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EDITORIAL / EDİTÖRYAL

Recent innovations in aortic valve surgery: True progress?

Aort kapak cerrahisinde son yenilikler: Gerçek bir ilerleme mi?

Henning F. Lausberg, Hans-Joachim Schäfers

Department of Thoracic and Cardiovascular Surgery, Saarland University Medical Center, Homburg, Germany

In 1953, the introduction of cardiopulmonary bypass marked the birth of modern cardiac surgery. It allowed for reproducible correction of acquired and congenital heart disease. Since then, the field has experienced tremendous evolution. Prosthetic valve replacement, the still developing field of valve repair and coronary artery bypass grafting (CABG) already reached a level of high quality in the 1990s. Given this perspective, one could assume that modern cardiac surgery is a stable, if not stagnating field.

Since then, cardiac surgery has continued to face numerous challenges. One was the introduction of interventional treatment of coronary artery disease (CAD). Currently, percutaneous coronary intervention (PCI) accounts for treatment of large proportions rather than selected cohorts of patients with coronary artery disease. Not all clinical practice is not always supported by scientific evidence.[1-5]

In analogy to CAD treatment, interventional techniques for treatment of structural heart disease (transcatheter aortic valve replacement [TAVR]), interventional mitral valve "repair" are currently suggested as alternative to the established surgical techniques. These interventional techniques were originally designed as an option for high-risk patients as alternative to conservative treatment. Currently, however, TAVR is increasingly propagated and used also in younger and lower risk cohorts.[6-8] Transcutaneous end-to-end repair (TEER) for primary mitral regurgitation are currently applied to high-age and high-risk patients.[9,10] Although residual regurgitation or procedure-induced mitral valve stenosis have been reported up to 15% and 25 to 30%, volumes continue to increase.[11,12]

In this reality, we have observed a decrease of caseload of both CABG - once the "bread-an-butter" operation - and aortic valve replacement in the past decade.[13] This creates a relevant pressure on our specialty, and some surgeons, particularly in smaller centers, find themselves in a "struggle for survival". Consequently, pressure for innovation is perceived and proposed to withstand interventional "competition". In coronary surgery, such innovations have been "off-pump"-coronary artery bypass (OPCAB) or total arterial revascularization (TAR). The hypothesis of OPCAB improving patient outcome could not be confirmed,[14,15] and the proportion of OPCAB procedures has decreased in the past decades in different countries.[13,16] Currently, TAR appears as the ideal concept.[17] The expected advantages of TAR, however, have not been observed unequivocally.[18-22]

In the past two decades, surgical efforts have also been made to innovate and improve treatment of valve disease, in particular of the aortic valve. Aortic valve surgery has traditionally consisted of valve replacement with a mechanical or biological substitute. This has long been a routine procedure with a low operative (2 to 4%), but relevant late mortality (1.5 to 2.4%/year).[23-26] For a life expectancy of 20 years after implantation, perioperative mortality thus accounts for only 10% of the cumulative mortality. The need for permanent pacemaker implantation occurs in 2 to 5% following conventional aortic valve replacement;[27-29] it is a relevant perioperative

Corresponding author: Henning F. Lausberg.
E-mail: henning.lausberg@uks.eu

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complication and associated with impaired survival.[28] Other valve-associated complications (structural valve deterioration, thromboembolism, bleeding) affect the long-term course has been reported with general low incidence of up to 3%/year depending on the prosthesis type.[23,24,26,30,31]

The choice of prosthesis type depends on the patient age. Traditionally, mechanical prostheses are recommended for younger patients (<50 years) and biological substitutes for older patients (>70 years). For the latter cohort, the decision is not difficult based on current experience. However, which advice needs to be given to the younger patients? For those ages 50 to 70 years, no unequivocal recommendations are available.[32] In recent years, a more liberal use of biological valve prosthesis has been observed,[33,34] often with the plan of interventional therapy ("valve-in-valve" concept) in the future. Recent data, however, revealed a high late mortality rate (2.39%/year) for younger patients following biological aortic valve replacement. Long-term mortality has been calculated between 1.7-fold increase for patients aged 50-60 years and 3.6-fold increase in patients aged 20-40.[23,35,36] Accordingly, the choice of a mechanical prosthesis appears to be reasonable as the "lesser evil". They are thought to have an "unlimited" lifetime. However, a meta-analysis also showed a significant lifetime risk (up to 15%) of reintervention for either non-structural valve dysfunction or endocarditis in younger patients. These patients had an increased late mortality rate of 1.55%/year. Microsimulation-based life expectancy was found to be only a little more than half of the life-expectancy of the age-matched general population.[26] One possible explanation could be the significant comorbidity associated with lifelong anticoagulation in historical cohorts.[25,30,37]

Transcutaneous aortic valve replacement has been introduced for high-risk patients, but recently been described to be superior to surgical valve replacement in low-risk patients after one year.[7,38] Based on this experience, it has been advocated as a therapeutic alternative to surgery, and it has been increasingly utilized even in younger patients.[39] However, currently no true long-term follow-up data are available.

The precise determination of frequency of valve-related complications is, thus, impossible. Two typical procedure-related complications of TAVR may influence long-term patient outcomes. Perivalvular leakage has been identified as a risk factor for morbidity and mortality.[40,41] It has been reported to be present in up to 80% of TAVR cases.[42] In addition, conduction disturbance following TAVR is a common phenomenon. The need for permanent pacemaker implantation shows a wide variety (2 to 51%); pooled implantation rate has been reported to be 13%.[43-46] This has been identified as an independent risk factor for death in the past.[29]

Currently, the results of TAVR have been reported with various results. In contrast to non-inferior results of most studies, analyses of registry data have indicated a different picture. Mostly these have constantly reported less favorable results.[28,47,48] A high degree of patient selection in the majority of studies may be an explanation of these differences. To what extent industry funding may have introduced a potential bias still remains speculative. Fact is that no sufficient data on long-term results (≥10 years) in representative patient numbers are currently available.

