USE OF FOLEY'S CATHETER AND PROSTAGLANDIN F-2 ALPHA IN SECOND TRIMESTER TERMINATION OF PREGNANCY

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Background: Termination of pregnancy (TOP) in the second trimester is associated with three to five times higher risk of maternal morbidity and mortality than termination during first trimester. The main concern of obstetrician is to provide the most effective and safest regimen which combines the shortest expulsion interval with least side effects. This study was undertaken to compare the use of Foley's catheter with extra-amniotic instillation of PGF_2 alpha for second trimester TOP so that a choice of the safer and cost-effective method could be available. **Methodology:** The study was conducted in Department of Obstetrics and Gynecology Unit 'B' at Ayub Teaching Hospital Abbottabad between August 2003 and July 2004. Sixty patients recommended for TOP (missed abortion or anencephalic fetus confirmed on ultrasonography) were randomly allocated into two groups. In group 'A', Foley's catheter alone was used while in group 'B' extra amniotic instillation of Prostaglandin F-2 alpha (PGF_2 alpha) was done via a Foley's catheter. After expulsion of catheters in both cases oxytocin infusion containing 30 units were started till the expulsion of fetus, placenta and membranes. The mean induction to expulsion time and the mean induction to delivery time for both groups were noted as well as total cost of treatment. **Results:** Difference in time interval with regard to induction to expulsion time of catheter and induction to delivery time between the two groups was significant being 3 hours and 5 hours respectively less in group 'B' ($p < 0.001$); however only 25% of patients in group 'B' had a significant short induction to delivery time as compared to group 'A'. The difference in costs of treatment between the groups was also significant ($p < 0.001$). **Conclusion:** Use of PGF_2 alpha is preferred, though for poor patients Foley's catheter may be used, but only in a tertiary care setting.

Key Words: Dinoprost, Abortion, Labor onset, Uterine contraction, Cervical ripening, Balloon dilatation.

INTRODUCTION

The ability to identify fetal abnormalities at an early stage by using ultrasonography and modern prenatal diagnostic techniques has increased the number of women requiring termination of pregnancy (TOP).[1] TOP is defined as elective expulsion or extraction of products of conception from uterus instead of spontaneous onset of process irrespective of duration of pregnancy. Most commonly second trimester TOP is done for missed abortion and congenitally abnormal fetus. Missed abortion is death of fetus in utero before 24 weeks of gestation but uterus fails to expel products of conception.[2] Regarding congenitally abnormal fetus mostly termination of pregnancy is done for neural tube defects i.e. anencephaly.

Uterine responsiveness to conventional methods of induction of labor increases as pregnancy approaches term. But second trimester TOP has always been a difficult task. TOP in second trimester is associated with three to five times higher risk of maternal morbidity and mortality then termination during first trimester.[3]

Various methods are being used for TOP in second trimester such as cervical dilatation with laminaria tents, passing Foley's catheter in cervix, oxytocin infusion and prostaglandins used through different routes.[4] 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.

Medical methods are often preferred for evacuation of uterus, especially where the uterine size exceeds twelve weeks.[5] Prostaglandins opened a new horizon in the management of such cases.[6] These play an essential role regarding process of labor. Absence of prostaglandins favors continuation of pregnancy and their presence initiates labor.[4] Prostaglandins are now commonly used to achieve termination of pregnancy. PGE_2 and PGF_2-a have potent oxytocic action. They have combined effects of priming or ripening the cervix prior to dilatation and inducing uterine contraction.[7]

The use of Foley's catheter has been recommended in many developing countries. The reports from Turkey[3], Egypt[8], Ethiopia[9], Israel[10] and Nigeria[11] have mentioned excellent results with the use of Foley's catheter either alone or in combination with prostaglandins.

Although the exact mode of action of Foley's catheter is not fully understood, yet it has been postulated that the catheter stimulates various unspecified regions of the uterus, elevates its excitability and causes regular uterine contractions.[12]

The aim of this study was to assess the use of Foley's catheter for second trimester TOP with

an idea to assess safety and to decrease the cost of treatment. This method is compared with extra-amniotic installation of PGF_2-a via a Foley's catheter.

