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ORIGINAL ARTICLE

Validation of the Risk Score for Maternal Cardiac Complications in Women with Cardiac Disease in Pregnancy: A Retrospective Study

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Abstract

Aim of the Study To validate the new cardiac risk scoring system, Sheela's Cardiac Disease in Pregnancy (SHE-CDIP), in predicting the cardiac complications in women with cardiac disease in pregnancy.

Materials and Methods The study was conducted at a tertiary care hospital in South India, over a period of 5 years from January 2010 to January 2015. Pregnant women with heart disease included in this study were 102, and data was collected from medical records. Risk Score was calculated at booking according to both the new scoring system (SHE-CDIP) and the standard CARPREG scoring system. The validation was done by assessing the ability of the new scoring system to predict maternal cardiac complications by comparing with the CARPREG scoring system.

Statistical Methods The validation of the SHE-CDIP score was done against CARPREG score using cross tabulation between current cardiac risk score with CARPREG score. McNemar square test was done to compare the proportion between two scoring methods. Agreement between CARPREG and SHE-CDIP risk score was analyzed using Kappa statistics, and accuracy was reported.

Results Comparing the two risk scores using Kappa statistics, accuracy and good agreement were noted (kappa = 0.70). Sensitivity of 83%, specificity of 88%, positive predictive value of 86% and negative predictive value of 84% for the SHE-CDIP scoring system were noted.

Conclusion The new risk score (SHE-CDIP) would be useful to stratify the risk in Indian cohort of women with cardiac disease in pregnancy as it is population specific.

Keywords Cardiac diseases · Pregnancy · Risk score · Pulmonary hypertension · CARPREG score

Introduction

Cardiac disease in pregnancy is one of the important causes of maternal and neonatal morbidity, though the mortality has now reduced. Cardiac disease complicates approximately 1–3% of pregnancies and is responsible for 10–15% of maternal mortality [1]. Identifying the risk factors for the maternal complications is of great help in counselling and management of these women with cardiac disease. Various risk scoring systems which can predict the maternal cardiac complications have been devised to stratify the risk in these women. The commonly accepted and used scoring systems are the Cardiac Disease in Pregnancy (CARPREG) score, ZAHARA score and the World Health Organization (WHO) scoring systems. As per the prospective study conducted by us [2] previously in our tertiary care hospital in South Indian population, NYHA class 3/4, myocardial dysfunction and pulmonary arterial hypertension were the risk factors

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for maternal cardiac complications in pregnancy. Based on this, we have devised a risk scoring system, SHE-CDIP scoring (Sheela's Cardiac Disease in Pregnancy Scoring), which would be applicable to Indian population in stratifying the risk of maternal cardiac complications in those with cardiac disease in pregnancy.

The current study was undertaken to validate this risk scoring system, based on our prospective study conducted on a similar cohort at our Institution, by comparing it with the standard CARPREG scoring system in terms of its ability to identify those women who are at risk of developing the cardiac complications during pregnancy.

Aim of the Study

To validate the new cardiac risk scoring system (SHE-CDIP) in predicting the cardiac complications in women with cardiac disease in pregnancy.

Materials and Methods

The study was conducted at a tertiary care hospital in South India, over a period of 5 years from January 2010 to January 2015. Totally, 102 pregnant women with heart disease were included in this study, and data was collected from medical records.

A chart review was undertaken in a similar cohort of women with cardiac disease as in our previous study and the risk score was calculated at booking according to both the new scoring system (SHE-CDIP) and the standard CARPREG scoring system. The course of pregnancy and the occurrence of cardiac complications in these women were noted till the time of discharge from the hospital. The validation was done by assessing the ability of the new scoring system (SHE-CDIP) to predict maternal cardiac complications by comparing with the CARPREG scoring system.

Inclusion and exclusion criteria, evaluation and investigations were similar to our earlier study [2] to avoid bias. Those women who delivered before 24 weeks of gestation and patients with isolated mitral valve prolapse were excluded from the study. All other women with rheumatic heart disease (RHD), congenital heart disease (CHD), cardiomyopathies and all types of arrhythmias diagnosed prior to pregnancy and requiring treatment and other acquired heart diseases were included in the study. The study was approved by Institutional Ethics committee of our institute. All women had been clinically evaluated by both obstetrician and a cardiologist. Electrocardiogram and echocardiogram were routinely performed. Additional investigations had been performed when indicated and as advised by the cardiologist.

