

## Mid Trimester Termination of Pregnancy in women with previous Caesarean Section: a comparison of Misoprostol, PGF2 $\alpha$ and Intra-Cervical Foley's Catheter Traction

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### ABSTRACT

**Aim:** To determine the efficacy of oral misoprostol, extra amniotic PGF2 $\alpha$  and intracervical Foley's catheter traction in termination of mid trimester pregnancy in women having previous cesarean section.

**Methods:** All women requiring therapeutic termination of pregnancy between 13 to 26 weeks of gestation having previous cesarean section were included in the study. They were randomized into three groups by lottery method. First group received five doses of oral misoprostol 200 $\mu$ g six hourly, second group received PGF2 $\alpha$  extra-amniotically and third group received intracervical Foley's catheter traction. The expulsion time and complications were noted to determine the efficacy of all three methods in women with scarred uterus.

**Results:** Total 150 women were studied 50 in each group. The success of termination was 82% in misoprostol, 58% in PGF2 $\alpha$  and 44% in Foley's catheter traction which was statistically significant (P=0.000). There was no scar rupture and rate of complications was not statistically significant in all three groups.

**Conclusion:** Misoprostol is safe to be used in mid trimester pregnancy termination and its more efficacious than PGF2 $\alpha$  or Foley's catheter cervical traction.

**Key words:** Mid trimester termination of pregnancy, misoprostol, PGF2 $\alpha$ , Foley's catheter traction,

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### INTRODUCTION

With the global trend of raised cesarean section rate, obstetricians are faced with the challenge of termination of pregnancy in women with a scarred uterus. This becomes more and more challenging as the number of previous cesareans increases and there is no consensus on the safest method of therapeutic abortion in such patients<sup>1</sup>.

Termination in second trimester could be surgical or medical but advancement in medicine have replaced high morbidity surgical procedures with safer and more effective methods like manual vacuum aspiration (MVA) of products of conception and cervical ripening in second trimester with prostaglandin preparations.<sup>2</sup> Second trimester termination cost is also higher but it remains a necessary procedure for obstetricians.

There is a wide range of prostaglandin preparations available which can be used for cervical ripening or induction of labour.<sup>3</sup> Among them PGF2 $\alpha$  is the drug of choice in early gestation but it is costly, requires temperature control in storage and transportation and is associated with pharmacological side effects<sup>4</sup>.

Misoprostol is a synthetic prostaglandin E1 analogue. It was first used in obstetrics to induce abortion in 1988<sup>5</sup>. Now it is widely used for induction of labour, termination of pregnancy and management of postpartum haemorrhage but still its use in obstetrics is not approved by FDA. Mechanical dilatation of cervix to induce abortion or labour is also known since 1833<sup>6</sup>.

The Foleys catheter traction is the cheapest, safest and successful mechanical method of cervical dilatation according to various studies<sup>7,8</sup>.

The decision regarding the effectiveness of any of the above three modality in women with previous cesarean is still a debate. There are various studies internationally<sup>9,10</sup> but there is no similarity in regimens of misoprostol used or in results of rate of termination of pregnancy by using foley's catheter, PGF2 $\alpha$  or misoprotol. We designed this study to determine the success and safety of these three methods of termination of mid trimester abortion in women with previous cesarean sections. Moreover there was no significant difference observed for three modalities locally so this study was planned. This study not only will lead to the decision regarding selection of appropriate method with less comorbidites but also add in the literature regarding the women health improvement that is a matter of concern in 21<sup>st</sup> century.

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## MATERIAL AND METHOD

This randomized controlled study was conducted in the Department Obstetrics and Gynaecology, Lady Willington Hospital, King Edward Medical University, Lahore during February 2013- March 2014

### Inclusion criteria:

- All women with previous cesarean section needing termination between 13 to 26 weeks of gestation
- Patients with singleton pregnancy
- Patients who consent to be part of the study

### Exclusion criteria:

- Women having low lying placenta
- Women having any complication of miscarriage like bleeding, chorioamnionitis, disseminated intravascular coagulopathy etc
- Women having multiple gestation
- Grand multipara i.e., gravida5 and above
- Women having any complication in previous cesarean like endometritis, re opening, scar dehiscence etc

**Data collection:** All women who presented through emergency or outdoor for therapeutic termination of pregnancy between 13 to 26 weeks of gestation having previous cesarean section and fulfilled inclusion criteria were included in the study. They were randomized into three groups by lottery method. One group received intracervical catheter traction only, other group received 2ml (5mg) PGF<sub>2</sub>α diluted to 20ml with normal saline and injected into the extra-amniotic space while the last group had misoprostol 200µg orally five doses six hours apart.

