13. Cutting Balloon Prior To Stenting

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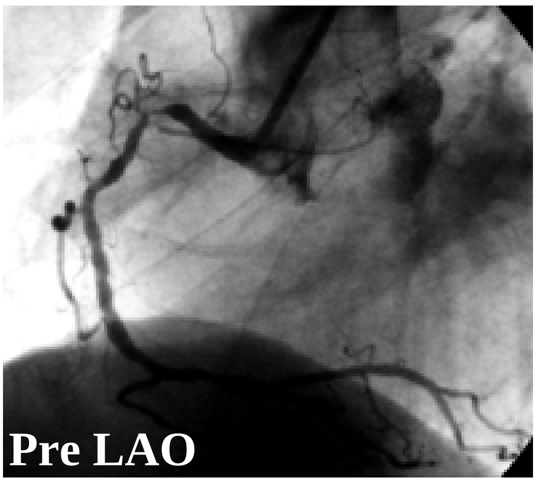
1. Different Principles Behind the Cutting Balloon & Conventional Balloon Angioplasty

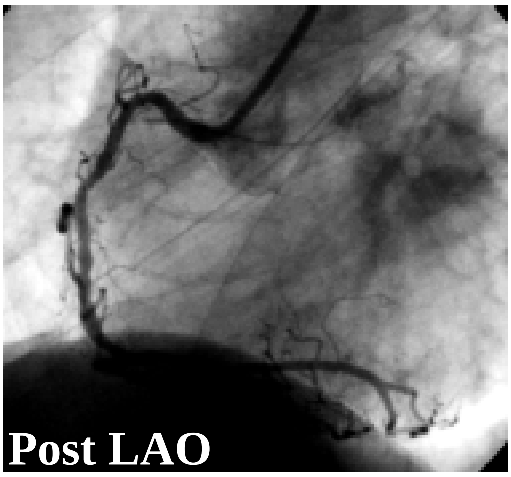
The Cutting Balloon (CB) was designed specifically to reduce trauma on the vessel wall and on the plaque which are a feature of conventional balloon angioplasty (PTCA), and to minimize the smooth muscle cell proliferation that accompanies it. The CB has 3 or 4 tiny stainless steel blades, 0.1~0.4mm thick, fitted along the surface of its balloon, and is available in various sizes from 2.0mm~4.00mm, and in two lengths of 10mm or 15mm. The non-compliant balloon has a rated burst pressure of 8atm. The concept behind the CB is that, when inflated, the blades create a point of reduced resistance, minimizing dissection in the plaque or media, and avoiding trauma to the plaque and elastic recoil to a much greater extent than with a conventional balloon. This reduces inadequate dilatation, acute occlusion, and long-term excessive smooth muscle cell proliferation. There are also reports that the CB has been used with good effect as a pre-dilatation device in calcified lesions that can not be dilated by conventional balloons, though this is a not a use for which the CB was originally intended. At our institution too, we have been able successfully to dilate heavily-calcified lesions using just the CB, as can be seen in the IVUS images below (See Case 1).

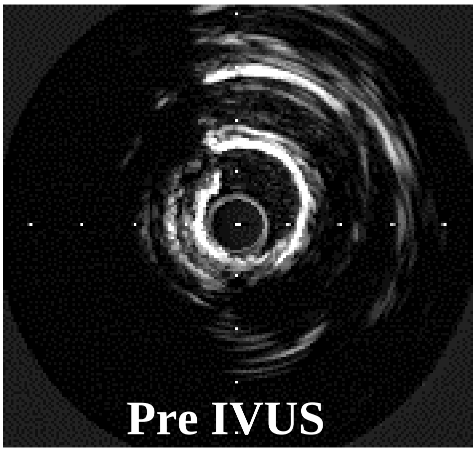
- Data from animal models suggest that there is none of the de-endothelialization, intimal injury, medial dissection, or trauma to the vessel wall usually seen with conventional angioplasty, and as the incisions caused by the blades penetrate to the intima, that the EEM of the vessel is increased.

