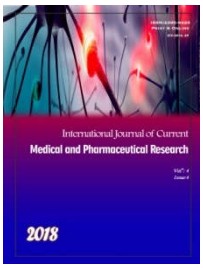
Research Article

INTERNATIONAL JOURNAL OF CURRENT MEDICAL AND PHARMACEUTICAL RESEARCH

ISSN: 2395-6429, Impact Factor: SJIF: 4.656
Available Online at www.journalcmpr.com
Volume 4; Issue 4(A); April 2018; Page No. 3220-3224
DOI: http://dx.doi.org/10.24327/23956429.ijcmpr20180429



A STUDY OF THE EFFECT OF A SINGLE I.M. 15 METHYL PGF2a INJECTION IN CERVICAL RIPENING ONE HOUR PRIOR TO SUCTION AND EVACUATION IN EARLY WEEKS (7 - 12) OF PREGNANCY

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ARTICLE INFO

Article History:
Received 26th January, 2018
Received in revised form 1st February, 2018
Accepted 24th March, 2018
Published online 28th April, 2018

Key words:
Intramuscular Injection,15-methyl $PGF_{2\alpha}$, Cervical Priming & Dilatation.

ABSTRACT

Subject: A study of the effect of a single i.m. $PGF_{2\alpha}$ injection in cervical ripening prior to suction & evacuation in early weeks (7-12) of pregnancy. **Methods**: Two hundred patients were selected randomly. The selection was restricted to the gestational period between 7 and 12 weeks. All these patients were hospitalized. A detailed history was taken and clinical examination was carried out to exclude any active respiratory, cardiac, renal, hepatic, epileptic and allergic disorders. Patient were divided into two groups- study groups consisted of 100 cases in whom 15 methyl- $PGF_{2\alpha}$ (Carboprost tromethamine 250µg) given I.M. one hour prior to suction and evacuation & control group consisted of 100 patients were not administered any injection and cervix was dilated mechanically during suction & evacuation**. Result**: Most of the cases (86%) in study group show good cervical dilatation along with ripening. In 14% cases cervical dilatation was only of fair degree. Poor cervical dilatation was not seen in any of the cases. The patients who had good cervical dilatation were multiparous. However, there are two nulliparae who had good cervical dilatation. The patients who had only fair cervical dilatation in study group were nulliparous. No relation was seen between cervical dilatation and the age of the patient. Effect of prostaglandin on cervical dilatation at noted gestational period was more in multiparous compared to nulliparous patients. In control group all cases need mechanical dilatation depending on parity more or less **.Conclusion**: The use of mechanical dilatation and evacuation of the uterus in first trimester pregnancy termination can cause trauma to the cervix if performed after the 12th weeks of gestation. The present study shows that these complications can be avoided, if the patient is pretreated with prostaglandin prior to the vacuum aspiration. The injection- abortion interval of one hour is very convenient and fairly efficient. Success rate in terms of abortion achieved completely was 100 percent. Thus it seems suitable to adopt this regime as a routine method to be used in hospitals for termination of first trimester pregnancy.

INTRODUCTION

The 21st century offers a bright vision of better health for all. It holds the prospect not merely for longer life but superior quality of life. This desire for a healthier and better world will be fulfilled only by controlling global population. Population explosion has become a worldwide problem leading to environmental imbalance like global warming and lack of drinking water. The global population was about 6054 millions in 2000 &7300 millions in 2015 will increase to about 8000 millions in 2025 AD. 1 million population are adding every week in the world population.

With the population of 1027 millions in 2001 & 1314 millions in 2015, India is the second most populous country in the world, next only to China and seventh in land area. With only 2.4% of world land area, our country is supporting 16% of the world population. Our population is currently increasing at the rate of 16 million each year. This indicates the value of contraceptive methods. But lack of awareness about contraceptive measures, moreover, limited access to effective contraception has made M.T.P. an integral part of natural population control programme. In our country about 6 million abortions take place every year, out of which 4 millions are induced. As unwanted pregnancies are unavoidable so the legalization of M.T.P. provides safe method for termination as contraceptive.