After taking informed consent, the women of Foley's catheter group were put in lithotomy position in examination room, vulva vagina were cleaned with pyodine and sterile Sim's speculum was introduced in the vagina, holding anterior cervical lip with sponge holding forceps and with the help of another sponge holding forceps a Foleys catheter no 14 Fr passed in the cervix into the extra amniotic space and balloon was inflated with 30ml saline. A urine bag filled with 500ml saline was attached to the catheter for traction. As soon as the catheter was expelled reassessment of the dilatation of the cervix was done and if needed infusion oxytocin was started.

In second group foley's catheter was inserted like in group one but instead of traction with saline bag it was clamped at the distal end and injection Prostaglandin F<sub>2</sub>α was given. One injection of PGF<sub>2</sub>α 1ml (5mg) was diluted with 19 ml of normal saline making 2ml of the solution equal to 0.50mg of PGF<sub>2</sub>α. Three ml of this solution was injected into the catheter, 1mls to fill the dead space and 2ml into the extra amniotic space, 2ml was injected one hourly till

the expulsion or till 48 hours have passed after which it was considered treatment failure.

In third group 200µg misoprostol tablet was inserted in the posterior fornix aseptically after every 6 hours till the expulsion or till maximum of five tablets were given. Amount of blood loss was estimated roughly from the soaked pads and from the changes in hemoglobin percentage before and after evacuation. Four hourly temperature record was kept. Events of chills, nausea and vomiting, diarrhea, headache and pain were noted.

The failure of the therapy was considered if there was no expulsion after 48 hours or there were serious side effects needing the treatment to be stopped. The effectiveness was determined by complete expulsion, need for surgical intervention and rate of complications e.g., infection, excessive vaginal bleeding, scar rupture etc

**Data analysis:** The data was collected on a structured questionnaire and analyzed. Descriptive statistics were calculated for each question. Anova was used to compare the three groups for significant difference of effectiveness keeping a p-value ≤0.05 as significant. Regression was also applied to check the dependency of outcome variable on three modalities which are misoprostol, PGF<sub>2</sub>α and Foley's catheter.

## RESULTS

To examine which method of termination of mid trimester pregnancy in women with previous caesarean section increases the risk of complications and is more successful, data of 150 pregnant women was entered into SPSS 14 and analyzed. The mean age of the pregnant women was 25.41±4.33 (Table-1). The mean duration of pregnancy was 21.22±3.07 (Table 2). As regards parity, majority of the women were para one 56(35.7%). Many women 66(42%) were noted with one previous caesarean section, 49(31.2%) with two previous caesarean section, 31(19.7%) with three previous cesarean sections and just 4(2.5%) were noted with 4 times cesarean sections. Indications of termination of pregnancy were same in three groups. Fetal demise was the most common indication in 65(41.4%).

Overall efficacy in terms of complete termination of pregnancy was noted in 92(61.3%) of pregnant women while 58(38.7%) were failed (Table-3). Individual efficacies of all the three treatments are mentioned in table-4. There was significant difference observed between all three methods of termination of pregnancy (p-value=0.000). No significant difference was found between PGF<sub>2</sub>α and intracervical catheter traction (p-value=0.16) (Table 4). Complications noted were nausea & vomiting, fever > 38, abdominal

pain, headache and dizziness, PPH and they were not statistically significant in three groups (table 5).

Table 1: Distribution of age in study groups

Group	Mean ± SD
Misoprostol	25.66±4.20
PGF2α	24.54±3.90
Intracervical catheter traction	26.04±4.81

Table 2: Characteristics of study groups

Parity	Frequency(n=150)	%age
1	56	35.7
2	51	32.5
3	23	14.6
4	15	9.6
5	4	2.5
6	1	4.5
Previous caesarean section		
1	66	42
2	49	31.2
3	31	19.7
4	4	2.5
Indication of termination		
Missed miscarriage	28	17.8
Fetal demise	65	41.4
Fetal anomaly	47	29.9
PPROM	8	5.1
Other	2	1.3

Table 3: Outcome of Termination of Pregnancy (TOP)

	Misoprostol (n= 50)	PGF2α (n= 50)	Foley's catheter (n= 50)
TOP in first 24 hrs	30 (60%)	18(36%)	10(20%)
TOP in 48 hrs	11(22%)	11(22%)	12(24%)
Successful TOP	41(82%)	29(58%)	22(44%)
TOP failure	9(18%)	21(42%)	28(56%)

Table 4: Comparison of efficacy in different groups

Method of termination used	Efficacy		Total
	Successful	Failed	
Misoprostol	41	9	50
PGF2α	29	21	50
Intracervical catheter traction	22	28	50

P-value= 0.000

	Efficacy		Total
	Successful	Failed	
Misoprostol	41	9	50
PGF2α	29	21	50

P-value=0.008

	Efficacy		Total
	Successful	Failed	
Misoprostol	41	9	50
Intracervical catheter traction	22	28	50

P-value=0.000

	Efficacy		Total
	Successful	Failed	
PGF2α	29	21	50
Intracervical catheter traction	22	28	50
Total	51	49	100

P-value=0.16

Table 5: Complications in different groups

	Misoprostol (n=50)	PGF2α (n=50)	Intracervical catheter traction(n=50)
Nausea & vomiting	36	11	3
Fever	15	11	3
Abdominal pain	14	20	29
Headache & dizziness	7	15	2
PPH	7	2	5
Uterine rupture	0	0	0

## DISCUSSION

Worldwide rate of termination of pregnancy is increasing due to better prenatal diagnostic modalities of fetal abnormalities and detection of early fetal demise due to good antenatal services. Out of the total terminations performed in America 10% -15% are in second trimester<sup>11</sup>.