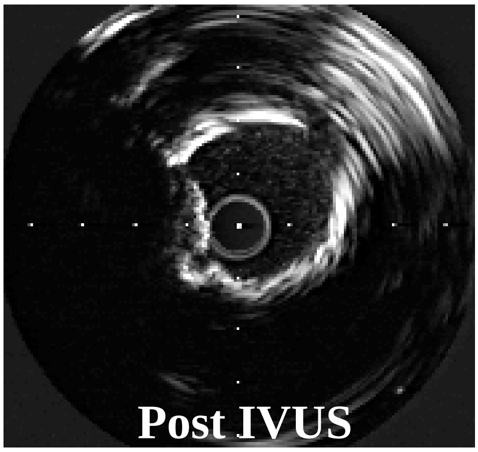
Case 1:

Proximal RCA lesion with 360° superficial calcification successfully cracked by cutting balloon





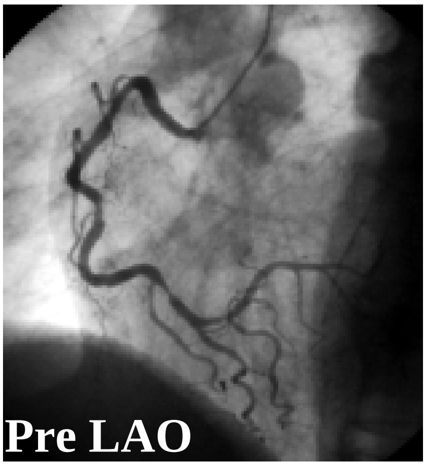


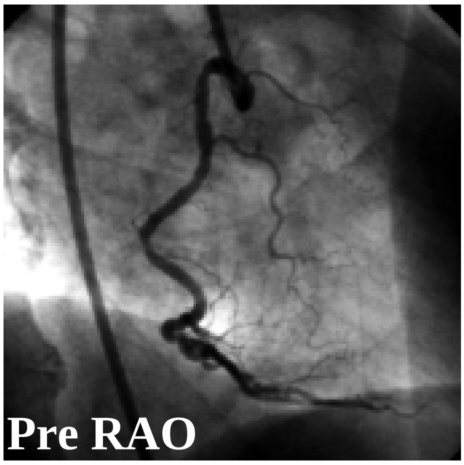


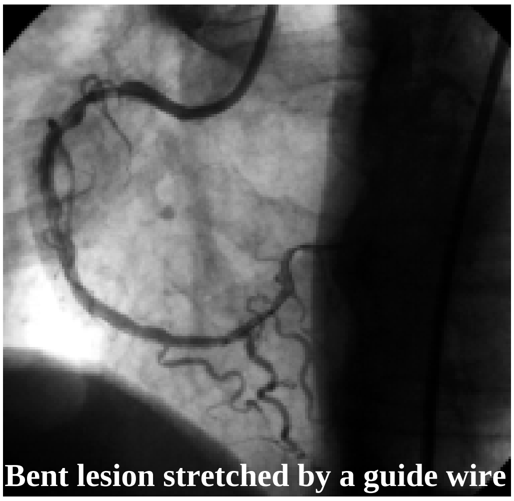
2. Lesions Indicated for Cutting Balloon Angioplasty

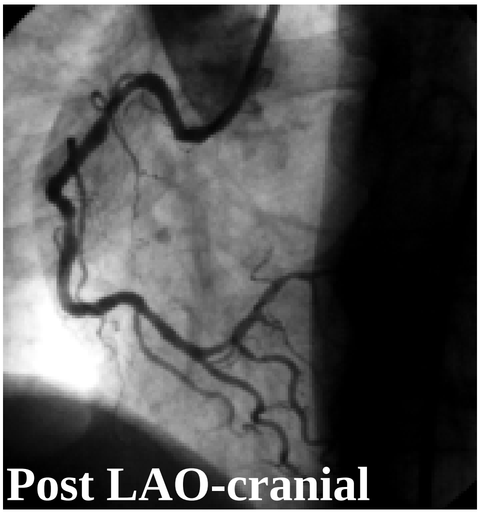
Lesions indicated for Cutting Balloon Angioplasty (CBA) are relatively short (<20mm) concentric lesions, in vessels with no more than moderate tortuosity or snaking (<45°) and with no significant thrombus presence. Lesions in small vessels <2.0mm in diameter, total occlusions, heavily-calcified lesions or >20mm in length are not considered appropriate for CBA. At our institution, however, we have had some success in heavily-calcified lesions using the CB in conjunction with the rotablator, and find that using a guiding catheter with very a strong back-up force and a guidewire with a strong shaft (Lifeline's Grandslam) enables us even to treat the majority of very tortuous vessels (See Case 2). We even have some experience of CBA being used to successfully recanalize total occlusions.

