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ORIGINAL ARTICLE

WILEY Congenital Heart Disease

# Complete atrioventricular canal repair with a decellularized porcine small intestinal submucosa patch

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## Abstract

**Background**: Congenital heart defects affect nearly 1% of all children born per year in the United States, and complete atrioventricular canal (CAVC) accounts for 2%-9%. While several patch materials have been used for septal defect closure during CAVC repair, clear superiority of one material over another has yet to be established.

**Methods**: A retrospective review of clinical outcomes following CAVC repair at Morgan Stanley Children's Hospital/Columbia University was performed on operations conducted from March 2010 to September 2017. Univariate and Kaplan-Meir survival analyses were utilized to evaluate primary outcomes of interest following CAVC repair in the modern surgical era.

**Results**: A total of 73 patients were analyzed, with an average operative age of 22 weeks. The majority (71%) of the patients underwent a 2-patch repair. A CorMatrix patch was used for ventricular septal defect(VSD) closure in 77% of the patients, and/or in 75% of atrial septal defect closures. There was one in-hospital mortality (1.4%) due to respiratory failure. One patient required a pacemaker. At mid-term follow-up (1.6 years), a total of 7 patients required 8 reoperations due to cardiac-related indications, including 5 for left atrioventricular valve (LAVV) repair, 1 for LAVV replacement, and 2 isolated residual VSDs.

**Conclusion**: A standardized repair for CAVC results in excellent outcomes in the current era, with low rates of reoperations. CorMatrix for the closure of CAVC has proven to produce good results with equivalent outcomes to other patch materials. Its ease of use and pliability make it an attractive alternative for consideration.

KEYWORDS
atrioventricular septal defect, common atrioventricular canal defect, congenital heart surgery, CorMatrix patch

## 1 | INTRODUCTION

Congenital heart defects (CHD) continue to affect nearly 1% of children born per year in the United States.[1,2] Complete atrioventricular canal (CAVC) defects represent a complex, wide spectrum of CHD lesions due to faulty development of embryonic endocardial cushions and account for approximately 2%-9% of all CHD.[3] While the first successful CAVC repair was reported over 60 years ago,[4] advances and refinements in surgical technique continue to evolve in an effort to improve surgical and clinical outcomes. One

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example is the performance of either single patch, 2-patch, or modified (Australian) single-patch repair techniques with no particular method demonstrating clear superiority over another for all CAVC repairs.[5,6]

Another variability seen in this repair is the type of patch material used for septal defect closure. While several materials are available for ventricular septal defect (VSD) closure in CAVC repair, including autologous pericardium, preserved xenopericardium, and various prosthetic materials (eg, polyethylene terepthalate [Dacron, DuPont, Wilmington, Delaware] and polytetrafluoroethylene [Gore-Tex, W. L. Gore & Associates, Inc, Flagstaff, Arizona], CorMatrix [Aziyo Biologics, Silver Springs, Maryland]), superiority of one material over another has yet to be definitively defined.

The primary goal of this study was to analyze contemporary surgical results using a standardized approach to CAVC repair. The secondary goal was to evaluate the success of an extracellular matrix material synthesized from decellularized porcine small intestinal submucosa (CorMatrix) as a VSD patch during repair.

## 2 | MATERIALS AND METHODS

### 2.1 | Patients and study design

This study was approved by the Columbia University Institutional Review Board (IRB-AAAM1908). All patients undergoing CAVC repair were entered prospectively into a certified institutional Society of Thoracic Surgeons (STS) Congenital Cardiac Surgery database. We performed a retrospective review of a single surgeon (EB) experience of all CAVC repairs performed at New York Presbyterian's Morgan Stanley Children's Hospital/Columbia University and Komansky Children's Hospital/Weill Cornell from March 2010 to September 2017.

