Cardiac magnetic resonance versus routine cardiac catheterization before bidirectional Glenn anastomosis: Long-term follow-up of a prospective randomized trial

David W. Brown, MD,^{a,d} Kimberlee Gauvreau, ScD,^{a,d} Andrew J. Powell, MD,^{a,d} Peter Lang, MD,^{a,d} Pedro J. del Nido, MD,^{b,e} Kirsten C. Odegard, MD,^{c,f} and Tal Geva, MD^{a,d}

Objectives: A previously published randomized clinical trial comparing cardiac magnetic resonance (CMR) versus routine catheterization in patients with functional single ventricle before bidirectional Glenn (BDG) operation demonstrated similar short-term post-BDG outcomes. We sought to assess late outcomes in this cohort to ascertain any long-term effects of this evaluation strategy.

Methods: Retrospective review of enrolled patients through most recent follow-up was performed on all 82 patients in the original cohort, at a median age of 8.8 years.

Results: Of these, 76 (93%) underwent Fontan operation; 2 died before Fontan. Baseline demographics, anatomic factors, and age at BDG did not differ between those randomized to CMR versus catheterization. Although pre-BDG CMR patients were younger at Fontan (2.4 vs 2.7 years; $P = .02$), baseline weight, body surface area, oxygen saturation, ventricular function, and degree of atrioventricular valve regurgitation were similar. Catheterization before Fontan ($n = 76$) demonstrated similar hemodynamic parameters including pulmonary vascular resistance and mean pulmonary artery, atrial, and ventricular end-diastolic pressures. CMR patients had comparable rates of transcatheter interventions (71% vs 79%; $P = .6$), including coil occlusion of systemic–pulmonary collaterals (66% vs 61%; $P = .29$). At Fontan surgery, short-term complications, hospital length of stay, and the percent meeting a 5-part definition of successful Fontan operation were not different (71% vs 55%; $P = .23$).

Conclusions: Pre-BDG CMR and catheterization groups had equivalent clinical and hemodynamic profiles before Fontan and similar post-Fontan outcomes at a median follow-up of 8 years after BDG. For selected patients, a pre-BDG evaluation with CMR is an acceptable alternative to catheterization. (J Thorac Cardiovasc Surg 2013;146:1172-8)

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Patients with congenital heart disease characterized by a functional single ventricle typically undergo a series of palliative operations that result in passive systemic venous flow through the pulmonary circulation and a functional single ventricle supporting the systemic circulation. Anastomosis of the superior vena cava to the pulmonary artery, or bidirectional Glenn (BDG) operation, is a palliative

procedure typically performed in infancy as an intermediate step before completion of a Fontan operation. For many years, routine pre-BDG cardiac catheterization in these patients has been considered the standard of care, providing the assessment of anatomic and hemodynamic suitability for surgery, as well as potential for catheter-based interventions. However, catheterization in this high-risk group of infants is associated with significant morbidity,^{1,2} and exposure to ionizing radiation in childhood has been linked to increased risk of subsequent cancer.³ Retrospective studies have demonstrated that patients are rarely excluded from BDG operation on the basis of findings at cardiac catheterization,^{1,4} and the benefit of some transcatheter interventions performed in this setting has been questioned.⁵⁻⁷

More recently, cardiac magnetic resonance (CMR) imaging has emerged as a useful diagnostic tool in the assessment of patients with a wide range of congenital heart disease, including those with functional single ventricle, allowing for the accurate evaluation of thoracic vascular anatomy,⁸ blood flow,⁹ ventricular volume and function,¹⁰ and myocardial viability. Unlike echocardiography, which greatly depends on acoustic windows and indeed has been demonstrated to correlate poorly with catheter angiography for the

From the Departments of Cardiology,^a Cardiovascular Surgery,^b and Anesthesia,^c Children's Hospital Boston, and Departments of Pediatrics,^d Surgery,^e and Anesthesia,^f Harvard Medical School, Boston, Mass.

