Mifepristone-misoprostol medical abortion promises to revolutionize reproductive health-care. Several simplifications of the standard three clinic visit regimen may be possible, however. Particularly in developing countries, access to the method can be greatly increased by eliminating the longest clinic visit. Indeed, shortly after mifepristone's introduction in Guadeloupe, a semi-developed Caribbean territory administered by France, in 1991, two of the authors conducted a small prospective study of a one treatment-visit regimen. The study regimen was subsequently adopted as the standard of care for medical abortion on the island. Women (n = 92) with amenorrhea of ≤49 days received 600 mg mifepristone under clinical supervision and were given 400 μg oral misoprostol for home administration 2 days later, returning 2 weeks later for follow-up. The success rate (95.4%) is comparable to rates found when both drugs are administered in the clinic and to rates from a similar study conducted recently in the United States. Adverse events were also comparable to protocols requiring in-clinic administration of misoprostol. Protocol adherence appeared to be excellent and loss to follow-up was rare. We suggest that home administration of misoprostol can be safe and effective in most nonindustrialized settings. CONTRACEPTION 1999;60:167–172 © 1999 Elsevier Science Inc. All rights reserved.

KEY WORDS: medical abortion, mifepristone, misoprostol, Guadeloupe

Introduction

In recent years, several medical abortion regimens have offered new options to women seeking to terminate their pregnancies.1 The most widely used of these regimens requires three supervised clinic visits and consists of 600 mg mifepristone and 400 μg oral misoprostol taken 2 days apart. Although the regimen has been shown to be safe and effective,2,3 several refinements of the regimen are currently under investigation.4–6 Among the most important of these refinements is whether the prostaglandin can be taken safely at home, reducing the number of visits required for a mifepristone-misoprostol abortion from three to two (i.e., one treatment visit and one follow-up visit). The number of required clinic visits is a potential logistical shortcoming of the method, especially when compared to surgical alternatives, and is rated by women and providers as one of the method’s worst features.7,8

If safe, effective, and acceptable, a mifepristone abortion regimen eliminating the longest of three previously required visits would be advantageous to both women and providers. Home administration of misoprostol would increase access to and convenience of medical abortion for women by reducing the need to interrupt work schedules, arrange for child care, and travel to the clinic. Additionally, such a regimen would greatly increase client privacy. From the provider perspective, allowing women to administer prostaglandin at home would decrease provider time per patient, as well as minimize patient demands on clinic facilities (such as restrooms and beds), and thus drastically reduce the cost of providing a mifepristone-misoprostol abortion.

Exploration of home administration of prostaglandin has begun in the United States. A recent study of mifepristone followed by vaginal misoprostol offered women the option of taking misoprostol themselves at home, with very promising results: >98% of women chose to administer misoprostol themselves at home.4 Additionally, some providers in the United States of another medical abortion regimen, methotrexate-misoprostol, have dispensed prostaglandin tablets to women at their first visit for later use at home. Providers of this regimen report success rates as high and complication rates as low as when the prostaglandin is administered under physician supervision.9–11

Although women in the United States and other
developed countries will certainly benefit from the adoption of a simplified regimen, it is in developing countries that a single treatment visit regimen could play the greatest role in increasing access to medical abortion. In most developing countries, abortion providers are concentrated in urban centers and, consequently, distances between home and clinic may be great. Indeed, in countries with poor infrastructure, traveling even short distances remains difficult. Additionally, resources for reproductive health care are scarce in most developing countries, and abortion services, in particular, are usually insufficient and overcrowded.

