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Original Research

Effectiveness and Safety of Medical Abortion with Mifepristone and Sublingual Misoprostol up to 63 Days of Gestation

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Abstract

Background: The use of medical abortion increases among unplanned pregnant women. The primary objective of this study is to assess the outcomes of using a combination of Mifepristone followed by sublingual Misoprostol for the termination of pregnancy up to 63 gestational days. The secondary objectives were identifying significant factors that contribute to an increased rate of incomplete abortions resulting in surgical intervention and evaluating the safety of this medical procedure. **Methods**: This retrospective cohort study was conducted at Siriraj Hospital, a tertiary care center in Thailand, from July 2021 to December 2023. Women were given 200 mg of oral Mifepristone at the clinic, followed by self-administration of 800 µg of sublingual Misoprostol at home 36–48 hours later. A follow-up visit was scheduled approximately 14 days later to confirm the outcome of the procedure. Demographic and medical data were collected from medical records and subsequently analyzed. The primary outcome was defined as the success of the procedure, indicated by complete abortion without the need for surgical intervention. Secondary outcomes included assessing side effects and complications following medication administration, as well as identifying factors associated with an increased rate of incomplete abortions. **Results**: The final analysis included follow-up data from 205 women. Medical abortion was successful in 70.7% (145 out of 205) of cases, with no ongoing pregancies recorded. No serious side effects or complications were detected. Diarrhea and chills were the most commonly observed side effects. The study found that women with a history of previous abortions and those experiencing significantly heavier bleeding after the procedure were at a higher risk of incomplete abortion, requiring surgical aspiration. **Conclusions**: The regimen of oral Mifepristone followed by sublingual Misoprostol for medical termination of pregnancy is effective and safe through 63 days of gestation. A history of previous abortion and experiencing heavier bleeding after the procedure were identified as risk factors for incomplete abortion.

Keywords: medical abortion; medical induced abortion; medical termination of pregnancy; Mifepristone; Misoprostol; incomplete abortion

1. Introduction

In 2021, Thailand amended its criminal law to allow pregnant women who do not wish to continue pregancy to legally terminate them. Abortion is legally permitted within the first 12 weeks of pregnancy without criminal liability, which has led to an increase in the use of medical abortions. According to a 2020 surveillance report on abortions in Thailand, the majority of women seeking abortion had pregnancies of less than 12 weeks, accounting for 73.7% of cases [1].

The World Health Organization (WHO) has continuously issued guidance on medication-induced abortion. In its latest document in 2022, the WHO states that pregnant women in the early stage of pregnancy can safely perform medical abortion at home without the need for a medical facility, provided that medical personnel provide guidance if necessary [2]. Based on various medical evidence, the WHO states that women with a pregnancy not exceeding 12 weeks can safely use a combination of medications. This regimen includes taking Mifepristone 200 mg orally followed by Misoprostol 800 µg, either buccally, sublingually, or inserted vaginally, at least 24 hours after the first medication [3]. The success rate of this combined medication regimen, as reported in research literature, is approximately 95% to 96.8% [4–7], indicating complete abortion without the need for repeated surgical procedure such as vacuum aspiration. Due to increasing evidence supporting the effectiveness of Mifepristone and buccal Misoprostol, Thailand approved the registration of a single blister pack containing both drugs (Medabon®), for use up to 63 days of gestation in 2014.

A systematic review published in July 2015 revealed a higher efficacy of Mifepristone followed by buccal Misoprostol with a 24- to 48-hour interval compared to a 24-hour interval [4]. However, studies within the 36- to 48-hour interval range are still limited, and there is a scarcity of research involving the Thai and Southeast Asian population. Moreover, although the WHO is flexible on administering Misoprostol through various routes, research on the sublingual route is sparse and limited to a 24-hour interval, with a

Table 1. Characteristics of women undergoing medical abortion procedure at Siriraj hospital.

