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RESEARCH ARTICLE

COMPARATIVE STUDY OF SUBLINGUAL AND VAGINAL MISOPROSTOL TABLET IN MISSED ABORTION

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Key words:-

Misoprostol Tablet, Missed Abortion,
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Abstract

Introduction: Management of missed abortion is matter of concern for obstetrician in terms of its methods and complications.

Objectives: To compare efficacy, side effects and complications of sublingual and vaginal misoprostol tablet in missed abortion case of less than 20 weeks of gestation.

Methods: Total 300 cases were taken, and out of those 300 cases, group A (150cases) included cases who were given sublingual misoprostol tablet, and group B (150 cases) included cases who were given vaginally misoprostol tablet.

Observation: Mean gestational age is 7.9 and 8 weeks in Group A and Group B respectively. P value is 0.94. (Not significant). Mean induction abortion interval is 11.6 hours and 12.9 hours in Group A and Group B respectively i.e., the induction abortion interval is slightly short in the Group A. P value is 0.9, means the difference is not statistically significant. Mean dose of misoprostol was 1004.6 microgm and 1080 microgm for group A and group B respectively. P value is 0.029 is significant. Incidence of side effects (nausea, vomiting, unpleasant taste) was higher in group A than group B. P value is <0.05 is significant. Success rate was 86% in group A and 80% in group B.

Conclusion: Sublingual and vaginal misoprostol tablet are both equally effective for medical management of missed abortion. Mean dose required for abortion is more in vaginal misoprostol but side-effects are more associated with sublingual misoprostol tablets.

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Introduction:-

Missed abortion is defined as retention of dead products of conception in utero for several weeks. It constitutes approximately 15% of clinically diagnosed pregnancies (1). Missed abortion is matter of concern not only to obstetrician causing blood coagulation defect and intrauterine infection, but also to the patients causing mental distress.

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Surgical evacuation of uterus was previously used as the standard management of missed abortions but is associated with complications like infection, perforation of uterus, Asherman syndrome and anesthesia related side effects. These increase morbidity and stay in hospital. Some studies have thus suggested that expectant or medical management might be more suitable instead of surgical evacuation (2, 3).

On the other hand, Misoprostol is easily available, cheap and can be stored at room temperature. And it can be administered by various 2 routes- oral, sublingual, vaginal, per rectal.

(Rationale of the study: Present study was conducted to compare repeated doses of sublingual with vaginal misoprostol tablet in the medical management of missed abortions.)

Aim

To compare the sublingual route to the vaginal route in the administration of misoprostol tablet for medical management in first and second trimester missed abortion.

Objectives:-

To compare the efficacy and side-effects of sublingual and vaginal misoprostol tablet for medical management in first and second trimester missed abortion.

Materials And Methods:-

Study period:

June 2020 to December 2020

Design:

Retrospective study

Study population:

PATIENTS having missed abortion with gestational age less than 20 weeks by sonography.

Sample size:

300

(Gestational age and cardiac activity confirmed by sonography).

Exclusion criteria:

Women having gestational age more than 20 weeks. → Women having ≥ 3 previous caesarean sections. → Any major medical disorder in past or present

Methodology:-

Total 300 cases were taken retrospectively and were divided in two groups A and B. Group A(150cases) included those cases who were given sublingual misoprostol tablet in three doses of 400 μ g every 4 hourly, while group B(150cases) included those cases who were given vaginal misoprostol in the same dosage regimen, for maximum 3 doses of misoprostol, Total of 1200microgm was given.

It was noted that the case papers included written consent of patient for medical management of abortion. Women with missed abortion were counselled regarding medical method of termination. Success rate, limitation, side effects of this method was thoroughly discussed with them on time of admission.

Case papers included treatment protocol given during minor side effects and Women with Rh negative blood group received anti-D immunoglobulin was documented.

Those cases with retained product of conception were examined and any product in cervix or in vagina were removed or emergency curettage were carried out to remove product of conception under necessary anesthesia. (8)

Observation And Discussion:-

To analyze the results with reference to following points (Induction – abortion interval, Success rate-failure rate, total dose of misoprostol required for complete abortion, Associated side effects and complications).

