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Comparison of side effects: "Vaginal versus oral misoprostol in the management of the first-trimester missed abortion"

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Abstract

Introduction: In recent years, the use of oral or vaginal misoprostol has grown in popularity. The therapeutic potential of misoprostol as an abortifacient has clearly been demonstrated in a randomized study. Misoprostol is active and safe both by oral and vaginal routes but the latter has been found to be better in many trials.

Aim of the Study: Aim of the objective is to compare the efficacy and safety of vaginal misoprostol to oral misoprostol for the treatment of first-trimester missed abortion.

Methods: The study was conducted in the Gynaecology and Obstetrics Department of Shaheed Ziaur Rahman Medical College Hospital in Bogra over a period of 6 months, from May 2015 to October 2015. The participants included women diagnosed with miscarriage, based on both their medical history and physical examinations, and referred from the outpatient department for admission. The diagnosis of missed miscarriage was confirmed by sonography. Only women who met the specified inclusion and exclusion criteria were enrolled, leading to a total sample size of 118 participants, divided into two groups of 59 each.

Results: In both groups most of the respondents were in the "20–25 years" age group; out of the 59 respondents each in groups, 33.9% of Group A and 42.4% of Group B were in the age group. Mean ± standard deviation (SD) of age was calculated to be, (24.60 ± 3.049) for Group A and Group B (23.98 ± 2.387). Both groups had a similar type of distribution of the length of menstrual cycle. Out of the 118 respondents, only 11 (9.3%) had a previous miscarriage. 89.8% of Group A and 91.5% of Group B had not experienced abortion before. About two-fifths of the respondents in both groups (42.4% Group A and 37.3% Group B) were primigravidae. Among 2nd gravidae Group B (18) were double in count to Group A (9). Mean ± SD was calculated for Group A (1.81 ± 1.004) and Group B (1.78 ± 1.018). About 10.9 weeks was the average period of gestation for both groups. Both Group A and Group B had similar types of distribution. More than three-fourths of group B (45 [76.3%]) had successfully achieved complete expulsion of the conceptus; while in group A less than half of that (22 [37.3%]) had complete expulsion. Incomplete expulsion accounted to be 2½ times higher in Group A and "No expulsion" was 4 times as high as Group B.

Conclusion: Per vaginal administration of Misoprostol in the posterior fornix is more effective than Oral Misoprostol. The former has a faster onset of action and better efficacy. Per vaginal Misoprostol has less side effects.

Keywords: Misoprostol, missed abortion, sonography.

Introduction

One of the most frequent pregnancy problems, first-trimester miscarriages occur in 10–15% of clinically recognized pregnancies.[1] Nearly one-third (30%) of maternal deaths worldwide occur in South Asia (Bangladesh, Nepal, India, Pakistan, and Sri Lanka), a heavily populated, resource-constrained, and undeveloped region. Of these, roughly 13% are related to abortions and its procedures.[2] The abortion rate in Pakistan is 29/1000 women aged 15–49 years, whereas 890,000 women present with missed or incomplete abortions each year. Over the past 50 years, dilatation and uterine evacuation have been the standard, well-recognized treatment for early pregnancy failure, with a success rate of over 95%.[3,4] The focus has shifted to expectant and medical management with a major cost advantage due to the difficulties (sepsis and hemorrhage) connected with the surgery when performed by unskilled personnel, which is prevalent in low-resource countries.[5] Although expectant management is an option for incomplete spontaneous abortion, patients may find it less appealing due to its suboptimal success rate (25–76%), unpredictable interval to spontaneous expulsion, uncertainty and anxiety, and emotional trauma associated with carrying a non-viable pregnancy.[6,7] For women who are unfit for general anesthesia or do not want to be admitted to the hospital, medical care for early pregnancy failure provides a safe, effective, and affordable alternative to surgery.[8] A safe alternative that is becoming more and more well-liked due to its uterotonic and cervical priming effects is misoprostol, an analog of prostaglandin E1. It is stable at room temperature and reasonably priced. The oral, vaginal, sublingual, and rectal routes of misoprostol delivery were examined in pharmacokinetic research.[9] Due to the buccal mucosa's strong vascularity, the sublingual route has the highest bioavailability when compared to other routes, avoids the first pass effect through the liver, and has the shortest time to peak concentration of 30 min as opposed to 75 min for the vaginal route. In addition, it avoids uncomfortable vaginal administration and is more convenient for women to consume.[10-12] Shivering, overheating, and gastrointestinal side effects are the main disadvantages.[12] Misoprostol's effectiveness in treating early pregnancy failure has been assessed in over 20 different trials; the success rate ranges from 13 to 100% and is impacted by a number of variables, including diagnosis, sac size, and dosage frequency. In comparison to a manual Hoover aspirator, two recent trials reported effectiveness rates of over 90%.[13,14] For first-trimester failures, there are several dose regimens published in the literature that are administered through various ways; however, very few use the sublingual route. When the embryo dies and fails to develop, the gestational sac is retained in the uterus for several weeks and even months, the condition is known as "Missed Abortion." Mild symptoms, such as those of threatened abortion are followed by the absence of usual signs of progress of pregnancy. Sometimes there may be no bleeding and the condition is diagnosed clinically when the doctor notices that the uterus is not increasing in size. The uterus may be found smaller than would be expected and an ultrasonographic scan will reveal the true state of affairs.[15] The standard treatment for missed abortions for the past 50 years has been dilatation and curettage which is typically done in an operating room, thus significantly increasing the costs.[16] The surgical method of abortion carries several risks, such as hemorrhage, uterine perforation, incomplete abortion, cervical injury, and intrauterine adhesions.[17] In recent years, the use of oral or vaginal misoprostol has grown in popularity. Infection, hemorrhage, acute hematometra, and retained tissue are among the most common complications. Induced abortion does not harm women's reproductive capacity. Pre-mature birth, infertility, ectopic pregnancy spontaneous abortion, and adverse pregnancy outcomes are not increased in frequency in abortion.[18] The aim of the objective is to compare the efficacy and safety of vaginal misoprostol to oral misoprostol for the treatment of first-trimester missed abortion.

