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# Editorial Note

Dear Colleagues/ Readers:

Starting from this volume, the *Ethiopian Journal of Reproductive Health (EJRH)* avails articles published in the *Obstetrics & Gynecology Journal*, a.k.a. *The Green Journal*, the scientific publication of the American College of Obstetrics and Gynecology (ACOG). The articles are selected by the *EJRH* editorial board and reprinted in our journal as part of the ongoing support of ACOG to the Ethiopian Society of Obstetricians and Gynecologists (ESOG) and after securing permission from the *Obstetrics & Gynecology Journal.*

In this volume, the two original articles that were previously published in the *Obstetrics & Gynecology Journal* and are republished in this issue of *EJRH* are:

1. Patricia A. Lahr et al. Simultaneous Compared with Interval Abortion Regimens where Home Use is Restricted. Obstet Gyncol 2018; 131: 635-641.
2. Lilian Padron et al. Manual Compared with Electric Vacuum Aspiration for Treatment of Molar Pregnancy. Obstet Gyncol 2018; 131: 652-659.

 The *EJRH* is thankful of the permission and continuous support provided.

Dr. Ahmed Abdella
Editor-in-Chief,
EJRH

# BACTERIAL ISOLATES AND THEIR CURRENT DRUG SUSCEPTIBILITY PROFILE FROM URINE AMONG ASYMPTOMATIC PREGNANT WOMEN ATTENDING AT A REFERRAL HOSPITAL, NORTHWEST ETHIOPIA; CROSS-SECTIONAL STUDY

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## ABSTRACT

### BACKGROUND:

Asymptomatic bacteriurias (ASB) are common during pregnancies thatcould have potentially serious consequences for maternal and fetal health. The rapid emergence of antimicrobial resistance necessitates continuous monitoring of the susceptibility patterns of pathogens.

### OBJECTIVE:

The purpose of this study was to identify bacterial pathogens from asymptomatic pregnant women attending antenatal clinic and by extension to determine the antimicrobial susceptibility profile of these isolates.

### METHOD:

A cross-sectional study was conducted at Felege Hiwot Referral Hospital (FHRH) from February 1 to May 30, 2016. Freshly voided clean catch midstream urine samples were collected and processed using conventional culture and biochemical tests as per the standard protocol. A concentration of >105 cfu/ml in urine sample was considered culture positive for ASB. Isolates were tested against the commonly used antibiotics by Kirby-Bauer disc diffusion methods. The degree of susceptibility pattern was determined based on the Clinical Laboratory Standards Institute. Descriptive and Chi-square test was done using SPSS version 22, $p < 0.05$ was considered to be significant.

### RESULTS:

A total of 234 study participants were involved in the study. The mean age of participants was 26.8 years (ranged 18–41 years). The majority, 139 (59.4%) of them were multigravida. Most of the participants at 134 (57.3%) were in the 3rd trimester. Among the study subjects, 20 (8.5%) were HIV sero-positive. Out of the 234 pregnant women 11.5 % (27/234) were positive for ASB. History of diabetes was significantly associated with ASB (p=0.019). A total of 27 bacterial uropathogens were identified. Out of these, Gram positives consisted at 20 (74.1%). The predominant isolates were S. saprophyticus at 48.2% (13/27) followed by S. aureus at 22.2% (6/27) and E. coli at 11.1% (3/27). Eleven (84.6%), 10 (76.9%) and nine (69.2%) of 13 isolates of S. saprophyticus were found resistant for co-trimoxazole, oxacilin and tetracycline, respectively.

### CONCLUSIONS:

In the studied area, the prevalence of ASB was at 11.5 %. Considerable drug susceptibility profile of the isolates was documented. Thus, efforts should be given to decrease the effect of ASB and antimicrobial resistance.

**KEY WORDS/PHRASES:** Asymptomatic bacteruria, antimicrobial resistance, Bahir Dar

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# INTRODUCTION

## BACKGROUND

Urinary tract infection is more prevalent in women [1]. Women's lifetime risk of having the infection in is >50%[1-3]. This may be due to the short urethra and its anatomical proximity to the anal orifice, absence of prostatic secretion, pregnancy and easy contamination of the urinary tract with faecal flora[4-9]. Different research findings showed that UTI is the most common medical complication during pregnancy[10-14]. A significant growth of uropathogens $>10^5$ bacterial colony forming units (cfu) per ml of urine without the client showing symptoms of UTI is termed as asymptomatic bacteriuria (ASB) [13, 17-18]. It is a major risk factor for the development of UTIs during pregnancy[5, 10]. Pregnancy enhances the progression from asymptomatic into symptomatic bacteriuria [6,7,10]. This is due to the apparent reduction in immunity of pregnant women [10, 13]. In addition, the physiological increase in plasma volume and glucosuria, that encourages bacterial growth in the urine plays an important role in the conversion of asymptomatic into symptomatic[8, 10].

Ultimately symptomatic bacteriuria could leads to pyelonephritis and adverse obstetric outcomes such as prematurity, low-birth weight and higher fetal mortality rates [6, 7, 10]. Pregnant women with ASB are more likely to deliver pre-mature or low-birth-weight infants[1, 15-16]. Furthermore, a 20 to 30-fold increased risk of developing pyelonephritis was reported among women with bacteriuria and untreated bacteriruia during pregnancy is associated with low birth weight and premature delivery [6-7, 9, 17, 19-20].Researchers reported that Escherichia coli, Klebsiella spp., P. mirabilis, P. aeruginosa, Staphylococcus spp. and Enterococcus spp. are the most causative agents of UTI 1, 4. Data on local

bacterial etiology and their susceptibility profile is worthy to trace any change in time. Thus, timely updated reference for empirical therapy of ASB can be made [21-22]. Antimicrobial resistance rates among common uropathogens have been increasing[23], and their susceptibility varies from place and time[21-22]. This call continuous monitoring of the susceptibility profile of uropathogens[16]. With this background information, this study was conducted aimed at determining the types and prevalence of local isolates from asymptomatic pregnant women and by extension to determine their antimicrobial susceptibility profile to the most commonly used antimicrobials.

# MATERIALS AND METHOD

## Study design and population

A prospective cross-sectional study was conducted from February 30- May1, 2016. The study was conducted at FHRH in Bahir Dar, which is the capital city of Amhara National Regional State, 565 km away from Addis Ababa. The hospital is a tertiary health care level hospital serving the population of Bahir Dar town and surrounding areas of Northwest Ethiopia. A total of 234 asymptomatic pregnant women, for UTI attending FHRH for antenatal service who did not take antibiotic therapy two weeks before the data collection period were included in the study. All clients who came to the hospital in the study period were included conveniently regardless of their period of pregnancy.

# VARIABLES

## Independent Variables:

Age, residence, educational background, history of catheterization, pregnancy, gestation period
Dependent variables: Asymptomatic bacteriuria, type of isolates, drug resistance profile of the isolates.

# DATA COLLECTION PROCEDURES

A structured and pretested questionnaire was used to collect demographic characteristics of the study participants and related clinical data. Clients were screened for UTI clinically by health practitioners in charge of attending them. In addition, the types of isolated bacterial uropathogens from urine culture with their respective antimicrobial susceptibility profiles were determined using microbiological laboratory procedures as per the standard protocol.

# LAB PROCEDURE:

## Urine sample collection

All the study participants were requested to bring 5 ml freshly voided, clean catch midstream urine

samples. The urine samples were collected using lick proof wide mouth plastic containers. All of the study subjects have no history of taking antimicrobials in the last two weeks. All of the specimens were analyzed 15-30 minutes after collection24.

Urine culture: Bacterial isolation and identification

Isolation of bacterial uropathogens were performed by a surface streak procedure of well mixed un-centrifuged urine on blood and Mac Conkey agar (Oxoid Ltd. Bashingstore Hampaire, UK) using calibrated loops (0.001 ml) for semi quantitative method and incubated aerobically at 370C overnight for 24 hours. Colonies were counted as colony forming units (CFU) per milliliter (ml) to check significant growth at >105. Identification of isolates was performed using colony characteristics, gram reaction of the organisms and panels of biochemical test following the standard procedures. Biochemical tests used in this study includes indole, citrate, oxidase, H2S production, lysine decarboxylase, lactose fermentation, urea hydrolysis, gas production, catalase, coagulase, manitol fermentation and novobiocin susceptibility testing 24-25

## ANTIMICROBIAL SUSCEPTIBILITY TESTING

Antimicrobial susceptibility testing was performed on Mueller Hinton agar (MHA) plate using Kirby-Bauer disk diffusion method. Pure culture bacterial suspensions were prepared in nutrient broth by picking similar colonies of the test organisms with a sterile wire loop. The turbidity of the suspension was equilibrated to match with 0.5McFarland standards. A sterile swab dipped into the suspension of the isolate in broth, and then speeded over the entire surface of Muller-Hinton agar plate (Oxoid, LTD). The antibiotic disks were placed on the surface of inoculated agar and incubated at 370C for 24-48 hours. After 24-48 hours the diameters of the discs growth inhibition were measured and interpreted as per CLSI24-26. The antimicrobials tested were obtained from Oxoid Ltd., England with the following concentrations: Clindamycin (CL,2mg), Ampicillin (AMP, 10mg), Tetracycline (TE, 30mg), Ciprofloxacin (CIP, 5mg), Trimethoprim+Sulphamethazole (SXT, 25mg), Gentamicin (CN, 10mg), Norfloxacin, amoxicilin + clavulinic acid (20/10mg), Nitrofurantion (300mg), Oxacilin and Cephalotin.

## QUALITY CONTROL

Proper specimen collection was made through explaining for the client. All of the specimens were analyzed within 15-30 minutes of collection to prevent contamination. Culture media and antibiotic discs were checked for their normal shelf life. All culture plates, biochemical test media and MHA were used after checking sterility and performance using ATCC strains. All culture plates and antibiotic discs were stored at the recommended refrigeration temperature (2-80C) after preparation and sterilized by autoclaving at 121 0C for 15 minutes24. The standard reference strains of E. coli (ATCC 25922), P. aeruginosa (ATCC 27853) and S.aureus (ATCC 25923), were used for quality control of culture and antimicrobial susceptibility testing.

## DATA ANALYSIS

Data were entered, cleaned and analysed using Statistical Software Package for Social Sciences (SPSS) version 22 (SPSS Inc., Chicago, IL, USA) for Windows. Generated data were compiled by frequency tables and figure and other statistical summary measures. Statistical association was employed to compare the proportion of bacterial isolates and antimicrobial resistances profile among participants. A P-value less than 0.05 was considered to indicate statistically significant difference.

## OPERATIONAL DEFINITIONS

In accordance with the national kidney and urologic diseases information (1) the following definitions were applied,

**Mid-stream urine sample:** a urine specimen obtained from the middle part of urine flow (the so called clean catch urine sample)

**Asymptomatic bacteriuria:** is the occurrenceof significant bacteruria (yielding positive cultures (≥ 105CFU/ml)) in the urine without symptoms.

## ETHICAL CONSIDERATION

Ethical clearance was obtained from Amhara Regional Health Bureau Ethics Committee located at Bahir Dar Regional Research Lab Center. After the research staff explained about the purpose of the study informed written consent was taken

from each participant. Bacteriological positive results were communicated for health professionals attending women. Individual records were coded and accessed only by research staff. All information from participants was kept confidential by using lab codes.

## RESULTS

### Socio-demographic characteristics

A total of 234 pregnant women were included in this study. Their ages ranged from 18 to 41 years, with a mean age of 26.8 years and SD 4.7. In this study Based on their gravidity, primigravida accounted at 87(37.2%), multigravida at 139 (59.4%) and gravidity >5 at eight (3.4%). When the number of registered pregnant women are stratified by trimester 17 (7.3%), 83 (35.4%) and 134 (57.3%) of them were in the 1st, 2nd and 3rd trimester of pregnancy respectively. Four (1.7%), 16 (6.8%) and 19(8.1%) of the study participants had history of diabetes, catheterization and urinary tract infection respectively (Table 1).

**Table1: Socio-demographic variables and magnitude of ASB among pregnant women (n= 234) attending antenatal clinic in FHRH, 2016.**

| Characteristics | Tested No (%) | Bacteriological culture result | | Chi-square ($X^2$) | P val |
|---|---|---|---|---|---|
| AGE GROUP IN YEARS | | Negative No (%) | Positive No (%) | | |
| 18-25 | 96 (41) | 86 (89.6) | 10 (10.4) | | |
| 26-33 | 114(48.7) | 102 (89.5) | 12 (10.5) | 13.5 | 0.633 |
| 34-41 | 24(10.3) | 19 (79.2) | 5 (20.8) | | |
| MARITAL STATUS | | | | | |
| SINGLE | 2(0.9) | 2 | 0 | 8 | 1.000 |
| MARRIED | 232(99.1) | 205 (88.4) | 27 (11.6) | | |
| RESIDENCE | | | | | |
| URBAN | 211(90.2) | 189 (89.6) | 22 (10.4) | 7.9 | 0.441 |
| RURAL | 23(9.8) | 18 (78.3) | 5 (21.7) | | |
| EDUCATION | | | | | |
| ILLITERATE | 38(16.2) | 32 (84.2) | 6 (15.8) | | |
| PRIMARY/SECONDARY SCHOOL COMPLETED | 122(52.1) | 110 (90.2) | 12 (9.8) | 13.1 | 0.668 |
| COLLEGE/UNIVERSITY GRADUATE | 74(31.7) | 65 (87.8) | 9 (12.2) | | |
| OCCUPATION | | | | | |
| HOUSE WIFE | 115(49.1) | 110 (95.7) | 5 (5.3) | | |
| GOVERNMENT EMPLOY | 71(30.3) | 64 (90.1) | 7 (9.9) | 33.0 | 0.104 |
| PRIVATE BUSINESS | 27(11.5) | 23 (85.2) | 4 (14.8) | | |
| OTHERS | 21(9.0) | 19 (90.5) | 2 | | |
| MONTHLY INCOME, ETB | | | | | |
| <1000 | 37(15.8) | 32 (86.5) | 5 (13.5) | 22.6 | 0.543 |
| 1000-1999 | 64(27.4) | 58 (90.6) | 6 (9.4) | | |
| 2000-2999 | 51(21.8) | 44 (86.3) | 7 (13.7) | | |
| >2999 | 82(35.0) | 73 (89.0) | 9 (11) | | |

| | | | | | |
|---|---|---|---|---|---|
| GRAVIDITY | | | | | |
| PRIMIGRAVIDA | 87(37.2) | 79 (90.8) | 8 (9.2) | | |
| MULTIGRAVIDA | 139(59.4) | 121 (87.1) | 18 (12.9) | 13.1 | 0.667 |
| GRAVIDITY >5 | 8(3.4) | 7 (87.5) | 1 | | |
| PERIOD OF GESTATION/ TRIMESTER | | | | | |
| 1ST | 17(7.3) | 16 (94.1) | 1 | | |
| 2ND | 83(35.4) | 73 (88) | 10 (12) | 20.4 | 0.202 |
| 3RD | 134(57.3) | 118 (88.1) | 16 (11.9) | | |
| HISTORY OF DIABETES | | | | | |
| YES | 4 (1.7) | 3 (75) | 1 | 18.4 | 0.019 |
| NO | 230(98.3) | 204 (88.7) | 26 (11.3) | | |
| HISTORY OF CATHETERIZATION | | | | | |
| YES | 16(6.8) | 15 (93.8) | 1 | 1.1 | 0.998 |
| NO | 281(93.2) | 192 (68.3) | 89 (31.7) | | |
| HISTORY OF UTI | | | | | |
| YES | 19(8.1) | 16 (84.2) | 3 (15.8) | 14.8 | 0.063 |
| NO | 215(91.9) | 191(88.3) | 24 (11.7) | | |
| ANAEMIC STATUS | | | | | |
| ANAEMIC | 8(3.4) | 7 (87.5) | 1 | 1.2 | 0.996 |
| NON-ANAEMIC | 226(96.6) | 200 (88.5) | 26 (11.5) | | |
| HIV SERO-STATUS | | | | | |
| POSITIVE | 20(8.5) | 17 (85) | 3 (15) | | |
| NEGATIVE | 209(89.3) | 186 (89) | 23 (11) | 19.3 | 0.254 |
| UNKNOWN | 5(2.1) | 4 (80) | 1 | | |

**Magnitude of asymptomatic bacteriuria (ASB)**

In this study 27 pregnant women harbor bacteria in their urine sample, this makes the overall prevalence of ASB at 11.5 % (27/234). In this study history of diabetes was significantly associated with ASB (X2=18.4, p=0.019) (Table1).

**Identified uropathogens and their current antimicrobial susceptibility profile**

The distribution patterns of bacterial uropathogens recovered from urine sample among pregnant women are found to be 27. Among these Gram-positive cocci constituted of 20 (74.1%) were Gram positives and 7(25.9%) were gram negatives. Out of the gram positives, the predominant isolate was S. saprophyticus at 48.2% (13/27) followed by S. aureus at 22.2% (6/27). Among gram negatives E. coli constituted of 11.1% (3/27) of the isolates. In this study S. agalactae, K. ozanae, K. rihinose, Enterobacter spp and Serratia spp were also identified (Figure 1).

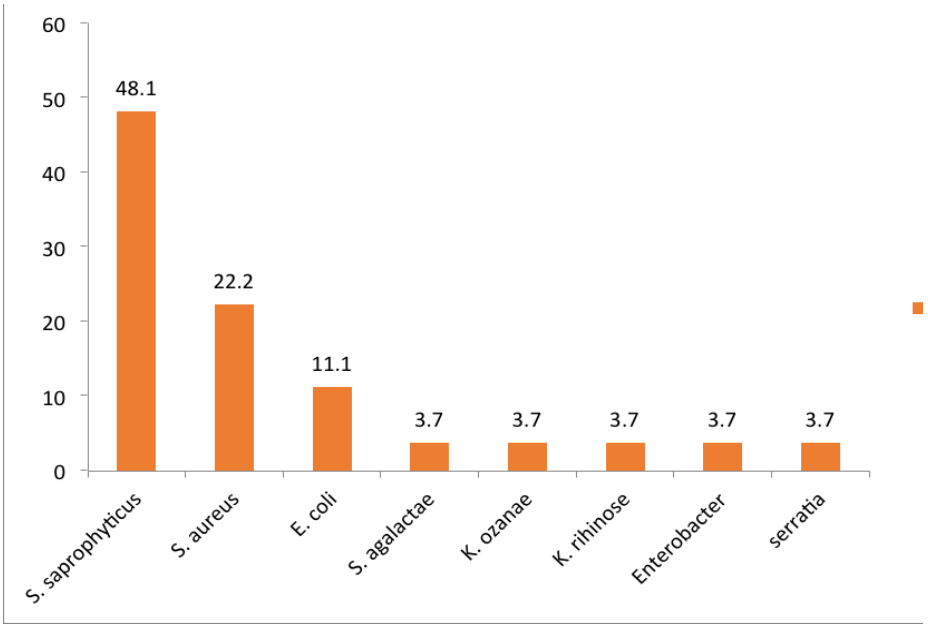


**Figure 1: Type and percentage distribution of uropathogens isolated from pregnant women with ASB in FHRH, 2016.**

With regard to antimicrobial susceptibility pattern of the isolates 11 (84.6%), 10 (76.9%) and nine (69.2%) of the 13 isolates of S. saprophyticus were found to be resistant to co-trimoxazole, oxacilin and tetracycline respectively. Similarly, five and three of 6 isolates of S. aureus were found resistant to tetracycline and co-trimoxazole respectively. No resistance (0%) was documented for amoxicillin-clavulinic acid and ciprofloxacin among gram positives. On top of this, all the three isolates of E. coli were resistant to tetracycline. However, all of them were sensitive to Norfloxacin (Table 2).

Table 2: Antimicrobial resistance profile of uropathogens identified from pregnant woman with ASB in FHRH, 2016.

| | | | RESISTANCE TO ANTIBIOTICS | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| TYPE OF ISOLATES | NO | PROFILE | AMP | AMC | CIP | CN | CLN | N | NOR | SXT | TTC | OXA | CEP |
| GRAM POSITIVES (20) | | | | | | | | | | | | | |
| S. SAPROPHYTICUS | 13 | R* | - | 0 | 0 | - | 0 | 1 | 4 | 11 | 9 | 10 | 3 |
| S. AUREUS | 6 | R | - | 0 | 0 | - | 0 | 0 | 0 | 3 | 5 | 0 | 1 |
| S. AGALACTAE | 1 | R | - | 0 | 0 | - | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| GRAM NEGATIVES (7) | | | | | | | | | | | | | |
| E. COLI | 3 | R | 2 | 2 | 1 | 0 | - | 1 | 0 | 1 | 3 | - | 1 |
| K. OZANAE | 1 | R | 1 | 0 | 0 | 0 | - | 0 | 0 | 1 | 1 | - | 0 |
| K. RIHINOSE | 1 | R | 1 | 0 | 0 | 0 | - | 0 | 0 | 0 | 1 | - | 0 |
| ENTEROBACTER | 1 | R | 1 | 1 | 0 | 0 | - | 0 | 1 | 1 | 1 | - | 1 |
| SERRATIA | 1 | R | 1 | 0 | 0 | 1 | - | 0 | 0 | 1 | 1 | - | 0 |
| TOTAL | 27 | R | 6 | 3 | 1 | 1 | 1 | 2 | 5 | 18 | 21 | 12 | 6 |

*R*= resistant, AMP = ampicillin, AMC = amoxicilin + clavulinic acid, CIP = ciprofloxacin, CN = gentamicin, CLN= Clindamycin, N=Nitrofurantion, NOR = norfloxacin, SXT = co-trimoxazole, TTC = tetracycline, OXA= oxacilin and CEP= Cephalotin*

## DISCUSSION

Most Ethiopian women are living in the rural settings where they are unable to get regular antenatal follow up during pregnancy. For those who live in urban and semi- urban areas government owned health centers and hospitals provide follow up for a minimum of four times throughout their pregnancy period for free. There is no routine urine culture test for pregnant women to screen ASB during follow up instead they tested urinalysis using urine chemical strip tests.

Asymptomatic bacteriruia (ASB) during pregnancy needs special consideration due to the absence of indication and its adverse consequences. An early detection and treatment of such cases may be of considerable importance not only to prevent acute pyelonephritis and chronic renal failure in the mother, but also to reduce the prematurity and fetal mortality16. In the present study the prevalence of asymptomatic bacteriuria was at 11.5% (27/234). Our findings are in agreement with data from other studies worldwide reported, including in Ethiopia ranges 16.1%-48%16, 27-30.

The design of the studies, including factors such as social habits and socio-economic status, practice of personal hygiene, and educational levels of the study subjects may have contributed for the discrepancies of the results. The study finding also showed that the prevalence of ASB among pregnant women with diabetes was significantly higher compared to those without diabetes (P = 0.019). Similar findings were reported from the studies conducted by Rizk et al (2001) that indicated diabetes mellitus could complicate up to 5% of the pregnancies and has been associated with an increased risk of both fetal and maternal morbidity [31].

In this study, we documented higher isolation rate of Gram positive bacteria at 20 (74.1%) compared to Gram-negatives at seven (25.9%). This proportion is higher than the proportions reported in Goner 11 but lower than in Hawassa27. In the present study, the predominant isolates from gram positive bactria were S. saprophyticus accounted at 13 (48.1%) E. coli was found to be the highest isolate at three (11.1%) among gram negatives from pregnanet women. The prevalence of staphylococci at 19(70.4%) in the present study was higher.

