

## ORIGINAL RESEARCH

## CARDIO-OBSTETRICS

# Mobile Cardiac Telemetry Use to Predict Adverse Pregnancy Outcomes in Patients With Congenital Heart Disease



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## ABSTRACT

**BACKGROUND** Patients with congenital heart disease (CHD) have a higher incidence of arrhythmias during pregnancy, yet the utility of mobile cardiac telemetry (MCT) to predict adverse outcomes is unknown.

**OBJECTIVES** The purpose of this study is to determine whether arrhythmias on screening MCT correlate with adverse pregnancy outcomes.

**METHODS** Patients with CHD prospectively enrolled in the Standardized Outcomes in Reproductive Cardiovascular Care initiative underwent 24-hour MCT (within 18 months prior to pregnancy). Positive findings on MCT were defined as episodes of bradyarrhythmia, symptomatic atrioventricular block, ectopic atrial or ventricular activity, and supraventricular or ventricular tachycardia. Clinically significant arrhythmia events (CSAEs) were those requiring medical or device intervention or an emergency room visit. Clinical events during the antepartum, intrapartum, and postpartum periods were compared using Fisher's exact test. Analyses were performed using Stata version 16.

**RESULTS** In 141 pregnancies in 118 patients with CHD, MCT detected positive findings in 17%. Adverse cardiac outcomes occurred in 11% of pregnancies, of which CSAE occurred in 3.5%. Positive MCT was significantly associated with subsequent CSAE (21% vs 0%,  $P < 0.001$ ) and cumulative adverse maternal cardiac outcomes (33% vs 7%,  $P = 0.001$ ) but did not correlate with obstetric (46% vs 41%,  $P = 0.660$ ) or neonatal outcomes (33% vs 31%,  $P = 0.810$ ). Of the patients with CSAE, 75% had  $\geq$ moderate CHD complexity.

**CONCLUSIONS** Patients with CHD had a high rate of positive MCT findings. This was associated with CSAE and adverse maternal cardiac outcomes. Patients with  $\geq$ moderate CHD complexity may benefit from screening MCT to improve preconceptional counseling and planning. (JACC Adv 2023;2:100593) © 2023 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

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**ABBREVIATIONS  
AND ACRONYMS****AV** = atrioventricular**CHD** = congenital heart disease**CSAE** = clinically significant arrhythmia events**ICD** = implantable cardioverter-defibrillator**MCT** = mobile cardiac telemetry**NICU** = neonatal intensive care unit**SGA** = small for gestational age**SVT** = supraventricular tachycardia**VT** = ventricular tachycardia

Pregnant patients with congenital heart disease (CHD) comprise one of the largest groups of heart disease in pregnancy. Guidelines from both the American Heart Association/American College of Cardiology and the European Society of Cardiology recommend that patients with CHD should receive prepregnancy counseling to determine maternal and fetal risks.<sup>1-3</sup> However, current recommendations for mobile cardiac telemetry (MCT) monitoring as part of risk stratification for these individuals are lacking. In fact, there is a paucity of data examining ambulatory rhythm monitoring in pregnant individuals. Shotan et al<sup>4</sup> reported a high rate of premature atrial and ventricular contractions discovered on Holter monitoring in 162 pregnant patients without evidence of structural heart disease; however, comparable data for pregnant patients with CHD are not available. Patients with CHD are at higher risk for cardiac, obstetric, and fetal complications given the complexity of their anatomy, multiple surgeries, and the palliative nature of some repairs.<sup>5-8</sup> Although most patients with cardiovascular disease tolerate the hemodynamic changes of pregnancy well, they are at higher risk to develop complications across gestation and through the postpartum period.<sup>9</sup> At least 15% of patients with heart disease experience an adverse cardiac event during pregnancy and the postpartum period, with arrhythmias being one of the most common complications.<sup>8,10</sup> Dramatic hemodynamic and hormonal changes during pregnancy may precipitate palpitations in individuals with underlying CHD, and it is important to determine which patients are at risk for significant arrhythmias during this time. A history of prior arrhythmic event is one of the strongest risk factors for an adverse maternal cardiac event during pregnancy.<sup>11</sup> Birth complications, including neonatal intensive care unit (NICU) admissions, low birth weight infants, and maternal mortality, are more common in patients with atrial tachyarrhythmias.<sup>12,13</sup> Additionally, neonatal death, preterm birth (<37 weeks), low birth weight infant (<2,500 g), and Apgar score <7 have been reported more often in patients with ventricular tachyarrhythmia.<sup>14</sup> We sought to evaluate the prevalence of arrhythmias in patients with CHD who experience pregnancy as documented by MCT monitoring, and the impact of arrhythmias on maternal and neonatal outcomes.

