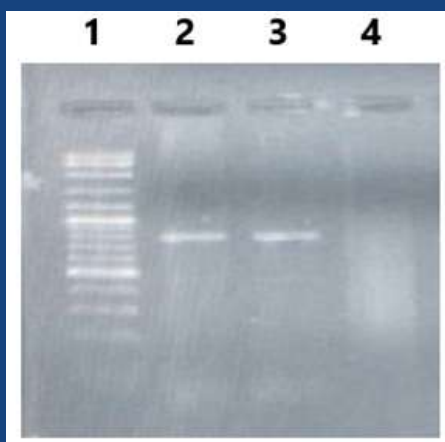


EFFECTIVENESS OF THEORY-BASED PEER EDUCATION ON KNOWLEDGE, ATTITUDES, AND UTILIZATION OF LONG-ACTING REVERSIBLE CONTRACEPTIVES AMONG PASTORAL WOMEN IN SOUTHERN ETHIOPIA

PAGE 1

PLACENTA ACCRETA SPECTRUM: EVALUATION OF ULTRASOUND DIAGNOSTIC CRITERIA IN AN ETHIOPIAN SETTING

PAGE 12



PROGRESSIVE RESISTANCE EXERCISES ALONG WITH DIETARY MODIFICATION ON THE LEVEL OF TSH IN SUBCLINICAL HYPOTHYROIDISM AMONG FEMALES WITH MENSTRUAL DISORDERS

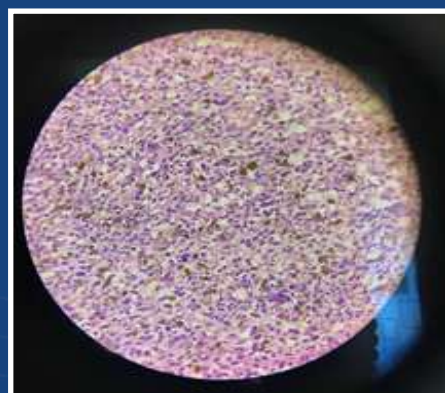
PAGE 19

RELATIONSHIP BETWEEN SERUM 25-HYDROXYVITAMIN D LEVEL AND PREECLAMPSIA COMPONENTS AND METABOLIC PARAMETERS AMONG OVERWEIGHT OR OBESE PREGNANT WOMEN

PAGE 28

TEENAGE PREGNANCY IN RURAL ETHIOPIA : THE CASE OF JIMA ARJO DISTRICT, EAST WALLAGA, WESTERN ETHIOPIA

PAGE 39



UPTAKE OF IMMEDIATE POSTPARTUM INTRAUTERINE DEVICE AND ASSOCIATED FACTORS AMONG MOTHERS WHO DELIVERED AT TWO PUBLIC HOSPITALS IN ADDIS ABABA, ETHIOPIA

PAGE 49

A RARE CASE REPORT OF OVOTESTICULAR DISORDER OF SEXUAL DIFFERENTIATION WITH LATE PRESENTATION

PAGE 59

ADVANCED MALIGNANT MELANOMA OF THE VULVA IN A 70 YEARS OLD WOMAN AT TIKUR ANBESSA SPECIALIZED HOSPITAL, ADDIS ABABA, ETHIOPIA: CASE REPORT

PAGE 64





# Ethiopian Journal of Reproductive Health (EJRH)

October, 2024

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# Ethiopian Journal of Reproductive Health (EJRH)

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Table of Contents	PAGE
Effectiveness of theory-based peer education on knowledge, attitudes, and utilization of long-acting reversible contraceptives among pastoral women in Southern Ethiopia .....	1
Placenta accreta spectrum: Evaluation of ultrasound diagnostic criteria in an Ethiopian setting .....	12
Progressive resistance exercises along with dietary modification on the level of TSH in subclinical hypothyroidism among females with menstrual disorders .....	19
Relationship between serum 25-hydroxyvitamin D level and preeclampsia components and metabolic parameters among overweight or obese pregnant women .....	28
Teenage pregnancy in rural Ethiopia: The case of Jima Arjo district, East Wallaga, Western Ethiopia .....	39
Uptake of immediate postpartum intrauterine device and associated factors among mothers who delivered at two public hospitals in Addis Ababa, Ethiopia .....	49
A rare case report of ovotesticular disorder of sexual differentiation with late presentation .....	59
Advanced malignant melanoma of the vulva in a 70 years old woman at Tikur Anbessa specialized hospital, Addis Ababa, Ethiopia: Case report .....	64

# EFFECTIVENESS OF THEORY-BASED PEER EDUCATION ON KNOWLEDGE, ATTITUDES, AND UTILIZATION OF LONG-ACTING REVERSIBLE CONTRACEPTIVES AMONG PASTORAL WOMEN IN SOUTHERN ETHIOPIA

Dawit Gelgelo<sup>1</sup>, Dejene Hailu<sup>2</sup>, Sileshi Garoma<sup>3</sup>

## ABSTRACT

**BACKGROUND:** Good knowledge and a positive attitude toward contraceptive methods are prerequisites for contraceptive utilization. Most reproductive-age women are unaware or have inaccurate knowledge regarding FP methods.

**OBJECTIVE:** To assess the effectiveness of theory-based peer education on knowledge, attitudes, and utilization of long-acting reversible contraceptives among pastoral women in Southern Ethiopia.

**METHODS:** A community-based quasi-experimental study was conducted with 192 pastoral women assigned to intervention and control groups, using pre- and post-intervention assessments. Eight trained healthcare workers delivered health education to the intervention group, incorporating the Theory of Reasoned Action and peer education to enhance knowledge, attitude, and promote the use of LARC. The control group received standard family planning counseling. A Difference-in-Difference model was used to compare mean knowledge and attitude scores, and the chi-square test assessed the difference in LARC utilization between the intervention and control groups.

**RESULTS:** The family planning (FP) health education intervention resulted in statistically significant improvements in both mean knowledge ( $p = 0.001$ ) and mean attitude ( $p = 0.001$ ) toward LARC in the intervention group compared to the control group. Additionally, a significant difference in LARC utilization was observed between the intervention group (57.3%) and the control group (32.6%) following the intervention ( $p = 0.045$ ).

**CONCLUSION:** Family planning health education, based on the Theory of Reasoned Action and peer education, is crucial for increasing the utilization of LARC. This intervention significantly improved participants' knowledge, attitudes, and LARC utilization compared to the control group. To enhance LARC adoption, national policies and FP guidelines should include components on contraceptive information and behavioral change theories, along with role model women in health education. These results highlight the importance of theory-based peer education in promoting reproductive health and suggest the need for further research on the long-term effects of these interventions.

**KEYWORDS:** Quasi-experimental study, LARC, Theory of Reasoned Action, peer education, pastoral women, Southern Ethiopia.

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## INTRODUCTION

Family planning (FP) is a crucial strategy in preventing 90% of abortions, 32% of maternal deaths, and 20% of pregnancy-related morbidities, and also reduces maternal mortality by 44% in low-income countries<sup>1,2</sup>. Ethiopia's countrywide coverage of contraceptive use has increased fivefold from 8% in 2000 to 41% in 2019, according to the 2019 mini EDHS survey, and the utilization of LARC is only 10%, which is far from the global FP target of 2030<sup>3</sup>. LARC are a modern family planning method that involves the use of an IUCD and subdermal implants. These methods are better than other methods because they have minimal contraindications, are highly effective at preventing undesired pregnancies, and do not need to be used continuously by the users<sup>4</sup>. Thus, LARC is particularly suitable for nomadic pastoralist women who are the most "hard-to-reach" populations for health-service delivery<sup>5</sup>.

In Ethiopia, several studies performed on knowledge, attitude, and utilization of FP revealed that many women, especially those living in rural and pastoralist areas, lack information about and have unfavorable attitudes toward FP due to the strong cultural and religious beliefs which encourage having many children and prohibit the use of FP<sup>2,6</sup>. Knowledge and attitudes regarding contraception are key motivators for FP utilization and some studies recommend the Theory of Reasoned Action (TRA) in behavior modification because it claims that a person's opinions and subjective norms influence their behavioral intentions<sup>7,8</sup>. In addition, friendship-based peer education is one of the ways that women get information about sexuality and contraceptive techniques because they share similar interests and concerns, which helps the messages retained and leads to changes in behaviors and perspectives<sup>9</sup>.

To date, most studies on FP and contraception in Ethiopia have focused solely on knowledge, attitudes, behaviors, and factors related to contraceptive utilization. However, there have been few interventional research studies on FP health

education that use peer education and behavioral models of instruction. Therefore, the purpose of this study was to investigate the effectiveness of theory-based peer education on long-acting reversible contraceptive knowledge, attitude, and utilization among pastoral women in Southern Ethiopia.

## Methods

### Study Area

This study was conducted in three pastoral districts of the West Guji Zone, Oromia Region, southern Ethiopia. According to 2023 West Guji Zone population data, the total number of women of reproductive age in the West Guji Zone was 199,543.

### Study Design and Population

A community-based quasi-experimental study design with baseline and end-line data collection was used to assess changes over time in the study outcome. The study included all married women of reproductive age (15–49) who had lived in the study area for at least six months, were eligible for FP in a randomly selected kebele (the lowest administrative unit), and were willing and had given consent to participate.

### Sample Size Determination

The sample size was calculated as follows:

$$\text{Sample size} = \frac{2SD^2 (Z_{\alpha/2} + Z_{\beta})^2}{d^2}$$

SD = standard deviation from previous studies = 0.3<sup>10</sup>

$Z_{\alpha/2} = Z_{0.05/2} = 1.96$  (from Z table)

$Z_{\beta} = Z_{0.20} = 0.842$  (from Z table) at 80% power

$d$  = effect size = difference between the mean scores of family planning utilization between baseline and end-line intervention) is 12.8%, based on previous studies conducted in the Afar pastoralist community.<sup>10</sup>

The calculated sample size for this study was 87 married women per group. After accounting for a 10% drop-out rate, 96 paired married women per group participated in health education.

### Sampling Procedure

All three pastoral districts (Dugda Dawa, Surro Barbuda, and Malka Soda) were included in this study. In total, 12 kebeles were selected from the three districts (4 kebeles per district) by



simple random sampling. The total number of reproductive-age women was obtained from the family planning registration books of kebele health posts in the three districts. Based on the number of reproductive-age women in each kebele, the calculated sample was allocated to each kebele using a proportionate allocation formula:  $x_i/N \cdot n$ , where  $x_i$  is the total number of reproductive-age women in each kebele,  $N$  is the total reproductive-age women in each district, and  $n$  is the sample size allocated to each district. Finally, 192 women were selected using tables of random numbers from different kebeles and enrolled in the interventional and control groups.

### Interventional Group

A draft of FP messages was prepared by health education and promotion experts and adapted from the WHO guide to FP, a theory-based intervention for contraception, and the Theory of Reasoned Action approach to health promotion. The draft was tested with FP experts and health extension workers, who provided constructive feedback to improve the messages.

Women were enrolled in the interventional and

control groups from different kebeles to avoid information contamination. A one-to-one ratio allocation of the interventional group with a control group was utilized. Health education was provided by trained health professionals and model women from selected kebeles through home visits to the interventional group, while the control group received routine family planning counseling. Before the intervention, baseline data on socio-demographic factors, knowledge, attitudes, and LARC utilization were collected in July 2023. Health education was provided in two sessions during the first month of intervention, on July 2 and 9, 2023. Each session lasted 50 minutes, and participants were followed for six months. The FP lecture covered various FP methods, the possible side effects of each method, and concerns about potential cancer risks. Additionally, the interventional group received peer education from model women who had used LARC, who shared their experiences and the health benefits of using LARC (Figure 1).

### Supplementary Materials

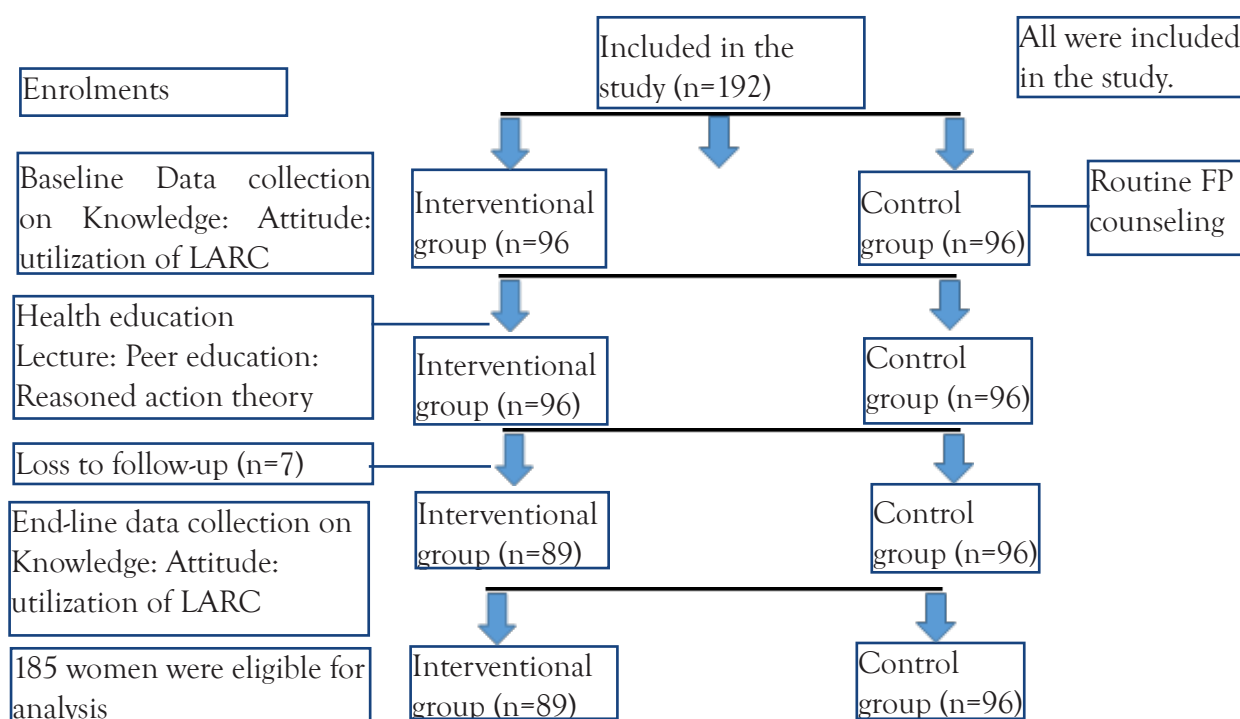


Figure 1: Flow diagram of study participants to evaluate the effectiveness of health education intervention among pastoral women of southern Ethiopia..



## Control Group

The control group did not receive the aforementioned interventions. They only received routine FP counseling in accordance with national FP guidelines, which consisted of a single one-hour educational session. Both the interventional and control groups were followed for six months, which was assumed to be sufficient time to effect a change in health-seeking behavior. After six months, end-line data were collected using the same questionnaire as at baseline, except for socio-demographic items, to assess knowledge, attitudes, and LARC utilization on November 12, 2023.

Data were collected using a pre-tested, interviewer-administered, semi-structured questionnaire written in English and translated into the regional working language (Afan Oromo) to ensure clarity and understanding. Eight trained data collectors were involved in the data collection for both the baseline and end-line periods.

## Measurement of Variables

The first outcome variable was knowledge of LARC, with each participant's score calculated based on the number of correct responses to knowledge question items. A total of ten knowledge item questions ranged from true (coded as 1) for correct responses to false (coded as 0) for incorrect responses. The responses were computed and summed using SPSS software to form a continuous knowledge outcome variable. The second outcome variable was participants' attitude, assessed using a total of ten questions with scores of one (disagree), two (not sure), and three (agree). The responses were computed and summed using SPSS software to form a continuous attitude outcome variable.

The third outcome variable in this study was the use of LARCs (implants and IUCDs). During the pre-treatment assessment, the question "Have you ever used LARC (implants/IUCD)?" was asked. For the post-treatment assessment, the question "When did you start?" was added. The responses were "yes" or "no".

## Data Processing and Analysis

All documented questionnaires were reviewed for completeness, consistency, and accuracy. The data were then cleaned, coded, and transferred to a computer for analysis using SPSS version 25.0 software. Descriptive statistical analysis was performed for socio-demographic characteristics, with the results presented in tables and graphics. A Difference-in-Difference model, a recent model for quasi-experimental studies, was used to compare mean knowledge and attitude scores, and the chi-square test ( $p < 0.05$ ) was used to compare LARC utilization between the interventional and control groups at baseline and end-line.

## Ethical Considerations

Ethical clearance was received from the Institutional Review Board of Bule Hora University (Ref No: BHU/RPD/1223/2023). The purpose of the study was explained to the participants, and verbal consent was obtained. Permission to conduct the study was granted by the ethics committee of the three district health offices. Data confidentiality was maintained.

## Result

### Socio-demographic and reproductive health characteristics of study participants

The study included 192 married reproductive-age group women, with a response rate of 185 (96.35%), of which 89 interventional groups and 96 control groups were able to complete the study. Lost to follow-up during 6 months was 3.65% for the interventional group. The reason for the loss to follow-up was migration to another place and others lost without reason.

