

MISUSE OF AN ABORTION PILL

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ABSTRACT

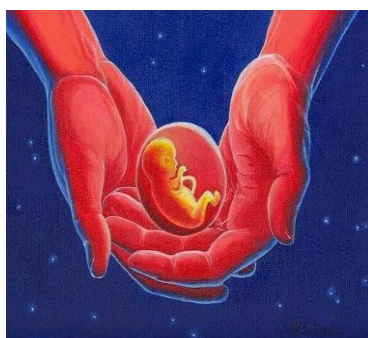
Medical termination of pregnancy has been legalized in India since 1971. Medical abortion pill is well effective in early weeks of pregnancy. It is safe only when it is used under medical supervision. This study was carried out to analyse the complications following self-medication of abortion pills and to suggest measures to prevent such practice. In present study 30 (75%) patients were in age group of 20-30 years. Illiterate patients were 22(55%). Half of the patients, 20(50%) were having three or more than three children. Majority of women 30(75%) had consumed the abortion pills 1-10 days before coming to the hospital and 14(35%) of patients had come with

complain of excessive bleeding per vagina. Incomplete abortion was present in 32 (80%) of patients. Instrumental evacuation was required in 28 (87.5%) patients. Laparotomy for ruptured ectopic and rupture uterus was performed in 1(2.5%) of each patient. 6(15%) patients were severely anaemic. Transfusion of blood was required in 9 (22.5%) of patients. Medical abortion is effective and safe when carried out under medical supervision. Unsupervised use of medical abortion pills was associated with many complications like incomplete abortion, rupture ectopic and ruptured uterus. So, over the counter sale of medical abortion pill should be restricted. Most sales appeared to be prescription driven, but some over the-counter sales did occur, especially when ability to pay seemed high or the chemist knew the customer. Chemists need accurate information on the drugs they sell as abortifacients, encouragement to promote pregnancy tests, training in encouraging women to see a provider prior to purchase, and visual and written material to hand out. Better adherence to existing regulations for all prescription drugs is important, but the best course is to increase the availability of low-cost, safe abortion services at primary care level.

INTRODUCTION

It has been estimated that each year 42 million induced abortions are performed worldwide. Approximately 13% of all maternal deaths are attributed to unsafe abortions. Lack of awareness about disastrous consequences combined with easy availability and ease of administration has led to rampant self medication of abortion pills without medical supervision at the cost of women's life. There has been no data till date about magnitude of complications arising out of its misuse. Therefore, this present study was planned to collect authentic data about awareness of correct use of abortion pills for termination of pregnancy upto 9 weeks of gestation and complications arising as a result of abortion pill misuse to decide policy for reducing maternal mortality.

Although abortion is illegal in many developing countries, abortion in India is legal. Official figures suggest that approximately one million abortions are performed each in India although vario year in India, although various studies suggest there are actually as many abortions. six times as many The biomedical dimensions of the regimen mifepristone and misoprostol are well documented. However, what is less understood is the impact of access to r o medical abortion via both traditional hospitals and clinics and less traditional channels such as pharmacies and community health workers. India is an important country to analyse because of its relatively and you to m liberal approach to medical abortion and the ease with which women and men can buy the drugs outside of the clinical setting. It should be noted that it is still illegal in India to acquire medical abortion l abortion. drugs without a prescription, although studies suggest that over-the-counter sales of the drugs is common practice.



In 1971, the Indian Government liberalised its abortion laws significantly by adopting the Medical Termination of Pregnancy (MTP) Act. Until then, the Indian penal code only permitted abortion if it was required to save I to save the life of the woman. Anyone caught performing an illegal abortion was liable to three years imprisonment and a fine. Women

terminating their pregnancy faced up to seven years in prison and a fine. Whilst this did not deter many women from seeking a termination, it did mean abortions were often carried out by unskilled practitioners in unsafe conditions. The resulting high maternal mortality rate prompted the government appointed Shah Committee to recommend legalising abortion in 1966 to encourage women to seek terminations in legal and safe settings.

