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Original Research Article

Retrospective Observational Assessment of the Hazards of OTC Availability of MTP Pills

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Abstract

Aim: The aim of this study was to study the implications of self-administration of abortion pills by pregnant women.

Material & Methods: This study was a retrospective observational study carried out in Department of Obstetrics & Gynecology, PMCH, Patna, Bihar, India after due permission from the hospital authorities. Case sheets were analyzed to obtain data regarding self-administration of abortion pills and complications secondary to its administration.

Results: Pregnancy was confirmed by 50 women with urine pregnancy test and 1 woman had undergone USG along with UPT. 48% women consumed pills after 1-5 days of hospital visit**.** 46% women showed > 10 grams of hemoglobin level. Majority of cases reported were of incomplete abortion (56%) followed by Failed abortion (10%) and Incomplete abortion with sepsis (10%).

Conclusion: Unsupervised medical abortion can lead to increased maternal morbidity and mortality. To curtail this harmful practice, strict legislations are required to monitor and also to restrict the sales of abortion pills over the counter and access to abortion pills for the public should be only through centers approved for MTP. Large scale prospective studies are required to assess the actual magnitude of this problem.

Keywords: Complications, Medical Abortion, Self-Administration, Unsafe Abortion.

Introduction

Unsafe abortion occurs when a pregnancy is terminated either by persons lacking the necessary skills or in an environment that does not confirm the minimal medical standards or both. [1]

According to first national study of the incidence of abortion and unintended pregnancy in India, an estimated 15.6 million abortions were performed in the country in 2015. This translates to an abortion rate of 47 per 1000 women aged 15 to 49 years, which is similar to abortion rate in the neighboring South Asian countries. [2]

The world health organization (WHO) recommendations on medical abortion are restricted to early first trimester (up to 63 days since first day of last menstrual period). [3]

The clinical safety, efficacy and acceptability of mifepristone with misoprostol in the Indian context have been well studied. [4-5] However, little has been systematically documented about their use or how key stakeholders perceive medical abortion. Ipas, in 2004, conducted a study in the states of Bihar and Jharkhand (where it has an ongoing programmatic commitment to improving access to safe abortion care), to gauge knowledge of and perceptions about medical abortion among women and men, and to study stocking and sales of abortifacient drugs by chemists and the use practices of mifepristone–misoprostol among abortion service providers. [6]

Thus, this study aims to study the implications of self-administration of abortion pills by pregnant women.

Material & Method

This study was a retrospective observational study carried out in Department of Obstetrics & Gynecology, PMCH, Patna, Bihar, India after due permission from the hospital authorities. All case records with the diagnosis of abortion whether spontaneous or induced were analyzed over a period of one year from medical records department and data was collected from case sheets in which pregnant women had given a history of induced abortion following self-administration of abortion pills and its complications.

By self-administration we mean that these pregnant women had no medical consultation with a registered medical practitioner and has taken abortion pills which was purchased from the pharmacy without any prescription either by self or by some close relative.

The following data was collected. Age, marital status, parity, duration of pregnancy as perceived by the women, confirmation of pregnancy, duration between pill intake and visit to hospital, whether any intervention done elsewhere, any known medical or surgical complications, Hb level on admission, whether patient was in shock, USG findings of incomplete abortion, complete or failed abortion, evidence of sepsis like fever and tenderness on pelvic examination, blood transfusion, treatment given and duration of hospital stay.

Management was based on whether patient was bleeding profusely, when surgical evacuation was performed whereas when bleeding was less and the amount of retained products as assessed by ultrasound was minimal medical methods were used.

Data was tabulated using SPSS software and a P value of 0.05 was considered significant.

Results

The total number of abortions in our institution including spontaneous and induced abortions over a period of one year was 135 of which 50 women had given a history of self-medication with abortion pills obtained without prior medical consultation.

In our study we found that 84.7% were married, 11.2% were unmarried and 4.1 woman were widow.

The finding that 28.5 % of patients had consumed abortion pills after 9 wk of pregnancy is significant, as medical abortion is permitted only upto 63 days of gestation. The maximum period of gestation of self-administration was done was at 20 wk of pregnancy and this patient presented with shock following expulsion of the fetus and came with retained placenta and underwent subsequent surgical evacuation. [Table 1]

Table 1: Timing of Consumption of Abortion Pills

S. No.	Gestational age	No	%
1	Early pregnancy to 7 wk	11	22
2	7 wk to 9 wk	21	42
3	9 wk to 12 wk	5	10
4	> 12 wk	9	18

Pregnancy was confirmed by 50 women with urine pregnancy test and 1 woman had undergone USG along with UPT. 48% women consumed pills after 1-5 days of hospital visit [Table 2].

