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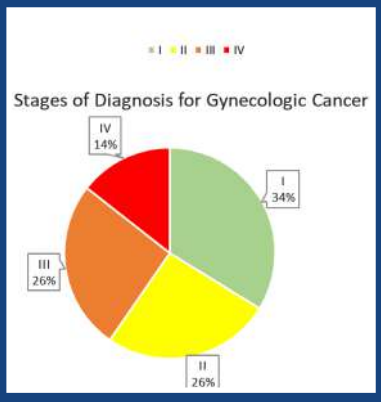

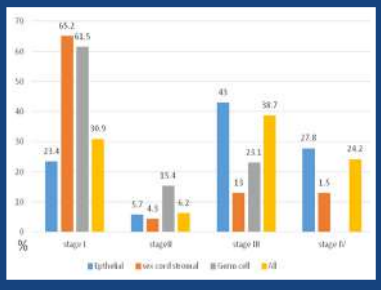

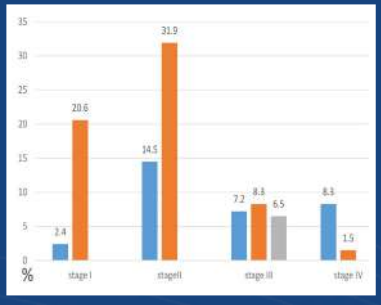

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A PILOT STUDY COMPARING MILD STIMULATION INVITRO-FERTILIZATION(IVF) VERSUS LONG PROTOCOL IVF AMONG WOMEN WITH ADVANCED MATERNAL AGE IN A DEVELOPING COUNTRY

Feiruz Surur[1], Mustefa Negash[1], Abel Teshome[1]

ABSTRACT

BACKGROUND: Due to the high costs involved with conventional Invitro-fertilization (IVF) methods, access to IVF is still restricted in many low- and middle-income nations. Mild stimulation IVF has been suggested as a cheaper alternative to conventional IVF to enhance access to IVF in places with limited resources since it employs lower doses of ovarian stimulating drugs. Introducing mild stimulation IVF in Ethiopia could help increase access to assisted reproductive services. There is no previous research in Ethiopia.

OBJECTIVE: This paper aimed to examine outcomes of a mild stimulation IVF pilot program at a clinic in Addis Ababa, Ethiopia. The primary outcome of the study is the biochemical pregnancy rate.

METHODS: This study was conducted at the Center for Reproductive Medicine IVF clinic. Ethical approval was obtained before the start of the data collection. A chart review of those infertile women who had undergone IVF in the past 3 years (April 1, 2019–April 1, 2022) was done. All of the electronic registrations at the clinic were complete for the data needed, and data abstraction was done using Open Data Kit (ODK). The ODK was tested on 5% of the study population and the validity checked before the start of data collection. The data was exported to Stata 14 for analysis. Summarization using frequency distribution was done for the clients' socio-demographic characteristics. We reported only the bivariate analysis since there is no statistically significant association with the outcome variable. We did not do multivariate analysis, but the intention was to do bivariate analysis followed by the multivariate analysis for those factors that have a significant association with the outcome variable. A p-value of less than 0.05 is considered statistically significant, with a 95% confidence interval.

RESULTS: A study of 296 IVF clients found that 69.3% were women whose age was less than or equal to 35 years, while 30.7% of women were older than 35. Of the 296 women, 288 (97.3%) had their B-HCG result known, with 62.5% being negative and 37.5% positive. The purpose of the study was to determine which procedure was best for older women (age higher than 35 years). A subgroup analysis of 83 women with advanced age found that there was no significant statistical difference in pregnancy rate between mild stimulation and long protocol IVF (COR=0.78, P-value=0.727, 95% C.I=0.22-2.85). However, cross-tabulation analysis shows that among the 17 cases who were positive for pregnancy, mild stimulation had higher pregnancy rate of 13 (76.5%) compared to the long protocol with 4 (23.5%) in this age group. The long protocol cases had a mean requirement of gonadotropin medication which was threefold higher than mild stimulation IVF. Although the statistical analysis didn't show statistical association, the cross-tabulation showed that there is a higher pregnancy rate among IVF clients of advanced maternal age who had undergone mild stimulation IVF. The gonadotropin requirement for the long protocol was threefold higher

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than the mild stimulation protocol, and this can be interpreted as indicating that the cost of mild stimulation IVF is threefold lower than that of long protocol IVF. Therefore, mild stimulation IVF is a cheaper alternative with a higher pregnancy rate.

CONCLUSION AND RECOMMENDATION: Even though there is no statistically significant difference between the two protocols, cross-tabulation showed that pregnancy rate is higher among mild stimulation cases. Additionally, the cost of gonadotropin treatment was three fold higher for long protocol IVF. Further prospective studies with a larger sample size should be conducted to confirm the results. However, based on the current findings, we recommend that mild stimulation IVF be considered as a better option for women with advanced maternal age in low resource settings, as it achieves a similar pregnancy rate at a lower cost.

(The Ethiopian Journal of Reproductive Health; 2024; 16;1-6)

INTRODUCTION

In vitro fertilization (IVF) is a method of treating infertility that is gaining popularity worldwide. However, due to the high costs involved with conventional IVF methods, access to IVF is still restricted in many low- and middle-income nations[1]. Mild stimulation IVF has been suggested as a cheaper alternative to conventional IVF to enhance access to IVF in places with limited resources since it employs lower doses of ovarian stimulating drugs[2]. In Ethiopia, the prevalence of infertility is 26.7 percent overall, that is very high when compared to the global occurrence[3]. Introducing mild stimulation IVF in Ethiopia could help increase access to assisted reproductive services. This paper examines outcomes of a mild stimulation IVF pilot program at a clinic in Addis Ababa, Ethiopia. We hypothesized that mild stimulation IVF could offer favourable pregnancy rates with reduced costs compared to conventional IVF. This initial data on the efficacy of mild stimulation IVF in an Ethiopian population could help inform future efforts to expand affordable IVF services in other low-income countries.

METHODS

This study was conducted at the Center for Reproductive Medicine (CFRM) clinic. The CFRM was established on April 1, 2019, and is a branch of Saint Paul's Hospital Millennium Medical College (SPHMMC). This clinic provides all reproductive health, endocrinology, and Invitro-fertilization (IVF) services in a dedicated building. There are four outpatient clinics: two of them are for reproductive health services, and the other two are for the evaluation of infertile couples and endocrinology clients. On average, 100 infertile clients visit the CFRM clinic on working days, and the clinic is open from 8:30–12:30 am and 1:30–5:30 pm, seven days per week. The service is run by Reproductive Health and Endocrinology (REI) fellows and specialists.

Ethical approval was obtained before the start of the data collection from the Institutional Review Board of St. Paul's Hospital Millennium Medical College. A chart review of those infertile women who had undergone IVF in the past 3 years (April 1, 2019–April 1, 2022) was done. All of the electronic registrations at the clinic were complete for the data needed, thus all of the charts of women who had undergone IVF were obtained for further data abstraction using the Open Data Kit (ODK). The data collection tool Open Data Kit(ODK) was tested on 5% of the study population and the validity checked before the start of data collection. The data was entered into ODK, cleaned, and then exported to Stata 14 for analysis. Summarization using frequency distribution was done for the clients' socio-demographic characteristics. A bivariate analysis was done to test associations between categorical variables and outcome variables. The intention was to do bivariate analysis followed by multivariate analysis for those factors that had significant association with outcome variable. A p-value of less than 0.05 is considered statistically significant, with a 95% confidence interval. The outcome variable was a biochemical pregnancy which is dichotomized as "positive" or "negative". The single predictor variable was the type of protocol (long versus mild stimulation protocol). There are two main types of protocols based on the type of gonadotropin-releasing hormone (GnRH) analogue used: agonist and antagonist protocols. During the long protocol, GnRH agonists are given during the luteal phase of the menstrual cycle, and ovarian stimulation using gonadotropins is started on days 2 or 3 of the menses. For the antagonist protocol, ovarian stimulation is started using gonadotropins on days 2 or 3 of menses, and the GnRH antagonist will be started when the dominant ovarian follicle reaches a size of 14 mm. Mild stimulation is a modification of the antagonist protocol where the ovarian stimulation is started on the 2nd day of menses using an oral aromatase inhibitor (Letrozole) or Clomiphene citrate and stimulation with gonadotropins is initiated on the

4th day. The woman will be started on antagonist medication when the dominant follicle reaches a size of 14 mm. A woman whose stated age is above 35 years is considered to have advanced maternal age[4].

RESULTS

A study of 296 IVF clients found that 69.3% were women whose age was less than or equal to 35 years, while 30.7% of women were older than 35. Of the 296 women, 97.3% had their B-HCG result known, with 62.5% being negative and 37.5% positive.

Table 1 Sociodemographic characteristics of women who undergone IVF at public IVF center in Addis Ababa, Ethiopia.(n=296)

	Number	Percent
Age(Years)		
Mean±SD	33.1±4.8	
Minimum, Maximum	20, 40	
Duration of infertility(Years)		
Mean±SD	7.2±3.6	
Minimum, Maximum	1,23	
Age category		
<=35	205	69.3%
>35	91	30.7%
Parity		
Nulliparous	264.0	89.2
Parous	32	10.8
Type-infertility		
Primary infertility	206.0	69.6
Secondary infertility	90	30.4
Address		
Addis Ababa	201.0	67.9
Outside of Addis Ababa	95	32.1

The study focused on assessing which protocol was preferred for women with advanced age (age higher than 35 years). A subgroup analysis of 83 women with advanced age found that there was no significant statistical difference in pregnancy rate between mild stimulation and long protocol IVF (COR=0.78, P-value=0.727, 95% C.I=0.22-2.85).

However, the cross-tabulation of the data showed that among the 17 cases, 13 (76.5%) women with advanced age who underwent long protocol IVF had a negative pregnancy test, while only 4 (23.5%) had a positive pregnancy test. Similarly, among the 66 cases 53 (80.3%) of women with advanced age who underwent mild stimulation IVF had a negative pregnancy test, 13 (19.7%) had a positive pregnancy test. Comparing pregnancy rate between long protocol and mild stimulation protocol among the 17 women who had positive pregnancy test, 13 (76.5%) had undergone mild stimulation IVF, whereas 4 (23.5%) had undergone long protocol IVF. This suggests that mild stimulation IVF may be a better option for women with advanced age, as it has a higher pregnancy rate to long protocol IVF but requires less medication.

This study found no statistically significant difference in pregnancy rates between mild stimulation and long protocol IVF for women over 35 years old, though the sample size was small (n=83) and likely underpowered. However, cross-tabulation analysis shows that among the 17 cases who are positive for pregnancy, mild stimulation has higher pregnancy rate 13 (76.5%) compared to the long protocol 4 (23.5%) in this age group.

The mean and standard deviation of the number of gonadotropin ampules for long protocol was 39.2 and 2.1, respectively, and the range of gonadotropin ampules used were from 32 to 40. Whereas the mean and standard deviation of the number of gonadotropin ampules for mild stimulation IVF was 13.2 and 4.7, respectively. The pregnancy rate is higher among those with mild stimulation IVF. The long protocol cases had a mean requirement of gonadotropin medication which is threefold higher than mild stimulation IVF.

DISCUSSION

This study found no statistically significant difference in pregnancy rates between mild stimulation and long protocol IVF for women over 35 years old, though the sample size was small (n=83) and likely underpowered. However, cross-tabulation analysis suggested higher pregnancy rates with the mild stimulation protocol (76.5%) compared to the long protocol (23.5%) in this age group.

These findings align with other studies showing comparable or slightly higher pregnancy rates with mild ovarian stimulation IVF compared to conventional long protocol IVF in women with advanced maternal age. A study found no difference in ongoing pregnancy rates per started cycle between mild stimulation and long protocol IVF in women with advanced maternal age[5, 6]. Another study also found similar clinical pregnancy rates between mild stimulation and conventional protocol IVF in women ≥35 years[7].

Among the 17 cases of women who had advance maternal age, the majority (76.5%) of women who had undergone mild stimulation IVF had positive pregnancy compared to 23.5 % of women who had undergone long protocol. Similarly, according to a study by Youssef et al., although there was no statistically significant difference, the study found a trend towards a higher pregnancy rate with mild stimulation IVF [8].Another study showed that there is a statistically significant higher pregnancy rate for women who had undergone mild stimulation IVF compared to conventional IVF[9].

The higher gonadotropin requirements and costs associated with the long protocol found in this study have also been reported elsewhere. Studies showed that mild ovarian stimulation IVF reduced gonadotropin use and cost compared to conventional IVF[7, 8]. The lower costs with mild IVF make it an attractive option for fertility treatment, especially in low resource settings.

Some limitations of the current study include the retrospective design and small sample size in the subgroup analysis of women ≥35 years old. Other factors that may affect the pregnancy outcomes were not also considered in this study. Additional randomized controlled trials with larger sample sizes would allow for more definitive conclusions about pregnancy rates between protocols in women with advanced maternal age.

In conclusion, the study found that there was no statistically significant difference in pregnancy rate between mild stimulation and long protocol IVF for women with advanced maternal age. However, the cross-tabulation showed that the pregnancy rate was higher among mild stimulation IVF cases. Additionally, the cost of gonadotropin treatment was three fold higher for long protocol IVF.

Based on these findings, we recommend that further studies with a larger sample size be conducted to confirm the results. However, based on the current findings, we recommend that mild stimulation IVF be considered as a better option for women with advanced maternal age in low resource settings, as it achieves a similar pregnancy rate at a lower cost.

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ADOLESCENT GIRLS' PARTICIPATION IN PEER-GROUP IMPROVED CONDOM USE AT SEXUAL DEBUT IN RURAL EASTERN ETHIOPIA: A COMMUNITY-BASED CROSS-SECTIONAL STUDY

Nebiyou Fasil[1], Alemayehu Worku[2], Lemessa Oljira[3], Amare Worku Tadesse[4,5], Yemane Berhane[6]

ABSTRACT

BACKGROUND: Adolescent girls engaged in sexual activity are unlikely to use condoms during their sexual debut. Younger adolescents are also not often targeted for sexual-related interventions because of the taboos associated with sexuality in traditional societies. This study examined the association between peer-group participation and condom use at sexual debut among young adolescent girls in rural Eastern Ethiopia.

DESIGN: The study used and analyzed data from end line survey of an implementation study involving 3,290 young adolescent girls aged 13-17 years. The intervention specifically targeted adolescent girls between the ages of 10 and 14 years who were part of a peer group. Unmarried sexually active adolescent girls and married adolescent girls who had their sexual debut before marriage were the study population. Multi-level mixed-effect logistic regression analysis was employed to examine associations using STATA/SE version 16 statistical software.

RESULTS: Among 3,290 adolescent girls surveyed, 258 (7.84%) reported engaging in sexual intercourse. The mean age (SD) age at sexual debut was 14.36 (+1.32), with no observed statistical difference between the intervention and control groups (p=0.1164). The magnitude of condom use at sexual debut was 22.46%, 95 % CI (14.11, 33.81%). Adolescent girls who participated in peer-groups had 11.51 (Adjusted OR: 11.51, 95% CI: 1.95, 67.84) higher odds of using condoms during sexual debut compared to those in the control group.

CONCLUSIONS: Peer group participation improved condom use at sexual debut. Peer groups can be critical for engaging adolescent girls in HIV and other sexually transmitted infection prevention and avoiding unwanted/ unplanned pregnancies. Further studies with larger sample size and specific design methodologies are imperative to gather robust evidence that support scale-up of this potentially lifesaving intervention.

KEYWORDS: Adolescent girls, condom use, peer-groups, premarital sex

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INTRODUCTION

The adolescent population is prone to risky sexual behavior emanating from a lack of knowledge and inadequate access to healthcare[1] that make them vulnerable to sexually transmitted infections (STIs)[2,3], especially adolescent girls[4]. In addition, adolescent sexual activity can be more risky depending on the age at sexual debut[5]. In Ethiopia, adolescents who reported having sex before the age of 15 years ranged from 2.1% - 6.3%, while 34.5% of adolescents reported having sex before the age of 18. These figures are higher in the rural areas[6,7].

Early sexual debut, non-marital sex, and unprotected sex are risky behaviors that increase the risk of HIV infection[8–10]. Early sexual debut can also indicate situations where adolescents may have initiated sexual intercourse without protection[5]. Hence, promoting condom use is a critical preventive strategy against the risk of HIV[11–14]. In Eastern and Southern Africa, the regions most affected by HIV, only 19% of adolescent girls aged 15-19 have been tested for HIV in the past 12 months and received the last test result.[15] In Ethiopia, this figure is around 12.4% for girls and 8.9% for adolescent boys (6). In Ethiopia, condom use at sexual debut among school-aged youth ranged from 29.5% - 55.6%, while age at sexual debut ranged from 14-16 years[16–19].

