Comprehensive experience with the Ross operation in Spain

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Abstract

Objective: Although the first pulmonary autograft operations were performed in Spain in 1991, this procedure has gained substantial interest and has been consolidated since 1997. The establishment of the Spanish Registry of the Ross Operation pretends to evaluate the results of this option in aortic valve disease patients in our setting.

Methods: In a yearly fashion, the cardiac surgery departments in Spain currently performing this intervention send data from new patients or follow-ups to the reference center. Preoperative, intraoperative and postoperative data are included in the registry, with special attention to morbidity, mortality, autograft and homograft dysfunction and need for reintervention.

Results: Since February 1991 to May 2002, 169 patients have been treated with this technique. The most prevalent aortic disease was regurgitation (72; 42.59%), congenital being the most frequent etiology (108; 63.9%). Four (2.36%) patients required intraoperative aortic counterpulsation. Operative mortality was 2.36% (n = 4). Follow-up is 98.7% complete, with an average of 36.08 $\pm$ 31.09 months (range 1–135), 84 patients (49.7%) were followed for more than 2 years. The autograft remains competent or with trivial to mild regurgitation in 161 patients (95.6%), presenting two (1.18%) with severe regurgitation. The homograft was normal or with mild stenosis in 159 patients (94.07%), presenting five (2.95%) with severe stenosis. Three (1.77%) required reintervention (surgical or interventional) on the right ventricular outflow tract and four (2.36%) required autograft replacement for a mechanical prosthesis. Actuarial survival is 95.99 $\pm$ 1.65% at 36 months, remaining 92.44 $\pm$ 2.55% free from reintervention in the same period.

Conclusions: The Ross operation is an increasingly popular surgical option in Spain, and although the number of patients and length of follow-up are still limited, initial results are at least as good as those reported internationally. It is important to continue a close follow-up of these patients to assess the long-term function of auto and homograft. With the available data, we believe that this therapeutic approach is a valid option for selected groups of patients with surgical aortic valve disease in Spain.

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1. Introduction

The first pulmonary autograft interventions for aortic valve disease in Spain were performed in 1991. Since then, the Ross operation (RP) has gained substantial popularity among cardiac surgeons in our country, increasing its annual frequency steadily. The 20-year follow-up report from the pioneer series of D. Ross in 1997 [1] and other long term reports [2], supported the renewal of the international interest about this technically demanding procedure, changing the concept from an ‘experimental’ treatment to a real clinical option. The low procedure related morbidity and mortality rate, ability to grow [3], outstanding hemodynamics [4], resistance to infection [5], absence of hemolysis, no thrombogenicity [6] and the silent performance of the pulmonary autograft make it a good candidate for what has been called the ‘ideal valve substitute’ [7]. Unfortunately, these advantages must be weighted against several drawbacks. First it is a technically demanding procedure with a significant learning curve. Second, the conversion of a single valve disease into a two-valve surgery increases...
the potential complications; and third, there are concerns about the long-term performance of the pulmonary autograft under systemic pressure, and the immuno-inflammatory reaction against the homograft.

The aim of the National Registry of the Ross Operation is to evaluate the indications, initial results and complications found in the follow-up of this technique in our country, with the intention to include and follow all the patients in the long term. The main endpoints of this multicentric study are early morbidity and mortality, incidence of autograft or homograft failure and the need for reintervention. We present the results of the Ross procedure in Spain with all the patients that have been operated until May 2002.

2. Materials and methods

Since its constitution in 1998, the National Registry is elaborated thanks to a standardized initial and follow-up protocol sent to the reference center (Reina Sofia University Hospital) on a yearly basis. All the procedures were performed according to the free root technique (so called modified Ross procedure) described previously [8,9]. Briefly, after the implantation of the pulmonary autograft in the aortic root and coronary ostia reimplantation, the right ventricular outflow tract was replaced with a cryopreserved pulmonary autograft in all but three patients. One of them received a Freestyle stentless prosthesis (Medtronic, Minneapolis, MN, USA), another patient received a Contegra valved conduit (Medtronic, Minneapolis, MN, USA), and in the last one, a cryopreserved aortic homograft was employed.

Edmunds' guidelines to reporting morbidity and mortality after heart valve operations were consulted [10]. Valvular performance was evaluated echocardiographically intra or perioperatively, 6 and 12 months after the operation, and then annually. In the present report we will refer to the results of the latest echo available for each patient. Intraoperative or pre-discharge echocardiograms were available from all of the patients and 6-month echoes were available from 140 patients. Echocardiographic data from the first, second, third, fourth and fifth years were available for 130, 91, 55, 26 and 12 patients, respectively. Measurements were focused on auto and homograft function, using internationally accepted regurgitation and stenosis scores.

The data received were included in our database and analyzed statistically with the SPSS v11.0 programme. Variables are shown as mean ± standard deviation. Long-term follow-up results were calculated according to the Kaplan–Meier method.

