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Research Article

MATERNAL AND FETAL FACTORS ASSOCIATED WITH MISOPROSTOL USE IN MUBENDE REGIONAL REFERRAL HOSPITAL, UGANDA

***Kizito OMONA*[1*]** ***Denis KOMAKETCH*[2]**

[1*]Uganda Martyrs University, Faculty of Health Sciences, Kampala, Uganda.
[2] Ministry of Health, Department of Non-communicable Diseases, Kampala, Uganda.
[*] Corresponding author; kizitoomona@gmail.com

Abstract: *There are numerous obstetric uses for misoprostol. It mimics the normal labor process by causing the uterus to contract strongly and by softening and dilating the cervix. This action makes it uterotonic. The maternal uses include cervical ripening, initiating labor, treating incomplete abortions, preventing, and treating postpartum haemorrhage, and causing abortions. This study sought to identify maternal and fetal risk factors related to misoprostol use among mothers who gave birth at the regional referral hospital in Mubende. A mixed-method analytical cross-sectional design was used with mothers, their infants, and healthcare professionals. 385 respondents made up the sample. Interviews, observation, and the review of documents were used to gather the data. 12.4% of mothers had ever used misoprostol. In comparison to mothers who lived in rural areas, urban mothers were two times more likely to have a positive history of misoprostol usage (COR=1.843, 95% CI (0.903-3.763)). Mothers with a parity of 2–4 had a 0.5x lower likelihood of using misoprostol [COR=0.514, 95% CI (0.166–1.595)]. Better APGAR scores of 4-7 (4 times) and 8-10 (2 times) in newborns were associated with a higher likelihood of a positive history of misoprostol use. In conclusion, misoprostol use poses dangers to both the mother and the fetus, necessitating careful observance.*

Keywords: *Misoprostol, Misoprostol use, Parity, Mubende Regional Referral Hospital, Uganda*

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1. Introduction

1.1. Background of the Study

Misoprostol is a synthetic prostaglandin E1 analog that also softens and dilates the cervical mucosa in addition to causing uterine contractions. This drug may be administered orally, vaginally, recto-rectally, buccally, or sublingually [1]. Misoprostol is used off-label for a number of indications in the practice of obstetrics and gynecology [2-4]. These indications encompass but are not limited to, medications for abortion, medical care of miscarriage, labor induction, cervical ripening prior to surgical procedures, and postpartum haemorrhage treatment. Due to its wide range of uses in the area of reproductive health, misoprostol is listed on the WHO Model List of Essential Medicines. Misoprostol causes uterine contractions, cervical softening and dilating, nausea, vomiting, diarrhea, fever, and chills, all of which are dose-dependent [1]. Unsafe abortions and postpartum haemorrhage continue to be the two main causes of maternal mortality worldwide, according to the results of a study that looked at the use of misoprostol in community settings to lower the risk of postpartum haemorrhage. To reduce maternal mortality among women who have limited access to skilled birth attendants, educating community-based birth attendants to administer misoprostol to prevent postpartum haemorrhage

showed promise for success. Therefore, it was believed that the introduction of misoprostol, a generic, low-cost, heat-stable, tablet-form uterotonic, would revolutionize the prevention and treatment of the two leading causes of death in women of reproductive age: postpartum haemorrhage (commonly known as PPH) and unsafe abortion. Misoprostol was found to be both risk-free and efficient in preventing both indications. Following popular acceptance of this viewpoint, Zambia started giving out misoprostol at prenatal appointments in 2010 to help avoid postpartum haemorrhage [5].

According to studies, postpartum haemorrhage (PPH) and unsafe abortions are the two main causes of death for women of reproductive age. Misoprostol's debut and use could revolutionize how these two conditions are prevented and treated. [1-4]. Misoprostol was found to be both risk-free and efficient in preventing both indications.

According to the results of numerous other researches, misoprostol may be used for a variety of obstetric purposes to treat maternal health-related difficulties [6]. It accomplishes this by acting as a uterotonic, which makes the uterus contract hard and also relaxes and dilates the cervix in a way similar to how labor naturally occurs. It has many uses in terms of maternal health, including the prevention and treatment of postpartum haemorrhage, labor induction, treatment of missed and incomplete abortions, treatment of miscarriage, induced abortion, ripening of the cervical cervix before delivery, and uterine instrumentation. Depending on the underlying medical problem being treated, several dosage regimes are used. For labor induction and cervical softening before birth, the dose can be as low as 25 milligrams; however, the dose must be between 400 and 800 milligrams for other purposes [6].

Misoprostol use, however, might have serious negative effects on the mother and fetus. The WHO investigated the efficacy of using various misoprostol doses due to the lack of adequate data from direct randomized comparisons of these doses. They aggregated the outcomes of trials using each dose of the medicine in order to determine the relative efficacy of two different misoprostol doses. The majority of the trials in that review were carried out in settings where the third stage of labor was regularly actively managed. Five trials reported maternal fatalities [7]. Out of the 11 deaths that were reported in these studies [8], eight (8) were among the misoprostol-treated women (RR: 2.0; 95% CI: 0.68-5.83; Peto OR: 2.49; 95% CI: 0.76-8.13). Six of the eight reported maternal deaths in the misoprostol group were related to postpartum haemorrhage [7].