Patient demographics and preoperative characteristics included patient-level comorbid disease, clinical features, and preoperative echocardiographic findings. Operative details included cardiopulmonary bypass (CPB) parameters, atrial septal defect (ASD) and VSD patch material type, and atrio-ventricular valve (AVV) cleft management. Perioperative outcomes included duration of intubation, intensive care unit (ICU) and hospital length of stay (LOS), perioperative complications and morbidity, operative mortality (death within 30 days or during same hospitalization), and predischarge echocardiographic data. Echocardiographic follow-up was obtained by review of institutional or referent cardiologist reports and included assessment of AVV function, degree of AVV regurgitation, presence of residual ASD or VSD, and ventricular function. For analysis of AVV regurgitation categories, a worse grade of regurgitation was categorized for those patients with severity assessed between grades (eg, categorized as moderate regurgitation when echocardiographic assessment was graded as mild-moderate). Short-term outcomes included requirement for permanent pacemaker (PPM) placement, reoperation for any reason, reoperation for left AVV dysfunction, residual septal defect, and mortality.

### 2.2 | Operative technique

A 2-patch technique using a combined CorMatrix patch for VSD closure and autologous pericardium for ASD closure was used to correct the CAVC defect in 52 (71%) patients, while 21 patients (29%) underwent a modified single-patch (Australian) technique. The left AVV cleft was closed or at least partially closed in 95% ($n$ = 69) patients; 4 patients (5%) had no closure of the left AVV cleft due to concerns for potential left AVV stenosis. The coronary sinus was committed to the right atrium in all cases during ASD closure.

### 2.3 | Surgical technique

A standardized approach was utilized for all CAVC repairs. Median sternotomy was first performed followed by subtotal thymectomy, patent ductus arteriosus (PDA) ligation, and institution of bicaval cardiopulmonary bypass (CPB) with a goal temperature of 32 degrees Celsius. One dose (20 cc/kg) of delNido cardioplegia was used for myocardial protection. The common AVV was then exposed and carefully studied with saline insufflation. The exact midpoint of the valve was marked with a fine polypropylene suture placed on the superior and inferior bridging leaflets, respectively. The tip of the cleft, marked by the most medial end of the chordal attachments, was also marked with fine polypropylene. Attachments of the AVV to the crest of the septum were studied and separated into left- and right-sided components. The extent of the VSD, both posteriorly/inferiorly and toward the membranous area, was studied and noted. If the VSD was shallow (2-3 mm), it was closed primarily using the "Australian repair" technique. The CorMatrix VSD patch was implanted with interrupted 5-0 braided Tevdeck pledgeted mattress sutures on the ventricular side. The edge of the VSD patch facing the AVV was sutured with interrupted 6-0 polypropylene mattress sutures placed through the patch, then through the transverse midline of the valve, and then through the inferior edge of the ASD (autologous pericardium) patch, which was then tied down sandwiching the valve between the VSD and ASD patches. The cleft was then inspected again and the valve insufflated with saline. The cleft was closed from its very tip (identified by where the chordae attach) to the center with interrupted simple 6-0 prolene sutures. We try in every case to close the cleft entirely. The presence of a left superior vena cava (SVC) with an enlarged coronary sinus is often seen with smaller left AVVs and poorly developed commissures whereby the cleft itself is the actual opening into the left ventricle (LV). In these case, the cleft has to be entirely left open or only partially closed. Pledget-supported Reed-style commissuroplasties at the level of the commissures are an invaluable adjunct to reduce the antero-posterior diameter of the valve without sacrificing effective orifice, and they were utilized very liberally. The ASD patch was then sutured to the edge of the ASD, leaving the CS on the right side. The infero-posterior line of suture passes along the edge of the top right corner of the left AVV until the CS is passed at which point the suture line can be taken back up more anterior to the true edge of the ASD. The right AVV was then tested. Deairing, aortic unclamping, and weaning off bypass as per routine were then performed. An intraoperative transesophageal echocardiography (TEE) is performed routinely to assess the cardiac function as well as the existence of residual defects.

