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Preconception Nursing Guideline: Its Effect on Pregnancy Outcome among Woman with Anti-Phospholipids Syndrome

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Abstract: **Antiphospholipid syndrome (APS) is a complex autoimmune disorder, is associated with thromboembolic events. Pregnancy in a woman with APS endures a high-risk situation with increased incidence of maternal and fetal mortality and morbidity. Aim of the study was to evaluate the impact of preconception nursing guideline on pregnancy outcome for APS women. A quasi experimental design was utilized to conduct this study. This study was conducted at Rheumatology, immunology and antenatal clinic, in addition to labor room at Fayoum University, and El Nabawy El Mohandes hospital. A purposive sample of 78 women diagnosed with APS (included 39 pregnant women control group and 39 APS women in study group, but only 30 women succeeded to get pregnancy and reach delivery phase) were recruited for conducting this study. Six tools were used for data collection named structured interviewing questionnaire, follow up diary, disease Index- in anti-phospholipids syndrome women, modified WHO partogram, Apgar score and Health Practices Questionnaire. Results: showed that there is a high statistical significant improvement in women's knowledge regarding APS and statistical significant improvement on APS women's compliance to percussion measure after implementation of the guideline. Moreover, there is a statistical significant decrease in degree of generalize pain and a highly statistically significant decrease in the mean score of APSDAI after implementation of the guideline. Pregnancy outcome revealed that most maternal complications for control group and study group was abortion that represents 23.1%, in control group, while, and represent 16.7%, in study group. Conclusion: The implementation of preconception nursing guideline has a statistically significant positive effect on improving pregnancy outcome for women with APS. Recommendations: Teaching program to improve nurse's knowledge and practice regarding nursing care of women with Antiphospholipid Syndrome in preconception period.**

Keywords: **Preconception nursing guideline, maternal and fetal mortality and morbidity, Anti-phospholipid antibody syndrome.**

1. INTRODUCTION

Anti-phospholipid antibody syndrome (commonly called anti-phospholipid syndrome or APS) is an autoimmune disease present mostly in young women. Those with APS make abnormal proteins called anti-phospholipid autoantibodies in the blood. This causes blood to flow improperly and can lead to dangerous clotting in arteries and veins, problems for a developing fetus and pregnancy miscarriage. People with this disorder may otherwise be healthy, or they also may suffer from an underlying disease, most frequently systemic lupus erythematous (SLE) .APS affects women five times more commonly than men. It is typically diagnosed between the ages of 30 and 40. While up to 40% of patients with SLE will test positive for the anti-phospholipid autoantibodies, only half will develop thrombosis and/or experience miscarriages. Like most autoimmune disorders, APS has a genetic component, although there is not a direct transmission from parent to offspring. [**1]**

Pregnant women with Anti-phospholipid Syndrome are considered high-risk obstetric patients. Recurrent miscarriage, early delivery, oligohydramnios, prematurity, intrauterine growth restriction, fetal distress, fetal or neonatal thrombosis, pre-eclampsia /eclampsia, HELLP syndrome, arterial or venous thrombosis and placental insufficiency are the most severe APS-related complication for pregnant women. Anti-phospholipid antibodies promote activation of endothelial cells, monocytes and platelets, causing an overproduction of tissue factor and thromboxane A2. Complement activation might have a central pathogenetic role. These factors, associated with the typical changes in the hemostatic system during normal pregnancy, result in a hypercoagulable state. This is responsible of thrombosis that is presumed to provoke many of the pregnancy complications associated with APS. **[2].**

The APS antibodies can cause different problems at different ages of the pregnancy indifferent women. In some women with APS, in the first 13 weeks, the antibodies can prevent the pregnancy from embedding properly in the womb, increasing the chances of a nearly miscarriage. In the second and third trimesters of pregnancy (from 14 weeks gestation until birth), APS in some women can cause blood clots in the placenta. This can lead to poor blood and oxygen supplies to the baby, causing poor growth, pre-eclampsia or even stillbirth. **[3]**

Pregnant women with APS can have successful pregnancy outcomes, especially when a collaborative approach between the rheumatologist, obstetrician, neonatologist and specialist midwife. Addressing women' knowledge of Anti-phospholipid antibodies , adopted the precaution measure and promote women involvement in safety by encouraging participation in recommended activities exercises and perfume regular investigation, it's very important issues to save pregnancy outcome among pregnant women with Anti-phospholipid syndrome.**[4]** Increased women's knowledge also promotes adherence to pharmacological thrombi prophylaxis, as one nursing study reported that women who did not understand the purpose of their medications occasionally refused the anticoagulant injections **. [5]**

Preconception health (PCH) refers to the health of women of reproductive age. Preconception care aims to improve the health of the future child and to enhance maternal health through risk assessment, health promotion, counseling and interventions. Risk assessment is the systematic identification and evaluation of risk factors for poor pregnancy outcomes. If risks are identified, additional screening, diagnostic tests and specialist consultations may be necessary**. [6]**

