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Original Research Article

Assessment of Efficacy of Prophylactic Ibuprofen for Analgesia in Medical Method of Abortion up to 49 Days of Gestation

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Conflict of interest: Nil

Abstract

Background: Abortion is one of the most common subjects of obstetric practice. Abortion is defined as the expulsion of the fetus until the 20th week and is clinically classified based on ultrasound evaluation. Pain in medical abortion is the most predictable side effect of medical abortion and is a point of concern for patient. Regarding pain in general, WHO advised on documenting pain scores as the fifth vital sign (the four others being temperature, pulse rate, respiratory rate and blood pressure) for all patients experiencing pain. Even for medical abortions, it is imperative to ensure that patients receive safe and effective pain management tailored to their needs. For women undergoing medical termination of pregnancy, this also means that the level of pain must be ascertained in the routine clinical practice.

Objectives: To evaluate and compare the quantitative efficacy and physiological impact of prophylactic ibuprofen for anakgesis in medical method of abortion up to 49 days of gestation.

Results: As compared to Group B, Group A had significantly less VAS at 2 hours (5.03 ± 1.12 vs 5.6 ± 0.93, P=0.002), significantly less VAS score at 4 hours (4.45 ± 1.21 vs 5.29 ± 1.12, p=0.0001), and comparable at 6 and 8 hours; comparable change in VAS score at 4, 6, and 8 hours; significantly less median VAS after 1 hour of rescue analgesia (3.5 vs 4, P=0.004); significantly less median highest VAS in patients experienced during hospital stay (5 vs 6, P=0.0002); and significantly less median VAS in 24 hours following discharge (3 vs 4, P<.0001).

Conclusion: We found that patients in Group A taking Ibuprofen had significantly lower VAS scores (2 hours and 4 hours after administration of misoprostol) in comparison to placebo, with significantly less need of rescue analgesia, less hospital stay, and more patient satisfaction. Our findings were in line with other studies which showed better efficacy of Ibuprofen for pain management in abortions.

Keywords: abortion, ibuprofen, medical termination of pregnancy, analgesics, misoprostol, mifepristone.

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Introduction

International institute for population sciences, Mumbai, the population council New Delhi & Guttmacher institute, New York reported 48.1million pregnancies in India in year 2015 and almost half of it was unwanted. Estimated 15.6% ended up in abortion out of which 81% were medical abortion, 14% were surgical abortion and 5% were by unsafe measure [1].

Unsafe abortions are responsible for 13% of maternal mortality every year [1]. Medical abortion was incorporated in population stabilization policy of Ministry of Health and Family Welfare of India in 2001. Presently Mifepristone (200mg) + Misoprostol (400 microgram) are approved for termination of pregnancy less than 49 days of gestation .Medical abortions has benefits of 95% efficacy, more confidentiality and lack of need of hospital stay and invasive procedure. Supervised home-based medical abortion relieves burden on medical facility. Pain in medical abortion is the most predictable side effect of medical abortion and is a point of concern for patient.

It associated with few more factors such as anxiety, fear, emotional component attached to termination

of pregnancy. Other factors which are supposedly associated with increased requirement of analgesic are greater gestational age, young age, white race and nulliparity [2]. Need of pain relief in the process of medical abortion is well accepted. Till now there is lack consensus on type, dose and timing of pain relief medicine. Different researches have experimented with a number of drugs including Ibuprofen and other NSAIDS, Opiates like Codeine and Tramodol, Acetaminophen, Alverine, and Metamizole. Even antiemetic like Metoclopramide & Dimenhydramine and Loperamide has also been tried in hope of pain relief in medical abortion [3].

Although WHO guideline on medical abortion (2014) has recommended use of Ibuprofen 400-800mg or Diazepam 5-10mg as per requirement but also Recommended "the need of further research for optimizing the pain relief in medical abortion" [4]. Our national guideline recommend use of NSAIDS like Ibuprofen or Opiates as per demand.

Aims and Objectives

Aim-To assess the efficacy of prophylactic Ibuprofen for pain relief in Medical Method of Abortion up to 49 days of gestation.

Objectives

- Maximum Visual Analogue Score and use of rescue analgesia in both groups (Ibuprofen versus Placebo).
- To analyze the effect of prophylactic Ibuprofen on success of medical abortion.

Material and Methods

Study Design: A prospective interventional randomized comparative study.