Methods

The study was conducted in the Gynecology and Obstetrics Department of Shaheed Ziaur Rahman

Medical College Hospital (SZMCH) in Bogra over a period of 6 months, from May 2015 to October 2015. The participants included women diagnosed with miscarriage, based on both their medical history and physical examinations, and referred from the outpatient department for admission. The diagnosis of missed miscarriage was confirmed by sonography. Only women who met the specified inclusion and exclusion criteria were enrolled, leading to a total sample size of 118 participants, divided into two groups of 59 each. The sampling technique employed was purposive and convenient. The inclusion criteria required participants to have a gestational period of <13 weeks, as confirmed by ultrasound (USG), to be hemodynamically stable with a hemoglobin level of more than 10 g/dL, to have a closed cervical os, an axillary temperature of <37.5°C, no history of inflammatory bowel disease, and no allergy to misoprostol. The exclusion criteria ruled out women with incomplete miscarriage, gestational age over 13 weeks, gravidity of five or more, retained products of conception, a history of cesarean section, cardiorespiratory disorders, hemoglobin levels below 8 g/dL, or those unwilling to give consent. The women selected were then sequentially allocated into one of two groups. Group A received oral misoprostol, and Group B received vaginal misoprostol. In Group A, 400 µg of misoprostol were administered orally and repeated every 4 h, up to a maximum of three doses if necessary. In Group B, 400 µg of misoprostol were inserted into the posterior vaginal fornix, with a second dose administered after 4 h if required. The outcome was assessed over the next 10–12 h using transabdominal sonography to document complete, incomplete, or no expulsion. Data analysis was conducted using the Statistical Package for the Social Sciences statistical software package (version 26 for Windows). This study received approval from the Ethical Committee of the Bangladesh College of Physicians and Surgeons.

Results

A total of 118 cases were included in this study and they were divided into two groups (Group A - 59 and Group B - 59) cases.

The table 1 shows that in both groups most of the respondents were in the "20–25 years" age group; out of the 59 respondents each in groups, 33.9% of Group A and 42.4% of Group B were in the age group. Mean ± standard deviation (SD) of age was calculated to be, (24.60 ± 3.049) for Group A and Group B (23.98 ± 2.387). The $P = 0.7597$ for the *t*-test and 0.7819 for the Chi-square, which means there was no statistical difference in age distribution between the groups.

The Figure 1 shows that, about two-fourth of the participants in group A (23 [39.0%]). And half of the participants in Group B (29 [49.2%]) were Rural dwellers. Urban dwellers were counted as (23 [39.0%]) among Group A and (21 [35.6%]) among Group B. There was no statistically significant difference in the distribution as chi square calculated the $P = 0.470011$.

The table 2 explains that, in both groups, respondents were basically from middle and low socio-economic classes. Chi-square calculates, $P = 0.6$; which explains that there was no significant statistical difference in the groups.