Health promotion means informing and educating women on certain health-promotion issues, including folic acid supplementation, avoiding alcohol or tobacco or take drugs without medical prescription and the importance of proper nutrition. Intervention means efforts to modify or eliminate risk factors. Nurses play a major role in improved the knowledge among the pregnant women with Anti-phospholipid antibodies which allows women to self-assess and self-report Anti-phospholipid antibodies symptoms, enabling women to obtain timely medical assistance. **[7]**

Nursing Guideline is an interdisciplinary approach to continuity of care and process that includes identification, assessment, goal setting, planning, implementation, coordination, and evaluation. Effective nursing guideline supports the continuity of health care; it is described as "the critical link between treatment received in hospital by the patient, and post-discharge care provided in the community**. [8]**

Nurses can positively affect pregnancy outcomes by playing an essential role in diagnosis and risk assessment, applying timely preventive methods and providing vital educational and psychological support for women with Anti-phospholipid antibodies, so skilled nursing intervention can be lifesaving**.** In addition, nurses should provide care that is based on guidelines according to national and local contexts. Guidelines are essential for all healthcare professionals to ensure safe and high-quality care. It has been demonstrated that structured implementation material supported nurses in the guidance of patients with complex treatment regimen. Guidelines have been found to support nurses' clinical decision-making skills with regard to assessment and treatment, referral, supplementary prescription and therefore contribute to evidence-based nursing and holistic care. **[9]**

Significant of the study

Anti-phospholipid syndrome (APS) is an autoimmune disease, which increases the risk for maternal, fetal morbidity and fetal mortality in pregnancy. According to Centers for Disease Control and Prevention, 2014**,[10]** APS have been reported to be present in up to 14% of women presenting with thrombosis and in 20% of women presenting with recurrent pregnancy losses and the mean age of symptom onset is approximately 34 years. While in Egypt no accurate incidence

represented, but according to **Rawhya, et al, 2016, [11]** reported the rate of fetal loss in Egypt among pregnant women with anti-phospholipid syndrome may exceed 90% in untreated women. In addition, APS is associated with 16% to 38% of fetal or embryonic deaths, 15% to 30% of fetal growth restriction, and 18% of preeclampsia in all pregnancies. There is strong evidence that approximately 75% to 80% of women with APS who receive treatment are able to have healthy, full-term pregnancies. But this must be combined with another parallel efforts to prevent occurs complication of the disease and save pregnancy outcome as; increase women awareness regarding the disease and discuss the benefit of the medication as well as inform the women with the precaution measure which can adopted to save her pregnancy. All the previous precaution will be benefit if start from preconception period to prevent disease complication and save pregnancy outcome. Establishing preconception evidence based guideline is crucial for reduce the adverse effect of the disease on the pregnancy and successful pregnancy outcome. In Egypt, limited researches are carried out to evaluate the effect of evidence-based guideline on pregnancy outcome among woman with anti-phospholipids syndrome. So, there was an urgent need to conduct this study.

Aims of the study

The aim of the current study is to determine the effect of preconception nursing guideline on pregnancy outcome among woman with anti-phospholipids syndrome through the following:

- Assessment of APS women's knowledge and health before apply the preconception nursing guideline.
- Apply the preconception nursing guideline on women with APS.
- Evaluate the effect of preconception nursing guideline on pregnancy outcome among women with APS.

Research Hypothesis: The current study hypothesized that: Apply the preconception nursing guideline for women with APS will be effective on improving the pregnancy outcome than APS pregnant women that receive routine care.

2. MATERIALS AND METHODS

Research Design

A quasi-experimental design was utilized to achieve the aim of this study.

Setting

The study carried out at Rheumatology, immunology and antenatal clinic, in addition to labor room at Fayoum University hospital, and El Nabawy El Mohandes (public hospital in Fayoum).

Sample

A purposive sample of 78 women diagnosed with APS was recruited in this study. The total participants were selected according to the following statistic formula n = Z21- α/2p (1-p)/d2. The sample were divided into two groups; (control group that include 39 pregnant women with APS received the routine care, and study group that include 39 APS women who received preconception nursing guideline; only 30 women succeeded to get pregnancy and reach delivery phase) and all women who participated in the study were selected according to the following inclusion criteria;

- Can read &write.
- Free from any other associated medical disorder.
- APS women planning to get pregnancy (for study group)
- Women had previous abortion due to the disease.
- Woman has inactive stage of APS at least for six months before getting pregnant.

Tools for data collection

The study data was collected through the following six tools:

Tool I. Structured interviewing questionnaire: It includes 4 parts as follows:

Part 1: Socio-demographic data of women: it was used to assess; (age, educational level, occupation, residence and monthly income).

Part 2: The second part represents the obstetric history of the women.

Part 3: History of APS through (duration of disease, disease complication….etc).

Part 4: Women knowledge regarding APS: it was self-administrated questionnaire to assess level of knowledge for women with APS regarding their disease. It was developed by the researchers based on review of literature. It entailed 24 multiple questions were formulated. It consist of four domains including: overview of the disease (2 item), causes and risk factors (3 items), manifestations (3 items), diagnosis (3 item), complication (6 item), and management (7 item). Each item was given a score. The total score ranged from 1-48 and it was then covered into percentage. Each correct answer responses were given two marks and the wrong answer was given one mark. The higher scores indicated the higher level of knowledge. Total score 48(100%), A score of <50% was considered as unsatisfactory knowledge and≥50% score was considered as satisfactory knowledge. Overall test- retest reliability coefficients were Cronbach's α values was 0.80 in this study.