This could be due to the poor genital hygienic practices by pregnant women who may find it difficult to clean their anal or genitalia properly after defecating or passing urine[27]. Senani in 2011 reported predominantly S. agalactia and E. coli. from pregnant women[10]. However, Alemu et al in Gondar, Ethiopia reported overall prevalence of UTI among pregnant women at 10.4% with the predominant isolate of E. coli at 47.5 % followed by coagulase-negative staphylococci at 22.5 %, S. aureus and K. pneumonia at 10% each[11]. Similarly, a study by Imade et al[13]. and Ezechi et al[31] reported E. coli followed by S. aureus and E. coli followed by Proteus mirabilis were the most commonly bacterial isolates from pregnant women. The difference on the pattern of the isolates as compared with the present study might be due to the difference in the sample size, the lab diagnostic procedure and urine sample collection as it needs clean catch urine sample.

Out of 13 isolates of *S. saprophyticus*; 11 (84.6%), 10 (76.9%) and nine (69.2%) were found to be resistant to co-trimoxazole, oxacilin and tetracycline respectively. Similarly, five and three of the six isolates of *S. aureus* were resistant to tetracycline and co-trimoxazole respectively. All isolates of *E. coli* were resistant to tetracycline however, they are found sensitive to Norfloxacin. Comparable antimicrobial resistant pattern was reported from Gonder and Hawassa, Ethiopia[11, 27] although there is elevated resistance level against tetracycline and better sensitivity to Norfloxacin in the present study. The upsurge in the antibiotic resistant pattern could be due to antibiotic abuse and self-medication. Furthermore, it is reported that antimicrobial resistance rates among commonly isolated uropathogens continue to evolve and appear to be increasing to many commonly used agents[23], and their susceptibility varies from place and time[21-22].

Urine sample was collected once from each study participant regardless of their period of gestation, which could influence to reveal the real status of ASB during the entire period of pregnancy. This study lacks data on extended spectrum betalactamase production status of the isolates due to limited resources available in laboratory.

# CONCLUSIONS

In the studied area, 11.5 % ASB was documented, which is an important health concern of pregnant women that needs to be addressed. Furthermore, pregnant women with the history of diabetes merit special attention. Larger studies are warranted in

the future to assess the associations more precisely. Both gram positive and gram-negative bacteria were isolated from pregnant women. If unrecognized and untreated, asymptomatic bacteriuria could lead to adverse maternal and perinatal outcomes. Hence screening and treatment of such cases should be incorporated as a routine procedure in antenatal cares.

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# FACTORS AFFECTING LONG-TERM AND PERMANENT CONTRACEPTIVE UPTAKE AMONG IMMEDIATE POST-PARTUM MOTHERS AT SAINT PAUL'S HOSPITAL MILLENNIUM MEDICAL COLLEGE, ADDIS ABABA, ETHIOPIA: A CROSS-SECTIONAL STUDY

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## ABSTRACT

### BACKGROUND

Postpartum family planning (PPFP) focuses on the prevention of unintended and closely spaced pregnancies through the first 12 months following childbirth.

### OBJECTIVE

This study assesses the barriers to uptake of long-term and permanent family planning methods among immediate post-partum mothers at Saint Paul's Hospital Millennium Medical College in Addis Ababa, Ethiopia.

### METHODOLOGY

An institution-based cross-sectional study was conducted from January 1 to June 30, 2017. The six months of study were used as strata and systematic sampling used to select participants in each month. Post-partum mothers were interviewed using pretested structured questionnaires. Data entry and analysis were done using SPSS version 17. Bivariate and multivariable logistic regressions were fitted to identify determinants of post-partum family planning uptake. A OR with 95% CIs were calculated, and p values set at 005 was used to determine statistical significance of associations.

### RESULTS

Four hundred and twenty-two post-partum women were interviewed. Two hundred sixty-eight (63%) women received counselling on family planning and 241 (66.8 %) got information about contraception. One hundred and nifty two (45%) of the women accepted long-term and permanent contraception on their immediate postpartum period before discharge. Contraceptive counselling (OR=2.13, 95% CI 1.004-3.331), getting information from the health facility (OR=15.15, 95% CI 1.848-19.242), and partner support (OR=1.367, 95% CI 1.175-2.771) were significantly associated with long-term and permanent contraception uptake.

### CONCLUSION

Postpartum counselling on family planning and provision of contraception information improves immediate postpartum FP acceptance, and, hence postpartum programs need to strengthen such services.

**KEY WORDS:** Contraception, Immediate postpartum, Long-term family planning.

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# INTRODUCTION

Postpartum family planning (PPFP) focuses on the prevention of unintended and closely spaced pregnancies through the first 12 months following childbirth [1]. The postpartum period is critical for addressing widespread unmet needs in family planning (FP) and for reducing the risks of closely spaced pregnancies [2]. FP can avert more than 30% of maternal deaths and 10% of child mortality if couples space their pregnancies more than 2 years apart [3]. If all couples waited 24 months to conceive again, under-five mortality would decrease by 13%. If couples waited 36 months, the decrease would be 25% (4). According to an analysis of Demographic and Health Surveys data from 27 countries, 95% of women who were 0–12 month's post-partum wants to avoid a pregnancy in the next 24 months; but 70% of them were not using contraception[5]. Research has shown prenatal visits[6][7], place of delivery[6][7][8], postnatal visits[7][9], family planning counseling during antenatal care (ANC) and postnatal care (PNC)[10][11] and resumption of menses after birth [7][9], to be key predictors of postpartum modern contraceptive use. In Ethiopia, evidence has shown that nearly half (47%) of all pregnancies occur within a short birth interval of less than 24 months after the preceding birth[12].

Postpartum women are an important group as they may not realize that they are at risk of pregnancy even if they are breastfeeding[13]; and the immediate post-partum period is the window of opportunity for our clients to address the unmet need for FP. The aim of the study therefore is to determine factors that affect uptake of long term and permanent contraceptive (LTPC) services among immediate post-partum mothers. Identifying such factors could inform clinicians and policy makers and suggest context specific strategies to improve contraceptive service provision amongst post-partum mothers in order to reduce unintended pregnancies with short interval and decrease maternal morbidity and mortality. Post-partum in this study refers mothers within one week of delivery and before discharge from hospital.

## METHOD

This is a hospital-based cross-sectional study .5around 8,677 deliveries were attended in 2016 G.C. Four hundred and twenty-two immediate post-partum women who were less than one week after delivery before discharged from hospital irrespective of mode of delivery and gave written informed consent from January 1 to June 30, 2017 participated in the study. Women who didn't fulfill WHO's medical eligibility criteria were excluded.

Sample size was calculated using single population proportion sample size estimation formula (n = Z2 p (1-p) / w2); where n was sample size; 1.96 and 95% were used for Z and confidence interval, respectively. P (proportion) of 21 % is modern contraceptive up take six months after delivery and was taken from EDHS[15] and with margin of error (W) of 5 %, substituting each in to the formula the sample size (n) was 255. With 1.5 multiplying design effect (DE) and 10% non-response, a sample size of 422 immediate postpartum women was used.

Data collection period was spread out for a period of six months to enable us capture any variations. The sample were divided among six months which gave us a sample of 70 participants in the first 4 months and 71 clients in the 5$^{th}$ and 6$^{th}$ month of study period. Considering average monthly delivery of 850 in the hospital and dividing by 70 which was sample size in each month yields 12, so every 12$^{th}$ delivery was sampled until sample size in each month was acheived.

Up take of long term and permanent contraceptive methods was the dependent variable considered while demographic and obstetric characteristics and FP counseling, information, prior use and partner support were considered as independent variables. A questionnaire was prepared in English and translated into Amharic and pretested at SPHMMC. Five data collectors and two supervisors were trained to facilitate data collection. Data was collected after obtaining informed written consent. The principal investigator and two research assistants supervised the data collection exercise. Data editing was done by the principal investigator to ensure consistence and completeness of data.

Data was entered and analyzed using Statistical Package of Social Sciences (SPSS) version 17.0.

Binary logistic regression was done and variables with p value <0.2 were selected for multivariable logistic regression analysis to see association of variables. A OR and 95% confidence interval and p value set at 0.05 were used to determine the statistical significance of the associations.

Ethical approval for the research was obtained from the SPHMMC Ethics and Research Committee. Informed consent was taken from each respondent before participation in the study. Questionnaires were coded and patients' names were not used. No incentives were given to the study participants. Privacy and confidentiality were safeguarded throughout the course of the study. Participants who desired LTPC were linked to and provided by family planning team. Data collectors introduced themselves to each participant and inform her of the nature and purpose of the study. The participants were participated in the study on a voluntary basis.

## RESULTS

Four hundred twenty-two (422) post-partum participants were interviewed before discharge with 100% response rate. The mean age of the respondents was 26.7 years (SD=4.7) years median parity of 2 (IQR 1-3). Majority of the women (n=296, 69.8 %) were housewife and residents inAddis Ababa (n=196, 46.2 %) (Table 1).
The mean number of live-children was 2 (SD=1.29) and 52(12.7 %) women had at least one abortion before the current delivery. The current pregnancy was planned pregnancy in 351(82.8 %). Majority of the women gave birth vaginally (n=249, 58.7 %) and had health neonate (n=355, 79%) (Table 2).
Table 2: Reproductive characteristics of post-partum mothers at Saint Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia, June 2017(n=422)

Table 1: Socio-demographic characteristics of post partum mothers at Saint Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia, June 2017(n=422)

| Variable | Frequency (%) |
|---|---|
| Religion | |
| Christian | 320(75) |
| Muslim. | 102(25) |
| Marital status | |
| single | 18(4.2) |
| Married | 401(94.6) |
| Divorced | 3(.7) |
| Educational status. | |
| Illiterate. | 76(17.9) |
| Primary school. | 187(44.1) |
| Secondary school. | 111(26.2) |
| College and above. | 48(11.3) |
| Occupation | |
| Daily laborer. | 6(1.4) |
| Student. | 11(2.6) |
| Employee. | 90(21.2) |
| House wife. | 296(69.8) |
| Others. | 19(4.5) |
| Address. | |
| Addis Ababa. | 196(46.2) |
| Out of Addis Ababa. | 224(52.8) |

| VARIABLE. | FREQUENCY (%) |
|---|---|
| PARITY | |
| 1-2 | 296(70.1) |
| 3-4 | 102(24.1) |
| ≥5 | 24(5.8) |
| ABORTION | |
| YES. | 52(12.7) |
| NO. | 370(87.3) |
| MODE OF DELIVERY VAGINALLY. | 249(58.7) |
| C/S. | 173(41.3) |
| DELIVERY OUTCOME ALIVE AND WITH MOTHER. | 355(79.5) |
| ALIVE AND REFERRED TO NICU. | 71(16.7) |
| STILL BIRTH | 16(3.8) |
| WAS THE PREGNANCY PLANNED? | |
| YES. | 351(82.8) |
| NO. | 71(17.2) |

Majority of the women (n=299, 70.9%) were aware of LTPC methods while 123 (29.1 %) had never heard of such methods. The main sources of family planning information were health facilities (n=241, 66.8 %). Two hundred and sixty-eight (63.2 %) of the post-partum women got FP counseling and majority of the counseling (n=175, 65.2%) were done post-partum (Figure 1).

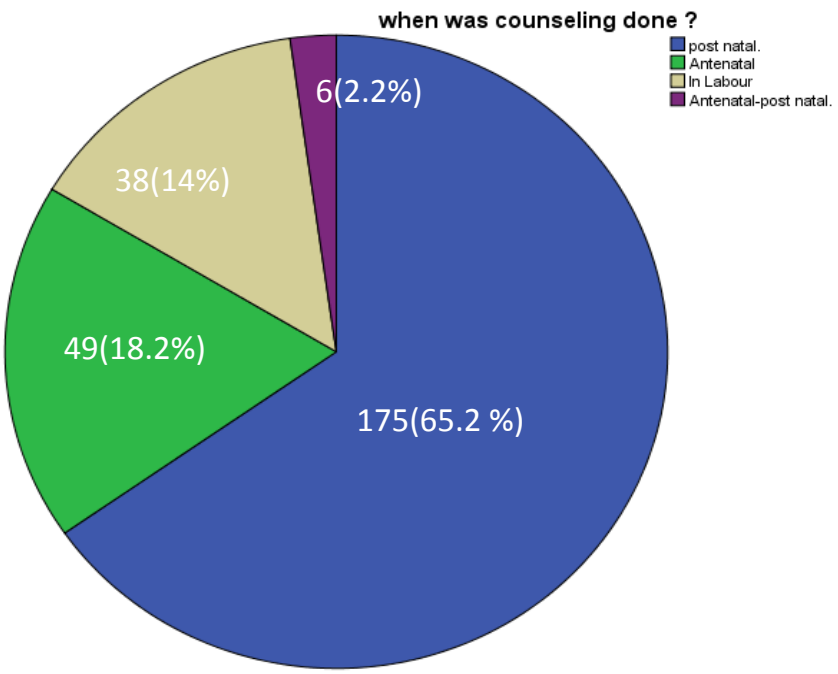


**Figure 1: Family planning counseling timing at Saint Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia, June 2017(n=268)**

Majority of the women 233 (55%) had support from their partners on the use of LTPC methods (Table 3).

**Table 3: Contraceptive awareness and utilization characteristics of post-partum mothers at Saint Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia, June 2017(n=422)**

| VARIABLE. | FREQUENCY (%) |
|---|---|
| TYPES OF CONTRACEPTIVE USED BEFORE | |
| OCP. | 44(10.4) |
| DMPA. | 153(36.1) |
| IMPLANT. | 44(10.4) |
| IUCD. | 14(3.3) |
| NEVER USED | 167(39.8) |
| AWARENESS OF LTCM | |
| YES. | 299(70.9) |
| NO. | 123(29.1) |
| WOULD LIKE/PREFER TO USE LONG TERM METHOD? | |
| YES. | 213(50.5) |
| NO. | 209(49.5) |
| PARTNER SUPPORT USE OF FAMILY PLANNING? | |
| YES. | 233(55) |
| NO. | 185(43.6) |
| NOT APPLICABLE. | 4(1.4) |
| FP INFORMATION | |
| HEALTH FACILITY | 241(57.1) |
| OTHERS (MEDIA, FRIENDS, RELATIVES) | 123(29.1) |
| NO INFORMATION. | 58(13.8) |
| CONTRACEPTIVE COUNSELING | |
| YES. | 268(63.6) |
| NO | 154(36.4) |

Almost half of women (n=213, 50.5 %) preferred using LTPC methods, among which 192(45.5%) accepted LTPC method before discharge from hospital, 64 Jadelle (15.1%), 90 Implanon (21.2%), 33 IUCD (7.8%) and 5 BTL (1.2%). The remaining 21(5%) who preferred LTPC wants to use it on interval method.

The study revealed that the odds of using LTPC was 2.3 times higher in women who deliver vaginally than by cesarean section, P=0.010, a OR=2.33(95% CI 1.125-3.545). Those who had secondary school education were 3.9 times more likely to use LTPC compared to those with no education, p=0.027, a OR=3.907(95%CI, 1.165-13.057). Government employee were six times likely to use LTPC compared with merchants p=0.037, a0R=6.347 (95% CI 1.237-33.161). The Odds of using LTPC was 77% lower in those with previous abortion history compared to those with no abortion. P=0.035, a OR=0.332(95% CI 0.119-0.926) (Table 4).

**Table 4: Socio demographic and reproductive characteristics verses LTPCs preference at Saint Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia, June 2017(n=422)**

| Variable | LTPCS PREFERENCE. | | COR (95% CI) | P VALUE | A OR (95% CI) |
|---|---|---|---|---|---|
| | Yes 213(50.2%) | No 209(49.5%) | | | |
| **Parity.** | | | | | |
| **1-2** | 133(62.4%) | 163(77.9%) | 2.97(1.199-7.391) | 0.019 | 3.81(0.231-4.051) |
| **3-4** | 63((29.5%) | 39(18.6%) | 1.50(0.572-3.952) | 0.408 | 1.35(1.000-1.695) |
| **≥5** | 17(7.9%) | 7(3.3%) | 1 | | |
| **Occupation** | | | | | |
| **Daily laborer** | **2(0.94%)** | **4(1.9%)** | **5.62(0.773-40.594)** | **0.880** | **2.07(1.920-3.467)** |
| **Student** | **4(1.87%)** | **7(3.34%)** | **4.91(0.992-24.208)** | **0.051** | **4.13(0.089-5.826)** |
| **Employee** | **36(16.9%)** | **54(25.8%)** | **4.20(1.391-12.678)** | **0.011** | **6.40(1.237-33.161) *** |
| **House wife** | **159(74.6%)** | **137(65.5%)** | **2.47(0.871-7.058)** | **0,089** | **3.17(1.250-4.567)** |
| **Merchant.** | **12(5.63%)** | **7(3.34%)** | **1** | | |
| **Marital status.** | | | | | |
| **Single.** | 6(2.8%) | 12(5.7%) | 4.12(0.299-53.468) | 0.295 | |
| **Married** | 205(96.2%) | 196(93.7%) | 1.91(0.172-21.207) | 0.598 | |
| **Divorced** | 2(0.9%) | 1(0.4%) | 1 | | |
| **Educational status** | | | | | |
| **College education.** | 49(23%) | 27(12.9%) | 0.59(0.287-1.250) | 0.172 | 0.09(0.583-1.240) |
| **Primary school.** | 96(45%) | 91(43.5%) | 1.03(0.546-1.944) | 0.926 | 1.37(0.999-1.890) |
| **Secondary school.** | 43(20%) | 68(32.5%) | 1.71(0.868-3.403) | 0.120 | 3.90(1.165-13.057) * |
| **Illiterate.** | 25(11.7%) | 23(11%) | 1 | | |
| **Abortion** | | | | | |
| **Yes.** | 20(9.3%) | 31(14.8%) | 0.59(0.329-1.088)1 | 0.092 | 0.33(0.119-0.926) * |
| **No.** | 192(90%) | 178(85.1%) | | | |
| **Mode of delivery** | | | | | |
| **Vaginally.** | 111(52.1%) | 138(66%) | 1.78(1.206-2.645) | 0.004 | 2.33(1.125-3.545) * |
| **C/S Delivery.** | 102(47.8) | 71(33.9%) | 1 | | |
| **Delivery outcome.** | | | | | |
| **Alive and with mother.** | 176(82.6%) | 159(76%) | 0.30(0.095-0.953) | 0. 041 | 0.20(0.182-2.850) |
| **NICU.** | 33(15.4%) | 38(18.1%) | 0.38(0.113-1.305) | 0.125 | 0.43(0.123-1.843) |
| **Still birth.** | 4(1.8%) | 12(5.7%) | 1 | | |
| **Planned pregnancy?** | | | | | |
| **Yes.** | 165(77.4%) | 186(88.9%) | 1.82(0.000) | 1.000 | |
| **No.** | 47(20.6%) | 23(11%) | 1 | | |

*p value<0.05

Those who get counseling were two times more likely to use LTPC**, a** OR=2.13(95%CI 1.004-3.331), **P=0.003** compared with those who has no FP counseling. Those women who get contraceptive information from health facility were 15 times more likely to use LTPC compared to those who hear from Medias, friends or relatives, OR=15.15(95% CI 1.848-19.242), p=0.011**.** Mothers who have Partner support for the use of LTPCs were 1.3 times more likely to uptake LTPC than those who has no partner support, a OR=1.367(95% CI 1.175-2.771), p = 0.008. Odds of LTPC uptake was 6 times higher in past OCP users compared to those never used contraception, a OR=6.033(95% CI 1.151-31-637), p=0.050 (Table 5).

**Table 5: Contraceptive knowledge and counseling versus LTCM preference at Saint Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia, June 2017(n=422)**

| Variable | LTPC preference. | | COR (95%CI) | P value. | A OR (95% CI) |
|---|---|---|---|---|---|
| | YES | NO | | | |
| | 213(50.2%) | 209(49.5%) | | | |
| Awareness of any contraceptive | | | | | |
| Yes. | 187(87.7%) | 176(84.2%) | 0.71(0.408-1.247) | 0.236 | |
| No. | 25(11.7%) | 33(15.7%) | 1 | | |
| Awareness of LTCM | | | | | |
| Yes. | 165(77.4%) | 134(64.1%) | 13(0.000) | 1.000 | |
| No. | 47(22%) | 75(35.8%) | 1 | | |
| Contraceptive used before | | | | | |
| OCP | 19(8.9%) | 25(11.9%) | 4.82(1.179-19.74) | 0.029 | 6.03(1.151-31-637* |
| DMPA | 76(35.6%) | 77(36.8%) | 3.71(0.997-13.84) | 0.050 | 3.23(1.231-4.240) |
| Implant. | 29(13.6%) | 15(7.1%) | 1.89(0.458-7.851) | 0.377 | 4.16(1.756-5.782) |
| IUCD. | 11(5.1%) | 3(1.4%) | 0.76(0.520-1.138) | 0.189 | 2.62(1.489-3.694) |
| Never used | 77(36.1%) | 89(42.5%) | 1 | | |
| Source of information | | | | | |
| Health facility | 133(62.4%) | 108(51.6%) | 2.66(0.133-3.334) | 0.070 | 15.15(1.848-19.242) * |
| Others (Media, friends, relatives) | 56(26.2%) | 68(32.5%) | 1 | | |
| Contraceptive counseling | | | | | |
| Yes. | 161(75.5%) | 107(51.2%) | 1.33(0.224-2.513) | 0.001 | 2.13(1.004-3.331) * |
| No. | 52(24.4%) | 102(48.8%) | 1 | | |
| Time of counseling | | | | | |
| Post-partum. | 89(41.7%) | 86(41.1%) | 156(0.000) | 0.999 | |
| Antenatal. | 34(15.9%) | 15(7.1%) | 712(0.000) | 0.999 | |
| In Labour. | 32(15%) | 6(2.8%) | 302(0.000) | 0.999 | |
| Antenatal-post-partum. | 6(2.8%) | - | 1 | | |
| Partner support. | | | | | |
| Yes. | 142(66.6%) | 91(43.5%) | 1.37(0.250-2.555) | 0.001 | 1.36(1.175-2.771) * |
| No. | 68(31.9%) | 117(55.9%) | 1 | | |

*p value <0.05

Participants report that fear of side effect 81 (38.8%), opposition from husband 52 (24.9%) and desire to have more children 27 (12.9%) were main reasons for not using long term and permanent FP methods. (Table 6)**.**

**Table 6: Reasons for non-use of LTPCs amongst immediate post-partum at Saint Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia, June 2017(n=209)**

| Maintained reasons. | Frequency | Percent |
|---|---|---|
| Desire to have more pregnancy | 27 | 12.9 |
| Peer/family Pressure | 7 | 3.3 |
| partner opposition | 52 | 24.9 |
| Lack of awareness | 12 | 5.7 |
| Fear of side effect | 81 | 38.8 |
| Religious influence. | 11 | 5.3 |
| Wants to use other method | 19 | 9.1 |
| Total | 209 | 100.0 |

## DISCUSSION

The findings showed that the prevalence of LTPC uptake at immediate post-partum was 45.5% (n=192) This finding is in line with studies conducted in town of Gondar (48.4%) [7], in Kenya and Zambia (46%),[14] in Rwanda (50%) [15], and in Mexico (47%) [16]. However, is above the national prevalence of use of LTPCs [17]. This might be because of facility based and our hospitals policy on counseling post-partum mothers on LTPC considering postnatal care a window of opportunity for information; education and communication to newly delivered mothers so that they will make appropriate choices especially towards care of infants and themselves and particularly take decisions on use of family planning methods. However, patients might discontinue the method any time making national prevalence low.

This study revealed family planning counseling rate of 63.2%. This is similar to a study done in Kenya, Namibia and Tanzania in 2011 which found that that only some of participants had discussed family planning with a health care provider (68% in Kenya, 40% in Namibia and 32% in Tanzania) [18]. In this study counseling on family planning in general increases up take of it but passing of family planning information specifically during antenatal clinic does not improve chances of a mother using a long term and permanent family planning method (p value=0.999). zbe because during pregnancy, family planning may not be a priority and the pregnant mother may be more concerned with the health of the fetus they are carrying. They may also be more interested of how to carry the pregnancy to term without any complications and issues of family planning uptake may be important only after delivery of the baby.