According to table 3, about two-fifths of the respondents in both groups (42.4% Group A and 37.3% Group B) were primigravidae. Mean ± SD was calculated for Group A (1.81 ± 1.004) and Group (1.78 ± 1.018). There was no statistically significant difference in gravidity among the groups ($P = 0.8722$ for the *t*-test and 0.571608 for the Chi-square).

Out of the 118 respondents, only 11 (9.3) had a previous miscarriage. As per the Figure 2, 89.8% of Group A and 91.5% of Group B had not experienced abortion before. There was no statistically significant difference ($P = 0.75183$).

The Table 4 shows that about 10.9 weeks was the average period of gestation for both groups. Both Group A and Group B had similar type of distribution and there was no statistically significant difference in gravidity among the groups ($P = 0.9839$ for the *t*-test and 0.9324 for Chi-square).

According to table 5, more than three-fourths of the Group B (45 [76.3%]) had successfully achieved complete expulsion of the conceptus; while in Group A less than half of that (22 [37.3%]) had complete expulsion. Incomplete expulsion accounted to be 2½ times higher in Group A and "No expulsion" was 4 times as high as Group B. There was a statistically significant difference in terms of achieving successful expulsion among the groups ($X^2 = 18.54$; df = 2; $P \leq 0.001$).

As per figure 3, the respondents with incomplete expulsion and the non-responsive were assessed for cervical permeability during surgical management; both groups showed similar patterns of distribution. This was also proved statistically as, $X^2 = 0.15$; df = 1; $P = 0.6985$.

The Table 6 shows that the incidence of nausea was higher among respondents of Group A (35.6%) than Group B (23.7%) (relative risk [RR] 1.5; odds ratio [OR] = 1.7763; 95% confidence interval [CI] = 0.7963–3.9626). Incidence of vomiting was higher among respondents of Group A (RR 2.33; OR = 2.5128; 95% CI = 0.617–10.2329). The higher number of respondents of Group A had experienced severe pain as a side effect of Misoprostol. (RR 1.40; OR = 1.4538; 95% CI = 0.4339–4.8713). Incidence of diarrhea had a similar rate of occurrence among respondents of both Groups. (RR 0.83; OR = 0.8179; 95% CI = 0.2353–2.843). Same number of respondents (3 [5.1%]) of both Groups had hyperpyrexia (RR = 1; OR = 1; 95% CI = 0.1935–5.1688).

Discussion

This study was aimed to compare the efficacy and safety of vaginal misoprostol to oral misoprostol for the treatment of missed abortion at SZMCH. Although efficacy was the primary subject of the study, socioeconomic variables and side effects have also been reported. A total of 118 respondents (59 Group A and 59 Group B) were included in this study. In both groups, most of the respondents were in the "20–25 years" age group; out of the 59 respondents each in groups, 33.9% of Group A and 42.4% of Group B were in the age group. Mean ± SD of age was calculated to be, (24.60 ± 3.049) for Group A and Group B (23.98 ± 2.387). The $P = 0.7597$ for the *t*-test and 0.7819 for the Chi-square, which means there was no statistical difference in age distribution between the groups. ($X^2 = 1.08$; df = 3; $P = 0.7819$) in the year 2002–2003 by Rita *et al*., compared two groups in age ($X^2 = 0.27$, df = 2, $P = 0.87$). Gravidity ($X^2 = 3.08$, df = 3, $P = 0.37$), residential status ($X^2 = 0.37$, df = 2, $P = 0.53$), and period of gestation ($X^2 = 0.60$, $P = 0.89$). There were no significant statistical differences.[17] Jalil S Nausheen V, Akhter AZ 2010 found the mean age of patients was 26.2 + 4.17.[19] About two-fourths of the participants in Group A (23 [39.0%]) and half of the participants in Group B (29 [49.2%]) were rural dwellers. Urban dwellers were counted as (23 [39.0%]) among Group A and (21 [35.6%]) among Group B. There was no statistically significant difference in the distribution as the Chi-square calculated the $P = 0.470011$. ($X^2 = 1.51$; df = 2) In both groups, respondents were basically from middle and low socioeconomic classes. The Chi-square calculates, $P = 0.6$; which explains that there was no significant statistical difference in the groups. There was statistically no difference between the two groups in the length of the menstrual cycle ($P = 0.4285$ for the *t*-test and 0.8437 for the Chi-square). Both groups had a similar type of distribution of the length of the menstrual cycle. ($X^2 = 0.34$; df = 2; $P = 0.8437$). Out of the 118 respondents, only 11 (9.3%) had a previous miscarriage. 89.8% of Group A and 91.5% of Group B had not experienced abortion before. There was no statistically significant difference. ($X^2 = 0.1$, df = 1; $P = 0.75183$). About two-fifths of the respondents in both groups (42.4% Group A and 37.3% Group B) were primigravidae. Among 2nd gravidae Group B (18) were double in count to Group A. (9) Mean ± SD was calculated for Group A (1.81 ± 1.004) and Group B (1.78 ± 1.018). There was no statistical significant difference in gravidity among the groups ($P = 0.8722$ for the *t*-test and 0.228 for the Chi-square). ($X^2 = 4.33$; df = 3). Out of the 118 respondents, only 11 (9.3) had a previous miscarriage. As per the above

