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Original Article

Obstetrics and Gynaecology Section

Efficacy of Vaginal Misoprostol Administered for Rapid Management of First Trimester Spontaneous Onset Incomplete Abortion in Comparison to Manual Vacuum Aspiration: A Randomised Clinical Trial

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ABSTRACT

Introduction: Both, surgical and medicinal techniques can be used vaginally to treat incomplete abortions. Although, Manual Vacuum Aspiration (MVA) is a safe and efficient surgical treatment for the management of incomplete abortion, it is not frequently offered and is not very cost effective in rural areas, especially in low resource settings. Misoprostol is an alternative to MVA for the treatment of incomplete abortion.

Aim: To assess the effectiveness and acceptability of using vaginal misoprostol for the management of first trimester spontaneous incomplete abortion as an alternative to MVA.

Materials and Methods: A randomised clinical trial was conducted between February 2020 to July 2021 in the Department of Obstetrics and Gynaecology, at RG Kar Medical College and Hospital, Kolkata, West Bengal, India. A total of 144 participants were randomised into two groups with 72 women in each group, to treatment with either MVA or 400 mcg vaginal at three hour intervals. The main outcome measures assessed at 24 hour follow-up were complete uterine evacuation confirmed by transvaginal sonography, and client acceptability and satisfaction were assessed from entry in data form by participants. Chi-square (χ^2) tests were used for categorical data, and the Student's paired t-test was used for continuous data. Statistical significance in all calculations was defined as $p<0.05$ and the study would follow the Intention To Treat (ITT) analysis while computing the results.

Results: The mean ages were 27.44 years (6.8) and 28.47 years (6.6) for the misoprostol and MVA groups respectively. For the gestational age, the mean gestational ages were 8.88 (2.01) and 8.90 (2.17) weeks for the misoprostol and MVA groups, respectively. A higher failure rate in terms of incomplete abortion was encountered in the misoprostol arm compared to the MVA arm. Although this difference in complete uterine evacuation rate did not reach statistical significance (RR=4, 95% Confidence Interval (CI) 0.879-18.192, p=0.0728). Pyrexia appeared to be a significant complication in the misoprostol group compared to MVA group (p=0.038). There was no significant difference in satisfaction in both groups (p=0.659) and no significant difference in acceptability.

Conclusion: As an alternative to surgical intervention, three 400 mcg misoprostol pills could be administered vaginally over the course of three hours to treat spontaneous first trimester uncomplicated incomplete abortion.

Keywords: Client acceptability, Complete uterine evacuation, Satisfaction

INTRODUCTION

According to estimates, up to 10% of clinically confirmed pregnancies and upto 26% of all pregnancies result in miscarriage [1]. Early pregnancy failure is a major public health problem throughout the world. Although, approximately 15% of all pregnancies end in spontaneous miscarriage [2]. Despite the fact that, abortion is legal in India, women still have to overcome significant obstacles that limit their access to safe abortion procedures and put their health at risk. Lack of trained abortion providers, limitations on the availability of services, and excessive costs, all offer challenges that women find unable to overcome quickly. One study estimated that, 15.6 million abortions took place in India in 2015. Of these, 3.4 million (22%) occurred in healthcare Institutions, 11.5 million (73%) were carried out using medical techniques outside of facilities, and 5% are anticipated to have been carried out using other techniques. The study also discovered that there are 47 abortions per 1000 women between the ages of 15 and 49. The report emphasises the necessity of improving the public health system in order to provide facilities for abortion services [3].

