The arterial switch operation in Europe for transposition of the great arteries: A multi-institutional study from the European Congenital Heart Surgeons Association

George E. Sarris, MD,[a] Andrew C. Chatzis, MD,[a] Nicolas M. Giannopoulos, MD,[a] George Kirvassilis, MD,[a] Hakan Berggren, MD,[b] Mark Hazekamp, MD,[c] Thierry Carrel, MD,[d] Juan V. Comas, MD,[e] Duccio Di Carlo, MD,[f] Willem Daenen, MD,[g] Tjark Ebels, MD,[h] Josè Fragata, MD,[i] Victor Hraska, MD,[j] Vladimir Ilyin, MD,[k] Harald L. Lindberg, MD,[l] Dominique Metras, MD,[m] Marco Pozzi, MD,[n] Jean Rubay, MD,[o] Heikki Sairanen, MD,[p] Giovanni Stellin, MD,[q] Andreas Urban, MD,[r] Carin Van Doorn, MD,[s] and Gerhard Ziemer, MD,[t] on behalf of the European Congenital Heart Surgeons Association

Dr Sarris

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Objectives: This study analyzes the results of the arterial switch operation for transposition of the great arteries in member institutions of the European Congenital Heart Surgeons Association.

Methods: The records of 613 patients who underwent primary arterial switch operations in each of 19 participating institutions in the period from January 1998 through December 2000 were reviewed retrospectively.

Results: A ventricular septal defect was present in 186 (30%) patients. Coronary anatomy was type A in 69% of the patients, and aortic arch pathology was present in 20% of patients with ventricular septal defect. Rashkind septostomy was performed in 75% of the patients, and 69% received prostaglandin. There were 37 hospital deaths (operative mortality, 6%), 13 (3%) for patients with an intact ventricular septum and 24 (13%) for those with a ventricular septal defect ($P < .001$). In 36% delayed sternal closure was performed, 8% required peritoneal dialysis, and 2% required mechanical circulatory support. Median ventilation time was 58 hours, and intensive care and hospital stay were 6 and 14 days, respectively. Although of various preoperative risk factors the presence of a ventricular septal defect, arch pathology, and coronary anomalies were univariate predictors of operative mortality, only the presence of a ventricular septal defect approached statistical significance ($P = .06$) on multivariable analysis. Of various operative parameters, aortic crossclamp time and delayed sternal closure were also univariate predictors; however, only the latter was an independent statistically significant predictor of death.

Conclusions: Results of the procedure in European centers are compatible with those in the literature. The presence of a ventricular septal defect is the clinically most important preoperative risk factor for operative death, approaching statistical significance on multivariable analysis.

From Onassis Cardiac Surgery Center,[a] Athens, Greece; Children's Heart Center,[b] Queen Silvia's Hospital for Children and Adolescents, Goteborg, Sweden; the Department of Cardiothoracic Surgery,[c] University Medical Center, Leiden, the Netherlands; Clinic for Cardiovascular Surgery,[d] University Hospital, Bern, Switzerland; Pediatric Heart Institute,[e] Hospital Universitario "12 de Octubre," Madrid, Spain; Ospedale Pediatrico Bambino Gesu,[f] Rome, Italy; Cardiac Surgery,[g] Gasthuisberg University Hospital, Leuven, Belgium; Thorax Centre,[h] Groningen University Medical Centre, the Netherlands; Hospital de Santa Marta,[i] Lisbon, Portugal; the Department of Cardiac Surgery,[j] Children's University Hospital, Bratislava, Slovakia; Bakulev Center for Cardiovascular Surgery,[k] Moscow, Russia; the Department of Thoracic and Cardiovascular Surgery,[l] University Hospital, Oslo, Norway; the Department of Cardiothoracic Surgery,[m] Hôpital de la Timone, Marseille, France; Alder Hey Cardiac Unit,[n] Royal Liverpool Children's Hospital, Liverpool, United Kingdom; Service de Chirurgie Cardivasculaire et Thoracique Université Catholique de Louvain,[o] Clinique Universitaires Saint-Luc, Brussels, Belgium; Hospital for Children and Adolescents,[p] University of Helsinki, Helsinki, Finland; University of Padova,[q] Padova, Italy; Deutsches Kinderherzzentrum,[r] St Augustin, Germany; The General Infirmary,[s] Leeds, United Kingdom; and Klinik für Thorax, Herz- und Gefässchirurgie,[t] Eberhard Karls Universitat, Tubingen, Germany.

