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EDITORIAL

From Evidence to Action: Improving Maternal and Newborn Health

This issue highlights key challenges and practical solutions to improve maternal, reproductive, and newborn health in sub-Saharan Africa. A common message emerges: many deaths and complications can be prevented with timely care, simple innovations, and stronger health systems.

Postpartum hemorrhage (PPH) remains a leading cause of maternal death. One study presents a simple surgical technique (COMOC-MG) that helped control bleeding and preserve the uterus in most high-risk cesarean cases. Although based on a small sample, it shows promise as a low-cost, life-saving option in resource-limited settings.

A study from Ethiopia found that pre-eclampsia, poor maternal nutrition, and a history of PPRM increase the risk of early membrane rupture. This highlights the need for better antenatal care, including early detection of high-risk conditions and improved nutrition.

Infertility care is also advancing. Data from Ethiopia's fertility center show a moderate success rate for assisted reproductive technology, with better outcomes linked to factors like younger age and good-quality embryos. These findings can help improve fertility services in similar settings.

A study from Nigeria shows that post-abortion care is still limited, especially in rural and primary care facilities. Improving access to trained staff and essential supplies is critical to reduce preventable deaths. There is encouraging progress in pediatric HIV care. High viral suppression rates were achieved with newer treatments, especially among children with good adherence and nutritional support. This shows that strong follow-up and family support are essential.

Newborn health is still at risk. Meconium aspiration syndrome remains a significant problem, especially in post-term pregnancies and poorly monitored labor. Better fetal monitoring and timely delivery can reduce these risks.

The case reports remind clinicians to stay alert to rare conditions and the importance of early diagnosis and counseling in complex cases.

Overall, these studies show that practical, affordable interventions, combined with better health systems, can make a real difference. Strengthening care across all levels is key to saving lives and improving outcomes.

Wondimu Gudu (Editor-in-Chief)

Ethiopian Journal of Reproductive Health (EJRH)

THE COMOC-MG SURGICAL TECHNIQUE FOR THE MANAGEMENT OF POSTPARTUM HAEMORRHAGE: CLINICAL EXPERIENCE FROM EAST AFRICA

Peter Gathoga¹, Deo Benyumiza²

ABSTRACT

BACKGROUND: Postpartum hemorrhage (PPH) remains the leading cause of maternal mortality worldwide, accounting for approximately 30–50% of maternal deaths, with sub-Saharan Africa carrying a disproportionate burden. The risk is further heightened in caesarean deliveries, where PPH contributes to nearly one-third of maternal deaths in low- and middle-income countries. The COMOC-MG technique, (Compression of Myometrium and Occlusion of Uterine Artery -Mahesh Gupta) a modified uterine compression suture that integrates myometrial compression with bilateral uterine artery occlusion, offers a promising, efficient, and uterus-preserving intervention, with reported success rates of up to 98%.

METHODS: This is a study of a small cohort of high-risk patients who developed atonic PPH during caesarean delivery, conducted at Jacaranda Maternity Hospital in Nairobi, Kenya. All patients had failed initial management with uterotonics and tranexamic acid before undergoing the COMOC-MG technique. Data were obtained from operative records, including clinical characteristics, intraoperative findings, estimated blood loss, transfusion requirements, and outcomes.

RESULTS: Seven patients aged 25–37 years underwent the COMOC-MG technique at gestational ages of 37–41 weeks. Uterine atony was confirmed intraoperatively in six of seven cases; the remaining case involved gross atony complicated by a uterine myoma requiring concurrent myomectomy. Estimated blood loss ranged from approximately 700 mL to 2000 mL. Blood transfusion requirements varied from none (two patients) to six units of whole blood (one patient with confirmed PAS). The COMOC-MG technique achieved hemostasis in six of seven patients (85.7%), preserving the uterus in all but one case. One patient with confirmed placenta accreta spectrum and disseminated intravascular coagulation (DIC) required peripartum hysterectomy despite all conservative measures. All patients were discharged with favorable maternal outcomes; all seven neonates were born alive, with one requiring neonatal intensive care unit admission.

CONCLUSION: Our experience with the COMOC-MG surgical technique in a small patient cohort in East Africa suggests that it can effectively achieve hemostasis and preserve the uterus in most high-risk cases of atonic PPH during Caesarean delivery. The observed uterine preservation rate of 85.7% aligns with existing literature. However, the findings should be interpreted cautiously due to the small sample size, single-center design, and lack of a comparison group. The technique appears to be a low-cost and feasible option where resources are limited. Larger prospective studies are needed to confirm its efficacy, safety, and broader applicability.

KEYWORDS: modified B-Lynch suture, COMOC-MG, Postpartum hemorrhage, Maternal mortality, Uterine atony

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INTRODUCTION

Postpartum hemorrhage (PPH) defined as blood loss of ≥ 500 ml from the genital tract following childbirth remains the leading cause of maternal mortality (MM) globally, accounting for approximately 30% to 50% of all maternal deaths. Sub-Saharan Africa (SSA) bears a disproportionately high burden, with one of the highest maternal mortality ratios (MMRs) globally, closely linked to the prevalence of PPH^{1,2}. Alarming, women in Africa are 50 times more likely to die after caesarean delivery (CD) than their counterparts in high-income countries, with haemorrhage identified as a key contributor³. The prevalence of PPH in Africa is estimated at 25.7%, with severe PPH (defined as ≥ 1000 ml blood loss) also highest in the region at 5.1%, compared to just 1.9% in Asia⁴.

In terms of national trends, Kenya saw a decline in its maternal mortality ratio (MMR) from 708 to 342 per 100,000 live births between 2000 and 2017 (uncertainty interval [UI]: 253–476). Nigeria, with nearly 67,000 maternal deaths in 2017, has the fourth-highest MMR globally, accounting for 23% of global maternal deaths (917 per 100,000; UI: 658–1320). South Africa also reported progress, with its MMR decreasing from 160 to 119 per 100,000 live births over the same period (UI: 69–153)⁵.

Despite a 40% reduction in MM across SSA over the past decade, the region continues to experience disproportionately high maternal death rates (1). Global efforts to reduce PPH-related deaths have been slow, highlighting the urgent need for scalable and effective interventions, particularly in resource-limited settings⁶.

PPH remains a significant concern in low- and middle-income countries (LMICs), where the majority of PPH-related deaths occur despite the availability of clinical guidelines and advances in both medical and surgical treatments^{2,3}. A systematic review by the World Health Organization (WHO) revealed that approximately 73% of maternal deaths in LMICs are attributable to PPH, with over 40% of these occurring in SSA alone⁵.

Among the primary causes of PPH is uterine atony,

the failure of the uterus to contract effectively after childbirth¹. Caesarean delivery, particularly in emergency settings, significantly increases the risk of PPH compared to vaginal birth. As cesarean rates continue to rise globally, the incidence of PPH during and after cesarean delivery has become a growing concern. In LMICs, PPH is implicated in 32% of maternal deaths following CD⁷.

While some maternal deaths may be unavoidable due to pre-existing high-risk conditions, many are attributable to “failure to rescue”—the inability to manage complications effectively during or after surgery. In Africa, the rate of such failures after cesarean delivery is estimated to be 17 times higher than in high-income countries³.

Following childbirth, 5–10 IU of oxytocin is routinely administered intramuscularly. In cases where uterine tone remains poor, uterine massage, bimanual compression, and additional uterotonics are used sequentially. If bleeding continues despite these conservative measures, the COMOC-MG (Compression of Myometrium and Occlusion of Uterine Artery by Mahesh Gupta) technique is considered—typically within 4 to 5 minutes after placental delivery—based on ongoing blood loss and uterine contractility⁸. The COMOC-MG technique uses polyglycolic acid double strand suture with 80 mm long straight taper point needle and 50-mm half circle round bodied needle (Truglyde®, Healthium Medtech, India) (Figure 1) for timely intervention in managing atonic PPH during cesarean delivery.



Figure 1: Suture and needles used in COMOC MG technique.

This technique combines the concept of the B-Lynch suture with uterine artery ligation, providing enhanced hemostatic control. Unlike the traditional approach, COMOC-MG technique involves a single puncture on either side of the

uterus, preserving the uterine cavity's integrity. Importantly, it does not require reopening the uterine incision, which simplifies the procedure and shortens operative time.

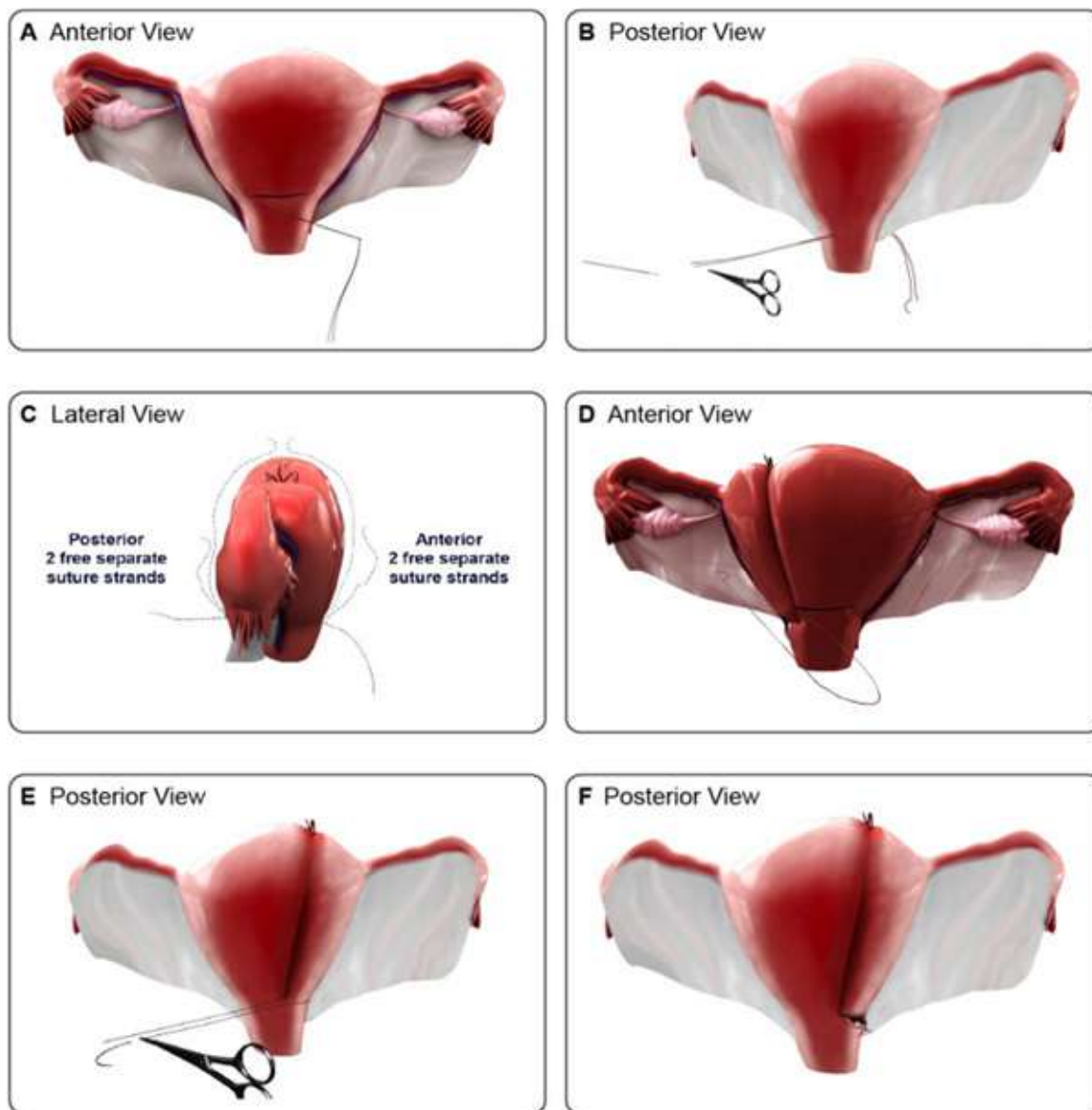


Figure 2: The COMOC-MG stitch is performed in a stepwise manner. (a) An approximately 80 mm straight taper-point needle is inserted into the uterus about 3 cm below and 3 cm medial to the lower edge of the uterine incision. (b) The loop around the eye of the needle is then cut, creating two free limbs posteriorly and two anteriorly. (c) From the resulting double strands, one strand is used to form a loop over the uterine fundus, similar to the Hayman suture, to provide uterine compression. (d) The second strand, mounted on a round-bodied needle, is passed through an avascular area just below the uterine incision at the same level on the posterior aspect. (e, f) Finally, both limbs of this second strand are tied firmly to occlude the uterine artery, thereby achieving effective hemostasis (Gupta, 2020). COMOC-MG stitch. Notes: a 80 mm long straight taper point needle is inserted into the uterus from 3 cm below and 3 cm medial to the lower cut edge of the uterus, b The loop around the eye of the needle is cut to obtain two free limbs

The COMOC-MG technique has demonstrated high success in preserving the uterus and fertility in cases of refractory atonic PPH³. Its simplicity, efficiency, and adaptability make it well-suited for use in settings with limited surgical resources. The technique requires minimal training, can be performed quickly, and avoids excessive intrauterine pressure postoperatively, thereby reducing the risk and associated complications.

Given its safety profile and effectiveness, the COMOC-MG technique should be considered the intervention of choice when medical therapy fails to control atonic PPH—particularly before resorting to radical procedures such as hysterectomy. It offers a reliable and fertility-preserving alternative to the B-Lynch or other modified compression sutures, making it a valuable addition for managing obstetric hemorrhage⁸.

Methods: This is a clinical experience from a small patient cohort on the use of the COMOC-MG technique for PPH, conducted at Jacaranda Maternity Hospital in Nairobi, Kenya. Seven consecutive high-risk obstetric patients who developed atonic PPH during cesarean delivery were included. All patients had failed initial conservative management with standard uterotonics (oxytocin, carboprost, misoprostol) and tranexamic acid, and subsequently underwent the COMOC-MG technique. Data were extracted from operative records and included patient demographics, obstetric history, gestational age, intraoperative findings, time to COMOC-MG application, estimated blood loss, transfusion requirements, and maternal and neonatal outcomes. No control group was used.

Experience from the seven cases

A total of seven patients, aged between 25 and 37 years, underwent cesarean deliveries at term gestations ranging from 37 to 41 weeks (Table 1). Risk factors identified across the cohort included multiple prior cesarean sections, placenta previa, moderate anemia, and coexisting uterine myomas. One of the most complex cases involved suspected placenta accreta spectrum (PAS) and

mild antepartum hemorrhage, managed via a scheduled elective cesarean section under high-risk surveillance.

Most patients had no trial of labor, and cesarean sections were primarily indicated due to prior uterine scars, placenta previa, delayed labor, poor progress, or failed induction. Neonatal birth weights ranged from 2300 g to 3755 g, and all neonates were born alive, with no perinatal complications in all patients except one case requiring postoperative neonatal intensive care unit admission following elective cesarean section for suspected PAS.

Intraoperative findings revealed a spectrum of placental separations: from difficult and adherent in PAS to slightly adherent in placenta previa, and easily separable in the remaining cases. Uterine atony was identified as the primary cause of intraoperative hemorrhage in six out of seven patients. Indications for COMOC-MG technique application included atonic postpartum hemorrhage (PPH) and gross atony in the presence of uterine myoma. All patients received standard uterotonic agents including oxytocin, carboprost, misoprostol, and tranexamic acid as part of hemorrhage management. Blood transfusion requirements varied from none to six units of whole blood or packed red cells, with some patients also receiving fresh frozen plasma (FFP).

One patient with confirmed placenta accreta spectrum underwent peripartum hysterectomy due to intractable bleeding despite all conservative measures. All patients were managed conservatively and discharged with favourable maternal and neonatal outcomes.

An especially critical case involved a patient presenting emergently with torrential vaginal bleeding and anuria. Intraoperatively, she was diagnosed with a grossly atonic uterus. She required extensive resuscitation and emergency laparotomy. Hemostasis was achieved using COMOC-MG technique by uterine compression and uterine vessel ligation. Approximately 300 mL of clots were evacuated, and the abdomen was closed in layers. The estimated blood loss was 2000 mL. Postoperatively, she was diagnosed with

massive obstetric hemorrhage, acute kidney injury (AKI), pre-eclampsia, and coagulopathy, requiring intensive multidisciplinary management.

Table.1: Details of the 7 patients where COMOC MG technique was used in managing PPH

Sr	Age No	Obstetric History	Gestational Age	Complications during pregnancy	Birth weight	Indication for CS	Placenta separation	Indication for COMOC-MG	Time between for uterine closure to COMOC-MG	Blood transfusion
1	37 yrs	G4P3L3	37 weeks	Placenta previa and Placenta accreta spectrum. Developed mild APH the night prior to the scheduled repeat elective C-section	2300 gm	APH	Difficult	Massive Hemorrhage	15 min	6 units of whole blood
2	25 yrs	G2P1L1	39 weeks	Nil	3100 gm	1 previous scar with Type 3 placenta previa	Slightly adherent	Atonic PPH	6 min	2 units of packed redcells
3	30 yrs	G2P1L1	40 weeks	Nil	3235 gm	Delayed second stage of labour	Easy	Atonic PPH	4 min	Nil
4	35 yrs	G5P3L2	38 weeks	Nil	3755 gm	Poor progress	Easy	Gross Atony with Uterine Myoma	15 min Myomectomy had to be done first	2 units of whole blood and 1 unit of packed red cells
5	30 yrs	G3P1L0	41 weeks	Nil	3600 gm	Failed induction of labour	Easy	Atonic PPH	4 min	Nil
6	35 yrs	G6P5L5	39 weeks	Anaemia (Hb-8 g/dl)	3100 gm	3 previous scars	Easy	Atonic PPH	6 min	4 units of whole blood
7	28 yrs	G1P0	37weeks	Anaemia (Hb-10g/dl) Pre-eclampsia with severe features	2235 gms	Fetal growth restriction with abnormal Umbilical artery Doppler velocimetry and a Pathological Non stress test	Easy	Atonic PPH	4min	2 units of FFPs with 3 units of whole blood/packed cells

Results

Seven patients aged 25–37 years underwent the COMOC-MG technique at gestational ages of 37–41 weeks. Risk factors included multiple prior caesarean sections, placenta previa, suspected placenta accreta spectrum (PAS), uterine myomas, and moderate-to-severe anemia (hemoglobin 8–10 g/dl). Uterine atony was confirmed intraoperatively in six of seven cases; the remaining case involved gross atony complicated by a uterine myoma requiring concurrent myomectomy. Estimated blood loss ranged from approximately 700 mL to 2000 mL. Blood transfusion requirements varied from none (two patients) to six units of whole blood (one patient with confirmed PAS). The COMOC-MG technique achieved hemostasis in six of seven patients (85.7%), preserving the uterus in all but one case. One patient with confirmed placenta accreta spectrum and disseminated intravascular coagulation (DIC) required peripartum hysterectomy despite all conservative measures. All patients were discharged with favorable maternal outcomes; all seven neonates were born alive, with one requiring neonatal intensive care unit admission.

DISCUSSION

Postpartum hemorrhage (PPH) imposes a significant economic burden on healthcare systems. A recent study conducted in Kenya, India, Nigeria, and Uganda found that the direct costs of hospital care for women with PPH can be as much as 2.8 times higher than for those without it ².

Women in psychological distress face an increased risk of MM, preeclampsia, and eclampsia. Additionally, anaemic women or those with lower hemoglobin levels upon hospital admission were found to develop PPH later ¹.

The World Health Organization (WHO) first issued guidelines for the prevention and treatment of PPH in 2012 and has since released multiple updates based on emerging evidence ⁶. These guidelines currently recommend 13 clinical interventions tailored to the type (minor, moderate, or severe) and context of PPH, including mode of delivery, birth setting, and timing of onset ².

A Delphi consensus study by Taylor et al. across the APORG network identified 28 effective and feasible strategies to reduce PPH associated with CD in Africa. Many of these interventions—such as access to second-line uterotonics, tranexamic acid (TXA), emergency blood products, and surgical measures like hysterectomy, uterine artery ligation, compression sutures, and balloon tamponade—remain underutilized across the continent. Additional recommendations include timely referrals, postpartum surveillance, simulation training, and the use of maternal early obstetric warning scores. While many of these measures are not costly, they are hindered by implementation gaps ³.

The International Federation of Gynecology and Obstetrics (FIGO) advises the routine use of uterotonics during the third stage of labor for all births. Oxytocin (10 IU IV/IM) is the first-line agent for both vaginal and cesarean deliveries. In settings where oxytocin is unavailable or unreliable, alternative uterotonics—ergometrine/methylergometrine (200 µg IM/IV), oral misoprostol (400–600 µg), or carbetocin (100 µg IM/IV)—are recommended for the prevention of PPH ⁹.

Intravenous oxytocin remains the first-line treatment for PPH. If unavailable or ineffective, intramuscular ergometrine, fixed-dose oxytocin-ergometrine, or prostaglandins (e.g., sublingual misoprostol, 800 µg) are appropriate alternatives. Isotonic crystalloids are preferred over colloids for initial fluid resuscitation. Early administration of IV TXA—ideally within 3 hours of birth—is strongly recommended. Bimanual uterine or external aortic compression should be used as a temporary measure in cases of uterine atony after vaginal birth ⁹.

In Kenya and South Africa, WHO guidelines are generally followed, while Nigeria often relies on the UK-based Royal College of Obstetricians and Gynaecologists (RCOG) protocols. Kenya and South Africa also use national guidelines, with healthcare providers receiving government-sponsored training such as BEmONC and ESMOE ⁵.

However, adherence to best practices is limited by several barriers. PPH is frequently undetected or

recognized too late due to reliance on visual blood loss estimation, which is known to be inaccurate and prone to underestimation². In South Africa, for example, clinicians often prioritize vital signs over blood loss for PPH detection, leading to delayed responses. Management is sometimes reactive, with a "wait and see" approach applied after initial treatment rather than immediate escalation⁶.

Limited human resources and inadequate care quality contribute to preventable maternal deaths after cesarean complications in resource-constrained settings. Postoperative monitoring is often insufficient, delaying the recognition of concealed or ongoing bleeding. In Kenya, Nigeria, South Africa, and Tanzania, TXA was often administered as a last resort. While oxytocin was widely available, second-line uterotonics were scarce, and TXA was only present in about 70% of hospitals. Carbetocin was the least available uterotonic, despite its proven benefits in low-resource settings and its inclusion on the WHO Model List of Essential Medicines. Blood component therapy is also limited across Africa, reducing the ability to manage severe hemorrhages and associated coagulopathies. A shortage of skilled personnel further exacerbates the situation, as confirmed by both the African Surgical Outcomes Study (ASOS) and survey data³. Other systemic challenges include delays in patient transfers due to ambulance shortages, inconsistent blood supplies (especially in Nigeria and South Africa), understaffing during emergencies, and a lack of accurate tools for measuring blood loss⁶.

To improve adherence to guidelines, the adoption of care bundles—sets of evidence-based interventions applied simultaneously or in rapid succession—has shown promise in standardizing care and improving outcomes⁶. One such intervention is the E-MOTIVE bundle, developed following WHO technical consultations. E-MOTIVE stands for:

- Early detection using a calibrated drape
- Massage of the uterus
- Oxytocic administration
- Tranexamic acid administration
- IntraVenous fluid resuscitation
- Examination and escalation if bleeding persists⁶

Prophylactic measures like the COMOC-MG technique, a modified B-Lynch suture have shown considerable promise in managing atonic PPH. In one study, 82% of patients achieved hemostasis with this technique, and only 2% required a hysterectomy¹⁰. Another study by Koirala et al. reported a 94.7% success rate, with just one case requiring cesarean hysterectomy due to ongoing bleeding¹¹.

