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Percutaneous cardiological intervention and cardiac surgery: patient-centered care. Position statement of the Spanish Society of Cardiology

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ABSTRACT

The percutaneous treatment of coronary artery disease and some structural cardiovascular diseases has undergone spectacular changes. More and more patients with different types of heart disease are being treated by percutaneous or transcatheter interventions, with no such increase in patients undergoing cardiac surgery. This situation has led to different types of approach, requiring an objective analysis that includes all the factors possibly influencing these changes. This document assesses the 2 scenarios where this problem is most evident: coronary revascularization and the treatment of aortic stenosis. The document analyzes the situation of coronary revascularization in Spain, and the causes that may explain the differences between the number of patients who currently undergo percutaneous revascularization and those who undergo coronary surgery. In contrast, treatment of aortic stenosis through transcatheter aortic valve implantation will lead to a foreseeable reduction in the number of candidates for surgical replacement. Several international scientific societies have published the requirements on training and experience and the necessary operator and center volumes to implement a transcatheter aortic valve implantation program, conditions that the Spanish Society of Cardiology, adopting a patient-centered approach, considers absolutely essential. Given that the 2 forms of intervention (percutaneous and surgical) are complementary, multidisciplinary patient assessment (Heart Team) remains crucial to offer the best treatment option. In this scenario of diverse approaches, a key figure is the clinical cardiologist. Finally, the changes currently occurring in the treatment of structural heart disease will, in future, lead to the performance of procedures requiring the participation of professionals from both specialties. This approach will require a redesign of current training programs.

Intervencionismo percutáneo cardiológico y cirugía cardiaca: el paciente en el centro de los procesos. Documento de posicionamiento de la Sociedad Española de Cardiología

Palabras clave:
Cirugía coronaria
Heart Team
Intervención coronaria percutánea
Requisitos de formación
Revascularización coronaria
Implante percutáneo de válvula aórtica
Volumen de los operadores

RESUMEN

El tratamiento percutáneo de la enfermedad coronaria y determinadas enfermedades cardiovasculares estructurales ha experimentado un desarrollo espectacular. Cada vez se trata a un mayor número de pacientes con diferentes tipos de cardiopatías mediante intervenciones percutáneas o transcatéter, mientras que este incremento no se observa en los pacientes sometidos a cirugía cardiaca. Esta situación ha motivado diferentes posicionamientos que requieren un análisis objetivo que considere todos los aspectos que pueden influir en esta evolución. En este documento se evalúan las 2 situaciones en que el problema es más manifiesto: la revascularización coronaria y el tratamiento de la estenosis aórtica. El artículo analiza la situación de la revascularización coronaria en España y las causas que pueden explicar las diferencias existentes entre el número de pacientes que actualmente se someten a revascularización percutánea respecto a los que se someten a cirugía coronaria. Por otra parte, el implante percutáneo de válvula aórtica mediante catéter en el tratamiento de la estenosis aórtica condicionará una previsible

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reducción del número de pacientes candidatos a tratamiento mediante recambio quirúrgico. Diferentes sociedades científicas internacionales han publicado los requisitos de formación y experiencia y los volúmenes exigidos a los operadores y centros para desarrollar un programa de implante percutáneo de válvula aórtica, condiciones que la Sociedad Española de Cardiología, situando al paciente en el centro del proceso asistencial, considera como absolutamente imprescindibles. Teniendo en cuenta que ambas formas de intervención (percutánea y quirúrgica) son procedimientos complementarios, la valoración multidisciplinaria de los pacientes *(Heart Team)* sigue siendo de extrema necesidad para poder ofrecerles la mejor opción de tratamiento. En este escenario de aproximaciones diversas, la figura del cardiólogo clínico adquiere una relevancia clave. Por último, la evolución que está experimentando el tratamiento de la enfermedad estructural obligará en el futuro a realizar procedimientos en los que se requiera la actuación conjunta de profesionales de ambas especialidades. Este acercamiento exigirá un rediseño de los programas de formación actualmente existentes.

