COMPARISON OF FOLEY'S CATHETER WITH EXTRA AMNIOTIC PROSTAGLANDIN F2 ALPHA IN TERMINATION OF SECOND TRIMESTER PREGNANCY

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ABSTRACT

Aims and objectives: *The aim of this study was to compare the efficacy, safety, adverse effects and cost effectiveness of extra-amniotic Foley's catheter balloon alone (group-I), with the combined use of Foley's catheter balloon and extra-amniotic prostaglandin F2-α (group-II) for termination of second trimester pregnancy.*

Material and Methods: *It was a experimental trial carried out in Obstetrics and Gynecology unit "A" of post-graduate medical institute, Lady Reading Hospital Peshawar, during September 2002 to September 2003.*

Hundred (100) patients having gestational age between 14-28 weeks and cervical score less than 4, were enrolled in the study, 50 patients for group-I and 50 patients for group-II. Indications for termination were either intrauterine fetal death or congenital malformations incompatible with life. Foley's catheter 16fr was passed in both the groups intra-cervically. Group-II patients in addition received extra amniotic PGF2alpha, (0.25mg/ml diluted solution), one ml at one hour interval, through the same catheter, till the expulsion of the balloon.

Results: *The mean induction to products expulsion interval was significantly shorter in the combined use of Foley's catheter and extra amniotic PGF2alpha (13.34±6.71 versus 33.74±8.941 hours). The rate of successful uterine expulsion with in 24 hrs was also significantly higher in group-11 (92% versus 24%). The frequency of diarrhea (04%), vomiting (06%), and uterine pain (06%) in group -11 was not statistically significant (P>0.05) but the frequency of temperature of 100 °F was significantly higher in group-1 (78%) as compared to group-11(18%).Group-11 patients had shorter average hospital stay (1.53±0.57 days versus 2.766±0.567 ingroup-1 i.e. P<0.1).*

Conclusion: *The combined use of Foley's catheter and extra amniotic PG F2 alpha is more rapid, safe, cost effective method for induction of therapeutic termination of second trimester pregnancy, resulting in greater number of successful uterine evacuation with in 24 hrs, than Foley's catheter balloon alone.*

Key Words: *Foley's catheter, Prostaglandin F2-alpha, second trimester pregnancy termination, missed abortion, congenital anomalies.*

INTRODUCTION

Termination of pregnancy means the removal of a pregnancy with out any expectation that the fetus will survive. The indications for terminating pregnancy are based on legal constraint [1]. The increasing use of ultra-sonography and serological screening has enhanced the ability of obstetricians to recognize potentially complicated pregnancies early in gestation. After counseling, many of these women elect to take the risks of continuing complicated pregnancy for the risk of a pregnancy termination.[2] The global incidence of spontaneous abortions is around 15% of all pregnancies. Similar figures have been quoted for Pakistan.[3] The ability to identify fetal abnormalities at an early stage by using ultrasonography has increased the number of women requiring termination of pregnancy.

PERIOD OF GESTATION

Gestation in weeks	Group-I		Group-II	
	By Dates	By Scan	By Dates	By Scan
14 weeks	26	24	12	13
14-16 weeks	09	09	16	13
16-18 weeks	10	10	05	05
18-20 weeks	02	02	03	05
20-22 weeks	03	03	08	06
22-24 weeks	01	01	03	04
24-26 weeks	0	0	03	02
28 weeks	01	01	0	01
	51	**20**	**50**	**49**

Table 1

Termination of pregnancy in second trimester is associated with 3-5 times high risk of maternal morbidity and mortality than during first trimester.[4] The decision about which method to use for inducing labor or terminating pregnancy is influenced by a variety of factors, including pregnancy gestation, maternal health and parity, indication for induction or termination, any primary or secondary pregnancy complications, cervical condition, maternal preference and obstetric unit facilities. Various methods are being used for termination of pregnancy in the second trimester; however the main concern of obstetrician is to provide the most effective and safest regimen, which combines the shortest expulsion interval with least side effects.[5]

Technologic advances in imaging modalities and more aggressive screening programs to detect genetically abnormal fetuses increase the need for safe methods of performing second trimester abortion.[6,7] The most common approach has been the administration of oxytocin either alone or after initial priming with other agents. Prostaglandins opened a new horizon in the management of such cases. Although the newer preparation containing PG F-2 alpha are considered to be safe and effective yet recent studies have high lighted many side effects.[8] More over the high cost of the PG. still remains an important factor in developing world.[9]

Second trimester abortion induction with Foley's catheter is considered and proved a simple procedure with minimum side effects, is efficacious mean of cervical ripening and is economical. This method is well tolerated by most of the women who can remain mobile while device in place. In comparison with the five different methods, the use of extra amniotic balloon was found to provide more effective treatment than intracervical PGE-2 and misoprostol.[10]

MATERIAL AND METHODS

This was a experimental study conducted during September 2002 – August 2003 in Gynae-"A" unit P.G.M.I. lady Reading Hospital, Which is a tertiary care hospital and serves low income urban and rural population.