Although, surgical procedures like Dilation and Curettage (D&C), Electric Vacuum Aspiration (EVA), and MVA have a high rate of success (91.5-100%), there is a small chance that, they could result in serious complications like infection, cervical laceration, uterine perforation, and frequently anaesthetic risks. Most importantly, due to a lack of skilled staff, restricted access to operating rooms or simply a lack of electricity, surgical management may not be possible in many contexts [4]. Misoprostol provides an effective, safe, and acceptable treatment option for women who do not have access to surgical treatment or who wish to avoid invasive procedures. Because sterile equipment, operating rooms, and professional personnel are not immediately necessary, misoprostol lowers the cost of Post-abortion Care (PAC) services [5]. It is inexpensive, does not require refrigeration, and may be administered by several different routes [6]. Many studies have been done in developed countries and in some African countries like Burkina Faso, Tanzania, South Africa and Uganda documenting the role of misoprostol as a solo agent in the management of early pregnancy failure. But, from author's search of literature, [7-10] very few studies have been done on its role in rapid management (within 24 hours) of early pregnancy failure with vaginal route, especially comparing it to the standard treatment by MVA [11-13]. To assess the full abortion rate within 12 hours, 48 hours, or seven days, inadequate data were available [14]. The present study was designed to fill a gap in the literature by testing the vaginal administration of misoprostol in first

trimester spontaneous incomplete miscarriage, in a hospital setting in a low income country and might find alternative access where those cases can be dealt with medical methods and consequently, could avoid the potential risks of surgical complications, anaesthetic hazards and at the same time, this form of management will lessen the burden over the already overloaded operation theatre.

MATERIALS AND METHODS

A randomised clinical study conducted between February 2020 to July 2021 in the Department of Obstetrics and Gynaecology, at RG Kar Medical College and Hospital, Kolkata, West Bengal, India. Institutional Ethical Committee approval was obtained (RKC/79).

Inclusion criteria: Women who were diagnosed with an incomplete abortion in the first trimester made up the study's subjects. Bimanual examination findings of uterine size 13 weeks gestation, clinical stability, absence of signs of pelvic infection (such as foul-smelling discharge or fever), severe anaemia (admission Haemoglobin (Hb) 7 gm/dL), history of asthma, and consent to hospital admission and study participation were required for inclusion.

Exclusion criteria: Women were uterine size >13 weeks gestation, haemodynamically unstable, cervical injury, product hanging from external Orifice (OS) and subsequently removed digitally, history of previous caesarean section, history of asthma, cardiac, renal, and liver disease and history of allergy to misoprostol were excluded from the study.

Sample size calculation: The present study would require 72 participants in each arm, with an alpha error of 0.05 and an 80% power of study with a 1:1 treatment ratio (a total of 144). Sample size was calculated by using the following formula:

$$n=(Z_{\alpha/2}+Z_{\beta})^2\{p_1(1-p_1)+p_2(1-p_2)\}/(p_1-p_2)^2$$

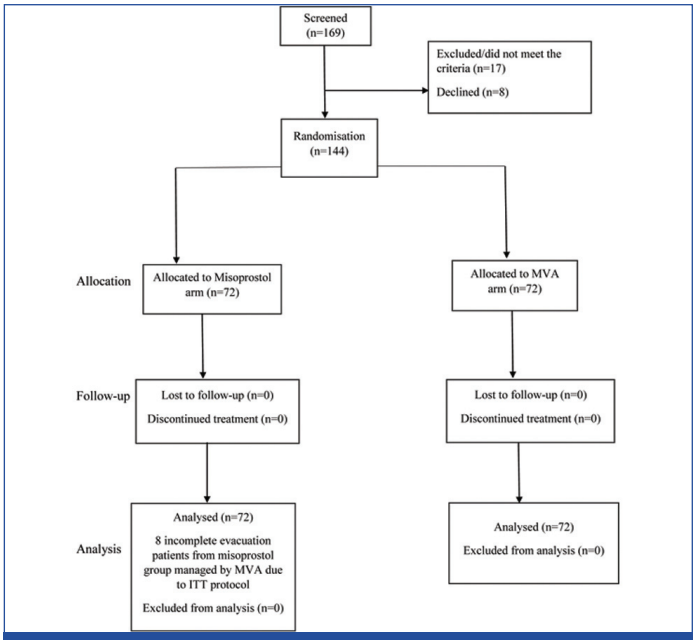
where, $Z_{\alpha/2}$ is the critical value of the normal distribution at $\alpha/2$ (e.g., for a confidence level of 95%, α is 0.05 and the critical value is 1.96), $Z\beta$ is the critical value of the normal distribution at β (e.g., for a power of 80%, β is 0.2 and the critical value is 0.84) and p_1 and p_2 are the expected sample proportions of the two groups.