Results also revealed information on maternal fatalities and serious morbidity as reported in studies comparing the contraceptive misoprostol to placebo or other uterotonics in the prevention or treatment of postpartum haemorrhage. Accordingly, when misoprostol was compared to other uterotonics, a similar number of adverse events were reported in both prevention and treatment trials: in the former, 1 of 32 women in both the treatment and control groups (RR: 1.0; 95% CI: 0.07-15.30); in the latter, 16 of 10281 versus 16 of 10292 women, respectively (RR: 1.0; 95% CI: 0.51-1.96). Both in prevention and treatment trials, where misoprostol was compared to a placebo, there were a few more adverse events reported in the misoprostol group: 8 of 2070 versus 5 of 2032 women, respectively (RR: 1.46; 95% CI: 0.52-4.09); 5 of 196 versus 2 of 202 women, respectively (RR: 2.06; 95% CI: 0.52-8.17).

In another investigation, gaps or limitations in the usage of misoprostol were identified. The discovered shortcomings were grouped into six broad thematic categories, including inconsistency in supplies and their delivery, insufficient staffing, providers' and end users' lack of awareness, the lack of drug registration, and concerns about its usage at the provider and policy level [9]. Three (3) incidences of maternal deaths following misoprostol use were documented in another study. However, in two of the cases, the medication was used to facilitate illegal abortions, while in the third, uterine rupture caused a maternal death after misoprostol was taken clinically to induce labor [10].

In Brazil in 1991, there were 288,700 women who needed hospitalization due to misoprostol-related complications from attempts at abortion. Misoprostol was outlawed in Brazil as a whole by Decree 344/98, which was decided upon by the Ministry of Health, as a result of it being discovered to

cause some congenital defects in newborns. Misoprostol use is carefully controlled and limited to hospitals, where it can only be given while being closely monitored by a doctor. One of the more serious issues that afflict a child who does not have an abortion is damage to the central nervous system, which frequently leads to the congenital anomaly known as Moebius syndrome. A facial look that lacks expression and convergent strabismus are both symptoms of Moebius syndrome. It frequently affects both sides of the face and is brought on by a congenital, non-progressive paralysis of cranial nerves VI and VII [11].

It was previously noted in another study that some patients suffered elevated temperatures of at least 40 degrees Celsius following the administration of misoprostol for the treatment of PPH at doses ranging from 600g to 1000g [7]. According to the results of a Brazilian cohort research on pregnant women who received prenatal care in six state capitals, misoprostol-exposed fetuses had a risk of congenital defect that was 2.74 times greater (95% confidence interval: 1,06-7,05) than that of unexposed fetuses in terms of malformations that were identified at birth. Misoprostol was found to have a significant correlation with congenital abnormalities (OR = 2.64; 95%CI: 1.03-6.75), while sex hormones had a positive correlation with congenital abnormalities (OR = 2.24; 95%CI: 1.06-4.74). According to the research, using sex hormones or misoprostol during pregnancy raises the likelihood of congenital abnormalities [12].

The aim of this study was to investigate the maternal and fetal parameters associated with misoprostol use in Mubende Regional Referral Hospital in light of the information provided above.

1.2. Research Questions

The study was guided by the following research questions

1) What is the proportion of misoprostol use among mothers who were delivered from Mubende regional referral hospital?
2) What are the maternal factors associated with misoprostol use among mothers who were delivered from Mubende regional referral hospital?
3) What are the fetal factors associated with misoprostol use among mothers who were delivered from Mubende regional referral hospital?
4) What are the healthcare provider's experiences with misoprostal use in Mubende regional referral Hospital?

1.3. Conceptual Framework

The study was guided by the conceptual diagram (Figure 1). The outcome, misoprostal use is dictated by the interaction of the independent variables ranging from maternal factors, and fetal factors to health provider experiences with misoprostol.

2. Materials and Methods

2.1. Study Design

The research employed a mixed-method analytical cross-sectional design (both qualitative and quantitative). In a cross-sectional study, data are gathered on the entire study population at one time to explore the link between disease (outcomes) and the other factors of interest is why the researcher chose this design (exposures).

