Case Report: Chocolate® PTCA Balloon Catheter for pre-dilatation of an occluded circumflex artery.

A case-based discussion of the use of Chocolate PTCA Balloon Catheter in complex cases

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Incomplete stent expansion and malapposed stent struts are a predictor of subacute and late stent thrombosis.

Appropriate lesion preparation prior to stent implantation is necessary to assure complete stent expansion and stent strut apposition. This is of particular importance in challenging lesions, in particular those with calcific plaque.

The goal of the pre-dilatation is to obtain optimal luminal diameter prior to stenting without causing any significant dissections. There are few devices available that are specifically designed to facilitate predictable dilatation while minimizing the risk of flow-limiting dissection.

Patient and Disease State

- 73 year old female with one de novo lesion in Cx.
- History of stable angina and previous PCI.
- The patient also has a pacemaker implant.
- Cx showed moderate tortuosity. The lesion was severely calcified (Type B) (Figure 1).

Procedural Steps

- Vascular access through femoral artery using 6F sheath and guide catheter. Hockey Stick (Merit Medical) and 0.014" BMW guidewire (Abbott Vascular) used to access Cx.
- Treatment strategy: implant a DES to cover the lesion.
- Due to severe calcification and to achieve optimal lesion preparation prior to stenting, a 3mm x 10mm Chocolate PTCA Balloon Catheter was used to predilate the lesion in three 10 second dilatations.
- First inflation at 14 ATM for 10 seconds (Figure 2).
- Second inflation at 16 ATM for 10 seconds.
- Third inflation at 16 ATM for 10 seconds.
- No accessories were required to facilitate the use of the Chocolate PTCA balloon catheter.
- Following predilatation with Chocolate PTCA (Figure 3), a Resolute drug eluting stent (Medtronic) was deployed to cover the lesion.
- The 4mm x 15mm Resolute stent was inflated to 15 ATM for 20 seconds.
Results
• The final angiographic result demonstrated satisfactory restoration of the artery flow.
• IVUS demonstrated no flow limiting dissection post intervention.

Chocolate offers predictable luminal gain while minimizing the risk of flow-limiting dissection*. Chocolate balloon inflation is uniquely:
• Predictable
• Controlled
• Uniform

Unique nitinol constraining structure offers key benefits:
• Constraining structure
  › Protects the vessel from shear stress caused by balloon inflation
• Dilatation pillows
  › Vessel dilatation without cutting or scoring
• Plaque channeling grooves
  › Stress relief zones

*Data on file at TriReme Medical. Based on MOA for the Chocolate and FEA analysis. Clinical data not available at this time.
**Physician statement.

Indications for Use: The Chocolate® PTCA Balloon Dilatation Catheter is indicated for balloon dilatation of the stenotic portion of coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. Contraindications: The Chocolate® PTCA Balloon Dilatation Catheter is contraindicated for use in unprotected left main artery, coronary spasm, crossing through stent struts. Warnings: Do not use in the presence of a freshly deployed stent. STERILE product. One time use only. Re-sterilizing or re-using may compromise the structural integrity of the device and may create a risk of contamination which, in turn, may result in health risks to patients. The inflated diameter of the balloon should correspond to the diameter of the vessel for treatment. See IFU for more detail.

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