Early repair of complete atrioventricular septal defect has better survival than staged repair after pulmonary artery banding: A propensity score–matched study

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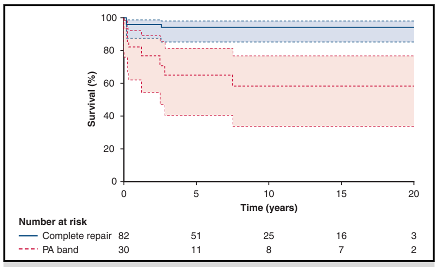
ABSTRACT

Objectives: Complete atrioventricular septal defect (cAVSD) repair is usually performed between 3 and 6 months of age. However, some children present with early heart failure requiring intervention. It is unclear whether primary complete repair or initial pulmonary artery banding (PAB) provides better outcomes.

Methods: All patients (n = 194) who underwent surgery for cAVSD younger than 3 months of age between 1990 and 2019 were included. Propensity score matching was performed on risk factors for mortality.

Results: Primary complete repair was performed in 77.8% (151/194), whereas PAB was performed in 22.2% (43/194). Children who had PAB were younger ($P < .01$), had lower weight ($P < .001$), and less trisomy 21 ($P = .04$). Interstage mortality for PAB was 18.6% (8/43), whereas early mortality for primary repair was 3.3% (5/151). Survival at 20 years was 92.0% (95% confidence interval [CI], 85.6%-95.7%) for primary repair and 63.2% (95% CI, 42.5%-78.1%) for PAB ($P < .001$). There was no difference in left atrioventricular valve (LAVV) reoperation rates ($P = .94$). Propensity score matching produced 2 well-matched groups. Survival at 20 years was 94.2% (95% CI, 85.1%-98.8%) for primary repair, and 58.4% (95% CI, 33.5%-76.7%) for PAB ($P = .001$). There was no difference in LAVV reoperation rates ($P = .71$). Neonatal repair was achieved with no early deaths and 100% survival at 10 years.

Conclusions: In children younger than 3 months of age, complete repair of cAVSD is associated with better survival than PAB. Both strategies have similar rates of LAVV reoperation. Neonatal repair of cAVSD can be achieved with excellent results. Primary repair of cAVSD should be the preferred strategy in children younger than 3 months of age. (J Thorac Cardiovasc Surg 2021;161:1594-601)



Survival of matched patients with cAVSD who underwent primary repair and PAB.

CENTRAL MESSAGE

When children with complete atrioventricular septal defect require surgery under 3 months of age, primary repair has better outcomes than pulmonary artery banding.

PERSPECTIVE

Patients with complete atrioventricular septal defect may require surgery under 3 months of age due to heart failure. In these patients, a strategy of early complete repair has better long-term survival than initial pulmonary artery banding. Complete repair can be safely achieved even in the neonatal period.

See Commentaries on pages 1602 and 1603.

Repair of complete atrioventricular septal defect with balanced ventricles (cAVSD) is routinely performed between the ages of 3 and 6 months, with low early mortality and excellent long-term survival.[1-6] However, there is a group of patients who develop heart failure or failure to thrive before 3 months of age and require earlier intervention. Although some groups have reported excellent results with complete repair in patients younger than 3 months of age,[7-10] others have reported increased early mortality and higher rate of reoperation.[2,6,11] There

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Abbreviations and Acronyms

cAVSD	= complete atrioventricular septal defect
CI	= confidence interval
LAVV	= left atrioventricular valve
LAVVR	= left atrioventricular valve regurgitation
PAB	= pulmonary artery banding

are particular concerns about left atrioventricular valve (LAVV) function with early repair, due to the friable leaflet tissue.[2,11] An alternative strategy is early pulmonary artery banding (PAB), with delayed complete repair.[12-14] However, it remains unclear which approach provides better outcomes in patients with balanced ventricles requiring early surgery, as there have been no comparative studies.[15,16] As such, we reviewed all patients who underwent surgery for cAVSD within the first 3 months of life to evaluate the results of early complete repair and PAB.

