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Review Article

Heart disease during pregnancy in the KSA: A suggested plan

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الملخص

أهداف البحث: إن أمراض القلب الخلقية لدى الحوامل هي السبب الرئيس لوفيات الأمهات في البلدان المتقدمة، بينما تعتبر الحمى الروماتزمية هي السبب الأكثر شيوعا لأمراض صمامات القلب لدى الحوامل في الدول النامية. وقد أسهم التطور في جراحة القلب لحديثي الولادة والأطفال في زيادة نسبة أمراض القلب الخلقية لدى الحوامل في جميع أنحاء العالم. والدراسات المنشورة حول أمراض القلب لدى الحوامل في المملكة العربية السعودية قليلة وقديمة نسبيا. تنظر هذه الدراسة في الوضع الحالي لأمراض القلب لدى الحوامل في المملكة العربية السعودية وتصف الخطة المقترحة لأمراض القلب لدى الحوامل في المملكة العربية السعودية، أي التسجيل السعودي لأمراض القلب والحمل **(رشداب)**.

طرق البحث: أجري بحث منهجي عن طريق "بروكويست" وقاعدة بيانات "ميدلاين" باستخدام مصطلح داء القلب لدى الحوامل. وروجعت دراسات داء القلب لدى الحوامل على نطاق واسع.

النتائج: تم العثور على أربع دراسات سعودية فقط حول داء القلب لدى الحوامل. ومن المتوقع أن تشكل دراسة "**رشداب**" الأساس للأبحاث السعودية في هذا المجال، وستشكل قاعدة بيانات واسعة كفيلة بإثراء المعرفة حول داء القلب لدى الحوامل. جميع السيدات المصابات بأمراض القلب في المملكة العربية السعودية والراغبات بالمشاركة، هم مؤهلات للالتحاق في هذه الدراسة .تتكون الدراسة من خمس مراحل، وسيتم تسجيل المعلومات مستقبليا، وسريا، واليكترونيا وترسل المعلومات من المراكز المشاركة إلى مكتب التنسيق المركزي، الذي سيقوم بإدارة البيانات وتحليلها.

الاستنتاجات: دراسة رشداب المقترحة في هذه المقالة ستوفر بيانات حديثة حول داء القلب لدى الحوامل في المملكة العربية السعودية، التي من شأنها تشجيع البحوث والحث على ممارسة الرعاية الطبية المبنية على البراهين للسيدات الحوامل المصابات بداء القلب.

الكلمات المفتاحية: إعتلال عضلة القلب؛ أمراض القلب الخلقية؛ الحمل؛ داء القلب الروماتزمي؛ التسجيل السعودي

Abstract

Objectives: Congenital heart disease in pregnancy is a leading cause of maternal death in developed countries while rheumatic fever is the commonest cause of valvular disease in pregnancy in developing countries. Improvement in neonatal and paediatric cardiac surgery has increased the incidence of congenital heart disease in pregnancy worldwide. Published data regarding heart disease in pregnancy (HDP) in KSA are scant and relatively old. This study examines the current status of HDP in KSA and describes the rationale and design of the suggested plan for HDP in KSA, i.e., the **R**egistry **O**f **S**audi **H**eart **D**isease **A**nd **P**regnancy (ROSHDAP).

Methods: A systematic search was conducted through the ProQuest MEDLINE® database using the keyword phrase "cardiovascular disease in pregnancy". An extensive literature review about heart disease in pregnancywas performed.

Results: There are only 4 available Saudi studies of HDP. The ROSHDAP study is expected to establish a foundation for Saudi research in this field and will create an extensive database that will enrich knowledge about HDP. All Saudi women with HDP who wish to participate are eligible for enrolment in the registry. Five phases are planned for the registry, and data will be collected prospectively, confidentially, and electronically. The data will be transmitted from participating centres to a central coordinating office for data management and analysis.

Conclusion: The ROSHDAP study suggested in this article will provide contemporary data on HDP in KSA that will promote research and encourage evidence-based medical care of pregnant women with heart disease.

