

Which Stent for In-Bare-Metal Stent Restenosis?

See related article
in this issue

Hongbing Yan¹, Bo Xu¹

Management of in-stent restenosis remains a problem.¹⁻³ Although bare-metal stents provide excellent angiographic results, high restenosis rates still shadow these results. The superiority of drug-eluting stents compared with balloon angioplasty and vascular brachytherapy for the treatment of patients with in-stent restenosis has been shown in randomized trials.⁴⁻⁶ At present, drug-eluting stents represent the therapy of choice for in-stent restenosis.¹⁻⁶

The Firebird™ sirolimus eluting stent (Microport Co. Ltd., Shanghai, China) combines a stainless steel platform (L316) of thin struts (0.0040"), a powerful anti-proliferative agent (sirolimus, at a dose of 9 µg/mm²) and a coating that includes three layers of a durable polymer, that controls drug release. Since the Firebird™ drug-eluting stent was approved by Chinese SDA (State Drug Administration) for commercial use in the beginning of 2005, the penetration of this drug-eluting stent use accounted for 28%-30% (personal communication) in China because of promising clinical results from using this drug-eluting stents.⁷⁻¹¹ However, no published data appeared regarding its performance in treating in-stent restenosis.

In this issue of the **Revista Brasileira de Cardiologia Invasiva**, Freitas et al.¹² presented their one year angiographic and ultrasonographic follow-up results of treating in-stent restenosis with the Firebird™ sirolimus eluting stent. This study show that the late luminal loss was 0.30 ± 0.24 mm, and no case of binary restenosis was identified at 12 months. And on intravascular ultrasound, the percentage of in-stent volumetric obstruction was 2.6 ± 1.9%. Accordingly, the authors concluded that the Firebird™ sirolimus eluting stent showed favorable angiographic and ultrasound results for the treatment of bare metal in-stent restenosis at 1 year follow-up. More recently, Liistro et al.⁶ confirmed 4-year effectiveness and safety of sirolimus eluting stent implantation for coronary in-stent restenosis. Therefore,

sirolimus eluting stents are currently considered the best possible care in the treatment of in-stent restenosis, especially in patients with bare-metal stents.

However, this study is inherently limited by a lack of valid control groups which did not enable a direct comparison with another drug-eluting stents. Another major limitation is small cohort of patients and relative shorter clinical follow-up, which did not allow a real estimation of the late catch-up phenomenon with drug-eluting stents in in-stent restenosis lesions.

Finally, two points are worth to be noted. First, although drug-eluting stents have dramatically reduced the rates of in-stent restenosis compared with bare-metal stents, a low rate of in-stent restenosis after drug-eluting stents still exists, and its prevalence is not negligible because the population treated with drug-eluting stents is large. Second, drug-eluting stents implantation after in-stent restenosis may further reduce the flexibility of the vessel and limit the repeatability of the procedure. Furthermore, concerns have been raised that such drug-eluting stents require long-lasting antiplatelet therapy to avoid late thrombotic complications. Treatment of coronary in-stent restenosis with the paclitaxel-coated balloon was at least as efficacious and as well tolerated as the paclitaxel-eluting stent and inhibition of re-restenosis does not require a second stent implantation.¹³

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

REFERENCES

1. Kastrati A, Mehilli J, von Beckerath N, Dibra A, Hausleiter J, Pache J, et al. Sirolimus-eluting stent or paclitaxel-eluting stent versus balloon angioplasty for prevention of recurrences in patients with coronary in-stent restenosis: a randomized controlled trial. *JAMA*. 2005;293(2):165-71.

¹ Cardiovascular Institute and Fu-Wai Hospital – Beijing, China.

