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Results of large pulmonary homograft implantation for right ventricular outflow tract reconstruction

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Abstract

Background : To evaluate the long-term results of implantation of homogeneous large size of pulmonary homograft (PH) for reconstruction of the right ventricular outflow tract (RVOT). Methods : Between January 2000 and December 2017, 107 patients were implanted with PH for reconstruction of the RVOT. Data were collected retrospectively in this single-center study. PH failure was defined as a peak of gradient > 40 mmHg and/or as a pulmonary regurgitation > grade 2. Primary endpoint was the re-operation of the RVOT during follow-up. Secondary endpoints were overall survival, occurrence of PH failure and the rate of re-operation for all cause. Results : Mean age of the recipients was 26.13 ? 13.59 years. Mean size of PH was 23.02 ? 6.87 mm. Re-operation of the RVOT occurred in 8 patients (7.8%). Time before re-operation was 2.74 years (Interquartile Range: 6.41). Freedom from re-operation for RVOT at 5 and 10 years was respectively 95.7% and 90.0%. Overall survival at 10 years was 95.2%. PH failure occurred in 13 patients (12.0%). Mean time before PH failure was 5.00 ? 4.35 years. Freedom from PH failure at 10 years was 81.6%. Re-operation for PH failure occurred in 4 patients (3.9%). Concomitant tricuspid valve surgery (p=0.037), initial pulmonary stenosis (p=0.04), recipient of PH < 16 years old (p=0.043) were risk factors of late reoperation in univariate analysis. Multivariate analysis showed no independent risk factor of late reoperation. Conclusions : Implantation of large PH for RVOT reconstruction provides excellent mid-term results in terms of re-operation.

Results of large pulmonary homograft implantation for right ventricular outflow tract reconstruction

Pulmonary homograft as right outflow tract

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Abstract :

Background :

To evaluate the long-term results of implantation of homogeneous large size of pulmonary homograft (PH) for reconstruction of the right ventricular outflow tract (RVOT).

Methods :

Between January 2000 and December 2017, 107 patients were implanted with PH for reconstruction of the RVOT. Data were collected retrospectively in this single-center study. PH failure was defined as a peak of gradient $>$ 40 mmHg and/or as a pulmonary regurgitation $>$ grade 2. Primary endpoint was the re-operation of the RVOT during follow-up. Secondary endpoints were overall survival, occurrence of PH failure and the rate of re-operation for all cause.

Results :

Mean age of the recipients was 26.13 $\pm$ 13.59 years. Mean size of PH was 23.02 $\pm$ 6.87 mm. Re-operation of the RVOT occurred in 8 patients (7.8%). Time before re-operation was 2.74 years (Interquartile Range: 6.41). Freedom from re-operation for RVOT at 5 and 10 years was respectively 95.7% and 90.0%. Overall survival at 10 years was 95.2%. PH failure occurred in 13 patients (12.0%). Mean time before PH failure was 5.00 $\pm$ 4.35 years. Freedom from PH failure at 10 years was 81.6%. Re-operation for PH failure occurred in 4 patients (3.9%). Concomitant tricuspid valve surgery (p=0.037), initial pulmonary stenosis (p=0.04), recipient of PH $<$ 16 years old (p=0.043) were risk factors of late reoperation in univariate analysis. Multivariate analysis showed no independent risk factor of late reoperation.

Conclusions :

Implantation of large PH for RVOT reconstruction provides excellent mid-term results in terms of re-operation.