Tool II. Follow up diary card: It was developed by the researchers. This tool designed to monitor women's APS manifestation, medications, diagnostic measures, pain, vitality and complications and others through preconception period. Overall test-retest reliability coefficients were cronbach's alpha values of 0.83.

Tool III. Disease Activity Index- in anti-phospholipids syndrome **women (DAIAPS)**: Adopted from **Ruiz-Irastorza et al. [12]** it consists of four domains and includes two types of clinical manifestations according to severity, vitality and laboratory findings. The total index score is the mean score of each group, which ranges from 0 to 2.6. APS flares are defined as a change in score of 0.25 or greater. Cronbach's alpha revealed an internal reliability of 0.93.

Tool IV. Modified WHO Partogram: Adopted from **Gans-Lartey, et al. [13]**. It was a graphical representation of the labor plotted against time. It used to monitoring labor and assess the labor outcome, used to monitor the two group(study and control group). Overall test-retest reliability coefficients were cronbach's alpha values of 0.92.

Tool V: Apgar score: Adopted from **Papile. [14]** It was used to assess neonatal condition after delivery at 1^{st} and 5^{th} minutes after delivery. The five criteria of the Apgar score are: activity, pulse, appearance, grimace and respiration. Each one of these criteria has score ranged from zero to two and then summing up of five criteria was obtained. The resulting Apgar score ranges from zero to 10. Overall test-retest reliability coefficients were cronbach's alpha values of 0.90.

Tool VI: Health Practices Questionnaire (HPQ):

This tool was designed by the researchers and used to measure the degree of the women in the study group to their compliance to the health practice as a percussion measure to save the pregnancy outcome. It contain 9 health practice related to ;(lab investigation, Medication, antenatal follow up, nutrition, exercise…) . The responses was scored as (3) for regular done, (2) for irregular done and (1) for not done. Cronbach's α of this tool was 0.71 in this study.

Preconception nursing guideline covers the following items:

This guideline was planned to cover knowledge of women regarding the anti-phospholipid syndrome and enhance the positive attitude of the women regarding the preventive measure which taken during the management period of the disease aiming to improve the pregnancy outcome. The content of guideline was developed after reviewing the related literatures; the content was translated into simple Arabic language. The guideline covered the following information (identification of the disease, causes, risk factors, singe and symptom, diagnostic test, complication, and symptoms which require immediate medical attention, preconception care which include; management of APS, precaution measure which the women must adopted to reduce the adverse effect of the disease even before and during the pregnancy.) .

Content validity and Reliability of the Tools:

Tools content validity ascertained by 5 jury expertise from nursing and medical staff members. The necessary modifications were made as rephrasing. Reliability: Alpha Cronbach test was used to measure the internal consistency of the tools used in the current study.

Pilot study

A pilot study was conducted for 10% of the participant to clarify the validity of the tools and to test the research feasibility, clarity and objectivity of the tools as well as to estimate the time needed for to answer the questions. Then modifications were done. Pilot study revealed that, the average length of time needed to complete the structured interview was approximately 30-45 minutes with each woman. Sample included in the pilot study were excluded from the study sample.

Ethical consideration

To carry out the study, the necessary official approval was obtained from director of hospital. The researchers introduced themselves to the women who met the inclusion criteria and oral consents were secured from each woman to participate after explaining the nature, purpose of the study. The researchers emphasized that participation in the study is entirely voluntary and the study posed no risk or hazards on their health. And participants can be withdrawn from the study and confidentiality was assured through coding the data.

Field Work:

Recruitment and follow-up of the participants were carried out from July 2018 to December 2019. The researchers were constructed and prepared the different data collection tools, designed the nursing guideline materials were developed by the researchers and Experts' opinion were obtained to ensure guideline's validity. And the written permission was obtained from the predetermined hospital before conducting the study. Data collection was carried out through three phases: assessment phase, implementation phase, and the evaluation phase.

Assessment phase

The researchers attended the pre-mentioned study setting three days per week alternatively (One day at obstetric and gynecological outpatient clinics to follow-up pregnant women with APS in control group and the other two days at outpatient rheumatology and immunology clinics to apply the guideline and follow up its effect) starting at 9.00 a.m. to 2.00 p.m. to collect the data. The researchers have introduced themselves to women who met the inclusion criteria and inform them about the purpose of this research to get their acceptance and cooperation to be recruited in it. Confidentiality of information was ensured to gain women confidence and trust. The tools of data collection required approximately 30-45 minutes from the participants to complete the data collection forms, the tools filled in this phase, tool I (part one, two and three) for control group and from part (1-4) for study group, tool III and VI for study group.

