

Comparative Study of Sequential Dose Misoprostol and Trans-Cervical Extra Amniotic Iodine Saline for Second Trimester Medical Termination Of Pregnancy

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ABSTRACT

Background: Second trimester termination of pregnancy is a controversial topic since long having many moral, emotional, social, technical and legal issues. Old methods are being increasingly replaced by prostaglandin analogues like PGE1, PGE2, PGF2 alpha etc. But there is need for more studies to establish their regime, efficacy, contraindications, complications and cost effectiveness.

Objective: To compare acceptability, safety, efficacy, complications, induction-abortion interval and cost effectiveness of Misoprostol and transcervical extra amniotic iodine saline method for mid trimester termination of pregnancy.

Method: Sixty women with valid legal indication of termination of 13-20 weeks of pregnancy were randomized in 2 groups. In group A, 400 µg of Misoprostol was given vaginally every 3 hours for a maximum of 5 doses (FIGO Protocol). In group B, 150 ml of 0.17% of sterile Povidone Iodine saline was instilled extra-amniotically with transcervical Foley's catheter. Incidence and indications of abortion, success rate, induction-abortion interval, complications and client satisfaction were studied and analyzed.

Results: Most common indication of second trimester termination of pregnancy was eugenic cause (73.33%). The mean induction-abortion interval was 16.84 hours in Misoprostol group and 25.77 hours in Iodine saline catheter group. The rate of complete abortion at 48 hours was 76.66% for Misoprostol and 63.33 % for Iodine saline group. The

average cost per procedure was lesser for Misoprostol group as compared to Iodine saline group. Rate of side-effects was more with Iodine saline (66.66%) as compared to Misoprostol (50.33%).

Conclusion: Misoprostol is highly efficacious with shorter induction – abortion interval, lesser need for post-abortion evacuation, lesser side effects and complications, higher safety profile, better cost effectiveness and hence better overall client satisfaction but in conditions where Misoprostol or other prostaglandins are better avoided or not available, Iodine saline catheter method seems to be a time tested, cheap, easily available and equally effective method.

Keywords: Second Trimester Termination of Pregnancy, Misoprostol, Induction, Extra Amniotic Iodine Saline.

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INTRODUCTION

"I am neither in favor of nor against abortion. But good maternal health needs better reproductive health and reproductive health include contraception and family planning and access to legal safe abortion"

Hilary Clinton

Pregnancy, ultimately leading to the motherhood is considered to be the greatest gift of Mother Nature to humans. But sometimes Nature denies it post facto and the pregnancy eventually gets spontaneously aborted. But when the Nature bestows the womanhood for continuation of pregnancy and human decides in favor of pregnancy termination, it essentially turns out to be an

induced abortion, defined as surgical or medical termination of a live fetus that has not reached viability.¹

It is estimated that currently, about 40% of approximately 213 million pregnancies that occur worldwide annually are unintended and about 50% of these end in induced abortion.^{2,3} Considering the large number of abortions performed worldwide annually, it seems that religious, social or emotional restrictions are never powerful enough to decrease the need for induced abortion but enough to compel women to indulge in unsafe practices without considering the dangerous consequences, if safer methods not available.

As per World Health Organization, between 2010 – 2014, around 56 million induced abortions occurred worldwide each year. Among these, about half i.e. 25 million were unsafe, almost all in developing countries.⁴ Between 4.7% - 13.2% of maternal deaths can be attributed to unsafe abortions each year.⁵

As per first national study of incidence of abortions and unintended pregnancy in India, almost half of the 48.1 million pregnancies in 2015 were unintended and as many as 33% of pregnancies end in induced abortions.⁶ This constituted nearly 15.6 million abortions in India in 2015, of which only 22% were obtained in health facilities.