3. Results

Since February 1991 to May 2002, 169 patients from 15 national centers have been included in the study. Only four Hospitals (Reina Sofía, Córdoba (n = 76); Do Meioxeiro, Vigo (n = 25); Juan Canalejo, A Coruña (n = 23); and La Fè, Valencia (n = 17)), reported more than 15 patients each, meaning 83.43% (n = 141) of the interventions registered. The annual incidence of the intervention has increased steadily in the past years, reaching about 40 patients annually (Fig. 1). Mean age was 29.93 ± 13.23 years (ranging from 1 month to 54 years), being 19 (11.24%) younger than 10 years and 134 (79.28%), males. Fig. 2 shows age distribution. Preoperative functional class was 2.37 ± 0.72 (I–IV) and ejection fraction was 59.2 ± 13%.

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Only five patients were included as preferential surgery, none were operated as an emergency and the rest were scheduled as elective.

The most prevalent aortic lesion was regurgitation ($n = 72$; 42.59%), followed by double lesion ($61$; 36.09%) and aortic stenosis ($n = 36$; 21.3%). Most were of congenital origin ($n = 108$; 63.9%), followed by rheumatic ($n = 38$; 22.48%) and infectious, including $14$ (8.28%) patients diagnosed of acute or subacute endocarditis.

A number of patients (36.09%) had suffered a previous procedure, aortic balloon valvuloplasty being the most prevalent (26; 14.37%) and open comisurotomy (23; 13.22%), followed by subaortic annulus enucleation (12; 6.9%) and correction of coarctation of the aorta (10; 5.75%). Fourteen patients (8.28%), had two or more previous procedures.

As for hemodynamics after surgery, 164 patients (97.04%) were stable, four (2.36%) needed intraaortic counterpulsation and one patient (with Shone syndrome previously operated) died intraoperatively (0.59%). Perioperative complications are shown in Table 1. Five patients (2.96%) suffered perioperative myocardial infarction, two of them requiring emergent revascularization with an inverted saphenous vein, one to the descending anterior artery and another to the right system. Only one myocardial infarction was considered to be due to injury of the first septal branch; the remaining four were related to coronary ostia malposition or kinking. It is important to note that two of these patients were reported to have congenitally aberrant coronary ostia implantation in association with bicuspid aortic valves. Eight (4.73%) patients required reexploration for bleeding.

Follow-up is 98.7% complete. Average follow-up was 36.08 ± 31.09 months (range 1–132), what represents a total of 431 patient-years.

Hospital mortality (<30 days) was 2.36% (four patients) and late death was 1.18% (two patients), one of them being non-procedure related (Table 2). Actuarial survival is depicted in Fig. 3.

According to the pulmonary autograft function, 144 patients (85.2%) showed a normal function, 17 patients (10.42%) trivial to mild regurgitation, six (3.55%) moderate and two (1.18%) severe insufficiency. Six patients (3.55%) required autograft reintervention, five due to severe perioperative regurgitation and one due to early endocarditis (0.59%); the neoaortic valve was replaced for a mechanical prosthesis in all cases. Another patient suffered late...
pulmonary autograft endocarditis (22 months after the procedure) that was successfully managed with antibiotics, although the patient suffered an intracranial mycotic aneurysm, complicated with a transient neurologic deficit; 94.64 ± 2.25% of the patients remain free from pulmonary autograft reintervention 36 months after the operation (Fig. 4).

During follow-up, the pulmonary homograft showed severe stenosis (peak gradient > 50 mmHg) in five patients (2.95%), moderate in five (2.95%), and mild in 10 (5.91%), the remaining 149 of them (88.16%) working properly. Pulmonary homograft endocarditis was diagnosed in two patients (1.18%). The first one was an active intravenous drug abuser and was managed successfully with antibiotics, resulting in a mild to moderate regurgitation. The second one was detected 1 year after the intervention due to a *Streptococcus viridans* infection; although medically controlled, the homograft required surgical replacement due to severe double lesion. Overall, three patients (1.77%) required right ventricular outflow tract revision: one of them required replacement for another homograft due to severe double lesion (the case described above), and the two remaining patients were treated percutaneously with placement of a stent (Palmaz) in the body of the homograft.

In this two cases the pulmonary valve remained competent and residual transhomograft gradient was 15 and 20 mmHg, respectively; 97.76 ± 1.2% remains free from reintervention upon the right ventricular outflow tract (Fig. 4).

Combined freedom from reintervention of the auto and homograft at 12, 24 and 36 months is 97.42% ± 1.28, 94.89 ± 1.9 and 92.44 ± 2.55%, respectively (Fig. 4).

Hemolysis, thrombosis, thromboembolism, or major hemorrhage were not detected in any patient after follow-up.

