

# TERMINATION OF SECOND TRIMESTER PREGNANCY: EXTRA AMNIOTIC FOLEY'S CATHETER BALLOON WITH TRACTION VERSUS COMBINED USE OF FOLEY'S CATHETER BALLOON AND EXTRA AMNIOTIC INSTILLATION OF PGF2 ALPHA

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## ABSTRACT

**Background:** Termination of pregnancy in second trimester due to intrauterine foetal death and foetal abnormalities is one of the big challenges faced by the obstetricians today. The objectives of this study were to determine the frequency of indications for termination of 2<sup>nd</sup> trimester pregnancy and to compare the efficacy of extra amniotic Foley's catheter balloon with traction vs. combined use of Foley's catheter balloon and extra amniotic instillation of PGF2 alpha for therapeutic termination of second trimester pregnancy.

**Material & Methods:** It was a comparative cross sectional study carried out in the Department of Obstetrics and Gynaecology of Saidu Group of Teaching Hospitals, Swat, Pakistan in year 2011. A sample of 73 patients was selected by convenience sampling. Inclusion criteria were pregnant women, 14-26 weeks of gestation with foetal intra uterine death or lethal congenital malformations. The exclusion criteria were placenta previa, unexplained vaginal bleeding and vaginal discharges, and those with absent membrane. Patients were randomised into two groups by simple lottery method. The group 1 patients were induced with Foley's catheter balloon alone with traction while group 2 patients were induced with combined Foley's catheter balloon and PGF2-alpha.

**Results:** Mean induction to products expulsion interval was significantly shorter in the group 2 as compared to group 1 (16.7±4 versus 26.2±11.019 hrs, p<0.005).

**Conclusion:** The combined use of Foley's catheter balloon with extra amniotic instillation of PGF2-alpha is more efficacious than the Foley's catheter balloon with traction alone.

**KEY WORDS:** Pregnancy, Second trimester, Therapeutic termination, Prostaglandin F2 alpha.

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## INTRODUCTION

Globally, 40% of women live in countries in which abortion is legal on request. For a further 23% abortion is available on psychosocial grounds. For 12 % broad-based medical grounds are required and in 25% abortion is only available in strictly life threatening situations.<sup>1</sup> Despite the recent advances in prenatal diagnosis in first trimester, termination

of pregnancy in second trimester due to foetal abnormalities and intrauterine foetal death still accounts for large number of abortions, and has increased the demand for rapid termination of pregnancy.<sup>2,3</sup> Achieving the termination of pregnancy in second trimester is one of the big challenges facing the obstetricians today. Disseminated intra vascular coagulopathy is important associated complication if a dead foetus failed to be expelled spontaneously within four weeks of the estimated foetal demise. Mother may also face psychological problem once she knows that she is carrying a dead or an abnormal foetus, in such circumstances, termination has to be achieved.<sup>4</sup> A variety of techniques for termination of second trimester pregnancy can

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be used, but there is no consensus about which is the best.<sup>5</sup> Use of the Foley's catheter for termination of pregnancy was first described by Krause in 1833.<sup>6</sup> In 1967, Embrey and Mollison<sup>7</sup> reported a 94% successful induction rate in 100 women with Foley's catheter. The direct mechanical dilatation and endogenous release of Prostaglandin are the mechanism of cervical ripening by Foley's catheter<sup>8</sup> and this effect is enhanced when traction is applied. The use of Foley's catheter balloon alone has shown better results in achieving cervical ripening than 3mg dinoprostone vaginal passery and it is also very economical.<sup>3,8-11</sup> The combined use of Foley's catheter balloon and instillation of extra amniotic PGF2-alpha at regular interval has resulted in very short mean induction to expulsion interval and with minimal side effects.<sup>12,13</sup>

The main concern of the obstetricians is to provide the most effective and safest method, which have shortest induction to expulsion time, ideally should be cost effective and with minimal side effects.

The objectives of this study were to determine the frequency of indications for termination of 2<sup>nd</sup> trimester pregnancy and to compare the efficacy of extra amniotic Foley's catheter balloon with traction vs. combined use of Foley's catheter balloon and extra amniotic instillation of PGF2 alpha for therapeutic termination of second trimester pregnancy.

