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CONCLUSION

According to the present study, the vaginal route of misoprostol was more effective than the oral route in induction of abortion. The result of the present study showed statistically significant difference in induction interval between vaginal and oral route. Although the result showed that vaginal route is more effective than oral route, but there was no difference in the side effects, the type of abortion and the hospital stay between the two routes.

RECOMMENDATION

Because this study was cross sectional study, we lack temporality. In the future we recommend performing more studies to evaluate the long-term effect of misoprostol on women's health, Trials needed to optimize the dose and dosage intervals of misoprostol in the second trimester termination of pregnancy. Also we recommend comparing other routes of misoprostol administration such as rectal and sublingual routes.

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uterine contractions and expulsion of gestational sac (Panditrao S A, 2005). Misoprostol (a prostaglandin E1 analogue) has several potential advantages: it is stable at room temperature, it is relatively inexpensive and it can be given via several routes (oral, vaginal, sublingual, and buccal) **(Abdel-Aleem H, 2011).**

The present study was cross sectional comparative study. We conducted this study to compare the efficacy between oral and vaginal misoprostol. There were many studies conducted to compare between vaginal and oral misoprostol. Our study shows statistically significant difference between the vaginal route and the oral route, in term of induction interval, type of miscarriage, successful of miscarriage in 48hrs, and the development of side effects. Our findings disagree with a study done by Feldman et al, 2003 which showed that induction to abortion interval and hospital stay were slightly shorter for the oral group than vaginal group **(Feldman DM, 2003)**. On the other hand our study is in agreement with that reported by Salem K et al 2010. In their study the induction to abortion interval was shorter in vaginal group (9.98 hrs) than in the oral group (13.3 hrs). In term of successful abortion our study showed that the percentage of women who had successful abortion within 48 hrs was higher in vaginal group than in oral group. This result is similar to the result reported by Salem K *et al* 2010, which showed that 95% of vaginal group had successful abortion within 24 hrs, while in oral group only 82% had successful abortion within 24 **(Salem K A, 2010).**

Many studies such as Salem K *et.al*., and El Refaey, et.al., reported that the incidence of gastrointestinal side effects was higher when misoprostol was given orally than when it was administered vaginally **(El-Refaey,1995)**. Our study showed that the percentage of women who had side effects was higher in oral group (52%) compared to the vaginal group (32%). In term of hospital stay our study shows slightly difference between the vaginal and the oral group. Feldman et al reported that hospital stay was shorter in oral group than in vaginal group, which disagree with our study.

In the current study, we noticed that the satisfaction rate was more in the oral group. As there is less invasiveness, self-administration, and may result in the same effects as vaginal approach. On the other hand some women from the oral group preferred vaginal application if they need such in the future. As patients did not accept the higher incidence of nausea and those patients thought the drug near the uterus, the better it works **(Salem K A, 2010).**

Table 8: The frequency of side effects, in oral and vaginal groups.

Complication	Oral group N (%)	Vaginal group N (%)	P value
No complication	29(48.3%)	41(68.3%)	0.211
Abdominal pain	7(11.7%)	3(5%)	0.211
Diarrhea	4(6.7%)	2(3.3%)	0.211
Fever	3(5%)	5(8.3%)	0.211
Headache	4(6.7%)	4(6.7%)	0.211
Nausea	8(13.3%)	3(5%)	0.211
Vomiting	5(8.3%)	2(3.3%)	0.211

The mean length of hospital stay (in days) in the oral group was somewhat (3.4) higher than the vaginal group (3).

Table 9: Comparison of hospital stay duration of misoprostol, in oral and vaginal groups.

parameter(days)	oral	vaginal
Mean hospital stay	3.4	3

DISCUSSION

Medical abortion offers great potential for improving abortion access and safety, as it requires less extensive infrastructure than surgical abortion (Wagner 2006). Medical abortion includes the use of prostaglandin analogue such as misoprostol, and the use of antiprogestogen such as mifepristone (Zhang J, 2005). Several studies have assessed the efficacy of prostaglandins (PGS) with or without mifepristone. It would be desirable to develop a regimen without mifepristone since it is expensive and not available in many countries (**Zhang J, 2005**).