Pregnancy is widely being divided into three trimesters and so is abortion. First trimester includes termination upto 12 weeks of pregnancy. Methods available are surgical like dilatation and curettage (D&C), electric vacuum aspiration (EVA) and manual vacuum aspiration (MVA) and medical abortion methods like with Mifepristone, Misoprostol and Methotrexate. Second trimester induced termination of pregnancy takes into account the upper limit of pregnancy upto last day of 20th week, as per Medical Termination of Pregnancy (MTP) Act, India.⁷

Worldwide about 85-90% of all abortions are first trimester abortions, while 10-15% are in second trimester of pregnancy.⁸ First trimester abortion is considered to be much safer due to lesser gestational age, lower uterine size and lesser chances of perforation/ rupture. Mid- trimester abortions are associated with higher mortality, morbidity and greater social and emotional challenges than first trimester abortions.⁹ It's said that for each successive gestational week after eight weeks, risk of death increases by about 38%.¹⁰

Safety of abortion procedure depends on multiple factors like liberalization of laws, access to the services, awareness of society, method of termination applied and also gestational age of fetus. Any attempt to reduce morbidity and mortality from this procedure can bring significant benefits to the quality of life for the women undergoing this procedure. Hence, justified is the need of best method for second trimester termination of pregnancy, which still continues to be debated.

In second trimester abortion induction, pre-procedure cervical ripening plays a big role. While osmotic laminaria tents and transcervical Foley's catheter can be used as mechanical methods, chemical methods like Misoprostol (Prostaglandin E1 analogue), Mifepristone, Prostaglandin-E2gel/tablets, etc. are also used. Through transcervical catheter, literature suggests role of extra-amniotic ethacridine lactate, normal saline, PGF2alpha, antibiotics, Iodine saline, etc. which act by mechanical separation of membranes and local release of natural Prostaglandins. Still no single method is proved best.

Misoprostol is a synthetic prostaglandin structurally related to prostaglandin E1, approved for obstetric indications since 2008. However, still studies are ongoing comparing the drug Misoprostol against other time tested methods and also for defining best suitable and safe dosage protocol of Misoprostol.

The present study is conducted to compare the acceptability, safety, efficacy, complications, cost effectiveness and client satisfaction between intra vaginal Misoprostol - in sequential multiple doses with extra-amniotic intra-uterine instillation of normal saline admixed with Povidone Iodine through transcervical Foley's catheter no. 18 - in a tertiary referral hospital catering to both rural and urban population.

MATERIALS AND METHODS

This was a prospective comparative study carried out from 1st May 2008 to 15th October 2010 at the Department of Obstetrics and Gynecology, M.P. Shah Medical College and Hospital, Jamnagar, Gujarat after obtaining IEC approval (letter no. MCI J/ILC/116/2010).

Pregnant women with valid indication of second trimester (13-20 weeks) termination of pregnancy within ambit of MTP Act – 1971, were taken up as the study population. After clinical assessment, proper informed written consent and filling of MTP forms, following inclusion and exclusion criteria were applied for assigning group A and Group B.

Inclusion Criteria (Both Groups)

All pregnant women opting for termination of pregnancy of 13-20 weeks of gestation with a valid legal indication as per MTP ACT 1971 & subsequent amendments.

Exclusion Criteria

Absolute

1. Acute Liver Disease
2. Severely compromised cardio-vascular disease
3. Coagulopathy or anti-coagulant use
4. Placenta Previa grade-3/4
5. History of hypersensitivity to Misoprostol / Povidone Iodine (respective group)

Relative

1. Local vaginal infection
2. Anemia

Group A: MISOPROSTOL

Exclusion criteria

1. Women with adrenal disease or with disorders requiring glucocorticoid therapy
2. Previous uterine scar e.g. Lower Segment Caesarean Section, Myomectomy etc.

METHODOLOGY

Group A (n = 30): First dose of 400 mcg of Misoprostol tablet was inserted in posterior fornix of vagina, observing aseptic and antiseptic techniques. Same dose was repeated, every 3 hourly for maximum of total 5 doses, as suggested by clinical guidelines by the expert group convened by WHO 2007 and now available as International Federation of Obstetrics and Gynecology FIGO Recommended Dosages Chart.¹¹

Group B (n=30): In dorsal lithotomy position, under aseptic precautions, Foley's catheter no. 18 was inserted transcervically and bulb inflated with 40 ml of normal saline above the level of internal os. 150 ml of 0.17% of sterile Iodine saline solution (prepared by admixing 5 ml of 5% Povidone-Iodine in 150 ml of normal saline) was instilled antegrade through draining channel of the Foley's catheter extra-amniotically. Catheter was kept blocked over next four hours and affixed to the inner aspect of thigh. Foley's catheter was removed after 24 hours unless it gets spontaneously expelled. After 24 hours, 10-unit Oxytocin infusion in 500 ml of Ringer Lactate in sequential dose was started at a rate of 14-16 drops/min and increased every hourly or so, till effective uterine activity is achieved. Women were observed for

lower abdominal pain, leaking or bleeding per vaginum, side effects expulsion of fetus, placenta and membranes (end-point) for the next 72 hours. Failure to achieve this end point or occurrence of systemic side effects prohibiting continuation of procedure was

considered failed method/induction. Proper post-abortion care was given including Anti D immunoglobulin to Rh negative females, ART center referral for HIV positive women, emotional support, proper contraceptive advice and follow up.