All those women were included in this study:

(i) Who presented with ultrasonic conformation of fetal death during mid trimester (i.e. from 14-28 weeks) or with sever congenital malformation (e.g. anenchaphalic, gross hydrocephalus with meningocele etc) not compatible with life presenting either as Gynae out patient clinic or received in emergency; (ii) Poor cervical score;

INDICATIONS FOR INDUCTION

Indications	Group-I		Group-II	
	No. of cases	Percentage	No. of cases	Percentage
Intrauterine fetal death	45	90%	45	90%
Congenital Anomalies and Anencephaly	03	6 %	05	10%
Others(hydrocephalus & hydrops)	02	4 %	0	0

Table 2

COMPLICATIONS RELATED TO INDUCTION

Complications	Group-I		Group-II		P-value
	No. of patients	Percentage	No. of Patients	Percentage	
Nausea & vomiting	01	1%	03	6%	NS
Diarrhea	0	0%	02	4%	NS
Pain	01	1%	03	6%	P<0.05
Fever	34	78%	09	18%	NS
Failure rates	02	4%	01	2%	NS

Table 3

(iii) Intact gestational sac. Exclusion criteria for catheter insertion were per-vaginal discharge, and fever indicating infection. All Patients with Gestational sac less than 14 weeks and more than 28 weeks, with significant medical disorders e.g. cardiac patients, glaucoma, asthma etc., or with contraindication to prostaglandin were excluded. Patients having any form of deranged coagulation profile were treated first, and then induced.

Total hundred (100) patients were included in this study and divided into two groups (50 cases in each group). On alternate days of admission, in group-I subjects only extra-amniotic Foley's catheter balloon was used. In group-II subjects extra-amniotic Foley's catheter balloon was combined with instillation of extra-amniotic prostaglandin F2-α. All the patients were hospitalized and were counseled with informed consent. Detailed history was recorded of gestational age, duration of pregnancy were calculated by last menstrual period. General physical examination and pelvic examination was performed to exclude infection and vaginal bleeding, to assess cervical score and uterine size. Essential investigations were performed, including mid stream urine specimen examination, blood grouping and Rh factor, blood complete profile, clotting profile including prothrombin time, activated thromboplastin time, and platelet count, FDPs and fibrinogen level, where indicated. Hemoglobin percentage before and after the procedure were done. Ultrasonic confirmation of fetal death, gestational age, and congenital abnormalities of the fetus confirmed. Serum uric acid and liver function tests were performed in patients with pre-eclampsia and eclampsia.

Foley's catheter 16fr was inserted through the internal os in group-I Patients. Group-II patients received PGF2-α in addition to Foley's catheter balloon. One milliliter of prostin F2-α containing 5mgs was diluted in 20ml disposable syringe by addition of 19ml of normal saline, to make total of 20mls solution. Two milliliters were instilled through the catheter after its insertion, extra-amniotically, and then 1ml was instilled at hourly interval till the expulsion of balloon of Foley's catheter.

Time of insertion and Foley's balloon expulsion was noted in both the groups. Soon after expulsion of Foley's catheter balloon, pelvic examination was performed to assess cervical score (dilatation of cervix, softness and effacement). 30units syntocinen in 100cc Ringer lactate solution was started in both cases, till expulsion of fetus and placenta either completely or incompletely; after which evacuation and curettage was performed under tramadol injection, time of expulsion evacuation was noted.

Amount of blood loss was estimated

COMPLICATIONS RELATED TO INDUCTION

Duration (in hrs)	Induction to Balloon expulsion interval				Induction to product expulsion interval			
	Group-I		Group-II		Group-I		Group-II	
	N	%	N	%	N	%	N	%
< 12	5	10%	5	10%	31	62%	31	62%
12-24	11	22%	11	22%	17	34%	17	34%
>24	26	52%	26	52%	02	4%	02	4%
> 48	8	16%	8	16%	0	0%	0	0%
Mean Interval	31.20±10.549		10.78 ± 18.17		33.74 ± 8.94		13.34 ± 6.71	
Difference	20.42				20.40			
P-value	P < 0.05				P < 0.05			

Table 4

DURATION OF STAY IN HOSPITAL

Days:	Group-I		Group-II	
	No. of patients	Percentage	No. of patients	Percentage
One day	01	2%	10	20%
Two days	18	36%	25	50%
Three days	17	34%	15	39%
Four days	09	18%	0	----
Five days	03	6%	0	----
Six days	02	4%	0	----

Table 5

HOSPITAL EXPENSES

Expenses of patients in Rupees	Group-I		Group-II	
	No. of patients	Percentage	No. of patients	Percentage
Up to 1000	04	8%	12	24%
Up to 2000	27	54%	30	64%
Up to 3000	09	18%	06	14%
Up to 4000 & above	10	20%	02	02%

Table 6

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. Data were analyzed for mean maternal age, mean parity, gestational age, induction to Foley's expulsion interval (incidence of complete abortion), and total hospital stay in days, total hospital expenses and complications noted.

