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Outcome of arterial switch operation for transposition of the great arteries. A 35-year follow-up study☆

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A B S T R A C T

Background: Arterial switch operation (ASO) is today the first-choice surgical treatment for patients with transposition of the great arteries. Long-term outcome data still remain scarce. Moreover, the course of these patients is not uneventful. Therefore, we wanted to evaluate long-term outcome and determine on which variables to focus during follow-up.

Methods: Clinical records of 318 patients who underwent ASO between October 1981 and July 2018 were reviewed. Perioperative, post-operative, and interventional data were collected to determine mortality and the need for re-intervention. Descriptive statistics and Kaplan-Meier survival analysis were performed.

Results: Mean follow-up time was 11.1 SD 8.5 years (range 0–35) with a mean age of 12.5 SD 9.0 years (range 0–37) at latest follow-up. In-hospital mortality was 7.5% and overall survival 90.9% for a maximum follow-up time of 35 years. Causes of early mortality were cardiogenic shock, severe pulmonary hypertension, septic shock and multiple organ failure. Causes of late mortality were cardiogenic shock, severe pulmonary hypertension, pacemaker lead fracture and fire death. Re-intervention free survival at 5-year was 91.6%, at 10-year 90.7%, at 20-year 79.2%. For all survivors, the most frequent sequelae after ASO were pulmonary artery stenosis (80.9%), of which 13.5% needed an intervention. The threshold for intervening on lesions at the level of the pulmonary artery bifurcation was higher and the percutaneous re-intervention rate was higher for non-bifurcation lesions.

Conclusions: Despite a relatively high peri-operative mortality, TGA patients have an excellent overall long-term survival. However, a large proportion of patients requires re-interventions, mainly for pulmonary artery stenosis.

1. Introduction

Transposition of the great arteries (TGA) is one of the most common cyanotic congenital heart defects and needs urgent treatment short after birth. TGA has a prevalence of approximately 1.6% to 7% of all adult congenital heart disease (CHD) and represents 20% of all cyanotic CHD with a male preponderance [1–4]. In TGA, the aorta is implanted on the morphological right ventricle and the pulmonary artery is connected to the morphological left ventricle, which leads to ventriculo-arterial discordance and a circulation that is incompatible with long life [5,6].

More than 4 decades ago, an *atrial switch repair* (Mustard or Senning operation) was the standard choice of treatment for TGA [7], but due to concerns on long-term outcome (arrhythmias, heart failure, reduced life expectancy [8]), this 'physiologic correction' has been replaced by the *arterial switch operation* (*ASO*) or 'anatomic correction' [9,10]. The surgeon successfully manages to switch the position of the great arteries shortly after birth so that the right ventricle remains to function as a sub-pulmonary ventricle and avoids systemic pressure load. The aorta is connected to the systemic left ventricle and as a consequence the coronary arteries need to be re-implanted.

Despite good overall survival, there is a substantial risk of (supra) valvular pulmonary stenosis as a result of the LeCompte maneuver. This surgical technique displaces the bifurcation of the pulmonary arteries anteriorly from the aorta. Unfortunately, any (chronic or

☆ All these authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation

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progressive) obstruction in the pulmonary circulation can cause pressure loading in the right ventricle and exposes the right ventricle to different degrees of chronic pressure overload. Consequently, several interventions may be required to decrease the pressure load of the right ventricle, ranging from balloon dilatation, to stenting and redo surgery.

Although a large cohort of ASO patients have already reached adulthood, data on long-term outcome of ASO remain scarce [11] and clear guidance for future clinical decisions for this adult population is still missing. Therefore, our aim was to evaluate mid- to long-term survival and characterize global cardiovascular outcome, with a special focus on the management of pulmonary artery stenosis.