The mean age of study participants in the interventional group was 28.2 years with a standard deviation of 6.4 years while in the control group 28.1 years with a standard deviation of 7.6 years. The majority of the women, 28 (31.50%) in the interventional group and 36 (37.50%) in the control groups did not attend any school. About, 41.60% women in the interventional group and 52 (54.20%) in the control group had unplanned pregnancies for their recent pregnancy. (Table 1)

**Table 1. Socio-demographic and reproductive health characteristics of the study participants to evaluate the effectiveness of health education intervention among pastoral women of southern Ethiopia, 2024 (N=Control=96, experimental=89)**

Variables	Categories	Group of Participants	
		N (%) Interventional group	N (%) Control group
Age	15-19	10(11.20)	8(8.40)
	20-24	24(27.00)	22(23.20)
	25-29	20(22.50)	29(30.50)
	30-34	20(22.50)	17(17.90)
	35-39	11(12.40)	13(13.70)
	40-44	3(3.40)	4(4.20)
	45-49	1(1.10)	2(2.10)
Residence	Urban	26(29.20)	28(29.20)
	Rural	63(70.80)	68(70.80)
Educational status	Never attended school	28(31.50)	36(37.50)
	Grades 1-4 completed	24(27.00)	22(22.90)
	Grades 5-8 completed	21(23.60)	25(26.00)
	Grades 9-10+ completed	16(18.00)	13(13.50)
Occupation	Has no job	41(46.10)	18(18.80)
	Farmer	19(21.30)	53(55.20)
	Government employee	18(20.20)	5(5.20)
	Trader	11(12.40)	20(20.80)
Status of last pregnancy	Unplanned	37(41.60)	52(54.20)
	Planned	52(58.40)	44(45.80)
ANC follow-up	No	30(33.70)	37(38.50)
	Yes	59(66.30)	59(61.50)
Partner support	No	40(44.90)	73(76.00)
	Yes	49(55.10)	23(24.00)
FP counseling	No	50(56.20)	65(67.70)
	Yes	39(43.80)	31(32.30)
Discuss with husband	No	46(51.70)	73(76.00)
	Yes	43(48.30)	23(24.00)
Place of delivery	Health facility	32(36.00)	28(29.20)
	Home	57(64.00)	62(64.60)
	Other	0(0.00)	6(6.30)

**Baseline and end-line comparison of long-acting reversible contraceptive knowledge between the interventional and control groups**

This study revealed that the knowledge score of women who said that the children of mothers who

use contraceptives have better education improved from 58.30% in the baseline interventional groups to 67.40% in the end-line interventional groups after they had obtained health education about contraceptives. (Table 2)

**Table 2. Baseline and end-line comparisons of long-acting reversible contraceptive knowledge to evaluate the effectiveness of health education intervention among pastoral women of southern Ethiopia, 2024**

Knowledge item questions	Response	Base Line		End Line	
		Interventional group N (%)	Control group N (%)	Interventional group N (%)	Control group N (%)
Children of families who use FP have better education	False	40(41.70)	76(79.20)	29(32.60)	77(80.20)
	True	56(58.30)	20(20.80)	60(67.40)	19(19.80)
IUCD is inserted in the uterus	False	41(42.70)	76(79.20)	30(33.70)	76(79.20)
	True	55(57.30)	20(20.80)	59(66.30)	20(20.80)
IUCD is not inserted for women with STD	False	40(41.70)	71(74.00)	53(59.60)	71(74.00)
	True	56(58.30)	25(26.00)	36(40.40)	25(26.00)
Implants prevent pregnancy for 5 yrs	False	23(24.00)	49(51.00)	24(27.00)	49(51.00)
	True	73(76.00)	47(49.00)	65(73.00)	47(49.00)
IUCD does not interfere with intercourse	False	30(31.30)	42(43.80)	24(27.00)	42(43.80)
	True	66(68.80)	54(56.30)	65(73.00)	54(56.30)
Implants inserted under arms' skin	False	32(33.30)	42(43.80)	11(12.40)	42(43.80)
	True	64(66.70)	54(56.30)	78(87.60)	54(56.30)
LARC is immediately reversible	False	36(37.50)	21(21.90)	7(7.90)	22(22.90)
	True	60(62.50)	75(78.10)	82(92.10)	74(77.10)
IUCD prevents pregnancy for > 10yrs	False	42(43.80)	53(55.20)	17(19.10)	53(55.20)
	True	54(56.30)	43(44.80)	72(80.90)	43(44.80)
Insertion of implant needs minor Surgery	False	34(35.40)	66(68.80)	20(22.50)	66(68.80)
	False	34(35.40)	30(31.30)	69(77.50)	30(31.30)
IUCD is not inserted for women less than 18 years	False	40(41.70)	66(68.80)	12(13.50)	66(68.80)
	True	56(58.30)	30(31.30)	77(86.50)	30(31.30)

### Difference-In-Difference Analysis of Baseline and End-Line Knowledge between Interventional and Control Group

Difference-in-Difference model is typically used to estimate the effects of health education by comparing the changes in women's knowledge over time between interventional and control groups. At baseline, the differences in knowledge between interventional and control groups were not statistically significant ( $p=0.068$ ). After treatment, a statistical difference between the interventional and control groups was observed ( $p=0.001$ ). (Table 3)

**Table 3: Difference-in-Difference analysis of baseline and end-line knowledge between interventional and control groups**

Outcomes	Knowledge	S. Err.	t	P> t
Before		0.033	7.18	0.068
Control	0.415			
Treated	0.548			
Diff (T-C)	0.133			
After		0.033	10.27	0.001*
Control	0.408			
Treated	0.743			
Diff (T-C)	0.334			
Diff-in-Diff	0.201	0.046	2.19	0.029*

R-square: 0.30

\* Significant  $p$ -value<0.05

**Baseline and end-line comparison of long-acting reversible contraceptive attitude between the interventional and control groups**

In the comparison of participants' attitudes, 76(79.20%) interventional and 40(41.70%) control

group women at baseline, and at the end line 30(33.70%) interventional and 40(41.70%) control women did not agree with the idea of LARC does not restrict daily activities respectively. (Table 4)

**Table 4. Baseline and end-line comparisons of long-acting reversible contraceptive attitude to evaluate the effectiveness of health education intervention among pastoral women of southern Ethiopia, 2024**

Attitude item questions	Response	Base Line		End Line	
		Interventional group N (%)	Control group N (%)	Interventional group N (%)	Control group N (%)
FP improves the standard of life	Not agree	74(77.10)	18(18.80)	39(43.80)	40(41.70)
	Not sure	4(4.20)	67(69.80)	6(6.70)	17(17.70)
	Agree	18(18.80)	11(11.50)	44(49.40)	39(40.60)
LARC does not restricts daily activities	Not agree	76(79.20)	40(41.70)	30(33.70)	40(41.70)
	Not sure	3(3.10)	17(17.70)	7(7.90)	17(17.70)
	Agree	17(17.70)	39(40.60)	52(58.40)	39(40.60)
IUCD insertion is not is shameful	Not agree	60(62.50)	36(37.50)	20(22.50)	36(37.50)
	Not sure	11(11.50)	12(12.50)	5(5.60)	12(12.50)
	Agree	25(26.00)	48(50.00)	64(71.90)	48(50.00)
Using IUCD/implant does not causes cancer	Not agree	53(55.20)	27(28.10)	10(11.20)	27(28.10)
	Not sure	16(16.70)	15(15.60)	6(6.70)	15(15.60)
	Agree	27(28.10)	54(56.30)	73(82.00)	54(56.30)
Using an implant causes does not regular bleeding	Not agree	74(77.10)	35(36.80)	24(27.00)	35(36.50)
	Not sure	7(7.30)	22(23.20)	5(5.60)	22(22.90)
	Agree	15(15.60)	38(40.00)	60(67.40)	39(40.60)
Insertion of IUCD is not painful	Not agree	66(68.80)	23(24.00)	31(34.80)	23(24.00)
	Not sure	18(18.80)	40(41.70)	25(28.10)	40(41.70)
	Agree	12(12.50)	33(34.40)	33(37.10)	33(34.40)
Using FP does not causes conflict in marriages	Not agree	84(87.50)	46(47.90)	33(37.10)	46(47.90)
	Not sure	9(9.40)	20(20.80)	21(23.60)	20(20.80)
	Agree	3(3.10)	30(31.30)	35(39.30)	30(31.30)
Using LARC does not causes infertility	Not agree	85(88.50)	51(53.10)	21(23.60)	51(53.10)
	Not sure	7(7.30)	17(17.70)	25(28.10)	17(17.70)
	Agree	4(4.20)	28(29.20)	43(48.30)	28(29.20)
Couples who practice FP have a happy life	Not agree	87(90.60)	55(57.30)	12(13.50)	55(57.30)
	Not sure	6(6.30)	17(17.70)	30(33.70)	17(17.70)
	Agree	3(3.10)	24(25.00)	47(52.80)	24(25.00)
Utilization of LARC require good nutrition	Not agree	88(91.70)	55(57.30)	10(11.20)	55(57.30)
	Not sure	5(5.20)	17(17.70)	31(34.80)	17(17.70)
	Agree	3(3.10)	24(25.00)	48(53.90)	24(25.00)

### Difference-In-Difference Analysis of Baseline and End-Line Attitude between Interventional and Control Group

At baseline, the differences in attitude between interventional and control groups were not statistically significant ( $p=0.544$ ). After the intervention, a statistical difference between the intervention and control group was observed ( $p=0.001$ ). (Table5)

**Table 5: Difference-in-Difference analysis of baseline and end-line attitude between interventional and control groups to evaluate the effectiveness of health education intervention among pastoral women of southern Ethiopia, 2024**

Outcomes	Attitude	S. Err.	t	P> t
Before		0.063	-9.71	0.544
Control	1.865			
Treated	1.325			
Diff (T-C)	0.54			
After		0.063	6.06	0.001*
Control	1.949			
Treated	2.334			
Diff (T-C)	0.384			
Diff-in-Diff	0.924	0.090	11.15	0.001*

R-square: 0.41

\* Significant p-value<0.05

Baseline and end-line comparisons of long-acting reversible contraceptive utilization between interventional and control groups

The cross-tabulation showed that there was no significant difference in LARC utilization between the interventional, 31(34.8%) and control groups, 12(13.5%) before FP health education intervention ( $p=0.907$ ). However, at the end-line, i.e. after FP health education intervention, a significant difference was observed between the interventional, 51(57.3%) and control group, 29(32.6%) ( $p=0.045$ ).

### DISCUSSION

The current study showed that a health education intervention supported by the theory of reasoned action model and peer education led to significant improvements in knowledge, attitudes, and

utilization of long-acting reversible contraception. These findings are consistent with results from quasi-experimental studies conducted in southwestern Ethiopia,<sup>18</sup> Nigeria,<sup>19</sup> Tanzania,<sup>20</sup> Egypt,<sup>21,22</sup> Thailand,<sup>23,24</sup> Brazil,<sup>25</sup> and Malaysia.<sup>26</sup> Similar to the present study, these studies provided health education using the information-motivation-behavioral skills model theory and peer education to the interventional group in their respective study settings. Additionally, there was a significant difference in mean attitude scores between the interventional and control groups at the end line, which aligns with studies conducted in northern Ethiopia,<sup>18</sup> Indonesia,<sup>27</sup> Iran,<sup>8</sup> Spain,<sup>9</sup> Nigeria,<sup>28</sup> and Tanzania.<sup>20</sup> Like in the current study, the interventional groups in these studies received health education supported by lectures, peer education, health talks, and counseling.

This study also revealed a much greater improvement in long-acting reversible contraceptive utilization among the interventional group than the control group. These findings align with those of a quasi-experimental study in central Ethiopia that used the health belief model in its health education intervention,<sup>29</sup> a study in southwest Ethiopia that utilized the information-motivation-behavioral skills model<sup>18</sup> and another quasi-experimental study in Indonesia that employed peer educators in its health education methods.<sup>27</sup>

Pastoral women engage in various socio-economic and cultural activities as well as conservation and management of natural resources. Therefore, strengthening existing health facilities and incorporating comprehensive family planning health education that considers contextual factors hindering family planning utilization among pastoralist women is crucial. In addition, national policy and family planning guidelines should include a specific component on contraceptive information and behavioral change theories and incorporate role model women into health education methods. A strength of the current study was its demonstration of the practicality of using the theory of reasoned action and peer education to improve contraceptive knowledge, attitudes,

and utilization among pastoral communities in Ethiopia. The study enrolled participants as both an interventional group and a control group from various study sites, thus minimizing potential information contamination. However, the results of this study cannot be generalized without a randomized controlled study.

### **Conclusion and Recommendation**

This study showed that FP health education supported by the theory of reasoned action and peer education methods is more effective in improving contraceptive knowledge, attitudes, and utilization than routine family planning counseling. Therefore, national policy and family planning guidelines should incorporate a specific component of contraceptive information and behavioral change theories, and include role model women in health education delivery methods.

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### **Data Availability Statements**

All relevant underlying data that support the findings of these study can be available through corresponding author.

### **Declaration of Conflicts of Interest**

The authors declare that they have no potential conflicts of interest concerning research, authorship, or publication of interest.

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# PLACENTA ACCRETA SPECTRUM: EVALUATION OF ULTRASOUND DIAGNOSTIC CRITERIA IN AN ETHIOPIAN SETTING

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## ABSTRACT

**BACKGROUND:** Placenta accreta spectrum (PAS) has increasingly become a major cause of obstetric hemorrhage. There is inadequate literature regarding the diagnostic accuracy of ultrasound in low-income settings such as the Sub-Saharan Africa. This study aimed to determine the diagnostic accuracy of 2D gray-scale ultrasound and color Doppler ultrasound for placenta accreta spectrum (PAS) among placenta previa cases in an Ethiopian setting

**METHODS:** Forty-nine cases of placenta previa that received maternity care at St. Paul's Hospital Millennium Medical College in Addis Ababa (Ethiopia) from June 2018 - October 2020 were retrospectively reviewed. A structured questionnaire was used to extract data from maternal charts. Data were analyzed using SPSS version 23. Simple descriptive statistics, and sensitivity and specificity tests were performed as appropriate. We used proportions and 95% CI to present the results.

**RESULTS:** Placenta accreta spectrum was detected at the time of Cesarean Delivery (CD) in 8 patients. Eight of them had complete placenta previa, 7 had anterior placenta while 1 had posterior placenta. Magnetic resonance imaging (MRI) was not done to confirm the diagnosis in all of the cases. The evaluated sonographic criteria showed good diagnostic performance: in placenta accreta spectrum (PAS) patients at least four out of five criteria were detected, with none of the criteria present in the cases without PAS. Thin myometrium was found to best predictor for the diagnosis of PAS, with high specificity and no false positive rate. Retro-placental hypoechoic space, bladder line: thinning/interruption, placental lacunae, and hypervascularity of uterine serosa-bladder interface were detected in majority of patients with PAS but there was high false positive rate.

**CONCLUSIONS:** In this study, the diagnostic performance of 2D and color Doppler ultrasound criteria for placenta accreta spectrum (PAS) was high. Presence of thin myometrium was found to be the single best predictor for the diagnosis of PAS. Gray scale ultrasound and color flow Doppler mapping should be used as first-line techniques for the identification of placenta accreta spectrum.

**KEYWORDS:** placenta accreta spectrum; PAS; Doppler ultrasound; low-income country; Sub-Saharan Africa; PPH

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## INTRODUCTION

Placenta accreta spectrum (PAS) includes the spectrum of placenta accreta, increta, and percreta and is a cause of major morbidity and mortality in pregnant women<sup>1</sup>. Abnormal vascularization results from the scarring process following uterine surgery with secondary localized hypoxia, leading to defective decidualization and excessive trophoblastic invasion<sup>2</sup>. In the last century, the incidence of PAS has risen from approximately 1 in 20,000 live births in 1928<sup>3</sup> to a rate of 1 in 533 in 2002<sup>4</sup>. This increase in the incidence of PAS has been mainly in low-middle income countries (LMICs) due to high birth and cesarean delivery rates<sup>5</sup>. Per a 2012 population-based study from the United Kingdom, this rate may be as low as 1.7 in 10,000 pregnancies overall but as high as 1 in 20 pregnancies in women with both placenta previa and a prior cesarean delivery<sup>6</sup>. An accurate prenatal diagnosis of placenta accreta spectrum (PAS) is required to reduce the risk of maternal/fetal morbidity and mortality<sup>7</sup>. Ultrasonography is used routinely for diagnosis of PAS, although diagnostic criteria and accuracy are still subject to debate<sup>8,9</sup>. Magnetic resonance imaging (MRI) can be helpful when the placenta is difficult to visualize on ultrasound due to the patient's body habitus or to a posterior location of the placenta<sup>10,11</sup>. Understanding the diagnostic accuracy of ultrasound for placenta accreta spectrum in low-income countries including the Sub-Saharan Africa is essential, as this diagnostic modality is cheaper and more universally available than MRI in these countries. Generating evidence on this positively impacts the care of women with PAS through timely access to a reliable diagnostic modality at an affordable cost that results in early detection of this spectrum with a planned delivery of maximum preparation. This study aimed to determine the diagnostic accuracy of 2D gray-scale ultrasound and color Doppler ultrasound for placenta accreta spectrum among placenta previa cases at a tertiary Ethiopian setting.

## Methods and Materials

### Study design, study setting, and study period

This retrospective review examined cases of placenta previa that received maternity and obstetric care at St. Paul's Hospital Millennium Medical College (SPHMMC) in Addis Ababa, Ethiopia, from June 2018 to October 2020. We evaluated the diagnostic accuracy of 2-D ultrasound and doppler ultrasound in diagnosing placenta accreta spectrum. SPHMMC is a tertiary and national referral Hospital in Ethiopia with various specialty and sub-specialty care and training programs, including Maternal-fetal medicine. Monthly, 850-950 deliveries are attended at the hospital, which is one of the highest in Ethiopia<sup>12</sup>.

The inclusion criteria were mothers who delivered at St. Paul's Hospital; who had initial conservative management in our maternity ward; placenta previa cases (including low-lying placenta) who had detailed obstetric ultrasound that documented placenta location and presence/absence of placenta accreta spectrum; The exclusion criteria were incomplete data.

### Sample size and sampling procedure

All the cases managed during the study period according to inclusion and exclusion criteria were included were included.

### Data collection

We reviewed medical records of placenta previa cases admitted to our maternity ward for conservative management. A structured questionnaire was used to extract data on reproductive characteristics, obstetric ultrasound and intra-operative findings, and maternal outcomes from maternal charts. using the results of 2D gray-scale transabdominal or transvaginal ultrasonography and color Doppler documented in the maternal chart, we retrospectively investigated the loss or irregularity of the echolucent area between the uterus and the placenta ('clear space'), thinning or interruption of the hyperechoic interface between the uterine serosa and the bladder wall and the presence of turbulent placental lacunae, myometrial wall thickness, and hypervascularity of the uterine serosa-bladder

interface. Ultrasound was performed by obstetrics and gynecology senior residents, maternal-fetal-medicine fellows and Ob-Gyn consultants. We had no aim of comparing the diagnostic skills difference among the physicians.

### Data analysis

Data was analyzed using SPSS version 23. Simple descriptive statistics was used to analyses baseline characteristics, obstetric characteristics, and treatment outcomes. Ultrasound findings were reviewed against the final diagnosis made during Cesarean section (CS). We performed also validity test-diagnostic sensitivity and specificity of the ultrasound criteria analyzed.

### Ethical clearance

Formal Ethical clearance letter was obtained from Institutional review board of St. Paul Hospital Millennium Medical College with a reference number PM23/693. The ethical clearance did not require obtaining informed consent from study subjects; hence it was not obtained from the participants of this study.

### Results

There were 49 cases of placenta previa cases during the study period. None of the cases had an MRI imaging. The mean gestational age at delivery was 36 weeks(Table-1). Majority of them (67%) had no history of previous CS scar and had posterior placentation (26/49). Twenty-eight were complete placenta previa cases while the rest were low-lying placenta previa cases. Out of these, there were 8 cases of placenta accreta spectrum (PAS) among 49 cases and all of them had complete placenta previa and previous Cesarean Section (CS) scar and were managed with classical CS and peripartum hysterectomy.

**Table 1: Baseline characteristics of placenta previa cases in Ethiopia, 2018-2020(N=49)**

Characteristics	Category	N	Percent
Maternal age	Mean	27.35	
Number of prior CS scar	No scar	33	67.3
	1	6	12.2
	2	7	14.3
	3	3	6.1
Previous surgical abortion	No	43	87.8
	Yes	6	12.2
Morbidly adherent placenta	No	41	83.7
	Yes	8	16.3
Placenta previa type	Complete placenta previa	28	57.1
	Low-lying placenta	21	42.9
Placenta location	Anterior	23	46.9
	Posterior	26	53.1
Indication for delivery	Elective delivery due date	29	61.7
	Recurrent bleeding	1	2.1
	Active bleeding	11	23.4
	Labor onset	5	10.6
	Emergency fetal indication	1	2.1
Mode of delivery	Lower uterine segment C/S	41	83.7
	Classic CS	8	16.3
Gestational age at delivery(Weeks)	Mean	36	
	No complication	43	87.8
Maternal complication	PPH	3	6.1
	PPH with massiven blood transfusio	3	6.1

In seven out of the eight cases of placenta accreta spectrum, the placenta was anterior(Table-2). Three cases had PPH, while another 3 cases had torrential bleeding which required massive blood transfusion. Only 3 out of eight had pathology results which revealed placenta accreta spectrum (2 placenta accreta and 1 placenta percereta).