Keywords:

Congenital heart disease, pulmonary homograft, right ventricular outflow tract, reoperation

Introduction :

Congenital heart diseases involving the right ventricular outflow tract (RVOT) such as tetralogy of Fallot (TOF), pulmonary atresia or truncus arteriosus are frequently observed in cardiopediatric pathology and require most of the time a surgical correction during childhood. Different techniques have raised to treat an obstruction of the RVOT: pulmonary enlargement with a patch of pericardium and insertion of a right ventricular-pulmonary artery (RV-PA) conduit for reconstruction of the RVOT. Pulmonary homograft (PH) implantation has become over the past decades the conduit of choice for surgical treatment of a RVOT obstruction [1]. Small size of PH implanted [2,3], blood group incompatibility [4,5], young age of the recipient [6] are reported as risk factors of PH failure. Nonetheless, such results have been described with series of PH implanted with wide range of homograft sizes, according to the body surface index of the recipients who were most of the time newborns and children. Results of PH implantation for RVOT reconstruction are less known in grown-up congenital heart disease (GUCH) patients, especially those who underwent a primary surgical correction of congenital heart disease during childhood. The aim of this study was to evaluate the

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long term results of the implantation of homogeneous sizes of PH in a grown-up population of patients with congenital heart disease.

Material and methods:

Patients:

Between January 2000 and December 2017, 232 patients underwent PH implantation for RVOT reconstruction. Only patients who received a PH for isolated RVOT reconstruction for correction of a right side congenital heart disease were included in this single-center retrospective study. Patients who received PH concomitant left ventricular outflow tract (Ross procedure, Ross-Konno Procedure, aortic valve replacement, Bentall or Tirone David procedures) reconstruction were excluded from the analysis. Clinical data and echocardiographic data were retrospectively collected using patient's clinical records and operative reports available in the University Hospital of Nantes during the study period.

Pulmonary homograft (PH):

PH implanted in the University Hospital of Nantes were provided by the European Homograft Bank (EHB) in Brussel (Belgium) [7]. PH were harvested from donors heart or explanted heart during heart transplantation. Morphological and quality assessment of the PH was systematically performed by EHB after harvesting. PH were incubated with 3 antibiotics (lincomycin, vancomycin andpolymixin B) during 20-48 hours, and cryopreserved at -150°C in a 10% dimethysulfoxid solution. The maximum period of cryopreservation of the PH was 5 years. All the cryopreserved PH was decellularized during the study period. The quality criterions of the EHB respected the European recommendations 2006/17/EC and 2006/86/EC.

Selection of the implanted PH:

The size of the implanted PH was determined with the body surface and the recipient age, following the Rowlatt table (range -2 < Z-Score < +2) [8]. PH were systematically oversized when implanted in young patients to provide acceptable hemodynamic performances at the end of growth. There was no patient – donor matching in terms of ABO group and Rhesus type.

PH implantation:

The PH was implanted by full sternotomy. Cardiopulmonary bypass (CPB) was established between standard aortic cannulation and selective venous cannulation of the superior and inferior vena cava. A left ventricle vent was inserted through the right superior pulmonary vein and surgery was performed in normothermia during CPB. PH was implanted under CPB and beating heart or with aortic cross clamping. Myocardial protection was provided by a warm blood cardioplegia injected every 10 min in child, every 20 min adult. First time of the surgery was the large resection of the RVOT, with the pulmonary valve and part of the right ventricular infundibulum. The pulmonary infundibulum was calibrated to the PH size, if necessary with the implantation of an autologous pericardial patch or with a Dacron® patch prosthesis. The PH was inserted and sutured to the pulmonary infundibulum and the pulmonary artery by continuous suture. More recently, a Dacron® tube prosthesis has been interposed between the pulmonary infundibulum and the PH if necessary. This maneuver helps to maintain a perfect sphericity of the PH. The distal anastomosis of the PH was sometimes associated with a pulmonary artery enlargement in case of pulmonary arteries stenosis.

PH failure criterions:

PH failure occurred when the peak of pulmonary gradient was > 40 mmHg, and / or when there was a significant pulmonary regurgitation > grade 2, as described in previous studies [9].

