Standardized outcomes in reproductive cardiovascular care: The STORCC initiative

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Abstract Background Validated protocols for diagnostic testing and management of pregnant women with cardiovascular disease (CVD) do not exist. Our objective was to establish a prospective standardized protocol for the clinical evaluation of pregnant women with CVD.

Methods The Standardized Outcomes in Reproductive Cardiovascular Care (STORCC) initiative prospectively enrolled pregnant women with CVD into a standardized diagnostic testing and assessment protocol. Detailed cardiac and obstetric data were collected during the antepartum, intrapartum, and postpartum periods. Each woman was assigned a STORCC color code of perceived risk at a monthly multidisciplinary conference.

Results In 250 pregnancies of 207 women with CVD, the standardized care protocol was followed in 136 and routine care in 114. The median age of the subjects was 32 years, and the most common form of heart disease was congenital heart disease (77%). Women enrolled in standardized care protocol had high compliance with second- and third-trimester visits (93%) and postpartum visits (76%). Maternal cardiac complications occurred in 10%. The STORCC cardiac and obstetric color codes predicted adverse outcomes within each respective category (P = .02, .01).

Conclusions The STORCC protocol for prospective diagnostic testing and follow-up of pregnant women with CVD was successfully established, and compliance was high. The strength of a standardized testing and care protocol as well as detailed classification of labor and delivery characteristics allows for robust analyses into specific questions regarding testing protocols, and mode and timing of delivery. (Am Heart J 2019;217:112-20.)

Several risk models have been published which estimate the maternal risks for women with cardiovascular disease (CVD) during pregnancy.[1-7] Although these models are helpful in initial maternal risk stratification, their application is limited in several ways. Decision to obtain testing to assess risk was not uniform, data collection and analyses were retrospective, and value of intrapartum testing and clinical follow-up were not assessed in relationship to either subspecialty (cardiac, obstetric, anesthesia) or composite risk and outcomes. As such, validated protocols for diagnostic testing and management of pregnant women with CVD do not exist. There are little data to guide the decisions regarding the frequency with which women with CVD should be clinically evaluated during pregnancy. The recommended follow-up for women with WHO Class II is every trimester; women with WHO Class III and IV should be seen monthly or bimonthly.[8]

As the number of women with CVD of childbearing age continues to grow, many clinical programs have developed multidisciplinary teams involving clinicians with expertise in CVD, maternal fetal medicine, obstetric anesthesia, and neonatology. The American Heart Association published a scientific statement on the management of pregnancy in women with complex congenital heart disease, emphasizing the need for this type of multidisciplinary decision making once the threshold of fetal viability has been reached to create a specific delivery plan.[9] However, despite such recommendations, the value of these meetings has not been well established.[10] Additionally, oftentimes, vital decisions need to be made prior to fetal viability.

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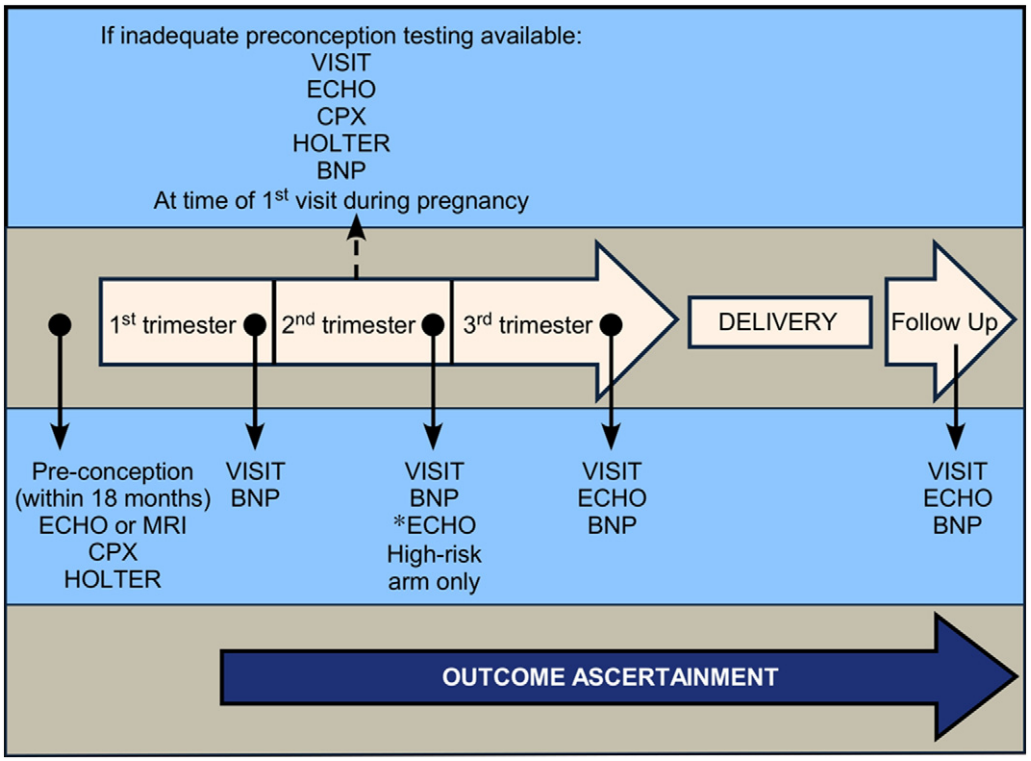
Figure 1



