

Title: 4 Trials To Change Your Practice With Dr Luigi Di Biase

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Dr Luigi Di Biase

"Hi, I'm Professor Luigi Di Biase from the Albert Einstein College of Medicine at the Monte Fiore Health System in New York. Today we are going to discuss the four trials from day one and day two of the late-breaking clinical trial sessions here at EHRA 23 in Barcelona.

POWER-FAST III

The first trial I would like to discuss is the Power Fast III trial, where the investigators assessed whether a high power short duration ablation with 70 watts was superior or non-inferior to low power, guided by ablation index either with the Biosense catheter or with the TaciCath catheter. This trial has a very important relevance. It's a randomized trial conducted herein Spain by Professor Merino. And this trial tells us that doing above 50watts, 70 watts does not improve the outcomes, the freedom from atrial fibrillation while increase thromboembolic complication, either stroke, TIA and silent cerebral lesions. So I think the trial adds good clinical information because we know now that about 50 watts is not dangerous, no better outcome. Now the trial does not discuss its high power short duration between 40 and 50 watts is still a good thing to do. I think it is. And the trial also does not discuss whether we should use catheters that are designed for high power short duration, such as Q dots for Biosense Webster or Diamond Temp for Medtronic's. So I think that we have trials that have been designed for high power short duration and this should be utilized. But if you don't have this catheter, probably no more than 50 watts is the power that you should use to avoid complications and improve the outcome. As this is being said, I think the author should provide information about the complication rate and the type of catheter utilized, because the two-catheter utilized are 3.5 and four millimetre. Therefore, I think that irrigation utilize isa little different and the possibility of popping and increasing the thrombombolic complication is different between the two catheters.

MANIFEST-PF

The second trial I would like to discuss is the registry of the MANIFEST trial. This trial investigated the use of a different energy source. So the PFA with the catheter from Boston Scientific and this trial gives us some very good information outcome of this new energy source. On thermal energy like pulsed-field ablation gives very good results both in paroxysmal and persistent patients. I would say not inferior to the standard radiofrequency and cryo while having no complications. So this trial I think adds some relevant information to the fact that we are going in the good direction with the non-thermal energy source for safer procedure, while maintaining very good outcomes.

TEMPO-HCM

The next trial I would like to discuss is a trial that is investigated a very maybe not that frequent population, hypertrophic cardiomyopathy patient, but a population that is difficult to manage because sometimes the guidelines are in a gray zone. So the trial investigated: "what if I look for arrhythmias using not a standard 24-hour alter monitoring, but an extended patch of 30 days. "And by quoting the statement the more you look, the more you found. We found out that if you look for 30days, you found almost double the incidence of atrial fibrillation and more non-sustained ventricular arrhythmia. More atrial fibrillation means we need probably to give oral anticoagulation to this patient to prevent stroke and more non-sustained BT means probably we need to implant ICD. So the overall management, clinical management of this patient may change. So extended monitoring with patch rather than loop recorder or as much as you can look for arrhythmias is very important in hypertrophic cardiomyopathy patients and a 24-hour holter is not enough. So very important clinical information for every clinician.

AdaptResponse

The next trial I would like to discuss is the Adaptive CRT trial. This is a trial of almost 4000 patients where the investigator compared biventricular pacing versus LV pacing with the adaptive LV algorithm, meaning LV pacing only versus biventricular pacing. The trial is negative, meaning that this algorithm did not add improvement in the

outcomes. Primary endpoint was improvement in mortality and heart failure hospitalization. But despite negative results, it answers an important question: we need to know if heart failure patients in need of a device benefit from resynchronization therapy. Because this trial showed that there is an overall improvement while you treat heart failure patients with resynchronization therapy, this algorithm didn't reach statistical significance. It has a trend in improvement and so unfortunately, it's not a way to improve the outcomes. But maybe there is a subset of patients where the outcome can be improved. Type two error is something that has a statistical meaning. We don't know actually what does it mean? There were events reported after COVID that may have jeopardised the overall statistical analysis. So despite a negative trial adds information and 4000 patients and a lot of female included, almost 43-45 % of female included. The largest number of females is included in a randomized trial with revascularization therapy. So kudos to the authors for conducting such a big and long trial.