



MG Lemma

Coronary artery bypass grafting: on-pump or off-pump?

With a growing evidence base surrounding off-pump cardiac surgery, Confluence spoke to Professor Massimo G Lemma, Luigi Sacco University General Hospital, Milan, Italy about how the results of his most recent study investigating on-pump versus off-pump coronary artery bypass surgery in high-risk patients might impact clinical practice.

What are the benefits and disadvantages of using an on-pump or off-pump technique to carry out coronary artery bypass grafting (CABG)?

The use of the cardiopulmonary bypass pump is a long-established technique in cardiac surgery. The distinct benefit of on-pump CABG is that you can stop the left ventricle completely, which allows you to manipulate and orientate the heart in any way during the operation, because the blood pressure is maintained by the cardiopulmonary bypass.

There are, however, a number of potential drawbacks to using an on-pump technique. Firstly, when the blood leaves the body and travels through the circuit of the pump, there is an inflammatory activation that can lead to numerous complications. The second issue is that most of the time, when performing CABG on-pump, surgeons cross-clamp the ascending aorta and then give a cardioplegic solution in order to arrest the left ventricle for up to 80 minutes, depending on the procedure. The close relationship between the period of ischaemia and damage to the left ventricle means that cardiac surgeons have limited time to perform the procedures.

In recent years, cardiac surgeons have been adopting an alternative off-pump technique, allowing surgeons to carry out coronary anastomoses without using the pump and without cross-clamping the ascending aorta. This, however, means that surgery is performed on the beating heart. During the operation, the left ventricle is pumping normally and the blood pressure is kept constant by the left ventricle itself. The advantage is that you don't have the inflammatory reaction due to the pump and you don't have any kind of ischaemia of the left ventricle, because it is working normally. The off-pump technique thereby considerably alleviates the time constraints.

Because the heart is constantly in motion, this technique is in general more technically demanding. When the heart is beating you must respect the rules of the ventricular contraction, which means that, where possible, the shape of the left ventricle must be kept normal. Thus, the possibility to change position of or to compress the left ventricle during an off-pump procedure is limited, which again means that alternative devices have to be used during the operation. These are mainly two types: the first is a coronary stabiliser like the Octopus® (Medtronic, Inc.) and the second is the heart positioner, like the Starfish® (Medtronic, Inc.). Using these devices you can change the position of the left ventricle in the pericardium, keeping the left ventricle in a normal function. Instead of needing to clamp the ascending aorta, a bloodless field can be created (without any ischaemia to the left ventricle) by exposing the coronary target and inserting a small shunt.

What is the clinical evidence for each of the techniques?

The average mortality and complication rates for coronary surgery are very low. However, it is important to evaluate whether the patient is at low risk of complications or at high risk. In Europe, we divide low-risk and high-risk patients using the EuroSCORE. Patients with a EuroSCORE from 0–5 are considered low-risk patients; those with a EuroSCORE of ≥ 6 are said to be high-risk patients. For low-risk patients, mortality for on-pump surgery is approximately 1%.¹ Therefore, studies to demonstrate the superiority of off-pump vs on-pump are logistically challenging, because they require the enrolment of thousands of patients in a prospectively randomized study. However, as on-pump mortality in high-risk patients is typically more than 5%, fewer patients are required to demonstrate a potential benefit for off-pump

procedures. Therefore, recent studies have focused on high-risk patients.

Could you explain a little about the study your group recently undertook investigating on-pump and off-pump CABG in high-risk patients?

Our group recently assessed the risk reduction of cardiopulmonary bypass complications between on-pump and off-pump during CABG procedures in high-risk patients.² To ensure the study took into account peri- and post-surgical complications, a composite primary endpoint comprising operative mortality, myocardial infarction, stroke, renal failure, re-operation for bleeding and adult respiratory distress syndrome within 30 days after surgery was determined. To ensure ideal treatment in both branches of the study, and due to the technical demands of off-pump surgery, only expert surgeons in the field of myocardial revascularization were engaged in the study. This meant only surgeons with more than five years' experience of both on- and off-pump surgery took part. The study was terminated prematurely, because in 411 patients included in the interim analysis, the rate of the composite primary endpoint was significantly lower (unadjusted $P=0.009$, adjusted $P=0.010$) in the off-pump group (5.8% vs 13.3%) according to the intention-to-treat analysis. Similarly, we found that the risk of experiencing the primary endpoint was higher for patients in the on-pump group (unadjusted odds ratio [OR], 2.51; 95% confidence interval [CI], 1.23–5.10; $P=0.011$; adjusted OR 3.07; 95% CI 1.32–7.14; $P=0.009$).

The approach and results of our study were different from those of a 2009 study by Shroyer and colleagues.³ The study showed that, at one year, patients in the off-pump group had worse composite outcomes and poorer graft patency than patients in the on-pump group. However, in that large, prospective trial, many of the surgeons were residents with limited experience of coronary surgery, especially off-pump procedures. The pre-study off-pump experience of the surgeons averaged 120 cases (median: 50) and at 16 of the study sites, cardiothoracic trainees were designated before randomization as the primary surgeon or first assistant surgeon. Although the study suggested that there was no difference in outcomes between operators with different levels of experience, we believe that this is an important factor. Indeed, a lack of experience might explain the large number

of crossovers from off-pump to on-pump seen in their study as opposed to ours. Indeed, in our study we had more crossover from on-pump to off-pump than vice versa. It means that in the end, this is further evidence for off-pump surgery being more beneficial for the patient, but more challenging for the surgeon. Indeed, I feel that surgeons must be well prepared for off-pump procedures before adopting them more widely with their patients.