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Keywords: Cardiomyopathy; Congenital heart disease; Pregnancy; Rheumatic heart disease; Saudi registry

Introduction

In developed Western countries, heart disease in pregnancy (HDP) has an incidence of 0.2%−4% and is the most frequent cause of maternal death.[1−3] Cardiac conditions that contribute to maternal death may present acutely and catastrophically.[2,3] Recognition of risk factors for these conditions may predict complications and permit the establishment of a plan to minimize or prevent complications.[3,4] Therefore, knowledge and experience in HDP are important so that health-care providers can deliver proper counselling and treatment.[3,5]

European HDP experts have recognized the need for better understanding of the relation between pregnancy and heart disease. In 2007, they launched an international Registry On Pregnancy and Cardiac Disease (ROPAC) under the umbrella of the European Society of Cardiology (ESC).[6,7] The registry enrolled 1321 women who had structural heart disease. Although most of the women were from developed countries (1136 women [86%]), some were from developing countries (185 women [14%]).[7] Significant differences between developed and developing countries were observed in this registry (Table 1).[7] These differences reflect the level of medical care in developed and developing countries. In developed countries, optimal care and preconception counselling were available in all centres, but few women in developing countries who had heart disease were assessed and appropriately counselled before conception.[7−9]

The purpose of this article is to explore the current status of heart disease in pregnancy in KSA and compare it to the current international situation with the goal of designing and describing the **R**egistry **O**f **S**audi **H**eart **D**isease **A**nd **P**regnancy (**ROSHDAP**).

Materials and Methods

Searching the ProQuest MEDLINE® search engine (MEDLINE® is a bibliographic database produced by the U.S. National Library of Medicine) using cardiovascular disease in pregnancy as a keyword phrase, an extensive literature review about heart disease in pregnancy was performed (see Figure 1). The search involved English-language peer review articles from 1945 through 2016. When the search was limited to Saudi publications about heart disease and pregnancy, only 10 relevant articles were found: 4 clinical retrospective studies, 4 case reports and 2 review articles (see Table 2). To enrich the search about cardiovascular disease in KSA regardless of pregnancy, multiple attempts with different logical entries were performed and 253 peer-reviewed Saudi articles were identified. Nevertheless, to obtain recent data about heart disease in pregnancy, the search for worldwide publications was narrowed toward more recently published papers between 2010 and 2016. After excluding case reports and review articles, 861 studies were identified and manually screened for close relevancy to HDP. In addition, 253 Saudi publications about cardiovascular disease were manually screened. Ultimately, 31 closely relevant articles were chosen to support this article.

Table 1: Comparison of outcomes of heart disease during pregnancy in developed and developing countries.[a]

Variable	Total	Developed	Developing	P value
Number of women	1321	1136	185	
Baseline				
Age, mean (range)	30 (12−62)	30 (16−53)	27 (18−45)	.001
NYHA class I (%)	70	74	47	.001
Type of heart disease				.001
Congenital (%)	66	74	18	
Valvular (%)	25	18	72	
Other (%)	9	8	10	
Prior cardiac surgery (%)	54	59	22	.001
Drug use before pregnancy (%)	28	26	37	.002
Nulliparous (%)	50	52	34	.001
Outcome				
Maternal				
Maternal mortality (%)	1	0.6	3.9	.001
Maternal hospital admission (%)	26	23	41	.001
Heart failure (%)	12	11	23	.001
Foetal				
Apgar score <7 (%)	10	8.7	17	.001
Preterm birth <37 wk (%)	15	16	11	NS
Foetal death (%)	1.7	0.9	6.5	.001
Neonatal death (%)	0.6	0.6	0.5	NS
Birth weight (g)	3010	3027	2899	.004

NYHA, New York Heart Association. †NS, not significant ($P > .05$).
[a] Reproduced with permission from Registry On Pregnancy and Cardiac disease (ROPAC).[7]

Results

Rationale for ROSHDAP

In developing countries, RHD is the most common cause of HDP (72%), increases the risk of pregnancy, and is a major non-obstetric cause of maternal death.[7,8,10,12] Although RHD might still be a major problem in KSA, current data about RHD are not available.