**METHODS**

**STUDY DESIGN.** This is a prospective cohort study of adult patients with CHD who were enrolled in the STORCC (Standardized Outcomes in Reproductive Cardiovascular Care) registry from 2011 to 2017.<sup>15</sup>

**ELIGIBILITY CRITERIA.** Patients with connective tissue disorders, patent foramen ovale, and those who experienced a spontaneous abortion or ectopic pregnancy were excluded. During the study period, as per STORCC protocol recommendations, a 24-hour MCT monitor was performed during the first trimester of pregnancy if it had not been performed within 18 months prior to conception.

**DATA COLLECTION.** Positive MCT monitor findings were defined as sick sinus syndrome (symptomatic sinus bradycardia <60 beats/min or symptomatic sinus pause >3 seconds), symptomatic Mobitz 1 second-degree atrioventricular (AV) block, Mobitz 2 AV block (regardless of symptoms), complete heart block, >5% burden of either supraventricular or ventricular ectopic beats, non-sustained supraventricular or ventricular tachycardia (SVT and VT, respectively)  $\geq 3$  beats at >100 beats/min, and/or sustained SVT or VT >30 seconds.<sup>16</sup> Five of the 141 pregnancies had alternative ambulatory monitoring based upon the presence of a dual chamber implantable cardioverter-defibrillator (ICD) interrogation that precluded the need for MCT. The monitor results were reviewed by 3 independent reviewers (V.D., S.C., T.T.). Clinically significant arrhythmia events (CSAE) during pregnancy were defined as arrhythmias requiring a medical intervention, emergency room visit, or ICD therapy. Maternal cardiac adverse outcomes included CSAE, heart failure requiring diuretic therapy, cerebrovascular accident, and acute valvar dysfunction. Maternal obstetric adverse events included hypertension, pre-eclampsia, preterm labor, and chorioamnionitis. Neonatal adverse outcomes included NICU admission for any indication, small for gestational age (SGA), hypoglycemia, and prematurity. We also reviewed significant arrhythmia events before pregnancy, which were defined as any of the following: SVT sustained at least 30 seconds; VT at least 30 seconds; non-sustained VT only if symptomatic; sick sinus syndrome (symptomatic sinus bradycardia <60 beats/min or symptomatic sinus pause at least 3 seconds); symptomatic Mobitz 1 second-degree AV block; Mobitz 2 AV block (regardless of symptoms); and complete heart block.

**TABLE 1 Baseline Cardiac and Obstetric Characteristics (N = 141)**

Mother's age, y	32 (21-41.0)
Median gestational age at delivery (wk)	39 (25.4-41.0)
Gravida	2 (1-6)
Parity	0 (0-4)
CHD classification <sup>a</sup>	
Anatomical	
I	24 (17%)
II	85 (60%)
III	32 (23%)
Physiological	
A	16 (11%)
B	53 (38%)
C	68 (48%)
D	4 (3%)
Medications	
Baseline	
Beta-blocker	24 (17%)
Antiarrhythmic	2 (1%)
During pregnancy	
Beta-blocker	25 (18%)
Anti-arrhythmic	3 (2%)
Values are median (range) or n (%). <sup>a</sup> Based on the 2018 AHA/ACC guidelines for management of adults with congenital heart disease. CHD = congenital heart disease.	

The classification of CHD complexity was according to the 2018 American Heart Association/American College of Cardiology guidelines for the management of adult CHD patients.<sup>1</sup> Baseline demographics, cardiac anatomy, comorbid conditions, and medications were collected as well as relevant cardiac and obstetric data during the antepartum, intrapartum, and postpartum periods. All patients provided informed consent and this protocol was approved by the Institutional Review Boards at Brigham and Women's Hospital and Boston Children's Hospital.

**STATISTICAL ANALYSIS.** Categorical variables are summarized as frequency (percentage), and continuous variables as median (range) unless otherwise indicated. Clinical outcomes were compared for pregnancies with positive vs negative screening MCT monitors, for those with and without history of arrhythmias, for those with and without a prior ablative procedure, and for those which did and did not utilize beta-blockers using Fisher's exact test. Analyses were performed using Stata version 16.