### 2.4 | Statistical analysis

Continuous data are presented as mean ±standard deviation for normally distributed data and median [25th,75th percentile] for non-normally distributed data. Categorical variables are presented as total number and frequency. Data comparisons were performed using chi-square testing for categorical data and either Student *t* test, the Fishers exact test, or the Mann-Whitney *U* test for continuous data where appropriate. Kaplan-Meier survival and freedom from event curves were utilized to examine cardiac-specific survival and freedom from reoperation. For all data comparisons, statistical significance was defined as $P < .05$. Statistical analyses were performed using the using SPSS version 21 (IBM Corp, Armonk, New York).

## 3 | RESULTS

### 3.1 | Demographics, preoperative imaging, and clinical status

The average patient age at the time of operations was 21.8 ± 22.7 weeks (range, 2.5 to 184.4 weeks). A total of 82% had trisomy 21, and 2 patients (3%) had previous PA banding (Table 1). One patient underwent concomitant coarctation/arch repair at age 4 weeks, and one patient underwent concomitant PA debanding.

#### 3.1.1 | Intraoperative features

A majority of patients (71%) underwent a 2-patch repair (Table 2). For the patients that underwent the modified single-patch "Australian" technique, the CorMatrix patch was used to close the atrial septal defect in 15 (20.5%) patients, autologous pericardium was used for 5 (6.8%) patients. The left AVV cleft was completely closed in 88%, and 7% had partial closure. As a result, 5% had no cleft closure in instances where cleft closure was anticipated to cause stenosis. AVV commissuroplasty was performed in 25 patients (34%). A total of 3 patients (4.1%) required a return to CPB: 2 for correction of left AVV stenosis and 1 for biventricular dysfunction which subsequently improved.

#### 3.1.2 | Perioperative events

Perioperative events are detailed in Table 2. Overall, 13 patients required reintubation (18%) with 4 requiring subsequent tracheostomy (6%). There was one in-hospital death (1.4%) which occurred in an ex-29-week premature infant who never left the Neonatal ICU preoperatively and had CAVC and left ventricular outflow obstruction (LVOTO) repair at the age of 3 months (3.4 kg). This patient died of respiratory failure in setting of pulmonary hypertension at 2 months postop with evidence for good cardiac repair on echo. One patient required a pacemaker for intermittent atrioventricular block.

**TABLE 1** Preoperative demographics and clinical status of patients ($n$ = 69)

| | Mean ±SD | Median (25th-75th percentile) |
|---|---|---|
| Preoperative demographics | | |
| Gender female | 40 (54.8%) | |
| Age at repair (weeks) | 21.8 ± 22.7 | 17.4 (12.1-24.0) |
| ≤ 1 month | 3 (4.1%) | |
| ≤ 3 months | 20 (27.4%) | |
| 3-6 months | 41 (56.2%) | |
| >6 months | 14 (19.2%) | |
| Weight (Kg) | 5.0 ± 1.5 | 4.8 (4.0-5.6) |
| Height (cm) | 58.4 ± 7.7 | 58.5 (52.0-63.0) |
| BSA (m2) | 0.27 ± 0.06 | 0.27 (0.23-0.30) |
| Trisomy 21 present | 60 (82.2%) | |
| Preoperative clinical status | | |
| Respiratory disease | 10 (13.7%) | |
| Infection | 7 (9.6%) | |
| Arrhythmia | 3 (4.1%) | |
| Kidney disease | 2 (2.7%) | |
| Liver disease | 0 (0%) | |
| Shock | 1 (1.4%) | |
| Cardiac drips | 2 (2.7%) | |
| Oral cardiac meds | 53 (72.6%) | |
| PDA | 46 (63.0%) | |
| Previous PA banding | 2 (2.7%) | |
| Previous PDA ligation | 2 (2.7%) | |
| Previous aortic arch repair | 1 (1.4%) | |
| Previous shunt | 0 (0%) | |
| Rastelli CAVC type | | |
| A | 50 (68.5%) | |
| B | 1 (1.4%) | |
| C | 18 (24.7%) | |

Continuous data are presented as the mean ±standard error and categoric data are presented as number of patients (% of cohort).
Abbreviations: BSA, body surface area; CAVC, complete atrioventricular canal; PA, pulmonary artery; PDA, patent ductus arteriosus; SD, standard deviation.