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Address for reprints: David W. Brown, MD, Department of Cardiology, Children's Hospital Boston, 300 Longwood Ave, Boston, MA 02115 (E-mail: david.brown@cardio.chboston.org).

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Abbreviations and Acronyms

AV	= atrioventricular
BDG	= bidirectional Glenn
CMR	= cardiac magnetic resonance
SPC	= systemic–pulmonary collateral

assessment of thoracic vasculature in these patients,¹¹ CMR is not hindered by acoustic windows or geometric constraints and has been proposed as a noninvasive imaging alternative to routine catheterization before BDG.^{1,8}

We² previously performed a single-center, prospective randomized clinical trial to test the hypothesis that a noninvasive imaging strategy using CMR could provide the necessary anatomic and functional information required to safely evaluate such patients (ClinicalTrials.gov number: NCT00112424). Eighty-two patients presenting for BDG were randomized to either CMR or catheterization before BDG and were followed up through the perioperative period to 3 months after BDG. Routine cardiac catheterization was associated with higher rates of minor adverse events (36 vs 3 patients; $P < .001$), longer hospital stay (2 vs days; $P < .001$), and higher hospital charges than CMR for the pre-BDG evaluation. In addition, the study also found no detectable differences in immediate and short-term postoperative outcomes.

However, the clinical follow-up period for this trial was only 3 months after BDG, raising issues regarding the potential for longer-term differences in outcomes between the 2 groups. Of particular interest was the fact that pre-BDG transcatheter interventions, which were not specified by trial design but left up to the discretion of the operator, were performed in 41% of patients in the catheterization arm of the study as opposed to 2% in the CMR group. This raises the possibility of a potential benefit for the catheterization group over the longer term from such interventions if there is a delayed therapeutic effect. We thus sought to determine whether longer-term effects of a noninvasive pre-BDG imaging strategy could be demonstrated through comprehensive follow-up of the original cohort including subsequent interventions, diagnostic imaging studies, operations, and clinical status at most recent follow-up.

METHODS

Patients

A complete description of the enrollment criteria and study design for the original trial may be found in the original report.² In brief, eligible patients were between the ages of 2 months and 5 years referred to Boston Children's Hospital for preoperative evaluation before BDG operation and had no contraindication to CMR (eg, pacemaker). After a protocol-mandated screening echocardiogram, patients were excluded for predefined indication(s) for cardiac catheterization, including pulmonary vein stenosis, pulmonary hypertension, severe ventricular dysfunction, severe atrioventricular (AV) valve regurgitation, known large systemic–

pulmonary artery or venous collateral vessels, or coarctation of the aorta (defined as $>50\%$ narrowing of the aortic isthmus relative to the descending aorta or ≥ 3 m/s peak Doppler flow velocity). In the absence of exclusion criteria and after informed consent, patients were enrolled and randomized in a 1:1 fashion to either cardiac catheterization or CMR; modality crossover after randomization was permitted. Data collection began at the time of enrollment and continued prospectively through preoperative evaluation, operative and postoperative hospitalization, and clinical assessment 3 months after surgery for the original study.

For the current investigation, continued follow-up of the original cohort was performed by review of clinical records through most recent clinical evaluation, loss to follow-up, or death. Data collected included clinical variables and outcomes between BDG operation and any subsequent interventions, including preoperative echocardiographic and cardiac catheterization data, operative and postoperative in-hospital clinical data, and subsequent course through the most recent clinical follow-up visit.