METHODS

Patients

All patients with a diagnosis of cAVSD who underwent either biventricular repair or PAB under the age of 3 months at the Royal Children's Hospital, Melbourne, from 1990 to 2019 were included in the study. Institutional ethics approval was granted by the Royal Children's Hospital Human Research Ethics Council (HREC 32047E on July 31, 2015). International patients were excluded, as follow-up data were not available for this group.

Data were collected by retrospective review of medical records. Follow-up data were obtained by correspondence with the patients' general practitioners and cardiologists. Follow-up was complete if the last confirmed patient contact occurred within 2 years of the end of the study period. Early death was defined as death occurring within 30 days of surgery or before discharge from hospital.

The degree of left atrioventricular valve regurgitation (LAVVR) was graded by echocardiography on an ordinal scale (0 = none, 1 = trivial, 2 = mild, 3 = moderate, 4 = severe). Significant LAVVR was considered to be present when AVVR was moderate or greater.

Failure to thrive was defined as a body weight less than the third centile predicted for age and sex. Heart failure was defined as a recorded diagnosis of heart failure at the time of presentation at multidisciplinary meeting who were also on diuretic therapy.

Operative Technique

PAB was performed via a median sternotomy without cardiopulmonary bypass. We use a strip of expanded polytetrafluoroethylene (W. L. Gore & Associates, Inc, Newark, Del), and adjust the tightness off the band to achieve a mean pulmonary artery pressure, which is approximately one half of the mean systemic arterial pressure and normal oxygen saturation.

We have previously published detailed description of our technique of cAVSD repair in simple and complex patients.[1,17] To summarize, complete repair is performed via a median sternotomy on full cardiopulmonary bypass at moderate hypothermia. Repair is performed through a right atriotomy, and a 2-patch approach is routinely used, with either expanded polytetrafluoroethylene patch (W. L. Gore & Associates, Inc) or autologous pericardium used for the ventricular septal defect component, and a patch of autologous pericardium used for the ostium primum. The decision to close the cleft is made at the individual surgeon's discretion, based on echocardiograph findings and intraoperative inspection of the valve.

Statistical Methods

All data were analyzed using STATA, version 13 (StataCorp, College Station, Tex). All continuous data are expressed as mean ± standard deviation unless otherwise specified. Continuous data were compared between groups using the Kruskal–Wallis test. Discrete variables were compared between groups using the χ^2 test, unless group size was less than 10, in which case the Fisher exact test was used. Time-dependent end points, specifically survival and freedom from LAVV operation, were analyzed using the Kaplan–Meier method, with time commencing at the time of PAB. Differences between groups were compared using the log-rank test. Progression to complete repair of cAVSD was analyzed using a competing risk framework, with death and complete repair as competing outcomes.

Propensity score matching was used to assess the impact of initial surgical strategy on clinical outcomes, as has been previously described in detail.[18] Propensity scores were generated using variables associated with mortality and reoperation after cAVSD repair (age, weight, preoperative LAVVR, trisomy 21, failure to thrive, heart failure, era of operation). Matching on the generated propensity scores was performed using 3:1 nearest-neighbor matching with a fixed caliper width set at 0.20 standard deviations of the logistic regression of the propensity score. This method was chosen after repeating the matching process with 1:1, 2:1, and 3:1 matching, all of which provided similar results, with 3:1 providing the greatest number of matches. The degree of balance of baseline characteristics between groups was assessed using standardized differences, where a difference of <10% was considered to reflect high degree of balance. Kaplan–Meier analysis was performed to estimate time dependent end points. An adjusted log-rank test stratified by quintiles of propensity scores was used to assess differences between matched groups for time-dependent variables.

RESULTS

Demographics

Of 463 patients who underwent surgery for cAVSD in the study period, 41.7% (193/463) were younger than 3 months of age at the time of their first operation (Figure 1). Primary complete repair was performed in 77.8% (151/194), whereas initial PAB with a plan for delayed complete repair was performed in 22.2% (43/194). Baseline characteristics are summarized in Table 1. Patients who had initial PAB were younger at the time of procedure (median 38 vs 68 days, $P < .01$), had lower weight (median 3.1 vs 3.9 kg, $P < .001$), and a lower proportion had trisomy 21 (55.8% vs 76.2%, $P = .04$).