The MTP Act allows any government-run hospital or certified private facility in India to perform abortions 20 weeks of up until any. Under pregnancy. the original Act, an abortion could only be performed by by an gynaecologist tor obstetrician another medical practitioner. who has undergone sufficient training and has been certified.

In 2002 and 2003, the Indian Parliament passed the Medical Termination of Pregnancy (Amendment) Act and the amended Rules and Regulations to strengthen the MTD Aut the MTP Act and improve the availability abortion the avaidilyn services. Most significantly, the amended MTP Rules sanctioned medical abortion. They allow an obstetrician may gynaecologist or another. certified medical practitioner to prow to provide mifepristone and misoprostol in a clinic setting until the seventh week of pregnancy.

Availability of drugs for menstrual regulation/abortion at chemist shops

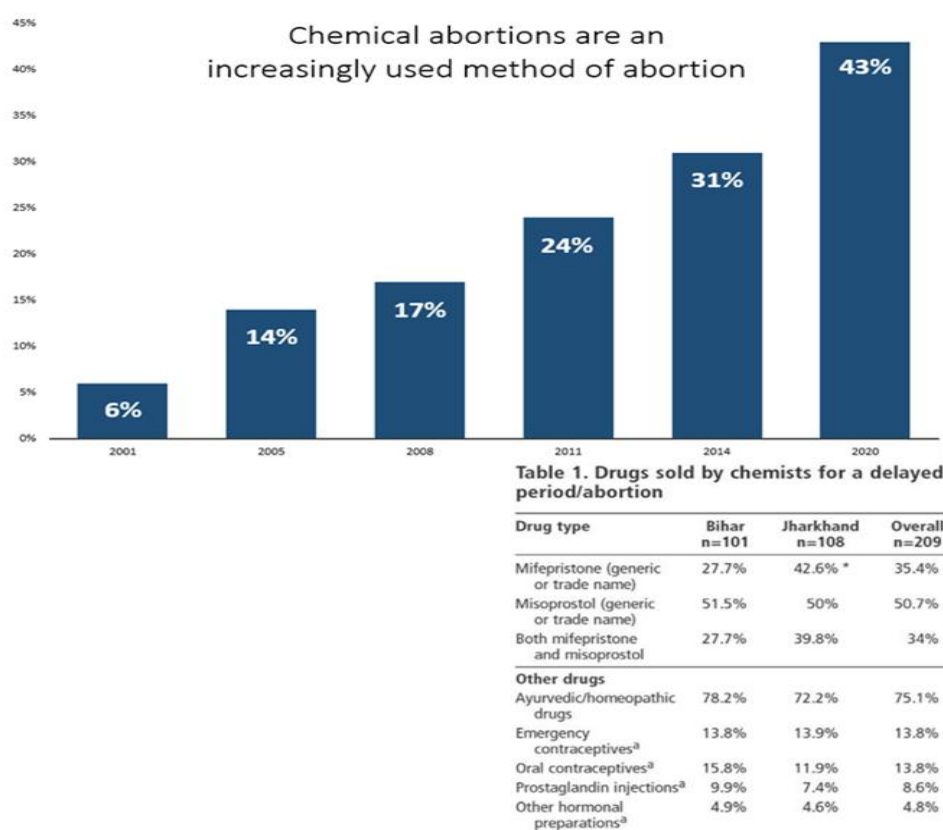


Table 1 represents the common drugs mentioned by chemists when asked to list drugs that they sold for a delayed period or abortion. Ayurvedic drugs were more likely to be sold than mifepristone or misoprostol. Only 34% of the surveyed chemists stocked both mifepristone and misoprostol tablets.

While the proportions of chemists selling other drugs as abortifacients was similar across states and chemist shop sizes, stocking patterns for mifepristone varied considerably. Stocking of mifepristone was significantly higher in Jharkhand than in Bihar, which may reflect a difference in the levels of urbanisation of the surveyed towns between the two states. Similarly, stocking was higher in the two state capitals (43.8% of chemists) than in the other district towns (32.9%). In both states, there was also a significantly higher probability of mifepristone being available at larger chemists (64.7% stocked it) than in medium-sized (22.9%) or small outlets (19.7%). Such variations were not seen with misoprostol, which has been in the Indian market for a longer time and is also a far cheaper drug.