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Address for reprints: George E. Sarris, MD, Onassis Cardiac Surgery Center, 356 Sygrou Ave, Kallithea, Athens, Greece 176 74 (E-mail: gsarris@hol.gr).

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After its introduction by Jatene and colleagues[1] in the early 1980s, as techniques in myocardial preservation improved and experience in coronary and congenital cardiac surgery accumulated, the arterial switch operation (ASO) evolved into the primary modality for treating transposition of the great arteries (TGA), by and large replacing the Mustard and Senning operations.[2-4] More recently, excellent results of the ASO have been reported from individual centers or collaborate studies.[5-8] Operative mortality for simple TGA is reported in the range of 2% to 7%, an impressive improvement compared with the mortality of approximately 15% found in earlier studies.[3,5-13] Risk factors for operative mortality have included the presence of a ventricular septal defect (VSD), older age at repair, coexisting anomalies, and anomalous or unusual coronary patterns.[3,11,12,14-18]

Although individual centers have reported excellent results,[6,8,13,19,20] the outcome of the ASO across European centers has not been studied. Therefore we sought to analyze the collective experience of participant centers of the European Congenital Heart Surgeons Association (ECHSA) in the current era, with an emphasis on characteristics of the patient population, associated anomalies, surgical results, and analysis of risk factors for adverse outcome.

Methods

The medical records of 613 patients with TGA who underwent primary ASO in each of the 19 participating ECHSA centers between January 1998 and December 2000 were reviewed retrospectively (Figure 1). Patients with complex TGA (TGA with VSD and pulmonary stenosis or the Taussig-Bing heart) were excluded. Demographic, functional, and interventional parameters were evaluated, including age, sex, weight, gestational age, coronary anatomy, associated lesions, the degree of cyanosis, use of prostaglandin infusion, preoperative Rashkind balloon septostomy, preoperative inotropic support, mechanical ventilation and dialysis, and other associated morbidities. Associated procedures and operative variables (lowest temperature and aortic crossclamp and circulatory arrest times) were recorded. Postoperative outcome parameters (open sternum, duration of mechanical ventilation, use of mechanical support, and length of intensive care unit [ICU] and hospital stay) were also noted.

Hospital mortality was defined as death during the operation or within 30 days of the operation, according to the definition used in the ECHSA's database (now the European Association of Cardiothoracic Surgery database). The univariate association between risk factors and postoperative outcome was assessed by using either a χ^2 test for categoric risk factors or a t test (or a Mann-Whitney test) for continuous risk factors. A univariate logistic regression model was also used to report the univariate odds for death along with 95% confidence intervals (CIs), and the Pearson correlation coefficient was used for other postoperative variables. Those risk factors that were found to be significant were then tested simultaneously in a multivariate logistic regression model.

Analyses were carried out with appropriate statistical software (Stata version 6.0; Stata Corp, College Station, Tex).

Abbreviations and Acronyms

ASO	= arterial switch operation
CI	= confidence interval
ECHSA	= European Congenital Heart Surgeons Association
ECMO	= extracorporeal membrane oxygenation
ICU	= intensive care unit
IVS	= intact ventricular septum
TGA	= transposition of the great arteries
VSD	= ventricular septal defect

Results

Patient age at the time of the operation ranged from 0 days to 22 months (median, 10 days; Figure 2), and weight ranged from 1.46 to 14.0 kg (median, 3.42 kg). Gestational age was 28 to 43 weeks (median, 39 weeks), and 428 (70%) of the patients were male. A VSD was present in 186 (30%) patients, the remaining having an intact ventricular septum (IVS). The distribution of associated lesions is shown in Table 1, and coronary type according to the Yacoub classification[14] is depicted in Figure 3.