Women with vaginally delivery were more likely use LTPC (p= 0.010) but previous abortion was negatively associated with uptake of LTPC, a OR=0.332(95%CI 0.119-0.926) P=0.035. This might be because of health professionals skewed counseling more of to those with normal vaginally delivery despite the fact that those who gave birth by cesarean section benefits more and people with abortion might be not using with lack of proper information thinking that infertility and abortion associated with long term contraception.

Getting information about contraception from health facility supports uptake of LTPC (p value=0.011). This may be due to adequate information to address the family planning needs of the clients at the health facility than from media, relatives or friends. Again, important to note is that in the study (70.9%) of mothers had been exposed to information on long term and permanent family planning methods, yet this did not increase the preference for LTPCs (p value1.000). This may be due to inadequate information to address the family planning needs of the clients. For example, the main reason why post-partum mothers were not using LTPCs was fear of side effect. This may also be because the mothers have a lot of unexplained questions specially to do with perceived side effects of LTPCs.

Despite availability of long term family planning methods services at immediate post-partum at SPHMMC, the preference for them was at 50.5 %. Among client related factors, the number of living children was not found to influence preference for LTPC uptake in this study. This is contrary to what other study reported(19). This could be explained by the study being done in an urban setting and by the positive attitudes of men towards FP services
This study revealed that 55% of men support use of LTPCs by their women and LTPC uptake was improved by partner support, a OR=1.368(95%CI 1.175-2.771) P=0.008. Male involvement in Reproductive health services is crucial to improve LTCMs uptake. This is similar finding with reports from different part of our country that wife-husband discussion increase LTPC up takes(7) [20].
The study revealed that prior use of OCP was associated with more LTPC uptake compared to none users of any contraception. This can be explained by the fact that women who are not satisfied with short-acting methods but still wish to avoid pregnancy need alternative family planning choices(21).

Level of education and occupation of the women associated with long term contraceptive uptake in this study. This is similar with other study [6][11][22][23].
The reasons stated by many women (38.8%) for not using LTPC were fear of side effect. Women also report opposition from husband, desire to have more children and few reported lacks of awareness about LTPC as reason for not using. This is similar finding with national report, EDHS 2016[17] and study done in Aksum, northern part of Ethiopia [24].

Level of education, occupation, vaginally delivery, previous abortion, partner support and prior use of OCP were associated with long term and permanent contraceptive method up take.

High proportion of post-partum mothers reported fear of side effect as a reason for not using LTPC, so detailed counseling with partner involvement would ensure the mothers receive accurate and complete information on LTPCs to reduce the myths and perceptions concerning the LTPC use during postpartum period and beyond.

## ACKNOWLEDGMENT

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## CONFLICT OF INTEREST

The authors have no conflicts of interest to declare for this study

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# KNOWLEDGE, ATTITUDE AND PRACTICE OF CERVICAL CANCER SCREENING AMONG WOMEN AGED 15-49 YEARS IN BISHOFTU TOWN, EAST SHEWA ZONE, OROMIA REGION, ETHIOPIA, 2016

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## ABSTRACT

### BACKGROUND

Every year more than 270.000 women die from cervical cancer, most of the morbidities and mortalities are from low and middle-income countries. Like other developing countries, its burden is also high in Ethiopia and about 7, 095 new cases are diagnosed annually and 4,732 women die from the disease.

### OBJECTIVE

This study aims at assessing the knowledge, attitude and practice of cervical cancer screening among women aged 15-49 years in Bishoftu town, East Shewa Zone, Oromia Region, Ethiopia.

### METHOD AND MATERIALS:

A community based cross-sectional study was conducted using multistage sampling technique among 845 reproductive aged women in Bishoftu town. Structured questionnaire was pretested and administered by interviewer to collect data and it was analyzed using SPSS version 20 software. Bivariate analysis was conducted to examine association between dependent and independent variables; Odds Ratios (ORs) and their 95% Confidence Intervals (CIs) were calculated. Then, multivariable logistic regression analysis model was used to control for confounders. Statistical significance was set at p-value less than 0.05.

### RESULTS

Among all study participants, 51.2% had good knowledge, 74.9% had favorable attitude, and 5.8% screened for cervical cancer. Level of education and source of information were associated with favorable attitude towards cervical cancer and its screening. Moreover, women who had good knowledge on cervical cancer and screening were more likely to have cervical cancer screening service uptake than those had poor knowledge (AOR=6.95, 95% CI (2.59-18.57)).

### CONCLUSION

The study indicates that more than half of the study participants had good knowledge on causes, risk factors and preventive methods of cervical cancer and its screening. Majority of the participants have favorable attitude towards cervical cancer screening but, the practice of pre-cervical cancer screening is still low. Thus, awareness raising health education on cervical cancer and its screening should be given to the community by trained health workers and emphasis should be given for health promotion via masmedia.

**KEYWORDS**: Cervical cancer; screening; Bishoftu; Eastern Ethiopia

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## INTRODUCTION

Cancer of the cervix is the fourth common cancer worldwide and the second commonest female cancer[1]. In Ethiopia, cervical cancer ranked as the second commonest female cancer among reproductive aged women[2]. Majority of cervical cancer is caused by sexually-acquired infection with Human Papillomavirus (HPV) worldwide and 70% of cases are caused by HPV types 16 and 18[3].

In low income countries, cervical cancer is associated with significant morbidity and mortality. This is mainly due to lack or poor access to screening options and treatment services[4,5].Cervical cancer screening is the testing for precancerous lesions. Currently, the available options of cervical cancer screening are Pap smear, Visual inspection with Acetic Acid and HPV testing for high risk HPV types. Early detection and treatment of precancerous lesions can prevent cervical cancers[6].

However, competing health care priorities, insufficient financial resources, weak health systems, and limited numbers of trained providers have made high coverage for cervical cancer screening difficult to achieve[7]. Globally, in 2012, there were nearly a billion eligible women for cervical cancer screening, most of whom have never been screened even once in their life[3]. In Ethiopia, only 0.6% of eligible women were screened for cervical cancer[2].

In Ethiopia to reduce the impact of cancer Recently, FMOH launches guideline for cancer control plan which aims to provide healthcare providers, implementing partners and other stake holders involved in the prevention and control of cervical cancer in the country with standardized cancer prevention and control health service delivery[8].

The success and benefits of screening at a national and regional level as a public health program to control and prevent cervical cancer depend to a great extent on the level of awareness of the potential beneficiaries. Ethiopia, still there is scanty information regarding knowledge, attitude, and practices related to cervical cancer and its screening. Because of numerous factors, the level of knowledge, Attitude and practice on cervical cancer is low in developing countries[4].

## METHODS

A community based cross-sectional study design was employed using both quantitative and qualitative methods to assess the knowledge, attitude and practice on cervical cancer screening among women aged 15-49 years in Bishoftu town, Eastern Ethiopia.

The source population was all reproductive (15-49) age women living in Bishoftu town and the study participants were all randomly selected women aged 15-49 years who live in selected kebeles of Bishoftu town. All sampled women aged 15-49 years, reside at least for six months in Bishoftu town and willing to participate in the study. Women who are seriously ill, who have been diagnosed for cervical cancer, who have hysterectomy and were health professional were excluded.

The required sample size for the quantitative study was determined by using Single Population Proportion formula based on the following assumptions. The proportion of attitude from similar study done in Kinshasa, the Democratic Republic of Congo was 52% (p=0.52, q=0.48), $Z_{\alpha/2}$= 1.96 (95% confidence interval) and d= 5% (0.05)[10]. Based on this assumption, the sample size become 384, but by considering design effect of 2 and none response rate of 10% the final sample size become 845.

Multistage sampling technique was used in this study. First, three out of nine Kebeles of Bishoftu Town were selected by simple random sampling technique. The sampling frame was prepared by using the house numbers and for households with more than one woman aged 15-49 years, only one woman was selected using lottery method. Then, individual household in the selected three Kebeles were selected using a simple random sampling technique. Finally, proportionate sample size allocation was used for each selected kebeles to get the final sample size. Closed houses during data collection were revisited by the interviewers three times at different intervals and those who were not available excluded from the survey and were replaced by the next nearest houses. Some incomplete data collected by the interviewers were completed in the next days on the field to achieve the maximum sample size.

A structured and pre-tested questionnaire was administered to collect data for the quantitative study. After reviewing similar studies, the questionnaire was originally prepared in English and was translated to regional working language, Afan Oromo, by professionals. Afan Oromo was translated back to English language in order to check its consistency. Fifteen female nurses were recruited and trained on procedures of data collection. All completed questionnaire was reviewed by the principal investigators.

Data entry was done using Epi-Info version 3.5.3 after checking for completeness. It was then cleaned and exported to SPSS Version 20 for analysis. Frequencies and other descriptive statistics were done. Bivariate analysis was used to examine the association between dependent and independent variables; Odds Ratios (ORs) and their 95% Confidence Intervals (CIs were calculated. Then, all variables that had P-value less than 0.2 in the bivariate analysis were included in the multivariate logistic regression analysis model to determine the factors associated with dependent variables. Statistical significance was set at p-value less than 0.05.

Three focus group discussions were conducted and a total of 30 reproductive aged women participated in the discussion. The total numbers of focus group discussion were determined by the level of saturation. The participants were selected purposively from selected zones (those who were not participated in the quantitative study) during data collection and a total of 9-11 participants were considered. Knowledge of the respondents on cervix cancer and pre-cancer cervical lesion screening was assessed by using some basic knowledge assessing questions. A total of 12 correct responses were documented from 8 multiple choice questions. Right and wrong responses were given 1 and 0 score respectively. The minimum score was 0 point and the maximum point was 12. Those respondents whose scored was less than the mean score were considered as they have poor knowledge and those respondents whose score is exceeds or equal to the mean score were assumed as they have good knowledge on cervical cancer and its screening.

Attitude of the study participants on cervical cancer and screening was assessed by using the following rules. First, seven questions with Likert scale were used. The questions on Likert's scale which ranges from strongly agree to strongly disagree had positive and negative responses. The responses were summed up and a total score was obtained for each respondent. A maximum and minimum score were expected to be 35 and 7 respectively. Finally, those whose score was exceeding or equal to the mean were considered favourable attitude and those whose scores is less than the mean was considered as unfavorable attitude.

The practice was assessed based on the respondents' experience towards screening for pre-cancer cervical lesion. Those respondents who screen for cervical cancer at least once and more were regarded as having practice and those respondents who were never screened for cervical cancer in life time were regarded as having no practice on screening.

For the qualitative study, audio recorder was used

as primary data collection tool with note taking during discussion process. Then, each discussion recorded with audio recorder, was transcribed and used for triangulation purpose.

The recorded data was transcribed to English language. Next, the raw qualitative data coded, categorized and labeled by using open code software and content analysis was employed to analyze the data. The codes used in open code software were categorized in to four different groups. Categories of groups were based on related ideas and concepts under some selected themes based on the guideline tools and the data summarized under the theme. Finally, the result used for triangulation purpose.

Ethical clearance was obtained from the Research Ethics Review Committee(RERC) of Wollega University. Bishoftu town health office was informed on study aim and objective and study permission were obtained. After informing the purpose and objective of the study, written informed consent was obtained from each study participants. Additionally, written consent was obtained from guardians for those aged below 18 years. The participants were assured that the information that they have given would be used only for the purpose of the study. Confidentiality was assured by not recording interviewee name on the questionnaire.

## RESULTS

A total of 845 reproductive aged women participated in the quantitative study, which yields a response rate of 100%. The age of the study participants ranges from 15-49 years with mean age of the 32 years (SD±6.8). Majority of the participants were married (73.3%), self-employed (43.4%), More than half of the participants (67.5%) had given birth one to four children and (94.2 %) had formal education.

The age at first sexual intercourse ranged from 14 to 29 years with the mean of 20 years(SD±2.4). One hundred-seven (13.4%) of the study participants had first sexual intercourse before 18 years. On the other hand, 8(1.0%) of respondents had more than one sexual partner. Majority of the respondents 602(71.2%) used modern contraceptive. Among the respondents who used modern contraceptive, 92 (15.3%) of them were 'current users' of oral contraceptive pills (OCP), 22(23.9%) of them used the OCP for 5 or more years. Of all the participants, 5(0.6%) had cigarette smoking habit. Seven hundred -ninety (93.5%) respondents were tested for HIV/AIDS and 23(2.9%) were HIV positive (Table1).

**Table 1: Risk exposure among the study participants, Bishoftu, 2016**

| Variables | Frequency | Percentage |
|---|---|---|
| Age at first sexual intercourse (n=798) | | |
| <18 years | 107 | 13.4 |
| ≥18 years | 691 | 86.6 |
| Number of sexual partners(n=798) | | |
| One | 790 | 99.0 |
| Two or more | 8 | 1.0 |
| Hormonal contraception use | | |
| Yes | 602 | 71.2 |
| No | 243 | 28.8 |
| Smoking habit | | |
| Yes | 5 | 0.6 |
| No | 840 | 99.4 |
| HIV test result (n=790) | | |
| Non-reactive | 767 | 97.1 |
| Reactive | 23 | 2.9 |

A 23 years old student participant stated that: "Since HIV/AIDS reduce our immunity and invite opportunistic infection, it also can be risk factor for cervical cancer." While another one stated that: "I heard about the risk factors for cervical cancer from FM radio first. I remembered that smoking, early sexual intercourse and a virus which is called HPV or similar to this name where broadcast through the radio and I learned that."

Of all the participants 650(76.9%) had heard about cancer in general while 619 (73.3%) had heard about cervical cancer in particular. The major source of information on cervical cancer were the media (n=312, 50.4%) and health professionals1(n=49, 24.1%). Ninety-eight (11.6%) knew that someone with cervical cancer. Among the participants who knew someone with cervical cancer, 20(20.4%) were their family members, 33 (33.7%) were their relatively and 28(28.6%) were their friends. In general, four hundred thirty -three (51.2%) had good and 412(48.8%) had poor knowledge.

A 34 years old mother participant stated that, she learned about cervical cancer first ".... at a church when the pastor preaches us. He told us it is a disease caused by having multiple sexual partners and due to not be faithful for our marriage."

A 22 years old computer science college student participant expressed her experience with a cervical patient as follows:
"I remembered how my aunt died after suffering for more than 5 years with cervical cancer. Before she died she told me that cervical cancer is caused by virus during sexual intercourse. I remember her every day and every night how she suffered. Due to that, I am scared to start relationship and sexual intercourse with anyone."

Regarding the causes of the disease, 228(25.8%) knew that two and more causes of cervical cancer. Among the respondents who knew causes of cervical cancer, majority 325(38.5%) were respond that cervical cancer caused by having multiple sexual partners. 338(40.5%) stated that vaginal bleeding as a symptom of cervical cancer and 368(43.6%) said vaginal foul smelling as a symptom of cervical cancer (Table 2).

**Table 2: knowledge on causes and symptoms of cervical cancer, Bishoftu, 2016**

| Variables | | Frequency | Percentage |
|---|---|---|---|
| Knowledge on cause of cervical cancer | | | |
| Having multiple sexual partner | Yes | 325 | 38.5 |
| | No | 520 | 61.5 |
| Early sexual intercourse | Yes | 291 | 34.4 |
| | No | 554 | 65.6 |
| Acquiring HPV virus | Yes | 47 | 5.6 |
| | No | 798 | 94.4 |
| Cigarette smoking | Yes | 60 | 7.1 |
| | No | 785 | 92.9 |
| **Symptom of cervical cancer** | | | |
| Vaginal bleeding | Yes | 338 | 40.0 |
| | No | 507 | 60.0 |
| Vaginal foul-smelling discharge | Yes | 368 | 43.6 |
| | No | 477 | 56.4 |

A 45 years old mother participant stated that: "In my opinion, cervical cancer is caused by lack of personal hygiene. If we properly protect our personal hygiene on daily base, we can prevent it."

A 27 years old mother participant stated that; "I heard from media that recurrent abnormal bleeding between menstruations is a major symptom for cervical cancer."

Of all the participants, 208(27.8%) knew two or more prevention methods for cervical cancer: 339(40.1%) knew avoiding multiple sexual partners as prevention method for cervical cancer. More than half of the respondents (n=527, 62.4%) knew that cervical cancer cured at early stage and 240(28.4%) believed the availability of screening procedure. Concerning treatment option for cervical cancer, only 61(7.2%) of the study participant knew two or more treatment options. From these respondents only 22(4.2%) believed that herbal remedies are treatment option for cervical cancer. 90(37.5%) knew that once every three years' cervical cancer screening done and 186(77.5%) stated that the screening procedure appropriate for women of aged 21 and more. 633 (74.9%) had favorable attitude and 212 (25.1%) had unfavorable attitude towards cervical cancer screening.

Almost half of the respondents 377 (44%) agreed and strongly agreed that cervical cancer was highly preventable and among the leading causes of death in our country. One hundred forty-eight (17.5%) of the respondents were strongly believe that any woman can acquire cervical cancer, 179 (21.2%) strongly agreed that screening helps in the prevention of cervical cancer and 207 (24.5%) of women were willing to undergo cervical cancer screening if it is charge free and the procedure cannot cause any harm. About, 268 (31.7%) of the respondents agreed that cervical cancer cannot transmitted from one person to another.

Of all the study participants, 49(5.8%) were screened and 796(94.2%) were not screened for cervical cancer. Among 49 respondents who screened for pre-cancer cervical lesion, 38(77.6%) were screened once and 30(61.2%) were screened within the past

3 years. Main reasons for not being screened f were: 302(37.9%) "they are healthy", 286(35.9%) "they don't have information or knowledge on cervical cancer screening" and 85(10.7%) did not decided to be screened. (Figure 1)

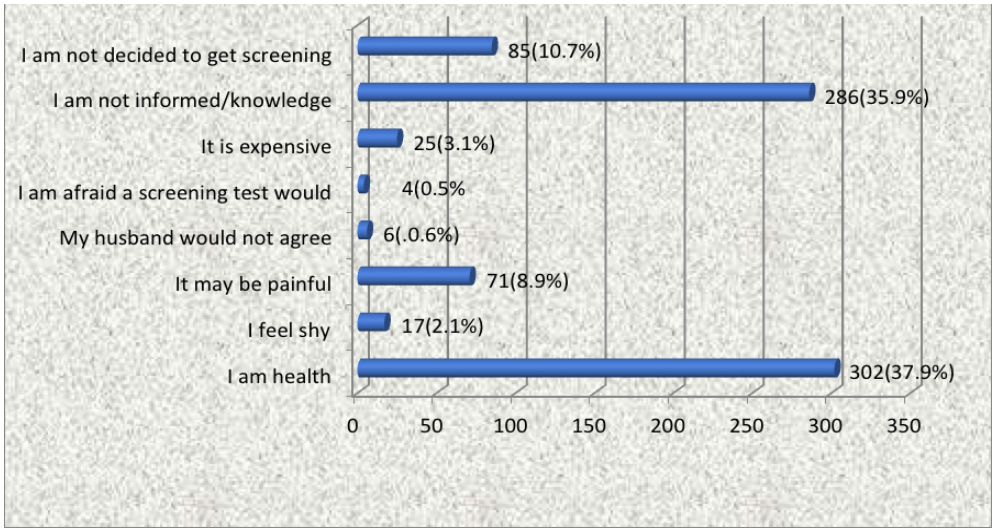


**Figure 1: Reason for not screened for cervical cancer mentioned by study participants, Bishoftu,2016**

Majority of study participants, 619 (73.3%), had information on cervical cancer. But 51.2% and 48.8% had good and poor knowledge score respectively. On the other hand, 46.7% and 47.2% of participants did not know the cause and prevention methods of cervical cancer respectively. Majority, 85%, reported availability of treatment options for cervical cancer. But, only 28.4% knew availability of screening methods. Among the total 845 study participants, only 5.8% were screened for cervical cancer. The main reason mentioned were lack of awareness about its screening (Table 3).

**Table 3: Attitude towards cervical cancer and screening, Bishoftu, 2016**

| Variables | Attitude status of the study participant on Likert scale | | | | |
|---|---|---|---|---|---|
| | Strongly agree | Agree | Neutral | Disagree | Strongly disagree |
| Cancer of the cervix is highly prevalent in Ethiopia and is one of leading cause of death from cancer | 124(14.7) | 253(29.9) | 20(2.4) | 335(39.6) | 113(13.4) |
| Any adult women including you can acquire cervical cancer | 148(17.5) | 422(49.9) | 18(2.1%) | 217(25.7) | 40(4.1) |
| Cancer of the cervix cannot be transmitted from one person to other | 124(14.7) | 268(31.7) | 41(4.9) | 313(37.0) | 99(11.7) |
| Screening helps in prevention of cancer of the cervix | 179(21.2) | 518(61.3) | 25(3.0) | 87(10.3) | 36(4.3) |
| Screening causes no harm to the client | 154(18.2) | 401(47.5) | 21(2.5) | 220(26.0) | 49(5.8) |
| Screening for pre-cancer cervical lesions is not expensive | 110(13.0) | 273(32.3) | 48(5.7) | 382(45.2) | 32(3.8) |
| If screening is free and causes no harm, will you screen? | 207(24.5) | 495(58.6) | 38(4.5) | 90(10.7) | 15(1.8) |

The result of multiple logistic regression models revealed that, level of education and source of information, were significantly associated with knowledge score. Women who are not formally educated (AOR=0.04, 95% CI (0.01-0.19)) and those women educated primary school (AOR=0.39, 95% CI (0.22-0.71)) were more likely to have poor knowledge than those had higher education. Those women who got information form health professional (AOR=3.12, 95%CI (1.74-5.59)) and medias (AOR=2.49, 95% CI (1.52-4.12)) on cervical cancer and screening were more likely to have good knowledge score than those got information from religious leaders, family members and teachers.

Women with no formal education (AOR=0.63, 95%CI (0.014-0.289)) and those women who had primary education (AOR=0.130, 95%CI (0.045-0.373)) were less likely to have favorable attitude. There was also positive association between source of information from media and positive attitude. Women's who got information from medias (AOR=3.021, 95%CI (1.644-5.551)) and health professional (AOR=2.167, 95%CI (1.079-4.325)) were more likely to have favorable attitude than those got information from family, religious leader and teacher.

Women who know someone diagnosed with cervical cancer were 2.88 times more likely to have practice on cervical cancer screening than those women who do not know someone diagnosed with cervical cancer (AOR=2.88, 95%CI (1.47-5.61). Women who had good knowledge on cervical cancer and its screening were more likely to have cervical cancer screening service uptake than those who had poor knowledge on cervical cancer screening service (AOR=6.95, 95% CI (2.59-18.57) (Table4).

