



POSITION STATEMENT

Position statement on transcatheter aortic valve implantation in Portugal[☆]



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Abstract

Objective: To evaluate the clinical indications and guidelines for transcatheter aortic valve implantation (TAVI) and to propose adaptations for its use in Portugal.

Methods and Results: The working group analyzed the epidemiology of aortic stenosis and current clinical recommendations in the light of current evidence, taking into consideration their own experience in Portugal.

The evidence shows that TAVI significantly reduces mortality in patients with severe aortic stenosis considered unsuitable for surgery. This technique has a comparable safety profile, efficacy and quality of life improvement to conventional surgery in patients with high surgical risk, when carefully selected by multidisciplinary teams.

TAVI procedures should be performed within multidisciplinary programs in centers with on-site cardiac surgery by experienced teams treating no fewer than 50 cases per year in order to maintain proficiency.

The technique is little used in Portugal, with seven implantations/year per million population, a seventh of the European average and the lowest rate in Europe.

From a societal standpoint, it is important to evaluate clinical outcomes and analyze the incremental cost involved in order to define the situations in which the technique is appropriate and should be used.

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PALAVRAS-CHAVE

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Conclusion: TAVI is the only treatment for severe aortic stenosis in patients unsuitable for surgery, and can also be applied in selected cases with high surgical risk.

Patients who are considered for this treatment should be evaluated in centers of excellence performing the technique and with a formal program of multidisciplinary team work. The first cases should be supervised until the team has established its routine. The program should perform the recommended minimum number of procedures per year in order to maintain proficiency and must keep a prospective clinical registry for monitoring purposes.

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Posição de consenso sobre válvulas aórticas percutâneas transcatéter em Portugal**Resumo**

Objetivo: Avaliar as indicações e recomendações clínicas sobre a implantação de válvulas aórticas percutâneas (VAP) e propor adaptações para a sua aplicabilidade em Portugal.

Métodos e resultados: O grupo de trabalho analisou a epidemiologia da estenose aórtica, avaliou as recomendações clínicas existentes à luz da evidência científica conhecida e baseou-se na sua experiência em Portugal.

A evidência demonstra que as biopróteses valvulares percutâneas reduzem de forma muito significativa a mortalidade dos doentes com estenose aórtica grave considerados inoperáveis. Comparada com a cirurgia convencional, esta técnica apresenta um padrão comparável de segurança, de eficácia e de melhoria da qualidade de vida em doentes de elevado risco cirúrgico, devidamente selecionados por equipas multidisciplinares. Porém há preocupações relativamente à sua durabilidade e segurança a longo prazo.

De forma a ser proficiente, a implantação de válvulas aórticas percutâneas deve ser realizada no âmbito de programas multidisciplinares integrados desenvolvidos em centros médico-cirúrgicos com equipas experientes, em número não inferior a 50 casos por centro/ano.

Em Portugal observa-se uma utilização muito reduzida desta terapêutica, com sete implantes/ano por milhão de habitantes, o que corresponde a cerca de sete vezes menos do que a média europeia, constituindo a taxa mais baixa da mesma.

Para a sociedade, é necessário avaliar os resultados clínicos e estudar o custo incremental associado para definir quais as indicações em que esta técnica pode e deve ser selecionada.

Conclusão: A implantação transcatéter de válvulas aórticas percutâneas constitui a única terapêutica para doentes inoperáveis portadores de estenose aórtica grave. Em casos selecionados pode ser aplicada também em doentes considerados de alto risco cirúrgico.

Os doentes candidatos a este tratamento devem ser avaliados em centros de excelência que realizam estas técnicas e possuam um programa formal de funcionamento com uma equipa multidisciplinar. Esta deve ser assessorada nos primeiros casos, até estar rotinada. O programa deve assegurar o mínimo recomendado de casos anuais para manter a sua proficiência, elaborando um registo prospetivo monitorizável.

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Preamble

The prevalence of calcific aortic stenosis is growing due to the increase in degenerative valve disease, which affects 2.5% of people aged over 65; it is estimated that at least 32000 individuals in Portugal have the condition.¹

The first-line treatment is surgical aortic valve replacement (SAVR).^{2,3} Outcomes are adversely affected by the presence of certain comorbidities, and so transcatheter aortic valve implantation (TAVI) was developed for patients considered unsuitable for surgery.⁴

The 2012 guidelines published jointly by the European Society of Cardiology (ESC) and the European Association of Cardio-Thoracic Surgery (EACTS) assign a class I or IIa recommendation for TAVI according to clinical indications.³

National data for Portugal indicate an annual rate of TAVI of seven procedures per million population, a third of the rate in Spain and the UK and a seventh of the European Union average of 45 implantations.^{5,6}

Current evidence on transcatheter aortic valve implantation and the situation in Portugal

The PARTNER trial, the only randomized study to date, reported a reduction in overall mortality in inoperable patients (cohort B) from 51% with optimal medical therapy to 31% with TAVI at one-year follow-up.⁷

Table 1 European Society of Cardiology/European Association for Cardio-Thoracic Surgery guidelines for the use of TAVI according to class of recommendation and level of evidence.³

ESC/EACTS recommendation	Class of recommendation	Level of evidence	Reference
TAVI should only be undertaken with a multidisciplinary 'heart team' including cardiologists and cardiac surgeons and other specialists if necessary.	I	C	
TAVI should only be performed in hospitals with cardiac surgery on-site.	I	C	
TAVI is indicated in patients with severe symptomatic aortic stenosis who are not suitable for SAVR and who are likely to gain improvement in their quality of life and to have a life expectancy of more than one year after consideration of their comorbidities.	I	B	7
TAVI should be considered in high-risk patients with severe symptomatic aortic stenosis who may still be suitable for surgery, but in whom TAVI is favored by a heart team based on the individual risk profile and anatomic suitability.	Ila	B	19

SAVR: surgical aortic valve replacement; TAVI: transcatheter aortic valve implantation.