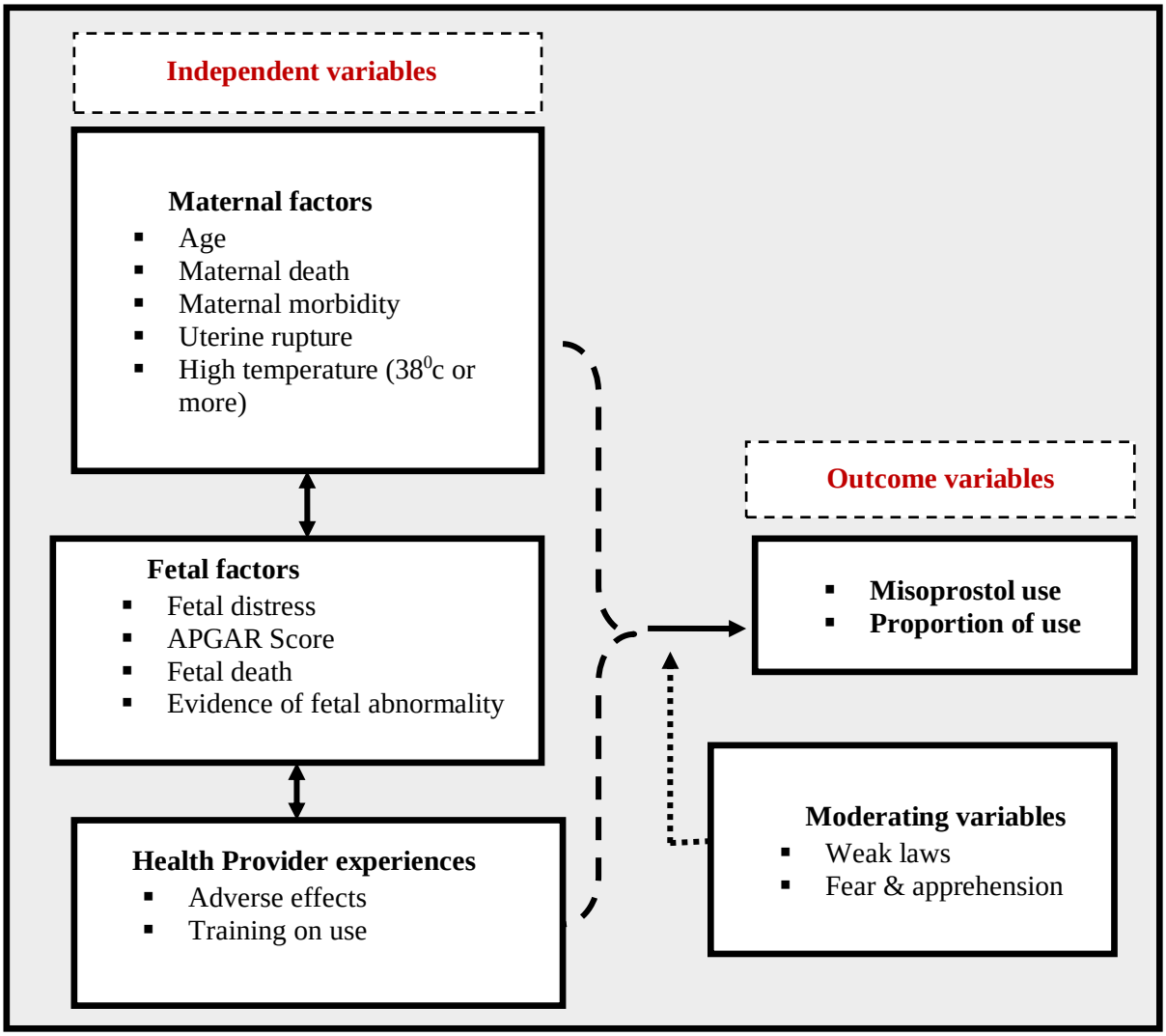

Figure 1. Conceptual Diagram

2.2. The Study Area

Mubende Regional Referral Hospital is in Mubende district in central Uganda, roughly 150 kilometers from Mulago National Referral Hospital. It can accommodate more than 200 beds. It serves the districts of Mityana, Mubende, Luweero, Nakasongola, Nakaseke, Kyankwanzi, Kiboga, and Kasanda as a teaching and regional referral hospital.

Mubende regional referral hospital is one of the over 16 regional referral hospitals supported by the Ugandan Ministry of Health where intern doctors are assigned for additional training by specialists and consultants in medical and surgical fields. The hospital's obstetrics and gynecology department, managed by a consultant obstetrician and gynecologist, treats more than 300 patients and clients per month [13].

2.3. Study Population

The participants in the study included both the mothers and their newborn babies who were delivered at the medical center. Providers of healthcare services were also investigated.

2.4. Eligibility Criteria

All mothers who delivered or babies who were delivered from Mubende regional referral hospital were included and misoprostol use was investigated. All mothers who didn’t deliver from Mubende

regional referral hospital or babies who weren't delivered from Mubende regional referral hospital were excluded from the study.

2.5. Sample Size Estimation

Cochran's formula for calculating sample size (n_0) when the population size (N) is infinite: Cochran (1977) was used [14].

Thus, $n_0 = \frac{Z^2 Pq}{e^2}$

where n_0 is the sample size, z is the specified critical value of desired confidence level, p is the estimated proportion of the attribute in the population = 50%

q= 1 - p

e is the desired level of precision = 5%

Thus; Samples (n_0): $n_0 = \frac{1.96^2 * (0.5) * (1-0.5)}{0.05^2} = \frac{(0.9604)}{(0.0025)}$ = 384.16 = 385 Respondents

Six healthcare providers, working in maternal child health departments were also sampled for qualitative interviews on misoprostol use.

2.6. Sampling Technique and Procedure

Systematic random sampling was used to select the respondents' mothers' patient files with birth information. The first file was ordered serially using a simple random process. Each seventh file was sampled. Repeated until enough samples from mothers and their infants were collected.

