

A STRUCTURED EVIDENCE-BASED APPROACH TO DECREASE CARDIOVASCULAR COMPLICATIONS AMONG PREGNANT WOMAN WITH RHEUMATIC DISEASE: A PILOT RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: Recent reports from the developing world have documented rheumatic fever (RE) incidence rates as high as 206/100 000 and Rheumatic Heart Disease (RHD) prevalence rates as high as 18.6/1000. The high frequency of RHD in the developing world necessitates aggressive prevention and control measures. **Aim:** The aim of the study was to examine the effect of intensive antenatal follow up program on decreasing cardiovascular complications among rheumatic pregnant woman. **Design:** Randomized controlled trial. **Setting:** This study was conducted at El Kasr-EL Aini, maternity hospital- Cairo- University Hospitals. **Sample:** A total of 100 rheumatic pregnant women that attended the antenatal clinic at El Kasr-EL Aini, maternity hospital who could read and write, had functional class I and II cardiac disease, primigravida, nullipara with single fetus were recruited to this study and assigned randomly into two groups. **Procedure:** Women who met the inclusion criteria were interviewed and baseline assessment was done. The intervention was an intensive antenatal follow up program for decreasing cardiovascular complications among rheumatic pregnant woman. Patients in the study group (SG) were offered an intervention at three levels, basic, intermediate and comprehensive. Evaluation of the program was carried out in term of assessment of maternal and neonatal outcome. **Results:** There were several significant differences between the study group (SG) and control group (CG). In the SG, antepartum complications was less common, gestational age at birth was higher, postnatal hospital stay shorter, birth weight higher, more had vaginal deliveries with episiotomy, fewer had caesarean section, forceps deliveries and termination of pregnancy, and cardiac class was better at follow up as compared to the CG. **Conclusion:** The difficult issues in pregnancy complications by cardiac disease are best managed through a team approach. Establishing a pre-pregnancy plan will foster a better therapeutic relationship between all parties and allow for better understanding of the patient's beliefs regarding pregnancy, her disease and attitude towards medications.

Mesh Terms:

- Rheumatic heart disease
- Female, Pregnancy
- Pregnancy Complications, Cardiovascular/mortality
- Pregnancy Outcome
- Neonatal, outcome, complications

BACKGROUND

Approximately 1-3% of pregnancies are complicated by cardiac disease and this situation is responsible for 10-15% of maternal mortality (Klein and Galan, 2004). The prevalence of pregnancy complicated by rheumatic heart disease has decreased in developed countries, but rheumatic heart disease continues to contribute significantly to maternal mortality and morbidity (Sawhney, Aggarwal and Suri, 2003). Maternal mortality varies directly with functional class, 0.4% for New York Heart Association (NYHA) class I and II and 6.8% for class III and IV (Oron, Hirsch and Ben-Haroush, 2004). Mitral stenosis is associated with a maternal mortality of 10% and even up to 50% in NYHA class III and IV. If atrial fibrillation is present, the risk of mortality rises by another 5-10% (Joubert and Dyer, 2005). Diagnosis for cardiac disease is harder depending on physiological changes during gestational period. Functional systolic murmur is frequently seen and edema is observed in lower extremity during the gestational period. Complaints for cardiac disease during pregnancy are progressive orthopnea, paroxysmal nocturnal dyspnea, hemoptysis, syncope occurred with exercise, chest pain, serious or progressive dyspnea. Findings of cardiac disease during pregnancy are cyanosis, digital clubbing, jugular venous distention, and systolic murmur more than grade 3/6, diastolic murmur, cardiomegaly, arrhythmia, pulmonary hypertension diagnosis and stable doubling of second heart sound (Asghar and Kokab, 2005). Furthermore, neonatal complications were noted in 20% of the pregnancies with heart disease (Hameed, Karaalp, and Tummala, 2001).