## RESULTS

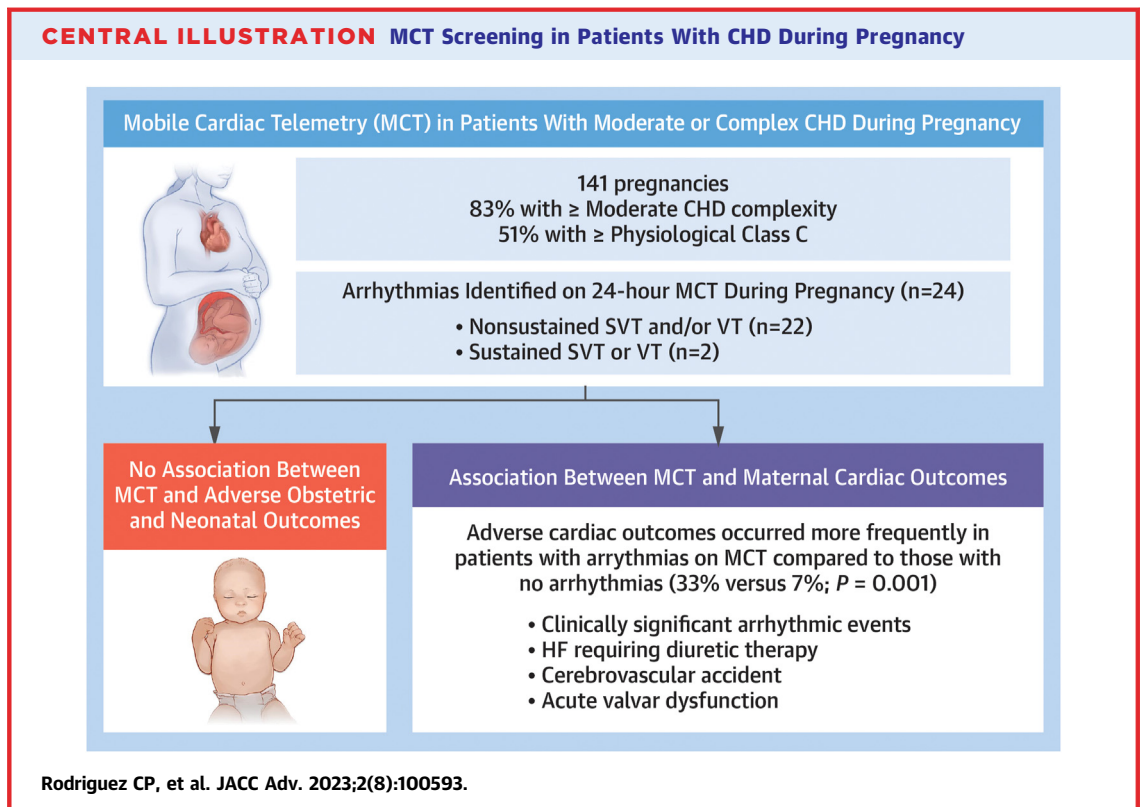
A total of 141 pregnancies in 118 patients were included. The median maternal age was 32 (range: 21-41) years. The clinical characteristics of the cohort are

described in **Table 1**, with 60% having moderate anatomic complexity and 48% with a physiological stage of C. The most common CHD lesions were right-sided lesions, followed by coarctation of the aorta and transposition of the great vessels. The median gestational age at delivery was 39 (range: 25.4-41.0) weeks. Seventy-one percent of patients underwent a spontaneous vaginal delivery, and the remainder had cesarean deliveries for obstetric indications (**Central Illustration**).

Of the 141 pregnancies, 24 (17%) had 1 or more positive MCT or device transmission findings, including 13 with nonsustained SVT only, 5 with nonsustained VT only, 4 with both, 1 with sustained SVT, and 1 with VT terminated by ICD anti-tachycardia pacing. Of the patients with positive MCT findings, 9 (38%) pregnancies required adjustment or initiation of anti-arrhythmic medication. Maternal adverse cardiac outcomes occurred in 16 of 141 pregnancies (11%). Ablation procedures before pregnancy were associated with a higher incidence of arrhythmia events ( $P = 0.002$ ) and any cardiac outcomes ( $P = 0.01$ ).