*Table 4: Association between practice on cervical cancer screening and different characteristics, Bishoftu, 2016*

| Variables | Practice on cervical cancer screening | | COR, 95% CI | AOR, 95% CI |
|---|---|---|---|---|
| | No practice (%) | Practice (%) | | |
| **Age** | | | | |
| 15-24 | 97(100) | 0 | 0.000 | |
| 25-34 | 392(93.3) | 28(6.7) | 1.04(0.58-1.87) | |
| 35-49 | 307(93.3) | 21(6.7) | 1 | NA |
| **Educational status** | | | | |
| No formal/primary | 297(97.1) | 9(2.9) | 1 | 1 |
| Secondary | 301(93.8) | 20(6.2) | 2.19 (0.98-4.89) | 1.31(0.56-3.02) |
| Higher education | 198(90.8) | 20(9.2) | 3.33(1.49-7.89) * | |
| **Age at first sex** | | | | **1.51(0.63-3.59)** |
| < 18 years | 100(93.5) | 7(6.5) | 1 | 1 |
| ≥18 years | 650(94.1) | 41(5.9) | 0.90 (0.39-2.06) | |
| **Knowing someone diagnosed with cervical cancer** | | | | |
| Yes | 83(84.7) | 15(15.3) | 3.79 (1.98-7.25) * | 2.88 (1.47-5.61) * |
| No | 713(95.4) | 34(4.6) | 1 | |
| **Knowledge score** | | | | |
| Poor | 407(98.8) | 5(1.2) | 1 | 1 |
| Good | 389(89.8) | 44(10.2) | 9.21 (3.61-23.46) * | 6.95 (2.59-18.57) * |
| Attitude | | | | |
| Favorable | 206(97.2) | 6(2.8) | 1 | 1 |
| unfavorable | 590(93.2) | 43(6.8) | 2.50 (1.05-5.96) * | 1.20 (0.47-3.07) |

| | | | | |
|---|---|---|---|---|
| Number of children | | | | |
| Nulliparous | 192(95.5) | 9(4.5) | 1 | NA |
| 1-4 children | 532(93.3) | 38(6.7) | 1.52(0.72-3.21) | |
| ≥5 children | 72(97.3) | 2(2.7) | 0.59(0.12-2.81) | |
| Religion | | | | |
| Orthodox | 517(95.5) | 26(4.8) | 0.56(0.30-1.06) | |
| Catholic | 13(92.9) | 1(7.1) | 0.86(0.10-7.01) | |
| Muslim | 75(93.8) | 5(6.2) | 0.74(0.26-2.10) | |
| Protestant | 191(91.8) | 17(8.2) | 1 | NA |

*COR: crude odds ratio: odds ratio by bivariate analysis. 95% CI: confidence interval at the 95% level.*

**: p –value ≤0.05, AOR-Adjusted OR: odds ratio by multiple logistic regression*

**: NA -not applicable*

## DISCUSSION

In this study majority (73.3%) of the study participants were heard about cervical cancer. This result is higher than studies done in Kenya [11],29%, and south Ghana,68.4% [12] which might be due to the current improved awareness creation about cervical cancer in Ethiopia. About 51.2% had good knowledge on cervical cancer and its screening. This finding is higher than study done in Congo and Northwest Ethiopia [7,11]. This discrepancy might be due to time difference on study period and the growing awareness on cervical cancer screening.

In this study, the major sources of information were mass media 60.8% and health professionals 34.9%. This result is consistent with study done in Ogun state, Nigeria where health professionals and mass media were commonest source of information for cervical cancer and its screening[13]. Like study conducted in Democratic Republic of Congo[10] and Ethiopia[4], higher level of education, information obtained from mass medias and health professionals were associated with increased level of knowledge about cervical cancer and its screening. This highlights the importance of educating the community and awareness creation via mass medias and health professionals.

This study showed that knowledge about risk factors of cervical cancer like smoking, having multiple sexual partner, sexual intercourse at early stage, multiparty and low socioeconomic status was very low (46.7%), among reproductive aged women of Bishoftu town. This finding is higher than studies done in Nigeria,5%, and Ghana ,8%,[12,13]. This could be explained by their difference in educational status. But it is lower than the study done in South Africa which showed that 64.0% of the respondents know at least one risk factors[12]. The difference might be attributed to the fact that South Africa is relatively fast-growing country with better socio-economic status[14].

In the presence of effective screening options, vaccination and effective treatment options for precancerous lesions, cervical cancer is preventable disease. In this study only 52.8% of participants mention the presence of at least one preventive option for cervical cancer. This is lower than other study done in Ethiopia,63.9%, and south Africa,57%[4, 14].The odd of getting good knowledge was 3 times more likely among women got information from health professionals and Medias than those got information from religious leader, family and teacher. This is consistent with study done in Tanzania[19].

In this study, 74.9% of study participants had favorable attitude towards cervical cancer screening. This finding is lower than another study conducted in Northeast Ethiopia,80%,[7] and India ,83.8%[15]. Higher level of education and source of information from mass medias and

health professionals were significantly associated with favorable attitude toward cervical cancer and its screening.

This study revealed that, only 5.8% of the respondents were tested for precancerous lesions of the cervix. The finding is consistent with other studies done in sub-Saharan Africa and other developing countries[4, 7,11, 16,17]. Women with good knowledge score and who know someone diagnosed with cervical cancer were more likely to have cervical cancer screening. This result is similar with study done in Ethiopia and Tanzania[7,18,19].

The study also revealed that women's knowledge is also implicated in screening practice. Women who had poor knowledge on cervical cancer and its screening were7.2 times less likely to avail for screening services than women who had good knowledge. Which is consistent with other studies conducted in Mekele, Tanzania and Songea state[18, 19,20]. Perceive oneself healthy (37.9%) and lack of information (35.9%) on cervical cancer screening were among the reason for not seek Pap test.

This study indicated that more than half of the study participants had good knowledge on causes, risk factors and preventive methods of cervical cancer and its screening. Majority of women have favorable attitude towards cervical cancer screening but, the practice of pre-cervical cancer screening is still low. Thus, awareness raising health education on cervical cancer and its screening should be given to the community by trained health workers and emphasis should be given for health promotion via using mass Medias like Television and Radio.

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# PREVALENCE OF VIA POSITIVE CERVICAL LESIONS AND DETERMINANT FACTORS AMONG WOMEN ATTENDING REGULAR GYNECOLOGY OUTPATIENT DEPARTMENT (RGOPD) AT SAINT PAUL'S HOSPITAL MILLENNIUM MEDICAL COLLEGE (SPHMMC)

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## ABSTRACT

### BACKGROUND

Cervical cancer is one of the leading causes of death for middle-aged women in the developing world. But it is a preventable disease by using relatively inexpensive technologies to detect abnormal cervical tissue before it progresses to invasive cervical cancer. In Ethiopia, the incidence of cervical cancer is 35.9 per 100,000 women. There is scarce data on prevalence of precancerous cervical lesions and the determinant factors in Ethiopia.

### OBJECTIVE

The main objective of this study is to determine the prevalence of VIA positive precancerous cervical lesion among women attending RGOPD at SPHMMC and to identify the determinant factors.

### METHODOLOGY

Hospital- based cross sectional descriptive analytic study was conducted among 226 women visiting RGOPD at SPHMMC. All women aged 30-45 attending RGOPD & willing to give consent were included until the required sample size was attained during the study period.

### RESULTS

A total of 224 questionnaires were collected for analysis with response rate of 99.1%. The mean age of the study participants was 35.7 years (SD 4.97). Fifty-four of the participants were found to have VIA positive precancerous cervical lesions making prevalence of VIA positive precancerous lesion 24.1%. Age at marriage and age first sexual intercourse were found to have strong association with risk of precancerous cervical lesion. Early age at birth of first child was found to be negatively associated with risk of having precancerous cervical lesion.

### CONCLUSION AND RECOMMENDATION

The prevalence of VIA positive precancerous cervical lesion is higher than reports of most studies and emphasis should be given on incorporation of cervical cancer screening program into other reproductive health services. Age at marriage and age at first sexual intercourse were factors identified to have strong association with prevalence of precancerous cervical lesion. Promoting delayed onset of sexual activity and delaying the age at marriage are important measures as a primary prevention approach.

**KEYWORDS:** VIA, cervical cancer

*(Ethiopian Journal of Reproductive Health* 2018; 10; 2:22-30)

## INTRODUCTION

Cervical cancer remains a major public health problem in developing countries. It kills about 270, 000 women every year and more than 85% of these deaths occur in the developing world[1]. In addition to the existing socio-economic factors, lack of cervical cancer screening programs in developing countries plays a significant part for the inequity. Historically, prevention efforts largely focused on Pap smear.

In developing countries where there is limited access to Pap smear, VIA is considered as alternative early detection method[1].In Ethiopia, less than 10% of women reported ever having had a pelvic examination and the screening prevalence is less than 1 %. There are very few studies done in Ethiopia concerning cervical cancer[2, 3, 4, 5,6].

A good VIA program can detect at least 90% of all precancerous cases. With a cure rate of 85% for cryotherapy, a combined program of VIA and cryotherapy would effectively prevent 76% of cervical cancer deaths[7]. More than 95 % of women in sub-Saharan Africa have never been screened[1]. Understanding factors associated with the precancerous cervical cancer lesion among women helps us to take an action in each factor to decrease the morbidity and mortality of cervical cancer. While waiting for clinically applicable vaccination programs, improving screening coverage to the widest possible population and close management and follow-up of women with precancerous lesions is one of the important measures that should be considered.

The results of this study will be an important input to the FMOH to inform the strategy for future scale-up of cervical cancer screening and better reach women with cervical cancer screening service. The result of the study will also show us the burden of precancerous cervical lesions hence helps bring the need for screening in front for future health planning.

Thus, this study was conducted to determine the prevalence of VIA positive precancerous cervical lesions among women attending RGOPD at SPHMMC and to identify the determinant factors.

## METHOD

This is a hospital based cross sectional study conducted at SPHMMC in Addis Ababa, Ethiopia in the year 2015. Cervical cancer screening program using VIA has been implemented in the hospital since 2009 for the detection of precancerous lesions among clients coming for routine HIV care. Since 2010, the screening service was extended to OBGYN department regular outpatient clinic. There are two trained nurses in each of the clinics working on regular basis.

All women aged 30 to 45 years attending

RGOD for gynecologic evaluation and willing to give consent were included in the study. Women with any of the following were excluded from the study: pregnant women, women who had already undergone hysterectomy, women who had treatment for precancerous cervical lesion in the past 24 months and women who have been screened previously and knew their results.

Sample size was determined using a single population proportion formula by taking P=16 %. (the anticipated prevalence of VIA positive precancerous cervical lesion from the study done in Sudan[8]. Sample size was determined to be 226. Women who fulfilled the inclusion criteria and willing to participate in the study were consecutively included in the study during the study period till the required sample size was met.

Ethical clearance was obtained from the IRB of the college. A written informed consent was obtained from each woman willing to participate in the study.
The test providers were three nurses and one health officer already trained on VIA. They were given training on data collection tool and procedures for one and half day by the principal investigator. Information on socio-demographic, reproductive and behavioral factors was collected using structured

questionnaires by the providers in each of the screening clinic. Code was given to each questionnaire after completion of the interview. The medical record number and the code were documented in a separate log book. For those women found to have VIA positive test; treatment was provided (cryotherapy) in the respective clinics. Data entry was done by the principal investigator using the statistical package for social sciences (SPSS) for window version 20. Initially bivariate analysis was done using more than 26 different independent variables. Factors with statistical significance from the bivariate analysis were again run into the multivariate analysis process.

## RESULTS

Among the 226 women recruited for the screening, two were excluded from the study as the VIA test finding was inconclusive (was difficult to visualize the SCJ). A total of 224 questionnaires were collected for analysis with response rate of 99.1%. The mean age of the study participants was 35.7 years (SD=4.97), majority being in the age group of 30 to 34 accounting for 46%. Majority of the participants, 206(92%) are urban dwellers (Table 1) depicts the socio demographic characteristics of the study participants.

**Table1: Socio-demographic characteristics of women screened for precancerous cervical lesion at SPHMMC, Addis Ababa, Ethiopia, 2015(n=224)**

| VARIABLES | FREQUENCY | PERCENTAGE | MEAN±SD |
|---|---|---|---|
| AGE (IN YEARS) | | | 35.7±4.97 |
| 30-34 | 102 | 46 | |
| 35-39 | 59 | 26 | |
| 40-45 | 63 | 28 | |
| RELIGION | | | |
| **ORTHODOX** | **148** | **66** | |
| **MUSLIM** | 45 | 20 | |
| PROTESTANT | 31 | 14 | |
| MARITAL STATUS | | | |
| **SINGLE** | **18** | **8** | |
| MARRIED | 190 | 84.8 | |
| DIVORCED | 10 | 4.5 | |
| **WIDOW** | **6** | **2.7** | |
| PLACE OF RESIDENCE | | | |
| **URBAN** | **206** | **92** | |
| **COUNTRY SIDE** | 18 | 8 | |
| EDUCATIONAL STATUS | | | |
| NO FORMAL EDUCATION | 43 | 19.2 | |
| PRIMARY SCHOOL | 42 | 18.8 | |
| **SECONDARY** | **90** | **40.2** | |

| | | |
|---|---|---|
| ABOVE SECONDARY | 49 | 21.9 |
| OCCUPATION | | |
| **GOV EMPLOYEE** | **64** | **28.6** |
| **MERCHANT** | **26** | **11.6** |
| **DAILY LABORER** | **10** | **4.5** |
| **HOUSEWIFE** | **86** | **38.4** |
| **FARMER** | **8** | **3.6** |
| **OTHER** | **30** | **13.4** |

The mean age of menarche was at 14.4 years(SD=8.9) and 150(67%) of the had their first menses at age less than 15 years. The sexual history showed that the mean age of coitarche was 19 years (SD=3.6) and 70.5% of the participants had single sexual partner, 29.5% of the had two or more lifetime sexual partners.

The mean age at marriage and at first child birth were 20 years (SD=8.1) and 21.4 years (SD=4.6) respectively. About 41.5% of the participants got married at age 18 years and less. Majority of them 128(57%) gave birth to their first child at age 19 years and above.

Thirty-six (16.1%) of participants stated every history of pelvic infection and self or partner history of STD, 13(5.8%). Only four (1.8%) of participants stated ever history of genital ulcer and 3(1.3%) of them had history of genital ulcer in the partner.

Nineteen (8.5%) of the women has family history of cervical cancer. Majority of them were non-reactive for RVI (74.1%), the rest 18.3 % their serostatus for RVI was unknown and 17(7.6%) were found to be reactive. Table 2 and table 3 show the reproductive health and behavioral characteristics respectively.

Table 2: Reproductive health characteristics of women screened for precancerous cervical lesion at SPHMMC, Addis Ababa, Ethiopia, 2015. (n=224)

| VARIABLES | FREQUENCY | PERCENTAGE | MEAN ± SD |
|---|---|---|---|
| AGE OF MENARCHE | | | **14.4±8.9** |
| **<15** | 150 | 67 | |
| **≥15** | 74 | 33 | |
| AGE AT FIRST MARRIAGE | | | 20±8.1 |
| **≤18** | 93 | 41.5 | |
| **≥19** | 113 | 50.4 | |
| AGE AT FIRST CHILD BIRTH | | | **21.4±4.6** |
| **≤18** | 56 | 25.6 | |
| **≥19** | 127 | 57 | |
| **NOT GAVE BIRTH** | 41 | 18.3 | |
| PARITY | | | **2.3±1.8** |
| **0** | 41 | 18.3 | |
| **1-4** | 153 | 68.3 | |
| **≥5** | 30 | 13.4 | |
| GRAVIDITY | | | **2.9±2.04** |

| | | |
|---|---|---|
| **0** | 28 | 12.5 |
| **1-4** | 153 | 68.3 |
| **≥5** | 43 | 19.2 |
| HISTORY OF ABORTION | | |
| **YES** | 100 | 44.6 |
| **NO** | 124 | 55.4 |
| HISTORY OF USE OF CONTRACEPTIVE | | |
| **YES** | 153 | 68.3 |
| **NO** | 71 | 31.7 |

Table 3: Behavioral characteristics of women screened for precancerous cervical lesion at SPHMMC, Addis Ababa, Ethiopia.2015 (n=224)

| VARIABLES | FREQUENCY | PERCENTAGE | MEAN± SD |
|---|---|---|---|
| AGE AT FIRST SEXUAL INTERCOURSE | | | 19(3.5) |
| **≤15** | 32 | 14.3 | |
| **≥16** | 192 | 85.7 | |
| LIFE TIME NUMBER OF SEXUAL PARTNERS | | | 1.4±0.7 |
| **1** | 158 | 70.5 | |
| **≥2** | 66 | 29.5 | |
| HISTORY OF SMOKING | | | |
| **YES** | 2 | 1 | |
| **NO** | 222 | 99 | |
| EVER HISTORY OF PELVIC INFECTION | | | |
| **YES** | 36 | 16.1 | |
| **NO** | 188 | 83.9 | |
| EVER HISTORY OF STD | | | |
| **YES** | 24 | 10.7 | |
| **NO** | 200 | 89.3 | |
| EVER HISTORY OF STD IN PARTNER | | | |
| **YES** | 13 | 5.8 | |
| **NO** | 211 | 94.2 | |
| EVER HISTORY OF GENITAL ULCER | | | |
| **YES** | 4 | 1.8 | |
| **NO** | 220 | 98.2 | |
| EVER HISTORY OF GENITAL ULCER IN PARTNER | | | |
| **YES** | 3 | 1.3 | |
| **NO** | 221 | 98.7 | |
| FAMILY HISTORY OF CERVICAL CANCER | | | |
| **YES** | 19 | 8.5 | |
| **NO** | 205 | 91.5 | |
| HIV SEROSTATUS | | | |
| **NR** | 166 | 74.1 | |
| **R** | 17 | 7.6 | |
| **UNKNOWN** | 41 | 18.3 | |
| VIA RESULT | | | |
| **POSITIVE** | 54 | 24.1 | |
| **NEGATIVE** | 170 | 75.9 | |

Of the total 224 participants, 54 of them were found to have VIA positive precancerous cervical lesions. In this study the prevalence of VIA positive precancerous cervical lesion is found to be 24.1%. The remaining 170 (75.9%) of the women were found to have negative VIA test.

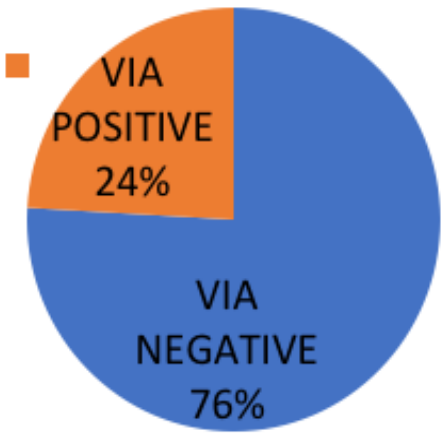


**Figure1: Proportion of women with respect the VIA test result; SPHMMC, Addis Ababa, Ethiopia, 2015**

About 62.9 % of those women with VIA positive precancerous lesion were found to had early age at marriage, and significant proportion of them stated single life time sexual partner 62.9% and only two of them had more than three life time sexual partner. Of those women who gave birth and found to have VIA positive lesion, 50 % they had their first birth at age ≥19years.

About 1/3 of them were in the age group ≥40 years and majority of them, about 77.7 % stated age at coitarche of above 16 yrs.

Table 4 shows the reproductive and sexual characteristics of those women found to have VIA positive cervical lesions.

Table 4: Reproductive and sexual characteristics of those women found to have VIA positive cervical precancer lesion, SPHMMC, Addis Ababa, Ethiopia, 2015

| VARIABLES | FREQUENCY | PERCENT |
|---|---|---|
| AGE | | |
| 30-34 | 21 | 38.8 |
| 35-39 | 14 | 25.9 |
| ≥40 | 19 | 35.1 |
| AGE AT COITARCHE | | |
| ≤15 | 12 | 22.2 |
| ≥16 | 42 | 77.7 |
| AGE AT MARRIAGE | | |
| ≤18 | 34 | 62.9 |
| ≥19 | 20 | 37.1 |
| AGE AT BIRTH OF FIRST CHILD | | |
| ≤18 | 22 | 40.7 |
| ≥19 | 27 | 50 |
| LIFE TIME SEXUAL PARTNER | | |
| 1 | 34 | 62.9 |
| 2-3 | 18 | 33.3 |
| >3 | 2 | 3.7 |

The results of bivariate analysis revealed that, early age at marriage (age≤18), age at coitarche (age<16) and age of the women above 40yrs are significantly associated with prevalence of VIA positive cervical lesions. (P value0.05)? Under the bivariate analysis, age at birth of first child was also found to have association with precancerous cervical lesion. Age <18yrs at birth of first child was with less odd of developing precancerous lesion.

Of those variables found to have association with prevalence of VIA positive lesions in the bivariate analysis, multivariate analysis revealed that three of the factors, age at marriage and age at first sexual intercourse, age at birth of first child to have significant association with 5% level of significance. After controlling the effect of factors including sexual partner number, age, and parity, those women who married at age less than 18 were found to have nearly three times odds of developing precancerous cervical lesion. (AOR=2.898, 95% CI:1.468,5.720).

The multivariate analysis on sexual behavior also revealed that those women who had their first sexual intercourse at age less than 16 had significant increased odds of having precancerous lesion. (AOR= 7.973, 95% CI:1.762,36.068,)

Women who had birth of their first child at age of less than 19 years were found to have 60% less odds having precancerous cervical lesion. (AOR=0.379, 95% CI: 0.166,0.865)

Table 5 shows the association of various factors with VIA positive cervical lesions on multivariate analysis.

Table 5: Association of various factors with VIA positive cervical lesions on multivariate analysis at SPHMMC, Addis Ababa, Ethiopia, 2015

| RISK FACTOR | VIA RESULT POSITIVE | COR | 95%CI | AOR | 95%CI | P-VAL |
|---|---|---|---|---|---|---|
| Age at marriage | | 2.680 | 1.411, 5.089 | 2.898 | 1.468,5.720 | <0.002 |
| ≤18 | 34(62.9%) | | | | | |
| ≥19 | 20(37.1%) | | | | | |
| Age at first sexual intercourse | | 6.510 | 2.331,18.185 | 7.973 | 1.762,36.086 | <0.007 |
| ≤15 | 42(77.7%) | | | | | |
| ≥16 | 12(22.2%) | | | | | |
| Age at birth of first child | | 0.413 | 0.208, 0.208 | 0.379 | 0.166,0.865 | <0.021 |
| ≤18 | 22 (40.7%). | | | | | |
| ≥19 | 27 (50%) | | | | | |

| Risk factor | AOR | 95%CI | P-value |
|---|---|---|---|
| Age at marriage | 2.898 | 1.468,5.720 | <0.002 |
| Age at first sexual intercourse | 7.973 | 1.762,36.086 | <0.007 |
| Age at birth of first child | 0.379 | 0.166,0.865 | <0.021 |

## DISCUSSION

The prevalence of VIA positive precancerous cervical lesion in this study was 24.1%. The finding of this is study higher than findings of most studies done in similar setups.

A comparative cross-sectional study conducted on prevalence and predictors of Pap smear cervical epithelial cell abnormality among HIV-positive and negative women attending gynecological examination at Debremarkos hospital (Ethiopia) revealed an overall prevalence of 14.1% (9). The findings of this study are consistent with a study done among 4,444 women aged 25–65 years in Kerla, India; 24.2% of women were tested VIA positive

which was using low threshold VIA test[10]This study is an institution-based study which included those women who came for certain gynecologic compliant and apparently healthy women were systematically excluded which may lead to overestimation of the burden of the problem. The other explanation for the high prevalence of precancerous cervical lesion in this study is, age of
women included in this study was between age 30 to 45 years, with mean age of 34 year but most of the studies with low prevalence included women of young age group in the study population (as young as 25 years).

This study result revealed that women who married at age less than 18 have nearly three times odds of developing precancerous cervical lesion. (AOR=2.898, 95% CI:1.468,5.720, p=0.002). This finding adds to the widely observed association between risk of cervical cancer and early age at marriage. Early marriage has been identified as one of the important risk factors in substantial number of studies[6, 11, 12].

According to the IARC/ICO series of case control studies, it was found that women reporting age at first sexual intercourse ≤16 years of age had a 2.3–2.5-fold risk of ICC and 1.8– 2.1-fold risk for age at first sexual intercourse 17– 20 years of age[13].
The finding of this study also showed that those women who had their first sexual intercourse at age less than 16 had significant increased odds of having precancerous lesion. (AOR= 7.973, 95% CI:1.762,36.068, p=0.007).

Studies which assessed reproductive behaviors revealed a positive association between younger age at birth of first child and risk of cervical cancer[11,14,15]. In this study it was found that women who had birth of their first child at age of less than 19 years were found to have 60% less odds having precancerous cervical lesion. (AOR=0.379,95%CI,0.166,0.865). This bears similarity with finding of a study from Rwanda, which showed older age at first pregnancy as a risk factor for precancerous cervical lesion (OR=2.10; 95% CI: 1.20,3.67)[16].