Study Centre: Department of Obstetrics and Gynaecology, VMMC and Safdarjung Hospital.

Study Duration: October 2019 to march 2020.

Sample Size: 124 patients, divided into 2 groups of 62 each.

Inclusion Criteria

- Women aged 18-45 years who chose to undergo medical method of abortion of pregnancy up to 7 weeks of gestation (49 days from the first day of the menstrual period in regular cycles of approximately 28 days or ultrasound documented)

Exclusion Criteria

- Any contraindication to medical Abortion itself such as anaemia, confirmed or suspected ectopic pregnancy, molar pregnancy, non-viable pregnancy.
- Any medical disorder contraindicating medical methods of abortion such as chronic renal disease (as per guidelines of Ministry of Health and family welfare for medical abortion).
- Any known allergy/Contraindication for Misoprostol or Mifepristone, Non-steroidal anti- inflammatory drugs or Tramadol.
- History of any interference/abortifacient intake in this pregnancy to attempt termination.
- Inability to return to the study site and no option for telephonic contact.
- Women started bleeding after Mifepristone intake, before misoprostol administration.

Consent: Informed and written consent was obtained from all participants of the study.

Methodology: Detailed history was recorded as per Performa in annexure Number III.

a) **Demographic profile:** age, religion, address, education, occupation, per capita income were recorded.
b) **Menstrual history**- Days of menstruation and duration of cycle, flow and history of dysmenorrheoa requiring medication, date of last menstruation.
c) **Obstetric history-** Parity, live births, abortion (induced and spontaneous), previous caesarean section, previous ectopic (if any), last child birth/abortion, presently lactating or not.
d) **History of pre-existing medical/surgical condition** such as Hypertension, heart disease, diabetes mellitus, epilepsy, asthma, renal disease, drug allergies, bleeding disorders, current medication, fibroid uterus, previous pelvic surgery, present medications if any.
e) **Contraceptive history-** Specifically intrauterine contraceptive device.
f) **Psychosocial assessment**- Fear, anxiety of women and family support were assessed.
g) **Examination**- general & systematic examination was done.
h) Pelvic examination including speculation examination and per vaginal examination including bimanual examination to confirm the duration of pregnancy and to rule out ectopic pregnancy was done.

Investigations

- Pregnancy test (if not done before)
- Hemoglobin, urine examination, ABO & Rh blood group
- Ultrasound for dating of pregnancy (optional/case to case basis)

Sample Size & Formula: For the sample size calculation, we defined a relevant difference of 20% in pain relief between two groups (Ibuprofen versus Placebo) in patients undergoing medical abortion. Using a two tailed alpha value (0.05) and a beta value (0.2), thus 62 patients per group would be sufficient to detect a significant difference where we chose a 70% baseline ratio of pain relief

in medical abortion of control group. The formula for calculated sample size is given below

$n = [z_{1-\alpha/2}.\sqrt{2P(1-P)} + z_{1-\beta}.\sqrt{\{P_1(1-P_1) + P_2(1-P_2)\}}]^2$

$(P1-P2)^2$

$= [1.96*0.566 + 0.842*0.548]^2$

$(0.2)^2$

$= [1.5699]^2$

0.04

= 61.61 where Zα/2 is the critical value of the Normal distribution at α/2 (e.g. for a confidence level of 95%, α is 0.05 and the critical value is 1.96), Zβ is the critical value of the Normal distribution at β (e.g. for a power of 80%, β is 0.2 and the critical value is 0.842) and p1 and p2 are the expected sample proportions of the two groups.

Data Analysis: Statistical testing was conducted with the statistical package for the social science system version SPSS 17.0. Continuous variables were presented as mean and SD or median (IQR) for non-normally distributed data. Categorical variables were expressed as frequencies and percentages. The comparison of normally distributed continuous variables between the groups was performed using Student's t test. Nominal categorical data between the groups was compared using Chi-squared test or Fisher's exact test as appropriate.

Non-normal distribution continuous variables were compared using Mann Whitney U test. For all statistical tests, a p value less than 0.05 was taken to indicate a significant difference.

