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COMPARATIVE OF MANAGEMENT OF MISSED ABORTION BY MEDICAL AND SURGICAL METHODS (INTRAVAGINAL MISOPROSTOL VERSUS SUCTION EVACUATION)

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ABSTRACT **BACKGROUND:** Nonviable intrauterine pregnancies, presenting as missed abortion spontaneous abortion, or incomplete abortion occur in approximately 15 % of all clinical pregnancies. Surgical evacuation under anaesthesia accounts for maximum operations performed now-a-days. However, it has certain morbidity such as the risk of anaesthesia, uterine perforation, and intrauterine adhesions. Another management is medical method of which Misoprostol is a prostaglandin E1 analogue that has a lower cost, a longer self-life at room temperature and fewer side effects and has particularly gained popularity for the management of miscarriage. **AIMS AND OBJECTIVES:** To compare the efficacy and safety of medical and surgical treatment in complete emptying of the uterus. **MATERIAL AND METHODS:** The present study was conducted on 100 patients of 18-50 years, in Department of Obstetrics and Gynaecology, Kamla Raja Hospital, Gajara Raja Medical College, Gwalior from 1st August 2004 to 31st August 2005, included missed abortion cases those were diagnosed by clinical and ultra sonographic finding as an embryonic pole 5-14 mm with no embryonic cardiac activity and an irregular intrauterine gestational sac with a mean sac diameter of ≥ 16 mm and no embryonic pole. **RESULTS:** The mean duration of the bleeding in our study came out to be 6.8 days in medical group and 2.65 days in the surgical group(P-<0.05). In our study success or completeness of the procedure was 82% in medical group. The success rate in the surgical group was observed to be 98% with only 1 failure case. The mean blood loss is 112.6 ml in the medical group and 87.56 ml in the surgical group. Those who were given single dose medical treatment had blood loss average 83.2ml and repeat dose patients' blood loss was average 109.6 ml. **CONCLUSION:** In our study we concluded that surgical treatment of missed abortion is better than medical treatment with misoprostol in terms of amount of blood loss, duration of bleeding and the rapid completeness of the process. However, the patient satisfaction is more with medical treatment.

KEYWORDS : missed abortion, misoprostol, suction evacuation

INTRODUCTION:

Nonviable intrauterine pregnancies, presenting as missed abortion (an embryonic pregnancy, early intrauterine death), spontaneous abortion, or incomplete abortion occur in approximately 15 % of all clinical pregnancies. Surgical evacuation is still the most commonly used treatment for miscarriage. Surgical evacuation under anaesthesia accounts for maximum operations performed now-a-days. However, dilation and suction evacuation of the uterus under anaesthesia has certain morbidity such as the risk of anaesthesia, uterine perforation, intrauterine adhesions, cervical trauma and infection leading to infertility, pelvic pain and increased chance of ectopic pregnancy. The alternative to surgical treatment is either expectant management, or medical management.

Expectant management of selected cases of miscarriage has been shown to have a similar outcome to dilation and curettage; whereas the result of another study showed that the success of expectant management of missed miscarriage was too low to justify its use in routine clinical practice. With expectant management there is great uncertainty as to when complete evacuation is to occur and the need for a prolonged follow-up is needed in order to identify this. This uncertainty can be quite stressful for most of the patients.

A treatment regimen that involves use of medications to affect complete expulsion would have advantage over either of these options. Specifically a medical management would allow complete evacuation of the abnormal early pregnancy without any uncertainty as to the timing of the passage (as compared to the expectant management), and would also avoid the potential complications associated with surgical procedure. Misoprostol is a prostaglandin E1 analogue that has a lower cost, a longer self-life at room temperature and fewer side effects and has particularly gained popularity for the management of miscarriage.

A study was conducted in the department of Obstetrics and Gynaecology, Kamla Raja Hospital, Gwalior to compare two different treatment regimens of missed abortions either medical method using prostaglandin E1 analogue or using surgical method i.e. suction and evacuation.

AIMS AND OBJECTIVES:

1. To compare the efficacy and safety of medical and surgical treatment in complete emptying of the uterus.
2. To compare the amount of blood loss in medical and surgical treatment.
3. To compare the severity of the side effects in the medical and surgical treatment.
4. To compare the magnitude of the patient satisfaction in medical and surgical treatment.