Prior to discharge, surveillance echocardiography revealed ≥moderate left AVV regurgitation in 1 patient (1.4%) who required subsequent re-repair during the same admission, and 1 patient (1.4%) had ≥mild LVOTO.

#### 3.1.3 | Short-term follow-up

Overall short-term follow-up was 100% with a mean of 1.6 ± 1.9 years. The incidence of reoperation was 9% ($n$ = 7, Table 3).

**TABLE 2** Operative details, perioperative course, and perioperative complications

| | Mean ±SD | Median (25th-75th percentile) |
|---|---|---|
| Operative course | | |
| CPB time (min) | 108.5 ± 23.4 | 104.5 (92.0-120.3) |
| XC time (min) | 79.2 ± 18.8 | 78.0 (64.5-89.0) |
| 2-patch technique | 52 (71.2%) | |
| Complete cleft closure | 64 (87.7%) | |
| Partial cleft closure | 5 (6.8%) | |
| CorMatrix VSD patch | 56 (76.7%) | |
| CorMatrix ASD patch | 55 (75.3%) | |
| iNO | 3 (4.1%) | |
| ECMO | 0 (0%) | |
| Back on pump | 3 (4.1%) | |
| Periop course | | |
| Intubation time (days) | 5.0 ± 10.4 | 2.0 (1.0-4.0) |
| LOS ICU (days) | 13.5 ± 24.6 | 6.0 (3.0-10.0) |
| LOS Hospital (days) | 17.1 ± 23.5 | 9.0 (6.0-18.0) |
| Periop complications | | |
| Reintubation | 13 (17.8%) | |
| Tracheostomy | 4 (5.5%) | |
| Pneumonia | 3 (4.1%) | |
| Sepsis | 2 (2.7%) | |
| AKI | 0 (0%) | |
| Reop for bleeding | 0 (0%) | |
| GI bleeding | 0 (0%) | |
| Stroke | 0 (0%) | |
| A-fib | 0 (0%) | |
| New dialysis | 0 (0%) | |
| Back to OR | 6 (8.2%) | |
| Noncardiac reasons | 5 (6.8%) | |
| Cardiac reason (MV repair) | 1 (1.4%) | |
| Mortality | 1 (1.4%) | |
| In-hospital mortality | 1 (1.4%) | |

Continuous data are presented as the mean ±standard error and categoric data are presented as number of patients (% of cohort).
Abbreviations: A-fib, atrial fibrillation; AKI, acute kidney injury; ASD, atrial septal defect; ECMO, extracorporeal membrane oxygenation; CPB, cardiopulmonary bypass; GI, gastrointestinal; ICU, intensive care unit; iNO, inhaled nitric oxide; LOS, length of stay; OR, operating room; periop, perioperative; SD, standard deviation; VSD, ventricular septal defect; XC, cross-clamp.

Seven patients (9%) required 8 reoperations due to cardiac-related indications (Figure 1). Reoperation on the left AVV occurred in 5 patients (7%) at a mean of 119 ± 63 days (range, 37 to 189 days) (Figure 2). Two (2.7%) patients required reoperation for a residual VSD alone, while one (1.4%) patient required reoperation due to a residual ASD alone.

**TABLE 3** Short-term reoperations

| Reoperations (7 patients, 9%) | N = 8 (11.0%) | | |
|---|---|---|---|
| Procedures performed | | Primary indication/ procedure | |
| Left AVV repair | 5 (6.8%) | Left AVV regurgitation | 3 |
| Left AVV replacement | 1 (1.3%) | Recurrent VSD | 2 |
| LVOT resection | 1(1.3%) | LVOTO | 1 |
| Recurrent ASD | 2 (2.7%) | Recurrent ASD | 1 |
| Recurrent VSD | 2 (2.7%) | Atrioventricular block | 1 |
| PPM | 1(1.3%) | | |

Categorical data are presented as number of patients (% of cohort).
Abbreviations: ASD, atrial septal defect; LAVV, left atrioventricular valve; LVOTO, left ventricular outflow tract obstruction; PPM, permanent pacemaker; VSD, ventricular septal defect.

