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Original Research Article

Expectant versus surgical management of incomplete abortions caused by self-intake of abortifacient drugs: results from a randomized controlled trial

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ABSTRACT

Background: Termination of unwanted pregnancies with medical method using recommended protocol based abortifacient drugs is a standard practice followed by obstetricians and gynaecologists worldwide which has a very successful outcome. However, self-administration of these drugs has become rampant because of certain social and practical issues resulting in complications and incomplete abortions as when these drugs are self-administered, recommended protocol is not generally followed. Traditionally incomplete abortions are managed by surgical curettage which itself is associated with procedure related complication and has been challenged by recent studies. Based on these studies many international guidelines have come out in support of expectant management of incomplete abortions. This study compared both of these management protocols to treat incomplete abortions caused by unprescribed intake of abortifacient drugs.

Methods: This was a one-year long prospective randomized controlled study in which total 782 females were randomized into two groups of 371 and 411. Group 1 was offered expectant management while group 2 was offered surgical curettage. Results were analysed using appropriate statistical tests.

Results: Group 1 showed a success rate of 86% while group 2 showed a success rate of 90% which was comparable. Overall complication rate was found to be higher in Surgical curettage group than in the group which underwent expectant management group.

Conclusions: Considering a very high number of patients coming with incomplete abortions caused by self-medication in present practice, expectant management seems to be a safer and more effective method and should be practice more widely.

Keywords: Abortifacient drugs, Incomplete abortions, Expectant management, Surgical curettage

INTRODUCTION

Abortions are legal in India since the enactment of MTP act 1971. MTP act provides clear guidelines and recommendation for termination of pregnancy which can be terminated only by registered medical practitioner after fulfilling certain conditions. According to MTP act 1971 which was amended in 2003, medical method of

termination using tablet mifepristone & misoprostol (abortifacient drugs), can only be administered by registered medical practitioners and gynaecologists upto 49 days from the first day of last menstrual period.² Inspite of clear guidelines, self-administration of abortion pills at home by pregnant women themselves without any medical consultation has become rampant, fear of getting stigmatized and poor accessibility to safe abortion services

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in peripheral areas being the responsible factors. When these abortion pills are self- administered, proper drug regimen is usually not followed which has further worsened the situation and increased the burden of complications caused by incomplete abortions induced by this kind of self-medication.^{3,4} Literature from previous studies suggest that approximately 2/3 rd of the total cases with incomplete abortion which seek hospital care are following self-administration of abortifacient has been responsible for high rate of surgical curettage.^{5,6} Surgical evacuation by dilatation and curettage (D&C) of the product of conception has been the most commonly performed standard treatment since the 1930s, despite complications such as haemorrhage, infection, cervical tears, bowel and bladder damage, pelvic infection, broad ligament hematoma, uterine perforations, secondary infertility, asherman syndrome, as well as anaesthetic complications, apart from this it increase the cost and burden on healthcare. ^{7,8} The incidence of serious morbidity following surgical evacuation has been estimated at 2.1% while the mortality is around 0.5% per 1,00,000.9 Expectant management is alternative treatment in clinical practice and have shown to be effective and safe. 10,11 It allows the continuation of the usual course of miscarriage, avoids complications from active management, and is more cost effective. A number of clinical studies describe that expectant management usually achieved complete evacuation within 2 weeks of diagnosis with low infection rate. 10-12

Recently, NICE guidelines and review by Cochrane also recommended that expectant management should be conducted in cases with uncomplicated abortions. ^{12,13} At present we don't have much literature available from Indian researchers supporting this line of management in cases of incomplete abortions caused by unauthorized oneself medication.

The aim of the study was to conduct randomized controlled trial which aimed to assess the efficacy and acceptance of expectant management in comparison with surgical curettage for cases presented with incomplete abortion following self- administration of abortifacient drugs.

METHODS

It was a prospective randomized controlled study done over a period of one year from April 2019 to March 2020 at Shyam Shah Medical College and associated hospitals, Rewa, India. Ethical approval was obtained by Institutional Ethical Committee (human studies), Shyam Shah Medical College, Rewa. Women in early pregnancy who fulfilled the inclusion criteria and gave consents to be a part of study were randomly categorized in two groups by the use of random number computer tables. Group 1 was allocated expectant management and group 2 was allocated surgical management in the form of curettage.

All women were explained about the warning signs and were followed up after 15 days and at 1 and 2 months after

first visit. Results were entered in a semi-structured format and were analysed subsequently.

Inclusion criteria

Inclusion criteria was patients as follows- (a) age>18 years, married; (b) history of taking pills for abortion for >2 weeks and < 3 weeks; (c) USG incomplete abortion with gestational age 8 gm/dl); (d) no sign of infection; and (e) no systemic medical or surgical illness.

Exclusion criteria

Patients with (a) complete miscarriage; (b) intact gestational sac on USG; (c) twin or high order pregnancy; (d) molar pregnancy; (e) haemodynamically unstable (Hb38 degree C, raised TLC, tachycardia, malodourous vaginal discharge, lower abdominal tenderness); (f) heavy vaginal bleeding; and (g) severe pain were excluded.