Abbreviations

PCI: percutaneous coronary intervention
SEC: Spanish Society of Cardiology
TAVI: transcatheter aortic valve implantation

INTRODUCTION

Cardiovascular disease remains the leading cause of death in Spain.[1] Although mortality has significantly decreased in recent decades, greater life expectancy has led to higher prevalence and therefore, in absolute values, to an increase in the number of deaths.[2] There has also been a parallel increase patients who are elderly, or have relevant comorbidities, and who also have cardiovascular disease. Cardiovascular disease remains the main cause of hospital admissions and is one of the conditions that is associated with high economic resource use in the health system.[3]

PROGRESS IN THE TREATMENT OF CARDIAC PATIENTS

Cardiovascular disease is one of the medical fields showing spectacular progress with a highly favorable impact on prognosis.[4] Major advances have been made in diagnostic methods, risk stratification, and therapeutic options, with new treatments that have led to new consensus and indications. One of the areas in which progress has been particularly striking is that of diagnostic techniques and percutaneous treatment associated with marked technological innovations in the development of new devices. A large number of controlled randomized clinical trials have provided support and scientific evidence for the introduction of these new treatments in clinical practice.

There has been a spectacular transformation in the percutaneous treatment of coronary heart disease and certain structural heart diseases. Percutaneous coronary intervention (PCI), with stenting, has been of immense benefit to many patients. Excellent short- and long-term results, low procedural morbidity and mortality, and ease of access have increased its indication and choice as the main form of coronary revascularization.[5,6] Structural percutaneous intervention, initially limited to the treatment of mitral or pulmonary stenosis (valvuloplasties), has been extended to the treatment of atrial septal defect, patent foramen ovale,[7] left atrial appendage occlusion,[8] mitral regurgitation,[9] and aortic stenosis with transcatheter aortic valve implantation (TAVI).[10]

Consequently, more patients with different types of heart disease are receiving treatment using percutaneous or transcatheter techniques, in contrast to the absence of an increase in patients undergoing classic cardiac surgery. Thus, the volume of patients undergoing surgery has not risen proportionally to the increase in the incidence of the disease caused by population aging, increased access to diagnosis, and the precise identification of the different cardiovascular diseases. This situation has led to the adoption of different positions and judgments, which we believe to be subjective,[11–13] that require objective analysis and interpretation while taking into account all the relevant aspects that have led to these changes.

THE SITUATION OF CORONARY REVASCULARIZATION

Several clinical practice guidelines have defined the patient subgroups that can derive the greatest benefit from either form of coronary revascularization: PCI or surgery.[14] Data from various controlled clinical trials, with very long follow-up analyses, have defined the profiles of patients who can preferentially benefit from one or other form of revascularization.[15] Bearing in mind that no new comparative studies are being conducted in this area, it is extremely likely that these recommendations will remain unchanged in the coming years.

Analysis of Spanish data shows that the number of coronary revascularization procedures per million inhabitants is strikingly lower than in most European countries.[5,6,11] This discrepancy may be explained by the lower prevalence of coronary heart disease in Mediterranean countries than in central and northern European countries. However, a particular aspect of the situation in Spain is that the ratio of surgical revascularization procedures to PCI in coronary patients is 1:9,[6,11] but is 1:6 in many European countries.[5] Possible causes for this difference include the typical preference of patients for less invasive procedures and treating physicians guiding patients toward PCI. Why does this situation occur?

Table 1 shows the number of hospitals performing percutaneous and surgical revascularization and the number of annual procedures per million inhabitants in Spain compared with 10 European countries.[5] Compared with the European average, fewer PCIs per million inhabitants per year are performed in Spain (−38%), but in fewer hospitals (−32%). Therefore, the annual volume of PCIs per hospital in Spain is similar to the average volume in European hospitals. By contrast, and in comparison with European countries, the number of coronary surgeries per million inhabitants per year in Spain is much lower than the European average (−60%) and they are performed in more hospitals (+3%).