2. Methods

2.1. Patient selection

All patients with arterial switch repair were selected from the pediatric and adult congenital heart disease database. Three hundred and thirty-nine patients underwent ASO between October 1981 and July 2018. Eighteen patients were lost to follow-up and had to be excluded as well as 3 patients with double discordance who underwent double switch repair. The study cohort finally comprises a total of 318 patients with complete dataset. Two hundred eighty- six patients were operated in UZ Leuven, 32 patients underwent arterial switch operation in an external hospital but were followed in our institution. Simple TGA included patients with atrial septal defect, patent foramen ovale, patent ductus arteriosus or no other accompanying defects. The study was approved by the KU Leuven Ethics Committee.

2.2. Data collection

All medical records were retrospectively reviewed from the detailed clinical database of UZ Leuven. Demographic data and associated anatomical lesions were assessed. Perioperative, post-operative, and interventional data were collected. Follow-up visits were reviewed mainly focusing on clinical outcome, echocardiographic findings and catheterization results if available.

2.3. Endpoints

Early mortality was defined as death occurring before hospital discharge or within 30 days after ASO. Late mortality was defined as death after 30 days and discharge. A heart failure episode was defined as (1) the need for hospitalization with initiation of diuretic therapy, (2) initiation of standard medical heart failure treatment with diuretic therapy or neurohormonal antagonists and (3) presence of ventricular dysfunction on transthoracic echocardiography with associated signs and symptoms of heart failure. Coronary dysfunction comprised all significant macrovascular lesions on the coronaries detected on angiography. Obstruction of the pulmonary artery (from valvular to peripheral pulmonary stenosis) was considered mild with an echocardiographic peak gradient between 10 and 36 mmHg, moderate between 36 and 64 mmHg and severe >64 mmHg. Indications for cardiac catheterization included a moderate to severe gradient on echocardiography, increased right ventricular systolic pressure > 2/3 of the systemic pressure or development of cardiac dyspnea/exercise intolerance. When indicated, cardiac catherization was used to evaluate the stenosis and determine its locations with angiography. In case of development of symptoms, progressive dilatation or dysfunction of the left ventricle for severe neo-aortic valve regurgitation, patients were also sent to the catheterization laboratory if the need for cardiac surgery was suspected. In addition, other non-interventional endpoints included complete heart block, pulmonary hypertension, supraventricular tachycardia, sick sinus syndrome, ventricular tachycardia, out-of-hospital arrest and endocarditis.

To determine overall event-free survival, a follow-up event was defined as death or intervention on the pulmonary artery, more specifically surgical or percutaneous intervention. Furthermore, other cardiac interventional endpoints included coronary revascularization and aortic valve/ascending aorta surgery.

2.4. Statistical analysis

Continuous variables are presented as mean ± standard deviation (SD) or as median (minimum – maximum range). For categorical variables, frequencies and percentages were used. To compare frequencies, a Chi-square test or Fisher's exact test was performed as appropriate. Survival and event-free survival analysis were performed by applying the Kaplan Meier method. Because survival in our study could be confounded by trends in all-cause mortality in the general population, net survival relative to the general Belgian population was determined. For each patient, expected survival by matching the patient to a Belgian patient from the general population by year of birth and age using the Belgian mortality tables was calculated. To compare early versus late years ASO, the dataset was divided in two groups, the first group included patients who underwent ASO before 1996, the second group had ASO in or after the year 1996. This coincided with the moment when stenting of pulmonary artery stenosis was implemented in our catherization laboratory. A two-sided p-value < 0.05 was considered to be statistically significant. All statistical analysis was performed using IBM SPSS Statistics version 25.0 (Armonk, NY: IBM Corp) for windows and R-version 3.4.0.

3. Results

3.1. Patient characteristics

A total of 318 patients (225 male patients, 71%) underwent ASO at a median age of 7 (range 0–770) days and were followed for a mean time of 11 SD 8.5 (range 0–35) years. One hundred thirty patients (41%) were defined as simple TGA and 188 patients (59%) were associated with more complex cardiac lesions. One hundred and twenty-five patients (39%) had ventricular septal defect, 24 patients (7%) coarctation of the aorta and 29 patients (9%) were diagnosed with pulmonary hypertension before ASO. Coronary anomalies were present in 83 patients (26%) and 17 patients (8%) were born with Taussig-Bing anomaly. Fifty-six patients (18%) underwent ASO before the year 1996, 11 patients (3%) in the year of 1996 but the majority of this cohort was operated after the year 1996 (251 patients, 79%). Baseline data are summarized in Table 1.