Recently the rate of cesarean section has increased worldwide and there is limited evidence available on safe second term pregnancy termination in these women. Vaginal delivery after cesarean (VBAC) has 0.4% risk of scar rupture but this increase if labour is induced with prostaglandins or oxytocin<sup>12</sup>.

Therefore, the decision to attempt pregnancy termination in the second trimester in cases with previous uterine scar should be made on a case-by-case basis, after consideration of the number of previous cesarean sections and gestational age, and careful labor monitoring of these patients. In our study the overall success rate of termination for all three methods was 61.3% (92 cases) without any scar rupture. In first group Foley's catheter insertion in the cervix and traction was successful in 40% of the patients which is lower than reported in literature.

In a series of 1064 patients who underwent second trimester dilation and evacuation, 70 patients had a previous uterine scar and there were no major complications<sup>13</sup>. Another recently published series reported on 91 patients with previous cesarean sections who had undergone dilation and evacuation, and there were no cases of uterine perforation or other major complication<sup>14</sup>. In 2004 Lichtenberg and Frederiksen<sup>15</sup> reported two cases of cesarean scar

dehiscence after a second trimester dilation and evacuation, the risk increases with increasing gestation.

In the second group of patients having PGF2 $\alpha$  injected in extra amniotic space the success rate was 58% which is higher than Foley's traction group but lower than has been documented in literature, may be the difference is due to the fact that they used a very high dose of PGF2 $\alpha$  and those studies were not done on scarred uteri<sup>16,17</sup>.

There are some case-series of women with previous cesarean sections, in which misoprostol was used for second trimester termination of pregnancy. However, many different protocols have been used with different doses of misoprostol and different intervals between doses and it is difficult to draw definite conclusions.

In our study we used 200 $\mu$ g of misoprostol orally every six hours for the maximum of 5 doses and achieved successful termination in 82% (41 cases). Misoprostol was found to be safe in our cohort of post-caesarean women and there was no case of scar rupture or dehiscence.

Another study in Turkey<sup>18</sup> reported 81.7% success rate with four doses of misoprostol 200 $\mu$ g vaginally every 6 hours with 3 uterine rupture out of 26 patients.

Mazouni<sup>19</sup> reported 98% success rate when misoprostol used with mifepristone in dose of 200 $\mu$ g vaginally every 3 hourly but there were 2 uterine scar ruptures in 50 patients.

While in a study from India<sup>20</sup> divided women with previous cesarean needing midtrimester termination into 2 groups and gave 400 $\mu$ g misoprostol vaginally or sublingually six hourly for 24 hours maximum, in gestation 13 to 20 weeks and 200 $\mu$ g in gestations 21 to 26 weeks. The success rate of termination was 70 % and there was no scar rupture reported. These results are comparable to our study results.

A study by Letourneur<sup>21</sup> reported uterine rupture by misoprostol even in an unscarred uterus but the dose used was very high (1400g).

Milani<sup>22</sup> compared 400 $\mu$ g misoprostol taken 3hourly to 400 $\mu$ g misoprostol taken 6 hourly and found that time of expulsion get shorter but side effects increased by shortening the interval.

In our study the difference in efficacy of termination between misoprostol and foley's catheter traction is statistically significant (P=0.000). The successful terminations in first 24 hour in misoprostol group is also high (60%) compared to Foleys group (20%). The success rate of PGF2 $\alpha$  was (58%) while with misoprostol was (82%) which is also statistically significant. (P=0.000)

The success rate of PGF2 $\alpha$  and Foley's catheter was not statistically significant which is same as

some earlier studies who found no difference in success rate of intracervical traction and prostaglandins<sup>23</sup>.

The most common complication observed by patients in any group was abdominal pain followed by nausea and vomiting, this is commonly reported in other studies due to uterine contractions<sup>24</sup>. The pain requiring analgesia was taking as significant in our study. There was no statistical difference in rate of complications among three groups.

There was no maternal morbidity like haemorrhage requiring blood transfusion, post evacuation infection, placental retention or scar rupture which goes with the mild and self limiting side effects of misoprostol in metaanalysis by Wildschut<sup>25</sup>.

## CONCLUSION

Misoprostol is safe and more efficacious than PGF2 $\alpha$  and intracervical traction with Foley's catheter for second trimester pregnancy termination in women with previous cesarean section when used in doses of 200 $\mu$ g six hourly by oral route.

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