For years, women with potentially serious systemic autoimmune diseases have been advised against getting pregnant. We now know that, with careful medical and obstetric management, most of these women can have

successful pregnancies. Successful, however, does not mean uneventful. Doctors and patients must be ready to deal with possible complications for both mother and child. Further, women should not consider getting pregnant until their rheumatic disease is under control (Abdel-Hady, El-Shamy, El-Rifai, Goda, Abdel-Samad and Moussa, 2009).

To our knowledge and after a PubMed search (May 2009, search strategy: pregnant women and heart diseases and Egypt) only two study were found (Abdel-Hady, El-Shamy, El-Rifai, Goda, Abdel-Samad and Moussa, 2009; and - Ashour, Fattah, and Hussein, 2000), which have been done regarding being pregnant with heart disease in a general hospital sample from Egypt.

In Egypt management of pregnant woman with heart diseases is a challenge for obstetrician. Factors contributing in delaying the actions toward decreasing risks and sequelae of disease are lack of awareness related to importance of antenatal follow up among lay people, limited roles of nurses in the antenatal clinics, absence of cooperation language between different specialties as well as lack of facilities to communicate them easily in the governmental hospitals. Till now, it is noticed that, the studies conducted in Egypt discussed the cardiac disease during pregnancy from a medical view of point. The other disciplines and the nurses' role are not being investigated at all, for examples, Abdel-Hady; et.al (2009) who deals with the disease from an obstetric perspective and Ashor, Fatah and Hussein (2000) who discussed their study from a cardiac perspective. The primary goal of nursing care for the pregnant woman and her family when cardiac disease complicates the pregnancy is to reduce potential risks of complications (American College of Obstetricians and Gynecologists, 2010). This is accomplished by education of the woman and partner; assessment of all systems involved on a routine basis; referral to appropriate nursing, nutritional, social and medical experts; and facilitation of patient participation in decisions. The nurse is often in the best position to advocate for the patient and coordinate the multidisciplinary team (a. a.). Early diagnosis, follow up and counseling are keys for reducing morbidity and mortality and this strategy requires a collaboration between obstetrician, cardiologists and nurses. This study is designed to examine the effect of intensive antenatal follow up program on decreasing cardiovascular complications among rheumatic pregnant woman.

THE AIM OF THE STUDY

The aim of the study is to examine the effect of intensive antenatal follow up program on decreasing cardiovascular complications among rheumatic pregnant women.

MATERIAL AND METHODS

Design:

Randomized controlled trial.

Setting:

This study was conducted at El Kasr-EL Aini, Cairo University Hospitals, at the antenatal clinics and labor and delivery rooms. The maternity hospital provides services for approximately 33660 pregnant women in the outpatient clinic, a total of 12455 deliveries; 7725 normal deliveries and 4730 caesarean section deliveries per year (local statistical unit 2009).

Sample:

A total of 100 rheumatic pregnant women that attended the clinic were recruited. The inclusion criteria were women who can read and write, having functional class I (asymptomatic at all degrees of activity, uncompromised) and II cardiac disease (symptomatic with increased activity, slightly compromised) according to New York Heart Association (NYHA), who had antenatal follow up, their age between 20-30 years, primigravida, nullipara with single fetus, +16 weeks gestation, had no history of abortion, had no other systematic disease, and no history of significant medical complications such as insulin dependent diabetes, renal disease, chronic hypertension, and without any physical limitations. The selected women were assigned randomly into two groups; one Study Group (SG) who followed a structured guidelines program of self care as well as intensive follow up and secondly the Control Group (CG) who received the routine antenatal follow up in terms of assessment of fetal wellbeing, weighing, check on vital signs and maternal medications. All women who had previous experience of cardiac rehabilitation program, those unable to sign consent, to attend regularly for follow up were excluded. The sample size has been determined utilizing power analysis and sample equation based on information from relevant studies and the daily numbers of admission into the outpatient clinics.