Implementation phase:

In this phase the researchers implement the preconception guideline on 39 women (study group) and assess the effect of guideline on the women's knowledge and women's health periodically, then continue the follow up after flare control by six months and involved 30 women only succeeded to get pregnancy and reach delivery stage. The intervention was administrated through individual and groups (3-5 women/session), according to the flow and the condition of the women with APS. The instructions were given to the women through 4 sessions, each one ranged from 35-45 min. The sessions focused on overview knowledge about antiphospholipid syndrome as definition, symptoms, causes, complications, effect on pregnancy, treatment, management and the preventive measure which taken to reduce the adverse outcome of the disease on the pregnancy. Teaching methods utilized lectures, and group discussions. All women in the study group received printed materials. During the classes, women were encouraged to ask questions interact their own experiences and receive feedback. Each session start with summary regarding the content of the previous session and end with summary regarding the content of the current session. The researchers give permission to the women to contact via phone to ask any question at any time. Follow up card was distributed and explained by the researchers among both groups (control & study groups) to record side effects of medication during pregnancy and other warning signs were reported. Researchers conduct phone call monthly with each case in the study group to keep patients' reassurance and confirm that women follow the instruction of guideline. In control group the researchers follow them at least two times. While, women in the study group who succeed to get pregnancy after implementation of the guideline was interviewed at least one time each trimester for follow up.

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Evaluation phase:

The effect of guideline on women's condition was assessed through comparing between study and control group as well as before and after implementation in the study group regarding their(knowledge, health "manifested through disease activity index", beside self-care practices to overcome side effects of medication , control on APS condition and pregnancy outcome), the researchers follow the cases through review the follow up card and sometimes through phone as well as through (WhatsApp) after three and 6 months from data collection started because some women faced difficulty in coming to the hospital due to the long distance. The tools used in this Phase tool I(part 4) , and from (II to VI) for study group and tool IV, V for control group .

Statistical analysis

Data entry and statistical analysis were done using the Statistical Package for Social Science (SPSS) version 22 statistical software package. Results were presented as the percentages, mean , standard deviation (SD), Paired T test, Chi square, and Fisher's test that were employed to compare quantitative and qualitative variables between the groups . Statistical significance was considered at p-value <0.05.

3. RESULTS

Table (1): Socio demographic characteristics, obstetric and APS history among the studied groups.

Items	Control group N=39	Study group N=39	X 2	P-value
	N (%)			
Socio-demographic items				
Age Mean ±SD	29.6±5.4	27.2±4.3	2.20 **t-test**	0.44
Educational level Read and write Primary Secondary Higher education	 4(10.2) 13(33.3) 16(41) 6(15.4)	 7(17.9) 12(30.7) 17(43.6) 3(7.7)	 0.12	 0.76
Occupation Working Housewife	 26(66.7) 13(33.3)	 23(59) 16(41)	 0.55	 0.72
Residence Rural Urban	 25(64.1) 14(35.9)	 19(48.7) 20(51.3)	 0.63	 0.77
Income Enough Not enough	 22(56.4) 17(43.6)	 25(64.1) 14(53.9)	 0.54	 0.52
APS history				
Duration of APS(year)	4.55 ±2.8	5.76±3.6	0.79	0.44
Obstetric history				
Previous pregnancy complication with APS@ • **Abortion** • **Preterm** • **Preeclampsia** • **GD** • **Placental abruption** • **IUGR** • **Flare**	 22(56.4) 7(17.9) 10(25.6) 8(20.5) 6(15.4) 4(10.3) 8(20.6)	 18(46.2) 5(12.8) 8(20.8) 6(15.4) 4(10.3) 3(7.7) 6(15.4)	0.98	0.74

@ Numbers are not mutually exclusive.

Table (1) shows the Socio demographic characteristics, obstetric and APS history among the studied groups. The mean age of the control group was 29.6±5.4 compared to 27.2±4.3 years of women in the study group. There is no statistical significant difference between both groups related to socio-demographic items. Also the table reveals that the abortion was the most common obstetric complication in previous pregnancy, and there was no statistical significant difference between both groups regarding previous obstetric and APS history.

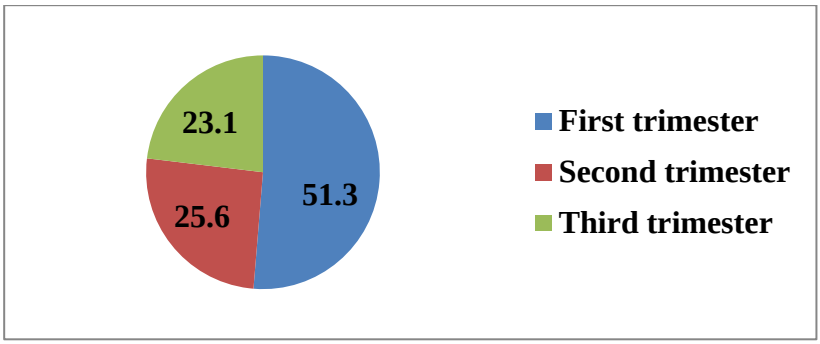

Figure (1) Distribution of the control group according to their current gestational age (n=39).

