EXPERT OPINION

The Zero-Tolerance Approach to Standard AVR

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Conventionally, aortic valve stenosis (AS) is treated by surgical replacement of the valve (AVR), a very standardized and usually simple procedure that, however, still carries a significant perioperative mortality and morbidity, besides being associated to the late complications of the prostheses used. This procedure has been challenged by the recent introduction of percutaneous aortic valve implantation (TAVI), allegedly with better periprocedural results and, at least, similar longterm outcomes. Indeed, some believe that it will result in the demise of the surgical procedure.

In this text, I intend to demonstrate that we can obtain much better results with AVR than our cardiologists and ourselves believe. Using the Six-sigma (6-σ) developed by the industry that assures that 99.99966% of the products manufactured are statistically expected to be free of defects (3.4 defective parts/million). I believe that this concept is applicable to surgery. Indeed, some reference surgical centers now routinely have perioperative mortalities for AVR lower than 1%. Several risk factors for death and other complications have been identified that can be modified pre-operatively, leading to lower mortality and morbidity rates. Also, technical aspects of the procedure can be adjusted or modified with the same goal. Finally, the Heart Team and of the surgical staff, medical and nursing, play an important role in the success of the surgery, which, in my view, will still be part of our surgical armamentarium for the foreseeable future.

Key words: Aortic valve; Aortic valve stenosis; Cardiac surgery, procedures; TAVI.

Convencionalmente, la estenosis aórtica es tratada mediante el reemplazo valvular aórtico, un procedimiento bien estandarizado y generalmente bastante simple. Sin embargo, en ocasiones conlleva una significativa morbimortalidad, además de estar asociado a las ulteriores complicaciones propias de las prótesis. Este procedimiento se ha convertido en un reto debido a la reciente introducción del TAVI, presuntamente con mejores resultados operatorios, o cuando menos, con resultados similares a largo plazo. En efecto, muchos creen que esto conllevará a la desaparición del procedimiento quirúrgico.

En este artículo, intentaré demostrar que nosotros podemos obtener mejores resultados con el implamte protésico aórtico quirúrigco convencional de lo que nuestros colegas cardiólogos y nostoros mismos creemos. Usando una metodología Six-sigma (6-σ) desarrollada por la industria que asegura que el 99.99966% de los productos manofacturados se espera que estén libres de defectos (3.4 partes defectuosas / millón). Creo que este concepto es aplicable a la cirugía. En efecto, algunos centros hospitalarios quirúrgicos ahora tienen una mortalidad operatoria rutinariamente para el reemplazo valvular aórtico menor a 1%. Algunos factores de riesgo para muerte y otras complicaciones han sido identificados y puede ser modificados preoperatoriamente, permitiendo menores tasas de morbimortalidad. A la vez, los aspectos técnicos del procedimiento pueden ser ajustados o modificados con el mismo fin. Finalmente, el Heart Team juega un papel importante en el éxito de la cirugía, la cual, desde un punto de vista personal, seguirá siendo todavía parte de nuestro armamentarium quirúrgico en el futuro inmediato.

Key words: **Válvula aórtica; Estenosis de la válvula aórtica; Procedimientos en cirugía cardiaca; TAVI.**

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The recent introduction of percutaneous aortic valve implantation (TAVI) caused a revolution in the field of treatment of aortic valve stenosis (AS). This affection is becoming the cardiac epidemic of the 21st century, because of its rapidly increasing incidence and of our inability to prevent

it, by contrast to the decrease in the incidence of coronary artery occlusive disease, which is, otherwise, preventable. Conventionally, AS is treated by surgical replacement of the valve (AVR), a very standardized and usually simple procedure that, however, still carries a significant perioperative mortality and morbidity, besides being associated to the late complications of the prostheses used.

It is precisely this association of adverse events that is mostly used for comparison with the outcomes after TAVI, although there is still a lack of evidence about the durability of the prostheses used in this procedure. The 2017 ESC/EACTS Guidelines for the management of valvular heart disease identify an STS / EuroSCORE II <4% (logistic EuroSCORE <10%) as the first clinical characteristic that favours the use of TAVI [1]. Hence, perioperative mortalities during AVR above 4%, still frequently reported, are the most powerful weapon used by interventional cardiologists to recommend TAVI and could ultimately result in the "demise" of the classical AVR [2].

