A COMPARATIVE STUDY OF MISOPROSTOL VERSUS SURGICAL MANAGEMENT OF INCOMPLETE AND MISSED ABORTION IN EARLY FIRST TRIMESTER

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ABSTRACT

BACKGROUND

Safe and effective treatment for incomplete abortion is an important way to reduce abortion related morbidity and mortality. Medical methods for treatment of incomplete abortion require few resources, are cost effective and can be administered by low and midlevel providers. Surgical methods are highly effective for treatment of incomplete abortion.

The aim of this study is to compare efficacy of using vaginal Misoprostol for management of incomplete and missed abortion in ≤ 9 weeks of pregnancy as an alternative to surgical evacuation in our setting and also to assess the patient acceptability and satisfaction for the medical method with surgical method in the same.

MATERIALS AND METHODS

This is a randomised controlled trial performed on randomly divided 100 patients with missed and incomplete abortion in ≤ 9 weeks in two groups. On the basis of previous study, the success rate of medical group being 80.7% and 100% in surgical group. Group one received Misoprostol tablet 800 mcg single dose per vaginally and second group underwent surgical vaginal evacuation directly under sedation. Both groups were compared in terms of success, complications, pain and patient's satisfaction.

RESULTS

In medical treatment group, success rates were 92% as compared to surgical group which had 98% success rates. Bleeding was more and prolonged in the patients managed by Misoprostol, 36% patients had moderate bleeding, but no patient required hospitalisation. Though bleeding was less in the surgical group, but all of them required the use of sedation and antibiotics. In the Misoprostol group 56% were very satisfied, while in surgical group 22% were moderately satisfied according to VAS score.

CONCLUSION

Misoprostol is effective in complete evacuation of uterus in both incomplete and missed abortion. It is as effective as surgical evacuation with much more patient satisfaction, especially where demand for services is high, but availability of skilled providers and resources is often scarce.

KEYWORDS

Incomplete Abortion, Missed Abortion, Misoprostol, Surgical Evacuation.

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BACKGROUND

Approximately, 11% - 15% of pregnancies end in spontaneous first trimester miscarriage.[1] The estimated abortion percentage of known pregnancies was at 21% worldwide with 26% in developed countries and 20% in developing countries.[2] Amongst these 56 million abortions occurring each year in the world, a little under half are done unsafely.[2,3] Unsafe abortions are defined by WHO as abortions performed by people lacking the necessary skills or in an environment that does not fulfil minimal medical standards or both.[4,5]

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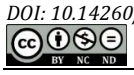

Unsafe abortions cause 47,000 deaths and 5 million hospital admissions each year.[6,7] Safe and effective treatment for incomplete abortion is an important way to reduce abortion related morbidity and mortality. Medical methods for treatment of incomplete abortion require few resources, are cost effective and can be administered by low and mid-level providers. Surgical methods are highly effective for treatment of incomplete abortion. However, these treatments require trained providers, special equipment, sterile conditions and often anaesthesia. All of these are limited in many settings. Therefore, this study was done to compare efficacy of medical management of incomplete and missed abortion with surgical evacuation in ≤ 9 weeks of pregnancy as well as comparison of the side effects and complications between the two methods.

MATERIALS AND METHODS

The present study was randomised controlled trial conducted in the Department of Obstetrics and Gynaecology, Dr. Baba Saheb Ambedkar Hospital, Rohini, New Delhi, during the period of November 2014 to May 2015. This is a prospective comparative study performed on 100 patients with first trimester incomplete and missed miscarriage ≤ 9 weeks.

On the basis of various studies, the success rate of medical group being 80.7% (95%, CI: 69.97 - 91.43) and surgical group being 100%, the minimum required sample size with 90% power of study and 5% level of significance was calculated to be 44 subjects in each group. Thus, to lower the margin of error, 100 subjects were selected (50 in each group). They were divided into two groups randomly. It was done on the basis of computerised block randomisation.

1. Received Misoprostol tablet 800 mcg single dose per vaginally.
2. Underwent surgical vaginal evacuation directly under sedation.

Patients included in this study were those which were haemodynamically stable and diagnosed with incomplete or missed abortion clinically and by ultrasonography with GA ≤ 9 weeks, retained products of conception of > 1.5 cm in ultrasonography and those who were willing for follow-up after 15 days.

In this study, the patients which were excluded were those diagnosed with gestational age > 9 weeks, threatened abortion, patients with active bleeding, haemodynamically unstable, having signs of infection, known allergy to prostaglandins, medical illness contraindicating the use of prostaglandins, severe anaemia (Hb < 7 gm%), previous 3 LSCS or previous h/o uterine rupture and suspected ectopic pregnancy.

Methodology

Patients admitted with complaints of amenorrhoea followed by bleeding

↓

Diagnosis of incomplete or missed abortion was confirmed by clinical and ultrasonography findings. Routine investigations done

↓

After applying exclusion criteria, patients were divided into 2 groups (randomly)

↓

Group A– 800 mcg Misoprostol vaginally
Group B– Evacuation under sedation and antibiotics

↓

Follow-up after 15 days.