Table (2): Distributions of women's knowledge in the study group regarding the APS before and after implementation the guideline (N = 39).

Knowledge	Pre	After implementation by 3 months	Follow up After implementation by 6 months	F test	P-value
		n (%)			
Definition Satisfactory Unsatisfactory	10(25.6) 29(74.4)	30(76.9) 9(23.1)	33(84.6) 6(15.3)	10.3	0 .001**
Causes Satisfactory Unsatisfactory	7(17.9) 32(82.1)	28(71.8) 11(28.2)	31(79.5) 8(20.5)	9.2	0 .003**
Risk factors Satisfactory Unsatisfactory	5(12.8) 34(87.2)	27(69.2) 12(30.8)	30(79.9) 9(23.1)	7.6	0 .001**
Signe & symptoms Satisfactory Unsatisfactory	14(35.9) 25(64.1)	26(66.6) 13(33.3)	34(87.1) 5(13.9)	12.1	0 .002**
Diagnostic test Satisfactory Unsatisfactory	10(25.6) 29(74.4)	27(69.2) 12(30.8)	32(82.1) 7(17.9)	10.1	0 .002**
Complication on pregnancy outcome Satisfactory Unsatisfactory	13(33.3) 26(66.6)	29(74.4) 10(25.6)	33(84.6) 6(15.4)	8.8	0 .001**
Management during preconception –pregnancy-labor- post- partum) Satisfactory Unsatisfactory	8(20.5) 31(79.5)	26(66.6) 13(33.3)	31(79.5) 8(20.5)	8.7	0 .001**
Total knowledge score Satisfactory Unsatisfactory	10(25.6) 29(74.4)	28(71.8) 11(28.2)	32(82.1) 7(17.9)	10.5	0.001**

(*) Statistically significant at p< .05 (**) highly statistically significant at p=0.001

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Table (2) reveals the distributions of women's knowledge in the study group regarding the APS before and after implementation the guideline. The results indicated that, there was highly statistically significant improvement in women's knowledge after implement the guideline.

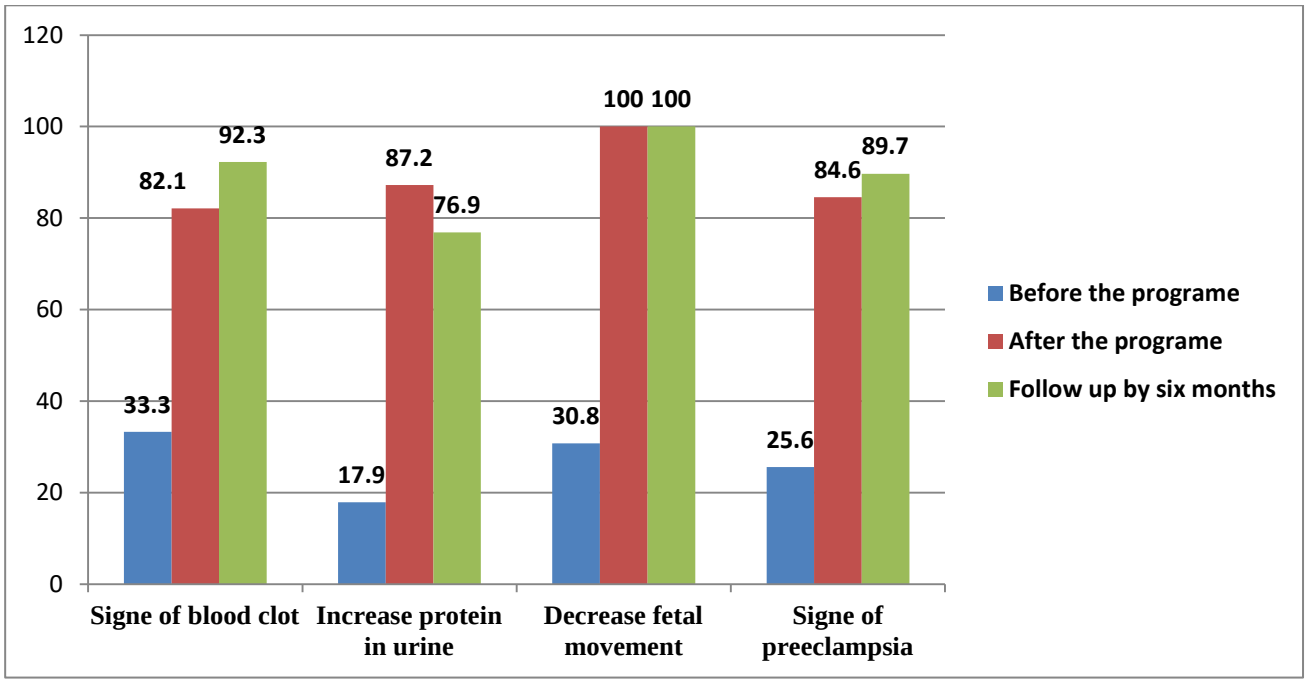

Figure (2) Percentage distributions of satisfactory women's knowledge in the study group regarding the symptoms which require immediate medical attention (N = 39).

