EuroIntervention

Informed consent in interventional cardiology

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Consensus is the most difficult aspect of medical practice. It requires knowledge of the risks and benefits of all the various available options, a daunting task when new key trials appear every year and transform our practice. It requires communication skills to simplify the message in layman's language. It requires professional integrity. The personal interest of having one more patient in your list should not influence your indication. Our question then is: can a professional who is also the provider of one of the treatment options offer unbiased information to patients?

The evolution of choice

Throughout the 1980s and up into the mid-90s, when angioplasty was a niche option offered to patients with unusually favourable anatomies – or simply not sick enough to justify surgery – no one questioned the role of the cardiologist who performed the angiogram as also being in the best position to take the final decision. Medico-surgical meetings were mainly devoted to ensuring that all comorbidities posing higher risks for surgery were appropriately investigated; only for patients at prohibitively high risk was angioplasty considered as an alternative and palliative option.

With stents eliminating the risk of unpredictable responses after balloon angioplasty, and with drug eluting stents (DES) dramatically reducing the risk of restenosis, the situation has changed dramatically over the last 10-15 years. The need of regular medico-surgical meetings has been questioned, and the indication has been simplified to a technical problem: can stents treat the main lesions causing symptoms?

Two more factors have played a major role in this drastic change in practice. Angioplasty has been shown to reduce mortality and morbidity in acute coronary syndromes, with the imperative need to eliminate time delays, especially for primary angioplasty during ST elevation myocardial infarction. Informed consent in these cases has become a formality and one which is not allowed to cause any delay, with treatment addressing the culprit lesion no matter where it is located – left main included – and no matter how severe the involvement of the remaining coronary tree might be. The second factor is "ad hoc" angioplasty; i.e., angioplasty immediately after diagnostic angiography; a growing trend which makes sense economically since it cuts cost, and clinically, since it reduces discomfort and avoids unnecessary delays between diagnosis and treatment.

The evolution of critical judgement

This so-called "golden era" of interventional cardiology has probably come to an end, and the sooner we realise this, the better. It is important that we are aware of this change, so that we can develop fair alternative practices justifiable before the wider medical community, before we see that community imposing stiffer paths on us and penalising interventional cardiology. Our critics use "conflict of interest" as the main argument against the single handed consent obtained by interventional cardiologists. In Europe we do not have the problem of an immediate financial interest, because most patients are covered by social security and the number of procedures has no direct influence on the doctor's salary. Still, a large individual and departmental practice means greater resources becoming available and an indirect incentive to recommend angioplasty rather than surgery or medical therapy. The European Society of Cardiology congress of Barcelona in 2006, as well as the ACC congress in New Orleans the following year, were probably the psychological turning point for most of us. We were used to being pampered as the progressive "elite" component of the cardiology community and were shocked to become the target of concentrated attacks from cardiac surgeons and non-invasive cardiologists alike. We were accused of neglecting evidence based medicine, of concealing from our patients worrisome figures concerning increased mortality after DES[1] and results of trials showing no benefit of PCI versus medical therapy in stable angina[2,3]. The enforcement of multidisciplinary meetings to discuss all indications for non-emergency angioplasty has been proposed – and occasionally adopted – in some countries and hospitals. Our response as a group has been sound and clear scientifically, but sparse and ineffective politically. Most general cardiologists,

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internists or GPs are still unaware of the overwhelming new evidence denying an increased late mortality with DES[4,5]. Trials, enrolling a precisely selected low risk population with results not applicable to general practice[2,3], have heavily influenced the new guidelines, which have become more and more conservative or biased towards surgery. The results of the first trial comparing surgery and DES in the most controversial indications, left main and three vessel disease, are a great success for angioplasty, with DES showing no differences in hard endpoints, even after treatment of very diffuse disease in those left main and three vessel disease patients[6]. And yet, they are often interpreted against angioplasty, because of an excess of new revascularisation at one year in the most complex angioplasty patients.

