Experience of heavily calcified BTK artery recanalization with Crosser system in hemodialysis patients.

Main arena 8:53-09:01, March 09.

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• Disclosure
• Speaker name: Tomoyasu Sato
• I have the following potential conflicts of interest to report:
  • □ Consulting
  • □ Employment in industry
  • □ Stockholder of a healthcare company
  • □ Owner of a healthcare company
  • □ Other(s)
• □ I do not have any potential conflict of interest
Background

Heavy calcification is one of the most challenging lesion characteristics for EVT especially in hemodialysis patients.

1. Difficulty in entering the proximal and distal cap.
2. Difficulty in crossing or dilating target lesion.
3. Difficulty in preserving accurate lumen after EVT.
A lot of dialysis patients are living in Japan. Due to increase of aged and diabetic people.

1/6 of hemodialysis patients are living in Japan.

Dialysis patients often has severe PAD.

(Annual review of Japanese society for dialysis therapy 2012)
We often experience these kind of cases in HD patients.

63y.o. male: DM, HT, 10 years history of hemodialysis
Intractable toe ulcers both foot.
SPP = 25mmHg

Unfavorable dilatation due to calcification

Unable to dilate

Unfavorable dilatation due to calcification
Most of the debulking devices are not available in JAPAN.
CROSSER®
CTO Recanalization Catheter

CTO Recanalization Via Atherectomy

High frequency vibration of the chip enable lesion crossing.

Catheter : 176,000 JPY (1,500 USD)
Generator: 3,950,000 JPY (34,000 USD)

It’s like a Rock drill.

Crosser is the only option for mechanical crossing and debulking of calcified lesions in Japan since 2014.
CROSSER was introduced to coronary CTO at first.

**Abstract**

**OBJECTIVES:** To evaluate safety and efficacy of the CROSSER CTO Recanalization System (CROSSER).

**BACKGROUND:** The CROSSER, a novel device dedicated to recanalization of chronic total occlusions (CTO), relies on a monorail catheter delivering vibrational energy to facilitate the crossing of occluded coronary arteries.

**METHODS:** We included de novo or restenotic occlusions in native coronary arteries with typically unfavorable characteristics and a prior failed guidewire attempt either performed in a previous procedure or just before the usage of the CROSSER. The end points analyzed were technical success (ability to cross or facilitate a guidewire crossing into the true lumen), angiographic success (<20% residual stenosis and TIMI flow grade 3), and clinical success (angiographic success and freedom from major adverse cardiac events at 30 days).

**RESULTS:** Twenty-eight patients (30 lesions) were included. The morphology was blunt in 83.3% and the length of the occlusion was >20 mm in 76.6%. The median age of the CTO was 9 months (range 3-60 months). Technical success was obtained in 19 (63%) occlusions and angiographic success in 16 (53%): 26.3% in lesions with prior procedural failure and 73.7% when CROSSER was attempted after initial guidewire failure. Complications were: one guidewire perforation without consequences and one peri-procedural myocardial infarction (MI). No events occurred within 30-day follow-up after discharge.

**CONCLUSIONS:** In our experience, the CROSSER System is safe and increases the success of opening CTO refractory to guidewires. This novel device may represent an useful adjunct to the armamentarium of the interventional cardiologist.

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2006, Coronary
30 cases of CTO refractory to guidewires
Success 19 cases (63%)
1 peri-procedural MI
Recanalization of Infrainguinal Chronic Total Occlusions With the Crosser System: Results of the PATRIOT Trial

Abstract: Purpose. To evaluate the angiographic and functional outcomes of a new CTO recanalization system used to facilitate crossing of CTOs using conventional guidewire techniques. Methods. Eighty-five patients were enrolled in the study. They attempted to cross a CTO using conventional guidewire techniques with a newly developed CTO crossing system. Oclusions were at least 30 days old and ≤30 cm in length. Occlusions were predominantly located at the iliac ostium and advancement of the recanalization system into or through the occlusions was attempted. Occlusions were crossed over a 9 Fr catheter and 100% advancement of the recanalization system into or through the occlusion was achieved. Results. The average age of occlusion was 16 months, the mean age of the patients was 55.7 years, and 55.7% had unfavorable morphology for crossing. The mean lesion length was 117.5 ± 84 mm. Superficial femoral artery (SFA) occlusions were most common (61.2%), followed by popliteal (20%), and tibioperoneal (16.5%) occlusions. The CTOs were successfully advanced into the distal true lumen in 83.5% of cases, with a mean residual stenosis of 20%. Conclusion. Use of the newly developed CTO crossing system facilitated crossing of guidewire-resistant, chronic, infrapopliteal occlusions that were located in the more tortuous and often clinically significant vessel perforators. Success rate 83.5%
We report our initial experience of Crosser.
Materials:

Between Aug. 2014 and Oct. 2015, 81 angioplasty using Crosser system were done for CLI patients (RCC 4,5). All patient has heavily calcified BTK lesions.