MATERIAL AND METHODS

The study was conducted in the Department of Obstetrics and Gynecology Unit B of the Ayub Teaching Hospital Abbottabad Pakistan from August 2003-July 2004. Sixty pregnant ladies with missed abortion or congenitally abnormal fetus were selected for the study. In this study women with ultrasonic confirmation of fetal death or severe malformation (i.e. anencephaly) not compatible with life were included. These were either nullipara or multipara with single pregnancy between 14 to 24 weeks. Bishop's Score (cervical state unfavorable) was same in all women included in the study.

Grand multipara with single or multiple pregnancy, medical disease like diabetes mellitus, hypertension, asthma, glaucoma, coagulopathy or with history of previous uterine surgery or with history of manipulation during current pregnancy were not included in study.

Selected patients were admitted in labor room and advised to stay in hospital till pregnancy was terminated.

Complete evaluation of each patient was done at admission. Detailed history as well as findings on medical and obstetric examination were recorded. Repeat ultrasonography (USG) was performed in labor room to confirm diagnosis of missed abortion or anencephaly. Coagulation screening was also done in all patients. Informed consents were taken after going through counseling regarding need of termination of pregnancy and possible method to be used for this purpose.

Selected patients were divided into two equal groups. In Group 'A' intra-cervical Foley's catheter was used alone for termination of pregnancy, while in Group 'B' the patients were given extra-amniotic instillation of PGF_2 alpha via a Foley's catheter. . In Group 'B' patients PGF_2-a was administered as 20 µg/ml solution prepared by diluting 5mg (1ml ampoule) of PGF_2-a in 19 ml of distilled water (Initial dose 750-1000 µg, subsequent dose 500 µg/2ml). The dose of 2 ml was repeated at two hourly intervals according to the response and progress of induction.

Both groups were observed for 24 hours. The time lapsed till expulsion of catheter was recorded to measure "induction to expulsion" time. As soon as the catheter was expelled per vaginum, examination was done to re-evaluate the condition of the cervix. An oxytocin infusion containing 30 units of oxytocin in 1000ml of Ringer's lactate solution was set up at a rate of 10 drops/min which was increased up to 60 drops/min in some patients. The strength of uterine contractions was assessed by maternal palpation of uterus through abdominal wall. If uterine contractions were occurring at an interval of less than 3 minutes and causing considerable discomfort to the patient, it was considered a hyper stimulation and narcotic analgesia was administered. The time lapsed until the expulsion of the fetus was also noted to calculate the "induction to delivery time".

Prophylactic intravenous antibiotics were given to all patients for 48 hours followed by oral antibiotic for a total of five days. Antibiotics included Ampicillin, 500mg I/V x 6 hrly, Gentacin, 80mg I/M x 8 hrly and Metronidazole, 100ml I/V x 8 hrly; Rh. negative patients were given Anti-D antibodies to prevent RH sensitization.

The data were analyzed by SPSS Version 10. Descriptive statistics were used to calculate means, frequencies and S.D. Chi square test was used to compare categorical variables for significance; the Student's t-test was used to test for significant differences between numerical variable.

RESULTS

There were a total of 29 (49.3%) cases of missed abortion (15, 50%, in each group) and 31 (51.7%) cases of anencephaly (14, 46.7%, in group A, 16, 53.3%, in group B) shown in Table 1.

Table 1: Basic obstetric data of patients (n=60).

Variables	All patients No. (%age)	Group A (n=30) No. (%age)	Group B (n=30) No. (%age)
Indications for TOP			
Missed abortion	29 (48.3)	15 (50)	14 (46.7)
Anencephaly	31 (51.7)	15 (50)	16 (53.3)
Gestational age (weeks)			
15 – 17	06 (10)	02 (6.7)	04 (13.4)
18 – 20	32 (53.3)	16 (53.3)	16 (53.3)
21 – 23	22 (36.7)	12 (40.0)	10 (33.3)
Mean ± S.D.	19.77 ± 1.96	20.07 ± 1.78	19.47 ± 2.11

Gestational ages of subjects ranged from 15 to 23 weeks, with a mean gestational age of 19.77 ± 1.96. The gestational ages of Group A patients ranged from 16 to 23 weeks with a mean of 20.07 ± 1.78 weeks; the gestational ages of Group B patients ranged from 15 to 23 weeks with a mean of 19.47 ± 2.11 weeks (Table 1).