**MATERIAL AND METHODS**

This was a comparative cross sectional study. The study was carried out in the Department of Obstetrics and Gynaecology in Saidu Group of Teaching Hospitals Swat, Pakistan from 1<sup>st</sup> January 2011 to 31<sup>st</sup> December 2011.

A sample of 73 patients was selected by convenience sampling. Inclusion criteria were pregnant women, 14-26 weeks of gestation with foetal intra uterine death or lethal congenital malformations. The exclusion criteria were placenta previa, unexplained

vaginal bleeding and vaginal discharges, and those with absent membrane. Informed consent was obtained from all patients. All patients were admitted in the hospital. Detail examination was carried out. Pelvic examination was done to asses cervical score and size of the uterus. Important investigations were carried including blood complete, blood grouping and Rh factor, urine analysis, coagulation profile and platelets count .Patients were randomised into two groups by simple lottery method. The group 1 patients were induced with Foley's catheter balloon alone with traction while group 2 patients were induced with combined Foley's catheter balloon and PGF2-alpha. In both groups by using sterile techniques, a size 20 French gauge Foley's catheter was inserted through the internal cervical os. The balloon was inflated with 40 ml distilled water and traction was applied by urinary bag filled with 500 ml water. To the group 2 patients, extra amniotic PGF2-alpha injection was given through the same catheter. One ml injection of PGF2-alpha was diluted with 19 ml normal saline in a 20 ml syringe, 2 ml were instilled through the draining end of the catheter immediately after insertion of the catheter and then 1ml at hourly interval till expulsion of the balloon .Intravenous oxytocin infusion was used for augmentation in both groups, once the cervical ripening was achieved. Evacuation and curettage was performed under propofol injection, when required.

Data were collected for maternal age in years, parity (number), gestational age in weeks as demographic variables and indications for termination of 2<sup>nd</sup> trimester pregnancy, induction to balloon expulsion interval and balloon expulsion to products expulsion interval as research variables.

Descriptive statistics for all the above numeric data were presented as minimum, maximum and mean and inferential statistics were carried out for the research variables by Independent Samples Student's t test using SPSS 11 (SPSS Inc., Chicago, Illinois, USA). The results were considered statistically significant with p<0.05.

**Table 1: Descriptive Statistics of Demographic Data of Patients for Termination of 2<sup>nd</sup> Trimester Pregnancy.**

Variables	Group	Sample size	Minimum	Maximum	Mean
Maternal age in weeks	Group 1	36	19	40	23.64
	Group 2	37	19	40	23.82
Parity (number)	Group 1	36	0	10	2.78
	Group 2	37	0	10	2.90
Gestational age in weeks	Group 1	36	14	28	21
	Group 2	37	14	28	21

## RESULTS

Total 73 patients were part of the study. Descriptive statistics of demographic data of patients for termination of 2<sup>nd</sup> trimester pregnancy are given in Table 1.

There was no significant difference between the two groups with respect to maternal age, parity and gestational age.

Over all the indications for termination of pregnancy were intra uterine foetal death for different reasons in 57 (78.09 %) cases while gross congenital foetal abnormalities mainly anencephaly were in 16 (21.91 %) cases. Group wise analysis is given in Table 2.

Table 3 gives comparative analysis of research data for the two groups.

All patients in group 2 expelled with one ampoule and within 24 hours. The group 1 patients required more than 24 hours stay in the hospital.

## DISCUSSION

The purpose of study was to compare the efficacy of intra cervical Foleys catheter balloon with traction with extra amniotic instillation of PGF2-alpha through intra cervical Foleys catheter. Mid trimester pregnancy terminations are necessary, when there is intra uterine foetal death or lethal foetal congenital abnormalities, but it is usually accompanied by

unfavourable cervix. To solve this problem, different methods of artificial cervical ripening have been developed. Different mechanical devices and pharmacological methods are in use for maturation of cervix.