For qualitative interviews, six healthcare providers working in maternal child health departments were purposively selected to participate in interviews on misoprostol use.

2.7. Study Variables

Misoprostol use was the dependent (outcome) variable, while the independent variables were maternal factors, fetal factors, and health provider experience.

Age, maternal demise, uterine rupture, and high temperatures were among the maternal variables (38^0C or more). Among the fetal factors were fetal distress, fetal death, and the APGAR score. The experiences of the healthcare practitioners included adverse events and prior misoprostol training. The factors were ineffective laws and apprehension.

2.8. Data Collection Tools and Methods

Document Review Guide (Observation guide) and Interview Guide (for primary data) were used as provided in several studies that have ever used Document Review Guides [15]. On this tool, the kinds of information needed to be taken from each respondent record. This made it easier for the researchers to get the information needed from each patient's record. This Sheet was used as a guide by the researchers to get the right information about each patient.

The qualitative interview guide was also designed for healthcare providers working in the maternal child health department. A set of questions were asked and responses related to misoprostol use were elicited and documented.

2.9. Data Entry, Analysis and Presentation

The SPSS package version 25 was used to process and code the data in accordance with the questions. The study's data were summarized and presented using descriptive statistics, which made use of frequency, tables, charts, and percentages as needed. The data gathered from the interviews with healthcare practitioners was used to establish patterns and linkages within and between categories of data collected.

Qualitative analysis from interviews with healthcare providers was analyzed verbatim.

2.10. Ethical Considerations

The study was approved by the Office of Research Ethics Committee of Mubende Regional Referral Hospital IRB. (Document Number: MRRH/REC/01/15/2019; Date:November 19, 2021). Written informed consent was obtained before enrolling eligible participants into the study. Informed consent was sought, and the consent forms were accessible in English, Luganda, and Runyoro. Confidentiality was maintained.

3. Results

3.1. Background Characteristics of Respondents

Univariate analysis of different background variables was done. The results are shown in Table 1.

Table 1. Background Characteristics of Respondents

Background Variables	n	%
Age in years		
Less than 20 years	80	21.1%
20-40years	298	78.4%
More than 40years	2	0.5%
Education level		
No educ.	262	68.9%
Primary educ.	70	18.4%
Post Primary educ.	32	8.4%
Tertiary educ.	16	4.2%
Residence		
Rural	306	80.5%
Urban	74	19.5%
History of ANC completion		
Completed ANC	320	84.2%
Never completed ANC	60	15.8%
Parity		
Para 1	169	44.5%
Para 2-4	159	41.8%
Para 5+	52	13.7%
Uterine rupture		
Yes	8	2.1%
No	372	97.9%

Table 1 shows that the majority of the respondents 78.4% were aged 20-40 years followed by those aged less than 20 years (21.1%). 68.9% of the respondents had no education followed by those with primary education at 18.4%. 80.5% of the respondents lived in rural areas and most of the respondents completed their antenatal visits (84.2%). Uterine rupture was recorded in 2.1% of the respondents.

3.2. Proportion of Misoprostol Use Among Mothers

The proportion of misoprostol use among mothers who were delivered from Mubende regional referral hospital was determined. Analysis was done using Microsoft Excel and the result is shown in Figure 2 below.