The ROPAC study showed that congenital heart disease (CHD) is the most frequent cause of HDP in developed countries (74%) and the second-most-frequent cause of HDP in developing countries (18%). The two factors of the KSA's

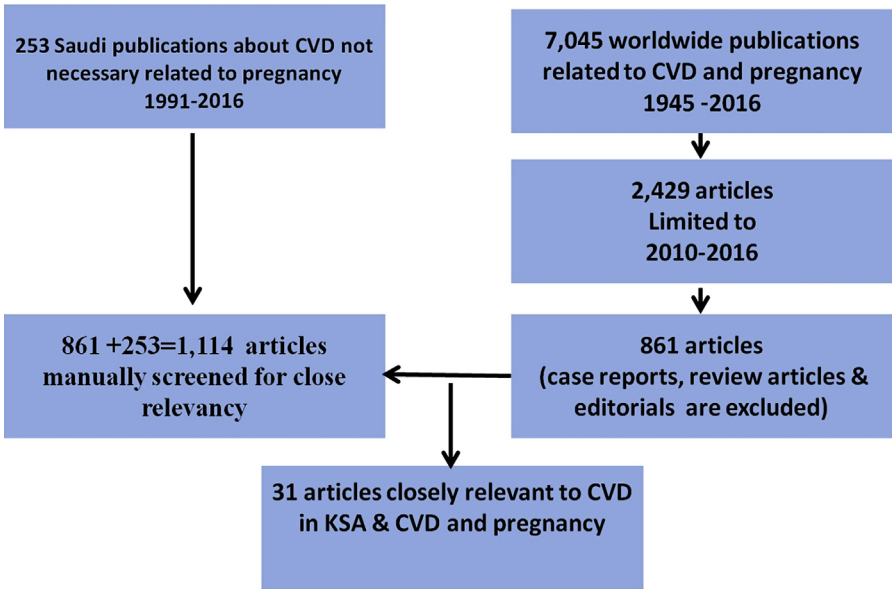

Figure 1: Flow chart showing ProQuest MEDLINE® search for CVD, cardiovascular disease; KSA.

high birth rate (22 births per 1000 population, twice that of Europe) and the high prevalence of consanguinity (57.7%) might enhance the prevalence of CHD in KSA.[12,13] Consanguineous marriages have been linked to congenital heart disease in children of marriages between first cousins in KSA.[14] Furthermore, the potential for girls who have complex congenital heart disease to reach reproductive age in good health and conceive has markedly improved in KSA because of advances in cardiac paediatric surgery and neonatal medicine. However, no published data are available about congenital heart disease in pregnant women in KSA.

Cardiomyopathies (dilated, restrictive, and hypertrophic) are a group of myocardial disorders characterized by structural and functional abnormalities of the ventricular myocardium that cannot be explained by coronary artery disease or abnormal loading conditions.[15] In the ROPAC study, cardiomyopathy was responsible for 7% of HDP.[7,16,17] Peripartum cardiomyopathy (PPCM) is a form of dilated cardiomyopathy related to pregnancy. Recently, a worldwide registry of PPCM has been launched for a better understanding of epidemiology, clinical characteristics and outcomes for inpatients and outpatients with PPCM, the diagnostic and therapeutic processes applied and their impact on outcomes.[18] There is only a limited amount of published data about cardiomyopathy in KSA.[18]

Although coronary artery disease (CAD) was reported as a major contributor to maternal mortality in the British enquiry 'Saving Mothers Lives,' it was rarely noted as a cause of structural heart disease in pregnancy in the ROPAC study.[19,7] In a relatively old (1995–2000) Saudi epidemiological study about CAD, the prevalence of CAD among reproductive-age women (30–39 years) was 3.9%.[20] The prevalence of CAD might have increased recently because of increasing CAD risk factors such as hypertension, diabetes, smoking, and obesity in KSA.[21,22]

Overall, the published data about HDP in KSA are minimal and relatively old.[23–26] In addition, the level of medical services in KSA is variable and includes a mixture of features observed in developed and developing countries. This variability in medical care can affect the epidemiology and outcomes of HDP. Therefore, a ROSHDAP study of women with HDP is necessary to characterize their problems, develop solutions, and generate future plans.

