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Medical abortion with mifepristone and home administration of misoprostol up to 63 days' gestation

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Conflict of interest
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Abstract

Objective. To evaluate the acceptability and efficacy of medical abortion at home up to 63 days' gestation without limits on travel distance to a registered institution. *Design.* Observational prospective study. *Setting.* Haukeland University Hospital between May 2006 and May 2009. *Population.* A total of 1018 women requesting abortion before 63 days' gestation who chose medical termination with mifepristone and home administration of misoprostol. *Methods.* The women took 200 mg mifepristone under nurse supervision and self-administered 800 μg misoprostol vaginally 36–48 h later at home. All were contacted by phone for follow-up and assessment of bleeding, pain and acceptability. *Main outcome measures.* Evacuation rate, pain, bleeding, acceptability, influence of distance on treatment. *Results.* Median gestational age was 50 (range 35–63) days and 70 (7.1%) of the women lived more than 60 min travel from the clinic. The rate of completed abortion was 93.6% and surgical evacuation was performed in 50 (4.9%) cases. Two women requested treatment on the day of misoprostol use. Moderate to strong pain was experienced by 68.4%, and 74.7% reported moderate to heavy bleeding. Parous women experienced less pain than nulliparous women (odds ratio 0.27; 95% confidence interval 0.19–0.34). In all, 95.1% of the women were satisfied with staying at home. Travel distance did not influence treatment outcome variables. *Conclusions.* In our experience, home administration of misoprostol is an effective and acceptable method for abortion up to 63 days of gestation and women should be eligible for this treatment option regardless of their travel distance from hospital.

Abbreviations: CI, confidence interval; hCG, human chorionic gonadotropin; OR, odds ratio.

Introduction

Medical abortion with mifepristone and misoprostol is a well-established and acceptable method (1). It has become the most common method in Norway since it was introduced in 1998 (2), and was in 80.5% of all medical abortions in 2012 (3). Norway has abortion on request, completely free of charge and easily accessible at every gynecology ward up to 12 weeks of gestation (4). The

Key Message

Women find home administration of misoprostol to be an acceptable method of abortion. As complications are few and occur several days after the administration of misoprostol, women should be offered this method even if they live far from hospital.

population (5 million) is distributed over a large area, with many people living in rural areas far from the nearest hospital. Increasing access to safe and acceptable treatment close to or at home would be an advantage.

Home administration of misoprostol for up to 9 weeks' gestation has been available in the USA since 2000 (5). In Europe, on the other hand, except Scandinavia, a more restrictive attitude towardds home administration of medical abortion has prevailed. Home administration has either not been allowed or has been restricted to a lower gestational age, most commonly up to 49 days (6).

Except for a Swedish study that found home administration of misoprostol just as acceptable at 50–63 days' gestation as at <50 days' gestation (7), very few studies from Europe have reported on home treatment beyond 56 days' gestation. Several studies, including Swedish studies, have limitations as to the travel time from provider for those who would like to administer misoprostol at home (7–9). A 1-h travel limit is not uncommon; however, none of these studies has looked at the importance of proximity to provider (7–9). Although the majority of women in Europe live close to a health facility, not all women do so, and internationally many women live in less urbanized settings with limited access to health facilities.

Medical abortion with home administration of misoprostol up to 63 days' gestation and no travel distance limitation was introduced at Haukeland University Hospital, Bergen, Norway, in 2006 with the objective to increase women's choice. It rapidly became the preferred procedure for women at this gestational age. Home administration is here defined as not conducted within the hospital.

The aim of this study was to evaluate the consequences of implementing home administration of misoprostol. This method was introduced to increase and facilitate women's access to medical abortion regardless of residence and travel distance from hospital.

