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STUDY OF MEDICAL METHOD OF ABORTION (MMA) BY MIFEPRISTONE AND VAGINAL MISOPROSTOL IN WOMEN WITH AMENORRHEA OF MORE THAN 63 DAYS UP TO 98 DAYS OF GESTATION IN A TERTIARY CARE HOSPITAL.

Obstetrics & Gynaecology

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ABSTRACT

Objective: was to study success rate, induction abortion interval, mean dose of misoprostol required and complications of medical method of abortion using mifepristone and vaginal misoprostol combination in women with amenorrhea of more than 63 days up to 98 days **Methods: Study Design:** Prospective Observational study **Study period:** October 2019 – September 2021 **Results:** Total 80 women met inclusion criteria and included in the study. The MMA was successful in 76 (95%) study women. Remaining 4 (5%) women required MVA (Manual vacuum Aspiration). Average duration of bleeding was 3.60 hours ± 2.07 with the range of 1-8 hours. Mean Induction abortion interval was 5.70 hours (SD±2.92) with minimum and maximum interval being 2 hours and 13 hours respectively. Mean dose of misoprostol required was 795ugm with range between 400-2000ugm. Minor side effects such as nausea, vomiting, headache and fever were noted in 7.5% women. No any other complications were seen. **Conclusion:** Present study demonstrated that use of MMA in the women between gestational age of more than 63 to up to 98 days was safe and effective with lesser side effects.

KEYWORDS

MMA, Success rate, induction abortion interval, complications

INTRODUCTION

All abortions up to 63 days of gestation are achieved medically[1]. For late first-trimester abortions the method used in most countries has been exclusively surgical[2,3], It is an effective method with a success rate of >95%[4]. However, it is associated with major morbidity in up to 1% of women and minor morbidity in 10%[5]. The complications of unsafe surgical abortion, including incomplete abortion, sepsis, hemorrhage and intra-abdominal injury, cause the majority of maternal deaths[6].Earlier the choice of medical termination of pregnancy using the combination of mifepristone and misoprostol was offered only to women with a pregnancy of less than 63 days[7]. However, over the last decade, medical abortion with the combination of Mifepristone and Misoprostol has been used for pregnancy termination both for late first-trimester[8] and second-trimester abortions as there are less complications and morbidity noted with medical abortion[9]. Several studies showed that medical abortion is feasible between 9–14 weeks gestation by using combination of Mifepristone and repeated doses of Misoprostol. Which is effective, safe, and acceptable[10], but within this gestational age range of 63 to 98 days there is little research has been done showing the efficacy of medical termination of pregnancy[11]. Keeping in this in mind, we conducted a study of MMA during this gestational age for assessing safety and efficacy between more than 63 days up to 98 days.

MATERIALS AND METHODS

Study Design: Prospective Observational study
Study Period: October 2019 – September 2021

Source of Study Population:
All the women who are willing for medical termination of pregnancy between more than 63 days up to 98 days of gestation at Tertiary Health Care Centre.

Sample Size: 80

Formula:
- n= z2 pq/d2 n- sample size z- confidence interval at 95% p- prevalence
- q=1-p d- absolute precision

Inclusion Criteria:
1. Women with more than 63 days up to 98 days of gestation admitted for medical Termination of Pregnancy.
2. Women who are willing to participate in study.

Exclusion Criteria:
1. Gestational age less than 63 days and more than 98 days.
2. Haemorrhagic disorders & treatment with anticoagulants
3. Women who are not willing to participate in study

Study Procedure:
After obtaining institutional ethical committee approval study was started. Women who fulfilled the above inclusion criteria were counselled and detailed information of the study was given. Informed written consent obtained from each woman after explaining the purpose of the study. All study participants were registered and Complete physical and bimanual pelvic examination was done to assess the size of the uterus and contraindications like ectopic pregnancy, fibroid or any infection was ruled out, further confirmed by ultrasound. Formalities for MMA ('I' and 'C' form) were completed and required MTP documentation was done. Baseline characteristics and detailed history was noted. Routine investigations were sent.

Each woman was given tab. Mifepristone 200 mg stat orally on day 1 of study and 48 hours later on day 3 tab. Misoprostol 400 ugm was inserted into posterior vaginal fornix after soaking in normal saline and the dose repeated every 4 hourly (maximum five doses i.e., up to 2000 ugm) until the expulsion of products of conception.

Oral antibiotics (Tab amoxicillin + clavulanic acid 625mg oral BD along with tab pantoprazole 40mg OD) were started after vaginal misoprostol administration and given for 3 days. Vitals were noted, pelvic examination was done every four hourly till the process was complete. The time of onset of pain in abdomen was recorded. Analgesics were given for pain management if required (Tab Paracetamol 650mg oral). Inj methergine 0.2mg I.M. was given after expulsion of products of conception. Injection Anti D (150 microgram) was given intramuscularly to Rh negative women.Any side effects like nausea, vomiting, diarrhoea, headache, fever, shivering was noted. Success of MMA was defined as the expulsion of all the products of conception (foetus and placenta) without operative interventions.

Medical method of abortion failure was considered if woman failed to abort even after 5 doses of Vaginal Misoprostol tablet or required surgical intervention to complete abortion process. Incomplete abortion was considered when the entire products of conception were not expelled instead a part of it was left inside the uterus or at the end of 5 doses or before; there is excessive bleeding due to retained products of conception.The induction-abortion interval was defined as time taken from initial insertion of tab. Misoprostol until expulsion of product of conception.

Complications were noted in the form of perforation of uterus, haemorrhage requiring of blood transfusion and sepsis. Average duration of bleeding was noted. Excessive bleeding was defined as using two or more pads in one hour or bleeding for more than 12 hours.