Induction to expulsion times for all patients ranged from 12 to 30 hours with a mean of 21.3 ± 3.75 hours. For Group A the time ranged from 17 to 30 hours with a mean of 22.93 ± 3.30 hours, while for Group B the time ranged from 12 to 30 hours with a mean of 19.65 ± 3.49 hours. This difference in means was statistically significant with a $p < 0.001$ (Table 2).

Table 2: Comparative data for Induction to Expulsion Time (IET) and Induction to Delivery Time (IDT) for both groups of patients (n = 60).

Variables	All Patients No. (%age)	Group A (30) No. (%age)	Group B (30) No. (%age)
IET (Hours)			
12 – 16	05 (8.3)	-	05 (16.7)
17 – 20	24 (40)	10 (33.3)	14 (46.7)
21 – 24	20 (33.4)	10 (33.3)	10 (33.3)
25 – 29	10 (16.7)	09 (33.3)	01(3.3)
30 - 34	02 (6.7)	01 (3.3)	-
Mean ± S.D.	21.30 ± 3.75	22.93 ± 3.30	19.65 ± 3.50*
IDT (Hours)			
12 – 16	03 (5.0)	-	03 (10.0)
17 – 20	02 (3.3)	-	02 (6.7)
21 – 24	27 (45.0)	12 (40.0)	15 (50.0)
25 – 29	24 (40.0)	16 (53.3)	08 (26.7)
30 - 34	03(5.0)	02 (6.7)	01 (3.3)
Mean ± S.D.	24.42 ± 3.65	25.97 ± 2.63	22.88 ± 3.90**

*p<0.001; **p=0.001

Induction to delivery time intervals for all patients ranged from 14.5 to 32 hours with a mean of 24.42 ± 3.65 hours. For Group A the time ranged from 22 to 32 hours with a mean of 25.97 ± 2.63 hours, while for Group B the time ranged from 14.5 to 32 hours with a mean of 22.88 ± 3.90 hours. This difference of means was statistically significant with a $p = 0.001$ (Table 2).

Table 3: Comparisons of termination times between Group A and Group B patients receiving one or two PGF2-a injections.

Times (hours)	Group A (n = 30)	Group B, one injection (n = 15)	Group B, two injections (n = 15)
IET	22.93 ± 3.30	17.20 ± 2.88*	22.10 ± 2.00
IDT	25.97 ± 2.63	20.27 ± 3.11*	25.50 ± 2.68

*p< 0.001 as compared to the times for Group A and Group B (two injections). P values between Group A and Group B (two injections) are not significant.

For Group B patients, 15 (50%) required the use of a single injection of PGF2-a for inducing expulsion and induction (Table 3). Moreover the mean times for both IET and IDT intervals were significantly different between the patients requiring one and two injections; the latter being similar to Group A patients (Table 3). This indicates that 25% (15/60) patients actually benefit from the use of a single injection of PGF_2-a.

The cost incurred by patients was documented only for the differences of Foley's catheter and PGF2-a injections between groups as all other costs (hospital stay, fees etc.) were equal between the groups. The mean cost for Group A was Rs. 80 ± 0.00, while for Group B it was Rs. 530 ± 152.56. This difference in means was highly significant with $p < 0.001$.

DISCUSSION

Introduction of prostaglandin has revolutionized the management protocols of termination of pregnancy (especially in second trimester), induction of labour and management of postpartum hemorrhage.

The results indicated that although there was generally good satisfaction of patients with both procedures used for termination of pregnancy, there were significant differences between the two groups in terms of times required for pregnancy termination as well as the costs incurred for termination procedures.

The number of patients having an induction to expulsion time within 24 hours was 49 (81.7%); in Group A there were 20 (66.7%) as compared to 29 (96.7%) in Group B (p=0.003). The mean induction to expulsion time required for Group A patients was 22.93 ± 3.30 hours while for Group B patients it was 19.65 ± 3.50 hours (Table 2), this difference being highly significant ($p<0.001$). This difference of over 3 hours would indicate that the use of PGF2-a injection as supplement to Foley's catheter for routine termination of pregnancy was justified, at least statistically, in preference to the use of Foley's catheter alone in patients.