The root of the problem

It is the purpose of this work to persuade the surgical fraternity that we can perform AVR with much better results than the cardiologists (and even ourselves) believe. In fact, several studies have consistently shown that the risk of AVR predicted by the currently available scores is overestimated [3]. On the other hand, there has been a progressive decrease in the mortality of the surgical procedure in the STS database, from 7.1% in 1999 to 3.8% in 2011, and it reached 2.2% for isolated AVR in 2016(all patients included). A similar trend has been shown in the mortalities observed with associated procedures, such as CABG and mitral valve surgery [4,5]. But the results of AVR can be even better than those observed in large databases. The Cleveland Clinic "guarantees" a mortality below 1% for isolated AVR. The difference is obviously related to the volume of procedures performed, well above a thousand per year in Cleveland, whereas there are many contributors to the STS database that perform less than 50 cases per year. Experience of the teams is, probably, the most important factor affecting mortality in this as well as in the vast majority of surgical procedures. In my own department's experience, the mortality for isolated AVR has been constantly below 1%, and averaged 0.44% for the last 10 years, with a mean volume of nearly 300 procedures per year (above 400 in the last 3 years). In this experience, the mean age of the patients was 74 years and it included 39.7% of patients older than 75 years and 16.7% above 80 years of age [Antunes MJ, unpublished data].

Furthermore, in a subset analysis of 798 high-risk patients (STS score, 5.8; logistic EuroSCORE, 17.2) with a mean age of 77 years, we had a mortality rate of 1.6%, and the incidence of cerebro vacular accident (CVA) (1.6%) and of permanent pacemaker implantation (4.8%) were lower than those usually reported for TAVI. In addition, there were no patients with a periprosthetic leak equal or greater than grade 2 at discharge. Similarly, in 51 patients who required AVR after a previous CABG at a mean interval of 7.1 years, the mortality was 2.0% and the incidence of CVA was 3.9% [6].

With these results in mind, one has to question the current trend observed in some developed (should say rich) countries, of which Germany and the USA are striking examples, where the number of patients submitted to TAVI is currently roughly the double of that of AVR **(Fig 1)** [7]. I am told that in Germany all patients older than 70 years of age are directly addressed to the percutaneous intervention, usually without the opinion of the surgeon. Besides the clearly off-label indication, against what is currently proposed by the guidelines, there is the question of the costs of the percutaneous procedure which are, in the majority of less rich countries, well above those of the surgical treatment, hence constituting an increasingly intolerable financial burden to the respective health services.