Case 2:Cutting balloon for highly bent lesion









3. CBA Procedural Points

For CBA, as with PTCA, a balloon/artery ratio of 1.1 should be the aim, at a low inflation pressure of 4-6atm for 1-2 minutes, and gradual inflation of the balloon to give the blades time to firmly incise the plaque. Where necessary, perform 2-3 low pressure inflations, and once the plaque has been incised fully at low pressure, a single short high-pressure dilatation may also be appropriate. We operate the CB up to a maximum pressure of 12atm, even thought the rated burst pressure is 8atm. Be warned that suddenly inflating the CB to high-pressure does not allow enough time for the blades to cut into the plaque sufficiently, and gives a result much the same as conventional PTCA.

4. CBA as a Primary Strategy

- The main issue with any kind of stenting is that in-stent restenosis (ISR) remains extremely difficult to treat. The advent of ticlopidine has improved matters, but the incidence of sub-acute occlusion and other problematic events reminds us that the stent remains a foreign body whose use should be avoided where possible. We prefer to use it as a last-resort to bail out cases of severe dissection or insufficient dilatation.
- When weighing the advantages of a conventional balloon and the CB, as your primary device, and not just as a pre-stenting tool, the data from one small trial suggests that CBA gives lower rates of restenosis than PTCA, but this was not corroborated by the larger-scale REDUCE I Trial which used B/A ratios of 1.0~1.2 and reported no significant difference in the two restenosis rates (29.3% (CBA) vs. 29.6% (PTCA)), or TLR rates (21.5% (CBA) vs. 23.3%) suggesting no benefit to either modality in terms of restenosis.
- Where CBA was clearly superior to PTCA was in terms of reduced injury to the vessel wall, with dissection significantly less common than in the PTCA cohort, producing a tendency to lower crossover to stenting.
- When considering which of the two will give lower restenosis rates when used as a pre-stenting device, the data from the smaller study suggests that CBA results in lower rates of restenosis, and we are still waiting for the results of bigger trials such as REDUCE III for

full confirmation. It may be that the lower restenosis rates associated with CBA are attributable to reduced vessel injury (namely, less vessel over-stretch and dissection) at the time of pre-dilatation. Also, since CBA results in less plaque shift and greater plaque compression, pre-dilating with a Cutting Balloon at low-pressure before stenting produces a greater stent area than a conventional balloon does, and therefore less restenosis due to the fact that reduced vessel trauma elicits a reduced proliferative response.

5. Complication Rates (REDUCE I)

Angiographic complications		***Clinical Complications***	
(a) coronary perforation	0%	(a) death	0%
(b) coronary dissection	25.5%	(b) QMI	0%
		(c) em-CABG	0%
		(d) non-QMI	1%

An explanation for the above figures may lie in the fact that our institution we use the CB as our primary device even for lesions not usually indicated for CBA, such as those with heavy calcification, or a high plaque burden, or severe vessel tortuosity.

One potential disadvantage with the Cutting Balloon is that is does not cross as easily as a conventional balloon, and if you are planning all along to put a stent in and think you may need to post-dilate, you may be better off, from the point of view of saving devices, using a conventional balloon instead for both pre- and post-dilatation. The conventional devices are not entirely without merit.

Rotablator Prior to Stenting

1. Unique Features

One feature of the rotablator is its uniformly high procedural success rate (about 95%), and it is also far less susceptible than other devices to lesion severity. The theory behind the rotablator is that tiny diamond fragments embedded in the tip of the burr selectively excise hard calcified tissue and not the more elastic softer material, and that this ablation mechanism leaves the lumen smoother, inhibiting turbulence during the healing process, and delivering a consequent reduction in restenosis. With an appropriate rotation speed and careful handling, the amount of debris ablated will amount to <10-15μm which is not enough to occlude the capillaries. Care must be taken to ensure that a too-slow rotation speed (<75,000rpm) doesn't create too much debris, or that the burr is not brought into too close contact with the lesion (causing the rotation speed to fall more than 5,000rpm) as this will generate excessive heat at the lesion.