Condom use among adolescents is determined by individual and societal factors[20]. Thus, interventions should prioritize specific values and beliefs that could lead to safe sexual practices in a particular context[21]. A systematic review of condom promotion programs among adolescents in low- and middle-income countries showed remarkable achievements in the uptake of condom use through communication and audience segmentation strategies[22]. Interventions tailored to condom application and intrapersonal skills have also been the hallmark of effective behavioral interventions in reducing HIV incidence[23]. This study aims to see whether participation in a peer-group can improve condom use at sexual debut among adolescent girls.

METHODS

Study design and participants

This study drew data from an end line survey conducted after the completion of implementation research project in the Western Hararghe Zone, Oromia Region, Ethiopia. The research implemented interventions to improve the sexual and reproductive health of adolescents. A peer group based intervention was implemented in three woredas (community areas) and another woreda served as a control. The peer group intervention involved organizing adolescent girls into girls' peer groups to discuss sexual and reproductive health issues, including family planning and condom use in the intervention arm. Details on the sampling procedure are available in a previously published article[24]. IFor this paper, a sub-sample of adolescent girls who reported engaging in sexual intercourse was taken for analysis.

Ethics and data protection

The research protocol was approved by the Institutional Review Board of Addis Continental Institute of Public Health (IRB registration/ identification No. 0029). Informed verbal consent was obtained from all study participants. For participants below the age of 15 years, additional parental/ guardian-informed verbal consent was obtained. All interviews took place in a private setting to ensure confidentiality. The data was de-identified when extracted from the larger dataset for this study.

Data collection tools, procedures, and data management

A structured and pretested interviewer-administered questionnaire designed in English and translated to the local language, Affaan Oromo, was used for data collection. The translation was checked by a panel of public health experts who were fluent in both languages. Interviewers and field supervisors were trained on survey procedures, study tools, and related issues for two weeks. Piloting was done in a

similar setting, not included in the main study, to test the appropriateness of the questions, language, flow, and understandability. Adolescent girls were interviewed at their residential compound in a private space. The Open Data Kit, an electronic data collection program, was used to collect the data. Data were uploaded on a secure server from the field whenever internet service was available.

Measures of condom use at sexual debut

For this study, reports from adolescent girls who reported engaging in sexual intercourse were taken for the analysis. Furthermore, to correctly identify condom use at sexual debut, only never married adolescent girls who reported having had sexual intercourse and ever-married adolescent girls who reported having had sexual intercourse before their marriage were included in the final analysis. For evaluating condom use at sexual debut, the question was "Did you/your partner use condoms during your first sexual intercourse?" The outcome variable had "Yes", "No" and "Don't know" response options. Those who said "Yes" were coded as "1" (used condom), "No" were coded as "0" (Didn't use condom), and "Don't know" were coded as missing. Finally, the outcome variable had "Used condom" and "Didn't use condom" response options.

Covariates

"Exposure"involved participating in peer groups organized by the parent implementation research; those who lived in the intervention woreda were taken as exposed, and those who lived in the control woreda were taken as non-exposed. Comprehensive HIV knowledge was operationally defined as correctly recalling three prevention methods of HIV transmission and rejecting two of the most common misconceptions of HIV[6]. Knowledge about condoms was operationally defined as answering correctly three condom knowledge questions. Condom use self-efficacy was operationally defined as being confident to refuse sex with that partner, ask about sexual history, discuss STIs, discuss condom use, and convince their partner to use condoms. Respondents with 3-5 positive ("yes") responses were coded as having self-efficacy; the remaining as not having self-efficacy[25]. Perceived confidence in negotiation skills was also defined as girls who responded to a single-item question about their level of confidence as "no/ little confidence", "moderate confidence" and "high confidence".

Other covariates considered in the analysis include adolescent girl's age, education (never attended school, grade 1-8, grade 9-12), marital status (ever married, never married), contact with health extension workers (yes, no) and age at sexual debut.

Statistical analysis

The data were analyzed using STATA/SE 16.0. The proportion of condom use at sexual debut was calculated as a percent with a 95% confidence interval. Cluster-ID was considered a random component. To examine associations, initially, a bivariate analysis was done, and then conceptually relevant covariates were included in the multivariable analysis. The intraclass correlation coefficient (ICC) was statistically significant; hence, multi-level mixed-effect logistic regression model was used. Associations were described using an odds ratio with 95% confidence intervals, and statistical significance was declared at $p<0.05$. Weighting was done to account for the complex survey design and analysis.

RESULTS

Of the 3,290 adolescent girls who participated in the parent study, 258 (7.84%) reported having had sexual intercourse. Most were ever-married (68.6%) and attended primary school education 75.58%. Among adolescent girls who reported having engaged in sexual intercourse, 145 (56.2%) were from the areas that participated in a peer group intervention, and 113 (43.8%) were from the areas that did not participate in the intervention. (Table 1)

Table 1: Background characteristics of adolescent girls who reported engaging in sexual intercourse, West Hararghe, Eastern Ethiopia, 2019 (n=258)

Characteristics	Frequency	Percent
Intervention group status		
Participated in Peer-group	145	56.2
Did not participate in Peer-group	113	43.8
Adolescent Girls' Age		
13	2	0.78
14	18	6.98
15	45	17.44
16	87	33.72
17	106	41.09
Adolescent Girls' educational status		
Never attended	51	19.77
Primary (1 – 8)	195	75.58
Secondary (9 – 12)	12	4.65
Adolescent Girls' marital status		
Never married	81	31.4
Ever married	177	68.6

Among adolescent girls who reported having had sexual intercourse, 81.62% had poor comprehensive knowledge of HIV, while 68.68% had poor knowledge about condoms. Half of adolescent girls who reported having had sexual intercourse had poor condom use self-efficacy, although 88.72% reported moderate to high confidence in their negotiation skills. (Table 2)

Table 2. Knowledge level and perceived skill characteristics of Adolescent girls reported engaging in sexual intercourse, West Hararghe, Eastern Ethiopia, 2019 (n=258)

Characteristics	Frequency	Percent(Weighted)
Comprehensive knowledge of HIV		
Good	48	18.38
Poor	210	81.62
Knowledge about condoms		
Good	82	31.32
Poor	176	68.68
Condom use self-efficacy		
Good	124	46.87
Poor	134	53.13
Ever had contact with Health extension workers		
Yes	65	27.43
No	193	72.57
Adolescent girls' perceived negotiation skill level		
Little/ No confidence	29	11.28
Moderate confidence	91	33.85
High confidence	138	54.87

Overall, the mean (+SD) age at sexual debut was 14.36 (+1.32). There was no statistical difference in mean age at sexual debut between the intervention and control groups (p=0.1164).

Condom use at sexual debut among adolescent girls

Condom use at sexual debut among adolescent girls was 22.46%, 95 % CI (14.11, 33.81%). There was a statistical difference in condom use at sexual debut between the intervention and control groups (p=0.018). The weighted mixed-effect logistic regression analysis showed that the odds of using condoms at sexual debut among adolescent girls participating in peer group was 11.51 times higher than those in the control group (Adjusted OR: 11.51, 95% CI: 1.95, 67.84). (Table 3)

Table 3: Multi-level mixed-effect Regression indicating factors associated with condom use at sexual debut among adolescent girls, West Hararghe, Eastern Ethiopia, 2019

Characteristics	Condom use at sexual debut		Unadjusted Bivariate (Weighted)		Adjusted Multivariable (Weighted)	
	Yes	No	COR (95% CI)	p-value	AOR (95% CI)	p-value
Adolescent girls' Participation in peer group						
Yes	18	32	9.75 (1.49, 63.59)	0.017	11.51 (1.95,67.84)	0.007
No	4	44	1		1	
Adolescent girls' comprehensive knowledge of HIV level						
Good knowledge	6	15	2,53 (0.45, 14.07)	0.289	1.95 (0.30, 12.59)	0.482
Poor knowledge	16	61	1		1	
Adolescent girls' knowledge of condoms						
Good knowledge	13	53	4.79 (1.02, 22.46)	0.047	4.47 (0.76, 26.31)	0.098
Poor knowledge	9	23	1		1	
Adolescent girls' self-efficacy for condom use						
Good	15	36	2.18 (0.49, 9.60)	0.303	1.00 (0.17, 5.71)	0.997
Poor	7	40	1		1	
Adolescent girls' contact with Health extension worker						
Yes	6	17	1.66 (0.17, 16.25)	0.662	1.05 (0.13, 8.49)	0.966
No	16	59	1		1	
Adolescent girls' perceived negotiation skills						
Little/ No confidence	4	35	1		1	
Moderate confidence	9	33	0.74 (0.11, 5.31)	0.771	0.33 (0.03, 3.62)	0.363
High confidence	9	8	0.71 (0.12, 4.22)	0.708	0.32 (0.04, 2.86)	0.309
Adolescent Girls' Age at sexual debut Mean(+SD)	14.09 (+1.23)	14.29 (+1.44)	0.98 *0.61, 1.58)	0.941	0.98 (0.001, 64.96)	0.941

DISCUSSION

This study showed that 7.84% of young adolescent girls reported having had sexual intercourse. The mean age at sexual debut was 14.36 years. Condom use at sexual debut among adolescent girls was 22.46%. Adolescent girls' participation in peer groups improved condom use at sexual debut.

Condom use at sexual debut was low compared to other studies conducted in Ethiopia[16–19]. The low condom use at sexual debut in the study could be explained by the relatively young adolescents involved in the study, the study area, which was rural, limited access to condoms, and the taboos related to condom use. Such observations are common in the studies conducted in areas where religious and cultural norms are strictly respected[26].

Peer-group participation was significantly associated with improved condom use at sexual debut. Emphasis given in the intervention on safe sexual practices could have helped adopt condom use at sexual debut. Previous studies indicated that it is easier to prevent problematic behaviors before initiated into the behaviors than alter

them once initiated and internalized[21]. Age and sex-appropriate interventions are instrumental in adopting healthy behaviors[27]. The study intervention was developed based on a formative assessment to develop appropriate messages for the peer groups. The study intervention seems promising to curtail the resurgence of HIV in Ethiopia. The intervention is feasible for implementation in Ethiopia and many similar settings as most adolescent girls are in school at an early age and organizing them into peer groups is not challenging. The materials used in the peer groups are could be adopted to a wider adolescent audience with little adaptation to specific socio-cultural settings.

No association was observed between HIV knowledge and condom use or knowledge about condoms and condom use. Some studies have indicated no direct association between HIV knowledge and sexual behaviors[28,29]. Moreover, a comparative study of socio-cognitive models for predicting condom use among adolescents also showed that the pathway, or association, or lack thereof, between knowledge about condoms and condom use was dependent on the type of model used[30]. Hence, using an appropriate socio-cognitive model is crucial. In addition, knowledge without the necessary skills to negotiate safer sex may not be sufficient to adopt health behaviors.

The study used data that was available from a relatively large number of adolescent girls. However, some limitations are noted. The sample sub-population available for this study was not sufficient, as can be observed from the wide confidence interval. As the parent study was not designed to specifically answer our study objective, some critical information related to condom use was not available. We were also not able to document the detailed implementation of the intervention as that was not part of the dataset available for analysis. Thus, the strong association observed in this study between condom use during sexual debut and the intervention could be due to uncontrolled confounding. Reporting and social desirability biases could also be the reason for the observed association. While reporting condom use can be underestimated due to cultural taboos, especially for adolescent girls, the social desirability bias could overestimate condom use particularly, among peer group participants. The generalizability of the study is also limited by the fact that it was conducted in one zone and only in rural areas.

CONCLUSION

Condom use at sexual debut was low. Participation in peer groups improved condom use at sexual debut. Further studies with larger sample size and specifically designed research are necessary to generate evidence for scale-up of this potentially lifesaving intervention.

DECELERATIONS

Availability of data and materials

All data relevant to the study are included in the manuscript.

Conflict of interest

All authors declare no conflict of interest

Authors contributions

N.F., Y.B., and A.W. were responsible for conceptualizing, reviewing, and editing the manuscript. N.F., A.W., and A.W.T were responsible for data cleaning. N.F. was responsible for formal analyses and writing the original draft. L.O. and A.W.T. contributed and critically revised the manuscript. All authors have read and given their approval for the publication.

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ASSESSING PREGNANCY OUTCOMES DURING AND BEFORE THE OUTBREAK COVID-19 PANDEMIC

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ABSTRACT

BACKGROUND: Due to its nature, the COVID-19 pandemic hadadverse effects on pregnant mothers, fetuses, and newborns.

OBJECTIVE: This study aimed to investigate pregnancy outcomes in obese women who gave birth during and before the COVID-19 pandemic outbreak.

METHODS: This descriptive-analytical study was conducted on 444 obese pregnant women in two groups - before and during the COVID-19 outbreak. The study investigated the pregnancy outcomes and the role of COVID-19 in their development. Data were collected through online questionnaires, and the analysis involved the use of a logistic regression model and odds ratio analysis.

RESULTS: The independent t-test between the two groups revealed an average BMI of 32.95 and 33.12, respectively. The statistical analysis showed that this difference was not significant (Pr (T > t) = 0.7076, t = -0.5469). Additionally, COVID-19 had no significant effect on pregnancy outcomes such as gestational vomiting, gestational diabetes, high blood pressure, pre-eclampsia, postpartum hemorrhage, and weight gain during pregnancy. However, it did increase the chances of urinary infections, the need for cesarean section, and premature delivery, although these increases were not significant.

CONCLUSION: The results of this study show that COVID-19 pandemic had consequences for obese pregnant women, that various issues can affect the risk of this consequence in this group, and that different aspects should be considered in futurestudies.

KEYWORDS: COVID-19 Pandemic; pregnancy outcomes; obesity; women; pregnancy

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INTRODUCTION

Pregnancy represents a crucial period in a woman's life, which influences the future health of both mother and children. A balanced diet and a proper weight gain during pregnancy are associated with better maternal and perinatal outcomes[1]. To assess nutrition status, most frequently, the body mass index (BMI) is calculated using the pre-pregnancy weight, which has a fundamental role in determining the total amount of weight gain, monitoring gestational development and providing nutritional counseling[2].

Obesity is measured based on body mass index, and people with a BMI greater than 30 are considered obese[3, 4]. The prevalence of obesity and weight gain in women of all age groups is increasing, especially in the range of 25 to 34 years. Considering that fertility is at the highest level in this age range, weight gain and obesity can be considered as an important issue in pregnancy care. The complications of obesity and being overweight include frequent miscarriages and congenital anomalies, increased blood pressure, pre-eclampsia, gestational diabetes and venous thromboembolism[5].

Maternal weight gain and obesity may lead to caesarean section. Also, babies born to overweight or obese mothers often have macrosomia and require long-term hospitalization.[5]. In this way, the obesity of the pregnant mothers can also affect the future health of the children[6]. There is a strong relationship between weight gain and maternal obesity and their adverse results on the health of the mothers and their babies during pregnancy, delivery and after delivery[7]. Pre-pregnancy weight, as well as weight gain during pregnancy, are important risk factors in the future weight gain of mothers and babies[7].

Doi et al. (2020) in a study titled Cohort Study of High Maternal Body Mass Index and the Risk of Adverse Pregnancy and Childbirth Outcomes in Scotland, it was found that compared to women with normal weight, the chances of gestational diabetes outcomes, preeclampsia, induction of labor, and emergency caesarean section for overweight and obese women, and pregnancy blood pressure has increased significantly[8].

The severe acute respiratory syndrome which is caused by corona virus, was named the COVID-19 pandemic by the World Health Organization and was first identified in December 2019 in the Chinese city of Wuhan. It can cause an asymptomatic to severe acute respiratory infection. Pregnant women and babies must receive more care and attention against this disease because there is a concern about possibility of transmission of this virus through mother to fetus. There are also related concerns about creation of abnormalities and transmission of the virus during delivery and breastfeeding[9]. Tagvi et al. (2021), in examined pregnancy, maternal, and newborn outcomes in COVID-19, compared to healthy pregnant women in Iran. Hormozgan studied 55 pregnant women with COVID-19 as case controls and 55 pregnant women as peer controls and showed that the pregnancy outcomes in the case control group - such as mode of delivery, premature rupture of the membranes, postpartum hemorrhage, perineal removal rate, birth weight of the baby, Apgar score and the rate of infant suffocation were similar to pregnant women without COVID-19 [10].