**Table 2: Clinical characteristics of placenta accreta spectrum(PAS) cases (n=8), 2018-2020, Ethiopia**

Variables	Category	N	Percent
Number of prior CS scar	1	3	37.5%
	2	4	50.0%
	3	1	12.5%
Placenta previa type	Complete placenta previa	8	100.0%
Placenta location	Anterior	7	87.5%
	Posterior	1	12.5%
Maternal complication	Peripartum hysterectomy	2	25.0%
	Peripartum hysterectomy + PPH	3	37.5%
	Peripartum hysterectomy +PPH +massive blood transfusion	3	37.5%
Pathology report	placenta accreta spectrum	3	37.5%
	No pathology report	5	62.5%

Analysis of sonographic criteria showed good diagnostic performance (Table-3); in PAS patients at least four criteria were detected (Table-4), with none of the criteria detected in patients without PAS. Thin myometrium (lower uterine segment myometrium thickness of less than 1 mm) was found to be the best predictor for PAS (Sensitivity=62.5%, Specificity=100%, PPV=100%, and NPV = 95%). Retro placental hypoechoic space, bladder line: thinning/interruption, placental lacunae, and hypervascularity of uterine serosa-bladder wall interface were detected in majority of patients with PAS but with a relatively high false positive rate (12.5%).

**Table 3: Statistical evaluation of sonographic diagnostic criteria for placenta accreta spectrum among placenta previa patients, 2018-2020, Ethiopia**

Ultrasound criteria	Status	N	Sensitivity	Specificity	PPV	NPV
			% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)
Retro placental hypoechoic space	Absent	7	87.5 (64, 100)	97.6 (87, 100)	87.5 (64, 100)	97.6 (93, 100)
	Present	42				
Bladder line: thinning/interruption	Present	6	75 (44, 100)	97.6 (87, 100)	85.7 (59, 100)	97.6 (89, 100)
	Absent	43				
Placental Lacunae	Present	7	87.5 (64, 100)	97.6 (87, 100)	87.5 (64, 100)	97.6 (93, 100)
	Absent	42				
Hypervascularity of uterine serosa-bladder wall interface	Present	7	87.5 (64, 100)	97.6 (87, 100)	87.5 (64, 100)	97.6 (93, 100)
	Absent	42				
Myometrium thickness	Thin	5	62.5 (28, 97)	100 (100, 100)	100 (100, 100)	95.3 (89, 100)
	Normal	44				

**Table4: Number of Ultrasound criteria among placenta accreta spectrum cases**

Diagnosis	US criteria(n)	N	%
Placenta previa	0	41	83.7%
Placenta accreta spectrum	4	4	8.2%
	5	4	8.2%

## DISCUSSION

The main objective of this study was to determine the diagnostic accuracy of 2D and color Doppler ultrasound criteria for the diagnosis of placenta accreta spectrum. We found high diagnostic performance of 2D and color Doppler ultrasound criteria for diagnosis of morbidly adherent placenta (MAP). Out of the ultrasound criteria we evaluated, thin myometrium was found to be the single best predictor for the diagnosis of PAS with high sensitivity, specificity, negative predictive value, and positive predictive value.

Ultrasound evaluation with grayscale and color Doppler imaging is the recommended first-line modality for diagnosing placenta accreta spectrum (PAS)<sup>13</sup>. According to a recent systematic review of 23 studies (3,707 pregnancies), ultrasound has an average sensitivity of 90.72% (95% CI, 87.2–93.6) and specificity of 96.94% (95% CI, 96.3–97.5%) for the diagnosis of PAS<sup>14</sup>.

Diagnostic criteria that suggested placenta accreta, increta, or percreta include  $\geq 1$  of the following situations: (a) placental lacunae; obliteration of clear space; interruption of bladder border; myometrium of less than 1 mm; hypervascularity of uterine serosa-bladder wall interface<sup>15-17</sup>. In the present study, consistent with findings of previous studies, retro placental hypoechoic space, bladder line: thinning/interruption, placental lacunae, thin myometrium, and hypervascularity of uterine serosa-bladder wall interface were found to be helpful in the diagnosis of morbidly adherent placenta<sup>18</sup>. Similarly, Cal`ı et al in 2013 found that these ultrasound criteria were useful in prenatal diagnosis of PAS<sup>19</sup>. Tovbin et al and colleagues also found that a scoring system using the same ultrasound criteria is highly predictive of MAP in patients at risk<sup>20</sup>. According to recent literature, from the ultrasound criteria, multiple lacunae and turbulent flow are strongly associated with placenta accreta spectrum<sup>21-23</sup>. This is further supported with findings of a recent multicenter cross-sectional study done in 2019, which similarly showed that irregularly shaped placental

lacunae, turbulent blood flow through the lacunae, and protrusion of the placenta into the bladder were the best predictors of morbidly adherent placenta<sup>24</sup>. On the contrary, a recent study done in Kuwait found that disruption of uterine serosa-bladder interface (81.8% sensitivity), exophytic mass invading bladder (94.9% specificity, 66.7% positive predictive value (PPV), and 84.1% negative predictive value [NPV]), and disruption of uterine serosa-bladder interface as the best parameters for the diagnosis of morbidly adherent placenta<sup>25</sup>. In this study, unlike in none of these previous study, thin myometrium (lower uterine segment myometrium less than 1 mm thick) was the best predictor of morbidly adherent placenta (Specificity=100%, PPV=100%, and 95% NPV). Furthermore, loss of retro placental hypoechoic space had high sensitivity (87.5%) in diagnosing placenta accreta spectrum (PAS) in our study, which is consistent previous reports and with findings of a recent study done in Egypt that reported a sensitivity of 86.96% for the same ultrasound criteria<sup>26</sup>.

Small sample size with no proper sample allocation is the main limitation of our study. Retrospective data collection and incomplete pathology report for all cases of placenta accreta spectrum are the other limitations of this study. In addition, we were not able to categorize ultrasound diagnostic accuracy according to the level of expertise (ultrasound performed by post-graduate students vs. Obstetricians and maternal fetal medicine specialists) and we did not compare diagnostic accuracy of ultrasound with that of MRI. Last but not least, this study lacks description of the role of multi-disciplinary team approach in the management of morbidly adherent cases (senior obstetricians, gynecologic oncologists, and urologists).

## Conclusion

The diagnostic performance of 2D and color Doppler ultrasound criteria for placenta accreta spectrum (PAS) was good. Presence of thin myometrium was found to be the single best predictor for the diagnosis of PAS. Gray scale ultrasound and color flow Doppler mapping should

be used as first-line techniques for the identification of morbidly adherent placenta.

#### **Ethical consideration**

Formal Ethical clearance letter was obtained from Institutional review board of St. Paul Hospital Millennium Medical College with a reference number PM23/693. The ethical clearance did not require obtaining informed consent from study subjects; hence it was not obtained from the participants of this study.

#### **AUTHOR CONTRIBUTIONS**

AFS and WG contributed conception and development of the study protocol. AFS and WG contributed data collection. AFS performed the data analysis. AFS, AN and WG contributed data interpretation and manuscript write up. All authors critically revised the article for intellectual content. All authors reviewed the final manuscript and approved its submission for publication.

#### **Conflicts of Interest**

Authors report no conflicts of interest

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#### **DATA AVAILABILITY STATEMENT**

Data are available up on reasonable request from authors

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# PROGRESSIVE RESISTANCE EXERCISES ALONG WITH DIETARY MODIFICATION ON THE LEVEL OF TSH IN SUBCLINICAL HYPOTHYROIDISM AMONG FEMALES WITH MENSTRUAL DISORDERS

Sadbhawna Dadia<sup>1&2</sup>, Sonia Singh<sup>2</sup>, Nitin Gupta<sup>3</sup>

## ABSTRACT

**OBJECTIVE:** Subclinical hypothyroidism and menstrual disorders are common clinical manifestations affecting women. The management of subclinical hypothyroidism remains sparse, considering it a mild disorder. The literature is ambiguous regarding the effect of exercises on TSH levels; thus, the present study was designed to identify the effect of progressive resistance exercises along with dietary modification on TSH levels among females with subclinical hypothyroidism.

**METHODS:** A total of 74 females aged 18–35 years suffering from menstrual disorders were recruited. All participants underwent thyroid profile testing (T3, T4, and TSH). Participants with normal T3, T4, and raised TSH (4.6–10  $\mu$ IU/mL) were included and divided into two groups. Participants in Group A received dietary modification, and Group B received progressive resistance exercises (PRE) along with dietary modification. A protocol of six weeks was administered to both groups, and TSH levels were compared with baseline readings after the completion of the protocol.

**RESULTS:** A paired t-test showed a significant improvement in TSH levels in both groups. Additionally, an unpaired t-test revealed that Group B was more effective than Group A.

**\*\*Conclusion:\*\*** Progressive resistance exercises along with dietary modification is an effective protocol for improving TSH levels in subclinical hypothyroidism among females with menstrual disorders.

**KEYWORDS:** Subclinical Hypothyroidism; Hypothyroidism; Progressive resistance exercises; Menstrual disorders.

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## INTRODUCTION

Thyroid dysfunctions often start during the reproductive period and can lead to various menstrual problems and infertility among women.<sup>1,2</sup> Past studies showed an association between thyroid dysfunctions and menstrual health in women.<sup>3-5</sup> Subclinical hypothyroidism (SCH) is a mild disorder (4–10 mIU/mL) associated with few or no symptoms/signs of hypothyroidism,<sup>6</sup> and it is often overlooked or underdiagnosed. However, if left untreated for a long time, it can lead to severe consequences, such as menstrual irregularities, fewer pregnancies, abortions, and even infertility,<sup>3, 7</sup> and it can progress to overt hypothyroidism. Common clinical manifestations of subclinical hypothyroidism include dry skin, poor memory, headache, slow thinking, muscle cramps, muscle weakness, fatigue, cold intolerance, puffy eyes, constipation, hoarseness, anxiety, and depression.<sup>8-11</sup> It may also be associated with hyperlipidemia, neuromuscular, and neuropsychiatric symptoms and an increased risk of cardiovascular disease.<sup>12</sup>

In order to prevent the consequences and progression of subclinical hypothyroidism, timely management is highly important. However, the treatment of subclinical hypothyroidism remains controversial. In addition to pharmacological agents, exercise and dietary modifications in the management of subclinical hypothyroidism have been proposed, though the outcomes remain controversial. TSH levels after exercise have shown varied results, with some studies reporting either an increase or decrease in TSH levels.<sup>13-18</sup>

On the other hand, some studies reported a reduction in TSH levels after exercise.<sup>17, 19-21</sup> As literature shows substantial gaps and diversity regarding the effect of various exercises on thyroid hormone levels, we aimed to examine the effect of progressive resistance exercises along with dietary modifications on TSH levels.

This study is intended to be novel research in establishing non-pharmacological treatment for subclinical hypothyroidism among females with menstrual disorders.

## Methods

After obtaining ethical clearance from the institutional committee of Punjabi University, Patiala, the study protocol adhered strictly to the Declaration of Helsinki (2013). In this experimental study, we recruited 74 females (aged 18–35 years) residing in Amritsar City, India. Females with normal T3 and T4 levels and raised TSH levels  $\geq 4.6$   $\mu$ IU/mL were included. The participants were then randomly divided into two groups (Group A and Group B). Each participant provided written consent and was briefed on the study protocol before confirming participation. Following this, anthropometric and demographic data were recorded. Participants were randomly assigned to one of two groups for six-week interventions using block randomization with sequentially numbered opaque sealed envelopes (SNOSE). There were four blocks in each row with 19 rows, creating a matrix design of  $4 \times 19$ . Each row had two blocks for Group A and two for Group B. Once one row was completed, the next block in the subsequent row was opened, and so on. This method ensured an approximately equal number of patients in both groups at any time and minimized allocation bias. Participants in Group A underwent dietary modification, while those in Group B received progressive resistance exercises along with dietary modification. All interventions were set for a duration of six weeks. The CONSORT flowchart of the study is displayed in Figure 1.

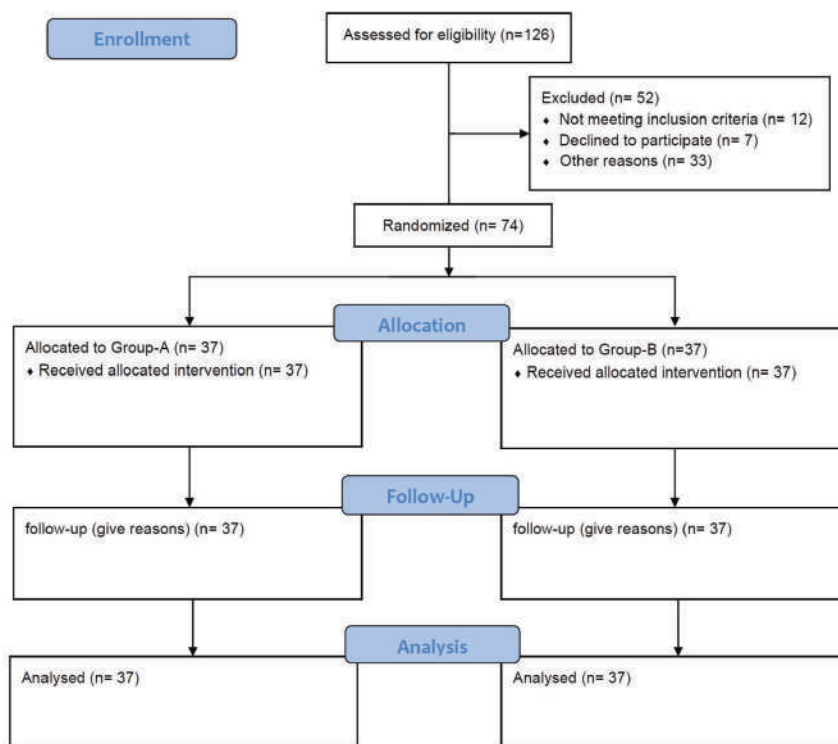


Figure 1: CONSORT flowchart of the study

The diet plan was kept constant for both groups. It was prepared by an expert dietician to provide 1800–2400 kcal per day, including 55g/d of protein, 25g/d of fat, 600mg/d of calcium, and 21mg/d of iron. The subjects were encouraged to follow the diet chart, and a record of compliance was maintained and signed by the researcher on a weekly basis. There was no restriction on the intake of water and roughage.

The resistance exercise protocol (Table 1) for Group B was partially adopted from Tracy et al. (1999)<sup>22</sup>. One repetition maximum (1 RM) is the maximum amount of weight that can be lifted once through a prescribed range of motion, and it was measured for all subjects. Thereafter, a total of five sets were performed by the subjects for the biceps, triceps, quadriceps, and hamstring muscles. The first set consisted of five repetitions at 50% of the 1 RM. The second set consisted of five repetitions at the current RM value. The third set consisted of ten repetitions, with the first five repetitions at the current RM value and the other five repetitions at 50% of the current RM. The fourth set consisted of

15 repetitions, with the first ten repetitions at the current RM value and the other five repetitions at 50% of the current RM. The fifth set consisted of 20 repetitions, with the first 15 repetitions at the current RM value and the other five repetitions at 50% of the current RM. The second, third, fourth, and fifth sets were preceded by rest periods lasting 30, 90, 150, and 180 seconds, respectively. Each session was followed by a cool-down period, including stretching of the biceps, triceps, quadriceps, and hamstrings. Every participant was instructed and supervised throughout the program by the investigator.

Any questions regarding the diet chart were addressed and managed personally by the investigator after discussion with the dietician. Before the actual start of the exercise program, three low-resistance training sessions with little or no resistance were conducted to familiarize the participants with the exercise program. The total duration of the protocol was 6 weeks, with sessions held 3 days per week. Each session took approximately 45 minutes for a subject to complete.

**Table 1: The resistance exercise protocol**

Warm up	Ten minutes warm up on bicycle ergometer and stretching of muscles (biceps, triceps, quadriceps, hamstrings)
Training	Resistance exercises: Three low resistance training session to make the subjects familiar with the exercises(biceps, triceps, quadriceps, hamstrings)
1 <sup>st</sup> set	5 rep at 10 % of 1 RM
Rest period	30 sec
2 <sup>nd</sup> set	5 rep of current RM
Rest period	90 sec
3 <sup>rd</sup> set	10 rep (First 5 rep at current RM + 5 rep with 50% of 1 RM)
Rest period	150 sec
4 <sup>th</sup> set	15 rep (10 rep with 1 RM + 5 with 50% of 1 RM)
Rest period	180 sec
5 <sup>th</sup> set	20 rep(15 rep with 1 RM + 5 with 50% of 1 RM)
Cool Down	Stretching of muscles (biceps, triceps, quadriceps, hamstrings)
Total Duration	6 weeks (3 days per week)

### Data Analysis

The normality of the collected data was assessed using the Kolmogorov-Smirnov test. As the data followed a normal distribution, the descriptive statistics of the collected data were expressed as mean ± standard deviation. If not, it would be reported as the geometric mean with a 95% confidence interval.

standard deviation. Their statistical significance was reported using paired t-tests and independent t-tests. For all statistical analyses, SPSS (Statistical Package for the Social Sciences) software, IBM SPSS 27 (27<sup>th</sup> version), was used, and the level of statistical significance was set at  $p < 0.05$ .