For first trimester abortion suction and evacuation is the most popular method which is fast, effective and a safe with few complications like cervical laceration, uterine perforation, haemorrhage, incomplete evacuation of the conceptus and cervical incompetence due to an insufficient or difficult mechanical dilatation. It has been shown that PGs cause cervical dilatation and thereby resulting in easy and more complete evacuation of the uterus.[1,2,3] Intramuscular injection

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of $PGF_2\alpha$ induces maturational changes of cervical ripening, which are modification of collagen and alteration in the relative concentrations of the glycosaminoglycans. So the single I.M. injection of 15-methyl $PGF_{:2\alpha}$ reduces the risk associated with mechanical dilatation prior to suction and evacuation because the dilatation becomes easy or unnecessary and the bleeding during the procedure is markedly reduced. The present study was undertaken to evaluate the role of single I.M. administration of 250µg of 15-methyl $PGF_2\alpha$ (carboprost tromethamine or prostodin) one hour prior to suction and evacuation in early weeks (7-12) of pregnancy to study it:

1. Effect on cervix
2. Effect on patient
3. To calculate the injection cervical priming interval

MATERIALS AND METHODS

Two hundred patients were selected from the outpatient department of obstetrics and Gynaecology, Rajendra institute of medical sciences Ranchi which were admitted for first trimester pregnancy termination during the period of January 2002 to May 2003. The selection of cases was random. The patient had uncomplicated pregnancy. These patients desired for termination of pregnancy as a means of spacing of family or due to socio-economic conditions. The selection was restricted to the gestational period between 7 and 12 weeks.

All these patients were hospitalized. A detailed history was taken and clinical examination was carried out to exclude any active respiratory, cardiac, renal, hepatic, epileptic and allergic disorders. Patient were divided into two groups-

1. ***Study Group:*** Consisted of 100 patients in whom 15-methyl $PGF_2\alpha$ (Carboprost tromethamine) was given I.M. one hour prior to suction and evacuation.
2. ***Control Group:*** Consisted of 100 patients were not administered any injection and cervix was dilated mechanically during suction and evacuation.

A full history was taken in each case with routine investigation

1. Blood -Hb%

TC and DC of W.B.C.
BT and CT
ABO and Rh typing

2. Urine - R/E of urine

Criteria for socio-economic status

Income groups Rs./P.A

Low income group - up to 20,000/-
Lower middle group- 20,001/-tO 40,000/-
Upper middle group - 40,001/- to 62,000/-
Higher INCOME group - 62,001 /- to 86.000/-

SOURCE —>MANUAL OF SOCIO-ECONOMIC STATUS SCALE OF KAPPUSWAMY (1976) and KUISHRESTHA S.P. (1975).

RESULT AND OBSERVATION

1. It was observed that non-tribal patients were much more 94% in study group and 91% in control group. Rest comprises the tribal population.
2. Maximum number of patients i.e 40% in the study group and 48% in control group comprise the poor socio-economic group.
3. M.T.P. is much more in Hindu population i.e. 83% in study group and 80% in control group than others.
4. Maximum number of patient were between 21-30 years i.e. 77% in study group and 72% in control group.
5. There was high incidence of patients having parity 2,3 and 4 in both the groups. Nulliparous women make only 8% and 4% in study group and control group respectively.
6. Number of married patients were much more than the number of unmarried in both the study and control groups.
7. Maximum numbers of patients in the study and control group were in 7 to 10 gestational weeks.
8. The dilatation of cervix in study and control group were increased with increasing period of gestation.
9. There was marked dilatation of cervix primed by prostaglandin (study group) shown in given table.

Mean cervical dilatation in two groups according to period of gestation in mm.