Although a study directly investigating home administration of misoprostol in two developing countries will soon be available,\(^4\) to date we must look to proxies for experience and insights as to how a simplified regimen might work in nonindustrialized settings. The successful medical abortion experience in Guadeloupe offers an apt example. As Guadeloupe is a Caribbean territory administered by France, mifepristone is available there. Yet unlike in metropolitan France, a simplified regimen in which women take the prostaglandin at home after supervised administration of mifepristone has been offered in Guadeloupe since shortly after the method’s introduction on the island 8 years ago.\(^b,12\)

Although administratively French, several of the island’s key socioeconomic and demographic indicators fall well below those of metropolitan France. For example, the estimated Gross Domestic Product per capita for Guadeloupe is approximately one-third that of France, which places the island, together with several neighboring Caribbean countries, in the middle-income country group according to the World Bank classification scheme. Moreover, the island’s perinatal mortality rate of 15.7 for 1000 live births in 1995 was more than twice that of metropolitan France for the same period.\(^13\) Consequently, the results of Guadeloupe’s experiment with a one treatment-visit protocol can assist policy makers and providers in nonindustrialized settings in deciding under which minimum socioeconomic conditions home administration of misoprostol can be safe.

### Guadeloupean Abortion Context

In 1975, the “Weil” law legalized abortion in metropolitan France and the overseas territories, including Guadeloupe. In 1995, approximately 4000 legal abortions were performed in Guadeloupe at about 12 authorized clinics.\(^14\) Mifepristone has been used for early pregnancy termination (i.e., ≤49 days since the last menstrual period, as specified by the French registration of the drug) on the island since June 1991.

As in metropolitan France, mifepristone was initially coupled with the injectable prostaglandin sulprostone. When the mifepristone-sulprostone regimen was introduced in Guadeloupe, however, providers raised several concerns about the method. First, they found that women disliked having to return to a medical service for their prostaglandin and having to remain there “under observation” for several hours. Additionally, providers were also concerned that discharging women 3–4 h after they received their prostaglandin, as is done in metropolitan France, would mean discharging women at the exact hour that they were most likely to pass the products of conception.\(^5,15\) Finally, as the postprostaglandin “semihospitalization” administratively required reserving a bed for the entire day, the waiting period was a drain on hospital and clinic resources. Consequently, women often waited for 4 h in nothing more than a chair in the hospital or clinic hallway, typically far from the restrooms.

When sulprostone was linked to cardiovascular complications and the oral prostaglandin misoprostol replaced sulprostone in mid-1992, however, two of the authors saw home administration of misoprostol as a way to simplify provision of the method across the island. They advocated for a change in the regimen among providers already offering medical abortion, such that, in September 1992, providers in Guadeloupe adopted a simplified regimen requiring two clinic visits rather than the traditional three. At the same time, in an effort to increase provider confidence in the method and to demonstrate that a simplified protocol could be used routinely without any decrease in the method’s safety and efficacy profile, they documented the early experience with the simplified regimen at one clinic in Guadeloupe. This article describes the results of that study.

### Data and Methodology

A prospective survey of 92 medical abortions performed at a private clinic in Pointe-à-Pitre was conducted over a 13-month period, from October 1992 to November 1993. The 92 cases represent all of the medical abortion clients of one of the clinic providers (and one of the authors), over half of all medical

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\(^{\text{a}}\) The Population Council recently completed a multisite study that allowed women in two developing countries the option to self-administer misoprostol.

\(^{\text{b}}\) Although both medical and surgical abortion in Guadeloupe require two clinic visits (one to initiate treatment and one for follow-up), French law introduces two additional visits that are mandatory for all abortion clients, regardless of the method used, to be completed before treatment begins. At the first of these visits, gestational age is assessed and a method of abortion is selected. At the second of these preliminary visits, the woman meets with a social worker for an obligatory interview. The law is designed to impose a “week of reflection” on women before they terminate an unwanted pregnancy.
abortion conducted at the clinic during the study period, and nearly one-quarter of medical abortions performed on the island during that period.

According to the French registration of mifepristone, distribution of mifepristone in the study clinic is strictly controlled by the residing pharmacist and subject to the same regulation as opiates. This control derives not from medical, but rather from political concerns. Women seeking pregnancy termination were offered medical abortion if their gestations were ≤49 days on the basis of clinical evaluation considering onset of last menstrual period, bimanual examination, and, typically, ultrasound, if they smoked <10 cigarettes per day; and if they did not have a medical condition contraindicated for either mifepristone or misoprostol. Although most study participants were <35 yrs old, a few were in their early forties. After selecting medical abortion, women underwent an interview with a social worker, initiating a reflection period of ≤1 wk required by French law for all pregnancy terminations. As is standard with both medical and surgical abortion in France, the reflection period was shortened if women were close to the gestational age cut-off of the method [i.e., 49 days LMP for medical abortion].