Also, previous findings in pregnant patients with obesity and COVID-19 indicate frequent thromboembolism and pre-eclampsia, higher risk of hospital-acquired infections, more hospitalizations in intensive care units, frequent use of invasive and non-invasive oxygen therapy, and maternal death[11]. Considering the quick spread of this pandemic and the lack of information on the relationship between pregnancy outcomes of women, especially obese individuals, and COVID-19, the present study investigated pregnancy outcomes in obese women who gave birth during the outbreak of the COVID-19 and before it. This study was conducted for the first time in Iran and can be considered in the field of health policy.

METHODS

Study Overview:

This descriptive-analytical study focused on obese women who gave birth and received care at Iran University of Medical Sciences from 2019 to 2021. Ethical approval (IR.IUMS.REC.1401.628) was obtained, and participants were informed. The sample included obese women with BMI above 30, identified from pre-pregnancy health files.

Sampling:

Purposive sampling through health care personnel identified eligible obese women. Health workers, trained for online questionnaires, contacted participants, and 444 women were sampled based on pilot study outcomes. The sample included 222 obese mothers pre-pandemic (2019) and 222 during the COVID-19 pandemic (2021).

Inclusion and Exclusion Criteria:

Inclusion criteria: obesity, non-smoker, second birth and later, uncomplicated previous pregnancies, exact gestational age (22-42 weeks), and no physical/ mental disorders. Exclusion criteria: unwillingness to participate and incomplete questionnaire responses.

Questionnaires:

Two questionnaires captured demographic data and pregnancy outcomes (vomiting, urinary infection, weight gain, gestational diabetes, preeclampsia, eclampsia, premature birth, cesarean section, small for gestational age (SGA), large for gestational age (LGA), postpartum bleeding).

Data Analysis:

SPSS and STATA software analyzed data. Descriptive statistics reported demographic and basic variables. T-test compared average BMI before and during the COVID-19 pandemic. Multinomial logistic regression assessed the impact of reduced pregnancy care on outcomes during the pandemic, and logistic regression examined the relationship between pregnancy outcomes during and before the pandemic.

RESULTS:

The age of most mothers in both groups before the outbreak of COVID-19 and during the period of it was between 18 and 35 years (81.07 and 70.72 percent), and most of them had an education below high school diploma. 98.20% in the the group of mothers before COVID19 and 97.30% in the mothers' group during the COVID-19 pandemic were housewives. The household income in both groups was almost the same, with most havinga medium income. Regarding the variable number of previous pregnancies, which was examined in 5 categories, the results showed that almost 50% of mothers had two previous pregnancies. The number of miscarriages in previous pregnancies also indicated that 18.80% of mothers in the group of mothers before covid-19 and 77.93% of mothers in the mothers' group during the covid-19 pandemic had no history of miscarriage. Regarding the consumption of vitamin D during pregnancy, 62.61% of mothers in the group of mothers before covid-19 and 69.82% in the mothers' group during the covid-19 were in the regular consumption category. The important variable in Table 1 is the number of routine pregnancy visits.

Table 1: Demographic and basic variables in the studied population

Variable	Class	Before the outbreak of COVID-19 pandemic		During the outbreak of COVID-19 pandemic	
		Frequency	Percentage	Frequency	Percentage
Mother's age during pregnancy	Under 18 years old	1	0.45	1	0.45
	18 to 35 years	180	81.8	157	70.72
	35 years and older	41	18.47	64	28.83
Education	High school	136	61.26	105	47.30
	Diploma	61	27.48	78	35.14
	University	25	11.26	39	17.75
Job	Housewife	218	98.20	216	97.30
	Employed	4	1.80	6	2.70
Family income	Low	86	38.74	78	35.14
	Medium	130	58.56	141	63.51
	High	6	2.70	3	1.35
Pregnancy number	1	1	0.45	3	1.35
	2	117	52.70	118	53.15
	3	71	31.98	69	31.08
	4	24	10.81	18	8.11
	More than 4	9	4.05	14	6.31
Number of miscarriages in previous pregnancies	0	178	80.18	173	77.93
	1	37	16.67	39	17.57
	2	7	3.15	10	4.50
Vitamin D intake during pregnancy	regular	139	62.61	155	69.82
	Irregular	51	22.97	53	23.87
	no	32	14.41	14	6.31
Number of routine pregnancy visits	Less than 4	16	7.21	24	10.81
	4 to 6	93	41.89	73	32.88
	6 to 8	113	50.90	125	56.31
Number		**222**	**100**	**222**	**100**

Half of the mothers received 6 to 8 visits . 41.89% of mothers in the group of mothers before covid-19 received 4 to 6 visits, while in the mothers' group during the COVID-19 pandemic,32.88% of mothers were in this category. It was also found that 7.21 and 10.81 percent of mothers in the two groups had received less than 4 prenatal visitsTable 2 reports the frequency of pregnancy outcomes before and during the outbreak of COVID-19 pandemic in the studied samples.

Table 2: Frequency of pregnancy outcomes before and during the outbreak of COVID-19 pandemic

Pregnancy outcome	Before the outbreak of COVID-19 pandemic			During the outbreak of COVID-19 pandemic		
	Frequency	Percentage	Standard error	Frequency	Percentage	Standard error
Pregnancy vomiting	56	21%	6.48	52	21%	6.32
Gestational diabetes	19	7%	4.17	21	8%	4.37
Increased blood pressure	12	5%	3.37	19	8%	4.17
Preeclampsia	3	1%	1.72	6	2%	2.42
Eclampsia	0	0%	0	2	1%	1.41
Hospitalization due to postpartum hemorrhage	1	0%	1	4	2%	1.98
Urinary infections	20	8%	4.27	22	9%	4.46
Natural childbirth	139	53%	7.22	102	41%	7.44
Preterm delivery	14	5%	3.62	21	8%	4.37

As can be seen in the above table, the frequency of all pregnancy outcomes during the outbreak of the COVID-19 pandemic have increased, the rate of natural childbirth has decreased, and cesarean section has increased, compared to before.Table 3 compares the average body mass index in the obese women who gave birth in the two groups, before and during the outbreak of COVID-19 pandemic.

Table 3: Average body mass index in obese women who gave birth in two groups

Group	Number of views	Average	Standard error	Standard deviation	95% confidence interval
The period before the outbreak of COVID-19 pandemic	222	32.95	0.21	3.19	33.37-32.53
The period of the outbreak of COVID-19 pandemic	222	33.12	0.23	3.43-57/	33-66/32
Combination of the two groups	444	33.03	0.15	3.31	34/33-72/32
Difference	0	-0.17	0.31		44/0-79/0-
Statistical characteristics		diff = mean(1) - mean(2)			t = -0.5469
		Ho: diff = 0		degrees of freedom =	442
		Ha: diff < 0	Ha: diff != 0		Ha: diff > 0
		Pr(T < t) = 0.2924	Pr(|T| > |t|) = 0.5847		Pr(T > t) = 0.7076

According to the results obtained from the independent t-test between the two groups, the average BMI in the two groups was 32.95 and 33.12, respectively, which indicates that this index is higher in women who got pregnant during the COVID-19 pandemic period, but considering the obtained statistics (Pr(T > t) = 0.7076 and t = -0.5469), this difference is not significant.In Table 4, the role of reducing the frequency of prenatal care on pregnancy outcomes is reported.

Table 4: Decreasing the frequency of pregnancy visits on the pregnancy outcomes

Pregnancy outcome	Period	Odds ratio	Standard error	Z	IP> I Z	Cl%95
Vomiting in pregnancy	The period before the outbreak of COVID-19 pandemic	1.23	0.3	0.86	0.39	0.1-76.98
	The period of the outbreak of COVID-19 pandemic	0.98	0.22	-0.08	0.93	0.1-62.55
Gestational diabetes	The period before the outbreak of COVID-19 pandemic	1.04	0.39	0.12	0.9	0.2-49.20
	The period of the outbreak of COVID-19 pandemic	2.13	0.65	2.46	0.01	1.3-16.09
Blood pressure	The period before the outbreak of COVID-19 pandemic	1.6	0.71	1.06	0.29	0.3-66.85
	The period of the outbreak of COVID-19 pandemic	0.95	0.34	-0.13	0.9	0.1-47.92
Preeclampsia	The period before the outbreak of COVID-19 pandemic	1.29	1.15	0.29	0.77	0.7-22.40
	The period of the outbreak of COVID-19 pandemic	1.75	0.95	1.03	0.3	0.5-6.12
Urinary infections	The period before the outbreak of COVID-19 pandemic	1.1	0.4	0.28	0.78	0.2-53.28
	The period of the outbreak of COVID-19 pandemic	0.6	0.23	-1.30	0.19	0.1-28.28
Hospitalization due to postpartum hemorrhage	The period before the outbreak of COVID-19 pandemic	2.67	3.88	0.68	0.49	0.46-15.25
	The period of the outbreak of COVID-19 pandemic	2.33	1.52	1.29	0.19	0.8-64.43
Weight gain during pregnancy	The period before the outbreak pregnancy	0.8	0.16	-1.04	0.29	0.1-53.21
	The period of the outbreak of COVID-19 pandemic	1.19	0.23	0.91	0.36	0.1-81.75
Type of delivery (caesarean section)	The period before the outbreak of COVID-19 pandemic	0.98	0.21	-0.06	0.95	0.1-63.52
	The period of the outbreak of COVID-19 pandemic	0.68	0.13	-1.88	0.06	0.1-45.08
Preterm delivery	The period before the outbreak of COVID-19 pandemic	1.75	0.72	1.36	0.17	0.3-78.95
	The period of the outbreak of COVID-19 pandemic	1.31	0.41	0.86	0.39	0.2-7.45
Weight gain of the baby at birth	The period before the outbreak	0.64	0.13	-2.05	0.04	0.0-42.98
	The period of the outbreak of COVID-19 pandemic	0.69	0.13	-1.91	0.05	0.1-47

As can be seen in the above table, the reduction in the number of routine pregnancy visits before the outbreak of COVID-19 pandemic led to an increase in pregnancy vomiting, gestational diabetes, increased blood pressure, increased pre-eclampsia, increased urinary infections, increased postpartum bleeding, and increased pre term delivery, but none of them were significant. In the group during the outbreak of COVID-19 pandemic, the decrease in the number of prenatal visits increased the chances of gestational diabetes, preeclampsia, postpartum hemorrhage, weight gain during pregnancy, and premature birth, butonly the increase in gestational diabetes was significant with p=01.In Table 5, the relationship between the COVID-19 infection and pregnancy outcomes has been investigated using the logistic test.

Table 5: Correlation between COVID-19 infection and pregnancy outcomes

Pregnancy outcome	Odds ratio	Standard error	Z	P>|z|	Cl%95
Vomiting in pregnancy	0.87	0.15	-0.79	0.42	0.1-61.21
Gestational diabetes	0.59	0.16	-1.89	0.05	0.1-34.02
Blood pressure	0.77	0.23	-0.87	0.38	0.1-42.38
Preeclampsia	0.32	0.21	-1.7	0.08	0.1-09.18
Urinary infections	1.14	0.28	0.56	0.57	0.7-1.87
Hospitalization due to postpartum hemorrhage	0.42	0.34	-1.06	0.29	0.2-08.01
Weight gain during pregnancy	0.97	0.13	-0.19	0.85	0.1-73.28
Type of delivery (caesarean section)	1.19	0.17	1.19	0.23	0.1-89.59
Preterm delivery	1.09	0.29	0.32	0.74	0.64-1.85
Weight gain of the baby at birth	0.74	0.1	-2.06	0.04	0.0-56.98

As can be seen in the above table, COVID-19 infection had no effect on pregnancy outcomes such as pregnancy vomiting, gestational diabetes, blood pressure, preeclampsia, postpartum bleeding and weight gain during pregnancy, but the chances of urinary infections and caesarean section increased. It also increased the chance of premature birth, although this increase is not significant.

DISCUSSION

Pregnancy outcomes in obese women during and before COVID-19 were studied, focusing on routine pregnancy visit frequencies. Results indicated an increase in the less than 4 and the 6 to 8 visits during the pandemic, with higher percentages before the outbreak for 4 to 8 visits.

All pregnancy outcomes saw an uptick during the COVID-19 period, with decreased natural childbirth and increased cesarean sections. COVID-19 impacted conditions like vomiting, gestational diabetes, blood pressure, and preeclampsia. No effects were observed on postpartum bleeding and weight gain, but chances of urinary infections, cesarean sections, and premature births increased, though not significantly.

Comparisons with Aj et al. and other studies supported increased hypertension and preeclampsia during the pandemic[12]. Similar prevalence rates and patterns were observed in relation to blood pressure levels. The rate of preeclampsia aligned with Wei et al.'s findings[13]. Cesarean section rates and increased premature deliveries during COVID-19 were consistent with Aj et al. and Saran et al[12, 14].

The average BMI before and during the pandemic indicated a slight increase, possibly linked to inactivity caused by social restrictions. Pourfarzi et al.'s report on obesity and diabetes doubling the probability of hospitalization during COVID-19 aligned with the findings[15].

A decrease in pregnancy visits from 6 to 8 to less than 4 during the pandemic led to increased adverse outcomes, although statistical significance wasn't reached. Limited cases with less than 4 visits may explain this absence.

Studies on pregnant teenagers' outcomes presented contradictory results, emphasizing the need for proper prenatal care[16]. Alexander et al.'s study in Carolina associated the number of care visits during pregnancy with favorable outcomes for both mothers and babies[17].

CONCLUSION

The results of this study showed that COVID-19 infection has no effect on pregnancy outcomes such as gestational vomiting, gestational diabetes, blood pressure, pre-eclampsia, postpartum bleeding, weight gain during pregnancy. But the chances of urinary infections, cesarean section and premature birth were increased, although this increase was not significant.

Of course, more investigations should be done on this group of mothers, taking into account more aspects such as place of residence, race, injection or non-injection of vaccine, type of vaccine, etc. Therefore, special attention should be paid to the identification of mothers with COVID-19 pandemic. These findings should serve as a guide for pregnant women and health care workers to strictly implement all recommended preventive measures for COVID-19, including vaccination.

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PARTOGRAPH UTILIZATION IS ASSOCIATED WITH EDUCATIONAL STATUS OF OBSTETRICS CARE GIVERS IN ILU ABA BOR ZONE, ETHIOPIA: A CROSS-SECTIONAL STUDY

Getamesay Aynalem Tesfaye[1], Fentaneh Teshome Chanie[2], Ebissa Negera Gemechu[3]

ABSTRACT

BACKGROUND: Worldwide, several thousands of mothers die every year due to pregnancy and birth related complications. Maternal deaths can be minimized by using partograph routinely. However, the level of utilization and associated factors among obstetrics care providers in Ilu Aba Bor Zone has not been studied.

OBJECTIVE: This study assessed the level of partograph utilization and its predictors among obstetric care givers working in public health institutions of Ilu Aba Bor Zone, South West Ethiopia.

METHODS: An institution-based cross-sectional study design was employed. A structured self-administered and pretested questionnaire adapted from available literature was used. In addition to descriptive statistics, logistic regression analysis was applied to assess association.

RESULTS: The level of partograph utilization among obstetrics care providers in the study area was 32.8%. Receiving on-the-job training on partograph (AOR (Adjusted Odds Ratio) = 2.21, 95%CI (Confidence Interval) = 1.19, 4.11), working in a hospital compared to working in a health center (AOR = 2.43, 95%CI = 1.01, 5.82), having BSc (Bachelor of Science) and above educational status in contrast to having Diploma (AOR = 3.12, 95%CI = 1.59, 6.12), and having partograph in a health facility (AOR= 4.19, 95%CI = 2.12, 8.29) were positively associated with partograph use.

CONCLUSIONS: Partograph utilization level was much lower than World Health Organization recommendation. On-job training on partograph, work place, educational status, and partograph availability were predictors of level of partograph utilization among the obstetric care givers.

KEY WORDS: Ethiopia, Ilu Aba Bor, maternal death, obstetrics care, partograph utilization

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INTRODUCTION

In 2015 globally, the annual number of maternal deaths was 303,000, while the approximate global lifetime risk of a maternal death was 1 in 180.[1] In the same year, approximately 99% (302,000) of the global maternal deaths occurred in developing countries, with sub-Saharan Africa alone accounting for roughly 66% (201,000) of maternal deaths. The 2016 Ethiopia Demographic and Health Survey estimated that maternal mortality ratio in Ethiopia is 412 deaths per 100,000 live births.[2]

Most maternal deaths are the direct result of complications arising during pregnancy, delivery, or the puerperium that includes hemorrhage, hypertensive disorders of pregnancy, sepsis, prolonged labor, and unsafe abortion.[3,4] If a woman with prolonged or obstructed labor does not get timely and effective management, she may die of uterine rupture or infection.