Primary and secondary endpoints:

Primary endpoint was the re-operation of the RVOT in patients who previously underwent RVOT reconstruction with a PH. Secondary endpoints were the overall survival of patients who underwent RVOT reconstruction with a PH, the rate of re-operation for all causes of the patients implanted with a PH for RVOT

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and the occurrence of PH failure (peak of pulmonary gradient > 40 mmHg and/or pulmonary regurgitation > grade 2).

Statistical analysis:

Statistical analysis were performed with SPSS Statistics® software (IBM Corporation, New York, USA). Categorial variables were expressed as numbers and percentages. Continuous variables were reported as mean +/- standard deviation (SD) and median with interquartile range (IR) when appropriated. Event-free survival curves were calculated using the Kaplan-Meier method. Univariate analysis was performed by comparing the Kaplan-Meier survival curves using the Log-Rank test to identify risk factors of late re-operation of the PH. Multivariate analysis was performed to identify independent risk factors of late re-operation of the PH, using a Cox regression model. P value <0.05 was retained for statistical significance.

Results:

Between January 2000 and December 2017, 107 had PH implantation for RVOT reconstruction. Patient's baseline characteristics are summarized in table 1. Mean age of the recipients was 26.13 ± 13.59 years. Most of recipient blood types were O-type and A-type (38.3% and 43.9%), and Rhesus positive for 91 patients (85.0%). The most common primary congenital heart disease was the Tetralogy of Fallot (TOF) (69 patients, 64.5%). Redo surgery was performed in 101 patients (94.4%). Primary surgery was performed during childhood and growth either to correct a congenital heart disease (surgical correction of Tetralogy of Fallot, pulmonary atresia, truncus arteriosus, Rastelli operation, RV-PA conduit implantation, arterial switch, REV technique, surgical closure of a septal or atrial septal defect, surgical pulmonary valvuloplasty), or to perform palliative techniques (Blalock-Taussig, central shunt). Some primary congenital heart diseases were associated at initial diagnosis (table 1): 4 patients had transposition of the great arteries (TGA) + ventricular septal defect (VSD) + pulmonary stenosis (PS), 1 patient had TGA + PS, 1 patient with Ebstein disease + PS, 4 patients had VSD + PS, 1 patient had a double outlet right ventricle + pulmonary stenosis, 1 patient had TOF + agenesia of the pulmonary valve, 2 patients had TGA + VSD. Mean age of the donors was 48.78 ± 11.29 years. ABO and Rhesus compatibility between recipient and donors was observed in 30 implantations of PH (28.0%). Isolated ABO compatibility and isolated Rhesus compatibility were respectively observed in 41 (38.3%) and 80 (74.8%) PH implantations. Mean size of the implanted PH was 23.02 ± 6.87 mm.

Operative characteristics are summarized in table 2. Indications for PH implantation were: pulmonary regurgitation (PR) (68.2%), pulmonary stenosis (PS) (25.2%), pulmonary endocarditis (5.6%) and changing PH during other cardiac surgery (0.9%). Among patients who underwent PH implantation for pulmonary regurgitation, 59 patients (80.8%) had previous surgical correction of a TOF, 4 patients (5.5%) had surgical a previous surgical treatment of pulmonary atresia, 1 patient (1.3%) had previous surgical correction of TOF + pulmonary agenesia, 7 patients (9.6%) had previous surgical treatment of a PS (3 commissuroplasty, 4 RV-PA conduit) and 2 patients (2.7%) had surgical correction of a double outlet right ventricle. Among patients who had PH implantation for PS, 8 patients (29.6%) had previous surgical treatment of truncus arteriosus, 5 patients (18.5%) had surgical correction for TOF, 5 patients (18.5%) had surgical treatment of transposition of the great arteries (TGA) + ventricular septal defect + PS, 1 patient (3.7%) was operated from TGA + VSD, 1 patient (3.7%) was operated from TGA + PS, 5 patients (18.5%) had previous surgical treatment of pulmonary atresia, 1 patient (3.7%) had surgical correction of aortic stenosis and 1 patient (3.7%) was operated from Ebstein disease + PS. Cross-clamping during PH implantation was performed for 89 patients (83.1%) and 18 patients (16.8%) had no cross-clamping during PH implantation. Multiple concomitant surgical procedures were performed in 43 patients (39.8%). Concomitant tricuspid valve surgery occurred in 23 (21.5%) patients (1 tricuspid valve replacement, 22 tricuspid valve repair). Atrial and ventricular surgeries were associated to PH implantation in 11 patients (10.2%). Of them, 5 patients (4.6%) had correction of an atrial septal defect (ASD), 2 (1.8%) patients had correction of VSD, and 2 (1.5%) patients had REV procedure. Surgical enlargement of the pulmonary arteries for pulmonary stenosis was performed in 10 (9.3%) patients. Concerning the overall survival of patients implanted with a PH (table 3): in-hospital mortality was 4.6%. Five patients died during the early postoperative period. Among these patients, 2 of