Table (3): Comparison between pre-conception APS women's compliance to percussion measure in the study group before and after implementation of guideline (n=39)

Attitude of the pregnant women	Pre	After implementation by 3 months	Follow up After implementation by 6 months	F test	P-value
	n (%)				
Ultra-sonography is recommended every month.					7.41
Done regular	9(23.1)	27(69.2)	26(66.7)	8.5	
Done (irregular)	7(17.9)	4(10.3)	7(17.9)		<0.05*
Not done	23(59)	8(20.5)	6(15.4)		
Follow platelet count every 4-6 weeks.					
Done regular	6(15.4)	24(61.5)	25(64.1)		5.33
Done (irregular)	11(28.2)	7(17.9)	8(20.5)	8.7	
Not done	22(56.4)	8(20.5)	6(15.4)		<0.05*
Measured blood pressure regularly.					
Done regular	9(23.1)	23(59)	25(64.1)		3.61
Done (irregular)	8(20.5)	8(20.5)	9(23.1)	9.6	
Not done	22(56.4)	8(20.5)	5(12.8)		<0.05*
Urine dipsticked for proteinuria every month.	7(17.9)	24(61.5)	26(66.7)	7.9	6.21
Done regular	11(28.2)	9(23.1)	8(20.5)		
Done (irregular)	21(53.8)	6(15.4)	5(12.8)		<0.05*
Not done					

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Follow the instructions of medication typically.					5.58
Done regular	18(49.2)	24(61.5)	28(71.8)	2.5	
Done (irregular)	8(20.5)	9(23.1)	6(15.4)		<0.05*
Not done	13(33.3)	6(15.4)	5(12.8)		
Take calcium and Vitamin D to avoid side effects of the anticoagulant drug.				6.9	7.58
Done regular	14(35.9)	24(61.5)	30(76.9)		
Done (irregular)	10(25.6)	9(23.1)	6(15.4)		<0.05*
Not done	15(38.5)	6(15.4)	3(7.7)		
Follow antenatal schedule visit for high risk women typically.					8.36
Done regular	8(20.5)	27(69.2)	26(66.7)		
Done (irregular)	25(64.1)	9(23.1)	10(25.6)	9.2	<0.05*
Not done	6(15.4)	3(7.7)	3(7.7)		
Adopted healthy nutrition.					8.99
Done regular	8(20.5)	22(56.4)	25(64.1)		
Done (irregular)	8(20.5)	10(25.6)	9(23.1)	2.8	<0.05*
Not done	28(71.8)	7(17.9)	5(12.8)		
Adopted regular exercise.					7.98
Done regular	6(15.4)	15(38.5)	21(53.8)	9.9	
Done (irregular)	7(17.9)	12(30.8)	8(20.5)		<0.05*
Not done	26(66.7)	12(30.8)	10(25.6)		
Total					
Done regular	9(23.1)	24(61.5)	28(71.8)	6.083	0.001**
Done (irregular)	10(25.6)	9(23.1)	6(15.4)		
Not done	20(51.3)	6(15.4)	5(12.8)		

(*) Statistically significant at p< .05 **highly significant difference obtained at P < 0.00l

Table (3): reveals the Comparison between pre-conception APS women's compliance to percussion measure in the study group before and after implementation of the guideline to reduce the risk of the disease. The results show that, there was a statically significant difference between pre, after three months and follow up after 6 months regarding all the items (p-value < 0.05). As well as there was a highly statistical significant difference between total women compliance (p=0.001).

Table (4): Comparison between APS women's health in the study group before and after implementation of guideline (n=39)

Items	Pre	After implementation by 3 months	Follow up After implementation by 6 months	X 2	P value
	No (%)				
Pain (severe)	29(74.4)	16(41)	9(23.1)	12.33	0.001**
Good vital signs	13(33.3)	22(56.4)	31(79.5)	10.45	
APS flare (severe flare)	19(48.7)	12(30.8)	7(17.9)	13.76	0.001**
Normal lab investigation	10(25.6)	21(53.8)	22(56.4)	9.94	0.001**
M±SD					
APSDAI	10.2±4.11	6.8±3.21	3.1±1.23	8.33	0.001**

APSDAI =Anti- phospholipid Syndrome disease activity index

Table (4) Display the comparison between APS women's health in the study group before and after implementation of guideline, and show there was improvement of vitality, control of pain, APS flare as well as lab investigation among study group after implementation of guideline by 6 months compared to before intervention.

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Table (5): Comparison between APS women in (control and study group) regarding the obstetric complication in the current pregnancy among.