Baseline characteristics like age, parity, NYHA class at booking, gestational age at first visit, prior cardiac complications, medications and anticoagulation, prior cardiac surgery/interventions, central cyanosis at first visit and nature of the cardiac lesions were noted. Those with central cyanosis at booking were included under NYHA class 3/4 for statistical purposes. As many patients had more than one lesion, the nature of the lesion was classified according to the basic pathophysiology. Definitions of these lesions remained the same as in our earlier study which were arrived at in consultation with the cardiologist, keeping in mind the physiological changes in pregnancy, and is shown in Table 1. These women were followed up through their pregnancy and delivery, till discharge from the hospital using medical records.

Adverse cardiac events in the present pregnancy were recorded, which included new onset cardiac failure including pulmonary edema, new onset symptomatic arrhythmias requiring treatment, stroke/transient ischemic attack (TIA) of cardiac origin and cardiac death. Cardiac failure was defined by Framingham criteria [3, 4].

Pulmonary artery hypertension was defined as pulmonary artery systolic pressure > 50 mm Hg (moderate to severe) as shown in Table 1 and was measured by 2D

Table 1 Definitions of cardiac pathology

Pathology	Definition
Shunt	Atrial/ventricular septal defect and patent ductus arteriosus
Left heart obstruction	Mitral valve area < 2 cm^2 or Aortic valve area < 1.5 cm^2 or left ventricular outflow tract mean pressure gradient of > 25 mmHg
Right heart obstruction	Tricuspid valve area < 2 cm^2 or right ventricular outflow tract mean gradient > 25 mmHg
Left heart regurgitation	Mitral valve jet area > 4 cm^2, Aortic valve pressure half time < 440 ms (moderate to severe regurgitation)
Right heart regurgitation	Moderate to severe regurgitation of tricuspid and pulmonary valves
Pulmonary arterial hypertension	Pulmonary artery systolic pressure of > 50 mmHg (moderate to severe)
Myocardial dysfunction	Systemic ventricular ejection fraction < 40%
Prior arrhythmias	Symptomatic arrhythmias diagnosed before pregnancy and on treatment

echocardiography. The definition was arrived at after consulting the cardiologist of our institution as described in our prior study [2].

Diagnosis of cardiac lesion and the complications had been arrived at by clinical evaluation and investigations in consultation with the cardiologist.

SHE-CDIP Scoring Method

As per the prospective study conducted by us previously [2], at our institution to identify the risk factors for maternal cardiac complications, we found that NYHA class 3/4, the presence of myocardial dysfunction and pulmonary arterial hypertension (PAH) were the risk factors in our study population. Based on this, we have devised a scoring system to stratify the risk of maternal cardiac complications in women with heart disease in pregnancy.

The new scoring system, referred to as Sheela's Cardiac disease In Pregnancy Scoring System (SHE-CDIP), was devised after elaborate discussions with the statistician. In order to develop a risk score, scoring was adopted for variables NYHA class, pulmonary arterial hypertension (PAH) and myocardial dysfunction. A score of 1 was given to each variable if present and a score of 0 was given when absent. The total score for each individual was computed. Total score of 1 or > 1 was considered as high risk, and a score of 0 was considered as low risk (Cardiac Risk Category). This was used for further statistical analysis to test association with maternal adverse events.

CARPREG Scoring System

CARPREG score includes history of prior cardiac event or arrhythmias, NYHA functional class > II or cyanosis, left heart obstruction (mitral valve area < 2 cm^2, aortic valve area < 1.5 cm^2 or left ventricular outflow tract gradient > 30 mmHg), left ventricular ejection fraction < 0.40. Each variable is scored as 1 if present and 0 if absent. Chance of cardiac complications is defined as follows: 0 points = 5%, 1 point = 27%, ≥ 2 points = 75%. A CARPREG score of 0 is taken as low risk and a score of ≥ 1 is taken as high risk.

Statistical Method

The validation of the current cardiac risk category (low risk/high risk) was done against CARPREG score (low risk/high risk) using cross tabulation between current cardiac risk score with CARPREG score. McNemar square test was done to compare the proportion between two scoring methods. Agreement between CARPREG and of SHE-CDIP risk score was analyzed using Kappa statistics, and accuracy was reported.