Operative Details

In patients who underwent initial PAB, 81.4% (35/43) survived to complete repair, whereas 18.6% (8/43) died without achieving repair. The median time from PAB to death was 3 months (interquartile range 0.3-5 months), including 3 early postoperative deaths (7.0%, 3/43) and 5 late deaths (5/43, 11.6%). The causes of the interstage deaths were as follows: sepsis in 6 patients, pulmonary hypertensive crisis in 1 patient, and aortoesophageal fistula from a Kommerell diverticulum of an aberrant right subclavian artery in 1 patient.

The mean time from PAB to complete repair was 1.1 ± 1.8 years (median 0.4 years, interquartile range

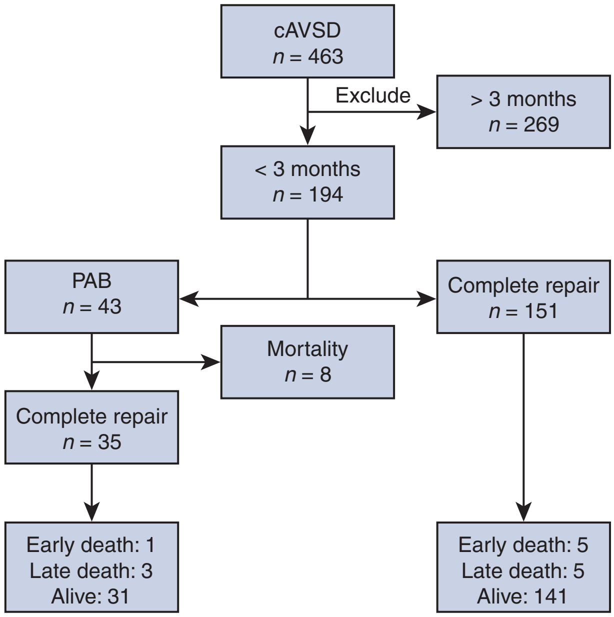

FIGURE 1. Distribution of procedures and outcomes for patients with cAVSD presenting for surgery at younger than 3 months of age. *cAVSD*, Complete atrioventricular septal defect; *PAB*, pulmonary artery banding.

0.1-1.0). The time from PAB to complete repair has decreased significantly in the second half of the study period compared to the first half (0.3 ± 0.1 vs 2.0 ± 0.5 years, $P = .001$). Reoperation for adjustment of the PAB was required in 7.0% (3/43) of patients. There was a significant increase in weight from the time of PAB to the time of complete repair (3.3 ± 0.1 kg vs 7.1 ± 0.9 kg, $P < .01$). There was no significant change in the grade of LAVVR after PAB (1.1 ± 0.1 vs 1.0 ± 0.2, $P = .24$). A competing risk model for complete repair and death following PAB is shown in Figure 2. The cumulative incidence of complete repair was 58.1% (95% confidence interval [CI], 42.1-72.1) at 1 year, 76.7% (95% CI, 61.1%-86.7%) at 5 years, and 81.4% (95% CI, 66.2%-90.2%) at 8 years.

At the time of complete repair, crossclamp (126.4 ± 9.0 minutes vs 103.1 ± 32 minutes, $P < .01$) and cardiopulmonary bypass times (182.5 ± 12.7 minutes vs 145 ± 4.1 minutes, $P < .01$) were both significantly longer in the patients who had previous PAB, compared with those who had primary complete repair. The rate of cleft closure did not differ between the 2 groups (61.5% vs 54.3%, $P = .7$).

In patients who underwent primary complete repair early mortality was 3.3% (5/151) compared with 2.9% (1/35) in those who underwent complete repair after initial PAB ($P = .69$).

Survival

Overall survival comparing those who underwent primary complete repair with those who had initial PAB is shown in Figure 3, *A*. Survival at 10 and 20 years was 92.0% (95% CI, 85.6%-95.7%) for primary repair, compared with 63.2% (95% CI, 42.5%-78.1%) in patients undergoing PAB ($P < .001$).

Survival following complete repair was 92.0% (95% CI, 85.6%-95.7%) at 10 years in those who underwent primary complete repair, compared with 87.8% (95% CI, 64.2%-96.3%) in those who underwent complete repair following initial PAB ($P = .67$).