Study Procedure

In the present study, an incomplete abortion was defined as having a history of amenrrhoea and vaginal bleeding, an open cervical os confirmed by digital and/or speculum examination, and ultrasound evidence of a retained foetus [15]. The efficacy of MVA in managing a case of incomplete abortion is as good as 98% (97-99%) [16-21].

After applying the exclusion criteria, eligible women were enrolled in the study [Table/Fig-1]. The procedure and complications were explained to the women. Written informed consent was obtained from each of them. The women were randomly selected as group A, women were laid in lithotomy position and under all aseptic condition, internal and external os was assessed and received misoprostol tablet (400 mcg) vaginally every three hour for a maximum of three doses regardless of the expulsion of Product Of Conception (POC). While group B, women were laid in lithotomy position and under all aseptic conditions and after assessing internal and external os underwent surgical evacuation by MVA under anaesthesia according to hospital protocol.

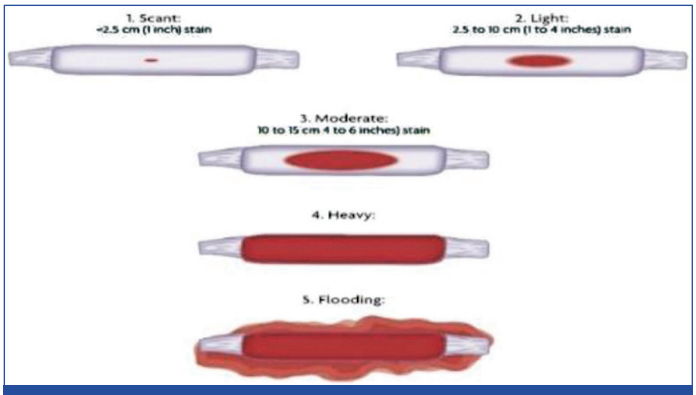
Random code produced by a computer was used for randomisation. An employee who was not a member of the research team utilised the code to seal cards, that said either misoprostol or MVA in sequentially numbered opaque envelopes. The next envelope in the numbered sequence was opened and the woman was given the treatment prescribed when a new participant was enrolled in the trial after meeting the criteria. As a result, neither the researcher nor the data analyst nor the participants was blinded to the allocation. The sonographer conducting the follow-up scan was not aware of the nature of the earlier procedures, though. Detailed history taking was done after counselling and informed permission. If not already



[Table/Fig-1]: The Consolidated Standards Of Reporting Trials (CONSORT) flowchart of the clients throughout the study.

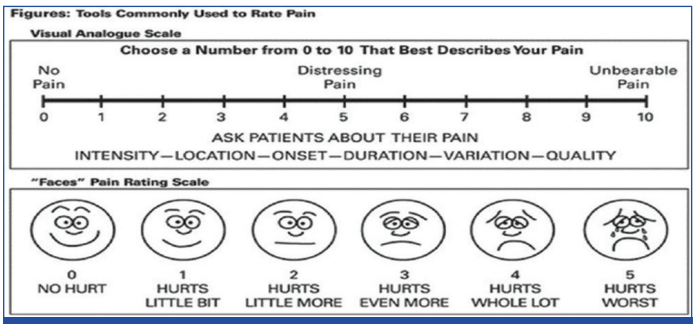
done, a clinical examination and a pregnancy urine test were conducted. All patients had basic autoanalyser Hb level testing using the cyanmethemoglobin technique, blood grouping, and Human Immunodeficiency Virus (HIV) screening. After 24 hours of treatment allocation, Hb testing was done to determine how much blood was lost. When the Hb level was below 7 gm%, blood was transfused.