Continuous variables were reported using mean ± SD (standard deviation). Categorical variables were reported using number and percentages. Chi-square test was used to find the association between Cardiac Risk Category variables. All the analysis was done using SPSS version 18.0. All the analysis was statistically significant at 5% level (p value < 0.05).

Results

Study was conducted at a tertiary care hospital in South India, over a period of 5 years from January 2010 to January 2015. Totally, 102 pregnant women with heart disease were included in this study, and data were collected from medical records. The demographic characteristics and the etiology of the lesions in women in our current study population were similar to that in our previous study, avoiding the bias in the current study and are shown in Tables 2 and 3, respectively.

Our study showed patients with left heart obstruction in 27 (29.4%), right heart obstruction in 12 (11.7%), left heart regurgitation in 27 (26.4%), right heart regurgitation in 19 (18.6%), arrhythmias in 1(0.9%), pulmonary hypertension in 27 (26.4%), myocardial dysfunction in 11 (10.7%) and shunts in 23 (22.5%) cases. At booking, risk scoring was obtained by applying our new scoring system (SHE-CDIP) as well as

Table 2 Baseline characteristics

Baseline characteristics	Prior study	Present study	p value
Mean age	24 years	25 years	1.00
Parity			
Primigravida	79 (54%)	47 (46%)	0.15
Multigravida	67 (46.5%)	55 (53.9%)	
NYHA Class at booking			
NYHA 1 and 2	132 (90%)	93 (91.1%)	1.00
NYHA 3 and 4	14 (10%)	9 (8.8%)	
Gestational age at booking			
< 20 weeks	121 (83%)	89 (87.2%)	0.37
> 20 weeks	25 (17%)	13 (12.7%)	
Prior cardiac complications	15 (10%)	8 (7.8%)	0.33
Prior cardiac surgery/intervention	50 (34%)	44 (43.1%)	0.14
Central cyanosis	5 (3.4%)	8 (7.8%)	0.15
Cardiac medications	37 (25%)	22 (21.5%)	0.29
Heparin/warfarin intake	13 (8.9%)	14 (13.7%)	0.16
Associated hypertension in pregnancy	30 (20.5%)	22 (21.5%)	0.87
Severe anemia at booking	13 (8.9%)	7 (6.8%)	0.46
Associated PPH	9 (6%)	6 (5.8%)	0.57

Table 3 Etiology of cardiac diseases

Etiology	Previous study	Present study	*p* value
Rheumatic	97 (67%)	71 (69.6%)	
Congenital	38 (26%)	27 (26.4%)	
Cardiomyopathy	7 (5%)	3 (2.9%)	
Arrhythmias	2 (1.3%)	1 (1%)	
Total	144 (100%)	102 (100%)	0.74

the standard CARPREG system. There was no significant difference in the numbers belonging to low risk and high risk by both the scoring systems (Table 4). On following these women through pregnancy till discharge from the hospital, 20 (19.6%) women developed cardiac complications (Cardiac Adverse Events). New onset cardiac failure were noted in 8 (7.8%), pulmonary edema in 8 (7.8%) and arrhythmias in 3 (2.9%) of cases. There were no cases of TIA/stroke or cardiac death. The number of cardiac adverse events in low risk and high risk was similar by both the scoring systems ($p = 0.931$).

Validation of SHE-CDIP risk score for variables like cardiac failure, pulmonary edema and arrhythmia, stroke/TIA of cardiac origin, cardiac death and need for ICU care was done. It showed a similarity between standard CARPREG score and newly derived score SHE-CDIP with significant p- value on variables like cardiac failure, pulmonary edema and need for ICU care (Table 5). Using the cross tabulation, it was noted that 85% of the subjects had concordance for low- and high-risk categories by both scoring methods. Only for 15% subjects, discordant results were noted. Analyzing the agreement between CARPREG and of SHE-CDIP risk scores using Kappa statistics, accuracy and good agreement was noted (kappa = 0.70) between current risk score with CARPREG scoring method. Sensitivity of 83% and specificity of 88%, positive predictive value (PPV) of 86% and the negative predictive value (NPV) of 84% for the SHE-CDIP scoring system were noted (Table 6).