LAVV Reoperation

Freedom from reoperation comparing those who underwent primary repair with those who had PAB is shown in Figure 3, *B*. Freedom from LAVV reoperation at 10 and

TABLE 1. Baseline characteristics comparing patients with cAVSD who underwent initial PAB with those who had primary complete repair

	PAB	Primary repair	*P* value	Standardized difference
n	43	151		
Age, d	37.9 ± 25.7 38 (IQR 16-60)	67.3 ± 17.4 68 (IQR 56-82)	<.001	134.2
Weight	3.2 ± 0.69 3.1 (IQR 2.9-3.7)	4.0 ± 0.80 3.9 (IQR 3.5-4.4)	<.001	101.5
Trisomy 21	24 (55.8)	115 (76.2)	.04	34.9
Moderate or greater LAVVR	10 (23.3)	26 (17.2)	.47	12.4
Associated CHD	31 (72.1)	128 (84.8)	.06	30.9
Heart failure	31 (72.1)	96 (63.6)	.22	22.0
Failure to thrive	21 (48.8)	63 (41.7)	.41	14.2
Era			.8	4.3
1990-2005	21 (48.8)	77 (51.0)		
2006-2019	22 (51.2)	74 (49.0)		

PAB, Pulmonary artery banding; *IQR*, interquartile range; *LAVVR*, left atrioventricular valve regurgitation; *CHD*, congenital heart disease.

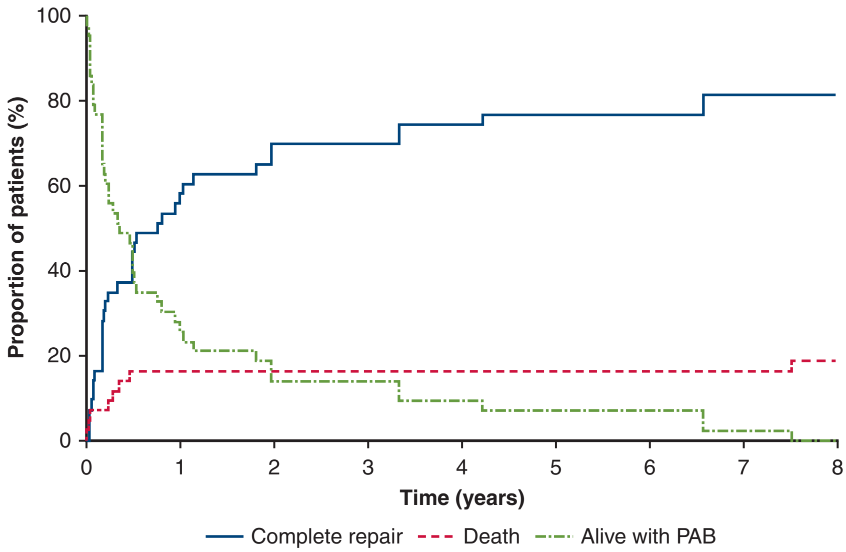

FIGURE 2. Competing risk model showing complete repair and death as competing outcomes for patients with cAVSD who underwent initial PAB. Time begins at the PAB operation. *PAB*, Pulmonary artery banding.

20 years was 77.9% (95% CI, 68.1%-85.0%) and 72.9% (95% CI, 59.0%-81.3%) in the primary repair group, compared with 75.7% (95% CI, 51.1%-89.0%) and 66.2% (95% CI, 37.4%-84.1%) in patients undergoing PAB ($P = .94$).

Propensity-Matched Cohort

Baseline characteristics comparing the matched cohorts of those who underwent went initial PAB with those who underwent complete repair are shown in Table 2. Notably patients were well matched for age, weight, and trisomy 21.

Overall survival, comparing those who underwent primary repair with those who had PAB are shown in Figure 4, *A*. Survival at 10 and 20 years was 94.2% (95% CI, 85.1%-97.8%) for primary repair, compared with 58.4% (95% CI, 33.5%-76.7%) in patients who underwent PAB ($P = .001$).

