



EFFECTIVENESS OF MISOPROSTOL COMBINED WITH FOLEY'S CATHETER DURING SECOND TRIMESTER TERMINATION OF PREGNANCY

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Abstract- Introduction: Among the various methods of termination of pregnancies the prostaglandins are the commonly used abortifacents. Misoprostol (cytotec) is recently prostaglandin E₁ used for labor induction, control of postpartum hemorrhage and termination of pregnancy. The use of Foley's catheter has been recommended in many developing countries. The reports from different countries have mentioned excellent results with the use of Foley's catheter in combination with prostaglandins. This study concentrate on effectiveness of Misoprostol combine with Foley's catheter.

Objective: To determine the effectiveness of misoprostol combined with Foley's Catheter during second trimester termination of pregnancy.

Study Design: Case series study.

Setting: Obstetrics and Gynaecology Unit-II Liaquat University Hospital, Hyderabad, Pakistan.

Duration of Study: Six months from November 03, 2010 to May 02, 2011.

Subjects & Methods: Total of 115 women from Out Patient Dept: in 2nd trimester of pregnancy and meet inclusion criteria were enrolled. For induction, the patient was administered 200 mcg misoprostol intra-vaginally along with passing Foley's catheter inflated with 50 ml distilled water. The dose of misoprostol was repeated 6 hourly up to max 800 mcg until expulsion. The effectiveness of combination therapy was assessed as mentioned in operational definition.

Results: Mean (\pm SD) age was 29.3 ± 7.8 yrs. The main indication for terminat-ion of pregnancy was intrauterine death observed in 60 (52.2%). Effectiveness of misoprostol combined with foley's catheter for second trimester termination of pregnancy, procedure was effective in 86 (74.8%) women.

Conclusion: Effectiveness of misoprostol combined with foley's catheter for second trimester termination of pregnancy was 74.8%. High percentage of effectiveness was seen in age between 21 - 30 yrs., in gestational age > 19 weeks and in primiparous women.

Keywords- 2nd Trimester, Misoprostol, Foley's catheter, Termination of pregnancy

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Introduction

Termination of pregnancy is defined as elective expulsion or extraction of products of conception from uterus instead of spontaneous onset of process irrespective of duration of pregnancy [1]. Congenital abnormality and missed abortion are the most common reason of second trimester termination of pregnancy. Missed abortion is death of fetus in utero before 24 weeks of gestation and uterus unable to expel products of conception [1]. It is associated with three to five times higher risk of maternal morbidity and mortality than termination of pregnancy during first trimester [1]. In intrauterine fetal death, expulsion may take several weeks. This is associat-

ed with psychological trauma, coagulopathy and intrauterine infection [2]. There are several advantages of using misoprostol as it is inexpensive, stable at room temperature and does not require refrigeration for storage [3]. It is active orally but more effective and better tolerated when administrated vaginally and has fewer side effects [4]. Vaginal route is preferred in first and second trimester [5,6]. The use of Foley's Catheter has been recommended in many developing countries. The reports from Turkey, Egypt, Ethiopia, Israel and Nigeria have mentioned excellent results use of Foley's Catheter either alone or in combination with prostaglandins [7]. The exact mode of action of Foley's Catheter is not fully understood, yet

it has been postulated that Catheter stimulated various unspecified regions of uterus which leads to increase its excitability and cause regular uterine contraction [1]. Foley's Catheter is economical, easily available, associated with minimal complication and thus provides a readily available and efficacious method of cervical ripening [8]. The effectiveness of misoprostol combine with Foley's catheter during second trimester termination of pregnancy has been reported as 26.4% [9]. Amjad, et al [7] and Atad, et al [8] were also studied the misoprostol combine with Foley's and claimed the superiority of such combination.

The current study conducted at tertiary care teaching hospital of Hyderabad and concentrate on effectiveness of Misoprostol combine with Foley's catheter. If found to be satisfactory the same combination modality used in some cases.

