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We are happy to announce the presentation of the results of the *Pacuba I Trial* by Dr. Kinstner (Vienna, Austria) in Lisbon during the CIRSE 2015 and to give you further insights into the data. This trial investigates the treatment of femoralpopliteal ISR with the FREEWAY DEB versus standard uncoated balloon.

Why is the Pacuba I Trial so important?

Endovascular treatment of peripheral arterial disease (PAD) of the superficial femoral artery (SFA) with bare metal stents has its limitations when it comes to intermediate and long term patency. Restenosis after treatment with nitinol stents occurs in up to 30% of patients at 12 months and up to 50% at 24 months [1,2,3]. In long lesions the restenosis rate may be even higher [4,5]. The rate of recurrent restenosis after PTA of an in-stent restenosis (ISR) within the SFA ranges up to 70% at 6 months [4].

A recent clinical trial suggested significant inhibition of restenosis after treatment of in-stent restenosis in peripheral by Paclitaxcel-eluting balloon (DEB) [6]. The purpose of the Pacuba I Trial was to test the hypothesis that DEB yields superior results compared to standard PTA for treatment of ISR [7].

References

1. Schillinger et al. N Engl J Med 2006
2. Schillinger et al. Circulation 2007
3. Lammer et al. J Am Coll Cardiol 2013
4. Dick et al. Radiology 2008
5. Lammer et al. Cardiovasc Intervent Radiol 2015
6. Stabile et al. J Am Coll Cardiol 2012
7. Kinstner et al. Poster presentation CIRSE 2015

PACUBA I Trial

- ***Study design:*** Prospective, dual centre, single-blind randomized (1:1) investigator sponsored clinical trial

- ***Principal investigator:*** Prof. Johannes Lammer (Vienna, Austria)

- ***Participating centers:*** Division of Cardiovascular and Interventional Radiology, Medical University of Vienna; Divison of Angiology, Medical University of Vienna

- ***Purpose:*** to the hypothesis that DEB yields superior results compared to standard PTA when treating ISR of femoropopliteal arteries

- ***Follow-up:***
  - clinical follow up and determination of ankle brachial index (ABI) at 1, 6 and 12 months and clinical FU at 12 months post procedure
  - Colour Doppler Duplex Ultrasound (CDUS) at 12h, 6 and 12 months post procedure
  - Computed tomography angiography (CTA) at 12 months post procedure

- ***Endpoints:***
  - Primary endpoint: Primary patency at 12 months post procedure defined as < 50% diameter stenosis in the absence of clinically driven target lesion revascularization (TLR) during follow up
  - Secondary endpoint: Technical success (< 30% residual stenosis after treatment), complication rate at 30 days post procedure, clinical success (improvement in Rutherford category), change in ABI and clinically driven TLR at 6 and 12 months post procedure

- ***Products used:*** Freeway DEB (Eurocor) vs. standard uncoated balloon (PTA)

- ***Number of patients:*** 35 (DEB) vs. 39 (PTA) patients with symptomatic in-stent restenosis of the SFA and P1 segment.

- ***Data presentation:*** Poster presentation at CIRSE 2015 (Lisbon, Portugal)

Main results

Below are enclosed the main results at 6 and 12 months.

- **The primary endpoint (primary patency at 12 months) has been reached. Patients treated with Freeway DEB had a significantly higher primary patency rate (40.7%) versus patients treated with standard balloon (PTA) (13.4%) at 12 months (p=0.02). (Figure 1)**

- Also at 6 months, the difference in primary patency could also be observed, DEB (58.8%) versus standard balloon (31.3%).

- The difference in primary patency at 12 months is more evident in short lesions (TASC A and B) (55% DEB vs. 9.5% PTA) (p=0.008) than in long lesions (TASC C and D). (Figure 2)

- DEB is also superior to PTA treatment regarding freedom of clinical driven target revascularization (TLR) rates at 6 months (88.2% vs. 83.8%) and 12 months (49% vs. 22.1%).

Figure 1: Primary patency rate of patients treated with DEB vs. PTA (Kaplan-Meier estimation)

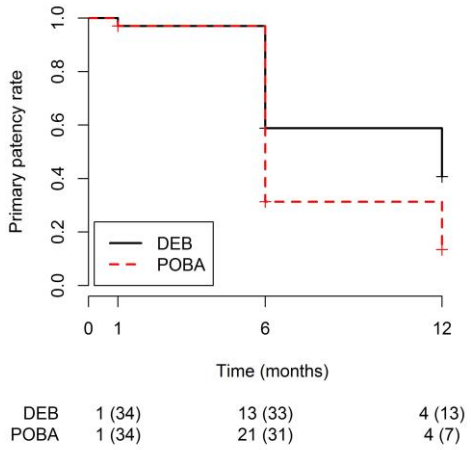
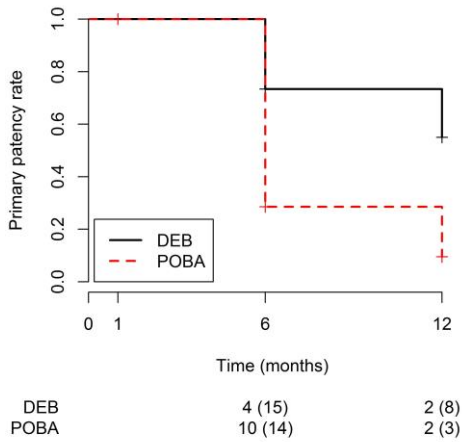


Figure 2: Primary patency rate of patients with TASC A and B lesions treated with DEB vs. PTA (Kaplan-Meier estimation)



Conclusion

- Patients with ISR treated with the Freeway **DEB had a significantly higher primary patency rate** of 40.7% versus standard PTA 13.4% at 12 months (p=0.02). This finding was more evident in short TASC A and B lesions (p=0.008) than in complex and long TASC C and D lesions, which are often treated by operation rather than interventional.

- The findings regarding the difference in primary patency is confirmed by the difference in freedom of TLR rates. Also here, DEB treatment is superior to PTA treatment at 12 months (49% vs. 22.1%).

Comparison to other studies

- The results of the Pacuba I Trial show a significantly higher primary patency rate in patients with ISR treated with DEB compared to PTA. This is in line with a lower TLR rate for patients treated with DEB compared to PTA treated patients. Trials investigating the efficacy of other DEB in patients with femoralpopliteal ISR also show superiority of the DEB versus PTA treatment. If you compare the absolute numbers, studies of competitors seems to provide better results, i.e. the FAIR trial (Krankenberg et al.) which shows a primary patency rate of 70.5% (DEB) vs. 37.5% (PTA) at 12 months. However, in these studies both groups (DEB and PTA) provide a better result. **To conclude, all three published randomised trials investigating DEB versus PTA in femoralpoliteal ISR (Pacuba I, Fair, Copa Cabana) show a benefit for patients treated with DEB versus PTA. However, absolute numbers seem to depend on the patient population included in the different study and not on the DEB used.**

If you have any questions or comments do not hesitate to contact us.

Kind regards,

Your Eurocor Clinical Trial Team

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