Results & Table-Specific Discussions

Table 1: Comparison of age (years) between group A and B

Age(years)	Group A (n=62)	Group B (n=62)	Total	P value	Test performed
<=30	37 (59.68%)	43 (69.35%)	80 (64.52%)	0.26	Chi square test,1.268
>30	25 (40.32%)	19 (30.65%)	44 (35.48%)		
Mean ± SD	29.11 ± 5.26	28.32 ± 4.15	28.72 ± 4.74	0.355	t test;0.929
Median(25th-75th percentile)	29(25-33)	28(25.25-31)	28.5(25-32)		
Range	20-44	18-40	18-44		

Discussion of Table 1: Age of patients ranged between 18 to 44 years.
Most of the patients were <=30 years. Minimum age in group A was 20 years and in group B was 18 years and Maximum age in group A was 44 years and in group B was 40 years. Distribution of age in group A and group B was comparable (<=30 years:-59.68% vs 69.35%), (>30 years:- 40.32% vs 30.65%) (p value = 0.26). Mean ±SD of age (years) in group A was 29.11 ±5.26 and group B was 28.32 ±4.15 with no significant difference between them. (p value=0.355)

Table 2: Comparison of parity between group A and B.

Parity	Group A (n=62)	Group B (n=62)	Total	P value	Test performed
0	6 (9.68%)	2 (3.23%)	8 (6.45%)	0.584	Fisher Exact test
1	13 (20.97%)	15 (24.19%)	28 (22.58%)		
2	33 (53.23%)	35 (56.45%)	68 (54.84%)		
>=3	10 (16.13%)	10 (16.13%)	20 (16.13%)		
Total	62 (100%)	62 (100%)	124 (100%)		

Discussion of Table 2: Distribution of parity in group A and group B was comparable (Parity 0:-9.68% vs 3.23% respectively), (Parity 1:- 20.97% vs 24.19% respectively), (Parity 2:- 53.23% vs 56.45% respectively) and (Parity>=3:- 16.13% vs 16.13% respectively) (p value = 0.584).

Table 3: Comparison of previous abortion between group A and B.

Previous abortion	Group A (n=62)	Group B (n=62)	Total	P value	Test performed
0	39 (62.90%)	42 (67.74%)	81 (65.32%)	0.571	Chi square test,0.32
1	23 (37.10%)	20 (32.26%)	43 (34.68%)		
Total	62 (100%)	62 (100%)	124 (100%)		

Discussion of Table 3: Distribution of previous abortion in group A and group B was comparable (No Abortion:- 62.90% vs 67.74% respectively) and (Previous abortion 1:- 37.10% vs 32.26% respectively) (p value = 0.571).

Table 4: Comparison of VAS between group A and B.

VAS score	Group A (n=62)	Group B (n=62)	Total	P value	Test performed
After 2 hours					
Mean ± SD	5.03 ± 1.12	5.6 ± 0.93	5.31 ± 1.06	0.002	Mann Whitney test;1351
Median(25th-75th percentile)	5(4-6)	6(5-6)	5(5-6)		
Range	2-7	3-8	2-8		
After 4 hours					
Mean ± SD	4.45 ± 1.21	5.29 ± 1.12	4.87 ± 1.24	0.0001	Mann Whitney test;1138
Median(25th-75th percentile)	4(4-5)	5(5-6)	5(4-6)		
Range	2-8	2-8	2-8		
After 6 hours					
Mean ± SD	3.82 ± 1.02	4.16 ± 1.18	3.99 ± 1.11	0.115	Mann Whitney test;1621
Median(25th-75th percentile)	4(3-4)	4(3.25-5)	4(3-5)		
Range	2-6	2-7	2-7		
After 8 hours					
Mean ± SD	3.18 ± 0.91	3.48 ± 1.02	3.33 ± 0.98	0.092	Mann Whitney test;1600.5
Median(25th-75th percentile)	3(3-4)	3(3-4)	3(3-4)		
Range	2-5	2-6	2-6		

Discussion of Table 4: Significant difference was seen in VAS score after 2 hours, after 4 hours between group A and B. (p value <.05) Median (25th-75th percentile) of VAS score after 2 hours, after 4 hours in group B was 6(5-6), 5(5-6) respectively which was significantly higher as compared to group A (5(4-6), 4(4-5)) respectively. Median (25th-75th percentile) of VAS score after 6 hours, after 8 hours in group A was 4(3-4), 3(3-4) and in group B was 4(3.25-5), 3(3-4) respectively with no significant difference between them. (p value>.05)

Table 5: Comparison of rescue analgesia demanded between group A and B.