Propose, not impose, choice

How to react? Go back to the real patients' needs. Treasure their support against attacks which are also sparked by vested interests of other professional categories, and not by these patients' best interests. We must deny ratification of practices and guidelines which are not focused on those few endpoints affecting survival and quality of life. If you feel technically confident that there is a high chance of complete revascularisation of all viable territories for your patient, there is no evidence to suggest that death and myocardial infarction are different with DES than with surgery. An equivalence in the incidence of death and myocardial infarction in left main and multivessel disease has been shown in the above mentioned randomised one year study[6], and confirmed by the results of large registries at 2-3 years[7], as well as by older data with BMS at 5-7 years[8]. Before undergoing an angiogram possibly leading to angioplasty, patients must be made aware of a higher risk of revascularisation after PCI. They should accept that planned serial procedures with a flawless final result can be preferable to rushed multivessel treatment in one go. Patients must be made aware that, in the initial period of several months, they will be dependent on double antiplatelet agents, and that this will result, not just in more nuisance bleeds and bruises, but will prevent most non-cardiac surgery, at least for the first 3-6 months. Uncommon events typical of PCI, such as stent thrombosis, should not be exaggerated, but fairly reported, as we would other uncommon events typical of surgery such as stroke or neurocognitive impairment post-CEC. All these elements must be provided to the patient together with a description of the risk and discomfort associated with various invasive procedures and side-effects of drugs. At the end of the day, however, the patient is asking your straight opinion, to know what you would do for yourself, if you have enough grey hair, or for your father, if you are much younger than he is. He is interested in knowing whether angioplasty can relieve his symptoms and offer the same prognostic benefit of complete surgical revascularisation. He is not interested in the impersonal view of a body of Consultants who have never met him, and who have never discussed personally with him about his specific symptoms and lifestyle. If, however, you also feel that both surgery and PCI are viable options, that the risk of PCI is higher than the generic risk discussed before angiography or in cases of moderate stable angina with limited ischaemic burden, then the wisest and most sensitive decision is to stop the procedure after the diagnostic angiogram in order to re-discuss results with your patient and seek, as well, the opinion of other specialists. Meeting a cardiac surgeon who can provide a different point of view is occasionally confusing, but the patient will eventually understand you want to make sure he is offered all the information needed to make up his mind. Nobody, however, can decide in place of the patient, especially when the decision in either direction is not based on strong evidence, but on subtle individual differences in risk perception.

What's the role of our Association and the national interventional societies in this process? They should convince all their members to break the old bad habits of performing elective angiography and angioplasty without having met the patient and discussing his status and needs. They should defend the right to perform "ad hoc" angioplasty in straightforward cases, or when the patient has been thoroughly informed and has expressed a clear preference. They should defend the freedom of the patient to make the final decision, unless a clear mortality benefit is present with one of the options.

References

1. Camenzind E, Steg PG, Wijns W.Stent thrombosis late after implantation of first-generation drug-eluting stents: a cause for concern. *Circulation*. 2007;115:1440-55; discussion 1455. Epub 2007 Mar 7

2. Boden WE, O'Rourke RA, Teo KK, Hartigan PM, Maron DJ, Kostuk WJ, Knudtson M, Dada M, Casperson P, Harris CL, Chaitman BR, Shaw L, Gosselin G, Nawaz S, Title LM, Gau G, Blaustein AS, Booth DC, Bates ER, Spertus JA, Berman DS, Mancini GB, Weintraub WS; COURAGE Trial Research Group. Optimal medical therapy with or without PCI for stable coronary disease. *N Engl J Med*. 2007;356:1503-16. Epub 2007 Mar 26.

3. Hochman JS, Lamas GA, Buller CE, Dzavik V, Reynolds HR, Abramsky SJ, Forman S, Ruzyllo W, Maggioni AP, White H, Sadowski Z, Carvalho AC, Rankin JM, Renkin JP, Steg PG, Mascette AM, Sopko G, Pfisterer ME, Leor J, Fridrich V, Mark DB, Knatterud GL; Occluded Artery Trial Investigators. Coronary intervention for persistent occlusion after myocardial infarction. *N Engl J Med*. 2006;355:2395-407. Epub 2006 Nov 14.

4. Marroquin OC, Selzer F, Mulukutla SR, Williams DO, Vlachos HA, Wilensky RL, Tanguay JF, Holper EM, Abbott JD, Lee JS, Smith C, Anderson WD, Kelsey SF, Kip KE.A comparison of bare-metal and drug-eluting stents for off-label indications. N Engl J Med. 2008;358:342-52.

5. Stone GW, Ellis SG, Colombo A, Dawkins KD, Grube E, Cutlip DE, Friedman M, Baim DS, Koglin J. Offsetting impact of thrombosis and restenosis on the occurrence of death and myocardial infarction after pacilitaxel-eluting and bare metal stent implantation. *Circulation*. 2007;115:2842-7. Epub 2007 May 21.

6. Serruys PW, Morice MC, Kappetein AP, Colombo A, Holmes DR, Mack MJ, Ståhle E, Feldman TE, van den Brand M, Bass EJ, Van Dyck N, Leadley K, Dawkins KD, Mohr FW; SYNTAX Investigators. Percutaneous coronary intervention versus coronary-artery bypass grafting for severe coronary artery disease. *N Engl J Med*. 2009;360:961-72.

7. Hlatky MA, Boothroyd DB, Bravata DM, Boersma E, Booth J, Brooks MM, Carrié D, Clayton TC, Danchin N, Flather M, Hamm CW, Hueb WA, Kähler J, Kelsey SF, King SB, Kosinski AS, Lopes N, McDonald KM, Rodriguez A, Serruys P, Sigwart U, Stables RH, Owens DK, Pocock SJ.Coronary artery bypass surgery compared with percutaneous coronary interventions for multivessel disease: a collaborative analysis of individual patient data from ten randomised trials. *Lancet*. 2009 ;373:1190-7. Epub 2009 Mar 19.

8. Pocock SJ. Safety of drug-eluting stents: demystifying network meta-analysis. *Lancet*. 2007;370:2099-100.