Table 1: Age Wise Distribution In The Study Population

Age (in years)	Group-A (n=30)		Group-B (n=30)		Total (n=60)	%
	No.	%	No.	%		
≤20	3	10	4	13.3	7	11.66
21-25	8	26.6	6	20	14	23.33
26-30	11	36.66	10	33.33	21	35.00
≥31	8	26.6	10	33.33	18	30.00
Total	30	100	30	100	60	100.00
Mean age of patient	28.16		29.33		28.64 years	
Mean parity	1.4		1.9		1.6	
Mean gestational age	16.04 ± 2.70 weeks		17.45 ± 2.11 weeks		16.55 ± 2.39 weeks	

Table 2: Indication of MTP In The Study Population

Indication of MTP	No. of cases (n=60)	%
Danger to life or physical health of woman	9	15.00
Danger to mental health (contraceptive failure)	7	11.66
(a) Lactational amenorrhea method (LAM)	3	
(b) Tubal ligation	2	
(c) IUCD	2	
Eugenic cause:	44	73.33
(a) Congenital somatic malformation	31	51.66
(b) HIV infected women (discordant couple)	1	2.27
(c) HIV infected couple	3	6.81
(d) Prenatally diagnosed thalassemia major	2	4.54
Aneuploidy	7	11.66
Pregnancy as a result of sexual assault	0	00

Table 3: Congenital Somatic Malformations

Somatic Malformation	No. of cases (n=31)	%
CNS	11	35.48
(a) Anencephaly	05	
(b) Hydrocephalus	02	
(c) Microcephaly	01	
(d) Holoprosencephaly	01	
(e) Dandy walker syndrome	01	
(f) Colpus callosus agenesis	01	
Spina Bifida With Meningocele	05	16.12
Major Cardiac Anomaly	04	12.90
Lethal Skeletal Dysplasia	02	06.45
GIT – Omphalocele	01	03.22
GUT	05	16.12
(a) Bilateral renal agenesis	02	
(b) Bilateral multicystic dysplastic kidneys	02	
(c) Bladder outlet obstruction	01	
Non-immune hydrops fetalis	03	09.67

Table 4: Cumulative Induction - Abortion Interval In The Study Population

I-A Interval (in hours)	Group-A Misoprostol (n=30)		Group-B Povidone-Iodine Saline (n=30)		Total (n=60)	
	No.	%	No.	%	No.	%
Within 24 hrs	23	76.66	14	46.66	37	61.66
Within 36 hrs	28	93.33	23	76.66	51	85.00
Within 48 hrs	28	93.33	27	90.00	55	91.66
Within 72 hrs	29	96.66	29	96.66	58	96.66
Failure	01	3.33	01	3.33	02	3.33

Table 5: Outcome of Induction Procedure in The Study Population

Outcome	Group-A		Group-B		Total (n=60)	
	Misoprostol (n=30)		Povidone-Iodine Saline (n=30)			
	No.	%	No.	%	No.	%
Complete expulsion	23	76.66	19	63.33	42	70.00
Incomplete expulsion	6	20.00	10	33.33	16	26.66
Success Rate	29	96.66	29	96.66	58	96.66
Failure	1	3.33	1	3.33	2	3.33
Total	30	100	30	100	60	100

Table 6: Side Effects in the Study Population

Side effects	Group-A		Group-B		Total (n=60)	
	Misoprostol (n=30)		Povidone-Iodine Saline (n=30)			
	No.	%	No.	%	No.	%
Nausea	3	10	6	20	9	15
Vomiting	4	13.33	3	10	7	11.66
Cramping Abdominal Pain	3	10	7	23.33	10	16.66
Chills	5	16.66	1	3.33	6	10
Fever	1	3.33	3	10	4	6.66
Infections	0	-	0	-	0	-
Diarrhoea	0	-	0	-	0	-
Skin rashes	0	-	0	-	0	-
Hemorrhage	0	-	0	-	0	-
Injury-Cervical/uterine	0	-	0	-	0	-
Others	0	-	0	-	0	-
Maternal death	0	-	0	-	0	-
Total	16	50.33	20	66.66	36	60

