Cutting Balloon Versus Conventional Balloon Angioplasty for the Treatment of Coronary Artery Disease

a report by

Dr Remo Albiero

Director, Cardiac Catheterisation Laboratory, Clinica San Rocco, Brescia

The cutting balloon (CB) is a special balloon catheter with three or four atherotomes (microsurgical blades) bonded longitudinally to its surface, suitable for creating discrete longitudinal incisions in the atherosclerotic target coronary segment during balloon inflation. With the cutting balloon, the increase in the vessel lumen diameter is obtained in a more controlled fashion and with a lower balloon inflation pressure than conventional percutaneous transluminal coronary angioplasty (PTCA) – this controlled dilatation could reduce the extent of vessel wall injury and the incidence of restenosis.

The Global trial, a multicentre, randomised trial on 1,238 patients, tested the hypothesis that ‘surgical’ dilatation using the CB (617 patients) could result in less arterial trauma, fewer dissections and less frequent restenosis than conventional PTCA (621 patients). The lesion selected in this study (simple type A/B1 lesions) were treated by a single cutting balloon inflation, with a balloon-artery ratio of 1.1:1. The controlled dilatation of the cutting balloon did not reduce the rate of angiographic restenosis compared with conventional PTCA (CB 31.4%, compared with PTCA 30.4%, \( p=0.75 \)). Five coronary perforations occurred only in the CB arm (0.8% compared with 0%, \( p=0.03 \)).

The results of the Global trial indicate that CB angioplasty in simple lesions is not superior to conventional PTCA for the prevention of restenosis and should probably be reserved for more complex lesions in which the controlled dilatation of the CB could provide better acute and mid-term results compared with conventional PTCA. In fact, this device is mainly used to treat in-stent restenosis (ISR), ostial lesions, bifurcation lesions and smaller vessels and to expand resistant fibrocalcified plaques not dilated by high pressure conventional PTCA balloons.

In-stent Restenosis

With the rapid explosion in stent use, ISR has become a significant clinical problem. Re-dilatation using a conventional PTCA balloon has been the most commonly used approach to treat ISR, but with a high recurrent restenosis rate, especially in the subgroup of patients with diffuse and/or severe ISR. Numerous small retrospective studies have shown the benefits of the CB for the prevention of the recurrence of ISR compared with conventional PTCA. These studies were followed by small pilot randomised studies that also showed a clinical benefit associated with the use of a CB.

The author’s prior observation demonstrated a greater capacity of cutting balloon angioplasty (CBA) to extrude a fibrous residual neo-intimal plaque out of the stent struts than conventional PTCA. The microblades of the cutting balloon were able to surgically incise the restenotic plaques up to the metallic stent cage – these incisions probably facilitated the maximum extrusion of the neo-intimal plaque. This hypothesis was confirmed by an intravascular ultrasound (IVUS) study that showed a larger luminal area acute gain after CBA (2.5 ± 0.8mm\(^2\)) than after conventional PTCA (1.8 ± 1.0mm\(^2\)), which translated into a lower restenosis rate at 5.4-month follow-up (CBA 24%, PTCA 59%).

Two large prospective, randomised, multicentre studies both failed to demonstrate an advantage of the CB over PTCA for the treatment of ISR:

- the Restenosis Cutting Balloon Evaluation Trial (RESCUT); and
- the Restenosis Reduction by Cutting Balloon Evaluation (REDUCE) II trial.

The RESCUT trial is a European study designed to assess the results of CB (\( n = 214 \)) compared with conventional PTCA (\( n = 214 \)) for the treatment of ISR. The study included lesions shorter than 25mm in native coronary arteries with all types of ISR patterns (focal, multifocal, diffuse and proliferative).

This large multicentre randomised study differed from previous reports in that the rates of clinical events (death, myocardial infarction (MI) and target lesion revascularisation (TLR)) were similar between the two groups (see Figure 1), as well as the rates of restenosis and its patterns (see Figure 2 and 3).
The CB demonstrated some practical advantages over conventional PTCA:

- balloon slippage was less frequent in the CB group (6.5% compared with PTCA 25%, p<0.01); and
- there was a trend towards a lower need for additional stenting (CB 3.9% compared with PTCA 8.0%, p=0.07), mainly due to a lower frequency of residual stenosis more than 30% and type D–F dissections.

