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ORIGINAL ARTICLE
Adult congenital heart disease

The modified WHO class is associated with maternal complications in women with congenital heart disease

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Aims

With a growing population of women with congenital heart disease (CHD), pregnancies in this group are expected to increase. However, pregnancy in women with CHD is associated with increased adverse outcomes for both mother and child. The aim of this study was to evaluate pregnancy and foetal complications in women with CHD and to test their association with the modified WHO (mWHO) classification.

Methods and results

Using two national registers, the national register for CHD and the Pregnancy Register, primiparous women giving birth between 2014 and 2019 were identified. Women with CHD, $n = 829$, and women without CHD, $n = 4137$, were matched by birth year and municipality in a ∼1:5 ratio. The women with CHD were classified according to the mWHO criteria. Caesarean deliveries (25.7 vs. 17.2%, $P < 0.001$), preterm delivery (10.3 vs. 6.4%, $P < 0.001$), and preeclampsia (6.2 vs. 4.1%, $P = 0.007$) were more common in women with CHD compared with controls. Using logistic regression, there was an association between high mWHO class (mWHO III, IV) and caesarean section [odds ratio (OR) 3.4, 95% confidence interval (CI) 1.8–6.7], preterm birth (<37 weeks) (OR 8.3, 95% CI 4.1–17.1), and preeclampsia (OR 3.8, 95% CI 1.5–9.9).

Conclusion

Pregnancy complications are more common in women with CHD. In women with CHD, the mWHO classification is associated with maternal complications and preterm birth. Thus, large national register data corroborate the advice provided in current guidelines, and the mWHO class is deemed a valuable risk stratification tool in women with CHD.

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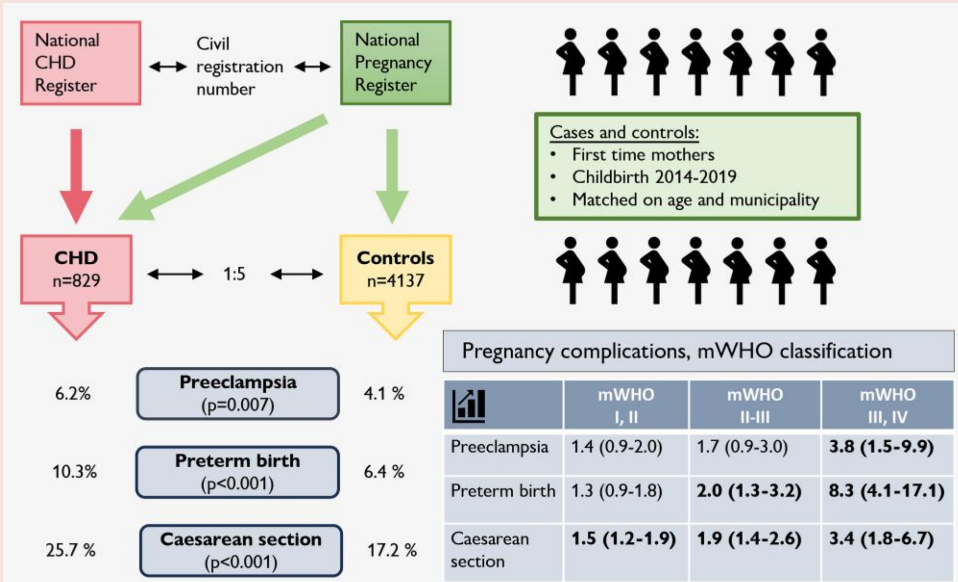
Graphical abstract



Keywords Adult congenital heart disease • Pregnancy • mWHO

Introduction

Due to improvements in diagnostics, surgical techniques, and follow-up care, the number of adults with congenital heart disease (CHD) has escalated over recent decades and long-term survival in this group has dramatically increased. Most children born today with CHD will survive their 18th birthday, and many can expect a long-term survival that is comparable to the general population.[1–3] Consequently, there is an increasing number of women with CHD in childbearing age and studies have confirmed increasing pregnancy numbers and rates among women with CHD.[4–6]

However, CHD and pregnancy are associated with an increased risk of complications for both mother and child. A pregnancy poses an immensely increased haemodynamic load on the cardiovascular system of the mother, and women with CHD might not be able to meet the demands of the physiological adjustments in the circulatory system needed during pregnancy, labour, and delivery. Previous research has shown that women with CHD have a higher risk of cardiovascular complications such as heart failure, arrhythmias, and thrombo-embolic events including stroke.[7–10] Additionally, there is an increased risk of assisted reproductive techniques (ART),[11] obstetric events such as preeclampsia, preterm labour, assisted vaginal delivery, caesarean delivery, and postpartum haemorrhage.[7,9,12,13]