Tools and measurements:

The tools which were used for data collection have included the following; 1) A printed out structured guidelines designed in Arabic language including reviewed literature and basic knowledge related to antenatal care, minor discomfort management, danger signs, schedule for antenatal visits as well as assessment of fetal movement, daily activities, sexual pattern and nutrition. 2) A structured interview questionnaire including socio-demographic and obstetrical data. 3) Patient self reports related to daily nutrition as well as medications, discomforts and activities. 4) Physicians reports include cardiologist's comment and dietitian plan of nutrition per week as well as obstetrician's comments related to pregnancy progress and fetal growth. 5) Medical records (previous and recent). 6) Echocardiogram reports, and 7) Laboratory investigations.

Procedure

Data was collected during a period of 15 months from the first of July 2008 to the end of September 2009.

The data collection procedure has been done through randomization and utilization of the nursing process in term of interviewing, history taking, assessment, implementation and outcome evaluation. A multi-dimensional follow up was designed through collaboration between cardiologist, dietitian, obstetrician and the researchers (nurses). The obstetrician started first with the follow up during the antenatal clinical visits, which started from \pm 16 weeks gestation till the end of pregnancy with two weeks interval till \pm 36 weeks gestation, and every week thereafter, unless any complication appeared. The second step started with every pregnant woman visiting the dietitian once to design a schedule of daily meals based on an estimation of the woman's nutrients' need. The third step in this intervention was the visits to cardiologist, once every trimester and more often if complications occurred. The fourth step was, approximately fourteen counseling and follow up sessions, 20 minutes for each session, done by the researchers and scheduled at the same time of antenatal visits. Besides, women in the CG followed the same antenatal visits and received guidelines for follow up and returned to the care of their obstetrician.

Recruitment of participants and randomization

An official permission was obtained from the administrative authorities of El Kasr-El Aini maternity hospital of Cairo University for conducting this study. A two steps selection process was used to ensure the randomization. The first of which was identifying the random sample. This step was done on the admission of women who met the eligibility criteria. Potential participants were recruited by direct announcements and poster at the outpatient's clinic, the designed poster included that, woman who is rheumatic, should be directed to the high risk clinic in the prenatal clinic, then the researchers assessed every woman for the illegibility criteria. Participants were sequentially recruited thereafter followed a random assignment of the sample into groups. The second step of the randomization started with the pregnant women being assigned to either the SG or the CG utilizing computer generated random numbers. Each number (from one to 100) was inserted separately into opaque envelopes by the investigator and these 100 sealed opaque envelopes were used for groups' assignment. All participants were informed about the purpose of the study, ensuring that all data obtained were to be strictly confidential. Women who agreed to participate in the study gave their acceptance after have being provided an information sheet containing the aim and details of the study and informed consent form, knowing that they could withdraw from the study at any time.

Interviewing and history taking

Women who met the inclusion criteria were interviewed in the antenatal clinic. After explaining the purpose of the study, socio-demographic and obstetrical data were collected utilizing a designed questionnaire.

Assessment (risk assessment)

Baseline assessment was done of cholesterol level, hemoglobin, blood glucose, blood pressure, and height and weight measurement. Results of physical examination, electrocardiography and echocardiography performed by cardiologist. Dietitian used the "Food Processor" nutrient analysis software to compute nutrient intakes and to guide for individualized recommendations, i.e. the dietary plan. The main emphasis of the dietary plan was put on decreasing the total intake of saturated fat and increasing intake of fruits and vegetables as well as increasing energy and correction of anemia. The patient's contact with dietitian was through patient referral to the institute of nutrition. After the visit the patient came back to the antenatal clinic to give us the written feedback.

