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Comparing traditional aortic valve surgery and transapical approach to transcatheter aortic valve implant

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During the last 15 years, transcatheter aortic valve implant (TAVI) has become a valid alternative to surgical aortic valve replacement in symptomatic patients with severe aortic stenosis, and high or intermediate operative risk. Transcatheter aortic valve implant could be approached through various access sites, among which the transapical has long been one of the most popular. Through the years, this procedure has shown results similar to the standard surgical approach, but not as good as the same procedure via the transfemoral approach. For this reason, along with continuous technological advances, the transfemoral approach is used, presently, in 90% of the patient, while the transapical route has been limited, progressively, to a minority of patients. Currently the Heart Team should decide, in every single patient, between conventional surgery and TAVI. In clinical practice, TAVI is favoured in high-risk patients, and in the elderly at intermediate surgical risk with favourable anatomical features. In patients in whom TAVI is preferable to surgery, but have 'non-usable' femoral approach, alternative routes, such as transaxillary or transapical, could be considered.

Introduction

Surgical aortic valve replacement is the gold standard for the treatment of symptomatic severe aortic stenosis, able to guarantee an improvement in symptoms and survival at the price of a low risk. However, some subgroups of patients, suffering from left ventricular dysfunction, concomitant diseases, or advanced age, have a higher operative risk of complications and mortality. For these reasons, new less invasive transcatheter procedures have been implemented for the treatment of aortic pathology [transcatheter aortic valve implant (TAVI)]. These procedures consist in inserting in an aortic position a biological valve prosthesis mounted on a stent, through the introduction of a catheter in the vascular stream.

Over the past 15 years, TAVI has progressively shown results in continuous improvement and, ultimately, overlapping with respect to surgery in patients at high risk and at intermediate risk. In some patients, treated with transfemoral approach, even a trend towards better survival with TAVI was observed compared to surgery.[1] For this reason, the transfemoral TAVI is expanding rapidly and is currently being studied in selected low-risk subjects.

At the moment, the guidelines of the European Society of Cardiology contemplate the application of TAVI in symptomatic patients suffering from severe aortic stenosis with high operative risk or intermediate risk (STS or EuroSCORE $\geq$ 4%) based on the collegial decision of the Heart Team. In principle, TAVI is currently favoured in elderly patients (>75 years), with favourable anatomy and susceptible to transfemoral approach.[2]

The catheters needed to implant the aforementioned valves can in fact be introduced through different accesses, each with its own advantages and disadvantages (*Figure 1*). Especially during the first years of technological development, when the size of the catheters was greater, these accesses were subject to a significant percentage of

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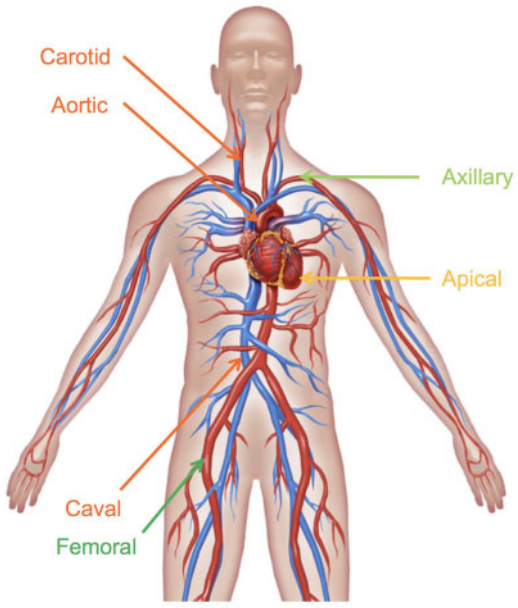

Figure 1 Main accesses for TAVI currently in use.

vascular complications, which in turn had a significant impact on patient mortality.[3]

In this context, since 2005 the possibility has been introduced of carrying out a TAVI by transapical route,[4] or of inserting the catheter and aortic prosthesis directly through the apex of the left ventricle. This approach quickly became the most frequently used alternative access for TAVI in the case of unfavourable peripheral vascular anatomy.

It allows in fact:

- completely bypass the entire vascular tree which is often severely compromised in TAVI candidate patients
- have excellent control over the catheter and the prosthesis, being the distance between the access and the target very short.

Conventional surgery vs. transapical approach

From a technical point of view, surgical valve replacement and transapical TAVI are characterized by important differences that have significant implications for the patient in the post-operative period and in the long term. *Table 1* summarizes the most important acute outcomes of traditional surgery and TAVI, while *Table 2* specifies some of the most important differences between traditional surgery, transapical TAVI, and transfemoral TAVI.

In surgical valve replacement, the patient undergoes general anaesthesia with intubation, a more or less extended opening of the chest, extracorporeal circulation, aortic clamping, and cardiac arrest. Each of these components represents an important source of morbidity for the entire body of the patient, and especially for the heart, lungs, and brain.