The COMOC-MG technique significantly reduced total blood loss, the need for transfusions, and reliance on blood products^{12,13}. Its effectiveness highlights its potential as a low-cost, high-impact intervention in settings with limited access to comprehensive surgical or transfusion services^{12,14}. This cases in this study underscore the multifactorial risks contributing to hemorrhagic complications during cesarean sections, including prior cesarean delivery, placenta previa, placenta accreta spectrum disorders, uterine atony, and anemia. In six of seven cases, timely application of the COMOC-MG technique achieved hemostasis through uterine compression and simultaneous bilateral uterine vessel ligation, without resorting to hysterectomy. The single hysterectomy performed involved a confirmed placenta accreta spectrum complicated by disseminated intravascular coagulation (DIC), illustrating the importance of prompt surgical decision-making in life-threatening scenarios. While these results are encouraging, they should be interpreted cautiously given the small sample size, heterogeneous case mix, and absence of a control group. The findings are hypothesis-generating and support the feasibility of the technique in a resource-limited African setting, but do not provide sufficient evidence to recommend its routine adoption or to project population-level impacts on maternal mortality across sub-Saharan Africa without further rigorous evaluation.

Limitations

This study has important limitations. The very small sample size (n=7) limits statistical power and the reliability of conclusions about the effectiveness and safety of the COMOC-MG technique. As an

uncontrolled, retrospective single-centre case series from Nairobi, Kenya, it lacks a comparison group and may not be generalizable to broader sub-Saharan African settings. The retrospective design also introduces selection bias and potential incomplete data capture, particularly for subjective blood loss estimation. Additionally, patient heterogeneity from uncomplicated atony to placenta accreta spectrum with DIC limits attribution of outcomes to the technique. Long-term outcomes such as menstrual function, fertility, and uterine integrity were not assessed, highlighting the need for prospective, controlled, multi-centre studies.

Conclusion

Our experience with the COMOC-MG surgical technique in a small patient cohort in East Africa suggests that it can effectively achieve hemostasis and preserve the uterus in most high-risk cases of atonic PPH during Cesarean delivery. The observed uterine preservation rate of 85.7% aligns with existing literature. However, the findings should be interpreted cautiously due to the small sample size, single-center design, and lack of a comparison group. The technique appears to be a low-cost and feasible option where resources are limited. Larger prospective studies are needed to confirm its efficacy, safety, and broader applicability.

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LIVE BIRTH RATE, TREATMENT OUTCOMES, AND PREDICTOR OF ASSISTED REPRODUCTIVE TECHNOLOGY AMONG INFERTILE COUPLES ATTENDING CENTER FOR FERTILITY AND REPRODUCTIVE MEDICINE IN ADDIS ABABA, ETHIOPIA

Heran Worku Dadi¹, Adesina Oladokun², & Dereje Bayissa Demissie³

ABSTRACT

BACKGROUND: Invitro fertilization has become a standard procedure with a record of more than 9 million births worldwide. One in every six couples is facing the problem of infertility. This infertility treatment is the only center in Ethiopia. The overall aim of this study was to investigate the live birth rate, treatment outcomes, and predictors of assisted reproductive technology among infertile couples attending a fertility center in Addis Ababa Ethiopia

METHODS: A retrospective study cohort study design was conducted at center for fertility and reproductive medicine of St. Paul's Hospital Millennium Medical College (SPHMMC) in Addis Ababa, Ethiopia, using structured checklists for extraction of data and phone interviews on infertile couples' treatment outcomes. Both binary and multivariable analysis, cox regression, and waiting time analyses were performed to identify predictors of treatment outcomes.

RESULT: The study found that the clinical pregnancy rate at the Fertility Center was 37.0% (n = 124). Among the 335 ART cycles analyzed, 88 resulted in live birth, yielding a live birth rate of 26.3% (95% CI: 21.5–31.0%). Factors significantly associated with increased odds of live birth included transfer of day-5 embryos compared with day-3 transfer (AOR = 2.48; 95% CI: 1.40–4.41), maternal age of 20–30 years compared with 31–40 years (AOR = 2.21; 95% CI: 1.28–3.83), optimal ovarian response defined as retrieval of 8–15 oocytes compared with poor response (≤ 4 oocytes) (AOR = 2.09; 95% CI: 1.05–4.20), and normal semen pH (7.2–8.0) compared with acidic semen pH (≤ 7.19) (AOR = 3.62; 95% CI: 1.01–12.99).

CONCLUSION: This study highlights actionable clinical factors that can improve ART success in Ethiopia. Prioritizing day-5 embryo transfer, optimizing ovarian response, focusing care on younger women, and addressing semen quality can significantly enhance live birth outcomes. Strengthening evidence-based, individualized ART practices will support better reproductive outcomes and guide quality improvement in fertility services.

KEYWORDS: Assisted Reproductive Techniques, Embryo Transfer, In Vitro Fertilization, Live Birth Rate, Treatment Outcome, Infertility, Oocyte Retrieval, Pregnancy Outcome, Predictive Factors

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INTRODUCTION

Assisted Reproductive Technology (ART) encompasses procedures involving the *in vitro* handling of human oocytes, sperm, and embryos, with the primary goal of achieving pregnancy by collecting gametes, creating embryos in the laboratory, and transferring the most viable embryo into the uterus. ART procedures including *in vitro* fertilization (IVF) and intracytoplasmic sperm injection (ICSI) have transformed infertility management, providing hope to millions of couples worldwide. Globally, more than five million births have resulted from IVF, reflecting rapid scientific and technological advancements that continue to expand the possibilities for individuals experiencing infertility¹⁻⁴.

Infertility remains a major reproductive health concern, defined as the inability to conceive after one year of unprotected intercourse. It affects approximately 15% of couples of reproductive age worldwide, with prevalence estimates ranging from 18% in the United States to 25% among Chinese couples⁵⁻⁸. More than 180 million couples in developing countries experience primary or secondary infertility, with infection-related tubal damage being the most common cause in sub-Saharan Africa⁹. Despite the growing need for fertility care, significant disparities in the availability, accessibility, and affordability of ART services persist between high-income and low-income settings.

The consequences of infertility are far-reaching and extend well beyond the inability to conceive. The Centers for Disease Control and Prevention (CDC) recognizes infertility as a public health concern due to its association with psychological distress, social stigma, economic strain, marital instability, and increased risk of chronic illnesses, including cardiovascular disease^{10, 11}. In many African contexts, infertility carries profound gendered implications, with women disproportionately experiencing blame, social exclusion, and even abuse. Couples often seek treatment from various sources including spiritual healers, traditional practitioners, and modern medical facilities

reflecting cultural beliefs about the origins of infertility and the limited availability of formal reproductive health services^{3, 12, 13}.

Although ART utilization is increasing worldwide, coverage in sub-Saharan Africa remains extremely low. Only a limited number of IVF centers operate across the region, and service accessibility is hampered by cost, infrastructure gaps, and shortages of trained specialists. An African registry analysis reported 153,917 ART procedures from 73 centers across 18 countries over five years, with clinical pregnancy rates remaining relatively stable (34.9% in 2013 and 31.7% in 2017)². The African Network and Registry for Assisted Reproductive Technology (ANARA) continues to emphasize the need for comprehensive ART data to guide policy and strengthen fertility care provision.

In Ethiopia, infertility affects 15–20% of couples, with prevalence varying by region from 2.5% in SNNP to 15.1% in Addis Ababa and increasing with women's educational level¹⁴. Saint Paul's Hospital Millennium Medical College is currently the only public institution offering IVF services, with treatment costs ranging from 25,000 to over 120,000 birr, contributing to long waiting times and limited access¹⁵. Although Ethiopia's National Reproductive Health Strategy has prioritized infertility care expansion, progress remains limited¹⁶. Studies from Ethiopia and elsewhere indicate that ART outcomes significantly influence quality of life; women with successful ART cycles report higher satisfaction compared to those with unsuccessful outcomes, who often experience more miscarriages, ectopic pregnancies, and repeated treatment attempts^{17, 18}. Given the limited availability of ART services in Ethiopia and the absence of comprehensive outcome data, it is crucial to assess treatment success rates and determinants of ART outcomes among infertile couples.

Methods

Study setting and design

A retrospective cohort study was conducted from April 2019 to September 2021 at St. Paul's Hospital Millennium Medical College and Hayahulet Fertility

Specialty Center in Addis Ababa, Ethiopia. The study included 1,742 infertile or subfertile couples who received assisted reproductive technology (ART) services at the center during this period. Eligible participants were couples diagnosed with infertility and registered in the center's medical records, including those treated for female, male, or combined factor infertility using homologous sperm, oocytes, and embryos through fresh or frozen-thawed embryo transfer.

Sample Size Determination and Sampling technique

The sample size was calculated using a single-population proportion formula based on a reported African clinical pregnancy rate (CPR) of 31.7% from a five-year regional ART trend analysis².

With a 95% confidence level ($Z = 1.96$), 5% margin of error, and 31.7% expected success rate, the initial sample size was computed and adjusted for a 10% non-response rate due to potential incomplete records, yielding a final sample size of 366. A computer-generated simple random sampling method was used to select records from the list of all couples who underwent ART between April 2019 and September 2021. Sampling was proportionally allocated by year and month, and selected records were retrieved and coded using SPSS version 25. Figure 1 presents the schematic sampling procedure. NB; Intrauterine insemination (IUI) cases ($n=27$) were excluded from the analysis. After exclusions, the final sample size included in the analysis was 335 ART cycles.

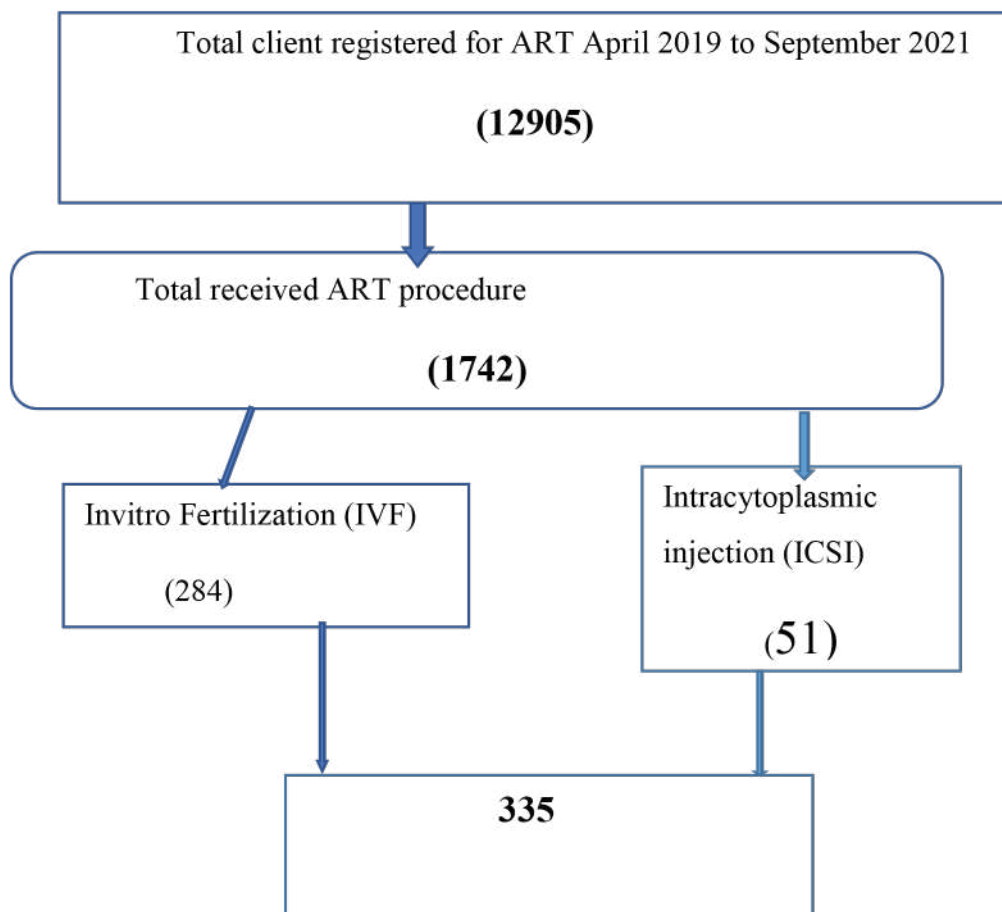


Figure 1: Schematic presentation of infertile couples in Ethiopia from April 2019 to September 2021 GC attended the Hayahulet Fertility Specialty Center at St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia

Data collection methods and techniques

Data were collected using a combination of structured checklists and telephone interviews. Three trained clinical nurses extracted information from patient medical records and contacted participants to obtain missing ART outcome data. Prior to data collection, the principal investigator provided training on the use of the checklist, document review procedures, and standardized phone-interview techniques. A pre-test was conducted on 5% of the sample to ensure clarity and validity of the instrument, and necessary adjustments were made accordingly. Because several ART outcome variables such as β -hCG test results, pregnancy status, live birth, abortion history, total treatment cost, mode of delivery, and waiting time were not consistently documented in medical records, telephone interviews were used to supplement and verify missing information. Data collection took place between January 18, 2022, and February 28, 2022, and all extracted data were accessed solely for research purposes. To maintain data quality, the investigator supervised data collectors, reviewed completed checklists daily, and addressed inconsistencies during data entry. Data cleaning was performed by examining frequencies and correcting errors prior to analysis.

Data Analysis Procedures and Management

Completed checklists were reviewed for completeness, and records with major missing information were excluded. Cleaned data were coded and entered into SPSS version 25 for analysis. Descriptive statistics were used to summarize socio-demographic and clinical characteristics. Binary and multivariable logistic regression analyses assessed the association between independent variables and delivery outcomes. Continuous variables were checked for normality using the Kolmogorov-Smirnov test. Survival analysis including life-table estimates, Kaplan-Meier curves, and Cox proportional hazards regression was conducted to evaluate time to successful pregnancy and identify predictors of live birth. Statistical significance was set at $p < 0.05$.

Operational and terms definitions

ART treatment outcome: In this study, ART treatment outcome was defined as the occurrence of clinical pregnancy and/or live birth among infertile couples who underwent assisted reproductive technology between April 2019 and September 2021. Outcomes were determined from medical records and, where necessary, supplemented by follow-up interviews. Only couples who received in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI) were included. **ART Treatment Success:** In this study, ART treatment success was defined as achieving a live birth.

Clinical pregnancy: Detection of fetal heartbeat by ultrasound at approximately seven weeks of gestation.

Live birth: Delivery of a live infant at ≥ 37 completed weeks via vaginal birth or cesarean section.

Waiting time for successful ART/IVF: Time from first ART attempt to achieving pregnancy (19, 20).

Infertility: Failure to conceive after ≥ 12 months of unprotected intercourse.

Cumulative Live Birth Rate (CLBR): Delivery of a live neonate following fresh or subsequent frozen-thawed embryo transfer cycles (19, 20).

Result

The study achieved a completed response rate of 91.5% (335/366). The mean maternal age was 33.29 years (SD \pm 4.83), ranging from 20 to 49 years, while the mean age of male partners was 41.36 years (SD \pm 6.77), ranging from 34 to 51 years. More than half of the female participants (199; 59.4%) were aged 31–40 years, and a similar proportion of male partners (199; 59.4%) were aged 35–44 years.

All participants (335; 100%) were married, with a mean marital duration of 6.79 years (SD \pm 3.63). Nearly half of the couples (162; 48.4%) had been married for 5–9 years without having a child. The average total cost incurred for ART procedures, including transportation, was USD 1,944.92 (SD \pm 857.13), based on an exchange rate of 1 USD=51.70 Ethiopian Birr at the time of treatment. Almost all participants (98.6%) resided in urban areas (Table 1).

Table 1: Demographic and socioeconomic characteristics of infertile couples in Ethiopia from April 2019 to September 2021 (N=335)

Demographic and Social Characteristics	Category	Frequency (%)
Maternal age in year (n=335)	20 - 30 years	121 (36.1)
	31-40 years	199 (59.4)
	41-49 years	15(4.5)
Paternal age (n=335)	<=34 years	42 (12.5)
	35-44 years	199 (59.4)
	45-50 years	63(18.8)
	>=51years and above	31(9.3)
Marital status	Married	335(100.0)
Marriage duration without child (n=335)	<= 4 years	102 (30.4)
	5-9 years	162 (48.4)
	>=10 years since married	71(21.2)
Residence (n=335)	Rural	5 (1.5)
	Urban	330(98.5)
The total cost of the ART and transportation for treatment	<= 1,353.97 USD	102(30.4)
	1,353.98 - 2,321.08 USD	115(34.3)
(n=335) Average cost in US Dollar 1,944.92 ± 857.13 (SD) USD while 1USD=51.70 Birr	>= 2,321.08 USD	118(35.2)

Reproductive and infertility history

The reproductive and infertility history of the study participants showed that 304 respondents (90.7%) had no prior medical or surgical interventions related to reproductive health. The majority of participants (321; 95.8%) were nulliparous, with no previous history of pregnancy. Based on medical record review, 269 cases (80.3%) were classified as primary infertility, with female-factor infertility identified as the leading cause in 213 cases (63.6%). A history of abortion or miscarriage was reported by 66 participants (19.7%), of whom 57.7% had experienced four or fewer abortion episodes.

Hormonal investigations among female participants indicated that most values were within normal reference ranges, including follicle-stimulating hormone (FSH) in 158 (83.2%), luteinizing hormone (LH) in 188 (78.3%), thyroid-stimulating hormone (TSH) in 177 (95.2%), estradiol in 82 (76.0%), and anti-Müllerian hormone (AMH) in

18 (21.2%) of those tested. All female participants (335; 100%) were screened for HIV, hepatitis B virus, and syphilis (VDRL/RPR), with documented results in their medical records.

Pelvic ultrasound examination revealed normal findings in 220 women (65.7%). Hysterosalpingography (HSG) results demonstrated bilateral tubal blockage in 123 participants (36.7%) and unilateral blockage in 62 participants (18.5%) (Supplementary Table 2).

Transvaginal Ultrasound Eggs identified and retrieved

Transvaginal ultrasound assessment showed that most women demonstrated an adequate to optimal ovarian response. Overall, 141 participants (42.1%) had a poor ovarian response with ≤4 oocytes retrieved, 80 (23.9%) had an adequate/normal response with 5–7 oocytes retrieved, and 114 (34.0%) achieved an optimal ovarian response with 8–15 oocytes retrieved.

Semen Analysis of male partners in Ethiopia from April 2019 to September 2021 (N=335)

Among the semen analyses reviewed, 30 male partners (9.0%) were diagnosed with azoospermia. Low sperm concentration was observed in 45 participants (12.5%), while 28 samples (8.4%) showed complete absence of sperm motility (progressive or non-progressive). Abnormal sperm morphology, defined as 0–3% normal forms, was identified in 67 samples (20.0%). Additionally, 28 participants (8.4%) had no measurable semen volume, and 43 (12.8%) reported an abstinence period of five days prior to semen sample collection. Furthermore, 30 participants (9.0%) had acidic semen pH (≤ 7.19). Detailed findings are presented in Supplementary Table 3.

ART Treatment and outcome

All respondents (335; 100%) were undergoing assisted reproductive technology (ART) for the first time, with no prior treatment cycles. Among the ovarian stimulation protocols used, the long protocol was the most frequently applied, accounting for 187 cases (51.8%). Regarding ovulation induction, 350 women (96.7%) had undergone ovulation induction prior to ART treatment.

Embryo Fertilization and Transfer Characteristics
With respect to fertilization methods, the majority of couples (284; 78.5%) underwent in vitro fertilization (IVF), while the remainder received intracytoplasmic sperm injection. Fresh embryo transfer was performed in 303 cycles (90.5%). Regarding embryo transfer practice, two embryos were most commonly transferred (230 cycles; 68.7%), followed by single-embryo transfers (74 cycles; 22.1%) and three-embryo transfers (31 cycles; 9.3%). Most embryos were transferred on day 3 (231; 69.0%), and 157 embryos (46.9%) were classified as grade-two quality.

Clinical Outcomes

Among all ART procedures, 124 cycles (37.0%) had positive human chorionic gonadotropin (hCG) test results. Fetal cardiac activity was confirmed in 88 pregnancies, including 71 singleton, 14 twin,

and 3 triplet gestations. Thirty-six cycles (10.7%) resulted in abortion or miscarriage. Overall, 88 couples (26.3%) achieved at least one live birth, yielding a total of 108 live births. No higher-order multiple pregnancies beyond triplets were observed (Supplementary Table 4).

Regarding delivery outcomes, 46 live births (52.3%) occurred at or before 37 weeks' gestation, and the majority of deliveries (86; 99.1%) were conducted via cesarean section. (see Supplementary Table 4).

Live Birth Delivery Rate

The live birth delivery rate, defined as the number of deliveries resulting in at least one live birth per 100 ART cycle attempts, was 32.2 per 100 cycles. This was calculated by dividing the total number of live births (108) by the number of first-cycle embryo transfers (335).

Overall, 627 embryos were transferred during first-attempt cycles, comprising 74 single-embryo, 230 two-embryo, and 31 three-embryo transfers. Accordingly, the live birth rate per embryo transferred was 17.2 per 100 embryos (108/627) (Supplementary Table 4).

ART Treatment Success

This study determined that the live birth rate among infertile couples attending the Hayahulet Fertility Specialty Center at St. Paul's Hospital Millennium Medical College, Ethiopia, was 26.3% (88/335; 95% CI: 21.5–31.0%) (Figure 3).

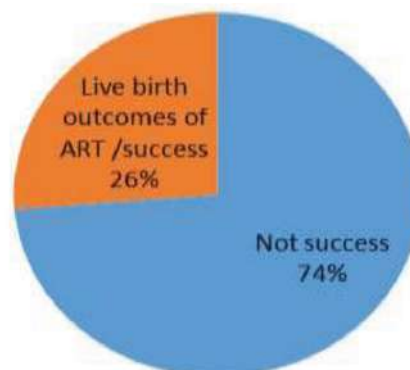


Figure 2: The proportion of success/ live birth of assisted reproductive technology among infertile couples at Hayahulet Fertility Specialty Center at St. Paul's Hospital Millennium Medical College, Ethiopia from April 2019 to September 2021.

This study determined ART outcomes (treatment success) were defined as a clinical pregnancy and revealed that the proportion of clinical pregnancy

outcomes of ART was 37.0% (124/335), which ranged from 95%CI, 32.2 to 42.1% see details in Figure 3).

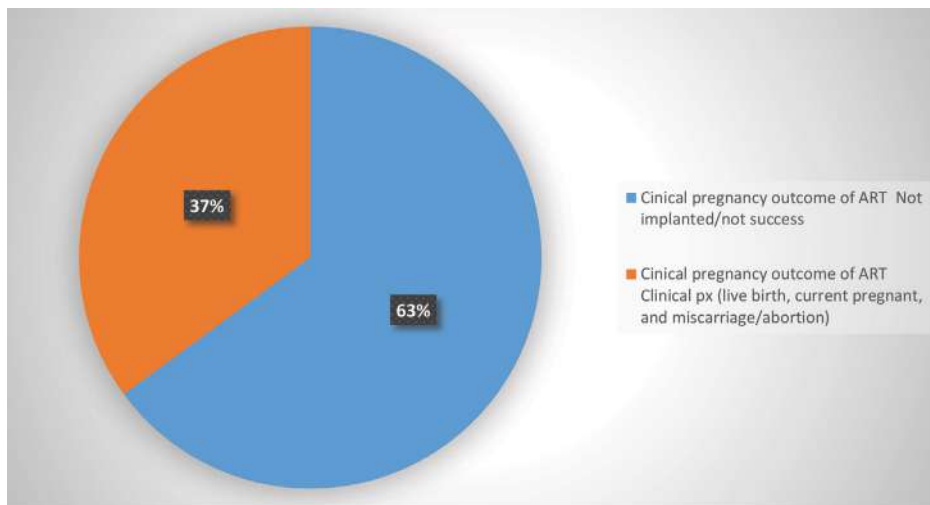


Figure 3: The proportion of clinical pregnancy outcomes of assisted reproductive technology among infertile couples in Ethiopia 2022.

The overall ovarian stimulation response was determined that 223(66.6%) had good responders

who had retrieved ≥ 4 oocytes which ranges with 95% CI 61.8 to 71.3%. see details in Fig4.

