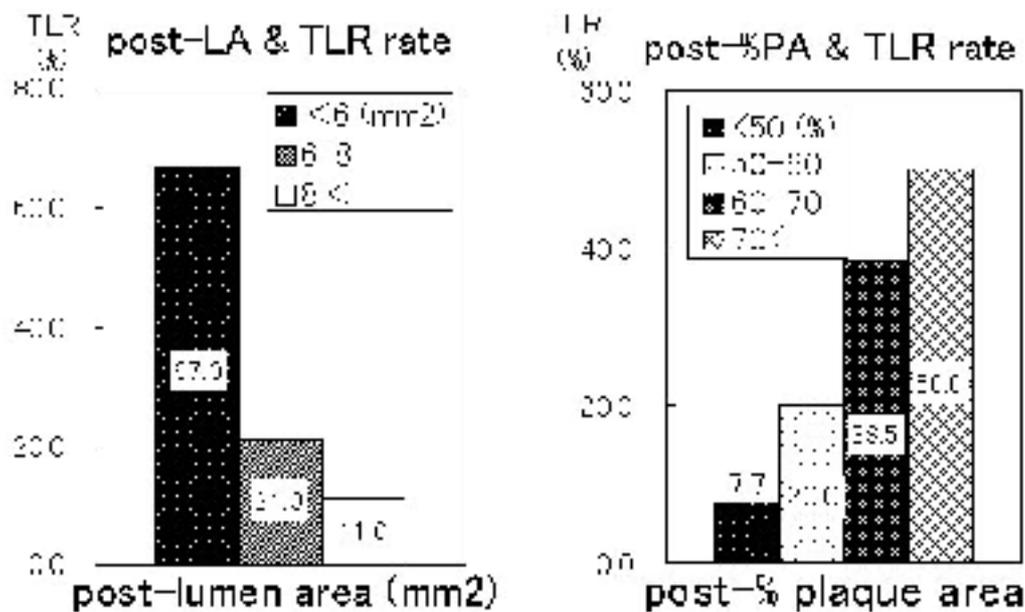
Among technically-challenging LMT bifurcation lesions, the followings factor present the greatest challenges;

- poor LV function (LVEF<40%)
- total occlusion or severe stenosis at the RCA
- multivessel disease
- LMT with heavy calcification (we recommend CABG)

Of these, we think of poor LV function as the highest-risk patients.

WE have also analyzed the relationship between the post-procedural lumen area and % residual plaque at the MLD site, and long-term TLR rates. As a result, and as is shown in figure 4, if either post-procedural lumen area is >10mm² or %plaque area <50% of post-procedural vessel CSA, the TLR rate is stable at around 10%. It follows that good patient prognosis can be expected by obtaining a large lumen and lowering residual plaque.

(figure 4)



10) Conclusions

With the continuing development of devices and the increasing technical sophistication of operators and co-medical staff, PCI for LMT lesions is becoming more common. Even following CABG, TLR causes the patient less stress both physically and mentally as compared to repeat thoracotomy. Also, in many cases, only single-day hospitalization is required in these cases. Nevertheless, compared to other coronary lesion locations, the risks remain higher, particularly for cases of PCI for bifurcation lesions, and the required techniques remain challenging for every operator. All things considered, and allowing for device selection, the cost may still be equal to that for CABG. Great care should be taken when evaluating which of these complex cases are suitable for PCI.

Lastly, it bears repeating that LMT lesions constitute a high-risk form of coronary artery disease which directly affect patient survival and prognosis. When selecting PCI for these patients, compromising and settling for a sub-optimal result is not an option. Excessive use of complex techniques should be avoided but if you choose to go for PCI, remember that your technique has to be perfect.