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EDITOR'S PAGE

Advise and Consent

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Catheterization conferences are a great start to the day, now even more so than before when I had to get to the cath lab or clinic or finish a paper I had been working on. Now my younger colleagues are doing all that while I continue to reflect on the interesting cases that had been presented or some random idea that drifts into my head because there is not a lot there to distract it. This morning was a case example. A visiting fireman (you know the definition of an expert: "someone from somewhere else with slides") was trying to convince the group of fellows and a few faculty that the laser was "a thing." I remembered when it was "a thing" many years ago. In fact, I did some work investigating intravascular laser therapy from laser balloon to "smart lasers" to the ablative laser that was being demonstrated today. It was "a thing" and then was "a doorstop" and then was given to the electrophysiologists to use for burning out pacemaker leads. Now it seems to be "a thing" again with advocates convinced that it is a helpful therapy for a range of applications from highly resistive lesions that are uncrossable with balloons to stents that cannot be fully expanded to thrombosed arteries to almost routine plaque preparation for stent or scaffold deployment. Some 25 to 30 years ago, we suggested some modifications to the excimer laser system, including a unilateral tip shield to protect the carina of bifurcations and the eccentric fiber optic array that I understand is now being discontinued. Well, at least those ideas were "a thing" in their time. The question from the fellows were appropriate and were mostly focused not on whether the laser could and did what it is supposed to do, but whether it is necessary for some of the things and whether other therapies could be better or worse in doing them. The answer is that most of the evidence is anecdotal.

Because I did not need to go to the clinic or scrub for a ST-segment elevation myocardial infarction (STEMI), I wondered why we did not find some of the answers to these questions. First, we suggested a trial of the excimer laser used in STEMI cases with extensive thrombus. After all, the studies of aspiration thrombectomy have been disappointing yet many continue to believe we should suck out all we can. Optimal coherence tomography imaging has shown that, even with vigorous aspiration, a lot of clot is left behind. Would more complete thrombus removal improve clinical outcomes? Would laser ablation of thrombus (after all, red color is highly absorptive of the wavelength used) be more efficient, and second, would its use translate to some clinical benefit? The other thought was stimulated by the nice-looking cases of uncrossable or undilatable lesions that yielded to the balloon and stent easily after laser ablation. It was pointed out that competitive technologies exist. Rotary ablation and orbital atherectomy are used for such lesions as well. Which should be used? Should any be used? Should we try to find answers for these persisting questions? If so, how could it be done? Suggestions for randomized trials seemed at first futile. Would you be able to randomize STEMI patients to laser or aspiration thrombectomy before performing the catheterization to discover whether there is extensive thrombus or not? How would informed consent be obtained? Would it be necessary?

Holy HEAT Trial! (How Effective Are Antithrombotic Therapies in Primary Percutaneous Coronary Intervention) (1). That study of STEMI patients treated with heparin or bivalirudin was a rare breed that randomized patients without informed consent. Both therapies were approved and either heparin or bivalirudin may have been chosen by the physician without patient input, but when it became a trial, the

criticism was intense. How could patients with STEMI be denied the chance to agree to participate in a trial with a random selection of approved therapies rather than to get the therapy favored by the doctor who happened to have been assigned to their case? For that trial, extensive review by institutional review boards and regional health commissions in the United Kingdom resulted in agreement that true informed consent could not be obtained in the emergency situation and that the study with almost 100% participation could not be carried out without the randomization sans informed consent. The patients were later invited to volunteer for follow-up to collect their outcome data, and almost all did consent. Nonetheless, this method remains hotly debated.

Let us take another scenario—undilatable lesions. These are almost never known before the attempt to cross or dilate. Yes, the patient on the table could be asked to sign a "consent" form, but this "on the table" process would certainly be considered coercion. Once while visiting Cairo, my wife and I were taken out in the desert on the back of camels. The young camel driver asked to take our picture. I consented and handed over my nice Nikon camera. He then asked for a tip. My perch above the camel in the desert with my camera in his hand was adequate coercion to cause me to cough up a substantial tip. I used to think about this experience when tempted to consider obtaining consent on the cath table. Because both mechanical atherectomy and laser atherectomy have indications, could a protocol be developed to test them without informed consent? There would be no way to know that the lesion was undilatable before trying so pre-cath informed consent would not be possible.

I do not know that there is any incentive from industry to study these things, but if we ever want to know whether a therapy should be preferred, it would need to be tested. Otherwise we can proceed with what is more convenient or cheaper, but we will never know what is better. The conflict of individual autonomy against common benefit is an ancient philosophical question. Perhaps the examples from this morning are not the most pressing, but we do need to reflect on whether, in some cases, the myth of informed consent is an ethical benchmark or simply a legal cover.

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