Applying the rotablator to the hard surface plaque produces an enlarged round smooth vessel lumen, with a lumen diameter 90-100% of the burr size. However, in the presence of fibro-fatty plaque, the vessel lumen surface is irregular, with a diameter normally about 30-40% smaller than the burr size. The may be because with soft plaque, ablation is less effective, and the risk of spasm increased.

2. Lesions indicated for rotablator

While it's true that essentially, the rotablator is less likely to be affected by lesion severity than other devices, it has not been shown to have any significant advantage over other devices in terms of reducing restenosis (in fact, there are a number of reports that suggest that rotablator may result in higher rates of restenosis), the recent consensus is that for difficult-to-treat severely-calcified lesions, rotablator is the best option. We can go further and say that lesions liable to problems with insufficient dilatation, such as ostial lesions, bifurcation lesions and 10-25mm diffuse calcified lesions are specifically indicated for rotablation.

On the question of in-stent restenosis, we are still waiting for the results of a randomized trial before drawing any conclusions about the rotablator's efficacy for this problematic clinical entity.

For lesions containing thrombus or located in ageing venous grafts, lesions >25mm long would seem to be contra-indicated for rotablator. Also, the risk of slow flow (associated with rotablator) means that this modality is inappropriate for patients with seriously impaired cardiac function, irrespective of lesion type, as it may lead to a further deterioration in cardiac function.

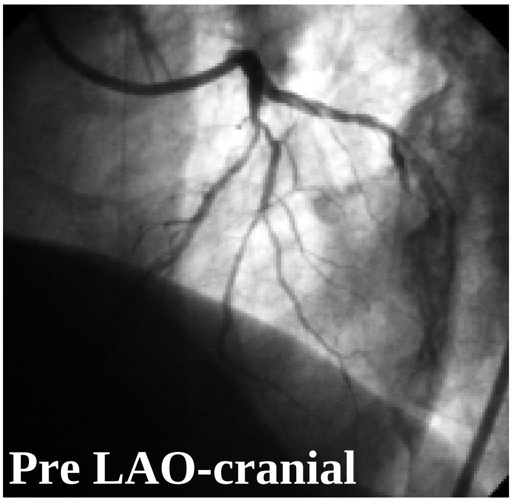
3. Strategy

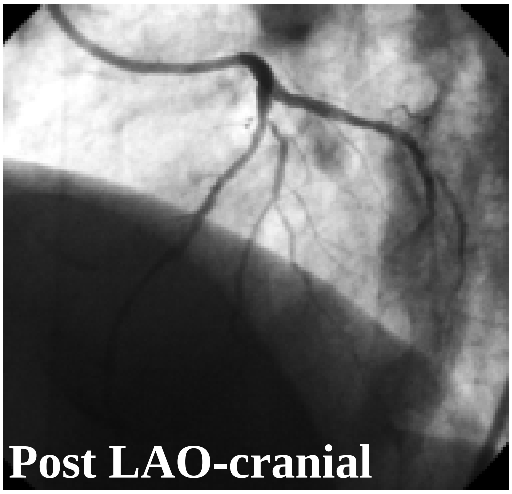
"Stand-alone" rota procedures are limited by the fact that burr sizes only go up to 2.5mm, while initial expectations of a reduction in restenosis have not been fulfilled by the device, a number of authors even reporting higher rates of restenosis than for conventional balloon angioplasty. For these reasons, rotablator is rarely used as a stand-alone therapeutic strategy for coronary stenosis, and is primarily used only for heavily calcified lesions. A burr/artery ratio of 0.6~0.8 is the norm, and while a higher burr/artery ratio might offer some hope of reduced restenosis, that would carry an increased risk of perforation. If the use of rotablator alone could produce favourable results, as a basic treatment option, it would not have to be used in conjunction with other devices, but for large vessels the only available data in the international literature describes rota- with adjunctive PTCA. At our hospital, we use the Cutting Balloon as an adjunctive therapy. The reason for this, as I mentioned in the section on CBA, is that the CB causes less dissection, and a reduced likelihood of bail-out stenting, and it is hospital policy to try wherever possible not to resort to stenting. Of course, we do put a stent in if we are faced with a dissection, or insufficient luminal dilatation. We use rotablator when we cannot cross a lesion with another device, or when there is a high risk of causing a severe dissection in a heavily calcified lesion, when we rotablate in order to enable us to tackle the lesion with a different device. Rotablator is not our primary therapeutic strategy.