Freedom from reoperation comparing those who underwent primary repair with those who had PAB are shown in Figure 4, *B*. Freedom from LAVV reoperation at 10 and 15 years was 81.1% (95% CI, 70.0%-88.4%) and 66.5% (95% CI, 46.9%-80.3%) in the primary repair group, compared with 75.2% (95% CI, 43.2%-90.8%)

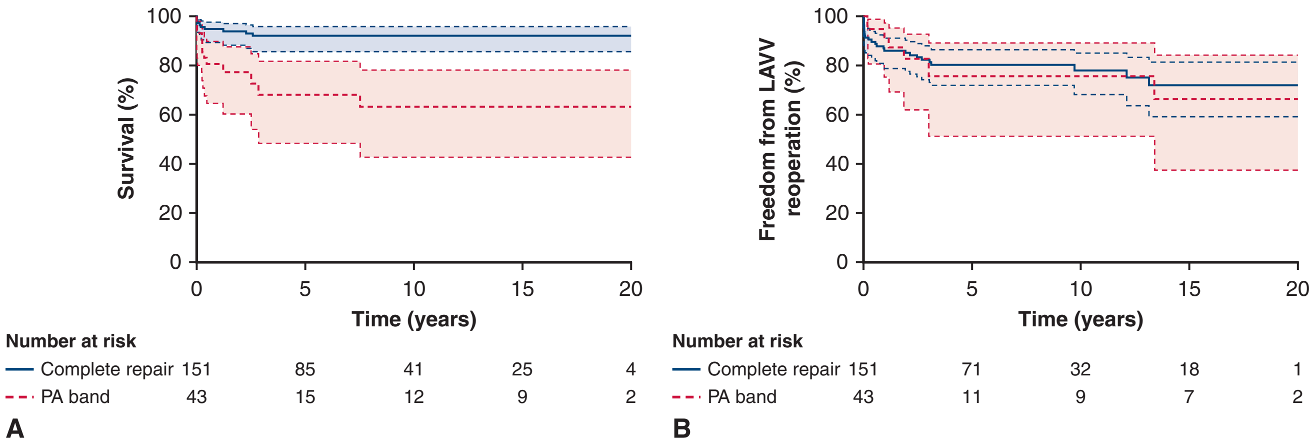

FIGURE 3. Kaplan–Meier curves for (A) survival and (B) freedom from LAVV reoperation comparing patients who had primary complete repair and those who had initial PAB. *PA*, Pulmonary artery; *LAVV*, left atrioventricular valve.

TABLE 2. Baseline characteristics comparing propensity score–matched groups of patients with cAVSD who underwent initial PAB with those who had primary complete repair

	PAB	Primary repair	*P* value	Standardized difference
n	30	82		
Age, d	45.2 ± 24.8 50.5 (IQR 19-65)	48.3 ± 18.6 49 (IQR 35-60)	.58	14.3
Weight	3.3 ± 0.7 3.2 (IQR 2.9-3.8)	3.4 ± 0.8 3.5 (IQR 3.0-4.0)	.84	5.2
Trisomy 21	17 (56.7)	50 (60.9)	.68	8.4
Moderate or greater LAVVR	7 (23.3)	23 (28.0)	.62	14.8
Associated CHD	21 (70.0)	50 (60.9)	.38	24.4
Heart failure	24 (80.0)	62 (75.6)	1.0	4.8
Failure to thrive	17 (56.7)	47 (57.3)	.95	3.3
Era			.65	9.9
1990-2005	15 (50)	34 (41.5)		
2006-2019	15 (50)	48 (58.5)		

PAB, Pulmonary artery banding; *IQR*, interquartile range; *LAVVR*, left atrioventricular valve regurgitation; *CHD*, congenital heart disease.

and 62.7% (95% CI, 27.7%-84.4%) in patients undergoing PAB ($P = .35$).

Neonatal Complete Repair

There were a total of 22 neonates who underwent complete repair of cAVSD, of whom 95.5% (21/22) underwent primary repair and 4.5% (1/22) underwent complete repair after initial PAB. There were no early deaths in neonates who underwent complete repair. Survival for neonates was 100% at 10 years, compared with 90.8% (95% CI, 83.5%-95%) for children aged 1 to 3 months ($P = .19$). Freedom from reoperation on the LAVV was 74.8% (95% CI, 45.8%-89.8%) at 10 years, compared with 77.1% (95% CI, 65.7%-85.1%) in older children ($P = .93$), Figure 5.