	Total = 205, N (%)
Age at procedure date, median (IQR)	33.58 (26.75–38.50)
BMI (kg/m^2), median (IQR)	21.23 (18.91–24.63)
Marital status	
Single (%)	55 (26.8)
Married (%)	143 (69.8)
Widowed/Divorced (%)	7 (3.4)
Gravidity, median (IQR)	1 (1–2)
Nulliparous (%)	130 (63.4)
Previous abortions (%)	45 (22)
Previous medical abortions (%)	5 (2.4)
Previous surgical abortions (%)	10 (4.9)
Gestational age at procedure date	
$\leq$42 days (%)	31 (15.1)
43–49 days (%)	85 (41.5)
50–56 days (%)	49 (23.9)
57–63 days (%)	40 (19.5)
Reasons for Termination of pregnancy	
Unintended pregnancy (%)	119 (58)
Financial problem (%)	55/119 (46.2)
Continuing education (%)	26/119 (21.8)
Contraceptive failure (%)	22/119 (18.5)
Separated/Divorced (%)	16/119 (13.5)
Any medical reasons (%)	14 (6.8)
Early embryonic death (%)	72 (35.1)

IQR, interquartile range; BMI, body mass index.

reported success rate of around 94% [8]. Hence, the objective of this study is to evaluate the efficacy of these medications administered sublingually at different intervals and investigate the association between various factors and incomplete abortions leading to surgical procedures.

2. Materials and Methods

After being approved by the ethics committee of Siriraj Institutional Review Board (SIRB Si 014/2024) with a waiver of informed consent, a retrospective cohort study was conducted at the Department of Obstetrics and Gynecology, Faculty of Medicine, Siriraj Hospital, a tertiary care center. The data used in the research was collected from medical records and obtained through interviews and examinations conducted on the day women underwent abortion procedures.

2.1 Methods

In general, individuals seeking medical abortion at Siriraj Hospital undergo confirmation of gestational age through ultrasound examination by obstetricians. If the gestational age is less than 63 days, they are eligible to self-administered abortion at home. Relevant medical and allergy history, along with legal reasons for abortion, are collected from qualifying recipients. Those meeting the criteria and without contraindications to medication receive information about Medabon® (comprising of Mifepristone and Misoprostol) , manufactured by Sun Pharmaceutical Industries Ltd., Gujarat, India. They are provided with comprehensive details on the mechanism of action, administration instructions, post-medication symptoms, and potential side effects by medical personnel. Women also have the opportunity to seek clarification before signing an informed consent to proceed with abortion using the first medication, 200 mg of Mifepristone, orally at the clinic. Subsequently, they are advised to take the second medication, 800 µg of Misoprostol, at home, sublingually 36–48 hours after the first medication. (Sublingual administration consists of placing tablets underneath the tongue for a duration of 20 minutes, followed by swallowing any remaining dissolved particles). Follow-up calls from staff occur approximately 24 hours later. Women will be asked about any side effects, the amount of vaginal bleeding compared to menstrual period, and their pain score using a visual analogue scale (VAS) ranging from 0–10, which is a standard method for assessing pain in medical abortion [9]. An appointment is scheduled for an ultrasound examination to confirm pregnancy termination around two weeks later. Incomplete abortions may lead to additional treatment options, including repeated use of Misoprostol [10] or uterine aspiration [11]. From the start of of pregancy termination, all women receive counseling on continuous contraception methods as recommended as soon as abortion is completed [12].

2.2 Patient Data

The participants selected for this study were pregnant women in the early stage of pregnancy (up to 63 days gestation) who made a voluntary decision to undergo medication-induced abortion for any reason that meets Thailand's legal requirements. To proceed, women must have no contraindications to Medabon® use, such as a history of hypersensitivity to Mifepristone or Misoprostol, inherited porphyria, abnormal bleeding tendencies or concurrent use of anticoagulants, chronic adrenal failure, an intrauterine device insertion, or suspected ectopic pregnancy. Data from a total of 226 eligible participants was collected comprehensively between 1 July 2021, and 31 December 2023.

2.3 Statistical Analysis

Descriptive statistics were used to summarize various demographic variables, presented as mean $\pm$ standard deviation (SD), number and percentage (%), as appropriate. Method efficacy was assessed in women with follow-up data who received ultrasound confirmation by obstetricians. Chi-square tests were used for categorical data and Mann-Whitney U tests for non-normally distributed data as median with interquartile range (IQR). Data was analyzed using version 26 of the Statistical Packages for the Social Sciences (SPSS, IBM Inc., Chicago, IL, USA), with results considered statistically significant at a p-value of$<$ 0.05.