Based on published data on pregnancy complications, several risk scores have been suggested to predict adverse events during pregnancy in women with CHD.[14–17] Some previous studies that explored the risks of CHD in relation to pregnancy are small and therefore contribute with limited data where inclusion criteria and/or endpoints may vary. Some studies include both women with CHD and women with other cardiovascular diseases such as acquired heart disease, e.g. ischaemic heart disease, cardiomyopathies, and arrhythmia. In many reports, there is also a selection bias, and perhaps most importantly, some of the studies build upon historical data.[18] Previous attempts to validate these risk scores, although on limited numbers of patients, have been in favour of the modified WHO (mWHO) classification system.[19–22] This classification is based on expert consensus and was published in the 2018 European Society of Cardiology (ESC) guidelines for the management of cardiovascular diseases during pregnancy.[15] Based on underlying cardiac lesion and functional status, the women are classified in risk Classes I–IV ranging from the lowest risk of mWHO Class I to the highest risk of mWHO Class IV.

Keeping in mind the development that has occurred over the last decades concerning survival, improved interventional techniques, and ameliorated follow-up of CHD, functional outcomes in this patient group have changed in many ways. Older studies acknowledge maternal mortality as an important complication during pregnancy; but in more recent studies, the maternal mortality is quite low or non-existent among women with CHD.[12,19,23] Currently, few population-based or register-based studies on a national level have been presented.

Hence, there is a need to continuously update knowledge in this field to meet the growing number of women with CHD who desire to become pregnant, and to use guidelines based on contemporary data based on scientific evidence. The goal of the present study was to investigate pregnancy complications and foetal outcome in women with CHD using data from large national registers, and to relate these complications to the mWHO classification.

Methods

This is a register study created by linking two national registers—the Swedish registry of congenital heart disease (SWEDCON) and the Swedish Pregnancy Register (*Graviditetsregistret*). SWEDCON is a national register that contains data on patients with CHD from before birth throughout their entire lives.[24] Since 1998, the register covers all health regions in Sweden, and data are collected by each hospital caring for adults with CHD. In 2019, the register contained data from ∼16 000 adults.

The Pregnancy Register is a national register for data on pregnancy and childbirth that covers more than 95% of the births in Sweden.[25] Data are collected starting at the first visit in antenatal care and ends at the follow-up visit after birth, 8–16 weeks postpartum. Since 2014, data from the delivery are automatically transferred to the register from medical charts.

Data collection

Data from SWEDCON include social and demographic data (e.g. marital status, housing, highest education level, and employment status), medical data (e.g. diagnosis and medication), physiological data (e.g. electrocardiogram and echocardiogram), general symptoms, and the New York Heart Association (NYHA) functional class. The Pregnancy Register contains data on demography (e.g. country of birth and marital status), reproductive health (e.g. previous pregnancies and ART) and maternal health (e.g. weight, height, and tobacco use), as well as pregnancy outcomes for the mother and the newborn (i.e. preeclampsia, delivery method, postpartum haemorrhage, laceration, gestational age, and birth weight).

The two registers were linked using the unique civil registration number that is assigned to Swedish citizens and persons residence permit at birth or upon immigration.

All women with CHD registered in SWEDCON and in the registry for pregnancy giving birth between 2014 and 2019 were included in the study.

The diagnoses were manually assessed, and only structural congenital heart disease (except patent foramen ovale and persistent ductus arteriosus) was included in the study.[26] The highest mWHO class was used when two or more were applicable, e.g. mild aortic stenosis (mWHO Class II–III) with aortic dimension 45–50 mm (mWHO Class III). An overview of congenital heart diagnoses is presented in Supplementary material online, *Table S1*. Patients giving birth below 18 years of age were excluded. The heart lesion was classified as mild, moderate, or severe according to the European Society of Cardiology (ESC) guidelines.[26] Based on available clinical data, the women were classified according to the mWHO class. Since aortic valve disease consists of many individuals with mild disease, i.e. with a well-functioning bicuspid valve, this group was presented separately in descriptive statistics but was, per definition of mWHO class, included in mWHO Class II–III for regression analyses.