It is interesting to hear that physician experience plays such a crucial role. How easy is the off-pump technique to learn and why should surgeons consider switching?

I think it is probably easier to train young surgeons in a centre that runs off-pump surgery on a daily basis, than a 45-year-old surgeon who is used to performing myocardial vascularization on-pump. Surgery is not an easy job, so when you learn a technique and you are confident with this, and you have good results with it, the question is, "Why do I have to change?"

I would say that our patient population is changing in the sense that our patient population is older; you might say that elderly patients are our daily bread. These patients are also more likely to be at high risk of complications. Therefore, if you want to be less invasive, to reduce complications and post-operative recovery time, cardiac surgeons must remember that the most invasive procedure is to put their patient on-pump and stop the left ventricle. When you work on the surface of the left ventricle on the coronary artery, it can be frustrating to see surgeons that keep going using the same, old on-pump technique, which requires cardioplegia and results in ischaemia. However, we must remember that on-pump techniques are still valuable: when it is necessary to work inside the left ventricle because, for example, you have to repair or replace a mitral or an aortic valve, the pump is indispensable.

Do patient co-morbidities or complications such as diabetes or aortic calcification play any role in deciding whether to treat on-pump or off-pump?

Yes, they do. This is an important consideration, especially in elderly patients. During the manipulation required to cross-clamp the ascending aorta during on-pump procedures we risk releasing debris from the vessel into the bloodstream,

which could potentially reach the brain. Indeed, neurological complications occur in 2–6% of elderly patients.¹ This means that you may save the life of the patient because we fixed the heart, but we destroyed the brain: this does not represent a satisfactory outcome. Clearly a technique whereby we don't touch the ascending aorta can help to minimize potential neurological complications. This can be achieved using an off-pump technique and what we call a composite Y-graft using the left internal mammary artery as a single source of blood for the left ventricle and putting all the grafts we need on this artery.

Is surgery with the pump applicable in hybrid surgery (CABG and PCI)?

The results of the SYNTAX trial show that despite similar peri-procedural and short-term post-procedural mortality, four-year survival for coronary surgery is superior to PCI.⁴ Furthermore, European guidelines recommend PCI as a primary intervention only in patients without stenosis on the proximal left anterior descending artery (LAD); in all the other cases, surgery is recommended.^{5,6} Having these data in our hands we can decide to go for a hybrid procedure, for instance, when we have very fragile elderly patients. Using an off-pump approach, we can insert a left internal mammary artery (LIMA) to the LAD, often using a minimal invasive approach without opening the sternum, and then complete the job using PCI in the other vessel territories. I feel that the ideal patient for such a procedure is generally elderly, when you need a relatively quick operation without the pump.

What trials need to be conducted to provide further evidence that people really should be moving to off-pump as much as possible?

To properly assess the safety and efficacy of these procedures, we need to ensure that the experience of the operators is taken into account. Our prospective randomized trial with expert surgeons demonstrated better results for off-pump

surgery. However, other studies couldn't show any advantage for off-pump over on-pump.³ As discussed previously, this discrepancy may likely be explained by the experience of the surgeons in the two studies: in our study, consultants had more than five years' experience operating on 50 to 100 patients per year during the last five years; in the latter study surgeons were generally inexperienced.

It is clear that the off-pump procedure is more technically demanding. For future studies we must try to define when a surgeon can be characterized as an expert in off-pump procedures: after six months training, after one year, after how many cases; 100, 200, 300? Clearly, however, this is not a simple decision because we know very well that surgeons, like patients, are all different.

Furthermore, we don't have enough long-term data. We are currently working on the one-year follow-up results from our study and we will be able to show whether the short-term benefits observed following off-pump surgery are maintained beyond one year after the operation. More such studies are needed.

Surgeons must also investigate new approaches to cardiac revascularization, using these innovative technologies and new techniques. Again, as we know, many of our patients are still treated on-pump with a technique that goes back 30 years.

What role does the wider Heart Team play in making decisions about these patients?

I think the role the Heart Team plays is definitely important. The team approach is beneficial because by discussing the patients and analyzing the results we can better decide the treatment of the patient, definitely. By having confidence in each others' abilities and, from a surgeon's point of view, by demonstrating that off-pump surgery can achieve good results, cardiologists know that you can give patients excellent care. Moreover, off-pump surgery offers the Heart Team a management strategy with very low mortality and few neurological complications; something that is not necessarily the case with on-pump procedures.

Address for correspondence
Massimo G Lemma
MD, PhD, FETCS
Director, Minimally Invasive
Cardiac Surgery Unit
Luigi Sacco University
Hospital, via G.B.
Grassi 74, 20157
Milan, Italy

lemma.massimo@hsacco.it
massimo.lemma@
biomed.polimi.it

DISCLOSURES: The opinions and factual claims herein are solely those of the authors and do not necessarily reflect those of the publisher, Editor-in-Chief, Editorial Board and supporting company. ML is a consultant for Medtronic Europe.

REFERENCES:

1. Toumpoulis I, et al. *Am J Cardiol* 2008;102(4):411-7.
2. Lemma MG, et al. *J Thorac Cardiovasc Surg* 2012;143(3):625-31.
3. Shroyer AL, et al. *N Engl J Med* 2009;361(19):1827-37.
4. Serruys PW, et al. *N Engl J Med* 2009;360(10):961-72.
5. Wijns W, et al. *Eur Heart J* 2010;31(20):2501-55.
6. Kolh P, et al. *Eur J Cardiothorac Surg* 2010;38(Supplement 1):S1-S52.