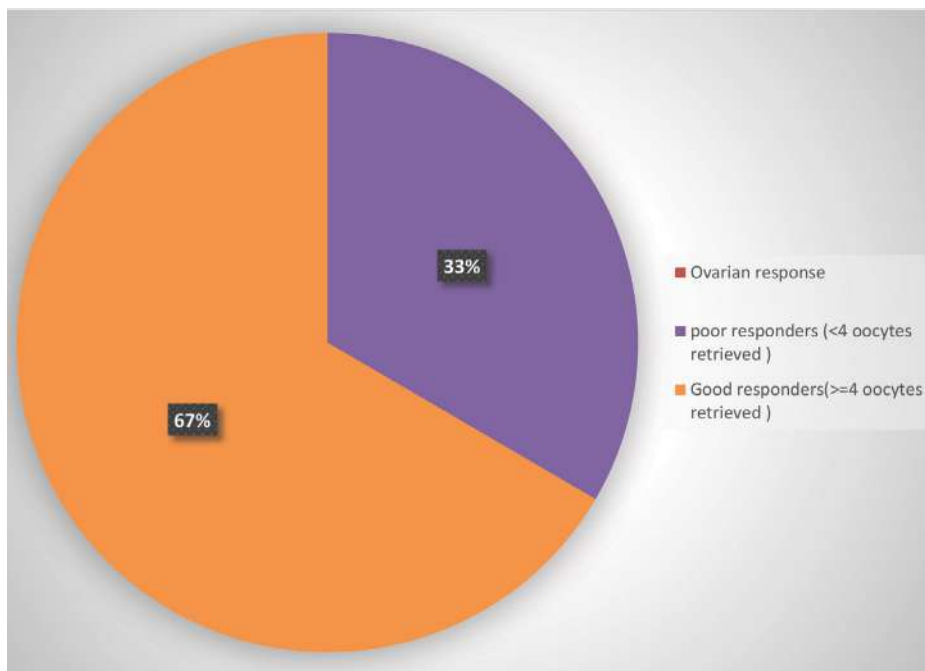


Figure 4: overall ovarian stimulation response of infertile female in Ethiopia from April 2019 to September 2021 (N=362)

Factors associated with the live birth outcome of assisted reproductive technology (ART)

Based on binary logistic regression analysis at $P < 0.05$, with 95%CI, the following variables were identified as candidates for multivariate logistic regression analysis: type of embryo used, number of embryo transfers (IVF/ICSI), days of embryo transfer, grade of embryos transferred, maternal age, retrieved egg (right and left), marital duration, and total cost of the procedures including transportation, respectively.

In the multivariable logistic regression analysis, several factors were independently associated with the live birth outcome of assisted reproductive technology (ART) among infertile couples attending the Hayahulet Fertility Specialty Center at St. Paul's Hospital Millennium Medical College, Ethiopia.

Embryo transfer on day 5 was significantly associated with higher odds of live birth compared with day-3 embryo transfer (AOR = 2.48; 95% CI: 1.40-4.41; $p = 0.002$). Maternal age was also a significant

predictor; women aged 20-30 years had more than twice the odds of achieving a live birth compared with those aged 31-40 years (AOR = 2.21; 95% CI: 1.28-3.83; $p = 0.005$). Maternal age 41-49 years was not significantly associated with live birth outcome. Ovarian response showed a significant association with live birth. Couples with an optimal ovarian response, defined as retrieval of 8-15 oocytes, had significantly higher odds of achieving a live birth compared with those with a poor response (≤ 4 oocytes retrieved) (AOR = 2.09; 95% CI: 1.05-4.20; $p = 0.040$). However, retrieval of 5-7 oocytes (adequate/normal response) did not show a statistically significant association with live birth outcome.

Semen pH was also significantly associated with ART success. Couples with normal semen pH (7.2-8.0) had significantly higher odds of achieving a live birth compared with those with acidic semen pH (≤ 7.19) (AOR = 3.62; 95% CI: 1.01-12.99; $p = 0.048$). see detail in Table 5).

Table 5: Factors associated with the outcome of assisted reproductive technology (ART) among infertile couples in Ethiopia from April 2019 to September 2021 (N=335) Ethiopia, 2022

Factors associated with ART outcomes		the outcome of assisted reproductive technology (ART)		P-value	AOR (95% CI)
		Successful (n=88)	Not successful (n=274)		
Days of embryo transferred	3	46(13.7%)	185(55.2%)	1:00	
	5	41(12.2%)	63(18.8%)	0.002	2.48(1.4-4.41)
Maternal age	20 - 30 years	48(13.3%)	81(22.4%)	0.005	2.21(1.28-3.83)
	31-40 years	39(10.8%)	178(49.2%)	1:00	
	41-49 years	48(13.3%)	81(22.4%)	0.279	0.32(0.04-2.53)
Ovarian Response	≤ 4 eggs retrieved (poor)	7.2%(24)	34.9%(117)	1:00	
	5-7 eggs retrieved (Adequate/normal)	5.97%(20)	17.9%(60)	0.641	1.201(.55- 2.597)
	8-15 eggs retrieved (Best/optimal)	13.1%(44)	20.9%(70)	0.04	2.086(1.05 -4.204)*
Semen PH	≤ 7.19	5(1.5%)	25(8.1%)		
	$> 7.2-8.0$	71(23.1%)	206(67.1%)	0.048	3.62(1.01-12.99)*

Key NB : *... P-value < 0.05 , **.... P-value < 0.01 & *** were significantly associated at the 0.001

predictor; women aged 20–30 years had more than twice the odds of achieving a live birth compared with those aged 31–40 years (AOR = 2.21; 95% CI: 1.28–3.83; $p = 0.005$). Maternal age 41–49 years was not significantly associated with live birth outcome. Ovarian response showed a significant association with live birth. Couples with an optimal ovarian response, defined as retrieval of 8–15 oocytes, had significantly higher odds of achieving a live birth compared with those with a poor response (≤ 4 oocytes retrieved) (AOR = 2.09; 95% CI:

1.05–4.20; $p = 0.040$). However, retrieval of 5–7 oocytes (adequate/normal response) did not show a statistically significant association with live birth outcome.

Semen pH was also significantly associated with ART success. Couples with normal semen pH (7.2–8.0) had significantly higher odds of achieving a live birth compared with those with acidic semen pH (≤ 7.19) (AOR = 3.62; 95% CI: 1.01–12.99; $p = 0.048$).see detail in Table 5).

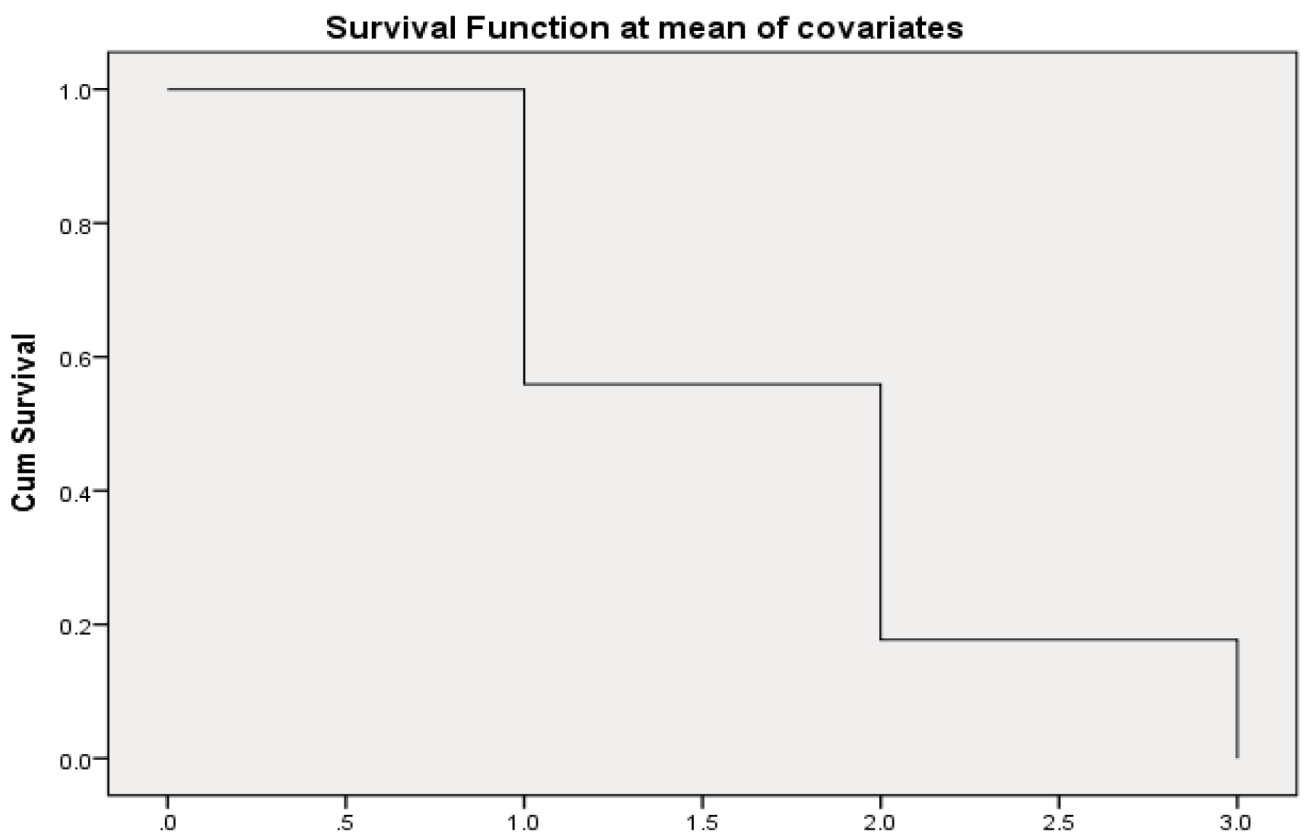


Figure 5: Relationship between the duration of treatment and the remaining couples for the treatment process. When treatment time is increased, the likelihood of survival success live birth is reduced

Predicting the likelihood of live birth of assisted reproductive technology outcomes among infertile couples

Infertile couples with a marital duration of 5–9 years without a biological child had 2.39 times higher odds of achieving a live birth following assisted reproductive technology compared with those married for ≤ 4 years (AHR = 2.39; 95% CI: 1.02–5.62). Transfer of frozen–thawed embryos was associated with substantially higher odds of live birth compared with fresh embryo transfer (AHR=8.00; 95% CI: 2.45–26.29).

The number of embryos transferred also predicted ART success; transferring two embryos increased the odds of live birth by 2.35 times compared with single-embryo transfer (AHR=2.35; 95% CI: 1.06–5.23). Ovarian response was significantly associated with live birth outcomes. Retrieval of 4–9 oocytes from the right ovary increased the odds of live birth by 2.02 times (AHR = 2.02; 95% CI: 1.19–3.44), while retrieval of ≥ 10 oocytes increased the odds by 1.70 times (AHR = 1.70; 95% CI: 1.18–6.15), compared with retrieval of 1–3 oocytes.

In addition, the total cost of ART procedures, including transportation, was significantly associated with live birth outcomes. Couples who spent 70,001–120,000 Ethiopian Birr had 2.66 times higher odds of achieving a live birth (AHR = 2.66; 95% CI: 1.32–5.35), while those who spent $\geq 120,001$ Birr had 3.78 times higher odds (AHR = 3.78; 95% CI: 1.86–7.66), compared with couples who spent $\leq 70,000$ Birr (Supplementary Table 6).

DISCUSSION

This study determined that the proportion of live births following assisted reproductive technology (ART) among infertile couples in Ethiopia was 26.3% (95% CI: 22.7%–31.0%). This rate is higher than that reported in a study conducted in Southern Brazil, where ART-related live births accounted for 0.4% of total live births in 2015²¹. The marked difference may be explained by variations in study design, outcome definitions,

population characteristics, and health-care systems, as the Brazilian study reported population-level data rather than ART-specific cycle outcomes. The live birth rate observed in the current study is comparable to findings from Rome, which reported a 23.9% positive ART outcome,²² and to a previous Ethiopian IVF study that documented a 25% live delivery rate¹⁴. In contrast, higher live birth rates have been reported in Iran, including a 45% overall live birth rate²³ and 29.7% success in the first cycle, increasing to 44.9% after multiple cycles¹⁹. These differences may be partly attributed to variations in maternal age distribution, as more than 65% of participants in the present study were older than 30 years, with a mean maternal age of 33 years, whereas the Iranian studies predominantly included women aged 20–29 years, a group known to have better reproductive potential and higher ART success rates. This study determined that the proportion of clinical pregnancy outcomes following assisted reproductive technology (ART) was 37.0% (95% CI: 32.0%–42.0%). This finding is consistent with a five-year trend analysis from Africa, which reported clinical pregnancy rates per embryo transfer ranging from 34.9% in 2013 to 31.7% in 2017², as well as with a previous Ethiopian study on IVF outcomes that reported an overall pregnancy rate of 30.1% in 2020¹⁴. The observed similarity may reflect comparable clinical practices, patient characteristics, and resource settings.

Regarding multiple gestations, the proportion of twin deliveries in the current study was 15.9% (14/88), while triplet deliveries accounted for 3.4% (3/88). These findings are comparable with the International Committee for Monitoring Assisted Reproductive Technologies (ICMART) report of 2014, which documented a decline in twin delivery rates following fresh non-donor embryo transfers from 20.4% in 2010 to 16.2% in 2014, alongside a reduction in triplet rates from 1.1% to 0.5%²⁴. The similarity suggests a gradual shift toward safer embryo transfer practices and improved adherence to guidelines aimed at reducing higher-order multiple pregnancies.

The present study found that 66.6% of participants demonstrated a good ovarian response, defined as retrieval of four or more oocytes. This finding is broadly consistent with a previous Ethiopian study reporting good ovarian response in 76.4% of cases¹⁴. The slight variation may reflect differences in participant age distribution, ovarian reserve, and stimulation protocols used across studies.

This study identified that women aged 20–30 years were significantly more likely to achieve a live birth compared with those aged 31–40 years, consistent with evidence that younger maternal age predicts better ART outcomes. Additionally, retrieval of more than four oocytes significantly increased live birth likelihood, supporting previous studies showing oocyte yield as an independent predictor^{14, 20, 25, 26}. This finding is strongly supported by previous studies, which consistently demonstrate that younger maternal age is a key predictor of successful ART outcomes. Additionally, retrieval of more than eight oocytes significantly increased live birth likelihood, supporting previous studies showing oocyte yield as an independent predictor. Higher oocyte numbers increase the chance of high-quality and surplus embryos, thereby improving live birth rates^{20,25,26}. The relationship is biologically plausible, as a higher number of retrieved oocytes increases the likelihood of obtaining high-quality embryos and surplus embryos for transfer or cryopreservation, ultimately improving live birth rates.

This study found a cumulative live birth rate of 24.3% following ART, with most live births occurring in the first year and progressively declining with longer waiting time. The rate was lower than reports from other settings, possibly due to fewer oocytes retrieved, inclusion of only a single ART attempt, and shorter follow-up duration^{19, 20}. These findings reinforce evidence that increased oocyte yield and repeated transfer opportunities improve cumulative live birth rates²⁰.

This study identified key predictors of live birth following ART, including the number of embryos transferred, oocyte yield, and use of frozen-thawed

embryos^{20, 25, 26}. These findings are consistent with prior studies showing that oocyte number and embryo quality independently predict live birth outcomes. Optimizing these factors may improve ART success and support more individualized patient counselling at St. Paul's Hospital.

Strengths and Limitations

This is the first Ethiopian study to assess ART outcomes, live birth survival, and predictors, providing a valuable baseline. However, its retrospective design may introduce selection bias. Prospective studies are needed to confirm and strengthen these findings.

Conclusions

This study identifies key modifiable factors to improve ART success in Ethiopia, including prioritizing day-5 embryo transfer, optimizing ovarian response, and focusing on younger maternal age, which is associated with better outcomes. Improving semen quality before treatment and adopting individualized, evidence-based ART practices such as tailored stimulation, careful embryo selection, and appropriate transfer strategies are essential. Patient-centered counseling, particularly regarding age and expectations, plays an important role, while early screening and timely initiation of ART can enhance live birth chances. In addition, policy support is needed to strengthen access, affordability, and quality of ART services, and further research using robust study designs is encouraged.

Declarations

Ethical Considerations

Ethical clearance was obtained from the Pan African University Ethical Review Board (Reference No. UI/EC/21/0742) and the St. Paul's Hospital Millennium Medical College Ethical Review Board (Reference No. PM23/326). Written permission to conduct the study was also obtained from the St. Paul's Hospital Millennium Medical College Fertility Specialty Center.

Given that birth outcomes were verified through medical records and follow-up interviews, verbal informed consent was obtained from all participants prior to contact, as approved by the respective ethical review boards. Participation was voluntary, and participants were informed of their right to decline or withdraw at any time without consequence.

Confidentiality and privacy were strictly maintained throughout the study. Personal identifiers were removed from the dataset, and all records were securely stored and accessed only by the research team.

Consent to publish: Not applicable

Availability of data and materials: Datasets used in the current study are available from the corresponding author upon reasonable request.

Competing interests: Authors declared that they have no competing interest

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Author Contributions

We would like to declare that Dr.Dereje Bayissa Demissie serve as the guarantor for this work. The guarantor accepts full responsibility for the overall content and integrity of the manuscript, ensuring that all authorship criteria have been met and that the work is accurately represented.

HWD contributed to the conception, design, conduct of the study, analyzed and interpreted the data, and prepared the manuscript contributed to the conception, design, and conduct of the study, analyzed and interpreted data, and prepared the manuscript

AO & DBD contributed to the design and conduct of the study, analyzed and interpreted the data, and prepared the manuscript. All authors read and approved the final manuscript.

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THE MAGNITUDE AND ASSOCIATED FACTORS OF MECONIUM ASPIRATION SYNDROME AMONG NEONATES ADMITTED TO THE NICU OF TIBEBE GHION SPECIALIZED HOSPITAL NORTH WEST ETHIOPIA

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ABSTRACT

BACKGROUND: Meconium aspiration syndrome is defined as respiratory distress in newborn infants born through meconium-stained amniotic fluid whose symptoms can't be explained otherwise. It is one of the common neonatal problems especially in developing countries leading to significant neonatal deaths. Understanding the burden of Meconium aspiration syndrome will help to give attention and decrease the risk factor.

OBJECTIVES: The aim of this study was to determine the proportion and associated factors of meconium aspiration syndrome in neonates admitted to neonatal intensive care unit, Tibebe Ghion Specialized Hospital Bahir Dar University, Ethiopia.

METHODS: Institutional based cross sectional study was conducted among neonates admitted to the NICU of TGSH from November 2023 to November 2024. Data were collected through chart reviewing by using systematic sampling technique. The data was collected using the Kobo tool box. After checking completeness and coding, data were exported to SPSS version 27 for analysis. Descriptive statistics like frequency and percentages were presented with texts and tables. bivariate analysis was made and all the variables with p-value less than 0.2 in bi-variable analysis were entered into the final multivariable logistic regression analysis. Statistically significant association was set at P-value less than 0.05 with 95% confidence interval.

RESULTS: In this study, the chart completeness was 96.9%. The study found that 8.5% (CI: 6.0-11.7) of neonates developed Meconium Aspiration Syndrome. Gestation age >40wk with AOR 5.179 (CI: 2.104-12.751), onset of labor with AOR 4.484 (CI: 1.259-15.962), and First minute APGAR<7 with AOR 7.463(CI: 2.783-20.016) were significantly associated with Meconium Aspiration Syndrome.

CONCLUSION AND RECOMMENDATIONS: The proportion of neonates that developed Meconium Aspiration Syndrome was high compared to data from previous studies. Enhanced Fetal Monitoring for Postdate and Post term Pregnancies: Close surveillance of pregnancies beyond 40 weeks detect fetal jeopardy early and Continuous fetal monitoring during labor are crucial to decrease the risk of MAS.

KEYWORDS: Meconium, Aspiration, Syndrome, Tibebe Ghion, north west Ethiopia

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BACKGROUND

Meconium aspiration syndrome (MAS) is defined as respiratory distress in newborn infants born through meconium stained amniotic fluid (MSAF) whose symptoms cannot be otherwise explained¹. Meconium is a thick, black-green, odorless material which is first recognized in the fetal intestine around 12 weeks of gestation and stored in the fetal colon throughout gestation².

Passage of meconium in the newborn infant is developmentally programmed. It normally occurs at 24 to 48 hours of birth. However, the fetus may pass meconium into amniotic fluid before birth due to different stressing events. This usually occurs after 37 weeks of gestation and it is not common in preterm³.

When a neonate aspirates meconium during intrauterine gasping or during initial breaths at birth, MAS ensues³. Fetal hypoxic stress or vagal stimulation due to cord compression stimulates peristalsis in the colon. The evidence is mounting for a chronic in-utero insult that may be more important for meconium passage as opposed to an acute peripartum event⁴. Hypoxia also causes fetal gasping that results in meconium aspiration. Term and post term fetuses are more likely to pass meconium in response to such a stress than preterm⁵. Gastrointestinal maturation may be inadequate in preterm to be able to pass meconium; although, both the presence of meconium and active intestinal peristalsis have been reported as early as 8 weeks of gestational age⁶.

Meconium aspiration syndrome, which occurs in 2 to 10% of infants born through meconium-stained amniotic fluid (MSAF), is the respiratory distress of the newborn due to the presence of meconium in the tracheobronchial airway. This causes airway obstruction, atelectasis, epithelial injury, surfactant inhibition, pneumothorax, pulmonary hypertension and respiratory failure⁷. The diagnosis of MAS is not well defined though term and post-term neonates with MSAF and respiratory distress soon after birth not otherwise explained have to be diagnosed MAS(8). Diagnosis of MAS is based

on the presence of respiratory distress in an infant born through MSAF, with no alternate cause for respiratory distress. Chest radiograph and blood gas analysis should be performed if necessary. Because of diverse mechanisms causing this disease, radiographic findings are different. The classic radiographic findings in MAS are overexpansion of the lungs with widespread coarse, patchy infiltrates⁹. Ultrasonography can be used routinely to diagnose MAS in an accurate, reliable, convenient, and non-invasive manner¹⁰. In severe cases it can cause MAS requiring neonatal intensive care units(NICU) with respiratory, hemodynamic and metabolic support⁶. Meconium aspiration syndrome is one of the common causes of neonatal admission. It accounts for 10 % of all causes of respiratory failure in neonates with mortality of 20 % in the developing countries¹¹. Despite the progress made in medicine, meconium aspiration syndrome is still one of the causes of newborn infants' mortality¹².

The burden of MAS is enormous, despite Variation depends on data sources, populations studied, and diagnostic criteria¹³. The burden is higher than in high income countries; especially Africa continues to face high MAS related morbidity and mortality, due to limited fetal monitoring and poor delivery care¹⁵. MAS is one of the common causes of neonatal admission and death in neonates. It mainly occurs in term and post term neonates. In developing countries like Ethiopia the burden is estimated to be high and we are admitting many newborns with MAS yearly¹³. However, there are only few studies so far in Ethiopia and the proportion is not well known in the study area.

Determining the burden of MAS is important to set goals on improving obstetric care to decrease MAS and to establish a better NICU set up for the management of MAS. Thus, this study aimed to assess the proportion of meconium aspiration syndrome and associated factors of neonates admitted to NICU at Tibebe Gion specialized hospital (TGSH) North West Ethiopia, from November 2023-November 2024G.C.

Methods and materials

Study setting

The study was conducted at Tibebe Gion Specialized Hospital, Bahir Dar, North West Ethiopia starting from November 2023 to November 2024. Bahir Dar, the capital of Amhara regional state is located Northern-west of Ethiopia, 565 Km far from Addis Ababa, capital city of Ethiopia.

Tibebe Ghion specialized hospital is a newly established Tertiary care Teaching hospital in Bahir Dar City founded in January, 2019GC. It is located about 10km south from the city center and it serves a total of around 5 million people. Currently, it provides 12 specialty programs and 3 sub-specialty programs. It has more than 450 bed capacity and gives for more than 94,000 clients (around 20,000 inpatient and 74,000 outpatient) services per year. Neonatal Intensive care unit (NICU) is one of the units in the pediatrics and child health department which has an average monthly admission rate of around 168 neonates and it has around 32 beds divided into term, preterm and kangaroo mother care (KMC). The service there is delivered by pediatricians, residents, interns and nurses.