Table 2: Interval between Pill Intake and Visit to Hospital

S. No.	No. of days Since Consumption of Pill to hospital visit	no (50)	%
1	1-5	24	48
2	6-10	13	26
3	11-15	6	12
4	16-20	1	2
5	21-25	0	0
6	26-30	3	6
7	>1month	3	6

Majority of women (86%) complained of Excessive bleeding per vagina, followed by bleeding with abdominal pain (4%) and abdominal pain (4%). [Table 3]

Table 3: Complaints at Presentation to Hospital

S. No	Complaints	no	%
1	Excessive bleeding per vagina	43	86
2	Irregular bleeding per vagina	1	2
3	Bleeding with abdominal pain	2	4
4	Abdominal pain	2	4
5	Fever with pain and irregular bleeding	1	2
6	Not expelled products	1	2

Severe anaemia was seen in 7 cases and Post caesarean pregnancy in 5 cases comprised of associated medical or surgical disorders. [Table 4]

Table 4: Associated Medical or Surgical Disorders

S. No.	Associated medical or Surgical disorders	no.
1	Severe anaemia (Hb < 7 grams)	7
2	Rh negative	3
3	Seizure disorder	2
4	Cardiac disease	3
5	Bronchial asthma	2
6	HIV positive	1
7	Post caesarean pregnancy	5

46% women showed > 10 grams of hemoglobin level. [Table 5]

Table 5: Hemoglobin Level on Admission

S. No	hemoglobin Level	no.	%
1	< -7grams	4	8
2	7 - 10 grams	18	36
3	> 10 grams	28	56

Majority of cases reported were of incomplete abortion (56%) followed by Failed abortion (10%) and Incomplete abortion with sepsis (10%). [Table 6]

Table 6: Outcome Following Self-administration

S. No	Outcome	no.	%
1	Incomplete abortion	28	56
2	Complete abortion	1	2
3	Failed abortion	14	28
4	Incomplete abortion with sepsis	5	10
5	Incomplete abortion with shock	2	4

70% of cases were solved by surgical evacuation only. Cases treated with Medical methods only (misoprostol repeated) were 16% and surgical evacuation with blood transfusion were 14% [Table 7].

Table 7: Management of complications

S. No	Management	no.	%
1	Medical methods only (misoprostol repeated)	8	16
2	No Intervention	1	2
3	Medical method and blood transfusion	1	2
4	Surgical evacuation only	35	70
5	Surgical evacuation with blood transfusion	7	14

40 cases required 1-5 days of hospital stay and 9 cases had 6-10 days stay at hospital. [Table 8]

Table 8: Duration of Hospital Stay

S. No.	No. of days (hospital stay)	no.
1	1-5	40
2	6 -.10	9
3	>10	1

Discussion

The MTP act of India, legalizing abortions was passed with the aim of reducing the number of maternal deaths due to unsafe abortions. But still 8% of maternal deaths are attributed to unsafe abortions in India. Any procedure which is performed outside the bounds of law tends to be unsafe and 5 million unsafe abortions are performed per year in India. [7]

In India, as in other South Asian countries,[8]a variety of over-the-counter medications for delayed periods/abortion remains in high demand because of low cost and because the perception that side effects are negligible makes the trade-off with low efficacy worthwhile. While the price of mifepristone in India is less than in many other countries, a single tablet still costs [8–10] times more than any ofthe other preparations and even in absolute terms can prove a considerable barrier in these two states, both of which have a per capita income considerably lower than the national average. The fact that higher than necessary doses of mifepristone continue to be prescribed and sold increases costs and further reduces access and therefore demand.

Findings reported by Thacker et al. [9] showed majority of patients presented with excessive/irregular bleeding (59.96%) followed by pain lower abdomen (25.55%).

The overall frequency of infection after medical abortion is <1% compared to surgical methods when done under prescribed settings [10]. But serious infections like fatal Clostridium sordellii infections have been reported following

medical abortions [11]. However, the complication of sepsis tends to be higher in women undergoing unsafe abortions. Studies comparing intake of abortion pills with medical supervision and self-administration showed that serious complications like anaemia, sepsis, failure and incomplete abortion is higher in women who self-administered the drug [12].

Studies comparing medical and surgical methods have shown that hemorrhage and incomplete abortion and rate of surgical evacuation was more after medical abortion [13].

The chance of failed abortion is 1 % following medical abortion and the possibility of teratogenesis due to misoprostol in the form of skull defects and limb abnormalities are documented and hence the process should be completed by surgical evacuation and continuation of pregnancy is not an alternative [14,15].

Conclusion:

Unsupervised medical abortion can lead to increased maternal morbidity and mortality. To curtail this harmful practice, strict legislations are required to monitor and also to restrict the sales of abortion pills over the counter and access to abortion pills for the public should be only through centers approved for MTP. Large scale prospective studies are required to assess the actual magnitude of this problem.

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