For each woman with CHD (cases), five women were randomly drawn from the Swedish Pregnancy Register (controls) matched on age and municipality. Only primiparous women (CHD and controls) were included in the study.

Demographic variables, comorbidities, pregnancy complications, and delivery events were compared between cases and controls. Pregnancy complications examined were frequency of gestational hypertension, preeclampsia, preterm delivery, prolonged pregnancy, and amount of haemorrhage at delivery. Preeclampsia was classified as mild (O139 and O140), moderate (O141A), severe (O141B), and HELLP (O141C and O142) according to ICD diagnosis. Prolonged pregnancy was defined as >41 weeks and 6 days gestation; preterm birth was defined as <37 weeks and 0 days gestation. Delivery events examined included use of induced labour and epidural anaesthesia, frequency of caesarean section, and operative vaginal delivery. Foetal death after gestational week 22 was classified as stillbirth.

The study was approved by the Swedish Ethical Review Authority (*Etikprövningsmyndigheten*) (reference 2020-0071). The data were anonymized when delivered from the register holders.

Statistics

Categorical variables are presented as percentages. Continuous variables are presented as means ± standard deviations. Student's *t*-test, χ^2, and Fisher's exact test were used to assess differences in means, rank, and ratios in demographic variables across groups. The associations between maternal characteristics, comorbidities, and complications were evaluated using univariable logistic regression analyses with controls as the reference group. Odds ratio (OR) with 95% confidence interval (CI) are presented. A two-sided *P*-value of ≤0.05 was considered significant throughout the study. All statistical analyses were performed by using the Statistical Package for Social Sciences (SPSS) version 29 (IBM, Armonk, NY, USA).

Results

In total, 829 primiparous women with CHD were compared with 4137 primiparous women without CHD. The characteristics of the study population are shown in *Table 1*. Among the women with CHD, there were 577 (69.6%) with simple lesions, 219 (26.4%) with moderate lesions, and 33 (4.0%) with severe lesions. According to the mWHO class, 556 (67.1%) were in Class I, 41 (4.9%) in Class II, 196 (23.6%) in Classes II–III, 35 (4.2%) in Class III, and 1 (0.1%) in Class IV (*Table 2*). The mean maternal age at time for delivery was similar for women with and without CHD, and there were no differences in maternal age at delivery when stratifying for the complexity of CHD. Educational level, body mass index (BMI), tobacco use at registration and during pregnancy, number of previous pregnancies (miscarriages, extrauterine pregnancies, and induced abortions), diabetes mellitus, endocrine diseases, and rheumatoid diseases were similar in both groups. Chronic kidney disease was more common among women with CHD (1.4 vs. 0.6%, $P = 0.017$) and so was chronic hypertension (1.5 vs. 0.4%, $P < 0.001$) (*Table 1*). Women with coarctation represent 50% of those with chronic hypertension.

Preeclampsia was more common in women with CHD compared with controls (6.2 vs. 4.1%, $P = 0.007$) (*Table 3*). When comparing mild, moderate, severe preeclampsia, and HELLP, there was also a difference between cases and controls (mild preeclampsia 3.4 vs. 2.9%, moderate preeclampsia 1.2 vs. 0.6%, severe preeclampsia 1.3 vs. 0.3%, HELLP 0.2 vs. 0.3%, $P = 0.03$). Giving birth prematurely was more common in cases compared with controls (10.3 vs. 6.4%, $P <$ 0.001). There was, however, no difference between the rate of prolonged pregnancy in cases compared with controls (5.4 vs. 7.0%, $P =$ 0.09). Postpartum haemorrhage >1000 mL (10.8 vs. 9.0%, $P = 0.12$) or perineal laceration Grade III and IV (2.5 vs. 3.7%, $P = 0.09$) did not differ between cases and controls (*Table 3*).

