ISSN No: - 2456 – 2165

Effectiveness of Mifepristone – Misoprostol Combination in Medical Termination of Early Pregnancy

Surg Lt. Dr Devdatt l Pitale [a *]
A Assistant Professor of Obstetrics and Gynaecology,
INHS Asvini, Colaba-400005.
dipu.pitale@gmail.com

Abstract-
Introduction: Unplanned and unwanted pregnancies are common worldwide despite of the medical advancements and wider availability of contraceptive methods. It is thus highly desirable to have a safe and cost effective method of abortion.
Aim: To study the effectiveness of Mifepristone 200 mg orally followed by Misoprostol 800 µg intravaginally 48 hours later in women undergoing medical termination of early pregnancy.
Materials and methods: This study included 50 pregnant women with gestational age up to 63 days from the day one of the L.M.P ,without any contraindications to the regimen.
Results: Majority of the pregnant women belonged to the age group between 26-30 years. 30% of these women were nulliparous and 70 % were multiparous. The period of gestation varied from 35-63 days.96% of the patients had complete abortion and 4% had incomplete abortion. All the patients expelled the products of conception within 24 hours of prostaglandin administration. The adverse effects reported were nausea reported by 20%, vomiting by 10% and diarrhea by 4% of the cases. None of the patients reported excess bleeding at the time of abortion, hospitalization or blood transfusion. This regimen has the effectiveness of complete abortion rate with few side effects.
Conclusion: The Mifepristone- Misoprostol combination offers an effective, acceptable, out-patient procedure and an alternative to surgical methods of abortion in medical termination of early pregnancy (up to 63 days of gestation).

Keywords:-Mifepristone, Misoprostol, Abortion.

Abbreviations

Surg- Surgeon
Lt- Lieutenant
Cmde- Commodore
MTP- Medical termination of pregnancy
INHS- Indian Naval Hospital Ship
Tab- Tablet
PG- Prostaglandin
L.M.P- Last Menstrual Period

I. INTRODUCTION

Unplanned and unwanted pregnancies are common worldwide despite of the medical advancements and wider availability of contraceptive methods. Medical abortion is preferred because of it's safety and is thus highly desirable to have a safe and cost effective method of abortion.

Induced abortions are mostly performed in the first trimester. Vacuum aspiration is, when performed by skilled professionals and with proper equipment, considered relatively safe but is not without risks. Medical abortion offers an alternative to surgical methods, and some of the complications related to surgery, such as uterine ruptures and cervical tears, as well as anesthesia related complications can be avoided.

Under the existing laws medical methods can only be administered by Gynecologists and Registered Medical Practitioners recognized for performing MTPs by the MTP Act of 1971.

II. MATERIALS AND METHODS

This study included 50 pregnant women in first trimester (up to 63 days of gestation) attending the department of Obstetrics and Gynecology at INHS Asvini during November 2016 to January 2017, requesting termination of pregnancy.

A. Inclusion criteria

- Women with gestational age up to 63 days from the day one of the L.M.P, with previous regular cycles.
- Women without medical or surgical contraindications to mifepristone and Misoprostol .

ISSN No: - 2456 – 2165

B. Exclusion Criteria

- Ectopic gestation.
- Intrauterine device in situ .
- Patients with cardiopulmonary diseases, seizure disorders, renalailments.
- Ongoinglong steroid and anticoagulant therapy
- Hemorrhagic disorders and porphyrias .

Fifty pregnant women who fulfilled the criteria were included in thestudy. A detailed case record was maintained. A thorough clinical examination along with investigations like complete urine examination, hemogram and random blood sugar were done. Transvaginal Ultrasonography was performed to confirm the gestational age. All the patients were informed about the regimen and a written informed consent was taken.

Mifepristone 200 mg tab was given orally on the day of the hospital visit or within the following two days. The women were allowed to go home after 30 minutes and advised to come back after 48 hours. Misoprostol 800ug tab was kept in the posterior fornix of vagina under strict aseptic precautions after 48 hours. Vitals were monitored half an hourly before and after the insertion of tablet. Patients were discharged after six hours and were advised to report immediately in case of heavy bleeding or any other undue complications.