**Table 2: Distribution of participants according to the categories of menstrual disorder**

Type of Menstrual Disorders	Total (N= 74)	
	N	%
Dysmenorrhea	36	48.6
Premenstrual Syndrome (PMS)	25	33.8
Menorrhagia	06	8.1
Oligomenorrhea	04	5.4
Amenorrhea	03	4.1

The distribution of participants according to the categories of menstrual disorder was reported as a percentage (%) with numbers (frequency). Pre- and post-intervention changes in T3, T4, and TSH in Group A and Group B were expressed as mean ±

**Table 3: Distribution of participants according to menstrual disorder in Group A and Group B**

Type of menstrual Disorder	Group A(N=37)		Group B(N=37)	
	n	%	n	%
Dysmenorrhea	18	48.6	18	48.6
Pre-Menstrual Syndrome	13	35.1	12	32.4
Menorrhagia	02	5.4	04	10.8
Oligmenorrhea	03	8.1	01	2.7
Amenorrhea	01	2.7	02	5.4

**Table 4: Distribution of participants according to age in Group A and B**

Age group (in years)	Group A (N=37)		Group B (N=37)	
	Number (n)	Percentage (%)	Number (n)	Percentage (%)
18-23	8	21.62	10	27.02
24-29	14	37.83	11	29.72
30-35	15	40.54	16	43.24

**Table 5: Distribution of the participants according to BMI in Group A and B**

BMI (kg/m2)	Group A (N=37)		Group B (N=37)	
	Number (n)	Percentage (%)	Number (n)	Percentage (%)
Normal (18.5- 24.9)	11	29.72	13	35.13
Pre-obese (25-29.9)	18	48.64	17	45.94
Obese (30.0-34.9)	8	21.62	7	18.91

**Table 6: Comparison of pre and post values of BMI in both the Groups**

BMI (kg/m2)	Mean ± SD		df	t
	Pre	Post		
Group A	27.28±3.27	26.09±2.54	36	4.201
Group B	26.80±3.16	26.30±2.60	36	3.090

\*p<0.05

**Table 7: Comparison of pre and post values of BMI in both the Groups**

Sr. No.	Thyroid Hormone	Group - A					Group - B					t	
		Mean± SD		SEM	95% confidence interval of the difference		t	Mean± SD		SEM	95% confidence interval of the difference		
		Pre	Post		Lower	Upper		Pre	Post		Lower		Upper
1.	T3 (ng/mL)	1.44±0.035	1.47±0.34	0.006	0.043	0.017	4.78*	1.20±0.32	1.42±0.32	0.43	0.308	0.133	5.10*
2.	T4 (ug/dL)	9.69±2.66	9.76±2.69	0.029	0.133	0.015	2.54	8.83±2.44	9.49±2.58	0.17	1.006	0.314	3.87*
3.	TSH (mIU/mL)	7.74±0.98	6.74±1.01	0.072	0.855	1.150	13.8*	7.51±1.41	5.45±0.76	0.19	1.672	2.444	10.82*



Table 8: Comparison of improvement score of T3, T4 and TSH between both the groups

Variable	Group	Mean Difference	SD	SEM	T
T3 (ng/mL)	Group A	0.22	0.26	0.043	4.34*
	Group B	0.03	0.03	0.006	
T4 (ug/dL)	Group A	0.66	1.03	0.17	3.38*
	Group B	0.07	0.17	0.02	
TSH (mIU/mL)	Group A	2.05	1.15	0.19	5.18*
	Group B	1.00	0.44	0.076	

## DISCUSSION

As subclinical hypothyroidism (SCH) is a modifiable risk factor for menstrual dysfunction, it should be included in the investigative process for females suffering from menstrual disorders to ensure early diagnosis and treatment. Timely treatment, if initiated, can prevent progression to overt hypothyroidism and may alleviate symptoms related to menstrual disorders. This study tested two non-pharmacological methods—progressive resistance exercises along with dietary modifications and dietary modifications alone—for their efficacy in managing SCH in females with menstrual disorders. Participants in Group A underwent a balanced dietary program focusing on content, quantity, and timing of diet intake over a six-week duration. Paired t-test results revealed a statistically significant decrease in TSH level ( $t=13.8$ ), a significant increase in T3 ( $t=4.78$ ), and a non-significant change in T4 level ( $t=2.54$ ) after the intervention, along with a significant decrease in BMI among participants in the dietary program. These findings align with the study by Soad and Lalia (2009), which suggested that thyroid hormones, especially T3, could stimulate metabolism and enhance tissue lipolysis, mobilizing triglycerides and promoting fatty acid lipogenesis. It is well known that a balanced diet plays a vital role in health and well-being. Moreover, dietary habits can significantly impact thyroid function, leading to fluctuations in thyroid levels.<sup>23</sup> Deficiencies in micronutrients such as iron, iodine, vitamin A, calcium, magnesium, sodium, chromium, cobalt, selenium, manganese, and zinc have been identified as causative factors for alterations in thyroid hormone production.<sup>24-31</sup> The current

study recommended a nutritious diet containing adequate protein, calcium, iron, fat, and other micronutrients, which is accessible to all social classes. This balanced diet helped improve thyroid function. Subclinical hypothyroidism is a common issue in obese individuals.<sup>32</sup> The reduction in BMI ( $t=3.090$ ) in this study may have contributed to lower TSH levels, in line with findings by Bansal et al.<sup>24,33</sup> Thus, dietary modifications can be a cost-effective treatment approach for subclinical hypothyroidism.

In Group B, results showed a significant decrease in TSH levels ( $t=10.82$ ) and a significant increase in T3 ( $t=5.10$ ) and T4 ( $t=3.87$ ) levels after six weeks of intervention. Additionally, a statistically significant difference between the groups suggested that progressive resistance exercises combined with dietary modification were more effective in managing subclinical hypothyroidism than diet alone.

Resistance exercises, or increased mechanical load on exercising muscles, can stimulate thyroid function, leading to a notable increase in T3 and T4 levels.<sup>34,35</sup> Moreover, during recovery from resistance exercises, metabolism increases to support tissue repair, which may contribute to increased T3 levels.<sup>18</sup> Similar results were observed in male rowers after three weeks of high-intensity resistance training<sup>17</sup> and in weight lifters after one week of intense strength training.<sup>22</sup> Based on these studies and the current study, strength training or progressive resistance exercises is an effective protocol for reducing TSH levels. Only one cited study reported no changes in TSH levels following a resistance training program.<sup>19</sup>



The present study also revealed a significant reduction in BMI ( $t=3.09$ ) following progressive resistance exercises and dietary intervention. The reduction in body weight or BMI observed here may also have contributed to the reduction in TSH levels. Furthermore, progressive resistance exercises increased the metabolic rate,<sup>14 15</sup> which likely influenced TSH levels. This indicates that progressive resistance exercises combined with dietary modifications is an effective protocol for reducing TSH levels. These findings imply that females with subclinical hypothyroidism should be educated about the role and importance of progressive resistance exercises combined with diet to manage their condition. Thus, the current study recommends diet and exercise as an effective strategy for managing subclinical hypothyroidism. Our recommendation—that resistance exercises combined with dietary modifications is an effective approach for managing subclinical hypothyroidism—is further supported by a study suggesting that diet and exercise should be initiated when TSH levels are mildly elevated to prevent progression.<sup>36</sup> Therefore, progressive resistance exercises combined with dietary modification were found to be more effective in decreasing TSH levels than dietary modification alone.

## CONCLUSION

The two interventions—progressive resistance exercises combined with dietary modification and dietary modification alone—tested in this study proved to be effective approaches for managing subclinical hypothyroidism. However, comparisons showed that resistance training, when added to dietary modifications, amplifies the effects in terms of TSH reduction, resulting in greater improvement in subclinical hypothyroidism. Therefore, this study recommends that progressive resistance exercise combined with dietary modification is an effective method for alleviating the burden of subclinical hypothyroidism in females with menstrual disorders.

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# RELATIONSHIP BETWEEN SERUM 25-HYDROXYVITAMIN D LEVEL AND PREECLAMPSIA COMPONENTS AND METABOLIC PARAMETERS AMONG OVERWEIGHT OR OBESE PREGNANT WOMEN

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## ABSTRACT

**BACKGROUND:** Studies have shown that vitamin D deficiency can be related to the occurrence of preeclampsia.

**OBJECTIVE:** The present study was conducted with the aim of determining the relationship between the serum level of 25-hydroxyvitamin D and preeclampsia and its related risk factors among obese or overweight pregnant women.

**METHODS:** This cross-sectional-analytical study was conducted on 83 pregnant obese or overweight women referred to comprehensive health service centers in Makoo city. Anthropometric indices and biochemical factors including vitamin D serum level, glycemic indices and lipid parameters were investigated in these women. In addition, the food intake of the participants was evaluated using an Food Frequency Questionnaire (FFQ).

**RESULTS:** The results showed that there is a direct correlation between vitamin D serum level and dietary fat level ( $r=0.269$ ,  $p=0.007$ ) and high-density lipoprotein (HDL-C) ( $r=0.478$ ,  $p<0.0001$ ). Also, there was an inverse correlation between serum vitamin D level and pre-pregnancy body mass index ( $r=-0.625$ ,  $p<0.0001$ ), systolic blood pressure ( $r=-0.592$ ,  $p<0.0001$ ), diastolic blood pressure ( $r=-0.592$ ,  $p<0.0001$ ), fasting blood sugar (FBS) ( $r=-0.511$ ,  $p<0.0001$ ), proteinuria ( $r=-0.422$ ,  $p<0.0001$ ), triglyceride (TG) ( $r=-0.36$ ,  $p = 0.011$ ), total cholesterol(TC) ( $r=-0.428$ ,  $p<0.0001$ ) and low-density lipoprotein (LDL-C) ( $r=-0.602$ ,  $p<0.0001$ ).

**CONCLUSION:** There is a direct relationship between dietary fat intake and serum vitamin D level. There is also a positive correlation between serum levels of this vitamin and serum HDL-C. On the other hand, there is an inverse relationship between the serum level of vitamin D and systolic blood pressure, degree of proteinuria, pre-pregnancy body mass index and fasting blood sugar total cholesterol and low-density lipoprotein .

**KEYWORDS:** Vitamin D, preeclampsia, pregnancy, Obesity, Glycemic Index, Body mass index

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## INTRODUCTION

Preeclampsia is a specific syndrome during pregnancy that manifests itself as high blood pressure and proteinuria in pregnant women who were healthy before pregnancy and usually appears in the 20<sup>th</sup> or later week of pregnancy. Preeclampsia occurs in approximately 5 to 7% of all pregnancies<sup>1</sup>. Of course, according to the new guidelines of the American College of Obstetricians and Gynecologists (ACOG), the diagnosis of preeclampsia does not need to determine proteinuria; in fact, high blood pressure is sufficient to confirm preeclampsia<sup>2</sup>. This disease is the most common medical complication of pregnancy and one of the causes of pregnant women death. Preeclampsia causes 50,000 deaths every year<sup>3</sup>. For this reason, WHO considered one of the Millennium Development Goals be reducing maternal mortality by 75% between 1990 and 2015<sup>4</sup>. Vitamin D is one of the body's essential fat-soluble vitamins that is not produced in the body and is present in small amounts in food sources. The most important source of this vitamin is sunlight. Vitamin D plays an essential role in bone metabolism, absorption of calcium and phosphorus, and maintenance of muscle function; thus vitamin D may play a role in the prevention of preeclampsia<sup>5</sup>. Also, recently, some studies have shown that there is a relationship between vitamin D deficiency and preeclampsia. A study that investigated the relationship between vitamin D and preeclampsia has shown that women with preeclampsia have a lower level of vitamin D than healthy women. Also, the body mass index (BMI) of them was in the range of overweight, while healthy women had normal weight<sup>6</sup>. Due to the fact that vitamin D is a fat-soluble vitamin, this is unavailable to the body in overweight and obese people due to its deposition in the fat tissue, which causes a deficiency of it in the body and causes its complications<sup>7</sup>. Two systematic reviews and meta-analyses with clinical trials method did not show any beneficial effect of vitamin D supplementation in preventing of preeclampsia<sup>8, 9</sup>. This difference in the results of the studies may be due to different

variables in the studied communities.

A pilot study in Iran showed that the concentration of 25 hydroxyvitamin D [25(OH)D] was less than 25 nmol/l in 80% of pregnant women<sup>10</sup>. Also, the prevalence of severe, moderate and mild deficiency of vitamin D was 9.5%, 57.6% and 14.2% respectively in a general Iranian population<sup>11</sup>.

In another study, the level of 25-hydroxyvitamin D in 552 pregnant mothers who had referred to the teaching hospitals of Tehran University of medical sciences was measured during delivery. The results showed that the prevalence of vitamin D deficiency in the maternal blood samples were 66.8% and there was a significant relationship between the concentration of vitamin D in the mothers' blood serums and umbilical cord<sup>12</sup>.

Makoo is a city in the West Azerbaijan province of northwest Iran, situated at a high latitude. It is one of the colder regions of Iran, receiving limited sunlight. Consequently, this study has been designed and conducted to explore the relationship between serum levels of 25-hydroxyvitamin D and preeclampsia, along with its associated risk factors, among overweight or obese pregnant women who visited the comprehensive health service centers in Makoo city.

## Method

The participants of this study were selected from those who were referred to health centers in Makoo city in 2019. This is an analytical cross sectional study. This project has been approved by the Ethics Committee of Tabriz University of Medical Sciences with tracking code "IR.TBZMED.REC.1399.1087". Sampling was done by the accessible random method. The records of pregnant women who were obese or overweighed before pregnancy were extracted from the SIB (system information health) system of three comprehensive urban health service centers. Based on the available information, if the pregnant women were in the 20<sup>th</sup> week of pregnancy or later during sampling, they were invited to participate in the study, with considering the inclusion and exclusion criteria.

The final confirmation was done the by the centers' physicians, based on the diagnostic criteria of preeclampsia.

The sample size was calculated based on the mean and standard deviation of the serum concentration of 25-hydroxyvitamin D in pregnant women suffering from preeclampsia. Data related to the mean and standard deviation of the serum concentration of 25-hydroxyvitamin D were determined using Cochran's formula<sup>13</sup>. In this research, considering 95% confidence and  $d= 0.03$ ,  $p=0.7$ , the sample size was 75. By including 10% non-response, the sample size was 83. It was considered<sup>14</sup>. The following formula was used for calculating the sample size:

$$N= \frac{Z^2 P(1-P)}{d^2}$$

The sampling process of mothers is shown in the figure 1.

In order to check the anthropometric indicators, height and weight of participants were measured and their body mass indexes were calculated. Their Systolic and diastolic blood pressure were measured twice, using a mercury sphygmomanometer from their right arms in sitting position with 15 minutes interval. The average of these two amounts was used to determine the participants' blood pressure. Data on food intake:

In order to determine the participants' food intake, a semi-quantitative Food Frequency Questionnaire (FFQ) with 80 items was used. The capability and reliability of this questionnaire for the Iranian adult community had already been examined and confirmed<sup>15</sup>. The questionnaire evaluated the consumption pattern of the participants in the past year and was completed face to face. The participants reported the frequency of each questionnaire item on a daily, weekly, monthly and yearly basis. The nutritional data were converted into standard values

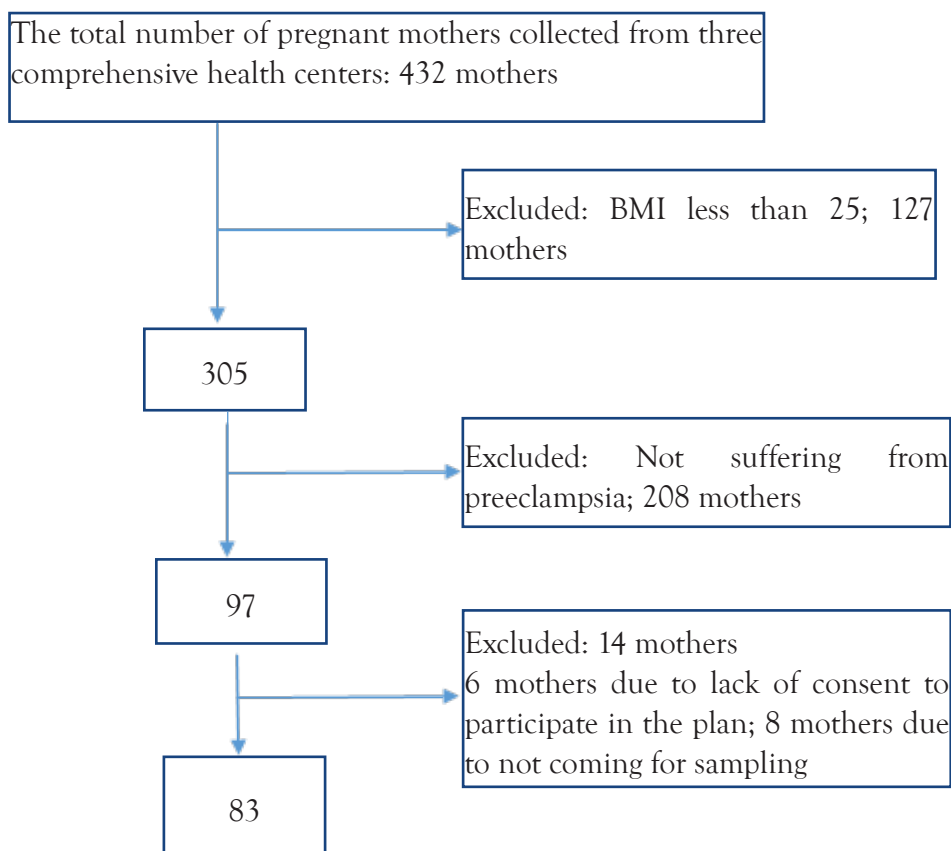


Figure 1: Sampling of mothers from 3 comprehensive health service centers



and then converted into grams using a home scale book. Due to the incompleteness of the table of Iranian food ingredients, some food items included in USDA food ingredients table to determine their energy and nutrients amounts. Also, the Iranian food ingredients table was used for Iranian foods that were not in the USDA food composition table, including food items such as curd.

**Examination of biochemical factors:**

To measure the biochemical factors, 5 cc of the venous blood samples were taken from the participants after 8 hours of fasting and their serum levels of 25-hydroxyvitamin D, fasting serum glucose, total cholesterol, triglyceride and HDL-C were measured. ECLA commercial kits were used to evaluate the serum levels of 25-hydroxyvitamin D. Serum concentration of fasting glucose, total cholesterol, triglyceride and HDL-C were measured by enzymatic colorimetric method by Pars Azmoon kits. In order to calculate serum LDL-C concentration, the Fried Ewald formula  $[TC (mg/dL) - HDL-C (mg/dL) - (TG(mg/dL) / 5) = LDL-C]$  was used (16). To measure proteinuria to diagnose preeclampsia, Med-test combi strip tests were used in the urine samples. In case of color change in favor of the presence of protein, sulfosalicylic acid solution was used to trace protein in urine. According to the degree of turbidity, it was scored from positive one to positive four.

**Data analysis:**

The obtained data was analyzed by “SPSS” software version 20. Kolmogorov smirnov test was used to determine the data distribution. Quantitative data were presented as mean and standard deviation and qualitative data were presented as frequency and percentage. If the data were normal, Pearson correlation coefficient was used; if they were not normal, Spearman correlation coefficient was used. Also, taking into account the confounding factors of the relationship evaluation, they were re-examined by Partial correlation. Multi linear regression tests were used to model and better understand the relationship between dependent and independent factors. P-value>0.05 was considered significant.

**Results**

83 pregnant women with average age of  $28.19 \pm 6.13$  years and gestational age of  $29.1 \pm 5.6$  weeks were included in the study. 68.7% of the samples were overweight and 31.3% were obese. Proteinuria 1+, 2+ and 3+ in the studied samples was 65.1, 32.5 and 2.4%, respectively. Average pre-pregnancy body mass index, serum level of 25-hydroxyvitamin D, systolic and diastolic blood pressure, as well as the average metabolic indexes is shown in Table 1.

**Table 1: Anthropometry and blood pressure in pregnant mothers participating in the study**

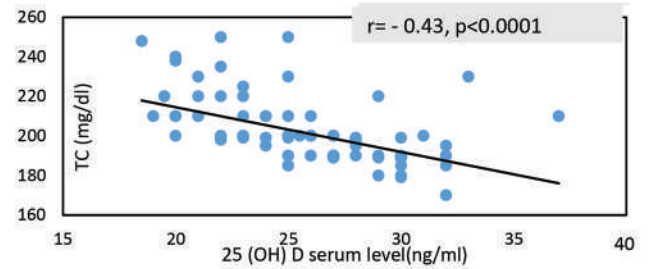
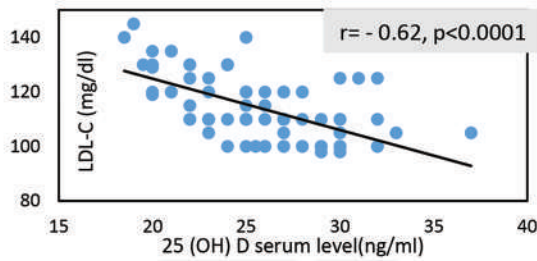
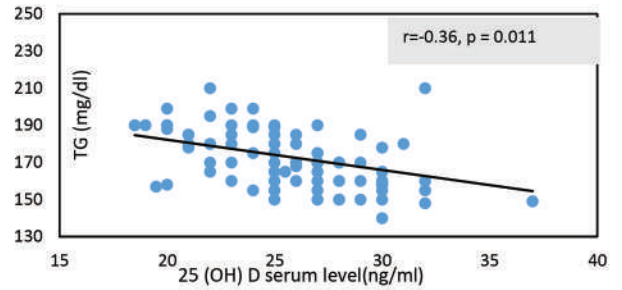
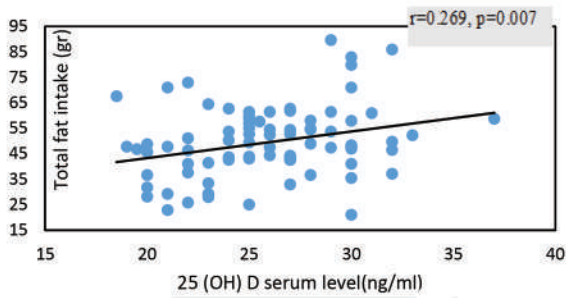
Variable	Mean ± SD
Body mass index before pregnancy (kg/m <sup>2</sup> )	29.59±3.56
25 (OH) Vitamin D (ng/ml)	3.80 ±25.88
Systolic Blood pressure (mmHg)	7.74 ±149.94
Diastolic Blood pressure (mmHg)	5.17±94.54
FBS (mg/dl)	17.79 ±91.00
TG (mg/dl)	19.87±173.23
TC (mg/dl)	20.11±201.16
LDL-C (mg/dl)	11.89 ±13.78
HDL-C (mg/dl)	4.40 ±45.05

25 (OH) D serum level was normal in 21.7% of the samples ( $\geq 30$ ng/ml) and insufficient in 74.7% of them (20-29 ng/ml). 3.6% of the samples were also suffering from vitamin D deficiency (<20 ng/ml).