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them died from heart failure (1 acute pulmonary edema, 1 severe right ventricle dysfunction caused by pulmonary hypertension), 1 died from sudden ventricular fibrillation, 1 died from respiratory failure and 1 died from acute liver failure. No death occurred during long-term follow-up. Mean follow-up interval was 4.68 ± 4.28 years (median (interquartile range): 2.99 years (6.19)). Overall survival during follow-up at 1, 5 and 10 years was 95.2%.

Re-operation of RVOT (table 3):

Re-operation of RVOT has been performed in 8 patients (7.8%). Mean time before re-operation was 5.48 ± 5.04 years. Among these patients, 4 (3.9%) had PH failure. Four patients (3.9%) were re-operated of RVOT without PH dysfunction: 1 patient for PH injury during pace maker implantation and 3 patients for stenosis of the pulmonary artery branches. Re-operation of the RVOT consisted in PH replacement with an other PH in 5 patients, percutaneous transcatheter valve implantation in pulmonary position (Edwards Lifesciences Sapien XT?, Irvine, CA, USA) in 2 patients and 1 RV-PA conduit implantation. Surgical enlargement of the branches of the pulmonary arteries was performed in 3 patients who presented stenosis of the pulmonary artery branches. Freedom from re-operation of PH during follow-up at 1, 5 and 10 years was respectively 100%, 95.7% and 90.0% (Figure 1). Bentall procedures were associated with PH replacement in 2 patients (1 ascending aorta aneurysm, 1 ascending aorta wound during surgery).

[Insert Figure 1]

PH failure (table 3):

PH failure occurred in 12 patients (11.7%) during follow-up. Mean time before PH failure was 5.00 +- 4.35 years. PH failure resulted in PH stenosis in 11 patients (10.1%) and 2 patients (1.8%) presented PH disease (significant PS and PR > grade 2). Among these patients, 4 (3.9%) were re-operated of the PH and the 8 others patients (7.7%) who presented PH failure were not re-operated because they did not present criteria for re-intervention according to the European Guidelines [10]. Freedom from PH failure at 1, 5 and 10 years was respectively 100%, 93.4% and 81.6% (Figure 2).

[Insert Figure 2]

Risk factors for late reoperation:

Univariate analysis of risk factors of late re-operation is summarized in table 4. Recipient < 16 years old (p=0.043), initial pulmonary stenosis (p=0.040), concomitant tricuspid surgery during PH implantation (p=0.037) were identified as significant risk factors for re-operation of the RVOT. Isolated PH failure (p=0.223), isolated stenosis of the pulmonary branches during follow-up (p=0.308), ABO-Rhesus compatibility (p=0.167), TOF (p=0.069), size of PH < 22 mm (p=0.205) and concomitant pulmonary arteries enlargement during PH implantation (p=0.361) were not significantly identified as risk factors of late re-operation of the RVOT during follow-up. Multivariate analysis is summarized in table 5. No independent risk factor of late re-operation was significantly identified.