Algorithm for the STORCC standardized care and diagnostic testing protocol.

To answer these questions, we established a single-center prospective initiative using a standardized care protocol for clinical visits and diagnostic testing during pregnancy and the postpartum period in women with CVD. This protocol included monthly review of all enrolled patients at a multidisciplinary subspecialty care services conference with assignment of risk scores for each subspecialty (cardiology, obstetrics, and anesthesia) and development of a plan of care for delivery. The goal of our study was to establish a prospective standardized protocol for the clinical evaluation and management of pregnant women with CVD.

Methods

The Standardized Outcomes in Reproductive Cardiovascular Care (STORCC) initiative prospectively enrolled pregnant women with CVD who were receiving care at the Brigham and Women's Hospital from September 2011 through November 2016. Women who experienced a miscarriage before 20 weeks' gestation were excluded. Pregnant women with CVD who presented to the Brigham and Women's Hospital Pregnancy and CVD Program were enrolled in either a standardized care protocol or a routine care cohort as described below. The Pregnancy and CVD Program was developed in an effort to optimize the care of these women by offering weekly specific cardiology and maternal fetal medicine clinics concurrently. Women often see both practices on the same day, and a dedicated research coordinator ensures that the protocol is being followed. The Institutional Review Boards of the Brigham and Women's Hospital and Boston Children's Hospital approved this protocol, and informed consent was obtained. The STORCC initiative was funded by the Brigham and Women's Hospital Watkins Discovery Award, the Barton and Weinberg Family Fund, the Boston Adult Congenital Heart Disease Program Dunlevie Fund, and Sarah Marie Liamos Fund for Adult Congenital Heart Disease Research. The authors are solely responsible for the design and conduct of this study, all study analyses, the drafting and editing of the paper, and its final contents.

Data collected at the first visit included baseline demographics, type of heart condition, comorbid conditions, medications, and certain parameters from the enrollment physical examination. Cardiac conditions were assigned a level of complexity (mild, moderate, severe) based upon criteria used within the American Heart Association/American College of Cardiology Guidelines for the Management of Adults with Congenital Heart

Table I. Baseline maternal characteristics

	Total pregnancies (n = 250)	Routine care (n = 114)	Protocol (n = 136)	*P* value
Maternal age at enrollment (y)	32 (19-42)	32 (19-42)	31 (20-40)	.97
Parity	1 (0-4)	1 (0-3)	1 (0-4)	.17
Multiple gestation	7 (3%)	3 (3%)	4 (3%)	1.0
Assisted reproductive technology	28 (11%)	13 (11%)	15 (11%)	1.0
Type of heart disease				<.001
Congenital heart disease	192 (77%)	70 (61%)	122 (90%)	
Connective tissue disease	28 (11%)	19 (17%)	9 (7%)	
Cardiomyopathy	22 (9%)	21 (18%)	1 (1%)	
Valvular	4 (2%)	3 (3%)	1 (1%)	
Vascular	4 (2%)	1 (1%)	3 (2%)	
Anatomic disease complexity				<.001
Simple	76 (30%)	37 (32%)	39 (29%)	
Moderate	76 (30%)	20 (18%)	56 (41%)	
Complex	98 (40%)	57 (50%)	41 (30%)	
Prior adverse cardiovascular event*	30 (12%)	19 (17%)	11 (8%)	.05
Baseline medications (prior to pregnancy)				
ACE inhibitors	13 (5%)	5 (4%)	8 (6%)	.78
Angiotensin II receptor blockers	2 (1%)	2 (2%)	0 (0%)	.21
β-Blockers	50 (20%)	29 (25%)	21 (15%)	.06
Diuretics	15 (6%)	8 (7%)	7 (5%)	.60
Antiarrhythmic	4 (2%)	2 (2%)	2 (1%)	1.0
ASA/other antiplatelet therapy	39 (16%)	14 (12%)	25 (18%)	.22
Anticoagulation	6 (2%)	2 (2%)	4 (3%)	.69
Selective serotonin reuptake inhibitor	14 (6%)	8 (7%)	6 (4%)	.42
Preexisting diabetes	5 (2%)	3 (3%)	2 (1%)	.66
Preexisting HTN	31 (12%)	16 (14%)	15 (11%)	.56

Median (range) or frequency (percent).
ACE, angiotensin-converting enzyme; *ASA*, acetylsalicylic acid.
*Defined as prior arrhythmia, heart failure, cardiomyopathy, endocarditis, or vascular event.