Study design and period

Institution based cross-sectional study was conducted from November 2023 to November 2024 among neonates admitted at NICU ward TGSB, North West Ethiopia.

Source population and Study population

All neonates admitted to NICU at TGSB were considered as the source population and all term and post-term neonates admitted to NICU at TGSB during study period were considered as study population.

Eligibility Criteria

While all term and post term neonates admitted to NICU during study period included, Neonates with congenital heart disease, and Neonates suspected to have chromosomal abnormality (example: Down syndrome) were excluded from this study.

Sampling technique and sample size determination

The sample size was calculated using a single population proportion formula assuming; 50% was taken as proportion of MAS with marginal error (d) of 5% and confidence interval of 95%.

$$n = Z^2 * P(1-P) / d^2, n = 1.96 * 1.96 * 0.5 (1-0.5) / 0.05 * 0.05 = 384$$

(Where n= sample size, p= prevalence, d= margin of error). By adding 10% non -response (chart incompleteness) rate total sample size was 423.

A systematic sampling technique was used to select 423 charts from neonatal ICU registration books. The first chart was selected randomly and the subsequent chart was selected based on Kth value which was 3.

Variables

The dependent variable was Meconium aspiration syndrome (Yes/No). The independent variables included under categories of; socio-demographics of the mother (age, residency), maternal, fetal and obstetrics related (mode of delivery, gestational age, antenatal care, sex of neonates, perinatal complications like, hypertension, diabetes, hemorrhage, onset of labor, duration of labor, rupture of membrane, APGAR score, birth weight), co-morbidities (sepsis, perinatal asphyxia, neonatal hyper bilirubinemia).

Operational definition and definition of terms

Neonate: an infant whose age is from birth up to 28 days of age

Meconium: a thick, black-green, odorless material which is first recognized in the fetal intestine around 12 weeks of gestation and stores in the fetal colon throughout gestation.

Meconium aspiration syndrome: is a clinical diagnosis of neonates with meconium stained amniotic fluid evidenced by meconium stained finger nail, umbilical stump and inter-nipple to chest circumference ratio $\geq 27\%$ and respiratory distress not explained by other diseases entity⁴.

Term neonate: a baby born at 37-41+6 weeks.

Post term neonate: a baby born after 42 weeks.

Postdate neonate: baby born between 40-42 weeks.

Preterm neonate: neonates born before 37 completed weeks.

APGAR: a score out of 10 given to new born during 1st and 5th minute based on five parameters (appearance, heart rate, respiratory rate, grimace and reflex) each having two scores(2).

Good APGAR: greater or equal to Seven(7)(2).

Low APGAR: less than Seven (7)(2).

Data collection tools and procedures

Data were collected from the patients' medical records by using an English structured questionnaire (check list). Data were collected by five trained residents who are working at TGSH NICU ward. The questionnaire was prepared reviewing the previous literature^{2,5,13,14,16,22}and incorporating the medical chart and registration book components.

Data quality control

Data collectors and supervisors were trained for one day on the objective of the study, content of questionnaire, and data collection procedure or on how to extract the data from the medical charts and registration books. The data extraction checklist was pre-tested at Felegehiwot hospital to make sure that all components of the chart and registration book variables were included; and some corrections were made accordingly. During the data collection period the collected data were checked daily for completeness by the principal investigator and supervisor.

Data processing and analysis

The collected data using the kobo collect tool (the prepared checklist was incorporated into the online kobo collect tool) were exported to SPSS version 27 for analysis. Descriptive summary was presented using frequencies, proportions, means, figures and tables. The association between independent variables and MAS was made using a binary logistic regression model. First bivariable analysis was made and all the variables with p-value less than 0.2 in

bi-variable analysis were entered into the final multivariable logistic regression analysis. Statistical significance was determined using adjusted odds ratio (AOR), with 95% confidence intervals and P-value less than 0.05 in the final model.

Ethical clearance

Ethical clearance was obtained from Bahir Dar University College of Medicine and Health science institutional review board (3029/2024). Then, a permission letter was written to have access to charts and help from the record and data center about the selected patients. Names of study participants were not mentioned in the questionnaire or other places so that confidentiality was assured.

Results

Study participant characteristics (Neonatal factors) In this study, the chart completeness rate was 96.9%. Seven (1.7%) had post-term pregnancies, which delivered after 42 weeks, and 37 (9.0%) had postdate pregnancies, which delivered between 41 and 42 weeks, the remaining 366 (89.3) had term pregnancy. A total of 102 (24.9%) neonates were less than or equal to 72 hours old at admission, whereas 308 (75.1%) were older than 72 hours.

There were 197 (48.0%) female neonates and 213 (52.0%) male neonates. Of the 402 neonates, 322 (80.1%) weighed between 2500 and 3999 grams at birth, 5 (1.2%) weighed 4000 grams and above, and 75 (18.7%) weighed less than 2500 grams. In the first minute, 360 neonates (89.6%) had an APGAR score of 7 or higher, whereas 42 neonates (10.4%) had a score of less than 7.

Spontaneous vaginal delivery (SVD) was the most common mode of delivery, occurring in 327 (79.8%) cases. Cesarean section (C/S) was performed in 78 (19.0%) cases, while 5 (1.2%) were instrumental assisted deliveries.

Among the 78 cesarean deliveries, 28 (35.9%) were due to maternal indications, while 50 (64.1%) were performed due to fetal reasons, specifically non-reassuring fetal heart rate (NRFHR).

Among the 28 cases where cesarean section was indicated for maternal reasons, 7 (25.0%) were due to eclampsia, 10 (35.7%) were due to poor maternal effort, 7 (25.0%) were due to placenta Previa, and 4 (14.3%) were attributed to other unspecified reasons (see Table 1).

Table 1: Study participant characteristics (term and post term neonates) admitted to NICU at Tibebe Gion specialized hospital (TGSH) North West Ethiopia, 2025.

Variables	Category	Frequency(n)	Percentage (%)
Gestational age (in weeks)	Term (37-40)	366	89.3
	Postdate (41-42)	37	9.0
	Post-term (>42)	7	1.7
Age of neonate during admission	≤72 hours	102	24.9
	>72 hours	308	75.1
Sex of neonate	Male	213	52.0
	Female	197	48.0
Birth weight (n=402)	<2500gm	75	18.7
	2500-3999gm	322	80.1
	≥4000gm	5	1.2
First Minute APGAR(n=402)	<7 score	42	10.4
	≥7 score	360	89.6
Fifth minute APGAR(n=402)	<7 score	125	30.1
	≥7 score	277	68.9
Mode of delivery	SVD	327	79.8
	C/S	78	19.0
	Instrumental assisted	5	1.2
If 'C/S' indication(n=78)	Maternal	28	35.9
	Fetal (NRFHR)	50	64.1
Maternal indication for C/S (n=28)	Eclampsia	7	25
	Poor effort	10	35.7
	Placenta Previa	7	25.0
	Others	4	14.3

Other comorbid conditions

Perinatal complications were reported in 26 (6.3%) mothers, among the 26 mothers who experienced perinatal complications, 5 (19.2%) had antepartum hemorrhage (APH), 4 (15.4%) had premature rupture of membranes (PROM), 13 (50.0%) developed preeclampsia or eclampsia, and 4 (15.4%) had diabetes mellitus (DM).

Among the neonates, 309 (75.4%) were diagnosed with sepsis, 38 (9.3%) had perinatal asphyxia (PNA),

55 (13.4%) had neonatal hyperbilirubinemia (NHB), and 60 (14.6%) were classified under surgical cases. Additionally, 16 (3.9%) had other diagnoses (see Table 2).

Table 2: Other comorbid conditions among term and post term neonates admitted to NICU at Tibebe Gion specialized hospital (TGSH) North West Ethiopia, 2025.

Variables	Category	Frequency(n)	Percentage (%)
Perinatal complications	Yes	26	6.3
	No	384	93.7
If 'yes' which complication (n=26)	APH	5	19.2
	PROM	4	15.4
	Pre/eclampsia	13	50.0
	DM	4	15.4
Was MSAF detected	Yes	37	9.0
	No	373	91.0
If 'yes' grade of Meconium (n=37)	Grade 1	7	18.9
	Grade 2	11	29.7
	Grade 3	19	51.4
Was there a diagnosis of MAS	Yes	35	8.5
	No	375	91.5
Other diagnosis	Sepsis	309	75.4
	PNA	38	9.3
	NHB	55	13.4
	Surgical cases	60	14.6
	Others	16	3.9

Maternal factors

Among mothers, 50 (12.2%) were younger than 25 years old, while the majority, 252 (61.5%), were between 25 and 34 years old. Additionally, 108 (26.3%) of the mothers were older than 34 years. A total of 199 (48.5%) mothers resided in rural areas, whereas 211 (51.5%) lived in urban areas.

Among the participants, 174 (42.4%) were primiparous, meaning they were experiencing childbirth for the first time. In contrast, 236 (57.6%) were multiparous, having given birth multiple times. Most of the mothers, 397 (96.8%), received antenatal care during pregnancy, whereas 13 (3.2%) did not receive any antenatal care.

Spontaneous labor occurred in 392 (95.6%) of the mothers, while labor induction was required for 18 (4.4%) of them. A total of 210 (51.2%) of the mothers experienced labor lasting less than 12 hours, whereas 200 (48.8%) had labor lasting 12 hours or longer

Among the mothers, 8 (2.0%) experienced rupture of membranes before the onset of labor, while the majority, 402 (98.0%), did not. A total of 208 (50.7%) mothers gave birth in a government hospital, while 194 (47.3%) delivered at a health center. Additionally, 8 (2.0%) mothers gave birth at home (see Table 3).

Table 3: Maternal factors among term and post-term neonates admitted in NICU, at Tibebe Gion specialized hospital (TGSH) North West Ethiopia, 2025.

Variables	Category	Frequency(n)	Percentage (%)
Age of the mother	<25	50	12.2
	25-34	252	61.5
	>34	108	26.3
Place of residency	Rural	199	48.5
	Urban	211	51.5
Parity	Primipara	174	42.4
	Multipara	236	57.6
Antenatal care	Yes	397	96.8
	No	13	3.2
Onset of labor	Spontaneous	392	95.6
	Induction	18	4.4
Duration of labor (in hours)	<12 hours	210	51.2
	≥12 hours	200	48.8
Rupture of membrane before onset of labor	Yes	8	2.0
	No	402	98.0
Place of delivery	Gov't hospital	208	50.7
	Health center	194	47.3
	Home	8	2.0

Proportion of Meconium aspiration syndrome

The proportion of Meconium aspiration syndrome (MAS) was 8.5% (CI: 6.0-11.7). Meconium-Stained Amniotic Fluid (MSAF) was detected in 37 (9.0%) of the cases, while 373 (91.0%) had clear amniotic fluid. Among the 37 cases with MSAF, 7 (18.9%) were classified as Grade 1, 11 (29.7%) as Grade 2, and 19 (51.4%) as Grade 3. Meconium aspiration syndrome was diagnosed in 35 (8.5%) neonates.

Meconium aspiration syndrome and its associated factors

The result of this study shows that gestational age, onset of labor, and first minute APGAR were significantly associated with meconium aspiration syndrome.

Newborns born post-date (>40 weeks) had five times higher odds of developing MAS compared to those born at term (37-40 weeks) (AOR: 5.179, 95% CI: 2.104-12.751)

Neonates born after labor induction had more than four times higher odds of MAS compared to those with spontaneous onset of labor (AOR: 4.484, 95% CI: 1.259-15.962).

Neonates with an APGAR score of less than 7 at the first minute had more than Seven times higher odds of MAS compared to those with a score of 7 or more (AOR: 7.463, 95% CI: 2.783-20.016). (see Table 4).

Table 4: Bivariable and multivariable logistic regression of Meconium aspiration syndrome (MAS) and its associated factors, among term and post-term neonates admitted in NICU, at Tibebe Gion specialized hospital (TGSH) North West Ethiopia, 2025.

Variables category	Meconium Aspiration Syndrome (MAS)		COR (95% CI)	AOR (95%CI)
	Yes	No		
Gestational age				
Term (37-40)	21	345	1	1
Post-date/term (>40)	14	30	7.667(3.541-16.597)	5.179(2.104-12.751) **
Onset of labor				
Induction	7	11	8.273(2.975-23.002)	4.484(1.259-15.962) *
Spontaneous	28	364	1	
First minute APGAR				
<7 score	14	28	8.072(3.706-17.579)	7.463(2.783-20.016) **
≥7 score	21	339	1	1
Fifth minute APGAR				
<7 score	19	106	2.924 (1.449-5.924)	1.415(0.571-3.507)
≥7 score	16	261	1	1
Mode of delivery				
C/S and Instrumental	12	71	2.234(1.061-4.702)	1.741(0.707- 4.284)
SVD	23	304	1	

Note: *p-value<0.05, **p-value<0.01

DISCUSSION

In this study we found that the proportion of meconium aspiration syndrome was 8.5% among term and post term neonates in TGSH. The current finding is lower than a study done in southern Ethiopia at Nigist Elleni Mohammed memorial hospital 30.6%²¹. The possible explanation for the difference might be due to the difference in high-risk mothers and quality of care.

However, our findings were higher than those from Nigeria (0.57%)¹⁹, South Africa (4%)¹⁸, Italy (2%)¹⁵, Pakistan (4.9%)²³, and Australia (2%)¹⁴. This difference might be due to the variations in the quality of care, study population or eligibility criteria. For example, the study in Nigeria included all neonates including preterm who were at very low risk for MAS.

Post term pregnancies are associated with an increased odds of MAS (AOR 5.179, 95% CI: 2.104-12.751). This finding is consistent with the studies done at Nepal¹³, and in Nigeria¹⁹. The likelihood

of meconium-stained amniotic fluid (MSAF) rises with gestational age, leading to a higher incidence of MAS in post term infants¹⁴.

Neonates born after labor induction had more than Four times higher odds of MAS compared to those with spontaneous labor (AOR: 4.484, 95% CI: 1.259-15.962). This suggests that labor induction is a significant risk factor for MAS. This finding is consistent with other findings; in North West Ethiopia⁶, Southern Ethiopia⁴, and South Gonder².

In contrast to a study done in Australia; induction of labor was associated with a reduced risk of MAS compared with women who were not induced, <40 weeks of gestation¹⁴. The possible explanation for this may be the set up for follow-up after starting induction and the gestational age cut off for induction indication which is usually greater than 42 weeks.

A low first-minute APGAR score (<7) is a significant

risk factor for MAS (AOR 7.463, 95% CI: 2.783-20.016). This finding is in line with studies done in South Africa, Johannesburg (18) and Nepal¹³ in neonates with poor Apgar score (<7) were more likely to have higher odds for MAS.

This study has several limitations that should be considered when interpreting the results. First, it relied on secondary data sources; second, it was conducted at a tertiary care center. Additionally, as a tertiary care center, the hospital is more likely to admit mothers with comorbidities, which may increase the risk of meconium aspiration syndrome (MAS).

Conclusion and Recommendation

Conclusion

The study found that the proportion of neonates developed Meconium Aspiration Syndrome (MAS), was high compared with other studies post term gestation and low first-minute APGAR scores and labor induction are significant risk factors for MAS. Close follow-up of pregnancies beyond 40 weeks, continuous fetal monitoring during labor, and increased awareness of postdate and post-term pregnancies are essential to help prevent meconium aspiration syndrome (MAS).

Contribution of Authors

All authors contribute throughout the whole research steps.

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Conflict of interest

The authors declared that there is no conflict of interest.

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AVAILABILITY AND QUALITY OF POST-ABORTION CARE SERVICES IN PUBLIC HEALTH FACILITIES IN OSUN STATE, NIGERIA

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ABSTRACT

BACKGROUND: Unsafe abortion contributes about 11% of maternal mortality in Nigeria. Post-abortion care (PAC) has the potential to reduce the maternal morbidity and mortality associated with unsafe abortion. The objective of this study was to assess the availability and quality of PAC in public healthcare facilities in Osun State, Nigeria.

MATERIALS AND METHODS: This cross-sectional study involved 223 (2 tertiary, 17 secondary, and 204 primary) public health facilities in Osun State. Data were collected using questionnaires and facility checklists developed according to global standards. Availability of PAC was measured by the presence of personnel and materials to render PAC at all times, while PAC quality was measured by the signal functions of PAC and the method used to evacuate retained products of conception. Univariate and bivariate analyses were undertaken and statistical significance was set at $p < 0.05$. Ethical approval was obtained from Obafemi Awolowo University Teaching Hospitals Complex.

RESULTS: Only 18.6% (31.4% urban vs 5.9% rural, $p < 0.001$) of primary health care (PHC) facilities had adequate availability of basic PAC, while 16.7% (27.5% urban vs 5.9% rural, $p < 0.001$) of PHC facilities had good quality basic PAC. Among the referral facilities, 42.1% had adequate availability, while 31.6% had good quality comprehensive PAC.

CONCLUSION: Post-abortion care availability and quality were poor in Osun State, particularly in rural areas, and at the PHC level compared with higher levels of care. Improving PAC availability and quality by providing adequate human and material resources will reduce maternal morbidity and mortality, and improve overall maternal health.

KEYWORDS: Abortion, Post-Abortion Care, Availability, Quality of care, Nigeria.

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INTRODUCTION

Abortion is defined as the expulsion or extraction of a foetus from the uterus before the age of viability¹. Abortion can be spontaneous or induced². Unsafe abortion occurs when a pregnancy is terminated either by persons lacking the necessary skills or in an environment that does not meet the minimal medical standards or both³. Unsafe abortion can be classified as less safe if only one of the two conditions (environment and skill) for safe abortion is met, or least safe if both conditions are not met³. Globally, unsafe abortion is a major cause of maternal mortality, with an estimated global incidence of 55.7 million cases per annum between 2010 and 2014.4 Out of this number, 25.1 million (45.1%) were unsafe abortions, with 24.3 million (97%) of these unsafe abortions occurring in developing countries⁴. According to the Guttmacher Institute, unsafe abortion accounted for about 8% of global maternal mortality in 2014 and at least 22,800 women die each year from complications of unsafe abortion⁵.

In Nigeria, unsafe abortion is a maternal health issue of concern, and a major cause of maternal morbidity and mortality. An estimated 1.25 million induced abortions occurred in Nigeria in 2012⁶. In the same year (2012), an estimated 212,000 women in Nigeria were treated in health facilities for complications of induced abortion. In addition to this, an estimated 285,000 women had complications from unsafe abortion serious enough to require treatment in health facilities, but did not obtain the care they needed⁶. However, as of 2018, the number of induced abortion cases in Nigeria increased to 1.85 million⁷.

The Nigeria Demographic and Health Survey (NDHS) of 2018 revealed that only 17% of all Nigerian women of reproductive age (15-49 years) were using any contraceptive method, and of this proportion, only 12% use a modern method⁸. Similarly, there was no significant difference in the contraceptive prevalence rate of the NDHS of 2013 (15%) and the NDHS of 2018 (17%)⁷.

In 2015, unsafe abortion was estimated to contribute about 11% of Nigeria's maternal mortality⁹. However, some regional hospital-based studies done subsequently (after 2015) reported higher contributions of unsafe abortion to maternal mortality. For instance, a five-year review by Emechebe et al (2016) at the Enugu State University Teaching Hospital revealed that induced abortion accounted for 22.8% of maternal mortality¹⁰, while a three-year review by Awowole et al (2018) in Obafemi Awolowo University Teaching Hospital Complex reported that induced abortion was responsible for 12.7% of maternal mortality¹¹. Nigeria has a restrictive abortion law, only allowing induced abortion when the pregnancy has become a threat to the life of the mother, or if the foetus has severe conditions/malformations that are incompatible with extra uterine life¹². The combination of the restrictive abortion law and low contraceptive prevalence in Nigeria (and other developing countries) often lead to women seeking unsafe induced abortion for unwanted pregnancy, which may result in a higher chance of complications such as bleeding, uterine perforation, infection, injury to the genital tract, obstetric fistulae, chronic pelvic or lower limb pain (that may affect gait), infertility, renal failure or even death¹⁰.

Post-abortion care (PAC) is a global approach towards reducing the incidence of maternal morbidity and mortality arising from complications of unsafe abortion. Its overall aim is to reduce to a barest minimum the maternal morbidity and mortality arising from unsafe abortion and its complications, and to improve women's sexual and reproductive health¹³. Post-abortion care is divided into the basic component (PAC services at 12 weeks or before 12 weeks of gestation), and the comprehensive component (PAC services after 12 weeks of gestation, blood transfusion and surgery), depending on the signal functions that are offered in the health facility. While primary health facilities are expected to offer basic PAC, the referral health facilities (secondary and tertiary) are expected to offer comprehensive PAC¹⁴.

Considering the high burden of unsafe abortion in Nigeria, it is essential that post-abortion care is readily available to care for these women, thereby limiting the immediate and delayed complications that they may experience from unsafe abortion. It is however unclear whether these services are readily available, and if they are, it is important to ensure that these services are of the right quality.

This study aimed to assess the availability and quality of PAC offered in public health facilities (primary, secondary, tertiary) in Osun State, Nigeria, and is expected to provide evidence for designing appropriate interventions to improve PAC services in public health facilities in the state.

Materials and Methods

This study was carried out in Osun State, located in the South-West geopolitical zone of Nigeria, and utilized a descriptive, cross-sectional study design. Public primary, secondary and tertiary health facilities registered and operating in the state, and whose heads gave permission to be part of the study were included in the study. Public primary, secondary and tertiary health facilities that were undergoing structural renovation or upgrade of their services at the time of this study were excluded from the study.

The two tertiary and 17 secondary healthcare facilities in the state were included in this study (total sampling). With regards to the public primary health facilities in the state, the sample size was determined using Cochran's formula.

The Performance Monitoring and Accountability 2020 (PMA 2020) group reported that 26.4% of public primary health facilities in Nigeria had the capacity to offer basic PAC of good quality.⁷ This figure (26.4% or 0.264) was used as the proportion to calculate the sample size for the primary health facilities. So, the final sample size was 204 primary health facilities after correcting for a finite population using the finite population correction formula.

A multi-stage sampling technique was used for the selection of the primary health facilities, thus:

Stage one: Total sampling was used to select the three senatorial zones in Osun State (Osun East, Osun Central and Osun West).

Stage two: Simple random sampling (computer-generated random numbers) was used to select four LGAs (two rural and two urban) from each of the three senatorial zones in the state, making a total of 12 LGAs (six rural and six urban). The selected rural LGAs were Atakunmosa West, Ayedire, Boripe, Ejigbo, Ifedayo, and Ife North. The selected urban LGAs were Ede North, Ife Central, Ila Orangun, Ilesa East, Irewole and Osogbo.

Stage three: Simple random sampling (computer-generated random numbers) was used to select 17 primary health facilities from each of the 12 LGAs giving a total of 204 primary facilities (102 rural and 102 urban) used for the study.

The research instruments were a semi-structured questionnaire and a checklist that were purpose-developed after an extensive literature search to ensure that the appropriate indices of PAC were adequately captured. The questionnaire had three sections, A to C. Section A contained the socio-demographic characteristics of the PAC service providers that responded to the questionnaire. Section B assessed the availability of PAC in the facilities while Section C assessed the quality of PAC in the facilities.

The research instruments were pretested for reliability using the test-retest method, and it involved one tertiary, two secondary (one rural and one urban) and 21 primary health facilities (11 rural and 10 urban) that were randomly selected from the three senatorial zones in Ogun State, Nigeria. The pretest offered the opportunity to ensure that the instruments achieve the objectives of the study, as well as to address ambiguities that arose from them before the main study.

The research instruments were validated by Consultants in Public Health and Community Medicine and Obstetrics and Gynaecology (O&G). The test-retest yielded correlation scores of 90% and 88% for the questionnaire and the checklist respectively. There was a 21-day interval between the test and the retest.