Women followed a protocol involving one treatment visit: Patients received 600 mg mifepristone at their initial treatment visit. There was no routine monitoring of women after mifepristone ingestion; women typically departed within minutes of receiving mifepristone. Before leaving the clinic, they were given three tablets of misoprostol (3 × 200 μg) for later use at home. They were instructed to ingest two tablets, or 400 μg of misoprostol, by mouth 2 days later. As the study providers believed that an additional dose of misoprostol could reduce the time to expulsion in cases in which mifepristone may have stopped the pregnancy but bleeding had not yet begun, women who had not begun bleeding within 6–12 h of mifepristone ingestion were instructed to take the remaining tablet of 200 μg misoprostol. All women were counseled about side effects and bleeding, and encouraged to take misoprostol in a “comfortable” environment that would not require them to travel. Women were informed that they could take analgesics but not antiinflammatory medications for relief of abdominal cramps. Some women apprehensive about potential pain were also given a prescription for Paracetemol with codeine to use at their discretion. A 24-hour on-call provider was available to respond to client questions or concerns by telephone. Women were also informed of a 24-hour walk-in emergency service available at the clinic. As is the case in metropolitan France, women returned 10 to 15 days after their first clinic visit for follow-up.

Providers collected information regarding patient characteristics on the day of mifepristone administration. At the discharge visits, providers confirmed that misoprostol had been taken as instructed and recorded details pertaining to the abortion and the side effects that women experienced, such as time of onset of bleeding and extent of cramping. Although women were asked to note the number of sanitary napkins they soaked in the hours after misoprostol ingestion, clinical measures of blood loss were not taken systematically. All women gave oral informed consent.

All data were entered using standard data entry software [Epi-Info, SPSS Inc., Chicago, IL]. Descriptive statistical techniques and χ² analyses were performed using standard statistical software [SPSS]. The p values of comparisons designated as statistically significant are ≤0.05.

Table 1 shows the baseline characteristics of the study participants. The mean age at survey was 30.2 years, and the mean gestational age was 5.9 weeks. Over one-quarter (28.3%) of the women were primigravid. About half (47.8%) reported a prior elective surgical or medical abortion, and 9.8% reported more than one previous abortion. Just under half (46.7%) of the women were in a stable, cohabiting union [married or common law], one-quarter were in a visiting union, an arrangement common to Caribbean cultures where a woman has a regular partner who does not live with her but is recognized as her partner by the community, and the remainder were not in a formal relationship, but had infrequent or casual intercourse. When asked about the reason for seeking an abortion, the majority of women (58.7%) explained that they wanted to space their children [some of them had children who were <6 months old] or that they did not want any more children (39.1%).

### Results

#### Characteristics of Respondents

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| Table 1. Client participants, by selected characteristics [n = 92] |
|-----------------|------------------|
| Mean age (years) | 30.2             |
| Mean gestational age [weeks] | 5.9 |
| Primigravid [%] | 28.3             |
| Married/in union [%] | 46.7 |
| Ever used contraception [%] | 89.1 |
| Previous induced abortion [%] | 47.8 |

—I. Although there is no consensus on the efficacy of such a practice among medical abortion experts, it appears to be increasingly common in France. 2
Protocol Adherence

Misoprostol administration. Women appeared to adhere remarkably well to the protocol. All but four women (4.4%) reportedly self-administered misoprostol 48 h after the administration of mifepristone, as instructed. One woman stated that she took misoprostol the same day that she was given mifepristone. The three remaining women who did not follow the protocol took their prostaglandin late: they all ingested misoprostol 72 h after mifepristone, erroneously believing that they did not need to take misoprostol because they had already begun bleeding. All three contacted the clinic, however, and were instructed to take misoprostol even though they had already begun bleeding. Despite the delayed administration of misoprostol, all three women had successful medical abortions.