Rashkind septostomy was performed in 450 (75%) patients, 387 (69%) received prostaglandin, 151 (30%) required preoperative ventilation, and 71 (13%) received inotropic support. At the time of the operation, the median lowest temperature was 22°C and crossclamp time was 87 minutes, whereas in 177 (37%) patients a period of circulatory arrest was necessary to complete the procedure.

There were 37 (6%) hospital deaths, 13 among patients with TGA/IVS (3%) and 24 (13%) among patients with TGA/VSD ($P < .001$; odds ratio, 4.72; 95% CI, 2.34-9.49), 76% of which were due to cardiac causes (Table 2). In 36% of the patients, delayed sternal closure was performed, 8% required peritoneal dialysis, and 2% required mechanical circulatory support. The median ventilation time was 58

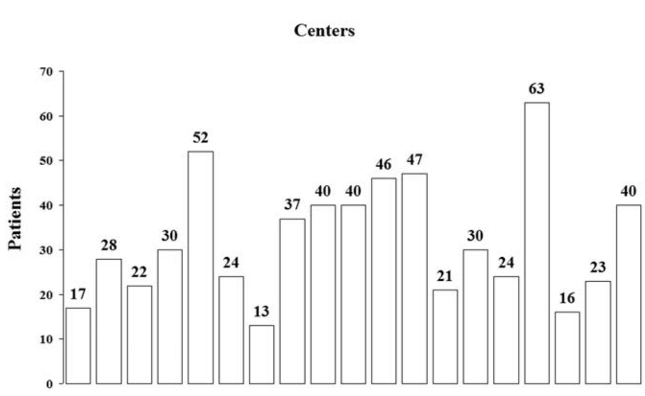

Figure 1. Contributing centers.

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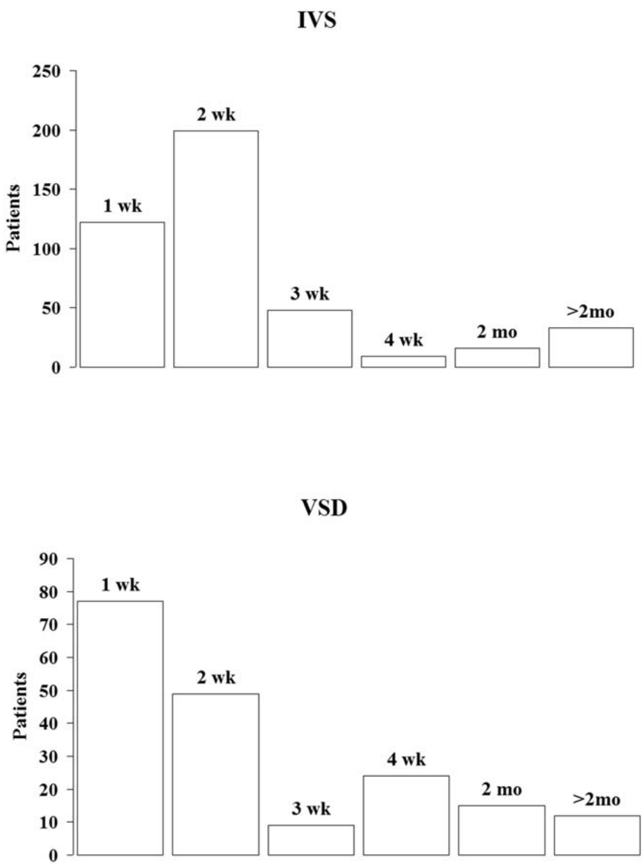

Figure 2. Age distribution. *IVS*, Intact ventricular septum; *VSD*, ventricular septal defect.