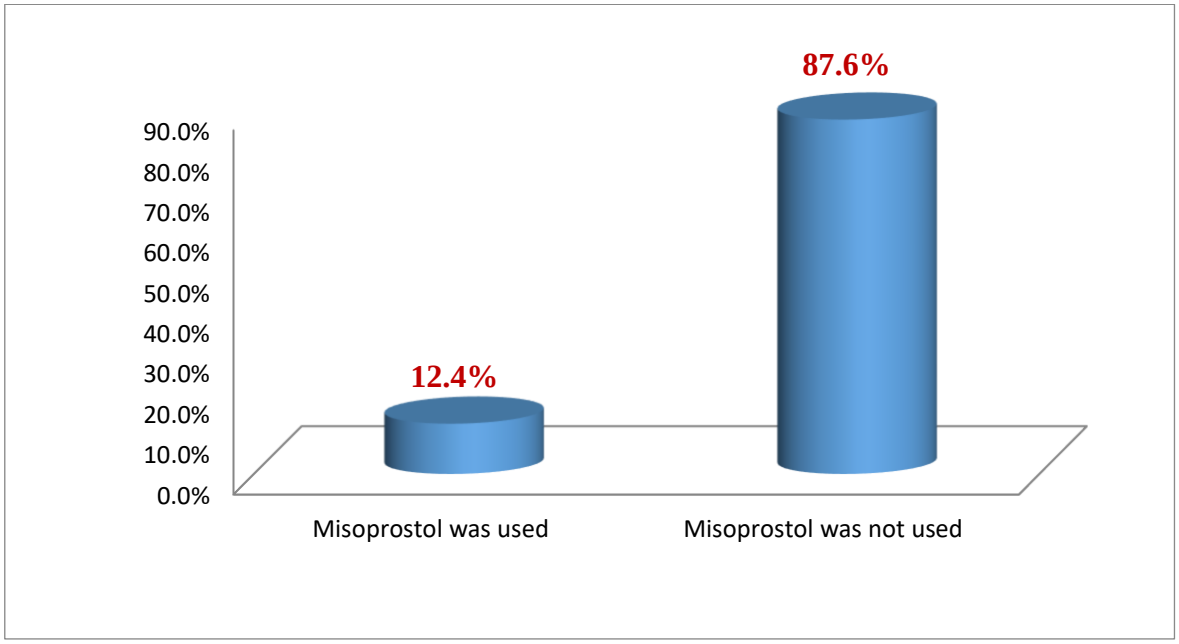

Figure 1. History of Misoprostol Use During Delivery

The study found that misoprostol was used by 47(12.4%) of the mothers during delivery whereas, for the majority 333 (87.6%) of the respondents, misoprostol was not used during their deliveries.

3.3. Maternal Factors Associated with Misoprostol Use Among Mothers

Bivariate regression analysis and cross-tabulation were done to determine the maternal factors associated with misoprostol use among mothers who delivered from Mubende regional referral hospital. The result of the analysis is shown in Table 2.

Table 2. Binary Logistic Regression Analysis of Maternal Factors for Misoprostol Use

Maternal Variables	History of Misoprostol Use		Total	COR, 95% CI(U-L)	P-value
	Used (n=47)	Not used (n=333)			
Age in years					
Less than 20years	8(2.1%)	72(18.9%)	80	Ref	
20-40years	39(10.3%)	259(68.2%)	298	0.778(0.347-1.744)	0.542
More than 40years	0(0.0%)	2(0.5%)	2	-	
Education level					
No educ.	32(8.4%)	230(60.5%)	262	Ref	0.976
Primary educ.	8(2.1%)	62(16.3%)	70	0.800(0.169-3.780)	0.778
Post Primary educ.	5(1.3%)	27(7.1%)	32	0.934(0.175-4.992)	0.937
Tertiary educ.	2(0.5%)	14(3.7%)	16	0.813(0.137-4.823)	0.820
Residence of mothers					
Rural	33(8.7%)	273(71.8%)	306	Ref	
Urban	14(3.7%)	60(15.8%)	76	1.843(0.903-3.763)	0.093

Table 2. Continued

Maternal Variables	History of Misoprostol Use		Total	COR, 95% CI(U-L)	P-value
	Used (n=47)	Not used (n=333)			
History of ANC completion					
Completed ANC	41(10.8%)	279(73.4%)	320	Ref	
Never completed ANC	6(1.6%)	54(14.2%)	60	0.777(0.310-1.951)	0.592
Parity of mothers					
Para 1	24(6.3%)	145(38.2%)	169	Ref	0.485
Para 2-4	19(5.0%)	140(36.8%)	159	0.514(0.166-1.595)	0.249
Para 5+	4(1.1%)	48(12.6%)	52	0.645(0.205-2.022)	0.452
Uterine rupture					
Yes	1(0.3%)	7(1.8%)	8	Ref	
No	46(12.1%)	326(85.8%)	372	0.305(0.023-4.084)	0.369
Co-morbidity					
Yes	1(0.3%)	16(4.2%)	17	Ref	
No	46(12.1%)	317(83.4%)	363	3.965(0.301-52.231)	0.295
History of high temperature					
Yes	0(0.0%)	2(0.5%)	2	Ref	
No	47(12.4%)	331(87.1%)	378	0.000(0.000-0.000)	0.999
Maternal death					
Yes	4(1.1%)	23(6.1%)	27	Ref	
No	43(11.3%)	310(81.6%)	353	0.588(0.174-1.985)	0.392

COR=Crude Odd Ratio, **CI**=Confidence Interval, **U**=Upper, **L**=Lower

Misoprostol was predominantly used on mothers aged 20-40 years (10.3%), with no education (8.3%) and of rural residence (8.7%). Although there was no statistical significance (p=0.093), mothers of urban residence were about 2times more likely to have had a positive history of misoprostol use during delivery [COR=1.843, 95% CI (0.903-3.763)] compared to those of rural residence. Misoprostol was predominantly used on mothers whose parity was one (6.3%) as opposed to those whose parity was more than one. The study found that mothers whose parity lies between 2-4 were 0.5 times less likely to have had misoprostol used during delivery [COR=0.514, 95% CI (0.166-1.595)]. Similarly, mothers whose parity was 5 and above were o.6times less likely to have had misoprostol used during delivery [COR=0.645, 95% CI (0.205-2.022)].

Misoprostol was majorly used on mothers with no co-morbidity (12.1%). The study found that having no co-morbidity was 4times more likely to predispose mothers to misoprostol use in Mubende regional referral hospital [COR=3.965, 95% CI (0.301-52.231)]. Again, mothers who didn't die had more misoprostol use (11.3%) than their counterparts who had maternal death. Most of the mothers who had maternal death (6.1%) didn't have a history of misoprostol use.