Disease.[11,12] Specific detailed cardiac and obstetric data were collected prospectively at each clinic visit, during all admissions, during the postpartum visit, and for up to 1 year following delivery.

Delivery data included mode of delivery (vaginal or cesarean delivery). Vaginal delivery was divided into spontaneous or assisted second stage (either vacuum or forceps). Cesarean delivery was defined as planned or unplanned. A *planned cesarean* refers to women who had elected a cesarean delivery and planned to avoid spontaneous labor. *Unplanned cesarean* refers to women who presented in labor with contraindications for vaginal birth or who had obstetric indication for cesarean delivery following attempt at vaginal birth. Anesthesia data were collected and included the type of labor analgesia (general, neuraxial, intravenous opiates, no labor analgesia).

Standardized care protocol

Women enrolled in the standardized care protocol had their first visit prior to 20 weeks' gestation and underwent a diagnostic testing protocol and were designated as low or high risk based upon an initial assessment of existing known maternal risk factors for adverse cardiac outcomes during pregnancy. Such initial maternal risk factors included a prior adverse cardiac event (including arrhythmia, heart failure, endocarditis, vascular event), New York Heart Association (NYHA) Class >II, oxygen saturation ≤90% on room air, systemic ventricular ejection fraction (EF) <40%, and left ventricular outflow tract peak gradient >30 mm Hg.[1] *Initial maternal cardiovascular high-risk status* was defined as the presence of 1 or more of these risk factors. Any patient with connective tissue disorder was also categorized as high risk in the standardized protocol group. Women designated high risk underwent an additional echocardiogram in the second trimester.

The STORCC protocol included diagnostic testing (cardiac imaging, Holter data, cardiopulmonary exercise testing) within 18 months of conception (Figure 1). Women without diagnostic testing within that time frame were asked to undergo evaluation prior to 20 weeks' gestation. Timing of review of interval history and examination were standardized, as was subsequent testing. All women underwent echocardiography in the third trimester and in the postpartum period. The protocol included β natriuretic peptide (BNP) values each trimester. Echocardiograms were reviewed by at least 2 investigators, and *significant changes* were defined as follows: decrease in ventricular function, accelerated increase in valvular gradient (>20 mm Hg), worsening in valvular regurgitation (≥2 grades), accelerated increase in aortic dimension (>5 mm), or new cardiac

Table II. Specific cardiac conditions classified by protocol risk level and routine care grouping

	Protocol high risk (n = 31)			Protocol low risk (n = 105)			Routine care (n = 114)
Congenital heart disease		20 (65%)			102 (97%)		70 (61%)
Shunts	Red	Yellow	Green	Red	Yellow	Green	
ASD	1*, 0	–	–	–	–	7, 5	8, 4
PAPVR	–	–	–	–	1, 0	0, 1	2, 1
VSD	–	–	–	–	–	3, 4	4, 2
AVSD	–	–	–	–	2, 0	5, 0	1, 0
PDA	–	–	–	–	–	–	2, 1
Right heart lesions							
PS	–	–	–	–	–	8, 1	1, 2
TOF	–	1, 0	–	–	2, 0	17, 0	6, 0
DCRV	–	–	–	–	–	1, 0	–
PAIVS	2, 0	–	–	–	–	–	–
Ebstein	1, 0	–	1, 0	–	–	–	2, 1
Left heart lesions							
Sub AS	–	–	–	–	–	–	0, 1
AS	3, 0	–	1, 0	–	–	–	4, 1
AR	–	–	–	–	–	–	0, 1
BAV	1, 1	–	0, 1	1, 0	0, 2	3, 0	2, 4
Coarctation	–	1, 0	–	3, 0	2, 0	11, 2	6, 2
Mitral valve disease	–	–	–	–	–	0, 1	0, 3
Malposed great arteries							
D-loop TGA (atrial switch)	–	1, 0	–	1, 0	1, 0	2, 0	2, 0
D-loop TGA (ASO)	–	–	–	–	–	1, 0	–
D-loop TGA (Rastelli)	–	–	–	1, 0	–	–	2, 0
L-loop TGA	–	0, 1	–		0, 1	0, 3	–
{I,D,D} (atrial Switch and Rastelli)	–	–	–	–	–	2, 0	–
Truncus	–	–	–	–	1, 0	2, 0	2, 0
Single ventricle							
Fontan physiology	3, 0	1, 0	–	–	–	–	1, 0
Other	–	–	–	–	–	3, 2	2, 0
Connective tissue disease		9 (29%)			0		19 (17%)
Marfan syndrome	3	–	–	–	–	–	9
Loeys-Dietz	2	–	–	–	–	–	4
Ehlers-Danlos	1	–	–	–	–	–	3
Undefined connective tissue disease	3	–	–	–	–	–	3
Cardiomyopathy		1 (3%)			0		21 (18%)
Dilated	1	–	–	–	–	–	3
Hypertrophic	–	–	–	–	–	–	6
Peripartum	–	–	–	–	–	–	8
NOS	–	–	–	–	–	–	4
Valvular		0			1 (1%)		3 (3%)
	–	–	–	–	–	1, 0	3
Vascular		1 (3%)			2 (2%)		1 (1%)
	–	–	1	1	1	–	1