Our results support the fact that antiprogestogens are not really necessary for medical termination of missed abortion, probably because progesterone levels are usually low and therefore only prostaglandins are required to initiate

Table 5: Comparison in mean induction to abortion interval, in oral and vaginal groups.

parameter	oral	vaginal	p value
Mean induction to abortion interval(hrs)	13.10	10.05	0.003

Table 6 shows the number of successful abortions within 48 hours (hrs) after the initial drug administration, it was higher in the vaginal group (91.7%) compared to the oral group (86.7%).

Table 6: Comparison of successful abortion within 48hrs, in oral and vaginal groups.

Parameter	Oral group N (%)	Vaginal group N (%)	P value
Successful abortion within 48 hrs	52(86.7%)	55(91.7%)	0.378
Failed abortion within 48 hrs	8(13.3%)	5(8.3%)	0.378

Table 7 shows a higher percentage of cases that had complete abortion in the vaginal group (58.2%) versus (42.3%) in the oral group

Table 7: Comparison of type of abortion, in oral and vaginal groups.

Type of abortion	Oral group N (%)	Vaginal group N (%)	P value
Complete	22(42.3%)	32(58.2%)	0.1
Incomplete	30(57.7%)	23(41.8%)	0.1

Table 8 shows that oral misoprostol had more side effects compared to the vaginal route, but these were not significant.

The mean length of hospital stay (in days) in the oral group was somewhat (3.4) higher than the vaginal group (3).

Table 3 shows the number of miscarriage for the both. In the oral group 58.3 % of the patients had no history of miscarriage with mean of 0.85 ± 1.2. On the other hand in the vaginal group 55% of the patients had no history of miscarriage with mean of 0.67 ± 0.98.

Table 3: Distribution of patients according to history of miscarriage, in oral and vaginal groups.

Number of Miscarriage	Oral group N (%)	Vaginal group N (%)
0	35 (58.3%)	33 (55%)
1	15 (25%)	14 (23.3%)
2	7 (11.7%)	8 (13.3%)
3	1 (1.7%)	1 (1.7%)
4 and more	2 (3.3%)	4 (6.7%)
Miscarriage, mean and SD	0.85 ± 1.2	0.67 ± 0.98

Table 4 shows that he mean gestational age (in weeks) according to last menstrual period in the oral group was (16.55±2.90) compared with (17.73±3.33) for vaginal group, which is statistically significant (P value <0.05).

Table 4: Comparison of mean gestational age, in oral and vaginal groups.

Gestational age(weeks)	Oral group	Vaginal group
Mean	16.55	17.73

Regarding the mean induction to abortion interval (in hours) in the vaginal group was clearly less than in the oral group (10.05 hrs versus 13.10± hrs, P=0.003), as shown in table 5.

RESULTS

Tables 1-3 show Sociodemographic characteristics of the studied patients

Table 1: shows the mean maternal age for the oral group was (32.32 ± 6.53 years) compared with the vaginal group (32.28 ± 6.31 years), (p value 0.977), statistically not significant.

Table1: Distribution of patients according to age in oral and vaginal groups.

Age(years)	Oral group N (%)	Vaginal group N (%)
19-30y	22(36.7%)	22(36.7%)
31-40y	33(55%)	34(56.7%)
> 40y	5(8.3%)	4(6.7%)
Age: mean and SD	32.32 ± 6.53 years	32.28 ± 6.31 years
Age :(Maximum-Minimum)	(19-46)	(19-45)

Table 2 shows distribution according to parity, the oral group with mean parity of 2.43 ± 2.16. The vaginal group with mean parity of 2.38 ± 1.50. Most of the patients were between para 0 and para 2, which was approximately 55%, 56% in oral group and vaginal group respectively.

Table 2: Distribution of patients according to parity, in oral and vaginal groups.