After the cardioplegic arrest of the heart, the aorta is opened, the aortic valve is carefully inspected under direct vision and removed. The aortic ring is decalcified, the prosthesis to be implanted is measured with dedicated instruments and it is possible to choose whether to implant a biological prosthesis or a mechanical one, both with a long clinical experience and with a generally estimated duration. The chosen prosthesis is then inserted and sutured to the heart, taking care to avoid as far as possible damage to the delicate surrounding structures (coronary, conduction tissue, and anterior mitral valve leaflet). The possibility of working with a non-beating heart under direct vision and the large experience accumulated over the decades make the surgical aortic valve replacement a technically extremely efficient operation with an incidence of paravalvular leaks close to zero and the need for a definitive pacemaker $<$10%. Recently, new rapid implant prostheses have been introduced in the surgical field.[5] Unlike traditional ones, these are implanted without or with minimal sutures. They guarantee greater valve areas with better haemodynamic performance, moreover they are faster to use and can therefore allow a reduction in surgical times, in addition to facilitating mini-invasive approaches (mini-sternotomy and mini-thoracotomy). On the other hand, since they are not sutured to the heart, they are characterized by a higher rate of paravalvular leaks and pacemakers.

After surgery, the standard regular course in the absence of complications usually involves a short stay in intensive care, a few days of hospitalization in the ward and then about 15 days of cardiac rehabilitation.

Similar to conventional surgery, in transapical TAVI, general anaesthesia remains with intubation and opening of the thorax with a left anterior even-small-thoracotomy (at the level of the cardiac apex) which often also involves opening of the pleural cavity. As in surgery, these aspects can be a problem especially in elderly and frail patients with cognitive or respiratory deficits. On the other hand, extracorporeal circulation, aortic clamping, and cardioplegia are avoided. In fact, once the cardiac apex is exposed, the left ventricle is punctured under ultrasound guidance and direct vision. The prosthesis—selected in advance on the basis of pre-operative examinations—is inserted through its own dedicated catheter and implanted with a beating heart assessing the result directly.

In this case, it is possible to use only biological prostheses and given the young age of these technologies, no data on long-term durability are still available. In addition, the advent of transcatheter prostheses has brought to light the phenomenon of prosthetic thrombosis: this appears to occur in a high percentage of TAVI valves even in a silent manner (15%), is associated with an increased risk of neurological events and can theoretically impact on durability. Unfortunately, this is a phenomenon not yet completely defined.

Once the valve is implanted, the catheter is removed and the heart breach is sutured. Most patients undergoing TAVI via the transapical route have a thick and resistant hypertrophic ventricle. However, in the case of dilated and dysfunctional ventricles as can occur in the presence of low-flow aortic stenosis and/or mitral insufficiency, the ventricular wall is thinned and more fragile. In this