Intervention

The overall intervention elements were grounded by the Orem self care theory (Orem, 2001) and Social cognitive theory (Bandura, 1977). Orem self care theory was implemented in term of detailed explanation of the health examination results and the individual risk. The participants were guided in how to make beneficial changes of their behavior and in how to promote continuous self care in order to improve their risk status (Orem, 2001). While the social cognitive theory was primarily implemented in the group counseling by trying to promote higher self-efficacy through goal setting. Social learning theory explains human behavior in terms of continuous reciprocal interaction between cognitive, behavioral, and environmental influences. The component processes underlying observational learning are: (1) attention, (2) retention, including symbolic coding, cognitive organization.3) motor reproduction, including physical capabilities, self-observation of reproduction, accuracy of feedback, and (4) motivation, including self reinforcement (Bandura, 1977). Based on the patient risk assessment, each woman had a lifestyle counseling focusing on daily physical activity, rest (e.g. sleeping at least 8 hours and 2 hours naps), diet (increase intake of vegetables, fruits, protein, grilled fish, meat, decreasing fat and salt intake and correction of anemia by diet and supplementations) sexual pattern (once per week), medications and antenatal follow up. The intervention at *Basic level* concerned with screening of risk factors and referral in first session while *intermediate level* focused on implementation of follow up scheduled program establishing referral system from 3 to 4 sessions. In addition, *comprehensive level* of the program provided continuous follow of the patients' steps in their implementation of the instructions, set the self help and recording behavior in their daily activities, discuss their written notes and progress reports, identifying any new complaints and reviewing laboratory results and consultants' comments. The comprehensive level also included joining group discussions with other mothers in the same condition and weeks of gestation who shared the same program through the minor mother classes and utilizing the role model. According to social learning theory, most human behavior is learned observationally through modeling: from observing others one forms an idea of how new behaviors are performed, and on later occasions this coded information serves as a guide for action (Bandura, 1977). The comprehensive level was activated from 5th session of the program and continued till the end of the 14 sessions.

Table 1. Levels of the intervention program and steps followed during the different levels

Level of the program	Steps followed
Basic level	- Screening of risk factors - Referral in first session
Intermediate level	- Implementation of follow up - Scheduled program - Referral system from 3 to 4 sessions
Comprehensive level	- Continuous follow up of the patients' steps in their implementation of the instruction - Set the self help and recording behavior in their daily activities - Discuss their written notes and progress reports - Identifying any new complaints - Reviewing laboratory results and consultants' comments - Joining the patient in group discussion with other mothers in same condition and weeks of gestation

Statistical analysis

Statistical package for the social science (SPSS) was used for statistical analysis of data. Regarding descriptive statistics, data was summarized using 1) the arithmetic mean as an average; describing the central tendency of observations for each variable studied; 2) The standard deviation as a measure of dispersion of results around the mean; 3) the frequency and percentage. Furthermore, inferential statistics included the students't-test for comparison of means of 2 independent groups. Chi- square test was used for comparison of the frequency and percentages of qualitative variables. Level of the significance was set at p- value less than 0.05.

Outcome evaluation

Evaluation of the program was carried out in term of assessment of maternal and neonatal outcome.

RESULTS

There were no statistical differences between groups in relation to their baseline data (table 2). All pregnant women were primigravida, nullipara, most of them were less than 30 years old with mean age of 24.68 ± 3.10 SD vs. 24.60 ± 2.68 SD in both the SG and the CG respectively ($p \geq 0.89$). According to the New York Heart Association classification (NYHA) 31(68.0%) vs. 29 (58.0%) had class I ($p 0.68$) and, 19 (38.0%) vs. 21 (42.0%) had class II in the SG and the CG respectively ($p \geq 0.68$). Rheumatic lesions were predominantly valvular in nature. The mitral valve was involved in 92.0% vs. 90.0%, the major mitral lesions was mitral incompetence 32.0% vs. 30.0% in the SG and the CG respectively ($p \geq 0.06$). Moreover, mild anemia was observed in both groups with mean of 9.84 ± 0.82 SD in the SG vs. 9.78 ± 2.81 SD in the CG ($p \geq 0.69$).