Partograph is one of the simplest tools employed to prevent maternal death by helping obstetrics health care providers identify slow progress in labor early, and initiate appropriate interventions to prevent prolonged and obstructed labor.[5,6] It can be highly effective in reducing complications from prolonged labor for the mother and for the new-born.[7-9]

Despite the invaluable and affordable significance of partograph in reducing maternal death, its utilization remains low in low - and middle - income countries.[10] A study conducted in Kenya revealed that less than half (45.5%) of nurses duly completed partograph training, while elsewhere in South Africa, four fifths (79.4%) routinely used partograph.[11,12] Similarly, studies in other parts of Africa showed that the use of partograph by health care providers is below World Health Organization (WHO) recommendation for its routine usage.[13-15] Even though Ethiopia has set the Sustainable Development Goal target of reducing maternal mortality to 199/100,000 in 2030,[16] the use of partograph to prevent maternal death is still low in various parts of the country.[17-19]

Different factors could hinder routine and proper utilization of partograph. For instance, a systematic review conducted in 2014 revealed that professional skills, clinical leadership and quality assurance, and the organizational environment within the wider provision of obstetric care were barriers to partograph use.[10] According to a cross sectional study in Nigeria, factors affecting utilization of partograph were little or no knowledge of the partograph, non-availability, shortage of staff, and the fact that it is time-consuming to use.[20] Getting on-the-job training, being knowledgeable on partograph, and having favorable attitude towards partograph were positively associated with partograph utilization in a study conducted in Central Ethiopia.[21]

Little has been known about partograph utilization and its determinants among obstetrics care providers working in public health institutions found in Ilu Aba Bor Zone, South West Ethiopia. Local health authorities pointed to maternal deaths as one of health problems of the study area. Hence, this study aimed at assessing the level of partograph utilization and associated factors among obstetric care givers in the study area. Eventually, this study will be substantial to reduce maternal mortality by encouraging partograph utilization among obstetrics care givers through tackling factors that hinder partograph utilization. This study will also provide base line information for managers and researchers.

METHOD

Study Area

The study was conducted in selected public health institutions in Ilu Aba Bor Zone, South West Ethiopia, with Mettu as its capital, situated 600 kilometers southwest of Addis Ababa. Ilu Aba Bor Zone spans an altitude of 1,500-2,000 meters above sea level, hosting 2 hospitals, 41 health centers, and 273 health posts, employing 840 health professionals, including 590 obstetrics care providers.

Study Design and Period

An institution-based cross-sectional study was conducted from July 1 to August 30, 2020.

Population

The source population was comprised of all obstetrics care givers in public health institutions of Ilu Aba Bor Zone. The study population included selected obstetrics care givers in randomly chosen public health institutions.

Eligibility Criteria

Included were 587 obstetrics care givers working in labor and delivery during regular duty hours. Excluded were 3 care givers on long-term leave or sick.

Sample Size Determination

Sample size was determined using a single proportion formula, based on a 40.2% partograph utilization rate in Central Ethiopia[21], a 95% confidence interval, and a 0.05 margin of error. The initial sample size of 369 was adjusted to 227 due to the small source population, and, after factoring in a 10% non-response rate, the final sample size became 250.

Sampling Technique

Twenty-seven health facilities (26 health centers and 1 hospital) were randomly selected from the 2 hospitals and 41 health centers in Ilu Aba Bor Zone. Sample size was allocated proportionally, and obstetric caregivers were randomly selected using a lottery method.

Operational Definitions

Educational Status: Diploma refers to a College Diploma, while BSc and above include Bachelor's, Master's, or Doctor of Philosophy degrees.

Public Health Institution: Government-operated health centers and hospitals.

Obstetric Caregivers: Health professionals overseeing labor follow-up and delivery services.[22]

Partograph Utilization: Routine use of partograph for all laboring mothers.[22]

Data Collection Procedure and Instruments

A self-administered questionnaire, validated with a Cronbach's alpha of 0.89, was adapted from existing literature.[23-25] It covered socio-demographic/professional characteristics and partograph utilization. Data collection involved three Health Officers supervised by two Master of Public Health professionals.

Data Quality Assurance

The questionnaire was translated into Afaan Oromo, pretested at Bilo Karo health center, and refined. Data collectors and supervisors underwent two days of training. Questionnaire completeness/clarity were ensured, and principal investigators visually checked for incompleteness.

Data Processing and Analysis

Data were coded, entered into EpiData 3.1, and analyzed using SPSS version 24. Descriptive and analytical statistics were employed. Bivariate logistic regression identified associations, with variables ($p<0.2$) considered for multivariate analysis. The Hosmer-Lemeshow goodness of fit test assessed model fitness. Odds Ratios with a 95% Confidence Interval measured associations, with significance set at $p=0.05$.

Ethical Considerations

Mettu University's Ethical Review Committee approved the study. Permission was obtained from Ilu Aba Bor Zone Health Department. Participants were informed of the study's purpose, procedures, risks, and benefits, with written consent obtained. Confidentiality was maintained by excluding personal identifiers, adhering to ethical standards per the 1964 Helsinki Declaration.

RESULTS

Socio-demographic and professional characteristics

Two hundred forty-one obstetrics care givers participated in the study, yielding a response rate of 96.4%. The mean age of the participants was 28.86 years (standard deviation= ±3.48 years). Most (56.8%) of obstetric care givers were female. Almost half (50.6%) of the obstetrics care givers had more than five years of service. According to respondents, almost all (94.6%) of them had attended less than 10 deliveries per day, and the majority (92.5%) of them said that there were less than four birth attendants per a working day (Table1).

Table 1: Socio-demographic and professional characteristics among obstetric care givers in Ilu Aba Bor Zone, southwest Ethiopia, 2020 (n = 241).

Variables	Category	Frequency	
		Number	Percent
Sex of respondent	Male	104	43.2
	Female	137	56.8
Educational status	Diploma	96	39.8
	BSc (Bachelor of Science) and above	145	60.2
Work place	Health center	207	85.9
	Hospital	34	14.1
Profession	Midwifery	89	36.9
	Other	152	63.1
Service year	<2	40	16.6
	2-5	79	32.8
	>5	122	50.6
Regularly working department	Delivery	35	14.5
	Other	206	85.5
Learned about partograph academically	No	32	13.3
	Yes	209	86.7
On-the-job training on partograph received	No	130	53.9
	Yes	111	46.1
Number of deliveries per day	<10	228	94.6
	≥10	13	5.4
Number of birth attendants per working day	<4	223	92.5
	≥4	18	7.5
Partograph available	No	106	44.0
	Yes	135	56.0

Utilization of partograph

Although 181 (75.1%) of all obstetric care givers used partograph in labor management, only 79 (32.8%) of all obstetric care givers used partograph routinely. Regarding recording labor activities information on partograph, 65.1%, obstetric care givers had recorded the information on partograph about cervical dilatation every 4 hours, 57.3% recorded fetal heart beat every 30 minutes, and 42.7% recorded maternal pulse rate every 30 minutes (Table 2)..

Table 2: Utilization of partograph among obstetric care givers in Ilu Aba Bor Zone, southwest Ethiopia, 2020 (n = 241).

Variables	Category	Frequency	
		Number	Percent
Use partograph in labor management	No	60	24.9
	Yes	181	75.1
Partograph use frequency	Routinely	79	32.8
	Sometimes	102	42.3
Uterine contraction plotted half hourly	No	68	28.2
	Yes	113	46.9
Initial cervical dilatation plotted	No	22	9.1
	Yes	159	66.0
Membrane intactness recorded	No	68	28.2
	Yes	113	46.9
Cervical dilatation plotted every 4hr	No	24	10.0
	Yes	157	65.1
Descent plotted every 4hr	No	68	28.2
	Yes	113	46.9
Fetal heart beat recorded every 30 min	No	43	17.8
	Yes	138	57.3
Color of liquor recorded	No	68	28.2
	Yes	113	46.9
Maternal blood pressure monitored every 4 hours	No	69	28.6
	Yes	112	46.5
Maternal pulse rate monitored every 30 minutes	No	78	32.4
	Yes	103	42.7
Action taken based on partograph	No	6	2.5
	Yes	175	72.6

Of the 60 obstetric care givers that do not use partograph, the top three reasons for not utilizing partograph were lack of partograph (56.7%), poor managerial support (45.0%), and absence of training of health professionals (33.3%) (Figure 1).

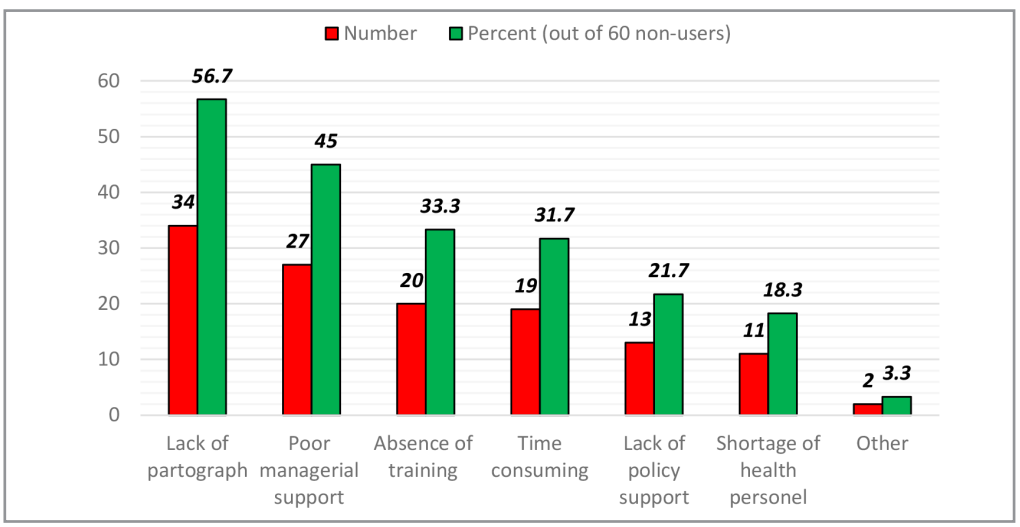

Fig 1: Reasons for not using partograph among obstetric care givers in Ilu Aba Bor Zone, southwest Ethiopia, 2020 (n= 60).

Factors associated with partograph utilization among obstetric caregivers

Using bivariate logistic regression analysis, the following ten variables were associated with partograph utilization: service year, on-job training on partograph, work place, educational status, regularly working department, profession, partograph availability, learning about partograph academically, number of deliveries per a day, and number of birth attendants per a day. However, only four variables (on-job training on partograph, work place, educational status, and partograph availability) were significantly associated with partograph utilization during multivariable analysis at p-value less than 0.05 with Hosmer and Lemeshow goodness of fit p=0.867 (Table 3).

Table 3: Multivariable analyses for factors associated with partograph utilization among obstetric care givers in Ilu Aba Bor Zone, southwest Ethiopia, 2020 (n = 241).

Variables	Category	Utilization of partograph		Adjusted odds ratio (95% CI)	P-value
		No	Yes		
On-job training on partograph received	No	100 (76.9%)	30 (23.1%)	1	0.012
	Yes	62 (55.9%)	49 (44.1%)	2.21(1.19-4.11)	
Work place	Health center	151(72.9%)	56 (27.1%)	1	0.047
	Hospital	11 (32.4%)	23 (67.6%)	2.43 (1.01-5.82)	
Educational status	Diploma	79 (82.3%)	17 (17.7%)	1	0.001
	BSc and above	83 (57.2%)	62 (42.8%)	3.12(1.59-6.12)	
Partograph available	No	90 (84.9%)	16 (15.1%)	1	<0.001
	Yes	72 (53.3%)	63 (46.7%)	4.19(2.12-8.29)	

This study found that those obstetric caregivers who received on-job training on partograph were almost two times more likely to use partograph compared to those who did not receive on-job training (Adjusted odds Ratio (AOR) = 2.21, 95% Confidence Interval (CI)= 1.19, 4.11). Obstetric care givers who were working in a hospital were more likely to use partograph than those who were working in a health center (AOR = 2.43, 95%CI = 1.01, 5.82), while having BSc and above educational status had tripled likelihood of using partograph in contrast to having Diploma educational status (AOR = 3.12, 95%CI = 1.59, 6.12). The study revealed that those participants who had partograph in their health facility were almost four times more likely to utilize partograph compared to those who had no partograph (AOR = 4.19, 95%CI = 2.12, 8.29).

DISCUSSION

This study involved obstetrics care givers working in selected public health institution of Ilu Aba Bor Zone to determine level of partograph utilization and associated factors. Eventually, it was found that only one third (32.8%) of participants were using partograph routinely as WHO recommendation, and on-job training on partograph, work place, educational status, and partograph availability were factors associated with partograph utilization. Although the effort is not enough, the government of Ethiopia is committed to reduce maternal mortality significantly by developing National Reproductive Health Strategy for the years 2016-2020, which identifies the routine use of partograph as one of the priorities.[26] Local health authorities have offered training on partograph use for some obstetric caregivers.

The level of partograph utilization routinely in this study is lower than those studies conducted in Tigray Region, Northern Ethiopia (73.3%),[23] and in the Eastern Province of Rwanda (41.22%).[27] The reason for higher partograph utilization in Tigray Region might be because of more participants with in service training about partograph. Similarly, more obstetrics caregivers in the study done in Eastern Province of Rwanda received training on partograph than this study, which obviously increase knowledge about partograph that in turn boost the tendency to use the chart. Moreover, difference in study area and population might be the reason for the discrepancy.

Lack of partograph, poor managerial support, absence of training of health professionals, being time consuming, lack of policy support, and shortage of health personnel were reasons for not utilizing partograph among obstetrics caregivers that were not utilizing the partograph. These reasons were in agreement with other studies conducted in Ethiopia and South Africa.[12,24,28]

This study revealed that those obstetric caregivers who received on-job training on partograph were almost two times more likely to use partograph compared to those who did not receive on-job training. This finding was in line with other studies conducted in the Ethiopia, Kenya and Rwanda.[11,21,27] The association between on-job training on partograph and use of partograph might be because training increase knowledge and attitude of participants about partograph that could in turn increase partograph use. On-job training enhances the competency and knowledge of obstetric caregivers in using partograph. This training likely covers the interpretation of various parameters on the partograph, enabling caregivers to make informed decisions during labor and delivery.

Obstetric care givers who were working in a hospital were more likely to use partograph than those who were working in a health center. This association was also observed in the study done in Hadiya Zone, Southern Ethiopia.[19] This could be because of the higher chance of access to information, infrastructures and training among obstetrics caregivers that work in hospitals, that are usually located in urban area, compared to participants who were working in a health center. Obstetric caregivers in hospitals may find it easier to access the necessary resources for employing partograph effectively. Moreover, the presence of skilled support staff in hospitals can positively influence the utilization of partograph.

Those obstetrics caregivers with BSc and above educational status were three times more likely to use partograph in contrast to those with Diploma educational status. This finding is in agreement with studies carried out in East Gojam Zone, Northern Ethiopia.[24] This association might be due to the fact that participants with BSc and above educational status have more comprehensive and elaborate knowledge about partograph compared to those with Diploma, and that will increase their possibility of using partograph. Individuals with tertiary education typically undergo comprehensive education, and are generally more aware of and inclined to adhere to established protocols and guidelines.

Furthermore, this study revealed that those participants who had partograph in their health facility were almost four times more likely to utilize partograph compared to those who had no partograph. The finding is in line with studies conducted in Ethiopia as well as in Nigeria.[20,29] This might be because a higher availability of partograph in the health facilities of obstetrics caregivers increases exposure and willingness of partograph use. When partograph is readily available in health facilities, obstetric caregivers can easily access them when needed. Due to the employment of cross-sectional study design, this study has weakness of not showing the temporal cause effect relationship between the partograph use and associated factors. Since self-administered questionnaires were used, there could be possibility of social desirability bias. Moreover, it would have been better to include obstetrics caregivers of private institutions in the study.

CONCLUSION AND RECOMMENDATIONS

This study found out that partograph utilization among obstetric care givers working in public health institutions found in Ilu Aba Bor Zone was very low. On-job training on partograph, work place, educational status, and partograph availability were factors associated with partograph utilization among the obstetric care givers. Therefore, the authors recommend concerned bodies to strive in order to achieve WHO recommendation of routine partograph use among obstetric care givers. Accordingly, efforts should be exerted to make partograph and infrastructures available in health facilities. Moreover, providing on-job training and academic development opportunity to obstetric care givers is anticipated to increase partograph utilization.

Abbreviations

AOR: Adjusted odds ratio; BSc: Bachelor of Science; **CI:** Confidence Interval; WHO; World Health Organization

DECLARATIONS

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Authors' contributions

G.A.T., F.T.C. and E.N.G. conceived the study, developed the tool, coordinated data collection, carried out the statistical analysis, and drafted the manuscript. All authors were involved in designing the study, data analysis and interpretation. All authors read and approved the final manuscript.