Proposed objectives of ROSHDAP

1. To determine of the magnitude of HDP in KSA, including the following:
   1.1. The incidence of HDP in participating centres and throughout KSA.
   1.2. Maternal and foetal morbidity and mortality during and 6 months after pregnancy.
   1.3. The frequency of utilization of costly medical resources in KSA, including the following:
      - Hospital admissions during pregnancy and within 6 months after delivery (mothers and neonates).
      - Invasive cardiac interventions such as cardiac surgery, balloon valvuloplasty, percutaneous valve implant, and coronary intervention.
      - Advanced foetal interventions.
      - Caesarean deliveries.
      - Epidural anaesthesia.
      - Medication used before and during pregnancy.
2. To assess obstacles to achieving safe medical care and to compare regional differences in KSA.
3. To document the frequency and type of heart disease—including RHD, congenital heart disease, cardiomyopathy, and CAD—among pregnant women in KSA.
4. To determine the incidence of consanguinity in women who have HDP in KSA.
5. To document the mode of birth in KSA in pregnant women with heart disease.
6. To determine the incidence of congenital heart disease in the neonates of Saudi women who have HDP.
7. To assess the effects of pregnancy on cardiac function during and 6 months after pregnancy, as determined by maternal echocardiography.

Table 2: Available Saudi publications about HDP.*

Serial number	Topic	Number of pts with HDP	Study type	Year of publication	First author	Journal
1	CHD** in pregnancy	1	Case report	2015	Elsherif, Zeinelabdien	BMJ+ Case Rep.
2	IHD⅄ in pregnancy	1	Review article	2012	Bondagji, Nabeel S.	Saudi Heart Assoc
3	Bioprosthetic valves in pregnancy	85	Retrospective Study	2005	El, Shaer Fayez	J. Heart Valve Dis.
4	Peripartum cardiomyopathy.	–	Review article	2003	Al-Shamiri, Mostafa Q.	Saudi Med. J.
5	Pregnancy and valvular heart disease.	166	Retrospective Study	2003	Faiz, Shakeel A.	Saudi Med. J.
6	The nineteenth pregnancy in a patient with cor- pulmonale	1	Case report	2003	Al-Mobeireek, Abdullah F.	Acta Obstet. Gynecol. Scand.
7	Mitral balloon valvotomy in pregnancy	23	Retrospective Study	2001	Fawzy, M. E.	J. Heart Valve Dis.
8	Anticoagulation for mechanical valve in pregnancy	1	Case report	2000	Berndt, N.	J. Heart Valve Dis
9	Pregnancy complicated by cardiac disease	229	Retrospective Study	2000	Rahman, J.	J. Obstet. Gynaecol.
10	Percutaneous mitral balloon valvotomy in pregnancy	1	Case report	1991	Ribeiro, P. A.	Rev. Port. Cardiol.

HDP*, Heart disease in pregnancy. CHD**, Congenital Heart Disease. IHD⅄, Ischemic Heart Disease. BMJ+, British Medical Journal.

8. To assess foetal anomalies, as determined by foetal echocardiography.
9. To study the results and frequency of complications from interventions performed during pregnancy.
10. To examine the World Health Organization (WHO) risk score and outcomes in our population.[27]

Proposed study design and population of ROSHDAP

The ROSHDAP study will be a prospective, multicentre, hospital-based nationwide registry program. It will be executed in 5 phases (Figure 2): (1) initiation: writing a proposal and applying for funding; (2) development (estimated duration, 6 mo): contacting co-investigators,