3.2. Survival and survival rate

A total of 29 out of 318 patients died (mortality rate of 9.1%). Twenty-four patients (7.5%) died in the early post-operative period of whom 3 patients deceased the day of surgery, 5 out of 318 patients (1.6%) died later in life.

Table 1
Baseline demographics.

Variable	N (%)
Female/male	93 (29)/225 (71)
Balloon septostomy	173 (54)
Median time to ASO TGA (days) (range)	7 (0–770)
Mean age at latest follow-up (years, SD) (range)	12.5 SD 9.0 (0–37)
Mean follow-up time (years, SD) (range)	11.1 SD 8.5 (0–35)
Arterial switch operation before/in or after 1996	56 (18)/262 (82)

ASO: arterial switch operation; TGA: transposition of the great arteries; SD: standard deviation.

The major cause of early mortality was cardiogenic shock in 12 patients of whom 5 patients died because of perioperative ischemia as a result of unsuccessful reimplantation of the coronary arteries. Seven others of these patients died of end-stage heart failure. Multiple organ failure was the major cause of death for 4 patients. Two patients died of severe post-operative pulmonary hypertension and two patients of septic shock. For 4 patients, the cause of in-hospital death could not be retrieved from the available files.

Of the five patients who died later in life, one died of cardiogenic shock as the result of end-stage biventricular heart failure (dilated cardiomyopathy after perioperative ischemia). One patient was known with pulmonary hypertension at birth and died from its complications. Furthermore, there was one death because of a fire accident. One patient, who was pacemaker-dependent, didn't survive an epicardial lead fracture. For 1 patient the exact cause of death could not be retrieved.

Fig. 1 presents the survival rate of ASO patients relative to the general Belgian population from birth. Overall survival rate for the TGA patients at 5, 10, 20 and 30 year was 92.1%, 91.7%, 89.6% and 89.6% respectively. The differences between survival was highly statistically significant (p-value < 0.0001). Once the patient survived the perioperative period, late mortality rate at 5-year follow-up was 0.4%, at 10-year 1.0%, at 15-year 2.6% and at 20-year follow-up 3.9%.

3.3. Complications after ASO

The late complications that occurred in the 289 survivors are summarized in Table 2.

Pulmonary artery stenosis was most frequent and found in 234 patients (80.9%), in case of 15 patients (6.4%) the stenosis was severe (>64 mmHg). The obstruction was usually located at the bifurcation of the pulmonary artery (158 patients, 68%). Thirty-four percent were isolated lesions at the bifurcation, but combined lesions did also occur. A more detailed distribution of all obstructions is illustrated in Fig. 2.

Table 2
Complications after arterial switch operation for all survivors.

Late complication	N (total 289 patients)	% of total population ASO survivors
Pulmonary artery stenosis	234	80.9
Complete AV block	10	3.4
Pulmonary hypertension	5	1.7
Left ventricular heart failure	4	1.4
Severe (neo) – aortic valve regurgitation, requiring surgery	3	1.0
Coronary revascularization (1 patient needed stenting, 1 patient LIMA to LAD)	2	0.7
Supraventricular tachycardia (atrial flutter)	2	0.7
Sick sinus syndrome	1	0.3
Monomorphic ventricular tachycardia, requiring ICD	1	0.3
Out-of-hospital cardiac arrest (ventricular fibrillation)	1	0.3
Endocarditis	1	0.3

ASO: arterial switch operation; ICD: implantable cardioverter defibrillator; AV: atrioventricular; LIMA: left internal mammaria interna; LAD: left coronary artery descendens.