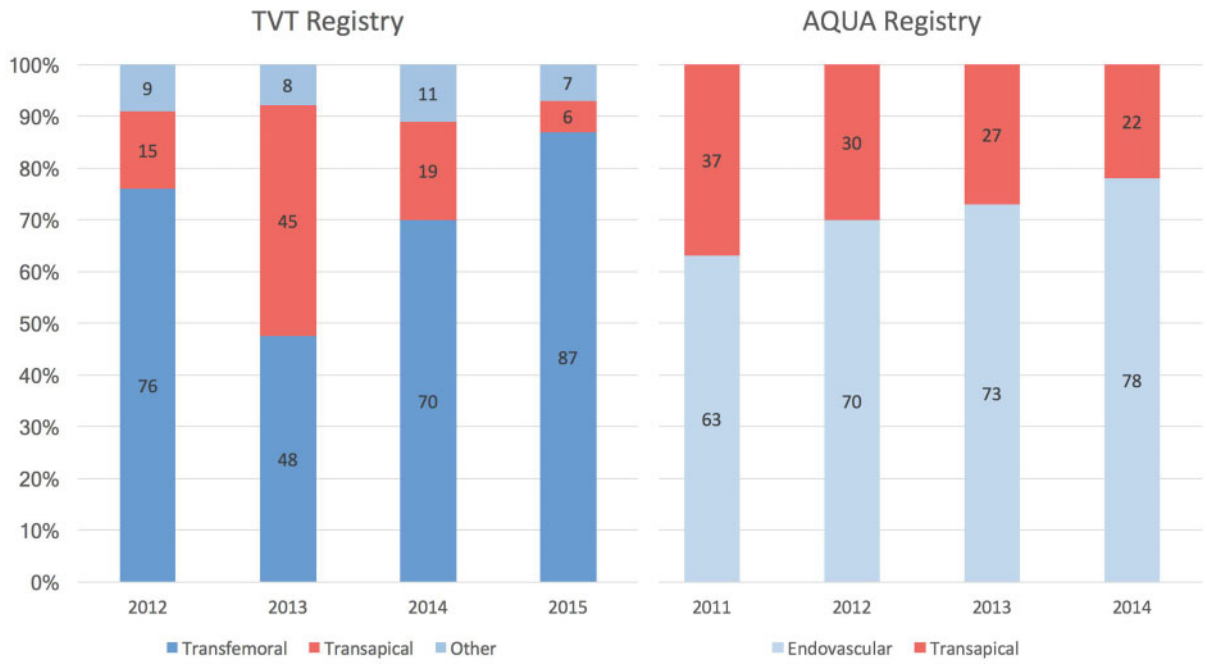

Figure 2 Trend of TAVI procedures in the United States (TVT Registry) and Germany (AQUA Registry): an increase in the proportion of endovascular (transfemoral) procedures corresponds to a decrease in transapical procedures.

Table 1 Summary of the main contemporary acute findings for surgical aortic valve replacement and TAVI

	Surgery	TAVI
Mortality	≈1%	≈1%
Stroke	≈3%	≈3%
Pacemaker implant	<10%	≈15%
Moderate-severe aortic insufficiency	≈0%	<5%
Access site complications	<1% (infections)	≈5% (vascular)

Table 2 Comparison of surgical aortic valve replacement and transapical and transfemoral aortic valvular implant

	Femorale	Apical	Surgery
Anaesthesia	Local	General	General
Access	Percutaneous	Surgical/percutaneous	Surgical
Extracorporeal circulation	No	No	Yes
Aortic-cross clamping	No	No	Yes
Cardiac arrest	No	No	Yes
Post-op recovery time	Short	Intermediate	Long

context, transapical access is a dangerous insult, which should be avoided/minimized as much as possible.

As with any TAVI procedure, the native valve is not removed but is crushed by the transcatheter prosthesis that rests on it due to the radial force of its stent. This implantation mechanism has important implications:[6]

- As they are not sutured on properly prepared tissue, transcatheter prostheses are characterized by a higher rate of paravalvular leaks. This has been greatly reduced over the years due to improved technology and moderate to severe aortic insufficiency is present in less than 3–5% of cases but most patients still have a mild degree. The impact and long-term evolution of such small degrees of aortic insufficiency are still unknown.
- The calcium of the native aortic valve can cause an asymmetric expansion of the prosthesis, which therefore remains not perfectly circular. This morphology could theoretically affect the long-term durability of

the aforementioned prostheses but at the moment data on this are not yet available.
- Due to the pressure they exert on surrounding tissues, transcatheter prostheses are characterized by a higher incidence of rhythm disorders requiring the implantation of a definitive pacemaker with respect to surgical procedures (currently around 15% overall).
- Transcatheter prostheses are not measured on the firm, flaccid, and empty heart but on the beating heart during pre-operative computerized tomography. They are also deliberately chosen with a certain degree of oversizing to ensure adequate anchorage to minimize the risk of paravalvular leaks. As a consequence transcatheter prostheses are generally larger than surgically implanted ones, thus offering greater valve area, lower gradients, and lower patient-prosthesis mismatch.[7]
- The passage of the catheters and the prosthesis itself in the ascending aorta and in the aortic arch, in addition to the valvular implant, can cause embolization of material to the brain with consequent neurological damage. In fact, despite the technical improvement of the last decade, the incidence of neurological events after TAVI remains around 3%. Dedicated systems to protect supra-aortic vessels promise to reduce this problem.

After the procedure, in the absence of problems, the patient is immediately awakened and can go directly to the ward. After a few days of observation, can return home directly.

The results of the transapical approach for TAVI were satisfactory, but the data currently available to directly compare conventional surgery with transapical TAVI are modest. It is legitimate to say that surgery guarantees lower residual aortic insufficiency and lower rate of pacemaker implantation. Transapical TAVI allows to obtain a better haemodynamics with minor patient-prosthesis mismatch and remains a less heavy intervention for the heart and the patient. Neurological complications are similar between the two groups, as is survival: in the meta-analysis performed by Siontis *et al.*[1] of four randomized studies between surgery and TAVI, the 'transthoracic' TAVI (transapical and transaortic) was associated with similar survival compared to conventional surgery after 2-year [hazard ratio (HR) 1.17, 95% confidence interval (CI) 0.88–1.56]. Also from the 5-year results of PARTNER 1A, there is no difference in terms of survival between transapical TAVI and conventional surgery (HR 1.37, 95% CI 0.98).