Women were observed in the wards for a minimum 24 hours after complete expulsion. In cases of failure and incomplete abortion, MVA was performed in women with gestational age less than 12 weeks and Laparotomy was done in women above 12 weeks of gestation.

Follow up was done on day 14 or earlier if required.

Gestational age group in days	Number of women	Bleeding duration in hours ± SD	Range in hours
63- 84	31	3.74 ± 2.18	2-8
85-98	45	3.42 ± 1.92	1-7.5
OVERALL	n=76	3.60 ± 2.07	1-8

Statistical analysis: After the completion of the study, data was entered in MS excel spread sheet and analysis was done using IBM SPSS (statistical package for social science) statistics version 28.0

OBSERVATIONS & RESULTS

Total 80 women met inclusion criteria and included in the study between October 2019 to October 2021.

Table 1: Distribution according to age

Age in years	Number of women	Percentage	Mean ±SD	Range in years
20 to 25	31	38.75%	28.1±6.1	20-42
26 to 30	24	30%		
31 to 35	17	21.25%		
> 35	8	10%		
Total	80	100%		

Amongst the total women, 38.75% of the women were in the age group of 20-25 years, 30% of women were in the age group of 26-30 years, 21.25% of the women were in the age group of 31-35 years and 10% women were above 35 years of age. 92.5% of women were multigravida, remaining 7.5% were primigravida. Most common indication for MTP was ground 5. Ground 2 and 3 were accounted for remaining 40%. The MMA was successful in 76 (95%) study women. Remaining 4 (5%) women required MVA (Manual vacuum Aspiration).

Table 2: Duration of bleeding according to gestational age.

Gestational age group in days	Number of women	Bleeding duration in hours ± SD	Range in hours
63- 84	31	3.74 ± 2.18	2-8
85-98	45	3.42 ± 1.92	1-7.5
OVERALL	n=76	3.60 ± 2.07	1-8

Average duration of bleeding was 3.60 hours ± 2.07 with the range of 1-8 hours.

Table 3: Induction abortion interval according to gestational age.

Gestational age group in days	Number of women	Mean interval in hours ± Standard deviation	Range in hours
63- 84	31	5.97 ± 3.02	2-13
85-98	45	5.43 ± 2.82	2-8
OVERALL	n=76	5.70 ± 2.92	2-13

In present study, mean induction abortion interval was 5.70 hours ± 2.92 with range of 2-13 hours. Which was marginally longer in 63-84 days gestational group (5.94 hours) as compared to 85-98 days age group (5.43 hours), which was statistically not significant (p value 0.87).

Table 4: Mean misoprostol dose according to gestational age.

Gestational age group in days	Number of women	Mean misoprostol required in ugm ± SD	Range in ugm
63- 84	31	827± 305.8	400-2000
85-98	45	763± 388.4	400-1600
OVERALL	n=76	795± 345.6	400-2000

The overall mean dose required was 795ugm ± 345.64 with range of 400 to 2000ugm. Women between 63-84 days of gestational age group required higher mean dose of 823ugm as compared to 85-98 days age group (763ugm), which was statistically significant (p value <0.001).

Table 5: Distribution of Side effects of MMA

Side Effect	Misoprostol	Mifepristone
Nausea	5(6.25%)	3(3.75%)
Vomiting	3(3.75%)	0
Fever	2(2.5%)	0
Shivering	2 (2.5%)	0
Headache	3(3.75%)	1(1.25%)
Loose stools	2(2.5%)	0

MMA was safe without any major side effects. Nausea was noted in 10 % women (6.25% after misoprostol intake and 3.75% after Mifepristone intake), vomiting was seen 3.75% women (after misoprostol intake), developed fever with chills which was subsided after medication and headache was noted in 5 % women (3.75% after misoprostol intake and 1.25% after Mifepristone intake). Loose stools were seen 2.5% women of misoprostol group. No any other side effect was noted.

DISCUSSION

There is still ambiguity regarding ideal method of abortion in women with gestational age between 63-98 days gestation. Previously surgical methods were used exclusively in this age group, although they were successful, but they associated with significant morbidity and longer hospital stay. Literature shows only couple of MMA studies conducted in gestational age of 63-98 days and there are no optimal MMA drug regimens to be used. So, we conducted this prospective observational study between October 2019 to October 2021 to fill the knowledge gap in MMA method of abortion in the gestational age between 63-98 days. In present study MMA was successful in 76(95%) women. Remaining 4(5%) women required MVA (Manual vacuum Aspiration). Which is comparable to the study findings of Gouk et al[12], Hamoda et al[13], Braken et al[14], Largeaud et al[15], Qian et al[16] and Partha et al[17].

Mean induction abortion interval in present study was 5.70 hours ±2.44 with a range of 2-13 hours. Similar findings were reported by Qian et al, Ashok et al, Lisbeth et al[18], Hamoda et al and Partha et al

The overall mean dose required was 795ugm ± 345.64 ugm with a of range 400 to 2000ugm. Which is comparable to the studies conducted by Hamoda et al61, Partha et al and Ngai et al.

In present study nausea was noted in 7 % women, vomiting was seen 4 % women and 2% women developed fever with chills which was subsided after medication. No any other side effect was noted. Similar rate of side effects was noted in other studies such as Hamoda et al, Li Ping et al, Parth et al and Hillary et al. Above comparison confirms the safety of MMA as no study reported any major side effects.

CONCLUSION

Present study demonstrated that use of MMA in the women between gestational age of more than 63 to up to 98 days was safe and effective with lesser side effects.

Conflict Of Interest: None

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