According to department protocol, two ultrasonographic examination were done, first one after 12 hours of starting first dose of misoprostol tablet and second one after 24 hours of starting first dose of misoprostol irrespective of abortion. After giving misoprostol tablet, pulse, BP, Temperature, systemic symptoms were monitored and documented in case papers

Following are the observation noted from the data collected from all 300 case papers

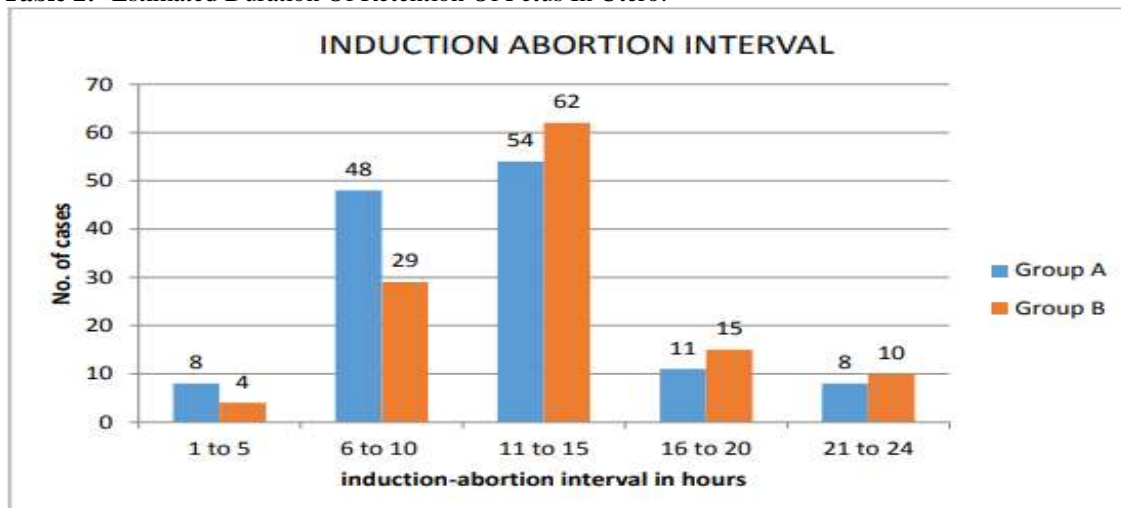
1. out of 300 cases ,132 were booked cases and 168 were emergency cases.
2. Majority of woman belong to the age group of 21 to 29 years.
3. Most woman presented with chief complaint of spotting / bleeding per vaginum.
4. Majority of woman fall in group 0 to 2 parity
5. Around 45% and 22.7% woman in group A and group B respectively showed absence of fetal pole on ultrasonography.
6. 97.3%and 96% of women in group A and group B respectively had single fetal ges

Table 1:- Gestational Age.

Gestational age in weeks (confirmed on USG)	Number	
	Group A (n=150)	Group B (n=150)
6-8	111 (74%)	110 (73.3%)
9-11	34 (22.7%)	33 (22%)
12-14	2 (1.3%)	3 (2%)
>14	3 (2%)	4 (2.7%)

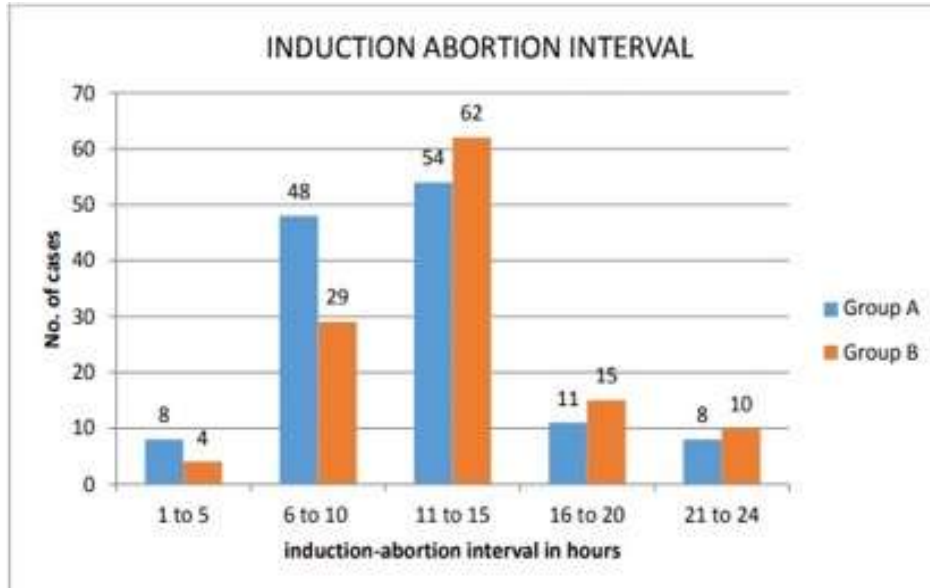
In our study, mean gestational age is 7.9 and 8 weeks in Group A and Group B respectively. P value is0.94. (Not significant)

Table 2:- Estimated Duration Of Retention Of Fetus In Utero.