Table 1: Distribution of the participants by their age (*n*=59)

Age	Group A	Group B	*t*-test	*P*-value
<20 years	15	12	0.3202	0.7597
20–25 years	20	25		
25–30 years	19	17		
>30 years	5	5		
Total	59	59		
Mean±SD	24.6±3.049	23.98±2.387		

X^2=1.08, df=3; *P*=0.7819. SD: Standard deviation

Table 2: Distribution of the patients by their socioeconomic status (*n*=59)

Socio-economic	Group A	Group B	X^2	*P*-value
High	7	6	0.6	0.74082
Middle	33	30		
Low	19	23		
Total	59	59		

Table 3: Distribution of the respondents by their gravidity (*n*=59)

Gravidity	Group A	Group B	*t*-test	*P*-value
Primi	25	22	0.1612	0.8722
Multi	34	37		
Total	59	59		
Mean±SD	1.81±1.004	1.78±1.018		

X^2=0.32; df=3; *P*=0.571608. SD: Standard deviation

Figure, 89.8% of Group A and 91.5% of Group B had not experienced abortion before. There was no statistically significant difference ($P = 0.75183$). About 10.9 weeks was the average period of gestation for both groups. Both Group A and Group B had similar type of distribution and there was no statistical significant difference of gravidity among the groups ($P = 0.9839$ for the *t*-test and 0.9324 for the Chi-square). ($X^2 = 0.14$; df = 3) Chawla 2006 found that. The gestational age ranged from 8 to 22 weeks. 21 out of 30 patients were primigravidae and the rest were multigravidae.[20] At Hamdard University Hospital, the majority of women were multiparous, median parity was 3, range (0–6). Mean gestational age 10.0 + 2.5 weeks. More than three-fourths of the

Table 4: Distribution of the respondents by their period of gestation (weeks)

Gravidity	Group A	Group B	Tt-test	*P*-value
<10 weeks	16	17	00.0202	00.9839
>10 weeks	26	24		
11–12 weeks	17	18		
Total	59	59		
Mean±SD	10.89±2.732	10.88±2.648		

X^2=0.14; df=3; *P*=0.9324. SD: Standard deviation

Table 5: Distribution of the respondents by their successful expulsion of conceptus effects (*n*=59)

Expulsion of conceptus	Group A (*n*=59)	Group B (*n*=59)	X^2-test	*P*-value
Complete	22	45	18.54	<0.001
Incomplete	29	12		
No	8	2		
Total	59	59		

group B (45 [76.3%]) had successfully achieved complete expulsion of the conceptus; while in group A less than half of that (22 [37.3%]) had complete expulsion. Incomplete expulsion accounted to be 2½ times higher in Group A and "No expulsion" was 4 times as high as Group B. There was a statistically significant difference in terms of achieving successful expulsion among the groups ($X^2 = 18.54$; df = 2; $P < 0.001$). For both the groups higher dose was required for successful expulsion. Mean number of doses for Group A was 2.41 and Group B was 1.69. The difference in the number of doses required was statistically significant ($P = 0.0201$ for the *t*-test and <0.0001 for the Chi-square). ($X^2 = 29.9$; df = 2). Respondents of the Group A required a longer duration to complete successful expulsion (Mean ± SD = 9.45 ± 1.405); whereas the Group B needed much less time (Mean ± SD = 7.69 ± 2.8906). The respondents with incomplete expulsion and the non-responsive were assessed for cervical permeability during surgical management; both groups showed similar patterns of distribution. This was also proved statistically as, $X^2 = 0.15$; df = 1; $P = 0.6985$. In Jammu, nearly 90% of women in both groups had