Material and methods

This observational study involved women (n = 1018) requesting medical abortion (4) at the Department of Obstetrics and Gynecology, Haukeland University Hospital, Bergen. All women who requested abortion between May 2006 and May 2009 with a documented pregnancy length of up to 63 days' gestation were eligible. Exceptions were age below 18 years or lacking the ability to understand and fulfill the treatment. No limits to travel time from home to the Hospital were made. Oral and written information about the method was given. The women chose by informed consent to undergo a medical termination with mifepristone intake under nurse supervision and self-administration of misoprostol at home, rather than under supervision by health professionals at the Hospital.

Since the objective of introducing home administration was to minimize the number of visits, only one consultation at the out-patient clinic was planned. The gestational age was established by a vaginal ultrasound which measured the crown–rump length with 23 mm as an upper limit (10) or a gestational sac with a present yolk sac. All women requesting abortion were screened for Chlamydia trachomatis and all received advice on post-abortion contraception use. Women were not screened for bacterial vaginosis and none received prophylactic antibiotics.

After counseling, women who chose home administration of misoprostol subsequently took mifepristone 200 mg orally under nurse supervision. According to Norwegian law, abortions should take place in hospitals. Administration of mifepristone in hospitals is defined to be in accordance with the law. All women were instructed to insert 800 μg misoprostol vaginally themselves 36–48 h later followed by 50 mg diclofenac and 600 mg paracetamol with 30 mg codeinsulfate orally as analgesics. Written information together with carefully labeled packets containing 800 μg misoprostol, diclofenac and paracetamol with codeine sulfate was given out together with a contact phone number for any questions and concerns. All women were advised to have an accompanying person with them on the day of misoprostol administration and all received a phone call from a trained nurse the day of misoprostol use, to follow up their treatment and wellbeing. During the conversation they were asked to self-assess the level of bleeding as none, light, moderate or heavy, and pain as none, light, moderate or strong. Additionally, they were questioned about the acceptability through the questions: (i) Would you rather have been at the hospital? and (ii) Are you content with being at home?

According to standard control at our Hospital, all women were instructed to take a blood test on the day of mifepristone intake and after 4 weeks to measure serum human chorionic gonadotropin (hCG) to confirm that they were no longer pregnant (11). The blood test could be taken at their local medical health center but all results were sent to our clinic for evaluation. Women who failed to have this follow-up blood test were contacted by phone two times and given a reminder. A systematic search through hospital files was done for all women to look for unscheduled visits and complications. Supplementary misoprostol, admission to hospital, infection and surgery were considered additional treatment. The number of days from administration of mifepristone until a complication occurred was also registered.

Travel time by car was measured using the web page "Visveg" (http://visveg.vegvesen.no/Visveg/mapviewer.jsf?

width=1280&height=512) of the Norwegian Public Roads Administration that calculates travel distance and time between two given addresses.

Serum hCG was measured with a commercial two-site chemiluminescent immunometric assay kit (Immulite 2000 HCG; Siemens Medical Solutions Diagnostics, Los Angeles, CA, USA). The assay has a detection limit of 3 U/L.

The Committee for Medical and Health Research Ethics, Western Norway, approved the study (number 2009/738) and found that according to Norwegian law a written consent form from each of the women was not needed. This is an observational, quality control study of an established procedure where the women themselves chose between home-based and hospital-based treatment. Guidelines for experimental clinical trials requiring individual written consent were found not to apply for this study approach.

Statistical analysis

To measure statistical significance and explore associations between given variables, odds ratios (ORs) were calculated by logistic regression. The mean number of terminations with home administration of misoprostol per month per year for the whole study period was used to illustrate the increased use of the method. Statistical analyses were carried out using the Statistical Package for Social Sciences for Windows, release 18 (SPSS Inc., Chicago, IL, USA).

Results

During the implementation period, 1018 women with gestational age of up to 63 days chose medical abortion with mifepristone and home administration of misoprostol as an alternative to staying in hospital during the expulsion of their pregnancy. Gestational age was determined by vaginal ultrasound in all women but information about the actual crown–rump length was not recorded for two women. In total, 70 (7.1%, 95% CI 5.5–8.7%) of the women lived more than 60 min travel by car away from the hospital. Characteristics of the women are given in Table 1. The number of women requesting abortion at this gestational age and the percentage of medical abortions remained stable during the study period. There was an increase in the use of the method among women who were eligible for the treatment alternative. By the end of the period, approximately 70% of all eligible women chose home administration of misoprostol. All women in the study inserted misoprostol themselves at home.