Regarding arrhythmias specifically, CSAE occurred in 5 of 141 pregnancies (3.5%) (**Table 2**). This occurred in 1 patient with simple CHD, 2 with moderate CHD complexity, and 1 patient with complex anatomy who completed 2 pregnancies. Thirty-three percent of pregnancies with positive screening MCT had adverse cardiac outcomes, compared with only 7% of pregnancies with negative screening MCT ( $P = 0.001$ ). The association persisted when restricting analysis to each patient's first pregnancy (adverse cardiac outcomes in 33% of first pregnancies with positive screening MCT vs 6% of those with negative screening MCT,  $P = 0.002$ ). Subsequent arrhythmias were more common in pregnancies with positive screening MCT with 5 of 24 (21%) experiencing a CSAE compared with no CSAE among the 117 pregnancies with negative screening MCT ( $P < 0.001$ ) (**Figure 1**). None of the pregnancies with positive MCT and CSAE required emergent invasive interventions, such as ablation, pacemaker, or ICD implantation.

Adverse maternal cardiac outcomes included 5 CSAE, 8 acute decompensated heart failure episodes requiring diuretics, 2 cerebrovascular accidents, and 1 episode of acute valvar dysfunction. No patients with acute decompensated heart failure episodes requiring diuretics had an arrhythmia event. Eleven adverse obstetric events occurred among the 24 pregnancies with positive MCT (46%) and 48 adverse obstetric events occurred among the 117 pregnancies with negative MCT (41%) ( $P = 0.66$ ).



There were 8 neonatal events among the 24 pregnancies with positive MCT (33%), and there were 36 neonatal events among the 117 pregnancies with negative MCT (31%) ( $P = 0.81$ ) (Figure 2). The most common neonatal outcomes included admission to the NICU ( $n = 35$ ), SGA ( $n = 14$ ), and hypoglycemia ( $n = 7$ ). More than 1 pregnancy had more than 1 neonatal outcome.

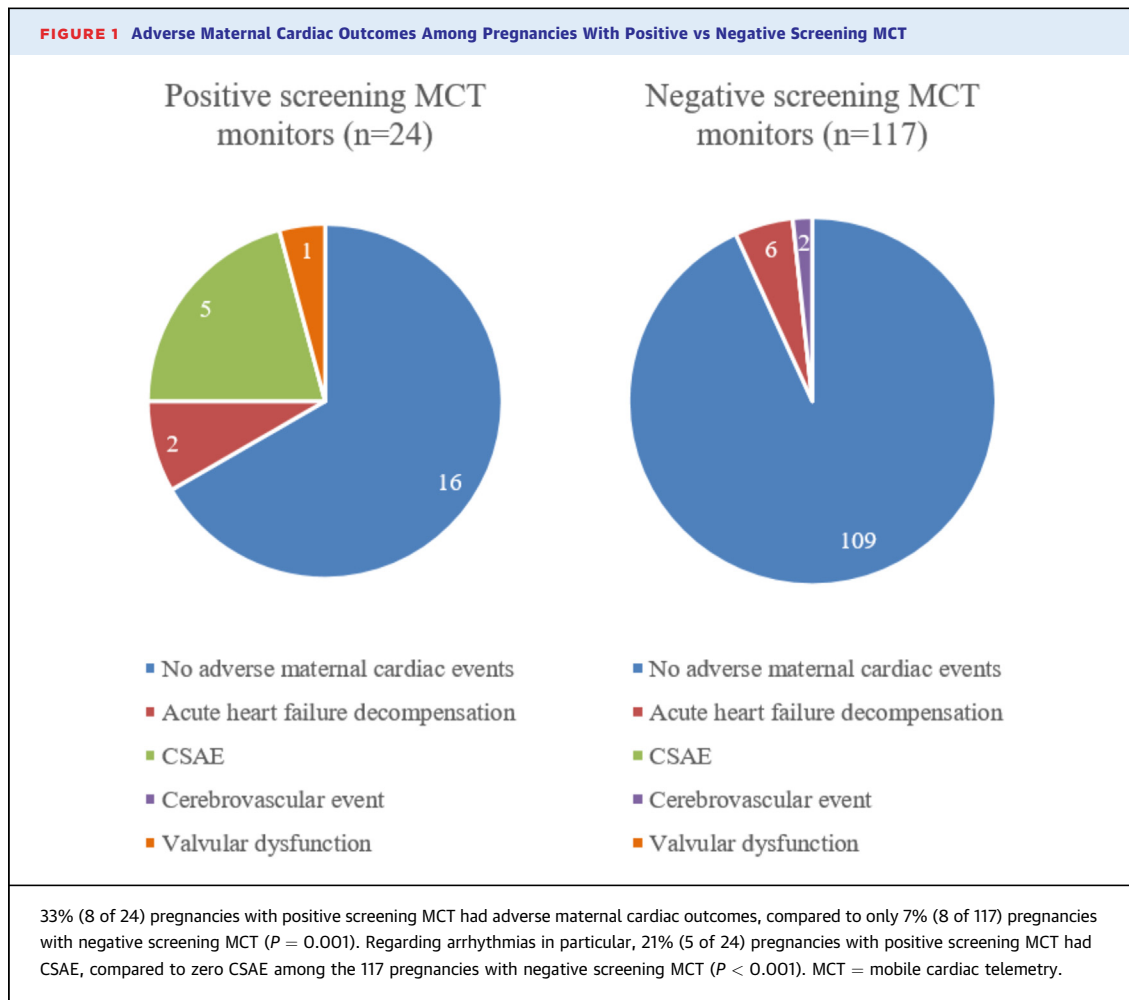
Patients with positive MCT were more likely to be taking beta-blockers prior to conception ( $P = 0.03$ )