Table 2. Outcomes of medical abortion with Mifepristone following by buccal Misoprostol and contraception after procedure.

	Total = 205, N (%)
Complete abortion	145 (70.7)
By gestational age categories	
≤42 days	25/31 (80.6)
43–49 days	59/85 (69.4)
50–56 days	32/49 (65.3)
57–63 days	29/40 (72.5)
Incomplete abortion undergoing surgical procedure (MVA)	60 (29.3)
Contraception	
None	76 (37.1)
Implant contraception	60 (29.3)
Injectable contraception (DMPA)	34 (16.6)
Oral contraceptive pills	24 (11.7)
Copper IUD	11 (5.4)
Contraceptive use categorized by reasons for termination of pregnancy	
Unintended pregnancy	115/119 (96.6)
Any medical reason	14/14 (100)
Early embryonic death	0/72 (0)

MVA, manual vacuum aspiration; DMPA, depot medroxyprogesterone acetate; IUD, intrauterine device.

3. Results

Out of a total 226 eligible participants, 205 returned for follow-up examinations and had complete data for the final analysis.

The demographic characteristics of all attendees are shown in Table 1. The median age and body mass index of women were 33.58 and 21.23 kg/m^2, respectively. Most were married (143/205, 69.8%) and had no prior children (130/205, 63.4%). About 22% of all women had reported at least one previous abortion. The majority of women visiting the abortion clinic (85/205, 41.5%) had a gestational age of 43 to 49 days, which aligns with previous larger cohorts. The primary reason for seeking abortion was unintended pregnancy (119/205, 58%), with nearly half citing financial issues (55/119, 46.2%) as a contributing factor. Early embryonic death accounted for 35.1% of cases.

Medical abortion with a blister pack of combined Mifepristone and Misoprostol was successful in 145 of 205 women, or a success rate of 70.7%. The success rate was highest at lower gestational ages, specifically under 42 days (80.6%), and decreased as gestational age increased, consistent with previous systematic reviews [4]. The exception was in the gestational age group of 57 to 63 days [13–16]. The mean duration between medications was 43.8 hours (±1.87). A significant number of women, up to 29.3% (60/205), experienced incomplete miscarriage and required uterine aspiration on follow-up examination (Table 2).

After completing the abortion service, the majority of women opted for birth control (129/205, 62.9%), with the most chosen option being implant contraception as shown in Table 2. Upon subgroup analysis, we found that among women who did not wish to become pregnant, contraceptive usage after the procedure was as high as 96.6% (115/119), and it reached 100% (14/14) among those with medical reasons. Although some women chose not to use contraceptive methods, almost all of them belonged to the group who terminated pregnancy due to early embryonic death and they ultimately desired to have children, hence opting not to use contraception during that time.

There were no serious adverse events or side effects documented during the study duration. We found that diarrhea (114/205, 55.6%) was the most commonly encountered side effect, similar to findings in several previous studies [7,14,15,17], followed by chills, which were also frequently observed. Some women experienced itching on the palms of their hands, a side effect not reported in other studies. Only 24 participants out of 205 (11.7%) reported no side effects. The median pain score was 8 on a visual analog scale of 0–10. Most women in the study encountered more bleeding than their usual menstrual period, with a notable 39.5% (81/205) reporting substantially heavier bleeding than previously experienced (Table 3).

Table 4 presents a comparison of factors between the complete and incomplete abortion groups. The age and gestational age of participants in both groups did not show significant differences. Similarly body mass index (BMI), whether categorized as underweight or overweight, did not increase the likelihood of incomplete abortion. However, a history of at least one previous abortion significantly increased the rate of incomplete abortion (33.3% compared with 20%, $p = 0.042$). The median pain score among both groups, measured using the visual analog scale (VAS), was

Table 3. Side effects of Mifepristone following by buccal Misoprostol.