Discussion:

In this present case series, late reoperation of the RVOT for PH failure after PH implantation for RVOT reconstruction is of 3.9% (4 patients), while late PH failure occurred in 12 patients (11.2%). PH implantation for reconstruction of the RVOT was first reported in 1966 by Fuller*et al* [11] in a 9 year-old girl presenting pulmonary atresia with VSD. Since then, PH gradually became the conduit of choice for RVOT [2,12], considered as the preferred substitute by many surgeons. However, durability of the PH implanted for RVOT reconstruction has been described in studies of children and young adults, and young age of PH implantation is known to be a determinant of the PH longevity [6]. In our study, mean age of PH implantation was higher with a mean age of 26.29 +- 13.62 years old and provided implantation of a quiet homogeneous range of PH sizes (23.06 +- 6.85 mm). Therefore, the confounding factor related to the small size of the PH implanted during childhood and the mismatch induced by the patients growth did not affect the results of our study.

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In a similar way, the need of an extra-anatomic PH implantation in children described by Wells *et al* [13] as a risk factor of PH has been avoided by routine anatomic PH implantation in this study population.

Patients who were implanted with PH in this study presented a large spectrum of congenital heart diseases, such as TOF, pulmonary atresia, truncus arteriosus or TGA. Therefore, results could be more representative of the PH performance in a wide range of RVOT reconstruction of different GUCH involving the RVOT. To our knowledge, most of the studies reporting the PH durability in GUCH are performed only with TOF patients [14].

Immunological mechanisms have been previously described as risk factors for accelerated PH failure by Baskett *et al* [5] in a study of children who were implanted with PH. ABO blood group and human antigen-DR were significantly identified as prognosis factors of early dysfunction of the PH. Da Costa *et al* [12] compared decellularized PH to standard PH implanted in children less than 12 years old and found a lower incidence of structural valve disorder in favor of the decellularized conduit. Decellularization of the PH may reduce the antigenicity of the implanted tissue. Dekens *et al*[15] also reported that matching ABO compatibility may improve the PH durability in PH more than 22 mm of diameter, but median age of implanted recipients was 15 years old and this conclusion was obtained in a sub-group univariate analysis. In our study, Rhesus and ABO blood group compatibility matching between the recipient and the donor was obtained in only 28.0% and was not identified as a risk factor of late re-operation for PH failure in univariate analysis (p=0.167), of adults implanted with large sizes of PH. This result supports the fact that a young age of implantation may be a confounding factor, and that immunological mechanisms of PH deterioration are maybe less important in adults than in children implanted.

Re-operation rate of PH is low in our study (7.8% of the patients implanted with PH, 3.9% for secondary PH failure) and is quiet similar to other studies [14]. However, the rate of PH failure during follow-up is higher than the re-operation rate because of non clinical or functional evidence of such PH dysfunction. This result emphasizes that current evaluation by echocardiography and magnetic resonance imaging of the PH performances has to be more effective and reliable with regard to the clinical status.

Concomitant tricuspid valve surgery was also identified as a risk factor of late re-operation of PH (p=0.037) univariate analysis, but not in multivariate analysis (p=0.504). Indication of tricuspid surgery was mostly moderate to severe tricuspid regurgitation and a great majority of the tricuspid surgery consisted in tricuspid annuloplasty with a prosthesis ring. Shaher *et al* [16] suggested that initial PR induced right ventricle dilatation and tricuspid regurgitation, resulting in deterioration of the right ventricle function. Meijer *et al* [17] supposed that the dilatation of the right ventricle may cause homograft PR, and suggested that reconstruction of the ventricular outflow tract should be associated to the PH implantation to restore a normal volume of the right ventricle.