### 3.2 | Echocardiography trends

Trends in preoperative, predischarge, and short-term follow-up echocardiography features for all patients are displayed in Figure 3. Although most patients demonstrated some degree of preoperative left and/or right AVV regurgitation (68% and 59%, respectively), significant improvement in postoperative valve function was observed for the majority of patients: a total of 18 patients (25%) demonstrated moderate left AVV regurgitation and 9 (12%) demonstrated moderate right AVV regurgitation at discharge, 2 (3%) patients demonstrated>moderate left AVV regurgitation. Similar results were observed at a mean of 1.6 years short-term follow-up: 48 patients (66%) demonstrated some degree of left AVV regurgitation, while 40 patients (55%) demonstrated some degree of right AVV regurgitation. Most importantly, however, there were no patients with greater than moderate regurgitation. There were no significant postoperative hemodynamic differences noted when comparing the two repair techniques.

## 4 | COMMENT

This study reports on the outcomes of a standardized surgical approach for CAVC repair, with particular attention on the effects of the use of CorMatrix patches for the closure of the VSD component of the repair. Our report of 73 successful CAVC repairs demonstrates the integrity and success of utilizing a CorMatrix patch during VSD closure. In addition, the low rates of reinterventions specifically for the left AVV demonstrate that a standardized approach to AVV cleft closure and reinforcement annuloplasty provides for a durable repair. Overall, these results expand upon previously reported approaches to CAVC repair to highlight the safety and efficacy of our surgical technique.