3.4. Overall event free survival

In order to compute an overall event-free survival Kaplan-Meier curve, a follow-up event was defined as death or intervention on the pulmonary artery, more specifically surgical or percutaneous intervention. Three patients died the day of surgery as reported. Re-intervention for pulmonary artery stenosis was required in up to 39 (13.5%) cases (balloon angioplasty, stenting or surgical augmentation). Despite improved interventional techniques (balloon angioplasty and/or stenting), eight patients required surgical re-intervention of whom 7 patients had pulmonary artery plasty and one patient (2.5%) needed a homograft implantation. Re-intervention free survival was at 5-year was 91.6%, at 10-year 90.7% and at 20-year 79.2%. No patients died in direct relationship with the (re-)intervention (Fig. 3).

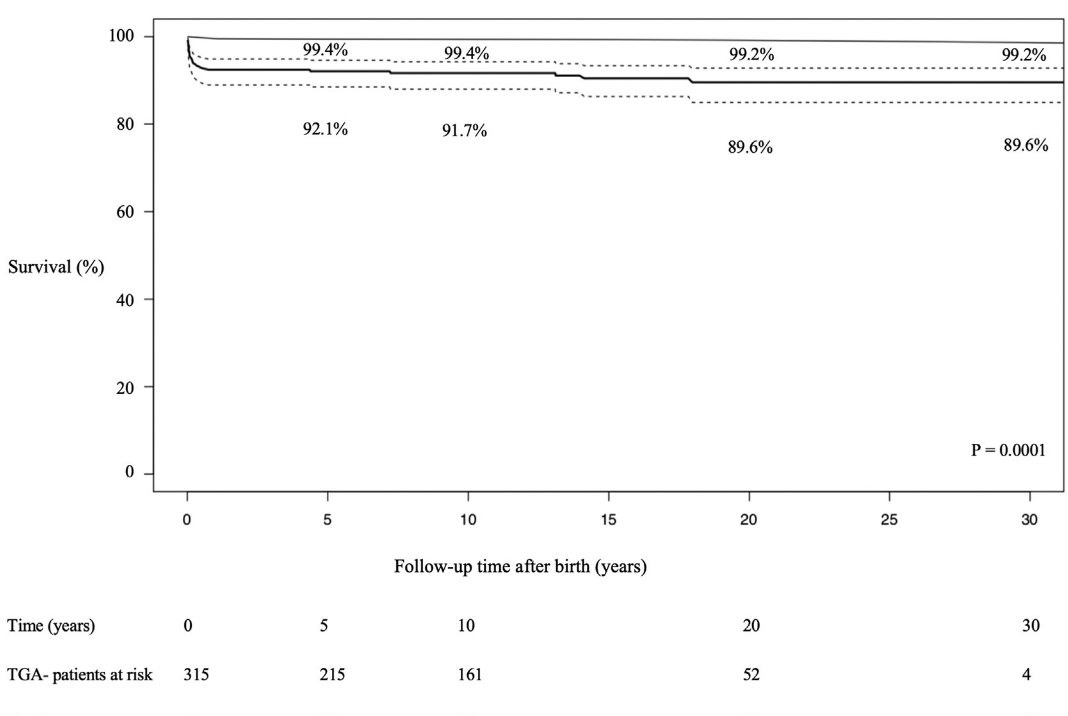


Fig. 1. Overall survival curve for all patients with transposition of the great arteries after arterial switch operation. Survival rate (%) is defined for TGA patients (thick line) and Belgian reference population (thin line).