An additional 24.4% of chemists said they were familiar with mifepristone but not willing to stock or sell it, mainly because of inadequate demand and the fact that it was expensive.

Although four brands each of mifepristone and misoprostol were available at the time of the survey, stocking of more than one brand was not common. Of the 74 chemists stocking mifepristone, 64% carried only a single brand, and 61% of the chemists stocking misoprostol also carried only a single brand.

In contrast, over 50 brands of Ayurvedic preparations were mentioned, the most common being Gynomic Forte, RP Forte and EP Forte. When asked how many Ayurvedic drugs he stocked for delayed periods, one chemist remarked: "How many names can I count? I keep so many."

The authors collected samples of over 30 different preparations. None of the labels mentioned abortion as an indication, though some brands used clear mnemonic labelling for example names like Abomil and DNC to suggest that they were abortifacients (see photos). Several Ayurvedic preparations had names similar to EP Forte (eg. Erca P Forte, E Pco. Forte), which we were told was to make them resemble the now banned hormonal preparation EP Forte, to leverage the large-scale name recognition of that product.

Attitudes to abortion

Women's knowledge about and attitudes to abortion, by whether or not they have had an abortion.

There was no difference between t in terms of women's knowledge of the legal status of abortion. Approximately two-thirds of women said abortion was illegal, and one quarter said it was legal. More of the women who themselves had an abortion said that it was legal (36% vs. 22% of women who had not had an abortion). In states, over half of the women who had had an abortion said that abortion was illegal.

For the men, there was no difference according to whether or not their wives had an abortion. Very few thought abortion was legal approximately 15% states.

Attitudes: when is abortion acceptable?

Attitudes to abortion and when it is acceptable were significantly different for all of the scenarios presented to the women. Generally, the i majority of women were in favour of abortion in the various scenarios: it the health of the woman is in danger; if the woman does not want another child; is unmarried; is pregnant as a result of rape: or there is a strong chance of a defect in the baby. In all of these cases, more women in Gujarat than Jharkhand said they agreed with abortion under these circumstance.

Among the women in, there was also a significant difference in attitude between women who had had an abortion and those who had not in terms of their attitude to abortion in the case of contraceptive failure: 96% of women who had had an abortion themselves were in favour compared with a somewhat lower figure of 87% of women who had not had an abortion (not shown).

Perceived social support for abortion

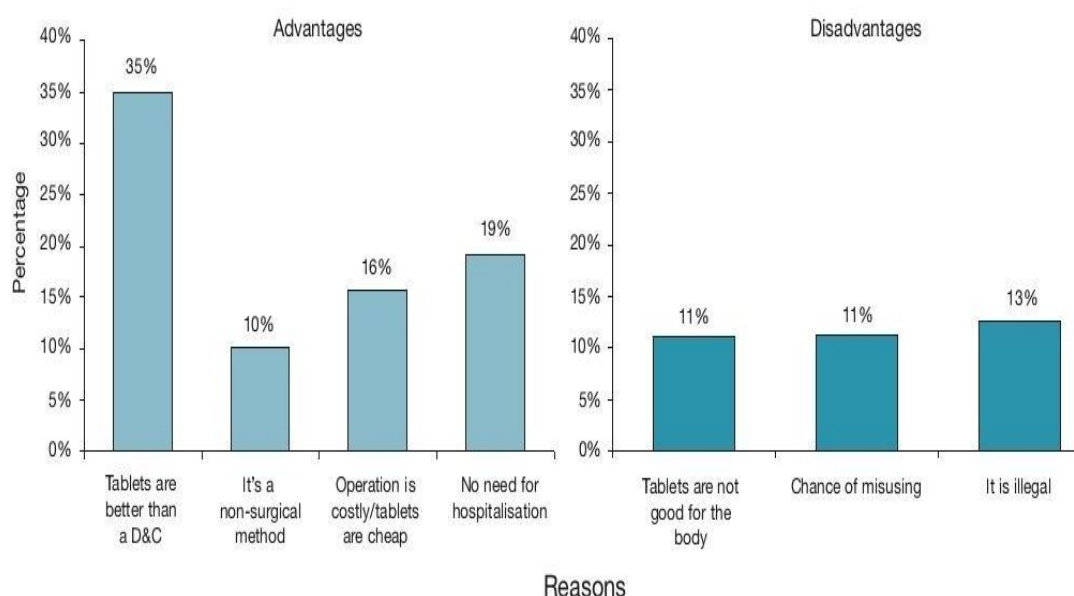
Women and men were asked various questions to try to understand their perceptions of social support for abortion. among their social networks. Women differed by state in their perceptions of social support around abortion. 32% of women agreed that only the man can decide whether or not his wife should have an abortion. However, the men did not agree.