Statistical analysis

Appropriate statistical tests were applied as per the need. We tested differences for statistical significance using chi square test and data were analysed using the Statistical Package of the Social Sciences (SPSS, version 21.0).

Study definitions

Incomplete abortion- Incomplete abortion defined as evidence of intra-uterine remnants or an antero-posterior diameter of the uterine cavity exceeding 10 mm in ultrasound scanning. Successful outcome- A successful outcome was defined as the finding of an empty uterus (total endometrial diameter of<10 mm) on ultrasound scan, at 2 weeks follow-up, or an uneventful clinical course during 4 weeks of follow-up without complications or the need for (re)interventions.

Written consent was obtained from the patients after explaining them the nature and purpose of the study. They were assured that confidentiality would be strictly maintained. The option to withdraw from the study was always open.

RESULTS

Total number of participants were 962 who were eligible for study, but 101 participants refused to participate, so 861 were enrolled in study. Group 1- 430 were managed using expectant management. Group 2- 431 were managed using surgical evacuation. 59 participants lost to follow up from group 1, and 20 participants were lost to follow up from group 2. Therefore, for data analysis 371 participants for expectant management and 411 participants for surgical evacuation were finally available.

Details of baseline characteristics, study outcomes and complication rates are mentioned in Table 1-3 respectively.

Table 1: Baseline characteristics of study population.

Baseline characteristic	Group 1 (N=371) (%)	Group 2 (N=411) (%)
Age in years, Mean (SD)	27.6 (3.44)	29.1 (7)
Nulliparous	86 (23)	117 (28.5)
Multiparous	285 (77)	294 (71.5)
Gestational age in weeks, mean (SD)	9.8 (2.6)	10 (2.1)
Haemoglobin g/dl (SD)	9.7 (0.67)	9.3 (0.69)

Table 2: Outcome of study groups.

Outcome	Group 1 (N=371) (%)	Group 2 (N=411) (%)
Successful	319 (86)	373 (90)
Unsuccessful	52 (14.02)	40 (9.7)
Acceptable	257 (69)	214(52)

Table 3: Complication rates of study groups.

Complication rates	Group 1 (N=371) (%)	Group 2 (N=411) (%)
Use of additional analgesia	286 (77)	322 (78)
Blood transfusion	10 (2.7)	7 (1.7)
Pelvic inflammatory disease	26 (7)	63 (15)
Cervical tear	0	18 (4.4)
Uterine perforation	0	15 (1.9)
Unplanned admission	22 (6)	20 (5)
Asherman syndrome	0	9 (2.1)

DISCUSSION

Since the legalization of MTP act, the rates of abortions have increased. The MTP Act 1971 (2003 Amendment) clearly define guidelines for medical termination of pregnancy which must be conducted by registered medical practitioners and gynaecologistsup to 49 days from the first day of last menstrual period.³ With strict adherence to these guidelines, failure rates i.e. incomplete abortion rate is very low. In spite of legalization and confidentiality, self-administration of abortifacient drugs to terminate the pregnancy is common. The factors responsible for opting abortion outside the accredited institution include absence of health care facility in rural areas, high cost in private hospitals, lack of awareness to the beneficiaries, poor perceived quality of care in government facilities as well as lack of confidentiality.¹⁴ However, failure rate as well as complication rate following self-administration is high.⁷ When such patients seek medical care, deciding appropriate line of management is necessary. Surgical evacuation is commonly followed, however, recent international guidelines recommend expectant management for such patients whenever possible. The present study was thus conducted at tertiary care centre to evaluate efficacy of expectant management in induced incomplete abortions resulting from self-administration of abortifacient drugs and to compare its efficacy with that of surgical management.

In present study success rate of expectant management and surgical management was found to be comparable, which was 82% and 95% respectively which is comparable to other stuudies. 15-19 Infection rate was found to be higher in surgical group as shown in other studies as well. 15,20 The rate of emergency blood transfusion was found to be higher in expectant group (2.7%) than surgical group (1.7%) which is in accordance with previous studies. Rate of procedure related complication like cervical perforation, uterine perforation and asherman syndrome was nil in expectant group while it was found to be in the range of 2-4% in surgical group. Need for additional analgesia was found to be high in surgical group for obvious reasons. These all are comparable with previous studies. 15,16,20 Acceptability of the allocated method was found to be significantly higher in expectant group than surgical group, most common reason being less pain and apprehension of undergoing a surgical intervention which has been supported by our own study done on this topic a year back with lesser number of study participants.⁶

Present study is one of its kind on a very relevant topic, however being a single institute study, generalization of results may not be prudent at this point of time, specially to rural population where loss to follow up while observing in expectant management can be a big obstacle.

CONCLUSION

Based on the findings of present study, it could be concluded that success rate of expectant management for incomplete abortion as effective as surgical evacuation but patients morbidity as determined by the requirement of antibiotic, duration of pain, bleeding and sick leave were significantly lower in expectant management group. Overall, complication rates were much lower in expectant management group when compared to surgical management group.

Incidence of incomplete abortion and unplanned admission were higher in expectant group whereas procedure related complications were higher in surgical evacuation group. To conclude, expectant management is an acceptable method with high success rate.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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