Mean estimated retention of fetus in utero is 2 weeks in both group A and group B. P value is 0.9 (not significant)

Table 3:- Induction Abortion Interval.



In our study, induction abortion interval was defined as interval between administration of first dose of misoprostol (400µg) to expulsion of foetus.

In Group A, out of 150 patients, 129 had complete abortion.

In Group B, out of 150 patients, 120 had complete abortion.

Mean induction abortion interval is 11.6 hours and 12.9 hours in Group A and Group B respectively i.e., the induction abortion interval is slightly short in the Group A. P value is 0.9, means the difference is not statistically significant.

Table 4:- Induction Abortion Interval: According To Gestational Age.

Gestational age in weeks	Number		Mean induction abortion interval(hours)	
	Group A (n=129)	Group B (n=120)	Group A	Group B
6-8	104	99	11.9	13.4
9-11	20	14	10.8	11.9
12-14	2	3	8	9.6
>14	3	4	6	7.2

Maximum women had gestational age of 6 to 8 weeks and aborted with mean induction abortion interval of 11.9 hours and 13.4 hours in Group A and Group B respectively

In our study, mean induction abortion interval decreased as the weeks of gestation increased in both Group A and Group B. P value is 0.5 i.e., the difference is not significant.

Table 5:- Total Dose Of Misoprostol.

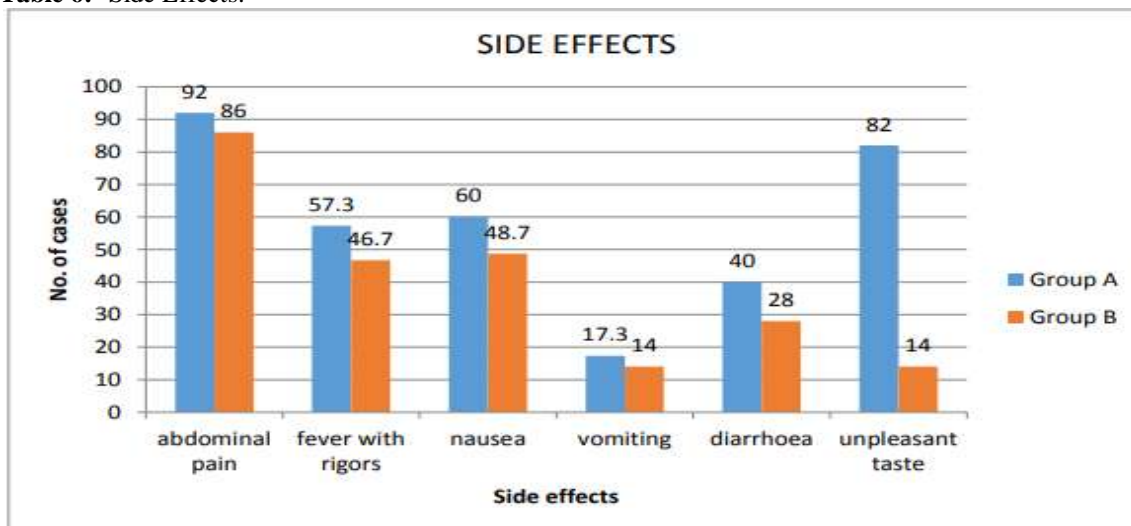
Total dose of misoprostol (micrograms)	Number	
	Group A (n=129)	Group B (n=120)
400	7 (5.4%)	3 (2.3%)
800	49 (37.9%)	30 (23.3%)
1200	73 (56.5%)	87 (67.55%)

In our study, mean dose of misoprostol was 1004.6 μ g and 1080 μ g for Group A and Group B respectively. P value is 0.029 i.e., the difference is statistically significant.

Table 6:- Mean Doses Of Misoprostol: According To Gestational Age.

Gestational age in weeks	Number		Mean dose of misoprostol(in micrograms)	
	Group A (n=129)	Group B (n=120)	Group A	Group B
6-8	104	99	1030	1111.1
9-11	20	14	1000	1028.6
12-14	2	3	800	1200
>14	3	4	666.6	800

The mean dose of misoprostol required for complete abortion decreased with increasing weeks of gestation in both Group A and Group B. The p value is 0.26 i.e., the difference is not significant.