Because these results were for the all the women versus all the men, we examined their responses in husband-wife pairs to see whether there was also disagreement within couples about a wife's idea of her husband's support of her use of medical abortion. In 55% of cases,

the responses of the husband and wife tallied - either they both thought the husband would not support use of abortion, or both agreed he would.

Overall, women tended to have an over-positive view of their husband's support for their possible use of medical abortion, thinking he would support them when in fact he said that he would not.

Pros and cons of promoting medical abortion: women's spontaneous reasons for saying the method should or should not be promoted.



What did chemists know about medical abortion?

Almost all of the 209 surveyed chemists (95%) mentioned medical representatives and doctors' prescriptions as their primary source of product information. Further, when the 109 chemists stocking mifepristone and or misoprostol were asked whether they thought the drugs needed to be prescribed alone or in combination, 51 (46.8%) thought both needed to be used, 39 (35.8%) thought misoprostol alone was adequate and five (4.6%) thought mifepristone could be used by itself. The remaining 12.8% thought either drug could be used alone.

Over half the chemists who knew of both drugs (51.3%) were unable to answer what they thought the doses were at which the two drugs were used together. Some 15.6% mentioned the use of 200mg mifepristone followed by 400mcg misoprostol, as in the current National Con sortium guidelines. An equal proportion thought. that mifepristone should be used in doses of 600mg with 400mcg of misoprostol. This may reflect wider prescribing patterns in

the study. areas as during the interviews with service providers, we found that 65.1% of doctors providing mifepristone-misoprostol were giving mifepristone in doses greater than 200mg.

Twenty-seven per cent of chemists mentioned that misoprostol should be used vaginally rather than orally, and 7% thought that mifepristone too was usually prescribed vaginally, not orally. Many chemists were unable to answer how many weeks of pregnancy the drugs could be used until. Those who did answer felt largely that the drug should not be used beyond either 45 or 60 days after the last menstrual period (LMP) (Table 2).

Two chemists thought misoprostol should be used the same way as emergency contraception (that is, within 72 hours of unprotected sex) and two chemists thought mifepristone should be used in this way.

When asked what the side effects of these drugs were, 73% of chemists were unable to list any. Among those who did mention something, excessive bleeding was the most common response for both the combination regimen and for mifepristone alone. However, nausea and vomiting were thought to be the most common side effects when misoprostol was used alone.

All chemists interviewed thought that their current knowledge levels about mifepristone and misoprostol were inadequate and expressed a strong interest in learning more about the side effects of the drugs, legal issues, efficacy and mechanisms of action.

How many customers come with prescriptions?

There appear to be three distinct patterns of customers who come in to buy abortifacient drugs: those who carry a doctor's prescription, those who have the name of a specific drug in mind or carry a wrapper, empty packet or brand name written on a piece of paper ("Chutki"), based on the recommendation of someone who has used these tablets successfully, and - those who rely on the chemist to recommend a suitable product.

Over 97% of surveyed chemists estimated that at least a few of their customers relied on them to recommend a suitable product, and nearly two-thirds of all chemists (61.7%) thought that more than half of their customers asked for a recommendation rather than a specific product.