TABLE 1. Distribution of associated lesions

Category	No. of patients (% of total)
IVS	427 (70%)
Situs inversus	2 (0.4%)
CoA	2 (0.4%)
Hypoplastic arch	1 (0.2%)
VSD	186 (30%)
Situs inversus	1 (0.5%)
Multiple	13 (6.9%)
CoA	21 (11.3%)
Hypoplastic arch	12 (6.4%)
Interrupted arch	3 (1.6%)

IVS, Intact ventricular septum; *VSD*, ventricular septal defect; *CoA*, aortic coarctation.

hours, and ICU and hospital stays were 6 and 14 days, respectively.

Univariate analysis of potential risk factors for operative death showed that VSD, coronary type overall, complex coronary type and single coronary artery in particular, associated aortic pathology, increased aortic crossclamp time, and open sternum were associated with increased mortality, whereas preoperative prostaglandin use was associated with decreased odds of death (Table 3). When the above risk factors were included in a multivariate model, only the presence of a VSD approached statistical significance ($P =$ .06) as an independent risk factor for operative death (Table 4). On the other hand, leaving the sternum open at the end of the operation was a statistically significant independent risk factor for death ($P =$ 004; odds ratio, 5.4; 95% CI, 1.72-16.9; Table 4).

Multivariate analysis also showed that lower body weight, longer aortic crossclamp time, and open sternum were statistically significant independent predictors of postoperative acute renal failure. Aortic crossclamp time, the use of circulatory arrest, and delayed sternal closure were statistically significant determinants of duration of postoperative mechanical ventilation. Aortic crossclamp time was the sole multivariate predictor for the use of mechanical circulatory support ($P < .05$). Preoperative increased arterial oxygen saturation, prostaglandin infusion, increased aortic crossclamp time, and delayed sternal closure were statistically significant independent risk factors for prolonged ICU stay. Prolonged hospital stay was statistically significantly associated with the presence of concomitant aortic arch pathology, increased aortic crossclamp time, circulatory arrest, and delayed sternal closure (Table 5).

Discussion

The clinical characteristics of the patient population in this study are similar to those generally found in anatomic repair of TGA. Most patients are neonates with a median age of 10

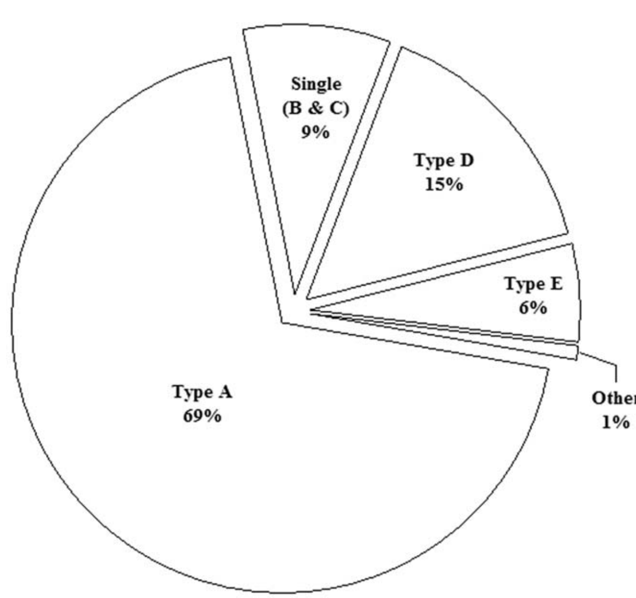

Figure 3. Coronary type.

