

Fetal Cardiac Interventions: A Review of The Current Literature

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Abstract

Congenital heart disease (CHD) is the most common birth defect. Fetal cardiac intervention (FCI) is a novel and evolving field that has enabled us to modify the progression of CHDs and favorably change the postnatal outcomes by altering in utero anatomy and physiology. FCIs are only indicated in specific CHDs; CHDs diagnosed during midgestation that may progress and worsen in utero and cause fetal mortality and neonatal morbidity/mortality may benefit from FCI. These include fetal aortic valvuloplasty in severe aortic stenosis evolving to hypoplastic left heart syndrome (HLHS), fetal pulmonary valvuloplasty in pulmonary atresia with intact ventricular septum, critical pulmonary stenosis, atrial septoplasty and/or atrial stent in established HLHS, and transposition of great vessels with restricted or intact atrial septum. This review focuses on commonly performed interventions, candidate selection criteria, technical details, and outcomes of these procedures, which have been previously reported in the literature. Literature data about FCIs have demonstrated that technical success has improved, FCIs have limited maternal risks, and they do not cause any significant complications. Careful selection of candidates suitable for FCI, a multi-team approach, and performing these interventions in specialized centers and in collaborations will further improve the results.

Keywords: Congenital heart disease, fetal intervention, fetal aortic valvuloplasty, fetal pulmonary valvuloplasty, hypoplastic left heart syndrome, pulmonary atresia with intact ventricular septum

Introduction

Congenital heart disease (CHD) is the most common birth defect, with an incidence of approximately 6 per 1000 live births⁽¹⁾. Advances in fetal imaging have

provided a better understanding of the evolution of CHDs in utero. Some CHDs may progress during fetal life and may cause significant morbidity and mortality. Fetal cardiac intervention (FCI) is a novel and evolving field



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that has enabled us to modify the progression of CHDs and favorably change postnatal outcomes by altering in utero anatomy and physiology.

FCIs are only indicated in specific CHDs; CHDs diagnosed during midgestation that may progress and worsen in utero and cause fetal mortality and neonatal morbidity/mortality may benefit from FCI. These include fetal aortic valvuloplasty (FAV) in severe aortic stenosis (AS) evolving to hypoplastic left heart syndrome (HLHS), fetal pulmonary valvuloplasty in pulmonary atresia with intact ventricular septum PA/IVS, critical pulmonary stenosis (CPS), atrial septoplasty and/or atrial stent in HLHS, and transposition of great vessels with restricted or intact atrial septum⁽²⁻⁵⁾. This review focuses on these commonly performed interventions, selection criteria of the candidates, technical details, and outcomes of these procedures that have been previously reported in the literature. FCs have started in 1975 to treat fetal ventricular tachycardia⁽⁶⁾. In 1987, the first fetal cardiac pacing was performed in a fetus with complete heart block and hydrops fetalis⁽⁷⁾. The first fetal aortic balloon valvuloplasty was performed in 1991, and the infant eventually underwent biventricular (BiV) repair⁽⁸⁾.

FAV In Severe AS with Evolving HLHS

FAV is the most commonly performed FCI. Severe AS may initially present as midgestational dilation and dysfunction. Subsequently, slowing and ultimate cessation of left ventricular (LV) growth is observed, leading to HLHS⁽⁹⁾. Despite advances in the surgical management of HLHS, medium-term survival is approximately 70%, and HLHS still causes significant morbidity, including arrhythmias, neurocognitive impairment, hepatic dysfunction, and fontan-specific complications (protein-losing enteropathy, plastic bronchitis etc.) after surgery. In fetuses with severe AS, if FAV is performed at an appropriate period, it may stop or reduce progression to HLHS, and reduction of LV pressure load may prevent the formation of endocardial and myocardial fibrosis. The aim of FCI is to achieve BiV circulation and improve postnatal outcomes^(10,11).