On the other hand, when asked to estimate the proportion of their mifepristone customers

who did not have a prescription, nearly a third of the respondents (32.1%) were unwilling to answer.. Of those who did, the overwhelming majority (77.1%) felt that 80% or more of all mifepristone customers carried a prescription. In fact, 47% of those who answered the question said that not a single mifepristone customer was without a prescription. Their answers may be related to the high awareness levels of the Schedule H status of these drugs. When asked at the end of the survey about any specific rules or regulations pertaining to the sale of mifepristone, the vast majority of chemists (92.9%) mentioned that mifepristone could not be sold without a prescription. A similar proportion were aware that misoprostol is also a prescription drug. Four per cent of chemists, in addition, mentioned the Drug Controller of India's stipulation of using mifepristone only under a gynaecologist's supervision.

During the in-depth interviews as well, chemists spoke about rules and the publicity around possible problems with misuse of the drugs, and in fact four chemists had refused to participate in an in-depth interview as they were concerned that the researchers might be drug inspectors.

Interestingly, when surveyed doctors were asked if they thought the drugs should be sold by chemists on prescription, only 13.4% were in favour of this. However, when the sub-set of these doctors who were actually providing medical abortion in their clinical practice were asked how they supplied the drugs to women, only 24.7% said they kept a stock of drugs at their clinic, the rest all wrote out prescriptions and asked women to purchase them from nearby chemists.

However some non-prescription sales also do occur. Doctors too confirmed this: 16.3% of obstetrician- gynaecologists providing medical abortion reported that in the previous six months they had also treated women (most often young, unmarried girls) who had come to them after having taken mifepristone and/or misoprostol obtained from a chemist.

How do chemists respond when asked to recommend drugs?

During the FGD discussions with men, they described a common pattern wherein the husband or other male relative of the woman with a missed period generally went to the chemist, described the problem and relied on the chemist to prescribe the appropriate medicine. Some men were said to approach the local chemist, not to obtain a medicine but to ask advice on the right doctor to consult for an abortion. Chemists reported that poorer customers were more likely to come in directly, without having first visited a doctor.



Many asked for tablets for a "menstrual cycle that has stopped". Others were more direct and explained that their wives did not want to continue the pregnancy. Most asked the chemist to suggest an appropriate drug, saying, for example: "Give me medicines according to your best understanding."

While it was not discussed during the survey, in the nine in-depth interviews we tried to understand the basis upon which chemists made such recommendations. A clear and consistent pattern emerged, with the chemists' decision seeming to depend on several factors:

- Knowing that the woman was pregnant and the duration of pregnancy Three of the nine chemists reported that they advised women to do a urine test to confirm pregnancy before taking any medicines. These chemists all sold the pregnancy test strips to the woman or her partner. Others said they asked the person to estimate the duration of pregnancy but admitted they had to rely on the person's own estimation.

Two chemists seemed to be aware of the distinction between menstrual irregularity (delayed periods) and an actual pregnancy; they felt that most of the Ayurvedic or hormonal drugs they stocked worked only if the woman was not pregnant. The other seven believed that these other drugs were effective as abortifacients if used early enough in pregnancy. Six of the nine chemists believed that all drugs worked equally well, with mifepristone-misoprostol being marginally more effective, and thus that there was little to choose between the various drugs. This was expressed in various ways:

"Mifepristone-misoprostol is good but Gynomic Forte is also effective, as there is demand for the product."

"Mifepristone-misoprostol has nearly 100% guarantee, but others are also 60-70%." "All drugs are effective for three months."

Some chemists did think that mifepristone and misoprostol were more effective than the other drugs; however, the belief that mifepristone was better was often due to its higher price, with cost being a proxy for quality.

Economic considerations

This factor usually overrode all others. Eight of the nine chemists reported deciding on which drug to prescribe based on their estimate of the customer's ability to pay. The bottom line for most chemists was to ensure that no one went away from the shop without buying a medicine.

"We see pockets first."