The numbers are listed by repaired defects, unrepaired defects in each column.
ASD, atrial septal defect; *PAPVR*, partial anomalous pulmonary venous return; *VSD*, ventricular septal defect; *AVSD*, atrioventricular septal defect; *PDA*, patent ductus arteriosus; *PS*, pulmonary stenosis; *TOF*, tetralogy of Fallot; *DCRV*, double chambered right ventricle; *PAIVS*, pulmonary atresia with intact ventricular septum; *Sub AS*, subvalvar aortic stenosis; *AS*, aortic valve stenosis; *AR*, aortic valve regurgitation; *BAV*, bicuspid aortic valve; *TGA*, transposition of the great arteries; *ASO*, arterial switch operation; *NOS*, not otherwise specified.
* Patient designated red due to history of ventricular arrhythmias.

finding (pericardial effusion, vegetation, aortic dissection). Deviations from the protocol were recorded.

Each woman in the standardized care cohort was discussed at a monthly multidisciplinary conference that included representatives from maternal fetal medicine, cardiology, obstetric anesthesia, and nursing. Based on the multidisciplinary team's consensus, a STORCC color code (green, yellow, red) was assigned to each woman as a visual adjunct to clinical classification of perceived low, intermediate, and high risk for adverse outcomes for each subspecialty care category (cardiac, obstetric, and anesthetic). The cardiac team determined at the onset of this protocol that all women with connective tissue disorders would be assigned a red cardiac code. STORCC color codes were recorded and readdressed on a monthly basis with the potential to change the code based on new findings. Labor and delivery plans were discussed monthly. Delivery discussions included location (labor and delivery, cardiac ICU, operating room, hybrid operating room, cardiac catheterization laboratory),

