The Prodigy™ and the CrossLock™: New Approaches to Aid Support During Complex Peripheral and Coronary Intervention

RICHARD R. HEUSER, MD, FACC, FACP, FESC, FSCAI

Chief of Cardiology, St. Luke’s Medical Center, Phoenix, Arizona

Professor of Medicine, Univ. of Arizona

College of Medicine, Phoenix, Arizona
Disclosures

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**Patents** -- RF, Snares, Wires, Balloon Catheters, Covered Stents, Devices for Arterial Venous Connection, Devices for LV and RV Closure
It’s ALL Case Based
Are there techniques that can be helpful using the “Antegrade Approach”?
Figure 3.5  Another kind of anchoring balloon technique. This is a scheme of another type of anchoring technique by using an over-the-wire (OTW) balloon. When the proximal fibrous cap cannot be penetrated even by using a stiff wire, an OTW balloon may be dilated proximal to the occlusion as a support catheter. The inflated balloon makes an extra back-up force for the wire tip to break down the proximal cap.
55 year old male with increasing chest pain symptoms
Single Center Experience in Radial Access for Treating Chronic Total Occlusions

Richard R. Heuser, MD, FACC, FACP, FESC, FSCAI; John E. Lassetter, MD, FACC, FSCAI
Phoenix Heart Center, St. Luke’s Medical Center, Phoenix AZ

BACKGROUND
The treatment of chronic total occlusion (CTO) is thought to be the final frontier in treating coronary artery disease percutaneously. Most chronic total occlusion patients are treated via the femoral route. Patients undergoing PCI via groin access experience a four fold increase in MACE compared to PCI via the radial approach.

METHODS
We became a radial first laboratory in April, 2010. Since becoming a radial first lab, we performed 17 radial CTO procedures amongst 60 consecutive chronic total occlusion procedures performed.

RESULTS
We treated patients at a mean age of 62.5 (48-77 range). Fourteen radial cases were male. One was female. Fourteen were RCA’s. Two were circumflex CTO’s, and one was in the LAD.

CONCLUSION
With our small single center experience, we have been highly successful with radial CTO procedures with no significant major adverse cardiovascular events. The radial approach may show promise in treating this difficult patient subset.

93.3% of Radial Cases Successful
93% of Groin Cases Successful
A Technique to Improve Success with CTO’s using the Antegrade Approach and an Improvement in Current Design: The Support Balloon

Richard R. Heuser1  Shishir Murarka2
1 St. Luke’s Medical Center, Phoenix AZ  2Banner Estrella Medical Center, Phoenix AZ

BACKGROUND
Success rate treating CTO’s has been improved by dedicated systems, excellent guiding support and physician experience. Most physicians feel more comfortable using the antegrade approach to treat CTO’s.

METHODS
The anchoring balloon technique has been used for several years to allow guiding catheter support to be reinforced with the use of an over-the-wire (OTW) conventional balloon. We have used this technique over the last 18 months successfully in 35 of 36 (97.5%) consecutive patients, all but four cases were in the right coronary artery (four were circumflex CTO’s) (Fig 1). The patient age range was 48 to 70 (mean 67 years). All the patients were male and the total occlusions ranged in age from 8 months to 35 years (mean 8.2 years). This technique has potential for complications. Trauma to the proximal vessels may result from the routine use of stiff Amplatz guide catheters, and sometimes it is difficult to place an OTW balloon with a relatively long length and tip (Fig. 2) without the guiding catheter being displaced from the coronary ostium. There is also the potential of barotrauma from the balloon with resultant dissection.

RESULTS
We developed a new system to potentially reduce the trauma (Fig. 3). Our system has a shorter tip, as well as a much shorter elastomeric balloon length measuring 5mm in length and less than 2mm in tip length.

In a silastic tube model, it has been shown to be more effective as a support system for crossing a putty type total occlusion compared to a conventional balloon (Sprinter, Medtronic) (Fig. 4). The balloon size can be dilated to 6mm and able to be used in multiple diameter size silastic vessels.

CONCLUSION
The support balloons have been effective in our small series; however, an improvement in the standard over the wire balloon may make it possible to safely treat larger numbers of patients with this technique. Improved antegrade approaches are essential in increasing rates in this difficult patient subset.

We were successful
35 of 36 cases (97.5%)
Optimal guiding catheter support is a prerequisite for successful angioplasty of CTO

- Fixed stiff guide catheter
- Anchoring balloon in main vessel
- Anchoring balloon in side branch
- Fixed stiff catheter can result in dissection
- Side branch is difficult if the vessel is small
- Small balloons don’t always allow wire manipulation
- All commercially available balloons are too long, tips too long and can cause barotrauma
Pathophysiology of CTOs

- Recent CTOs: soft lipids, thrombus
- Matrix composed of fibrin & proteoglycans
- More than 75% CTOs not blocked on histology
Pathophysiology of CTOs (cont)

- With time, collagen replaces thrombus & lipids, especially at proximal/distal ends or caps
- Increasingly dense fibrous collagen & calcification occurs
A 62 year old man presented with recurrence of angina and a RCA CTO with inferior ischemia. Attempted recanalization was unsuccessful at an outside center. He was status post CABG with an occluded RCA graft.
A 51 year old male presented with chronic angina and inferior ischemia. Outside angio revealed a CTO of the RCA.
9 Cases

- 7 RCA
- 1 Cx
- 1 LAD
- All successful
- All radial
- 7 outpatients
The Prodigy catheter makes the antegrade procedure go more quickly and you can accelerate wire usage to easily cross most lesions. This approach has significantly reduced our procedures times and necessity to use the retrograde approach in CTOs.
"LASERS"
A 75 year old woman presents with resting left foot pain. Her ABI on the left is .5
Pedal Access

- Retrograde wire passage via pedal artery (ultrasound vs angiographic guidance).
- Antegrade snare and externalization of pedal wire.
- Reversal of wire; avoid passage of devices via pedal arteries.
A 75 year old woman presents with resting left foot pain. Her ABI on the left is .5
With Proper Case Selection and Experience, There is No Reason That Most (80%-90%) of CTOs Cannot Be Successfully Opened
The Use of the Prodigy™ and CrossLock™ Catheter for Treatment of Complex PCI Lesions and CTO’s

Conclusion

• With CTOs, we preferentially try to approach with the radial approach particularly in RCA CTOs

• The Prodigy™ and CrossLock™ will help in crossing coronary CTO’s

Continued…
The CrossLock™ is a unique way a support catheter that centers the balloon to make crossing CTO’s more effective and may play an even larger role in peripheral CTO’s.

The Use of the Prodigy™ and CrossLock™ Catheter for Treatment of Complex PCI Lesions and CTO’s

- The CrossLock™ is a unique way a support catheter that centers the balloon to make crossing CTO’s more effective and may play an even larger role in peripheral CTO’s.
Thank You
Are there techniques that can be helpful using the Antegrad Approach?”
Figure 3.5  Another kind of anchoring balloon technique. This is a scheme of another type of anchoring technique by using an over-the-wire (OTW) balloon. When the proximal fibrous cap cannot be penetrated even by using a stiff wire, an OTW balloon may be dilated proximal to the occlusion as a support catheter. The inflated balloon makes an extra back-up force for the wire tip to break down the proximal cap.