Diagnostic Data

Echocardiographic parameters of cardiovascular anatomy and function deemed relevant in this setting¹² were collected from the report of the interpreting staff echocardiographer for the pre-Fontan echocardiogram. In brief, this included assessment of systemic and pulmonary veins, atrial septum, AV valve(s) structure and function, ventricular anatomy and function, outflow tract(s) and semilunar valve function, aortic arch, and mediastinal branch pulmonary arteries. Secondary review of images was performed in a blinded fashion to verify any missing information or to establish degree of aortic arch obstruction or pulmonary artery stenosis. Pulmonary artery stenosis was graded as moderate or greater with 50% or greater narrowing of the affected segment relative to the adjacent unobstructed luminal diameter. Distal aortic arch obstruction by echocardiogram was defined as a Doppler maximum velocity, corrected for proximal velocity, of 1.5 m/s or more. AV valve regurgitation was categorized as none/trivial, mild, moderate, or severe; although grading definitions were not prespecified by the trial, typical assessment in our echocardiography laboratory is based on width of the vena contracta by color Doppler relative to systemic AV valve annulus diameter, visualized from 2 orthogonal views. Similarly, systemic ventricular function was graded qualitatively as normal (ejection fraction $\geq 50\%$), mild (ejection fraction 40%–50%), moderate (ejection fraction 30%–40%), and severe dysfunction (ejection fraction $<30\%$).

Patients who had subsequent cardiac catheterizations underwent the procedure according to clinical practice in our laboratory, which were performed under intravenous sedation or general anesthesia as deemed appropriate by the managing team.¹³ Hemodynamic and angiographic parameters and type and number of any interventions performed were recorded. For patients whose interventions included coil occlusion of systemic–pulmonary collateral (SPC) vessels, all angiograms underwent secondary review by a single investigator blinded to original randomization (double-blind) to assess the number of vascular territories addressed by coil occlusion (eg, excessive SPC circulation arising from the right internal thoracic artery was categorized as 1 vascular territory).

Outcomes

For those who proceeded to Fontan surgery, outcomes from Fontan surgery included the following: (1) intraoperative and postoperative complications; (2) a composite score of a successful Fontan procedure, comprised of (a) hospital length of stay of 14 days or less, (b) thoracostomy tube drainage of 10 days or less, (c) oxygen saturation of 85% or more at the time of hospital discharge, (d) no unplanned postoperative interventions or procedures, and (e) no hospital readmission within 30 days of discharge; and (3) clinical assessment at most recent follow-up including cutaneous oxygen saturation, clinical well-being, and frequency of new diagnoses or re-intervention. Clinical well-being included no decline in New York Heart Association functional class, no decline in ventricular function, and

worsening of AV valve regurgitation. The aforementioned 5-element definition of a successful Fontan procedure was developed using a modified Delphi method¹⁴ by a committee of senior pediatric cardiologists and a congenital heart surgeon from our institution not associated with the study.

Statistical Analysis

Analyses were performed on an intention-to-treat basis according to the original trial randomization. Patient characteristics and outcomes were compared for those randomized to CMR versus catheterization using the 2-sample *t* test or Wilcoxon rank sum test for continuous variables and Fisher's exact test for categorical variables. A secondary analysis for actual treatment received per protocol before BDG was also performed.

The study complies with the Declaration of Helsinki and was approved by the Boston Children's Hospital Committee on Clinical Investigation. Informed, written consent was obtained from all parents or legal guardians. We had full access to and take full responsibility for the integrity of the data. We have all read and agree to the manuscript as written.

RESULTS

Patient Characteristics

Of the 92 patients eligible for inclusion in the original study, 10 were not enrolled on the basis of exclusion criteria by screening echocardiogram (aortic coarctation in 7 patients and pulmonary vein stenosis, restrictive atrial septum, and suspected pulmonary hypertension in 1 each). All remaining 82 patients had informed consent obtained, were enrolled in the study, and randomized. Three patients in the original study crossed over to the alternative preoperative evaluation arm and underwent both CMR and catheterization. No patients withdrew from the study; all patients underwent BDG anastomosis and were subsequently followed up through most recent clinical evaluation. No patients were lost to follow-up. Baseline characteristics were similar between groups in age, gender, race, ventricular anatomy, prior operations, body surface area, and oxygen saturation (Table 1).