Table 2. Distribution of the sample by their Characteristics

	The SG (n=50)		The CG (n=50)		t	P value
	Mean	SD	Mean	SD		
Age	24.68	3.10	24.60	2.68	1.38	0.89
Hemoglobin level	9.84	0.82	9.78	2.81	0.39	0.69
Vulvular lesions	Freq.	%	Freq.	%	X2	P value
Mitral stenosis alone	9	18.0	8	16.0	2.61	0.11
Mitral incompetence alone	16	32.0	15	30.0	3.50	0.06
Mitral stenosis with incompetence	11	22.0	10	20.0	0.60	0.81
Mitral and aortic	7	14.0	9	18.0	0.30	0.59
Mitral and tricuspid	3	6.0	3	6.0	0.001	1.00
Aortic only	4	8.0	5	10.0	0.122	0.73
Total	50	100.0	50	100.0		
Cardiac class (NYHA)						
Class I	31	68.0	29	58.0	0.167	0.68
Class II	19	38.0	21	42.0	0.167	0.68
Total	50	100.0	50	100.0		

NYHA = New York Heart Association classification

Level of significance less than 0.05

Circulatory complications in this study included arrhythmia in 20.0% of the SG as compared to 36.0% in the CG, arrhythmia appeared in form of atrial fibrillation which was the most common (10.0% vs. 16.0%) followed by sinus tachycardia (6.0% vs. 10.0%), nodal tachycardia (2.0% vs. 8.0%) and 2.0% ventricular extra-systoles in the SG and

the CG respectively. Furthermore, infective complications in this study included upper respiratory tract infection (10.0% vs. 6.0%), urinary tract infection (8.0% vs. 12.0%), and lower respiratory tract infection (8.0% vs. 6.0%) in both the SG and the CG respectively. Finally, the obstetric complications included anemia of pregnancy in (4.0% vs.12.0 %) and pre-eclampsia (4.0% vs.14.0%). It was noticed that, 50.0% of the SG had no antepartum complications as compared with 8.0% of the CG ($p \leq 0.001$), (table 3).

Table 3. Distribution of the sample regarding antepartum complications

	The SG (n=50)		The CG (n=50)		X2	P value
	Freq.	%	Freq.	%		
Circulatory complications						
Arrhythmia	10	20.0	18	36.0	3.17	0.07
Angina	1	2.0	3	6.0	1.04	0.31
Infective complications						
Upper respiratory tract Infection	5	10.0	3	6.0	2.17	0.14
Bronchitis	4	8.0	3	6.0	0.15	0.69
Urinary tract infection	1	2.0	6	12.0	3.84	0.05
Obstetrics complications						
Anemia	2	4.0	6	12.0	3.05	0.08
Pre-eclampsia	2	4.0	7	14.0	3.05	0.08
No complications	25	50.0	4	8.0	19.05	0.0001

Level of significance less than 0.05

Most deliveries were vaginal deliveries with episiotomy, 36 (72.0%) vs. 22 (44.0%), while 12 (24.0%) vs. 17 (34.0%) had caesarean section due to obstetrics indications and fetal distress, in the SG and the CG respectively ($p \leq 0.02$ and $p \leq 0.001$) (Table 4). Moreover, 4.0% of the SG suffered from atonic uterus and postpartum hemorrhage as compared with the 14.0% of the CG in relation to marked anemia and retained placental membrane ($x^2=25.9$, $p \leq 0.001$). Regarding fetal and neonatal outcome, there was a statistical significant difference between both groups in relation to their gestational age at birth, with mean of 38.58 ± 1.18 SD in the SG as compared with 37.82 ± 1.06 SD in the CG ($p \leq 0.001$). But there was no statistical significant difference in relation to the admission of the neonatal incubator ($p=0.84$), and premature birth ($p=0.33$). A deterioration in cardiac class was noticed in both groups. Cardiac class was better in the SG at follow up as compared to in the CG ($p \leq 0.001$) (Table, 4)