The superiority of Foleys catheter balloon for cervical ripening in second trimester of pregnancy is documented in different studies.<sup>3,14-16</sup> Favourable results are documented in the literature about the use of extra amniotic Foleys catheter balloon combined with extra amniotic instillation of PGF2 alpha.<sup>12,13</sup>

In our study we found that intra cervical Foleys catheter balloon along with extra amniotic instillation of PGF2 alpha is the most effective, safe and cost effective method for therapeutic termination of second trimester pregnancy with minimal side effects and good patients compliance. The psychological tension of the patient and their attendants awaiting termination of unwanted pregnancy for prolonged hours was considerably reduced in group-II patients.

In the study conducted by Tasleem A<sup>5</sup> the result of intra cervical Foleys catheter balloon with PGF2 Alpha were supportive of our results that is induction to Foleys catheter balloon expulsion interval (13.17+hours) and induction to products expulsion interval (16.67+6.71 hrs) but with the use of Foleys catheter balloon alone the mean values were contrary very short that is Foleys catheter balloon expulsion interval (16.45±4.99 hrs) and induction to product expulsion interval

**Table 2: Indications for Termination of 2<sup>nd</sup> Trimester Pregnancy.**

Variable	Sample size	Group 1		Group 2	
		Number	% age	Number	% age
Intra uterine foetal death	36	28	77.77	29	78.37
Congenital abnormality	37	8	22.23	8	21.63
Total	73	36	100 %	37	100 %

**Table 3: Inferential Statistics of Research Data of Patients for Termination of 2<sup>nd</sup> Trimester Pregnancy. (Group 1 n=36 & Group 2 n=37).**

Research Variables	Group 1 (hours)	Group 2 (hours)	Difference (hours)	p-value
Mean induction to balloon expulsion interval	25	15.5	9.5	<0.005
Mean balloon expulsion to products expulsion interval	1.2	1.2	0	>0.05
Mean induction to products expulsion interval	26.2	16.7	9.5	<0.005

(19.95±5.56 hrs), which have made the difference in the interval between the two groups in their study statistically non-significant ( $p>0.05$ ).

The study conducted by Halimi M<sup>17</sup> the mean induction to Foleys catheter expulsion interval with combined use of Foleys catheter balloon and extra amniotic PGF2 alpha (13.21±8.69 hours) compare to Foleys catheter balloon alone (33.88±11.345 hrs) ( $p<0.005$ ) were very close to our study. Similarly the mean induction to foetus expulsion intervals were group 2 compared to group 1 (16.50±8.82 versus 37.76±1.019 hrs) which is statistically a highly significant difference ( $p<0.005$ ) which is again very close to our study.

In the study conducted by Pushpa Sirichand S<sup>14</sup> the mean induction to abortion interval with Foleys catheter balloon was 26.3±8.2 hrs, which is closer to our results in group 1. The mean induction to abortion interval of 12.3±6.4 hrs by Perry KG Jr<sup>18</sup> with intra amniotic PGF2 alpha injection and 17.5±8.6 with continuous extra ovular instillation through balloon catheter are [12] comparable to our study in group 1.

A study was conducted by Altaf F<sup>19</sup> showed induction-abortion interval of 20.23 hrs ± SD 11.49 hrs in PGF2 alpha group. Their results are also closed to our study.

A study was conducted by Imran F<sup>20</sup> to compare misoprostol with extra amniotic Prostaglandin F2 alpha instillation and was found to be of same success rate. Mean induction to expulsion duration for Prostaglandin F2 alpha was 16.04±6.22 hrs, which is very close to our study. In their study complication profile was very low in both preparations which are again in favours of our study. They successfully managed 92 % cases with PF2 alpha.

Complete abortion rate was same in both groups 75.23 % in group 1 compared to 78.12 % in group 2 ( $p>0.05$ ). Successful termination rate of 94 % ( $p<0.005$ ) within 24 hours in our study was comparable with 88% achieved with intra amniotic injection of PGF2 alpha<sup>17</sup> and 96% with the use of continuous instillation of PGF2 alpha through double balloon catheter.<sup>11</sup> Only 7.0% patients were successfully terminated within 24 hrs in Foleys catheter balloon with traction only group.

## CONCLUSION

The combined use of Foley's catheter balloon with extra amniotic instillation of PGF2-alpha is more efficacious than the Foley's catheter balloon with traction alone.

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