Consent for publication

Not applicable.

Availability of data and materials

All data generated or analyzed during this study are included in this article.

Competing interests

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PREVALENCE AND PREDICTORS OF OVARIAN HYPER STIMULATION SYNDROME AMONG WOMEN WHO HAD UNDERGONE CONTROLLED OVARIAN STIMULATION: A RETROSPECTIVE STUDY AT THE CENTER FOR FERTILITY AND REPRODUCTIVE MEDICINE, PUBLIC INVITRO FERTILIZATION CENTER, ETHIOPIA

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ABSTRACT

BACKGROUND: Infertility affects fifteen percent of couples who wish to conceive. The mainstay of artificial re-productive technologies is in vitro fertilization and embryo transfer (IVF-ET), in which aspirated oocytes are fertilized, followed by the trans cervical replacement of an embryo(s) into the uterine cavity. However, the practice of assisted reproductive technology is loaded with short- and long-term complications. Complications may occur during the course of stimulation, ovum pickup, or embryo transfer. Ample studies are done on in vitro fertilization, but the frequency and im-portance of complications of IVF in low-resource settings where the treatment itself is not widely available are not well known.

OBJECTIVE: This study aimed to determine the rate of ovarian hyper stimulation syndrome (OHSS) and asso-ciated factors among women who underwent controlled ovarian stimulation and IVF in a public IVF center in Ethiopia.

METHODOLOGY: A retrospective cohort study was conducted to review the medical records of women who have undergone ovarian stimulation and IVF treatment at the Saint Paul's Hospital Center for Repro-ductive Medicine and IVF.

RESULTS: A total of 428 clients had controlled ovarian stimulation and IVF. The mean age of the partici-pants was 33 years. Among 428 couples who had IVF, majority 245 (57%) had IVF for female fac-tor infertility, followed by male factor infertility 89 (20%), and unexplained causes 53 (12%).

The incidence of OHSS in our IVF population was 19 (4.4%) out of 428 women. Out of the 19 patients with OHSS, 17 (89%) developed mild and moderate symptons,and 2 out of 19 (10 %) had severe OHSS. The odds of developing OHSS was 6 times higher among those with PCOS, OR 5.78 CI (1.19, 28.22), p value of 0.03.

CONCLUSIONS AND RECOMMENDATIONS: The overall rate of ovarian hyper stimulation syndrome is higher in our IVF population. Emphasis should be given on thorough counseling and risk minimizing measures when women with PCOS undergo controlled ovarian stimulation.

KEY WORDS: IVF complications, fertility, reproductive-medicine, ovarian hyperstimulation syn-drome

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INTRODUCTION

Infertility impacts 15% of couples aspiring to conceive, with in vitro fertilization and embryo transfer (IVF-ET) being the primary artificial reproductive technologies. IVF's history spans over 50 years, marked by the first non-human mammal birth through IVF in 1959 and the first IVF-conceived baby in 1978. Initially designed for tubal factor infertility, IVF is now recommended for various infertility conditions, with male factor infertility being the most common indication.[1-3]

The evolution of IVF treatments has seen the development of controlled ovarian stimulation (COS) as a crucial element for successful assisted reproductive technology (ART) outcomes. Ovarian reserve markers, such as antral follicle count (AFC) and anti-Müllerian hormone (AMH), guide individualized stimulation strategies. Ultrasound-guided transvaginal route (US-TV) has become the gold standard for oocyte collection during IVF cycles since its introduction in 1983.[4-8]

Despite IVF's promising success rates, it comes with short and long-term medical complications. Ovarian hyperstimulation syndrome (OHSS) stands out as a serious complication, linked to hormonal and surgical aspects of the procedure. OHSS is theorized to result from vasoactive media-tors released due to ovarian hyperstimulation, leading to increased capillary permeability and fluid extravasation, causing hemoconcentration and related complications.[9, 10]

Women at higher risk of OHSS include those who are young, have polycystic ovary syndrome (PCOS), undergo profound hyperstimulation protocols, and have a large number of preovulato-rygraafian follicles. Studies show that the incidence of severe OHSS increases significantly with the number of oocytes retrieved, particularly exceeding 18. Reported OHSS incidence varies, ranging from 3.1% to 8% of IVF cycles, potentially reaching 20% in high-risk women.[11-13]

Experienced IVF centers adopt strategies like antagonist protocols with agonist triggers and elective cryopreservation of embryos to mitigate OHSS risk. However, in settings lacking widespread access to agonist triggers and facing logistical challenges with cryopreservation, the risk of OHSS remains high. Our study aims to fill this gap by assessing the incidence and predictors of OHSS in our specific setting, providing valuable insights for reproductive health practitioners and research-ers.

METHOD AND MATERIALS

This study was conducted at the Center for Reproductive Medicine and IVF Center, St. Paul's Hospital Millennium Medical College, the first public IVF center in Ethiopia, inaugurated in February 2011. The research involved a retrospective review of medical records for couples undergo-ing IVF treatment. Inclusion criteria comprised women who underwent controlled ovarian stimu-lation and ovum pickup. The primary outcome was the development of ovarian hyperstimulation syndrome (OHSS), assessed clinically through symptoms such as abdominal pain, distension, nau-sea, and ultrasound evidence of peritoneal fluid collection. Severity levels (mild, moderate, or se-vere) were determined by physicians and documented in patient charts. Baseline characteristics, including age, antral follicle count (AFC), body mass index (BMI), anti-Mullerian hormone (AMH) level, day 3 follicle-stimulating hormone (FSH), ovarian stimulation protocol, and presence of ovulatory disorders, were also evaluated.

IVF Treatment Practice of the Center

The center employed three ovarian stimulation protocols: long, antagonist (flexible), and mild stimulation, based on patient ovarian reserve and age. The long protocol involved zoladex injection on the 21st day, followed by gonadotrophin injections. Monitoring was conducted via transvaginal ultrasound. Mild stimulation used oral ovulation induction drugs like letrozole, followed by low-dose gonadotrophin and the antagonist cetrotide. The antagonist protocol, reserved for low ovarian reserve or advanced age, initiated

gonadotrophin stimulation and GnRH antagonist when the leading follicle reached 14 mm. Common strategies to prevent OHSS included coasting, reducing HCG trigger dose, and freezing all embryos.

Treatment of OHSS

Patients with anticipated OHSS received cabergoline. Management for mild cases involved outpa-tient care with oral hydration and follow-up tests, while moderate-to-severe cases required IV hy-dration, peritoneal tapping, and thromboprophylaxis. Vital signs and laboratory tests were regu-larly monitored.

Dependent and Independent Variables

The dependent variable was the development of OHSS, dichotomized as "yes" or "no." Independent variables included age, AFC, BMI, AMH, Day 3 FSH, ovarian stimulation protocol and ovula-tory disorders (PCOS).

Inclusion criteria: Women who had undergone controlled ovarian stimulation, ovumpickp and embryo transfer

Exclusion criteria: Women with cancelled cycles due to poor response

Sample Size Determination

The sample size, determined using a single population proportion formula, by taking P= 50 %. (The anticipated rate of complications of IVF and controlled ovarian stimulation was 422, with a 95% confidence interval, 5% margin of error, and 10% non-response rate.

Sampling Technique and Data Collection

Simple random sampling was employed. Every 4th case((1600÷422) was selected from the registra-tion book. Data were collected using Open Data Kit (ODK) with structured questionnaires, re-trieving information from patient charts, electronic medical records (EMR), and registration logs. Ethical clearance was obtained from the Institutional Board Review of St. Paul's Hospital Millen-nium Medical College. In order to maintain patients' confidentiality, data from patients' charts was abstracted anonymously.

Data Analysis

Data were processed using Stata Statistical Software. Univariate analyses employed proportions and means or medians. The rate of major complications was computed, and associations between OHSS and variables were assessed using Fisher's exact test, independent t-test, or bivariate logistic regression. A significance level of 0.05 was applied.

RESULTS

A total of 428 women who had undergone controlled ovarian stimulation and IVF were included in the analysis. As outlined in Table 1, of the 428 cases, 327 (80%) had primary infertility, with a female factor being the cause in 245 (57%), a male factor in 89 (20%), and an unexplained factor in 53 (12%). Among the 245 cases with female factors infertility, 211 (87%) of them were diag-nosed with tubal factors, and 31 (13%) were diagnosed with ovulatory dysfunction.

Obstructive azoospermia was the leading cause among male factor infertility (62/89, 70%) fol-lowed by oligospermia and asthenospermia.PCOS was the most common underlying endocrino-logic abnormality, identified in 39 out of 428 women (9%).

Day 3 FSH was done for 55% (233 out of 428) of the cases, the mean being 7.3.Among those who had AMH, 89 out of 428 (20% of cases) the mean AMH level was 1.6 with ± SD 1.9. Antral folli-cle count was done for nearly 100% the cases. The mean AFC was found to be 10 with± SD of 7.

Table 1: Characteristics of women and fertility profiles of couples who have undergone COS and IVF, at CFRM, SPHMMC, Addis Ababa Ethiopia

Variables	No.	%
Age		
20–24 years	14	3.3
25–29 years	100	23.4
30–34 years	142	33.2
35–39 years	142	33.2
≥40 years	30	7
BMI category		
Underweight	5	6.9
Normal Weight	40	55.6
Overweight	21	29.2
Obesity	6	8.3
Type of infertility		
Primary	327	76.4
Secondary	101	23.6
Cause of Infertility		
Female factor	245	57.2
Male factor	89	20.8
Both	41	9.6
Unexplained	53	12.4
Female factor cause		
Tubal	211	86.1
Ovulatory	31	12.7
Uterine	3	1.2
Male factor cause		
Oligospermia	15	16.9
Asthenospermia	12	13.5
Obstructive Azoospermia	62	69.7
Endocrinology abnormality		
None	381	89.0
PCOS	39	9.1
Hypothyroidism	6	1.4

Table 2: Controlled ovarian hyperstimulation and IVF treatment outcomes of women who have undergone COS and IVF, at CFRM, SPHMMC, Addis Ababa Ethiopia

Variables	No.	%
Type of protocol		
Long agonist	148	34.6
Antagonist	17	4
Ministim	263	61.4
Embryo transfer done		
No58	13.6	
Yes	370	86.4
Stage of transferred embryo		
Day 3	296	80
Day 5	74	20
Level of Physician who have done ET		
2nd Year Fellow	43	11.6
Subspecialist	327	88.4
Pregnancy test		
Negative	306	72.5
Positive	116	27.5

Among the 428 cases, the majority (263, or 61%) of them had minimal stimulation, followed by long agonists (148, or 34%). Among those who had stimulation and ovum pickup, 370 (86%) of them had embryo transfers, with 80% (296/370) day 3 transfers and 20 % (74/370) day 5 transfers. The rest (3.5%) had no oocyte retrieved (15), 37 (8.6%) failed fertilization of retrieved oocytes, and 6 (1.5%) postponed embryo transfer (freeze all).

As noted in Table 3, of the total 428 women who have undergone COH, 4.4% (19) of them de-veloped ovarian hyperstimulation syndrome. The majority were mild or moderate (47% (9/19) and 8 out of 19 (42%), respectively), and the rest (10%) were severe. Most of them had early onset, detected before the OPU and embryo transfer (14 or74%); the rest (5 or 26%), detected pregnan-cy tests confirmed to be positive. Of those who developed OHSS, 11 (58%) of them were man-aged as outpatients, and 8 (42%) were managed as inpatients.

Table 3: Rate of ovarian hyperstimulation syndrome of women who have undergone COS and IVF, at CFRM, SPHMMC, Addis Ababa Ethiopia

Complications	No.	%
Ovarian Hyperstimulation Syndrome		
No	409	95.6
Yes	19	4.4
Severity of OHSS		
Mild	9	47.4
Moderate	8	42.1
Severe	2	10.5
Time of onset of OHSS		
Before OPU	1	5.3
Before ET	13	68.4
After positive pregnancy	5	26.3
Place of management of OHSS		
Outpatient	11	57.9
Inpatient	8	42.1
Presence of pleural effusion		
No	16	84.2
Yes	3	15.7

The median age of women with OHSS was 29 years, versus 33 for those without OHSS. Upon bivariate analysis, a statistically significant association was found between the age of the women and the rate of OHSS. The median AFC was 20 for those with OHSS and 8 for the group with no OHSS. The median number of mature follicles was 27 for the group with OHSS and 5 for the group with no OHSS. The median number of oocytes retrieved was 18 and 5 for the groups with OHSS and no OHSS, respectively. A higher dose of gonadotrophins was used in those with OHSS, the median being 225 IU versus 150 IU in those with no OHSS. As an outcome of bivari-ate analysis, there was also a statistically significant association between the baseline AFC, the numbers of mature follicles at the time of trigger, the number of oocytes retrieved, and the rate of OHSS. Women who had an underlying endocrinology abnormality of PCOS were found to have a statistically significant higher rate of OHSS. Long agonist stimulation protocols resulted in a higher rate of OHSS (95% of OHSS cases were stimulated with a long agonist protocol) (Tables 4 and 5)

Table 4: Bivarate analysis of factors determining the rate of OHSS at the CFRM, SPHMMC, Ad-dis Ababa, Ethiopia

Variables/ Factors	Ovarian Hyper stimulation		p-value*
	No (n=409)	Yes (n=19)	
Age in Years, median (IQR)**	33.0(29.0,36.0)	29.0 (27.0, 32.0)	<0.001
Day 3 FSH, median (IQR)	6.3 (4.2, 8.8)	5.4 (3.8, 7.2)	0.25
AFC, median (IQR)	8.0 (4.0, 12.0)	20.0 (16.0, 29.0)	<0.001
Dose of Gonadotropins per day(in IU/day), median (IQR)	150.0(150.0, 225.0)	225.0 (225.0,300.0)	0.002
Total No of mature follicles>13mm in diameter , median (IQR)	5.0 (3.0, 9.0)	27.0 (14.0, 37.0)	<0.001

P-values were calculated based on non-parametric test of difference of medians (Mann Whitney U test).**IQR=Inter quartile range

Table 5: Bivarate analysis of factors determining the rate of OHSS at CFRM, SPHMMC, Adddis Ababa, Ethiopia

Variables	Ovarian Hyper stimulation		p-value*
	No (n=409)	Yes (n=19)	
Age			
20–24 years	14 (3.4%)	0 (0.0%)	0.006
25–29 years	90 (22.0%)	10 (52.6%)	
30–34 years	134 (32.8%)	8 (42.1%)	
35–39 years	141 (34.5%)	1 (5.3%)	
≥40 years	30 (7.3%)	0 (0.0%)	
Day 3 FSH			
<=7 IU/L	137 (62.6%)	10 (71.4%)	0.58
>7 IU/L	82 (37.4%)	4 (28.6%)	
AFC			
<15	335 (82.1%)	3 (15.8%)	<0.001
>=15	73 (17.9%)	16 (84.2%)	
Total No of mature follicles>13mm			
<=18	384 (93.9%)	8 (42.1%)	<0.001
>18	25 (6.1%)	11 (57.9%)	
Serum Pregnancy test			
Negative	299 (73.3%)	7 (50.0%)	0.069
Positive	109 (26.7%)	7 (50.0%)	
Cause of Infertility			
Female factor	235 (57.5%)	10 (52.6%)	0.098
Male factor	87 (21.3%)	2 (10.5%)	
Both	36 (8.8%)	5 (26.3%)	
Unexplained	51 (12.5%)	2 (10.5%)	
Type of protocol			
Long agonist	130 (31.8%)	18 (94.7%)	<0.001
Antagonist	17 (4.2%)	0 (0.0%)	
Ministim	262 (64.1%)	1 (5.3%)	
PCOS			
No	383 (93.6%)	6 (31.6%)	<0.001
Yes	26 (6.4%)	13 (68.4%)	

Percentages are calculated from the column total, *P-values were calculated using Fisher's exact test

Table 6: Multivaratelogistic Regression: factors determining the rate ofOHSSat the CFRM, SPHMMC, Addis Ababa, Ethiopia

Factors	Ovarian Hyper Stimulation Syndrome		AOR	P-value	95%	CI
	No (n=409)	Yes (n=19)				
AFC						
<15	335 (82.1%)	3 (15.8%)				
>=15	73 (17.9%)	16 (84.2%)	6.30	0.06	0.93	42.82
Total no of mature follicles>13mm						
<=18	384 (93.9%)	8 (42.1%)				
>18	25 (6.1%)	11 (57.9%)	1.92	0.39	0.44	8.37
PCOS						
No	383 (93.6%)	6 (31.6%)				
Yes	26 (6.4%)	13 (68.4%)	5.78	0.03	1.19	28.22

On multivariate logistic regression analysis having PCOS was independent predictors of the rate of OHSS,the odds of developing OHSS was 6 times more like among those with PCOS, OR 5.78 CI(1.19,28.22), p value of 0.03.