RESULTS

During the study period of two years and 5 months, out of 76,109 pregnant women registered in ANC OPD, 1507 (1.98%) ended in spontaneous abortion. 1500 (1.97%) women opted for MTP, among which 93.46% were first trimester and 6.53% were second trimester MTP. Out of 98 total second trimester abortions carried out at our institute during study period, 38 cases (2.53%) are not included in the study due to use of other methods or combination of methods used depending on preference of consulting obstetrician.

Most common indication (Table – 2) for termination of pregnancy was eugenic cause as in 44 out of 60 (73.33%) cases, where there was a substantial risk that the child, if born, would be seriously handicapped due to physical and mental abnormalities.

Among these, 31 cases (51.66%) were having major congenital somatic malformation (Table – 3) diagnosed in antenatal ultrasonography. 7 patients (11.66%) had aneuploidy in fetus and 2 (4.54%) were diagnosed to have thalassemia major in fetus with the help of chorionic villi sampling and amniocentesis. 4 cases (9.09%) were of HIV infected pregnant women, who requested for termination of pregnancy to prevent HIV transmission to unborn child, upon PPTCT counseling. Danger to mental health was considered in 7 (11.66%) patients with pregnancy due to contraceptive failure. In 9 (15%) women suffering from rheumatic heart disease (2.26%), Takayasu arteritis (2.26%), carcinoma breast (2.26%), chronic renal disease (4.54%), epilepsy (4.54%) and uncontrolled hypertension (4.54%), MTP was indicated for preventing grave injury to physical health of women.

Mean gestational age of the study population was 16.55 ± 2.39 weeks. 61.66% of patients belong to 13-16 weeks of gestation while only 38.33% belonged to 17 – 20 weeks of pregnancy.

In group A of Misoprostol, 23 (76.66%) of cases were complete within first 24 hours of induction while only 14 (46.66%) were complete within first 24 hours in group B (p value = 0.033 i.e. significant). Greater number of cases got expelled in next 24 hours i.e. within 48 hours of induction in Iodine saline group. There was one case in each group (3.33%) where product did not get expelled even after 72 hours of induction and hence considered failure of abortion method (Table 4).

Our study showed that in Misoprostol group, out of 29 successful inductions, 23 (76.66%) were complete and 6 (20%) were incomplete needing further evacuation by curettage for retained bits of placental tissue. While in group B, 19 (63.33%) were complete and 10 (33.3%) were incomplete (p value = 0.3786, insignificant). There were 2 failures out of 60 cases (3.33%), one in each group and success rate of medical methods of second trimester termination of pregnancy was 96.66% (Table 5).

On comparing parity, age and induction-abortion interval (I-A interval) in both groups, it was observed that majority of women with age < 30 years had shorter I-A interval (< 36 hours) while women of ≥ 31 years had longer interval. None of primigravida or para 1 women had I-A interval ≥ 36 hours in either group.

In Misoprostol group, 3 patients (10%) had nausea, 4 (13.33%) had vomiting, 3 women (10%) had cramping abdominal pains, 5 (16.66%) had chills and 1 (3.33%) had fever of 99.4°F once after misoprostol. Hence, 50.33% had minor side effects as compared to group B with 66.66% having such side effects. There were no cases of complaints of diarrhea, rashes, intra or post-abort hemorrhage. There was no case of cervical or uterine injury or maternal death. 4 out of 60 (6.66%) cases were having previous LSCS (1, 2 or even previous 3), all were included in group B and had mean I-A interval of 37.9 hours. (Table 6).

Contraception after pregnancy termination carries a great significance. About 73.33% of women opted contraception among which 23.33% underwent permanent tubal ligation and 50% opted for temporary methods of contraception.

DISCUSSION

In our study, comparison is made between two methods of second trimester medical termination of pregnancy. As per data available, in 2010-2014 worldwide, induced abortion rate is 35 per 1,000 women of reproductive age and abortion ratio is 25.3 for every 1,000 live births in India.⁶

In present study, abortion ratio is 17.74, which much lower than that of the world or of India. This may be due to larger number of live births occurring at our institute in relation to number of abortion care cases. Better abortions services at private or periphery level hospitals in our area may be a contributing factor.