Parity	Oral group N (%)	Vaginal group N (%)
0-2	34(56.7%)	33(55%)
3-5	21(35%)	25(41.7%)
6-8	4(6.7%)	2(3.3%)
>8	1(1.7%)	0(0%)
Parity mean and SD	2.43 ± 2.16	2.38 ± 1.50

group, 60 Patients for each group. All patients received equivalent dose of 600 microgram of misoprostol as primary dosage then 400 microgram every four hours, up to three doses. The vaginal misoprostol was inserted in posterior vaginal fornix. All patients were followed in the ward every four hours with observation of pulse rate, blood pressure, temperature and occurrence of side effects. Before the next dose was given uterine contractions and cervical status were assessed by abdominal and vaginal examination. No additional misoprostol dose was repeated if abortion is imminent (patient had at least 70% cervical effacement with 2cm opening). The induction considered to be started when the patient received the first dose of misoprostol and abortion defined as the time when the fetus was expelled (incomplete abortion) although in some cases placenta delivered at the same time (complete abortion). After abortion ultrasonographic examination was done to confirm that the products of gestation (fetus and placenta) had been successfully removed to establish that the abortion was complete. After delivery of fetus all patients received 20 units of oxytocin in 5% normal saline. If the placenta is expelled within 2 hrs of expulsion of fetus the abortion is considered to be complete. However, surgical evacuation was performed in case of heavy vaginal bleeding or when any retained products of the placenta are not delivered spontaneously 2 hrs after delivery of the fetus.

Patients were observed for 6 hrs after complete abortion. All patients received 500 mg ampicillin intramuscularly 6 hourly till discharge. Rh-negative women were given anti D immunoglobulin. Patients were discharged from the hospital in the next day and asked to report if bleeding did not cease in five days, or if they experienced cramps or fever. Also they were asked to return for a check-up a week later. Failure of induction is considered if the patient did not abort within 48hours; those women who failed to abort were managed later by dilatation and evacuation under general anesthesia.

Statistical analysis: Statistical analysis was computerized using the Statistical Program for Social Sciences (**SPSS version 16.0**) that is used for data entry and analysis. Descriptive statistics were used and all results are presented as frequencies, means ± standard deviation and percentages. The t-test of significance was used to compare quantitative data where appropriate, while categorical data were compared using the Chi-square test and Fisher's exact test if appropriate. A P-value of less than or equal to 0.05was considered statistically significant.

defined in terms of both the need for surgical intervention and the length of time from the administration of the prostaglandin to abortion. This randomized cross sectional study was conducted to compare the safety and efficacy of misoprostol (600*mg*) administered vaginally with the safety and efficacy of the same dose administered orally as primary dosage then 400 microgram every 4hours(hrs) up to three doses. Clinical outcome, time taken for expulsion, side effects and duration of hospital stay were compared in two groups.

The Objectives: To compare the effectiveness of equivalent doses of oral misoprostol versus vaginal misoprostol in terms of the time taken for second trimester missed abortion to be accomplished, effectiveness of each route to induce complete abortion, to determine frequency of side effects of each route, and to compare the length of hospital stay of patients with each route.

MATERIAL AND METHODS: It a cross-sectional comparative study, it was conducted in Department of Obstetrics and Gynaecology at Tripoli Medical Centre (TMC).during the year 2013-2014**.** It included one hundred and twenty patients, selected randomly. The patients were admitted to the ward as cases of second trimester missed abortion from the outpatient department (OPD). The diagnosis of missed abortion was established by abdominal ultrasonography (U/S). The demographic characteristics of each patient were addressed including age, gravidity, parity, history of previous miscarriage, and gestational age which was determined by the last menstrual period and by U/S, the medical method of pregnancy termination was explained, and consent was obtained.

In the ward they were subjected to investigation, including complete blood picture, renal function test, blood group, Rhesus factor, and plasma fibrinogen, beside to abdominal U/S for confirmation of diagnosis. All patients had pelvic examination, and evaluation of basal cervical dilatation.

Inclusion criteria: Women in the age-group of 19-46 years with a parity ranging from primigravidae to gravida 4 and above, gestational age from13 to 24 weeks, ,haemodynamically stable, closed cervical os, axillary temperature of less than 37.50 C, and no previous history of inflammatory bowel disease or allergy to misoprostol.

Exclusion criteria: Patients with abnormal results of investigations, and vaginal bleeding on examination.