DISCUSSION

The overall rate of OHSS in our study was found to be 4.4%., 9 (2.1%) cases were mild, 8 (1.8%) were moderate, and 2 (0.5%) were severe.

The reported prevalence of the severe form of OHSS varies widely. A rate ranging from 0.5 to 5% has been reported for severe OHSS[12]. A study done in 2005 using data from the Finnish registry reported an incidence of severe OHSS of 1.4% per cycle, with an individual risk per pa-tient of 2.3% over a mean number of 3.3 cycles[14].

In a study that assessed the incidence of OHSS among women undergoing fresh in vitro fertilization (IVF) cycles between 2000 and 2004, among high-risk women (with peak serum estradiol levels >2500 pg/mL and presumed to be at risk for OHSS), the overall incidence was 20.2% (38 out of 188) and the incidence in the whole IVF population was 38 out of 1002 (3.8%).[13]

The moderate and severe forms may occur in 3% to 10% of all ART cycles, and the incidence may reach 20% among high-risk women.[15]

The rate of OHSS in our study population is 4.4%, which is in the reported range of the general IVF populations of other studies, but lower than the high-risk population OHSS rate, which is ex-plained by the fact that our study population included all groups of patients with respect to the risk category.

Baseline ovarian reserve tests as a predictor of ovarian response and risk of OHSS have been studied. Prediction of in vitro fertilization outcome at different antral follicle count thresholds in a prospective cohort of 1,012 women revealed antral follicle count was predictive of ovarian re-sponse, with the risk of moderate or severe OHSS. 2.2% with an AFC of less than or equal to 24; the risk increased to 8.6% at an AFC of more than 24.[16]

In a study by Kwee et al., an antral follicle count (AFC) > 14 had the highest sensitivity (82%), specificity (89%), and positive predictive value for ovarian hyper-response.[17]

Basal anti-Müllerian hormone (AMH) levels prior to COS have also been shown to be predictive for OHSS. A systematic review and meta-analysis of the existing literature were performed. Nine studies reporting on AMH and five reporting on AFC were found, with the accuracy of AMH in excessive response prediction having a sensitivity of 82% and specificity of 76%. The clinical value of basal levels of FSH and AMH as well as antral follicle count (AFC) as a predictor of ovarian re-sponse for ovulation induction and IVF has been studied,

and it has been found that AMH has the ability to predict excessive response independent of age and PCOS. Basal AMH levels ~ ≥3.5 ng/mL were predictive of hyper-response or OHSS with high sensitivity and specificity.[18-20]

There is a significant and consistent relationship between PCO and OHSS. In a systematic review of ten studies done to assess and quantify the relationship between polycystic ovaries (PCOs) and ovarian hyperstimulation syndrome (OHSS), when PCOs were present, the combined odds ratio for OHSS was found to be 6.8 (95% confidence interval 4.9–96).[21]

In a study done to evaluate if gonadotropin-releasing hormone agonist (GnRHa) trigger is a better alternative to human chorionic gonadotropin (hCG) in polycystic ovary syndrome (PCOS) of Indian origin undergoing in vitro fertilization, (IVF) cycles with GnRH antagonist for the prevention of ovarian hyper stimulation syndrome (OHSS), the incidence of moderate to severe OHSS in the hCG group was found to be as high as 37.6%.[22]

Similarly, our study findings identified PCOS as an independent predictor of the rate of OHSS. The odds of developing OHSS were six times higher among those with PCOS, OR 5.78 CI (1.19, 28.22), p value of 0.03. The other baseline reserve tests, including age and AFC > 15, which were found to have significant associations upon bivariate analysis, were not found to be independent predictors upon logistic regression. The possible explanation for the loss of association is the smaller sample size (evidenced by a wider CI).

In a study that analyzed data from 256,381 IVF cycles using the 2008–2010 Society for Assisted Reproductive Technology national registry, retrieval of >15 oocytes significantly increased OHSS risk [23].

In another study, which was done to determine the incidence of ovarian hyper stimula-tion syndrome (OHSS) in a large series of GnRH antagonist-stimulated cycles and to assess the predictive value of E2 and the number of follicles on the day of hCG administration, 53 patients were hospitalized because of OHSS (2.1%; 95% confidence interval [CI]: 1.6–2.8). The combina-tion of a threshold of more than or equal to 18 follicles and/or an E2 of ≥5,000 ng/L yields an 83% sensitivity rate with a specificity as high as 84% for severe OHSS cases.[23].

Numerous study findings have shown the number of follicles at oocyte aspiration, the number of aspirated oocytes, and the total number of medium- or large-sized follicles before hCG as independent predictors of OHSS.

In a recent retrospective analysis of all consecutive IVF/intracytoplasmic injection cycles per-formed during a 5-year period (2009–2014) in a single university fertility center, the number of follicles ≥10 mm on the day of triggering final oocyte maturation represented the best predictor of severe OHSS in IVF cycles.[24-26]

The lack of association between the well-known risk factors, high doses of gonadotropins, high or large numbers of large and medium-sized follicles, and large numbers of eggs retrieved, in our logistic regression is again explained by the smaller sample size, as evidenced by the wide CI.

CONCLUSION AND RECOMMENDATION

The overall rate of ovarian hyperstimulation syndrome is higher in our IVF population. PCOS, an endocrinology disorder, has been found to be an independent predictor of the risk of OHSS. It is important to stick to OHSS risk-reducing strategies, including using antagonist protocols and possible agonist triggers, followed by freeze all, especially in patients with PCOS. In order to iden-tify the other important determinant factors for the complications of ovulation induction and IVF, studies with a larger sample size and a possible multicenter (including private) setup should be conducted.

LIMITATIONS OF THE STUDY

Some important baseline characteristics were omitted from analysis (BMI, cause of infertility) due to incomplete data from the electronic medical records. On the basis of logistic regression analysis, the finding of a wide range for the CI indicates that

a much larger sample size is needed to identi-fy the determinant factors of complications.

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PROFILE OF GYNECOLOLGIC CANCERS AT A TERTIARY HOSPITAL ADDIS ABABA, ETHIOPIA, A 4 YEARS REVIEW

Malede Birara[1], Tadesse Urgie, Abraham Fessehaye Sium

ABSTRACT

BACKGROUND: Gynecologic cancers are related of to morbidity and mortality among women globally. The trend and incidence, however, varies according to different geographical settings and demographic differences. The main aim this study was to review the profile of gynecologic cancers managed at a Saint Paul Hospital Millennium Medical College, in Addis Ababa, Ethiopia.

METHODS: A retrospective chart review was done for all patients managed at the hospital from 2016 to 2020. The relevant information was retrieved from patient charts and pathology reports; the data was entered and analyzed using SPSS software version 24.

RESULT: A total of 768 Gynecologic cancer cases were seen at the hospital and 700 of them were analyzed, the rest were excluded because of chart incompleteness. The most common primary tumor origin was cervix 339 (48.35%) followed by ovarian 194 (27.67%), gestational trophoblastic malignancies (GTN) 90 (12.8%), uterine 46(6.56%), and vulvar 29(4.1%). Most patients with cervical cancer present in a late stage. Only 37.5 % were early stage and surgically operable and the median age was 46 years. The majority of ovarian cancer patients present at advanced stage.

CONCLUSION: Cervical cancer emerged as the most common gynecologic cancer in women requiring admission, constituting a substantial cause of cancer-related morbidity. Despite being largely preventable through effective screening programs, cervical cancer remains insufficiently addressed. Awareness creation for people from rural area is essential so that early health seeking behavior will be established.

KEY WORDS: Cervical cancer, gynecologic cancer, Ethiopia

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INTRODUCTION

Gynecological malignancies are those involving the genital tract and include cancers of the ovary, cervix, uterus, vulva, vagina and gestational trophoblastic neoplasia (GTN). These are the second most common cancer of females after breast cancer, accounting for about 17% of all new malignancies in women[1].The burden of gynecological cancers in developing countries appears large, at approximately 25 percent of all cancers, compared to 16 percent in developed countries. Gynecologic cancers continue to be a serious public health problem as an important cause of cancer related mortality in women[2, 3]

Globally, cervical cancer is the most common gynecologic cancer, accounting for 6.9% of all women's cancer and 41% of female genital tract malignancy, followed by ovarian and uterine corpus[4]. The proportion of cervical cancer is even much higher in low income countries which account for 80% of new gynecologic cancers. And this is despite cervical cancer being largely preventable. This prevention is challenging due to the absence of effective nationally organized screening and vaccination programs in developing countries. But in high income countries, uterine corpus and ovarian cancer are the most common cancers of female genital tract[5].

Globally, cervical cancer constituted 487,300 new cases and 269,500 new deaths; uterine cancer had 233,300 new cases and 61,400 new deaths; ovarian cancer was 230,00 new cases and 140,100 new deaths. Many patients are unable to access complete preventive, diagnostic and therapeutic services due to inadequate health care financing. There is an increasing trend in the incidence of gynecological cancer over the past three decades[3, 4]

Studies from African countries like Nigeria, Ghana, and Mozambique reported cervical cancer as the most common gynecologic cancer followed by ovarian cancer and uterine cancers[6, 7] In Ethiopia, data from Tikur Anbessa Specialized Hospital oncology center and Gondar university hospital showed genital cancers are the most common cancers in females, followed by breast cancer., Cervical cancer was the most common gynecologic cancer [8-10].

The pattern of gynecological malignancies and associated risk factors varies across geographic areas and population demographics. However, in Ethiopia, the lack of a cancer registry makes it challenging to obtain accurate data. Currently, hospital-based data remains the primary method for estimating the burden of this health issue. Notably, only one study has been conducted in southern Ethiopia, focusing on patients referred for medical oncology treatment. Unfortunately, this study may not accurately reflect the actual pattern of gynecological malignancies.

To address this gap, our study aims to include all gynecologic oncology cases treated at Saint Paul Hospital Millennium Medical College (SPHMMC) for both surgical and medical purposes. The evidence generated from this comprehensive approach will contribute valuable insights into disease patterns and risk factors. The primary objective of this review is to assess the profile of different gynecologic cancers at SPHMMC, a tertiary-level center where many cases are referred.

METHODS AND MATERIALS:

This hospital-based retrospective study covers the period from September 2016 to August 2020. We reviewed the charts of all patients with gynecologic malignancies registered at SPHMMC during this timeframe, ensuring availability of case notes in the hospital registration archive. Patients with incomplete information and those with benign tumors were excluded from the study. The inclusion criteria focused on admitted patients with gynecological malignancies diagnosed pathologically, excluding GTN. Data collected included information on ages, clinical presentations, physical examinations, investigations, necessary surgical procedures, staging (clinical, surgical, or histopathological), and the final histological type of cancer. Confirmation of diagnosis relied on

histopathology of samples obtained during surgery or, in the case of GTN, on either beta HCG levels or histopathology. Data were entered and analyzed using SPSS version 24, with descriptive statistics such as frequencies, percentages, means, medians, and standard deviations utilized to characterize the data.

RESULT

A total of 768 new cases of gynecologic malignancies were reported and treated at St. Paul's Hospital Millennium Medical College gynecologic oncology unit between January 2016 and December 2020. For the current study, 67 patient charts were excluded because of incomplete histologic findings or lack of major variables that were important to characterize the patient profile.

The age of 701 cases ranges from 13 to 83 with a mean age of 46.28 years with SD+ 13.4. The median age for cervical cancer was 50 years and for ovarian cancer 45 years. About two-third (67.1%) of gynecological cancers occurred in women older than 40. 53.8 % of patients were of reproductive age, while 45.6% were post- menopausal. Only 0.5% were premenarchal girls.

Half of the women had up to four children, while 11 % were nulliparous. The majority of care seekers were from outside of the capital city Addis Ababa (58.6%). (Table 1).

Table 1: Socio-demographic and obstetric characteristics of gynecologic cancer patients at St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia: September 2016 and August 2020

Demographic Variables n=701	Category	Type of Gynecologic malignancy: Cervix	Ovary	GTN	Uterus	Vulva	FT	Vagina	Frequency (%)
Age	<20)	1	9	3	0	0	0	0	13 (1.9)
	20-29	2	23	42	0	1	1	1	69 (9.8)
	30-39	59	36	33	8	13	0	0	149(21.3)
	40-49	77	46	12	6	8	0	0	150(21.4)
	50-59	120	39	0	10	4	0	1	173(24.7)
	>60	80	41	0	22	3	1	0	147(21.0)
	Sum	339	194	90	46	29	2	1	701(100)
Address	Addis Ababa	117	93	40	21	18	0	1	290 (41.4)
	Out of Addis Ababa	222	101	50	25	11	2	0	411(58.6)
	Sum	339	194	90	46	29	2	1	701(100)
Parity	0	7	46	21	7	7	1	0	89 (12.7)
	1-4	147	100	57	26	18	1	1	350(49.9)
	5-9	148	41	11	10	2	0	0	212(30.2)
	10-15	37	7	1	3	2	0	0	50(7.1)

Vaginal bleeding, abdominal pain, weight loss, and abdominal distension were most common symptoms reported by 65%, 54.5%, 45.1 and 26.5% of patients, respectively. Vaginal bleeding and abdominal pain were the most common symptoms for cervical cancer and uterine tumors. Weight loss and abdominal distension were the most common for ovarian cancer.

Almost all patients (97.9%) had ultrasound imaging for diagnostic work up. However, less than a quarter of patients had further imaging, either with CT scan (19.8%) or MRI (23. 5%). Abdominopelvic mass (57.8%), ascites (19.4%), hydronephrosis (5.4%) and pleural effusion (3.6%) were the imaging findings reported most often.

The most common primary tumor origin was cervix 339 (48.35%), followed by ovarian 194 (27.67%), GTN 90 (12.8%), uterine 46(6.56%), and vulvar 29 (4.1%). Fallopian tube and vaginal malignancies were rare, contributing to less than 0.5 % of the cases.

Squamous cell carcinoma was the most common histologic type among cervix and vulvar malignancies, at 91.4% and 89.7% respectively. Only 9 out of 339 (2.7 %) of patients with cervical cancer had a history of screening for cervical cancer. Out of 166 patients with cervical cancer whose sero status was known, 35 (21.1%) were positive for HIV.

Epithelial histology was most common among ovarian malignancies (81.4%), followed by sex cord stromal (11.9%) and germ cell types (6.7%). Endometroid and serous histology were the most prevalent type among endometrial cancer, accounting for 51.5 and 30.3%, respectively. (Table 2)

Table 2: Organ of origin and Histologic pattern of common gynecologic malignancy at St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia: September 2016 and August 2020

Organ of origin	Histologic type	Number (%)
Cervix	Squamous cell carcinoma	310(91.4)
	Adenocarcinoma	23(6.8)
	Others	6(1.8)
	TOTAL	**339 (48.35) ***
Ovary	**Epithelial**	**158(81.4%)**
	Serous	100 (63.3)
	Mucinous	25(15.8)
	Endometroid	6 (3.8)
	Clear cell	3(1.9)
	Boarderline	7(4.4)
	Others	17(10.8)
	Sex cord	23(11.9%)
	Granulosa cell	19 (82.6)
	Other	4(17.4)
	Germ cell	13(6.7%)
	Dysgerminoma	8 (61.5)
	Yolk sac	4(30.7)
	Immature teratoma	1(7.7)
	TOTAL	**194 (27.67)***
Uterine body	**Endometrial carcinoma**	**33(71.7%)**
	Endometroid	17(51.5)
	Serous	10(30.3)
	Carcinosarcoma	2(6)
	others	4(12.1)
	Uterine sarcoma	**13(28.3%)**
	leiomyosarcoma	10(77)
	Endometrial stromal sarcoma	3(23)
	TOTAL	**46(6.6%)***
Vulva	Squamous cell carcinoma	26(89.7%)
	Basal cell carcinoma	2(6.9%)
	Adenocarcinoma	1(3.4%)
	TOTAL	**29(4.1)***
GTN	Unknown	64 (71.1%)
	Invasive mole	17(18.9%)
	Choriocarcinoma	9 (10%)
	TOTAL	90(12.8%)

Key * % from all types of Cancer

GTN was the third most common gynecologic malignancy, accounting for 12.8% of cases. 64 cases (71.1%) had no histologic diagnosis while invasive mole and choriocarcinoma accounted for 18.9% and 10%, respectively. Similarly, 71.1% of the cases were low risk with WHO prognostic score of less than seven, while 24.4% and 4.4% of the cases were high risk and ultrahigh risk, respectively.