Selection of Candidates

The main challenge in performing FAV is to identify fetuses that will progress to HLHS if left untreated. Mäkilä et al.⁽¹²⁾ demonstrated that significant LV dysfunction, narrow aortic jet with a Doppler velocity >2 m/s, retrograde aortic arch flow, left-to-right flow across the patent foramen ovale, monophasic mitral inflow, neo-development of mitral regurgitation, and abnormal pulmonary vein flow are predictive of progression to HLHS at birth. The mitral valve, aortic valve, ascending aortic diameter Z-score, and LV length were not found to be significant parameters of progression to HLHS at birth.

Careful selection of candidates for whom LV recovery may support systemic circulation after FAV is also important. Fetuses with LV hypoplasia (long-axis Z-score <-2), mitral valve hypoplasia (Z-score <-2) or low LV pressure assessed by mitral regurgitation or AS jet velocity (estimated LV pressure <30 mmHg) should not undergo FCI, as these factors are predictors of low probability of LV recovery and strong predictors of single ventricle circulation despite technically successful FAV. McElhinney et al.⁽¹³⁾ presented a multivariate scoring system to predict criteria for a BiV outcome. At least four of the following criteria predicted a BiV outcome: (1) LV long-axis Z-score >0 , (2) LV short-axis Z-score >0 , (3) aortic annulus Z-score >-3.5 , (4) mitral valve annulus Z-score >-2 , and (5) AS (or mitral regurgitation) with a maximum systolic gradient of ≥ 20 mmHg⁽¹³⁾. In 2018, Friedman et al.⁽¹⁴⁾ analyzed 123 fetuses that underwent FAV for evolving HLHS at Boston Children's Hospital between 2000 and 2015. They reported that LV pressure >47 mmHg and ascending aortic Z-score >0.57 are predictors of BiV circulation with 92% probability. Fetuses with a lower LV pressure or mitral valve Z-score <0.1 and mitral valve inflow time Z-score <-2 were unlikely to have BiV circulation with a 9% probability. The remaining fetuses had an intermediate (~ 40 -60%) probability of BiV circulation.

Technical Aspects and Outcomes

The procedure is performed percutaneously with ultrasound guidance under regional (spinal/epidural) or local anesthesia or both between 21 and 32 gestational weeks. The most important aspect of successful procedure is the fetal position, with the fetal chest lying anteriorly. Intramuscular fetal anesthesia and muscle relaxants are used to facilitate fetal pain relief and appropriate fetal positioning. With ultrasound guidance, passing through the maternal abdomen, uterine wall, anterior fetal chest, and LV, 18-G/19-G Hawkins Atkins needle/Chiba needle/M3 coaxial needle and stylet is advanced into the LV apex. A 0.014" coronary guidewire is then maneuvered across the LV outflow tract, and the Maverick/Hiyuru/Relysis coronary artery balloon is positioned at the aortic annulus (Figure 1). The balloon-to-annulus ratio of 1-1.2 (range: 0.7-1.4) provides the best results. The balloon is then inflated, usually twice. After the procedure, technical success was confirmed by Colozr-Doppler findings of a broader jet of anterograde flow across the aortic valve and/or new aortic regurgitation⁽¹⁰⁾. Complications include pericardial effusion, tamponade, and bradycardia, which require immediate intervention with pericardiocentesis