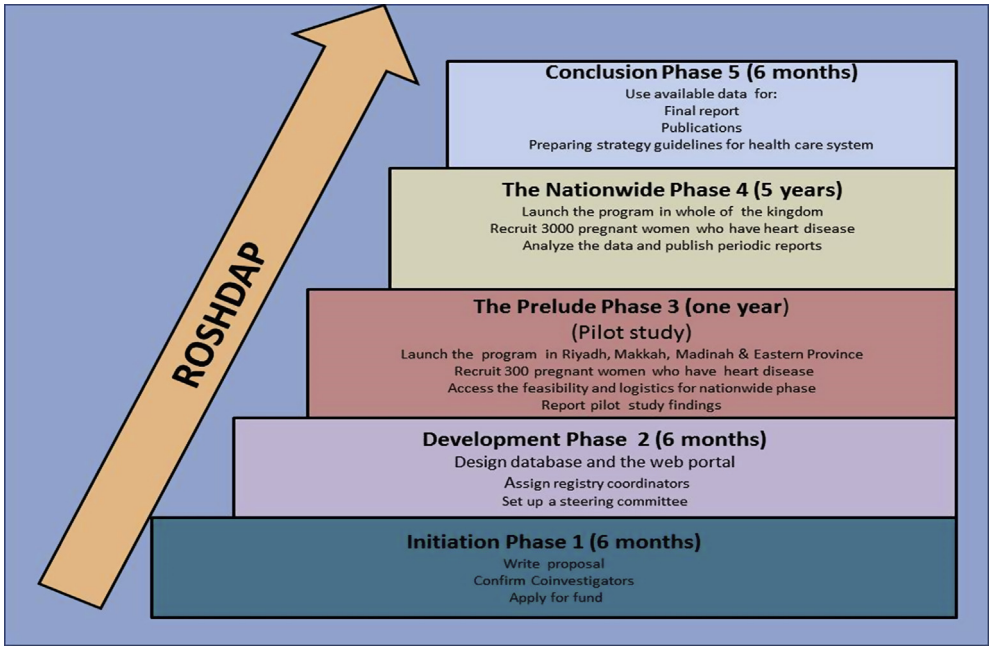

Figure 2: Schematic representation of the phases for the Registry of Saudi Heart Disease And Pregnancy (ROSHDAP).

assigning coordinators to the participating centres, establishing a steering committee, and developing the database and Web portal; (3) prelude and pilot study (with a duration of one year): launching the registry in 4 large provinces (Riyadh, Mekkah, Almadinah Almunawwarah, and Eastern Provinces) and enrolling 300 pregnant women who have HDP to assess the feasibility and logistics of generalizing the registry in existing settings and to provide preliminary data to increase the nationwide registry; (4) nationwide (with a duration of five years): expanding the registry to involve more centres in KSA and enrolling 3000 patients who have HDP; and (5) conclusion: using the data to write a final report, publish research papers about HDP, and prepare strategic guidelines for health care systems.

Proposed eligibility criteria for ROSHDAP

All pregnant women who have heart disease and who are evaluated at participating centres will be eligible for inclusion in ROSHDAP. Patients who do not provide informed consent will be excluded from ROSHDAP.

Proposed database and web portal for ROSHDAP: technical details

A relational database management system will be constructed to develop a repository of every HDP case in KSA. The database will be developed and stored using cloud computing technology, a database server (SQL Server, Microsoft, Redmond, WA, USA), and a software framework (.NET, Microsoft). The participating centres will be provided with protected database access for data entry. The populated data will be accessed for statistical analysis by authorized central coordinator office investigators.

Data collection for ROSHDAP

The ROSHDAP database will store information about maternal preconception counselling, antenatal follow-up, foetal status, labour, postnatal maternal and neonatal follow-up, and paternal data. Data will include clinical information, laboratory test results, cardiac studies (electrocardiography, echocardiography, and cardiotocography), and treatment information (medications, hospital admissions, and therapeutic procedures). The National Identity Number (NIN) of each participating patient will be used to avoid double counting during a single pregnancy. Neonatal follow-up data will be recorded with maternal data.