When analysing the association between mWHO class and preterm birth, there was a stronger association with increasing mWHO class: mWHO I, II (OR 1.3, 95% CI 0.9–1.8), mWHO II–III (OR 2.0, 95% CI 1.3–3.2), and mWHO III, IV (OR 8.3, 95% CI 4.1–17.1). There was

Table 1 Characteristics of study population

	CHD *n* = 829	Controls *n* = 4137	*P*-value
Age (at delivery, years)	28.9 (4.7)	28.5 (4.5)	0.22
Simple CHD	28.7 (4.7)		
Moderate/severe CHD	29.1 (4.6)		
Number of previous pregnancies	0: 498 (60.1)	0: 2512 (60.7)	0.92
	1: 164 (19.8)	1: 816 (19.7)	
	≥2: 167 (20.1)	≥2: 809 (19.6)	
BMI	24.4 (4.5)	24.5 (4.6)	0.63
Education	≤12: 384 (51.1)	≤12: 2014 (53.2)	0.31
	>12: 367 (48.9)	>12: 1774 (46.8)	
Chronic hypertension	12 (1.5)	16 (0.4)	**0.001**
Chronic kidney disease	11 (1.4)	24 (0.6)	**0.017**
Diabetes mellitus	18 (1.1)	87 (1.1)	0.872
CHD classification		-	
Simple	577 (69.6)		
Moderate	219 (26.4)		
Severe	33 (4.0)		

Bold values denote statistical significance.
CHD, congenital heart disease; BMI, body mass index.

Table 2 Overview of type of delivery by modified WHO class as well as overall compared with matched controls

	mWHO I	mWHO II	Aortic valve disease	mWHO II–III	mWHO III	mWHO IV	CHD	Controls	*P*-value[a]
n (% of total)	556 (67.1)	41 (4.9)	74 (8.9)	122 (14.7)	35 (4.2)	1 (0.1)	829 (100)	4137 (100)	—
Induced labour, *n* (%)[b]	120 (21.6)	9 (22.0)	23 (31.1)	39 (32.0)	5 (14.3)	—	196 (25.1)	808 (20.5)	**0.004**
Epidural anaesthesia, *n* (%)[b]	21 (3.8)	—	3 (4.1)	7 (5.7)	2 (5.7)	—	33 (4.0)	125 (8.9)	0.16
Non-instrumental delivery, *n* (%)[b]	379 (68.2)	21 (51.2)	46 (62.2)	74 (60.7)	19 (54.3)	—	539 (65)	3027 (73.2)	**0.001**
Caesarean section, *n* (%)[b]	128 (23.0)	15 (36.6)	21 (28.4)	34 (27.9)	14 (40.0)	1 (100)	213 (25.7)	716 (17.3)	**0.001**

Bold values denote statistical significance.
CHD, congenital heart disease; mWHO, modified World Health Organization classification.
[a]Comparison between CHD and controls.
[b]Per cent within mWHO class.

also an association between the mWHO class III, IV and preeclampsia (OR 3.8, 95% CI 1.5–9.9), but not for preeclampsia and the mWHO Class I, II (OR 1.4, 95% CI 0.9–2.0) or the mWHO Class II–III (OR 1.7, 95% CI 0.9–3.0) (*Table 4*).

Table 2 illustrates the mode of delivery by mWHO class. Caesarean section was more common in women with CHD than controls (25.7 vs. 17.3%, $P < 0.001$). Among the women who delivered by caesarean section, the number of non-elective caesarean section was similar between women with CHD and women without CHD (52.1 vs. 55.9%, $P = 0.471$). The type of anaesthesia (general anaesthesia, spinal, or epidural) did not differ between cases and controls. Among women giving birth vaginally, the use of epidural anaesthesia was similar between CHD and controls. Induced labour was more common among cases than controls (25.1 vs. 20.5%, $P = 0.004$). The rate of non-instrumental delivery (not vacuum extraction or forceps delivery) was lower in cases compared with controls (65 vs. 73.2%, $P < 0.001$). Overall, the number of stillbirths was low, three in cases and nine in controls, and did not differ between groups ($P = 0.44$) (*Table 3*).

The association between mWHO class and type of delivery is presented in *Table 4*. There was an association between all mWHO classes and caesarean section—mWHO I, II (OR 1.5, 95% CI 1.2–1.9), mWHO II–III (OR 1.9, 95% CI 1.4–2.6), and mWHO III, IV (OR 3.4, 95% CI 1.8–6.7). There was also an association between induced labour and mWHO Class II–III (OR 2.0, 95% CI 1.5–2.8), but not for mWHO Class I, II (OR 1.2, 95% CI 0.9–1.4) or mWHO Class III, IV (OR 0.6, 95% CI 0.3–1.8).

Discussion

In this study, we report on maternal and foetal outcome, and apply the mWHO-classification risk stratification using data obtained from two large national registers. Our main finding is that the risk stratification according to the mWHO classification effectively identifies patients at risk. We also report that many pregnancy complications are more common in patients with CHD.

