

TAVI in Europe – that was then and this is now

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This month sees two important meetings taking place in rapid succession, the annual ESC congress, this year in Amsterdam, and then, two weeks later just across the English Channel, the annual PCR London Valves meeting. Thinking of these, it is the topic of dedicated structural heart interventions that draws most of my attention this month, particularly in light of some recent interesting findings.

But first, let me take you back five years ago. In 2008, I gave a keynote lecture during EuroPCR on TAVI¹, during which I referred to market research in the then young field of TAVI. The forecasts at the time were that the field of percutaneous heart valve therapies would be valued at 700 million US dollars and that the ratio of the number of transcatheter heart valve procedures to total heart valve procedures would increase from <1% to 40% from 2007 to 2012. However, I noted physicians might also become tempted towards a process of the self-referral of younger patients with fewer comorbidities, the current so-called “surgical candidates”.

Now, five years later, a publication in JACC had discussed TAVI adoption in Europe based on data in a time period stretching from 2007 to 2011 in 11 European countries². What is striking is that despite a nine fold increase of implanting centres in these 11 countries (37 in 2007 to 342 in 2011, of which 90 are in Germany alone) and a 33-fold increase in the number of implants (455 in 2007 to 14,946 in 2011), there is an underutilisation of TAVI in high-risk groups in two thirds of the 11 countries studied. The authors calculated the weighted average TAVI penetration rate to be 17.9% – only Germany, Switzerland and Denmark had a higher rate; the other eight countries were lower. Naturally, reimbursement issues coupled with – in some cases – very severe economic austerity policies could account for this. Encouragingly, the authors estimated that in 2011 there were 28,400 living TAVI recipients from potentially 158,371 candidates!

On a multinational level, the ESC recently initiated the ESC EURObservational Study Programme, in which TAVI in Europe (European Sentinel Registry of Transcatheter Aortic Valve Implantation)

was studied in 4,571 patients from 10 pilot countries³. The general objective of the Sentinel Registries of the ESC EUR Observational Research Study is to independently monitor the application of new technologies in Europe, detect regional differences in indications and techniques and assess adherence to guidelines. The authors reported that TAVI in Europe is still reserved for very old patients or patients with severe comorbidities and high surgical risk, typically an average age approaching 82 years and a EuroSCORE >20. This particularly allays, to some degree, my fears for the referring of younger, lower surgical risk patients for TAVI.

Although we doctors and scientists are generally suspicious of the financial community as their primary task is to maximise benefits for shareholders, we cannot help but admit that the financial expert analyses generally reflect well the current state of research within any given field. Besides this, their predictions and forecasts make for interesting reading.

A recent report from J.P. Morgan surveyed interventionalists in 50 US centres⁴. Of the respondents, 85% aim to commit more of their daily work to TAVI, which contrasts with the fact that these US interventionalists earn 53% less with TAVI procedures when compared to stent procedures (45% of their hospitals lose money on TAVI procedures). The respondents' interest in TAVI is obviously still high. Our US colleagues report, very similar to what we find here in Europe, that reimbursement is a big issue, with 75% considering it a challenge to overcome. A recent study in JACC estimated that, under the current indications, there are nearly 18,000 new TAVI candidates in Europe and 9,200 in North America, annually⁵.

It is quite frankly amazing to look back at the predictions five years ago and compare them to today's outcomes. What is obvious is that the structural heart interventional field remains not only very dynamic and interesting, but is also expanding beyond our wildest dreams; see, for instance, the new developments in percutaneous mitral repair and the first cautious steps in percutaneous mitral replacement. Back in 2007, both the CoreValve Revalving System

(Medtronic Inc., Minneapolis, MN, USA) and the Edwards LifeSciences SAPIEN (Edwards Lifesciences, Irvine, CA, USA) prosthetic heart valve obtained CE mark approval. Today, five additional new devices are CE marked: the Direct Flow Medical valve (Direct Flow Medical Inc., Santa Rosa, CA, USA) that is both retrievable and repositionable, the Jena Valve (JenaValve, Munich, Germany) and the Portico (St. Jude Medical, St Paul, MN, USA) that are both retrievable until being fully deployed, and the Engager (Medtronic Inc.) and the Symetis® Acurate™ (Symetis SA, Ecublens, Switzerland) that are only repositionable⁶.

Also, another five devices are currently in the development stage: the SAPIEN III (Edwards Lifesciences) which has a low crossing profile (requiring a 16 Fr sheath) and incorporates an additional cuff that covers the frame of the valve, which is anticipated to reduce the incidence of paravalvular leak, the Lotus valve (Boston Scientific, Natick, MA, USA) and the CoreValve Evolut R (Medtronic Inc.) that are both retrievable and repositionable, the self-expanding Centera (Edwards Lifesciences) valve that is also repositionable and has a low placement of the leaflets to minimise the risk of pacemaker implantation as well as the HLTs™ (HTL, Inc., Maple Grove, MN, USA) valve. Let's not forget the numerous TAVI enabling devices which are currently being studied along with the various new imaging software packages for TAVI-related imaging modalities.

Evidence collection, coming from the major registries and randomised controlled studies, is growing immensely. More studies are being developed to confirm long-term efficacy as well as adding to a significant body of published work (1,711 papers using the simple key phrase “transcatheter aortic valve implantation” on PubMed). In fact, this month our journal will be publishing an updated supplement centred on PCR London Valves 2013, to be distributed at the meeting in London (15-17 September) under the astute Guest Editorship of Martyn Thomas and Stephan Windecker.

All those years ago, back then in Barcelona at EuroPCR 2008, I don't think we could have honestly and truly imagined how great today's “this is now” has turned out to be.

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