All Metal Stents Are Not Alike in the SFA: What Is the Impact of Stent Fractures and Will Biodegradable Stents Help?

NOTES

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Intravascular stents have been advocated to improve the long-term patency rate in femoropopliteal lesions. However, the results of the use of balloon-expandable stents and of self-expanding stainless steel stents have not been convincing.

The initial positive experience with a new generation of self-expanding nitinol stents promised an improvement in long-term patency. Unfortunately, this has not yet been followed by studies comparing different stent types according to short- and long-term patency. In the meantime, a new "nightmare" for SFA stenting has been evidenced: stent fractures. In fact, after implantation in the SFA, metal stents are subjected to compression, elongation, shortening, and distortion over the entire length of the vessel.

A systematic radiographic screening for stent fractures was performed in 93 patients. In total, 121 legs treated by implantation of self-expanding nitinol stents were investigated after a mean follow-up time of 10.7 months. The mean length of the stented segment was 15.7 cm. Overall, stent fractures were detected in 45 of 121 treated legs (37.2%). In a stent-based analysis, 64 of 261 stents (24.5%) showed fractures that were classified as minor (single strut fracture) in 31 cases (48.4%), moderate (fracture of > one strut) in 17 cases (26.6%), and severe (complete separation of stent segments) in 16 cases (25.0%). Fracture rates were 13.2% for stented length < 8 cm, 42.4% for stented length > 8 to 16 cm, and 52.0% for stented length >16 cm. In 21 cases (32.8%), there was a restenosis of > 50% diameter reduction at the site of stent fracture. In 22 cases (34.4%) with stent fracture, there was a total stent reocclusion.

According to Kaplan-Meier estimates, the primary patency rate at 12 months was significantly lower for patients with stent fractures (41.1% versus 84.3%, $p < .0001$).

Conclusions

There is a considerable risk of stent fractures after long-segment femoral artery stenting, which is associated with a higher in-stent restenosis and reocclusion rate. Stents especially constructed for the SFA using highly flexible bioabsorbable material could potentially overcome many problems related to the permanent implantation of the metal prostheses. In animal studies, it could be demonstrated that PLLA (poly-l-lactic acid) is an adequate material for the construction of stents, showing an absorption within 6 to 12 months. The first in-human coronary applications confirmed safety and efficacy of this type of stent.

The dedicated stents for the SFA (Igaki Medical Planning Co., Ltd., Kyoto, Japan) show a zigzag helical coil design with a strut thickness of 0.24 mm. The usable length of the stents is 36 or 78 mm and the diameter 5 mm (expandable to 7mm). The stent is not radiopaque and non-ferromagnetic. Two markers at the ends of the stent permit an exact placement. The longitudinal flexibility and torquability are excellent. The stent shows partial self-expandable force, however, in the delivery system is implementing a balloon, permitting the complete adaptation of the stent to the vessel wall.

With the aim to demonstrate the feasibility and safety of the IGAKI-TAMAI Stent, 45 patients with de novo lesions (± 6 cm) of the SFA (types B and C) were included in a first, nonrandomized, single-center study. The primary technical success rate, controlled by IVUS and angiography, was 100%. No serious adverse events were observed. The ratio of occurrence for TLR within 3 months after stenting was 5%; after 6 months the angiographically controlled restenosis rate (> 50%) was 30%. All restenoses could be successfully retreated showing a primary assisted patency rate of 91% at a mean follow-up of 9 months. No reocclusions were observed. These encouraging results have to be validated in larger trials including more complex lesions.

In conclusion, this new technology could open new possibilities in the treatment of femorotibial lesions, including also the uploading of different drugs on the struts of the stents.