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PROSPECTIVE OBSERVATIONAL STUDY OF MEDICAL MANAGEMENT OF PREGNANCY LOSS UP TO 14 WEEKS OF GESTATIONAL AGE

Obstetrics & Gynaecology

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ABSTRACT

In India, pregnancy failure is a pressing reproductive health issue, with an estimated 10-15% of clinically recognized, pregnancies resulting in miscarriage. The purpose of this prospective observational study was conducted to evaluate the medical method of abortion with Tab. Mifepristone and sublingual Tab. Misoprostol in the medical management of pregnancy failure up to 14 weeks of gestational age. This was a prospective observation study conducted among 110 women aged 18-45 years with ultrasound diagnosed cases of pregnancy loss up to 14 weeks. The mean age was 26.22±2.54 years. About 59(53.64%) were age 18-25 years 7 60(54.55%) were residing in urban area. Most of the women were Hindu 69(62.73%) by religion. About 66 (60%) women were para one. Most common risk factor was previous LSCS 7(6.36%) followed by Rh negative blood group of mother 5(4.55%). About 67 (60.90%) women required 1200 mcg (2 doses) of tab Misoprostol for complete expulsion. The success rate of medical management of pregnancy loss in this study was 96.36%. Most common side effects was shivering 30.91% followed by nausea 19.09%. From this study we conclude that, continued use of misoprostol and mifepristone as a first-line treatment for pregnancy failure, providing a secure, safe & non-invasive alternative to surgical procedures.

KEYWORDS

Pregnancy failure, Tab. Mifepristone and sublingual Tab. Misoprostol

INTRODUCTION:

Pregnancy failure (PF) commonly referred to as miscarriage, is a distressing event affecting millions of women globally each year. It has significant emotional, physical and psychological challenges for affected individuals and their families. In India, pregnancy failure is a pressing reproductive health issue, with an estimated 10-15% of clinically recognized, pregnancies resulting in miscarriage, although underreporting and cultural factors may influence these figures [1]

Technological developments in transvaginal sonography have led to the diagnosis of EPL increased frequently prior to clinical signs or spontaneous expulsion (sometimes known as a missed miscarriage). There are three recognized therapeutic options for this situation: The surgery i.e. dilatation and curettage (D&C), expectant management (waiting) or the medical induction [2, 3].

The medical management provides an option for women who choose to avoid surgery while yet wanting active care. According to studies, starting with misoprostol, a prostaglandin E1 analog, is a safe and efficient strategy [4–7]. According to recent evidence, mifepristone should be used further to enhance achievement even more [8, 9]. However, current information regarding the use of misoprostol and mifepristone together In an EPL setting is still uncommon. The purpose of this prospective observational study was conducted to evaluate the medical method of abortion with Tab. Mifepristone and sublingual Tab. Misoprostol in the medical management of pregnancy failure up to 14 weeks of gestational age.

This was a prospective observation study conducted among women aged 18-45 years & willing for medical management of pregnancy failure up to 14 weeks of gestational age over a period of 1 year. The calculated sample size was 100 with prevalence of EPL was 7%[10]. By adding 10% nonresponding rate, final sample size was 110. Women with confirmed or suspected ectopic pregnancy, not willing to participate in study, on long term systemic corticosteroid therapy, adrenal failure, history of septic abortion, Hb <8gm% & pregnancy failure more than 14 weeks of gestational age were excluded.

After obtaining institutional ethical committee approval, women who fulfilled the above inclusion were enrolled in study. All participants were registered and socio-demographic data and high-risk factors were noted. A complete physical and bimanual pelvic examination was done to assess the size of the uterus.

On Day 1: Tab. Mifepristone 200 mg administered orally

On Day 2: Tab. Misoprostol 600 mcg administered sublingually. At the end of 3 hours if women didn't abort repeat Tab. Misoprostol 600 mcg sublingually was given (maximum 3 doses).

