Editorial comment

Cutting balloon and the search for an optimal treatment for in-stent restenosis

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Cutting balloon (CB) angioplasty was introduced in 1990 as a system for the dilation of coronary lesions with the intent of minimizing trauma and lowering stretch on the vessel wall[1]. A randomized trial evaluated CB angioplasty vs conventional coronary angioplasty (PTCA) failing to demonstrate any additional advantage of CB in terms of angiographic restenosis (31.4% for CB and 30.4% for PTCA, p = 0.75) or major cardiac events (13.6% for CB and 15.1% for PTCA, p = 0.34)[2]. The introduction of coronary stents decreased interest in CB angioplasty. Paradoxically, it was the stent, the same device that contributed to the decline of CB, to create in-stent restenosis an area where CB found its major application. The main reason why CB is utilized to treat in-stent restenosis is the fact that the 3 or 4 blades (depending on the size of the CB) which protrude from the surface of the balloon score the fibrous tissue of in-stent restenosis and maintain the stability of the dilating balloon[3]. The major mode of lumen enlargement after PTCA for in-stent restenosis is further stent expansion with some plaque compression and redistribution. With CB angioplasty, stent expansion is minimal and most of the effect is due to intimal hyperplasia extrusion behind the stent and toward the proximal and distal edges[4]. This mode of action was thought to contribute to improve the immediate result and to lower the trauma, consequent to further stent expansion, to the vessel wall. This theory became the supporting observation for the use of CB angioplasty to treat in-stent restenosis.

There are several observational and small randomized studies reporting the advantages of CB angioplasty vs PTCA or other modalities for the treatment of in-stent restenosis[5-10]. The RESCUT (Restenosis Cutting Balloon Evaluation Trial) evaluated, in a multicenter randomized trial on 428 patients, the effectiveness of CB angioplasty vs standard PTCA to treat in-stent restenosis. The results of this trial showed that at the 7-month angiographic follow-up, the binary restenosis rate was not different between the groups (29% for CB and 31.3% for PTCA, p = 0.82), with a similar pattern of recurrent restenosis. Clinical events at 7 months were also similar[11].

In this issue of the Journal, Montorsi et al.[12] evaluate in 50 patients with in-stent restenosis randomized to CB or PTCA, the acute angiographic and intravascular ultrasound (IVUS) results and correlate these results with the subsequent clinical follow-up. The unique features of this study are the fact that the patients had device sizing performed according to the IVUS measurements with a 1:1 device to stent ratio and the fact that no particular attempts were made to optimize stent expansion when the IVUS evaluation showed that the stent was not adequately dilated. This latter approach was motivated by the theory that any further stent expansion may trigger more proliferation[13]. The immediate results were similar for both strategies with a 37% diameter stenosis decrease for PTCA and a 45% decrease for CB. Unique to this study was the finding that the mechanism of luminal enlargement was similar for both strategies with 20% of the luminal gain due to additional stent expansion and the rest due to a reduction in the restenosis area (plaque outside the stent and toward the lumen). By trial design, all patients had re-

peat angiography and IVUS 24 hours following the index procedure. Of great interest was that at 24 hours, the repeat IVUS exam showed a smaller lumen in the group treated with PTCA compared to the group treated with CB (5.45 and 6.9 mm^2 respectively). Clinical follow-up was obtained at 6 ± 1 months and demonstrated a cumulative need for a second procedure on the target lesions of 40% in the group treated with PTCA compared to 12.5% in the group treated with CB ($p < 0.05$).

These results are certainly of interest but are shadowed by the results of a large randomized trial[11] and by current clinical practice in which the CB has mainly acquired the position of a preparatory device before performing intracoronary brachytherapy. The better outcome at 24 hours demonstrated by Montorsi et al. with usage of the CB is an important explanation why this device became standard preparation before intracoronary delivery of gamma or beta-radiation.

A major drawback of conventional angioplasty employed to treat in-stent restenosis is the instability of the standard balloon inside the restenotic segment. This condition, defined "water melon seeding effect", is particularly deleterious in the setting of vascular brachytherapy which has been the major modality for the treatment of in-stent restenosis. The dilation of the restenotic stent before delivering radiant energy needs to be performed inside the diseased segment avoiding any trauma to the areas which will not be radiated. The stability of the CB seems to have improved the results of intracoronary brachytherapy for the treatment of in-stent restenosis[14-16]. In a large European registry (RENO - Radiation in Europe NOvoste registry) evaluating beta-radiation for the treatment of in-stent restenosis, the investigators reported a lower need for a second procedure in the restenotic lesions treated with the CB compared to standard balloon before delivery of beta-radiation (10.2 vs 16.6% respectively, $p = 0.04$)[16].

The recent introduction of drug-eluting stents has again challenged the field of application of the CB by lowering the incidence of restenosis and by competing with brachytherapy as a treatment modality for in-stent restenosis. Will the CB, as a preparatory device in some fibrocalcific lesions before delivery of a drug-eluting stent, be resurrected again? Will the CB maintain its position of the state of the art device for the preparation of a restenotic stent before delivery of a drug-eluting stent?

The results reported by Montorsi et al. are certainly encouraging and may point in this direction. The time has come again to evaluate the CB in a randomized trial as a preparatory device in selected lesions (native and restenotic) before drug-eluting stent delivery.

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