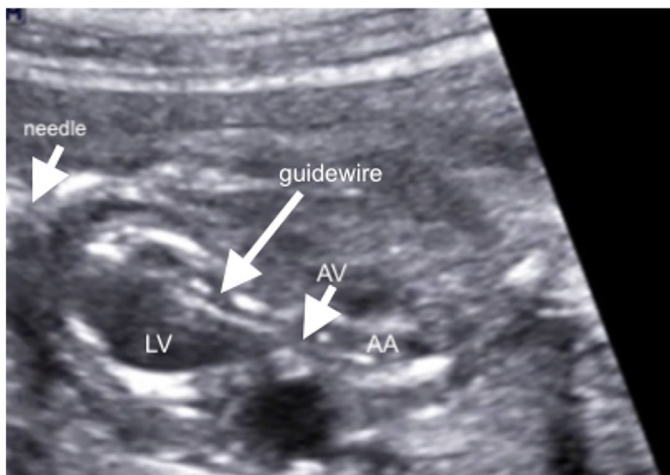


Figure 1. Ultrasound view showing an 18-G needle passing through the maternal abdomen, uterus, fetal anterior chest, and left ventricular apex (24). The coronary guidewire was advanced through the needle, passing through the aortic valve and ascending aorta. LV: Left ventricular, AV: Aortic valve, AA: Ascending aorta

or intracardiac administration of epinephrine or atropine, respectively. Fetal aortic regurgitation is the most common complication that resolves within a few weeks.

In 2014, Freud et al.⁽¹¹⁾ analyzed the short- and intermediate-term survival of fetuses who underwent FAV in Boston Children's Hospital between 2000-2013. They reported a technical success rate of 77% in 100 FAV procedures, fetal demise rate of 11%, and 43% of these patients underwent BiV repair. Among all live-born patients, those who underwent a technically successful intervention were significantly more likely to have a BiV outcome than those in whom the FAV was unsuccessful (odds ratio, 5.0; 95% confidence interval, 1.3-18.8; $p=0.01$). The 10-year survival of the cohort was 72%, which is comparable to the 10-year survival reported for patients with HLHS in other contemporary series.

According to the International Fetal Cardiac Intervention Registry (IFCIR) data in 2015, which included FCI results between 2001 and 2014, in which 18 centers participated, a technical success rate of 81% was achieved in additional 86 FAV procedures, and a fetal demise rate of 17%. In this series, there was a suggestion

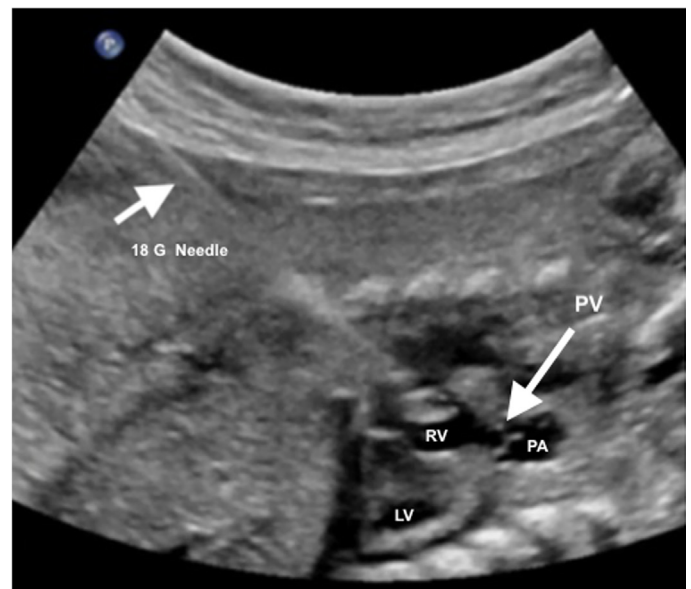


Figure 2. Ultrasound image showing an 18-G needle passing through the maternal abdomen, uterus, fetal anterior chest wall, and right ventricle (24). LV: Left ventricle, PA: Pulmonary artery, PV: Pulmonary valve, RV: Right ventricular, 18-G: 18-Gauge

of improved survival to discharge with BiV circulation; 42.9% in the FAV group versus 19.4% in patients in whom FAV was not performed or were technically unsuccessful, respectively⁽²⁾.

The largest reported series of FAVs (n=136) were from Boston Children's Hospital. In 2018, Friedman et al.⁽¹⁴⁾ evaluated whether technical success and BiV outcomes after FAV have changed from an earlier (2000-2008) to a more recent (2009-2015) era. In this cohort, the technical success rate was initially 73% and increased to 94%, whereas the fetal demise rate was initially 9.8% and reduced to 6%. BiV circulation was achieved in 41% of live births, with a higher rate of 59%, more recently.