## CONCLUSION

The analysis of this study revealed that the prevalence of precancerous cervical lesion is 24.1%. This figure is much higher than the findings of many of the studies and could be considered high for the general population. Considering the setup where the study is conducted, SPHMMC which receives clients from different parts of the country as well as from 14 catchment health centers in Addis Ababa, the finding of this proportion of VIA positive precancerous lesion may not be an exaggerated one.

Early age at first sexual debut and early marriage were found have strong association with prevalence of VIA positive cervical lesion.

Emphasis should be given on increasing knowledge of women and the society at large about the adverse consequences early marriage.

Delaying the age at marriage and age at initiation of sexual activity are important primary preventive approaches to decrease the burden of cervical cancer.

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# SURVIVAL OF VERY LOW BIRTH WEIGHT NEONATES FOR AGE 0-7 DAYS AMONG DELIVERIES IN SAINT PAUL'S HOSPITAL MILLENNIUM MEDICAL COLLEGE (SPHMMC), ONE YEAR CROSS SECTIONAL STUDY

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## ABSTRACT

### BACKGROUND:

Very low birth weight babies are neonates with birth weights of 1000-1499g, constituting approximately 4–7% of all live births. Very low birth weight infants are known to have high morbidity and mortality.

### OBJECTIVE:

The purpose of this study is to determine the early neonatal survival rate and to determine the prognostic indicators for the survival of very low birth weight neonates delivered at St Paul's Hospital Millennium Medical College (SPHMMC).

### METHOD:

All neonates delivered from January 1- December 31, 2016 were consecutively included in the study. A total of 161 very low birth weight infants were included in the study. Newborns were followed for the first seven days of life, or time of discharge, or time of death as confirmed by the managing physician. The first of these was considered during the last data collection. Statistical analysis was carried out using SPSS version 20. The mean, 95% confidence intervals and two-tailed *P* values were calculated.

### RESULTS:

Very low birth weight infants account for 2.7% of all deliveries in this study. Early neonatal survival was found to be 77%. Gestational age, birth weight and APGAR score were found to be associated with survival rate with p-value of <0.05. Maternal obstetrics complication, antenatal use of corticosteroid, and management in Neonatal Intensive Care Unit were not found to be associated with neonatal outcome.

**Key Words**: Very Low Birth Weight, preterm birth, Neonatal Intensive Care Unit

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## INTRODUCTION

Three quarters of neonatal deaths occur in the first week, and more than one-quarter occur in the first 24 hours. Neonatal death accounts for 40% of deaths under the age of 5 years worldwide[1, 2]. Preterm birth is one of the major clinical problems in obstetrics and neonatology as it is associated with low perinatal survival, serious neonatal morbidity, and in some cases, childhood disability[1, 2, 3].
Very low birth weight (VLBW) babies are neonates with birth weights of 1000-1499gram, which constitute approximately 4–7% of all live births. The primary cause of VLBW is prematurity. Mortality of VLBW neonates is 30 times more than that of normal weight[1, 2]. They are also associated with high hospital charges and long hospital stays. In 2006, the Institute of Medicine estimated the annual cost of preterm births in the United States at $26 billion[6].

Over the last few decades various studies have been conducted that indicate a decline in neonatal mortality in the developed world. This decline in mortality was achieved through advanced intensive neonatal care and improvement in the care of high-risk mothers.(2, 3, 4) However African studies are still showing unacceptably high neonatal mortality rates[8, 9].

Ethiopia is one of the countries with high neonatal and infant mortality rates. According to the 2016 Ethiopia Demographic and Health Surveys (DHS), the country is experiencing a high neonatal mortality rate at 29 per 1000 live births[18].
Although the outcome of VLBW has been reported extensively in developed countries, less is known from developing countries[4, 7]. Thus, it is hard for obstetricians to predict the chance of survival when multiple factors are involved[5].

In the case of VLBW newborns, the study of neonatal survival and factors associated with survival may lead to the critical analysis of healthcare services and actions aimed at improving care for this group. Therefore, our study may help to identify the different healthcare needs and provide subsidies for interventions aimed at reducing infant death during the early prenatal period[11].

## MATERIALS AND METHOD

A hospital based cross-sectional analytic study was conducted from January 1 to December 31, 2016 to determine the survival rate of VLBW infants, and to identify prognostic indicators of the survival of VLBW infants delivered at St. Paul's Hospital Millennium Medical College (SPHMMC), Addis Ababa, Ethiopia. All neonates delivered alive with birth weights of 1000-1499gm at SPHMMC in the study period were consecutively included, but newborns with lethal congenital anomalies were excluded.
Early neonatal survival was defined as neonates survived till the seventh day of life or discharged from hospital, whichever comes first[1].

The study was approved by the Institutional Review board of SPHMMC. Data was collected with structured questionnaire by trained nurses by reviewing the chart and interviewing the mother. Informed consent was obtained from each study participants after the objectives of the study are explained. The participants were also informed that confidentiality of the information collected would be insured. Data were collected until the 7th day of life of the newborn, or up to the time of discharge, or up to the time of death as confirmed by the managing physician. (Whichever comes first was considered as the last day of data collection). Data were entered and analyzed using SPSS version 20. Descriptive statistics (mean, medians and proportions) were used to characterize the variables and, bivariate and multivariate analyses were performed to determine the relationship between dependent and independent variables. Statistical significance

was considered to be a P value of <0.05. The survival rate of VLBW neonates for age 0-7 days was the dependent variable of the study. Gestational age, birth weight, APGAR score, antepartum use of steroid, mode of delivery, and NICU set up were the independent variables.

## RESULTS

Among the 9,531 deliveries attended at SPHMMC from January 1 to December 31, 2016, there were 9,883 babies born. Out of all the babies, there were 264(2.7%) VLBW infants; 193 were delivered alive.

The remaining 71 were IUFDs, so automatically excluded. Among live born VLBW infants, 161 infants were recruited for the study, and 32 were excluded because of lethal congenital anomalies.

The mean maternal age of the study participants was found to be 26.65 (SD=5.25). A significant proportion of the women were Orthodox by religion 120 (74.5%) and married 158 (98.1%) (Table 1).

Table1. Socio-demographic characteristics of mothers of VLBW infants, (n=161), SPHMMC

| VARIABLES | FREQUENCY | PERCENTAGE | MEAN ±SD |
|---|---|---|---|
| AGE (IN YEARS) | | | 26.65±5.25 |
| <=14 | 0 | | |
| **15-19** | 13 | 8.1 | |
| **20-29** | 105 | 65.2 | |
| **30-39** | 39 | 24.2 | |
| **>=40** | 4 | 2.5 | |
| RELIGION | | | |
| **ORTHODOX** | 120 | 74.5 | |
| **MUSLIM** | 31 | 19.3 | |
| **PROTESTANT** | 10 | 6.2 | |
| MARITAL STATUS | | | |
| **SINGLE** | 1 | 0.6 | |
| **MARRIED** | 158 | 98 | |
| **DIVORCED** | 2 | 1.2 | |
| ETHNICITY | | | |
| **AMHARA** | 44 | 27.3 | |
| **OROMO** | 102 | 63.4 | |
| **GURAGE** | 7 | 4.3 | |
| **TIGRE** | 3 | 1.9 | |
| **OTHER** | 5 | 3.1 | |
| PLACE OF RESIDENCY | | | |
| **URBAN** | 112 | 69.6 | |
| **COUNTRY SIDE** | 49 | 30.4 | |
| EDUCATIONAL STATUS | | | |
| **NO FORMAL EDUCATION** | 60 | 37.3 | |
| **PRIMARY SCHOOL** | 48 | 29.8 | |
| **SECONDARY** | 33 | 20.5 | |
| **ABOVE SECONDARY** | 20 | 11.8 | |
| OCCUPATION | | | |
| **GOVERNMENT. EMPLOYEE** | 19 | 11.8 | |
| **MERCHANT** | 25 | 15.5 | |
| **DAILY LABORER** | 13 | 8.1 | |
| **HOUSEWIFE** | 92 | 57.1 | |
| **FARMER** | 8 | 5 | |
| **OTHER** | 4 | 2.5 | |

The majority of the mothers (100 (62.1%)) didn't receive dexamethasone for lung maturity. A full course of dexamethasone (4 doses) was given for 39 mothers (24.2%). The remaining took incomplete dose that were discontinued for emergency conditions per hospital protocol.

With regards to mode of delivery, the majority of the mothers (103 (64.0%)) had cesarean sections; of whom 48 mothers had cesarean sections after spontaneous onset of labor or after the start of induction for obstetrics indications per hospital protocol. Hypertensive disorder of pregnancy was the most common obstetrics complication found in this study participants. A total of 78 (48.4%) mothers were diagnosed with hypertension, from which 62 mothers had pregnancy-induced hypertension and 16 had chronic hypertension with superimposition of preeclampsia.

Majority of the mothers 50. (31.0%) had gestational ages between 34-36+6weeks, while 37 mothers (23.0%) had gestational ages less than 32 weeks. However, 32 of the mothers (19.9%) didn't recall their LNMP, and also didn't have early mile stones. In addition, the majority of the newborns had birth weights between 1400-1499 gm 84, (52.2%), and 52.8% had good APGAR scores of 8 and above.

There were five (3.1%) neonatal deaths at the labor ward, and the other newborns (156, (96.9%) were transferred to the NICU. Hyaline membrane disease (HMD) was the top diagnosis at the NICU, accounting for 103 (64.0%) newborns, followed by Early Onset Neonatal Sepsis (EONS) 32 (19.9%) newborns. Hypothermia was diagnosed in approximately 152 (94.4%) newborns, of which the temperature was corrected within 6 hours of admission in 76%. Among newborns who were transferred to NICU, 63.3% were managed with IV antibiotics and CPAP, while antibiotics only were used for 15.5% of the newborns. A total of 21.2% of the newborns were admitted to NICU for observation and feeding purposes only. At the 7$^{th}$ day of life, 91 newborns were still in the ward, accounting for 56.5% of the study groups. A total of 33, (20.5%) newborns were discharged after observation at the NICU, with the mean stay at the NICU of 2.9 days.

There were 37(23%) neonatal deaths, of which 21 (56.8%) of the neonatal death occurred after 24 hours of life, and 16(43.2%) were deaths within 24 hours of life, which includes five deaths in the labor ward (Table 2 and table 3).

Table 2. Obstetrics characteristics of mothers of VLBW neonates, SPHMMC, Addis Ababa, Ethiopia

| VARIABLES | FREQUENCY | PERCENTAGE |
|---|---|---|
| PARITY | | |
| **PRIMIPAROUS** | 76 | 47.2 |
| **MULTIPAROUS** | 85 | 52.8 |
| ANC FOLLOW-UP | | |
| **YES** | 154 | 95.7 |
| **NO** | 7 | 4.3 |
| DEXAMETHASONE USE | | |
| **NONE** | 100 | 62.1 |
| **ONE DOSE** | 10 | 6.2 |
| **2-3 DOSES** | 12 | 7.5 |
| **4 DOSES** | 39 | 24.2 |
| ONSET OF LABOR | | |
| **SPONTANEOUS** | 86 | 53.4 |
| **INDUCED** | 20 | 12.4 |
| **DIRECT CESAREAN SECTION** | 55 | 34.2 |
| MODE OF DELIVERY | | |
| **SVD** | 56 | 34.8 |
| **C/S** | 103 | 64 |
| **INSTRUMENTAL DELIVERY** | 1 | 0.6 |

| | | |
|---|---|---|
| **ABD** | 1 | 0.6 |
| INTRAPARTUM AMPICILLIN USE | | |
| **YES** | 66 | 41 |
| **NO** | 95 | 59 |
| OBSTETRIC & MEDICAL COMPLICATIONS | | |
| **HYPERTENSION** | 78 | 48.4 |
| **PPROM** | 45 | 28 |
| **APH** | 12 | 7.5 |
| **DM** | 3 | 1.9 |

Table 3 Characteristics of VLBW neonates (n=161), SPHMMC, Addis Ababa, Ethiopia

| Variables | Frequency | Percentage |
|---|---|---|
| **Sex** | | |
| Male | 82 | 50.9 |
| Female | 79 | 49.1 |
| **Multiple gestation** | | |
| Yes | 43 | 26.7 |
| No | 118 | 73.3 |
| **Gestational age** | | |
| <32 weeks | 37 | 23 |
| 32-33+6 weeks | 33 | 20.5 |
| 34-36+6 weeks | 50 | 31.1 |
| >=37 weeks | 9 | 5.6 |
| Unknown date | 32 | 19.9 |
| **Birth weight** | | |
| 1000-1199 gm | 33 | 20.5 |
| 1200-1399 gm | 44 | 27.3 |
| 1400-1499 gm | 84 | 52.2 |
| **5th min APGAR scorew** | | |
| **<=4** | 8 | 5 |
| 5-7 | 68 | 42.2 |
| 8-10 | 85 | 52.8 |
| **NICU admission diagnosis (156)** | | |
| HMD | 103 | 66 |
| EONS | 32 | 20.5 |
| OTHERS | 21 | 13.5 |
| **Management in NICU** | | |
| Antibiotics | 123 | 76.4 |
| CPAP | 118 | 73.3 |
| Observation | 33 | 20.5 |
| **Out come at 7th day of life** | | |
| Still in the ward | 91 | 56.5 |
| Discharged | 33 | 20.5 |
| Death within 24 hours | 16 | 9.9 |
| Death after 24 hours of life | 21 | 13 |

## DISCUSSION

In our study, VLBW newborns accounted for 2.7% of babies delivered in SPHMMC. This number is comparable to a report from Chris Hani Baragwanath Hospital, Johannesburg at 3.0%, but lower than a report from Iran at 4.3% (12, 17).

The early neonatal survival rate was found to be 77.0% (Figure 1), which is comparable to Survival in Thailand (63.4-81.0%), and Johannesburg, South Africa (72-74%), (12, 14). The result was higher than previous reports in Ethiopia (Jimmaa from January 2012 to December 2012, 56%; and Tikur Anbessa Hospital from July 2011 to June 2012, 60.8%)[10,16]. However, this result is lower than reports from developed countries (84-89%)[10, 16].

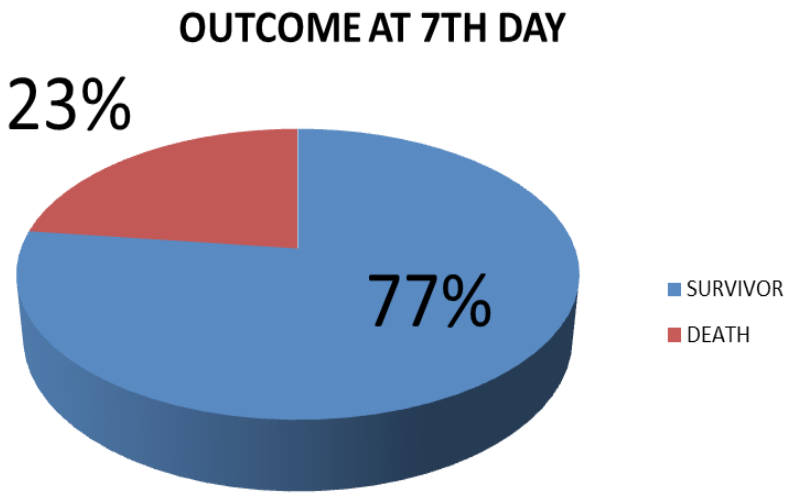


**Figure1: Proportion of VLBW newborns with respect to the 7th day outcome; SPHMMC, Addis Ababa, Ethiopia**

The mean maternal age was found to be comparable between the two groups, so no association was found with the survival of VLBW infants. Additionally, no association was found with place of residency, or parity of the mother between the two groups (Table 4).

Antenatal clinic attendance helps in identifying patients at risk for delivering preterm, and this would allow better monitoring and early hospital admission of these patients (12). ANC coverage was found to be 95.7% in this study, which is higher than the national figure reported in 2016 by Ethiopian Demographic Health Survey (EDHS) (62.0%) (18). Because of the high ANC coverage, a significant association between ANC follow-up and the neonatal survival rate (p=0.139) was not found. Only 37.9% of mothers were given at least one dose of dexamethasone, with 24.2% of mothers receiving a complete course of antenatal corticosteroids. Antenatal corticosteroid use in gestational age less than 34 weeks was only 50%. Different papers conclude that use of antenatal corticosteroid significantly improves the survival rate[11], but this was not found in our study, likely because of low use (p=0.445) (Table 4).

Table 4. Association between maternal variables and the survival of VLBW newborns at SPHMMC Addis Ababa, Ethiopia (n=161).

| VARIABLES | DEATH | | SURVIVOR | | | | |
|---|---|---|---|---|---|---|---|
| | NO | % | NO. | % | COR | P-VALUE | C/I |
| AGE | | | | | | | |
| <20 | 4 | 10.8 | 8 | 6.5 | 1.7 | 0.381 | 0.498-6.202 |
| >=20 | 33 | 89.2 | 116 | 93.5 | | | |
| PLACE OF RESIDENCY URBAN | 22 | 59.5 | 90 | 72.6 | 2.3 | 0.131 | 0.258-1.192 |
| RURAL | 15 | 40.5 | 34 | 27.4 | | | |
| PARITY | | | | | | | |
| PRIMIPAROUS | 15 | 40.5 | 60 | 48.4 | 0.7 | 0.402 | 0.345-1.532 |
| MULTIPAROUS | 22 | 59.5 | 64 | 51.6 | | | |
| ANTENATAL CORTICOSTEROID | | | | | | | |
| GIVEN | 16 | 43.2 | 45 | 36.3 | 0.7 | 0.455 | 0.354-1.577 |
| NOT GIVEN | 21 | 56.8 | 79 | 63.7 | | | |
| MODE OF DELIVERY | | | | | | | |
| VAGINAL | 15 | 40.5 | 44 | 35.5 | 1.2 | 0.577 | 0.584-2.631 |
| CESAREAN SECTION | 22 | 59.5 | 81 | 64.5 | | | |
| HYPERTENSION | | | | | | | |
| YES | 14 | 37.8 | 64 | 51.6 | 0.5 | 0.138 | 0.290-1.210 |
| NO | 23 | 62.2 | 60 | 48.4 | | | |

Obstetric complications correlated significantly with the survival of the infants. It could be explained that, VLBW infants who were born to mothers with obstetric complications were taken care better than other types of mother. These include giving dexamethasone and early communication with NICU teams[5].

Hypertensive disorder of pregnancy was found to be the most common (48.1%) obstetrics complication associated with delivery of VLBW newborn in this study. But significant association was not found in our study (P=0.138).

With Similar reason to obstetrics complications, an association of improved survival with cesarean section was reported in other studies[2, 7, 12]. However, mode of delivery was not found to be associated with the survival of VLBW newborns in this study (p=0.576). This might be due to a higher cesarean section rate in this study's groups, which amounts to 64% (Table 4).

The sex distribution was found to be comparable in this study. Unlike other studies, female gender has continued to show its advantage over male gender[12], this was not found to be associated with the survival rate. (p=0.665) (Table 5).

**Table 5. Association between infant variable and survival of VLBW newborns at SPHMMC Addis Ababa, Ethiopia. (n=161)**

| VARIABLES | DEATH | | SURVIVOR | | | | |
|---|---|---|---|---|---|---|---|
| | NO. | % | NO. | % | COR | P-VALUE | C/I |
| SEX | | | | | | | |
| **MALE** | **20** | **54** | **62** | **50** | **1** | **0.665** | **0.401-1.775** |
| **FEMALE** | **17** | **46** | **62** | **50** | | | |
| 5TH MIN APGAR SCORE | | | | | | | |
| <8 | 25 | 67.6 | 47 | 37.9 | 3.41 | 0.01 | 1.844-13.069 |
| >=8 | 12 | 32.4 | 77 | 62.1 | | | |
| BIRTH WEIGHT | | | | | | | |
| <1200 | 16 | 43.2 | 17 | 13.7 | 4.79 | 0.001 | 2.096-10.971 |
| >=1200 | 21 | 56.8 | 107 | 86.3 | | | |
| GESTATIONAL AGE (129) | | | | | | | |
| <34 | 24 | 80 | 46 | 46.5 | 4.9 | 0.001 | 1.844-13.069 |
| >=34 | 6 | 20 | 53 | 53.5 | | | |
| MULTIPLE GESTATION | | | | | | | |
| YES | 10 | 27 | 33 | 26.6 | 1 | 0.960 | 0.446-2.337 |
| NO | 27 | 73 | 91 | 73.4 | | | |

Newborns with 5th minute APGAR scores of eight and above were found to have 3.55 times higher survival. (p=0.006). Newborns with birth weights of 1200 grams or above were found to have 2.88 times higher survival than newborns with birth weights less than 1200 gram (p=0.029). This finding is consistent with different previous studies[5] (Table 6).

*Table 6 -Association of various factors with the survival of VLBW newborns using multivariate analysis at SPHMMC, Addis Ababa, Ethiopia*

| VARIABLES | DEATH | | SURVIVOR | | | | |
|---|---|---|---|---|---|---|---|
| | **No** | % | **No.** | % | **AOR** | **P.VALUE** | **C/I** |
| GESTATIONAL AGE | | | | | | | |
| **<34** | 24 | 80 | 46 | 46.5 | 3.09 | 0.013 | 1.25-10.219 |
| **>=34** | 6 | 20 | 53 | 53.5 | | | |
| BIRTH WEIGHT | | | | | | | |
| **<1200 GM** | 16 | 43.2 | 17 | 13.7 | 2.88 | 0.029 | 1.276-6.427 |
| **>=1200 GM** | 21 | 56.8 | 107 | 86.3 | | | |
| 5TH MIN APGAR SCORE | | | | | | | |
| **<8** | 25 | 67.6 | 47 | 37.9 | 3.55 | 0.006 | 1.275-9.896 |
| **>=8** | 12 | 32.4 | 77 | 62.1 | | | |

The neonatal survival rate was evaluated for each 100-gram increment. Weight below 50 grams was averaged down and above 50 grams was averaged up. For every 100-gram increment in birth weight, there was an improvement in the survival of the newborns (Figure 2).

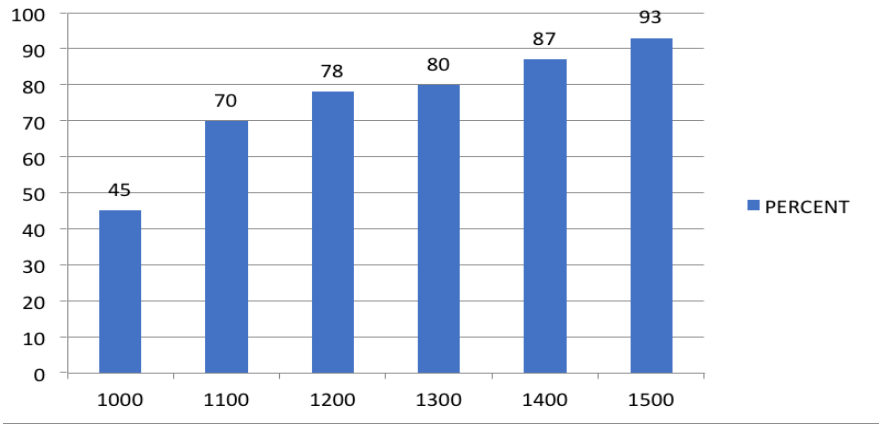


**Figure 2- Survival rates of VLBW infants according to birth weight in grams (numbers at the top of the bars are percentages).**

In this study 32 (19.9%) mothers didn't recall their LNMP and did not have early mile stones of pregnancy. Because of this limitation and the known discrepancy between antenatal and postnatal assessment of GA, for the association of gestational age and survival of VLBW infants, excluding such mothers was found to be a more practical approach. This problem has also been mentioned in similar papers from other developing countries (12, 17). The remaining 129 women were analyzed for the association between gestational age and survival of VLBW newborns. Newborns with gestational ages at or above 34 weeks were found to have a 3.09 times higher early neonatal survival than those with gestational ages less than 34 weeks(p=0.013) (Table 6).