Patients Not Referred for Fontan Completion

Of the 82 patients in the original study cohort, 6 (7%) were not referred for Fontan completion. Two patients with mild left ventricular hypoplasia were referred for BDG takedown and 2-ventricle repair, both in the CMR arm of the original study. In 2 patients BDG was the definitive palliation, both with pulmonary atresia and intact ventricular septum and moderate right ventricular hypoplasia, with 1 patient in each arm of the original study. There were 2 (2.4%) deaths that occurred in the period between BDG and planned Fontan operation, both patients with hypoplastic left heart syndrome, progressive tricuspid regurgitation, and right ventricular failure; both were randomized to the catheterization arm. One patient died at age 10 months of heart failure awaiting heart transplantation and the other died suddenly out of the hospital at age 14 months. No patients were lost to follow-up. The remaining 76 underwent pre-Fontan evaluation including catheterization followed by Fontan completion.

TABLE 1. Patient characteristics

	Catheterization (n = 41)	CMR (n = 41)	P value
Age at BDG (mo)	4.8 (2.0-11.9)	5.4 (2.2-10.4)	.14
Gender			
Male	25 (61)	24 (59)	1.0
Female	16 (39)	17 (41)	
Race			
White	28 (68)	29 (71)	.77
Black	9 (22)	6 (15)	
Hispanic	4 (10)	5 (12)	
Asian	0	1 (2)	
Ventricular anatomy			
HLHS	23 (56)	20 (49)	.68
Tricuspid atresia	4 (10)	7 (17)	
PA/IVS	2 (5)	5 (12)	
Double-inlet LV	5 (12)	5 (12)	
Single RV	4 (10)	1 (2)	
Complex 2-ventricle	2 (5)	2 (5)	
Unbalanced AV canal	1 (2)	1 (2)	
Underwent Fontan	38 (93%)	38 (93%)	1.0
Pre-Fontan echo data	n = 38	n = 38	
Body surface area (m ²)	0.57 (0.43-0.66)	0.53 (0.43-0.66)	.36
Oxygen saturation (%)	85 (65-93)	84 (76-90)	.08
Ventricular dysfunction			
None	28 (74)	34 (89)	.13
Mild	8 (21)	2 (5)	
Moderate	2 (5)	2 (5)	
Systemic AV valve regurgitation			
None/trivial	15 (39)	29 (76)	.002
Mild	22 (58)	9 (24)	
Moderate	1 (3)	0 (0)	
Suspected aortic arch obstruction*	9 (24)	5 (13)	.38
LPA stenosis			
None	13 (34)	16 (42)	.61
Mild (25%-50%)	4 (11)	2 (5)	
Not visualized	21 (55)	20 (53)	
RPA stenosis			
None	19 (50)	23 (61)	.49
Mild (25%-50%)	0 (0)	0 (0)	
Not visualized	19 (50)	15 (39)	
Pulmonary venous obstruction			
None	34 (89)	32 (84)	.74
Mild	0 (0)	1 (3)	
Not visualized	4 (11)	5 (13)	

Values are median (range) or count (percent). CMR, Cardiac magnetic resonance; BDG, bidirectional Glenn; HLHS, hypoplastic left heart syndrome; PA/IVS, pulmonary atresia with intact ventricular septum; LV, left ventricle; RV, right ventricle; AV, atrioventricular; LPA, left pulmonary artery; RPA, right pulmonary artery. *See Methods section.

Pre-Fontan Imaging Data

For those referred for pre-Fontan evaluation (n = 76), preoperative echocardiographic findings were similar in the 2 study groups (Table 1). Most patients had mild (or less) ventricular dysfunction and mild (or less) AV

valvular regurgitation. Suspected distal aortic arch obstruction by echocardiogram was common but occurred with similar frequency in the 2 groups. Mediastinal branch pulmonary arteries were frequently not able to be adequately visualized, as has been reported in this setting,¹¹ but when visualized, stenosis was uncommon in both groups. Pulmonary vein stenosis was present in 1 patient.