They were under the antibiotic cover of Tab Doxycycline 100 mg bid and Tab Tinidazole 500mg bid for 7 days . Patients were instructed to report on the 14th day if no complications occurred in between. Transvaginal Ultrasonography was repeated on day 14th and complete expulsion of the products of conception was noted. Surgical intervention was offered to the no responders.

III. RESULTS

Results were analyzed according to the maternal age and parity, gestational age, induction to abortion interval, abortion completeness, surgical intervention and complications.

In these study youngest women was 21 years old while the eldest was 30years old, around 40% belonged to 21-25 years. In the present study, 30% were primigravidas , 60% were second gravida and 10% were third gravida. Most of the patients were second gravida.Most of the patients (60%) in the present study were between 35-50 days of gestational age (**Table -1**).

%	**No. of Patients**	**Age (Years)**
40	20	21-25
60	30	26-30
		Gravidity
30	15	Primigravida
60	30	Second gravida
10	5	Third gravida
		Gestational age in days
60	30	35-50
40	20	51-66

Table 1: Demographic Distribution.

70% of the patients aborted within 12 hours and all the patients aborted within 24 hours (Figure – 1).

ISSN No: - 2456 – 2165

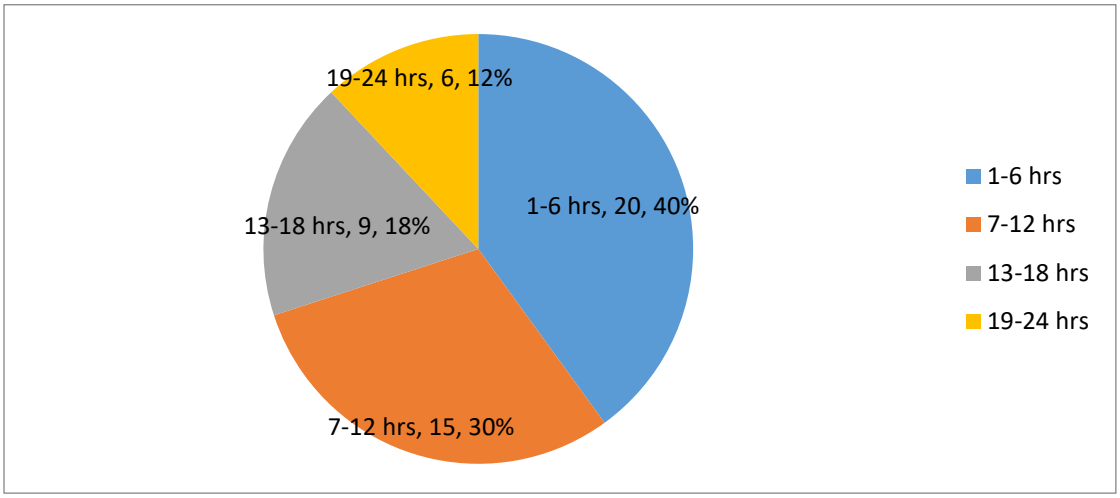

Figure – 1: Induction to Abortion Interval.

In the present study, two patients had retained products of conception on repeat ultra-sonogram, which needed surgical intervention. Out of these one was second gravida with gestational age 56 days and the other was third gravida with gestational age of 60 days. In the present study complications like Nausea, vomiting and diarrhea were observed in about 20%, 10%, and 4% of patients respectively. Procedure complications declined progressively and by day 14 reports were rare except for mild bleeding and spotting (**Table-2)**

%	**No. of cases**	**Abortion**
96	48	Complete
4	2	Incomplete
		Complications
20	10	Nausea
10	5	Vomiting
4	2	Diarrhoea

Table - 2: Abortion Completeness and Complications.

IV. DISCUSSION

Each year about 42 million induced abortions are estimated to be performed worldwide. Of these an estimated 20 million abortions are unsafe with developing nations burdened with 97%.Unsafe abortion is a leading cause of maternal mortality. There has been a constant endeavor to make abortion safer and accessible to women.

Mifepristone is an antiprogestin that blocks the progesterone receptors and prostaglandin induces uterine contractions to expel the products of conception .Misoprostol is cheap can be stored at room temperature and has minimal side effects .

There is enough universal evidence to recognize the effectiveness and safety of combining mifepristone-misoprostol for inducing abortion up to 63 days as approved for use by the Drug Controller of India. Many studies have

evaluated the combination in terminating early pregnancy The complete abortion rates have been reported from 92.1% to 95.5% in this studies.