	Total = 205, N (%)
Reported side effects	
Diarrhea	114 (55.6)
Chill	112 (54.6)
Nausea	67 (32.7)
Vomiting	51 (24.9)
Fever	36 (17.6)
Rash	19 (9.3)
Hand itching	9 (4.4)
Dizziness	7 (3.4)
No side effects reported	24 (11.7)
Pain score (VAS of 0–10), median (IQR)	8 (6–9)
Bleeding (compared to menstruation), median (IQR)	3 (3–4)
Less than (1)	9 (4.4)
Equal to (2)	26 (12.7)
More than (3)	89 (43.4)
Much more than (4)	81 (39.5)

VAS, visual analogue scale; IQR, interquartile range.

8, indicating equal levels of pain. Those in the incomplete abortion group experienced significantly heavier bleeding compared to their usual menstrual period. (56.7% compared to 32.4%, $p = 0.001$).

4. Discussion

Our study demosntrated that outpatient medical abortion with oral 200 mg Mifepristone followed by buccal 800 µg Misoprostol 36–48 hours later, up to 63 days of gestation, is a safe method without any serious complications. Although we found a higher rate of vacuum aspiration due to incomplete abortion compared to other studies, medication usage still yielded an efficacy rate of 70.7%.

There are several possible reasons for the lower efficacy rate in our study compared to others. The primary outcome was the the complete expulsion of the conceptus without using any surgical procedure. Participants underwent trans-vaginal ultrasound on the follow-up day to assess for ongoing pregnancy. While no ongoing pregancies were detected in this study, approximately 29.3% of women were suspected of incomplete abortion based on ultrasound or clinical examination of ongoing bleeding. These individuals received guidance on expectant management, an additional dose of buccal Misoprostol, or even vacuum aspiration for further termination of pregnancy, as recommended by various guidelines. All women in the study chose vacuum aspiration, leading to a notably lower success rate compared to other studies. A large systematic review involving 33,846 women discusses the use of a second dose of Misoprostol or expectant management as effective methods in medical abortion [4]. However, it does not provide data on the rate of expulsion after such management, and instead summarizes that most women would naturally expel the pregnancy unless it is an ongoing pregnancy [18]. Therefore, the study could yield different outcomes, potentially increasing the efficacy rate, if women were encouraged to these methods instead of opting for vacuum aspiration to resolve the issue.

In addition, the study excluded 9.3% of women who did not attend follow-up appointments, where participants typically return immediately if they encounter any issues [19]. Therefore, it can be stated that these women may consist of a cohort with no concerns regarding the procedure's safety and effectiveness. However, if they had attended follow-up appointments, it could have increased the documented success rate of the procedure.

Another notable aspect is the utilization of ultrasound to evaluate abortion outcomes, which may introduce bias due to variability in the expertise of the providers. This might result in the misclassification of cases with complete abortion into the incomplete abortion group, as ultrasound findings could be misleading due to blood clots [20] or a thick, heterogeneous appearance of the endometrium [21]. The diagnosis of incomplete abortion should not solely rely on ultrasound criteria; instead, it should involve a quantitative human chorionic gonadotropin (hCG) testing and/or clinical evaluation for a comprehensive assessment [22–24].

Even though ultrasound findings can influence providers' treatment decisions, the study ultimately found a high incidence of uterine vacuum aspiration, up to 29.3%. In 34 out of 38 (89.5%) cases that underwent tissue examination, varying degrees of chorionic villi were found, confirming incomplete abortion. Meanwhile, the other four cases pathologically examined showed only decidua and inflammation. However, despite the unavailability of data for the remaining 22 cases, as they were not submitted for pathology examination, the high confirmation rate of incomplete abortion (89.5%) in those examined supports the

Table 4. Factors compared between complete and incomplete abortion followed by procedure.