Pre-Fontan Catheterizations

All patients who proceeded to Fontan operation underwent preoperative cardiac catheterization (n = 76, Table 2). Four patients had more than 1 catheterization between BDG and Fontan operations: 2 with recurrent coarctation had repeat catheterizations for balloon dilation, 1 with elevated filling pressures and excessive SPC vessels had a repeat hemodynamic catheterization, and 1 with stenosis of the left upper pulmonary vein underwent repeat catheterization for balloon dilation. Patients in the CMR arm of the study underwent catheterization at a younger age and sooner after BDG than those in the catheterization arm. Patients in the CMR arm had slightly higher measured cardiac index, but all other

hemodynamic parameters obtained at catheterization were similar between groups, including common atrial and ventricular end-diastolic pressures, mean pulmonary artery pressure, pulmonary/systemic flow ratio, and calculated pulmonary vascular resistance. The frequencies of distal arch obstruction and pulmonary artery stenosis were similar between groups.

Transcatheter Interventions

Interventions performed at pre-Fontan catheterization were common, occurring in approximately 70% of the whole cohort, with no difference between patients in the 2 study arms (Table 3). The most common intervention performed was coil occlusion of excessive SPC vessels (Figure 1), which occurred in about two thirds of patients and did not differ between groups. When SPC interventions were analyzed by the number of vascular territories addressed by coil occlusion, the median number of vascular territories (2) was also similar between groups, as were the number of patients in each group with 3 to 4 vascular territories addressed. Other less commonly performed interventions, such as balloon dilation of branch pulmonary arteries or recurrent coarctation, did not differ between groups.

TABLE 2. Pre-Fontan catheterization

	Catheterization (n = 38)	CMR (n = 38)	P value
Age at pre-Fontan catheterization* (y)	2.7 (1.8-4.3)	2.3 (1.5-3.8)	.003
Time from BDG to pre-Fontan catheterization (y)	2.2 (1.3-4.0)	1.7 (1.0-3.2)	.001
Less than 1 pre-Fontan catheterization†	1 (3)	3 (8)	.62
Fluoroscopy time (min)	51 (20-93)	45 (22-112)	.25
Aortic saturation (%)	86 (72-91)	85 (73-96)	.17
Cardiac index (L · min ⁻¹ · m ⁻²)	3.4 (2.1-9.4)	3.9 (2.1-5.7)	.04
Common atrial mean pressure (mm Hg)	8 (4-16)	9 (3-14)	.79
Ventricular end-diastolic pressure (mm Hg)	8 (4-16)	8 (3-14)	.85
Pulmonary artery mean pressure (mm Hg)	12 (8-22)	13 (8-23)	.75
Qp:Qs ratio	0.7 (0.4-1.8)	0.6 (0.4-1.0)	.06
Pulmonary vascular resistance (Wood units/m ²)	1.5 (0.5-3.8)	1.5 (0.9-3.1)	.67
Distal aortic arch obstruction (≥10 mm Hg)	3 (8)	2 (5)	.79
≥Moderate LPA stenosis‡	2 (5)	1 (3)	.79
≥Moderate RPA stenosis	1 (3)	1 (3)	1.0

Values are median (range) or count (percent). CMR, Cardiac magnetic resonance; BDG, bidirectional Glenn; Qp:Qs, pulmonary flow/systemic flow; LPA, left pulmonary artery; RPA, right pulmonary artery. *For the 4 patients with more than 1 catheterization in the interval between BDG and Fontan operations, hemodynamic data from the study intended to be the pre-Fontan study are presented. †Repeat balloon dilation of recurrent coarctation in 2 patients, repeat dilation of isolated pulmonary vein stenosis in 1 patient, and repeat assessment of elevated filling pressures in 1 patient. ‡Moderate stenosis defined as 50% or greater narrowing relative to the adjacent unobstructed lumen diameter; see Methods section for details.