In follow-up, USG was done to confirm complete evacuation of the retained products. Also amount of bleeding, sepsis, pain, requirement for re-evacuation and further interventions like blood transfusion and hospitalisation were assessed by a detailed proforma. Success of any method was defined as complete evacuation of products of conception by an ultrasound and absence of any clinical symptoms. Patient's satisfaction and acceptability were evaluated on the basis of discomfort/ abdominal pain, duration and amount of vaginal bleeding and requirement of hospital admission. This was noted on VAS (Visual Analogue Scale).[8]

Statistical Analysis

In this study VAS score was compared using unpaired t–test, while qualitative variables were compared using Chi-square test/ Fisher's exact test. A p-value < 0.05 was considered statistically significant.

RESULTS

All the women belonged to low socioeconomic status. Distribution of cases were comparable in both the groups (Table 1).

Cases	Medical (n= 50)		Surgical (n= 50)	
	No.	%	No.	%
Incomplete	12	24	15	30
Missed	38	76	35	70
Total	**50**	**100**	**50**	**100**

Table 1. Distribution of Cases

In the present study 24% patients in medical group and 30% patients in surgical group were incomplete cases, while 76% patients in medical group and 70% patients in surgical group were missed abortions. In both groups, age and parity of women were comparable.

In medical group 92% success rates were obtained, while in surgical group it was 98% which had no statistical significant difference (p > 0.005) and thus were comparable. The incidences of side effects were more in medical group and statistically significant. The numbers of patients with post-abortal bleeding were more in the medical group. It was statistically correlated and found to be significant (p value < 0.005). All women required sedation and antibiotic in surgical group, whereas no sedation was given in medical group and two women were given antibiotics due to prolonged bleeding. Surprisingly, no patient required a re-evacuation in both the groups. There was no perforation in the surgical group (Table 2).

Outcome	Medical		Surgical	
	No.	%	No.	%
Success of treatment method	46	92	49	98
Incidence of side effects	43	86	8	16
Incidence of excessive post abortive bleeding	18	36	1	2

Table 2. Clinical Outcome of the Study Group

The mean of VAS score (patient's satisfaction level) in medical group was 4.28, whereas in surgical group it was only 2.76 (p < 0.0005) which was statistically significant. Medical group patients were highly satisfied as compared to surgical group (Table 3).

VAS Score	Medical (n= 50)		Surgical (n= 50)		Total
	No.	%	No.	%	
1	4	8	4	8	8
2	0	0	15	30	15
3	1	2	20	40	21
4	17	34	11	22	28
5	28	56	0	0	28
Total	**50**	**100**	**50**	**100**	**100**

Table 3. Patient's Satisfaction (VAS)

DISCUSSION

Medical and surgical methods are the only treatments to be used for incomplete and missed abortion. In medical treatment according to the recommendations by FIGO in < 13 weeks gestation of missed abortion, 800 mcg Misoprostol is

given per vaginally (P/V) every 3 hours (2 doses) or 600 mcg sublingual (S/L) every 3 hours (2 doses) and for incomplete abortion it is single dose misoprostol of 600 mcg orally or 400 mcg S/L or 400 - 800 mcg P/V.[9] But in our study as women were of low socioeconomic status, they were likely to be lost for follow-up. Therefore, we had used single dose of Misoprostol for both missed and incomplete abortion.

Success rate in both groups were comparable and no statistical significant difference was found between the two groups ($p > 0.005$). High success rates have been found in many studies, which also showed no statistical significant difference between the two methods in 1st trimester abortion as in our study.[10,11,12]

In present study, the number of women with post abortal bleeding were more in the medical group. It was statistically correlated and found to be significant (p value < 0.005). Many studies conducted indicate similar results to our study.[13,14] No patients in both the groups underwent surgical re-evacuation later or any blood transfusion.

In our study the mean of VAS score (patient's satisfaction level) in medical group was 4.28, whereas in surgical group it was only 2.76 ($p < 0.0005$) which was significant. Comparable results were found in other studies, where patient's satisfaction level was more in medical than the surgical group and was statistically significant.[10,15,16] Despite that in medical group more side effects and excessive post abortal bleeding was noticed, it was well tolerated in comparison to surgical group.

Professional associations such as the American College of Obstetricians and Gynaecologists recommend Misoprostol for post-abortion care and the World Health Organisation has added Misoprostol for the management of incomplete abortion and miscarriage to its Model List of Essential Medicines.[17]

The available Cochrane systematic review evidence suggest that expectant care as well as medical treatment with Misoprostol are acceptable alternatives to routine vaginal surgical evacuation.[18]

Despite the fact that so many studies prove the benefits of medical treatment, the services go unreached to many strata of population owing to the widespread illiteracy and the unmet availability of resources and trained personnel, that many are lost for follow-up as well as availability of Misoprostol over-the-counter in our country has led to misuse of this wonder drug.

Limitations

This study was done on a small and restricted population group. Studies are required which include larger groups with diverse population strata.

CONCLUSION

Given its safety, efficacy and ease of use, misoprostol is an important option for the treatment of women with incomplete abortion. It is the need of hour that widespread resources and services be provided to overcome all the associated obstacles in decreasing maternal morbidity and mortality.

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