Psychological acceptability of the procedures, symptoms experienced before and after procedures were assessed by interviewing the patients after the procedure.

Treatment failure was defined as failures to expel with in 24hrs after insertion of Foley's catheter, where other alternative method was used for evacuation they were excluded from induction evacuation calculation. The primary out come measures were successful uterine evacuation within 24hrs.

Statistical significance was calculated using student "t" test.

RESULTS

Gestational age ranged from 14-28 weeks by dates and 14-26 weeks by scan in both the groups. Mean gestational age had no significant difference between the two groups both by dates (17.04±4.16 versus 18.00±4.10) and by scan (16.08±4.10 versus17.76±4.28) i.e. P>0.05 as shown in table-I. Indications for termination were similar between two groups. Majority of the patients had termination for intrauterine deaths, 45 patients in group-I (90%) and 45 patients in group-II (90%). In group-I, 03 patients had anencephalic fetuses (06%) and in group-II, 05 patients (10%) presented with anencephalic fetuses. 2 patients (4%) in group-I presented hydrops fetalis(Table-II). The side effects in group-II were minimal, only 3 patients (6%) complained of nausea and vomiting, 2 patients (4%) had diarrhea, and 3 patients having uterine pain, compared to one patient having vomiting, one having pain and none had diarrhea in group-I, which is not significant. A significant number of patients (34 i.e. 78%, P<0.05) in group-I had temperature spike of 100°F on one occasion compared to 9 cases (18%) in group-II(Table-III).

AVERAGE HEMOGLOBIN DEFICIT IN GRAMS PER DECILITER (GM/DL):

	Pre-operative	Post-operative	Difference
Group-I	11.865 ± 1.308	11.39 ± 1.289	0.475, P > 0.05
Group-II	11.22 ± 1.11	10.92 ± 1.053	0.30, P > 0.05

Table 7

Greater number of patients in group-II reach the main out-come of successful uterine evacuation within 24hrs than group-I (96% v s 32%) and 100% cases expelled the products within 48hrs in group-II compared to 84% in Group-I (P< 0.01) (Table-IV). As indicated in table-V, group-I patients had to stay in the hospital for significantly longer duration than group-II patients (2.766 ± 0.567 versus 1.533 ± 0.57 days, P < 0.01). The average expenses of group-I= 2500 ± 314.610 and for group-II= 1960 ± 44.721 making a difference of 540 rupees (P < 0.05) which shows the cost effectiveness of group-II (Table-VI). The average hemoglobin deficit after expulsion of products was 0.475gm/dl in group-I patients and 0.03gm/dl in group-II patients, which is statistically non-significant (P > 0.05) (Table-VII).

DISCUSSION

In our study we found that the mean induction to Foley's balloon expulsion interval was considerably shorter in the group-II, compared to group-I, 13.34 ± 6.71 hours versus 33.74 ± 8.941 hours (P < 0.01). Similarly the mean induction to product expulsion interval was shorter by 21.02 hours in group-II compared to group-I (10.78 ± 18.17 versus 31.20 ± 10.549 hours), which is statistically a highly significant difference (P < 0.01).

In the study conducted in Agha Khan hospital by Amjad-T et al, the induction to Foley's balloon expulsion interval (13.17 ± 4.37 hours) and induction to product expulsion interval (16.67 ± 6.71 hours) for the combined use of Foley's catheter balloon and extra-amniotic PGF2-a were similar to our results. But the induction to Foley's balloon expulsion interval (16.45 ± 4.99 hours) and induction to product expulsion (19.95 ± 5.56 hours) with the use of Foley's catheter alone, in contrary to our study were much shorter, making the difference in the intervals between the two groups in their study, statistically non-significant (P < 0.05).3 The mean interval between Foley's balloon expulsion and products expulsion in their study was 3.5 hours in both the groups, which is similar to our study (3.06 ± 3.14 hours in group-II versus 2.54 ± 3.24 hours in group-I) and the difference is statistically non-significant (P <0.05).

In the study conducted by Puspha Sirichand Sachdev, the mean induction to abortion interval with Foley's catheter balloon was 26.3 ± 8.2 hours, which is closer to our results in group-I (31.20 ± 10.549 hours).