Table 6:- Side Effects.

In our study, the incidence of side effects like nausea, diarrhea and unpleasant taste was significantly higher in Group A than in the Group B. The difference is statistically significant as p value is < 0.05 . The incidence of fever with chills was almost similar in both groups and the difference was not statistically significant ($p=0.06$).

→ Mean induction abortion interval was shorter in parous women than in nulliparous in both Group A and Group B.

→ Mean induction abortion interval decreased as weeks of gestation increased in both Group A and Group B.

→ The mean dose of misoprostol required was less in parous women than in nulliparous women in both Group A and Group B.

→ 14% and 20% of women in Group A and Group B respectively required check curettage due to incomplete abortion. None of them had any complication.(4)

Shah et al. found that the mean times the expulsion were also similar in respect of both the groups (13.07+- 6.95 h for sublingual versus 13.29+-5.63 h for vaginal group)

While tanha et al. found that mean time to expulsion was shorter (9.68 h,SD=5.51,95%CI=8.61-10.57) in the sublingual group than that in the vaginal group (16.64 h,SD =14.01,95%CI=13.8-19.48), $P=0.000$.the reason for the contraindications between the previous two studies and this study, in relation to the rapid action of vaginal route ,is that those studies have used higher doses of misoprostol than the present study.

Tanha FD et al. who showed that the sublingual group showed more complications as diarrhea was present in 70% of cases in sublingual group versus 35% in vaginal group , fever in20% of sublingual versus 10%in vaginal , severe abdominal cramps in 70% in sublingual versus 40% in vaginal.

Mitchell D2006: they concluded that misoprostol treatment for early pregnancy failure is highly successful in select woman , primarily those with active bleeding and nulliparity.

In a study by ahmad H Naguib et al. (2010) on vaginal misoprotol for second trimester pregnancy termination after one previous caesarean delivery, the author concluded that inducing abortion with lower misoprostol doses appear to be safe and effective. No cases of scar dehiscence of uterine rupture were observed.

In our study the difference in mean induction -abortion interval between group A and group B was not statistically significant, as in case with study by pooja Sharma et al and Ahmed Abdelshafy et al. this may be explained by difference in dose administered in their study.

In a study by Dr HHAH EI Sökkary et al. (2015), sublingual misoprostol is more effective than vaginal misoprostol and that it requires fewer dosages in both cervical dilatation and expulsion of the conceptus, but with some side effects.

In a study by NUSART SHAH ET AL. (2010), mean number of doses required for complete miscarriage was 4.44+-1.04 and 4.52+-0.96 in sublingual and vaginal group respectively value was 0.779 that is statistically not significant.

Tanha et al. (2010). There was no difference between vaginal and sublingual groups in term of tablets mean dose of misoprostol applied

In our study, the difference in mean dose between both the groups was statistically significant which was not in case with the study by Nusart shah et al.,this may be due to difference in dose administered.

According to the systematic review of Cochrane databases, sublingual misoprostol is as effective as vaginal misoprostol in causing complete miscarriage but is associated with more frequent diarrhea.

It has been shown that absorption through vaginal route is inconsistent and undissolved misoprostol tablet are found several hours after vaginal administration. (5)

Surgical evacuation of missed abortion has its own hazards, as the products of conception may be adherent to uterine wall, in addition cervix may be closed. Complications like uterine perforation, intrauterine remnants, and sepsis (10) are common. Although this procedure was introduced to reduce the risk of hemorrhage, it is reported to be associated with many complications including cervical trauma, perforation of uterus and endometritis. In addition,

uterine synechia, reduced fertility, tubal damage, and pelvic pain have been reported as long-term complications. (6)
Medical methods of uterine evacuation are safer and accepted by the patients. (7)

The use of mifepristone will increase the cost of the medical abortion.

Therefore, there is need to develop an effective regimen without mifepristone. Misoprostol has been studied extensively in this regard as it is cheap and stable at room temperature.

Conclusion:-

Sublingual and vaginal misoprostol are both equally effective for the medical management of missed abortions. However, induction abortion interval was slightly longer in vaginal route. And mean dose required for complete abortion was also more in vaginal group. But sublingual misoprostol is associated with more side effects especially unpleasant taste.

None of the patients experienced major complication of medical abortion like heavy bleeding or rupture. Minor side effects were present which were treated accordingly.

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