After 3 doses, an additional dose of tab. Misoprostol 600 mcg sublingual was given if she was having an inevitable abortion.

Oral antibiotics (Tab amoxicillin + clavulanic acid 625mg oral BD along with tab pantoprazole 40mg OD) were started after sublingual Misoprostol administration and continued for 3 days. Vitals were noted, pelvic examination was done every three hours till the process was complete. Analgesics were given for pain management if required (Tab. Paracetamol 650 mg orally). Injection Anti D 300 mcg was given intramuscularly to Rh-negative women. Any side effects like nausea, vomiting, diarrhoea, headache, fever, and shivering were noted. The medical method of abortion failure was considered if the woman failed to abort even after 3 doses of sublingual Misoprostol tablet or required surgical intervention to complete the abortion process. Women were observed in the wards for a minimum of 24 hours after complete expulsion. In cases of failure and incomplete abortion, MVA was performed. Follow-up was done on day 14 or earlier if required.

Data was fed in master chart by using MS excel. Data was expressed as numbers and percentages, means, standard deviations and range in tabular and graphical format. Statistical comparison between two groups was made using the Chi-square test (categorical variables). p-values are two tailed. Statistical significance was set at p =/<0.05 as statistically significant and p=/<0.01 statistically highly significant. All calculations were made using the SPSS 26.0 trial version.

RESULTS:

Total 110 women with ultrasound diagnosed cases of pregnancy loss up to 14 weeks of gestational age were enrolled in this study with mean age was 26.22±2.54 years. About 59(53.64%) were age 18-25 years 7 60(54.55%) were residing in urban area. Most of the women were Hindu 69(62.73%) by religion. About 66 (60%) women were para one. (Table 1)

Most common risk factor was previous LSCS 7(6.36%) followed by Rh negative blood group of mother 5(4.55%).(Table 2)

Table 1: Distribution of women according to socio-demographic data

Parameter		Frequency	Percentage
Age Groups	**18-25**	59	53.64
	26-30	43	39.09
	31-35	8	7.27
Residence	**Rural**	50	45.45
	Urban	60	54.55
Religion	**Hindu**	69	62.73
	Muslim	37	33.64
	Christian	4	3.64

Parity	**P0**	33	30.00
	P1	66	60.00
	P2-4	10	9.09
	P≥5	1	0.91

Table 2: Distribution of women according to high risk factor

High-risk factor	Frequency	Percentage
Previous 1 LSCS	7	6.36
RH Negative	5	4.55
Operated case of laparotomy	2	1.82
Hypothyroidism on treatment	2	1.82
Chronic HTN	2	1.82
Overt DM	1	0.91

Most of the women 27(24.55%) present with pregnancy loss at the 56-62 days of gestational age. (Table 3)

Table 4 showing mean gestational age of presentation, mean IAI & mean duration of bleeding.

About 67 (60.90%) women required 1200 mcg (2 doses) of tab Misoprostol for complete expulsion followed by 27 (24.54%) cases required 1800 mcg (3 doses) & 16 (14.56%) required 400 mcg (1 dose).(Table 5)

Table 3: Distribution of women according to gestational age of presentation

Gestational age in days	Frequency	Percentage
49-55	17	15.45
56-62	27	24.55
63-70	21	19.09
71-77	15	13.64
78-84	14	12.73
85-91	7	6.36
>91	9	8.18
Total	**110**	**100.00**

Table 4:Mean gestational age of presentation, Mean IAI & Mean duration of bleeding.