Two of the 8 patients who were re-operated for PH had implantation of transcatheter bioprosthetic valve Sapien XT? (Edwards Lifesciences, Irvine, CA, USA) in the pulmonary position. Since the first transcatheter pulmonary valve implantation reported by Bonhoeffer *et al* [18], this innovative technique has gradually expanded and became a good alternative to pulmonary valve replacement, with similar short and mid-term results [19]. However, long-term performance of surgical pulmonary valve replacement with bioprothesis is well known [5]. Bell *et al* [20] found that pulmonary valve replacement with a bioprosthetic valve was more than 8 times at risk of re-operation (Hazard Ratio = 8.34) compared to PH implantation for RVOT reconstruction. These different results may suggest that the conduit of choice for RVOT reconstruction is a PH in the setting of GUCH involving the RVOT, but long-term analysis of transcatheter procedures and improvement of the endovascular technology may change clinical practice.

Study limitations:

Results of this present study should be considered with regard to the inherent limitations resulting in the design of this retrospective single-center observational analysis of a historical series of selected patients with GUCH. Data collection was not optimal, in terms of clinical and echocardiographic parameters collected during follow-up, without specific protocol of follow-up. Thereby, data were not collected at the same time

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of follow-up, and were not complete because of patients lost from follow-up. Mean time of follow-up is low and longer follow-up is required to draw consistent conclusions from this case series.

Conclusions:

Large sizes of PH implantation for RVOT reconstruction in a grown-up population of congenital heart diseases involving the RVOT, except from the congenital heart diseases involving the left ventricle outflow tract, provide excellent mid-term results in terms of re-operation and PH failure.

Figures Captions:

Figure 1: freedom from re-operation of PH during follow-up

PH: pulmonary homograft. No patient underwent surgery during follow-up without PH replacement.

Figure 2: Freedom from PH failure during follow-up

PH: pulmonary homograft

Tables captions:

Table 1: Population baseline characteristics

IR: Interquartile range, PH: pulmonary homograft, SD: standard deviation, TOF: Tetralogy Of Fallot

*: some patients had multiple primary congenital heart diseases

Table 2: operative characteristics

CABG: coronary artery bypass graft, IR: Interquartile range, SD: standard deviation.

*: 43 patients had concomitant other surgical procedures during pulmonary homograft (PH) implantation. Some of them underwent more than 2 concomitant procedures associated with PH implantation. 1 patient had concomitant tricuspid valve surgery and ventricular septal defect closure, 4 patients underwent concomitant tricuspid valve surgery and pulmonary arteries enlargement, and 1 patient underwent concomitant ventricular septal defect closure and pulmonary arteries enlargement.

**: 1 dead patient had no concomitant procedure. 4 other patients dead within 30 days after surgery had concomitant procedure associated with PH implantation (3 ventricular septal defect closure, 1 tricuspid valve replacement + pulmonary arteries enlargement).

Table 3: clinical data during follow-up

SD: standard deviation, IR: Interquartile range, PH: pulmonary homograft

*: 1 patient had pulmonary endocarditis, 1 patient presented refractory sepsis in the early postoperative period, without evidence of endocarditis

Table 4: Univariate analysis: risk factors of late re-operation

PH: pulmonary homograft, TOF: tetralogy of Fallot

Table 5: Multivariate analysis: risk factor of late re-operation

CI: confidence interval, PH: pulmonary homograft, PS: pulmonary stenosis, SE: standard error, TOF: Tetralogy Of Fallot,