The mean induction to delivery interval of 12.3 ±6.4 hours[11] and 17.5 ± 8.6 hours[12] shown by the use of intra-amniotic injection of PGF2-α is contrary to that of our study (10.79 ± 18.17 hours), with the combined use of Foley's catheter balloon and extra-amniotic PGF2-α. They have also reported minimal side effects of nausea, vomiting, Pyrexia, and uterine cramps similar to our study.

The study of Amjad-T et al also does not agree to our study in respect of cost effectiveness of the combined use of PGF2-α. In our study the average hospitals stay required by patients in group-I was 1.223 days longer than group-II patients, (2.766 ± 0.567 versus 1.533 ± 0.57 days), which raised their hospital expenses by 540 rupees more (2500 ± 314.610 versus 1960 ± 44.721 rupees). The difference reached statistically significance P < 0.05, making the combined use of extra-amniotic PGF2-α and Foley's catheter balloon more cost effective. In addition the psychological tension of the patient and their attendants waiting termination of unwanted pregnancy for prolonged hours was considerably reduced in group-II patients.

Complete abortion state was similar between the two groups, 72.27% in group-I compared to 76.66% in group-II (P < 0.05). Successful termination state within 24hours of 92% in our study was consistent the 88% achieved with intra-amniotic injection of 15-methyle PGF2-α[12] and 96% with extra-ovular instillation of PGF2-α via double balloon catheter. At 48 hours complete abortion rate in group-I was 92% and in group-II 100%.

The average blood loss evident from pre-operative and post-operative hemoglobin deficit was minimal (P > 0.05) in both the groups (0.475 in group-I versus 0.30 in group-II), which is comparable to other studies.[3],[12]

The frequency of pyrexia in contrast to other studies[3, 4] was significantly higher 23.64% in group-I comparable to 3.33% in group-II, P < 0.05 in the Foley's balloon group 23.64% compared to 3.33% in group-II (P < 0.05) probably because of prolonged induction to abortion interval.

CONCLUSION

So conclusion was made that combined use of Foley's catheter and extra amniotic PG F2 alpha is more rapid, safe, cost effective method for induction of therapeutic termination of second trimester pregnancy, resulting in greater number of successful uterine evacuation with in 24 hrs, than Foley's catheter balloon alone.

It is cost effective in terms of reducing the duration of hospital stay and expenses by causing rapid termination.

It is associated with minimal side effects,

is well tolerated and more acceptable to the patient.

REFERENCES

1. James DK, Steer PJ, Weiner CP, Ganik B, editors. London: WB Sander, 1999;1079-96.
2. Chapman SJ, Crispens M, Owen J, Savage K. 'Complications of mid trimester pregnancy termination: the effect of prior caesarian section'. Am J Obstet Gyneacol 1996;175:889-92.
3. Akhter AJ, Termination of pregnancy with fetal death in second trimester. Foley's catheter versus extra amniotic prostaglandins. J Coll Physicians Surg Pak 1999; 9: 403-5.
4. Sirichand SP. Termination of second trimester pregnancy. Comparison of prostaglandin vaginal pessaries versus Foley's catheter insertion. J Coll Physicians Surg Pak 1999; 9:400-2.
5. Atad J, Hallak M, Ben- David Y, Auslender R, Vicih A. Ripening and dilatation of the unfavorable cervix for induction of labour by double balloon device experience with 250 cases. Br J Obstet Gynecol 1997; 04: 29-32.
6. Jain JK, Daniel R, Mishel Jr. The comparison of misoprostol with out lamanaria tents for induction of second trimester abortion. Am J Obstet Gynecol 1996; 175: 173-177.
7. Grimes DA. Clinicians who provide abortion; the thinning ranks. Obstet Gyneacol 1992; 80: 719-23.
8. Karim SM, Trussel RR, Patel RC, Hilliesk. Response of pregnant human uterus to PG –F-2 alpha, induction of labour. BMJ 1968; 4:621-3.
9. Fait T, CaldaP, Zizka Z, Pavlista D, Hruskora H, Zivnyj. 'Termination of 128 pregnancies in the second trimester using Prostaglandins15methyl f 2 alpha. Ceska Gynecol 2000; 65:451-5.
10. Yapar EG, Senoz S, Urkutur M. Batioglu S, Goknen O. Second trimester pregnancy termination including fetal death: Comparison of five different methods.Eur J Obstet Gynecol Reprod Biol 1996; 69:97-102.
11. Perry KG Jr, Roberts WE, Martin RW, Magann EF, Sullivan DC, Morrison JC. Comparison of intra amniotic (155) 15-methyle PGF2alpha and intra vaginal prostaglandin E2 for second trimester uterine evacuation. J Perinatol 1998; 18:24-7.
12. Kaunitz AM, Hughes MJ (1985) causes of maternal mortality in United states Obstet Gynecol 1985; 65; 605-12.

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