DISCUSSION

Children with cAVSD typically undergo complete repair electively between 3 and 6 months of age.[1-6] Results of elective cAVSD repair have improved markedly in recent decades, with early mortality of 1.5% to 3%, and 20-year survival of around 85% to 90%.[1-6] However, there is a group of patients who present with early failure to thrive or heart failure and require intervention before 3 months of age.[13-16] It has been unclear whether these patients would be best treated with early PAB and delayed complete repair, or primary complete repair.[14,16]

It appears that potential disadvantages of PAB in the setting of cAVSD might be a failure to adequately protect the pulmonary circulation and progression of LAVV regurgitation. Nevertheless, there have been few reports of PAB

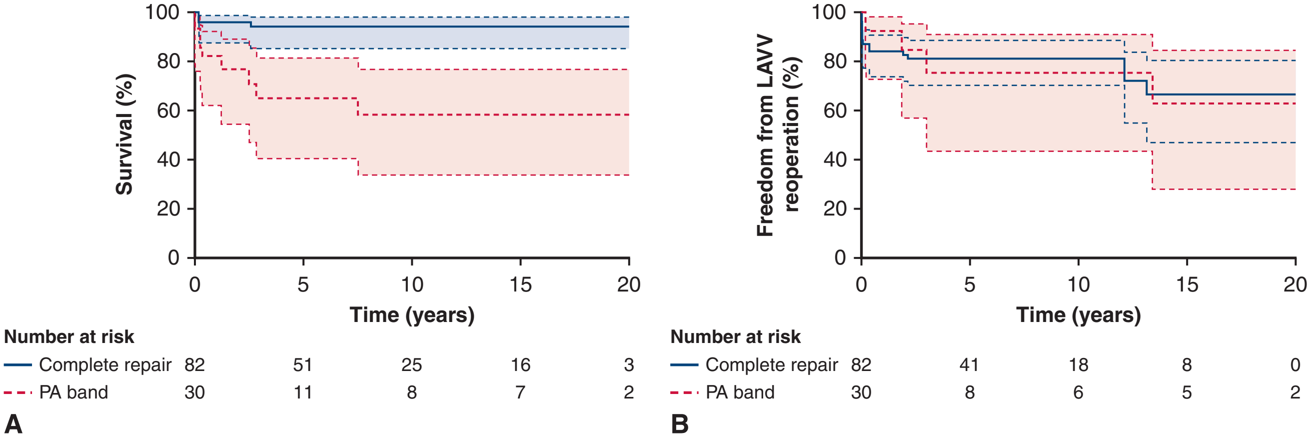

FIGURE 4. Kaplan–Meier curves for (A) survival and (B) freedom from LAVV reoperation comparing patients who had primary complete repair and those who had initial PAB in the propensity-matched cohort. *PA*, Pulmonary artery; *LAVV*, left atrioventricular valve.

