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ONLY QUALITY CAN SAVE SURGERY

Reply to the Editor:

The letter of Santarpino and colleagues¹ nicely echoed my previous Editorial Commentary² concerning the potential limitation of short-term “equivalent” comparisons between transcatheter aortic valve implantation (TAVI) and surgical aortic valve replacement (SAVR). Several concerns are still intrinsically associated with TAVI. For instance, the cost of a TAVI device is much higher than that of a conventional aortic bioprosthesis. Compared with SAVR, TAVI is associated with a much higher incidence of postoperative residual aortic regurgitation or paravalvular leakage, and also with a much higher rate of new-onset atrioventricular block and the subsequent requirement for permanent pacemaker implantation. Most importantly, in contrast to SAVR, the durability of the TAVI prosthesis is yet to be verified. Taking these factors together, the possible negative impact of TAVI on the quality of long-term survival of patients with aortic valve disease at intermediate and low risk should not be ignored. Unless positive evidence is revealed soon, the indication for TAVI therapy in these patient subgroups (particularly those younger than 70 years) is highly doubtful.²

In their letter, Santarpino and colleagues¹ questioned why “scientific publications...tend to put the various approaches in competition.” Unfortunately, like it or not, this is the reality. If the indication for TAVI in patients at low risk were to be validated, this competition would eventually become much stronger and, worst of the worst, surgeons might lose their jobs because of the lack of demand for SAVR. Does this pessimistic prediction sound familiar? Indeed, we heard the same statement many years ago when percutaneous coronary intervention (PCI) with the use of drug-eluting stents became popular. Decades later, coronary surgeons are still busy, because evolving evidence has confirmed the long-term survival advantage of coronary artery bypass grafting (CABG) relative to PCI in the majority of cases (eg, those of patients with diabetes or severe triple vessel disease).

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To date, many surgeons share a common view that we should master transcatheter technologies to make sure that “we have the future.” In a way, this is indeed a timely wake-up call, one that none of us can afford to ignore. Nevertheless, history has also taught us important lessons. First, mastering PCI technology will not help surgeons to save CABG. The fundamental principle of CABG (that it “addresses the existing lesion and also the future culprit lesions”),³ especially with arterial grafting, guarantees better long-term outcomes, which explains why CABG has stood the test of time. Second, as long as the sole concern is the level of invasiveness, minimally invasive techniques alone will not help surgeons to save CABG, simply because PCI can always beat CABG in terms of causing less trauma to patients. Minimally invasive approaches are important surgical advances⁴ only when they provide long-term outcomes equal or better than those of “conventional” operations. Although TAVI should be seen as a valuable complement rather than as a tough challenger to SAVR, only superior outcomes can truly save SAVR—namely, longer prosthesis durability, zero paravalvular leakage, and fewer postoperative permanent pacemaker implantations. Although the competition may always exist, the importance of the finest quality of “conventional” surgical training can never be overemphasized. We should aim to be better surgeons and to provide our patients safely with durable valves: “The goal is to make the patient feel better and live longer.”⁵ This is, in fact, what we are paid for. Henceforth, only time will tell.

In surgery, as in life, failing to advance is to go back.

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INNOVATIVE VALVE DISEASE THERAPIES, A POTENTIAL BENEFIT FOR PATIENTS BUT CALLING FOR MORE CLINICAL EVALUATION

Reply to the Editor:

Although we did not take their letter as a critique of our recent study comparing transcatheter aortic valve implantation with surgical aortic valve replacement,¹ we read with great interest the commentary by Santarpino and colleagues² and welcome the opportunity to reply.

The treatment of aortic valve disease has been the theater of outstanding progress during the last 2 decades, with the emergence of such breakthrough health technologies as transcatheter aortic valve implantation. The same tends to be observed for mitral valve therapies, with promising approaches such as percutaneous repair³; however, higher-level evidence remains to be generated.⁴

There is no doubt that the growing number and the wider diversity of health technologies represented by innovative medical devices and surgical approaches should be welcomed. These have the potential to improve survival and other clinical outcomes, as well as quality of life, and to provide alternatives in clinical situations with high unmet needs.

The expansion of therapeutic armamentarium can become such that the medical decision making is complexified, however, unless it is guided by evidence from various sources of clinical effectiveness and safety data. This is why scientific publications reporting clinical evaluation of health technologies, here used for aortic valve therapy, should be encouraged rather than been seen as putting various approaches in competition.

Clinical evaluation of new health technologies using comparative methods is crucial to generate evidence and can be complemented by systematic review methods that synthesize the best available evidence. This process, together with individual clinical expertise and patient preference, contributes to evidence-based medicine,⁵ which should be consistently promoted because it strengthens the choice for an optimal tailored approach to the individual patient as advocated by Santarpino et al.² The need for more clinical evaluation should be even further emphasized for medical devices, because they are generally less evaluated than medicines as a result of less stringent regulation, especially in Europe.

Randomized, controlled trials are the most robust design, offering the major advantage of generating strictly comparable groups, thus allowing the best measure of a new treatment

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efficacy. The disadvantage of randomized, controlled trials is that often the evidence is based on a highly selected population, which can raise issues of generalizability. This is why complementary sources of data, such as those from observational “real-world” studies, are worthy of being considered. Our recent study that compared clinical outcomes of transcatheter aortic valve implantation and surgical aortic valve replacement with a nationwide database is one such example.¹ Unlike theoretically based randomized, controlled trials, “real-world” studies provide a comprehensive view of the effectiveness of a new intervention in a more representative population, yet with a slightly higher risk of generating groups of patients that are not strictly comparable.

Irrespective of the design chosen to generate evidence, we fully agree with Santarpino and colleagues² that follow-up durations of patients in these studies should be sufficient to capture long-term clinical outcomes. Similarly, as emphasized by Santarpino and colleagues,² economic evaluation conducted alongside clinical studies should be promoted because of the substantial costs of some of these new health technologies.

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