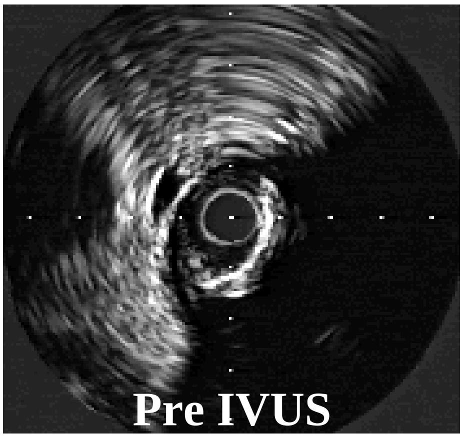
Below are two cases from our hospital. In the first (Case 3), good dilatation was achieved using rotablator alone, and in the other (Case 4) a favourable result obtained with Rota + Cutting Balloon.

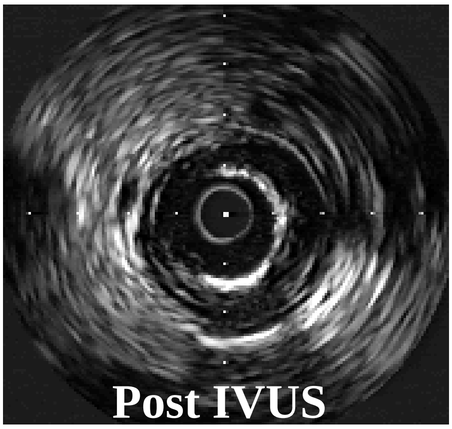
One strategy is which the efficacy of the rotablator is specifically recognised is in debulking heavily-calcified lesions prior to stenting. The rotablator can also be a useful pre-conditioning option when pre-dilatation by balloon is impossible, or when a calcification spike results in stent delivery failure. Studies into the effect of different burr sizes on restenosis rates suggest no significant difference. Slightly down-sizing the burr (a burr/artery ratio of 0.5), as has been said, can make it easier to treat a lesion with another device, and compared to a larger burr, may mean less risk of distal embolization, and therefore reduced flow. It may also reduce the incidence of myocardial infarction from stent-related thrombosis and embolization, which is obviously an important consideration. In the event of slow-flow being observed following the implantation of a stent, adjunctive anti-coagulation therapy should be given for 12-24 hours.