Gestational Weeks	Mean cervical dilatation in mm	
	Study group	Control group
7 - 8	8.3	2.3
9 - 10	9.9	2.7
11 - 12	10.8	3.2

10. The effect of prostaglandin on cervical dilatation in nalliparous and multiparous patients shows that at noted gestational period cervical dilatation was more in multiparous patients compared to nalliparous patients. The table given below.

Gestational Weeks	Nulliparous		Multiparous	
	No. of Cases	Dilatation(mm) mean value	No. of Cases	Dilatation(mm) mean value
7 - 8	2	7	34	8.4
9 - 1 0	4	7	32	10.3
1 1 - 1 2	2	8	26	11.0

11. Mean blood loss with conceptus is increased with increasing period of gestation in both the groups. This table also shows that mean blood loss with conceptus is more in control group than the study group.

Gestational Age in Weeks	Mean blood loss with conceptus in ml	
	Study group	Control group
7 - 8	76.15	100.80
9 - 1 0	113.10	128.50
11 - 12	137.3	158.95

12. No side effects were observed in 30% cases while in 70% cases side effects were observed.

There was high incidence of gastrointestinal side effects in spite of giving antiemetics and antidiarrhoeals. Table given below.

Incidence of side effects and complications in patients of study groups:-

Side effects and Complication	No. of cases	Percentage
No side effects	30	30.0
Pain abdomen	70	70.0
Bleeding PV	62	62.0
Diarrhea	13	13.0
Vomiting	18	18.0
Diarrhoea and Vomiting	06	06.0
Skin flush	10	10.0
Pyrexia	-	-
Haemorrhage	01	01.0
Cervical tear	fe»<;'	-
Cervico-vaginal fistula	-	■

13. No side effects were observed in 92% cases while in 8% cases complications were observed i.e. haemorrhage in control group.

DISCUSSION

Suction and evacuation is the most commonly used method for termination of first trimester pregnancy. Dilatation of the cervix with the Hager's dilator prior to evacuation may result in traumatic complications with its sequelae on reproductive life. Several methods have been advocated to initiate priming of the cervix which stimulates the physiological process. Several natural and synthetic substances have been used in an attempt to resolve the above problems. Laminaria tents, Isopgul tents, rubber balloons catheter, flexible dilator. oxytocin, urea and prostaglandin are some of the adjuvant that have been used as an effort to avoid traumatic damage to the cervix. So, the prostaglandin has been used for cervical priming in the study group.

Race: In the present series the non-tribal patients were much more than the tribal ones in both the study and control groups. In study group 94% of the patients were non-tribal and 6% were tribal. In control groups 91% of the patients were non-tribal and 9% were tribal. Although the area of Jharkhand is tribal but majority of the population is non-tribal. Moreover, due to lack of awareness about contraception, legal termination of pregnancy and transportation, tribal patients usually do not voluntarily attend the hospital for legal abortion They have also economy problem. They are unaware of availability of free facility of government for termination of pregnancy.

Socio-economic Status: Majority of the patients belong to poor class (40% in study and 48% in control group). The incidence of pregnancy termination in the poor class seems to be due to lack of education and unavailability of cost effective contraceptive measures. Purandare and Das *et al* (1975) also found that majority of the patients coming for first trimester abortions are of low socio-economic group. Dutta *et al* 1979 reported that 56% of cases were from poor families.

Religion: It seems that most of the patients are Hindu in study as well as in control group (83% and 80% respectively). Low incidence of M.T.P. among Muslims and Christians are because of some religious bindings, which inhibit abortion in spite of liberalisation of the abortion law.

The age ranged from 16 to 40 years in both the groups. Maximum numbers of patients were of 21 - 30 years in both the groups. This can be explained by the maximum fertility rate and sexual activity in this age group. Dhall *et al* (1976) reported the range to be 18-45 years. Sharma *et al* (1976) reported the range to be 15 - 42 years. Rajan *et al* (1979) reported almost the same range.

