

Cardioleaks



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There is an aspect that is interesting to consider among those concerning the evolution of cardiology conferences in the age of digital communication and the Medtech code^{1,2}. For some time now, the main results of the most awaited clinical trials in cardiology and beyond are presented during dedicated sessions that take place in the main arenas of the most important international meetings. These sessions are organised as “events within the event”, and attract hundreds if not thousands of participants who are eager to understand in which direction the discipline will shortly be moving. Often, the presentation of these trials coincides with their simultaneous publication in a journal with a high impact factor. I cannot imagine a greater academic satisfaction than completing the presentation of an important trial and concluding the talk with words such as “if you want to learn more, the full paper is available online in the *New England Journal of Medicine*”. In research, this circumstance is a real *en plein* and marks the completion of a long (and sometimes very long) journey, starting from the conception of the study and arriving at one of the most prestigious publications of all, passing through years of work to bring the study to completion. I can imagine what goes through the minds of investigators who at the moment of the final round of applause see their efforts being repaid, and who know well that such applause must be shared among all the investigators without forgetting the fundamental contribution of the participating patients.

From the purely dramaturgical point of view, the sessions I am talking about are usually organised in a simply excellent manner. Before the congress, the “late breakers” are advertised through social media and targeted communication campaigns in order to generate a sense of expectation and awareness in the community. During the conference there is an absolute embargo on the early communication of trial results. A press conference takes place shortly before the session to allow the agencies to prepare their stories, which are kept secret until the very last moment. The presentation takes place in a rigorous manner during a time slot that is generally adequate to understand the essential aspects of the study. Presenters often contribute to the suspense effect by stopping their presentation at the time of revealing the main result. After a brief pause, a simple but effective slide animation technique consists

in first showing the result of the control group followed shortly after by the result of the experimental group and the traditional parameters that express the level of statistical significance. This simple theatrical trick seems to have been specially designed to add gravitas and make the audience reflect on the importance of the moment. And it succeeds well. When the trial is positive, for example, a usually left-to-right fading transition shows the survival curves diverging progressively over time and a thrill of satisfaction is perceptible among the spectators. From that moment, the rest of the presentation is aimed at understanding better the reasons for that benefit and at putting the new results into context. The revelation of the primary endpoint represents the peak of the spectacularisation of these events. For enthusiasts of evidence-based medicine, speaking about spectacularisation and even entertainment may not be risky if we consider some recent episodes.

During the last TCT in San Diego, Gregg Stone presented the results of the COAPT study, the most awaited trial in the field of percutaneous mitral valve repair in patients with functional mitral regurgitation³. The presentation occurred a few months after the publication of the MITRA-FR study, which threw the supporters of the MitraClip procedure into confusion because of its indisputably negative results⁴. In front of a packed room, Gregg Stone presented the results of COAPT with, as always, a compelling and impeccable slide progression. I do not think that I have ever witnessed the presentation of a late-breaking trial interrupted by a round of applause, but on that occasion everything contributed to making the moment a special one: the sense of expectation, the frustration of an entire field that turned into triumph, the visible emotion of the presenter, and the enthusiasm for a technique that may help very complex patients with few valid treatment options available. Engaged by a sense of rhythm and suspense, I was struck by a slide where a list was first shown with numerous secondary endpoints for what we call “hierarchical testing”. The same slide was shown shortly after the presentation for the primary endpoint (first applause) with an animation which, after a short pause in apnoea, rapidly showed a string of statistically significant p-values. This was a sign that the trial was not only positive, but positive beyond any reasonable doubt, with consistency of directionally similar effects,

biological plausibility and all those things that – rightly – lead you to applaud once more. I finally counted three rounds of applause during the presentation (the last one for the Kaplan-Meier curves showing a benefit on mortality); it is unusual to listen to one round of applause during a presentation rather than at the end, let alone three. For those who were present, there was a striking emotion and the feeling that they were attending a kind of historic moment in the field of interventional cardiology.

Another historic moment took place a few months later during the scientific sessions of the American College of Cardiology in New Orleans, but this time however in a slightly different way. Earlier this year, after years of gestation, the TAVI trials in patients at low surgical risk were finally ready for their solemn revelation – likely to open a new chapter in the history of this wonder technology. The agenda of the American College of Cardiology meeting scheduled on the first day the Apple Watch Study, a mega study of wearables applied to the detection of atrial fibrillation. Cardiologists were notified weeks in advance that on the second day the late-breaking trial session would be mainly dedicated to the PARTNER 3 and Evolut LR studies, anticipated with great expectations and curiosity. There was a feeling in the air that there might be new thunderous applause to interrupt the presentations of the two announced speakers, Martin Leon and Michael Reardon. However, something unexpected occurred. To the surprise of those present at the meeting, the results of the two studies were published in the *New England Journal of Medicine* a day earlier than the official presentation^{5,6}. The reason for this unusual event – at least for a cardiology forum – was a breach of confidentiality by a Reuters journalist. In the following weeks, the same agency would apologise for the mistake (and the agency banned from next meeting); however, the damage was already done. The breaking of the embargo, in spite of the rule agreed with the congress organisers, led to the results of the studies coming to the attention of most congress participants, amplified by word of mouth and social media. Needless to say, this annoyed many participants by what seemed a blatant violation of the right to enjoy the presentation of the results in the usual way.

One thing I have learned, however, is that nothing can affect the solemnity of certain announced triumphs. On a second day where there was a risk of gravitas being lacking, Martyn Leon and Michael Reardon made their presentation in a regular fashion. It seemed a bit like watching a movie where you already know the ending, but how many times has that happened, for example when you watch a movie based on a true story? If you are relatively little interested in the suspense, at that point you can concentrate better on other aspects – in the case of a movie, perhaps on the photography and editing and, in the case of a presentation, on the charisma of the speakers and on the impact of the results. In that sense, nobody could have been disappointed that day. “A historic day for cardiology”, according to Eugene Braunwald sitting among the panelists of the session, who not by chance chose solemn words to reposition the two trials affected by the breach of confidentiality once more among the elite of the most important interventional trials ever. And if the presentations went according

to plan, the discussion saw the two speakers next to each other on the podium, united in a beautiful image that better than any other symbolises the Heart Team 2019 edition. When leaving the stage, despite the buzzkill leak, even TAVI – like MitraClip months before – carved out its rightful moment of celebration – obviously thunderous applause, but also a standing ovation (another unprecedented episode in such a context, as far as I’m aware).

So, this time it went well but, as a passionate consumer of these sessions, I am launching a heartfelt appeal to the press agencies (in particular to those in the mood for this type of joke): don’t do it again, please. Don’t spoil the magic of such solemn moments with your “cardioleaks”. Participate in the show with the professionalism that we expect. Leave the show alone for those who simply want to enjoy it.

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