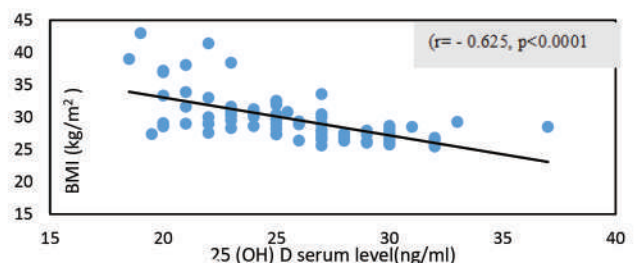
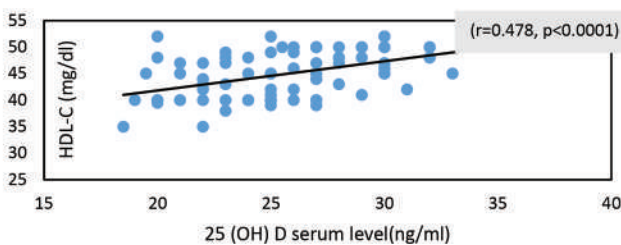
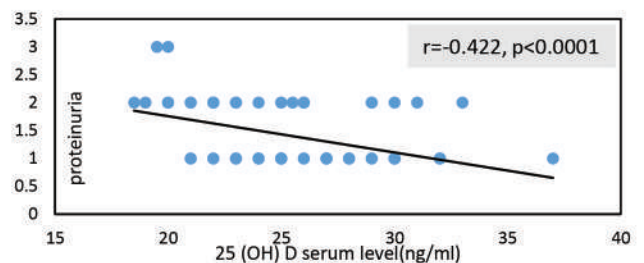
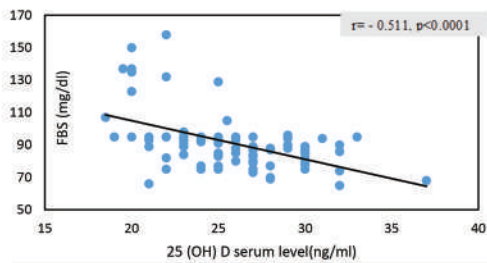
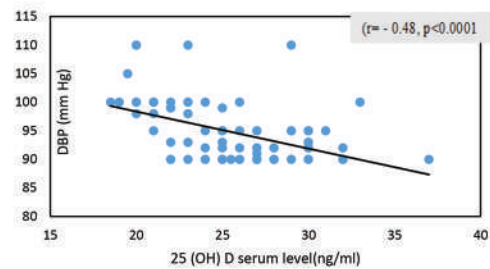
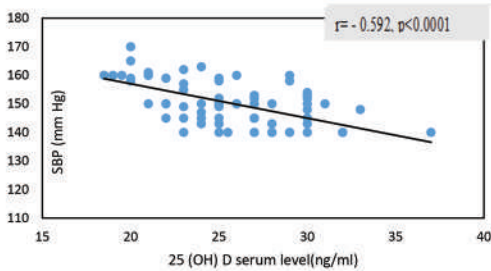
A positive and significant correlation was observed between serum level of vitamin D with the level of fat intake and HDL-C, in contrast to a negative and significant correlation between serum vitamin D or preeclampsia components (systolic and diastolic blood pressure and proteinuria), FBS, TG, TC and LDL-C(Graph 1 and 2).



**Graf1: Correlation of serum 25 hydroxy vitamin D with fat intake and lipid profil**



**Graf 2: Correlation of serum hydroxyvitamin D with fasting blood sugar, body mass index and systolic and diastolic blood pressure**



The results of multiple linear regression analysis showed a positive and significant relationship between fat intake and serum vitamin D level and no correlation between calories, protein and carbohydrate intake (Table 2).

**Table 2: Linear regression results of daily food intake and serum vitamin D level**

Variable	model	$\beta$ estimate	P value
2energy	0	-0.15	0.17
	1	-0.12	0.24
	2	-0.10	0.23
Carbohydrate	0	-0.21	0.08
	1	-0.21	0.09
	2	-0.18	0.13
Protein	0	0.06	0.16
	1	0.06	0.60
	2	0.01	0.90
Fat	0	0.27	0.005
	1	0.27	0.005
	2	0.19	0.010
Pre-pregnancy BMI	0	-0.62	0.000
	1	-0.62	0.000
	2	-0.59	0.000

25-hydroxy vitamin D as dependent variable

Model 0 = crude model

Model 1 = after adjustment for age

Model 2= after adjustment for age, Use of sunscreen, exposure to sunlight, type of Clothing and physical activity

After removing the effect of confounding factors of age, body mass index and daily intake of energy and macronutrients, multiple linear regression analysis showed an inverse and significant relationship between serum level of vitamin D and systolic and diastolic blood pressure levels, proteinuria, FBS, TC and LDL-C. There was a direct and significant relationship between serum level of vitamin D and HDL-C level (Table 3).

**Table 3: The results of linear regression of the relationship between serum level of vitamin D and preeclampsia components and the studied metabolic indicators**

Variables	model	$\beta$ estimate	P value
Systolic blood pressure	0	-0.59	0.000
	1	-0.41	0.000
	2	-0.38	0.004
Diastolic blood pressure	0	-0.48	0.000
	1	-0.35	0.006
	2	-0.26	0.067
Proteinuria	0	-0.42	0.000
	1	-0.37	0.002
	2	-0.35	0.013
FBS	0	-0.51	0.000
	1	-0.46	0.000
	2	-0.56	0.000
TG	0	-0.36	0.011
	1	-0.04	0.75
	2	-0.10	0.54
TC	0	-0.43	0.000
	1	-0.25	0.046
	2	-0.24	0.08
LDL	0	-0.61	0.000
	1	-0.47	0.000
	2	-0.53	0.000
HDL	0	0.48	0.000
	1	0.29	0.020
	2	0.39	0.004

25-hydroxy vitamin D as independent variable

Model 0 = crude model

Model 1 = after adjustment for before pregnancy BMI

Model 2= after adjustment for age, before pregnancy BMI, energy and macronutrients Consumption and physical activity

## DISCUSSION

In the current study, 97% of pregnant women had mild preeclampsia, with 83% reporting insufficient vitamin D status and 9.6% indicating a deficiency in vitamin D, and none were taking vitamin D supplements. Additionally, analyses conducted on the energy intake and macronutrient data of participants in this study showed that there was only a correlation between vitamin D levels and dietary fat intake, with no significant relationship to other macronutrients. Regression analyses also indicated that only serum vitamin D levels had a relationship with fat intake. Vitamin D is a fat-soluble vitamin that is found in limited food sources including eggs, liver, and fish in small amounts, and the consumption of these foods can play a crucial role in achieving adequate vitamin D levels in the body<sup>17</sup>.

One suitable strategy for increasing vitamin D intake and improving vitamin D status in the community is through educating about proper nutrition, utilizing food sources rich in vitamin D, and the fortification of food products. Considering that vitamin D is a fat-soluble vitamin and oils are essential food items consumed daily for cooking, this food category could be an appropriate choice for fortification, as in many countries around the world, oils are fortified with vitamin D<sup>18</sup>. Statistical analyses of the data regarding blood pressure and proteinuria from this study indicated that there is an inverse correlation between systolic and diastolic blood pressure and proteinuria with vitamin D status in overweight and obese pregnant women suffering from preeclampsia.

Razavand and colleagues conducted a study in 2018 aimed at examining the relationship between vitamin D status and blood pressure, preeclampsia, and body mass index in pregnant women. The results of this study indicated that serum vitamin D levels in pregnant women with preeclampsia were lower than those in healthy pregnant women; furthermore, lower vitamin D levels were associated with higher blood pressure in pregnant women suffering from preeclampsia<sup>19</sup>. Singla and colleagues investigated vitamin D status and its

relationship with preeclampsia in 74 pregnant women, and statistical analyses in this study showed that serum vitamin D levels in the control group were lower than in the study group ( $p=0.0001$ ). Additionally, systolic and diastolic blood pressure levels in the study group were found to be higher compared to the control group<sup>20</sup>. Moreover, Al-shaikh and colleagues conducted a descriptive study in 2016 to investigate the relationship between vitamin D status and pregnancy outcomes in mothers and newborns. A total of 1,000 pregnant women participated in this descriptive study. The results revealed that the prevalence of vitamin D deficiency in the first trimester of pregnancy was 82.8%. Pregnancy-related hypertension and preeclampsia were reported only in women who had vitamin D deficiency<sup>21</sup>.

Several mechanisms have been mentioned regarding the role of vitamin D in preventing the onset of preeclampsia; a reduction in vitamin D levels leads to inflammatory responses and an increase in oxidative stress in the body, which contributes to endothelial dysfunction of the blood vessels, resulting in elevated blood pressure and preeclampsia<sup>22, 23</sup>. Additionally, this vitamin affects the expression of genes involved in angiogenesis and trophoblast invasion, which may play a role in the pathophysiology of preeclampsia<sup>24</sup>. Deficiencies in the body's immune and vascular systems can lead to poor placental invasion, which results in the release of vasoconstrictor factors derived from the placenta and, consequently, leads to maternal hypertension and proteinuria<sup>25</sup>. Vitamin D receptors on the heart and blood vessels indicate that vitamin D has a protective effect on the heart and can influence the function of endothelial smooth muscle cells as well as control inflammation and regulate blood pressure through its impact on the renin-angiotensin-aldosterone system. Vitamin D is one of the strongest hormones that suppresses the renin-angiotensin system, thereby regulating blood pressure. Additionally, vitamin D can reduce the risk of preeclampsia through its influence on angiogenesis<sup>26</sup>. The present study reports an average body mass index of  $29.59 \pm 3.56$  kg/m<sup>2</sup> in the women

studied, and an average serum vitamin D level of  $49.63 \pm 15.06$  ng/ml. Statistical analyses also indicate a significant and inverse relationship, which remains significant even after adjusting for confounders of serum vitamin D levels. Bodnar and colleagues conducted a study in 2007 aimed at examining the relationship between the body mass index of pregnant mothers and the vitamin D status of mothers and infants. This study found an independent relationship between vitamin D status and body mass index after adjusting for potential confounders such as race, season of blood sampling, gestational age, physical activity, and multivitamin use. Furthermore, a comparison between underweight and obese women revealed that underweight pregnant women had lower serum levels of vitamin D during weeks 4 to 22 of pregnancy (56.5 nmol/L versus 62.7 nmol/L), and vitamin D deficiency was more prevalent (61% versus 36%)<sup>27</sup>.

Various reasons have been cited for the inverse relationship between body mass index and serum vitamin D levels. For instance, obese individuals, due to reduced social acceptance, may spend less time outdoors, leading to decreased sun exposure and subsequent vitamin D synthesis<sup>28</sup>. Additionally, fat tissue in the human body retains vitamin D metabolites produced through sunlight exposure or obtained from dietary sources, preventing their transport to the liver for hydroxylation<sup>29</sup>

Furthermore, a significant amount of the activity of the enzyme alpha-1-hydroxylase in the fat cells of obese individuals is directed towards the local utilization of vitamin D<sup>28, 29</sup>

For this reason, changes in the stores of 25-hydroxy vitamin D may be directly correlated with the amount of subcutaneous fat. Statistical analyses of the findings from the present study showed that serum vitamin D levels had an inverse correlation with fasting blood sugar, triglycerides, total cholesterol, and LDL-C in overweight and obese pregnant women, while showing a direct correlation with HDL-C levels. However, there was no significant relationship with triglycerides. Lithy and colleagues conducted a study aimed at investigating

the relationship between serum vitamin D levels and glycemic control in pregnant women. The results of this study indicated an inverse relationship between serum vitamin D levels with fasting blood sugar ( $r=-0.386$ ) and HbA1c ( $r=-0.492$ )<sup>30</sup>.

Mansouri and colleagues conducted a study in 2018 to examine the relationship between vitamin D status and metabolic syndrome in the Iranian adult population. The findings of this study revealed an inverse relationship between serum vitamin D levels and blood sugar (OR=0.40), abdominal obesity (OR=0.41), and blood pressure (OR=0.37), but no relationship was observed between vitamin D and lipid parameters<sup>31</sup>. The results of the study by Shakri et al., conducted to examine the relationship between vitamin D and biochemical parameters in pregnant mothers, showed that the average level of 25-hydroxyvitamin D in the mothers was 22.52 nanomoles per liter. 7.33% of the mothers had a vitamin D deficiency, 76.6% had insufficient vitamin D levels, and 15.9% were within the normal range. Additionally, there was an inverse relationship between the serum vitamin D level in mothers and fasting blood glucose; however, no correlation was observed between serum vitamin D levels and lipid parameters in these individuals<sup>29</sup>.

The mechanism by which vitamin D affects glycemic control is not only through the regulation of plasma calcium levels in the synthesis and secretion of insulin but also by improving the sensitivity of target cells (liver, skeletal muscle, and fat) to insulin. Moreover, vitamin D directly enhances and improves the function of  $\beta$ -cells while protecting them against harmful immune attacks, and it indirectly affects various immune cells, including inflammatory macrophages and different types of T-lymphocytes, all of which play a role in regulating local immune responses<sup>32</sup>.

Limitations of the study: One of the weaknesses of this study is that due to financial constraints, it was not possible to conduct the study with a larger sample size, and it was carried out as a cross-sectional analytical study. The absence of a control group made it impossible to

achieve a better and more comprehensive comparison. It is suggested that the levels of many substances present in the blood decrease during pregnancy, which can occur for various reasons, including dilution, and that normal values are generally not standardized. Therefore, there is a need to establish a standard normal range for vitamin D during pregnancy.

### **Conclusion**

There was an inverse relationship between serum 25-hydroxyvitamin D levels and systolic and diastolic blood pressure, proteinuria. Based on the findings of this study, it is recommended that maintaining a balanced level of vitamin D plays a crucial role in preventing hypereclampsia in pregnant women. Therefore, it is essential to obtain this vitamin through dietary intake, particularly from fat-containing foods due to the fat-soluble nature of this vitamin. It is important to note that global guidelines suggest a daily supplement of 1000 IU of vitamin D for pregnant mothers, which can be safer and help prevent excessive weight gain during pregnancy that may result from overconsumption. It is advisable to limit foods, especially those high in fats.

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## TEENAGE PREGNANCY IN RURAL ETHIOPIA : THE CASE OF JIMA ARJO DISTRICT, EAST WALLAGA, WESTERN ETHIOPIA

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### ABSTRACT

**BACKGROUND:** Teenage pregnancy is a significant public health problem in developing nations such as Ethiopia, leading to numerous associated financial and health consequences.

**Objective:** To determine the magnitude and associated factors of teenage pregnancy among teenagers visiting public health facilities in Jima Arjo district, East Wallaga, Western Ethiopia.

**METHODS:** A facility-based cross-sectional study was conducted among 421 teenage females in Jima Arjo District from February 15 to May 30, 2022. Data were collected using a standardized questionnaire, cleaned, and analyzed using Epidata version 3.1. The level of significance of association was determined at a p-value <0.05.

**RESULTS:** In this study, the magnitude of teenage pregnancy was 17.1%. Being married, attending secondary school, lack of awareness of family planning, not living with parents, and having a sister with a history of teenage pregnancy were significantly associated with teenage pregnancy.

**CONCLUSION AND RECOMMENDATION:** This study found that the magnitude of teenage pregnancy was high. Given the above associated factors, it is recommended that key stakeholders work on the prevention of early marriage, raise awareness of family planning, and encourage women's education.

**KEYWORDS:** magnitude, associated factors, teenage pregnancy, Jima Arjo, East Wallaga

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## INTRODUCTION

According to the World Health Organization (WHO), the terms “teenager” and “adolescent” are often used interchangeably. Pregnancy in a female between the ages of 10 and 19 is considered an “adolescent or teenage pregnancy.”<sup>1</sup> Around 1 in 6 individuals worldwide are between the ages of 10 and 19, with the majority of them living in sub-Saharan Africa and being vulnerable to teenage pregnancies.<sup>2,3</sup>

Teenage pregnancy has emerged as a significant public health issue, particularly in Africa,<sup>3</sup> where educational opportunities are scarce and poverty is pervasive.<sup>4</sup> In developing regions, approximately 2 million girls under the age of 15 and 21 million girls between the ages of 15 and 19 become pregnant each year.<sup>5</sup> In Africa and the East Africa sub-region, the prevalence of teen pregnancy was 18.8% and 21.5%, respectively.<sup>3</sup> In Ethiopia, the 2016 Ethiopia Demographic Health Survey indicated that 13% of women between the ages of 15 and 19 had already given birth.<sup>6</sup>

Teenage pregnancy is linked to high maternal and child morbidity and mortality, impacting the socio-economic development of a country.<sup>3,7, 8</sup> For this reason, various governmental and non-governmental organizations are working to prevent child marriage and thereby reduce teenage pregnancies.<sup>9</sup> This is emphasized in Sustainable Development Goals (SDG), targets 3.1 and 3.7.<sup>10</sup>

Teenage pregnancy in sub-Saharan Africa is a multifaceted issue with various underlying causes, such as poverty, gender-based violence, substance abuse, limited access to contraceptives, cultural beliefs, attitudes and behaviors of healthcare professionals, high levels of illiteracy, and insufficient sexual and reproductive health (SRH) education.<sup>4, 11, 12, 13, 14</sup>

While numerous national-level studies have been conducted on teenage pregnancy in Ethiopia, there has been a lack of specific research on teenage pregnancy in the Jima Arjo district of East Wallaga, Western Ethiopia. Therefore, this study aims to determine the prevalence of teenage pregnancy and

identify associated factors among teenage females who visit public health facilities in this area.

## **\*\*METHODS\*\***

### **\*\*Study area and setting\*\***

The study was conducted at public health facilities in the Jima Arjo district. Jima Arjo district is located in the East Wallaga zone, between the Nekemte town and Buno Bedele Zone. It is 378 km away from Addis Ababa and 48 km away from Nekemte town. The district has a total population of 127,312. The Arjo district has one primary hospital, six health centers, and 20 health posts. Additionally, there are 12 private health facilities. These health facilities provide various healthcare services to the community.

### **\*\*Study period\*\***

From February 15 to May 30, 2022

### **\*\*Study Design\*\***

A health facility-based cross-sectional study design was conducted.

### **\*\*Source population\*\***

All teenage females from 10 to 19 years old who visited public health facilities in the Jima Arjo district.

### **\*\*Study population\*\***

Teenage females from 10 to 19 years old who visited Jima Arjo public health facilities for different health services during the study period.