Parity: The parity varied between 0 to 5 and above. The majority of cases were multiparous having parity 2, 3 and 4 in both the groups. This can be explained by fact that multiparous women recognize the pregnancy state earlier and report earlier for termination. Majority of the patients were para 2 to 4 in both the groups coming for first trimester abortion are married and come for M.T.P. for socio-economic reasons as a means to limit their family size. These pregnancies were unplanned and some of these resulted from failure of contraceptive device. Most of these women underwent tubectomy after M.T.P. Only 8% and 4% of the patients were nulliparous in study and control groups respectively. The nulliparous were mostly unmarried.

Marital Status: In both group **92%** of the patients were married and **8%** were unmarried married women being well acquainted with the legalization of M.T.P. law, get support from their husband also. So they report earlier for first trimester pregnancy termination. Most of the married patients agreed for ligation / tubectomy in the same sitting, who had complete their families. As the pregnancy in unmarried women is usually an illegal one, resulting from illegitimate relationship, these women report late for M.T.P. and conceal their guilt. Pregnancy in unmarried is the widely discussed problem all over the world. Smith *et al* **(1979),** reported an incidence of **84%** of the second trimester abortion in unmarried women. Mishra and Gupta **(1979)** reported almost the same data.

Duration of gestation: Duration of pregnancy varied between **7-12** weeks. In the study group maximum numbers of cases **(36%)** were having **9-10** weeks and **40%** of control group were having **9-10** weeks of pregnancy.

Cervical Dilatation: The assessment of cervical dilatation and resistance at operation is relatively subjective. In the present series, cervical dilatation achieved one hour after intramuscular injection of $PGF_2\alpha$ has been categorized into 3 groups:-

1. Good dilatation, when cervix dilated upto 8 mm or more
2. Fair dilatation, when cervix dilated between 4 - 8 mm
3. Poor dilatation, when cervix dilated between 0 - 4 mm.

In our study, observation 8 - 1 0 compares the cervical dilatation at a given gestational age among the study and control group. Most of the cases (86%) in study group show good cervical dilatation along with ripening. In 14% cases cervical dilatation was only of fair degree. Poor cervical dilatation was not seen in any of the cases. The patients who had good cervical dilatation were multiparous. However, there are two nulliparae who had good cervical dilatation. The patients who had only fair cervical dilatation in study group were nulliparous. No relation was seen between cervical dilatation and the age of the patient. Effect of prostaglandin on cervical dilatation at noted gestational period was more in multiparous compared to nulliparous patients.

In good cervical dilatation cases, no further mechanical dilatation was needed prior to suction and evacuation. In those with fair cervical dilatation further dilatation was needed in two nulliparous patients with 7 - 8 weeks of gestation and in four of the nulliparous group with 9 - 1 0 weeks of gestation, by Hager's dilators. Dilatation of the cervix was very easy and there was no resistance felt, as the cervix was very soft. In all these cases, abortion was complete and in none there was any excessive bleeding.

In control cases, cervix was dilated by Hager's dilators. Resistance was felt in these cases while dilating the cervix. There was more resistance felt in dilating the nulliparous cervix. An attempt to overcome the resistance offered by the cervix resulted in the haemorrhage (8%) due to rupture of the circular fibres of the anterior lip of the cervix.

The cervical dilatation was increasing with advancing gestational period in both the study and control group.

Dilatation was minimum in control cases at the beginning of suction and evacuation.

But mean cervical" dilatation was relatively more in the study group compared to the control group. Cervical dilatation and priming by prostaglandin reported by several investigators.[4,5,6,7,8,9,10,11,12,13,14,15]

The mean blood loss increased with advancing period of gestation (observation-11) but mean blood loss was lower in study group as compared to control group. This was suggested by Csapo, Mocsary, Nagi (1972) in the mechanism of abortifacient action by prostaglandins. Csapo & Pulkkinen (1979) also suggested the stimulant effect of prostaglandins on uterus and uterine and placental blood vessels.