Exit interview. In total, 11 women (12.0%) did not return for their scheduled follow-up visits at the study clinic. Three of these women gave results by phone or fax. Two more returned to their regular gynecologists for their follow-up visits. Another two returned to the clinic 2 months after mifepristone administration for continued spotting or bleeding. One of the women who returned late to the clinic eventually received a surgical intervention. The other one was treated with medication. Only four women (4.4%) were ultimately lost to follow-up.

Efficacy

Any medical abortion patient who ultimately underwent a surgical intervention within 2 months of taking mifepristone was considered a treatment failure. Medical abortion failures include surgical interventions that are medically indicated, requested by the client, or required when the regimen fails to terminate the pregnancy completely.16

The total success rate among women with known outcomes [i.e., 88 of the 92 women enrolled in the study or 95.6%] was 95.4%. Gestational age was not statistically associated with failure, although we note that our power to detect such an association is very low, given the limited sample size. Additionally, there was no significant association between having a failure and having had a previous abortion [p = 0.35] or bleeding for >8 days [p = 0.73].

We looked in some detail at the four women who received surgical interventions. They presented with 5-week (n = 2), 6-week (n = 1), and 7-week (n = 1) gestations. None of the four reported any bleeding in the 48 h before or the 24 h after taking misoprostol. Ultrasound conducted at the discharge visit confirmed ongoing pregnancies in two of the women and an incomplete abortion in a third. The fourth woman failed to return for her scheduled follow-up but returned 2 months after mifepristone administration as noted earlier. At that time, she reported having bled for 3 weeks after misoprostol, but returned to the clinic when she began to bleed again 3 weeks later. She was diagnosed as having an incomplete abortion and was treated with curettage.

Side effects

There were no serious side effects. Not a single client required a transfusion or intravenous fluids. Minor side effects, however, were more frequent. Table 2 shows the symptoms noted by clients for each medication.

Bleeding. Nearly one-fifth [19.6%] of clients reported bleeding after taking mifepristone. Among those women who bled after taking mifepristone, the average onset of bleeding was 16.7 h after mifepristone. As is to be expected, many more women reported bleeding after misoprostol (68.2%) than after mifepristone. For the women who bled after misoprostol, bleeding began, on average, 3.4 h after they took the prostaglandin. Some women, however, began bleeding within 15 min of taking misoprostol, whereas for others bleeding did not begin for 48 h.

Despite the large number of women who reported some bleeding after misoprostol, heavy bleeding in the 24 h after misoprostol was not frequent (7.6%). Four women (4.3%) reported soaking 10 to 20 sanitary napkins in the immediate 24 h after misoprostol, and another three women (3.3%) soaked >20 pads in the same period. None of these women, however, ultimately required surgical intervention to stop their bleeding. Most women [81.5%] bled for <8 days after taking misoprostol. Only one woman (1.1%) had heavy bleeding for >15 days.

Other side effects. Nine women (9.8%) reported vomiting after mifepristone, and slightly fewer (7.6%) vomited after misoprostol. Among those women who vomited after administration of mifepristone, the time to vomiting ranged from 30 min after ingestion of mifepristone to 24 h later, with a mean time to vomiting of 4.6 h. The mean time to vomiting after misoprostol was 3.5 h. Some of this vomiting is clearly attributable to the baseline nausea of pregnancy.
Discussion
The pilot experience of one private clinic in Guadeloupe with a simplified medical abortion regimen provides preliminary evidence that allowing women to take their prostaglandin at home is safe, effective, and feasible in a nonindustrialized setting. The failure rate of 4.6% is comparable to that found in protocols requiring strict medical supervision of mifepristone and misoprostol, as well as to that of a recent study conducted in the United States using a simplified regimen.4