None of the previous studies reported maternal mortality or significant complications related to FCI. Approximately 50% of patients with BiV circulation require aortic valve balloon dilation within the first few years of life, whereas the rest require multiple cardiac catheterizations and surgeries. The postnatal evaluation of BiV post-FAV patients demonstrated that these patients still have LV systolic/diastolic dysfunction and aortic and mitral valve abnormalities. Most patients require interventions after birth, including interventions to the aortic and mitral valve and aortic arch, and endocardial fibroelastosis resection⁽¹¹⁾. LV diastolic dysfunction/non-compliance is common, and the development of restrictive LV physiology with left atrial (LA) and pulmonary hypertension remains a concern⁽¹¹⁾.

In conclusion, the proportion of patients achieving BiV outcomes after FAV has improved because of the improved technical success rate and modification of the selection criteria. Although the initial short-term results and postnatal outcomes are encouraging, medium- and long-term survival data are not yet available.

Pulmonary Valve (PV) Perforation and FPV in PA/IVS or CPS

In fetuses with PA/IVS or CPS, elevated right ventricular (RV) afterload results in RV hypertrophy and

reduced compliance, a lack of flow through the right side of the heart, which leads to progressive RV and tricuspid valve (TV) growth arrest, and secondary damage of the RV myocardium. Most fetuses with PA/IVS or CPS with hypoplastic right heart syndrome survive until birth, but they have high morbidity and mortality in postnatal life. In selected fetuses, in utero FPV may lead to a larger RV by reducing afterload and increased filling, thus improving the likelihood of a BiV outcome. The procedure is usually performed between 21 and 32 weeks of gestation in fetuses with membranous PA/IVS or CPS. The exclusion criteria were muscular atresia of the right ventricular outflow tract (RVOT), severe TR with low velocity (<2.5 m/s), severe fetal edema, and presence of large RV sinusoids.

Technical Aspects

Fetal pulmonary valvuloplasty is associated with more technical challenges than FAV. Unlike the LV dilation found in severe AS with evolving HLHS, the RV in these fetuses is small, hypertrophied, and the RV is located under the sternum. The fetal position is again critical for the success of the procedure. The procedure is performed percutaneously with ultrasound guidance under maternal regional (spinal/epidural) or local anesthesia or both. With ultrasound confirmation, an 18 G or 19 G needle is passed through the maternal abdomen, uterus, amniotic cavity, anterior fetal chest wall, and advanced into the RVOT. The RVOT is approached through an intercostal space next to the sternum or by a subcostal approach (Figure 2). The cannula is directed toward the PV and inserted into the RVOT with 10-15-degree angulation. A balloon-annulus ratio of 1.2-1.3 gives the best results. A balloon length of 8-10 mm is usually preferred to prevent RV free wall dilatation⁽¹⁵⁾. The balloon is placed across the PV and dilated to a balloon-to-valve ratio of at least 80%. Technical success was defined as improved antegrade blood flow through the PV, with subsequent improvement in antegrade flow on color Doppler imaging with or without pulmonary regurgitation. Complications include hemopericardium and bradycardia.

Selection of Candidates and Outcomes

Compared with FAV, there are fewer data on the predictors of disease progression in PA/IVS; therefore, selection criteria are not well established.

TV, Z-score and RV size assessment are currently used. Fetuses with TV Z-score >-2.5 usually have BiV circulation with postnatal interventions, whereas those with TV Z-score <-4 have severe RV hypoplasia that is unlikely to support BiV circulation after FPV. Fetuses with TV Z-score between -2.5 and -4 and qualitatively mild or moderate RV hypoplasia are candidates for FPV.