Following 24 hours from the last dose of misoprostol or surgical evacuation, follow-up Ultrasonography (USG) was done in every case to determine whether the surgery was successful. The primary outcome of the procedure, which was a success, was therefore, either no foetus in a follow-up ultrasound or no need for curettage or repeat curettage. Failure was defined as the presence of heterogeneous and irregular tissue along with a disturbed endometrial echo measuring more than 15 mm in the anteroposterior plane [22,23]. When POC was retained or there was severe vaginal bleeding after misoprostol therapy, surgical evacuation was required. The quantity of procedure related blood loss, any adverse effects, and patient satisfaction were considered secondary outcomes. The change in Hb percentage and the number of pads changed within the first 24 hours of treatment allocation were used to calculate the quantity of blood loss. Only when the pads' exterior surface became soiled did women receive instructions to change them [Table/Fig-2]. Procedure related complications included both subjective and objectively measurable ones, such as fever (100.4°F body temperature) {severe pain judged by a Visual Analogue Scale (VAS) over 7}. From the data form that participants filled out before being discharged, the perceived pain in each group was evaluated and compared.



[Table/Fig-2]: Quantitative visual estimation of bleeding.

The VAS defines 0 as no pain, 1-3 as mild pain, 4-6 as moderate pain, and 7-10 as severe pain [Table/Fig-3] [24]. Anti-D globulin 50 mcg were administered in Rh-negative women. The following day, subjects who had no issues were released. The outcomes were recorded in the format of a predefined proforma. Thus, the effectiveness or completeness of the procedure, safety and side-effects, satisfaction and acceptance were all compared between the two groups. Each participant was questioned whether, she was content or dissatisfied with the therapy, as well as, whether she would choose it again or recommend it to a friend (a retrospective method was employed with verbal probe). The answers provided by the participants to these questions were categorised and quantitatively analysed.



[Table/Fig-3]: Visual Analogue Scale (VAS) for pain.

STATISTICAL ANALYSIS

Information was entered into Statistical Package for Social Sciences (SPSS) version 26.0 (SPSS Inc., Chicago, IL, USA). Analysis was done with the treatment goal in mind. Student's paired t-tests were used for continuous data, and Chi-square (χ^2) tests (with the use of the 2-tailed Fisher's-exact test, when appropriate) were employed for categorical data. The p-value <0.05 was used to determine statistical significance in all analyses, and the study used the ITT approach to compute the results. As a result, it would not take into account noncompliance, protocol violations, withdrawal, or anything that occurs after randomisation. It would only include every subject who was randomised in accordance with the randomised treatment assignment.

RESULTS

A total of 144 women with incomplete abortions were recruited for the study with 72 participants randomly assigned to either misoprostol or MVA treatment. Eight patients with incomplete abortion from misoprostol group were managed by MVA due to ITT protocol. No patient was excluded from the analysis. Participants' ages ranged from 15-45 years. The mean ages were 27.44 years (6.8) and 28.47 years (6.6) for the misoprostol and MVA groups respectively. For the gestational age, the mean gestational ages were 8.88 (2.01) and 8.90 (2.17) weeks for the misoprostol and MVA groups, respectively [Table/Fig-4].