Trained research staff assisted in the data collection for the study. The questionnaire for the availability and quality of PAC in the facilities was self-administered and the data were collected from the Head of the Units/Departments offering PAC (e.g. Obstetrics and Gynaecology), or other senior staff in the unit. Then, after the filled questionnaires were retrieved, the researcher and the research assistants ticked the checklist accordingly to indicate the personnel and materials available and utilized for the provision of PAC services. The checklist was ticked after the materials and personnel were seen and confirmed to be available.

The availability of PAC was measured by the presence of personnel (at least a Nurse/Midwife for basic PAC and a Doctor for comprehensive PAC) and materials to offer 24 hours of PAC services in the facilities on every day of the week. This was regarded as adequate availability while anything short of that was inadequate availability because PAC services are expected to be available in health facilities at all times. Basic and comprehensive PAC services are expected to be adequately available in the primary and higher tier facilities respectively.

The structure component of the quality of basic and comprehensive PAC was assessed in the primary and higher tier facilities respectively using the basic and comprehensive PAC signal functions that are actually offered in the facilities.

The basic PAC signal functions are: removal of retained products less than or equal to 12 weeks, parenteral antibiotics, parenteral uterotonic, intravenous fluids, pain relief, a modern short-acting method of family planning, communication with a referral/higher centre and a vehicle with fuel to transport any patient needing referral^{14,15}.

The comprehensive PAC signal functions are: all the basic PAC signal functions plus removal of retained products more than 12 weeks, a modern long-acting method of family planning, blood transfusion and surgery/laparotomy^{14,15}.

The process component of the quality of PAC was assessed by the procedures carried out to evacuate retained products of conception in relation to the gestational age at which the abortion occurred.

This assessment was according to the WHO recommendation that pregnancies less than or equal to 12 weeks may be managed by manual vacuum aspiration or electric vacuum aspiration, or medically with misoprostol. For pregnancies that have advanced more than 12 weeks of gestation, misoprostol and or dilatation and evacuation should be used to evacuate retained products of conception.

The presence of all these signal functions was regarded as good quality while the lack of any was regarded as poor quality^{14,15}. The materials involved in rendering PAC were checked and confirmed to be functioning (e.g. the manual vacuum aspiration apparatus, the theatre or procedure room, the ambulance etc.), and ticked accordingly in the checklist.

Ethical approval for this study was obtained from the Ethics and Research Committee of the Obafemi Awolowo University Teaching Hospitals Complex, Ile-Ife (ERC/2021/03/21), and the Ladoke Akintola University Teaching Hospital, Osogbo (UTH/EC/2022/02/576). Ethical approval was also obtained from the Osun State Ministry of Health (OSHREC/PRS/569T/221), while permission was obtained from the Osun State Primary Health Care Development Board, the Medical Directors of the selected secondary and tertiary health facilities, and the Officers-in-Charge of the primary health facilities.

Participation of the respondents in this study was voluntary. A written informed consent to participate in the study was obtained from respondents after an adequate explanation of the objectives of the study. Respondents were also assured of the confidentiality of the data (for research only), as well as the anonymity of their identities and the health facilities where they provide PAC. Respondents were also at liberty to opt out of the study at any time without any consequence.

Results

This section presents the results of this study. A total of 223 questionnaires were distributed, filled and returned, giving a response rate of 100%. Table 1

Table 1: Socio-demographic Characteristics of Respondents

Characteristics	Frequency n = 223	Percent (%)
Age (years)		
30-39	143	64.2
40-49	77	34.5
50 and above	3	1.3
Gender		
Male	51	22.9
Female	172	77.1
Marital Status		
Single	33	14.8
Married	190	85.2
Professional cadre		
Doctors	15	6.7
Nurses/Midwives	48	21.5
Community Health Officer	43	19.3
Community Health Extension Worker	117	52.5
Current Level		
Consultant	2	0.9
Chief Medical Officer	2	0.9
Principal Medical Officer	6	2.7
Senior Medical Officer	5	2.2
Chief Nursing Officer	2	0.9
Principal Nursing Officer	2	0.9
Senior Nursing Officer	3	1.3
Nursing Officer	41	18.4
Community Health Officer 1	12	5.4
Community Health Officer 2	31	13.9
Community Health Extension Worker 1	33	14.8
Community Health Extension Worker 2	84	37.7
Years in practice		
6-10	137	61.5
11-15	73	32.7
16-20	9	4.0
Above 20	4	1.8
Years of practice in current facility		
1-5	139	62.4
6-10	76	34.1
11-15	5	2.2
16-20	3	1.3

presents the socio-demographic characteristics of the respondents that filled the questionnaires that assessed the availability and quality of PAC in their various health facilities.

Almost two-thirds of the respondents (64.2%) were aged 30-39 years, while 77.1% were females. Also, 21.5% were nurses/midwives while 18.4% were at the rank of Nursing Officers. In addition, almost two-thirds (61.5%) had practiced for 6 - 10 years.

Table 2: Level of Health Facilities by Location

Characteristics	Rural Freq. (%) n1=108	Urban Freq. (%) n2=115	Total (%) n=223
Level of facility			
Primary	102 (94.4)	102 (88.7)	204 (91.5)
Secondary	6 (5.6)	11 (9.6)	17 (7.6)
Tertiary	0 (0.0)	2 (1.7)	2 (0.9)

Table 3: Availability of PAC Services in the Health Facilities

Availability of basic PAC in primary health facilities	Rural Freq. (%) n1=102	Urban Freq. (%) n2=102	Total (%)n=204
Hours in a day the facility is open			
Less than 12 hours	12 (11.8)	6 (5.9)	18 (8.8)
More than 12 hours but less than 24 hours	69 (67.6)	47 (46.1)	116 (56.9)
24 hours	21 (20.6)	49 (48.0)	70 (34.3)
Days in a week the facility is open			
More than 3 days but less than 7 days	35 (34.3)	12 (11.8)	47 (23.0)
7 days	67 (65.7)	90 (88.2)	157 (77.0)
Availability of personnel and materials for PAC			
Often	96 (94.1)	64 (62.7)	169 (78.4)
Always	6 (5.9)	38 (37.3)	44 (21.6)
Highest level of personnel available for PAC			
Community Health Extension Worker	81 (79.4)	36 (35.3)	117 (57.4)
Community Health Officer	15 (14.7)	28 (27.5)	43 (21.1)
Nurse/Midwife	3 (2.9)	30 (29.4)	33 (16.2)
Doctor	3 (2.9)	8 (7.8)	11 (5.4)
Overall Availability of basic PAC			
Inadequate Availability of basic PAC	96 (94.1)	70 (68.8)	166 (81.4)
Adequate Availability of basic PAC	6 (5.9)	32 (31.4)	38 (18.6)
Availability of Comprehensive PAC in referral health facilities	n1=6	n2=13	n=19
Hours in a day the facility is open			
24 hours	6 (100.0)	13 (100.0)	19 (100.0)
Days in a week the facility is open			
7 days	6 (100.0)	13 (100.0)	19 (100.0)
Availability of personnel and materials for PAC			
Often	6 (100.0)	5 (38.5)	11 (57.9)
Always	0 (0.0)	8 (61.5)	8 (42.1)
Highest level of personnel available for PAC			
Doctor	6 (100.0)	13 (100.0)	19 (100.0)
Overall Comprehensive PAC Availability			
Inadequate Availability of comprehensive PAC	6 (100.0)	5 (38.5)	11 (57.9)
Adequate Availability of comprehensive PAC	0 (0.0)	8 (61.5)	8 (42.1)

Overall, less than one-fifth (18.6%) of the primary health centres had adequate availability of basic PAC (basic PAC services at all times by at least a nurse/midwife); while less than half (42.1%) of the referral (secondary and tertiary) health facilities had adequate availability of comprehensive PAC (comprehensive PAC services at all times by at least a doctor).

Table 4: Quality of PAC Services in the Health Facilities

Quality of basic PAC in the primary health facilities	Rural Freq. (%) n1=102	Urban Freq. (%) n2=102	Total Freq. (%) n=204
Structure/Inputs			
Removal of retained products less than 12 weeks gestation	6 (5.9)	38 (37.3)	44 (21.6)
Parenteral uterotonics	6 (5.9)	38 (37.3)	44 (21.6)
Pain relief	102 (100.0)	102 (100.0)	204 (100.0)
Parenteral antibiotics	6 (5.9)	38 (37.3)	44 (21.6)
Modern short-acting contraceptive	88 (86.3)	102 (100.0)	190 (93.1)
Counselling	102 (100.0)	102 (100.0)	204 (100.0)
Intravenous fluid	6 (5.9)	38 (37.3)	44 (21.6)
Facility phone for communication	27 (26.5)	43 (42.2)	70 (34.3)
Facility vehicle for referral	6 (5.9)	28 (27.5)	34 (16.7)
Evacuation methods for retained products less than 12 weeks gestation (Process)			
Misoprostol	5 (4.9)	17 (16.7)	22 (10.8)
Manual Vacuum Aspiration	1 (1.0)	13 (12.7)	14 (6.9)
Manual Vacuum Aspiration and Misoprostol	0 (0.0)	8 (7.8)	8 (3.9)
Overall Quality of Basic Post-Abortion Care			
Poor Quality of Basic PAC	96 (94.1)	74 (72.5)	170 (83.3)
Good Quality of Basic PAC	6 (5.9)	28 (27.5)	34 (16.7)
Quality of Comprehensive PAC in the referral facilities	n1=6	n2=13	n=19
Structure/Inputs			
Evacuation of retained products more than 12 weeks gestation	0 (0.0)	12 (92.3)	12 (63.2)
Modern long-acting contraceptive	4 (66.7)	12 (92.3)	16 (84.2)
Blood transfusion	1 (16.7)	10 (76.9)	11 (57.9)
Laparotomy	0 (0.0)	6 (46.2)	6 (31.6)
Evacuation methods for retained products more than 12 weeks gestation (Process)			
Misoprostol	0 (0.0)	5 (38.5)	5 (26.3)
Dilatation and Evacuation	0 (0.0)	2 (15.4)	2 (10.5)
Dilatation and Evacuation and Misoprostol	0 (0.0)	5 (38.5)	5 (26.3)
Overall Quality of Comprehensive Post-Abortion Care			
Poor Quality of Comprehensive PAC	6 (100.0)	7 (53.8)	13 (68.4)
Good Quality of Comprehensive PAC	0 (0.0)	6 (46.2)	6 (31.6)

Overall, less than one-fifth (16.7%) of the primary health facilities had good quality of basic PAC (all signal functions of basic PAC present); while less than one-third (31.6%) of the referral (secondary and tertiary) health facilities had good quality of comprehensive PAC (all signal functions of comprehensive PAC present).

Table 5: Observed Inputs for PAC in the Health Facilities

Inputs for basic PAC in the primary health facilities	Seen		
	Rural Freq. (%) n1=102	Urban Freq. (%) n2=102	Total Freq. (%) n=204
Misoprostol	6 (5.9)	25 (24.5)	31 (15.2)
Couch	18 (17.6)	49 (48.0)	67 (32.8)
Parenteral analgesia	6 (5.9)	44 (43.1)	50 (24.5)
Parenteral antibiotics	10 (9.8)	43 (42.2)	53 (26.0)
Intravenous Cannulas	9 (8.8)	40 (39.2)	49 (24.0)
Drip-giving set	9 (8.8)	39 (38.2)	48 (23.5)
Syringes and needles	18 (17.6)	46 (45.1)	64 (31.4)
Parenteral uterotonics	7 (6.9)	43 (42.2)	50 (24.5)
Intravenous fluid	9 (8.8)	43 (42.2)	52 (25.5)
Modern short-acting contraceptive	91 (89.2)	102 (100.0)	193 (94.6)
PAC service providers	102 (100.0)	102 (100.0)	204 (100.0)
Inputs seen and working			
MVA Apparatus	6 (5.9)	38 (37.3)	44 (21.6)
Mobile phone	27 (26.5)	43 (42.2)	70 (34.3)
Vehicle for referral	6 (5.9)	28 (27.5)	34 (16.7)
Inputs for Comprehensive PAC in the referral health facilities	Seen		
	n1=6	n2=13	n=19
Modern long-acting contraceptive	4 (66.7)	12 (92.3)	16 (84.2)
Blood-giving set	2 (33.3)	12 (92.3)	14 (73.7)
Cervical dilators	5 (83.3)	13 (100.0)	18 (94.7)
Surgical instruments for laparotomy	0 (0.0)	8 (61.5)	8 (42.1)
Inputs seen and working			
Autoclave	0 (0.0)	9 (69.2)	9 (47.4)
Blood bank	0 (0.0)	8 (61.5)	8 (42.1)
Operating theatre	0 (0.0)	12 (92.3)	12 (63.2)

For basic PAC, less than one-fifth (15.2%) of the facilities had Misoprostol, 26% had parenteral antibiotics, 24.5% had parenteral uterotonics, 94.6% had modern short-acting contraceptives, while 21.6% of the facilities had their MVA apparatus seen and working. For comprehensive PAC, more than four-fifths of the facilities had a modern long-acting contraceptive while 42.1% had surgical instruments for laparotomy; 42.1% and 63.2% of the facilities had their blood banks and operating theatres seen and working respectively.

Table 6: Association between the Location of the Health Facilities and PAC

Location	Availability of Basic PAC		Total Freq. (%)	Test Statistics
	Inadequate Availability	Adequate Availability Freq. (%)		
Rural	96 (94.1)	6 (5.9)	102 (100.0)	$\chi^2 = 21.862$ df = 1 *p < 0.001
Urban	70 (68.6)	32 (31.4)	102 (100.0)	
Total	166 (81.4)	38 (18.6)	204 (100.0)	
Location	Availability of Comprehensive PAC		Total Freq. (%)	Test Statistics
	Inadequate Availability	Adequate Availability Freq. (%)		
Rural	6 (100.0)	0 (0.0)	6 (100.0)	$\chi^2 = 6.378$ df = 1 *p = 0.018 (Fisher's Exact)
Urban	5 (38.5)	8 (61.5)	13 (100.0)	
Total	11 (57.9)	8 (42.1)	19 (100.0)	
Location	Quality of Basic PAC		Total Freq. (%)	Test Statistics
	Poor Quality Freq. (%)	Good Quality Freq. (%)		
Rural	96 (94.1)	6 (5.9)	102 (100.0)	$\chi^2 = 17.082$ df = 1 *p < 0.001
Urban	74 (72.5)	28 (27.5)	102 (100.0)	
Total	170 (83.3)	34 (16.7)	204 (100.0)	
Location	Quality of Comprehensive PAC		Total Freq. (%)	Test Statistics
	Poor Quality Freq. (%)	Good Quality Freq. (%)		
Rural	6 (100.0)	0 (0.0)	6 (100.0)	$\chi^2 = 4.047$ df = 1 p = 0.109 (Fisher's Exact)
Urban	7 (53.8)	6 (46.2)	13 (100.0)	
Total	13 (68.4)	6 (31.6)	19 (100.0)	

More facilities in the urban areas compared to the rural areas (31.4% vs 5.9%) had adequate availability of basic PAC, and the difference was statistically significant ($p < 0.001$). Furthermore, none of the facilities in the rural areas (0.0%) and eight facilities (61.5%) in the urban areas had adequate availability of comprehensive PAC, and this difference was statistically significant ($p = 0.018$).

More facilities in the urban areas compared to the rural areas (27.5% vs 5.9%) had good quality of basic PAC, and this difference was statistically significant ($p < 0.001$). Furthermore, none of the

facilities (0.0%) in the rural areas and six facilities (46.2%) in the urban areas had good quality of comprehensive PAC, but the difference was not statistically significant ($p = 0.109$).

DISCUSSION

Availability of PAC in Public Health Facilities in Osun State

Less than one-fifth (18.6%) of the public primary health facilities assessed in the state had adequate availability of basic PAC. This low level of adequate availability of basic PAC in the primary health facilities was because some of the facilities do not operate for seven days in a week, especially during weekends and public holidays. In addition, most of these facilities do not operate for 24 hours on the days that they are open.

Also, even some facilities that are open on every day of the week do not operate for 24 hours especially in the rural areas. Some of the reasons given by the health workers for this situation include inadequate staff, difficult terrain of some areas, high cost of transportation, lack of incentives and insecurity.

Furthermore, the materials and personnel for basic PAC were not available at all times in some facilities even while they were open. The implication of this poor availability of basic PAC in the primary health facilities is that some patients especially in the rural areas may not get PAC services when they need it, hence, they may have to go to a secondary or a tertiary facility to get basic PAC services. As a result, more time is spent before they can get to a facility where PAC is available, contributing to the delay before receiving care, sometimes with dire consequences.

Less than one-third (31.6%) of the public referral health facilities (secondary and tertiary) had adequate availability of comprehensive PAC. This may have resulted because although all the secondary and tertiary facilities were open all the time (24 hours a day, seven days a week), some secondary facilities did not always have the materials and

personnel to render PAC. Incidentally, none of the secondary facilities in the rural areas had materials and personnel for PAC all the time.

This means that such secondary facilities with inadequate availability of comprehensive PAC will not be able to manage patients referred to them from the primary facilities, and such patients will have to go to another secondary facility or a tertiary facility, thereby prolonging the time spent before accessing care.

The availability of basic and comprehensive PAC obtained from this study was lower than the findings of a similar study carried out in Nigeria in 2021, which reported an availability of 48.4% and 82.2% for basic and comprehensive PAC respectively.¹⁶ However, the comparison study involved public and private facilities in the selected states unlike this study that was on public health facilities only. This difference may have also resulted because some states in Nigeria are more metropolitan than others, and the various state governments have different levels of commitment to health.

Quality of PAC in Public Health Facilities in Osun State

Less than one-fifth (16.7%) of the public primary health facilities assessed in the state had good quality of basic PAC. Good quality of basic PAC was regarded as having all the signal functions of basic PAC. This may be because most of the primary facilities, and especially those located in the rural areas were not offering some signal functions of basic PAC either because the materials were not available, or the personnel needed to perform the signal function was not available, or both.

Most of the rural primary facilities had Community Health Officers (CHOs) and Community Health Extension Workers (CHEWs) as the highest PAC personnel available, and there are basic PAC signal functions that should not be performed by CHOs and CHEWs.¹⁷ Signal functions of basic PAC such as evacuation of retained products of gestation less than 12 weeks, administration of parenteral uterotonics and administration of parenteral antibiotics are to be performed by at least a nurse/midwife.¹⁷ Consequently, these three signal functions were not offered by most of the rural facilities and they actually constitute the hallmark of basic PAC because they prevent two major complications of unsafe abortion (haemorrhage and sepsis).

The implication of this situation is that some patients who received PAC in most of the primary facilities may not have received all the signal functions they required, thereby reducing the quality of care received. Furthermore, some patients that presented for PAC in the primary facilities were referred to higher centres because some of the signal functions they needed were not available especially evacuation of retained products. This may have contributed to the delay in receiving care with its possible attendant effect on maternal morbidity and mortality.

On the other hand, less than one-third (31.6%) of the public referral (secondary and tertiary) facilities had good quality of comprehensive PAC. Good quality of comprehensive PAC was regarded as having all the signal functions of comprehensive PAC. The two tertiary health facilities in the state had good quality of comprehensive PAC, so, the shortfall was from the secondary facilities, and especially, secondary facilities in the rural areas.

While most of the referral facilities offered

evacuation of retained products of gestation more than 12 weeks, some offered blood transfusion while few offered surgery/laparotomy. Some of the reasons the service providers in the affected secondary facilities gave for this situation included lack of the materials needed to perform certain signal functions even when the personnel are available, and poor or no power supply which served as a major limitation to their work especially at night.

All the secondary facilities in the rural areas and some secondary facilities in the urban areas had poor quality of comprehensive PAC. This means that most of the referral facilities in the state are deficient in their quality of comprehensive PAC, particularly, the referral facilities in the rural areas of the state. As a result, the patients that will present to these secondary facilities with poor quality of comprehensive PAC will either receive sub-optimal quality of care or will be referred to another secondary facility or a higher (tertiary) facility for proper care, thereby, contributing to care delays and increasing the patient load in the facilities with good quality of comprehensive PAC.

The quality of basic and comprehensive PAC in this study was similar to the findings from a survey done in Nigeria in 2018 by the Performance Monitoring and Accountability 2020 (PMA 2020) group.⁷ This study's result on the quality of PAC was also similar to the findings from another survey carried out in Nigeria in 2020 by the African Population and Health Research Centre as part of a continental survey on the quality of PAC in Sub-Saharan Africa.¹⁸ The similarities may have resulted because this study and the comparison surveys were all done in Nigeria.

This study did not involve private health facilities (especially private secondary facilities), and may not give a wholistic view of PAC service availability and provision in Osun State. It was a cross-sectional study; hence, temporality may not be established. In addition, the assessment of the availability and quality of PAC in this study was by the all-or-none method which did not make room for public health facilities that fulfilled some of the criteria that were assessed. Furthermore, there may have some reporter or observer bias during data collection. These were mitigated by encouraging the respondents to be as honest as possible after assuring them of anonymity and confidentiality; and ensuring that the research assistants were well-trained before data collection.

Conclusion and Recommendations

The availability and quality of post-abortion care in Osun State were inadequate, particularly in rural primary and secondary health facilities, posing a barrier to reducing abortion-related maternal mortality and ensuring women's reproductive health rights. Strengthening PAC services in Osun State requires adequate staffing, essential supplies and infrastructure, reliable electricity and security, sufficient funding, and regular monitoring and evaluation, particularly in rural areas.

Funding Declaration

This study was funded by the lead/corresponding author, and did not receive any other funding from any source.

Data Availability

The data generated during this study may be available from the corresponding author on a reasonable request by qualified researchers.

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Conflict of Interest

The authors declare no conflict of interest.

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HIV VIRAL SUPPRESSION STATUS AND ASSOCIATED FACTORS AMONG CHILDREN AND ADOLESCENTS RECEIVING A DOLUTEGRAVIR-BASED ART REGIMEN

Simon Yirsaw¹, Kasim Muhammad², Seman K Ousman²

ABSTRACT

BACKGROUND: Anti-Retroviral Treatment (ART) reduces morbidity and mortality, promotes normal growth and development, and improves the quality of life for children and adolescents living with HIV. Dolutegravir (DTG) based treatment has highly potent antiviral activity, a high genetic barrier to resistance, and a high safety profile. But, the effect of DTG on viral suppression in children and adolescents is not understood in Ethiopian context.

OBJECTIVE: To assess the HIV viral load suppression status and associated factors among children and adolescents on DTG based Anti-Retroviral (AR) regimen, Addis Ababa, Ethiopia.

METHODS: We employed a health facility based cross-sectional study design on children and adolescents receiving dolutegravir based ART regimen for at least 12 months. Stratified sampling technique was employed to get 430 samples. Binary logistic regression model was carried out to identify predictors associated with viral load suppression. Model fitness was checked using Hosmer and Lemeshow test for goodness of fit. Odds ratio with a 95% confidence level was used to measure the strength of association. Variables with $p < 0.05$ were considered statistically significant.

RESULT: Out of 430 participants, 428 (97.2%) responded. The proportion of viral suppression was 89.1%. In multivariable analysis, good medication adherence (AOR = 3.83, 95% CI: 1.49-9.86), pre-DTG viral suppression (AOR = 3.05, 95% CI: 1.35-6.89), normal nutritional status (AOR = 3.65, 95% CI: 1.36-9.63), and having both parents alive (AOR = 3.31, 95% CI: 1.44-9.56) were independently associated with higher odds of virologic suppression. Conversely, being on a second-line regimen (AOR = 0.21, 95% CI: 0.07-0.67) and having a caregiver with only primary education (AOR = 0.21, 95% CI: 0.06-0.76) were associated with significantly lower odds of suppression.

CONCLUSION: Dolutegravir based regimen maintains high viral suppression rate (89.1%) and improves medication adherence significantly compared to previous regimen. Implementing effective mechanism to enhance tailored treatment strategies that specifically address the unique needs of children and adolescents are imperative.