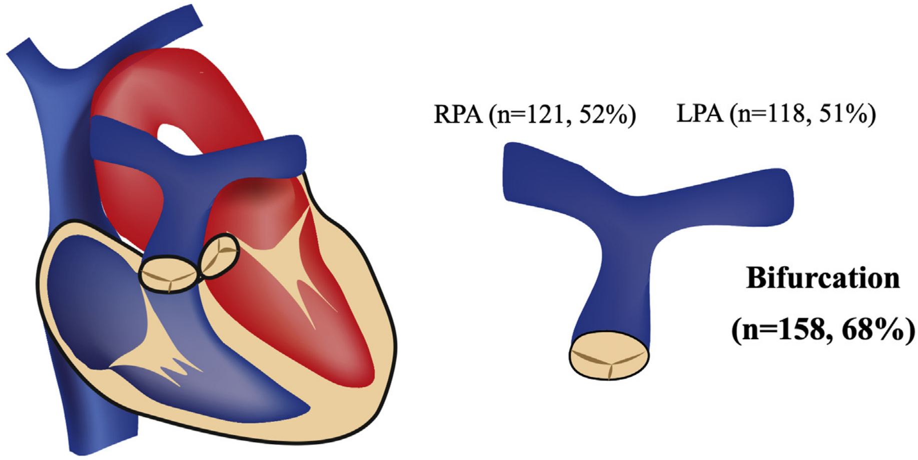


Fig. 2. Localization of pulmonary artery stenosis. LPA: left pulmonary artery; RPA: right pulmonary artery. Combined lesions did occur.

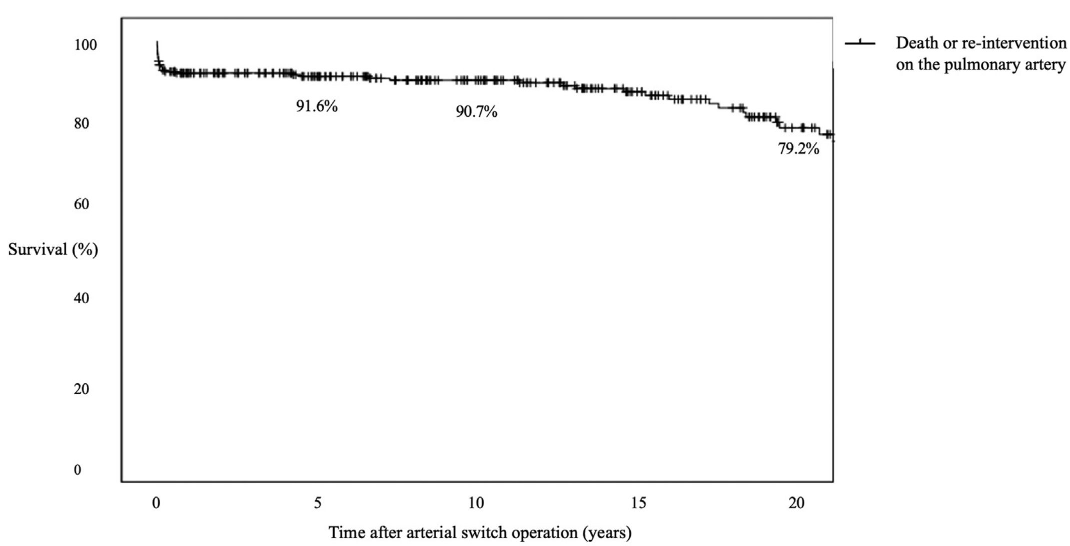
Site-specific intervention outcome analysis showed that the threshold for intervening on lesions at the bifurcation of the pulmonary artery was higher than for non-bifurcation lesions and surgical treatment was then preferred. The percutaneous re-intervention rate was higher for non-bifurcation lesions (Table 3). Fig. 4 illustrates the comparison re-intervention free follow-up for survivors before and after the first stent implementation in 1996 in the catheterization lab.

4. Discussion

We reviewed the records of all patients who underwent ASO between October 1981 and July 2018 at our institution. For a maximum follow-up time of 35 years, we identified the causes of mortality, the late complications, and the type and frequency of (re-)interventions. The total mortality rate of our studied cohort was 9.1% and was the highest in the peri-operative period. Pulmonary artery stenosis was the most frequent late complication (80.9%) and was mainly located at the bifurcation. Re-intervention on the pulmonary artery was required in 13.5% of all cases. (Re-)intervention was not related with increased death rate. A sub-analysis between early and late years ASO showed a lower burden of (re-)intervention since the introduction of pulmonary artery stenting in our temporary cohort of patients.