In an interview with health workers, the reported observed side effects of misoprostol use ranged from 'Rigors, PPH AND Uterus Rupture' (11.1%) to 'Rigors, Maternal Death AND Uterus Rupture' (33.3%). Other observed side effects were 'Rigors AND Uterus Rupture' (22.2%) and 'PPH AND Uterus Rupture' (33.3%). Only 33.3% of the health workers were adequately trained on the use of misoprostol. When multivariate logistic regression analysis was run, there was no significant finding to report.

3.4. Fetal Factors Associated with Misoprostol Use Among Mothers

Bivariate regression analysis and cross-tabulation were done to determine the fetal factors associated with misoprostol use among mothers who delivered from Mubende regional referral hospital. The result of the analysis is shown in Table 3.

Table 3. Binary Logistic Regression Analysis of Fetal Factors for Misoprostol Use

Fetal Variables	History of Misoprostol Use Used (n=47)	Not used (n=333)	Total	COR, 95% CI(U-L)	P-value
Fetal distress					
Yes	5(1.3%)	20(5.3%)	25	Ref	
No	42(11.1%)	313(82.4%)	355	0.508(0.166-1.557)	0.236
APGAR Score					
0-3	2(0.5%)	34(8.9%)	36	Ref	0.195
4-7	4(1.1%)	49(12.9%)	53	3.932(0.543-28.448)	0.175
8-10	41(10.8%)	250(65.8%)	291	2.043(0.694-6.014)	0.195
Fetal abnormality					
Yes	2(0.5%)	4(1.1%)	6	Ref	
No	45(11.8%)	329(86.6%)	374	0.232(0.033-1.613)	0.140
Fetal death					
Yes	3(0.8%)	34(8.9%)	37	Ref	
No	44(11.6%)	299(78.7%)	343	1.014(0.197-5.214)	0.987

COR=Crude Odd Ratio, **CI**=Confidence Interval, **U**=Upper, **L**=Lower

Of the 25 babies who had fetal distress, only 5(1.3%) had a positive history of misoprostol use during delivery. Babies with no fetal distress were 0.5 times less likely to have had a positive history of misoprostol use during their delivery [COR=0.508, 95% CI (0.166-1.557)]. Babies with better APGAR scores of 4-7 and 8-10 were 4 times and 2 times more likely to have had a positive history of misoprostol use during their deliveries [COR=3.932, 95% CI (0.543-28.448)] and [COR=2.043, 95% CI (0.694-6.014)] respectively. Fetal abnormality was less likely associated with misoprostol use.

Again, when multivariate logistic regression analysis was run, there was no significant finding to report.

3.5. Healthcare Provider Experiences with Misoprostal Use

To determine the healthcare provider experiences with misoprostol use in Mubende regional referral hospital, an interview with six (6) selected healthcare providers was held. In mothers, the reported observed side effects of misoprostol use ranged from 'Rigors, PPH AND Uterus Rupture' (11.1%) to 'Rigors, Maternal Death AND Uterus Rupture' (33.3%). Other observed side effects were 'Rigors AND Uterus Rupture' (22.2%) and 'PPH AND Uterus Rupture' (33.3%). See Figure 3 (a). In newborn babies, the reported observed side effects of misoprostol use ranged from 'IUFD' (11.1%) to 'IUFD and Asphysia' (45%%). See Figure 3 (b).

The study found that only 33.3% of the health workers were adequately trained on the use of misoprostol, presenting poor experience. No observed fetal abnormality was reported by healthcare providers in Mubende regional referral hospital.