Use of TAVI was further consolidated following publication of the second arm of the trial (cohort A), in which the percutaneous technique, via a transfemoral or transaortic approach, was compared with SAVR. Outcomes for TAVI tended to be better in terms of 30-day mortality (3.4% in the TAVI group vs. 6.5% in the SAVR group, $p=0.07$), but there was no significant difference in two-year mortality (33.9% TAVI vs. 35% SAVR),⁸ both groups presenting significant functional improvement at two-year follow-up.^{8,9}

Numerous registries have been published suggesting that the efficacy and safety of TAVI are generally good when performed outside of trials. Piazza et al.¹⁴ published one of the first in 2008, reporting 30-day mortality of 8.0% and a combined major event rate – death, myocardial infarction and stroke – of 9.3%. Four years later, in the UK TAVI registry of 870 patients, 30-day mortality was 7.1%, but rose to 26.3% at two-year follow-up. The landmark FRANCE 2 registry, a mandatory official registry, with 3195 patients, covering all types of valve and approaches, including subclavian and transaortic, reports 30-day and one-year mortality of 9.7% and 24%, respectively.¹⁰

The only registry directly comparing TAVI with SAVR is an Italian one analyzing 618 patients that used three methods of statistical adjustment, including propensity scores. The annual major event rate based on the Valve Academic Research Consortium (VARC) criteria was 11.8%, with no significant differences between the two techniques in occurrence of death, stroke or myocardial infarction.¹¹

The impact on quality of life has been the focus of much interest since the evidence consistently shows marked improvement from one month after TAVI.^{9,12}

In general, the technique is used in patients who are judged inoperable or at high surgical risk due to older age, comorbidities, female gender, higher functional class, emergency operation, left ventricular dysfunction, pulmonary hypertension, coexisting coronary artery disease, or previous cardiac surgery, including for bioprosthetic valve failure.^{3,13}

It should be stressed that implementation of TAVI programs has generally involved highly motivated teams with proctoring in the first 5–15 cases.¹⁴

Notwithstanding the good results obtained, certain aspects give rise to concern. Various peri-procedural

complications can require particular attention.^{15,16} Periprosthetic regurgitation, mitral regurgitation and need for pacing appear to adversely affect long-term outcomes.^{10,17–19} Medium-term non-cardiovascular mortality is high, reaching 59% in a study by Rodés-Cabau et al. of 339 patients followed for 42 months, which suggests that patient selection needs to be improved.²⁰

SAVR can be a costly procedure in high-risk patients, with an additional cost of 2400 euros in hospital charges for each 1% increase in the Society of Thoracic Surgeons score,²¹ but it is not known whether TAVI can reduce these costs. In the US, the additional cost of TAVI per life-year gained is around 40 000 euros compared with standard care in inoperable patients.^{21,22} The PARTNER trial recently demonstrated that in 80% of cases the costs of SAVR and TAVI do not differ significantly at one year of follow-up.

It was against this background that the ESC/EACTS guidelines on the management of valvular heart disease were issued, which demonstrate the importance of this sophisticated and revolutionary technique in patients considered unsuitable for SAVR.²³

Minimum technical conditions, clinical indications, additional costs, and outcome assessment

The Working Group recognizes the importance of TAVI programs being run by formally established multidisciplinary teams in centers of excellence with on-site cardiac surgery. Each team should include at least a cardiac surgeon, an interventional cardiologist, an anesthesiologist and a cardiologist experienced in echocardiography. The procedures should be performed in a hybrid operating room, a cardiac catheterization laboratory equipped as an operating room, or an operating room equipped with an imaging system of appropriate quality. Extracorporeal circulation should be available if required.

With regard to the clinical indications in the guidelines (Table 1), we should bear in mind the constraints of the International Monetary Fund financial bailout in Portugal and the publications suggesting that TAVI should only be performed in carefully selected patients in centers with

a minimum annual volume of 50 procedures, in order to keep additional costs at an acceptable level and to maintain proficiency.¹⁵

It is therefore recommended that TAVI programs should preferentially treat inoperable patients with a class I recommendation.³

Patients with a class IIa recommendation should be considered for TAVI if:

- the risk-benefit ratio is favorable in terms of quality of life as assessed by the heart team;
- the center considers that the indication is compatible with the experience of the team and the predicted annual volume of procedures¹⁵;
- the procedure is performed under the scope of investigational studies or registries.

The consensus is that the use of TAVI should be rigorously monitored, preferably through a national multicenter registry using the current VARC criteria to ensure quality and transparency.^{24,25} It is recommended that all patients be followed for seven years and that nationwide studies be undertaken in Portugal to assess the costs of the technique.

The Working Group hopes that this document will be useful to health professionals, institutions, departments and decision-making bodies dealing with this important and rapidly developing treatment.

Conclusion

TAVI is the only effective treatment for patients with aortic stenosis who are considered unsuitable for surgery.

The technique should be performed in centers of excellence that have a formally established and trained multidisciplinary heart team, treat a minimum of 50 cases a year, have appropriate technical conditions, and keep a prospective registry for monitoring purposes.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that no patient data appear in this article.

Right to privacy and informed consent. The authors declare that no patient data appear in this article.

Conflict of interest

The authors have no conflict of interest to declare.

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