	Complete abortion	Incomplete abortion	χ^2/Z-score	*p*-value
	N = 145	N = 60		
GA ≥49 days	61 (42.1)	28 (46.7)	0.365	0.546
Teenage Pregnancy (<20 years)	16 (11.0)	4 (6.7)	0.920	0.338
Advanced maternal age (≥35 years)	63 (43.4)	27 (45.0)	0.041	0.839
Nulliparous	95 (65.5)	35 (58.3)	0.944	0.331
BMI (kg/m^2)			1.896	0.388
Underweight (<18.5 kg/m^2)	25 (17.2)	12 (20.0)		
Normal weight	83 (57.3)	38 (63.3)		
Obesity (≥25 kg/m^2)	37 (25.5)	10 (16.7)		
Previous abortion	29 (20.0)	20 (33.3)	4.148	0.042
Previous surgical abortion	8 (5.5)	2 (3.3)	0.436	0.509
Early embryonic death	52 (35.9)	20 (33.3)	0.119	0.731
Pain score (VAS of 0–10), median (IQR)	8 (6–10)	8 (5–9)	–0.544	0.725
Bleeding (compared to menstruation)			10.445	0.001
Less than to more than (1, 2, 3)	98 (67.6)	26 (43.3)		
Much more than (4)	47 (32.4)	34 (56.7)		
Duration between medications (hours), median (IQR)	44 (42.9–45)	44.4 (43.1–45.3)	–1.212	0.176

BMI, body mass index; GA, gestational age; VAS, visual analogue scale; IQR, interquartile range.

appropriateness of of providers' decisions to proceed with uterine aspiration based on patient preferences.

We found that characteristics such as age, gestational age, body mass index, or primigravida status did not significantly affect the completion of miscarriage following medication use. However, due to the relatively small sample sizes of subgroups such as teenage pregnancy and morbid obesity, we cannot definitively determine whether these factors impact the outcome. In contrast, prior abortion history and blood loss following medication use had statistically significant effects on treatment outcomes. Consistent with earlier studies, women with a history of at least one previous abortion may have a higher likelihood of experiencing surgical aspiration [25]. Similarly, individuals who experienced considerably heavier bleeding than their usual menstrual period after using medication were at an increased risk of incomplete abortion.

There were several limitations in this study. First, there was a lack of data in almost 10% of women participating in our study. Although non-attendance at follow-up appointments might suggest no issues, it cannot be said whether these women may have sought treatment at other hospitals, preventing us from reaching a definitive conclusion on true efficacy of the treatment. However, our study is probably one of the earliest efforts to gather and analyze data on women seeking medical abortion in Thailand. Conducted at a tertiary care center with specialized obstetricians, it provides a representative sample of the broader population. Furthermore, the study population reflects a sample of the Southeast Asian population, which has previously been studied only in Vietnam [14,15] and Singapore [7], with a limited number compared to other global populations.

Due to the significant and clear difference in outcomes between our research and prior studies, further studies should be conducted to determine whether using expectant management or administering additional doses of Misoprostol [11,26] would decrease the rate of surgical abortion, thereby enhancing the effectiveness of medical abortion. While women usually decide to opt for surgical intervention after a follow-up examination based on their own preferences, clinicians should provide information about alternative options if there are no contraindications. Systematic reviews have discussed that the increased rate of surgical intervention is partly due to impatience among both providers and patients [27]. Therefore, greater confidence among providers may also result in a greater willingness to recommend expectant management for incomplete abortions, potentially leading to higher success rates.

5. Conclusions

The regimen of oral Mifepristone followed by buccal Misoprostol for medical termination of pregnancy is highly effective and safe for gestations of less than 64 days. No serious adverse complications were recorded. However, there is a notably high occurrence of surgical procedures, reaching up to 29.3%, which statistically correlates with a history of prior abortions and excessive bleeding post-medication administration. Another contributing factor could be women's preferences, potentially leading to a higher incidence compared to other studies. In response, providers should offer information and guidance regarding expectant management or consider re-administering Misoprostol.

Availability of Data and Materials

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

Author Contributions

NiP and PS designed and performed the experiments. NiP, PS, TW, NaP & NSP collected the data. NiP and PS analyzed the data. All authors drafted and reviewed the manuscript. All authors read and approved the final manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

The research protocol was approved by the Siriraj Institutional Review Board (SIRB Si 014/2024). Informed consent was waived due to the retrospective nature of the study.

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Conflict of Interest

The authors declare no conflict of interest.

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