As per WHO and Guttmacher Institute data, worldwide 85-90% of induced abortions are performed in first trimester and only 10-15% in second trimester. At our institute, 93.46% of induced abortions were in first trimester and only 6.53% in second trimester. This is probably due to increased awareness among population regarding availability of safe abortion services and earlier consultation by couples. This change in trend is better as first trimester MTP is considered much safer than the second trimester. In our study 73.33% of cases are terminated due to eugenic indications. This is

comparable to the study by Veena L et al (2017)¹² about review of MTP profile in patients. 82.8% of mid-trimester abortions were for eugenic cause as compared in 1981 where eugenic indications accounted for hardly 4% of abortions. This highlights about self-motivated demand to undergo ultrasonographic evaluation, widespread use of good ultrasonography, biochemical screening tests and other prenatal diagnostic methods in detecting anomalous fetus.

Majority (58.33%) of study population belonged to 21-30 years of age group, likely as this group comprises age group of maximum fertility. Unmet need of contraception should be addressed to these couples. 30% of women were of age >31 years and all were multiparous. After MTP, majority of such women opted for permanent tubal ligation. Age incidence for both groups is comparable to that of study by Choudhary et al.¹³ (2006) and Bishwas Chandra et al.¹⁴ (2007), which compared Ethacridine lactate and Misoprostol.

Though success rate of both methods is same, mean induction abortion interval of Misoprostol is 16.84 hours which is only two-third of that of extra-amniotic iodine saline i.e. 25.77 hours. This demonstrates better efficacy and faster action of intravaginal Misoprostol in multiple sequential doses as proved in studies of Rezk MA et al. (2014)¹⁵, though in their study, combining transcervical Foley's and Misoprostol had the shortest induction abortion interval. Extra-amniotic methods take time to act and process usually needs augmentation by Oxytocin etc.

Cramping abdominal pain, nausea and chills were seen in 12%, 4% and 16% of cases of Misoprostol in Bishwas Chandra¹⁴ study as compared to 10%, 10% and 16.66% respectively in present study. Chills were the most common side effect in both the studies. In study by Choudhury et al.¹³ cramping abdominal pain, fever and undue hemorrhage were seen in 24%, 4% and 8% of cases respectively with Ethacridine lactate. In present study with Povidone Iodine saline, rate of cramping abdominal pain (23.3%) and fever (10%) were comparable. This discussion points out towards safety of Misoprostol over Iodine saline and Ethacridine lactate. No major side effects or complications were seen in any of the studies. Patient with prior caesarean undergoing MTP by medical methods need to be managed more carefully.

When market price of Misoprostol (Rs. 166/-) and normal saline admixed with Iodine saline with transcervical Foley's catheter (Rs. 220/-) is compared, it was higher in group B. Also, women found the catheterization and instillation procedure followed by carrying the catheter attached to thigh more cumbersome. But, at the end, all the women were satisfied with the procedure and care given. However, there have been issues with availability of Misoprostol at some places. Iodine saline and catheter are easily available at all resource settings.

CONCLUSION

There have been continuous efforts to improve the abortion technology in terms of effectiveness, technical ease of performance, acceptability and reduction of side effects and complications. Now a day, medical methods are preferred over surgical ones and have become safer & more accessible.

Second trimester abortion incidence is still 10-15% of total induced abortions. Though, now indication has shifted to eugenic cause due to higher antenatal hospital registrations, awareness and acceptance of prenatal diagnostic techniques like

ultrasonography and availability of invasive techniques for genetic abnormalities.

We conclude that Misoprostol is highly efficacious with shorter induction – abortion interval, lesser need for post-abortion evacuation, lesser side effects and complications, higher safety profile, better cost effectiveness and hence better overall client satisfaction as compared to extra-amniotic iodine saline catheter method. However, in conditions where Misoprostol or other prostaglandins are better avoided or not available, Iodine saline catheter method seems to be a time tested, cheap, easily available and equally effective method.

Apart from technical and procedural advancements, improving literacy rate, spreading public awareness regarding contraceptive and family planning, early antenatal registrations, good care, timely universal anomaly scans and improving access to safe legal abortion services will go a long way in contributing to maternal and reproductive health of a country.

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