In the present study, 200 mg of mifepristone orally and 800 µg of misoprostol intravaginally was used in women less than 63 days of gestation. Complete abortion occurred in 96% of cases comparable to study done by Ashok P.W. et al and Elaine, et al., using the same regimen (**Table –3**).

Success rate	**RU 486 and PG dose**	**Duration of pregnancy (no. of patients)**	**Study done by**
98.5%, 96.7%	200 mg + 800 µg misoprostol vaginally	<49 days (928) 49-63 days (1072)	Ashok P.W. et al.
94.5%	200 mg + 800 µg misoprostol vaginally	63-83 days (253)	Gouk V. E, et al.
96%	200 mg + 800 µg misoprostol vaginally	< 63 days (50)	Present study

Table - 3: Different Studies with Different Dosage Regimen and Their Outcome.

The gastrointestinal adverse effects were the most common. Heavy bleeding was reported in 2.8% of cases in Gouk V.E, et al.,study compared to nil in the present study.

Similar study done by Hill C.W. N reported 95% success rate.13% vomited after PG treatment and 10% had diarrhea. WHO task force conducted a study on 1182 patients with an early pregnancy <56 . They were divided into 3 groups (200 mg; 400 mg or 600 mg of mifepristone)orally followed 48 hours later by vaginal pessary of 1 mg of PGE analogue. Complete abortion was reported in 93.8% of 200 mg group , 94.1% and 94.3% in 400 mg and 600 mg groups repectively. Gouk V.E , et al., studied patients with 63 to 83 days of gestation by giving 200 mg of mifepristone 800 mcg of Misoprostol and found 94.5% success rate. Ashok P.W. et al.,conducted similar study with a success rate of 97.5%.

V. CONCLUSION

The Mifepristone- Misoprostol combination offers an effective, acceptable, out-patient procedure and an alternative to surgical methods of abortion in medical termination of early pregnancy (up to 63 days of gestation).

A. Conflicts of Interest

The author declares no conflicts of interest.

Author Contributions

Principal Author - Surg Lt. Dr Devdatt L Pitale , Contribution to the paper - Performed analysis, interpretation of data , manuscript writing and acted as corresponding author.

VI. ACKNOWLEDGEMENTS

This research was supported by the Indian Naval hospital ship, Asvini. I thank my colleagues from Asvini for their constant support.I thank Surg.cmde Dr Anupam Kapur, Head of the department of Obstetrics and Gynecology ,Asvini for his assistance with methodology and for comments that greatly improved the manuscript.

REFERENCES

[1]. Ashok PW , Penny GC, Flet GM , Templeton A (1998). An effective regimen for early medical abortion: 2000consecutive cases. Hum Reprod;13(10): 2962-5.
[2]. Crenin M,Grossman D(2014).Committee on Practice Bulletins:March,Number 143.
[3]. Faundes A, Fiala C ,Tang ,Velasco A(2007). Misoprostol for the termination of pregnancy. International Journal of Gynecology and Obstetrics:99,S172-S177.
[4]. FOGSI ICOG Good Clinical Practice Recommendation(2011). The Journal Obstetrics and Gynecologyof India :90-92.
[5]. Gouk V.E ,Lincoln K ,Khair A, Haslock J, Knight J, Crucickshank D (1999). Medicaltermination of pregnancy at 63 to 83days of gestation. Br J ObstetGynaecol;106: 535-539.
[6]. Honkanen H (2004). Medical Abortion with Mifepristone and Misoprostol in the first trimester.Helsinki University

Hospital,Finland:ISBN 952-10-1569-1.
[7]. Hill C.W N ,Ferguson J,Mackenzie I.Z(1990). The efficacy of oral Mifepristone (RU 38,486)with a prostaglandin E1 analogue vaginal pessary for the terminationof early pregnancy: Complications and patient acceptability. Am J ObstetGynecol;162: 414-17. DOI: http://dx.doi.org/10.1016/0002-9378(90)90398-Q.
[8]. Vani P.Y S, Devi N.A(2016). Efficacy of Mifepristone and Misoprostol combination in termination of early pregnancy. IAIM; 3(12): 48-54.