In the misoprostol group, eight women, and in the MVA group, two women had incomplete evacuation they required an additional evacuation by MVA after initial treatment. There was no statistically significant difference in the rates of full evacuation of foetal products between the two therapy groups {RR=4, 95% CI 0.879-18.192, p-value=0.0728} [Table/Fig-5]. The mean induction-abortion interval shown in misoprostol group was about nine hours (8.53±4.43) shown in [Table/Fig-6]. Women with parity 3 or more had significantly shorter induction-abortion intervals compared to primigravida (~5 hours vs ~10 hours) and the more the parity less the tablets requirement were there. The mean requirement of misoprostol in the whole misoprostol group which was 994.45±276.75 mcg. More the parity lesser the requirement of misoprostol tablets i.e., primigravida patients required more tablets compared to multigravida [Table/Fig-7]. There was no significant difference in terms of satisfaction in both groups (p-value=0.659). All the women who had complete evacuation with misoprostol would choose the method again, similarly, the majority of women in MVA group would choose the method again. Reasons for choosing misoprostol again as it is an effective method and to avoid instrumentation (χ^2=39.114, p=<0.001) whereas, the effective and quick (χ^2=30.340, p=<0.001) method are the reasons for choosing MVA again [Table/Fig-8].

The present study encountered vomiting (5/72 in misoprostol vs 2/72 in MVA group) and diarrhoea (2/72 in miso vs 0/72 in MVA group)

Characteristics	Misoprostol n=72 (%)	MVA n=72 (%)	p-value
Age group (years)			
≤17	5 (6.9)	2 (2.8)	
18-24	18 (25)	17 (23.6)	
25-31	31 (43.1)	30 (41.7)	
32-38	14 (19.4)	18 (25)	
39-45	4 (5.6)	5 (6.9)	
Mean±SD	27.44±6.8	28.47±6.6	0.358*
Marital status			
Single	6 (8.3)	4 (5.6)	0.743#
Married	66 (91.7)	68 (94.4)	
Education level			
No formal education	21 (29.2)	13 (18.1)	
Primary	13 (18.1)	15 (20.8)	
Secondary	28 (38.9)	39 (54.2)	0.566#
Postsecondary	7 (9.7)	3 (4.1)	
Postgraduation	3 (4.1)	2 (2.8)	
Occupation			
Student	3 (4.2)	2 (2.8)	
House wife	33 (45.8)	36 (50)	0.831#
Employed	7 (9.7)	9 (12.5)	
Unemployed	29 (40.3)	25 (34.7)	
Parity			
0	24 (33.3)	21 (29.2)	
1	27 (37.5)	32 (44.4)	
2-4	13 (18.1)	12 (16.7)	
>5	8 (11.1)	7 (9.7)	
Mean±SD	1.54±1.81	1.48±1.72	0.838*
Gestational age (weeks)			
5-7	16 (22.2)	18 (25)	
8-10	39 (54.2)	35 (48.6)	
11-13	17 (23.6)	19 (26.4)	
Mean±SD	8.88±2.01	8.90±2.17	0.954*

[Table/Fig-4]: Sociodemographic and other characteristics.
*Student's t-test was used for comparison; SD: Standard deviation; #p-value calculated using Chi-square test

Outcome	Misoprostol n=72 (%)	MVA n=72 (%)	RR (95% CI)	p-value
Complete evacuation	64 (88.9)	70 (97.2)	4.00 (0.879-18.192)	0.0728
Moderate to severe abdominal pain	48 (66.7)	67 (93.1)	0.716 (0.60-0.85)	0.0002
Moderate vaginal bleeding	14 (19.4)	8 (11.1)	2.088 (0.43-4.65)	0.0713
Mean pretreatment Hb (SD) g/dL	9.15 (1.45)	9.57 (1.68)	-	0.110*
Mean post treatment Hb (SD) g/dL	8.87 (1.17)	9.30 (1.53)	-	0.060*

[Table/Fig-5]: Clinical outcome comparison between both the groups.
*Student t-test was used for comparison; SD: Standard deviation; CI: Confidence interval

