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STUDY ON USE OF ORAL MISOPROSTOL FOR MEDICAL EVACUATION OF MISSED ABORTION

Gynaecology

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ABSTRACT

Background:. Missed abortion occurs in 11% of clinically recognized pregnancies and is not only associated with substantial healthcare and financial burden but non continuing pregnancy is upsetting for mother. Majority of missed abortion occurs spontaneously however some pregnancies simply stop growing without any obvious symptoms, with a deferment in expulsion of conceptus. Misoprostol is a Prostaglandin analogue being widely used for termination of pregnancy, considering it efficacious, low cost and long shelf life (2 years) at room temperature.
Objectives: To assess and evaluate the efficacy of misoprostol by oral route, for the medical management of first trimester missed abortion.
Material and Methods: This was a prospective study which was conducted at the Gynecology Department of Career Institute of Medical Sciences and Hospital over a period of one year from January, 2016 till December 2016 in which 250 eligible participants were included. All women eligible to be recruited in this study were admitted in hospital and given 200 µg of misoprostol orally at 12 hour interval for 2 successive days, with a maximum of 4 doses. For the present study ethical approval was granted by the institutional ethical review committee of Career Institute of Medical Sciences and Hospital. Written informed consent was obtained from all participants prior to recruitment having explained comprehensively the process involved, intervention given (Misoprostol) and benefits/ risks of being the part this research.
Results: Among 250 participants, success in abortion with Misoprostol was observed in 225 (90%) of patients with majority (80.2%) success being achieved with two doses. The most common side effects observed with Misoprostol dose of 200 µg was cramping/ abdominal pain (36%). The mean gestational age in weeks and parity were 10.01 weeks and 2.5 respectively.
Conclusion: The study highlighted high success rate and minimal side effects with the use of 200 µg of oral misoprostol for missed abortion

KEYWORDS

Missed Abortion, Misoprostol.

Termination of pregnancy on account different maternal factors or due to foetal condition is a common obstetrical problem. Missed abortion during the first trimester is characterized by the foetal development arrest with ultrasound findings reporting an empty gestational sac or fetus with no cardiac activity [1]. It occurs in 11% of clinically recognized pregnancies and is not only associated with substantial healthcare and financial burden but non continuing pregnancy is upsetting for mother [2]. The percentage of missed abortion is increasing having diagnosed on routine ultrasound screening [3, 4]. Majority of missed abortion occurs spontaneously however some pregnancies simply stop growing without any obvious symptoms, with a deferment in expulsion of conceptus [5]. Similarly to the effective care required during labor for child birth, safe induction of abortion is sensitive and requires effective and high quality of meticulous medical care. Different surgical and medical methods are available for the termination of pregnancy however medical methods are preferred considering demonstrated lower rates of maternal morbidity and mortality. Surgical evacuation, irrespective of being quick and effective procedure when performed by a well-trained physician, however carries a risk of injury, bleeding and infection, along with possible complications from the anesthesia [6]. Misoprostol is a Prostaglandin analogue being widely used for termination of pregnancy, considering it efficacious, low cost and long shelf life (2 years) at room temperature [7, 8]. Though both oral and vaginal route of administration are present but women however prefer oral route as to avoid inconvenience due to vaginal examination.

Aims and objectives:
To assess and evaluate the efficacy of misoprostol by oral route, for the medical management of first trimester missed abortion.

Material and methods:
This was a prospective study which was conducted at the Gynecology Department of Career Institute of Medical Sciences and Hospital over a period of one year from January, 2016 till December 2016 in which 250 eligible participants were included. The hospital has a well established Gynecological department and women residing in both rural and urban areas nearby visits for routine ante natal checkups, deliveries and gynecological problems.

Women with confirmed diagnosis of missed abortion on ultrasound, age duration 18-45 years, gestational age ≤ 12 weeks, closed cervix on bimanual pelvic examination and hemoglobin ≥ 9 gm/dl, place of residence within 10 km from hospital, willingness to abstain from intercourse for first two weeks after intervention given and comply with the follow-up schedule were invited to participate in this prospective study. Women with history of inflammatory bowel disease, asthma or liver diseases, hemodynamically unstable, severe infection (assessed by the presence of at least one of the following; fever above 38 deg C, foul smelly discharge and uterine tenderness), deranged coagulation profile (Prothrombin index ≤ 85%), ectopic pregnancy and contraindicated to prostaglandin use were excluded.

After baseline investigation and ultrasonographic confirmation of missed abortion data on age, parity and gestational week were recorded. All women eligible to be recruited in this study were admitted in hospital and given 200 µg of misoprostol orally at 12 hour interval for 2 successive days, with a maximum of 4 doses. The pills were swallowed with sip of water in the presence of clinician. The outcome was assessed after 12 hours following the last dose of misoprostol. The primary outcome of the study was defined as Success (non surgical evacuation of product of conception confirmed on ultrasound) or Failure (incomplete expulsion of products of conception or excessive bleeding with retained product of conception where surgical evacuation was performed). Patients were monitored for 24 hours following complete abortion or surgical evacuation and then discharged. They were prescribed analgesics and prophylactic antibiotics for 5 days.