KEYWORDS: Anti-retroviral, dolutegravir, viral load, children, adolescents , Ethiopia

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1. INTRODUCTION

Approximately 2.58 million children aged 0-19 were living with HIV globally (4% of the total population living with HIV)¹. Even though there has been significant progress in preventing new HIV infections and reducing AIDS-related deaths and in expanding access to treatment, approximately 1.54 million (87%) of children (0-14 years) and 1.7 million (82%) of adolescents (10-19 years) living with HIV are found in sub-Saharan Africa (SSA)². Eastern and Southern Africa carries a huge share of the global HIV burden in children and adolescents. According to the report done by United Nations Children's Fund (UNICEF) in 2023, in this region, Children (0-14 years) living with HIV 940,000 (63%), new infection 60,000 (46%) and AIDS related deaths 36,000 (43%). Whereas older adolescents (15-19 years) living with HIV 69,000 (69%), new infection 77,000 (55%) and AIDS related deaths 10,000 (67%) were found to be of the global total².

In Ethiopia, the prevalence of HIV/AIDS aged 15-59 years is estimated to be 0.9%³. The burden varies depending on factors such as gender, age, and residency. According to the Ethiopian Public Health Institute (EPHI), HIV related estimates and projections in Ethiopia for the year 2022-2023, the total number of People Living with HIV (PLWHIV) were decreased from 610,350 in 2022 to 603,537 in 2023, bringing national HIV prevalence of aged 15 years and above to 0.87% in 2023 which was slightly decreased from 0.9% by 2022 but children with HIV (aged 0-14) was estimated to be 33,026 which was about 5.5% of the total in 2023⁴. In Addis Ababa, peoples living with HIV total (all ages) was estimated to be 112,185 in 2022 but 110,289 in 2023 which makes the prevalence to be 3.47% in 2023. Whereas children with HIV (aged 0-14) were 3,206 in 2022 but 2,793 in 2023³.

In Ethiopia, according to the President's Emergency Plan for AIDS Relief (PEPFAR-Ethiopia), in PEPFAR supported regions as of May 2021 final report, 79% of estimated PLHIV know their status, 97% of people living with HIV who know their

status were on ART and 91% of people who were on ART achieved viral suppression⁴. However, this report showed that only 64% of children under 15 years of age were know their status, 69% accessed ART and 75% virally suppressed⁴. This indicates that children are lags behind towards the UNAIDS 95-95-95 target by 2025 as compared to adults 15 years and above.

Dolutegravir (DTG) is a second-generation integrase inhibitor with the advantage of once-daily dosing, a good short-term safety profile, low pharmacokinetic (PK) variability, few drug-to-drug interactions, rapid and robust virological response and better drug palatability as compared to protease inhibitors (PIs) and nucleoside reverse-transcriptase inhibitors (NRTIs)⁵⁻⁸. Minister of Health, Ethiopia adopted a guideline in 2018 which recommended two NRTIs combined with DTG for Adults and adolescents 10 years & above with body weight >30 kg following WHO update on ART guideline in 2018⁹. However, the remaining groups were unchanged.

DTG treatment has highly potent antiviral activity, a high genetic barrier to resistance, and a high safety profile. Even though dolutegravir has been approved in children and adolescents recently, the evidence of level of medication adherence and viral load suppression rate is not well justified. Moreover, the role of DTG in children and adolescents where the variations in pharmacogenetics, nutritional status, and other socio-demographic characteristics may significantly affect the effectiveness and safety of the regimen not well understood in Ethiopian context. Therefore, this study aimed to assess virological suppression and its associated factors of dolutegravir based regimen among children and adolescents receiving ART in Addis Ababa, Ethiopia.

2.0 Materials and Methods

2.1 Study area and period

There were 11 governments owned hospital providing ART service of which 5 were federal hospitals and 6 were regional hospitals governed by Addis Ababa City Health Bureau (AACHB). Eight hospitals were providing pediatric ART services

at time of the study. This were, St Paul Hospital Millennium Medical College, Yekatit 12 Hospital Medical College, Alert Specialized Hospital, St Peter Specialized Hospital, Zewditu Memorial Hospital, Minilik II Specialized Hospital and Tirunesh Beijing General Hospital. These hospitals were high load and high impact facilities with high number of adult and pediatric clients on ART. According to AACHB report as of September 2023, there were about 96607 total clients on ART, 95281 clients were 15 years and above but 1326 clients were below 15 years of age of which 753 (57 %) of children below 15 years were found in the above hospitals. Among children whose follow up were in hospitals, 752 (99%) receiving DTG based regimen. On the other hand, the numbers of older adolescents from 15-19 years who have follow up at hospitals were 1148 from which 1125(98%) adolescents were on DTG based regimen. The study was conducted from June 15/2024 to August 30/2024.

2.2 Study design

This was a facility-based cross-sectional study. To obtain historical exposure data, a concurrent retrospective review of participants' medical records was conducted covering the 12-month period prior to DTG initiation.

2.3 Population

2.3.1 Source population

The source populations were all HIV positive children and adolescents (0-19 years) in the selected government hospitals in Addis Ababa, Ethiopia.

2.3.2 Study population

All children and adolescents who were shifted to a DTG-based antiretroviral

2.4 Eligibility criteria

2.4.1 Inclusion criteria

All children (0-9) and adolescents aged (10-19) years who were on DTG based ART regimen for at least 12 months and with documented viral load result in the selected Hospitals.

2.4.2 Exclusion criteria

Adolescents who were on ART for less than 12 months' duration, pending or unknown Viral Load (VL), lost to follow up, transfer out to other treatment facility or deceased clients.

2.5 Sample size determination

The sample size was determined using a single population proportion formula with a 95% confidence interval, considering the proportion of viral suppression 50% as no previous study done in the study area with a relative precision 5% and 12% non-response rate in order to recruit the estimated sample size of 430.

2.6 Sampling technique/ procedure

About 1901 participants who were on DTG based ART regimen documented in the study hospitals. A multistage sampling method was employed and then proportional to sample size, allocation was computed to include participants from each selected hospital. Finally, each participant in each health facility was selected using a simple random sampling technique.

2.7 Data collection tools and techniques

Data was collected by using semi-structured and pre-tested questionnaire. It was contextualized based on the research objective from revised literature^{4, 7, 10}. Face to face interview (for socio-demographic and behavioral variables) and EMR (ART smart care) extraction as well as medical record reviews using data extraction checklist. The questionnaire was translated into Amharic and back to English by language experts to ensure its consistency. The data was collected by data clerks and health officer was assigned for supervision following 2 days training.

2.8 Variables in the study

2.8.1 Dependent variable

- HIV viral load suppression: (categorized as Suppressed/Yes or Unsuppressed/No).

2.8.2 Independent variables

- **Socio demographic factors:** Age, sex, educational level, occupation, residence, marital status of caregivers, orphanage status, religion, PMTCT F/UP, relation, pregnancy status, care giver on ART.
- **Clinical and medication related factors:** Knowledge about ART, medication adherence level, previous regimen before shifted to DTG, current regimen with DTG, MMD, duration on ART (in months), base line CD4 level, current CD4, OI, BMI, WHO clinical staging, DTG based regimen, Base line viral load, Perinatal infection.
- **Behavioral factors:** Alcohol, chat, disclosure status and using reminder.
- **Psycho-social Factor:** Stigma, major depressive disorder (MDD) and anxiety disorder.

2.9 Operational definition

- **Viral load suppressed** –a viral copy of less than or equal to 50 copies /ml (11).
- **Children** -individuals with age less than 15 years old (12).
- **Adolescent** -defined by WHO as the second decade of life (10-19 years of age)(12).

2.10 Data quality management

Two-days training was given to data collectors on data collection, entry and how to approach to participants. The trained data collectors were assigned to a single supervisor. In order to assure the quality of data before starting the actual data collection, pre-test was done on 5% of children and adolescents on dolutegravir based regimen at Tikur Anbessa specialized hospital. Daily supervision was done during data collection period. The questionnaire was reviewed and checked for completeness, accuracy and consistency by supervisor and principal investigator. Double entry of 5 % data was carried out to ensure consistency and validity.

2.11 Methods of data analysis

Data entry was done using Epi-info version 7 and then exported to Statistical Package for Social Sciences (SPSS) version 26 for further analysis. Descriptive statistics were calculated for relevant variables. To compare pre- and post-intervention measurements, the Wilcoxon signed-rank test was used, given the non-normal distribution of the paired differences.

Binary logistic regression model was carried out to identify predictors that could independently associate with viral load suppression. Variables whose p-value less than 0.25 in the bivariate analysis was considered as a candidate variable for Multivariable model. Adjusted Odds ratio (AOR) along with a 95% confidence level were used to measure the strength of association. Variables were interpreted as having a statistically significant association if the p-value was < 0.05. Model fitness was checked using Hosmer and Lemeshow test for goodness of fit. Multicollinearity was also checked¹³.

2.12 Ethical considerations

Ethical approval was obtained from the Research and Ethical Committee of the SPHMMC (IRB ref no: PM23/1233), and Addis Ababa Health Bureau Research directorate (IRB ref no: A/A/H/20669/227). A letter of cooperation was written from the School of public Health, SPHMMC to Addis Ababa Health Bureau and to hospitals where the research was conducted. In order to maintain privacy and confidentiality of study participants, data was recorded anonymously.

3. Results

3.1 Socio-demographic characteristics of the study participants

Most of respondents were in the age groups 15-19 years 175 (40.9%). Half 217 (50.7%) of participants were female and majority 316 (73.8%) were orthodox by religion. Nearly two third 290 (67.8%) of respondents were married. Almost similar proportion of respondent's 148 (34.6%) had primary and 146 (34.1%) seconders educational

level. Whereas, one-fourth of 107 (25 %) of study participants were private organization employee and majority 366 (85%) of them were living in Addis Ababa (Table 1).

Table 1. Socio-demographic characteristics of the study participants in selected Governmental Hospitals, Addis Ababa, 2024 (N=428).

Variable	Sub-group	N(%)
Age in years	< 10	94 (22.0)
	10 -14	159 (37.1)
	15-19	175 (40.9)
Sex	Female	217 (50.7)
	Male	211 (49.3)
Marital status	Single	50 (11.7)
	Married	290 (67.8)
	Divorced	62 (14.5)
	Widowed	26 (6.0)
Religion	Muslim	52 (12.1)
	Orthodox	316 (73.8)
	Protestant	58 (13.6)
	Catholic	2 (0.5)
Education level	No formal education	36 (8.4)
	Primary	148 (34.6)
	Secondary	146 (34.1)
	Tertiary	98 (22.9)
Place of residence	Addis Ababa	366 (85.5)
	Out of Addis Ababa	62 (14.5)
Occupation	House wife	87 (20.3)
	Daily laborer	97 (22.7)
	Government employee	73 (17.1)
	Private employee	107 (25)
	Merchant	50 (11.7)
	Retired	2 (0.5)
	Others	12 (2.8)

N.B: a=Primary education indicates 1–8th grades; secondary education indicates 9–12th grades; Tertiary education indicates college & above.

3.2 Psychosocial, behavioral and caregiver’s knowledge

The majority of CALHIV (313; 73.1%) disclosed their HIV status. Almost equal proportions were diagnosed with anxiety (22; 5.1%) and major depressive disorder (23; 5.3%). Nearly all participants (407; 95.1%) reported no history

of perceived or confirmed stigma. On the other hand, only 3 (0.7%) participants had a history of chewing Kchat, and 2 (0.5%) participants reported a history of alcohol consumption. Nearly half of the participants (211; 49.3%) had a low level of knowledge regarding medication adherence (result not shown).

3.3 Clinical and medication related characteristics

The majority of participants (397; 92.8%) were on a first-line regimen. A total of 238 (55.6%) participants were taking the TDF/3TC/DTG (TLD) regimen, while 173 (40.4%) participants were prescribed ABC/3TC/DTG following the shift to a DTG-based regimen. Half of the clients (214; 50%) had previously been prescribed a Nevirapine-based regimen before transitioning to DTG. In addition, 383 (89.5%) participants received TB prophylaxis, and 392 (91.6%) received Cotrimoxazole prophylaxis. However, only 77 (18.0%) participants received antiretroviral prophylaxis. Mild to moderate malnutrition was observed in 45 (10.5%) participants.

Among the study participants, only 10 (2.3%) developed side effects and 18 (4.2%) experienced opportunistic infections (OIs) following initiation of the DTG-based regimen. All participants had acquired HIV through mother-to-child transmission. The majority (336; 78.5%) reported using reminders to adhere to medication timing. Approximately two-thirds (290; 67.0%) were enrolled in the three-month multi-month dispensing (3MMD) model. Prior to transitioning to the DTG-based regimen, only 285(66.6%) participants were virally suppressed (Table 2).

Table 2. Clinical and medication related characteristics of the participants at selected government Hospitals, Addis Ababa, 2024(N=428)

Variable	Sub-group	N(%)
Line of regimen	First line	397 (92.8)
	Second line	31 (7.2)
Current regimen after shifted	ABC3TC DTG	173 (40.4)
	AZT 3TC DTG	17 (4.0)
	TDF 3TC DTG	238 (55.6)
Previous regimen	Nevrapine	214 (50.0)
	Lopinavir/r	127 (29.7)
	Efavirenze	77 (18.0)
	Atazanavir	10 (2.3)
TB prophylaxis	Yes	383(89.5)
	No	45 (10.5)
Cotrimoxazole/CPT prophylaxis	Yes	392(91.6)
	No	36(8.4)
ARV prophylaxis	Yes	77(18.0)
	No	351(82.0)
Nutritional status	Malnutrition	45(10.5)
	Normal	383(89.5)
OI	Yes	18(4.2)
	No	410(95.8)
Side effect	Yes	10(2.3)
	No	418(97.7)
Perinatal infection	Yes	428(100)
	No	0 (0.0)
Using Reminder	Yes	336(78.5)
	No	92(21.5)
MMD	<3 MMD	133(31.1)
	3-5 MMD	290(67.8)
	6 MMD	5(1.2)
VS before	<=51	143(33.4)
	>51	285(66.6)

NB. ARV=Anti-retro Viral; OI= Opportunistic infection;
MMD= Multi-month dispensing; VS= Viral suppression

3.4 Clinical characteristics of pre and post Dolutegravir based regimen

The study showed that 48 (11.2%) participants developed tuberculosis prior to initiating the DTG-based regimen, whereas only 16 (3.7%) participants developed and were treated for TB after the transition. Similarly, 353 (82.5%) participants were classified as WHO Stage I before initiation, increasing to 420 (98.1%) after initiating the DTG-based regimen. Regarding medication adherence, 321 (75.0%) participants demonstrated good adherence prior to DTG initiation, compared to 370 (86.4%) following the switch to DTG (data not shown).

3.5 Virologic outcome of Dolutegravir based anti-retro viral Regimen

Among the 428 study participants, 382 (89.3%) achieved viral suppression after one year of treatment with the dolutegravir (DTG)-based regimen. In contrast, only 285 (66.6%) had achieved viral suppression prior to transitioning to DTG. Nearly two-thirds of participants, 268 (70.0%), were virally suppressed both before and after initiation of the DTG-based regimen. Among the 143 previously unsuppressed individuals, 114 (79.7%) attained viral suppression following the switch to DTG (data not shown).

3.6 Factors associated with Virologic outcome of Dalutagravir based regimen

Bivariate and multivariate analysis was conducted to determine predictor of viral load suppression. In bivariate analysis Age, Educational level, Orphanage status, relation to child or adolescent, Line of regimen, Anxiety, MDD, Stigma, Base line WHO staging, Nutritional status, Reminder for medication timing, previous viral load suppression status and Post DTG medication adherence were significantly associated with viral load suppression. Factors independently associated with viral load suppression included Post DTG medication adherence, nutritional status, line of regimen, previous viral load suppression status, parents /care giver's educational level and Orphanage status.

Participants with good medication adherence had nearly four times higher odds of achieving Virologic suppression compared to those with poor adherence (AOR = 3.832; 95% CI: 1.489-9.860). The odds of Virologic suppression were three times higher among those who were virally suppressed prior to initiating DTG therapy (AOR = 3.051; 95% CI: 1.350-6.890). Similarly, participants with normal nutritional status had greater odds of Virologic suppression than those with mild to moderate malnutrition (AOR = 3.650; 95% CI: 1.356-9.634).

Those whose parents were alive had higher odds of suppression compared to orphans (AOR = 3.308; 95% CI: 1.440-9.560). In contrast, participants on second-line regimens had significantly lower odds of Virologic suppression than those on first-line treatment (AOR = 0.211; 95% CI: 0.070-0.670). Moreover, participants whose caregivers had only primary education had reduced odds of suppression compared to those with tertiary education (AOR = 0.208; 95% CI: 0.057-0.762) (Table 3).

Table 3. Association between predictors and Virologic Suppression among CALWHIV on DTG-Based ART Regimen in Government Hospitals, Addis Ababa, 2024

Variable	Suppressed		COR with 95%CI	P-value	AOR with 95%CI		P-value
	Yes	No					
Medication adherence after DTG							
Poor /<85% (ref)	39	19	1		1		
Good />95% and above	343	27	6.18 (3.15-12.14)	0.000	3.832(1.489-9.86)		0.005**
Parents/care givers Education status							
Illiterate	34	2	0.723 (0.127-4.130)	0.716	0.21(0.14-37.76)		0.198
Primary	120	28	0.182 (0.062-0.538)	0.002	0.208 (0.057-0.762)		0.018 *
Secondary	134	12	0.475 (0.149-1.519)	0.209	0.46 (0.124-1.77)		0.264
Tertiary (ref)	94	4	1		1		
Viral suppression pre DTG							
>=51 (ref)	114	29	1		1		
<51	268	17	4.01(2.12-7.87)	0.000	3.051(1.35-6.89)		0.007**
Nutritional status							
Malnutrition (ref)	30	15	1		1		
Normal	332	51	5.67(2.76-11.66)	0.000	3.65 (1.356-9.634)		0.010**
Orphan status							
Orphaned (ref)	57	12	1		1		
Parent alive	325	34	2.012(0.9844-1.17)	0.05	3.308 (1.44- 9.56)		0.027*
Line of regimen							
First line	364	33	1		1		
Second line	18	13	0.126 (0.057-0.279)	0.000	0.211(0.066-0.673)		0.009**

NB: Ref= reference; COR= Crude Odd Ratios; AOR=Adjusted Odd Ratios.

4.0 DISCUSSION

In this study, the viral load suppression (VLS) rate among children and adolescents receiving ART was 89.3%. This finding aligns with studies conducted in Cameroon and Nigeria, which reported VLS rates of 88.2% and 88.4%, respectively¹⁴⁻¹⁵. Conversely, a comparative study in Kenya reported a slightly higher VLS rate of 93% among a similar population¹⁶. This difference may be attributed to the study's use of a lower threshold for suppression, defining VLS as a viral load below 400 copies/ml. Additionally, a study conducted in Tanga, Tanzania, found that 92.76% of children and adolescents achieved viral suppression, slightly exceeding the rate observed in the current study¹⁷. This difference might be due to variations in outcome measurement; the Tanzanian study defined VLS as a viral load of ≤ 1000 copies/m.

This study also demonstrated a higher viral suppression rate following the initiation of a Dolutegravir-based regimen compared to the pre-Dolutegravir regimen (89.3% vs. 66.6%, $Z = -10.741$, $p < 0.001$). This result aligns with findings from a study conducted in Nigeria among children and adolescents¹⁸. Furthermore, the study revealed that 70% of previously suppressed participants remained virologically suppressed, a finding consistent with similar research on this population in Nigeria¹⁸. However, the suppression rate observed in this study was lower than that reported in a pre-post study conducted in western Zimbabwe, which showed rates of 76% and 95%, respectively. This discrepancy may be attributed to differences in sample size and outcome measurement methods, as the Zimbabwean study defined viral suppression as a viral load of ≤ 1000 copies/mL¹⁹.

Following the initiation of a Dolutegravir-based regimen, the proportion of clients demonstrating good adherence significantly increased from 75% to 86.4% (McNemar's test, $Z = -2.834$, $p = 0.005$). This finding supports the notion that Dolutegravir is associated with fewer side effects and improved palatability, contributing to better treatment compliance compared to previous regimens. In

addition, the proportion of clients with a history of tuberculosis treatment declined from 11.2% to 3.7% ($\chi^2 = 26.694$, $p < 0.001$), suggesting that the Dolutegravir-based regimen may contribute to more rapid immune recovery and enhanced host immune function⁸.

The present study demonstrates that the viral suppression rate was three times higher among participants with good adherence compared to those with poor adherence. This finding is supported by studies conducted in Hawassa, Southern Ethiopia, and Nigeria, which identified good adherence as a key determinant of viral suppression outcomes^{18,20}. Similarly, the study identified that previously suppressed viral load and nutritional status were independently associated with favorable viral suppression outcomes. This finding aligns with studies conducted in Kisumu, Kenya, and Tanzania among children and adolescents receiving Dolutegravir-based regimens^{17, 21}. In contrast, a primary education level was associated with poorer viral suppression outcomes compared to tertiary education. This result is consistent with findings from a study conducted in North Wollo, East Amhara region, Ethiopia²². Lastly, with regard to orphanage status, children and adolescents who had living parents were three times more likely to achieve favorable viral suppression compared to their counterparts. This finding is consistent with studies conducted in Addis Ababa, Ethiopia, and southern Tanzania among similar study populations^{6, 10}.

One of the strengths of this study is its inclusion of all government hospitals in Addis Ababa, Ethiopia providing pediatric HIV care and treatment services, which enhances the generalizability of the findings to the broader population. Both primary and secondary data sources were utilized to incorporate key variables and minimize potential confounders. To reduce documentation errors, data were cross-checked against ART Smart Care records and patient charts. A limitation of this study is the exclusion of ART-naïve clients, which precludes assessment of viral suppression status among this subgroup,

despite evidence suggesting that Dolutegravir-based regimens offer superior viral suppression outcomes compared to earlier treatment protocols. Additionally, the cross-sectional design limits the ability to infer causal relationships. Some responses may be subject to recall bias and social desirability bias, particularly due to the use of interview-administered questionnaires.

Conclusion

The study found that 89.3% of children and adolescents achieved viral suppression, falling short of the $\geq 95\%$ UNAIDS target set for 2025. Our findings also highlighted several factors influencing viral suppression, including good adherence, the educational status of parents or caregivers, previous viral suppression while under parental care, nutritional status, orphan status, and the type of antiretroviral regimen. Moreover, the study revealed that Dolutegravir-based regimens not only improve viral suppression outcomes but also promote better medication adherence emphasizing the need for tailored treatment strategies that specifically address the unique needs of children and adolescents.

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Data Availability Statements: All relevant underlying data that support the findings of this study can be accessed through the corresponding author.

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SOCIODEMOGRAPHIC AND CLINICAL FACTORS ASSOCIATED WITH PRETERM PREMATURE RUPTURE OF MEMBRANES AMONG PREGNANT WOMEN ADMITTED TO PUBLIC HOSPITALS OF WEST SHEWA ZONE, CENTRAL ETHIOPIA

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ABSTRACT

BACKGROUND: Preterm Premature Rupture of Membranes (PPROM) poses a critical public health challenge, especially in low- and middle-income countries where it leads to substantial maternal and perinatal morbidity and mortality. However, the specific factors influencing PPRM have not been well understood in Ethiopia. Therefore, this study sought to uncover factors associated with PPRM among pregnant women admitted to public Hospitals of West Shewa Zone, central Ethiopia.

METHODS: A hospital-based unmatched case-control study was conducted from January 1 to February 28, 2024, in four randomly selected public hospitals of West Shewa Zone. A total of 142 cases and 284 controls were recruited using systematic sampling. PPRM was confirmed by sterile speculum examination and clinical features. Data was collected through interviewer-administered questionnaires and analyzed using SPSS version 27. Bivariate and multivariable binary logistic regression analyses were performed to identify independent predictors, with statistical significance set at $p < 0.05$. Data was analyzed using SPSS software. Bivariate and multivariable logistic regression analyses were performed to assess the association between dependent and independent variables, with statistical significance set at a p -value < 0.05 .