Patients were randomly assigned to two groups, oral group and vaginal

Introduction

Expected 30 million abortions are performed worldwide each year (**Henshaw SK., 2009**).The safety of the procedure is therefore of global public health importance. Most miscarriages happen before the pregnancy is 12 weeks advanced (**Decherney AH, 2003**). After the 12th week, the chances of a miscarriage drop to below 10%. This fact, however, does not remove the chance of a mid-trimester loss (**Wyatt PR, 2005**). Second trimester miscarriage occurs between13 and 24 weeks of gestation (**Baker PN, 2006**) and complicates approximately <3% of all pregnancy outcomes (**Edmonds D, 2007**). After the 24th week, the loss of a pregnancy is termed as stillbirth (**Wyatt PR, 2005**). Medical advances have replaced high-morbidity procedures (such as intra-amniotic hypertonic saline and hysterotomy) with safer and more effective methods including dilation and evacuation (D&E) and medical abortion (labour induction). Although modern methods of abortion in the second trimester have low morbidity overall, risks of second-trimester abortion are higher than those in the first trimester, and increase with advancing gestational age (**Pazol K, 2012**). In the United Kingdom misoprostol is licensed for use with gemeprost up to 63 days from the start of amenorrhea (**UK approval for mifepristone, 2011).** Gemeprost is safe but expensive and requires specific conditions for storage and transfer, which may hinder its use in other parts of the world (**Misoprostol and legal medical abortion, 2010**). Misoprostol, an orally active prostaglandin E analogue, has attracted attention because it is inexpensive and can be taken orally (**Misoprostol and legal medical abortion, 2010).** Misoprostol had been widely used for the treatment and prevention of peptic ulcer disease for almost a decade before it was investigated as an agent to induce abortion. Although the initial results were encouraging, several reports have indicated that the combination of mifepristone and misoprostol appears to be less effective than the combination of mifepristone with sulprostone or gemeprost (**Thong KJ, Baird DT, 2005- el-Refaey H, Templeton A, 2006**). In addition to the high rate of complete abortion, the interval from the administration of the prostaglandin to abortion is an important attribute that influences the acceptability of the procedure. The percentage of patients having an abortion within four hours after the oral administration of misoprostol in conjunction with mifepristone has ranged from 61 to 87 percent (**Peyron R, Aubény E, Targosz V, et al, 2007**). Recent studies reported an apparent increase in the efficacy of misoprostol when it was administered vaginally, (**el-Refaey H, Templeton A, 2012**) with efficacy

Efficacy of Oral versus Vaginal Misoprostol for Termination of Second Trimester Missed Abortion

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Abstract

There has been continuous attempts to find out an ideal method for second trimester pregnancy termination. Second trimester abortions are important from public health point of view because they are responsible for more than half of preventable deaths. Misoprostol is introduced as a new armamentarium in medical management of missed abortion. The ideal dose, route and frequency of administration of misoprostol are still under investigation. The objective of present study was done to compare the safety and efficacy of misoprostol administered orally and vaginally for medical management of second trimester missed abortion. ***Methodology*:** During the year 2013-2014 a cross-sectional comparative study was carried out in the department of Obstetrics and Gynaecology at Tripoli Medical Centre (TMC), 120 patients who had second trimester missed abortion, were randomly assigned to receive either oral misoprostol tablets (60 patients), or vaginal misoprostol tablets (60patients) All patients received 600 microgram of misoprostol as a primary dose then 400 microgram every 4hours (hrs) up to three doses. The patients were followed for 48 hrs. Clinical outcome, time taken for expulsion, side effects and duration of hospital stay were compared in the two groups. ***Result:*** The mean induction to abortion interval (in hours) in the vaginal group was significantly shorter than in the oral group (10.05 hrs versus 13.10± hrs, P=0.003). The percentage of failed abortion was higher in oral group (13.3%) compared to vaginal group. The result shows higher percentage of cases that had complete abortion in the vaginal group (58.2%) versus (42.3%) in the oral group. Regarding the side effect of misoprostol, the oral group shows more side effects compared to the vaginal group. Whilst the duration of hospital stay was almost equal. ***Conclusion:*** Vaginal misoprostol was found to be more effective and safer as compared to oral misoprostol.

Key words: isoprostol, Oral route, vaginal route, missed abortion, Second trimester.

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