MATERIAL AND METHODS:

The present study to compare the management of missed abortion by medical and surgical methods was conducted in Department of Obstetrics and Gynaecology, KAMLA RAJA Hospital, GAJARA RAJA Medical College, Gwalior from 1st August 2004 to 31st August 2005

Sample size - 100 patients were selected

Inclusion criteria: Age group 18-50 years.

Missed abortion cases those were diagnosed by clinical diagnosis and ultra sonographic finding. According to USG, missed abortion was diagnosed when

- An embryonic pole 5-14 mm with no embryonic cardiac activity.
- An irregular intrauterine gestational sac with a mean sac diameter of ≥ 16 mm and no embryonic pole.

Exclusion criteria:

I. An inability to confirm pregnancy failure or intrauterine location of gestation.
II. An inability or refusals of the patient to adhere to study follow up requirement.
III. Excessive vaginal spotting
IV. Anaemia
V. Unable vital sign
VI. Signs and symptoms of infection
VII. History of asthma and cardiac disease
VIII. Known maternal allergy to prostaglandins or previous adverse reaction

All patients are thoroughly counseled with regards to potential risks and written informed consent was obtained before study participation. General physical, systemic examination, obstetric examination, per vaginal examination was done. Before enrollment all subjects

underwent ultrasonography to confirmed fetal non viability. Initial laboratory investigations included relevant investigations like Hb%, urine RM, bleeding time and clotting time. Hundred patients were divided into following two groups (50 each) of treatment according to the mode of treatment they choose.

Group A- misoprostol group (Medical arm): In the medical arm of the study, irrespective of the size of embryo/gestation 800µgm of misoprostol was placed in the posterior fornix. Subjects were observed for 2 hrs. Patients were contacted 6 hours later and questioned about the presence of uterine bleeding, diarrhea, fever, chills, nausea, or emesis or other problems. Subjects were instructed to return 24 hours after medication dosing, at which if clinical examination revealed the presence of persistent pregnancy, another 800µgm dose of vaginal misoprostol was administered into the posterior fornix. Twenty four hours later i.e. on study day3, the women returned for another clinical examination. If the pregnancy still persists, medical treatment was considered a failure and the patient underwent surgical treatment.

Group B- suction and evacuation (surgical group)

Fifty patients who were randomly selected were scheduled for surgical evacuation of the uterus by suction and evacuation. All surgical procedures were performed by obstetric residents in the operating room under direct staff supervision. Subjects were administered intravenous sedation. In group A patients following parameters were taken into consideration:

1. Agent used-its dose and frequency with which it's used.
2. Induction-abortion interval
3. Augmentation drugs or adjunctive therapy if required
4. Side effects during treatment, immediately after and 10 days after treatment
5. Failure or success
6. Success of treatment –success was defined as complete evacuation obtained within 3 days without the need for surgical evacuation.
7. Need for i/v fluid and blood transfusion
8. Complications in terms of drug reaction, duration of bleeding, pain due to process
9. Need for urgent evacuation
10. Patients satisfaction

The following outcomes were considered in Group B i.e. surgical group

1. Method done and dilatation required
2. Side effect during, immediately after and 10 days after treatment
3. Failure or success of treatment complete evacuation
4. Need for I/V fluid
5. fluid and blood transfusion
6. Blood loss both intraoperative and postoperatively
7. Pain and after complications due to procedure
8. Patient satisfaction

OBSERVATION:

Table -1

Parameters		Group A (medical) – 50 cases		Group B (Surgical)- 50 cases		P-value
		No	%	No	%	
Booking Status	Booked	0	0	0	0	
	Unbooked	50	100	50	100	
Age (years)	<20	5	10	2	4	0.209 Non-significant
	21-30	33	66	29	58	
	31-40	12	24	19	38	
	>40	0	0	0	0	
Gravidity	G-I	12	24	7	14	0.24 Non-significant
	G-II	16	32	12	24	
	G-III	12	24	24	48	
	G-IV	2	4	3	6	
	G-V	4	8	2	4	
	G-VI	4	8	2	4	
Gestational age (weeks)	<6 wks	20	40	17	34	0.24 Non-significant
	6-8wks	8	16	16	32	
	8-10wks	8	16	10	20	
	10-12wks	12	24	6	12	
	>12wks	2	4	1	2	
Pre abortion Hb%	<9gm%	4	8	2	4	0.21 Non-significant
	9-11gm%	31	62	39	78	
	>11gm%	15	30	9	18	
Days of bleeding	1-4	6	12	43	86	
	5-8	35	70	7	14	
	9-12	8	16	0	0	
	13-16	1	2	0	0	
Complete evacuation(within 3 days)	success	41	82	49	98	0.399(Non-significant)
	failure	9	18	1	2	0.011(Significant)
Nature of pain	Mild	26	52	31	62	0.29 (Non-Significant)
	Moderate	18	36	17	34	
	Severe	6	12	2	4	
Duration of pain in days	1-2days	20	40	18	36	0.193(Non-Significant)
	3-4days	26	52	32	64	
	5-6days	2	4	0	0	
	>6days	2	4	0	0	
Blood loss in ml	<60	4	8	1	2	0.001 (significant)
	60-100	12	24	30	60	
	>100	34	68	19	38	
Need of IV Fluids		0	0	40	80	
Need of blood transfusion		0	0	1	2	
Patient satisfaction	Satisfied	40	20	29	58	0.017(significant)
	unsatisfied	10	80	21	42	
Side effects	No S/E	3	6	29	58	0.005
	Nausea	23	46	13	26	0.09
	Vomiting	6	12	8	16	0.598
	Diarrhoea	14	28	0	0	0.001
	fever	4	8	0	0	0.04

Table-2 Distribution of patients in group A (50 cases)-

Dose of misoprostol (800Mcg)		No	%	P- value
	Single dose	29	58	
	Double dose	21	42	
Average blood Loss in ml	Single dose	83.2ml		0.193 Non-significant
	Double dose	109.6ml		

DISCUSSION:

In our study mean age of the patients in medical group is 27.24 years and in the surgical group is 27.04 years. In our study the mean gestational gravidity of the patients in the medical group was 2.72 and in the surgical group 2.5. The mean gestational age is 8.47 weeks in medical group and 8.6 weeks in the surgical group.

The **mean duration of the bleeding** in our study came out to be 6.8 days in medical group and 2.65 days in the surgical group, a value which is statistically significant in our study. **Grunlound** et al recorded the mean duration of bleeding in the medical group to be7.1 days while in the surgical group it was recorded to be 2.6 days. **Demetroutis** in their study found that 40% of the patient in the medical group had no bleeding, 50% had mild bleeding and 10 % had moderate bleeding while in the surgical group 45 % had no bleeding, 52.5% had mild bleeding, and 2.5% had moderate bleeding. In term of mean duration of bleeding in medical group 4.7±2.4 days and in surgical group mean duration 4.9±3.9.

In our study the mean Hb% was 10.56% in the medical group and 11.01% in the surgical group. **Demetrotuis et al** mean Hb% was 12.2±1.0 in gm/dl in the medical group and 11.9±0.9 in the surgical group which shows there was no statistically difference between the two groups.

In our study success or completeness of the procedure was defined as ability of the procedure to cause complete uterine evacuation within3 days of initial misoprostol treatment. In the medical group, in our study success was obtained in 82%.Whereas in the surgical group, the completeness of the procedure was defined as the ability of the procedure to cause complete uterine evacuation without the need for repeat curettage. The success rate in the surgical group was observed to be 98% with only 1 failure case. It was thus observed that suction and Evacuation has more guarantees towards completeness of the expulsion while in the medical group there are reported percentages of failure cases due to many reasons (P-0.011.)

Table -3 In studies in which both medical and surgical methods were used and compared

Study conducted by	Success rate (medical group)	Success rate (surgical group)
Graziosci et al	53.2%	96%
Muffley et al	60%	100%
Demetroulis et al	82.5%	100%
Our study	82%	98%

Nature and duration of pain- The mean duration of pain in medical group was 3.8 days and in surgical group was 1.7 days. In the study of **Ekachai**, lower abdominal pain was found in 74.1% of cases who were treated by misoprostol compared to 2.2% in the placebo group. **Herbutya et al** observed that out of told 35 women in the misoprostol group, two women required pethidine for pain and none in the placebo group. In the study of **D. Ayres et al**, 98.6% subjects experienced abdominal pain when the 600microgram misoprostol tablet was used to treat them. In the study of **Thomas Belsey** abdominal pain was experienced as moderate and severe by 10% patients but unbearable pain requiring narcotic analgesia was present only 1 out of 60 patients. The need for analgesic was around1.7 days and 1.5 days in medical and surgical group of **Grounland** study.