- Total: 81 cases
- Hemodialysis: 61 cases (75.3%)
- De novo lesion: 45 cases
- Reintervention: 36 cases
  - (Reintervention after crosser: 3 cases)
- Male: 53 cases
- Female: 28 cases
- Mean age: 71.1 yo (50 – 85 yo)
Results:

Approaching methods:
- Contralateral: 9 cases
- Ipsilateral: 72 cases

Catheters used:
- 14P: 11
- 14S: 72 (change from 14P to 14S in 3 cases)

Crossing methods:
- Crosser first: 4 cases
- After guidewire crossing: 77 cases
Results:

Arteries treated) : (among 81 cases)

<table>
<thead>
<tr>
<th>Artery</th>
<th>Count</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFA</td>
<td>2</td>
<td>ATK 24/134 (17.9%)</td>
</tr>
<tr>
<td>SFA</td>
<td>20</td>
<td>Pop 97/102 (95%)</td>
</tr>
<tr>
<td>Pop</td>
<td>2</td>
<td>ATA 110/134 (82.1%)</td>
</tr>
<tr>
<td>ATA</td>
<td>46</td>
<td>PTA 27/134</td>
</tr>
<tr>
<td>PTA</td>
<td>27</td>
<td>Per 29/134</td>
</tr>
<tr>
<td>Per</td>
<td>29</td>
<td>foot 8</td>
</tr>
<tr>
<td>Total</td>
<td>134</td>
<td>regions</td>
</tr>
</tbody>
</table>

Mean treated arteries: 1.7 regions / case

Success rate of lesion crossing by Crosser:

- SFA, Pop: 20/22 arteries (95%)
- BTK (except BTA): 97/102 arteries (95%)
Representative Crosser cases:

Case 1.
Case: 71yo male  HD, DM
PTA was done 3 month ago due to ulcer of fingers.
Rest foot pain, coldness (RCC4)
Representative Crosser cases:

Case 2.

Dose Crosser first strategy really works in BTK?
Case: 64yo male, DM HD
CC: Rest pain, small ulcers in his fingers (RCC5).
PTA recanalization was done.

Most of the cases crosser first strategy dose not works well.
We use Crosser after guidewire crossing.
Representative cases:

Case 3.

Bidirectional approach (pull through) enhance Crosser effect
Case: 77yo male. HD
He noticed small ulcers in his Rt. Foot fingers and heel (RCC5). Antegrade TPT recanalization was failed and distal puncture was done.
Distal peroneal puncture:

Wire rendez-vous and Pull through

Crosser
Final angiogram

One straight line could be established.
Representative cases:

Case 4.

Crosser may work even in pedal arch.
Case: 73yo male, HD
CC: Rest pain, small ulcers in his fingers and heel.

Cruse wire was inserted planter artery through the arch. Crosser 14P was used.
Change of the Balloon Rupture after introducing Crosser

<table>
<thead>
<tr>
<th></th>
<th>Before Crosser</th>
<th>After Crosser</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>(4 months)</td>
<td>(6 months)</td>
</tr>
<tr>
<td>No. BTK cases</td>
<td>33</td>
<td>40</td>
</tr>
<tr>
<td>Total BTK balloon used</td>
<td>109</td>
<td>98</td>
</tr>
<tr>
<td>Ruptured balloon</td>
<td>13</td>
<td>3</td>
</tr>
<tr>
<td>Rupture rate (case)</td>
<td>30%</td>
<td>3.2%</td>
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</table>
Results:

Troubles of revascularization in the 102 BTK arteries:

- **Failed passage**: 5 / 102 arteries (4.9%)
- **Perforation**: 0 / 102 arteries (0%)
- **Slow flow**: 7 / 102 arteries (6.8%)
- **Severe no flow**: 4 / 102 arteries (3.9%)
- **Catheter trouble**: 17 / 102 arteries (16.7%)

### Results:

1. **Catheter Breakage**: 12 arteries
2. **Tip separation/ core wire breakage**: 5 arteries
Representative cases:

Case 5.

Crosser catheter trouble:
1. Catheter Breakage
2. Tip separation
Case: 82yo female
She had a history of HD for 10 years.
She had gangrene for her 4, 5th finger (RCC5).

Peroneal a.

PTA. Destocking and separation of catheter was seen.

Due to heavily calcified, rugged and irregular surface of the arterial wall.
Representative cases:

Case 6.

Crosser catheter trouble:
1. Catheter Breakage
2. Tip separation
Case: 70 yo male. HD due to DM for 20 years.

He noticed toe ulcer again and angioplasty was done (RCC5).

Crosser: First recanalization was done.
Crosser was done at DPA again after wire crossing. TIP separation occurred.

Crosser catheter is fragile for calcified arteries

Retrograde sheath insertion.
3F→POBA→4F
Conclusion

Recanalization of heavily calcified BTK arteries is still challenging.

By dedicated guidewires and crossing catheters, success rate is improving even in conventional procedures.

Crosser system may contribute to improve initial success rate of recanalization. We have to aware of catheter related troubles when using this device.

We need to confirm safety and effectiveness of this device in larger patient population.
Thank you for your kind attention.

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