Items	Control group N=39	Study group N=30	X 2	P-value
	N (%)			
APS flares during pregnancy 1st trimester 2nd trimester 3rd trimester	 12(30.8) 9(23.1) 5(12.8)	 4(14.8) 2(7.4) 2(7.4)	9.12	0.001**
Obstetric complications • Non • Abortion • Preterm • Preeclampsia • GD • Placental abruption • IUGR • Low birth weight	 0(0) 9(23.1) 7(17.9) 6(15.4) 5(12.8) 2(5.1) 4(10.3) 3(7.7)	 16(53.3) 5(16.7) 3(10) 2(6.7) 1(3.3) 0(0) 1(3.3) 2(6.7)	8.55	0.001**

N.B: 30 women (only success to get pregnancy in study group)

Table (5) reveals the comparison between APS women in (control and study group) regarding the obstetric complication in the current pregnancy, shows that 30.8 % of women in control group had APS flares during the 1st trimester in current pregnancy compared to14.8% of women in study group and 23.1% of women in control group had abortion compared to 16.7% of women in study group. As well as there was highly significant difference between two groups regarding the obstetric complication in the current pregnancy

Table (6): Comparison between study and control group according to labor outcome:

Items	Control group N=39	Study group N=30	X 2	P-value
	N (%)			
Labor outcome				
Mode of delivery Vaginal delivery Caesarean delivery	 16(41) 23(69)	 20(66.7) 10(33.3)	10.34	0.001**
Apgar Score	**(M±SD)**		**T-test**	**P-value**
1st minute 2nd minute	6.23±0.12 7.08±0.91	8.99±1.09 9.04±0.88	6.78	0.04*

Table (6): Comparison between APS women in (control and study group) according to labor and fetal outcome, the result display that, 66.7% of women in study group delivered by normal vaginal delivery compared to 41% of women in control group . As well as there was significant difference between two groups regarding labor and fetal outcome and Apgar score.

4. DISCUSSION

Antiphospholipid Syndrome (APS) is an autoimmune thrombophilic condition that is marked by the presence in blood of antibodies that recognize and attack phospholipid-binding proteins. The clinical manifestations of APS include vascular thrombosis and pregnancy complications especially recurrent miscarriage, early delivery, oligohydramnios, prematurity, intrauterine growth restriction, fetal distress, fetal or neonatal thrombosis, pre-eclampsia/eclampsia are the most severe

APS-related complication for pregnant women. The first step in reduce adverse pregnancy outcome is increase women awareness regarding the disease and the protocol of care. So the study aimed to determine the efficacy of advanced educational program on knowledge and attitude of pregnant women with anti phospholipids syndrome**. [15]**

The results of the present study showed that the mean age of the women in control group was 29.6±5.4 compared to 27.2±4.3 of women in study group. These findings was consistent with **[16]** who stated that anti-phospholipids syndrome usually happens between the ages of 35-45 years.

The current result revealed that the abortion is the most previous pregnancy complication among APS women in study and control group followed by preeclampsia and represent about half of the sample and about quarter of sample respectively. This finding is consistent with **[17]** who stated that about half of the women with anti-phospholipids syndrome in the first 13weeks of gestation, the antibodies prevent the pregnancy from embedding properly in the womb, increasing the chances of miscarriage.

The previous finding also supported by **[18],** who studied that the effect of anti-phospholipids syndrome on pregnancy outcome, he reported that about two third of the pregnant women with anti-phospholipids syndrome had at least three unexplained early miscarriages that occurred before the tenth week of pregnancy and at least one unexplained late-term miscarriage (tenth week of pregnancy onwards).

Also the results supported by **[19],** who reported that Purely obstetric antiphospholipid antibody syndrome (APS) is clinically characterized by pregnancy morbidity as premature birth before the 34th week because of preeclampsia , Hemolysis, Elevated Liver enzymes, Low Platelets (HELLP) syndrome. Also reported 188 pregnancies were documented early pregnancy loss (16.5%), intra-uterine growth restriction (26.3%), and prematurity (48.2%) were common.

The current result reveals that, there was improvement between pre, 3 month after and follows up after 6 months of implementation the guideline among the study group regarding the women's knowledge about the disease and its causes, risk factors, singe and symptom, diagnostic test, complication and management during preconception ,pregnancy, labor and post- partum. Moreover total knowledge scores were improved from quarter of the women in study group achieved the satisfactory level to more than three quarter of the sample after the implementation by 6 months. This result may be due to, in Egypt the health care provider hasn't time to give the women overview about the disease specially when the mother follow in governmental hospital due to the flow rate of the women, as well as the nursing staff all their knowledge depend on their experience if the case is common otherwise that they not receive any educational program about full details regarding to this diseases.

This result similarly to the study of **[20]** who study the evaluation of a multidisciplinary patient education program for pregnant women's knowledge with autoimmune disease, he found that the pregnant women before the program have unsatisfactory knowledge about the overview of the disease and the precaution measure which must be adopted. This finding is in agreement with **[21]** who reported that three quarters of women with APS are usually acquiring information about the nature of disease, pathology, treatment, prognosis and life style changes. Moreover, the current study finding is not also consistent with the finding of **[22]** who evaluated the health education program about antiphospholipid syndrome among pregnant women, stated that more than two fifth of their sample got information regarding antiphospholipid syndrome from the health care provider during pregnancy.

Also the results of the current study revealed that, there were improvements in satisfactory women's knowledge in the study group regarding the symptoms which require immediate medical attention as singe of blood clot, singe of preclampsis comparing between pre ,after three and six months. This may due to that , women previously had bad experiences regarding her previous pregnancy outcome due to the disease , for this reason the women evoke to full attended well to the researcher regarding to each knowledge related to the disease and how to overcome it.