Over all, most patients presented with advanced malignancy; only 34 % were diagnosed at stage I, while the remaining 66% had either local, regional or distant metastasis. (Fig1)

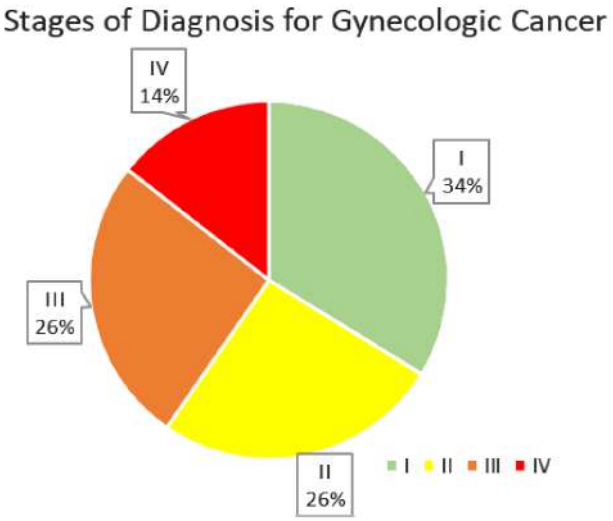

Fig 1: Stages at diagnosis for gynecologic malignancy at St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia: September 2016 and August 2020

The most common histologic type of cervical cancer was squamous cell carcinoma; the majority (70%) of them presented with stage I and II. However only 37.5 % of them were in early operable stage, which is below stage IIA and surgically operable and managed by primary radical hysterectomy and pelvic lymph node dissection. Those in stage IIB were given Neoadjuvant chemotherapy, followed by surgery. 30% of cervical cancer patients were in advanced stage and referred for chemotherapy or radiation. (Fig 2)

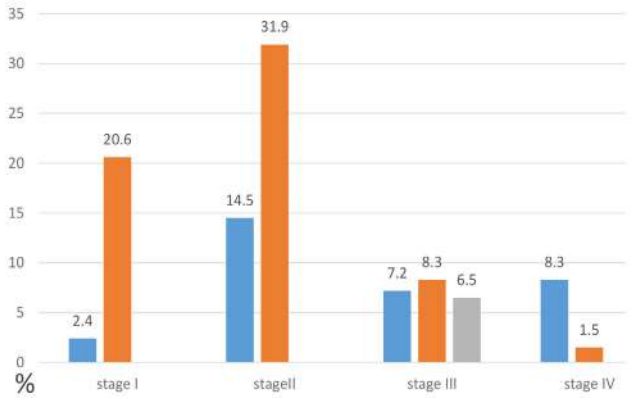

Fig 2: Stages at diagnosis for cervical cancer at St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia: September 2016 and August 2020

The stage at diagnosis of patients with ovarian cancer differed with the histologic type. Only 23.4% of epithelial histology was diagnosed at stage 1. However, 65.2 % and 61.5% of patients with sex cord stromal tumor and germ cell types were diagnosed at stage I, respectively. Overall, only 30.9% of ovarian cancer was diagnosed at stage I. (Fig3)

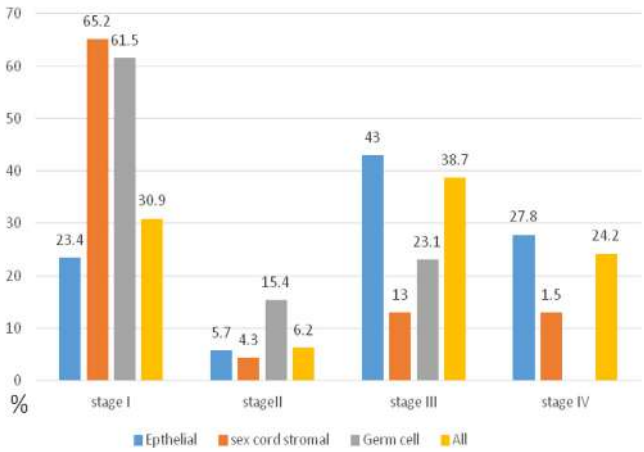

Fig 3: Stages at diagnosis for Ovarian Cancer at St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia: September 2016 and August 2020.

DISCUSSION

Gynecologic cancers represent a significant global health concern, contributing significantly to morbidity and mortality rates in women. At SPHMMC, gynecologic cancers have emerged as a leading cause of admission, with nearly 760 cases observed over a five-year study period. This figure surpasses similar timeframes in previous reports[8, 11, 12]. This heightened incidence can be attributed to the centralized cancer care provided by our tertiary center. The inception of gynecologic oncologic subspecialty services in 2016 has resulted in an increased number of referrals from across the country, particularly for advanced surgical and chemotherapy services.

In our study, cervical cancer was the most prevalent gynecologic cancer, accounting for 48% of cases, followed by ovarian cancer (29%) and GTN (12%). Cervical cancer's prominence aligns with findings from various developing countries, primarily due to the high prevalence of HPV infection in these regions. HPV variant 16, a high-risk strain, was identified in approximately 70% of infections in East Africa, including Ethiopia[13]. Moreover, the high incidence of HIV co-infection, found in 10% of cervical cancer patients and 59% of vulvar cancer patients, adds another risk factor for cervical cancer, given its classification as an AIDS-defining disease. Interestingly, the incidence of cervical cancer in our study was lower than rates reported in other parts of South Ethiopia (78%), India (86%), and Mozambique (64%) [7, 14-16]. This discrepancy may warrant further investigation, possibly due to the availability of cervical cancer screening and treatment programs, particularly in Addis Ababa.

Ovarian cancer ranked as the second most common cancer in our study, aligning with reports from Ghana, Nigeria, and Pakistan. In contrast, uterine cancers were less prevalent in our study than in developed countries, which may be due to early-stage cases being managed at peripheral hospitals. Gestational trophoblastic neoplasia (GTN) ranked third in our study with a 12% incidence, significantly higher than reported rates in Mozambique, Nigeria, and India. The higher incidence in our study aligns with the notion that GTN is more prevalent in Africa and the Middle East, warranting further investigation. Endometrial cancer ranked fourth, consistent with other African reports, which is attributed to the lower life expectancy in these regions[17].

The median age of cancer patients in our study was younger than Western reports, with most patients falling within the fourth to sixth decades, a trend similar to findings in Nigeria and India. Notably, the youngest case in our study was a 13-year-old with germ cell ovarian cancer, prompting further investigation into the prevalence of BRCA-related ovarian cancers, which tend to occur at a young age. The pediatric age group in our study predominantly had ovarian cancer cases, with one case of cervical cancer in individuals under 20 years old. Among women under 30, GTN (11%), cervical cancer (8.5%), and ovarian cancer (8.1%) were the most common gynecologic cancers, consistent with findings from Nigeria[17]. Other studies reported ovarian tumors as the most common in this age group, with cervical cancer being less common[8].

The median age for cervical cancer in our study was higher than reported in other African studies at 47 years, although it reached 52 years in Ghana. This difference lacks a clear explanation, but it may relate to the age at first sexual debut as teenage pregnancy and high parity are common in Ethiopia. However, 30% of cervical cancer cases in our study were younger than 30 years old, which is higher than the 4% reported in India[20]. The median age for vulvar cancer was significantly lower in our study, possibly due to a higher prevalence of HPV and HIV infections, as evidenced by increased HIV incidence in this patient group[5, 18]. Nearly half of uterine cancers in our study were in this old age group, consistent with the notion that old age is a significant risk factor for these cancers[19]

Gynecologic cancers were more common among multiparous women, with ovarian cancer being the most prevalent among nulliparous women, in line with a common risk factor. However, the incidence

was higher than reported in India (2.3%)[12, 20]. The median parity in our study ranged from 1 to 4, lower than reported in Nigeria and Ghana, where a higher parity of 7 was observed[19, 21]. Most cases in our study originated from rural areas, which corresponds with findings in India and Mozambique, highlighting the association between rural populations and lower socioeconomic status and limited access to healthcare information and services[19]. Unfortunately, a significant portion of patients in our study presented at an advanced stage, potentially due to a lack of awareness about symptoms. Only 34% of all patients presented at stage I, a finding similar to Ghana[8]. Only 37% of cervical cancer patients presented at an early and operable stage (stage I and IIA), while ovarian cancer patients predominantly presented at advanced stages, which is a common global phenomenon.

CONCLUSION

Cervical cancer emerges as the most common gynecologic cancer in women requiring admission, constituting a substantial cause of cancer-related morbidity. Despite being preventable through effective screening programs, cervical cancer remains insufficiently addressed. Of particular concern is late presentation in a locally advanced stage, which makes the cancer inoperable. It is imperative to strengthen cervical cancer screening programs and make them more accessible to rural communities. The majority of gynecologic cancer patients in our study presented at advanced stages, underscoring the need for increased awareness of common symptoms to facilitate early intervention. Ovarian cancer and GTN are also prevalent and require a centralized approach to clinical and surgical oncologic services, alongside early referral systems. Further research is warranted to explore the reasons behind the high incidence of GTN in this region and to determine the actual incidence of uterine cancer[22], In general, gynecologic cancers need attention in terms of expanding the service delivery units, wider screening, early referral and more research on the area.

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PERINATAL AND MATERNAL OUTCOME OF PREECLAMPSIA WITH SEVERITY FEATURE MANAGED EXPECTANTLY AT ST. PAUL'S HOSPITAL MILLENNIUM MEDICAL COLLEGE (SPHMMC), 2021, ADDIS ABABA, ETHIOPIA, A CROSS SECTIONAL STUDY

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ABSTRACT

BACKGROUND: Preeclampsia refers to the new onset of hypertension and proteinuria after 20 weeks of gestation in a previously normotensive woman. It is labeled as preeclampsia with severe features when one of the severity signs occurs (1). Worldwide, preeclampsia occurs in up to 7.5 percent of pregnancies.10 - 15 % of direct maternal deaths are associated with preeclampsia and eclampsia.The majority of adverse maternal and perinatal outcome occur in preeclampsia with severe features and when preeclampsia occurs remote from term (1, 2).

OBJECTIVE: The main objective of this study was to determine the maternal and perinatal outcome of preeclampsia with severe features managed expectantly at SPHMMC in one year period.

MATERIALS AND METHODS: A facility based cross-sectional study was conducted. The study participants were selected consecutively by including all mothers admitted during the study period (January 2021 to December 2021 G.C.) with the diagnosis of preeclampsia with severe features to SPHMMC that fulfill the inclusion criteria. Data was obtained from patient charts and a direct patient interview using pre-tested & structured questionnaire. Collected data was entered in to Epi info version 7 and analysis was made through SPSS version 25. Descriptive statistics, tables, and figures were used to describe the study findings.

RESULT: The mean days of prolongation of pregnancy was 11.5 days with slight increment of maternal complication from expected proportion that completely resolved postpartum. The most common maternal complications were HELLP syndrome (15.1%) and abruptio placenta (7.2%). There were 21 perinatal deaths (8 still births and 13 neonatal deaths) that give perinatal mortality rates of 276 per 1000 live births. The rate of NICU admission was 66.7% and the neonatal survival to seventh day was 71.7%.

Only 66(90.4%) of the women were a good candidate for expectant management. Magnesium sulphate and steroid (dexamethasone) at admission was given to100% but 8.2% of the mothers didnot get magnesium sulphate during intrapartum or postpartum period. Among mothers admitted to SPHMMC for the purpose of expectant management 36(49.3%) of them had optimal maternal and fetal monitoring/surveillance in the ward.

CONCLUSION / RECOMMENDATION: Proper selection of pregnant mothers with pre-eclampsia with severity feature and close and frequent maternal and fetal surveillance during expectant management is associated with a good perinatal outcome without significant difference in maternal complication.

KEYWORDS: pre-eclampsia ,perinatal outcome, maternal complication.

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INTRODUCTION

Preeclampsia refers to the new onset of hypertension and proteinuria after 20 weeks of gestation in a previously normotensive woman. It is labeled with severity feature when one of the following conditions occurs : cerebral symptoms (visual disturbance, headache), symptoms of liver capsule distention (Right upper quadrant or epigastric pain),hepatocellular injury(serum transaminase concentration ≥ twice normal), severe blood pressure elevation(systolic blood pressure ≥160 mm Hg or diastolic blood pressure ≥110 mm Hg on two occasions at least four hours apart), thrombocytopenia(<100,000 platelets/microL), or pulmonary edema or cyanosis[1].

Preeclampsia occurs in up to 7.5 percent of pregnancies worldwide[2].Women with preeclampsia are at an increased risk for life-threatening events, including placental abruption, acute renal failure, cerebral hemorrhage, hepatic failure or rupture, pulmonary edema, disseminated intravascular coagulation, and progression to eclampsia(1.2). Abruptio placenta is infrequent (less than 1 percent) in women with preeclampsia without severe features, but has been reported in 3 percent of those with severe disease[3].

Worldwide, 10 to 15 percent of direct maternal deaths are associated with preeclampsia and eclampsia[4]. In the United States, preeclampsia/eclampsia is one of four leading causes of maternal death, along with hemorrhage, cardiovascular conditions, and thromboembolism[5-7]. There is approximately one maternal death due to preeclampsia-eclampsia per 100,000 live births, with a case-fatality rate of 6.4 deaths per 10,000 cases[8, 9].

According to the World Health Organization (WHO) in 2008, hypertensive disorders in pregnancy contributed to 12% of maternal deaths. It is the second most common cause of maternal death, following hemorrhage (accounting for 27%) in developing countries[10].

In Ethiopia, pregnancy and childbirth complications are among the leading causes of mortality among women, with an estimated maternal mortality rate (MMR) of 402per100,000 livebirths in2015 and a neonatal mortality rate of 37 deaths per 1,000 live births[11].

Pre-eclampsia/eclampsia complicated 1.2% of all institutional deliveries in Ethiopia. Given the low institutional delivery rate and an expected incidence of 2% to 8% of all deliveries, this implies that only a small fraction (3.8%) of all women with pre-eclampsia/eclampsia received care at health facilities; 11% of all maternal deaths and 16% of direct maternal deaths were due to this obstetric complication[12].

Women with preeclampsia with severity features are usually delivered promptly to prevent maternal and fetal complications. Since the disease is progressive and there is no medical treatment, delivery is always in the best interest of the mother. However, preterm delivery is not always in the best interest of the fetus; therefore, a decision to delay delivery can be considered under certain circumstances[9].

The rationale for delaying delivery in these pregnancies is to reduce perinatal morbidity and mortality by delivery of a more mature fetus and, to a lesser degree, to achieve a more favorable cervix for vaginal birth. The risk of prolonging pregnancy is worsening maternal endothelial dysfunction and continued poor perfusion of major maternal organs with the potential for severe end organ damage to the brain, liver, kidneys, placenta/fetus, and hematologic and vascular systems[13, 14,15].

Given the fact that our neonatal set up is not well developed, aggressively managing preeclampsia with severity futures at the time of diagnosis will adversely affect the perinatal outcome.Therefore some selected patients who can fulfill the criteria for expectant management are admitted to hospital, despite its risks on the maternal health, by balancing the maturity of fetus. The institutional protocol is to consider expectant management in cases of preeclampsia with severe features less than 34 weeks of gestation and in some selected cases of less than

37 weeks based on individualization using WHO 2011 criteria after appropriate patient selection using maternal and fetal criteria. Since there are no data that evaluate the safety of this management option in our setting , this study will add additional evidence to this management option[16,17]. This study will also be a very important input for developing national management guideline.

METHODS AND MATERIALS

Study design /setting

This is a facility (institution) based cross-sectional study done to assess the maternal and perinatal outcome of preeclampsia with severity features managed expectantly between January 1st, 2021 to December 31st, 2021 at SPHMMC , Addis Ababa, Ethiopia. SPHMMC is one of the national referral and teaching hospitals. The hospital provides services for those referred from all corners of the country. The hospital provides service under different clinical disciplines including obstetrics and pediatrics. The college is peculiar in the country because of its new and integrated modular and hybrid problem-based curriculum. The college has both Obstetrics and Gynaecology postgraduate and fellowship program in different disciplines.

Sample size and sampling procedure

Convenience sampling technique was used to include all pregnant women with the gestational age of 28 completed weeks to 33 weeks plus 6 days, who were admitted with the diagnosis of preeclampsia with severe features to maternity wards of SPHMMC for the purpose of expectant management from January 1st, 2021 to December 31st, 2021.

The study participants were selected consecutively by including all mothers admitted during the study periodthat fulfill the inclusion criteria However, women managed expeditiously (whose pregnancy was terminated with in 48 hrs of admission for any reasons), women admitted with the diagnosis of severe preeclampsia only for completion of corticosteroid,and those women who declined to give consent were excluded.