Registry management for ROSHDAP

Each participating province will have a designated ROSHDAP coordinator to facilitate the tasks of every centre in the province and to coordinate with the central coordinating office. The central coordinating office will have responsibility and authority for all registry data. A ROSHDAP steering committee will be organized with investigators from all participating centres; this committee will monitor the registry and information stored in the database and will be responsible for making policy about statistical analysis and publishing the findings. Co-investigators at participating centres will supervise data collection and recording to ensure data integrity and authenticity. Standardized data collection forms will be used to collect the data, which will be recorded directly onto the Web portal, attempting to minimize missing variables. The co-investigators will have full access to their data and will be updated periodically about other centres' performance.

Follow-up for ROSHDAP

Patients will undergo 3 follow-up visits: upon entry to the registry, at delivery, and 6 months postpartum. An echocardiogram will be performed for mothers during pregnancy and at 6 months postpartum. Foetal ultrasound will be performed between 18 and 22 weeks gestation and neonatal echocardiography will be performed in the first 6 months after birth. Assessment for outcomes will be performed at follow-up. Standardized definitions will be used for maternal, foetal, neonatal, and infant complications (Tables 3 and 4). Deaths and causes of death will be recorded. Morbidity will be recorded from a review of hospital records for new symptoms, clinical findings, investigations, treatment, and nonsurgical and surgical intervention. Other necessary information will be obtained by contacting treating physicians, patients, or patient families. Audits of the collected data (including outcomes) will be performed every 3 months.

Ethical concerns of ROSHDAP

The registry must be approved by the ethical committee of Taibah University. In addition, an agreement to participate and release data will be obtained from the ethical committees at all participating centres. All participating patients will be informed about the registry and asked to complete a consent form. Consent will be scanned and recorded electronically with the patient data and strict confidentiality will be observed.

Statistical analysis for ROSHDAP

The stored data will be accessed and formatted to enable statistical analysis. Data analyses will be performed with statistical software (SPSS, version 17.0, SPSS Inc., Chicago, IL, USA). Descriptive data will be summarized as the mean and standard deviations for continuous variables and as percentages for categorical variables. The incidence of all outcome events will be presented as frequency using Kaplan–Meier method. The association of risk factors with pregnancy outcomes will be evaluated using Cox's proportional hazard regression. Comparisons of variables between provinces will be performed using either a t test or a chi-square test. Statistical significance will be defined by $P \leq .05$ (2-sided test) unless otherwise noted.

Table 3: Maternal complications at any time from registry entry until 6 months after delivery.

Complication	Diagnostic Criteria
General	
Death	Any cause
Congestive heart failure	Based on Framingham criteria[29]
Acute coronary syndrome	ACC/AHA criteria[a,31]
Stroke	Sudden occurrence of neurologic deficit for ≥24 h
Transient ischemic attack	Neurologic deficit for <24 h
Peripheral embolism	Evidence of end-organ ischemia (such as ischemic limb pain or gangrene)
New-onset major arrhythmia (atrial or ventricular)	Electrocardiographic evidence
Infective endocarditis	Modified Duke criteria[30]
Cardiac surgery	Any cardiac surgical intervention
Percutaneous intervention	Catheter-based intervention for any part of cardiovascular system
Prosthetic valve thrombosis	Confirmed by echocardiography and/or cinefluoroscopy
Hospital admission	≥1 day
Intra- or extracardiac vascular conduit thrombosis	Confirmed by ultrasonography and/or any other imaging modality
Major bleeding	Bleeding that causes reduction of haemoglobin by ≥1 g or requires blood transfusion
Obstetric	
Pregnancy-induced hypertension	Blood pressure >140/90 mm Hg documented after 20 weeks of gestation
Preeclampsia	Pregnancy-induced hypertension criteria and >0.3 g proteinuria in 24-h urine
Eclampsia	Preeclampsia and seizures
Premature rupture of membranes	Membrane rupture before onset of uterine contractions
Antepartum haemorrhage	Vaginal bleeding during the second half of pregnancy (after 20 weeks of gestation)
Assisted delivery	Suction device and/or forceps
Caesarean delivery	(1) Cardiac indication, (2) Obstetric indication
Postpartum haemorrhage	Vaginal delivery, haemorrhage >500 mL, caesarean delivery >1000 ml, or requiring transfusion

[a] ACA/AHA, American College of Cardiology/American Heart Association.[31]

Table 4: Foetal, newborn, and infant complications from registry entry until 6 months after delivery.