RESULTS: Pre-eclampsia during current pregnancy (AOR=6.41, 95% CI: 2.62-15.6), MUAC less than 23 cm (AOR=4.74, 95% CI: 2.08-10.7) and previous history of preterm PROM AOR=2.44, (95% CI: 1.21-4.91) were found to be significant determinants of preterm PROM.

CONCLUSION: This study identified pre eclampsia, maternal undernutrition, and previous history of preterm PROM as key determinants of preterm premature rupture of membranes. Strengthening antenatal care to enable early detection and management of hypertensive disorders, integrating maternal nutrition programs, and ensuring close follow up for women with prior PPRM are critical strategies to reduce recurrence and improve perinatal outcomes.

KEYWORDS: Preterm premature rupture of membrane, Central Ethiopia, Determinants, West Shewa Zone, premature rupture of membrane

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INTRODUCTION

Preterm premature rupture of membranes (PPROM) is defined as rupture of the amniotic sac before 37 completed weeks of gestation, resulting in painless leakage of amniotic fluid^{1, 2}. Towards the end of pregnancy, the amniotic sac typically ruptures due to a combination of factors. These factors include programmed cell death, the activation of enzymes that degrade collagen, and physical pressure exerted by the fetus³.

Globally, PPRM complicates about 3% of pregnancies⁴. Its impact weighs heaviest in low- and middle-income countries (LMICs), which bear most prematurity-associated neonatal deaths⁵. A cross-sectional Ugandan study, for instance, documented PPRM in 7.5% of pregnant women⁶. In Ethiopia, available studies reveal PPRM rates ranging from 1.34%⁷ to 22.76%⁸, with recent meta-analyses estimating a pooled prevalence of 6.58%⁹.

Preterm PROM imposes substantial risks on both maternal and fetal health, accounting for one-third of preterm births (10). It drives approximately 15% of perinatal mortality and 33% of perinatal morbidity (11). Neonates face common complications such as respiratory distress syndrome, necrotizing enterocolitis, intraventricular hemorrhage, and hyperbilirubinemia^{12,13}, while mothers encounter heightened dangers including infection, disseminated intravascular coagulation, cervical incompetence, cord prolapse, placental abruption, and postpartum hemorrhage^{13, 14}.

The specific cause that leads to PPRM has not been documented. However previously conducted studies reported several factors associated with PPRM such as cigarette smoking, having history of previous preterm birth, urinary tract infection during recent pregnancy, being multiple pregnancy, having history abortion, gestational Diabetes mellitus, history of preterm PROM, abnormal vaginal discharge, vaginal bleeding, Middle upper arm circumference (MUAC<23cm)¹⁵⁻¹⁷.

PPROM happens in many premature births; is the cause for greater than quarter of preterm birth (PTB)^{18, 19}; births before the full 37th week of

gestation, and PTB is the leading cause of perinatal morbidity and mortality and the second leading cause under-five mortality, with numerous short- and long-term health threats affecting the world. Around 75% of the death could be prevented with early identification of risk factors and prompt intervention. In 2019, preterm births accounted for approximately 16% of deaths in this age group and 35% of neonatal deaths^{20, 21}. Similar to other countries, complication from prematurity is the leading cause for neonatal mortality rate in Ethiopia. The three biggest causes of neonatal death are preterm delivery, complications of presumptive birth asphyxia, and infection in which majority of these problems are caused by PPRM²².

Apart from mortality, complications arising from prematurity also contribute significantly to severe morbidity, necessitating prolonged hospital stays. These complications encompass respiratory issues, metabolic disturbances, neurological challenges, and infections such as intra-amniotic and postpartum infections²³⁻²⁷.

The Ministry of Health has rolled out multiple initiatives, including scaling up advanced obstetric and neonatal services alongside tailored training manuals and guidelines, to enhance healthcare providers' competencies in managing and referring obstetric emergencies²⁸. Despite substantial efforts by the Ethiopian government, maternal and neonatal mortality remain persistently high²⁹. Therefore, in order to meet the Sustainable Development Goals, set by the United Nations for 2030, it is crucial to identify the risk factors that contribute to the occurrence of PPRM^{30, 31}.

Despite its impact on foetal and maternal health, the specific determinants of PPRM in Ethiopia have not been clearly elucidated, with previous studies often focusing broadly on premature rupture of membranes. Furthermore, the use of cross-sectional study designs in earlier research limited their ability to identify critical factors associated with PPRM. Therefore, this study aimed to identify Sociodemographic and Clinical factors associated with Preterm Premature Rupture of Membranes among Pregnant Women admitted

to Public Hospitals of West Shewa Zone of Central Ethiopia. The findings of this research are expected to inform policymakers, stakeholders, and relevant bodies in developing and implementing strategies aimed at improving maternal and neonatal health, thereby reducing adverse pregnancy outcomes.

Methods

Study design, area and period

An institution based unmatched case control study was conducted in West Shewa zone of Oromia regional state, central Ethiopia. West Shewa zone is one of the twenty-one²¹ zones of Oromia and Ambo town is the zonal administrative of West Shewa which is located 114Km west of the capital Addis. According to the 2007 Census conducted by the Central Statistical Agency of Ethiopia (CSA), the total population of the zone is about 2,058,676, of whom 1,028,501 are men and 1,030,175 are women. The Zone has eight⁸ functional public hospitals and ninety-six health centers. The study was conducted from January 01, 2024 to February 30, 2024.

Population of the study

The source population for this study comprised all pregnant women with a gestational age between 280/7th to 366/7th completed weeks who were admitted to the maternity wards, including both labour and high-risk units, of public hospitals in the West Shewa Zone during the study period. Cases were defined as women admitted with a diagnosis of PPRM, including those with additional obstetric complications, while controls were women admitted with diagnoses other than PPRM. Gestational age was primarily determined based on a reliable last normal menstrual period (LNMP) or, when LNMP was uncertain, by an early ultrasound scan performed before 24 weeks of gestation. In the absence of both, gestational age was estimated using fundal height measurements and clinical records. The diagnosis of PPRM was confirmed clinically by a painless gush of fluid per vagina, sterile speculum examination showing pooling of amniotic fluid in the posterior fornix,

and supportive findings such as changes in uterine size or amniotic fluid volume.

Sample size determination

EPI info software version 7.1.1 was used to calculate the sample size using the double population proportion formula to estimate the sample size required for an unmatched case-control study. The following assumptions were considered to estimate the required sample size for the study: a 95% confidence level, 80% power, Vaginal bleeding as a risk factor with a lowest odds ratio of 2.58 (16), the proportion of controls with exposure 79.3%, and the proportion of cases with exposure 90.8%. Case to control ratio of 1:2 was employed. The final estimated sample size with assuming of 10% non-response rate was 426 with 142 cases and 284 controls.

Sampling techniques and procedure

Among eight public hospitals in the zone, four hospitals were randomly selected namely; Ambo general hospital, Gedo general Hospital, Inchini general hospital and Ambo University referral hospital. Cases were recruited using a convenience sampling approach and controls were selected using systematic random sampling technique. Prior to study commencement, hospital records were reviewed across participating facilities to identify eligible cases and controls. The sample size was then allocated proportionally to each hospital according to the anticipated number of cases and controls, as illustrated in the diagram below (Figure 1).

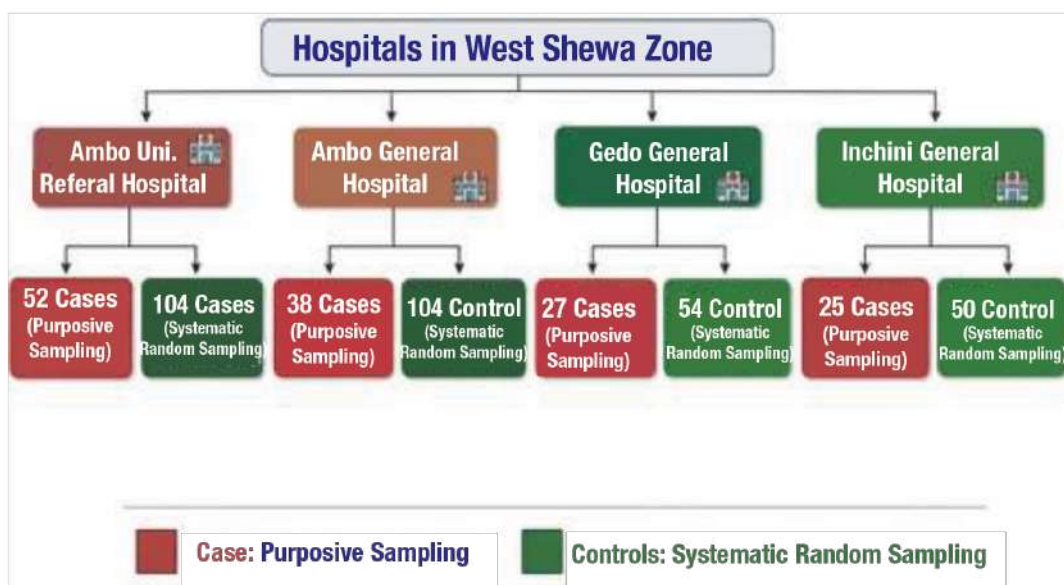


Figure 1: Schematic presentation of sampling procedure.

Variable of the study

Dependent variable: Preterm premature rupture of membrane

The independent variables in this study were grouped into four major categories. Socio-demographic factors comprised maternal age, marital status, residence, educational status, occupational status, and religion. Obstetric factors encompassed gestational age, antenatal care contacts, gravidity, parity, history of vaginal bleeding during pregnancy, prior PROM, previous preterm birth, abortion history, foetal presentation, and sexual intercourse during the third trimester of pregnancy. Medical factors consisted of pre-eclampsia, chronic cough, maternal anaemia, underweight, urinary tract infection, and gestational diabetes mellitus (GDM). Behavioural and reproductive health factors covered abnormal vaginal discharge, lower genital tract infections, smoking, khat chewing, and sleep habits.

Measurements

Preterm premature rupture of membrane (PROM), the dependent variable, was confirmed by clinical features (painless gush of fluid that leaks out of the vagina and a change in color or a decrease in the size of the uterus) and sterile speculum examination.

Cases are mothers who were admitted to maternity wards of the selected hospitals and confirmed to have preterm premature rupture of membrane before the initiation of labor. Similarly, controls were mothers who were admitted to maternity wards of the selected hospitals with the diagnosis other than preterm premature rupture of membrane³².

Gestational age was measured from reliable last normal menstrual period or early ultrasound scan before 24 weeks gestation to estimate gestational age³³.

Mid upper arm circumference was measured halfway between the tip of the shoulder (olecranon process) and the tip of the elbow (acromion process) to the nearest 0.1 cm. An insertion type MUAC tape that is non-elastic and non-stretchable was used to take the measurement. The measurement was taken at the mid-point on the relaxed non-dominant arm, without any clothing and with optimal tape tension (not too loose or not too tight) following the standard instructions and steps. An average of the two measurements was used for analysis. Women with average MUAC measurements of less than 23 cm were classified as having “undernutrition” while those with MUAC \geq 23 cm as “no undernutrition³⁴.”

Data collection tool and procedure

A questionnaire was adapted from different literature [16, 17, 32, 35] and was designed to obtain participant information on socio-demographic characteristics, obstetric and gynaecologic characteristics, medical and behavioural characteristics. The questionnaire was initially developed in English and translated into the local languages (Afaan Oromo) before being translated back to English. Statistically, Cronbach's alpha was performed, which is a measure used to assess the quality of our employed instruments. The result was 0.89, which was within acceptable ranges. Data were collected by interviewer-administered questionnaires by eight midwives and supervised by two master's holders.

Data quality control

Two days training was given to all the data collectors and supervisors. A pre-test was carried out on 5% (22 women) in Ginchi Primary hospital, which is located in West Shewa Zone but was not included among the study hospitals. Based on the findings of the pre-test, some modifications were undertaken. Data was also collected in Afan Oromo, the local language to prevent misinterpretation and pretest was conducted. To minimize recall bias, we limited questions to pregnancy related events that mothers could reasonably remember, and whenever possible, responses were cross checked against clinical records. Interviewer bias was reduced through standardized training of data collectors, use of a structured and pre tested questionnaire translated into the local language, and close supervision during data collection. Finally, double data entry was performed to check the consistency of the data.

Data processing and analysis

The collected data were coded, cleaned and entered into Epi data version 3.1 and exported to SPSS version 27 for analysis. Descriptive statistics such as mean, median, frequency, and percentage were used. Bivariate logistic regression analysis was used to identify candidate variables for multivariable logistic regression. Variables with p-value less than

0.05 were entered to multivariable logistic regression analysis to identify an independent determinant factor among explanatory variables. Adjusted odds ratio (AOR), 95% confidence interval (CI), and p-value less than or equal to 0.05 was used to decide a statistically significant association with the outcome variable. Hosmer-Lemeshow model test were done to check the model fitness before the final regression model and it was found to be 0.692. Multicollinearity was checked by using variance inflation factor (VIF).

Results

Socio-demographic Characteristics of Study Participants

A total of 426 pregnant women (142 cases and 284 controls) participated in this study making a response rate of 100%. The age of respondents ranged from 18 to 37 years with the mean age of 24 ± 4 years for cases and 27 ± 5 years for controls. Majority of cases 138 (97.2%) and 278 (97.9%) of controls were married. One hundred forty (98.6%) of cases and 278 (97.9%) of controls were Oromo in Ethnicity. Regarding their educational status, 54 (38%) of cases and 95 (33.5%) of controls haven't attended formal education (Table 1).

Table 1: Socio-demographic characteristics of pregnant women admitted in public hospitals of the West Shewa zone, central Ethiopia, 2024 (N=426).

Variables	Categories	Cases (%)	Controls (%)
Age	18-24	79 (55.7)	154 (54.2)
	25-34	57 (40.1)	123 (43.3)
	≥ 35	6 (4.2)	7 (2.5)
Marital Status	Single	4 (2.8)	6 (2.1)
	Married	138 (97.2)	278 (97.9)
Place of residence	Urban	88 (62)	182 (64.1)
	Rural	54 (38)	102 (35.9)
Religion	Orthodox	67 (47.2)	137 (48.3)
	Muslim	26 (18.3)	60 (21.1)
	Protestant	44 (31)	77 (27.1)
	Others®	5 (3.5)	10 (3.5)
Educational status	No formal Education	54 (38)	95 (33.5)
	Primary (1-8)	35 (24.6)	60 (21.1)
	Secondary (9-12)	37 (26.1)	73 (25.7)
	Certificate and above	16 (11.3)	56 (19.7)
Mothers Occupation	Government Employee	29 (20.4)	66 (23.2)
	Private Business	32 (22.5)	65 (22.9)
	Housewife	76 (53.5)	143 (50.4)
	Daily Labourer	5 (3.5)	10 (3.5)

® Wakefata, Catholic and Adventist

Obstetrics Characteristics of the Respondents

There was no significant difference among cases and controls regarding ANC contacts. Almost all 130 (91.5%) of cases and 276 (97.2%) of controls had ANC contacts for their current pregnancy. Majority of cases 91 (64.1%) and 166 (58.5%) controls were attending their ANC at Hospitals. About two third of cases and controls had cephalic presentation. Eighty-one (57%) of cases and 143 (50.5%) of controls were primigravida. Among multigravida mothers nearly two thirds of case (62.1%) and 68.4% of controls had the preceding birth interval of 24 months. The proportion of mothers who had multiple pregnancy and polyhydramnios were low both among cases and controls (Table 2).

Table 2: Obstetrics characteristics of pregnant women admitted in public hospitals of the West Shewa zone, central Ethiopia, 2024.

Variables	Categories	Cases (%)	Controls (%)
Gravida	Primigravida	81 (57)	143 (50.5)
	Multigravida	61 (43)	141 (49.5)
Parity	Nulliparous	81 (57)	143 (50.5)
	Primiparous	32 (22.6)	76 (26.7)
	Multiparous	29 (20.4)	65 (22.8)
ANC contacts	No	12(8.5)	8(2.8)
	Yes	130(91.5)	276(97.2)
History of vaginal bleeding	No	102 (71.8)	264 (93)
	Yes	40 (28.2)	20 (7)
History of preterm birth	No	33 (54.1)	77 (54.6)
	Yes	28 (45.9)	64 (45.4)
History of PROM	No	34 (55.7)	76 (54.6)
	Yes	27 (44.3)	65 (46.1)
Foetal Presentation	Cephalic	90 (63.4)	181 (63.7)
	Breech	49 (34.5)	94 (33.1)
	Shoulder	3 (2.1)	9 (3.2)
Indication of admission	Pre-eclampsia	42 (29.6)	64 (22.5)
	Oligohydramnios	37 (26.1)	63 (22.2)
	APH	10 (7.0)	28 (9.9)
	Decreased foetal movement	10 (7.0)	16 (5.6)
	Others*	43 (30.3)	113 (39.8)
Abnormal Vaginal discharge	No	124 (87.3)	245 (86.3)
	Yes	18 (12.7)	39 (13.7)
Sexual intercourse after 7 months	No	120 (84.5)	220 (77.5)
	Yes	22 (15.5)	64 (22.5)

Footnote: *Severe anaemia, preterm labour, gestational DM and foetal growth restriction

Medical Characteristics of the Respondents

Concerning maternal medical problem about 12% of cases and 23% of controls have experienced different medical illnesses during this pregnancy. Among the mentioned medical illnesses, Pre-eclampsia accounts for 29.6% of cases and 22.2% of controls. History of chronic cough was reported among 21 (14.8%) of cases and 36 (12.7%) of controls.

Behavioural Characteristics of the Respondents

Regarding behavioural characteristics of respondents about 10% of cases and controls had sexually transmitted infection during their current pregnancy. None of the cases and controls had

history of using cigarette, cocaine, and chat. About 3% of both cases and controls have history of lifting heavy weight since they become pregnant. Fall injury was reported among 13 (9.2%) of cases and 11 (3.9%) of controls. Regarding the sleep habit nearly half (46.9%) of the cases and about one third (32.4%) of the controls reported to sleep less than 8 hour per day. Genital tract infection was reported among 54 (38%) of cases and 37 (13%) of controls.

Determinants of Preterm PROM

The bivariate binary logistic regression revealed that variables like educational status, ANC contacts, place of residency, history of preterm labor, pre-eclampsia, history of vaginal bleeding, previous

history of PPRM, MUAC and genital tract infection have shown statistical association with PPRM

After controlling for the possible effects of confounders in multivariable binary logistic regression; MUAC <23 cm, Pre-eclampsia and previous history of preterm PROM have shown statistical association with PPRM.

As a result, pregnant women with a MUAC cm of less than 23 cm had five-fold increased odds of PPRM (AOR=4.74, 95% CI: 2.08-10.7). Similarly, among pregnant women diagnosed with Pre-eclampsia, the odds of PPRM were about six times greater (AOR=6.41, 95% CI: 2.62-15.6). Moreover, pregnant women with previous history of preterm PROM had 2.44fold increased odds of PPRM (AOR=2.44, 95% CI: 1.21-4.91) (Table 3).

Table 3: Bivariate and Multivariable logistic regression analysis for factors associated with PPRM among women admitted to public hospitals in West Shewa Zone, Central Ethiopia, 2024 (N=426)

Variables	Categories	PPROM		COR (95% CI)	AOR (95% CI)
		Cases (%)	Controls(%)		
Educational status	No formal Education	54 (38)	95 (33.5)	1.98 (1.04-3.80)	1.0 (0.41-2.43)
	Primary	35 (24.6)	60 (21.1)	2.04 (1.02-4.09)	1.11 (0.38-3.26)
	Secondary	37 (26.1)	73 (25.7)	1.77 (0.89-3.51)	0.66 (0.22-1.94)
	Certificate and above	16 (11.3)	56 (19.7)	1	1
ANC contacts	No	12(8.5)	8(2.8)	2.421(1.28-4.54)	1.41 (0.39-4.11)*
	Yes	130(91.5)	276(97.2)	1	1
Residence	Urban	98 (69)	244 (85.9)	1	1
	Rural	44 (31)	40 (14.1)	2.74 (1.68-4.46)	0.48 (0.09-2.40)
History of preterm labour	No	22 (22.7)	75 (77.3)	1	1
	Yes	39 (37.1)	66 (62.9)	2.01 (1.09-3.74)	0.86(0.21-3.65)
MUAC	<23 cm	123 (86.6)	149 (52.5)	5.87 (3.43-10.1)	4.74 (2.08-10.7)
	≥23 cm	19 (13.4)	135 (47.5)	1	1
Pre-eclampsia	No	99 (69.7)	267 (94)	1	1
	Yes	43 (30.3)	17 (6)	6.82 (3.72-12.5)	6.41 (2.62-15.6)*
Vaginal Bleeding	No	102 (71.8)	264 (93)	1	1
	Yes	40 (28.2)	20 (7)	5.18 (2.89-9.27)	1.83 (0.31-10.8)
Previous history of PPRM	No	20 (22.2)	70 (77.8)	1	1
	Yes	41 (36.6)	71 (63.4)	2.02 (1.08-3.79)	2.44 (1.21-4.91)*
Genital tract infection	No	88 (62)	247 (87)	1	1
	Yes	54 (38)	37 (13)	4.09 (2.53-6.65)	1.54 (0.35-6.71)

1-Reference category, *: p-value less than 0.05

DISCUSSION

This unmatched case-control study aimed to investigate the factors influencing PPRM. The study findings indicated that having a MUAC of less than 23 cm, experiencing pre-eclampsia, and no ANC contacts were statistically associated with PPRM.

Pregnant women diagnosed with Pre-eclampsia, the odds of experiencing PPRM were nearly five times higher. This finding aligns with results from a study conducted in southern Ethiopia, indicating consistency in the relationship between hypertensive disorders and PPRM across different regions³⁵. The increased risk of PPRM in women with hypertensive disorders during pregnancy may be attributed to several physiological mechanisms. Pre-eclampsia may lead to reduced blood flow to the uterus, which affects the normal invasion of cytotrophoblasts into spiral arterioles. This abnormal invasion, coupled with endothelial dysfunction, can result in placental ischemia and damage to placental endothelial cells. These conditions contribute to premature weakening of the fetal membranes and increase the likelihood of early rupture³⁶.

Pregnant women with a MUAC cm of less than 23 had four-fold increased odds of PPRM. This is in line with the results of the study conducted in Southern and North West Ethiopia^{16, 35}. This is related with collagen formation being impaired by nutritional deficits, especially those involving micronutrients like vitamin C or ascorbic acid. The body is shielded by ascorbic acid against oxidative stress-related degenerative processes. Collagen must also be boosted and stabilized by serving as an enzymatic cofactor. Micronutrient deficiencies in the diet can cause capillary hemorrhage and weakened collagen, which can result in PPRM³⁷. This study also revealed that a previous history of preterm PROM was significantly associated with recurrence of PPRM in the current pregnancy. This finding aligns with global evidence, which consistently demonstrates that women with prior PPRM are at increased risk of recurrence³⁸.

Similar study conducted in Ethiopia also highlighted recurrence as a well-established risk factor⁹. The possible justification for this recurrence lies in several mechanisms. Structural or biological predispositions such as cervical insufficiency, uterine anomalies, or persistent connective tissue weakness, may render the membranes more vulnerable to rupture^{39, 40}. Additionally, subclinical intrauterine infections and chronic inflammatory processes can compromise membrane integrity across pregnancies⁴¹. Therefore, women with a history of PPRM should be considered a high-risk group in subsequent pregnancies, warranting closer surveillance, early interventions, and preventive strategies such as cervical length monitoring, infection screening, and timely referral to specialized care.

Conclusion

This study identified pre-eclampsia, maternal undernutrition, and previous history of preterm PROM as determinants of preterm premature rupture of membranes. These findings emphasize the need for integrated antenatal strategies—strengthening maternal nutrition, vigilant monitoring of hypertensive disorders, and targeted follow up for women with prior PPRM to mitigate recurrence and improve maternal and neonatal outcomes. Targeted interventions addressing these modifiable risk factors could substantially improve maternal and neonatal outcomes, particularly in resource-limited settings like Ethiopia.