Finally, two patients required a permanent pacemaker due to complete a-v block, although one of them presented the conduction impairment before the operation.

4. Discussion

Since the communication of the first results of this technique in our country [9,11], pulmonary autograft replacement of the aortic valve is becoming a popular intervention in Spain. The increased availability of cryopreserved homografts due to the development of Regional Tissue Banks, plus the increasing familiarization with the surgical technique has turned this intervention into a real option in our country. Although comparisons with the international registry is methodologically incorrect, the resemblance of our results is an important support to follow this path [12]. On the other hand, the technical complexity of the procedure, the still insufficient knowledge about this option by surgeons and cardiologists, and maybe the geographical dispersion of the centers engaged preclude many potential candidates from the benefits of the Ross procedure. In fact, we believe that we are still far from the ceiling of the yearly incidence of this operation in our country. According to the Spanish Registry of Cardiac Interventions [13] (hosted by the Spanish Society of Cardiovascular Surgery), isolated aortic valve replacement was the most prevalent valve surgery performed during year 2000, mounting to 3,082 interventions (65.6% of all valvular interventions). Although, most of these patients belong to the group of degenerative and age-related aortic
valve disease, a significant subset must be below 35–40 years old. For instance, if we assume that only 5% of these patients belong to that particular age group, we can estimate that some 154 patients could be chosen every year for a pulmonary autograft, a figure that is still far from the present annual incidence. It is true that the absolute recommendation of this technique could only be done after large and methodologically refined randomized trials, controlled by mechanical aortic prosthesis or even aortic homografts; but we already have a large amount of evidence from clinical series, backing this option more and more everyday. The remarkable hemodynamics, and therefore, the effects on ventricular remodeling [4] have only been matched by aortic homografts and some commercially available stentless valves [14]. The pulmonary autograft nevertheless offers superior durability as compared to these other biological substitutes, especially in young patients [15]. Doubts about the adequate performance of the pulmonary autograft under systemic pressure have been resolved, at least in the short- and mid-term [16]. Although the sinus part of the autograft is expected to dilate, this does not undermine valvar coaptation and very few require reoperation due to excessive root diameter [17]. The pulmonary autograft has also proven an outstanding ability to adapt to intense physical activity [18]. Finally, the Ross procedure is considered to be a cost-effective option [19]. In fact, this option is recommended by the American Heart Association [20] as the operation of choice for young adults, and especially, for children and women in childbearing age. In this study some patients were close to 60 years old. Although these patients have a shorter life expectancy and the cumulative risk of anticoagulation related complications is probably lower than in younger ones, we believe that selected patients over 50 years old could benefit from the Ross operation [21]. In fact, older patients show an ameliorated immune reaction against the homograft and they have been shown to fare better in the medium term [22]. Although according to the latter, the pulmonary autograft is close to the concept of the ‘ideal valve substitute’, some points deserve further investigation, such as long term autograft function and dilatation on one side [17], and pulmonary homograft dysfunction on the other [23,24].

In order to prevent autograft dysfunction, most of us have adopted several technical modifications. A pericardial strip is used constantly at the inflow suture line although we expect it to be more hemostatic than supportive. Elkins’ annuloplasty is performed if a discordance greater than 2 mm is found between the autograft and the aortic annulus, since this modification has shown a reduction in the incidence of early autograft regurgitation [6]. Longitudinal aortoplasty and/or the extension of the autograft with a Dacron ring are used to correct the geometric mismatch found in cases of dilated, dissected or truly aneurismatic ascending aorta [23,25]. These simple measures seem to be efficacious and in fact early autograft dysfunction has not been reported after they were fully adopted (although this may be masked by the effects of the learning curve). Most of the regurgitations registered were present at discharge, and in general they did not tend to increase with time significantly. Although formal studies are lacking, we believe that strict blood pressure control below 130/75 mmHg is important to prevent late dilatation of the autograft. Regarding the right ventricular outflow tract, this consecutive series counts with at least 10 cases (5.91%) of moderate to severe pulmonary homograft stenosis. This complication progressed with time, being detected most often between the 6- and 12-month echo and reaching a plateau after 2 years. To date, only three patients required reintervention for this reason, but we believe that the detection of risk factors and the reliable prevention and treatment of this complication must be elucidated if we wish to extend this technique, without any doubt, to the majority of candidates.

The incidence of perioperative morbidity and mortality does not seem to differ between low and high volume institutions, but the number of events is still low to reach any statistical significant conclusion. However, most complications related to autograft failure were registered in the initial experience of most centers.

In conclusion: (1) the incidence of morbidity, mortality, homograft and autograft dysfunction after the Ross operation was low in this initial experience. (2) Technical complexity is probably the major reason for its still limited application, but the yearly incidence of the procedure is increasing steadily. (3) The Ross operation can be carried out safely in our country, and it should be readily offered to selected candidates.

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