These advantages could be explained as follows: conventional PTCA balloons, particularly short balloons when positioned within in-stent restenotic lesions, tend to move forwards or backwards during inflation into larger segments with lower resistance, because the hyperplastic tissue has a smooth slippery surface. With a CB this problem is prevented by the blades, which anchor the balloon to the plaque during balloon inflation, reducing the risk of dissection at the stent margins. This fact could be important when there is the need to carefully control the boundaries of the injured segment, for example before coronary brachytherapy, as demonstrated in the Registry Novoste (RENO) where pre-treatment with CB before brachytherapy (performed using beta radiation) significantly reduced six-month target-vessel revascularisation compared with conventional angioplasty (10.2% compared with 16.6%; p=0.04). The use of CBs could not translate into clinical or angiographic benefits for patients with ISR treated with drug-eluting stents (DES), as a result of the procedural differences in the treatment of ISR using adjunctive brachytherapy compared with restenting using a DES. In the first case (before adjunctive brachytherapy), it is recommended to optimally treat ISR by conventional/CBA or atherectomy, avoiding additional stenting to reduce the risk of late stent thrombosis. In the case of restenting with a DES, an optimal balloon pre-treatment of ISR is not necessary, nor is the use of a CB to avoid balloon slippage, because the operator can reduce the risk of vessel injury at the stent edges, even in the event of balloon slippage, by simply predilating the ISR lesion using an undersized non-compliant conventional PTCA balloon.

The second randomised multicentre trial to be discussed is the Japanese REDUCE II trial on 416 patients. The six-month result of this study (not yet published at the time of press) were not different between the two groups – binary restenosis was 24% in the CB group compared with 22% in the PTCA arm and TLR was 20% in both arms.
Ostial or Bifurcation Lesions

The CB may provide an advantage over conventional PTCA in complex lesions such as ostial or bifurcation lesions; however, a large retrospective study of 1,580 patients did not show a lower TLR in patients treated with the CB compared with conventional PTCA in ostial or bifurcation lesions.17

Small Vessels

Small vessel size represents a critical risk factor for an adverse outcome after both conventional PTCA and stenting. A recent study in small coronary arteries evaluated the clinical and angiographic benefits of gradual and prolonged balloon angioplasty (GPBA) using a perfusion balloon, to cause less arterial trauma, compared with CB angioplasty and conventional PTCA. A total of 263 patients with a lesion in a small vessel (reference diameters less than 3mm) were randomly assigned to undergo GPBA (n=85), CBA (n=88), or conventional PTCA (n=90). The cumulative inflation time was more than 10 minutes in GPBA. Compared with conventional PTCA, GPBA resulted in a lower final residual diameter stenosis (27.3% compared with 34.2%, p=0.01) and decreased the need for stent placement (8.0% compared with 22.2%, p=0.031). At follow-up, the restenosis rates were lower with GPBA (31.3%, p=0.034) and CBA (32.9%, p=0.059) than conventional PTCA (50.6%). Target lesion revascularisation was less frequently needed with GPBA (20.5%, p=0.043) and CBA (20.0%, p=0.033) than conventional ‘plain old balloon angioplasty’ (POBA) (37.6%).18

Another retrospective study in small coronary arteries evaluated the clinical and angiographic benefits of stenting compared with CB angioplasty and conventional PTCA. A total of 327 lesions in small vessels (reference diameters less than 2.5mm by quantitative coronary angiography (QCA)) were analysed – stenting (n=110), CB (n=87) and conventional PTCA (n=130). Angiographic restenosis was encountered in 43.9% of the stent, 31% of the CB and 46.5% of the conventional PTCA groups (p = 0.048).

Major adverse coronary events (MACE; death, MI and TLR) at follow-up were significantly lower in the CB compared with other groups (CB, 20.3%; conventional PTCA, 37.3%; stent, 33.3%; p=0.036). In conclusion, in small vessels less than 2.5mm, the CB procedure provided superior angiographic and clinical outcomes to stenting or conventional PTCA.19

Before Stenting

By favourably scoring the plaque prior to stent implantation, CBA may be preferable (compared with a conventional balloon) before stent placement. This hypothesis was evaluated in the REDUCE III study, a Japanese prospective, randomised multicentre trial on 520 patients. At six-month follow-up, restenosis rate was significantly lower in the CB compared with other groups (CB, 20.3%; conventional PTCA, 37.3%; stent, 33.3%; p=0.036).

In conclusion, in small vessels less than 2.5mm, the CB procedure provided superior angiographic and clinical outcomes to stenting or conventional PTCA.19

Ostial or Bifurcation Lesions

The CB may provide an advantage over conventional PTCA in complex lesions such as ostial or bifurcation lesions; however, a large retrospective study of 1,580 patients did not show a lower TLR in patients treated with the CB compared with conventional PTCA in ostial or bifurcation lesions.17