Table 4. Distribution of sample regarding pregnancy and neonatal outcome

	The SG (n=50)		The CG (n=50)		t	P value
	Mean	SD	Mean	SD		
Gestational age at birth	38.58	1.18	37.82	1.06	3.38	0.001
Postnatal hospital staying	4.02	1.41	6.00	0.86	-8.49	0.0001
Birth weigh	3.02	0.18	2.63	0.34	7.100	0.0001
	Freq.	%	Freq.	%	X2	P value
Neonatal incubators	4	8.0	10	20.0	2.99	0.84
Premature birth	4	8.0	4	8.0	0.91	0.33
Deliveries and bleeding						
Vaginal deliveries with episiotomy	36	72.0	22	44.0	9.68	0.02
Forceps deliveries	0	00.0	2	4.0	42.3	0.001
Termination of pregnancy	0	00.0	2	4.0	42.3	0.001
Caesarean section	12	24.0	17	34.0	13.5	0.001
Postpartum bleeding	2	4.0	7	14.0	25.9	0.001
Total	50	100.0	50	100.0		
Cardiac class (NYHA)						
Class I	25	50.0	20	40.0	0.00	1.000
Class II	18	36.0	16	32.0	3.9	0.04
Class III	7	14.0	14	28.0	25.9	0.001
Total	50	100.0	50	100.0		

NYHA = New York Heart Association classification

Level of significance less than 0.05

DISCUSSION

Methodological considerations

In the present study, all pregnant women were primigravida, nullipara, most of them were about 25 years old with mean of 24.68 vs. 24.60 years in both the SG and the CG respectively. Being younger may help in less complications and better prognosis than if being older and having developed more severe heart disease. However, these characteristics are going on the same line with the study of Asghar and Kokab (2005), The 50 pregnant cardiac patients were included, 64% of women were primipara and their age ranged between 26-35 years. Congenital Heart Disease (CHD) was found to be present in 28% of the cases and 66% had Rheumatic Heart Disease (RHD) and mitral stenosis which was the dominant lesion.

Follow up and referral as well as revising the follow up date and data till delivery with each participant to avoid dropout rate were difficult issues. The difficulties come from the lack of communication between the different specialties within governmental hospitals. This put extra pressure upon the researchers in establishing proper contact and communication skills between the patient and different specialties by following the outcomes of the meetings between patient and staff. According to Bastani et al, 2004, standard definitions of what constitutes appropriate follow-up are lacking, which may limit comparability of findings across studies. However, the validity of various methods of obtaining outcome data has not been clearly established (Bastani et al, 2004) and more research is needed on interventions targeting provider, system, and policy-level factors.

Results discussion

Rheumatic heart disease (RHD) continues to be a common health problem in the developing world, causing morbidity and mortality among both children and adults. Although little longitudinal data are available, evidence suggests that there has been little if any decline in the occurrence of RHD over the past few decades. Doctors and patients must be ready to deal with possible complications for both mother and child (Abdel-Hady, El-Shamy, El-Rifai, Goda, Abdel-Samad and Moussa, 2009). Minimizing the maternal and fetal risks in a pregnant woman with concomitant heart disease requires the combined efforts of experienced specialists who are familiar with their management. This team should involve the obstetrician, cardiologists, dietitian and nurses. A combined clinic is preferable which allow counseling regarding any potential maternal or fetal risks and the outcome of pregnancy. Once pregnant women with heart disease are seen as early as possible in the combined clinic. Most will have no hemodynamic problems and will require little or no intervention, while a few may exhibit signs of cardiac decompensation (Chia, Chia and Subramaniam, 2002). There were several significant differences between the SG and CG in the present study. In the SG, antepartum complications was less common, gestational age at birth was higher, postnatal hospital stay shorter, birth weight higher, more had vaginal deliveries with episiotomy, fewer had caesarean section, forceps deliveries and termination of pregnancy, and cardiac class was better at follow up as compared to in the CG.

In the present study mitral valve involvement was most common, with functional class I and II. These findings are in the same vein with the studies of Hameed, Karaalp, Tummala (2001); Sawhney, Aggarwal, Suri, et al (2003) and Asghar, Kokab (2005) who reported that, the incidence of rheumatic heart disease with mitral stenosis (MS) as the predominant lesion, being 69.6%, 89.2% and 42% respectively. The functional class has a direct bearing on both the maternal and fetal outcome (Sawhney, Aggarwal, Suri, et al, 2003), and in an Egyptian study, 89.5% of patients were rheumatic and 60 % of patients were classified as NYHA classes' I-II (Abdel-Hady, El-Shamy, El-Rifai, Goda, Abdel-Samad, Moussa, 2005). This incidence may be related to lack of health awareness regarding follow up that may delay early detection as well as early medical management.