Strengths and limitations of the study

The strength of this study lies in its ability to efficiently investigate numerous potential risk factors for PPRM in a resource-constrained environment where this significant pregnancy complication is prevalent. By comparing pregnant women diagnosed with PPRM to a control group unaffected by the condition, the study has identified critical sociodemographic and clinical factors contributing to PPRM within this specific population.

As a hospital-based case-control study, the risk of Berkson's bias cannot be entirely excluded, since both cases and controls were drawn from admitted patients. We attempted to mitigate this by restricting controls to admissions unrelated to PPRM and adjusting for confounders. Additionally, recall bias and the limited geographic scope may affect the generalizability of the findings.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with to the research, authorship, and/or publication of this article.

Author Contribution

Both authors conceived and designed the study, establishing the research framework and methodology. D.N.G collected data, and performed the analysis. G.G.B. provided critical insights during the data interpretation and supervised the overall project. Both authors contributed to drafting the manuscript, with D.N.G. leading the initial writing and G.G.B. providing revisions and critical feedback. Both authors reviewed and approved the final version of the manuscript.

Ethics statement

The study adhered to the Declaration of Helsinki. Ethical approval was obtained from the Ambo University Ethical Review Committee (Ref. No. PG 23/480/2024). Subsequently support was secured from the Arsi Zonal Health Department and the participating health facilities. After providing a comprehensive explanation of the study's objectives, potential risks, and benefits, written informed consent was obtained from all participants. Confidentiality and anonymity were assured, and participants had the right to withdraw at any time.

Data availability Statement

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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ABDOMINAL WALL ENDOMETRIOSIS: A CASE REPORT FROM JIMMA UNIVERSITY MEDICAL CENTRE, ETHIOPIA

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ABSTRACT

BACKGROUND: Abdominal wall endometriosis is a rare condition, often occurring as a complication following gynecologic surgery, especially cesarean section. Its diagnosis is frequently delayed due to non-specific symptoms and a wide range of differential diagnoses. We report here a case of abdominal wall endometriosis following caesarean delivery in a young woman.

CASE PRESENTATION: A 25-year-old woman, para 1 (caesarean section), presented with cyclic left lower abdominal pain and swelling, worsening during menstruation. Physical examination revealed a firm, nontender mass near the caesarean scar on the left lower abdominal quadrant. Imaging studies including ultrasound and color Doppler identified a hypoechoic lesion in the rectus abdominis muscle with internal vascularity. Fine needle aspiration cytology supported a diagnosis of endometriosis. Surgical excision under spinal anaesthesia was performed in complete removal of the lesion, with no postoperative complications. The patient remained symptom-free at six-month follow-up.

CONCLUSION: This case highlights the importance of considering abdominal wall endometriosis in women with cyclical pain and prior uterine surgery. Imaging and histopathology are key to diagnosis, while complete surgical excision remains the definitive treatment.

KEYWORDS: Endometriosis, Abdominal wall, Surgical excision, Ethiopia

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INTRODUCTION

Endometrial tissue outside the uterus is known as endometriosis, can lead to infertility and chronic pain¹. Of women of reproductive age, about 10% are affected and can also show up in the intestine, urinary system, lymph nodes, abdominal wall, and surgical scars, though it is most frequently found in the pelvis. The most frequent extrapelvic site is the abdominal wall, which is typically connected to prior gynecologic surgeries^{2, 3}. A diagnosis is frequently made using imaging techniques like ultrasound, CT, or MRI, and it is subsequently verified histologically after surgical excision. A proper diagnosis is crucial since differentiating between abscesses, tumors, granulomas, and cancers is crucial⁴. We reported here a case report of abdominal wall endometriosis, which developed in the previous scar of caesarean section.

Case presentation

This is a 25-year-old para 1 (delivered by caesarean section 5 years back) woman whose last menstruation was one week back before presented at Jimma University Medical Centre (JUMC) gynecologic emergency department with complaints of pain and swelling in her lower left quadrant of abdomen. The pain was cyclic, dull aching and aggravated during monthly menstruation. The patient's

medical history included one caesarean delivery through a Pfannenstiel incision. She was treated repeatedly by unspecified antipain medications and seen multiple times but didn't get any relieve from the pain. Otherwise, she has no history of bleeding from other sites, vomiting, loss of appetite, loss of weight and substance use like alcohol or smoking. The vital signs were normal with blood pressure 110/70mmhg, pulse rate 82bpm, respiratory rate 22bpm, and temperature 36.7°C. The remarkable finding was on abdominal examination, that revealed a firm lump in the left lower quadrant measuring about 3*2cm which is nontender and located on the left side of the caesarean scar. Abdominal ultrasonography showed a 41*19mm well defined hypoechoic lesion with internal anechoic areas in the left rectus abdominialis muscle at the site of the lateral margin of the caesarean section scar which has internal vascularity on color doppler study concluding as scar site endometriosis. She also underwent fine aspiration needle cytology (FNAC) revealing low cellular yield containing few flat epithelial clusters, foamy histiocytes and old haemorrhage concluding as endometriosis. She was also imaged abdominopelvic with pre and post contrast CT scan which showed no abnormality. Laboratory investigations results are shown in the Table 1.

Table 1: Laboratory investigations of a patient managed for abdominal scar site endometriosis at JUMC, 2025

Types of investigations	Dates done			Remarks
	7/2/2017	11/2/2017	16/2/2017	
WBC	6900	8250	13,180	
Hgb	14.2	14.4	13.2	
Plt	271,000	291,000	305,000	
HBSAg	Negative			
VDRL	negative			
Urinalysis	Nonrevealing			
Blood group and Rh	O+ve			
Creatinine	0.59			

WBC: white blood cells; Hgb: haemoglobin; Plt: platelet; HBSAg: hepatitis b surface antigen; VDRL: Venereal Disease Research Laboratory test; Rh: rhesus factor

Patient was counselled on the diagnosis and management and informed consent was obtained for surgery. Under spinal anaesthesia, wide local resection of the masses measuring 60*40mm was done. The rectus sheath was opened and adhesion of the mass with fascia and muscle released while dissecting the mass from surrounding structure but the peritoneum was not entered. The tissue was sent for histopathology (Figure 1) and that confirmed the diagnosis of endometriosis. The abdominal wall was then closed by absorbable suture.

of the caesarean section scar which has internal vascularity on color doppler with features of typical endometriosis. Clinically, rectus abdominis muscle mass lesions may be diagnosed as benign or malignant tumors, hernias, lipomas, hematomas, or abscesses⁶. Endometriosis's pathogenesis is still unknown. The most widely accepted hypothesis of implantation, Sampson's, states that endometrial tissue implantation on the peritoneum and ovary occurs as a result of endometrial fragments refluxing via the fallopian tubes during menstruation^{7,8}.

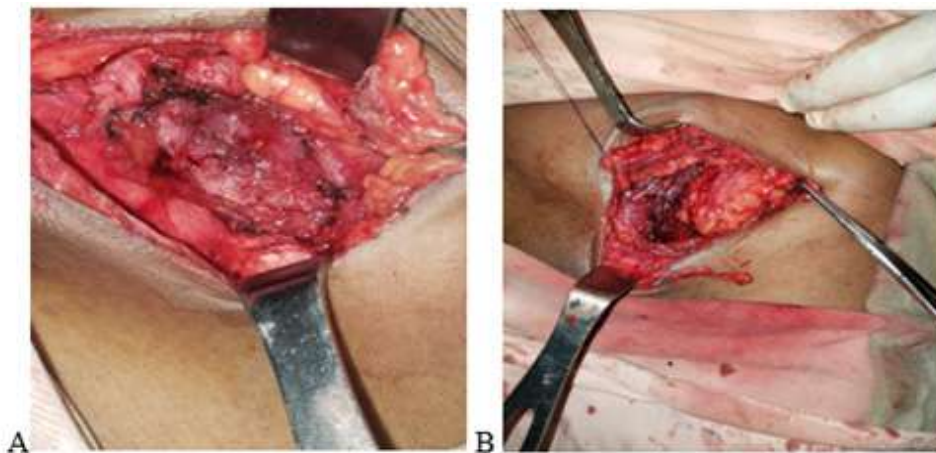


Figure 1: intraoperative mass showing abdominal wall endometriosis: A (Before resection); B (After resection)

There were no complications postoperatively and the patient discharged four days later. The woman was symptom free for endometriosis after 6 months at her scheduled follow up appointment that she was scanned with abdominal ultrasound and normal.

DISCUSSION

The existence of functional endometrial tissue outside the uterus is known as endometriosis. Scar endometriosis is an uncommon condition that can be challenging to diagnose because of its vague symptoms⁵ which made our patient to be diagnosed late after several unspecified antipain medications. In our case it was diagnosed with ultrasound showed a well-defined hypoechoic lesion with internal anechoic areas in the left rectus abdominis muscle at the site of the lateral margin

The formation of endometrial tissue may be caused by abnormal migration or differentiation of the Mullerian ducts⁹. The coelomic metaplasia theory provides an explanation for ovarian endometriosis^{10,11}.

The endometriosis averagely presented at age of 31 years. It affects 6%–10% of all women and about 35–50% of women who have pelvic pain and infertility. Abdominal wall endometriosis is a rare condition that can develop after open uterine surgeries¹²⁻¹⁶. There are few case reports in Ethiopia on scar endometriosis which is mostly after caesarean section like in our case¹⁶. Endometrial tissue in the abdominal wall may become implanted by the needle that passes through the endometrium during a caesarean section if the same needle is used to suture it¹⁷.

The ectopic endometrial tissue is linked to an excess of prostaglandins, cytokines, and chemokines, which is why endometriosis should be seen as a chronic inflammatory illness¹⁸. There is strong evidence that estrogen plays a role in endometrial tissue cells that is not only proliferative but also proinflammatory and antiapoptotic¹⁹. In women with endometriosis, where local estradiol promotes both inflammation and cell survival, these effects appear to be amplified. The imaging techniques are not specific for the diagnosis, and the symptoms do not always have a cyclical nature^{17, 20}. The real incidence of scar endometriosis is estimated at 0.03% to 0.15% with the first symptoms starting around five years after the procedure has launched^{21, 22}. Infertility and discomfort, whether cyclic or not, are the primary clinical signs of endometriosis. Up to 30 to 50% of individuals experience endometriosis-associated infertility, which can be brought on by pelvic adhesions, dyspareunia, anomalies of the ectopic endometrium, loss of ovarian function, changes in the fertilization process, and potential ovarian surgery^{1, 23}.

Early menarche, shorter than 27-day menstrual cycles, few births, age 25–29, Caucasian race, daily heavy alcohol use, excessive consumption of red meat, and smoking are risk factors for endometriosis²⁴. The ultrasound is the best choice for the diagnosis of the endometriosis²⁵. The mass is characterized as hypoechoic and heterogeneous with scattered internal echoes. In some cases, the masses appear totally solid but occasionally some cystic changes may be seen. Magnetic resonance imaging outweighs ultrasound because of its ability to detect masses that imitate endometriosis on the abdominal wall and should be regarded as the second-line imaging technique. Computed tomography findings depend on the phase of the menstrual cycle. Masses might appear mostly solid, cystic, or as a mixed appearance of both elements^{26–28}. It has been suggested to utilize FNAC to examine endometriotic lesions since they can manifest as a mass lesion, frequently with the guidance of ultrasound or CT²⁹.

Oral contraceptive pills, progestogens, and danazol are not effective medical treatments that cure patients; instead, they only partially relieve symptoms and can have a number of negative side effects. Abdominal wall endometriosis has not shown the same clinical improvement with hormonal treatment as endometriotic implants in other sites^{15, 30}. Patch grafting of the defect and extensive surgical excision with a minimum 1 cm margin are the preferred treatments for abdominal wall endometriosis³¹. In our case it is treated with wide local resection including the 1cm margins of around tissue.

Scar endometriosis may be avoided with appropriate attention and surgical methods during caesarean sections. It has been proposed that thorough cleaning with high jet saline solution prior to closure following surgery, particularly uterine and tube manipulations, could reduce the relative chance of developing endometriosis^{32, 33} even though in our case the previous caesarean section was not known. Because endometriosis has a significant chance of reoccurring, patients with this condition require follow-up at least for 2 to 3 years. Additionally, in cases with persistent recurrence, the risk of cancer should be ruled out. The risk of developing endometriosis is up to six times higher for first-degree relatives of endometriosis patients. The genetic basis of the illness is still unknown, despite twin studies showing that heritability is roughly 50%^{34, 35}.

Conclusion

This case emphasizes the significance of considering scar endometriosis in women who experience cyclical pain and have had previous uterine surgery. Imaging and histopathology are critical for diagnosis, while total surgical excision remains the only definitive treatment. Proper surgical methods during caesarean section may lower the likelihood of this syndrome.

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Declaration of conflicting interests

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Informed consent/ Patient consent

The patient signed informed consent for the use of case, details and images for publication and scientific purposes.

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PRENATAL DIAGNOSIS OF PENTALOGY OF CANTRELL WITH ABSENT LIMB: A RARE CASE REPORT FROM ETHIOPIA

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ABSTRACT

BACKGROUND: Pentalogy of Cantrell is rare and serious condition that affects roughly 5.5 out of every 1,000,000 live newborns. It comprises five characteristics defects: omphalocele, cardiac ectopia, absences of the anterior diaphragm, the lower sternum, and of the parietal diaphragmatic pericardium. We report a case of severe form of pentalogy of Cantrell categorized as class 1 having all five of the diagnostic defects and associated with absent upper left limb (amelia).

CASE PRESENTATION: A 21-year-old primigravida mother with 8 months amenorrhea presented at our hospital for routine antenatal care visit. A detailed obstetric ultrasound scanning was performed and revealed characteristic findings of pentalogy of Cantrell. A multidisciplinary team discussed with the mother and the family about the severity of the fetal anomaly as well as its poor prognosis and the pregnancy was terminated medically. A 1600gm male newborn was delivered vaginally which later passed away after 10 minutes with no maternal complication.

CONCLUSION: In the context of complicated pentalogy of Cantrell, this case highlights the vital importance of prompt prenatal screening, thorough counselling, and individualized management planning by multidisciplinary team.

KEYWORDS: Pentalogy of Cantrell, Ectopia cordis, Omphalocele, Amelia, Case report, Ethiopia

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INTRODUCTION

The first description of the Cantrell pentalogy was published in 1958. It is severe and rare congenital condition characterized by five anomalies: a midline supraumbilical abdominal wall defect; lower sternal defect; anterior diaphragmatic defect; diaphragmatic pericardial defect, and congenital abnormalities of the heart¹. Its incidence is about 5.5 out of every 1,000,000 live newborns and more prevalent in male gender than female which is nearly three times higher². Globally, the prevalence of congenital anomaly is about 3-6% of births, while in Africa varies between countries and its pooled estimates are between 2-3%^{3,4}.

Here we reported a class 1 category of pentalogy of cantrell (characterized by a midline defect, upper abdominal wall abnormality; lower sternal defect; anterior diaphragmatic defect; and diaphragmatic pericardial defect) associated with absent limb which is rarely reported case globally and challenging to diagnose in resource- limited settings like Ethiopia.

Case Presentation

A 21 -year- old primigravida presented after eight months of amenorrhea, referred from a nearby General Hospital with the diagnosis of omphalocele

and 3rd trimester pregnancy in her third antenatal visit for further evaluation and management. The mother had two ANC contacts starting from four months of amenorrhea. She has no family history of fetal congenital anomalies and took folate and iron supplementation during the current pregnancy. The mother is housewife farmer and had no history of any use of medication. Physical examination revealed, normal vital signs, pink conjunctiva, a 30-week-sized gravid uterus, longitudinal lie, cephalic presentation, and positive fetal heartbeat. Other physical exam findings were unremarkable.

Diagnostic Assessment

Obstetric ultrasound scan done by Feto-Maternal Medicine (FMM) confirmed singleton intrauterine pregnancy at 31week plus 4 days, positive fetal heartbeat, fundal - posterior placenta, large abdominal wall defect with floating of liver, bowel loops and kidney in the amniotic fluid with no covering membrane, heart is located completely outside the thoracic cavity floating in the amniotic fluid, and single deepest pocket is 8.5cm. This conclusion from the ultrasound features was: 3rd trimester pregnancy + pentalogy of Cantrell +mild polyhydramnios (see Figure 1).



Figure 1: Tran-abdominal obstetric ultrasound A (heart floating in the amniotic fluid), B (liver and bowel outside abdominal cavity)

Investigations were done and all were in the normal range (see Table 1).

Table 1: Details of laboratory investigations

Lists of investigations	Dates		Remark
	June 24, 2025	June 30, 2025	
Random blood sugar (mg/dl)	95		
Complete blood count			
White blood cell (count/UL)	13.1*10 ³	17.2*10 ³	
Hemoglobin (g/dl)	12.4	12.7	
Hematocrit (%)	35.9	38.3	
Platelet (count/uL)	290*10 ³ /	283*10 ³	
VDRL	Negative		
HBSAg	Negative		
Urinalysis	Nonrevealing		
Blood group	O		
Rh status	Negative		
Indirect coombs test	Negative		

NB: mg/dl: milligram per decilitre, g/dl: gram per decilitre, %: percent, UL: unilitre, VDRL: Venereal Disease Research Laboratory, HBSAg: Hepatitis B surface antigen, Rh: Rhesus

Therapeutic Intervention and Outcomes

After the diagnosis was confirmed the prognosis of the pregnancy was discussed with the mother and family thoroughly about the lethal nature of the anomaly and its prognosis. She was admitted to maternity ward for pregnancy termination. Cervical ripening was done with 25micg misoprostol three doses and induction of labor with Pitocin following the protocol of hospital OBGYN department. A 1600gm male newborn was delivered vaginally that

later passed away after 10 minutes with no maternal complication.

Then the neonate was evaluated with senior physician and the findings were as follows: there is midline anterior abdominal wall defect extending from umbilicus to lower third of sternum through which liver, bowel lops and heart are eviscerated with no covering membrane. The newborn is born with absent left upper extremity (see Figure 2 below).

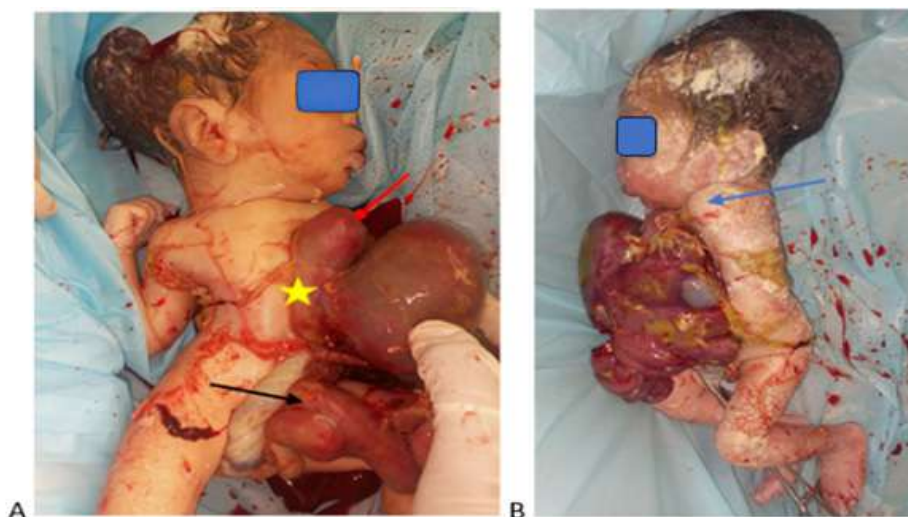


Figure 2: pictures of the neonate immediately taken after delivery: A, eviscerated thoraco-abdominal organs: bowel loops (black arrow), liver (yellow star), heart (red arrow) and B, Absent left upper extremity (blue arrow).

DISCUSSION

In 1958, Cantrell was the first to identify the pentalogy of Cantrell, a severe and rare congenital condition characterized by five anomalies: a midline, upper abdominal wall abnormality; lower sternal defect; anterior diaphragmatic defect; diaphragmatic pericardial defect, and congenital abnormalities of the heart¹. Its incidence is about 5.5 out of every 1,000,000 live newborns live births and the prevalence is nearly three times higher in men than in women^{2,5}.

Cantrell pentalogy's precise etiology is unknown; however, it is most likely complex, involving a mix of environmental and genetic variables⁶. It is hypothesized that a section of the lateral mesoderm failed to form during 14–18 days of gestation and that the rupture of the yolk sac and chorion prevented the chest wall from properly fusing in the midline^{1,7}. Genetic factors implicated in the development of pentalogy of Cantrell include mutations in BMP2 (bone morphogenetic protein2), which is responsible for the normal development of midline structures, and ALDH1A2, which is crucial for the conversion of vitamin A to retinoic acid, which plays a major role in organogenesis, pleuroperitoneal folding, and diaphragmatic embryogenesis^{1,8,9}. The majority of Cantrell pentalogy cases are sporadic. There have been few documented cases linked to trisomy 18 and X linked inheritance^{10,11}.

In 1972, Toyama divided the Cantrell pentalogy into three categories¹². Class 1 (definitive diagnosis), which exhibited all five significant defects and additional primary and minor anomalies. Class 2, probable diagnosis, with four defects present, including intracardiac and ventral wall abnormalities; and class 3, incomplete expression, with various combinations of defects present, including a sternal abnormality. Our case report has all five defects which definitely categorized as class 1.

Malformations can occasionally be so subtle that they are challenging to detect, even after delivery. In 80% of cases, ectopia cordis is frequently linked

to this syndrome^{6,13,14}. For the screening and diagnosis of pentalogy of Cantrell, ultrasound is a vital tool. Pentalogy of Cantrell has been diagnosed by sonography as early as 10–12 weeks of pregnancy, and it should be suspected if an omphalocele and an ectopia cordis are found¹⁵. While high-resolution 2D ultrasound is just as effective as 3D in the early stages of pregnancy [5], employing 3D ultrasound as an adjuvant may improve the visibility of fetal abnormalities in several orthogonal planes¹⁶. In our case we detected all five anomalies on prenatal ultrasound despite the late presentation in the 3rd trimester pregnancy which makes it different from previous case reports from Ethiopia that were diagnosed postpartum^{17,18}.

Critical anatomic features, measurements, and structural information all benefit from three-dimensional CT reconstruction. MRI provides the best evaluation of this syndrome by characterizing ultrasound results and providing additional diagnostic details¹⁹. Additionally, when there is significant oligohydramnios, which makes it impossible to see the fetal parts clearly with ultrasound, MRI can be very beneficial²⁰. But in our case, we didn't offer CT scan and MRI imaging modalities since ultrasound features were typical of pentalogy of Cantrell. The diagnosis is confirmed during postnatal examination (after delivery).

Numerous related abnormalities, such as limb malformations like tibia and radius absence, hypodactyly, and even phocomelia, as well as craniofacial and central nervous system abnormalities such cleft lip and palate, encephalocele, hydrocephalus, and craniorachisis have been documented in the literature^{21,22}. In our case it is associated with phocomelia (absent left upper arm).

Pentalogy of Cantrell is mostly managed based on the severity of the malformations and related abnormalities. The majority of cases carry an extremely poor prognosis, and it is recommended that the pregnancy be terminated. Because of the thoracic cage's hypoplasia, which makes it impossible to contain the ectopic heart,

surgically correcting the abdominal wall defect is frequently challenging in complex situations^{9,23}. A multidisciplinary team must establish the optimal timing of birth and appropriate surgical therapies for mild forms of pentalogy Cantrell. Clearly, those with mild abnormalities have better results^{11,24}. In our case since the prognosis is poor the termination of pregnancy was determined after a thorough discussion with the family.

Conclusion

In the context of complicated pentalogy of Cantrell, this case highlights the vital importance of prompt prenatal screening, thorough counselling, and individualized management planning. We recommend the hospitals to make anatomic scan at 18 to 22 weeks as a routine service pregnant mother.

Ethical Approval

We conducted the case report in compliance with the Declaration of Helsinki, Good Clinical Practices, institutional regulatory requirements. Jimma University Medical Centre Ethical Committee approved it.

Consent for Publication

The patient signed informed consent forms for the use of case details and images for publication and for scientific purposes.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published;

have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work

Disclosure

The author reports no conflicts of interest in this work.

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