Small Vessels

Small vessel size represents a critical risk factor for an adverse outcome after both conventional PTCA and stenting. A recent study in small coronary arteries evaluated the clinical and angiographic benefits of gradual and prolonged balloon angioplasty (GPBA) using a perfusion balloon, to cause less arterial trauma, compared with CB angioplasty and conventional PTCA. A total of 263 patients with a lesion in a small vessel (reference diameters less than 3mm) were randomly assigned to undergo GPBA (n=85), CBA (n=88), or conventional PTCA (n=90). The cumulative inflation time was more than 10 minutes in GPBA. Compared with conventional PTCA, GPBA resulted in a lower final residual diameter stenosis (27.3% compared with 34.2%, p=0.01) and decreased the need for stent placement (8.0% compared with 22.2%, p=0.031). At follow-up, the restenosis rates were lower with GPBA (31.3%, p=0.034) and CBA (32.9%, p=0.059) than conventional PTCA (50.6%). Target lesion revascularisation was less frequently needed with GPBA (20.5%, p=0.043) and CBA (20.0%, p=0.033) than conventional ‘plain old balloon angioplasty’ (POBA) (37.6%).18

Another retrospective study in small coronary arteries evaluated the clinical and angiographic benefits of stenting compared with CB angioplasty and conventional PTCA. A total of 327 lesions in small vessels (reference diameters less than 2.5mm by quantitative coronary angiography (QCA)) were analysed – stenting (n=110), CB (n=87) and conventional PTCA (n=130). Angiographic restenosis was encountered in 43.9% of the stent, 31% of the CB and 46.5% of the conventional PTCA groups (p = 0.048).

Major adverse coronary events (MACE; death, MI and TLR) at follow-up were significantly lower in the CB compared with other groups (CB, 20.3%; conventional PTCA, 37.3%; stent, 33.3%; p=0.036). In conclusion, in small vessels less than 2.5mm, the CB procedure provided superior angiographic and clinical outcomes to stenting or conventional PTCA.19

Before Stenting

By favourably scoring the plaque prior to stent implantation, CBA may be preferable (compared with a conventional balloon) before stent placement. This hypothesis was evaluated in the REDUCE III study, a Japanese prospective, randomised multicentre trial on 520 patients. At six-month follow-up, restenosis rate was significantly lower in the CB compared with other groups (CB, 20.3%; conventional PTCA, 37.3%; stent, 33.3%; p=0.036).

In conclusion, in small vessels less than 2.5mm, the CB procedure provided superior angiographic and clinical outcomes to stenting or conventional PTCA.19

CB Complications and Drawbacks

A trend for higher complication rates have been reported with the use of CB, including vessel perforation when using oversized balloons or when the CB is used outside the stent,20,21 dissection,22,23
Cutting Balloon Versus Conventional Balloon Angioplasty for the Treatment of CAD

spasm and entrapment. The co-existence of many, rather than a single, anatomical and procedural characteristics may increase the risk of vascular complications following CB angioplasty. The lesion eccentricity is probably the most important factor, followed by vessel calcification and a large balloon–artery ratio. The appearance, at angiography, of an overdilated vessel after CBA should raise suspicion of an excessively deep cut of the device. Finally, the cost of the CB is higher (US$1,000 compared with US$250 for conventional PTCA balloon).

Conclusions

Based on the available data, the CB can be used:

- to treat in-stent restenosis, due to some procedural advantages over conventional PTCA – the microblades (atherotomes) prevent balloon slippage (melon-seeding), reducing the injury zone and edge dissection;
- to treat small vessels, although a gradual and prolonged CBA using a perfusion balloon could be equally effective in reducing restenosis;
- based on anecdotal data, to reduce plaque shift in ostial/bifurcation lesions;
- based on anecdotal data, to treat ‘resistant’ lesions, although rotational atherectomy is preferred (CB is difficult to deliver in moderate to severe calcified lesions); and
- before stenting using a bare-metal stent (REDUCE III).

<table>
<thead>
<tr>
<th>Table 1: Reasons to Use the Cutting Balloon Before Implantation of a DES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of lesion</strong></td>
</tr>
</tbody>
</table>
| In-stent restenosis (ISR) | • Conventional PTCA balloon slips causing injury distally.  
• CB scores the intimal hyperplasia which favours plaque extrusion through original stent struts, maximising lumen area before DES placement. |
| Small vessel | • CB compressed the plaque, creating a larger lumen area for stent placement. |
| Bifurcation | • CB reduces plaque shift, while direct stenting and POBA cause it.  
• In highly fibrotic lesions, CB severs the fibrotic strands.  
• In focal lesions, the 6mm long CB controls the injury zone. |
| Ostial (side branch and aorta) | • CB reduce plaque shift, while direct stenting and POBA cause it.  
• In highly fibrotic lesions, CB severs the fibrotic strands.  
• In focal lesions, the 6mm long CB controls the injury zone. |
| Resistant (hard plaque and calcium) | • POBA and stenting do not resolve the stenosis.  
• Easier to use than rotational atherectomy. |

New Vascular Horizons

PEOPLE. IDEAS. PASSION.

Stroke Management

Emboli Management

Peripheral Intervention

Peripheral Embolisation

www.ev3.net
References


17. Bair et al., J. Am. Coll. Cardiol. (2003);41:5A