TABLE 2. Operative mortality

	Dead	Alive	*P* value
IVS (total)	13 (3%)	414 (97%)	<.001
VSD (total)	24 (13%)	162 (87%)	
IVS (>4 wk, n = 52)	1 (2%)	51 (98%)	.02
VSD (>4 wk, n = 62)	9 (9%)	53 (98%)	
IVS (>8 wk, n = 36)	1 (3%)	35 (97%)	.39, NS
VSD (>8 wk, n = 50)	5 (10%)	45 (90%)	
IVS (≤4 wk, n = 375)	12 (3%)	363 (97%)	1.0, NS
IVS (>4 wk, n = 52)	1 (2%)	51 (98%)	
IVS (≤4 wk, n = 375)	12 (3%)	363 (97%)	1.0, NS
IVS (>8 wk, n = 36)	1 (3%)	35 (97%)	
VSD (≤4 wk, n = 124)	15 (12%)	109 (88%)	.64, NS
VSD (>4 wk, n = 62)	9 (15%)	53 (85%)	
VSD (≤4 wk, n = 124)	15 (12%)	109 (88%)	.79, NS
VSD (>8 wk, n = 50)	5 (10%)	45 (90%)	

NS, Nonsignificant.

days, with no difference between those with TGA/IVS and those with TGA/VSD. Interestingly, a number of patients had 1-stage ASO beyond 4 weeks of age (Table 2 and Figure 2). A recent report supports safe 1-stage repair of TGA/IVS beyond 3 weeks (range, 21-185 days) of age.[8] On average, however, ASO is not delayed in participating ECHSA centers. Of significant interest is the presence of associated anomalies, particularly aortic arch pathology; this was rare in patients with TGA/IVS but occurred in up to 19.3% of patients with TGA/VSD, 2-fold higher than previously reported.[7] Conversely, the incidence of unusual coronary patterns was similar to that seen in the literature, with 69% of patients having type A and 9% having a single coronary artery (Figure 3).[2,14,21]

Most procedures were performed without deep hypothermic circulatory arrest, which was used in 37% of the patients. Because the duration of deep hypothermic circulatory arrest was variable, its use (for more than a few minutes to close the atrial septal defect) appears limited to cases with aortic arch pathology, yet did not appear to influence outcome (Table 1).

Although duration of crossclamp time is similar to that seen in published reports, this factor was a univariate predictor of death (Table 3) and the sole multivariate predictor for the postoperative use of mechanical circulatory support (Table 5). However, the large overlap in crossclamp times between survivors versus nonsurvivors, as well as between extracorporeal membrane oxygenation (ECMO) and non-ECMO cases, precluded determination of useful upper or lower cutoff crossclamp time values for mortality or the use of ECMO. It is likely that aortic crossclamp time might serve as a surrogate variable for a more complex procedure or other factors.

The use of delayed sternal closure is comparably high.[22] In some institutions delayed sternal closure was practiced routinely, whereas in others selective use was recorded. Therefore in this retrospective study it was not possible to distinguish cases in which delayed sternal closure was entirely "elective" from those in which it was necessary because of mediastinal-cardiac edema.

Overall surgical outcome is comparable with reported results, with an overall operative mortality of 6%.[5-8,10-13] There was a significant difference in mortality between patients with TGA/IVS (3%) and patients with TGA/VSD (13%). The reason for this clinically significant difference remains unclear.

Of note is that high center volume was not a statistically significant factor for predicting lower mortality. Univariate analysis did show an increased risk of death for VSD and certain types of coronary anatomy, arch pathology, and increased crossclamp time, but these other factors did not retain statistical significance on multivariable analysis, whereas the presence of a VSD nearly achieved statistical significance ($P = .06$). Thus although one could speculate that excess mortality in patients with TGA/VSD pertains to increased crossclamp time (which in itself is a univariate predictor of operative mortality) or to an excess of patients with arch pathology or abnormal coronary arteries, multivariate analysis did not support this hypothesis. Perhaps the presence of a VSD serves as a marker or surrogate variable for other interrelated undefined factors that lead to increased mortality, but in any case it is unequivocal that VSD presence is a clinically significant and easily identifiable risk factor for operative death in our series.[6,7,12,20]

Clearly, delayed sternal closure as an operative outcome variable is associated with increased mortality. Interestingly, 52 patients with IVS who were older than 4 weeks of age (of which 36 were older than 8 weeks of age) underwent a primary ASO (Table 2 and Figure 2) with mortality comparable with that of the IVS subgroup of patients less than 4 weeks of age and significantly less than that of the patients with TGA/VSD aged more than 4 weeks (Table 2). Of course, patients with IVS in these age cohorts who had 2-stage repair have not been included in this report.