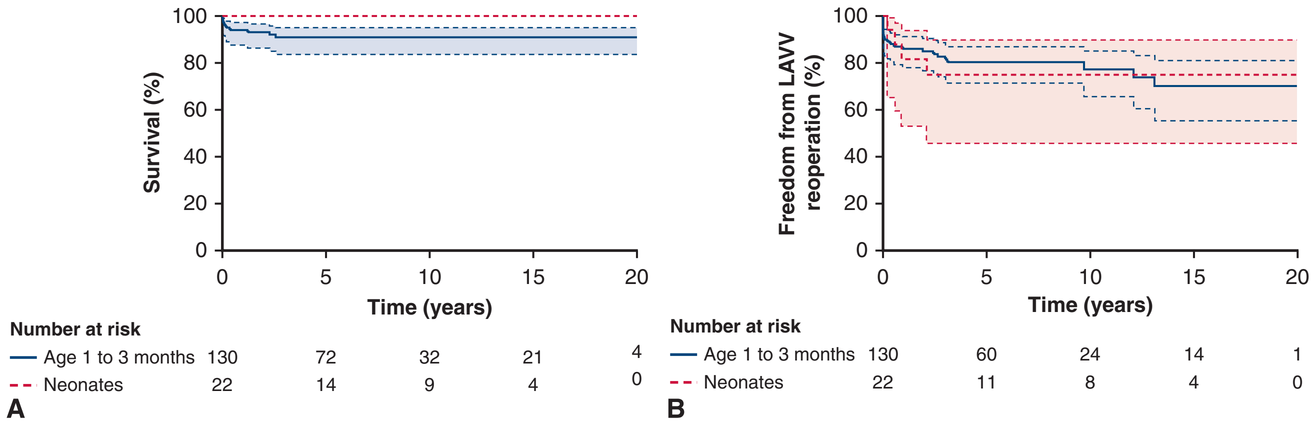

FIGURE 5. Kaplan–Meier curves for (A) survival and (B) freedom from LAVV reoperation comparing patients who had complete repair of cAVSD in the neonatal period, with children who were 1 to 3 months of age. *LAVV*, Left atrioventricular valve

in this setting. Historical series demonstrated early mortality greater than 30% when PAB was used to palliate cAVSD.[12,19,20] Our group has previously demonstrated that 80% of patients with cAVSD who undergo PAB achieve a complete biventricular repair.[13] Survival was 73% at 20 years, which is less than expected for patients with cAVSD. However, it was unclear whether this was due to the greater-risk population or the effect of PAB, as we did not have a propensity score–matched comparison group of children who underwent primary complete cAVSD repair. Devlin and colleagues[14] recently reported 25 patients with cAVSD who underwent PAB between 2012 and 2018. Of the 25 patients, 92% achieved complete repair, 4% died, and 4% were awaiting complete repair. They demonstrated similar survival between children who had a primary repair and those survivors of PAB who achieved complete repair, at a median follow-up of 2.3 years. Interestingly, both of these studies found that PAB did not worsen LAVVR in these children.

Outcomes of complete repair in children younger than 3 months of age have been published by several groups, with variable results. Importantly, St Louis and colleagues[6] published the results of 2399 children with cAVSD who underwent surgery between 2008 and 2011 from the Society of Thoracic Surgeons Congenital Heart Surgery Database. They reported an in-hospital mortality of 9.5% for children younger than 2.5 months of age, and 15.2% for children less than 3.5 kg. In contrast, others have reported that outcomes for complete repair of cAVSD younger than 3 months are equivalent to those in older children.[7-10]

Given the uncertainty regarding the best initial operation for patients with cAVSD requiring early surgery, we retrospectively studied all patients with cAVSD who had either complete repair or PAB younger than 3 months of age (Figure 6). At our institution, although there has not been a protocolled approach to this group of children, we found that the majority underwent primary complete repair. The patients who underwent PAB were younger, had lower weight, and a lower proportion had trisomy 21, all of which are known risk factors for poorer survival. We found that nearly 20% of patients who underwent PAB did not survive to complete repair. The operative mortality for complete repair was 3%, and it was similar regardless of whether complete repair was performed as a primary procedure or following initial PAB. Overall survival at 20 years was significantly better in patients who underwent primary complete repair compared with those who underwent initial PAB with a plan for subsequent complete repair. Following complete cAVSD repair, there was no difference in the need for LAVV surgery between the 2 groups. Furthermore, when comparing survival following complete repair, there was no significant difference between the groups. This indicates that the majority of the excess mortality in the group who underwent PAB was in the interstage period. The excess interstage mortality may result from failure of PAB to effectively control pulmonary overcirculation and alleviate heart failure in some patients. Once these patients achieved complete repair, their survival was no different than those who had primary complete repair. This is similar to the findings of Devlin and colleagues.[14]

We performed propensity score matching to adjust for the baseline differences between the groups. Importantly, age, weight, and the rate of trisomy 21 were well matched between the groups. Despite matching, there was still a significant survival advantage for initial complete repair. However, there was no difference between the groups in terms of reoperation on the LAVV.

Finally, we analyzed outcomes for neonatal patients who underwent complete repair. In neonates, there was 100% survival for patients who underwent initial complete repair.

