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Announcement of the winners of the LINC 2020 poster award

Challenging Cases

LINC Clinical case of successful acute aortic dissection of DeBakey type III treatment complicated with rupture and massive left hemothorax
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Introduction:
 In point A, there is a 60-year-old smoker who is not committed to antihypertensive therapy, with a suspected rupture of the thoracic aorta. Hemodynamics is stable (controlled hypotension). Clinical, laboratory and instrumental signs of severe acute blood loss, hemothorax, severe dyspnea. From point A to the Saint-Petersburg 350 km (~4.5 hours by car) + preparation for transportation.
 Question: what is the probability (in %) for a cardiovascular surgeon to go to the final of "The Avengers" this evening, when a man lifts high weights at his countryside in the far region?

Figure 1. X-ray examination after admission
 What we found on CT scan?
 *Strange can manipulate matter, move through space, time, and dimensions. He has ability to telepathy and teleportation, can absorb energy, cause illusions and put power barriers.

Not without the help of MARVEL heroes...
 EchoCG: EF 60%
 Hb 7.56 g/dl
 Serum creatinine 98 mmol/l
 Malperfusion of visceral branches is clinically questionable
 Neurological status without features

Figure 2. 3D and axial CT-angiography before procedure.
 Accesses: right CFA (true lumen), left brachial artery.
 Step-by-step contrast of the lumen

Figure 3. Axial CT-angiography before procedure.
 Arrows indicate true lumen

Figure 4. Intraoperative angiography

Figure 5. [A] Intraoperative angiography, proximal tear closed. [B] True lumen extension.

Figure 6. HB dynamics within 5 days

Day	HB, G/L
1	75,0
2	89
3	95
4	104
5	111
5	121

Drainage of the left pleural cavity 16 hours after surgery and 18 hours after admission. The duration of drainage is 4 days. A total of about 3 liters of drainage

Not without the help of MARVEL heroes:
 Minimal partial thrombosis of the lumen. Significant difference in false lumen density (HUI) in the thoracic and abdominal aorta. Retrograde filling of the lumen. When discharged from the clinic on the 10th day: No fever; Echo EF 60%; Hb 12,8 g/dl; Creatinine 95 mmol/l. Patient is happy and satisfied

Dr. Nikolai Zherdev

Clinical case of successful acute aortic dissection of debakey Type III treatment complicated with rupture and massive left hemothorax

Original Research

Usage of Contemporary Drug-Eluting Stent by Japanese Interventional Radiologists for Femoropopliteal In-Stent Restenosis lesions -COMBAT-ISR study-

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Background

In-Stent Restenosis (ISR) after femoropopliteal (FP) interventions is an increasing problem. Because rate of recurrent ISR was high, in particular when stent occlusion occurred, the rate of re-ISR was 83.3% (1). There are some solutions including drug stent technology to avoid re-ISR. There were already some reports to prevent re-ISR using drug eluting stent (Zilver-PTX) (2). In addition, it has been recently reported that new Drug-Eluting Stent (Elixir stent) was better than Zilver-PTX for FP disease (3). This new Drug-Eluting Stent has also been expected to avoid re-ISR. In February 2019, Elixir stent became available in Japan. Therefore no published studies have examined Elixir Drug-Eluting Stent in the treatment of FP-ISR in Japanese population.

Objective

This study will seek to evaluate the outcomes of Elixir stent treatment for femoropopliteal ISR.

Materials & Methods

A prospective study was conducted at least 17 medical centers in Japan (Table 1). COMBAT-ISR study had been enrolled from March 2019 to December 2019 with a target number of 100 patients. COMBAT-ISR study included patients who had Symptomatic ISR in the femoropopliteal artery. Inclusion/Exclusion Criteria was shown in Table 2.