Material & Methods

Study Setting: Obstetrics and Gynaecology Unit-II Liaquat University Hospital, Hyderabad

Study Design: Case series study.

Duration of Study: Six months from November 03, 2010 to May, 02 2011.

Sample Size: Taking the prevalence of effectiveness of combination of misoprostol and Foley's catheter during second trimester of pregnancy = 26.4%, d = 8 %, n = 115 patients with second trimester of pregnancy.

Sample Technique: Non - probability Purposive sampling.

Sample Selection: Following patients were included in this study:

- Gestational age 14 to 24 weeks (on ultrasound)
- Singleton pregnancy
- Intrauterine death
- Congenital fetal anomaly
- Missed abortion

Exclusion Criteria

- Case of placenta previa
- Associated Systemic disease (Hypertensive Disorder, Diabetes)
- Hypersensitive to prostaglandins
- Scarred uterus

Data Collection Procedure

All women who came through outdoor patient department in second trimester of pregnancy and meet inclusion and exclusion criteria were enroll and entered in study. A well explained consent was taken from patients. For induction, the patient was administered 200 mcg misoprostol intra-vaginally along with passing Foley's catheter (adult size) inflated with 50 ml distilled water. The dose of misoprostol was repeated 6 hourly up to max 800 mcg until expulsion/delivery.

Data Analyses

The data was entered and analyzed in SPSS version 11.00. The frequency and percentage for effectiveness and indications of termination (i.e. Intra uterine death, congenital anomalies and missed abortion) were calculated. Mean \pm Standard deviation (SD) was calculated for age of the patient as well as for gestational age, effective dose and induction to expulsion time. The stratification was done to control the effect modifiers like age, gestational age, parity,

IUDS, congenital abnormalities and missed abortion.

Results

In this study, a total of 115 pregnant women with indication for pregnancy termination were included. Procedure was effective in 86 (74.8%) women. Average effective dose was 475 ± 113 mcg while Induction to expulsion times for all patients ranged from 12 to 30 hours with a mean of 18.1 ± 6.5 hours. The stratification was done to control the effect modifiers like age, gestational age, parity termination of pregnancy (i.e. IUDS, congenital abnormalities and missed abortion). Procedure was effective in age between 21 - 30 yrs. 47(78.3%), in women with intra uterine death 46 (76.7%), in gestational age > 19 weeks 51 (78.5%) and in primiparous women 40 (78.4%) [Table-1],[Table-2],[Table-3],[Table-4].

Table 1- Effectiveness of misoprostol combine with foley's catheter with respect to age n = 115

Age years	Total	Effective	Percentage
21 - 30	60	47	78.30%
> 30	55	39	70.90%

Table 2- Effectiveness of misoprostol combines with foley's catheter with respect to indications of termination n = 115

Indications	Total	Effective	Percentage
Intra uterine death	60	46	76.70%
Missed abortion	42	31	73.80%
Congenital anomalies	13	9	69.20%

Table 3- Effectiveness of misoprostol combine with foley's catheter with respect gestational age n = 115

Gestational weeks Age	Total	Effective	Percentage
14 - 19	50	35	70.00%
> 19	65	51	78.50%

Table 4- Effectiveness of misoprostol combine with foley's catheter with respect to parity n = 115

Parity	Total	Effective	Percentage
Primiparous	51	40	78.40%
Multiparous	37	28	75.70%
Grand multiparous	27	18	66.70%