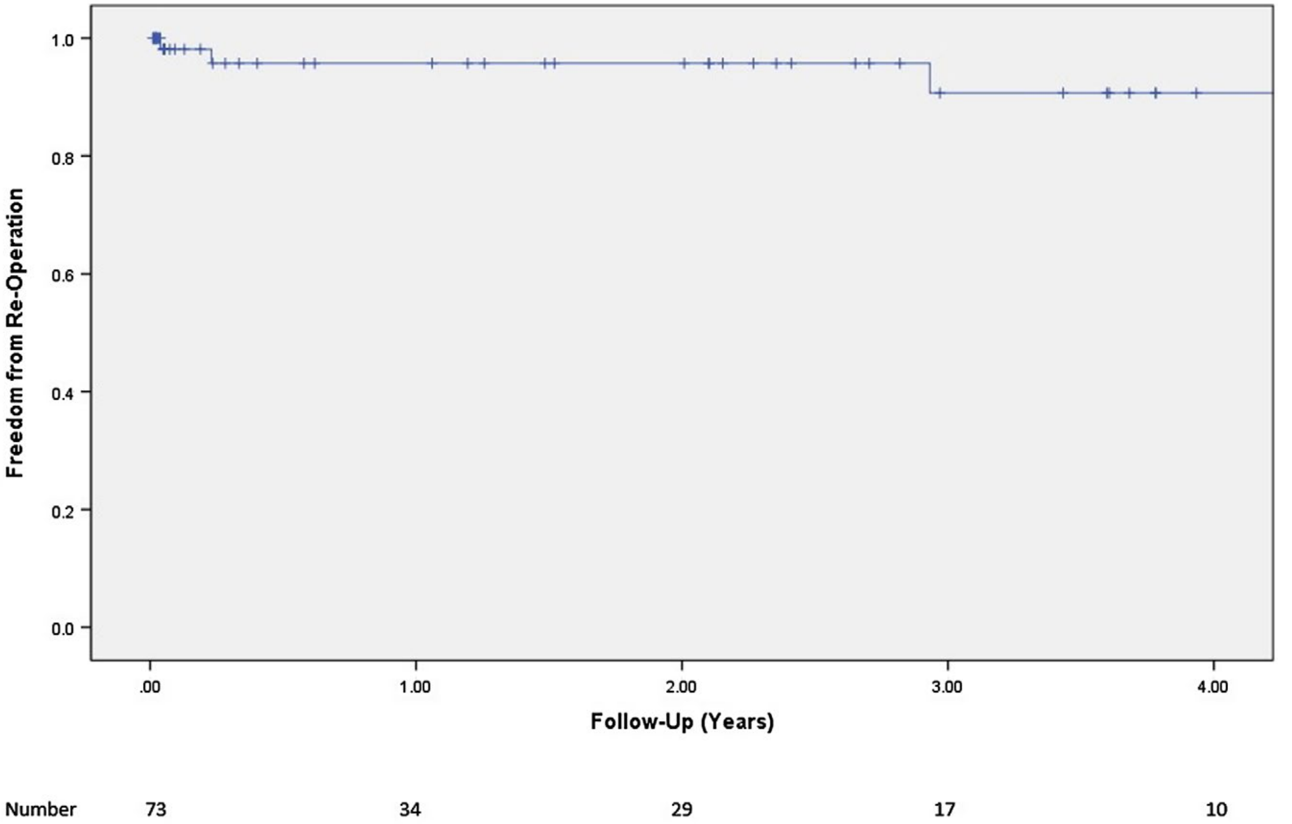


**FIGURE 1** Freedom from reoperation [Colour figure can be viewed at wileyonlinelibrary.com]

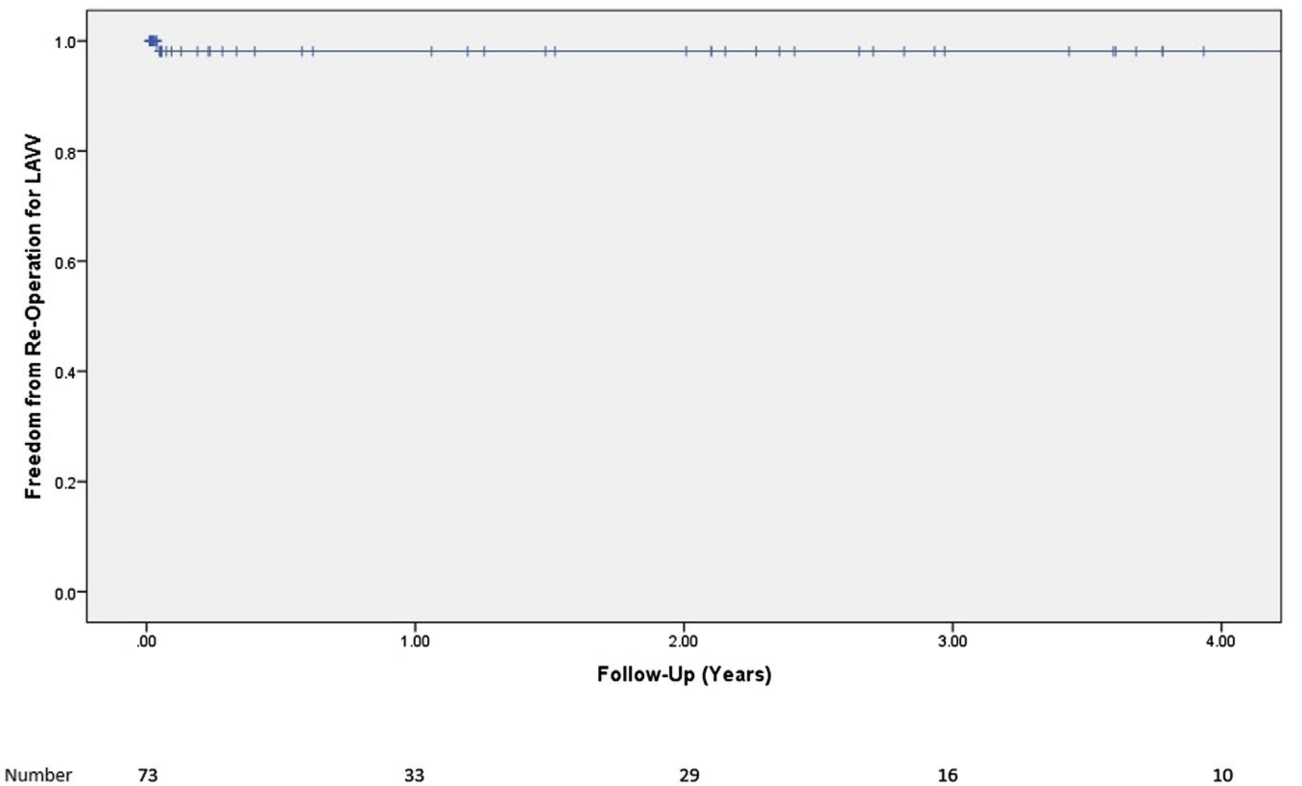


**FIGURE 2** Freedom from reoperation for LAVV [Colour figure can be viewed at wileyonlinelibrary.com]

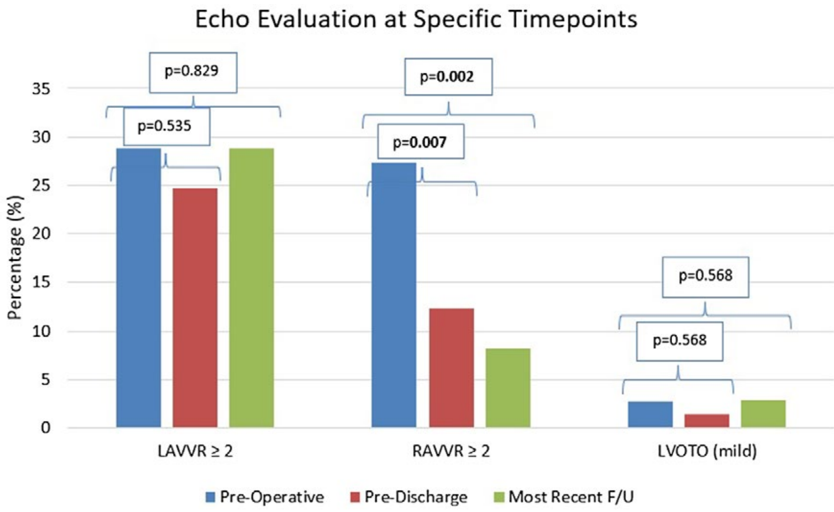


**FIGURE 3** Echocardiography evaluation at different time points [Colour figure can be viewed at wileyonlinelibrary.com]

Surgical correction of atrioventricular canals has undergone continuous improvements regarding the employed surgical techniques, myocardial protection, preoperative management, and decreased age at repair.[7,8] The realization that the atrioventricular valves in hearts with endocardial cushion defects are actually unique structures, and not merely distortions of the usual mitral or tricuspid valves,[9] has been critical for the surgical approach to repair. This factor alone has resulted in the various attempts at enhancement of surgical techniques and methods for the management of this condition. As a result, significant improvement in surgical outcomes for CAVC patients has been realized in recent decades, with a decline in early mortality to 2%, an estimated 10-year survival of 90%, and freedom from reoperation of 83%-95%.[8,10,11] Nevertheless, postoperative short-term and long-term AVV dysfunction, late LVOTO, and residual VSDs remain problematic,[10,12] all of which are affected, in part, by the technique of VSD patch closure.

The ideal patch material for septal defect closure used in congenital cardiac surgery would theoretically be compatible with growth, pliable, resistant to tearing/calcification/shrinkage, would accept sutures without difficulty yet would be hemostatic, and would heal without scar formation. Bovine and autologous pericardial patches are currently the most commonly used materials for cardiac repairs; however, long-term results demonstrate calcification, thickening, and retraction of the patch. Polytetrafluoroethylene (Gore-Tex) is another common patch material but has also shown progressive calcification,[13] which predisposes to paravalvular leak in the annular position. CorMatrix is a novel extracellular matrix (ECM) material synthesized from decellularized porcine small intestinal submucosa, known to be rich in matrix elements, including matrix-bound growth factors that are thought to support cell growth and differentiation, making it in theory an ideal tissue scaffold.[14,15] Its use for the repair of CAVC defects has been investigated in a large series.