Surgical Fontan Data

Similar to age at catheterization, patients in the CMR arm were slightly younger at the time of the Fontan operation (Table 4). The majority of patients underwent lateral tunnel fenestrated Fontan with no difference in Fontan type between groups. Patients in the catheterization arm underwent more additional intraoperative procedures. There was 1 intraoperative complication in each group: a patient with Fontan pathway obstruction required baffle revision and

TABLE 3. Pre-Fontan catheterization interventions

	Catheterization (n = 38)	CMR (n = 38)	P value
Patients with any catheterization intervention	30 (79)	27 (71)	.60
Interventions type	30	27	.44
Coil occlusion SPC	23	25	.81
Coil occlusion VV collateral	5	3	.71
Pulmonary artery balloon dilation	6	4	.74
Coarctation balloon dilation	5	1	.20
If coil occlusion of SPCs, median No. of vascular territories addressed*	2 (1-4)	2 (1-3)	.15
1 vascular territory	8	12	.29
2 vascular territories	10	12	
3 vascular territories	4	1	
4 vascular territories	1	0	

Values are median (range) or count (percent). CMR, Cardiac magnetic resonance; SPC, systemic-pulmonary collateral; VV, venovenous. *For excessive SPC collateral flow, vascular territories were defined by feeding blood vessel arterial supply; see Methods section for details.

FIGURE 1. Systemic–pulmonary collateral vessels. Catheter angiogram in a patient undergoing pre-Fontan evaluation shows an injection into the proximal right internal thoracic artery in an anteroposterior projection. The right internal thoracic artery is dilated with multiple systemic–pulmonary artery connections to the right lung vasculature. For the purposes of comparison of the extent of such collaterals among patients who underwent coil occlusion, this would be categorized as 1 vascular territory.

another patient with hypotension and bradycardia required cardiopulmonary resuscitation for approximately 1 minute. Total cardiopulmonary bypass times, postoperative Fontan baffle pressure, and mean atrial pressure did not differ between groups.

Postoperative Fontan Outcomes

There were no postoperative deaths (Table 4). Major complications occurred in 2 patients, both in the catheterization group; 1 patient with mediastinitis required surgical debridement, and 1 patient had a postoperative seizure. Minor postoperative complications occurred with similar frequency in both groups; the majority of these were transient junctional rhythm requiring temporary external pacing. There were no significant differences between groups in duration of mechanical ventilation, thoracostomy tube drainage, length of stay in the intensive care unit, length of hospital stay, and oxygen saturation at discharge. The number of unplanned postoperative procedures did not significantly differ between groups, the majority of which were postoperative interventional catheterizations (10 patients) and placement of additional thoracostomy tubes (5 patients). Hospital readmission rates within 30 days of discharge were similar between groups.

Patients in both groups met the 5-element definition of a clinically successful Fontan operation with similar