Correspondence: Hongbing Yan. 15th Division – Cardiovascular Institute and Fu-Wai Hospital – Chinese Academy of Medical Sciences – A 167, Beilishi Road – Xicheng District – Beijing, China – 100037

E-mail: yan591204@yahoo.com.cn

Received on: 11/24/2010 • Accepted on: 11/25/2010

2. Alfonso F, Perez-Vizcayno MJ, Hernandez R, Bethencourt A, Martí V, López-Mínguez JR, et al. A randomized comparison of sirolimus-eluting stent with balloon angioplasty in patients with in-stent restenosis: results of the Restenosis Intrastent Balloon Angioplasty versus Elective Sirolimus-Eluting Stenting (RIBS II) trial. *J Am Coll Cardiol*. 2006;47(11):2152-60.
3. Fujii K, Mintz GS, Kobayashi Y, Carlier SG, Takebayashi H, Yasuda T, et al. Contribution of stent underexpansion to recurrence after sirolimus-eluting stent implantation for in-stent restenosis. *Circulation*. 2004;109(9):1085-8.
4. Ellis SG, O'Shaughnessy CD, Martin SL, Kent K, McGarry T, Turco MA, et al., on behalf of the TAXUS V ISR Investigators. Two-year clinical outcomes after paclitaxel-eluting stent or brachytherapy treatment for bare metal stent restenosis: the TAXUS V ISR trial. *Eur Heart J*. 2008;29(13):1625-34.
5. Holmes DR Jr, Teirstein PS, Satler L, Sketch MH Jr, Popma JJ, Mauri L, et al. 3-year follow-up of the SISR (Sirolimus-Eluting Stents Versus Vascular Brachytherapy for In-Stent Restenosis) trial. *JACC Cardiovasc Interv*. 2008;1(4):439-48.
6. Liistro F, Fineschi M, Grotti S, Angioli P, Carrera A, Ducci K, et al. Long-term effectiveness and safety of sirolimus stent implantation for coronary in-stent restenosis: results of the TRUE (Tuscany Registry of Sirolimus for Unselected In-Stent Restenosis) registry at 4 years. *J Am Coll Cardiol*. 2010;55(7): 613-6.
7. Ni J, Shen WF, Zhang J. Clinical utility of Firebird drug-eluting stent in the treatment of de novo native coronary artery lesions. *J Interv Radiol*. 2004;13(5):396-8.
8. Liu HB, Xu Bo, Gao RL, Yang YJ, Yao M, Qin XW, et al. Outcomes of using Firebird rapamycin eluting stents in routine coronary intervention practice: one-year results from the pilot study of Firebird in China registry. *Chin Med J*. 2006;119(7): 609-11.
9. Zhang Q, Zhang RY, Zhang JS, Hu J, Yang ZK, Ni J, et al. One-year clinical outcomes of Chinese sirolimus-eluting stent in the treatment of unselected patients with coronary artery disease. *Chin Med J*. 2006;119(2):165-8.
10. Gao H, Yan HB, Zhu XL, Li N, Ai H, Wang J, et al. Firebird sirolimus eluting stent versus bare metal stent in patients with ST-segment elevation myocardial infarction. *Chin Med J*. 2007;120(10):863-7.
11. Zhang Q, Xu B, Yang YJ, Qiao SB, Zhang RY, Zhang JS, et al. Long-term efficacy and safety of Chinese made sirolimus eluting stents: results, including off label usage, from two centers over three years. *Chin Med J*. 2008;121(17):1670-4.
12. Freitas LZF, Feres F, Costa Jr JR, Abizaid A, Staico R, Costa R, et al. Tratamento de reestenose intrastent com o novo stent farmacológico Firebird™, liberador de sirolimus – resultados angiográficos e ultrassonográficos de um ano de evolução. *Rev Bras Cardiol Invasiva*. 2010;18(4):???-???
13. Unverdorben M, Vallbracht C, Cremers B, Heuer H, Hengstenberg C, Maikowski C, et al. Paclitaxel-coated balloon catheter versus paclitaxel-coated stent for the treatment of coronary in-stent restenosis. *Circulation*. 2009; 119(23):2986-94.