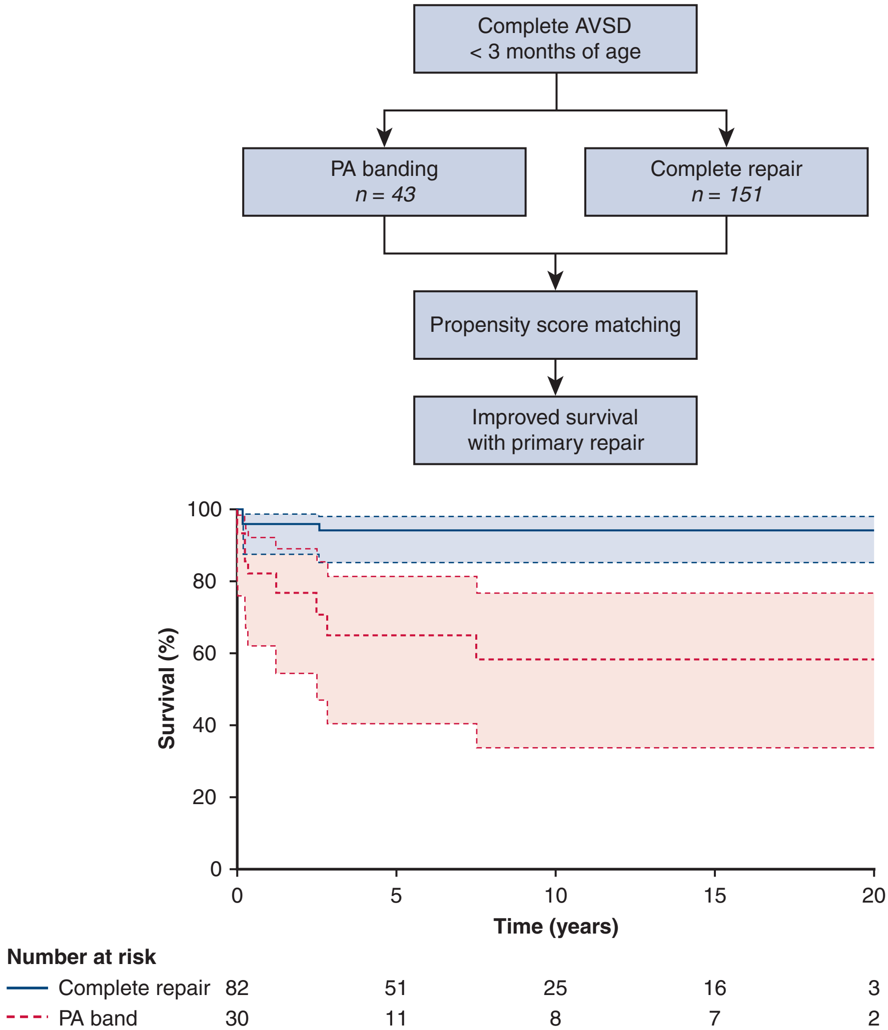

FIGURE 6. In a propensity-matched analysis, primary complete repair is associated with better survival than initial PA banding in patients with cAVSD requiring surgery at younger than 3 months of age. *AVSD*, Atrioventricular septal defect; *PA*, pulmonary artery.

Furthermore, freedom from reoperation on the LAVV was no different in those who underwent complete repair in neonatal period and older child, who had repair before 3 months of age.

Overall, the use of PAB to allow staged repair of cAVSD appears to be associated with increased mortality, predominantly in the interstage period. Although it is difficult to speculate on the exact cause of the high interstage mortality, it appears that PAB rendered an unstable circulation in patients with cAVSD that was very sensitive to any changes to systemic or pulmonary resistance; as such, 75% of deaths were due to sepsis and 12.5% were due to pulmonary hypertensive crisis. By comparison, results of neonatal complete repair of cAVSD appear to be excellent.

Limitations

This study is limited by its retrospective natures and the relatively small number of patients who underwent PAB. Although propensity score matching achieved a high degree of balance, it cannot account for all sources of bias that affected the initial decision to offer PAB or complete repair.

CONCLUSIONS

In children younger than 3 months of age, complete repair of cAVSD is associated with better survival than initial PAB followed by delayed complete repair. Both strategies have similar rates of LAVV reoperation. Neonatal complete repair of cAVSD can be achieved with excellent results. Thus, primary complete repair of cAVSD should be the preferred strategy in children who require surgery at younger than 3 months of age.

Conflict of Interest Statement

Dr Yves d'Udekem is a consultant for Actelion and MSD. Dr Christian Brizard serves on the advisory board of Admedus. All other authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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