This view is further reinforced by the differences obtained between the two groups for mean induction to delivery times as shown in Table 2 (Group A, 25.97 ± 2.63 hours, Group B, 22.88 ± 3.90 hours, $p = 0.001$). The number of patients with induction to delivery time within 24 hours were 32 (53.3%); in Group A there were 12 (40.0%) as compared to 20 (66.7%) in Group B (p=0.02); by 30 hours there were equal number of patients in each group (29, 96.7%). It would appear that PGF2-a initiates and maintains uterine contractions of a sufficient intensity and duration to allow significant shortening of the time required for termination of pregnancy.[7]

The mean times for termination of pregnancy compare favorably with other studies. The induction to abortion time mentioned in a study from Hyderabad, Pakistan[13] is 26.3 ± 8.2 hours for the Foley's catheter group (30 patients) and 32.17 ± 9.7 hours for the prostaglandin E2 group (40 patients). A study from Lahore, Pakistan[5] mentions an induction to delivery interval of 19.95 ± 5.56 hours for the Foley's catheter group (20 patients) and 16.67 ± 6.71 hours for the PGF2-a group (20 patients).

There were no complications noted with the use of PGF2-a in Group B patients, except for the occurrence of mild symptoms of nausea and fever in 4 cases. These were transient in nature and easily controlled with routinely available medications at no significant increase in costs.

A study from India[14] has however pointed out that use of prostaglandins is not without hazard. They studied 124 cases of medical termination of pregnancy between 10-20 weeks; 30 cases were given intra amniotic and 94 cases were given extra amniotic prostaglandin injections. Side effects and complications experienced included vomiting in 60% cases, diarrhea in 6% cases, rise of temperature up to 100^0F after expulsion of fetus in 3.33%, cervical tear requiring suturing in 2 cases, flushing of faces after injection in 3 cases, dyspnoea following injection in one case, anaphylactic shock in one and death in one due to uncontrollable hemorrhage.

Thus use of PGF_2-a injections is justifiable only in 25% of patients overall, as only this number of patients show significant reductions in termination times; in this group the cost of single injections can also be justified. In this group, the time saved amounted to over 5 hours as compared to all other patients.

Justification of PGF_2-a use for termination of pregnancy would be further rationalized if it were possible to identify the patients most likely to respond to the first injection. In this study it was not possible to proceed in this direction as the objectives were not formulated towards this purpose. However further studies would be helpful in bringing out a more useful role for Prostaglandin F2a use in termination of pregnancy in selected patients.

It is not possible to recommend the use of PGF_2-a injection for all patients requiring termination of pregnancy, as the frequency of justifiable cases (requiring one injection) is only 25%. The saving of over 5 hours time in this group is commendable as it would not only cut down on patient time but also on Obstetrician time allowing care for a larger number of patients. However the present situation of not being able to identify patients who would respond to one injection severely curtails the use of Prostaglandin F2a injections.

Studies from Pakistan[5,.13] have concluded that the use of Foley's catheter is to be preferred over prostaglandins because Foley's catheter was considered simple, safe, effective, convenient and economical. These conclusions and recommendations are supported in the present study as well, except for 25% of patients in whom prostaglandins markedly reduced the times required for termination of pregnancy. In this group of patients, if they happen to be in a satisfactory socio-economic group, prostaglandins may be preferred over simple Foley's catheter.

Other regional studies [3, 8-11] have also supported the use of Foley's catheter over prostaglandins. Some studies from India[15, 16] have also preferred the use of Foley's catheter in routine practice for similar reasons.

Though many studies advocate the use of prostaglandins of various types for termination of pregnancy in the second trimester,[17-20] all the studies comparing Foley's catheter and prostaglandins have justified the use of the former. This would indicate that developed nations prefer the use of prostaglandins used alone and have generally abandoned the use of Foley's catheter.

Despite the usefulness of PGF_2 alpha in significantly reducing the time required for termination of pregnancy in 25% patients, its use was associated with increased cost, some patient complications and practical difficulties for both patients and obstetricians in routine practice.

For obvious reasons the mean costs of procedures between the two groups were significantly different, as only Group B cases received PGF_2-a injections. The increase of Rs. 300 to 600 (for one or two injections) is not unaffordable for most patients, except the very poor, but it has to be justified in terms of advantages of time saved and possible side effects complained of by patients receiving Prostaglandin F2a.

Use of Foley's catheter for termination of pregnancy was without complications, cheaper and very convenient for both patients and obstetricians.

The present study supports the use of prostaglandins for termination of pregnancy in the second trimester in preference to Foley's catheter. Moreover the use of Foley's catheter outside of a tertiary care setting, particularly by untrained personnel in unhygienic settings should not to be allowed.

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