The reported results of this study are comparable to previously reported data. Specifically, when comparing our results to previously published papers, including a prior series of our own that included surgeons who do not use CorMatrix for VSD closure, we demonstrated similar rates of complications and reinterventions.[16-18] Both patients who required reoperations for residual VSDs were in fact technical errors; in one, the true posterior-inferior edge of the VSD was misjudged and in the other, a second posterior muscular VSD, separated by a muscle bar from the true inlet VSD, was missed entirely. Thus, neither residual VSD was due to patch failure or patch dehiscence. Furthermore, in the present series, only 3 (4%) patients required reoperation *specifically* for their left AVV, which compared favorably with previously published reports.[6,8,11,15,18-25] The rate of left AVV plasty or replacement is higher at 5 (6.8%) and 1 (1.3%), respectively, because some of the patients who had reoperations for residual septal defects also underwent “touch-up” procedures on their AVV’s that they wouldn’t have needed otherwise. Finally, the incidence of LVOTO requiring reintervention after primary repair of CAVC reported in the literature varies from 0.5% to 4.5%,[15,26-29] which again compares favorably with our rate of 1.3%. A study conducted by Ashfaq et al[30] followed 15 patients who had undergone CAVC repair using CorMatrix as a patch for an average of 3.7 years. They were able to demonstrate excellent results however considered their sample size too small to reach a definitive conclusion on this patch material. Another interesting observation from our study was the choice of repair made. While some surgeons opt to perform all CAVC repairs using a 2-patch technique, while others prefer treating their patients with the modified single-patch repair, at our institution, the choice of repair depends on the VSD. The extent of the VSD, both posteriorly/inferiorly and toward the membranous area, is studied intraoperatively and noted. If the VSD was seen of being shallow in nature (2-3 mm), it is closed primarily using the modified single-patch “Australian repair” technique, while the two-patch technique is utilized for VSD’s of a deeper nature. This individualistic stratification scheme for the repair of CAVC’s has been seen to produce the best results at our institution.

This study has limitations. The retrospective study design is subject to inherent selection bias. A single institution and single surgeon experience may not be generalizable to other surgeons and institutions. However, the present single surgeon report reduces the degree of confounding that often exists in surgical series due to variations in surgical technique for CAVC repair. The reported results are limited to a medical record review at our institution as well as follow-up with families and referring cardiologists; therefore, it is possible that reoperations could have occurred at other institutions without our knowledge. The reported results are limited to short-term follow-up and do not provide perspective on long-term durability of CAVC repair and the effects of using a CorMatrix VSD patch. Further analysis regarding this population is warranted, including longer follow-up echocardiography to assess current valve function. Nevertheless, to our knowledge, this study represents the largest analysis of CAVC repair with routine use of CorMatrix VSD closure and addresses a current gap in clinical and surgical knowledge regarding the use of this material within existing literature.

## 5 | CONCLUSIONS

Based upon the present results, a standardized approach to CAVC repair utilizing a CorMatrix patch for VSD closure produces good results with equivalent outcomes to other commonly used patch materials when compared to other series in the literature. CorMatrix provides a surgeon-friendly material with ease of use and pliability. While clinically significant left atrioventricular valve regurgitation continues to be a potential long-term problem following CAVC repair, future analyses will help determine whether our standardized approach with CorMatrix VSD patch closure coupled with reinforced annuloplasty will improve upon currently reported AVV reintervention rates.

## ETHICAL APPROVAL

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

## CONFLICTS OF INTEREST

Dr Emile Bacha is an Advisory Board Member at Aziyo. The remaining authors declare that they have no conflict of interest.

## AUTHOR CONTRIBUTIONS

*Eliana Al Haddad*: data collection, data analysis/interpretation, drafting article, statistics.

*Damien J. LaPar*: data analysis/interpretation, critical revision of the article, approval of the article.

*Jeffrey Dayton*: data analysis, data interpretation, statistics.

*Elizabeth H. Stephens*: data collection, data analysis/interpretation.

*Emile Bacha*: concept/design of the study, critical revision of the article, approval of the article.

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