The first follow-up visit was at one week after discharge to confirm their clinical status. In the event of continued heavy bleeding, enlarged uterus, or suspicion of ectopic pregnancy, women were referred for ultrasound and follow-up care. In the event of continued incomplete abortion surgical evacuation was performed. Such cases were considered as failure on account of the recourse of surgery. Finally, all participants recruited in this prospective study were advised to visit

hospital anytime for any query or complication. For the present study ethical approval was granted by the institutional ethical review committee of Career Institute of Medical Sciences and Hospital. Written informed consent was obtained from all participants prior to recruitment having explained comprehensively the process involved, intervention given (Misoprostol) and benefits/ risks of being the part this research. It was ensured that anonymity and confidentiality of recruited participant's data was maintained throughout the research and no unauthorized person had an access to the data. The participants had a right to withdraw at any point of this prospective study. The data was analysed using SPSS version 21. Descriptive statistics were performed. The qualitative variables were presented as frequency/ percentage whereas the quantitative variables were presented as mean ± SD.

Results:

The table 1 gives characteristics of the study participants enrolled. The mean (SD) age in years was 28.5(4.5) with majority (62%) were in age category 26-34 years. The mean gestational age in weeks and parity were 10.01 weeks and 2.5 respectively. Majority (84%) had gestational age as less than or equal to 10 weeks while the highest proportion of patients (60%) had parity 2 to 3.

Characteristics	Mean ± SD or n (%)
Age in years	28.5±4.5
Age categories	
<25 years	80(32%)
26-34 years	155(62%)
≥35 years	15(6%)
Gestational age in weeks	10.01±2.5
Gestational age categories	
<10 weeks	210(84%)
11-12 weeks	40(16%)
Mean parity	
Parity	
≤1	75(30%)
2-3	150(60%)
≥4	25(10%)

Table 1: Baseline characteristics of study participants

The most common side effects observed with Misoprostol dose of 200 µg was cramping/ abdominal pain (36%), followed by non profuse bleeding (18%), severe bleeding (20%), nausea/ vomiting (16%), fever/ chills (4%), headache (4%) and diarrhea (2%) as shown in table 2

Side effects	n(%)
Cramping abdominal pain	90(36%)
Increased bleeding (not profuse)	50(20%)
Profuse (severe) bleeding	45(18%)
Nausea/vomiting	40(16%)
Fever/chills	10(4%)
Diarrhea	05(2%)
Headache	10(4%)

Table 2: Side effect profile of study participants

Among 250 participants, success in abortion with Misoprostol was observed in 225 (90%) of patients with majority (80.2%) success being achieved with two doses (Table 3). Among 10 patients where failure was documented, excessive bleeding (50%) was most prevalent followed by incomplete abortion (40%) and patient request (10%).

Clinical outcomes	Mean ± SD or n (%)
Efficacy of Misoprostol	
Success	225 (90%)
Failure	25 (10%)
Success with respect to doses	
One dose	27 (14.5%)
Two doses	150 (80.2%)
Three to four doses	10 (5.3%)
Failure cases where surgical evacuation was performed	
Incomplete abortion	04 (40%)
Excessive bleeding	05 (50%)
Patient's request	01 (10%)
Mean duration of hospital stay in hours	30.5±4.5

Table 3: Clinical outcomes amongst patients

Discussion:

The results of the prospective study reported a high efficacy of Misoprostol with failure rate as around 10 percent. Cramping abdominal pain was highlighted as the most common side effect as being reported in around 36% of patients. Other adverse events being reported were increased bleeding, nausea/ vomiting, fever/ chills, headache and diarrhea.

The findings of the current study were similar to some extent with the evidence in literature reporting the efficacy of Misoprostol. A prospective clinical study from Yemen, where patient received single dose of oral misoprostol 600 µg reported a success rate as 75%, while 40% women required surgical evacuation within the first 48 hours due to considerable vaginal bleeding and 60% of evacuation after 7 days due to incomplete miscarriage [9]. Another clinical study reported a success rate as around 61% within the first 48 hours of receiving a single dose of oral misoprostol 600 µg while around 39% of women recruited required further surgical evacuation during the same period [10]. Another clinical trial reported a higher success rate 97.9% in the first 72 hours and this may be accounted due to using of single dose of oral misoprostol in the management of incomplete abortion not missed abortion as in our study [11]. A clinical study that compared the two regimens of oral misoprostol, single dose (600 µg) and repeated dose (1200 µg) in the treatment of incomplete abortion reported an overall success rate as 87%

Limitations of study:

As it is a single centre study with a relatively small study population, results cannot be generalized to the entire population.

Conclusion:

The study highlighted high success rate and minimal side effects with the use of 200 µg of oral misoprostol for missed abortion. It should only be prescribed to patients once admitted in hospital settings. Its prescription for missed at primary healthcare facilities where appropriate healthcare management are frequently not available could result in high morbidity and mortality especially in developing countries.

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