Nurses sometimes manage and maintain required self care for persons by performing some but not all care measures through instructing and guiding individuals move toward self care (Orem, 2001). Orem's self-care deficit theory provided a theoretical framework to guide assistance of rheumatic pregnant women to meet self-management requirements (Orem, 2001). Ideally, the interpersonal relationship between a nurse and a client contributes to the alleviation of the client's stress, enabling the client to act responsibly in matters of health (Orem, 2001). This assessment and plan of care utilized Orem's four client-related concepts (self-care, self-care agency, therapeutic self-care demand, and self-care deficit) and two concepts that relate to nurses and their roles (nursing agency and nursing system). In the present study, Orem's concept of self-care was applied in the clinical practice. The major goal as a nurse is to assist the pregnant woman in learning what she needs to know in order to do self care as dictated by the structured guidelines. While social learning theory (Bandura, 1977) applied in term of counseling sessions those offer problem solving as well as brief healthy instructions using educational media in an attractive way, depending upon the component processes involved (such as attention or motivation), we may model the behavior shown in educational media and take a positive action when knowledge integrated with the daily routine life. These concepts may to some extent offer an explanation to the positive differences between the study group and the control group in the present results.

Data in the present study revealed that, there were a statistically significant differences between groups related to arrhythmia. These results are parallel with Jian-Ming, Carol Nguyen, Jose Joglar, Mohamed and Richard (2008) who reported that, supra ventricular tachycardia (SVT) was one of the most common complicated cardiac arrhythmias during pregnancy. The most common rhythm disturbances during pregnancy were sinus tachycardia (ST), sinus bradycardia (SB), or sinus arrhythmia (SA) (104 episodes/100,000 pregnancies). This was followed by paroxysmal supra ventricular tachycardia (PSVT) and premature beats, with a frequency of 24/100,000 and 33/100,000, respectively. Moreover, the present study demonstrated that, the frequency of anemia in pregnancy and pre-eclampsia were higher in the CG compared to the SG. Although the results are not statistically significant, may be related to the

sample size, but the frequencies of the complications reflect the effect of the follow up care. Ashour, Fattah and Hussein (2000) in their Egyptian study of 348 women who were followed up in the prosthetic valve clinic reported that the maternal complications were all pregnancy related. These included toxemia of pregnancy and postpartum hemorrhage due to retained placenta.

One explanation for the better outcome in the SG could be that the NYHA class was better at follow up in comparison to in the CG. In a study of 65 pregnant women with rheumatic heart disease, gestational age was ± 34.6 weeks and the birth weight was 2176 g averagely, with significant differences between those in NYHA class IV group compared to in NYHA class I group ($P < 0.05$), (Lin, Jian-Hua, Ling, Wan-Wen, Liang and A-Juan, 2007). Even though comparisons between different NYHA groups were not made in this study, the findings from Lin et al. (2007) highlight the impact NYHA has on outcome. NYHA was better in the SG than in the CG at follow up. Results in the present study demonstrated better outcome related to gestational age and birth weight, these results may be regarded to the planned diary that the mother received throughout the antenatal follow up based on her nutrient's need, her weight and fetal growth. These explanations may contradict with the study of Madazli, Sal, Cift, Guralp, Goymen (2009) who reported that, there were no significant difference in birth weight, gestational age at delivery and perinatal morbidity between the NYHA stage I-II versus stage III-IV groups ($P > 0.05$). However, the findings from the present study confirmed with the study of Abdel-Hady, El-Shamy, El-Rifai, Goda, Abdel-Samad and (2005) who reported that, birth weight of babies born to mothers with functional classes III and IV were significantly lower than those of functional classes I-II. Besides, premature birth was seen in 8.0% of both groups in our study. The corresponding incidence in other studies was higher, i.e. 14% (Asghar F, Kokab, 2005), 12% (Sawhney Aggarwal, Suri, 2003) and 23% (Hameed, Karaalp, Tummala, et al, 2001). Thus stabilizing, preserving or minimizing the worsening of cardiac class can possibly be an important goal for ensuring a positive outcome.