Table III. Outcomes

	Total (n = 250)	Routine care (n = 114)	Protocol (n = 136)	*P* value
Cardiac				
Any cardiac outcome	25 (10%)	13 (11%)	12 (9%)	.53
Congestive heart failure	12 (5%)	6 (5%)	6 (4%)	
Sustained arrhythmia	6 (2%)	1 (1%)	5 (4%)	
Cerebral vascular event	1 (<1%)	1 (1%)	0 (0%)	
Cardiac intervention	6 (2%)	6 (5%)	0 (0%)	
Valvular dysfunction	2 (1%)	1 (1%)	1 (1%)	
Endocarditis	1 (<1%)	1 (1%)	0 (0%)	
Aortic dissection	1 (<1%)	1 (1%)	0 (0%)	
Severe HTN	0 (0%)	0 (0%)	0 (0%)	
Obstetric				
Any obstetric outcome	110 (44%)	46 (40%)	64 (47%)	.31
Antenatal characteristics				
Hypertensive disorder (gestational acquired)	34 (14%)	15 (13%)	19 (14%)	
Placental abruption	12 (5%)	3 (3%)	9 (7%)	
Gestational diabetes	8 (3%)	2 (2%)	6 (4%)	
Cervical insufficiency	7 (3%)	5 (4%)	2 (1%)	
Labor and delivery characteristics				
Gestational age at delivery (wk)	39 (25-41)	39 (28-41)	39 (25-41)	
Infant birth weight at delivery (kg) (n = 116, 137)	3.1 (0.8-4.3)	3.1 (1.2-4.2)	3.0 (0.8-4.3)	
Type of delivery (n = 246)				
Vaginal delivery	154 (63%)	64 (57%)	90 (68%)	
Spontaneous	135 (88%)	52 (81%)	83 (92%)	
If vaginal, assisted second stage	19 (12%)	12 (19%)	7 (8%)	
Cesarean section (planned)	52 (21%)	29 (26%)	23 (17%)	
Cesarean section (unplanned)	40 (16%)	20 (18%)	20 (15%)	
Vaginal laceration (3rd and 4th degree)	3 (2%)	0 (0%)	3 (3%)	
Postpartum hemorrhage	23 (9%)	10 (9%)	13 (10%)	
Need for blood transfusion	2 (1%)	1 (1%)	1 (1%)	
Chorioamnionitis	16 (6%)	5 (4%)	11 (8%)	
Preterm delivery	30 (12%)	15 (13%)	15 (11%)	
Preterm premature rupture of membranes	11 (4%)	2 (2%)	9 (7%)	
Wound complication	4 (2%)	3 (3%)	1 (1%)	
Endometritis	2 (1%)	0 (0%)	2 (1%)	
Neonatal				
Any neonatal outcome	80 (32%)	32 (28%)	48 (35%)	.28
Neonatal death within 3 m after birth	1 (<1%)	0 (0%)	1 (1%)	
Neonatal intensive care unit admission	65 (26%)	26 (23%)	39 (29%)	
Apgar score less than <7 at 5 min	6 (2%)	1 (1%)	5 (4%)	
Hypoglycemia	8 (3%)	3 (3%)	5 (4%)	
Other neonatal injuries	2 (1%)	0 (0%)	2 (1%)	
Neonatal congenital heart disease	14 (6%)	8 (7%)	6 (4%)	
Neonatal renal complications	3 (1%)	1 (1%)	2 (1%)	
Neonatal respiratory distress	19 (8%)	7 (6%)	12 (9%)	
Neonatal other congenital defect	7 (3%)	3 (3%)	4 (3%)	
Neonatal arrhythmia	2 (1%)	1 (1%)	1 (1%)	
Small for gestational age	20 (8%)	5 (4%)	15 (11%)	

Median (range) or frequency (percent).

monitoring (telemetry, invasive hemodynamic monitoring, continuous pulse oximetry), and management of the second stage of labor (duration of Valsalva, forceps or vacuum-assisted delivery).

Routine care cohort

Women not enrolled in the standardized care protocol were consented to be included in a routine care cohort in which management was dictated according to provider discretion, and all clinical data were recorded. This group primarily consisted of women who presented at greater than 20 weeks' gestation but also included women with CVD who did not consent to the standardized protocol.

Women in both arms completed a survey at enrollment and in the postpartum period, which included information pertaining to access to care, baseline knowledge of

their individual risks of pregnancy, activity level and habits, preparation for pregnancy, and their confidence and satisfaction with their clinical care.

Outcomes

Maternal cardiac, obstetric, neonatal, and other medical outcomes were collected. *Cardiac events* were defined as congestive heart failure (diagnosed by physical examination and treated with diuresis), sustained symptomatic arrhythmia (>30 seconds in duration), cerebral vascular event, new or worsening valvar dysfunction, endocarditis, aortic dissection, cardiac intervention, cardiac arrest, and cardiac death.

Obstetrical outcomes were defined as gestational hypertension (HTN), gestational diabetes, subchorionic hematoma, cervical insufficiency, intrauterine growth restriction, preterm labor, preterm delivery, placental abruption, placenta accreta, preterm premature rupture of membranes, vaginal lacerations (third or fourth degree), postpartum hemorrhage (>500 mL vaginal delivery, >1000 mL cesarean delivery), blood transfusion, wound complications, chorioamnionitis, endometritis, and noncardiac death.

Neonatal outcomes included prematurity, small for gestational age (<10%tile), admission to the neonatal intensive care unit, APGAR score <7 at 5 minutes, hypoglycemia, other neonatal injuries, renal disease, respiratory distress, congenital heart disease or other congenital defects, arrhythmia, and neonatal death (within 3 months after birth).

Statistical methods

Patient characteristics and clinical data were summarized using frequencies and percentages for categorical variables and either median with range or mean with standard deviation for continuous variables. Categorical variables were compared for women enrolled in the protocol versus routine care arms using Fisher exact test. Continuous variables were compared using the unpaired *t* test or Wilcoxon rank-sum test. Logistic regression analysis was used to compare the proportions of women with outcomes for each treatment group, adjusting for type of heart disease and disease complexity. A 2-sided *P* value of less than .05 was considered to indicate statistical significance. Statistical analyses were performed using Stata V14 (StataCorp, College Station, TX).