and more likely to be taking beta-blockers ( $P = 0.002$ ) and anti-arrhythmic medications (flecainide, digoxin) ( $P = 0.075$ ) during pregnancy. In the entire cohort, 18% of pregnancies were associated with beta-blocker use. Cumulative neonatal adverse outcomes occurred in 36% of pregnancies with beta-blockers and in 30% of pregnancies without beta-blocker use ( $P = 0.64$ ). In particular, SGA occurred in 20% of pregnancies with beta-blocker use and in 8% of pregnancies without beta-blocker use ( $P = 0.13$ ). Neonatal hypoglycemia

**TABLE 2 Clinically Significant Arrhythmia Events During Pregnancy**

Patient	Anatomy	Maternal CSAE	Treatment
1	Shone complex s/p balloon dilation of mitral valve. ASD s/p device closure. Aortic coarctation s/p surgical repair.	Sustained SVT prompting hospital admission at 14 wk gestation	Metoprolol and flecainide
2 <sup>a</sup>	Pulmonary atresia with intact ventricular septum s/p PVR. BAV s/p AVR and ascending aorta replacement.	Sustained SVT prompting emergency room visits	Uptitration of metoprolol
3	D-loop transposition of the great arteries s/p mustard repair	Sustained SVT prompting emergency room visit	Valsalva maneuvers
4	ASD, VSD s/p surgical closure. Arrhythmogenic right ventricular cardiomyopathy s/p ablation and ICD.	Accelerated idioventricular rhythm salvos during labor	Magnesium infusion
5 <sup>a</sup>	Pulmonary atresia with intact ventricular septum s/p PVR. BAV s/p AVR and ascending aortic replacement.	Sustained SVT	Metoprolol, flecainide, and elective repeat cesarean delivery

<sup>a</sup>Same patient, different pregnancies.  
ASD = atrial septal defect; AVR = aortic valve replacement; BAV = bicuspid aortic valve; ICD = implantable cardioverter-defibrillator; PVR = pulmonary valve replacement; SVT = supraventricular tachycardia.



occurred in 8% of pregnancies with beta-blocker use and in 4% of pregnancies without beta-blocker use ( $P = 0.61$ ).

Among the 141 pregnancies, there were 12 cases that had experienced a significant arrhythmic event before pregnancy (based upon chart review including prior telemetry recordings and electrophysiology procedures). While the incidence of having a positive MCT (33%,  $P = 0.12$ ), cardiac event (25%,  $P = 0.14$ ), or neonatal event (50%,  $P = 0.19$ ) were higher in this group with arrhythmias before pregnancy, none of these differences achieved statistical significance.