Whereas the annual volume of PCIs per hospital and operator recommended by the European Society of Cardiology guidelines[14] ($\geq$ 400 PCI per hospital and $\geq$ 75 procedures per operator) is achieved

Table 1
Coronary revascularization in Spain and Europe

	Spain	10 European countries (average)	Relative difference between Spain and the 10 European countries
PCI (per million inhabitants)			
Number of hospitals	2.2	3.22[a]	−32%
Number of annual PCIs	1414	2268	−38%
CS (per million inhabitants)			
Number of hospitals	1.2	1.16[b]	+3%
Number of annual CSs	159	394	−60%

CS, coronary surgery; PCI, percutaneous coronary intervention.
Infrastructure and annual procedures in Spain vs 10 of the main European countries. The selection of the 10 European countries was based on the following criteria: gross domestic product greater than or equal to that of Spain, population more than 4.5 million, and complete data in the report. The 10 countries included in the analysis were Belgium, Denmark, Finland, France, Germany, Ireland, Italy, the Netherlands, Norway, and Sweden. Austria, the United Kingdom, and Switzerland were excluded because of incomplete data.
[a] Seven countries have more PCI hospitals per million inhabitants than Spain: Belgium (4.2), Finland (4), France (3), Germany (6), Ireland (3.5), Italy (4.3), and Sweden (2.8).
[b] Only 2 countries have a higher number of CS hospitals per million inhabitants than Spain: Belgium (2.2) and Italy (1.5).Data obtained from Timms et al.[5]

in most Spanish hospitals, the recommended volume of annual surgeries per hospital[14] (≥ 200 coronary interventions) is not achieved in most of them. In 2017, 94% of Spanish public hospitals performed more than the 400 PCIs recommended by the European guidelines,[6] whereas in the same year each hospital performed an average of 82 coronary interventions,[11] which is very far from the volume recommended by the European guidelines. In Spain, the ratio of PCI to surgical revascularization (9: 1) is very similar to that of nearby countries,[5] such as France (8:1) or Italy (9:1).

Several studies have shown a clear association between mortality associated with coronary revascularization procedures (surgical or PCI) and the annual volume of procedures per hospital and per operator.[16–18] In the absence of reliable audited data, the actual mortality rate associated with coronary revascularization procedures in Spain remains unknown. In practice, the main source of information is voluntary clinical records. However, the data are typically incomplete and may show selection bias and variability in the quality of data entry.

A recently published study using the Minimum Data Set of all coronary interventions performed in Spain and England between 2007 and 2009 found a strikingly higher risk of mortality in Spain (odds ratio, 2.66), even after adjustment for comorbidities and related procedures.[19] There were marked differences in mortality between Spanish hospitals, with unadjusted absolute mortalities of 0.5% to 9.0%. The authors suggested that the significant differences in mortality rates between the 2 countries could be associated with procedural quality due to the lower volume of interventions in Spanish hospitals and their impact on mortality rates.[19] These results may be partly explained by the excessive number of cardiac surgery services in Spain compared with the annual volume of procedures and the treated population. This elevated number of services has been a consequence, among other factors, of the decentralized approach to health care planning in Spain, where each autonomous community can organize and develop its own health care system.

Several factors can explain the coronary revascularization situation in Spain. On the one hand, obtaining the optimal results recommended for PCI is less complex, because PCI requires volumes of activity that are far easier to achieve than those recommended for surgery. The only limitation of PCI in most clinical settings is the need for repeat revascularization procedures during follow-up: however, clinicians and patients are aware of this risk and do not consider it excessive. In addition, whereas the scientific evidence in favor of PCI in acute coronary syndrome and stable ischemic heart disease has been supported by countless randomized clinical trials involving hundreds of thousands of patients in different situations, the evidence related to surgery in acute coronary syndrome is practically nonexistent and is almost exclusively confined to stable ischemic heart disease. In Spain, it is highly likely that this perception is shared by Spanish cardiologists, who guide patients more frequently toward PCI than toward surgical revascularization. The marked success of PCI in the treatment of acute myocardial infarction patients[20] has given rise to strong confidence in this form of revascularization in clinicians directly responsible for the care of coronary patients.