ISR procedure

Patients were treated with the ELIUSA drug eluting vascular stent (Boston Scientific, Marlborough, MA, USA, Indiana). The protocol specified planned treatment with a maximum of 3 ELIUSA drug eluting vascular stents per patient (maximum length 300cm). The acute post dilation was performed at the interventional discretion. Unfractionated heparin was administered during the procedure to maintain an activated clotting time over 250 seconds. Dual antiplatelet agent (Aspirin 81 to 100 mg and Clopidogrel 75 mg) was administered at least 24 h before the procedure. Following treatment, Dual antiplatelet therapy was continued for 90 days and mono antiplatelet therapy was continued indefinitely.

Endpoints

The primary endpoint is primary patency at 6, 12-month follow-up. Secondary endpoints are technical success rate, and the occurrence of major adverse events, defined as stent thrombosis and all causes of death through 1 month, major amputation of the target limb through 12 months, or target lesion revascularization through 12 months. Primary vessel patency was defined as duplex ultrasound peak systolic velocity ratio ≤ 2.4 , without clinically driven target lesion revascularization (TLR) or bypass of the target lesion.

Results

Thirty-two patients were enrolled from February 2019 to December 2019 (Table 2). We didn't reach the target number, therefore the enrollment will be ended by March 2020. Full baseline and procedural characteristics are summarized in Table 3. Technical success was 100% (36 of 36) of ISR lesions. Stent thrombosis occurred in one patient (2.8%) at 2 weeks postoperative days. This case seemed to be associated with clopidogrel resistance. Because VerifyNow showed PRU (P2Y12 reaction units) was 235 on emergency re-admission. No death occurred in any patients.

At 6 months, the primary patency rate was 95.6% (23/24). The Kaplan-Meier estimate of primary patency was 94.4% at 6 months (Figure 1).

Center	Investigator	Patients
Ichikawa Yaso General Hospital, Yao, Japan	Ichihashi S, Kichikawa K	10
Nara Medical University, Kashihara, Japan	Ichihashi S, Kichikawa K	10
Ichikawa Yaso General Hospital, Yao, Japan	Ichihashi S, Kichikawa K	10
Ichikawa Yaso General Hospital, Yao, Japan	Ichihashi S, Kichikawa K	10
Ichikawa Yaso General Hospital, Yao, Japan	Ichihashi S, Kichikawa K	10
Ichikawa Yaso General Hospital, Yao, Japan	Ichihashi S, Kichikawa K	10
Ichikawa Yaso General Hospital, Yao, Japan	Ichihashi S, Kichikawa K	10
Ichikawa Yaso General Hospital, Yao, Japan	Ichihashi S, Kichikawa K	10
Ichikawa Yaso General Hospital, Yao, Japan	Ichihashi S, Kichikawa K	10
Ichikawa Yaso General Hospital, Yao, Japan	Ichihashi S, Kichikawa K	10

Table 1. Medical Centers and Investigators of COMBAT-ISR Study

Major inclusion criteria

- 1) Age > 40 years
- 2) Symptomatic ISR (Rutherford-Baker category 2 to 5), ISR >50% in the SFA and P1 segment of the popliteal artery, and a distal runoff of at least 1 artery

Major Exclusion criteria

- 1) Inability to give written informed consent;
- 2) Known allergy, hypersensitivity or intolerance to radiologic contrast media, aspirin, clopidogrel and Pafizelal
- 3) Creatinine >2.5 mg/dl (except hemodialysis patients)

Table 2. Major Inclusion Criteria and Exclusion Criteria of COMBAT-ISR Study

During follow-up, the MAE rate was 3.6% (2/56). MAEs were observed in one patient. This patient who stent thrombosis occurred in and underwent TLR. No death and target limb amputations occurred.

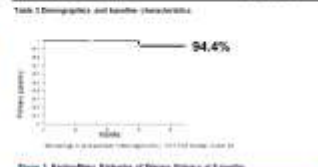
Discussion

Zeller et al. (2) reported 108 patients and 108 lesion who were enrolled in the Zilver-PTX angioplasty study which a Paclitaxel-coated stent. The mean lesion length was 13.3 cm. Primary patency was 78.8% at 1 year. Primary patency in this study was better than conventional PDBA (1).