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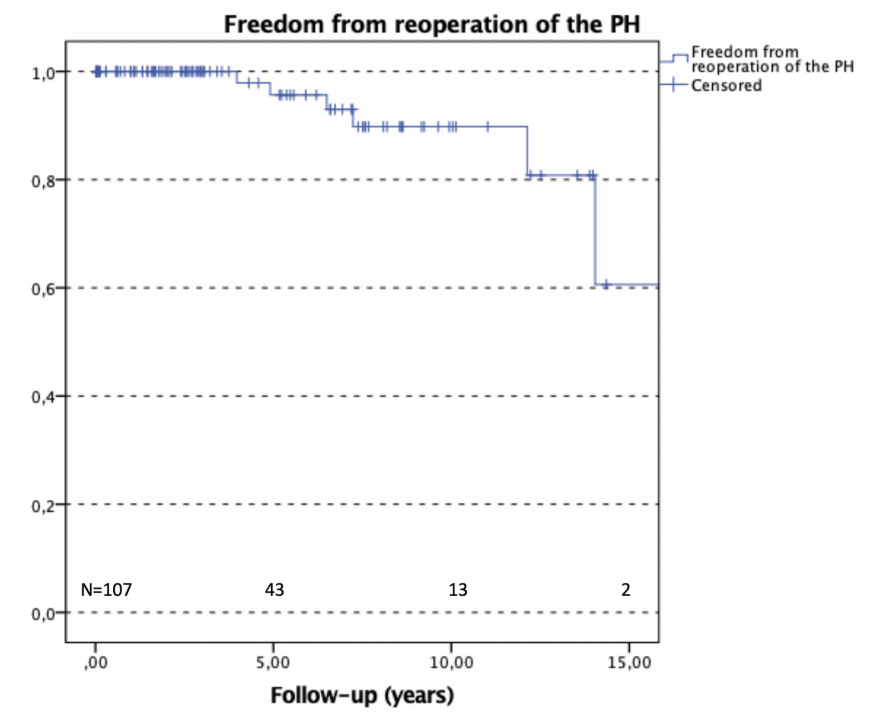

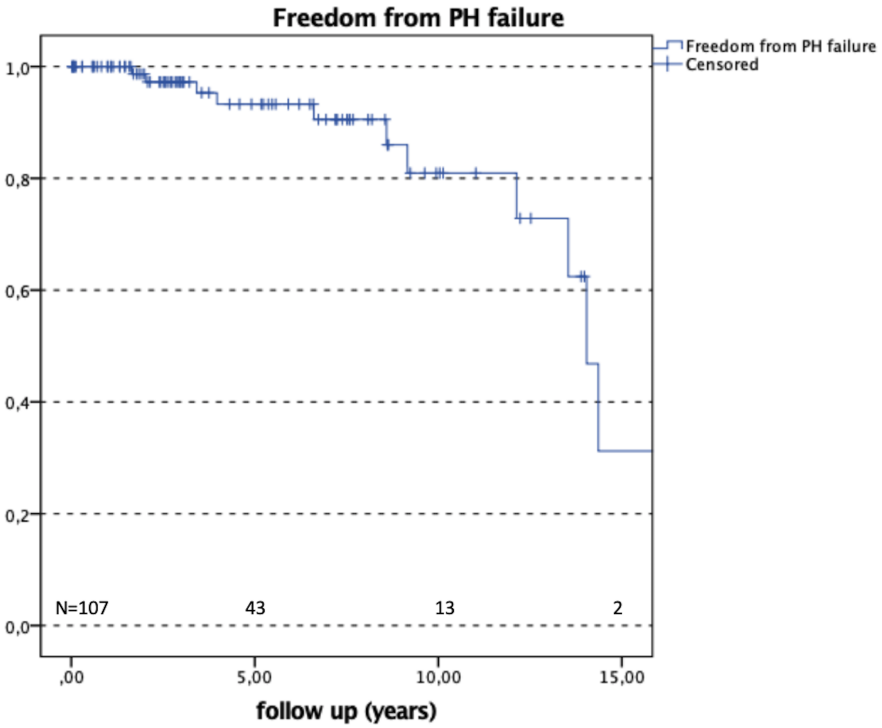

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Table 4 HomoGr.docx available at https://authorea.com/users/334345/articles/460336-results-of-large-pulmonary-homograft-implantation-for-right-ventricular-outflow-tract-reconstruction

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Table 5 HomoGr.docx available at https://authorea.com/users/334345/articles/460336-results-of-large-pulmonary-homograft-implantation-for-right-ventricular-outflow-tract-reconstruction

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