Parity	Time interval (hours)	Distribution of patients (n=72)	Mean±SD
P_0	✓ 1-4 h ✓ 5-9 h ✓ 10-14 h ✓ 15-19 h ✓ 20-24 h	✓ 2 ✓ 8 ✓ 9 ✓ 2 ✓ 1 } 22	9.86±4.19
P_1	✓ 1-4 h ✓ 5-9 h ✓ 10-14 h ✓ 15-19 h ✓ 20-24 h	✓ 2 ✓ 8 ✓ 11 ✓ 2 ✓ 1 } 24	9.83±4.12
P_{2-4}	✓ 1-4 h ✓ 5-9 h ✓ 10-14 h ✓ 15-19 h ✓ 20-24 h	✓ 7 ✓ 2 ✓ 2 ✓ 0 ✓ 0 } 11	5.27±3.62
$P_{>5}$	✓ 1-4 h ✓ 5-9 h ✓ 10-14 h ✓ 15-19 h ✓ 20-24 h	✓ 3 ✓ 3 ✓ 1 ✓ 0 ✓ 0 } 7	4.79±3.27
Successful abortion by 24 hours	64		8.53±4.43
Failure	8		-

[Table/Fig-6]: Induction-abortion interval.

Parity (No. of patients)	Dose (mcg)	Distribution of patients	Mean±SD
P_0 (24)	400	2	1050±258.76
	800	5	
	1200	17	
P_1 (27)	400	2	1037.03±254.42
	800	7	
	1200	18	
P_{2-4} (13)	400	2	892.30±290.01
	800	6	
	1200	5	
$P_{>5}$ (8)	400	2	850±333.81
	800	3	
	1200	3	
Whole group		72	994.45±276.75

[Table/Fig-7]: Total doses of misoprostol given for induction.

Questionnaire	Misoprostol n=72 (%)	MVA n=72 (%)	χ^2	p-value*
Satisfied with method				
• Yes	58 (80.6)	61 (84.7)	0.194	0.659
• No	14 (19.4)	11 (15.3)		
Would choose same method again				
• Yes	61 (84.7)	64 (88.9)	0.242	0.622
• No	11 (15.3)	8 (11.1)		
Reason for choosing method again				
• Effective method	59 (81.9)	67 (93.1)	3.111	0.078
• Quick and easy treatment	29 (4.1)	61 (84.7)	30.340	<0.001
• Avoid instrumentation	61 (84.7)	23 (31.9)	39.114	<0.001
Would recommend chosen method to friend				
• Yes	58 (80.6)	64 (88.9)	1.341	0.247
• No	14 (19.4)	8 (11.1)		

[Table/Fig-8]: Client acceptability and satisfaction.
*Chi-square statistic (χ^2) p-value calculated with Yates correction

as Gastrointestinal (GI) side-effects but, they were not statistically significant (p-value=0.264 and p-value=0.296, respectively). The present study revealed that, 40.3% (29/72) of women in misoprostol arm experienced a fever of or more than 100.0°F in comparison to no women (0/72) in the surgical arm. This appeared statistically significant (p-value=0.0038).

DISCUSSION

The present trial demonstrated that, for the treatment of uncomplicated spontaneous onset incomplete abortion in the first trimester, three doses of 400 mcg misoprostol, given vaginally at 3 hour intervals, were nearly as successful as MVA. In the present trial, MVA was more efficacious than misoprostol for treating incomplete miscarriage at 97.2% versus 88.9%. The high success rate observed in the misoprostol group is similar to that reported by Fawole A et al., in Ibadan, Ibiyemi KF et al., in Ilorin, Dim C in Enugu, and Chigbu B et al., in Abia [Table/Fig-9] [7,8,25,26]. Similarly, the result of the present study is consistent with studies done in Tanzania, Egypt and Burkina Faso, and also with a recent cochrane review, which indicates that, surgical management is a lot seemingly to induce complete evacuation of the uterus than medical management, though, it failed to reach statistically significant difference in these studies [9,10,27,28]. Weeks A et al., study in Uganda showed results that are the opposite of the ones shown here, with the misoprostol cluster having a little greater success rate than the MVA cluster, albeit the difference was not statistically significant (96.3% versus 91.5%; p=0.43) [29]. The results of the current study demonstrated that MVA is superior to misoprostol in treating incomplete abortion in women between the ages of 8 and 10 weeks' gestation. However, the effectiveness of misoprostol and MVA treatments depends on the doctors' expertise and the misoprostol's quality. Results were clearly different between studies when taking into account a variety of variables, including the dosage of misoprostol administered, the route of administration, the gestational age considered, the centre-specific ultrasonographic definition of a complete abortion, and the permissible time frame before considering the procedure a "failure".