Serious side effects and complications were not seen in the study group. Gastrointestinal side effects (observation - 12) observed in this series were vomiting in 18% and diarrhea in 13% and both (diarrhea and vomiting) in 6%. The patient had single or two episodes of loose motion and vomiting Dhall *et al* (1976) observed vomiting in 52.7% and diarrhea in 74.5% cases. Rajan *et al* (1979) reported vomiting in 20% and diarrhea in 56% with a dose of 250µg, 15 - methyl $PGF_2\alpha$ administered 3 hourly. A much lower incidence of these side effects in patients with antidiarrhoeal (loperamide) and antiemetic (metochlopramide).

In this series 10% of the patient developed skin flush, which did not need any treatment. It disappeared after sometime. Pyrexia was not observed.30% patient had no side effects. Haemorrhage (1%) observed. Cervical injury and cervico-vaginal fistula were not seen. Sharma *et al* (1976) have reported skin flush in 26.6% cases and temperature elevation of 0.5° F to 2° F in 20% cases which returned to the normal within six hours after injection of 15-methyl $PGF_2\alpha$. Lauersen *et al* (1976) also found in his series, temperature elevation of 1° F in eight out of 35 cases. However, a high incidence of rupture of cervix or cervico-vaginal fistula has been reported following induction of abortion by prostodin. The incidence of this problem has been estimated to be 5% (Mackenzie, Hillier and Embrecy 1975) and 4% (Kajanoja *et al* 1975). Rajan and Usha (1979) have reported an incidence of1.5% of cervical rupture in mid-trimester abortion by prostaglandin. Cervical injury was predominantly a complication in nulliparous.

In control group, 8% of the patients had haemorrhage (observation-13) during dilatation. None had cervical tear or uterine perforation. No mortality was seen. But there is now evidence that rapid mechanical dilatation is associated with both immediate and late complications including the outcome of subsequent pregnancy (Fusey and Sonone 1991).

In the present series there were no serious side effects and complications following the prostaglandin injection in a single dose. Furthermore, there was high efficacy of drug and safety observed. Proper selection of cases is a prerequisite and careful monitoring of every case is required. So in the expert hands, 15-methyl $PGF_2\alpha$ is a safe drug, given I.M. in a single dose, to achieve cervical priming one hour prior to suction and evacuation of early trimester (7 - 1 2 weeks) pregnancy.

CONCLUSION

It may be concluded from the present study, that pretreatment with single I.M. injection of 15-methyl $PGF_2\alpha$, offers an effective method for preoperative priming of cervix in first trimester abortion and makes the vacuum aspiration, a simple and easy procedure. In some patients cervical dilatation was also observed and no further dilatation was necessary'. Even in those patients in whom cervical dilatation was carried out, the procedure become very easy and no difficulty was experienced during dilatation. The side effects produced were acceptable and were further minimized by premedication with metochlopramide and loperamide. These drug did not interfere with the efficacy of prostodin.

The use of mechanical dilatation and evacuation of the uterus in first trimester pregnancy termination can cause trauma to the cervix if performed after the 12th weeks of gestation. Grimes *et al* reported, that cervical injury' was twice as frequent as with saline infusion technique from previous experience and the present study shows that these complications can be avoided, if the patient is pretreated with prostaglandin prior to the vacuum aspiration. The injection-abortion interval of one hour is very convenient and fairly efficient. Success rate in terms of abortion achieved completely was 100 percent.

Thus it seems suitable to adopt this regime as a routine method to be used in hospitals for termination of first trimester pregnancy.

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How to cite this article:

Pramod Kumar and Asha Singh (2018) 'A study of the effect of a single i.m. 15 methyl pgf2a injection in cervical ripening one hour prior to suction and evacuation in early weeks (7 - 12) of pregnancy', *International Journal of Current Medical And Pharmaceutical Research,* 04(4), pp. 3220-3224.

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