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Increasing access to safe abortion services in rural India: experiences with medical abortion in a primary health center

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Abstract

Introduction: To increase access to safe abortion in rural India, the feasibility and acceptability of mifepristone—misoprostol abortion was assessed in a typical government run primary health center (PHC) in Nagpur district, Maharashtra State, that does not offer surgical abortion services and must refer off-site for emergency and backup services.

Materials and Methods: Consenting pregnant women (n=149) with ≤ 56 days amenorrhea seeking terminations received 200 mg mifepristone, and returned 48 h later for 400-µg sublingual misoprostol and 12 days later for abortion confirmation. Surgical backup was conducted at a nearby community health center (CHC).

Results: Nearly all women (98.6%) with known outcomes had successful medical abortions, and those who did not (1.4%) were successfully referred to the CHC for surgical backup. Women reported the method's ease and simplicity as the best features.

Conclusion: Medical abortion provision is feasible and acceptable in an Indian rural PHC that does not offer surgical abortion services. This study suggests that introduction of medical abortion at lower levels of the health-care system could increase access to safe abortion in rural India.

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1. Introduction

While abortion has been legal in India for more than 30 years following the enactment of the Medical Termination of Pregnancy (MTP) Act, unsafe abortion persists, particularly in rural areas¹, where it accounts for 12% of all maternal deaths [1]. The MTP Act stipulates that all public sector facilities at the primary health center (PHC) level and higher are to provide abortion services, but such services are rarely available at the lower levels of the public health care system, which often serve as the first access point for reproductive health care, including abortion. Indeed, recent multistate abortion facility assessments estimate that only 5–58% of

PHCs offer abortion services [2]. PHCs not offering these services commonly cite the absence of a provider trained in surgical methods or the lack of equipment and/or infrastructure required to provide surgical abortion services as barriers.

In this context, mifepristone—misoprostol abortion, a noninvasive alternative for early pregnancy termination, holds great promise to increase access to safe abortion. In April 2002, the Drugs Controller of India approved 600 mg mifepristone coupled with 400 µg oral misoprostol for pregnancy termination in gestations of 49 days or less. While over 15 years of research has consistently demonstrated the safety, efficacy and acceptability of medical abortion worldwide and, in India at the facilities that provide surgical services [3–7], the present study expands on those overwhelmingly positive results to assess the feasibility of medical abortion provision in a rural PHC, which had not previously provided abortion services and did not have onsite surgical services for backup.

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¹ Rural India includes areas where 75% or more of the male population is engaged in agriculture as their main occupation.

Although the efficacy of 200 mg of mifepristone for early medical abortion has been proven in numerous studies and endorsed by the World Health Organization [8-11], no consensus has been reached on the ideal dose and route of misoprostol. A pharmacokinetic analysis showed that sublingual misoprostol acts as quickly as oral misoprostol, quicker than vaginal misoprostol, and has a higher systemic bioavailability than all other routes of administration [12]. A recent observational study conducted in India using 400 µg oral misoprostol following 200 mg mifepristone in one clinic and 400 μg sublingual misoprostol following 200 mg mifepristone in another clinic reported higher efficacy for the sublingual route. Given these experiences, we tested a regimen consisting of 200 mg mifepristone followed 48 h later by 400 µg sublingual misoprostol administered in the PHC for women with gestations of 56 days or less.

2. Materials and methods

The study was conducted at the government run PHC in a village in Nagpur district, Maharashtra state. The village, with a population of 35,000, is situated 10 km from a town where a community health center (CHC), a secondary care center, is located, and 50 km from the city of Nagpur where the Nagpur Government Medical College, a tertiary referral center, is located. The PHC is fairly typical for the State of Maharashtra: it has six beds, an operating theater and a labor room, where approximately seven uncomplicated vaginal deliveries occur weekly. The PHC does not have an ultrasound machine. At the time of the study, the PHC was staffed by two medical officers and three paramedical personnel.

Although the PHC is mandated by law to offer abortion services and the medical officers were trained to conduct surgical terminations under the government Reproductive and Child Health Program, as the medical officers were not confident in their surgical abortion skills due to limited practice during their training, the service was offered onsite only when medical officers from the CHC visited to conduct monthly sterilization camps.² Until the study was initiated, women who presented for abortion were asked to return during a sterilization camp or referred to the CHC or Nagpur Government Medical College for more immediate services.

In preparation for the study, the two medical officers at the PHC and the chief medical officer from the CHC received a 2-day training session, which emphasized gestational age dating in early pregnancy using menstrual history and pelvic examination, abortion status confirmation using clinical parameters, clinical management of medical abortion and counselling techniques. Case studies on assessing abortion status and abnormal bleeding patterns were used during the

training. The medical officers were not trained to conduct surgical interventions for failed medical abortion but, rather, were instructed to refer all such cases to the CHC in the nearby town or to Nagpur Government Medical College, both of which have established surgical abortion services. While the PHC had a vehicle when the study was initiated, the study team ensured that it would be available with fuel and a driver 24 h a day to transport women referred for surgical intervention or requiring emergency backup care. This transport service was provided free of cost to women.

All women seeking pregnancy termination at the PHC between August 2004 and October 2005 were screened for eligibility. Women were eligible to participate in the study if they had a positive urine pregnancy test, an intrauterine pregnancy of 56 days or less since the last menstrual period based on clinical exam and menstrual history, were in general good health, had no contraindications to mifepristone or misoprostol, lived within an hour of the PHC and were willing to return for at least two additional visits. Eligible women were informed about the availability of medical abortion at the PHC and of surgical abortion at the CHC and Nagpur Government Medical College. Those who opted for medical abortion were enrolled in the study after giving written informed consent, either by providing their signature or their thumbprint. Women were not compensated for participating in the study or reimbursed for their travel to the PHC. The study protocol was approved by the institutional review boards at the Population Council and Nagpur Government Medical College.

The study protocol entailed a minimum of three clinic visits. On the first visit, women swallowed 200 mg mifepristone and were observed for about 15 min. Women returned to the clinic 48 h later for two sublingual 200-µg tablets of misoprostol. The provider ensured that the tablets were placed sublingually and also observed the woman for 4–6 h. On the day of misoprostol administration, women were told to expect bleeding and/or pain and were given an analgesic (paracetamol, 500 mg) to be used at their discretion. Women returned for follow-up 12 days later at which point a pelvic exam was done to assess abortion status. Those with complete abortion were discharged from the study. Women with incomplete abortions or ongoing pregnancies (assessed by pelvic examination and selfreported signs and symptoms) were referred to either the CHC or Nagpur Government Medical College for backup services. Women were also referred for surgical intervention if medically necessary and/or requested by the woman at any time during the study. Women were advised to return to or call the PHC at any time, either on the landline or the medical officer's mobile telephone if they had any problems or questions.

At each clinic visit, medical officers collected clinical, experiential and acceptability data from women using standardized questionnaires that had been used in several medical abortion studies in India and other developing countries [3,4,6,7]. Women also completed a low-literacy

² Sterilization camps refer to sterilization procedures carried out on a mass and monthly basis at a PHC for eligible, consenting men and women. Non-PHC providers travel to the PHC to assist with the sterilizations.

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