TABLE 4. Fontan surgical data by treatment assignment

	Catheterization (n = 38)	CMR (n = 38)	P value
Operative data			
Age at Fontan operation (y)	2.7 (1.9-4.3)	2.4 (1.6-3.8)	.02
Fontan type			.74
Lateral tunnel fenestrated	34 (89)	32 (84)	
Extracardiac conduit	4 (11)	6 (16)	
Other surgical procedures	26 (68)	15 (39)	.02
Pulmonary arterioplasty	11	8	
Atrioventricular valve	4	2	
plasty			
Cardiopulmonary bypass	106 (64-180)	101 (63-192)	.64
time (min)			
Aortic crossclamp time (min)	49 (0-104)	48 (0-91)	.97
Any intraoperative	1 (3)	1 (3)	1.0
complication*			
Fontan pathway pressure	14 (10-18)	14 (8-17)	.20
(mm Hg)†			
Common atrial pressure	7 (4-13)	7 (4-10)	.25
(mm Hg)†			
Postoperative course			
In-hospital mortality	0	0	1.0
Length of mechanical	2 (1-27)	2 (1-25)	.37
ventilation (d)			
Thoracostomy tube time (d)	7 (3-30)	7 (4-31)	.88
CICU length of stay (d)	4 (2-37)	4 (2-41)	.74
Hospital length of stay (d)	11 (6-52)	10 (6-72)	.83
Oxygen saturation at	86 (80-98)	86 (75-100)	.79
discharge (%)			
Any major postoperative	2 (5)	0 (0)	.49
complication‡			
Any minor postoperative	24 (63)	23 (61)	1.0
complication			
Arrhythmia requiring	18 (47)	19 (50)	1.0
treatment§			
Reintubation	3 (8)	2 (5)	1.0
Pneumonia or urinary	1 (3)	2 (5)	1.0
tract infection			
Line infection	1 (3)	1 (3)	1.0
Unplanned procedure ≤30	12 (32)	5 (13)	.10
days after Fontan			
Hospital readmission ≤30	3 (8)	1 (3)	.62
days of discharge			

Values are median (range) or count (percent). CMR, Cardiac magnetic resonance; CICU, cardiac intensive care unit. *Excludes transient arrhythmias. Fontan baffle revision required in 1 patient, hypotension requiring 1 minute of cardiopulmonary resuscitation in 1 patient. †Mean postoperative value in mm Hg over first 24 hours. ‡Includes mediastinitis requiring debridement, and postoperative seizure. §Most commonly transient junctional rhythm requiring temporary pacing.

frequencies (55% in the catheterization group vs 71% in the CMR group; $P = .23$) (Table 5 and Figure 2).

Late Follow-up

All patients who underwent the Fontan operation were alive and clinically well at a median age of 8.8 years

TABLE 5. Outcome of Fontan operation

	Catheterization (n = 38)	CMR (n = 38)	P value
Clinically successful Fontan operation*			
Hospital LOS ≤14 d	30 (79)	31 (82)	1.0
Thoracostomy tube drains ≤10 d	33 (87)	31 (82)	.75
Discharge oxygen saturation ≥85%	24 (63)	26 (68)	.81
No unplanned postoperative procedure	26 (68)	33 (87)	.10
No readmission within 30 d of discharge	35 (92)	37 (97)	.62
Meets all 5 criteria	21 (55)	27 (71)	.23

CMR, Cardiac magnetic resonance; LOS, length of stay. *Component measures defined by consensus panel; see Methods section for details.

(Table 6). Cutaneous oxygen saturation was similar in both groups at 95%. Less than half of the patients in both groups underwent subsequent procedures, the majority of which were catheterizations for device closure of baffle fenestrations (n = 25). No patients had worsening New York Heart Association functional class, deterioration in ventricular function, or worsening AV valve regurgitation at most recent follow-up.

These results represent an intention-to-treat analysis from the original randomized treatment assignment before BDG. When analyzed per protocol for actual treatment received before BDG, the results are similar with no statistically significant changes in the outcomes reported above.

FIGURE 2. Post-Fontan outcomes. Component definitions of a successful outcome from Fontan surgery developed by consensus panel are demonstrated by the study's original treatment assignment before bidirectional Glenn operation—cardiac magnetic resonance (CMR) or catheterization. Components included hospital length of stay (LOS) of 14 days or less, chest tube drains in for 10 days or less, discharge oxygen saturation of 85% or more, no unplanned post-Fontan procedures, and no hospital readmission in 30 days or less of discharge.

TABLE 6. Late follow-up after Fontan operation

	Catheterization (n = 38)	CMR (n = 38)	P value
Age at most recent follow-up (y)	8.8 (6.9-10.2)	8.8 (6.9-10.1)	.95
Patient alive	38 (100)	38 (100)	1.0
Cutaneous oxygen saturation (%)	94 (80-99)	95 (82-100)	.31
Any procedure after Fontan*	18 (47)	15 (39)	.64
Clinically well†	38 (100)	38 (100)	1.0

CMR, Cardiac magnetic resonance. *Most common interventions included device closure Fontan fenestration in 25, pulmonary artery dilation in 4, and pacemaker implantation in 3. †Defined as no decline in New York Heart Association class and no decline in ventricular function or worsening atrioventricular valve regurgitation.