This result supported by **[23]** who found the significance between women's knowledge regarding the autoimmune disease and how to save their pregnancy during this condition were significantly higher when exposed to educational session. Also, the current study results were supported by **[24]** who studied the effectiveness of structured teaching program regarding knowledge on systemic lupus among the pregnant women. It showed that before program the majority of women had inadequate knowledge, whereas (9.17%) of them had moderate knowledge. As he reported there was improvement in the knowledge level of the women.

In addition the current study revealed there was improvement in pre-conception APS women's compliance to percussion measure in the study group before and after implementation of guideline, the total compliance raised from about quarter of the sample before the implementation to the majority of the sample after the implementation. There was a highly statically significant difference between pre, post and follow up regarding women compliance to the precaution items to save the pregnancy outcome. This result may be due to the women want to do anything to save her pregnancy, especially the women in the sample were young women and mostly of them from rural area. This finding is at variance with the finding of **[25]** during his study to determine the knowledge, and attitude of antithrombotic therapy and prevention of thrombosis among pregnant women; he discovered that 88% of the respondents had positive attitude during pregnancy regarding the measure percussion before and after educational session. The reason for the positive attitude may possibly be due to their high level of knowledge which was acquired during ante natal visits, concern for the baby and to facilitate safe pregnancy.

While the current study result synchronized by **[26]** who reported that 61.2% of the respondents had negative attitude towards the preventive measure during the disease, because she didn't know the important of it. While after educational session the majority of the respondents (92.4%) had positive attitude.

The current study reflects that there was improvement in APS women's health in the study group before and after the implementation of the guideline. Moreover, the current study findings showed that more than three quarter of APS women in the study group had good vitality after implementation of guideline by 6 months compared to one third of them before intervention. Also about less than one quarter of women had severe degree of pain after implementation of guideline by 6 months compared to three fourth of them before intervention. Also the result of the lab investigation become normal among more than half of the sample after the implementation by 6 months compared to quarter of the sample before the implementation. As well as there was a highly statistically significant difference regarding APS disease activity index among the studied woman before and after implementation the guideline

This finding is in the same lines **[27]** who reported that the women health of women complained from autoimmune disease during the pregnancy improved after educational sessions compared to women not follow the guideline. They compared pre-post changes (from baseline to 4 months after the intervention) in health status , They reported that among health status outcomes assessed, only the physical components showed significant improvement post-intervention.

Also, our study finding is supported by **[28]** who conducted an intervention study to evaluate the effectiveness of a standardized educational intervention to improve pain, fatigue, sleep and health-related quality of life (HRQoL) in patients with systemic lupus erythematosus and mentioned that educational intervention had positive effects on pain, sleep and HRQoL in SLE patients at 3 and 6 months. Furthermore, the severity of disease flare was minimized from nearly half before implementation of guideline to one fifth after implementation of guideline. That proved by highly statistical significant decrease in clinical manifestation of disease presented on decrease mean score of SLEDAI index after implementation of guideline. Our study finding is in accordance with **[29]** who conducted a Pilot Study of standardized educational program for improvement of chronic pain and fatigue in systemic lupus erythematosus and mentioned that there was significant decrease on SLEDAI after 3 and six months compared to baseline assessment (SLEDAI mean score at baseline was 2.8±2, at 3 months was 2.73±1.52 and at 6 months was 2.54±2.2).

Finally, concerning the pregnancy outcome, the current study indicated to about more than two third among the women in study group delivered by normal vaginal delivery compared to about one third in the control group. Also the Apgar score among women in study group was good and higher than in control group. Our study finding is in accordance with **[30]** who performed a retrospective analysis of 41 systemic lupus patients (55 pregnancies) and mentioned that vaginal deliveries occurred in 29 pregnancies (71%), while cesarean section (CS) was necessary in 12 pregnancies (29%, including one twin birth). The indications for CS were six cases of non-reassuring fetal status, two cases of abruption of placenta (including one twin birth), one case of late deceleration threatened premature delivery, parental deterioration of renal function and parental convulsion. Also Our study finding is supported with **[31]** who mentioned that low Apgar score (less than 7) at 1 min (p ($p<0.0001$) and 5 min ($p=0.0002$) between two groups (group of systemic lupus disease activity(30.6%) and group of systemic lupus disease stable in (69.4%) women.

5. CONCLUSIONS

The findings of the current study supported the hypothesis of this study which stated that implementation preconception nursing guideline for APS women will be effective on improving their pregnancy outcome than APS pregnant women that receive routine care.

6. RECOMMENDATIONS

In the light of the previous results of the present study the following recommendations are suggested that:

- Teaching program to improve nurse's knowledge and practice regarding nursing care of women with Antiphospholipid Syndrome in preconception period.
- Application of Preconception nursing guideline for APS Women at rheumatology, immunology clinics at Fayoum University and El Nabawy El Mohandes hospital.
- Evaluate the effect of different preventive strategies on improving pregnancy outcome among APS women.

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