Neonatal survival was also analyzed with respect to the gestational age range. The survival rate for gestational age between 28-31+6 weeks was found to be 85.0% (17 out of 37), for gestational age between 32-33+6 weeks found to be 87.9% (29 out of 33), and for gestational age between 34-36+6 weeks was found to be 92.0%. The survival rate of VLBW newborns with gestational ages of 37 weeks and above was found to be 77.8% (7 out of 9); this low survival may have found due to the associated severe IUGR (Figure 3).

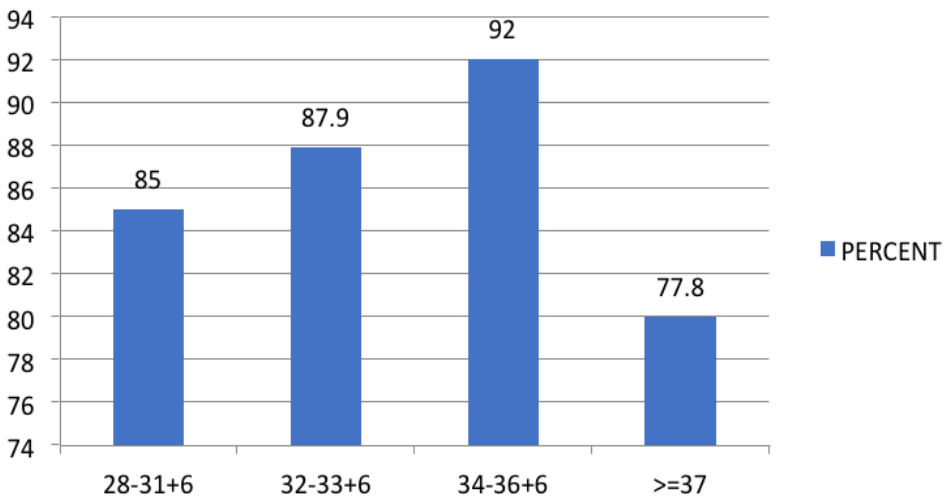


**Figure 3- Survival rates of VLBW infants according to gestational age in weeks (numbers at the top of the bars are percentages).**

The improvement of intensive neonatal care unit and medical technologies plays a major role in the increased survival rate of VLBW infants in recent decades[14]. However, for cases in this study, the primary management was IV antibiotics and CPAP. Neither Surfactants nor mechanical ventilators were used for management because they were not available in the hospital.

## CONCLUSION

The analysis of this study revealed that VLBW newborns account for 2.7% of deliveries at SPHMMC. The survival of VLBW newborns for the first seven days of life was found to be 77.0%. In this study, Gestational age, birth weight & 5th minute APGAR score were found to be associated with the survival of VLBW infants. However, maternal obstetric complications, antenatal use of corticosteroids, or mode of delivery was not found to be associated with neonatal outcome. Further study is recommended to determine the long-term neonatal out comes of very low birth weight. In addition, a comparative study with normal birth-weight newborns is recommended to see the actual effect of variables on neonatal survival.

## CONFLICT OF INTEREST

None

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# PARTIAL MOLE WITH COEXISTING TERM FETUS- A CASE REPORT

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## ABSTRACT

Partial molar pregnancy is a rare entity in which there is usually abnormal fetus associated with a large placenta with cystic changes. The incidence of a normal fetus at is extremely rare. Here we report a 24-year-old primigravid with gestational age of 39 weeks + five days who present with decrease fetal movement of three days. Ultrasound was done and there was normally appearing fetus, but no measurable fluid. Other biophysical parameters were reassuring. The whole placenta had snow storm appearance and enlarged. Cesarean section was done for the indication of sever oligohydraminosis with unfavorable bishop with the outcome of 2.2 kg alive female neonate with APGAR score of seven and eight in the first and fifth minute respectively. The placenta was sent for histopathology and report as partial hydatidiform mole.

**KEYWORD:** partial hydatidiform mole, Placenta, congenital malformation

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# INTRODUCTION

Hydatidiform mole is characterized by abnormal fetoplacental development and trophoblastic hyperplasia due to excessive paternally derived genetic material[1]. Hydatidiform mole is classified as partial (PM) or complete (CM), on the basis of distinctive histopathological features and genetic abnormalities[2]. In PM there is partial replacement with hydropic villi and visible abnormal fetal parts mostly leading to termination of pregnancy in the first trimester[3]. Partial mole with living fetus without any congenital anomaly or chromosomal stigma is a very rare entity. Singleton living fetus with partial mole is still rarer. Such an occurrence has been found only few times in extensively searched medical literature[4-6].

## CASE REPORT

A 24-year-old primigravida lady with gestational age by date of 39 weeks + five days with no antenatal care present with decrease fetal movement of three days duration. She had no pushing down pain, passage of liquor amini or vaginal bleeding. Pregnancy was uneventful. On physical examination, she was comfortable. Her pulse rate was 78 beats per minute, and Blood pressure was 110\70mmhg. Pertinent finding was on abdomen, where there was 36 weeks size gravid uterus, longitudinal lie and cephalic presentation, with positive fetal heartbeat. On per vaginal examination, cervix was closed, firm and posterior. Obstetrics ultrasound was done and there was no measurable fluid. Other biophysical parameters were reassuring.

The whole placenta had snow stormappearance and enlarged. Fetus showed no obvious congenital abnormality. A cesarean section was done for indication of sever oligohydraminosis with unfavorable bishop and the outcome was 2.2 kg alive female neonate with APGAR score of seven and eight in the first and fifth minute respectively. The newborn had wrinkled skin, long nail and hair (Figure 1).

**Figure 1: Newborn on Immediate Day of Delivery**

The newborn was stable and with the mother. The gross placenta measures 17 x 11 x 13 cm with associated membrane. The weight of the placenta was 1100gram (including the cord and membrane). There were diffuse solid and cystic components all over the placenta (Figure2).

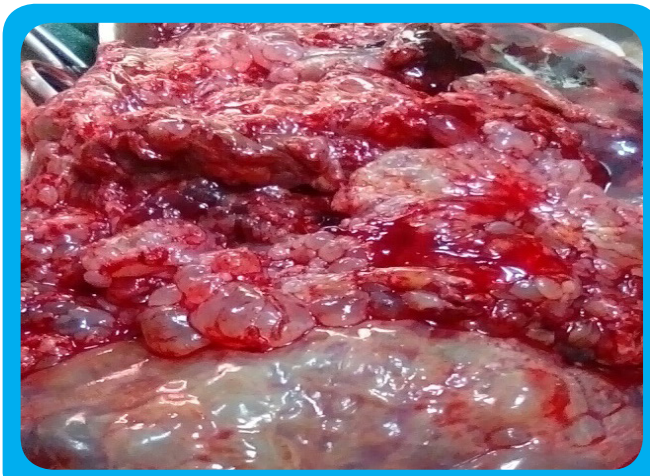

**Figure 2: Gross Placenta**

On microscopy, there were hydropic chorionic villi with circumferential proliferation of throphoblastic cells. Placental villi show features of chorioagniosis. Final pathologic conclusion was partial hydatidiform mole. The mother and the newborn discharged from the hospital on the 3rd day with appointment for follow up.

## DISCUSSION

The above case of partial hydatidiform mole with singleton living term fetus represents the rarity in obstetric World[1,2,3,4]. Such an association has been divided into three types. The first and most common is a twin pregnancy with one normal fetus having a normal placenta and another complete mole, second type is a twin pregnancy with normal fetus and placenta and another partial mole and the third is a singleton normal fetus with partial molar placenta. The third type of molar pregnancy is the most uncommon occurrence[3]. Such a fetus should have a normal karyotype to survive to term, though placenta may have variation, from diploidy of the amnion to triploidy of the chorionic villi[1].

The complications of coexisting fetus with molar pregnancy include bleeding, persistent gestational trophoblastic disease, preterm labor, late abortion, pregnancy induced hypertension, and growth restriction of the fetus. In our case, the newborn had birth weight less than 5$^{th}$ centile for the gestational age. But there was no other maternal complication.

Several factors influence the outcome of the fetus in partial molar pregnancy most important being karyotype of the fetus. The present case had no obvious congenital anomaly. Other factors include the size of the molar placenta, the speed of molar degeneration and fetal anemia. The cases we report probably had sufficient placental circulation to sustain through the first and second trimester[1,2].Antenatal detection of molar pregnancy co existing with a viable fetus should warrant genetic analysis and search for gross malformation of the fetus[6]. Since our cases were un-booked and the diagnosis was made in the last trimester, termination of pregnancy was done by caesarian section to deliver a healthy female child. Management of the pregnancy in such rare conditions should be determined on one-to-one basis and the possibility of increased complications should be discussed with the family and prognosis explained. Unfortunately, the karyotype of the newborn in our case was not determined because of financial issue.

Though some authors questioned the follow up of patient with partial hydatidiform mole by serum hCG, such patients should be followed up at regular interval maximum for one year[7,8].

## CONCLUSION

To conclude pregnancies with normal live fetus coexistent and partial molar placenta is extremely rare because of numerous maternal and fetal complications. Even if karyotype was not determined in our case, Since the fetus was normal at birth and the child continues to be growing normally, the abnormal cell population might appear to be confined to the placenta. Complete evaluation of the placental tissue is important even in cases with normal fetal outcome as focal molar changes which might be unsuspected during antenatal period, may affect the future obstetrical outcome.

## ACKNOWLEDGEMENT:

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**CONFLICT OF INTEREST: None**

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# ABDOMINAL PREGNANCY: A CASE REVIEW

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## ABSTRACT

Abdominal pregnancy is a rare type of ectopic pregnancy which occurs in 1 in 10,000 ectopic pregnancies. It has a higher risk of maternal mortality and morbidity. We presented a case of a primigravida mother who presented with a complaint of abdominal pain. Ultrasound result showed abdominal pregnancy and she was operated and macerated fetus and placenta was removed. The pain was resolved and patient was discharged with improvement.

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## INTRODUCTION

Abdominal pregnancy is defined as pregnancy in the peritoneum cavity outside the uterus and fallopian tube. The pregnancy can implant in the peritoneal cavity or broad ligament. It is a rare type of ectopic pregnancy with an incidence of 1 in 10,000[1] The pregnancy can occur primarily from a fertilization that takes place in the abdomen or secondary to an aborted tubal pregnancy or after in-vitro fertilization. The maternal morbidity and mortality is increased in these pregnancies [1,2]. Few abdominal pregnancies continue to the third trimester and to birth. In most of the cases fetal demise occurs[3]. This case reports an abdominal pregnancy which probably continues to the mid second trimester but failed.

## CASE REPORT

A 25-years old, South Sudanese primigravida who was referred from a private hospital as a case of missed abortion presented at the hospital with amenorrhea of eight months, intermittent abdominal pain of five months, and abdominal distention of six months. The pain was aggravated with movement and alleviates with rest. She started to feel decreasing fetal movement following the abdominal pain and the fetal movement ceased a month before her presentation to the hospital. In South Sudan, she was admitted and given medications during the last three months. A month ago, she was told that the fetus was not alive and she was given oral medication for three days to expel the dead fetus which was not successful. Then, she had an operation with the intent of removing the dead fetus, but when the abdomen was opened, it was found that there was no fetus in the uterus and abdomen was closed and she was discharged after few days. The abdominal pain was not resolved so she came to Myungsung Christian Medical Center.

On physical examination, she had a slightly pale conjunctiva and on abdominal examination, there was a vertical midline scar below the umbilicus about 8 cm and there was a 26-weeks size mass. There was no fetal heartbeat. On vaginal examination, the cervix was closed. Ultrasound showed abdominal pregnancy. (Figure 1) Laparotomy was done and thick-walled sac containing macerated fetus and placenta was removed (Figure 2). The amniotic membrane was attached to the anterior and lateral wall of the abdominal cavity. There was an estimated blood loss of 750 ml during the operation. After the surgery, the pain was resolved and the patient was discharged improved.

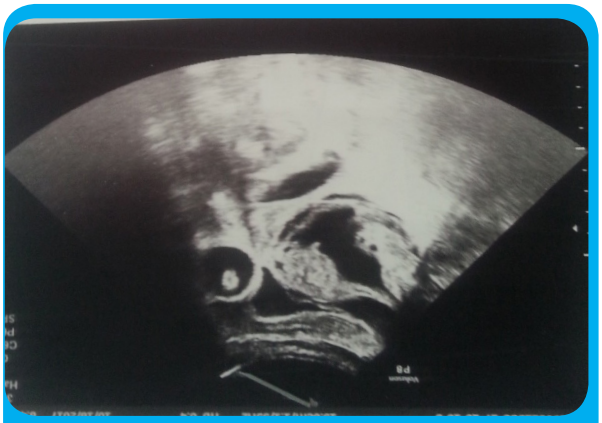

**Figure 1: Abdominal ultrasound of the patient**

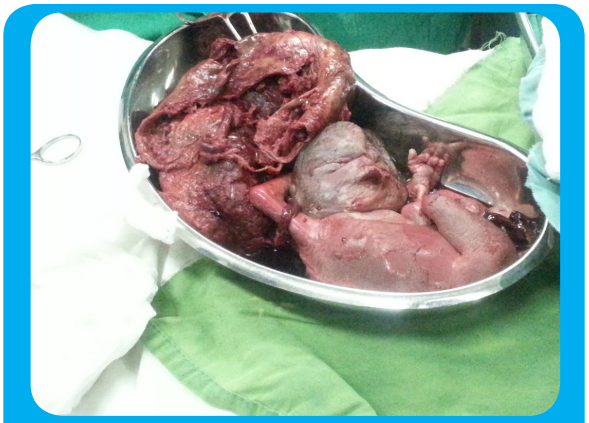

**Figure 2: The removed macerated fetus and the placenta**

## DISCUSSION

Abdominal pregnancy is a rare type of ectopic pregnancy, one in 10,000 births in USA[1]and one in 654 births in Nigeria[4], which is formed through three mechanisms. Primary abdominal pregnancy is when the egg and the sperm cell meet outside in the abdominal cavity. Secondary abdominal pregnancy is formed after an abortion of fertilized egg from the fallopian tube to the abdominal cavity. Lastly, abdominal pregnancy can be formed by artificial reproductive method after salpingectomies[1,2].

Although it is difficult to differentiate the first two, secondary abdominal pregnancy is common[5]. Abdominal pregnancy has a high risk of mortality, with 7-8 x greater than tubal ectopic pregnancy and 50x greater than from intrauterine pregnancy[1].
Abdominal pregnancy has variable presentations so is difficult to diagnose it. Some of the clinical presentations of the patients are abdominal pain, vaginal bleeding, nausea, vomiting, painful fetal movements, easily palpable fetal parts, malpresentations and usually transverse lie, and very rarely can have signs of acute abdomen and shock due to severe if there is intra-abdominal hemorrhage, secondary to separation of the placenta, and as a case of failed induction. They can also be asymptomatic[6-8]. Our patient came with abdominal pain which is one but she didn't have the other clinical features of abdominal pregnancy.

Abdominal pregnancy can be diagnosed by an ultrasonography with typical findings of intraabdominal and extrauterine fetus and placenta. But it can be missed if the pregnancy is close to the intestines or in later stages of the pregnancy[9,10]. MRI and CT scan are the alternatives to diagnose the abdominal pregnancy. The site of the placenta can be accurately localized on MRI than on ultrasound[3]. Localizing will help us to plan our management and to decide whether to continue the pregnancy or not[9].

If the pregnancy is detected early, terminating the pregnancy is safe. We can use different methods to terminate the pregnancy depending on the physical condition of the pregnant and the number of weeks. Laparoscopic or open surgery, arterial embolization, and intracapsular injection of potassium chloride in the abdominal pregnancy sac are the treatment options to terminate the pregnancy[9]. The most feared complication of surgical treatment is the risk of massive hemorrhage due to the placental attachment to the extrauterine structures including large vessels. Poole et al. mentioned that the mean blood loss is 1450 ml with a range of 50 – 7500 ml, 25% of the women need blood transfusion[11]. According to one review the most common site of placental attachment was to the uterus and adnexa (47%) followed by the bowel (30%) and the anterior and posterior pouches (8%). The liver (4%), the omentum (4%) and the abdominal wall (4%) were less frequent sites of placental attachment[3]. In our case, the placenta was attached to the anterior and lateral abdominal wall which is one of the less frequent sites of placental attachment in abdominal pregnancy. Generally, leaving the placenta in the abdomen with follow ups with serum hCG is recommended but removal of the placenta has a better prognosis. The decision to remove the placenta depends on particular case and the risk of hemorrhage[4].

There are some reported cases of advanced abdominal pregnancy (AAP) and delivery of term live birth babies after AAP. Due to compression of the fetus secondary to absence of the amniotic fluid buffer, birth defects common (21%). The common birth defect is congenital foot malformations followed by joint contractures, facial asymmetry, mild spasticity and intrauterine growth restriction[3,12].

## CONCLUSION

Abdominal pregnancy is a rare type of ectopic pregnancy. A high index of suspicion should be made if there are indicative clinical features although the presentations are variable. Ultrasonography with an experienced physician can help to diagnose it early and to act accordingly.

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*Original Research*

# Manual Compared With Electric Vacuum Aspiration for Treatment of Molar Pregnancy

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**OBJECTIVE:** To evaluate uterine evacuation of patients with molar pregnancy, comparing manual with electric vacuum aspiration.

**METHODS:** This is a retrospective cohort study of patients with molar pregnancy followed at the Rio de Janeiro Trophoblastic Disease Center from January 2007 to December 2016. The individual primary study outcomes were incomplete uterine evacuation, uterine perforation, development of uterine synechia, and development of postmolar gestational trophoblastic neoplasia. Secondary endpoints were other features of the perioperative outcomes (operative time, rate of transfusion, hemoglobin change, length of stay) and the clinical course of neoplasia (Prognostic Risk Score, presence of metastases, time to remission, and need for multiagent chemotherapy).

**RESULTS:** Among 1,727 patients with molar pregnancy, 1,206 underwent electric vacuum aspiration and 521 underwent manual vacuum aspiration. After human chorionic gonadotropin normalization, patients with benign molar pregnancy were followed for 6 months and patients treated for gestational trophoblastic neoplasia were followed for 12 months. Baseline risk factors for gestational trophoblastic neoplasia and demographic features were similar between the treatment groups. Uterine synechia developed less frequently after manual vacuum aspiration than after electric vacuum aspiration, 6 of 521 vs 63 of 1,206 (adjusted odds ratio [OR] 0.21, 95% CI 0.09–0.49), despite no differences in the occurrence of incomplete uterine evacuation, 65 of 521 vs 161 of 1,206 (adjusted OR 0.93, 95% CI 0.69–1.27), development of postmolar gestational trophoblastic neoplasia, 90 of 521 vs 171 of 1,206 (adjusted OR 1.26, 95% CI 0.96–1.67), or the need for multiagent chemotherapy, 22 of 521 vs 41 of 1,206 (adjusted OR 0.81, 95% CI 0.73–1.28).

**CONCLUSION:** Manual vacuum aspiration appears to be similar to electric vacuum aspiration for treatment of molar pregnancy and may be associated with less development of uterine synechia.

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*Each author has indicated that he or she has met the journal's requirements for authorship.*

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Molar pregnancies are the most common form of gestational trophoblastic disease.[1–3] Although molar pregnancy is benign, there is a risk of progression to malignancy, known as gestational trophoblastic neoplasia.[4–9]

Techniques for molar uterine evacuation have changed over time.[10–13] In North America, electric

vacuum aspiration is the predominant technique but is not available uniformly throughout the world. In Brazil, manual vacuum aspiration is used in 70% of gestational trophoblastic disease reference centers.[5] This likely reflects the legal restrictions on the use of electric vacuum aspiration devices related to the criminalization of elective termination of pregnancy in Brazil, as in many parts of Latin America.[3–5]

The optimal method of molar uterine evacuation is uncertain and many factors such as the urgency of the procedure, uterine size, availability of electric or manual vacuum suction equipment, and the costs of the materials needed for evacuation may influence the choice.[5,10,14,15] There are limited data comparing the different techniques of molar evacuation.[11–15]

The aim of this article is to evaluate our experience with molar uterine evacuation, comparing the two most commonly used techniques for suction evacuation in Brazil: electric compared with manual vacuum aspiration. We particularly wanted to evaluate and report our experience with the use of manual vacuum aspiration in the treatment of women with molar pregnancy, which may be of particular interest and value to clinicians in regions where electric vacuum aspiration is not routinely available.

## MATERIALS AND METHODS

This is a retrospective cohort study of patients with molar pregnancy followed at the Rio de Janeiro Trophoblastic Disease Center (Maternity Ward of Santa Casa da Misericórdia do Rio de Janeiro, Maternity School of Rio de Janeiro Federal University, and Antonio Pedro University Hospital of Fluminense Federal University) from January 2007 to December 2016.

The patients who participated in this study comprised all patients who had been diagnosed with molar pregnancy and underwent uterine aspiration in one of the hospitals associated with the Rio de Janeiro Trophoblastic Disease Center. The diagnosis of molar pregnancy was confirmed by histopathology using the morphologic criteria described by Sebire et al[16] as well as $p57^{KIP2}$ immunohistochemical analysis to confirm the diagnosis of the type of hydatidiform mole (complete or partial hydatidiform mole).[17] All patients included in this study were in complete human chorionic gonadotropin (hCG) remission after either benign molar pregnancy or postmolar gestational trophoblastic neoplasia, defined as normal hCG levels for at least 6 or 12 months, respectively. Patients whose medical records were incomplete, who discontinued follow-up, or who underwent uterine evacuation using misoprostol or sharp curettage as the sole method of evacuation were excluded from this study.

Before uterine aspiration, the patients with molar pregnancy underwent a clinical and preanesthetic evaluation, including a complete metabolic profile, complete blood count, chest radiograph, and serum quantitative hCG. Pelvic–transvaginal ultrasonography was performed in all patients. For patients with a uterus larger than 20 cm measured suprapubic–fundus on physical examination (confirmed by ultrasonography), thyroid-stimulating hormone, free thyroxine, and electrocardiogram were also obtained to assess thyroid and cardiac function. In all patients, two units of packed red blood cells were reserved.

For uterine evacuation, preparation of the cervix with misoprostol was not performed. If necessary, cervical dilators were used. Most patients treated at the Maternity Ward of Santa Casa da Misericórdia do Rio de Janeiro and Maternity School of Rio de Janeiro Federal University underwent electric vacuum aspiration. Electric vacuum aspiration was the procedure of choice unless the machine was unavailable (there being one machine for the facility). Patients treated at Antonio Pedro University Hospital of Fluminense Federal University underwent only manual vacuum aspiration (Appendix 1, available online at http://links.lww.com/AOG/B75) because an electric device is not available at this institution. In cases of an enlarged uterus for gestational age (defined as a uterus measuring at least 4 cm more than expected for gestational age), or by clinical decision, the uterine vacuum aspiration procedure was guided by transabdominal ultrasonography. After molar uterine vacuum aspiration, either with electric or manual vacuum aspiration, gentle sharp curettage was performed to ensure complete uterine evacuation.