According to blood loss- **D Ayres de Compos** reported that out of 74 cases who took part in their study and were treated by vaginal misoprostol, vaginal bleeding was referred by all but one women (98.6%) who required a surgical evacuation bleeding was referred as slight by 32.4% women, moderate by 63.5% and internse by 2.7%. **Grazioscі** declared in his study that the severity of bleeding was higher in the misoprostol treated patients as compared with those treated by curettage. **Demetroulis** found that in the misoprostol group of patients, 90%had mild bleeding while 10% and moderate bleeding while in the surgically treated patients it was 79% and 21% respectively. In our study the mean blood loss is 112.6 ml in the medical group and 87.56 ml in the surgical group. Those who were given single dose medical treatment had blood loss average 83.2ml and repeat dose patients' blood loss was 109.6 ml average.

Table-4 Distribution of cases according to patient satisfaction-

Study conducted by	Patient satisfaction (Medical group)	Patient Satisfaction (Surgical group)
Autry et al	75%	-
Wood et al	91%	-
Demetroulis et al	82.5%	58%
Our study	80%	58%

In our study patients of group are satisfied as a surgical procedure was very often avoided and it is also cost effective as the cost of misoprostol one tablet is-while suction evacuation cost much more depending on the treatment center. The main reasons given by the subjects who were not satisfied by the medical treatment were unsuccessful treatment in their cases, length of bleeding and pain.

Induction Abortion interval- In the study of **Thomas Betsey**, mean insertion to expulsion time was 9.7±5.6 hours when 400µg of vaginal misoprostol was used for 2 doses 24 hours apart. **Zalanyi** observed the mean induction to expulsion time to be 6.1 hours when 200 µg vaginal misoprostol tablets were used every 4 hours to a maximum of 6 doses. **Herbutya** on using 200µg vaginal misoprostol or placebo filters before planned surgical evacuation of the uterus on the next day found the mean induction abortion interval to be 11.63±5.43hours for the placebo group. In the study by **Muffley** et al the mean time from medication to initial tissue expulsion was 12.6±2.7 hours in the medical group. In our study, the mean I-A interval was 9.16 hours in the medical group.

SUMMARY:

1. All the cases in each group were unbooked cases.
2. In group A, 30% patients were from rural area and 70% from urban area while in group B, it was 34% and66% respectively.
3. The mean age of the patients in group A was 27.24 years and in group B was 27.04 years
4. The mean gravidity of patient in Group A was 2.72 and in Group B it was 2.5.
5. The mean gestational age in the group A was 8.47 weeks and in group B was 8.6 weeks
6. The mean pre abortion hemoglobin in group was 10.56%gm/dl and in Group B was 11.01gm/dl.
7. The mean duration of bleeding in the group A was 6.8days and in group was 2.65 days
8. The average amount of blood loss in group A was 112.6 and in group B was 85.6
9. The success rate with medical treatment was 82% and with surgical treatment it was 98%.
10. The mean duration of pain in the medical group was 3.8 days and in group was 1.7 days
11. Eighty percentage of the patient in group B required i/v fluids and 2% required blood transfusion while group A patient required nothing
12. Patient satisfaction was 80% in the group A while 58% in the group B
13. There was significant difference in terms of side effects between the two especially in terms of diarrhea
14. The mean duration of bleeding in Group A patients who were treated with single dose (800µgm) regimen, was 83.2 ml and in repeat 800µgm regimen it was 109.6 ml
15. The mean Induction to abortion interval was 9.3 hours in Group A patients.
16. The side effects were comparatively more with more doses of misoprostol

CONCLUSION:

From this study we compared the management of missed abortion by medical and surgical treatment we came to the conclusion that surgical treatment of missed abortion is better than medical treatment with misoprostol in terms of b amount of blood loss, duration of bleeding and the rapid completeness of the process. However, the patient satisfaction is more with medical treatment as compared to the surgical treatment because privacy of the process is maintained and there is no need for hospitalization. Further studies are needed to assess the risk and benefit as regards the morbidity due to pelvic inflammatory disease and further reproductive potential following surgical intervention compared with medical abortion. Though the side effects are more common in the medical treatment they are not as grave and dangerous as can occur in the surgical treatment if they do.

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