Discussion

Identifying the risk factors for the maternal complications and risk stratification is of utmost importance in counselling and care of the pregnant women with cardiac disease in pregnancy. Management can be planned accordingly, to optimize the outcome for the woman and her baby. Several studies [5–11] have validated and reported that the risk scoring systems such as the CARPREG and (modified WHO) mWHO scoring systems are useful in predicting the maternal cardiac complications and they are widely used.

But a recent study published in 2017 [12], The Registry Of Pregnancy And Cardiac disease which is a worldwide

Table 4 Comparing the number of cases in each score in CARPREG and SHE-CDIP scoring methods

Score	CARPREG *n* (%)	SHE-CDIP *n* (%)	*p* value
0	56 (54.9)	57 (55.8)	0.437
1	28 (27.4)	37 (36.2)	
2	18 (17.6)	8 (7.8)	

Table 5 Validating SHE-CDIP score and it's comparison with standard CARPREG score

Variables	High risk Number (%)	Low risk Number (%)	*p* value
Validation SHE-CDIP score			
Cardiac failure			
Yes	8 (17.8)	0	0.001
No	37 (82.2)	57 (100)	
Pulmonary edema			
Yes	8 (17.8)	0	0.001
No	37 (82.2)	57 (100)	
Arrhythmia			
Yes	3 (6.7)	0	0.04
No	42 (93.3)	57 (100)	
Stroke			
Yes	0	0	–
No	45 (100)	**57** (100)	
Cardiac death			
Yes	0	0	–
No	45 (100)	**57** (100)	
ICU CARE			
Yes	10 (22.2)	0	< 0.001
No	35 (77.8)	57 (100)	
Standard CARPREG score			
Cardiac failure			
Yes	8 (17.4)	0	0.001
No	38 (82.6)	56 (100)	
Pulmonary edema			
Yes	8 (17.4)	0	0.001
No	38 (82.6)	56 (100)	
Arrhythmia			
Yes	3 (6.5)	0	0.05
No	43 (93.5)	56 (100)	
Stroke			
Yes	45 (100)	**57** (100)	–[a]
No			
Cardiac death			
Yes	45 (100)	**57** (100)	–
No			
ICU CARE			
Yes	10 (21.7)	0	< 0.001
No	36 (78.3)	56 (100)	

[a]No statistics calculated as stroke are constant

Table 6 Predictive value, sensitivity and specificity of SHE-CDIP and CARPREG scoring systems

	CARPREG scoring system		Sensitivity	Specificity	PPV	NPV
SHE-CDIP scoring system	Low risk	High risk	82.6%	87.5%	86%	84%
Low Risk	49	8				
High Risk	7	38				

ongoing prospective registry that enrolled 2742 pregnancies in women with known cardiac disease (mainly congenital and valvular disease) before pregnancy, from January 2008 up to April 2014, concluded that the mWHO classification is not suitable for prediction of obstetric and fetal events in women with cardiac disease. So also, the results of a registry from the European Society of Cardiology [13] (Global cardiac risk assessment in the Registry Of Pregnancy And Cardiac disease) concluded that the mWHO risk classification is a useful tool for predicting cardiac events during pregnancy in women with established cardiac disease in advanced countries, but seems less effective in emerging countries.

It is therefore clear that the risk factors are population specific and the scoring systems have to be devised for specific population depending on the risk factors for that particular population. The risk scoring system (SHE-CDIP) which we have devised is based on the risk factors identified in the similar cohort of women with cardiac disease in pregnancy at our institution [2] and hence is more relevant to our population. Our scoring system also incorporates pulmonary arterial hypertension which is an important risk factor [14–18] and determines maternal mortality and morbidity. Most common cause of pulmonary hypertension in our study was left heart obstruction.

Validating our scoring system by comparing with the standard CARPREG system, we found that there was a sensitivity and specificity of 82.6% and 87.5% with a PPV and NPV of 86% and 84%, respectively. Therefore, this simple and uncomplicated scoring system may be useful to predict maternal cardiac complications in our population and subsequently plan the management in women with cardiac disease who are contemplating or going through pregnancy.

However, since this was a retrospective analysis, we plan to conduct a prospective study to validate this risk score which would be more authentic.

Conclusion

The new risk score (SHE-CDIP) would be useful to stratify the risk in cohort of Indian women with cardiac disease in pregnancy as it is population specific.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical Approval All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 (5).

Informed consent As it was a retrospective study, formal informed consent was not required.

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