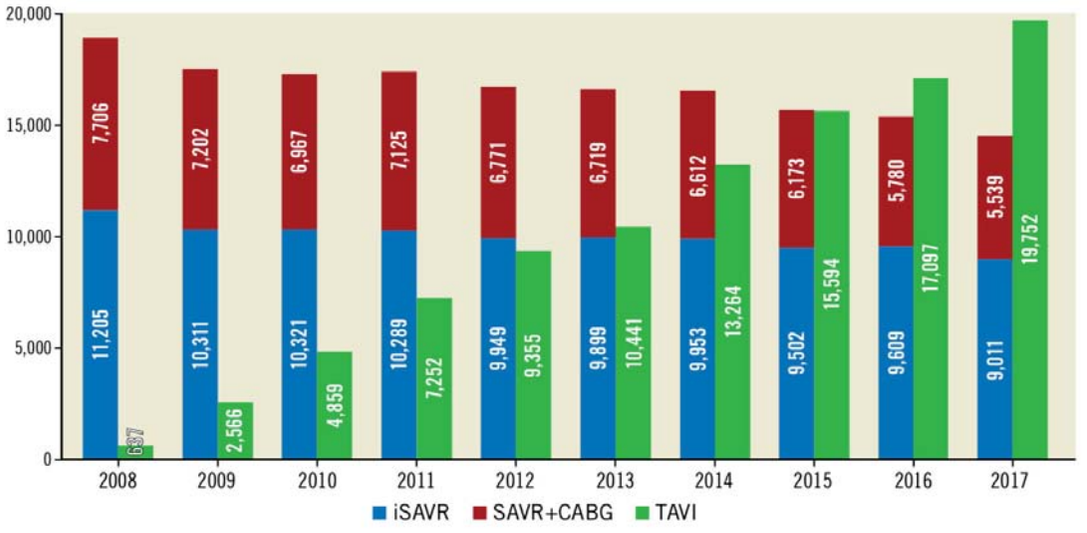

Figure 1. Annual procedure numbers for TAVI, isolated SAVR and SAVR plus CABG in Germany between 2008 and 2017 (from Eggebrecht and Mehta [7]).

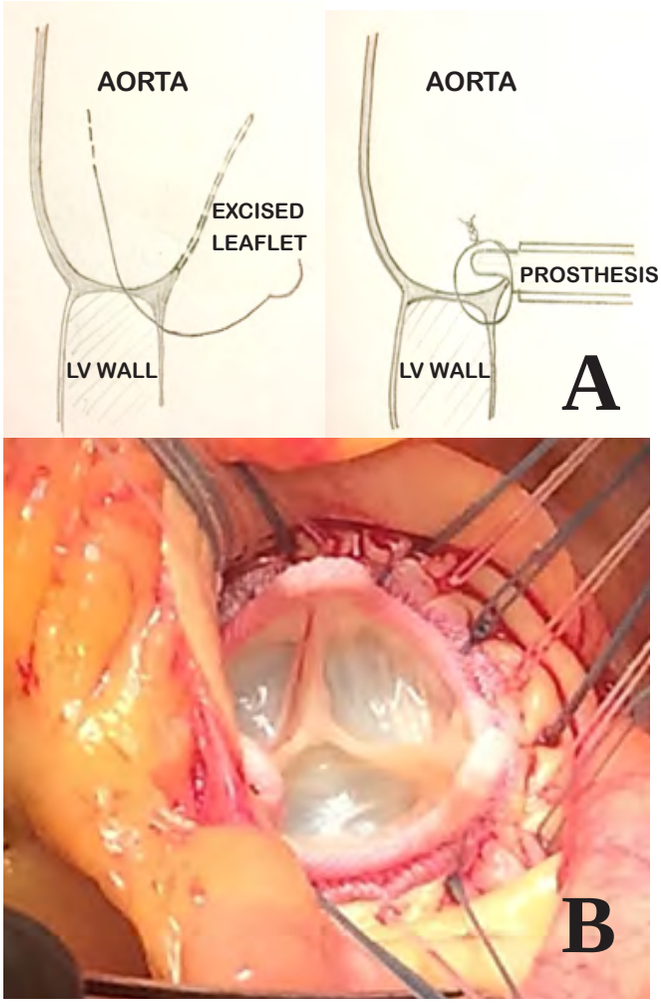

Figure 2 A: Simple interrupted sutures for aortic valve replacement. A detail of suture placement. B: Simple interrupted sutures for aortic valve replacement. Valve in place.
LV: Left ventricle

Then, how and what can we do differently?

Although I suspect that the "war" is already lost, in behoves us, surgeons, to demonstrate that we can do better. It is worth introducing here the six-sigma (6-σ) concept developed in 1980 by Motorola, in which 99.99966% of the products manufactured are statistically expected to be free of defects (3.4 defective parts/million). It seeks to improve the quality of the output of a process by identifying and removing the causes of defects and minimizing variability in manufacturing and business processes. The implications are that: 1- continuous efforts to achieve stable and predictable process results (i.e., reduce process variation) are of vital importance; 2- manufacturing and business processes have characteristics that can be measured, analyzed, controlled and improved; 3- achieving sustained quality improvement requires commitment from the entire organization, particularly from top-level management.