With regard to the use of ECMO and dialysis, as well as length of ICU and hospital stay, these parameters are within the spectrum of what is reported in the literature.[8,12,19] Multivariate analysis of risk factors for these parameters points to the clinically intuitive factors, such as increased crossclamp time, further underscoring the need to minimize ischemic time to improve outcome.

In summary, our study shows that results of ASO for TGA in participating ECHSA centers are comparable with those seen in the literature, although with significantly higher operative mortality for TGA/VSD compared with TGA/IVS. Although the presence of VSD was the only preoperative factor that approached statistical significance on multivariable analysis as a predictor of mortality, the finding on univariate analysis that coronary anomalies and arch pathology are associated with in-

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TABLE 3. Univariate analysis of risk factors for operative death

Risk factors	Dead	Alive	Odds ratio (95% CI)	*P* value
Sex				.15, NS
Male	22 (5%)	407 (95%)	1.0	
Female	15 (8%)	169 (2%)	1.64 (0.83-3.23)	
Gestation age (wk)				
Median (range)	38 (36-40)	39 (28-43)	0.87 (0.73-1.05)	.15, NS
Age at operation (days)				
Median (range)	9 (2-507)	10 (0-660)	1.0 (0.99-1.003)	.98, NS
Weight at operation (kg)				
Mean (SD)	3.42 (1.08)	3.52 (0.95)	0.87 (0.57-1.33)	.52, NS
IVS	13 (3%)	414 (97%)	1.0	**<.001**
VSD	24 (13%)	162 (87%)	4.72 (2.34-9.49)	
Coronary type				
A	13 (3%)	369 (97%)	1.0	**.003**
D	6 (7%)	78 (93%)	2.18 (0.80-5.92)	.12, NS
Single coronary	5 (11%)	42 (89%)	3.38 (1.15-9.95)	**.03**
Other	6 (16%)	32 (84%)	5.32 (1.89-14.9)	**.002**
Multiple VSDs				.10, NS
No	29 (5%)	541 (95%)	1.0	
Yes	2 (15%)	11 (85%)	3.39 (0.72-16.01)	
Aortic pathology (CoA, hypoplastic, interrupted arch)				**.003**
No	30 (6%)	490 (94%)	1.0	
Any	6 (21%)	23 (79%)	4.26 (1.61-11.2)	
Sa_{O_2} (%)				
Median (range)	84 (25-98)	80 (25-98)	1.01 (0.98-1.05)	.40, NS
Inotropes				.40, NS
No	25 (5%)	467 (95%)	1.0	
Yes	2 (3%)	69 (97%)	0.54 (0.12-2.33)	
Ventilation				.58, NS
No	21 (6%)	338 (94%)	1.0	
Yes	7 (5%)	144 (95%)	0.78 (0.32-1.88)	
Rashkind				.26, NS
No	12 (8%)	144 (92%)	1.0	
Yes	24 (5%)	426 (95%)	0.66 (0.32-1.36)	
Prostaglandin				**.03**
No	14 (8%)	158 (92%)	1.0	
Yes	14 (4%)	373 (96%)	0.42 (0.19-0.91)	
Lowest temperature (ºC)				
Median (range)	22 (13.2-35)	22 (13-36)	0.97 (0.89-1.05)	.43, NS
Aortic crossclamp time (min)				
Median (range)	113 (72-330)	85 (27-348)	1.01 (1.008-1.02)	**<.001**
Open sternum				**<.001**
No	11 (3%)	383 (97%)	1.0	
Yes	25 (12%)	192 (88%)	4.53 (2.18-9.41)	
Morbidity				.51, NS
No	30 (6%)	477 (94%)	—	
Yes	0 (0 %)	7 (100%)		
Circulatory arrest time				
0 min	16 (5%)	287 (95%)	1.0	.74, NS
1-10 min	5 (5%)	103 (95%)	0.87 (0.31-2.43)	.79, NS
>10 min	5 (7%)	64 (93%)	1.40 (0.49-3.96)	.52, NS