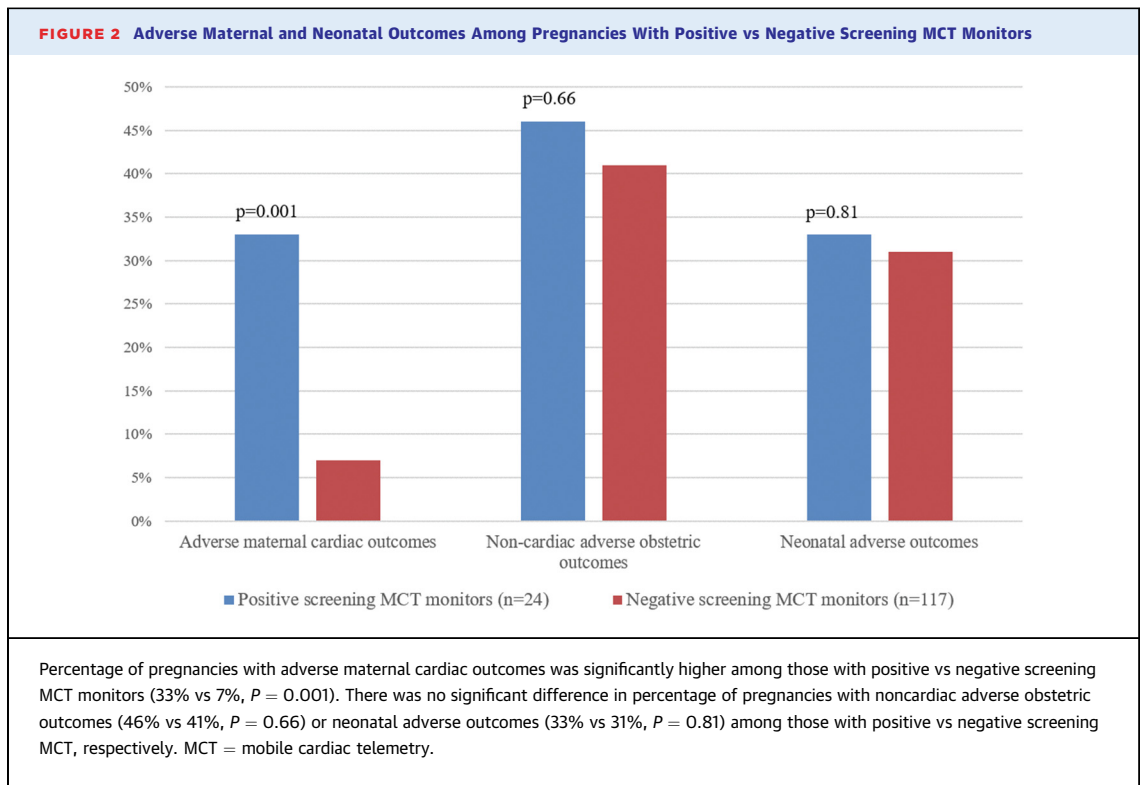
## DISCUSSION

The principal findings of this study are the following.

1) Among patients with CHD who were anticipating pregnancy or who were early in pregnancy, positive screening MCT correlated significantly with maternal cardiac events. 2) In particular, positive screening

MCT correlated significantly with subsequent CSAE during pregnancy. 3) There was no correlation between positive screening MCT and either obstetric or neonatal adverse outcomes. 4) Beta-blocker use during pregnancy did not correlate with SGA, neonatal hypoglycemia, or cumulative adverse neonatal outcomes.

To the best of our knowledge, this is the first prospective study to evaluate screening MCT for risk stratification of pregnancy among patients with CHD. In a retrospective study involving >7,500 pregnancies in patients with CHD, Lammers et al<sup>17</sup> found that the incidence of new arrhythmia during pregnancy was 0.82%, and maternal arrhythmia history did not correlate significantly with severe neonatal complications (OR: 0.73; 95% CI: 0.53-1.01;  $P = 0.055$ ). Our study cohort had a higher incidence of arrhythmia (4%), likely due to a higher proportion of moderate CHD complexity (60% vs 21%) and a lower proportion of simple CHD complexity (17% vs 68%).



Similar to Lammers et al, our study did not find a correlation between maternal arrhythmia and adverse neonatal events.