Surgical procedures were performed by a stable team of physicians who were experienced in the uterine aspiration procedures. The choice of uterine evacuation technique as noted previously was dictated primarily by the availability of techniques at the treating facility. All patients received the same anesthetic care, including total intravenous anesthesia with a propofol infusion and fentanyl boluses as needed. Oxytocin was not routinely administered during the surgery and was reserved for patients with an enlarged uterine size for gestational age, with poor uterine tone, or in patients in whom there was copious hemorrhage during the procedure. It is worth noting that the three reference centers in gestational trophoblastic disease have adopted the same criteria for blood transfusion: hematocrit less than 21%, hemoglobin less than 7.0 g/dL with signs of hypovolemia or aggravating medical factors such as cardiovascular disease, or acute bleeding. Prophylactic antibiotic therapy was not routinely administered. Once the surgery

was finished, all patients were transferred to the postoperative care unit with continuous monitoring and with the following minimal prescription: 1,000 mL saline with 10 units of oxytocin intravenously for infusion over 6 hours, 500 mg paracetamol intravenously every 8 hours, and 20 mg tenoxicam (a nonsteroidal antiinflammatory drug) once daily. In case of pain reported by the patient, the frequency of paracetamol was increased to every 4 or 6 hours (maximum of 3 g per day).

All patients were hospitalized for at least 24 hours. Before discharge, they underwent a complete medical evaluation, had a new complete blood count, received prescriptions (which included hormonal contraception and usually a nonopioid analgesic), and the schedule for the postmolar follow-up. The patients started contraception at discharge after uterine evacuation for treatment of molar pregnancy. Hormonal contraception was given free to all patients who wished to use this form of contraception.[18]

Follow-up was performed with weekly measurement of serum hCG using the Siemens Diagnostic Products Corporation Immulite assay. Remission was defined as three consecutive weekly hCG values below 5 international units/L.[4,5] After that, medical visits and measurement of hCG levels continued monthly for 6 months in the case of spontaneous remission and 12 months after completion of chemotherapy in the cases of gestational trophoblastic neoplasia. When patients did not attend the scheduled visits, a social worker and hospital psychologist actively tried to contact them by phone and telegram to identify what was hindering compliance and to motivate them to return for follow-up.

Progression to postmolar gestational trophoblastic neoplasia was diagnosed using the criteria established by the International Federation of Gynecology and Obstetrics 2000, presented in Appendix 2, available online at http://links.lww.com/AOG/B75.[19] Before chemotherapy was started, all patients were evaluated for metastatic disease with physical examination, including a pelvic examination, uterine Doppler ultrasonography, and chest radiograph. In case of metastasis, the investigation was complemented by brain, abdominal, and pelvic magnetic resonance imaging and chest computed tomography. Prognostic scoring for resistance to chemotherapy followed the International Federation of Gynecology and Obstetrics and World Health Organization Prognostic Scoring System, as shown in Appendix 2 (http://links.lww.com/AOG/B75).[2]

The 8-day methotrexate and folinic acid (leucovorin) rescue regimen with 1 mg/kg methotrexate intramuscularly on days 1, 3, 5, and 7 alternating with 0.1 mg/kg folinic acid orally on days 2, 4, 6, and 8 was used as a first-line treatment in all cases of low-risk gestational trophoblastic neoplasia. In cases of chemoresistance, second-line chemotherapy was initiated with 1.25 mg/m$^2$ actinomycin-D intravenous pulse every 15 days. The third-line chemotherapy treatment was etoposide, methotrexate, actinomycin-D, cyclophosphamide, and vincristine, reserving etoposide, cisplatin, methotrexate, actinomycin-D for the fourth line. Additional lines of therapy were selected at treating physician discretion.

Preoperative demographic and clinical information was collected from the medical charts, including age at diagnosis, reproductive history, gestational age at diagnosis, preoperative hCG, and medical complications on presentation (anemia–hemoglobin less than 9 g/dL, bleeding, enlarged uterus for gestational age, theca lutein cysts–ovarian cysts 6 cm or greater as assessed by ultrasonography, preeclampsia, hyperthyroidism, and acute respiratory distress syndrome). Details of the procedure, including the selection of evacuation method, administration of oxytocin, and use of ultrasonography, were abstracted from the operative notes. Postoperative variables included final surgical pathology, postevacuation hCG, in cases of gestational trophoblastic neoplasia, Prognostic Risk Score,[19] selection and duration of chemotherapy treatment, and use of adjuvant procedures. The individual primary study outcomes were incomplete uterine evacuation (determined by clinical, hormonal, and ultrasonography evaluation and in cases of doubt by hysteroscopic evaluation), uterine perforation, development of symptomatic uterine synechia (suspected as a result of amenorrhea and confirmed by hysteroscopy in all cases), and development of postmolar gestational trophoblastic neoplasia. Secondary endpoints were other perioperative outcomes (operative time, rate of transfusion, hemoglobin change, length of stay) and the clinical course of neoplasia (Prognostic Risk Score, presence of metastases, time to remission, and need for multiagent chemotherapy).

This study was approved by the Maternity School of Rio de Janeiro Federal University institutional review board under protocol number 2.092.118.

From prior studies comparing manual with electric vacuum aspiration for nonmolar gestations, we assumed a baseline 2.5% risk for complications in the electric vacuum aspiration group.[14] With our sample size, this gave us 80% power with a 95% two-sided CI to detect differences with the use of manual evacuation corresponding to a reduction in a complication to 0.5% or less or an increase in a complication to 5.5% or greater using the Fleiss method with continuity correction.

The distributions of qualitative variables were evaluated using the $\chi^2$ statistic. For continuous variables, the Shapiro-Wilk test was used to verify the normality of the distribution. The differences of means were evaluated with a Student *t* test for variables with normal distributions and nonparametric Kruskal-Wallis test when data were not normally distributed. To analyze uterine evacuation in relation to the qualitative variables, the $\chi^2$ test or, when appropriate, the Fisher exact test was used.

For outcomes of interest, crude and adjusted odds ratios with 95% CIs were calculated using the Wald test for logistic regression. Variables were selected for inclusion into the multivariate model by the Akaike Information Criteria. Corrections for multiple testing were performed using the Holm-Šidák test. All statistical analyses were carried out using the R statistical package.

## RESULTS

Figure 1 presents a flow diagram showing the selection of the study population. Among 2,563 patients with molar pregnancy followed during the study period, 1,950 women underwent uterine aspiration at the Rio de Janeiro Gestational Trophoblastic Disease Reference Center. We excluded 53 patients with incomplete medical records, 87 patients who discontinued follow-up, 45 cases of partial hydatidiform mole of more than 13 weeks of gestation that had undergone uterine evacuation using misoprostol, and 38 cases of uterine evacuation done by sharp curettage as a result of suspicion of early abortion and diagnosed later by histopathology as molar pregnancy. These exclusion criteria did not differ among the three specialized services of the Rio de Janeiro Gestational Trophoblastic Disease Reference Center, as shown in Appendix 3, available online at http://links.lww.com/AOG/B75. Thus, among the 1,727 patients with molar pregnancy included in this study, 1,206 underwent electric and 521 underwent manual vacuum aspiration.

As indicated in Table 1, patients undergoing electric or manual vacuum aspiration were similar with regard to demographics, clinical presentation, final diagnosis, use of ultrasonography to monitor the evacuation and oxytocin during the uterine evacuation, and major perioperative complications. The only significant difference was the reference center, which as noted in the methods was expected as a result of the study design.

There was incomplete uterine evacuation in approximately 13% of all patients with molar pregnancy, regardless of the method for uterine aspiration (Table 2; $P$=.949). Patients undergoing uterine electric vacuum aspiration had significantly greater changes in the hemoglobin levels after evacuation (−0.3 vs −0.19 g/dL, $P$<.001) and shorter operative times for uterine evacuation (25.3 vs 34.2 minutes, $P$<.001) when compared with patients who underwent manual vacuum aspiration (Table 2). The uterine evacuation technique was not associated with the development of postmolar gestational trophoblastic neoplasia (14.2% vs 17.3%, $P$=.074) or its aggressiveness (metastatic disease: 19.9% vs 17.8%, $P$=.082; high-risk prognostic score: 22.8% vs 23.3%, $P$=.082; need for multiagent chemotherapy: 24.0% vs 24.4%, $P$=.096). The most notable difference between electric and manual vacuum aspiration was the risk of uterine synechia after the procedure (5.2% vs 1.2%, $P$<.001). Although there was no clinical diagnosis of uterine perforation among the patients undergoing manual vacuum aspiration, there were nine cases of uterine perforations among those undergoing electric vacuum aspiration (0.7%); however, our study was not adequately powered to assess this outcome.

Multivariate logistic regression was performed to identify the variables associated with early or late complications (Appendices 4 and 5, available online at http://links.lww.com/AOG/B75). The odds ratios were adjusted for age, medical complication on presentation, gestational age at diagnosis, pre-evacuation hCG level, histology of molar pregnancy, use of ultrasonography to monitor the uterine evacuation, use of oxytocin during the uterine evacuation, and setting of the study. After adjustment, manual vacuum aspiration was associated with a lower risk of blood transfusion (adjusted odds ratio [OR] 0.63, 95% CI 0.44–0.83, $P$<.001), but the adjusted OR was relatively weak and falls within the zone of potential bias for a cohort study.[20] More notably, uterine synechia developed less frequently after manual vacuum aspiration than after electric vacuum aspiration, 6 of 521 vs 63 of 1,206 (adjusted OR 0.21, 95% CI 0.09–0.49, $P$<.001) despite no differences in the occurrence of incomplete uterine evacuation, 65 of 521 vs 161 of 1,206 (adjusted OR 0.93, 95% CI 0.69–1.27), development of postmolar gestational trophoblastic neoplasia, 90 of 521 vs 171 of 1,206 (adjusted OR 1.26, 95% CI 0.96–1.67), or the need for multiagent chemotherapy, 22 of 521 vs 41 of 1,206 (adjusted OR 0.81, 95% CI 0.73–1.28) (Table 3).

## DISCUSSION

Since the introduction of uterine vacuum aspiration techniques,[21,22] manual vacuum aspiration has been less widely used than electric worldwide, because

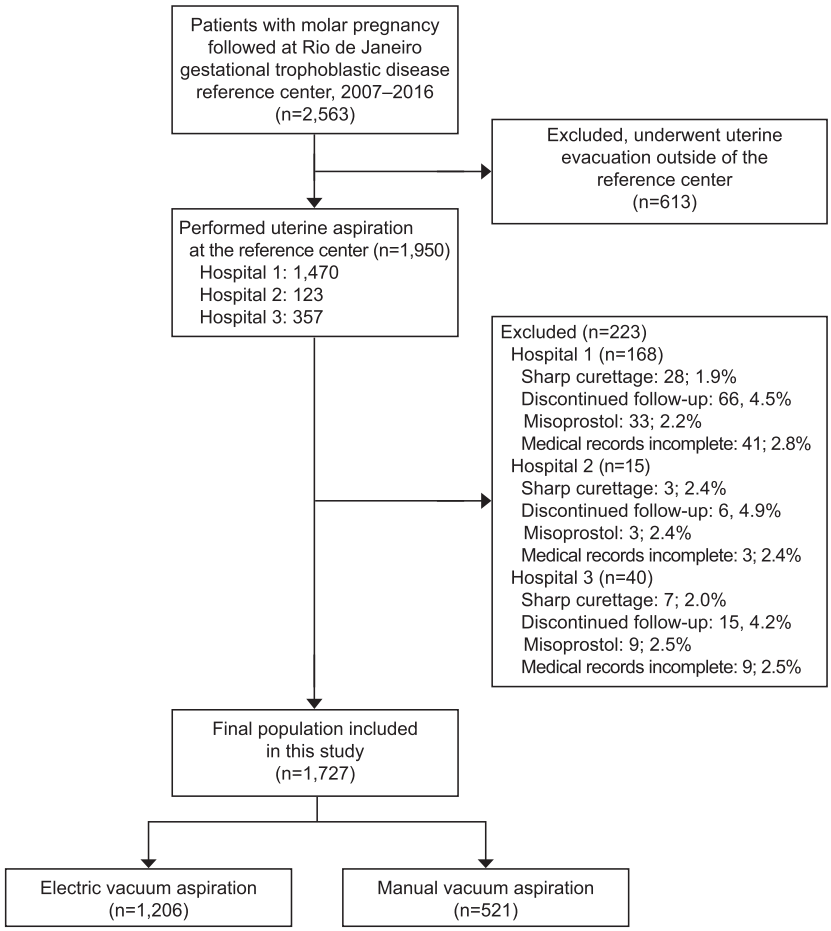


**Fig. 1.** Flow diagram summarizing the derivation of the study population. Hospital 1, Maternity Ward of Santa Casa da Misericórdia do Rio de Janeiro; Hospital 2, Maternity School of Rio de Janeiro Federal University; Hospital 3, Antonio Pedro University Hospital of Fluminense Federal University.

*Padrón. Manual Vacuum Aspiration for Molar Pregnancy. Obstet Gynecol 2018.*

there is more limited evidence to support its safety, efficacy, and acceptability among women with an indication of termination of pregnancy.[10–15] When we consider the comparison of these techniques with molar uterine vacuum aspiration, the studies are even smaller and less conclusive.[10,13,23,24]

In this study of 1,727 patients with molar pregnancy, manual vacuum aspiration seems to be as acceptable and effective a method for molar uterine evacuation as electric. In addition, manual vacuum aspiration appears to be associated with less development of symptomatic synechia.

One concern regarding manual vacuum aspiration has been incomplete uterine evacuation. Both manual and electric vacuum aspiration have high complete abortion rates (97.9% vs 97.5%) in cases of first-trimester nonmolar abortion.[11] In our sample, formed exclusively by patients with molar pregnancy, the rate of complete uterine emptying did not reach 90% with either technique. This may reflect not only the greater amount of molar trophoblastic tissue compared with an abortion, but also the invasiveness of molar trophoblastic cells into the maternal decidua.[25]

Another concern with evacuation of a molar pregnancy is the risk of uterine perforation because uteri with molar pregnancy are generally softer and larger than at the time of a first-trimester abortion.[26,27] However, we did not observe a significantly increased risk of uterine perforation with either manual or electric vacuum aspiration. Although differences in rates of uterine perforation as well as prolonged length of stay were not statistically different between the groups, both of these were rare events, and we lacked sufficient power to detect differences in rare outcomes.

Although the pressure exerted by the manual vacuum aspiration is advertised as similar to an electric device,[28] in fact, the vacuum pressure of the electric vacuum aspiration is approximately 100 mm Hg higher than manual.[29,30] Perhaps, the increased suction pressure is responsible not only for faster uterine evacuation with the electric device, but also for more intense decidual detachment, trauma, and greater risk of synechia.

**Table 1. Demographic Characteristics of Patients With Molar Pregnancy Followed at the Rio de Janeiro Gestational Trophoblastic Disease Reference Center According to the Technique of Uterine Evacuation**

| Variable | EVA (n=1,206) | MVA (n=521) | *P* |
|---|---|---|---|
| Age (y) | 24.8 (13–57) | 28.9 (12–55) | .067* |
| Gravidity | 2.1 (1–3) | 1.9 (1–3) | .071* |
| Parity | 0.8 [0–3] | 0.7 [0–4] | .170* |
| Gestational age at diagnosis (wk) | 11.4 (5–14) | 10.8 (6–15) | .198* |
| Reference center | | | |
| Maternity Ward of Santa Casa | 1,103 (91.5) | 199 (38.2) | <.001† |
| Antonio Pedro University Hospital of Fluminense Federal University | 0 | 317 (60.8) | |
| Maternity School of Rio De Janeiro Federal University | 103 (8.5) | 5 (1.0) | |
| Medical complication on presentation | | | |
| Bleeding | 892 (74.0) | 375 (72.0) | .225† |
| Anemia | 87 (7.2) | 46 (8.8) | .109† |
| Enlarged uterus for gestational age | 395 (32.8) | 136 (26.1) | .098† |
| Theca lutein cysts | 321 (26.6) | 125 (24.0) | .187† |
| Preeclampsia | 26 (2.2) | 19 (3.6) | .091† |
| Hyperemesis | 144 (11.9) | 52 (10.0) | .112† |
| Hyperthyroidism | 36 (3.0) | 19 (3.6) | .151† |
| Acute respiratory distress syndrome | 32 (2.7) | 20 (3.8) | .093† |
| hCG pre-evacuation level (international units/L) | 175,994 (323–4,168,000) | 131,715 (5,736–3,793,000) | .381* |
| Histology of molar pregnancy | | | |
| Complete hydatidiform mole | 984 (81.6) | 397 (76.2) | .084† |
| Partial hydatidiform mole | 222 (18.4) | 124 (23.8) | |
| Use of ultrasonography to monitor the evacuation | 621 (51.5) | 260 (49.8) | .174† |
| Use of oxytocin during the uterine evacuation | 699 (58.0) | 290 (55.7) | .187‡ |

EVA, electric vacuum aspiration; MVA, manual vacuum aspiration; hCG, human chorionic gonadotropin.
Data are median (range), mean [interquartile range], or n (%) unless otherwise specified.
* Nonparametric Kruskal-Wallis test.
† Chi-squared test.
‡ Fisher exact test.

Although the secondary outcomes of need for transfusion and need for extra analgesia postoperatively were statistically different between the electric and manual vacuum aspiration groups, we note that the adjusted ORs were relatively weak, falling within the zone of potential bias for a cohort study.[20] In contrast, the effect size for reduction in uterine synechia is likely of greatest clinical relevance. In addition, we wish to emphasize that for the primary outcomes of incomplete evacuation and development of postmolar gestational trophoblastic neoplasia, the two evacuation techniques appear to be comparable. Importantly, our study demonstrates that neither of these vacuum aspiration methods influences the progression of hydatidiform mole into gestational trophoblastic neoplasia or its severity. In fact, these data are very similar to those in the literature[2,4,7,9,10] and did not differ between patients who underwent electric or manual vacuum aspiration.

Our study does have important limitations. The main limitation of this study was its retrospective design and nonrandomization of treatments. However, Table 1 shows that the population undergoing electric or manual vacuum aspiration had very similar demographic and presentation characteristics. The patients all came from roughly the same geographic area. Although the data were collected from different databases of three different hospitals, the maintenance of these databases as well as the insertion of the data is the responsibility of the same researcher (A.B.), who also guarantees that they use the same protocols and medical records for patients with molar pregnancy. A major strength of this study is the substantial number of patients evaluated undergoing molar evacuation and the depth and completeness of its data collection.

In conclusion, our article represents the experience of molar uterine evacuation at the Rio de Janeiro Trophoblastic Disease Center, the largest trophoblastic reference center in the Americas, which manages more than 300 new patients with gestational trophoblastic disease per year. Despite being simple, inexpensive, and easy to handle, manual vacuum aspiration use in most hospitals is limited as a result

**Table 2. Clinical Outcomes for Patients With Molar Pregnancy According to the Technique of Uterine Evacuation**

| Variable | EVA (n=1,206) | MVA (n=521) | *P* |
|---|---|---|---|
| Complete uterine evacuation | 1,045 (86.7) | 456 (87.5) | .949* |
| Uterine perforation | 9 (0.7) | 0 (0) | .051† |
| Preoperative hemoglobin (g/dL) | 11 [6–13] | 10 [5–13] | .089‡ |
| Postoperative hemoglobin (g/dL) | 10 [3–13] | 10 [3–13] | .056‡ |
| Change in the hemoglobin levels after uterine evacuation (g/dL) | −0.3 (−5.1 to −0.1) | −0.19 (−4.9 to −0.1) | <.001‡ |
| Need for blood transfusion | 76 (6.3) | 45 (8.6) | .714† |
| Duration of surgery (min) | 25.3 (16–31) | 34.2 (26–41) | <.001‡ |
| Need for extra postoperative analgesia | 160 (13.3) | 92 (17.7) | .071* |
| Postoperative infection | 11 (0.9) | 7 (1.3) | .509† |
| Hospital stay (d) | 1 [1–5] | 1 [1–5] | .512‡ |
| Patients had length of stay greater than 3 d | 112 (9.3) | 49 (9.4) | .982† |
| Occurrence of postmolar GTN | 171 (14.2) | 90 (17.3) | .074* |
| Presence of metastatic disease | 34 (19.9) | 16 (17.8) | .082† |
| WHO-FIGO§ Prognostic Risk Score of GTN | 3 (1–12) | 2 (1–11) | .081‡ |
| 7 or greater | 39 (22.8) | 21 (23.3) | .082* |
| Need for chemotherapy with multiagent regimen | 41 (24.0) | 22 (24.4) | .096† |
| Occurrence of synechia | 63 (5.2) | 6 (1.2) | <.001† |

EVA, electric vacuum aspiration; MVA, manual vacuum aspiration; GTN, gestational trophoblastic neoplasia; WHO, World Health Organization; FIGO, International Federation of Gynecology and Obstetrics.
Data are median (range), mean [range], or n (%) unless otherwise specified.
* $\chi^2$ test.
† Fisher exact test.
‡ Nonparametric Kruskal-Wallis test.
§ The WHO prognostic scoring system as adapted by FIGO.

of unfamiliarity of the clinicians with its use.[13] Our results showed that manual vacuum aspiration appears to be similar to electric vacuum aspiration for treatment of molar pregnancy and may be associated with less development of uterine synechia.[10] Manual vacuum aspiration therefore appears to be a reasonable effective substitute to electric vacuum aspiration in the treatment of molar pregnancy.

**Table 3. Multivariate Logistic Regression Analyzing the Influence of Manual Vacuum Aspiration for Treatment of Molar Pregnancy in Relation to Electric Vacuum Aspiration on the Occurrence of Early or Late Complications**

| | Manual vs Electric Vacuum Aspiration for Treatment of Molar Pregnancy | | |
|---|---|---|---|
| Variable | Crude OR (95% CI)* | Adjusted OR (95% CI)* | *P* |
| Early complication | | | |
| Uterine perforation | 0 (0) | 0 (0) | .993 |
| Need for extra postoperative analgesia | 0.65 (0.48–0.81) | 0.78 (0.54–0.92) | .018 |
| Need for blood transfusion | 0.58 (0.28–0.92) | 0.63 (0.44–0.83) | <.001 |
| Length of hospital stay 3 d or greater | 1.09 (0.76–2.09) | 1.37 (0.87–2.14) | .171 |
| Late complication | | | |
| Incomplete evacuation | 0.86 (0.61–1.23) | 0.93 (0.69–1.27) | .661 |
| Development of postmolar gestational trophoblastic neoplasia | 0.91 (0.72–1.20) | 1.26 (0.96–1.67) | .102 |
| WHO-FIGO† Prognostic Risk Score of GTN 7 or greater | 0.60 (0.35–2.01) | 0.71 (0.23–2.19) | .550 |
| Need for chemotherapy with multiagent regimen for postmolar GTN | 0.76 (0.69–1.25) | 0.81 (0.73–1.28) | .673 |
| Occurrence of synechia | 0.19 (0.07–0.46) | 0.21 (0.09–0.49) | <.001 |

OR, odds ratio; GTN, gestational trophoblastic neoplasia.
* Wald test for logistic regression adjusted by age, gestational age at diagnosis, medical complication, pre-evacuation human chorionic gonadotropin, histology of molar pregnancy, use of ultrasonography to monitor the uterine evacuation, use of oxytocin during the uterine evacuation, and setting of the study.
† The WHO prognostic scoring system as adapted by FIGO.

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*Original Research*

# Simultaneous Compared With Interval Medical Abortion Regimens Where Home Use Is Restricted

*Patricia A. Lohr, MD, MPH, Jennifer E. Starling, MSc, James G. Scott, PhD, and Abigail R. A. Aiken, MD, PhD*

**OBJECTIVE:** To evaluate outcomes with simultaneous administration of mifepristone and misoprostol for medical abortion at 63 days of gestation or less in the year after its implementation in a British clinic system.

**METHODS:** We conducted a retrospective cohort study using deidentified data from the electronic booking and complications databases and medical records of women who underwent medical abortion at British Pregnancy Advisory Service. Our primary outcome was treatment success with simultaneous dosing compared with a regimen with a 24- to 48-hour interval between medications. We defined success as complete abortion without surgical evacuation and without continuing pregnancy. To assess relative regimen effectiveness while accounting for self-assignment to simultaneous or interval dosing, we modeled the probability of treatment success using logistic regression with propensity score adjustment for demographic and clinical characteristics. Secondary outcomes were reasons for abortion failure and clinically significant adverse events (hospital admission, blood transfusion, intravenous antibiotic administration).