DISCUSSION

The long-term follow-up of this cohort from a randomized clinical trial showed that patients managed with a non-invasive imaging strategy using echocardiography and CMR before BDG, versus routine cardiac catheterization, had no detectable differences in clinical outcomes after Fontan operation at a median age of 8.8 years. Furthermore, the clinical course before and after Fontan operation, hemodynamic profile at pre-Fontan catheterization, postoperative course, and post-Fontan outcomes were indistinguishable between the groups.

It is worth noting that the only statistically significant differences between groups were age at pre-Fontan evaluation and age at Fontan, which was younger at both in the CMR group. The reason for this finding is not entirely clear, as in all other respects the 2 groups were similar, including clinical profile, hemodynamic findings at catheterization, and types and frequencies of catheter intervention. Moreover, the vast majority of patients in both groups were clinically well and referred for elective evaluation for candidacy for Fontan. It is conceivable that the CMR group was referred at a younger age because many of these patients had never undergone catheterization, which may have influenced provider practice and resulted in earlier referrals for pre-Fontan catheterization and surgery. Nevertheless, aside from slightly younger age at Fontan, the groups had no appreciable differences in outcomes at a comparable age at latest follow-up.

One of the main purposes of this study was to determine whether there was any evidence of a delayed therapeutic effect from transcatheter pre-BDG interventions, primarily coil occlusion of SPCs. Given that the frequency of coil occlusion of SPCs before BDG was much lower in the CMR group as compared with the catheterization group, it is possible that the beneficial effects of this intervention, if any, may manifest during follow-up. However, we did not find any evidence for such an effect; indeed, the frequency of intervention for coil occlusion at pre-Fontan

catheterization was identical in the 2 groups. We attempted to further quantify the overall burden of SPC flow at pre-Fontan catheterization by assessing the number of vascular territories addressed by coil occlusion, which did not differ between groups. Although this is only semiquantitative, it demonstrates that patients in the CMR group did not have disproportionately more extensive SPCs than patients in the catheterization arm. Considering that 20% of patients in the catheterization arm of the study had already undergone coil occlusion of SPCs before BDG, the results suggest that coil occlusion of such vessels may only provide a temporary reduction in SPC flow, and as this had no impact on course during and after BDG, the utility of routine occlusion of such vessels may need to be reevaluated. The recent development of a new CMR technique to quantify SPC flow^{15,16} provides an opportunity not only to study the hemodynamic burden and natural history of SPCs in patients with functional single ventricle, but also to facilitate prospective investigations designed to determine the indications and efficacy of coil occlusion of SPCs.

Limitations

This was a single-center trial carried out in a high-volume referral institution with expertise in CMR, and the results may not be generalizable to other practice settings; confirmation of the results from a multicenter study would be desirable. The study cohort was a selected group of patients based on screening echocardiogram, and these results should not be extrapolated to higher risk candidates for BDG. In addition, the study was powered to measure a modest difference in the incidence of adverse events for the pre-BDG evaluation, not to demonstrate the equivalency of long-term impact and outcomes after transcatheter interventions; it is conceivable that with a larger sample size and longer follow-up period, some differences in long-term outcomes of such interventions would be more apparent.

CONCLUSIONS

Compared with routine pre-BDG cardiac catheterization, patients evaluated with a noninvasive strategy alone had equivalent clinical and hemodynamic profiles before Fontan, similar post-Fontan outcomes, and similar

clinical status at a median follow-up of 6 years after Fontan. For selected patients, a pre-BDG evaluation with echocardiography and CMR is an acceptable alternative to catheterization.

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