4.1. Early and late mortality after arterial switch operation

Total mortality of the studied cohort was 9.1%. This percentage was mainly driven by a high perioperative mortality (7.5%), which corresponds to the results of other studies where mortality rates ranged from 3% to 20% [12,13]. Cause of death was mostly dominated by peri-operative ischemia causing cardiogenic shock. In neonatal cardiac surgery, the ASO remains one of the most complex neonatal operations [4] in which transfer of the coronary artery origins is the key to success. In line with other reports, we could confirm that late mortality was low (1.6%). As a consequence TGA patients after ASO do have an excellent overall survival [14]. The survival rate after 30 years was as expected lower than the Belgian reference population. Once the patient survived



Time (years)	0	5	10	20
Patients at risk	315	215	161	52
Total events	3	27	29	41

Fig. 3. Event-free survival of all TGA patients up to 20 years after arterial switch repair. Follow-up event was defined as death or re-intervention on the pulmonary artery.

Table 3
Comparison patients' characteristics intervention versus no intervention on the pulmonary artery.

Variable	Intervention	No intervention	p-Value
Total (n = 234)	39	195	
Male, n (%)	26 (67)	140 (72)	0.52
TGA			
Simple TGA, n (%)	17 (44)	84 (43)	0.95
Complex TGA, n (%)	22 (56)	111 (57)	
Balloon septostomy, n (%)	21 (55)	111 (57)	0.85
Associated anomalies			
VSD, n (%)	14 (36)	74 (38)	0.81
Coarctation of the aorta, n (%)	2 (5)	14 (7)	0.64
Coronary anomalies, n (%)	10 (26)	46 (24)	0.78
Pulmonary hypertension, n (%)	8 (20)	9 (5)	<0.001*
Taussig/Bing, n (%)	3 (8)	7 (4)	0.25
Localization			
Bifurcation, n (%)	8 (21)	89 (46)	<0.001*
LPA, n (%)	3 (8)	7 (4)	0.25
RPA, n (%)	3 (8)	9 (5)	0.43
LPA + RPA, n (%)	13 (33)	42 (22)	0.12
LPA + bifurcation, n (%)	2 (5)	4 (2)	0.27
RPA + bifurcation, n (%)	0 (0)	7 (4)	0.23
LPA + RPA + bifurcation, n (%)	10 (26)	3 (18)	0.27

ASO: arterial switch operation; LPA: left pulmonary artery; RPA: right pulmonary artery; TGA: transposition of the great arteries; VSD: ventricular septal defect.
*p-level <0.05.

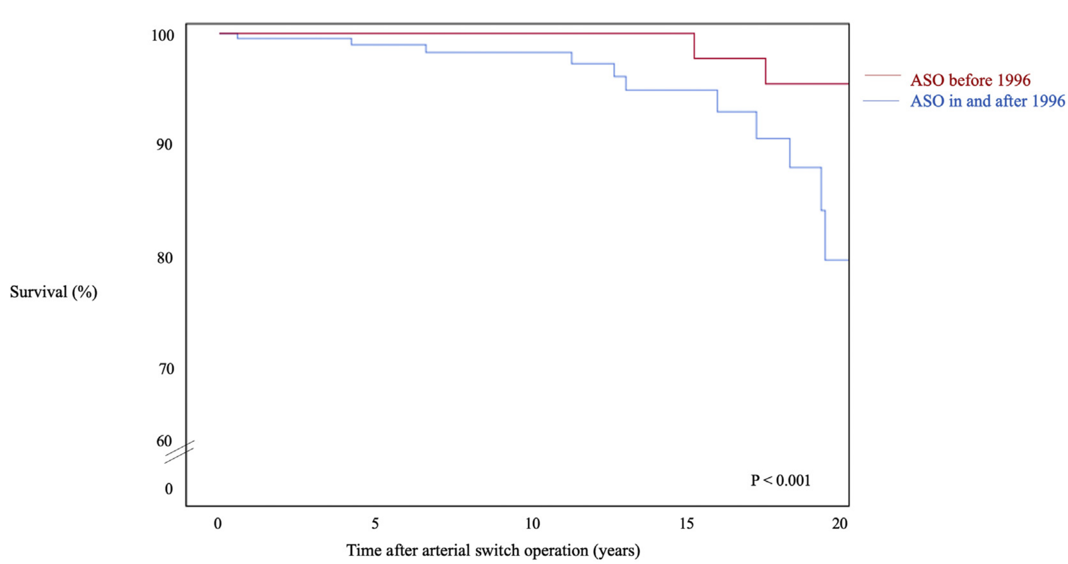
the peri-operative period, mortality rate at 5-year follow-up was 0.4%, at 10-year 1.0%, at 15-year 2.6% and at 20-year follow-up 3.9%. However, it is not clear how the mortality rates will evolve in the future, as experience with the procedure has grown over years. On one hand improved surgical experience and more expertise in intensive care management might reduce the peri-operative mortality. On the other hand, it could be that more and more complex cases will undergo ASO and offset the potential reduction in peri-operative mortality. Moreover, how these patients will perform >4 decades after ASO remains still unclear.