Discussion

Second trimester termination of pregnancy (TOP) is a social, emotional, and management challenge that most clinicians would be glad to avoid. Most commonly second trimester TOP is done for missed abortion and congenitally abnormal fetus [10]. Termination of second-trimester pregnancy can be accomplished by various methods such as cervical dilatation with laminaria tents, passing Foley's catheter in the cervix, oxytocin infusion and prostaglandins used through different routes. Also, trans-cervical Foley catheter and oral misoprostol have been shown to be safe and efficacious in cervical ripening [11]. Misoprostol, a synthetic (PGE1) analogue, originally developed as gastrocytoprotective agent, is being evaluated for labor induction. Advantages of misoprostol include effectiveness, low cost, stability at room temperature and ease of administration [12]. Misoprostol has also a potent oxytocic action; it has combined effect of priming or ripening the cervix prior to dilatation and inducing uterine contractions. Misoprostol has also been given orally for cervical ripening and induction of labor, but using this

route of administration has not been as extensively studied [13]. The use of Foley's catheter has been recommended in many developing countries. The reports from different countries have mentioned excellent results with the use of Foley's catheter either alone or in combination with prostaglandins [8]. Two studies found transcervical Foley's catheter appears to offer significant advantages over prostaglandin preparations which have lead to an increased use of trans-cervical Foley's catheter for preinduction cervical ripening and induction of labor. In a larger randomized trial, it was found that the Foley's catheter was more effective and more economical than prostaglandin E1 [14].

In this study, a total of 115 pregnant women with indication for pregnancy termination were included. The mean and the standard variation of age was 29.3 ± 7.8 yrs. Mean gestational age was 21.1 ± 3.4 weeks. The main indication for termination of pregnancy was intrauterine uterine death observed in 52.2% women, followed by missed abortion in 36.5% while congenital abnormality of the fetus was the indication for 11.3% women. The majority of the women were primiparous 44.3% while 32.2% women were multiparous and 23.5% of women were grand multiparous. A study from Thailand studied Ninety four pregnant women indicated for termination of pregnancy during the second trimester; they reported Mean maternal age was 29.4 yrs. The mean gestational age was 20.3 weeks. The majority of the women were nulliparous (60.6%), 37 women were multiparous (39.4%). Seventy two (76.6%) pregnant women had viable fetuses, and the others had intrauterine fetal death (23.4%) [15].

Effectiveness (Time required for induction to delivery within 36 hours if delivery occurred considered as effective) of misoprostol combined with foley's catheter for termination of pregnancy was 74.8%. Average effective dose was 475 ± 113 mcg while Induction to expulsion times for all patients ranged from 12 to 30 hours with a mean of 18.1 ± 6.5 hours. Procedure was more effective in age between 21 - 30 yrs. 47(78.3%), in women with intra uterine death 46 (76.7%), in gestational age > 19 weeks 51 (78.5%) and in primiparous women 40 (78.4%). The findings are supported by a number of national & international studies [16,17]. Prachasilpchai, et al [15] from Thailand reported the success rate 89.4% and Herabutya et al demonstrated using misoprostol 400 µg every 12 hours for second-trimester termination, the success rate was 82%. Studies did not stratify their results based on parity, which could influence the relative effectiveness of each induction method. Effectiveness is associated with the volume of foley's catheter and dose of misoprostol There is evidence that a higher volume Foley (60 or 80 ml) is more effective than one of 30 ml. [4].

It can be concluded that misoprostol combine with Foley's catheter is effective and safe in the induction of labour/abortion in the 2nd trimester pregnancies associated with fetal demise in our setting and no factors affected the success rate significantly. In addition use of Foley's catheter for termination of pregnancy was cheaper and very convenient for both patients and obstetricians. The present study supports the use of misoprostol combine with Foley's catheter.

Recommendation

Further larger studies should be carried out to confirm the efficacy & safety of a drug which is cheap, has no storage issues especially for developing tropical countries like Pakistan where its other alternatives Mifepristone an anti progestational agent is not available

and PGE2 is very expensive and has serious storage issues as it needs maintenance of cold chain.

Conclusion

Effectiveness of misoprostol combined with foley's catheter for second trimester termination of pregnancy was 74.8%. High percentage of effectiveness was seen in age between 21 - 30 yrs., in gestational age > 19 weeks and in primiparous women.

The results of this study suggest that vaginal misoprostol with foley's catheter is a fairly safe, efficient and non-invasive method in second trimester pregnancy termination.

Conflicts of Interest: None declared.

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