In relation to mode of delivery, Robson, Hunter, Boys, Dunlop (1989) reported, delivery and early postpartum period are risky periods especially for patients with cardiac disease. There is a 10-65% increase in heart beating volume in labor and during the delivery. It raises the load of heart which is already working with a limited capacity. Sartain (2008), states that most patients suffering from RHD can be delivered vaginally, and assisted delivery is recommended in high-risk patients to avoid straining and to shorten the second stage. The major indications for caesarean delivery are obstetric. In our study, most of the women in the SG had vaginal delivery with episiotomy. These results may reflect the patients' cardiac status to tolerate the normal vaginal delivery as well as the role of the antenatal follow up that prevent the deterioration. These results go parallel with some other studies (Hameed, Karaalp, Tummala, 2001; Sawhney, Aggarwal, Suri, et al., 2003; Asghar and Kokab, 2005) who reported a rate of the vaginal deliveries as 86%, 91%, and 92% respectively. However, Forceps-assisted delivery was performed in 4.0% of the vaginal deliveries in the CG, moreover, 4.0% of the women in the CG underwent labor induction, and these manipulations may be due to efforts to reduce the rate of the caesarean section. Similar findings have been reported in other studies, 4.25% of Asghar and Kokab (2005); 8.4% of Sawhney, Aggarwal, Suri, et al. (2003) respectively regarding caesarean section rate. While caesarean section rate in the present study was due to obstetrics indications and fetal distress, the purpose of the study was not to correlate it to the cardiac class. Shime, et. al. (1987) observed primary cesarean rate as 21.8% in pregnant women with congenital cardiac disease. In addition, the cesarean rate was reported as 32.5% in the series of 86 of rheumatic pregnant women, whereas maternal morbidity and cesarean delivery rates were significantly higher in the NYHA stage III-IV group ($P < 0.001$) by Madazli et. al. (1999).

In present study, bleedings were not so common in the study group (4%) as compared to the CG (14%), these results regarded to marked anemia and retained placental membrane, reflects the role of follow up and the benefit of the planned diet. These results are parallel with the study of Rachdi, et.al. (1999) among women with rheumatic valve lesion, the prevalence of bleeding at the time of delivery was 12.4%.

Finally the present data revealed that, the rate of women with class III was 14% in the SG as compared with 28% in the CG. The worsening of NYHA class in both groups may relate to the overexertion on the heart during the pregnancy and delivery that worsen the state. The differences between groups at follow-up may reflect the effect of the offered program on the risk reduction.

CONCLUSION

The difficult issues in pregnancy complications by cardiac disease are best managed through a team approach, cardiologist, family physician, obstetrician, dietitian and any other specialist(s) involved. Although most patients being pregnant with mild to moderate symptoms associated with their cardiac disease, these can change dramatically as gestation progress. Labor, delivery and the immediate postpartum period are associated with significant hemodynamic challenges and patients should be monitored throughout. Establishing a pre-pregnancy plan will foster a better therapeutic relationship between all parties and allow for better understanding of the patient's beliefs regarding pregnancy, her disease and attitude towards medications.

Limitations of the study:

Follow up and referral as well as revising the follow up date and data till delivery with each participant to avoid dropout rate were difficult issues.

Recommendations:

Early disclosure of pregnancy to all caregivers including the rheumatologist, dietitian, family physician, obstetrician, and maternal-fetal medicine specialist; apply nursing care protocols for cardiac women during antenatal, labor and postpartum period; as well as further randomized controlled trials with large samples are needed in the future to confirm and generalize the results.

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