On the other hand, Gray et al. (3) has reported 465 patients who were randomly assigned to Elixir (n=230) or to Zilver-PTX (n=135). The mean lesion length was 8.03 cm. Primary patency at 1 year was significantly higher in the Elixir group (88.8%) than in the Zilver-PTX group (81.5%). Therefore the present study regarding ISR also is expected to show that the primary patency is better in Elixir than in Zilver-PTX.

However, there is one biggest concern about Elixir stent. Katsuno et al. reported that there is increased risk of death following application of paclitaxel-coated balloons and stents in the femoropopliteal artery of the lower limbs (4). Elixir was not included in those meta-analysis. Plus, there were quite different regarding the total volume of the drug and the duration of the drug release between these stents. Therefore Elixir stent will be expected not to be associated with increased risk of death, because there was no evidence to prove increased risk of death following application of paclitaxel-coated stents in coronary beds. That is why the total volume of drug and the duration of the drug release may be associated with increased risk of death following application of paclitaxel-coated balloon and stents.

	n (%)	n (%)
Mean age (n=32)	75.7 (23.4)	22 (61.1%)
Age range (n=32)	29 (90.6%)	15 (41.7%)
Diabetes (n=32)	24 (75.0%)	11 (30.6%)
Previous smoking (n=32)	19 (59.4%)	11 (30.6%)
Active smoking (n=32)	13 (40.6%)	11 (30.6%)
Coronary artery disease (n=32)	11 (34.4%)	11 (30.6%)
Cardiovascular disease (n=32)	20 (62.5%)	11 (30.6%)
Arteriovenous fistula (n=32)	4 (12.5%)	11 (30.6%)
Arteriovenous fistula (n=32)	4 (12.5%)	11 (30.6%)
Stent		
In-stent stenosis	24 (66.7%)	11 (30.6%)
Target lesion	12 (33.3%)	11 (30.6%)
Length of the in-stent stenosis (mean \pm SD) (cm)	10.3 \pm 4.8	11 (30.6%)
The number of stents put off		
0	22 (61.1%)	11 (30.6%)
1	10 (31.9%)	11 (30.6%)
2	4 (12.5%)	11 (30.6%)
3	0	11 (30.6%)
4	0	11 (30.6%)
5	0	11 (30.6%)
6	0	11 (30.6%)
7	0	11 (30.6%)
8	0	11 (30.6%)
9	0	11 (30.6%)
10	0	11 (30.6%)
11	0	11 (30.6%)
12	0	11 (30.6%)
13	0	11 (30.6%)
14	0	11 (30.6%)
15	0	11 (30.6%)
16	0	11 (30.6%)
17	0	11 (30.6%)
18	0	11 (30.6%)
19	0	11 (30.6%)
20	0	11 (30.6%)
21	0	11 (30.6%)
22	0	11 (30.6%)
23	0	11 (30.6%)
24	0	11 (30.6%)
25	0	11 (30.6%)
26	0	11 (30.6%)
27	0	11 (30.6%)
28	0	11 (30.6%)
29	0	11 (30.6%)
30	0	11 (30.6%)
31	0	11 (30.6%)
32	0	11 (30.6%)



Conclusion

Treatment of femoropopliteal ISR with Elixir stent was expected to result in favorable acute and midterm outcomes.

References

- (1) Tebbe A et al. Comparison and impact of restenosis after femoropopliteal angioplasty. Am J Cardiol 2012; 110: 193-201.
- (2) Zeller T et al. Treatment of femoropopliteal in-stent restenosis with paclitaxel-coated balloons. JAMA Cardiol 2019; 2019;24:1-11.
- (3) Gray ET et al. Paclitaxel-coated, drug-eluting stent (Elixir) versus a conventional paclitaxel-coated stent (Zilver PTX) for in-stent restenosis after femoropopliteal angioplasty: a randomized, non-inferiority trial.
- (4) Katsuno M et al. Risk of Death Following Application of Paclitaxel-Coated Balloons and Stents in the Femoropopliteal Artery of the Leg: A Systematic Review and Meta-Analysis of Randomized Controlled Trials and Prospective Cohort Studies. Circ J 2018; 82: 1941-1949.

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