"It's just like gambling. It all depends on what they want and can afford."

"I'm a businessman, and I have to see to the needs according to their pockets. I assess them by how they look; I mean, their dress-up and the way they talk. Whom I consider to be poor, I give them drugs which cost Rs.40-50. And whom I consider to be rich and can afford, I cannot give them cheap drugs because they won't believe in it. So my recommendation completely depends on their pockets."

Whether or not the chemist knows the customer personally

Chemists were more willing to "take risks" with people known to them personally in that they were more likely to provide mifepristone in the absence of a prescription. Six chemists mentioned this and the authors had a chance to observe this firsthand when, during one in-depth interview, a male customer walked in and told the chemist his wife was pregnant and wanted to abort. The man said that he "needed some good medicine. for the purpose". The chemist asked him, "How many months have passed?" The man said it was a little less than one and a half months since the first day of the last period. The chemist told the man to return in the evening for the medicine. and instructions on how to use it.

The chemist, continuing with the interview, explained to the interviewers that he would be recommending the mifepristone-misoprostol combination, as the man was a regular customer to the shop and known to the shop owner.

The most interesting differential in recommendations came in response to the question of what chemists would advise a family member or close friend who needed to have an abortion. Except for one chemist who claimed his advice was the same no matter for whom, the other eight said that for a family member, they would never want to take a risk and would always advise visiting a doctor before taking any kind of medication. "Our people are ours."

What information is passed on to customers?

Not a single surveyed chemist passed on the product insert of the drugs when selling them, and no other written material or instructions were available from any chemist. However, 54.1% said they instructed the customer verbally to go to a doctor in case of problems like excessive bleeding, vomiting or if the abortion does not take place. Only 5.5% mentioned that they gave information on dosage.

When probed specifically on whether they advised consulting a doctor prior to starting the tablets, almost all chemists (91.7%) said that they did emphasise this, irrespective of whether the customer had a prescription.

CONCLUSION

Lack of awareness was the most common cited reason for self intake of abortion pills converting a safe abortion into an unsafe practice. The burden of unsafe abortion affects not only women but also has financial impact on public health system because of increased requirement of blood products, antibiotics and oxytocics.

This coupled with fact that not all chemists were convinced of or educated about the comparative advantage of mifepristone-misoprostol and were unwilling to risk possible failure or complications may be responsible for the fact that while over-the-counter sales do happen, the majority of transactions still appear to be prescription driven. Additionally, awareness of the rules relating to the drugs and publicity around potential misuse have also been high.

It is possible that with time, as prescription sales increase and customer demand rises, chemists own perceptions will change and non-prescription sales will likely increase as well. Hence, the current scenario provides us with a window of opportunity for action.

The confusion between emergency contraceptives and abortifacients among some chemists is a cause for concern, as is the lack of understanding among many chemists of the efficacy or otherwise of the innumerable drugs that they stock as abortifacients. Even if not harmful,

their use delays care-seeking and means abortions are finally carried out later than necessary. Dissemination of accurate information on these drugs to chemists, as well as on mifepristone-misoprostol, is essential. Research is also needed to determine whether any of the Ayurvedic drugs is effective as well. Encouraging chemists to stock and promote the use of inexpensive and easily available pregnancy tests can help to shift abortion care seeking to earlier in pregnancy and would serve as appropriate advice of the first step to take for those who come in and ask about dealing with an unwanted pregnancy.

While chemists may not be obliged to provide any additional information, and there may be some who argue that providing people with additional product information may only add to more over-the-counter sales, the fact remains that even customers carrying a prescription for mifepristone and misoprostol ask chemists to confirm dosage and directions for use; hence, basic information about these drugs is needed by chemists. The fact that most surveyed chemists.

Hence women and health care providers need to be educated about abortion pills risks, limitations and need for medical supervision. Also, there is an urgent need for strict legislations on supply of abortion pills. Everyone should be informed about availability and accessibility of legal and safe medical abortion facility in government sector so that in case of need women can come early enough to the health centre in order to qualify for this method.

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