### **\*\*Inclusion and exclusion criteria\*\***

Study participants aged 10 to 19, residing in the area for over six months, were included. Critically ill individuals during data collection and those who were unwilling to participate in the study were excluded.

### **\*\*Sample size determination\*\***

The sample size was calculated using a single population proportion with the following assumptions: 95% confidence level, marginal error

of 4%, and prevalence of teenage pregnancy (35.4%) from the Farta Woreda study.<sup>15</sup> After adding 10% for possible non-response, a total sample size of 421 was obtained.

#### **\*\*Study variables\*\***

- **\*\*Dependent variable:\*\*** Teenage pregnancy  
- **\*\*Independent variables:\*\*** Age, religion, residency, marital status, ethnicity, educational status, income, occupation, sexual education, family planning, age at marriage, age at first sexual intercourse, history of teenage pregnancy, parental communication on reproductive health.

#### **\*\*Sampling procedures\*\***

The district has one primary hospital and six health centers. The total of 421 samples was distributed among these 7 health facilities proportionately to their estimated monthly patient volume using the proportion-to-population-size formula. After proportionally allocating the required sample size to each health facility, study participants were selected by a systematic random sampling method. The sample interval (k) for the study was determined by dividing the total number of teenagers served (N) in the month before data collection by the sample size (n). Accordingly, every third participant was interviewed during exit time in each health facility.

#### **\*\*Data collection tools and procedure\*\***

Data were collected by 7 data collectors using interviewer-administered questionnaires, which were adapted from reviewed literature on teenage pregnancy.<sup>15-19</sup> The study tool was validated. The questionnaire was first created in English and then translated into Afan Oromo by language experts. To ensure consistency of meaning, the Afan Oromo version was then translated back into English.

#### **\*\*Data analysis\*\***

The data were entered into Epi-data window version 3.1 and then exported to SPSS Windows version 24 for further analysis. Both bivariable and multivariable logistic regression analyses were

conducted. We checked for violations of regression model assumptions by inspecting multicollinearity and variance inflation factors. Model goodness-of-fit was tested using the Hosmer-Lemeshow test. We considered a p-value of <0.05 and a 95% confidence level as indicative of statistical significance.

#### **\*\*Data quality assurance\*\***

Data quality was ensured by pre-testing the questionnaire on 21 (5%) teenagers, who were later excluded from the actual study. Training was provided to data collectors and supervisors, and overall supervision was carried out by the investigators.

## **RESULTS**

### **Socio-demographic characteristics of the study participants**

Out of four hundred twenty-one teenagers, 416 were included in the study, making the response rate 98.8%. The average age of the study participants was 16.1 years. Three hundred and five (73.3%) participants lived in rural areas. The majority of the participants were from the Oromo ethnic group (87.5%), protestant Christians (50.5%), and attended primary-level education (50.2%). Two hundred ninety-nine (71.9%) participants were students, and 94 (22.2%) were housewives. One hundred forty-two (34.1%) of participants were ever married, with the mean age at first marriage being 17.1 years (Table 1).

**Table 1: Socio-demographic characteristics of study participants visiting health facilities in Jima Arjo district, East wallaga, western Ethiopia, 2022**

Socio demographic variables		Frequency	Percent
Age in years(mean age=16.1)	10 to 14	103	24.8
	15 to 17	131	31.5
	18 to 19	182	43.8
Residence	Urban	111	26.7
	Rural	305	73.3
Ethnicity	Oromo	364	87.5
	Amhara	52	12.5
Religion	Orthodox	158	38
	Protestant	210	50.5
	Muslim	48	11.5
Educational status	Cannot read and write	21	5.0
	Can read and write	28	6.7
	Primary education	209	50.2
	Secondary education	158	38.0
	Above secondary	0	0.0
Marital status	Single	274	65.9
	Married	142	34.1
Age at marriage(mean age=17.1) (n=142)	14 to 15	21	14.8
	16 to 17	54	38.0
	18 to 19	67	47.2
Occupational status	Student	299	71.9
	House wife	94	22.6
	Others*	23	5.5
Marital status of the parents	Live together	335	96.8
	Not live together	11	3.2

\*Others(self- employer, house maid, merchant)

### **Reproductive health characteristics, teenage pregnancy and associated factors**

A total of 360 individuals (86.5%) said that they had no discussion with their parents about reproductive health issues. Seventy-six percent of participants (close to three out of four) did not receive sexual education in school.Regarding the knowledge of study participants on family planning methods, 203 (48.8%) of them knew about family planning methods. All of them, 203 (100%), knew where to find them(Table 2).

**Table 2: Reproductive health characteristics of study participants visiting health facilities in Jima Arjo district, East wallaga, western Ethiopia, 2022**

Variables		Frequency	Percent
Communication with parents on reproductive health issues	No	360	86.5
	Yes	56	13.5
Sexual education at school	No	256	74.2
	Yes	89	25.8
Sexually active study participant	No	266	63.2
	Yes	155	36.8
Age at first sexual intercourse (in years)(n=155)	14 to 15	27	17.4
	16 to 17	70	45.2
	18 to 19	58	37.4
Knowledge about Family planning (n=416)	No	213	51.2
	Yes	203	48.8
Knowledge about where to get family planning methods (n=203)	No	0	0.0
	Yes	203	100
Family planning uptake (n=203)	No	97	47.8
	Yes	106	52.2
History of teenage pregnancy	No	345	82.9
	Yes	71	17.1
Age at first pregnancy(n=71)	14 to 16	31	43.7
	17 to 19	40	56.3
History of participant's sister with teenage pregnancy	No	370	88.9
	Yes	46	11.1

Out of 142 ever-married participants, 52.8% had married before the age of 18. Among study participants, 71 had their first pregnancy in the age range of 14 to 19 years, making the magnitude of teenage pregnancy 17.1%. Forty-six (11.1%) of the participant's sisters had a history of teenage pregnancy. Forty-six (11.1%) of the participant's sisters had a history of teenage pregnancy (Table 2). Using logistic regression analysis, a number of risk factors emerged as highly significant predictors of adolescent pregnancy when the coefficient was expressed as an adjusted OR in relation to the referent group (Table 3).

**Table 3: Factors associated with teenage pregnancy among study participants visiting health facilities in Jima Arjo district, East wallaga, western Ethiopia, 2022**

Variables	Teenage pregnancy		OR and 95%CI		P. value
	No N (%)	Yes N (%)	COR	AOR	
<b>Age</b>					
10 to 14	101(29.3)	2(2.8)	1	1	
15 to 17	107(31.0)	24(33.8)	11.33(2.61-49.16)	1.45(0.2-10.9)	0.721
18 to 19	137(39.7)	45(63.8)	16.58(3.93-69.97)	3.9(0.5-31.8)	0.202
<b>Residence</b>					
Urban	108(31.3)	3(4.2)	1	1	
Rural	237(68.7)	68(95.8)	10.33(3.18-33.56)	2.99(0.66-13.65)	0.156
<b>Educational level</b>					
Cannot read and write	7(2.0)	14(19.7)	1	1	
Can read and write	12(3.5)	16(22.5)	0.67(0.21-2.16)	1.15(0.2-7.4)	0.882
Primary	178(51.6)	31(43.7)	0.08(0.03-0.23)	0.54(0.12-2.52)	0.432
Secondary	148(42.9)	10(14.1)	0.03(0.01-0.10)	0.18(0.031-0.98)	0.049*
<b>Marital status</b>					
Single	267(77.4)	7(9.9)	1	1	
Ever married	78(22.6)	64(90.1)	31.29(13.78-71.06)	12.4(2.58-59.3)	0.002*
<b>Occupational status</b>					
Student	277(80.3)	22(31.0)	1	1	
House wife	47(13.6)	47(66.2)	12.6(6.95-22.78)	0.46(0.15-1.46)	0.188
Others	21(6.1)	2(2.8)	1.19(0.26-5.45)	0.37(0.05-2.6)	0.318
<b>Knowledge about family planning</b>					
No	171(49.6)	42(59.2)	1.47(0.878-2.474)	10.3(3.3-32.0)	0.000*
Yes	174(50.4)	29(40.8)	1	1	
<b>Marital status of parents</b>					
Live together	335(96.8)		62(87.3)	1	1
Did not live together	11(3.2)	9(12.7)	4.4(1.75-11.0)	5.6(1.04-29.9)	0.045*
<b>History of participant's sister with teenage pregnancy</b>					
No	329(97.7)	41(57.7)	1	1	
Yes	16(4.6)	30(42.3)	15.0(7.56-29.94)	6.4(2.0-20.4)	0.002*

\* significant

The results of this study revealed that married participants had a 12.4 times [AOR = 12.4, 95% CI: 2.58-59.3] higher risk of teenage pregnancies than unmarried respondents. Education level is the other factor that has a substantial correlation with teenage pregnancy. Participants who attended secondary education were 0.18 times less likely than participants who could not read or write to have a teenage pregnancy [AOR = 0.18, 95% CI: 0.03-0.98].

Teenage pregnancy was found to be significantly associated with family planning knowledge. It was discovered that participants who were unaware of family planning had a 10.3 higher

likelihood of becoming pregnant as teenagers than those who were aware of it [AOR = 10.3, 95% CI: 3.3-32.0]. Another element that revealed a significant connection was the marital status of the parents. Participants with separate households were 5.6 times [AOR = 5.6, 95% CI: 1.0-29.9] more likely to become pregnant as teenagers than those whose parents shared a home.

Having a sister with a history of teenage pregnancy has shown a significant association with teenage pregnancy. Participants whose sisters have a history of teenage pregnancies were 6.4 times more likely to have a teenage pregnancy [AOR = 6.4, 95% CI: 2.0-20.4] compared to their counterparts.

## DISCUSSION

**\*\*This study\*\*** investigated the magnitude of teenage pregnancy and its associated factors in the Jima Arjo district, West Oromia. The prevalence of teenage pregnancy in this study was 17.1%. Being married, having awareness of contraceptives, living with a single parent, better educational status, and having a sister with a history of teenage pregnancy were all found to be associated with teenage pregnancy.

The rate of teenage pregnancy varies widely across the world.<sup>3</sup> This variation may be due to differences in the socio-demographic, cultural, sexual, and reproductive health factors of teenagers. In the current study, the prevalence of teenage pregnancy is comparable to a study conducted in rural Ethiopia (16.3%).<sup>20</sup> This similarity could be attributed to common socio-demographic factors, such as rural residence, as the majority of participants in both studies were from rural areas.<sup>20</sup> The rate of teenage pregnancy reported in the current study is higher than the 13% reported in the 2016 National EDHS report.<sup>6</sup> This difference could be due to the fact that the EDHS study included all regions, both urban and rural, and used a larger sample size than the current study, which was limited to one rural district in the western Oromia Region. Additionally, the current finding is lower than the teen pregnancy rates reported in other studies conducted in different regions of Ethiopia, such as Assosa (20.4%),<sup>19</sup> Farta Wereda (North West Ethiopia) (25.4%),<sup>15</sup> Wogedi (North East Ethiopia) (28.5%),<sup>17</sup> and Harar (East Ethiopia) (30.2%).<sup>18</sup> This variation in rates could be attributed to differences in socio-demographic factors among the study areas.

Studies have found a positive link between marital status and teenage pregnancy. This aligns with similar research conducted in the Tigray region,<sup>24</sup> Harar,<sup>18</sup> and Nigeria,<sup>22</sup> which revealed that married study participants were more likely to experience teenage pregnancy compared to single participants. Marriage might lead teenagers to cut short their education, miss out on future economic opportunities, and diminish a woman's decision-making power. It also sparks greater interest and

concern in teenagers and their families about having a baby.<sup>21,23</sup>

In the current study, better educational status and teenage pregnancy showed a negative association. Participants who attended secondary schools were less likely to become pregnant as teenagers than participants who could not read or write. This finding is in line with a study conducted in East Africa<sup>25</sup> and in rural Ethiopia,<sup>20</sup> where adolescent females who attended secondary school or higher experienced less teenage pregnancy than participants who had only primary education. This may be explained by the fact that education increases autonomy and decision-making power, leading to economic independence, which in turn may result in delaying marriage and reducing fertility.

Knowledge about family planning was found to have a significant association with teenage pregnancy. This finding is similar to that of the Farta Wereda<sup>15</sup> and Wogedi studies.<sup>17</sup> This could be attributed to the fact that knowledge and proper use of contraception can delay pregnancy until desired.

Parental marital status was another factor that showed a significant association. Participants whose families did not live together were more likely to experience teenage pregnancy compared to those whose parents lived together. This finding is consistent with those conducted in Wogedi<sup>17</sup> and Harar.<sup>18</sup> This is attributed to the reduced level of parental control and communication about sexual and reproductive issues among divorced parents compared to married ones. This leads to an increase in early sexual debut and risky sexual behaviors, which in turn exposes teenagers to the risks of teenage pregnancy.

The presence of a sister with a history of teenage pregnancy is significantly linked to teenage pregnancy. Participants with a sister who had been pregnant as a teenager were more likely to experience teenage pregnancy themselves compared to those without a sister who had a history of teenage pregnancy. This finding is similar to the study conducted in Harar.<sup>18</sup> This similarity could



be due to the influence of family members on an individual's attitudes and values regarding teenage pregnancy. Families share social risks that can impact the likelihood of teenage pregnancy. Based on social learning and modeling theories, younger sisters are more likely to become pregnant if their older sisters were teenage mothers.

In this study, it is acknowledged that social desirability bias may impact responses to outcome and independent variable measurements. To mitigate this bias, interviews were exclusively conducted by experienced female data collectors in private settings, and culturally sensitive sexual terminology was employed.

## CONCLUSIONS AND RECOMMENDATIONS\*\*

The magnitude of teenage pregnancy in this study was high. Key stakeholders should work on the prevention of early marriage, raise awareness of family planning, and encourage women's education in the study area.

### Abbreviations/Acronyms

**AIDS:** Acquired Immunodeficiency Syndrome;  
**ART:** Anti-retroviral therapy;  
**EDHS:** Ethiopia Demographic and Health Survey ;  
**EPI:** Expanded Programme of Immunization;  
**HIV:** Human Immunodeficiency Virus;  
**OPD:** Out patient department;  
**SRH:** sexual and reproductive health;  
**SDG:** Sustainable Development Goals;  
**TB:** tuberculosis;  
**WHO:** World Health Organization,

## DECLARATIONS

### Declaration of conflicting interests

The authors have stated that there are no potential conflicts of interest related to the research, authorship, and/or publication of this article.

### Funding

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### Informed consent

Written informed consent was obtained from each

eligible study participant or their legally authorized representative, as approved by IRB number/WU/RD/547/2014.

### Ethical approval

Ethical clearance was obtained from the Research Ethics Committee of the Institute of Health Sciences at Wollega University with reference number /WU/RD/547/2014. Then, a support letter was written to the study zones for the necessary support within different districts and facilities in the zone. No identifying information was included in the questionnaire to ensure privacy and confidentiality. All methods were conducted in accordance with the relevant guidelines and regulations.

### Authors' contributions

**ZM** and **TT** were involved in Conceptualization, Data curation, Funding acquisition, Investigation, Methodology, Project administration, Supervision, Writing - original draft, and Writing - review & editing

**ZM**, **TT**, **FG**, **RO** and **GM** were involved in Conceptualization, Formal analysis, Investigation, Methodology, Resources, Software, Writing - original draft, and Writing - review & editing

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# UPTAKE OF IMMEDIATE POSTPARTUM INTRAUTERINE DEVICE AND ASSOCIATED FACTORS AMONG MOTHERS WHO DELIVERED AT TWO PUBLIC HOSPITALS IN ADDIS ABABA, ETHIOPIA

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## ABSTRACT

**BACKGROUND:** Most women do not desire pregnancy immediately after delivery and are highly motivated to accept family planning methods. The post-partum intrauterine device is one of the family planning methods that can address this need. However, intrauterine device use has been very low in low- and middle-income countries.

**OBJECTIVE:** To assess the utilization and factors associated with the uptake of postpartum intrauterine devices among mothers who delivered at two public hospitals in Addis Ababa, Ethiopia.

**METHOD:** This was a hospital-based cross-sectional study conducted using a standardized questionnaire. A simple random sampling method was used to select study participants, and 412 eligible participants were included. SPSS version 25 statistical software was used for data analysis. Descriptive statistics were used to present data, and regression analyses were employed to determine the strength of association between postpartum intrauterine device uptake and explanatory variables. A p-value of < 0.05 was used as a cutoff point for statistical significance.

**RESULT:** In this study, the uptake of postpartum intrauterine contraceptive devices was 11% (95% CI = 8.0, 14). The barriers to the non-uptake of postpartum intrauterine devices were fear and concern (61.6%), religious values regarding family planning (16.9%), husband and relative opinions (7%), cultural norms (5%), and health provider-related factors (5%). Increasing parity and assisted vaginal delivery were significantly associated with increased odds of postpartum intrauterine device uptake ( $p < 0.05$ ). The odds of intrauterine device utilization for mothers with a previous number of deliveries of  $\geq 3$  were 35 times higher (AOR = 34.8, 95% CI = 7.33, 165.4) than those with no previous delivery. In addition, assisted vaginal delivery had 11 times increased odds of intrauterine device uptake compared to spontaneous vaginal delivery (AOR = 11.06, 95% CI = 3.26, 37.5).

**CONCLUSION AND RECOMMENDATIONS:** The uptake of postpartum intrauterine devices was low (11%). The main reasons for the low uptake were fear and concern due to myths and misconceptions, religious values regarding family planning, husband and relative opinions, cultural norms, and health provider-related factors. Identifying and addressing reasons for gaps in awareness and clearing public misconceptions and fears, as well as conducting further large-scale studies, are recommended.

**KEYWORDS:** PPIUD, Contraception, postpartum, barriers, Ethiopia.

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## INTRODUCTION

Family planning is defined as a way to enable couples to anticipate and attain their desired number of children and the spacing and timing of their births through the use of contraceptive methods and the treatment of infertility.<sup>1</sup> Globally, in 2021, it was estimated that 164 million women of reproductive age, mostly in low-income countries, want to avoid pregnancy but are not using modern contraceptives.<sup>2,3</sup> Postpartum family planning (PPFP), the prevention of unintended pregnancy and closely spaced pregnancies during the first 12 months following childbirth, is recognized as one of the key life-saving interventions for mothers and their children.<sup>4</sup> Short birth intervals are associated with adverse pregnancy outcomes, such as induced abortions, miscarriages, preterm births, stillbirths, and neonatal and child mortalities.<sup>5,6</sup>

Research has demonstrated that long-acting methods, such as intrauterine devices (IUDs), are a cost-effective and sustainable way of reducing unmet need and unintended pregnancy in low-resource settings.<sup>7</sup> Most women do not desire a pregnancy immediately after delivery but are unclear about contraceptive usage in the postpartum period. This results in unplanned and undesired pregnancies, which in turn increases induced abortion rates and consequently maternal morbidity and mortality.<sup>8</sup>

The postpartum intrauterine device (PPIUD) is one of the PPFP methods that can address this gap and improve maternal and newborn health by preventing obstetric complications, such as maternal and newborn mortality and other health-related complications associated with closely spaced pregnancies.<sup>9</sup> The immediate postpartum period is an ideal time for PPIUD insertion, as women are highly motivated to accept family planning methods.<sup>10,11</sup> The immediate postpartum period presents a great opportunity for PPIUD service providers to introduce the method, especially in settings where women have difficulty meeting with healthcare providers due to geographical barriers.<sup>12</sup> Nowadays, more women are being encouraged to deliver in facilities, providing increased

opportunities for the immediate postpartum insertion of an intrauterine device (IUD).