Data collection tool and procedures

The study was approved by the institutional review board of SPHMMC. Prior to the main study, a 2 days training was given for the data collectors. A standardized, structured pre-tested questionnaire which includes all the necessary variables in accordance with the objective of the study was prepared. The questionnaire has variables on the socio-demographic, obstetric, and maternal and neonatal outcome extracted from the participants and their charts.

Two trained residents filled the socio demographic, obstetric and clinical data. Consistency of filled data was checked by one supervisor every other day. Five percent of the filled data was checked for accuracy by the supervisors.

Data analysis

Collected data was entered in to Epi info version 7 and analysis was made through SPSS version 25.Frequency output and sorting was used to check missing values and outliers. Descriptive statistics, tables,and figures were used to describe the study finding.

Operational definition

- Expectant management of sever preeclampsia- the decision of prolonging the pregnancy beyond 48 hours after completing steroid.
- Candidate for expectant management - A mother with preeclampsia with severity feature after 28weeks of gestation who fulfill the international maternal and fetal criteria for expectant management
- Maternal complications - mother who developed any consequence of preeclampsia with severity feature that leads to termination of the pregnancy
- Good/ optimal follow up - is considered when all of the following are fulfilled: fetal surveillance done daily, CBC and OFT-done every other day, preeclampsia chart filled twice a day, and

kick chart filled daily.
- Suboptimal follow up of the mother is considered when one of the monitoring parameter is filled incompletely
- Good APGAR score – If fifth minute APGAR is greater than seven.

RESULTS

During the study period, 9531 women delivered in SPHMMC. Seventy three mothers with the diagnosis of preeclampsia with severe features between 28 and 34 weeks of gestation were admitted to maternity wards for expectant management. The mean age of the mother at admission was 25.6yrs and 28(40.6%) were primigravida. (Table1).

The mean number of days of pregnancy prolongation was 11.5 days. The days gained were significantly higher among those who had expectant management between 28.1 and 30 weeks (22.2 days), compared with the other two groups—30.1–32 weeks (14 days) and 32.1–34 weeks (7 days). The mean GA at admission calculated from 45 mothers who know their GA was 30.3wks and the mean weight was 1642.8gm.

Table-1. Baseline characteristics of the mothers admitted to SPHMMC for expectant management of preeclampsia with severity features, 2021.

	Numbers	Percentages
Religion		
Orthodox	31	42.5
Muslim	22	30.1
Protestant	18	24.7
Other	2	2.7
Ethnicity		
Amhara	13	17.8
Oromo	37	50.7
Gurage	8	11.0
Tigre	5	6.8
Other	10	13.7
Marital status		
Married	65	89.0
Single	4	5.5
Divorced	3	4.1
Widowed	1	1.4
Place of residence		
Urban	48	65.8
Rural	25	34.2
Educational status		
No formal education	22	30.1
Primary school	32	43.8
Secondary school	16	21.9
Above Secondary school	3	4.1
Occupational status		
Government Employee	11	15.1
Merchant	12	16.4
Daily laborer	5	6.8
House wife	30	41.1
Farmer	7	9.6
Other	8	11.0

Raised blood pressure that required antihypertensive was found in 94.5% of mothers as isolated criteria for admission and in 33.8% of mothers with other severity features, mainly cerebral symptom. (Table 2)

Table-2 Criteria for admission for mothers with preeclampsia with severity features admitted to SPHMMC for expectant management,2021.

	Numbers	Percentages
Raised BP that required antihypertensive	69	94.5
Transient thrombocytopenia	5	6.8
Cerebral symptoms	43	58.9
Others	2	2.7

There were 11(15.1%) cases of HELLP syndrome, 5 (7.2%) abruptio placentas, and 6(8.7%) pulmonary edema. Despite the use of magnesium sulfate, two of the mothers developed eclampsia in the hospital. (Table 3) There were no instances of maternal death, cerebrovascular accident, or DIC among the 73 women. None of them required adult intensive care admission.

Table-3 The maternal complications developed in the ward for those mothers admitted to SPHMMC for expectant management of preeclampsia with severe features, 2021.

Complications	Numbers	Percentages
Uncontrolled blood pressure	8	11.0
Low Platelets	5	6.8
Raised LFT	4	5.5
Raised RFT	6	8.2
Abruption	5	6.8
Persistent Cerebral symptoms	3	4.1
Pulmonary edema	6	8.2
Eclampsia	2	2.7
HELLP	2	2.7
Total	**50**	**68.4**

In 20.5% of the mothers the pregnancy was terminated because of attainment of gestational age of ≥ 34wks; the rest of the mothers' pregnancy was terminated as the result of complications/ end points like (severe growth restriction, uncontrolled blood pressure, eclampsia, HELLP syndrome, pulmonary edema, and abruptio placenta) that developed during the expectant management. (Table 4)

Table -4 -Indications for termination of pregnancy of the mothers admitted to SPHMMC for expectant management of preeclampsia with severe features, 2021.

Complications	No	Percentage
Abruption	3	4.1
Eclampsia	2	2.7
EFW>2.5 kg	2	1.4
GA of ≥ 34 weeks	15	21.9
HELLP syndrome	4	5.5
IUFD	4	5.5
IUGR with AEDV	7	9.6
low platelet (<100,000)	4	5.5
NRBPP	4	5.5
Persistent cerebral symptopm	3	4.1
Preterm labour	2	2.7
Pulmonary edema	6	8.2
Raised LFT	3	4.1
Raised RFT	6	8.2
Uncontrolled HTN	8	11.0

18(24.7%) of all mothers had co-morbidities at admission and the most common co-morbiditiy was chronic hypertension in 38.8% of mothers.

The rates of caesarian deliveries (CD) in these mothers were 53.4 (Figure 1). The most common indications were non-reassuring fetal heart rate pattern (NRFHRP) in 41% of the cases, followed with failed induction that contributed for 20.5%.

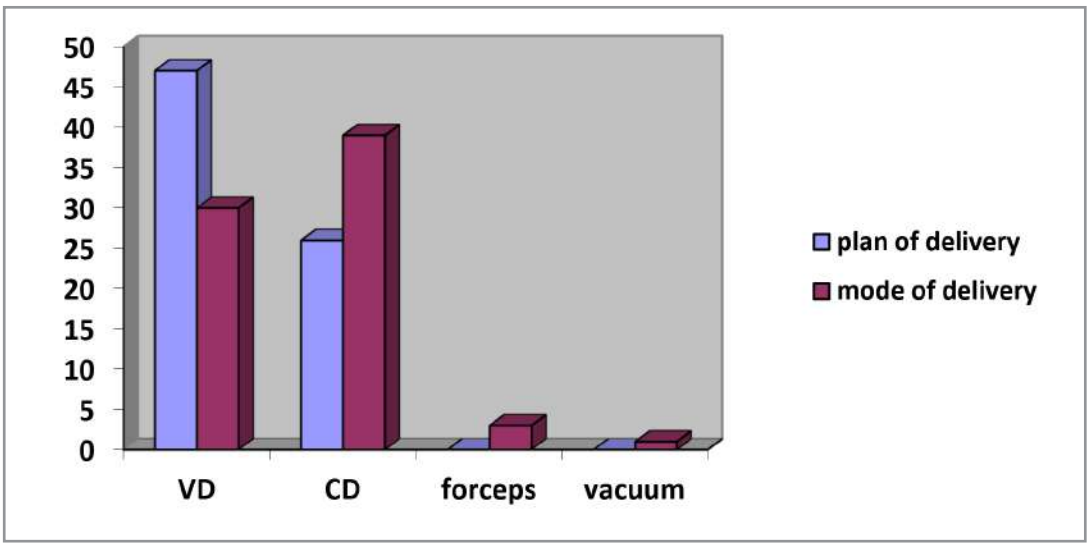

Figure 1. Planned and actual mode of delivery of mothers admitted to SPHMMC for expectant management of preeclampsia with severity features, 2021.

Out of all mothers admitted to the ward 68(93.2%) of them required antihypertensive drugs and 50 (68.5%) of them took single drug that was methyldopa., The other 18 mothers required an additional drug (nifedipine).(Figure 2).

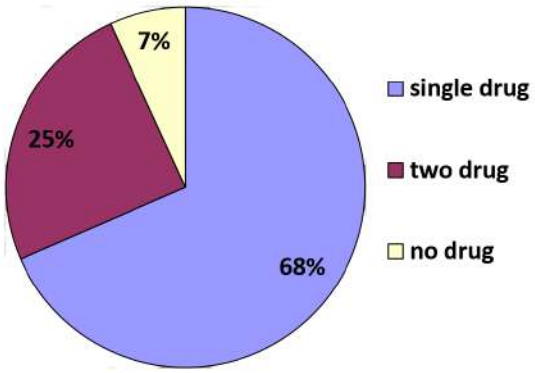

Figure 2- Antihypertensive drug use among women admitted to SPHMMC for the purpose of expectant management of preeclampsia with severe features, 2021

Out of 73 mothers included in the study, there were 3 twin pregnancies that make the total number of babies born 76. There were 8 (10.9%) stillborn and 68 of the babies were born alive. The total NICU admission rate was 66.7%. (Table 6) Two thirds of live born neonate had 5th minute APGAR score of > 7. (Figure 3)

Table-6 Perinatal outcome mothers admitted to SPHMMC for expectant management of preeclampsia with severe features, 2021.

Perinatal outcome	Numbers	Percentages
Still birth	8	10.5
Live born	68	93.2
Fifth minute APGAR score > 7	34	46.67
NICU referral (69 live born)	46	66.7

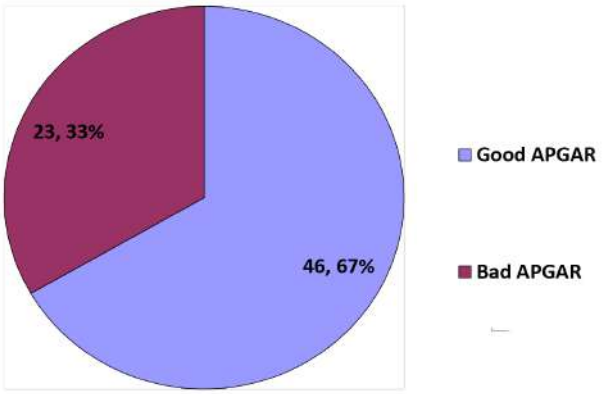

Figure 3-Fifth minute APGAR score of neonate delivered from the mother admitted to SPHMMC for expectant management of preeclampsia with severe features, 2021.

The median gestational age of the liveborn babies was 33.1weeks and the median birth weight was 2002g. Neonatal survival up to 7days of their life was 71.7%. (Table 7).

There were 21 perinatal deaths (13 neonates died in NICU and 8 stillbirths) that give perinatal mortality rates of 276 per 1000 live birth.

Table -7 Neonatal status at seventh day of NICU of newborns of the mothers admitted to SPHMMC for expectant management of preeclampsia with severe features, 2021.

Neonatal conditions	Numbers	Percentages
Discharged with improvement	6	13
At NICU with good condition	16	34.8
At NICU with bad condition(critical)	11	23.9
Died	13	28.3
Total	46	100

Only 66(90.4%) of the women were a good candidate for expectant management. Magnesium sulphate and steroid (dexamethasone) at admission was given 100% of the time, but 8.2% of the mothers didnot get magnesium sulphate during intrapartum or postpartum period. Among mothers admitted for the purpose of expectant management, 36(49.3%) of them had optimal maternal and fetal monitoring/ surveillance that meet the recommendation given by ACOG (1), while 18(24.7%) of them had incomplete preeclampsia follow up charts and 7(9.6%) of them had incompletely filled kick charts. (Figure 4)

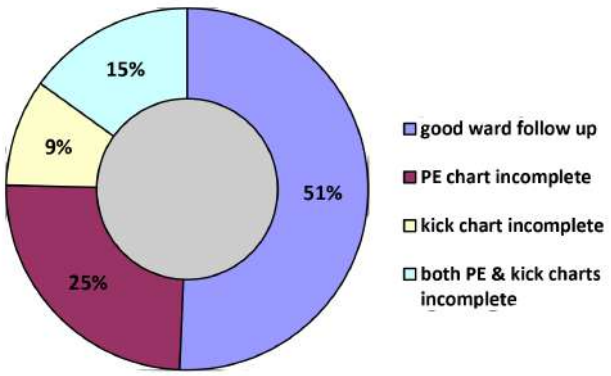

Figure 4- Follow up patterns of mothers admitted to SPHMMC for expectant management of preeclampsia with severe features, 2021.

DISCUSSION

The study was undertaken to determine duration of pregnancy prolongation and maternal and perinatal outcome of preeclampsia with severe featuresbetween 28 and 34 weeks of gestation.

The analysis of this study revealed that the mean number of days of pregnancy prolongation was 11.5 days with a significantly greater period gained at earlier gestations. The mean days gained is comparable with most of other studies and a systematic review done by Magee et al. in 2009, which varies between 7 to 15.3 days.[3,8, 9].

Two prospective randomized controlled trials comparing expectant management with interventionist management have been published[3,8]. The first study, which included 38 patients, found a mean pregnancy prolongation of 7.1 days in the group of women who were given expectant management[8]. In a larger randomized controlled trial in which 95 patients were included, the mean pregnancy prolongation was 15.4 days[3]. In a similar study done by Swamy et al.with94 mothers, the mean duration of days was only 5 days, which was smaller than our study. The study done by Swamy et al. included clients starting from GA of 24 weeks, which is different patient selection from our study and may contribute to small duration of pregnancy prolongation[13].

The days gained were significantly higher among those who had expectant management between 28.1 and 30 weeks (22.2 days) compared with the other two groups—30.1–32 weeks (14 days) and 32.1–34 weeks (7 days). This finding is in line with other studies studies done by Odendaalet al. in 1990,Sibaiet al. in 1994 and Swamy et al. in 2012, though the study done by Swamy et al. include clients starting from GA of 24 weeks, which is differentpatient selection from our study[3,8,13.14].

The rate of maternal complications is similar to those reported in previous studies[13,18,14,19]. The rate of eclampsia was also in agreement with the finding of similar studies in India[13]. Severe maternal complications were less frequently observed. There were, however, no instances of

maternal deaths, cerebrovascular accidents, or severe acute renal failure necessitating dialysis in our study. On the whole, major complications resolved quickly without the need for adult intensive care admission, which is a reassuring finding. Despite the use of magnesium sulfate and careful control of blood pressure, we had two cases of eclampsia. The rate of eclampsia was also in agreement with the finding of similar studies in India[13]. It is important to note, however, that in the MAGPIE trial, magnesium sulfate was not associated with a significantly decreased rate of eclampsia in the subgroup of women included from countries with a low perinatal mortality[19].

Neonatal morbidity was clearly related to the gestational age at the onset of expectant management and this is in agreement with previous studies[13,15]. Increasing gestational age correlated with a reduction of respiratory distress syndrome[13,15].

Regarding perinatal and neonatal mortality rates, our observed perinatal and neonatal mortality rates were 10.4 and 18.8 %, respectively, which are acceptable in a developing country setting and the result is in agreement with the study done in India by Swamy et al. in 2012 which included clients starting from GA of 24 weeks, which is different to patient selection from our study[13].In contrast, our results are not in agreement with results of the trial which was undertaken in a developed country[3,8,14,15]. The study done by Sibai et al. on aggressive versus expectant management of severe preeclampsia did not have instances of perinatal deaths in women expectantly managed at 30 or more weeks of gestation[3]. More than half of the fetal deaths in our study were caused by abruptio placenta. Therefore our study cannot answer all inquiries that possibly arise in this area because we have not compared expectant management with interventionist management, which is one of the limitations of our study.

Only 66(90.4%) of the women were a good candidate for expectant management.Among mothers admitted to SPHMMC for the purpose of expectant management, 36(49.3%) of them had optimal maternal and fetal monitoring/ surveillance.

Our in-patient monitoring of mothers admitted to SPHMMC showed lower frequency of assessment of the parameters that could help to detect early appearance of complications as compared with other studies[3,8,14]. In our cases all mothers complete the course of corticosteroid,whichishigher than in the others studies. 8.2% of the mothers did not get magnesium sulphate during intrapartum or postpartum period.Gross audit of the quality of care implies the need for large scale in depth audit of expectant management of preeclampsia with severe features to explore practice of appropriate patient selection and optimal maternal and fetal monitoring/ surveillance with respect to the gold standard.

As a conclusion,proper selection of pregnant mothers with preeclampsia with severity feature, and close and frequent observation of maternal and fetal status during expectant management, is associated with a good perinatal outcome without increased risk for the mother. The main limitations of the study were: the result was limited to short term outcome during hospital stay. In addition, the study may lack generalizability as it has small sample size and it is a single center study. Therefore, further multicenter study with longer study period is recommended to know the actual maternal and neonatal outcome of preeclampsia with severity feature and also to determine possible associated factors.

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