4.2. Complications after arterial switch operation

Survival into adulthood is common but the course of these ASO patients is not uneventful: for the follow-up time of 30 years only 25% remained event free.

One of the major concerns after ASO is late coronary kinking. A few studies suggest an incidence of 8–10% [15,16] although some report that it occurs rather uncommon (0–0.3%) [4,17]. Computed tomography is the method of choice for assessing the proximal segments of the coronaries for cooperative patients but optimal management of coronary lesions remains to be determined [16]. Currently, surgical revascularization is performed in patients with significant coronary lesions and myocardial ischemia. In our study, there were two patients (0.7%) who needed coronary revascularization, respectively 10 and 12 years after ASO. One patient was symptomatic (stable angina) but didn't present with an acute coronary syndrome. Coronary angiography raised no signs of atherosclerosis and the coronary lesion was based on kinking of the left anterior descending artery. The second patient was admitted after out-of-hospital cardiac arrest for ventricular fibrillation based on kinking of the left anterior descending for which a successful percutaneous intervention with a drug eluting stent was performed. We can conclude that also in our population the risk for coronary artery problems is rather high in the peri-operative period but low in child- or adulthood. For asymptomatic patients this remains still unclear since there was no surveillance imaging of the coronary arteries performed (except for the systematic transthoracic echocardiography follow-up of the ventricular function).

In contrast with atrial switch repair, there is a low incidence of atrial tachy-arrhythmia [14,18]. Tachy-arrhythmia (both ventricular and supraventricular) in the perioperative period are suspect for myocardial ischemia and coronary obstruction. In our study, the incidence of late tachy-arrhythmias was low (1.0%) and similar to the findings reported in other studies (2.4 to 9.6%) [2,4,8]. However, ICD-implantation was needed in one patient for a documented monomorphic refractory ventricular tachycardia.



Time (years)	0	5	10	20
ASO before first stenting				
Patients at risk	48	48	48	41
Total events	0	0	0	2
ASO after first stenting				
Patients at risk	239	165	114	16
Total events	0	2	3	11

Fig. 4. Comparison re-intervention free follow-up for survivors before and after stent implementation in 1996 in the catherization lab. ASO: arterial switch operation.

Brady-arrhythmia occurred mainly in the peri-operative period. Pacemaker implantation was needed in 0.3% for sick sinus syndrome in 1 patient or complete AV block in 10 patients. Right atriotomy for repair of ASD or VSD was considered as the main risk factor.

Another major concern after ASO is the risk for the development of neo-aortic valve regurgitation [4,8]. The anastomosis site of the neo-aorta or the size discrepancy of the great arteries are considered to be responsible for aortic root dilatation and, as a consequence aortic valve regurgitation. In our series we found only 3 cases (1.0%) of severe aortic valve regurgitation that required surgical intervention. Re-intervention on the neo-aortic valve was rare and in line with the numbers reported in other studies [19–21]. In addition, 12% (35 patients) of all survivors had moderate to severe (2-4/4) neo-aortic regurgitation at latest follow-up. We assume that surgical intervention for neo-aortic insufficiency may increase with longer follow-up (age > 25–35 years). Nevertheless, in this study one patient needed surgery at the age of 3-year, 1 patient between the age of 10–20 years and only one patient at the age of 25 years. As a consequence of missing quantitative data for aortic root dilatation, we decided not to include numbers of quantitative measurements in the analysis and focused only on the hard endpoint of surgical intervention.