Gómez et al.⁽¹⁶⁾ reported that tricuspid /mitral annulus ratio (TV/MV) ≤ 0.83 , RV/LV length ratio ≤ 0.64 , pulmonary annulus/aortic annulus ratio ≤ 0.75 , tricuspid inflow duration/cardiac cycle length $\leq 36.5\%$ can predict a single ventricular outcome with 100% sensitivity and 98% specificity if three of the four criteria are fulfilled⁽¹⁶⁾.

Some centers have reported good results. Tulzer et al.⁽¹⁷⁾ assessed the immediate effects of FPV on fetal RV size and function, in utero RV growth, and postnatal outcomes. Between 2000 and 2017, 35 FPVs were performed on 23 fetuses with PA/IVS (n=15) or CPS (n=8). The median gestational age was 28 ± 4 weeks. There was no fetal demise. Immediately 1-3 days after successful intervention, RV/LV length and TV/MV ratios, RV filling time, and TV-velocity time integral $\times$ HR increased significantly, and TR velocity decreased significantly. In fetuses followed longitudinally to delivery (n=5), RV/LV length and TV/MV ratios improved further or remained constant until birth. Fetuses with unsuccessful intervention (n=2) became univentricular; all others (n=21) had either a BiV (n=15), one-and-a-half ventricular (n=3), or still undetermined (n=3) outcome. Five of the nine fetuses with a predicted non-BiV outcome, in which the procedure was successful, became BiV, while two of the nine had an undetermined circulation. The authors concluded that FPV immediately led to a larger RV and thus improved the likelihood of BiV outcomes even in fetuses with a predicted non-BiV circulation.

In another single-center study in 2023, FPVs were performed in 13 fetuses with PA/IVS (n=10) or CPS (n=3)⁽¹⁸⁾. The median gestational age was 28 ± 4 weeks. All interventions were successful, and no fetal demise were encountered. Pericardial effusion and persistent bradycardia occurred in 15.4% and 38.5% of patients, respectively. The median follow-up period was 11.5 months (6-17). The median postnatal TV Z-score was 1.57 (1.71-0.83). Postnatally, six patients underwent percutaneous pulmonary valvuloplasty and patent ductus arteriosus stenting at the same time (BiV circulation were achieved in four, two had undetermined circulation), three patients were treated with pulmonary balloon valvuloplasty alone, and one patient did not need any intervention.

According to IFCIR data in 2020, in which 14 centers have participated, between 2001 and 2018, among 70 fetuses who were evaluated as PA/IVS and CPS, 58 underwent FPV, and in 12 fetuses, FPV was not attempted⁽¹⁹⁾. The median gestational age was 26.1 weeks (21.9-31.0) and fetal complications occurred in 55% of the patients (most common pericardial effusion requiring drainage (48%) or bradycardia requiring treatment (36%), including 7 deaths and 2 delayed fetal losses (12%). Among the fetuses who had FPV, 41/58 patients (71%) had technically successful and 15/58 patients (26%) had unsuccessful intervention, and 2 (58) had unknown data. Measurement of TV increased by 0.32 ± 0.17 mm/week from intervention to birth among those who underwent successful FPV and were higher compared with those who did not have FPV or unsuccessful FPV (0.19 ± 0.15 mm/week). Among 60 liveborn with known outcomes, there was a higher percentage of patients with BiV circulation following successful FPV compared to those who had no FPV or unsuccessful FPV (87% vs. 43%).

In conclusion, FPV may be beneficial for PA/IVS or CPS, although the rates of technically unsuccessful procedures and procedure-related complications, including fetal loss, are significant. Because the FCI criteria for FPV are extremely variable, comparison of patients with intervention and nonintervention are challenging.

Therefore, there is a need for prospective case-controlled studies on fetuses with PA/IVS and CPS using uniform criteria for FPV.