The ZAHARA (Zwangerschap bij Aangeboren HARTafwijkingen, pregnancy in CHD) study retrospectively assessed >1,300 pregnancies in patients with CHD to search for clinical predictors of adverse cardiac, obstetric, and neonatal outcomes.<sup>18</sup> The most common maternal cardiac complications were arrhythmias, occurring in 4.7%, and heart failure, occurring in 1.6%. Among all clinical covariates assessed, history of arrhythmia was among the top 5 highest factors associated with maternal cardiac complications (OR: 5.0; 95% CI: 2.3-11.0;  $P < 0.001$ ). History of arrhythmia was not associated with obstetric or neonatal complications. These findings are consistent with our study findings.

The CARPREG II study followed >1,900 pregnancies (including >1,200 pregnancies in patients with CHD) prospectively to identify predictors of cardiac complications.<sup>11</sup> Adverse cardiac events occurred in 16% of pregnancies, and the most common cardiac complications were arrhythmias which occurred in

9%. Arrhythmias were most frequent during the second and third trimesters, compared to all other periods antepartum and postpartum. Among the clinical covariates assessed, a composite of prior cardiac events or arrhythmia had the highest odds ratio for predicting maternal cardiac adverse events (OR: 5.9; 95% CI: 4.2-8.4;  $P < 0.001$ ). These findings support our conclusion that utilizing a screening MCT monitor may be useful for predicting maternal adverse events to assist in preconception counseling as well as to determine the frequency of antepartum clinical surveillance.

Regarding beta-blocker use, it is hypothesized that the potential adverse effects of beta-blockers in neonates depend in part on the type of beta-blocker and other confounders, such as maternal hypertension, which could influence fetal growth.<sup>19-21</sup> Additional proposed risk of maternal beta-blocker use includes neonatal hypoglycemia secondary to interruption of newborn glycogenolysis. In contrast to many studies, our study found no significant correlation between maternal beta-blocker use and adverse neonatal outcomes, such as SGA or newborn hypoglycemia. The

reason for our observed findings may be small sample size, lower doses, or the specific beta-blocker prescribed.

In conclusion, arrhythmia events in pregnancy are more common in patients with moderate and complex forms of CHD and in patients with prior arrhythmic events. In our data, prior electrophysiological interventions portend a higher incidence of sustained arrhythmias during pregnancy. This prospective study found that arrhythmia noted on screening MCT monitoring in patients with CHD was predictive of maternal cardiac events and CSAE. This finding suggests that a screening MCT monitor should be considered for patients with CHD (particularly those with moderate and complex CHD) who are considering pregnancy for the purposes of counseling, risk stratification, and determination of frequency of routine surveillance during pregnancy.

**STUDY LIMITATIONS.** There are several limitations to this study. Despite a protocol designed to enhance compliance with standardized diagnostic testing at appropriate time intervals, only 82% of patients in the STORCC protocol completed MCT. Additionally, the timing of MCT was not standardized in this cohort, which may lead to a discrepancy between events and the timing during pregnancy. Lastly, most of the MCT were 24 hours of duration which could have potentially missed less frequent arrhythmias. Patients were followed at a tertiary center wherein there is a potential bias toward a more complex patient population. In terms of CSAE, there could be a potential underestimation of numbers, as we did not count those who may have had an event but never presented for medical care or who had no change in medical therapy due to an absence of symptoms. The fact that 9 patients had therapy changed based on MCT findings may have affected the amount CSAE, as this medical therapy may have prevented subsequent events during the same pregnancy.

## CONCLUSIONS

In this standardized prospective pregnancy cohort, patients with CHD had a high rate of positive findings on MCT, and this was associated with CSAE and adverse maternal cardiac outcomes. Patients with moderate or complex forms of CHD may benefit from screening MCT to improve preconception counseling and pregnancy planning.

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## PERSPECTIVES

**COMPETENCY IN PATIENT CARE:** Arrhythmias are one of the most common adverse cardiac events during pregnancy in patients with CHD. Patients with moderate or complex forms of CHD were more likely to have positive MCT results and CSAE during pregnancy.

**TRANSLATIONAL OUTLOOK:** These findings may be used to effectively counsel patients considering pregnancy regarding maternal and neonatal risk as well as help triage our highest risk CHD patients toward centers with cardio-obstetric teams, telemetry availability, and appropriate cardiology and obstetric support. We recommend patients with moderate or complex forms of CHD to undergo MCT for risk stratification during pregnancy.

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**KEY WORDS** ambulatory heart rhythm monitoring, arrhythmias, cardio-obstetrics, congenital heart disease, pregnancy