All of these aspects require deep reflection. During the period of the economic crisis, certain countries took measures to concentrate the main cardiological procedures in high-volume hospitals.[21,22] This approach has led to clear improvements in the results, together with increased efficiency and resource optimization. Such measures were not applied in Spain, and there was even greater decentralization in certain communities. Taking these considerations into account, a thorough rethinking is needed to establish consensus-based centralization strategies that, in addition to making the system more sustainable, can offer patients the best results through the various coronary revascularization procedures.

SITUATION OF AORTIC STENOSIS TREATMENT

In recent years, there has been a radical change in the treatment of aortic stenosis. Although initial studies found that the greatest benefit of TAVI was documented in patients with contraindications for surgery or at very high surgical risk,[23] the most recent studies suggest that TAVI and aortic valve replacement surgery have similar benefits in intermediate risk patients.[24] Two very recent studies have shown that, also in patients with low-risk aortic stenosis, in the first year of follow-up TAVI is associated with a prognosis[25] that is similar to or even more favorable[26] than that of surgical valve replacement. Given the similar benefit of the 2 forms of treatment, as well as greater accessibility, lower risk, lower morbidity, and faster recovery, a significant increase in indications for TAVI in Spain is only hindered by the high cost of the devices.

In Spain, surgical aortic valve replacement alone comprises 43% of all valvular surgery and 25% of all major cardiac surgery.[11] An increase in the numbers of TAVI procedures will entail a foreseeable reduction in the number of patients who are candidates for surgical treatment. This change in indications and activity is leading to a particular situation in Spain, in which cardiac surgeons, who are not trained in interventional cardiology, are rethinking the training

criteria, skills, and requirements needed to perform TAVI, and specifically in relation to transfemoral TAVI.[12,13]

The analysis of position documents published by various international scientific societies[27–32] can provide very valuable objective information on the education, training, and volumes needed by operators and hospitals to develop a TAVI program (Table 2). There is agreement among the Cardiac Society and Society of Cardiac and Thoracic Surgeons of Australia and New Zealand, the German Society of Cardiology of Germany, the American Association for Thoracic Surgery/American College of Cardiology/Society for Cardiovascular Angiography and Interventions/Society of Thoracic Surgeons of the United States, and the *Società Italiana di Cardiologia Interventistica* of Italy that interventional cardiologists who will perform TAVI must have extensive training in interventional cardiology, including extensive experience in coronary and noncoronary diagnostic and therapeutic procedures, and be accredited or certified to perform this procedure.[28,29,31,32] They also suggest that these cardiologists should follow an additional TAVI training program. In addition, they state that TAVI training programs should aim to provide cardiac surgeons with extensive experience of high-risk aortic valve replacement, apical and transthoracic access, and surgical approaches to possible procedural complications.[28,29,31,32] Two documents state that transfemoral TAVI[29] or transfemoral/subclavian TAVI[32] programs should be led by interventional cardiologists. However, 2 societies that do not provide details on the level of training required suggest that professionals who join the programs should have attended a minimum of a 1-year training period in structural procedures[27] or that an interventional cardiologist should always be present during transfemoral TAVI procedures.[30] The level of training and experience required in these documents clearly indicates that transfemoral TAVI procedures should be under the direct responsibility of and led by interventional cardiologists, whereas transapical TAVI procedures should be led by cardiac surgeons. In Spain, transfemoral TAVI has been conducted for more than a decade and has always been led by interventional cardiologists.

Recent opinion in Spain suggests that the level of experience acquired by cardiac surgeons during their specialist training period is sufficient to enable them to perform percutaneous transfemoral TAVI.[12,13] However, the training period for cardiac surgeons is shorter than that recommended by the aforementioned scientific societies, which also recommend the inclusion of further aspects of training and experience. The Spanish Society of Cardiology (SEC) has avoided taking a corporate position on this issue and has placed patients and their maximum benefit at the center of the care process. It considers that a set of training and experience criteria in interventional cardiology[33] must be met before starting a transfemoral TAVI program for the following reasons:

1. Transcatheter coronary and cardiac diagnostic and therapeutic procedures can only be performed by specifically educated and trained professionals. The initial phase of such education and training is formally regulated and requires that, after completing training to become specialized in cardiology, knowledge and additional theoretical-practical training must be acquired within a specific and structured program. This program is objectively assessed and accredited by the SEC and is required for all professionals who wish to perform diagnostic and therapeutic procedures in interventional cardiology.
2. The training interventional cardiology program includes a supervised and mentored stay (2 years, full time) in a SEC-accredited hospital. The program requires the trainee to complete a minimum number of externally certified and audited procedures as first and second operator. After the trainee has completed this training period and passed the subsequent assessment procedure, the SEC grants the cardiologist Accreditation in Hemodynamics and Interventional Cardiology. This program is structured and fully in line with the training program of the European Association of Percutaneous Cardiovascular Interventions of the European Society of Cardiology.
3. Following this certified period of specific training, the SEC recommends that professionals who wish to practice structural percutaneous interventionism pursue a specific additional training program in a hospital with experience in this type of procedure. Due to the small volume and high complexity of structural percutaneous procedures, it is recommended that they are performed in conjunction with the interventional cardiologists with the highest level of expertise in each hospital. This allows this procedure to be concentrated in a small number of operators, thus ensuring the best patient outcomes.

Taking the above points into account, it is impossible to accept that transfemoral TAVI can be performed by any professional without specific knowledge, education, or previous training in interventional cardiology and without extensive experience in percutaneous transcatheter coronary and structural procedures. Based on this perspective, the SEC wishes to make explicit its position regarding the responsibility of professionals who practice PCI and structural procedures in relation to the following aspects:

1. It is essential to have knowledge of the different indications, techniques, materials needed, skills, limitations, specific risks, problem-solving methods, and approaches to complications so that percutaneous transcatheter techniques can be performed at the recommended levels of safety and efficacy. In the absence of such training and knowledge, interventions may expose patients to an unacceptable risk of procedural failure or related complications.2.
2. The only way to acquire the knowledge and training required is to complete a full training, certification, or accreditation program in interventional cardiology. To perform these procedures, this type of training is required by the SEC[33] and also by other renowned international scientific societies.[28,29,31,32] The main objective of this requirement is to guarantee the minimum level of experience and quality among operators to ensure that the patients achieve the best possible outcomes.

Any other perspective regarding these aspects will place the patient outside of the center of the care process. We must not forget our responsibility to provide patients with the best treatment offered by the best professionals who meet the appropriate criteria of knowledge, training, skills, and experience. Currently, these criteria cannot be met by any professional who has not been accredited or certified as an interventional cardiologist.

ROLE OF THE JOINT MULTIDISCIPLINARY APPROACH TO DECISION-MAKING

Percutaneous and surgical intervention techniques are complementary procedures that should coexist and be used in an appropriate manner to provide maximum benefit. For this reason, the multidisciplinary assessment of patients requiring complex coronary or cardiac interventions by the Heart Team is of maximum utility.[34] To this end, the exchange of opinions and experiences by the professionals involved must be incorporated in a structured way into standard clinical practice to offer the best strategy, the most appropriate procedure, and the support needed for each patient. In this scenario of diverse approaches and sometimes divergent opinions, clinical cardiologists are key figures because they are the specialists with the highest level of direct responsibility in interactions with the patient and their decisions. These are the

Table 2
Position of the scientific societies and their requirements for operators and hospitals regarding TAVI programs