Gestational age in days	Mean Gaof presentation ± S.D. (days)	Induction abortion interval (Days in Mean±S.D.)	The average duration of bleeding (Days in Mean±S.D.)
49-55	51.15±3.5	5.20±1.13	2.31±0.83
56-62	55.63±3.92	4.31±1.65	2.33±0.97
63-70	63.30±3.78	4.09±1.17	2.36±0.90
71-77	68.02±3.22	4.02±1.65	2.32±0.87
78-84	76.84±3.5	4.53±1.65	2.68±0.84
85-91	87.9±6.37	4.22±1.58	2.44±0.71
>91	90.08±2.59	3.88±1.95	2.48±1.06
Overall	**65.46±12.74**	**4.28±1.54**	**2.76±0.88**

Table 5 : Distribution of women according to number doses of Tab Misoprostol required

Doses of Tab Misoprostol in mcg	Frequency	Percentage
3 doses (1800 mcg)	27	24.54
2 doses (1200 mcg)	67	60.90
1 dose (600 mcg)	16	14.56
Total	**110**	**100**

Fig 1 shows the success rate of medical method of management for pregnancy loss. The success rate of the present study was 96.36%. The failure rate was 3.64%. Fig 2 shows, most common side effects was shivering 30.91% followed by nausea 19.09%.

Fig 1: Success rate of medical method of management for pregnancy loss

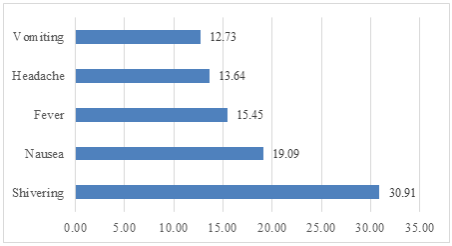

Fig 2: Distribution according to Side effect

DISCUSSION:

The present study was a prospective observational study involving 110 cases of pregnancy failure up to 14 weeks of gestational age. The study focused on the mean induction abortion interval, average duration of bleeding, success rate, side effects. In this study with mean age was 26.22±2.54 years which is corelated with the mean age observed in studies conducted by Kumari P et al. [11] & Gluck O et al [12]. In present study, 70% were multigravida & 30% were primigravida. A similar results observed in study conducted by Gluck O et al [12]. Study conducted by Kumari P et al [11] primigravida constituted 50.3%. This may be due to variations in the study populations, possibly influenced by demographic, geographical or healthcare access factors. In the present study, the mean dose of misoprostol required was 1257 mcg for the complete expulsion of the product of conception which was comparable with the study conducted by Akkenapally et al[13]. A relatively lower mean dose was required in the study conducted by Hamoda et al [14]. The variation in the dosage requirements could be attributed to differences in gestational age, study protocols and population characteristics.

The mean induction abortion interval in the present study was 4.28±1.54. Similar findings were reported by Kumari P et al (6.19±1.80 hours)[11], Gluck O et al (mean 6.45±0.83 hours)[12], Akkenapally et al (mean 6.19±2.7 hours)[13] & Hamoda et al (mean 4.25 hours)[14]. Variations in induction abortion interval were possibly due to gestational age, study protocols and women's demographics.

In the present study success rate of the medical method of abortion was 96.36%. About 4 (3.64%) women managed with surgical methods i.e. MVA. The similar study findings observed in study conducted by Davis et al [15], Chaudhuri P et al [16], & Lakeland M et al [17]. The above findings are in favour of medical management in pregnancy failure up to 14 weeks of gestational age case. In the present study major side effect was shivering followed by nausea. Similar side effects were noted in a study conducted by Dabash et al[10], Akkenapally et al [13], Hamoda et al[14], Chaudhari P et al[16], Chen MJ et al[18] and Beaman J et al.[19]

CONCLUSION:

The current prospective observational study on the use of Tab. misoprostol and Tab. mifepristone for medical management of pregnancy loss up to 14 weeks of gestational age showed a high success rate in obtaining a complete abortion with few complications and surgical intervention. With a 96.36% success rate, the combo therapy was determined to be both safe and effective. The effectiveness of this regimen in treating pregnancy failure was demonstrated by the fact that the majority of women had the intended result with little problems. Additionally, the study found that side effects like shivering, nausea, and vomiting were tolerable and did not compromise the treatment's overall safety. The findings back up the continued use of misoprostol and mifepristone as a first-line treatment for pregnancy failure, providing a secure, safe & non-invasive alternative to surgical procedures.

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