PPIUD use is particularly important in sub-Saharan African countries because there is a large unmet need for long-acting and permanent methods during the postpartum period. Moreover, in developing countries, women who go back home after delivery do not return for even a routine postpartum check-up, let alone for contraception. Thus, immediate postpartum contraceptive services need to be emphasized to ensure that women leave the hospital with effective contraception in place.<sup>8,13</sup>

Despite the benefits of PPIUDs, such as preventing unwanted pregnancies due to early resumption of sexual activities and unpredictable ovulation after delivery, their uptake is low in many settings. According to a study conducted by Pradhan et al., only 2% of contraceptive users opted for PPIUDs.<sup>14</sup> This is due to various barriers to its utilization. According to a study report from Rwanda, barriers to immediate PPIUD use include fear of side effects (10%), inadequate knowledge of the method (12%), and partner disapproval (10%) for the method.<sup>15</sup> According to the Ethiopia Demographic Health Survey 2019 report, IUD use has been minimal within the contraceptive method mix. It showed that, from 41% of modern family planning (FP) method choices, the use of IUDs contributed only 2%. The report also implied that there was almost no focus on immediate PPIUD use.<sup>16</sup> A study conducted in Addis Ababa revealed that a housewife occupation and the necessity of partner approval had negative influences, whereas spousal discussion about PPIUDs, counseling during pregnancy, and having good knowledge had positive influences on its utilization.<sup>17</sup>

The PPIUD uptake in Ethiopia is not well documented, and there is little information on the factors that hinder its uptake. Studies on the use of immediate PPIUDs are limited in Ethiopia and other African countries. The main objective of this study was to assess the utilization and factors associated with the uptake of immediate PPIUDs among mothers who delivered at the study hospitals.

Here's the edited text for the METHODS section, including the Results introduction, with attention to grammar, punctuation, spelling, and citation accuracy:

## **METHODS**

**Study Design:** This is a cross-sectional descriptive study. It was conducted at Tikur Anbassa Specialized Hospital (TASH) and Gandhi Memorial Hospital (GMH) in Addis Ababa, Ethiopia, from December 2021 to March 2022. Women who delivered at the hospitals during the study period and were eligible for the PPIUD were included in the study. Those who refused to participate were excluded.

**Sampling:** A single population proportion formula was used to calculate the sample size. Considering the absence of previous data in Ethiopia, an assumption of 50% ( $p = 0.5$  to achieve maximum variability) regarding barriers to the uptake of immediate PPIUD and the desired confidence level and precision of 95% and  $\pm 5\%$ , respectively, were used to calculate the sample size. The calculated sample size, considering a 10% non-response rate, was 422.

**Data Collection Tool and Procedure:** The data collection tool was adapted from the literature and modified based on contextual situations. The tool was pre-tested on 5% of the sample size of a similar study population prior to data collection to ensure consistency and to modify it accordingly if necessary. The tool included socio-demographic data (age, marital status, religion, occupation, family income, and level of education), obstetric variables (parity, antenatal care (ANC) follow-up, gestational age of the pregnancy, and number of children), and awareness of family planning (FP)/PPIUD. It also contained questions on potential barriers to PPIUD uptake, such as fear and concern, husband and relative opinions, cultural norms, and health provider-related factors.

Data were collected by trained health providers and supervised by the principal investigator. Women who fulfilled the inclusion criteria were included in the study. Data were then collected by interviewing

eligible participants and reviewing their medical records until the sample size was fulfilled. The collected data were reviewed and checked for completeness and consistency by the principal investigator.

**Data Analysis:** The collected data were coded, cleaned, and analyzed using SPSS version 25 statistical software. The proportion of barriers to the uptake of PPIUD was computed using descriptive statistics. A stepwise bivariate and multivariable logistic regression was then conducted to explore the presence and strength of associations between the independent variables and the uptake of PPIUD. Factors that had a significance level of  $\leq 0.2$  in the bivariate logistic regression analysis were considered in the multivariable logistic regression analysis. The presence and degree of association between the outcome and independent variables were assessed using odds ratios with 95% confidence intervals (CIs), and a  $p$ -value  $< 0.05$  was set for significant statistical associations.

### **Operational Definitions:**

**PPIUD:** A long-acting reversible contraceptive method inserted immediately into the uterine cavity following the delivery of the placenta or up to 48 hours after giving birth.<sup>18</sup>

**PPIUD Uptake:** The actual usage of an IUD during the first 48 hours after birth and before discharge to home following any mode of delivery.

## **Results**

### **Socio-Demographic Characteristics:**

In this study, 412 eligible participants were included. Forty-five percent (186/412) of the study participants were in the age group of 25-29 years, with a mean age of 26.9 (SD  $\pm 4.3$ ). The majority of the participants were from Addis Ababa and were married, accounting for 88.1% (363/412) and 92.5% (381/412), respectively. Fifty-nine percent of the participants were Orthodox in religion, 43% (177/412) had a primary education level, and 46.8% (193/412) were housewives. (Table 1)



**Table 1: Socio-demographic characteristics of study participants who delivered at two public hospitals, December 2021 to March 2022 (n = 412).**

Variable	Frequency	Percent (%)
<b>Age of the study participants</b>		
≤24	122	29.6
25-29	186	45.1
30-34	80	19.4
≥35	24	5.8
<b>Residence</b>		
Addis Ababa	363	88.1
Outside of Addis Ababa	49	11.9
<b>Marital status</b>		
Single	8	1.9
Married	381	92.5
Divorced	18	4.4
Widowed	5	1.2
<b>Religion status</b>		
Protestant	40	9.7
Muslim	128	31.1
Orthodox	244	59.2
<b>Education status</b>		
Illiterate	28	6.8
Primary	177	43.0
Secondary	85	20.6
Collage/university	122	29.6
<b>Occupation status</b>		
Unemployed	44	10.7
Housewife	193	46.8
Self-employed	94	22.8
Government employee	53	12.9
Daily labor	28	6.8

## Reproductive characteristics

ANC status was un-booked in 2.7% (11/412) of the study participants. Majority had spontaneous vaginal delivery (SVD), 1-3 deliveries and 1-3 children with proportions of 71.1% (293/412), 79.1% (326/412) and 60.9% (251/412) respectively. Eighty three percent of the participants wished to have more children. Majority of those who plan more delivery, 66.9% (228/341), wish to have their next pregnancy in 2-5 years time. Birth outcome of the last delivery was alive in 97.1%. (Table 2)

**Table 2. Reproductive characteristics and wishes of study participants who delivered at two public Hospitals, Dec. 2021 to March 2022. (=412)**

Variable	Frequency	Percent (%)
<b>ANC follow-up status</b>		
Booked	401	97.3
Un-booked	11	2.7
<b>Mode of delivery</b>		
SVD	293	71.1
Assisted delivery	23	5.6
Cesarean section	96	23.3
<b>Number of previous deliveries</b>		
None	70	17
1-3	326	79.1
>3	16	3.9
<b>Number of alive children</b>		
None	147	35.7
1-3	251	60.9
>3	14	3.4
<b>Wish to have more children</b>		
Yes	341	82.8
No	71	17.2
<b>If yes, when do you wish to have another pregnancy</b>		
< 2 years	29	8.5
2-5years	228	66.9
> 5 years	71	20.8
Not decided	13	3.8
<b>Outcome of last delivery</b>		
Alive	400	97.1
Dead	12	2.9

## Study participants' awareness and utilization of modern family planning methods

Injectable and implant contraceptives were known by most of the study participants known by 76.7% (316/412) and 72.6% (299/412) participants, respectively. IUD was the fourth known method mentioned by 66% (272/412) of the participants. Majority, 82.3% (339/412), reported to have ever used modern contraceptive methods. Injectable and implants were the methods ever used reported by 43.5% (148/339) and 40.3% (137/339) of participants, respectively. IUDs were ever utilized before the last delivery by only 7.3% (30/339).



**Table 3. Awareness and utilization of modern family planning methods by participants among mothers who delivered at two public Hospitals, Dec. 2021 to March 2022.**

Variable	Frequency	Percent (%)
<b>List of modern contraceptives known by participants</b>		
Injectable	316	76.7
Implant	299	72.6
Pills	296	71.8
Intrauterine device	272	66.0
Condom	176	42.7
<b>History of ever used any modern family planning method</b>		
Yes	339	82.3
No	73	17.7
<b>Types of family planning ever used before last delivery</b>		
Injectable	148	43.5
Implant	137	40.3
Pills	71	17.2
IUD	30	7.3
Condom	11	3.2

### Uptake and barriers of immediate PPIUD

Only 11% (45/412) of the participants had immediate PPIUD inserted. Various reasons were stated for not opting for PPIUD. Fear and concerns of myths and misconceptions were the commonest reason for not opting for PPIUD stated by 61.6% (226/367) of participants. Religion was the second commonest reason stated by 18% (62/367) participants. Health provider related factor was reported by 5% (17/367) of the participants. (Figure 1)

### Factors associated with PPIUD use:

Age of participants, mode of deliveries, number of previous deliveries, participants wish to have more children, and awareness about IUD were variables associated with PPIUD use in the bivariate logistic regression with P-value of 0.2. Hence these variables were included in multivariate logistic regression model.

The most significant association was seen between parity and PPIUD uptake. As parity increased the prevalence of PPIUD utilization increased. The odds of PPIUD utilization for mothers with previous number of deliveries of  $\geq 3$  and 1-2 were 35 (AOR=34.8, 95% CI=7.33, 165.4) and 4 (AOR=4.2, 95%CI=1.47, 12.07) times higher than those with no previous delivery. In addition, assisted vaginal delivery had 11 (AOR=11.06, 95% CI=3.26, 37.5) times increased odds of PPIUD uptake than SVD. On the other hand, participants who wish to have pting for PPIUD uptake but the association was lost on multivariate analysis. (Table 4)

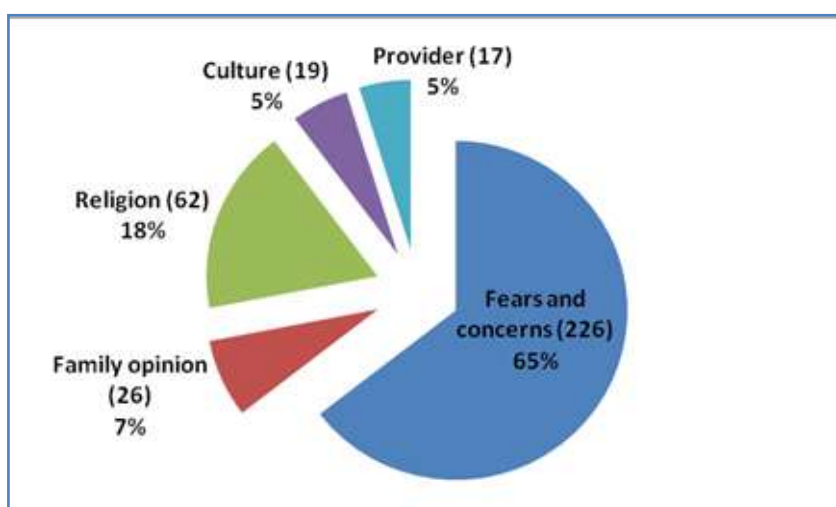


Figure 1. Reasons for not using post-partum intrauterine device among mothers who delivered at two public Hospitals, Dec. 2021 to March 2022.

Table 4. The logistic regression analysis of independent variable and PPIUD uptake among the study participants who delivered at two public Hospitals, Dec. 2021 to March 2022.

Variable	PPIUD uptake		p-value	COR (95%)	P-value	AOR (95%CI)
	Yes	No				
<b>Age of the study participants</b>						
≤24	8	114	1		1	
25-29	25	161	0.061	2.2(0.96, 5.08)	0.052	2.64 (0.99, 7.04)
30-34	11	69	0.093	2.3(0.87, 5.92)	0.347	1.7(0.56, 5.33)
≥35	1	23	0.659	0.62(0.07, 5.19)	0.617	0.56(0.06, 5.36)
<b>Mode of delivery</b>						
Spontaneous vaginal delivery	26	267	1		1	
Assisted delivery	7	16	0.003	4.5(1.69, 11.91)	0.000	11.06(3.26, 37.5)
Cesarean section	12	84	0.301	1.47(0.71, 3.03)	0.264	1.56(0.74, 3.42)
<b>Number of previous deliveries</b>						
None	6	141	1		1	
1-2	32	219	0.007	3.4(1.40, 8.42)	0.007	4.22(1.47, 12.07)
≥3	7	7	0.000	3.5(2.22, 8.72)	0.000	34.8(7.33, 165.4)
<b>Participants wish to have more children</b>						
Yes	33	313	1		1	
No	12	54	0.043	2.1(1.02, 4.33)	0.704	1.18 (0.50, 2.79)
<b>Knows Intra Uterine Contraceptive Device</b>						
Yes	38	234	1		1	
No	7	133	0.008	0.32(0.14, 0.75)	0.85	0.45 (0.19, 1.11)

## DISCUSSION

In this study, the uptake of PPIUD was 11% (95% CI = 8.0, 14). This finding is within the range of prior reports, which ranged from 2% to 46%<sup>14,19</sup>. It is lower than a report from a systematic review and meta-analysis of twelve full-article studies conducted in Ethiopia, which revealed a pooled prevalence of PPIUD use of 21.63%<sup>20</sup>. Our finding was higher than only 3 out of the 12 reports included in the systematic review. It is also much lower than the study conducted at Muhima Rwanda Hospital (28%) and a recent study done in Addis Ababa (26.6%)<sup>15, 17</sup>. This difference may be due to the socio-demographic differences among the study participants, variations in health models, and family planning practices in the study areas.

However, this finding is higher than reports from Tigray (9.4%), Debretabor (3.3%), and Uganda (9.6%)<sup>6, 21, 22</sup>. It is also higher than the Ethiopia Mini Demographic and Health Survey (2019 EMDHS), which reported a national IUD

utilization prevalence of 2%<sup>16</sup>. The difference with the EMDHS report is attributed to the fact that the EDHS included all forms of IUD use and not specifically just PPIUD, which have different denominators. This indicates that there is better PPIUD uptake during the immediate postpartum period compared to the interval period. The low uptake of PPIUD use calls for more action to increase this uptake by leveraging the opportunities that the immediate postpartum period provides to reach the levels achieved by others. This can be accomplished by identifying and tackling context-specific barriers.

The major reason for not utilizing PPIUD identified in the current study was fears and concerns about IUD use, as reported by 61.5% of the participants. This finding was supported by studies conducted in rural settings in Ghana and at Debre Tabor General Hospital<sup>21, 23</sup>. This may be due to the quality of counseling provided to the participants, which in turn may reflect providers' attitudes toward PPIUD

and the timing of counseling for PPIUD use. These have been long-standing obstacles to IUD uptake in general, necessitating further investigation to identify and address the exact sources of these fears and concerns.

The number of children has been identified as an important individual characteristic influencing women's reproductive health behaviors, including uptake of immediate postpartum family planning. Parity was associated with the uptake of PPIUD; women with higher parity were more likely to use PPIUD than those with lower parity. This simply reflects that women with high parity require long-term contraceptives for spacing. Additionally, multiparous women are more likely to repeatedly meet health service providers and obtain more information regarding family planning methods, which helps alleviate their concerns and misconceptions. These findings are consistent with reports from many prior studies that reported a higher acceptance rate for PPIUD among multiparous women<sup>11, 15, 21, 24-27</sup>.

The mode of delivery also contributed to the uptake of immediate PPIUD insertion. In this study, women who underwent operative delivery were more likely to use PPIUD compared to those with spontaneous vaginal delivery (SVD). This could be related to the level of health care providers conducting operative deliveries. Operative deliveries in the study hospitals are performed by more experienced and senior clinicians, which may lead to better quality of counseling and increased confidence in inserting PPIUD.

Awareness about IUD was not associated with the uptake of immediate PPIUD in the present study. This may be due to inadequate knowledge that did not change attitudes enough to break down barriers such as fear, misconceptions, and cultural norms regarding PPIUD. This finding is contrary to study results from Gondar Hospital in Northwest Ethiopia<sup>24</sup>. A limitation of the present study is that it was an institutional-based study conducted in Addis Ababa; hence, the findings may not fully reflect the actual situation at the country level.

## Conclusion

The findings indicate that the uptake of immediate PPIUD is significantly low (11%). The main barriers identified for the non-uptake of PPIUD were fears and concerns stemming from myths and misconceptions, religious values regarding family planning, opinions of husbands and relatives, cultural norms, and negative attitudes from staff. The determinant factors affecting the uptake of PPIUD were parity and mode of delivery. The low uptake of PPIUD calls for more action to leverage the opportunities presented by the immediate postpartum period. Identifying and addressing the reasons for gaps in knowledge regarding PPIUD, as well as clearing public misconceptions and fears, are recommended for further large-scale studies. Wider public education on PPIUD use could be one intervention to improve uptake.

### List of abbreviations:

**ANC:** Antenatal care,

**EDHS:** Ethiopia Demographic and Health Survey,

**FP:** Family Planning,

**GMH:** Gandhi Memorial Hospital,

**IUD:** Intrauterine Device,

**PPIUD:** Post Partum Intrauterine Device,

**PPFP:** Postpartum family planning,

**SVD:** Spontaneous Vaginal Delivery,

**TASH:** Tikur Anbassa Specialized Hospital.

### DECLARATIONS:

#### Ethics approval and consent to participate:

Ethical clearance was obtained from the Research and Publication Committee (RPC) of the Department of Gynecology and Obstetrics, College of Health Sciences, Addis Ababa University. Permission was also obtained from the study facilities to collect data. Participation in the study was completely voluntary and informed consent was acquired from every participant before participation. All the information obtained from the medical record was held with confidentiality and used only for the intended purpose.

#### Competing interests:

The authors declare that they have no competing interests.

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# A RARE CASE REPORT OF OVOTESTICULAR DISORDER OF SEXUAL DIFFERENTIATION WITH LATE PRESENTATION

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## ABSTRACT

### BACKGROUND

Disorder of Sex Development (DSD) is a condition where there is a misalignment of gonads or chromosomes with the genitalia. One of the rarest forms of DSD is Ovotesticular DSD (OT-DSD), which is characterized by the presence of both ovarian and testicular tissues in the same individual and a diverse range of phenotypes with various penetrations.

### CASE SUMMARY

A 16-year-old patient who was raised as a female presented with ambiguous genitalia and regular menstrual cycles. Ultrasound examination revealed a normal-sized uterus and three gonads. Cy-togenetic analysis showed a mosaic karyotype, and PCR testing for the SRY gene was positive. Postoperative histology indicated the presence of two ovaries and one ovotestis gonad.

### CONCLUSION

In low-resource healthcare settings, caregivers should remain vigilant for ambiguous genitalia and ensure timely referral for accurate diagnosis and counseling before sex assignment. This case highlights the importance of maintaining a high level of suspicion for DSD in adolescents displaying abnormal pubertal development or atypical genital findings.