Data based on self-reports at the follow-up visit suggest nearly universal adherence to the protocol. All but four women reportedly took their misoprostol at the recommended time, belying claims that if given misoprostol for home administration, women will neglect to take the prostaglandin as instructed. As women reported on the time of misoprostol administration nearly 2 weeks after their scheduled time of administration, however, we cannot rule out the possibility that women may have actually taken misoprostol earlier or later than stated. Nonetheless, despite the reduced scope for counseling regarding the need to return for follow-up, loss to follow-up was rare and was comparable to that documented in studies requiring in-clinic administration of misoprostol.2–4,15 The potential risk of adverse birth outcomes in ongoing pregnancy after treatment with mifepristone-misoprostol should be clearly explained to women interested in medical abortion, and the importance of follow-up stressed. As demonstrated in our study, however, this can be done effectively when a home-use protocol is adopted and, indeed, women using such a protocol may find follow-up more acceptable given that fewer clinic visits are required.

A small group of women reported vomiting after ingestion of the prostaglandin, and many noted experiencing bleeding, as has been found in other protocols. Of course, as self-reports of side effects were done at the follow-up visit, they may have been colored by women’s overall experiences with the method. Regardless, women were able to manage the vomiting and bleeding, as well as additional undocumented side effects such as diarrhea and nausea, on their own. Although women were informed of the availability of 24-h emergency services at the study clinic at their first visit, none came in person for guidance or treatment before the follow-up visit. Of the few women who did contact the clinic by telephone with questions or concerns about bleeding, all were counseled by telephone to closely monitor their bleeding and to contact the clinic again if the bleeding had not stopped within several hours. Ultimately, none of these women requested a surgical interven-

tion. Given the inherent subjectivity of measuring blood loss through sanitary napkin use, women were not counseled to seek further care based on a maximum number of sanitary napkins soaked.

The Guadeloupean experience also suggests that women are able to discern when they need care and seek care at those instances. Two of the women who failed to return for their scheduled follow-up visits returned in 2 months time when they grew concerned about continued bleeding. One of these women was diagnosed with an incomplete abortion and received a surgical intervention. The other woman was treated with medication.

Our preliminary results indicate that a simplified regimen allowing women to take misoprostol at home is safe and effective in a non-industrialized setting. Indeed, in Guadeloupe, the simplified regimen described in this article was adopted as the island’s standard of care for medical abortion in 1992 and continues to be the only medical abortion regimen offered there.

In Guadeloupe, although women self-administer misoprostol, medical conventions and French legislation ensure strict monitoring of mifepristone and misoprostol distribution and encourage intensive patient follow-up. Of all the conditions in place there, several seem indispensable for adoption of even further simplified regimens in other nonindustrialized settings. First, as there is only preliminary evidence that women in developing countries can accurately calculate their gestational age,17 for the time being providers should assist women in determining whether the duration of their pregnancy is within the selected cut-off of 49, 56, or 63 days LMP. Ultrasound, although facilitating accurate assessment of gestational age, is not imperative, as the regimen does not cease to be effective immediately after 49, 56, or 63 days LMP. Second, mifepristone administration should be controlled by a provider. Although there is no clinical reason to suggest that provider supervision of mifepristone is necessary, given the current political climate surrounding medical abortion this convention should be maintained for the moment. Supervision of mifepristone administration, however, need not be done by a medical doctor. Nurses and other paramedical staff can be easily trained to administer mifepristone. In stable political environments, moreover, even this rule could be relaxed. Third, back-up care should be available for the treatment of complications or method failures. Established surgical services, however, are not obligatory as the techniques typically employed to manage complications and method failures in medical abortion are analogous to those used to manage spontaneous abortion. In this context, in countries in which distances between
home and the [still rare] medical abortion provider may be large, women need not necessarily return to the provider who initiated their treatment and may be able to seek follow-up care at facilities treating miscarriage. Finally, the success of a simplified regimen lies above all with the clients. Detailed instructions about when to take misoprostol, what side effects to expect, and when to return for follow-up are critical. These four conditions can be ensured in almost all developing countries. On the whole, then, the option of home administration of misoprostol should be made available to women in many developing countries.

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