CI, Confidence interval; *NS*, nonsignificant; *SD*, standard deviation; *IVS*, intact ventricular septum; *VSD*, ventricular septal defect; *CoA*, aortic coarctation; Sa_{O_2}, arterial oxygen saturation.

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TABLE 4. Multivariate analysis of univariate predictors for operative deaths

Risk factors	Multivariate odds ratio (95% CI)	*P* value
IVS	1.0	
VSD	2.71 (0.96-7.68)	.06, NS
Coronary type A	1.0	.47, NS
Coronary type D	1.56 (0.49-4.95)	.45, NS
Single coronary	2.03 (0.55-7.47)	.28, NS
Other	2.57 (0.67-9.76)	.16, NS
Aortic pathology (CoA, hypoplastic, interrupted arch)		.42, NS
No	1.0	
Any	1.75 (0.45-6.83)	
Prostaglandin		.92, NS
No	1.0	
Yes	0.95 (0.36-2.49)	
Aortic crossclamp time	1.0 (0.99-1.01)	.21, NS
Open sternum		**.004**
No	1.0	
Yes	5.4 (1.72-16.9)	

CI, Confidence interval; *IVS*, intact ventricular septum; *VSD*, ventricular septal defect; *NS*, nonsignificant; *CoA*, aortic coarctation.

creased mortality is clinically relevant. Furthermore, the finding of a univariate association of increased cross-clamp time and adverse outcome calls for increased efforts to limit ischemic time as much as possible.

This is a retrospective multi-institutional study with significant variation in the number of patients contributed by each center. Furthermore, there was no uniform approach regarding surgical management, technique, and postoperative care protocols. An important limitation remains that this study was not designed to assess long-term follow-up.

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TABLE 5. Multivariate analysis of univariate predictors for postoperative outcome

Outcome parameter / Risk factors	Postoperative dialysis	Postoperative mechanical ventilation	Postoperative mechanical circulatory support (ECMO)	ICU stay	Hospital stay
Sex	NS	NS	NS	NS	NS
Gestation age (wk)	NS	NS	NS	NS	NS
Age at operation (days)	NS	NS	NS	NS	NS
Weight at operation (kg)	**.005**	NS	NS	NS	NS
IVS/VSD	NS	NS	NS	NS	NS
Coronary type	NS	NS	NS	NS	NS
Multiple VSDs	NS	NS	NS	NS	NS
Aortic pathology	NS	NS	NS	NS	**.005**
Preoperative Sa_{O_2} (%)	NS	NS	NS	**.004**	NS
Inotropes	NS	NS	NS	NS	NS
Preoperative ventilation	NS	NS	NS	NS	NS
Rashkind	NS	NS	NS	NS	NS
Preoperative prostaglandin	NS	NS	NS	**.001**	NS
Lowest temperature (°C)	NS	NS	NS	NS	NS
Aortic crossclamp time (min)	**.001**	**<.001**	**.047**	**<.001**	**<.001**
Open sternum	**.001**	**<.001**	NS	**<.001**	**.02**
Morbidity	NS	NS	NS	NS	NS
Circulatory arrest time	NS	NS	NS	NS	**<.001**
1-10 min	NS	**.015**	NS	NS	**.002**
>10 min	NS	NS	NS	NS	**.001**

ECMO, extracorporeal membrane oxygenation; *ICU*, intensive care unit; *NS*, nonsignificant; *IVS*, intact ventricular septum; *VSD*, ventricular septal defect; Sa_{O_2}, arterial oxygen saturation.

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