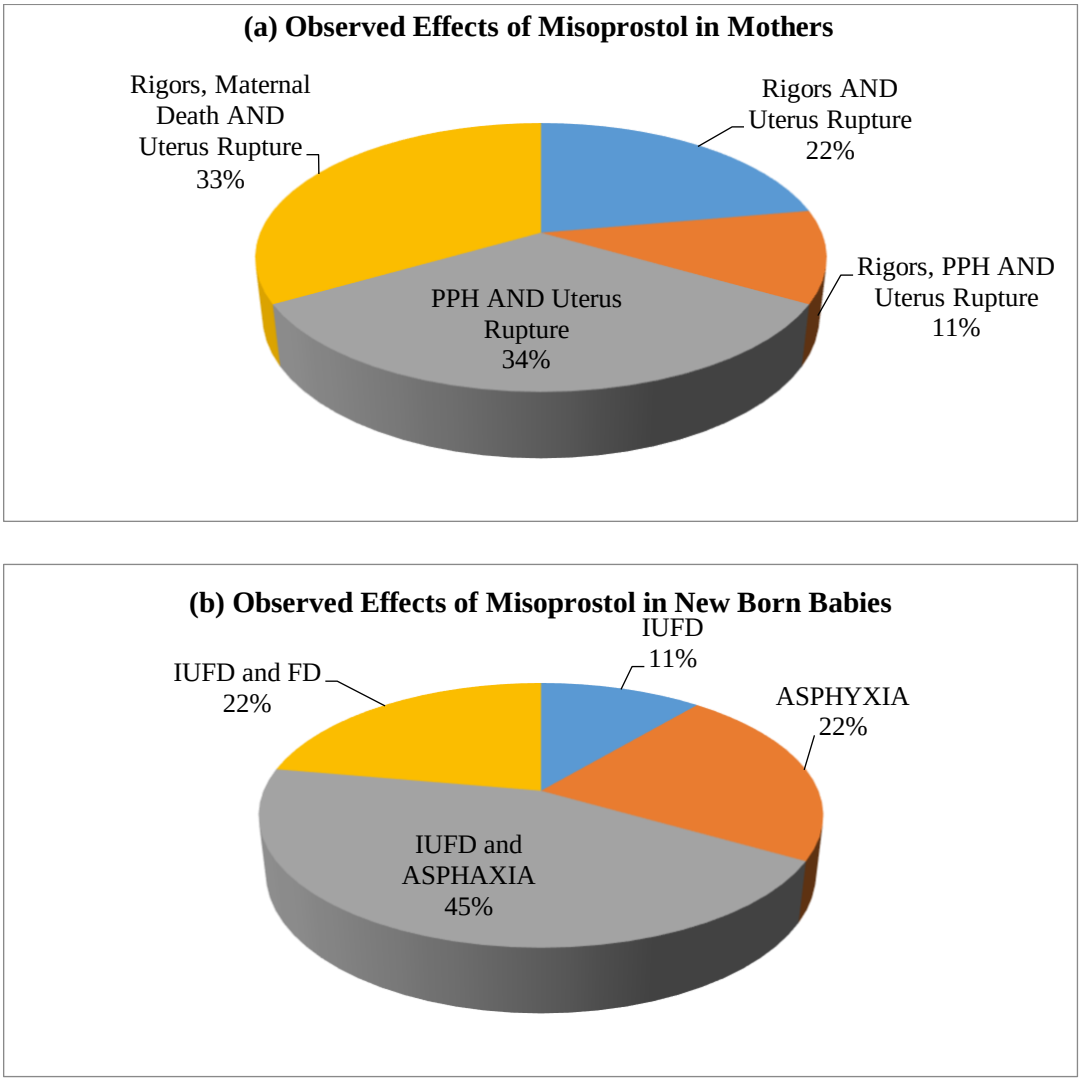

Figure 2. Observed Effects of Misoprostol Use in Mothers & New Born Babies

3.6. Summary of Results

The study found that 12.4% of mothers had previously used misoprostol during childbirth. Although there was no statistical significance (p=0.093), urban mothers were approximately twice as likely as rural mothers to have a positive history of misoprostol use during delivery [COR=1.843, 95% CI (0.903-3.763)]. Misoprostol was predominantly administered to single-parity mothers (6.3%), as opposed to those with multiple births.

The study found that mothers with parity between 2 and 4 were half as likely to have received misoprostol during childbirth [COR=0.514, 95% CI (0.166-1.595)]. Similarly, mothers with a parity of five or more were 0.6% less likely to have used misoprostol during childbirth [COR=0.645, 95% CI (0.205-2.022)]. Misoprostol was predominantly administered to mothers without co-morbidities (12.1%). The study found that the absence of co-morbidities was four times more likely to predispose mothers to misoprostol use at the regional referral hospital in Mubende [COR=3.965, 95% CI (0.301-52.231)]. Again, non-dead mothers had a higher misoprostol usage (11.3%) than their counterparts who experienced maternal mortality. The majority of mothers who experienced maternal death (6.1%) had no history of misoprostol use.

Babies with APGAR scores of 4-7 and 8-10 were 4 and 2 times more likely, respectively, to have a positive history of misoprostol use during delivery [COR=3.932, 95% CI (0.543-28.448) and [COR=2.043, 95% CI (0.694-6.014)].

4. Discussion

4.1. Proportion of Misoprostol Use Among Mothers

According to this study, misoprostol was administered to 47 (12.4%) of the mothers during childbirth. In a recent study to determine maternal outcomes and factors associated with different methods of induction of labour in Zambia [16], misoprostol was used to induce labour in the majority of patients with the vaginal route used by the majority of patients (73.0%).

In a separate study conducted in South West Nigeria, 41 (23.2%) women reported using misoprostol for the first time to induce an abortion [17]. Although few studies have been conducted on the proportion of mothers who use misoprostol, it is evident that its use at the regional referral hospital in Mubende is significantly lower than elsewhere.