Complication	Diagnostic Criteria
Abortion	Spontaneous expulsion of the foetus during the first 12 weeks of gestation
Foetal death	Death after 22 weeks of gestation or foetal weight >500 g
Neonatal death	**Death** of a baby within the first 28 days after birth
Infant death	**Death** of an infant from >28 days to 1 year after birth
Intrauterine growth restriction	Foetal weight estimation and/or birth weight <10th percentile
Low Apgar score	Score <7 at 1 and 5 min
Congenital heart disease	Documented by echocardiography
Congenital anomalies	World Health Organization definition: structural or functional anomalies (such as metabolic disorders) that occur during intrauterine life and can be identified prenatally, at birth, or later in life
Neonatal bradycardia	Heart rate <100 beats per minute

Discussion

Recently, research in the field of heart disease during pregnancy has attracted more attention: clinical studies, registries, and guideline articles are emerging from all over the world, especially from Europe and the USA.[2–8,11,16,17,19,27,28] That notwithstanding, the situation in KSA is unfortunately different: Saudi publications about HDP are old and few in number.[23–26] In 2000, Jessica et al. published KSA's first HDP study, which was a single-centre experience and reported old data of 229 patients with HDP delivered between 1982 and 1997.[23] They described a 0.6% incidence of HDP, with rheumatic fever the most frequent aetiology (75.9%) followed by congenital heart disease (17.9%). The study reflects a typical situation of HDP in developing countries at that time. The second Saudi study, published in 2001, described the success and safety of balloon valvoplasty in 23 pregnant women with severe mitral valve stenosis. In the third Saudi study, published in 2003 and reporting on 166 patients with HDP, the description of cardiac lesions was superficial and ambiguous.[25] In the most recent Saudi study about HDP, published in 2005, El-shaer et al. conclude that pregnancy did not accelerate the degeneration of bioprosthetic valves in 49 patients who had repeated pregnancies and followed up to maximum of 18 years.[26]

Considering the absence of contemporary data about HDP in KSA, the research in this field is becoming both urgent and obligatory. Thus, this article's primary goal is to activate this task by constructing the ROSHDAP study, which will create an extensive database concerning HDP in KSA. The pilot study should be encouraging because it involves tertiary hospitals in KSA with expertise in this field. The data that will be collected will include detailed information about pre-pregnancy counselling, consanguinity, psychosocial factors, the aetiology of HDP, clinical factors, laboratory issues, electrography, echocardiography, therapeutic interventions, mode of delivery, complications, and foetal and maternal outcome of pregnancy and the first 6 months post natal. Thus, we will be able to calculate the current incidence of HDP in KSA, identify the aetiology of HDP, obtain detailed information about consanguinity, conduct preconception counselling and identify risks of foetal and maternal complications.

We expect to identify multiple risks of maternal and foetal complications; these risks will be compared to previously

reported risks in developed and developing countries.[5,7,27] An attempt to build new risk scores and compare them to previously validated risk scores, such as that of the WHO, will be performed.[5,6,28] The ROSHDAP study will document the current level of health care provision to women with HDP in KSA and data for comparison among KSA regions will be available. This approach will create opportunities to correct and rectify health care system, services and plans for this group of patients. Considering the absence of contemporary data about HDP in KSA, the research in this field is becoming an urgent and obligatory task.

Conclusion

Recent research about HDP in KSA is unavailable. The suggested ROSHDAP study in this article will represent a substantial opportunity to collect contemporary data on HDP in KSA that will aid in developing management guidelines, research programs, and health strategies, eventually improving HDP care.

Conflict of interest

The author has no conflict of interest to declare.

Author's contribution

FOA testifies that he is the sole author of the review article entitled: "Heart disease during pregnancy in the KSA: A suggested plan". He rendered efforts to produce the article starting from the idea, midline research, collecting the data, drawing figures, creating tables and writing the manuscript. He states that the article is free from unacceptable quoting. He reviewed and approved the final draft and is solely responsible about the article content.

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