Country, y	Participating society	Interventional cardiologist	Cardiac surgeon	Hospital
Canada[25] (2012)	Canadian Cardiovascular Society	• The responsibilities are not detailed • The new professionals who join must have completed 12-month training in structural procedures • Start: 5-10 cases with proctor		• With cardiac surgery • Extensive experience in AVR • Volume: 20-50 TAVI/y
Australia/New Zealand[26] (2015)	Cardiac Society and Society of Cardiac and Thoracic Surgeons	• Competencies in interventional cardiology according to the Cardiac Society (eg, coronary angiography, PCI, AVP, MVP, PVP, percutaneous arterial access and closure, IA balloon, peripheral intervention) • Training: 100 previous structural cases or 20 previous structural cases/y (10 AVP) • Start: 10 cases with proctor	• Experience in high-risk AVR (or 25 AVR/y), transapical access, thoracotomy, hemithoracotomy, retroperitoneal access, and peripheral bypass • Start: 10 cases with proctor	• With cardiac surgery • At least 1000 catheterizations/y • At least 400 PCI/y • At least 50 AVR/y • Volume: ≥ 20 TAVI/y
Germany[27] (2015)	German Cardiac Society (criteria limited to transfemoral TAVI)	• The interventional cardiologist should head the transfemoral TAVI program • Training: at least 5 y of experience in PCI and structural interventionism	• Responsibility: immediate availability for the treatment of complications via urgent cardiac surgery	• Volume: ≥ 50 TAVI/y
France[28] (2018)	French Interventional Group (GACI) for TAVI	• The responsibilities are not detailed • For transfemoral implants, 2 operators are recommended, of whom at least 1 must be an interventional cardiologist		• With cardiac surgery • In 2017, hospitals in France performed a mean of 180-200 TAVI
United States[29] (2018)	American Association for Thoracic Surgery/American College of Cardiology/Society for Cardiovascular Angiography and Interventions/Society of Thoracic Surgeons	• Certificate in Interventional Cardiology (eg, coronary angiography, PCI, AVP, percutaneous arterial access and closure, leak closure, mastery of material, guidewires, radiation, contrast) • Training: hospital with TAVI activity • Participation in 100 transfemoral TAVIs and at least 50 as the first operator	• Experience in at least 100 AVR • Experience in vascular, axillary, subclavian, and transapical surgical access and post-procedural repair • Training: in nonfemoral TAVI, 30-40 cases to achieve consistency in time and results	• With cardiac surgery • At least 300 PCI/y • Volume: ≥ 50 TAVI/y
Italy[30] (2018)	*Società Italiana di Cardiologia Interventistica (SICI-GISE)*	• Team leader in transfemoral and subclavian TAVI • Training: ≥ 5 years (coronary angiography + PCI, transradial, transfemoral, removal of material, AVP, pericardiocentesis, peripheral intervention) • Start: 10 cases with proctor	• Team leader in transapical and transaortic TAVI • Skill in the treatment of complications that require surgical intervention • Start: 5 cases with proctor	• With cardiac surgery • At least 1000 catheterizations/y • At least 400 PCI/y • Volume: ≥ 60 TAVI/y

AVP, aortic valvuloplasty; AVR, aortic valve replacement; IA, intra-aortic; MVP, mitral valvuloplasty; PCI, percutaneous coronary intervention; PVP, pulmonary valvuloplasty; TAVI, transcatheter aortic valve implantation.

professionals who have to take the final decisions after weighing up all the clinical information, the results of the different diagnostic tests, local experience, and the opinions of other members of the multidisciplinary team. After patients have been clearly and objectively informed of the advantages, disadvantages, and risks of the various options, they should be encouraged to express their own values ??and preferences in a calm environment that gives them confidence and security. This approach to decision-making is probably the most appropriate and objective.

A COMMON TRAINING PROGRAM IN CARDIOVASCULAR PATHOLOGY: THE SOLUTION FOR THE FUTURE?

The progressive development of devices and new technical approaches for other structural diseases may lead to the establishment of new indications, which might demand procedures requiring the joint experience of an interventional cardiologist and a cardiac surgeon. It is more than possible that this type of shared activity is the best option to provide patients with the best outcomes. However, this approach would require a thorough overhaul of existing training programs. The current Spanish cardiovascular surgery training program devotes very little time to training in cardiology. Therefore, it would be advisable not only to increase the length of the current training program, but also to add a final period that includes both specialties and then, without interruption, continue with a common training program specifically designed and developed for the study of structural cardiology. Current progress in the care of structural disease demands the creation of a new approach in which patients can receive the best treatment based on the joint and collaborative work of both specialties.

CONFLICTS OF INTEREST

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