4.3. Pulmonary artery stenosis and re-intervention

Pulmonary artery stenosis was the most frequent late complication (80.9%) in our dataset and the obstruction was mainly located at the bifurcation of the pulmonary trunk (in 68% of all cases), in line with most other studies [22–24], except for one in which only 17.1% developed pulmonary stenosis (PS). However in this study PS was defined as a stenosis that needed re-operation or catheter intervention, so that the real incidence of PS is presumably underestimated [25]. A rather large proportion of our patients required re-intervention (13.5%) because of the pressure load of the sub-pulmonary right ventricle. When comparing the patients who underwent a re-intervention on the pulmonary artery or not, we observed no gender differences. The occurrence of pulmonary artery stenosis was the same for simple as for complex TGA which is similar to the results from previous reports [23].

However, pre-operative pulmonary hypertension was more prevalent in patients who needed a re-intervention on the pulmonary circulation. We hypothesize that the hypoplasia of pulmonary branches at birth could interfere with the LeCompte maneuver where the pulmonary artery is repositioned in front of the aorta. Although in most cases the pulmonary artery stenosis is related to mechanical traction or squeezing between the aorta and the sternum the real pathophysiological background remains unclear. Since we thought that the surgical learning curve and improvements in peri-operative management may have had an influence on the pulmonary artery complications. For this reason, we split our data set in early and late years ASO. We decided to take 1996 as the cut off between early and late as the first stenting of the pulmonary artery was done in our institution in that year. Before stenting we were only able to balloon dilate the stenosis with limited success and as a consequence less interventions were performed. Remarkably, but not that unexpected, we found that the median re-intervention free survival time was significantly shorter for patients who underwent ASO after introduction of stenting the pulmonary artery. Besides surgical treatment, this new technique offered a more permanent solution compared to mere balloon dilatation. In addition, the threshold for intervening on lesions at the bifurcation of the pulmonary artery was larger and the rate of percutaneous re-interventions was higher for the non-bifurcation lesions. In previous studies [19] a bimodal distribution in reoperation was found with an initial rise in the early years after ASO and a second rise later in life. We could not find a similar distribution in our dataset.

In summary, the analysis of this contemporary cohort of ASO patients revealed that in a substantial number of patients the sub-pulmonary ventricle is submitted to a persistent or longstanding pressure overload. The long-term effects of this pressure load on the right heart remain unknown and motivate a careful follow-up.

5. Limitations

The study is retrospective and therefore limited inherent to observational investigations. The patient population included in this study represents the early era of ASO. As well as the surgical experience of arterial switch operation as treatment of pulmonary artery stenosis evolved over years.

Lower late complications rates may be expected in the future. Low event rates for outcomes such as late mortality preclude formal assessment of associated factors.

6. Conclusions

Despite a relatively high mortality shortly after ASO, TGA patients have an excellent overall long-term survival. However, as these patients reach adulthood, a large proportion of patients requires re-interventions. Most frequent re-interventions were for pulmonary artery stenosis. The introduction of stenting the pulmonary arteries lowered the burden to intervene. As a result of evolving surgical experience, pulmonary artery stenosis may decrease over time. However, the long-term effects of pressure load on the right heart remain unknown and motivate a careful follow-up.

CRediT authorship contribution statement

Béatrice Santens: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Visualization, Writing - original draft. **Alexander Van De Bruaene:** Writing - review & editing. **Pieter De Meester:** Writing - review & editing. **Marc Gewillig:** Writing - review & editing. **Els Troost:** Writing - review & editing. **Piet Claus:** Writing - review & editing. **Jan Bogaert:** Writing - review & editing. **Werner Budts:** Conceptualization, Data curation, Project administration, Resources, Supervision, Validation, Writing - review & editing.

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Declaration of competing interest

There is no conflict of interest.

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