Authors	Place and year of the study	N	Treatment	Success rate (%)
Fawole A et al., [7]	Ibadan, 2012	Miso 90	400 mcg sublingual misoprostol	Miso-92.2
Ibiyemi KF et al., [8]	Ilorin, 2019	Miso 100 MVA 100	600 mcg oral misoprostol and MVA	Miso-83 MVA-99
Dim C [25]	Enugu, 2015	Miso 102 MVA 101	400 mcg sublingual misoprostol and MVA	Miso-86.3 MVA-100
Chigbu B et al., [26]	Abia, 2012	Miso 160 MVA 160	600 mcg oral misoprostol and MVA	Miso-98.8 MVA-100
Shwekerela B et al., [10]	Tanzania, 2007	Miso 150	600 mcg oral misoprostol	Miso-99
Present Study	Kolkata, 2021	Miso-72 MVA-72	400 mcg pervaginal misoprostol 3 h interval maximum 1200 mcg and MVA	Miso-88.9 MVA-97.2

[Table/Fig-9]: Data from various studies shows the comparison of misoprostol vs MVA and their success rate in the management of 1st trimester incomplete abortion [7,8,10,25,26].
Miso: Misoprostol

Similar studies were done in the past that often fell into two categories and banked on two different ways to administer misoprostol for treating incomplete miscarriage. In the first category, the effectiveness of treating incomplete abortion with a single dose of 600 mcg of oral misoprostol versus MVA was evaluated [10,27,29,30]. In the other kind of research, the vaginal route of misoprostol in doses between 600 and 1,200 mcg was employed [25,31-33]. In a study of 148 women, Wong KS et al., showed that, the regimen of vaginal 400 mcg every three hours was more effective than 400 mcg every six hour [34]. The group receiving 400 mcg every three hour had a greater success rate and mean induction-abortion interval within 48 hour. According to Wong KS et al., women who are nulliparous can achieve greater results with 6-hour regimes, whereas, those who have had previous pregnancies benefit more from a 3-hour regimen [34]. Present study also showed similar findings.

The primary follow-up was scheduled 1 to 2 weeks after the administration of misoprostol to assess completion, keeping the

subject in the process of expulsion for the same period, according to the point made in these investigations. However, due to the ambiguity surrounding the completeness, amount of bleeding, and infection, leaving the woman unattended after the administration of misoprostol and fixing the follow-up seven to 14 days later to ensure completion was unacceptable in present situations. With the background of an economical high turnover management strategy, authors had a tendency to therefore, fastened the study protocol for a small period otherwise. Within 24 hours of the end of therapy, authors wanted to assess the procedure's effectiveness, whatever that might be, and then urgently manage the dubious "failures" with surgical intervention. Misoprostol dosages needed to be repeated frequently in the hopes of a quick clearance of POC. The previous researchers chose schedules of either oral 600 mcg single or vaginal 600-1, 200 mcg single to split dosing for carrying out their experiments [10,27,29-33]. Once more, a different study shown that misoprostol vaginally administered for treating incomplete abortions has comparable effectiveness but fewer side-effects than oral treatment [35]. Somewhat lower dose schedule was chosen of 400 mcg misoprostol given vaginally, but to repeat it at short intervals of three hours in order to speed up the process and take into account the low body weight of Indian women (1,200 mcg total). A substantially smaller misoprostol dose also guaranteed that patients would comply with a lower chance of adverse medication effects.