The transapical approach today: comparison with the transfemoral and new scenarios

After being for many years one of the most used accesses worldwide, the transapical approach for TAVI has progressively been reduced in recent years for the advent of transfemoral access which is less invasive, and is currently used only in rare cases.[8] Specifically, this shift is related to two aspects:

(1) With the progress of technology, the incidence of peripheral vascular complications has progressively decreased.[6] In fact the calibre of the catheters used to introduce the prosthesis has been reduced and their flexibility has increased, as has the experience of the operators. Currently, it is possible to treat patients with peripheral accesses up to 5.5 mm lumen easily via the femoral artery, which means that more than 90% of patients undergoing TAVI can be treated transfemoral. Even patients with smaller vessel calibres have been treated in the past but at the price of an increased rate of complications[9] and therefore, until the technology improves further, it is not currently advisable to pursue the transfemoral pathway in extreme cases. Particularly fearsome is the association of reduced calibres and concentric calcifications of the vessel. These, in fact, obstructing the expansion of the vessel during the passage of the valve increase the risk of rupture. In these cases, alternative approaches to the transfemoral approach should be considered.

(2) Numerous observational studies/registries have reported in the past a higher mortality with the transapical approach compared to the transfemoral one; however, these results were vitiated by differences in the pre-operative risk profile. In fact, transapical patients are usually 'sicker' than transfemoral ones (typically they are vasculopathic patients rejected for the femoral approach). Even after propensity-matching, however, the transapical approach remains with respect to the transfemoral one associated with increased mortality and morbidity (increased duration of hospitalization, bleeding, and reduced recovery of left ventricular function).[10,11] It should be noted that, unlike the transapical one, another type of totally percutaneous access, such as the transaxillary one, has shown results comparable to the transfemoral ones.[12] Therefore in different centres, the axillary approach is today considered the second choice to be preferred when the femoral is not advisable and the transapical remains the third choice after the axillary approach.[13]

It is worth highlighting that with the shift of TAVI towards younger subjects at lower risk it is difficult to imagine an increase in transapical procedures. In fact in these patients, with reduced comorbidity, femoral access will be possible in more and more cases. Furthermore, the great added value of TAVI with respect to surgery is its lower invasiveness. This is maximized by the transfemoral approach, which in fact has shown a benefit in terms of survival with respect to surgery in patients treated so far, unlike the transapical approach. However, compared to surgery, all TAVI, femoral, and apical, pay the price of a still 'imperfect' aortic valve result. Therefore, in the case of an unfavourable anatomy for femoral access, the lower the age and risk of the patient, the more conventional surgery will remain the preferable solution.

Although the number of transapical procedures for TAVI is now extremely small, transapical access continues to be of interest and used for other valvular treatments.[14]

In the mitral field, for example, it is currently possible to implant artificial chordae for correction of mitral valve prolapse/flail insufficiency through the apex of the heart.

In addition, transcatheter mitral valve replacement has also been added to the cardiology scene in recent years. This procedure is still at an early stage and unlike its aortic counterpart, much more complex. It currently uses very large catheters that often do not allow a transfemoral-transseptal approach so most of these procedures are currently performed transapically.

Transcatheter closure of aortic and mitral paraprosthetic leaks is another fertile substrate for transapical access. These procedures are particularly difficult from the technical point of view and often the apical access, allowing to work near the target, can make them easier.

Finally, we recall that although in the vast majority of cases the cardiac apex is exposed and closed surgically, as well as the chest wall, techniques for a totally percutaneous transapical access with dedicated systems are already available.[15]

The aforementioned new technologies currently use an apical approach because they are still at an early stage of development and/or because they suffer from technical difficulties. With the technological and technical improvement the neo-chordae and valve prosthesis implantation aims to become transseptal, completely avoiding interfering with the cardiac ventricle, an aspect that may be particularly important in a context, for example, of secondary mitral insufficiency with hypokinetic dilated cardiomyopathy.

Conclusions

The transapical approach has long been one of the most used for TAVI procedures, with good results comparable to conventional surgery in terms of survival. Compared to the transfemoral approach, however, it is characterized by greater invasiveness which results in unfavourable outcomes. For this reason, in parallel with the improvement of transfemoral technologies, the number of transapical procedures has been decreasing with the passage of time. Other valve procedures under development are currently performed apically, but similarly to what happened with the aorta, with technological improvement, natural evolution can only be far from the apex of the heart, towards a totally percutaneous approach, really minimally invasive.

Aortic transcatheter treatment represents the vanguard of valvular therapies of the future. It is evolving and on the wings of promising results in recent years it is moving quickly towards increasingly young and low-risk patients. The opportunity to apply TAVI in these patients remains to be demonstrated, and in this panorama, a rational multidisciplinary approach that puts the patient at the centre is fundamental to guarantee every single person the best possible treatment.

Conflict of interest: none declared.

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