**KEYWORDS:** Ovotesticular DSD, SRY gene, true hermaphrodite

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## INTRODUCTION

Disorders of sex differentiation (DSD) are medical and psychosocial emergencies that require an expert multidisciplinary team for proper management and favorable long-term outcomes.<sup>1,2</sup> The incidence of DSD ranges between 1:4500 and 1:5000 live births, with ovotesticular DSD (OT-DSD) (true hermaphroditism) accounting for 4% to 10% of all DSD cases.<sup>3</sup> The condition appears to be more common in African countries such as Kenya, South Africa, and Sudan.<sup>4,5</sup> Patients with OT-DSD usually present as under-virilized males with female karyotypes (46,XX).<sup>4</sup>

The diagnosis of OT-DSD involves a series of costly tests, such as chromosomal and molecular genetic analysis, hormone testing, ultrasound or MRI, and gonadal biopsy. Access to these tests and their high cost pose significant challenges, particularly in low-income countries, resulting in delays in diagnosis. Additionally, even in developed countries, addressing this condition requires a multidisciplinary approach due to its diverse presentation, potential impact on fertility, risk of gender dysphoria, gonadal malignancy, and implications for gender assignment.<sup>6</sup>

The disease is commonly identified in neonates based on genital abnormalities or in adolescents who present with abnormal sexual development at puberty. The management of OT-DSD requires a multidisciplinary approach, including pediatric endocrinology, pediatric surgery or urology, radiology, genetics, psychology or child psychiatry, and pediatrics.<sup>7</sup> This approach is necessary to address potential sexual function, genitourinary function, future fertility issues, gender dysphoria, and long-term follow-up for potential surgical complications and functional outcomes.<sup>8</sup> Psychological assessment and counseling for both the family and the patient are critical when making shared decisions about treatment, including sex assignment, hormonal therapy, and surgical intervention.<sup>4,7</sup> Herein, we report a late presentation of a unique case of OT-DSD, with three gonads and a functioning Mullerian structure.

## Case Presentation

A 16-year-old, single female, reared as a female, presented to the Elite Center for Genetics Diagnosis, Khartoum, Sudan, complaining of an abnormal external genitalia shape (Figure 1). Her regular cycle started at 14 years old, and she denied any familial history of genital ambiguity. She had no other complaints.

Clinical examination showed stable vital signs, a female phenotype with Tanner stage 3 breasts, and female axillary and pubic hair distribution. External genitalia examination revealed a 5 cm penis with a urethral opening on the tip of the glans, absent labia majora, and atrophied labia minora (Figure 1). She had a normal-looking vagina with an intact hymen and a left palpable inguinal structure. Per rectal examination revealed an intact sphincter and an impalpable prostate gland. Examination of other systems was unremarkable.



Figure 1: Patient's external genitalia

An ultrasound scan revealed a normal-sized uterus, bilateral ovaries, and a left inguinal testicular-like structure. Chromosomal analysis revealed mosaic karyotype (46,XX/46,XY) (Figure 2).

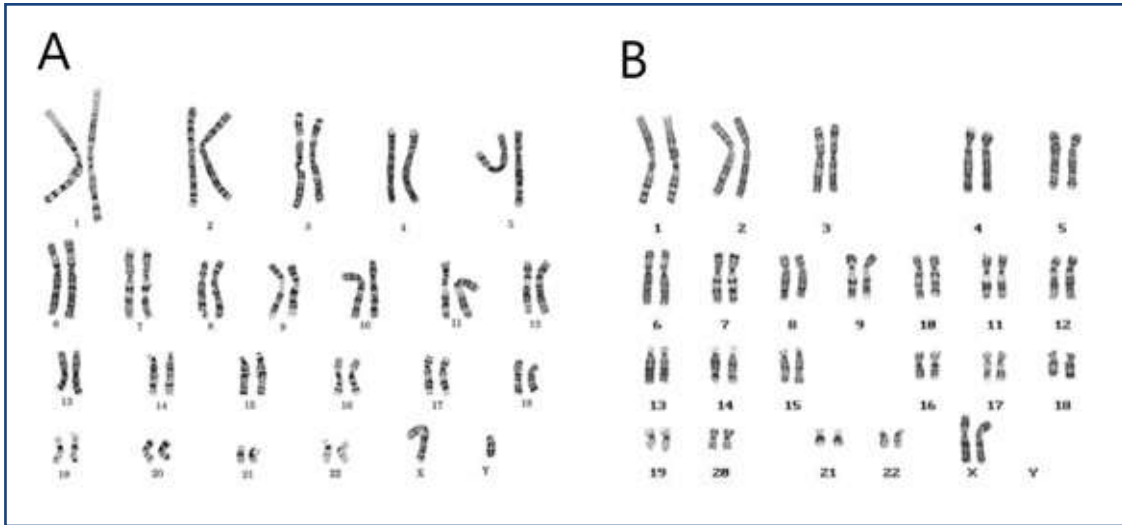


Figure 2: Mosaic karyotype of the patient showing (A) 46,XY and (B) 46,XX

Molecular study using PCR analysis for the SRY gene revealed the presence of the SRY gene sequence (Figure 3).

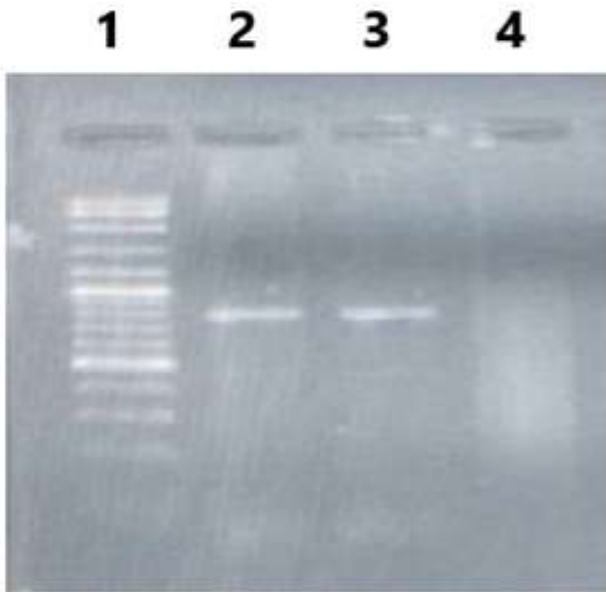


Figure 3 PCR amplification of the SRY gene: (lane 1) 100 bp ladder; (lane 2) +ve control (fertile female); (lane 3) patient, (lane 4) -ve control (fertile male).

A sexual orientation study using the Minnesota Multiphasic Personality Inventory (MMPI) showed a strong female personality.

The diagnosis of OT-DSD was reached, and following several counseling sessions by the Sudanese Intersex Working Group (SIWG), the patient and her family agreed that the patient should continue being reared as a female. Left orchiectomy and phallus reduction were performed with an uneventful post-operative course.

Post-operative histopathology revealed spindle cell stroma supporting degenerative tubules, suggesting ovotestis for the first specimen. In contrast, the second specimen showed stratified squamous epithelium. The fibrovascular stroma indicates penile tissue.

The case report received ethical approval from the ethical committee of Al Neelain Stem Cell Center, Al Neelain University. The data were anonymized and informed consent was obtained from the parents of the patients.

## DISCUSSION

Sudan, as a vast nation with diverse cultures and deeply ingrained belief systems, faces a high prevalence of illiteracy, particularly in rural areas. Within this societal context, individuals affected by DSD are often perceived as having either a spiritual gift, a curse, or a social stigma, leading to parental reluctance in seeking medical advice or Western treatment.<sup>10</sup> Families who pursue medical assistance for their DSD-affected children may face social isolation, rejection, job loss, and may even need to relocate.<sup>11</sup> The substantial psychological burden on patients and their families often results in concealing the condition, contributing to delayed diagnoses seen in developing countries compared to developed nations.<sup>12</sup>

Most DSD cases in Sudan, including our patient, are delivered at home (64.8%) and assigned a gender by non-trained personnel. This practice leads to delayed diagnosis in 40% of patients, with early diagnosis occurring in only 4.9% of cases.<sup>7</sup> Incorrect sex assignment can result in lifelong consequences, especially for XY DSD individuals wrongly assigned as female, who may undergo female genital mutilation (FGM). This practice leads to irreversible damage to the genital organs and greatly impacts reassignment decisions.<sup>4,7</sup> Fortunately, our patient avoided FGM, allowing for reconstructive surgery limited to reducing the phallus size and ensuring a potential for a normal sexual life.

A recent 5-year study in Sudan observed that OT-DSD accounted for 6.7% of XY DSD cases and 3.2% of XX DSD cases.<sup>13</sup> Patients with OT-DSD typically presented in three patterns: lateral (20%) with a testis on one side and an ovary on the other, bilateral (30%) with both testicular and ovarian tissue bilaterally, often as ovotestis, and unilateral (50%) with an ovotestis on one side and an ovary or testis on the other. The ovary was more frequently on the left side, while the testis was more commonly on the right in lateral OT-DSD cases.<sup>7,13</sup>

Notable findings in our case include the presence of three gonads (two ovaries and one ovotestis) and

fully developed functioning Mullerian structures, resulting in a normal-sized uterus and regular menstrual cycles.<sup>14</sup> The patient sought medical attention solely due to ambiguous genitalia (a large phallus, later identified as a penis). She was treated by the Sudanese Intersex Working Group (SIWG), a multidisciplinary team established 20 years ago and based in Khartoum, that includes a psychiatrist, obstetrician, urologist, pediatric surgeon, pediatrician, and clinical geneticist to elevate the diagnosis and management of DSD cases in Sudan.<sup>8</sup> However, as the team is based in Khartoum, only patients able to travel to the capital can receive their care. Despite this limitation, SIWG's media campaign has encouraged rural populations to seek assistance, expanding its role to include social support and providing free investigations and genetic workup for financially disadvantaged patients.

## CONCLUSION

In low-resource healthcare settings, it is essential for caregivers to remain vigilant for ambiguous genitalia and to facilitate timely referrals for accurate diagnosis and counseling before sex assignment. Given the heterogeneity and complexity of DSD, a multidisciplinary approach is crucial in providing optimal care. This case emphasizes the importance of maintaining a high index of suspicion for DSD in adolescents presenting with abnormal pubertal development or atypical genital findings.

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# ADVANCED MALIGNANT MELANOMA OF THE VULVA IN A 70 YEARS OLD WOMAN AT TIKUR ANBESSA SPECIALIZED HOSPITAL, ADDIS ABABA, ETHIOPIA: CASE REPORT

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## ABSTRACT

**BACKGROUND:** Vulvar melanoma is a rare malignant tumor of the female genital tract that tends to occur in older women, with a high tendency to metastasize due to delayed diagnosis.<sup>1</sup> In this case report, we present a 70-year-old para 8 woman who presented with a progressively increasing vulvar swelling over two years and had multiple visits to healthcare institutions. Examination revealed a 7 cm diameter multi-nodular mass with areas of dark and dark blue-violet color, filling the introitus and involving the clitoris, labia minora, the lower third of the anterior vagina, and urethra. An incisional biopsy from the mass showed malignant melanoma. Imaging with a CT scan revealed bilateral lung metastasis. Palliative chemotherapy was planned, but the patient was lost to follow-up.

**KEYWORDS:** Case report, vulvar cancer, metastasis

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## INTRODUCTION

Malignant melanoma of the female genital tract is rare, accounting for 1-3% of all melanomas in women, and is associated with a poor prognosis.<sup>2</sup> Vulvar malignant melanoma (VMM) accounts for 5-10% of all primary vulvar malignancies.<sup>1,2</sup> It predominantly occurs in postmenopausal white women, most commonly affecting the clitoris and labia. In addition to age, chronic inflammatory diseases and human papillomavirus (HPV) infection are proposed risk factors for vulvar melanoma. Activating alterations in the KIT gene are frequently associated with vulvar melanoma.<sup>3,4,5</sup> Symptoms in women with malignant melanoma of the vulva include color changes, lumps or swelling, itching, bleeding or discharge, and pain, with lesions presenting in various colors. Diagnosis is based on histopathologic examination of excisional or punch biopsy from the lesion. Comprehensive skin and eye examinations are necessary to rule out other primary sites. Whole-body positron emission tomography (PET)/CT scans should be conducted to assess the extent of disease and inform therapeutic decisions.<sup>6,7</sup> Surgery is the cornerstone of treatment for malignant melanoma, while systemic chemotherapy is used for metastatic and recurrent disease.<sup>1,6</sup> This case report describes a woman with a delayed diagnosis of malignant melanoma.

## Case and Observation

We present a 70-year-old para 8 woman referred for a complaint of a two-year history of vulvar swelling. The mass had been increasing in size rapidly and was associated with bleeding over the past two months, requiring one or two pad changes per day. She reported no vulvar itching, vaginal discharge, or changes in bowel or bladder habits and had multiple visits to healthcare facilities before this referral. She had undergone a total abdominal hysterectomy three years ago for cervical intraepithelial neoplasia grade 3 and had no known chronic illnesses. She also reported no family history of malignancy.

On physical examination, the patient was in good functional status. Pelvic examination revealed a 7 cm diameter multi-nodular mass with dark and dark blue-violet areas filling the introitus, involving the clitoris, labia minora, the lower third of the anterior vagina, and the urethra. Examination of the breast, inguinal lymph nodes, eyes, skin, and abdomen showed no remarkable findings. Cystourethroscopy was attempted, but the urethral meatus could not be assessed due to obstruction by the mass. Histopathologic evaluation of excisional biopsies from the mass revealed tissue composed of stratified squamous epithelium with surface ulceration, underlying stroma consisting of sheets of pleomorphic oval to spindle cells with prominent nuclei and intracytoplasmic melanin pigment with pagetoid spread. Mitosis was also observed (Figure 2).

An MRI of the pelvis and abdomen revealed a 5 cm by 4 cm mass with heterogeneous hyperintense signal in both T2 and T1 sequences, infiltrating the anterior wall of the vagina and vulva and encasing the urethra, without regional nodal or distant metastasis. Chest CT showed bilateral lung metastasis. Palliative chemotherapy was planned with dacarbazine at a dose of 250 mg/m<sup>2</sup> IV daily for five days, to be repeated every three weeks for six cycles, with an evaluation of chemotherapy response after three cycles. However, the patient was lost to follow-up as she was from a war-torn area with limited access to transportation.





Figure 1. Dark red nodular 6 by 7cm Vulvar mass involving clitoris, lower third of anterior vagina and lower third of urethra is visible.

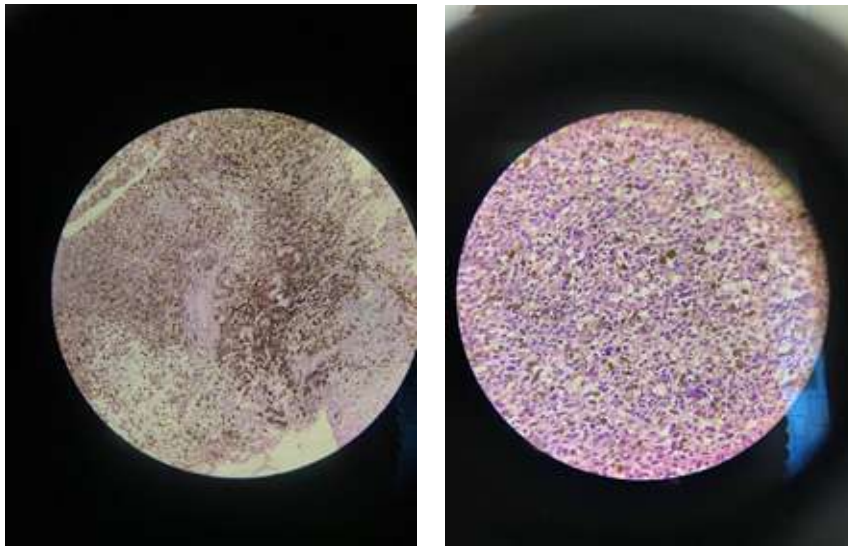


Figure 2. pleomorphic oval to spindle cells having prominent nuclei and intracytoplasmic melanin pigment with Pagetoid spread



## DISCUSSION

Female genital tract malignant melanoma, a devastating disease, is rare, accounting for 1-3% of all melanomas in women.<sup>2</sup> It has a poor prognosis, with a 15% 5-year survival rate.<sup>1, 2, 8</sup> Vulvar malignant melanoma (VMM) is responsible for 5-10% of all primary vulvar malignancies.<sup>1, 2</sup> Most cases of vulvar malignant melanoma present at age 68 and above, although cases in younger, premenopausal HIV-positive women have been reported.<sup>1</sup> The risk of onset increases with age; cases rise from 0.11 per 1 million inhabitants in the 15–29-year age range to 3.5 per 1 million inhabitants in those over 60 years old.<sup>1</sup> In addition to age, chronic inflammatory disease and human papillomavirus (HPV) infection are proposed risk factors for the development of vulvar melanoma. Activating alterations in the KIT gene are commonly associated with vulvar melanoma.<sup>3, 4, 5</sup>

There is no specific screening test for vulvar cancer in general. Early detection of any vulvar lesion and biopsy by clinicians during gynecologic exams can prevent or reduce the incidence of malignant vulvar lesions.<sup>10</sup> Any pigmented vulvar lesion, unless it has been present for some time without change, should be biopsied for diagnosis.<sup>11</sup> Most patients with vulvar malignant melanomas are asymptomatic and diagnosed late, which may be due to the anatomic position of the lesion. Some women, however, present with symptoms such as lump or swelling, itching, bleeding, discharge, and pain, particularly as the disease progresses.<sup>1</sup> Approximately one-third of patients present with lymph node metastasis.<sup>1</sup> Our patient presented at age 70 with distant metastasis to the lungs. She had previously undergone screening for cervical cancer and a hysterectomy for cervical intraepithelial neoplasia grade 3 a year before her current symptoms. This could have been an opportunity for early detection of the vulvar lesion in this case. Although she sought care for genital complaints, a diagnosis was not reached, possibly contributing to the advanced

stage at presentation. Amelanotic melanomas account for only 2% of all vulvar melanomas.<sup>1, 6, 7</sup> Complete skin and eye examinations are necessary to rule out other primary sites. A whole-body positron emission tomography (PET)/CT scan should be obtained to assess the disease extent and plan the therapeutic approach.<sup>6, 7</sup> The staging of vulvar melanoma is based on the 8<sup>th</sup> edition of the American Joint Committee on Cancer (AJCC) staging system.<sup>12</sup> Surgery is the mainstay treatment for vulvar malignant melanoma. Systemic dacarbazine-based chemotherapy is recommended for advanced stages.<sup>1, 6</sup> Typically, follow-up appointments are recommended every 3 to 6 months for the first 2 years and then every 6 to 12 months thereafter.

The overall prognosis is poor. The 5-year disease-specific survival rates for those with localized, regional, and distant disease are 75.5%, 38.7%, and 22.1%, respectively.<sup>6, 7, 12</sup> This case presented at an advanced stage, which entails a poor prognosis. Similar to this case, Ramesh et al. reported a case of vulvar melanoma in a 32-year-old patient managed with surgery followed by radiotherapy. In another study, Soumiya et al. reported an advanced, inoperable vulvar melanoma in a postmenopausal woman, describing an aggressive tumor similar to this case. In another case series, most patients were treated surgically, as most presented at an early stage.<sup>13, 14, 15</sup>

## Conclusion

Neglecting a thorough gynecologic examination and failing to diagnose malignant vulvar melanoma can result in a devastating disease with a poor outcome. Patients attending cervical cancer screening may benefit from a comprehensive genital examination. Early diagnosis in patients with vulvar complaints can alter the treatment plan and improve patient outcomes. We recommend routine ano-genital examinations for patients presenting to outpatient clinics for various gynecologic concerns.

**Sources of funding**

Nothing to declare.

**Consent**

For the purpose of publishing this case report and the associated photographs, the patient's written informed consent was acquired. The Editor-in-Chief of this journal can examine a copy of the written consent upon request.

**Declaration of competing interest**

Nothing to declare.

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