Atrial Septoplasty and/or Atrial Stenting in HLHS with Intact or Restricted Atrial Septum (IAS)

HLHS with intact or restricted IAS causes increased LA and increased pulmonary vascular pressure, which increases morbidity and mortality after stage 1 palliation. These patients have higher mortality risks due to increased LA pressure and low cardiac output than HLHS patients with unrestricted atrial septum. Therefore, atrial septoplasty and/or atrial stenting should be performed in the second trimester to prevent pulmonary vascular changes.

Selection of Candidates

The indications for intervention include restricted/intact IAS (≤ 1 mm atrial communication), prominent pulmonary vein flow reversal, and pulmonary venous Doppler forward/reverse velocity time integral ratio < 3 ⁽²⁰⁾.

Technical Aspects and Outcomes

The right or left atrium is punctured perpendicular to the interatrial septum with an 18-G/17-G needle, the stylet, or a 22-G Chiba needle, and atrial septoplasty is performed. Then, a short-length stent (3.5x13 mm) can be inserted. Complications include hemopericardium, stent malposition, and embolization.

According to IFCIR data in 2015, atrial septoplasty was performed in 37 fetuses, and 65% of the patients had successful intervention. However, there was no difference in discharge survival between FCI and non-FCI fetuses⁽²⁾.

The largest single-center experience described 21 atrial septoplasty interventions, 13/21 interventions resulted in an atrial communication ≥ 2.5 mm, and the pulmonary vein Doppler profile improved in all such patients. The authors concluded that creation of > 3 -mm atrial communication was associated with higher postnatal oxygen saturation and better outcomes after stage 1 palliation⁽²¹⁾.

Another IFCIR study evaluated 47 fetuses who had FCI; 27 with atrial septoplasty alone (atrial perforation/balloon dilation) and 20 with atrial septal stent placement⁽²²⁾. The procedural success rate was 77%, fetal complications were common, and procedure-related fetal demise occurred in 13%. Cesarean delivery, planned immediate postnatal intervention, restrictive foramen ovale (FO), and neonatal resuscitation were less common in those who underwent procedurally successful FCI than in those with unsuccessful FCI or no FCI. There was a trend toward stents performing better than septoplasties in maintaining a nonrestrictive FO at delivery after procedural success (75% versus 39%). The 1-year survival rate was higher (59%) in FCI fetuses with unrestricted FO at birth compared to in non-FCI fetuses (19%).

A recent systematic review and meta-analysis in 2024, which included 31 studies, compared the results of fetal atrial septal intervention (FASI) and expectant management (EM) in fetuses diagnosed with HLHS and intact/restrictive IAS⁽²³⁾. Among 746 fetuses, 123 fetuses had FASI and 623 fetuses had EM. Among the fetuses who had FASI, 87% had a technically successful intervention. Age at neonatal death was higher in the FASI group than in the EM group (17 days vs. 7.2 days). The postnatal atrial restrictive septum was lower in the FASI group (38%), compared to the EM group (88%). Neonatal outcomes, including live birth, neonatal death, and survival to hospital discharge, were similar between the groups.

Conclusion

In conclusion, more studies concerning short, medium and long-term benefits of fetal atrial septoplasty and/or atrial stenting in fetuses with HLHS and intact/restricted IAS are necessary.

We have recently reported our initial experience of FCI in our country⁽²⁴⁾. We performed a total of five FCIs at our university hospital between 26+3 and 28+2 gestational weeks. The procedures were technically successful in two fetuses with CPS and one fetus with critical AS. FPV

was unsuccessful in a fetus with PA/IVS. No fetal death occurred, and there were no procedure-related significant maternal complications. Three interventions were complicated by fetal bradycardia and pericardial effusion necessitating treatment.

International registry data have demonstrated that FCIs have limited maternal risks and can improve technical success. Careful selection of candidates suitable for FCI, a multi-team approach, and performing these interventions in specialized centers and in collaborations will further improve the results.

Footnotes

Conflict of Interest: The author declare no conflicts of interest concerning the authorship or publication of this article.

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