4.2. Maternal Factors Associated with Misoprostol Use Among Mothers

In this study, misoprostol was primarily administered to mothers aged 20 to 40 (10.3%), with no formal education (8.3%), and residing in rural areas (8.3%). Although there was no statistical significance (p=0.093), urban mothers were approximately twice as likely as rural mothers to have a positive history of misoprostol use during delivery [COR=1.843, 95% CI (0.903-3.763)]. The study also found that mothers with parity between 2 and 4 were half as likely to have used misoprostol during childbirth. Similarly, mothers with a parity of five or more were 0.6% less likely to have used misoprostol during childbirth [COR=0.645, 95% CI (0.205-2.022)]. Misoprostol was predominantly administered to mothers without co-morbidities (12.1%). A lack of co-morbidity was fourfold more likely to predispose mothers to misoprostol use at the Mubende regional referral hospital [COR=3.965, 95% CI [(0.301-52.231)]]. Adeniyi et al. [18] conducted a study in Nigeria to compare the efficacy of two dosing regimens of vaginal misoprostol for cervical ripening and labour induction (2014). Pregnant women with single, low-risk pregnancies at term were randomly assigned to receive either 25 g or 50 g of vaginal Misoprostol. The group receiving 50 g of Misoprostol experienced more labour complications, including premature labour, tachysystole, and abnormal fetal heart rate changes. In Zambia [16], logistic regression analysis demonstrated that induction of labour (IOL) with misoprostol was associated with maternal age (p 0.001), gravidity (p 0.001), and Parity (p 0.001). In terms of age and parity, there are similarities between this study and a previous one.

4.3. Fetal Factors Associated with Misoprostol Use Among Mothers

In this study, babies born without fetal distress were 0.5 times less likely to have a positive history of misoprostol use during delivery [COR = 0.508, 95% CI = 0.166-1.557%]. Babies with APGAR scores of 4-7 and 8-10 were four- and twofold more likely, respectively, to have a positive history of misoprostol use during delivery. No other comparable study was found to compare with these results.

In this study, fetal abnormality was less likely to be associated with misoprostol use, whereas in Brazil, fetuses exposed to misoprostol had a birth-diagnosed risk of congenital anomaly 2.74 times higher (95% confidence interval [CI]: 1,06-7,05) than those not exposed. Misoprostol was found to be positively associated with congenital anomalies (OR = 2.64; 95%CI: 1.03 to 6.75). Contrary to the findings of the present study, Pizzol et al. [12] found that the use of misoprostol during pregnancy increases the risk of congenital anomalies. Misoprostol is considered a teratogen, according to Allen and O'Brien [2]. Misoprostol exposure during early pregnancy is associated with congenital defects such as

skull defects, bladder exstrophy, arthrogryposis, cranial nerve palsies, facial malformations, terminal transverse limb defects, and Moebius sequence [1, 2]. This result resembles those of a few other studies [19] and those of Orioli and Castillo [20].

4.4. Experiences of Healthcare Professionals with Misoprostal Use

In this study, the adverse effects of misoprostol use in mothers ranged from 'Rigors, PPH AND Uterus Rupture' (11.1% of cases) to 'Rigors, Maternal Death AND Uterus Rupture' (33.3% of cases). 'Rigors AND Uterus Rupture' (22,2%) and 'PPH AND Uterus Rupture' (33,3%) were also observed. The reported adverse effects of misoprostol use in newborns ranged from IUFD (11.1%) to IUFD and Asphyxia (45%). Misoprostol is considered a teratogen [2]. Misoprostol exposure during early pregnancy is associated with congenital defects such as skull defects, bladder exstrophy, arthrogryposis, cranial nerve palsies, facial malformations, terminal transverse limb defects, and Moebius sequence [1]. This result resembles those of Orioli and Castillo [20] and a few other studies [19]. None of these were observed in the current investigation. However, experiences of the effects of misoprostol vary among healthcare providers [19].

5. Conclusion

Even though no congenital abnormalities were observed in this study, this does not negate the fact that misoprostol use may predispose infants to the documented abnormalities. Indeed, misoprostol use poses both maternal and fetal risks, necessitating strict adherence to guideline for use of misoprostol by healthcare professionals who administer this medication. In this study, in an interview with health workers, the reported observed side effects of misoprostol use ranged from ‘Rigors, PPH AND Uterus Rupture’ (11.1%) to ‘Rigors, Maternal Death AND Uterus Rupture’ (33.3%). Other observed side effects were ‘Rigors AND Uterus Rupture’ (22.2%) and ‘PPH AND Uterus Rupture’ (33.3%). Babies with no fetal distress were less likely to have a positive history of misoprostol use during delivery, whereas babies with APGAR scores of 4-7 and 8-10 were four- and twofold more likely to have a positive history of misoprostol use during delivery. Misoprostol use was prevalent among mothers with fewer births.

Additional research is still required on the use of misoprostol. Data related to the study are available with the corresponding author and can be availed on reasonable request.

6. Recommendations

The researcher recommends the following in light of the study's findings:

1) Misoprostol use must be regulated in healthcare facilities by facility managers.
2) Healthcare providers who administer misoprostol to mothers must be more cognizant of the risks posed to both mothers and newborns. Ideally, it should only be used when medically necessary and using the provided guideline for use by the Ministry of Health.
3) Researchers recommend additional research on the use of misoprostol in and outside Uganda in order to bolster the available evidence.

Ethical Statement

The study was approved by the Office of Research Ethics Committee of Mubende Regional Referral Hospital IRB. (Document Number: MRRH/REC/01/15/2019; Date: November 19, 2021). Written informed consent was obtained before enrolling eligible participants into the study. Informed consent was sought, and the consent forms were accessible in English, Luganda, and Runyoro. Confidentiality was maintained.

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Conflict of interest

The authors declare no conflict of interest and declare that there was no external funding for this study

Authors' Contributions

The authors contributed equally to this work.

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