Herein we show that a higher mWHO class is in general incrementally associated with more pregnancy complications and more complicated deliveries. Because the mWHO classification is based on previous reports on maternal complications in women with CHD, it is currently not fully evaluated by real-world data. Even if previous studies are pooled together, our study is larger and represents a more contemporary cohort. Furthermore, we only report on primiparous women; therefore, our study avoids the bias of repeated pregnancies in the same woman. It must be pointed out that even if the groups did not differ concerning age, BMI, smoking, and diabetes mellitus, several risk factors together in a specific individual can increase the total risk for maternal complications. Examples of such shared risk factors are age over 35 years, obesity, diabetes, other comorbidities, and smoking.[27] These factors are probably even more important in women with ischaemic heart disease, but they also affect maternal morbidity in women with CHD and must also be considered in the overall individual assessment.

The women with CHD in our study more frequently had chronic hypertension. However, no difference was found regarding the development of hypertension of pregnancy between women with CHD and controls. Regarding preeclampsia, there was, however, a difference between women with CHD and controls. These results reflect previous studies.[13,28,29] A possible explanation to this might be the fact that chronic hypertension is more common in women with CHD. This is an interesting and important finding since preeclampsia is one of the major causes of maternal deaths and maternal morbidity.[30] Placental abnormalities are associated with foetal growth restriction[31] and is in itself a risk factor for cardiovascular morbidity and mortality later in life for women.[32] In addition, an association between preeclampsia and lower cardiac output has been described.[33,34] Preeclampsia in women with CHD, from both the aspects of mother and child, is therefore an important issue for future research.

In the present study, stillbirth was equally common in women with CHD compared with controls and the overall number was low. Comparisons of our result with previous findings should, however, be made cautiously since the definition of foetal death may differ among studies, partly due to legislative differences between countries.[35] In Sweden, death at or after gestational week 22 is registered as stillbirth, whereas death before gestational week 22 is registered as miscarriage. In fact, we report few cases of stillbirth, potentially indicating that current practice is adequate at least in our large national cohort.

The overall proportion of caesarean section was one-fourth among women with CHD in our study. This is lower than many of the previously reported studies,[7,12,13,36] but is similar to levels reported by Bottega *et al.*[5] There might be several possible explanations for these differences. Given that a caesarean section is more common in women with moderate or severe CHD, a higher proportion of moderate and severe CHD in a cohort would yield a higher percentage of caesarean sections. Nevertheless, our findings are still much lower than Schlichting *et al.*[7] who presented a percentage exceeding 40% caesarean section among mild/moderate CHD in the USA. An alternative explanation to our result is that it simply reflects an overall lower level of caesarean sections in Sweden compared with many other countries. In 2019, the level of caesarean sections among all women giving birth in Sweden was 17.7%, whereas the level in many other European countries was much higher.[37,38] This study found that induced labour was wore common among women with CHD compared with controls and that induced

Table 3 Overview of pregnancy complications by modified WHO class as well as overall compared with matched controls

		mWHO I	mWHO II	Aortic valve disease	mWHO II–III	mWHO III	mWHO IV	CHD	Controls	*P*-value[a]
n (% of total CHD)	*n* (%)	556 (67.1)	41 (4.9)	74 (8.9)	122 (14.7)	35 (4.2)	1 (0,1)	829 (100)	4137 (100)	—
Gestational hypertension	*n* (%)[b]	19 (2.2)	1 (0.1)	5 (0.6)	2 (0.2)	3 (0.4)	0	30 (3.6)	125 (3.0)	0.34[c]
Preeclampsia	*n* (%)[b]	28 (5.0)	5 (12.2)	9 (12.2)	4 (3.3)	5 (14.3)	0	51 (6.2)	168 (4.1)	**0.007**
Postpartum haemorrhage (≥1000 mL)	*n* (%)[b]	54 (9.7)	3 (7.3)	6 (8.1)	16 (13.1)	5 (14.3)	0	84 (10.8)	354 (9.0)	0.12
Perineal laceration (Grade III–IV)	*n* (%)[b]	15 (2.7)	2 (4.9))	2 (2.7)	2 (1.6)	0	0	21 (2.5)	154 (3.7)	0.09
Gestational age (weeks)	Mean (SD)	39.4 (2.2)	38.4 (2.7)	38.7 (2.7)	38.5 (2.8)	36.8 (4.5)	33.0 (–)	39.0 (2.6)	39.4 (2.0)	**<0.001**
Preterm birth (<37 weeks + 0 days)	*n* (%)[b]	43 (7.7)	4 (9.8)	8 (10.8)	14 (11.5)	11 (31.4)	1 (100)	81 (10.3)	254 (6.4)	**<0.001**
Prolonged pregnancy (>41 weeks + 6 days)	*n* (%)[b]	37 (6.7)	1 (2.4)	3 (4.1)	1 (0.8)	1 (2.9)	0	42 (5.4)	277 (7.0)	0.093
Stillbirth	*n* (%)[b]	2 (0.4)	0	0	1 (0.8)	0	0	3 (0.4)	9 (0.2)	$P = 0.43$[d]