Results

Patient characteristics

The STORCC program enrolled 214 pregnant women with heart disease who experienced 257 pregnancies over the 5-year period. Seven women were excluded because of early miscarriage. Of the remaining 250 pregnancies, 136 agreed to standardized care protocol and 114 were followed in the routine care cohort. The baseline maternal characteristics of these women are listed in Table I. Forty women experienced 2 pregnancies, and 3 women experienced 3 pregnancies during the study period. The median age at the time of enrollment was 32 years, and median BMI was 24 kg/m^2. The most common type of heart disease was congenital heart disease (77%) followed by aortic conditions associated with connective tissue disease (11%), cardiomyopathy (9%), valvular heart disease (2%), and vascular disease (2%) (Table II). There was a spectrum of anatomic disease complexity: 30% of women had mild forms of heart disease, 30% moderate complexity, and 40% severely complex heart disease. The most common reported medical comorbidities included reactive airway disease (18%), preexisting HTN (12%), thyroid disorders (10%), and anxiety and/or depression (33%). Twenty-eight women (11%) conceived via assisted reproductive technology.

Of the 136 standardized care patients, 23% were classified as high risk and 77% as low risk. With respect to cardiac risk level, 13% of patients were designated yellow and 18% red; 29% and 1% of patients were, respectively, assigned yellow or red obstetric risk level, and 15% were determined to be yellow anesthesia risk level and 1% red. Among the high-risk group, 13% experienced a prior adverse cardiac event, 8% had a resting left ventricular outflow tract gradient >30 mm Hg, and 1 had cyanosis (room air oxygen saturation <90%). Most women were NYHA Class I, with only 6 women Class II and 2 Class III. Of note, no one experienced a change in NYHA class during pregnancy.

Of the women in the standardized care protocol, 94% had normal systemic ventricular function. Ninety percent (122/136) of women did not have any significant changes measured by transthoracic echocardiography. Fourteen women had significant changes as follows: decrease in systemic ventricular function (4), decrease in pulmonary ventricular function (1), accelerated increase in valve gradient (4), pericardial effusion (3), valvular vegetation (1), and aortic dissection (1). These findings resulted in changes to the management plan in 4 of the 14 women (transcatheter aortic valve placement during the second trimester [1], admission to the cardiac intensive care unit [1], and change in location of delivery [2]).

Overall adherence to scheduled follow-up echocardiograms was higher in the low-risk group than in the high-risk group (90% vs 74%). Twenty-four women did not have a postpartum echocardiogram, and 33 women (24%) underwent additional echocardiograms during the protocol period for a variety of symptoms or to follow new pericardial effusions. None of the information from the additional echocardiograms changed patient management.

In the standardized care protocol, 93 (68%) of the women completed a cardiopulmonary exercise test. Most women had decreased exercise capacity with a median predicted peak oxygen consumption of 20 mL/kg/min, which was

69% predicted. However, there was a large range of exercise capacity with peak oxygen consumption values from 9 to 40 mL/kg/min. Only 18% of women had a chronotropic index >0.85, although this did not correlate with maternal cardiac outcomes (0% vs 9.2%, $P = .34$). Eighty-two percent of women completed a Holter monitor. The average heart rate was 79 (52-99) beat/min. Fifteen women (13%) had nonsustained supraventricular tachycardia, and 9 women (8%) had nonsustained ventricular tachycardia captured on ambulatory monitoring. Importantly, within the standardized protocol arm, there was no difference in cardiac outcomes between women who did and did not have an exercise test (8% vs 12%, $P = .52$) or between those who did and did not have Holter monitoring (9% vs 8%, $P = 1.0$).

BNP values were obtained in 184 women from both standardized and routine care cohorts. Although the median BNP values were within normal limits, women with BNP values above the reference range had a greater chance of adverse cardiac outcomes (43% vs 9%, $P = .02$). Patient compliance with standardized protocol clinical visits was high with 252/272 completed visits (93%) in the second and third trimesters and 104/136 (76%) completed postpartum visits.

Of the 250 women in this study, 204 completed postpartum surveys that addressed patient satisfaction: 116 in the standardized protocol and 88 in the routine care group. There was no difference in patient satisfaction in either cardiac or obstetric care ($P = .27$ and .31, respectively).

Outcomes

Ten percent of pregnancies were associated with an adverse cardiac outcome, 44% experienced at least 1 obstetrical adverse outcome, and 32% had adverse neonatal outcomes (Table III). Outcomes did not differ between the standardized care and routine care cohorts; this remained true after adjusting for type of heart disease or disease complexity. Two women underwent cardiac intervention during pregnancy (dilation of branch pulmonary arteries in a woman with Alagille syndrome and implantable cardiac defibrillator in a woman with newly diagnosed hypertrophic cardiomyopathy). Four women had interventions in the immediate postpartum period including 2 valve replacements, 1 percutaneous closure of an atrial septal defect, and 1 repair of an aortic dissection.