I sustain that these 3 principles can be applied to surgery. There are several already identified and modifiable preoperative factors that contribute to the mortality and morbidity associated to cardiac surgery, in general, and to AVR, in special. For example, preoperative creatinine levels have clearly been demonstrated to be independently associated to mortality. Furthermore, it has been demonstrated that correction of these levels in preparation to cardiac surgery lowers the rate of complications, including mortality [8]. In a previous study from our own group, we have shown a linear correlation between operative mortality and creatinine levels [9]. Similarly, preoperative haemoglobin levels have been shown to be directly associated to perioperative morbidity and mortality, and can be adequately compensated before surgery [10]. Other factors, such as glycemia can and should be modulated in preparation for and during surgery.

On the other hand, several technical aspects should be considered in connection to perioperative adverse events. One of them is cardioplegia. The type (crystalloid or sanguineous and their respective formulas), the method (intermittent or continuous, antegrade or retrograde), frequency and interval of administration, and the temperature of both the formula and of the patient are important factors in myocardial preservation. For example, the Del Nido formula, which requires less frequent administrations, thus impacting the duration of the operation, has recently been associated to improved results [11].

The choice of prosthesis if of paramount importance: mechanical prostheses and bioprostheses have individual characteristics that can influence immediate results. In this regard, it is fundamental to adapt the prosthesis to the native annulus. The use of small-size bioprostheses may lead to intolerable patient-prosthesis mismatch (PPM) and must be avoided. But it may well be preferable to adapt the annulus to the prosthesis by generalising the use of annular enlargement. We now do it in more than 20% of the cases and have demonstrated no impact on the perioperative rate of complications [12]. In fact, we have shown that the technique we use and have described, a modification of the Manoughian procedure which does not impact on the mitral valve, to be simple, secure and reproducible [13].

The suture technique for the implantation of the prosthesis also has an impact on the results because of its relationship with the duration of the procedure. The use of pledgeted sutures, whether sub or supra-anular, has gained the preference of the majority of surgeons because of the perceived protection against periprosthetic leakage. But they have a narrowing effect on the annulus with the potential to generate PPM. I have always preferred single interrupted sutures (**Fig 2**); it is a simpler, faster and less obstructive method, thus permitting the use of larger prostheses and has not been demonstrated to increase the incidence of periprosthetic leaks [14]. Alternatively, continuous sutures are preferred by other groups, similarly with good results.

It is also important to stress that, although AVR is generally a relatively simple and reproducible technique, some an-

atomical and perioperative patient conditions may render the procedure riskier in some circumstances, hence it is important that surgical teams adopt specific allocation measures to preferentially allocate these patients to surgeons with a higher level of experience. "You don't have to be an artist to make beautiful art"… but it helps!

Finally, I want to stress the important role of the surgical team in the management of the patient in the ICU. This is the most important stage in defining the final result of surgery. I don't particularly like the current trend of leaving post-operative care of cardiac patients to the exclusive responsibility of intensivists. However prepared they may be for this specific task, they lack the information about the patients' hemodynamic evolution throughout the surgery, which can never be fully transmitted. In my department, the ICU care has always been primarily the responsibility of the surgeons and I believe that that is one of the secrets for the results obtained.

Otherwise, there are some important points to have in mind: 1- Inotropes are not the "panacea"; they often cause vasoconstriction, which should be avoided as much as possible; 2- Careful (restrictive) fluid replenishment (diastolic dysfunction); 3- Avoidance of vasoconstrictors (systolic dysfunction); 4- Liberal use of vasodilators (favour output over pressure); and 5- Early extubation (6-8 hours) and mobilization (first postop day).

Conclusion

The question of the indications of TAVI versus AVR remains largely unanswered and the discussion often deviates from scientific reasoning and, most importantly, common sense. The concept of heart team, which should be always involved in the decision, remains, by and large, a mirage; interventionalists are the gate-keepers and succeed in convincing patients of the advantages of a "simpler" procedure. The results of AVR, especially mortality, can be significantly improved. This passes through a thorough preoperative study and preparation of the patients (e.g. creatinine, anemia and glycemia). A carefully planned and conducted technique is absolutely essential; if you need help, don't hesitate to call for it! Appropriate / good ICU care is an absolute must.

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