Bold values denote statistical significance.
CHD, congenital heart disease; mWHO, modified World Health Organization classification.
[a]Comparison between CHD and controls.
[b]Per cent within mWHO class.
[c]Cases with chronic hypertension excluded.
[d]Fisher's exact test.

Table 4 Logistic regression, associations with modified WHO class in women with congenital heart disease with the control group as reference

	OR	95% CI	*P*-value
Induction			
mWHO I, II	1.2	0.93–1.41	0.21
mWHO II–III	2.0	1.47–2.77	**<0.001**
mWHO III, IV	0.6	0.27–1.80	0.45
Caesarean section			
mWHO I, II	1.5	1.24–1.86	**<0.001**
mWHO II–III	1.9	1.36–2.59	**<0.001**
mWHO III, IV	3.4	1.77–6.71	**<0.001**
Preterm birth			
mWHO I, II	1.3	0.95–1.82	0.098
mWHO II–III	2.0	1.25–3.16	**0.004**
mWHO III, IV	8.3	4.05–17.09	**<0.001**
Preeclampsia			
mWHO I, II	1.4	0.94–2.03	0.098
mWHO II–III	1.7	0.94–3.01	0.082
mWHO III, IV	3.8	1.46–9.92	**0.006**

Bold values denote statistical significance.
CHD, congenital heart disease; mWHO, modified World Health Organization classification; OR, odds ratio; CI, confidence interval.

labour was associated with mWHO Class II–III but not to mWHO Class I, II or mWHO Class III, IV. Several factors might explain this observation. Firstly, given the current recommendation that induced labour should be considered at term (40 weeks)[15] and that more women in higher mWHO classes give birth premature, caesarean section will probably more likely be chosen as delivery method for these women if the maternal or neonatal risk of ongoing pregnancy is considered higher than the risk of delivery. Secondly, contraindications to vaginal birth such as treatment with oral anticoagulants or important ascending aortic disease will also affect the choice of delivery method. There were in total four women with CHD who were treated with oral anticoagulation (warfarin). In general, these women will be shifted to low-molecular anticoagulation therapy at the end of pregnancy. Surprisingly, this study did not find any difference in prolonged pregnancy between cases and controls. However, there were very few women with prolonged pregnancy in mWHO Classes II, II–III, and III. During the years 2016–18, a national study of induction at gestational week 41 as intervention was conducted in Sweden.[39] The management of late-term pregnancies was changed after this study due to lower perinatal mortality in the early induction group.

Limitations

This is a register study that is limited to the data within the register. As in all observational studies, causality cannot be determined. Our data cover women who have given birth and cover births after gestational week 22. Therefore, there is no information about miscarriages. We do not have access to data on cardiac complication as heart failure and arrhythmia during pregnancy.

Conclusion

This study shows that the mWHO classification is associated with outcomes such as preeclampsia and preterm birth in women with CHD.

Our data reflect a real-world setting where women in mWHO Classes I and II dominate. This large national register cohort corroborates the advice provided in current guidelines. The mWHO class appears to be a valuable risk stratification tool in women with CHD.

Lead author biography

Sara Jonsson, MD is a paediatric cardiologist working at the University Hospital of Umeå, Sweden. She studied medicine at Umeå University and Henri Poincaré University, Nancy and Charité Humboldt University, Berlin. She completed her paediatric residency and subspecialization in paediatric cardiology at the University Hospital of Umeå and Queen Silvias Children's Hospital, Gothenburg. She is a part-time PhD candidate in cardiology at the Department of Public Health and Clinical Sciences, Umeå University. Her research focus is on reproductive health in women with congenital heart disease.

Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

Supplementary material

Supplementary material is available at *European Heart Journal Open* online.

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