Table 6: Distribution of the respondents by their side effects

Side effects	Group A	Group B	RR	OR	95% CI
Nausea	21	14	1.5	1.7763	0.7963–3.9626
Vomiting	7	3	2.33	2.5128	0.617–10.2329
Severe pain	7	5	1.4	1.4538	0.4339–4.8713
Diarrhea	5	6	0.83	0.8179	0.2353–2.843
Hyperpyrexia	2	3	1	1	0.1935–5.1688
Total	42	31			

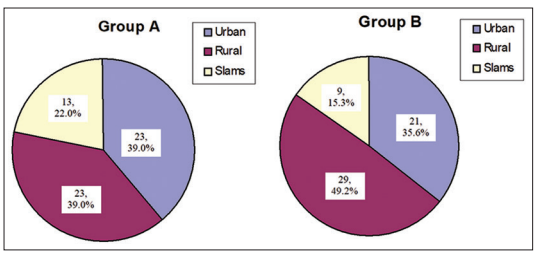

Figure 1: Distribution of the respondent by their area of residence. X^2=1.51; df=2; *P*=0.470011

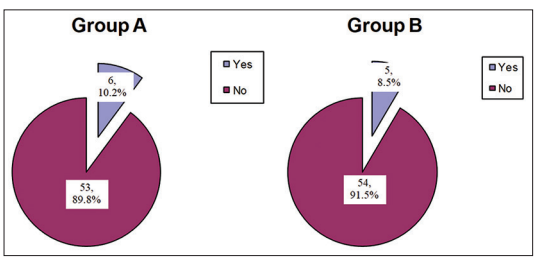

Figure 2: Distribution of the respondents by their previous history of abortion. X^2=0.1; df=1; *P*=0.75183

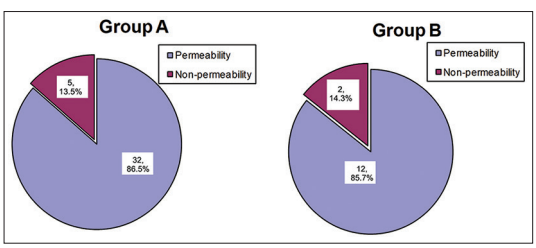

Figure 3: Distribution of the respondents by their permeability of cervix in unsuccessful cases. X^2=0.15; df=1; *P*=0.6985

good cervical dilatation before surgical evacuation (*P* = 0.75, Fisher's Exact 0.65).[3] Incidence of side effects was higher among respondents of Group A; that is, nausea (35.6%) than Group B (23.7%) (OR = 1.7763; 95% CI = 0.7963–3.9626); vomiting (RR 2.33; OR = 2.5128; 95% CI = 0.617–10.2329); severe pain as the side effect of Misoprostol, (RR 1.40; OR = 1.6941; 95% CI = 0.52–5.5193) Same number of respondents (3 [5.1%]) of both Groups had hyperpyrexia (RR = 1; OR = 1; 95% CI = 0.1935–5.1688) and also diarrhea had a similar rate of occurrence. (RR 0.83; OR = 0.8179; 95% CI = 0.2353–2.843) Chawla 2006 expressed that, the side effects were abdominal pain (16.6%), fever, (10.0%), vomiting (6.7%) and diarrhea (3.3%). Same number of respondents (3 [5.1%]) of both Groups had hyperpyrexia (RR = 1; OR = 1; 95% CI = 0.1935–5.1688). Bleeding lasted for <4 days in 11, for 5–6 days in nine, and for 7–8 days in eight patients. None passes clots. Two patients had irregular vaginal bleeding after 2 weeks with retained products on USG, of which one patient was <8 weeks and the other <11 weeks of gestation.[20] Rita *et al*. 2006 concluded that although the incidence of side effects, such as nausea, vomiting, diarrhea, severe pain, hyperpyrexia, and excessive blood loss was higher in Group A but the differences were not very significant.[17] Hence, vaginal misoprostol was found to be more effective and safer as compared to oral misoprostol. Regarding side effects at Hamdard University Hospital only 20% observed diarrhea, 5% shivering, 2% nausea, and 15% unpleasant taste.

Limitations of the study

This study was conducted in SZMCH in a smaller scale. Hence, the study findings may not reflect the exact scenario of all around the country regarding

Missed abortion. In Bangladesh, a study of Missed abortion in the perspective of the objective of the current study is rare and for this it was tough.

Conclusion

Per vaginal administration of Misoprostol in posterior fornix is more effective than Oral Misoprostol. The former has a faster onset of action and better efficacy. Per vaginal Misoprostol has less side effects.

Recommendation

This was a small-scale study done at a single center over a brief duration. A large-scale, multi-center study over a long duration will give an elaborate picture on the management of missed abortion.

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