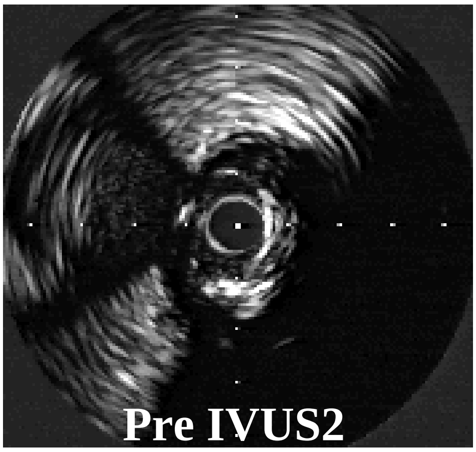
Case3:Rotablator alone case

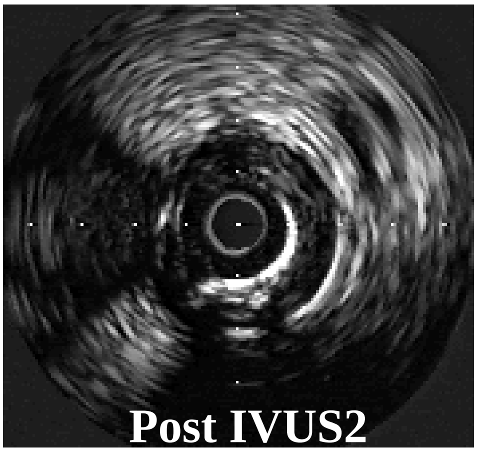




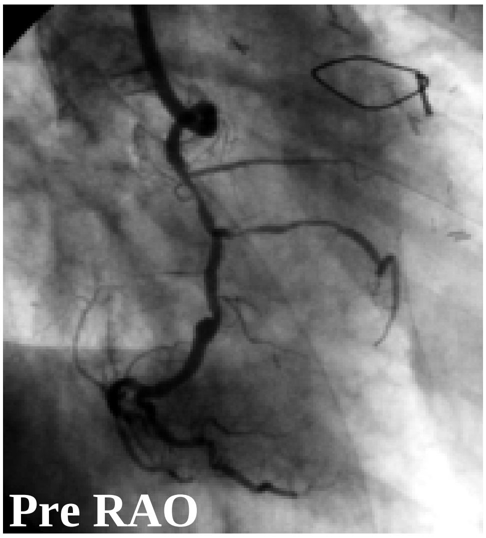


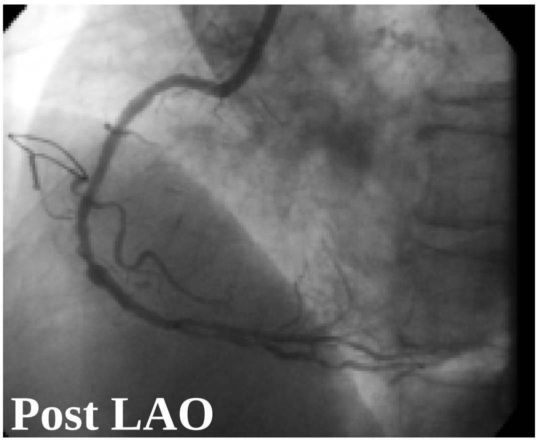


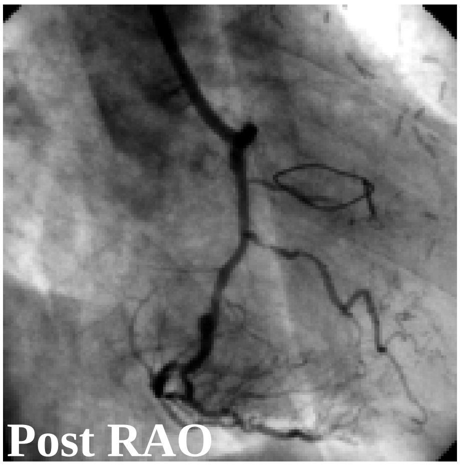


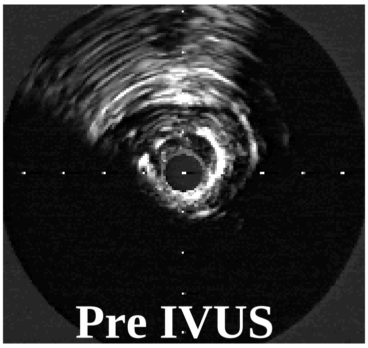


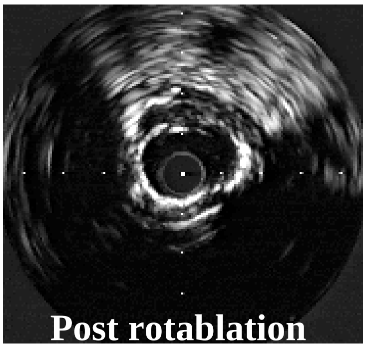
Case4:Rotablation followed by cutting balloon

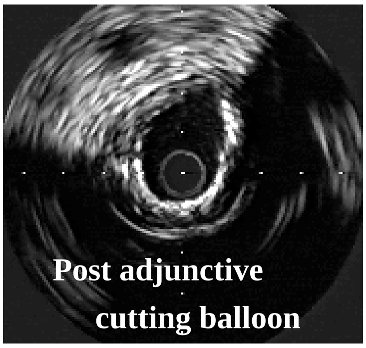












4. Complications and Treatment Methods

Angiographic complications

a. Dissection (10~13%)….treated by PTCA and stenting
b. Abrupt closure (1.8~11.2%)….treated by PTCA and stenting
c. Slow-flow phenomenon (1.2%~7.6%)…..treated by intracoronary and systemic administration of nicorandil
d. Perforation (0.4~1.5%)…..treated by perfusion balloon and cardiocentesis
e. Spasm (30%)….treated by large dose administration of intracoronary vasodilators

Clinical Complications

a. Death (0.9%)
b. Q-wave MI (1.3%)
c. Emergency CABG (2.0%)
d. Elevated CK-MB >2 times the normal value or non-Q-wave MI (6%)