The success of TAVR in high-risk patients remains undisputed, in selected cases of intermediate risk, it may be a therapeutic alternative to be considered. At two years, survival of patients with both intermediate and low risks following TAVR has been described to be comparable to surgical patients in randomized studies.[7,38] Various "real-life" experiences have shown a worse outcome after TAVR in general, mostly beyond two years.[28,49] Considering this, liberal extension of TAVR to younger and low-risk patients thus appears premature.[39]

In the past two decades, the concept of "minimally invasive" aortic valve replacement has been increasingly advocated. Minimally invasive procedure would significantly reduce the side effects of extracorporeal circulation, myocardial ischemia, and aortic manipulation. The currently used techniques, however, fail to meet or even address these expectations. Except for the surgical access, every other procedural step (extracorporeal circulation, myocardial ischemia, aortic manipulation) is similar to conventional surgery. The term "minimally invasive" is, thus, incorrectly used, as it only refers to a limited incisions.[50,51] It is not surprising in most studies, the benefit for the patient consists of an average reduction of blood loss and intensive care unit (ICU) stay.[52-54] Occasional reports of a reduction of respiratory complications could not be confirmed equivocally. These soft study endpoints (ICU or hospital stay, blood loss) are susceptible to surgical bias. A surgeon who is convinced of the benefit of a procedure would be more likely to spend more time on hemostasis or make decisions that shorten hospital or ICU stay. In addition, so-called minimal access procedures would be more likely performed by more experienced surgeons, leaving standard procedures to the less experienced colleagues. Trials may, thus, end up as comparisons between surgeons rather than comparisons of treatment protocols. This can be supported by the fact that most studies do not find a significant difference in perfusion and cross-clamp times, something that can be related to a systematic error induced by the surgical team.

Potential differences in survival are difficult to judge. Since operative mortality for conventional AVR is already very low, larger patient numbers (>2,000 patients in each arm) are required to prove any significant difference of this hard endpoint,[53] thereby leaving the available studies underpowered due to significantly smaller patient numbers. Also, most investigations show a high degree of heterogeneity (different surgical techniques, non-uniformity and non-randomization) impeding comparison.

The use of sutureless of rapid-deployment aortic valve prosthesis for minimal access surgery may reduce myocardial ischemic time and, thus, reduce morbidity. This potential benefit is balanced by typical device-related complications, such as increased rates of permanent pacemaker implantation and stroke.[55,56]

Considering these facts, the surgeon may be in a dilemma to not be able to offer good long-term solutions. To avoid prosthesis-associated comorbidities, therapeutic alternatives with reproducible and superior results are needed. Interestingly, the stentless aortic valve has recently demonstrated excellent results, comparable to the aortic homograft, when implanted as root replacement.[57] This valve may become a good option for patients over the age of 55 to 60 years.

For aortic valve regurgitation, surgical repair has evolved from individual case reports and sporadic success to a reproducible treatment alternative with excellent long-term results.[58-60] Being applied clinically already for some decades, only the systematic analysis of the functional anatomy has revealed different pathophysiological components,[61,62] thereby leading to an individualized therapeutic regimen. The identification of effective and geometric height for cusp function along with the introduction of a caliper have markedly improved the reproducibility.[63] The systematic and complete consideration of all pathologies during correction has resulted in excellent long-term repair stability, even in more complex diseased valves.[64,65] Following aortic valve repair, patients benefit from better hemodynamics and improved survival and quality of life.[66,67]

For younger patients not eligible for primary repair or those with repair failure, valve replacement with a pulmonary autograft remains a valuable option. Although the Ross procedure has demonstrated improved survival and quality of life, it only accounts for a very small percentage of all adult aortic valve replacements.[68] Most likely individual concerns and perceptions about operative risks and rate of reoperation and a possible reluctance to apply this more complex procedure explain this underuse. Truth is, however, that the use of external stabilization has proven to minimize the risk of failure caused by autograft dilatation with excellent long-term results.[69-71]

This brief overview emphasizes that not all innovations have contributed to true progress in patient care, as defined by true advantages to the patients. Continued innovation are necessary, but it must be accompanied by critical reflection regarding its value to the patient. This reflection must look beyond the implantation or perioperative period; instead, the long-term results is what the patient truly needs. Such an approach can be painstaking, since any study investigating long-term benefits requires much longer times of data collection and does not invite to a few quick publications based on limited data. In addition, it is outside the current trend of considering two- or five-year data as long-term.[42,72,73] Nonetheless, we have to accommodate the needs of our patients and pursue their interests responsibly, if we do not want to become mere "technicians" fighting for a "market share".

Continuous improvement will be essential, and we must be critically open to new transcatheter techniques. The spectrum of diseases, however, will not change much in the future. The "easy" cases will probably be treated by transcatheter techniques, and surgeons will be faced with a negative selection. In addition, the treatment of complications of transcatheter interventions contributes to a higher complexity of cardiovascular pathology requiring surgery in the future. We should keep in mind, however, that surgeons focusing on "wire skills" may lose core competence in their original arena. This may create a difficult scenario, if surgical training places too little emphasis on the core values. Trying to do "a little bit of both" can be the path to mediocrity. Our focus should not only be to maintain the current level of expertise resulting from almost seven decades of surgical experience, but continue to improve it without increasing the role of the surgeon as a risk factor.[74]

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