Of the 250 women enrolled, 4 delivered at other institutions, and therefore, their labor and delivery data were not included in Table III. The median gestational age at the time of delivery was 39 weeks, with a wide range (25-41 weeks), and the median birth weight was 3.1 kg (0.81-4.3 kg). For the 30 mothers who delivered preterm, gestational age ranged from 25.4 to 36.7 weeks. More than half of the group underwent induction of labor (66%). Of the 190 patients who attempted vaginal delivery, all were allowed to Valsalva during the second stage of labor, and 81% had a successful vaginal delivery. Nineteen women had an assisted second stage with 14 vacuum and 5 forceps-assisted deliveries. Of these, 1 woman experienced a fourth-degree vaginal laceration after an assisted second stage. Episiotomy was performed in 5% of deliveries, and 1 woman experienced a third-degree laceration following episiotomy. Among the entire cohort, 2% of women had a third- or fourth-degree laceration. The remainder of the women underwent a cesarean delivery, 16% of which were unplanned. One woman underwent a cesarean delivery specifically for a cardiac indication (Marfan syndrome and a type B aortic dissection in the early third trimester). Nine percent of women had a postpartum hemorrhage.

Eighty-five percent of women were transferred to the postpartum obstetric floor with routine obstetric monitoring. Of the remaining 34 women, 15 were monitored with cardiac telemetry on the labor floor, 7 in the step-down unit, 6 in the intensive care unit, and 6 remained on the labor floor for obstetric indications.

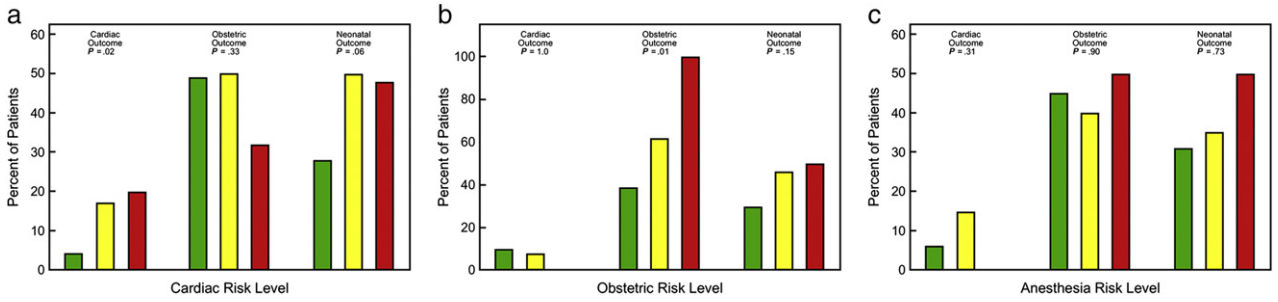
Of the 154 women who underwent a vaginal delivery, 94% had neuraxial analgesia. Intravenous opioids were administered to 1 patient, and 9 women had no neuraxial or intravenous labor analgesia. The remaining 92 women in the cohort underwent cesarean delivery; 96% had neuraxial anesthesia, and the remaining 4% underwent general endotracheal anesthesia.

There was a 32% rate of neonatal complications, with 26% of newborns requiring a neonatal intensive care unit admission. All women with congenital heart disease underwent a dedicated fetal echocardiogram, and 14 neonates had congenital heart disease, 1 of whom died following initial surgical palliation for tetralogy of Fallot with pulmonary valve atresia.

STORCC clinical care codings

Most women (93%) did not experience a change in STORCC color code during pregnancy. Six women had a color code change in their cardiac designation, and 10 women experienced a color code change from an obstetric perspective. Three women experienced an upcoding in their designation due to recognition of worsening prosthetic valve stenosis, an episode of supraventricular tachycardia, and decrease in systemic ventricular function, respectively, during the pregnancy. An additional 3 women had downgrading of initial color codes from red to yellow and green based on their high functional class during pregnancy despite initially concerning hemodynamic data. Ninety-three percent of women maintained their initial STORCC obstetric color code, whereas 10 women experienced an increase code from green to yellow (based on intrauterine growth restriction, preterm labor, or abnormal placentation). The cardiac and obstetric color codes were predictive of adverse outcomes within each respective category (Figure 2, $P = .02$, .01).

Figure 2



STORCC color code designations and clinical outcomes associations.