**RESULTS:** Of 28,901 women treated between May 2015 and April 2016, 85% chose simultaneous dosing. Overall success rates were high with both regimens but lower with simultaneous than with interval dosing (94.5% vs 97.1%, respectively, adjusted relative risk 0.973, 95% CI 0.967–0.979). For both regimens, success rates were lower at higher gestational ages, but the relative effectiveness of simultaneous dosing did not vary significantly with gestational age ($P$=.268). Surgical intervention rates for continuing pregnancy were lowest at 49 days of gestation or less (1.4% simultaneous vs 0.2% interval, $P$<.001) and highest at 57–63 days of gestation (5.0% and 2.2%, $P$<.001). The rate of clinically significant adverse events was 0.2% and did not differ by regimen ($P$=.972).

**CONCLUSION:** Simultaneous administration of mifepristone and misoprostol is 97% as effective as a 24- to 48-hour interval at all gestational ages 63 days or less with no increase in the risk of clinically significant adverse events. Pragmatic use of simultaneous dosing is reasonable given the small difference in effectiveness.

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Home use of mifepristone and misoprostol for early medical abortion is safe and acceptable, and women prefer it over use in a clinic.[1,2] In England and Wales, however, current application of the abortion law does not permit the use of abortion medications outside of registered medical facilities.[3,4] The recommended regimen for medical abortion at 63 days of gestation or less in Britain is 200 mg oral mifepristone followed by 800 micrograms vaginal misoprostol 24–48 hours later.[5] This regimen requires at

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least two clinic visits, which may be inconvenient and costly, and may negatively affect women's attitudes toward medical abortion.[6,7]

To create a more accessible medical abortion service, British Pregnancy Advisory Service–a nonprofit abortion provider with 60 clinics in England and Wales–introduced the option of simultaneous administration of mifepristone and misoprostol in 2015. Prior research shows that simultaneous dosing is effective for early medical abortion, although the rate of side effects may be higher and the need for more than one dose of misoprostol to achieve a complete abortion may arise more frequently than with a 24-hour interval between medications.[8–12] To avoid a second clinic visit, however, women may still prefer simultaneous dosing in settings where home use of misoprostol is restricted, despite potential differences between regimens. Our primary objective was to compare effectiveness of the simultaneous regimen to one with a 24- to 48-hour interval between medications, both overall and across gestational age categories. We also compared uptake, reasons for failure, and rates of clinically significant adverse events between regimens.

## MATERIALS AND METHODS

We conducted a retrospective cohort study using data from early medical abortions provided at British Pregnancy Advisory Service from May 1, 2015, to April 30, 2016. We obtained data from British Pregnancy Advisory Service's electronic Booking and Invoicing System, which contains the services provided to clients as well as demographic and selected clinical characteristics. These data are initially entered by operators at British Pregnancy Advisory Service's telephone contact center and are validated by clinicians at in-person consultations and at the time of treatment. To link these data with adverse events, client identification numbers were cross-referenced with British Pregnancy Advisory Service's electronic complications database. Complications are identified during follow-up visits or notified by other care providers (eg, general practitioners, hospitals) to British Pregnancy Advisory Service or by women themselves. When possible, hospital discharge summaries or letters from general practitioners are obtained to confirm diagnoses and interventions. Complications are recorded on incident forms that are coded using standardized definitions[13] and sent to British Pregnancy Advisory Service head office. Codes are checked for accuracy by a clinical lead before entry into the database by a data manager. To ensure complete reporting of surgical interventions, staff cross-checked the booking and invoicing system for any appointments at British Pregnancy Advisory Service after the date(s) of treatment and hand-checked medical records if a continuing pregnancy, retained nonviable gestational sac or embryo, or incomplete abortion was recorded in the complications database. This study was approved and exempted from full human subjects review by British Pregnancy Advisory Service's Research and Ethics Committee and the institutional review board at The University of Texas at Austin because all data were pre-existing and provided in a fully deidentified format.

Women with pregnancies of 63 days of gestation or less as determined by abdominal or vaginal ultrasonography, who wanted a medical abortion, and who had no contraindications were offered a choice between 200 mg oral mifepristone followed by 800 micrograms vaginal misoprostol within 15 minutes (simultaneous administration) or 24–72 hours later. They chose their preferred regimen after being informed of expected differences in side effects and outcomes. Our analytic sample consists of women who chose simultaneous dosing or a 24- to 48-hour interval between medications.

Two weeks posttreatment, women could choose to return for a vaginal ultrasonogram or to use a low-sensitivity urine pregnancy test (detection limit 1,000 international units human chorionic gonadotrophin) and symptom checklist to determine the outcome of the abortion themselves.[14] Women could schedule a visit at any time if they had concerns or signs and symptoms of a possible complication (eg, persistent pain, still feeling pregnant). Women diagnosed at a follow-up visit with a retained nonviable sac or embryo or with an incomplete abortion could choose to receive another dose of 800 micrograms vaginal misoprostol or have surgical management. Women diagnosed with continuing pregnancies were offered surgical evacuation. Uterine evacuation was also performed at any time if it was clinically necessary, for example, for hemorrhage, or if a woman requested it.

Our primary outcome was treatment success. We created a binary variable for successful medical abortion (1=success, 0=failure). Success was defined as complete expulsion of the uterine contents without surgical intervention and without continuing pregnancy with reference to the Medical Abortion Reporting of Efficacy Guidelines.[15]

In our primary outcome analysis, we compared unadjusted and adjusted rates of successful abortion between regimens. To estimate unadjusted success rates, we calculated binomial CIs for each regimen, both overall and by gestational age group: 49 days or

less, 50–56 days, and 57–63 days of gestation. We compared the regimens with two-sample tests for a difference in proportions (Appendices 1 and 2, available online at http://links.lww.com/AOG/B76). However, because women self-assigned to regimen, there is the potential for these unadjusted success rates to be confounded by differences in pretreatment characteristics. We therefore modeled the probability of treatment success using logistic regression with propensity score adjustment.[16–19] The propensity score represents the estimated conditional probability of assignment to the simultaneous or interval dosing regimen given client characteristics. Incorporating the propensity score in our model allows us to assess how the probability of successful abortion varies by regimen and gestational age, controlling for observed pretreatment characteristics that may affect regimen choice.

To estimate propensity scores, we constructed a random forest classification model[16,20] using each woman's pretreatment characteristics as features for predicting her chosen regimen (0=interval, 1=simultaneous). Pretreatment characteristics included were age in years; body mass index (calculated as weight (kg)/[height (m)]$^2$); self-identified race or ethnicity; previous births, abortions, miscarriages, and cesarean deliveries; and gestational age group on the day of mifepristone administration. The random forest model allows use of propensity scores without making strong parametric assumptions about the functional form of the relationship between client-level features and treatment assignment. It also offers the added benefit of handling complex interactions among the features (Appendices 3 and 4, available online at http://links.lww.com/AOG/B76).

**Table 1. Descriptive Characteristics of Women Choosing Simultaneous or Interval Administration of Mifepristone and Misoprostol for Early Medical Abortion From May 1, 2015, to April 30, 2016, at British Pregnancy Advisory Service (N=28,901)**

| Characteristic | Simultaneous (n=24,543) | Interval (n=4,358) | *P** |
|---|---|---|---|
| Age (y) | 27.0±6.6 | 26.8±6.7 | .028 |
| BMI category (kg/m$^2$) | | | .551 |
| Underweight (18.5 or less) | 7.4 (1,821) | 7.6 (330) | |
| Normal (18.5–24.9) | 50.8 (12,459) | 50.7 (2,221) | |
| Overweight (25.0–29.9) | 25.6 (6,285) | 24.8 (1,081) | |
| Obese (30.0 or greater) | 16.2 (3,978) | 16.9 (736) | |
| Race or ethnicity | | | <.001 |
| White | 77.9 (19,115) | 74.0 (3,227) | |
| Asian | 8.6 (2,100) | 11.7 (510) | |
| Black | 6.2 (1,532) | 7.1 (310) | |
| Other | 5.4 (1,322) | 5.7 (247) | |
| Not reported | 1.9 (474) | 1.5 (64) | |
| Previous abortions | | | <.001 |
| 0 | 62.8 (15,407) | 67.8 (2,953) | |
| 1 or more | 37.2 (9,136) | 32.2 (1,405) | |
| Previous births | | | <.001 |
| 0 | 47.0 (11,526) | 53.5 (2,330) | |
| 1 or more | 53.0 (13,017) | 46.5 (2,028) | |
| Previous cesarean deliveries | | | .045 |
| 0 | 88.3 (21,680) | 89.4 (3,896) | |
| 1 or more | 11.7 (2,863) | 10.6 (462) | |
| Previous miscarriages | | | <.001 |
| 0 | 82.2 (20,179) | 84.7 (3,691) | |
| 1 or more | 17.8 (4,364) | 15.3 (667) | |
| Gestational age (d) | | | <.001 |
| 49 or less | 57.1 (14,016) | 46.0 (2,005) | |
| 50–56 | 25.8 (6,321) | 30.2 (1,316) | |
| 57–63 | 17.1 (4,206) | 23.8 (1,037) | |
| Median±IQR | 48±11 | 50±11 | <.001 |

IQR, interquartile range; BMI, body mass index.
Data are mean±SD or n (%) unless otherwise specified.
* Chi-squared test for characteristics; null hypothesis is that the joint distribution of the counts in the contingency tables is the product of row and column marginal distributions. For means and SDs, *P* values are for *t*-tests to compare treatment vs control group means; null hypothesis is that groups have equal means. For gestational age, the *P* value is for a Mann-Whitney test.

Estimated propensity score quintiles[21] were included as a covariate in our logistic regression models for successful abortion. We first fit an overall model across all gestational ages using abortion regimen, gestational age, and propensity score quintile as predictors. We also fit models separately by gestational age group using abortion regimen and propensity score quintile as predictors. We used the method described by Greenland[22] to estimate an adjusted relative risk for the simultaneous regimen from each logistic regression model. This yielded an overall adjusted relative risk across all gestational ages as well as an adjusted relative risk specific to each gestational age group. We used Tukey's range test to assess whether the relative risk of success for the simultaneous regimen compared with the interval regimen varied across gestational age groups (Appendices 3 and 4, available online at http://links.lww.com/AOG/B76).

Secondary outcomes were clinically significant adverse events and medical abortion failure. Failure was defined as 1) the need for surgical uterine evacuation or 2) continuing pregnancy identified at a follow-up visit in which the women either chose not to complete the abortion or was lost to follow-up after diagnosis. Clinically significant adverse events were defined as hospitalization, blood transfusion, and intravenous antibiotic administration. We compared each adverse event category and a combined "any" category. Women could experience more than one adverse event, but each woman appears only once in the "any" category. All secondary outcome analyses were conducted using binomial CIs and two-sample tests for a difference in proportion, both overall and separately by gestational age group. Data analyses were conducted using the R statistical software package version 3.3.3. A $P$ value of $<.05$ was considered statistically significant.

## RESULTS

A total of 28,901 women underwent early medical abortion during the 12-month study period. Of these, 24,543 (84.9%) chose the simultaneous regimen and 4,358 (15.1%) chose the 24- to 48-hour interval regimen. Women who chose the simultaneous regimen were more likely to be older ($P=.028$); to self-identify as white ($P<.001$); to have had one or more previous births ($P<.001$), abortions ($P<.001$), or miscarriages ($P<.001$); and to be of a lower gestational age ($P<.001$; Table 1).

Results for the primary outcome analysis (successful medical abortion) are detailed in Table 2, which reports both unadjusted and adjusted rates and relative risks. Statistical adjustment using propensity scores made only modest differences to the raw success rates, which reassuringly suggests that confounding resulting from observed patient characteristics was weak. Nonetheless, we focus here on the adjusted numbers arising from our logistic regression models (Appendices 5–15, available online at http://links.lww.com/AOG/B76).

The overall success rate was high for both regimens but was slightly lower overall with simultaneous dosing than with interval dosing: 94.5% vs 97.1%, respectively (absolute difference of 2.6%, $P<.001$). Overall, the relative risk of success for simultaneous dosing was 0.973 (95% CI 0.967–0.979, $P<.001$). In this context, "relative risk" is a statistically correct but potentially confusing term given that our outcome is successful medical abortion. For this

**Table 2. Unadjusted and Adjusted Medical Abortion Outcome in Women Choosing Simultaneous or Interval Administration of Mifepristone and Misoprostol for Early Medical Abortion From May 1, 2015, to April 30, 2016, at British Pregnancy Advisory Service (N=28,901)**

| Gestational Age Group (d) | n | Simultaneous Success Rate (%) | Interval Success Rate (%) | RR | *P* for RR=1 | NNT |
|---|---|---|---|---|---|---|
| Unadjusted RR estimate (95% CI) | | | | | | |
| Overall | 28,901 | 94.5 (94.2–94.8) | 97.1 (96.6–97.6) | 0.973 (0.967–0.979) | <.001 | 38 (32–49) |
| 49 or less | 16,021 | 95.7 (95.4–96.0) | 98.1 (97.5–98.7) | 0.976 (0.969–0.983) | <.001 | 43 (33–61) |
| 50–56 | 7,637 | 93.7 (93.1–94.3) | 97.3 (96.4–98.2) | 0.963 (0.952–0.974) | <.001 | 28 (22–40) |
| 57–63 | 5,243 | 91.6 (90.8–92.4) | 95.1 (93.8–96.4) | 0.964 (0.948–0.980) | <.001 | 29 (20–53) |
| Adjusted RR estimate (95% CI) | | | | | | |
| Overall | 28,901 | 94.5 (94.2–94.8) | 97.1 (96.6–97.6) | 0.973 (0.967–0.979) | <.001 | 38 (30–48) |
| 49 or less | 16,021 | 95.8 (95.5–96.1) | 97.9 (97.3–98.5) | 0.978 (0.97–0.985) | <.001 | 46 (33–65) |
| 50–56 | 7,637 | 93.8 (93.2–94.4) | 97.1 (96.2–98.0) | 0.965 (0.954–0.977) | <.001 | 30 (21–42) |
| 57–63 | 5,243 | 91.7 (90.9–92.5) | 94.9 (93.6–96.2) | 0.967 (0.950–0.984) | <.001 | 32 (19–54) |

RR, relative risk; NNT, number needed to treat.

reason, the relative risk of 0.973 is best interpreted as "97.3% relative effectiveness" of the simultaneous regimen compared with the interval regimen.

Treatment success rates declined as gestational age increased with both regimens, but the relative risk (RR) of success of simultaneous compared with interval dosing remained nearly constant within each gestational age category (49 days: RR 0.978, 95% CI 0.970–0.985; 50–56 days: RR 0.965, 95% CI 0.954–0.977); 57–63 days: RR 0.967, 95% CI 0.950–0.984). Tukey's range test showed that the RR of success of the simultaneous regimen compared with the interval regimen did not vary significantly across gestational age groups ($P$=.268) despite the relatively large sample sizes (Appendix 9, available online at http://links.lww.com/AOG/B76).

Results for the first of our two secondary outcome analyses (reasons for medical abortion failure) are detailed in Table 3. Continuing pregnancy after treatment was diagnosed in 596 women who chose the simultaneous regimen and 39 who chose the interval regimen: 2.4% (95% CI 2.2%–2.5%) vs 0.9% (95% CI 0.6%–1.2%), respectively ($P$<.001). Rates of surgical intervention for continuing pregnancy were lowest in both groups at 49 days of gestation or less (1.4% simultaneous vs 0.2% interval, $P$<.001), but increased with gestational age and were highest in the 57- to 63-day group (5.0% simultaneous vs 2.2% interval, $P$<.001). Eighteen women with continuing pregnancies in the simultaneous group, and one in the interval group, either chose not to complete the abortion or were lost to follow-up after diagnosis. We analyzed surgical evacuation for nonviable retained gestational sac or embryo and incomplete abortion together as a result of the small number in each category when separated by gestational age group. Surgical evacuation for a retained nonviable gestational sac or embryo or for incomplete abortion was more common with the simultaneous regimen overall: 3.1% simultaneous (95% CI 2.8–3.3%) vs 2.0% interval (95% CI 1.6%–2.5%, $P$<.001). When considered separately by gestational age, the difference between regimens was significant at 49 days or gestation or less (2.9% vs 1.7%, $P$=.003) and 50–56 days of gestation (3.5% vs 2.0%, $P$=.007), but not at 57–63 days of gestation (3.1% vs 2.6%, $P$=.447). Table 3 shows all CIs separated by gestational age. No other indications for surgical uterine evacuation were reported.

Results for our secondary outcome analysis of clinically significant adverse events are shown in Table 4. Rates of clinically significant adverse events were low with both regimens. Forty-nine of 24,543 women in the simultaneous group (0.20%, 95% CI 0.15–026%) vs 8 of 4,358 women in the interval group (0.18%, 95% CI 0.08–0.36%) experienced any clinically significant adverse event ($P$=.972). There were no significant differences between regimens within each individual adverse event category. However, there were very few cases of intravenous antibiotic administration (one event in the simultaneous group, one in the interval group) or of blood transfusion (eight simultaneous, four interval), limiting our power to detect small rate differences within these individual adverse event categories.

## DISCUSSION

In this retrospective cohort study, we observed that simultaneous administration of mifepristone and

**Table 3. Reasons for Medical Abortion Failure Among Women Choosing Simultaneous or Interval Administration of Mifepristone and Misoprostol for Early Medical Abortion From May 1, 2015, to April 30, 2016, at British Pregnancy Advisory Service (N=28,901)**

| | Simultaneous (n=24,543) | Interval (n=4,358) | P |
|---|---|---|---|
| Continuing pregnancy (total) | 596 | 39 | |
| Opted against surgical intervention | 18 | 1 | |
| Indications for surgical evacuation | | | |
| Continuing pregnancy (d) | | | |
| Overall | 2.4 [2.2–2.5] (578) | 0.9 [0.6–1.2] (38) | <.001 |
| 49 or less | 1.4 [1.2–1.6] (192) | 0.2 [0.1–0.6] (5) | <.001 |
| 50–56 | 2.8 [2.4–3.2] (174) | 0.8 [0.4–1.4] (10) | <.001 |
| 57–63 | 5.0 [4.4–5.8] (212) | 2.2 [1.4–3.3] (23) | <.001 |
| Retained nonviable gestational sac or incomplete abortion (d) | | | |
| Overall | 3.1 [2.8–3.3] (752) | 2.0 [1.6–2.5] (87) | <.001 |
| 49 or less | 2.9 [2.6–3.2] (403) | 1.7 [1.2–2.4] (34) | .003 |
| 50–56 | 3.5 [3.0–3.9] (218) | 2.0 [1.3–2.9] (26) | .007 |
| 57–63 | 3.1 [2.6–3.7] (131) | 2.6 [1.7–3.8] (23) | .447 |

Data are n or % [95% CI] (n) unless otherwise specified.

**Table 4. Clinically Significant Adverse Events Associated With Early Medical Abortion With Simultaneous or Interval Administration of Mifepristone and Misoprostol From May 1, 2015, to April 30, 2016, at British Pregnancy Advisory Service (N=28,901)***

| Clinically Significant Adverse Event | Simultaneous (n=24,543) | Interval (n=4,358) | *P* |
|---|---|---|---|
| Any | 0.20 [0.15–0.26] (49) | 0.18 [0.08–0.36] (8) | .972 |
| IV antibiotics | 0.000 [0.00–0.02] (1) | 0.02 [0.00–0.13] (1) | .695 |
| Blood transfusion | 0.03 [0.01–0.06] (8) | 0.09 [0.03–0.23] (4) | .173 |
| Hospital admission | 0.20 [0.14–0.26] (48) | 0.16 [0.06–0.33] (7) | .765 |

IV, intravenous.
Data are n or % [95% CI] (n) unless otherwise specified.
* An individual woman may experience more than one significant adverse event. Each woman is counted only once in the "Any" category, which represents a combined variable for each of the three categories: IV antibiotics, blood transfusion, and hospital admission.

misoprostol for medical abortion is 97% as effective as a regimen with a 24- to 48-hour interval between medications at all gestational ages up to and including 63 days, even after adjusting for self-selection to regimen. As gestational age increases, absolute success rates decline with both regimens, but the relative effectiveness of the simultaneous regimen remains constant. Moreover, the safety profiles of both regimens are similar with low rates of clinically significant adverse events. Likely reflecting its greater convenience, women overwhelmingly chose simultaneous over interval administration.

Two randomized trials have compared outcomes with simultaneous and 24-hour interval regimens for early medical abortion. Goel et al[11] randomized 80 women to either simultaneous use or a 24-hour interval at 7 weeks of gestation or less and observed success rates of 95.0% and 97.5%, respectively (*P*=.56). A randomized noninferiority study by Creinin et al[10] found that a simultaneous regimen was noninferior to a 24-hour interval at 63 days of gestation or less. Our overall success rates were similar to those found in both studies, and the significant difference in effectiveness we documented between regimens was within the margin Creinin et al thought clinically acceptable. The Creinin trial found no decrease in treatment success rates with either regimen at higher gestational ages. By contrast, we observed that success rates were lower at higher gestational ages with both regimens. Our findings are consistent with a systematic review of medical abortion trials involving more than 45,000 women using 200 mg oral mifepristone and a range of misoprostol regimens and intervals, which found a higher risk of failure (defined as need for surgical evacuation) in groups that had greater than 25% of women in the ninth week of pregnancy compared with lower gestations.[23] Our study makes two unique contributions by examining regimen preference in a setting where women must return to the clinic to receive misoprostol and by examining whether there is a change in the relative effectiveness of the two regimens as gestational age advances.

We observed a slightly higher overall rate of clinically significant adverse events than previously reported by Cleland et al[24] in their evaluation of 233,805 medical abortions performed over 2 years in Planned Parenthood clinics. Although our rates of intravenous antibiotic administration and blood transfusion were similar to those found by Cleland et al, we observed higher rates of hospital admission. This difference may be a function of care in a publically funded health system in Britain rather than an actual difference in the severity of incidents.

One limitation of our study is a lack of information about factors influencing women's choice of regimen. Women received counseling on the expected differences in side effects based on published data and on outcomes from a small pilot study of simultaneous administration conducted at British Pregnancy Advisory Service. We do not know, however, whether or how counseling affected women's decision-making or experience. Clinicians refer to comparison tables in a printed client guide when informing clients about treatment options and provide women with the guide for future reference, but counseling is not otherwise standardized. A second limitation is that despite efforts to ensure complete reporting of complications, some women may still have received treatment that British Pregnancy Advisory Service clinicians were unable to confirm. Moreover, management of the same adverse event can differ between clinicians and across institutions. Finally, women were not randomized to abortion regimen. We accounted for this limitation using propensity scores, and although the unadjusted and adjusted findings were reassuringly similar, we cannot entirely eliminate the possibility of unobserved confounding factors (Appendices 10 and 11, available online at http://links.lww.com/AOG/B76).

Our findings have several important implications for clinical practice and policy. In settings such as England and Wales, where the use of abortion medications outside of a registered facility is prohibited, interval regimens require at least two clinic trips, which creates substantial access barriers and limits treatment acceptability.[25] When given the choice of avoiding multiple clinic visits, women in our sample overwhelmingly opted for simultaneous over interval administration. Our findings also indicate that women can be offered the simultaneous regimen at all gestational ages up to and including 63 days without concern that its relative effectiveness will deteriorate significantly compared with the interval regimen. A 24- to 48-hour interval between mifepristone and misoprostol is commonly recommended based on the greatest chance of success.[5] However, in light of its potential to better meet the needs of women while still achieving a successful abortion in most cases, medical abortion guidelines should include the option of simultaneous dosing up to and including 63 days of gestation.

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