Clinical evaluation of the subjects' follow-up was an option. Completeness is frequently determined by the cessation of bleeding or pain, shrinkage, and firm consistency of the uterus. In fact, the majority of research recommends this clinical follow-up [9,10,29,30]. However, the project strategy for the present study was created with the idea of an early follow-up schedule after the administration of the misoprostol dosage described above. Investigators felt responsible for the early treatment of these so-called "failures" and remained concerned about the possibility of an increase in their frequency. Anywhere that misoprostol was used to treat incomplete abortions, vaginal bleeding looked to be a frequent consequence. The majority of research showed that, misoprostol treatment resulted in more days of vaginal bleeding than surgery [9,29,30,36]. In the present study, the matter with utmost importance was reviewed as most of the women of rural India are already anaemic. The present study showed that, 19.4% (14/72) women in misoprostol and 11.1% (8/72) women in surgical arm experienced mild to moderate bleeding episodes. This difference, though, didn't seem to matter statistically. The difference in pre and post-treatment Hb percentages and the quantity of blood-soaked pads thrown away within the first 24 hours can both be used to measure blood loss indirectly. The current investigation found no statistically significant difference between the two groups in regards to the aforementioned criteria. The authors presume that, because the study was limited to hospitalised patients and finished quickly, there was very little chance of missed blood loss or a lack of appropriate care, when it was actually needed.

Misoprostol's side-effects can include pyrexia, vomiting, diarrhoea, and shivering. When bigger doses are given orally or sublingually, the incidence increases. However, all other comparable studies showed no statistically significant increase in gastrointestinal side-effects when compared to surgical methods, where misoprostol was applied vaginally, with the exception of the study by Zhang J et al., who observed a higher incidence of gastrointestinal side-effects in their cohort using a higher single vaginal dose of 800 mcg [31-33,37]. The present study encountered vomiting (5/72 in miso vs 2/72 in MVA group) and diarrhoea (2/72 in miso vs 0/72 in MVA group) as Gastrointestinal (GI) side-effects but they were not statistically significant (p-value=0.264 and p-value=0.296, respectively). As a parameter of comparison, fever, another typical side-effect brought on by the drug's action (prostaglandin E1 analogue) on the central thermoregulatory centre, could be quantitatively quantified. The current subjects reported excellent satisfaction with both misoprostol and MVA, as in prior trials [9,29]. In research by Shwekerela B et al., the misoprostol group had a considerably higher percentage of participant satisfaction than the MVA group (75% versus 55%; p=0.001) [10]. This conclusion was in contrast to other studies' findings. In line with the findings of Dao B et al., a sizably high proportion of participants in both groups in the present study showed a wish to recommend their treatment method to a friend and would use the same approach again [9]. The difficulty and anxiety associated with MVA in the MVA group, as well as, the simplicity of merely inserting three misoprostol tablets may have contributed to lower customer acceptance and satisfaction among women who underwent MVA.

Limitation(s)

It was not possible to apply blinding of any form in the study because of the study design. Because, it was a single centre study, the findings could be generalised to the entire study area. The external validity is thus, constrained. As the present study was a hospital-based study, the authors captured only women seeking specialist medical care. Within 24 hours of the end of therapy, the authors wanted to assess the procedure's effectiveness, whatever that might be, and then quickly manage the ostensible "failures" with surgical intervention. If a second follow-up was scheduled for the so-called "failures" after one week, rather than choosing to have the surgery immediately cleared, the success percentage might be higher. Long-term follow-ups to cases and subsequent pregnancy rates in both arms of the study were not carried out.

CONCLUSION(S)

As an alternative to surgical intervention, three 400 mcg misoprostol pills could be administered vaginally over the course of three hours to treat spontaneous first trimester uncomplicated incomplete abortion. This dose regimen is thought to be very efficient and secure for completing the abortion process in under 24 hours.

Acknowledgement

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