Discussion

The STORCC initiative provides a standard diagnostic protocol for pregnant women with CVD in which the frequency of testing is based on prior established risk factors. The detailed classification of labor and delivery characteristics, as well as anesthetic considerations, allows for robust analyses of specific questions regarding mode and timing of delivery. We included women who were managed outside the standardized care protocol in a routine care cohort, where the individual testing was based on clinician discretion; these women often presented for care after 20 weeks' gestation, which precluded entry into the standardized protocol arm. A key feature of this protocol was a monthly review at a multidisciplinary conference at which time an individual STORCC color code was assigned to each woman for cardiac, obstetric, and anesthesia clinical care concerns based on consensus. Of note, at the onset of the STORCC initiative, all women with connective tissue disorders were designated with a red STORCC cardiac code. This classification was based upon recognition of the increased risk of dissection in pregnant women with Marfan syndrome compared to the general population and by guidelines from the American Thoracic Society that recommend bimonthly echocardiograms for pregnant women with Marfan syndrome.[13,14]

Our data indicate that the multidisciplinary team's evaluation of individual women's risk using the color codes correlated strongly with maternal cardiac and obstetric outcomes. Interestingly, most cardiovascular diagnostic testing obtained in pregnancy rarely resulted in change in management during the antepartum period. Only 12% of women had a significant change noted on echocardiography, and management plans were adjusted accordingly. Moreover, 33/136 (24%) of women underwent an additional echocardiogram as a deviation from the standard protocol for a variety of clinical indications, yet none of these studies resulted in a change in management. Cardiopulmonary exercise testing revealed a wide range of cardiac fitness, yet no specific variables were correlated with maternal outcomes. Additionally, there were many nonsustained arrhythmias (13% supraventricular tachycardia, 8% ventricular tachycardia) identified by Holter monitoring, yet these were not clinically significant. The overall rate of maternal cardiac complications was 10%, which is similar to the event rate in previously described cohorts.[1,15]

Practice patterns vary greatly with respect to the timing and mode of delivery in women with CVD. Of the 190 patients who delivered vaginally or underwent an unplanned cesarean delivery, all patients were allowed a trial of Valsalva. Importantly, only 1 woman had a cesarean delivery specifically for a cardiac indication. This was a patient with Marfan syndrome who, although she had a prior vaginal delivery, experienced a type B aortic dissection at 30 weeks and underwent a cesarean delivery to expedite surgical aortic repair. The high rate of vaginal delivery and trial of Valsalva supports recent society guidelines that vaginal delivery is appropriate for most women with cardiac disease in pregnancy.[9,16,17] In addition, it offers new evidence that, even among higher-risk women, vaginal delivery may be equally safe. The rate of obstetric complications was 44%, and 8% of the neonates were small for gestational age. This is consistent with prior cohort studies acknowledging the stable rate of growth restriction among women with CVD.[18]

There are several limitations to our study. Most women in the standardized protocol were designated to be low risk, which may, in part, account for the lack of difference in outcomes between this group and the routine care group. Despite a protocol designed to enhance compliance with standardized diagnostic testing at appropriate time intervals, protocol deviations did occur. One common deviation was in the group of low-risk women who did not have a preconception echocardiogram and presented for care following the first trimester. Additionally, women with connective tissue disorders were classified as high risk based on the increased incidence of aortic dissection in pregnant women with Marfan syndrome and the recommendation for frequent echocardiography in these women.[14] However, fewer than half of the women in our cohort

(43%) with connective tissue disorders had the diagnosis of Marfan syndrome, and many of the women with unspecified connective tissue disorders did not undergo a second-trimester echocardiogram. Only 68% of women in the protocol arm completed cardiopulmonary exercise testing, and 82% of women had Holter monitor data. Reasons for not undergoing these diagnostic tests were largely based on patient preference. Lastly, although clinical care codes were subjective, they were based on multidisciplinary team findings and allowed for real-time refinement of risk assessment throughout the protocol.

In conclusion, this is the first prospective single-center study of women with heart disease who underwent a standardized protocol for diagnostic testing and clinical visits during pregnancy. We were unable to demonstrate that the results of standardized diagnostic testing were predictive of maternal outcomes. However, the clinical care codes developed at the monthly disciplinary team meetings were strongly correlated with both maternal cardiac and obstetric outcomes. This effort has resulted in a refinement of the STORCC protocol. Specifically, we no longer require Holter data to be collected, and cardiopulmonary exercise testing is limited to women with clinical indications. Additionally, we have now revised the designation of high-risk connective disease to include only those women with Ehlers-Danlos type IV (vascular type), Marfan, and Loeys-Dietz syndromes, thus eliminating the need for a second-trimester echocardiogram in many women. Lastly, the lack of correlation of echocardiographic findings and outcomes raises the question of how often echocardiography is necessary during pregnancy. In this era of increased examination of resource utilization, continued exploration of evidence-based strategies for monitoring of pregnant women with CVD is necessary.

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