Rescue analgesia demanded	Group A (n=62)	Group B (n=62)	Total	P value	Test performed
No	54 (87.10%)	40 (64.52%)	94 (75.81%)	0.003	Chi square test,8.618
Yes	8 (12.90%)	22 (35.48%)	30 (24.19%)		
Total	62 (100%)	62 (100%)	124 (100%)		

Discussion of Table 5: Proportion of patients who demanded rescue analgesia was significantly higher in group B as compared to group A (35.48% vs 12.90% respectively) (p value = 0.003).

Table 6: Distribution of 2nd dose of Ibuprofen after 8 hour if needed of study subjects in Ibuprofen group.

2nd dose of Ibuprofen after 8 hour if needed	Frequency	Percentage
No	45	72.58%
Yes	17	27.42%
Total	62	100.00%

Discussion of Table 6: In present study, in majority (72.58%) of patients, 2nd dose of Ibuprofen after 8 hour was not needed and was needed in only 17 out of 62 patients (27.42%).

Table 7: Comparison of VAS after 1 hour of rescue analgesia between group A and B.

VAS after 1 hour of rescue analgesia	A (n=62)	B (n=62)	Total	P value	Test performed
Mean ± SD	3.5 ± 0.53	4.23 ± 0.53	4.03 ± 0.61	0.004	Mann Whitney test;36
Median(25th-75th percentile)	3.5 (3-4)	4 (4-4.75)	4 (4-4)		
Range	3-4	3-5	3-5		

Discussion of Table 7: Median (25th-75th percentile) of VAS aftre 1 hour of rescue analgesia in B was 4(4-4.75) which was significantly higher as compared to A (3.5(3-4)). (p value=0.004)

Table 8: Comparison of VAS in 24 hours following discharge from hospital between group A and B.

VAS after discharge from hospital	Group A (n=62)	Group B (n=62)	Total	P value	Test performed
Mean ± SD	3.08 ±0.77	3.97 ±0.81	3.52 ±0.91	<.0001	Mann Whitney test;883.5
Median(25th-75th percentile)	3(3-3)	4(3-5)	3(3-4)		
Range	2-5	2-5	2-5		

Discussion of Table 7: Median (25th-75th percentile) of VAS after discharge from hospital in group B was 4(3-5) which was significantly higher as compared to group A (3(3-3)). (p value<.0001)

Discussion

The present study was a randomized case control trial on 124 women [62 cases who were given Ibuprofen and 62 age matched controls who were given placebo treatment] where we compared the efficacy, pain management and safety of Ibuprofen on medical method of abortion of pregnancy up to 7 weeks of gestation.

Pain is often cited by women as one of the worst aspects of the MA experience. Individual experiences and responses to pain and pain medication are complex and may differ according to ethnicity, socio-economic status, cultural factors, physiology and genetics.

The study demographics of the population showed that the cases were comparable to controls in terms of age, area of residence, education, wife occupation, gestational age, parity, and contraceptive history. This was mainly due to randomization which ensured that these factors did not have any effect on the outcomes of abortion. Among other comparative studies also, the baseline demographic characteristics were comparable (p>0.05).

We found that patients in Group A taking Ibuprofen had significantly lower VAS scores (2 hours and 4 hours after administration of misoprostol) in comparison to placebo, with significantly less need of rescue analgesia, less hospital stay, and more patient satisfaction. Our findings were in line with other studies which showed better efficacy of Ibuprofen for pain management in abortions.

Limitations:

1. Our study was conducted in a setting which caters to patients belonging primarily to the lower or middle socio-economic strata and the data primarily reflects the situation in this cohort.
2. Being a single centered study, it may not include the representative samples which make the generalization of the study finding appalling.
3. Also, though the randomization ensured the comparable baseline characteristics of the patients of both groups but we could not do blinding of the procedures for the operator.
4. The study lacked assessment of ibuprofen to other analgesics that are generally prescribed after medical abortion. Thus, the better analgesic among the list of used drugs could not be determined.

Conclusion

We observed that in a mifepristone and misoprostol protocol for medical abortion, patients who received Ibuprofen had significantly lower VAS scores (2 hours and 4 hours) in comparison to placebo, with significantly less need of rescue analgesia, less hospital visits, and more patient satisfaction. The use of Ibuprofen was not associated with an increased rate of incomplete abortion. Minor side effects such as nausea, vomiting, fever and epigastric pain were noticed which were managed without any significant morbidity and mortality.

In conclusion, Ibuprofen is safe and effective in pain management during medical abortions.

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