In all, 766 women completed the serum hCG blood test (75.2%, 95% CI 72.6–77.9%). Through hospital files or phone consultations, follow-up information on a further 204 (20.0%) women was obtained. A remaining 48 women were lost to follow up (4.7%).

The complete termination rate with no unplanned visits was 953/1018, 93.6% (95% CI 92.1–95.1%). Information about all additional contacts is shown in Table S1. Three women had a failed treatment with an ongoing, viable pregnancy (0.3%, CI 0.04–0.6%). None of them lived further than 60 min travel away from hospital. Two of these women had a gestational age of between 56 and 63 days when the procedure was started. One woman was 15 weeks pregnant when the ongoing pregnancy was detected. She fulfilled the treatment medically according to our clinic's second trimester procedure (12). The remaining two pregnancies were terminated surgically.

A total of 50 women underwent surgical intervention. Median gestational age for those who underwent surgery was 50 days (range 35–62 days). Women with a gestational age of 56–63 days had a higher risk of requiring surgery (OR 2.06; 95% CI 1.08–3.92) compared with the

Table 1. Characteristics of 1018 women undergoing medical abortion through self-administered vaginal misoprostol at home, by gestational age.

	Gestational age				
	<49 days	49–55 days	56–63 days	All	>60 min travel
n (%)	436 (42.8)	310 (30.5)	270 (26.5)	1018 (100.0)	70
Age in days, median (range)	27 (18–48)	27 (18–44)	28 (18–46)	27 (18–48)	29 (18–43)
Previous births, median (range)	0 (0–9)	1 (0–7)	1 (0–4)	0 (0–9)	1 (0–6)
Nulliparous, *n* (%)	393 (90.1)	145 (46.8)	115 (42.6)	653 (64,1)	23 (32.9)
Prior abortions median (range)	0 (0–3)	0 (0–4)	0 (0–4)	0 (0–4)	0 (0–3)
No prior abortion, *n* (%)	265 (60.8)	189 (61.0)	169 (62.6)	623 (61.2)	42 (60.0)
Travel time to provider in minutes: median (range)	15 (1–540)	16 (1–215)	15.5 (1–416)	15 (1–540)	113 (62–540)
>60 min, *n* (%)	28/419 (6.7)	22/305 (7.2)	20/264 (7.6)	70/988 (7.1)	
Lost to follow up, *n* (%)	21 (4.8)	15 (4.8)	12 (4.4)	48 (4.7)	6 (8.6)

Table 2. Indications for surgery (*n* = 50; 4.9%).

Gestational age	<49 days (*n* = 436)	49–55 days (*n* = 310)	56–63 days (*n* = 270)	Total (*n* = 1018)
Indications for surgery, *n* (%)	18/436 (4.1%)	10/310 (3.2%)	22/270 (8.1%)	50/1018 (4.9%)
Continuing pregnancy	0	0	2	2 (4%)
Incomplete abortion	0	1	2	3 (6%)
Infection	1	3	5	9 (18%)
Profuse bleeding	1	0	3	4 (8%)
Prolonged bleeding	16	6	10	32 (64%)

Table 3. Incomplete abortions, pain, bleeding and surgical evacuation at different gestational ages. Pain and bleeding is evaluated by the women themselves at the day of misoprostol use.

	Gestational age			
	<49 days	49–55 days	56–63 days	All
n (%)	436 (42.8)	310 (30.5)	270 (26.5)	1018 (100)[a]
Pain	*n* = 421	*n* = 300	*n* = 259	*n* = 983
None, *n* (%)	23 (5.5)	10 (3.3)	8 (3.1)	41 (4.2)
Light, *n* (%)	123 (29.2)	83 (27.7)	63 (24.3)	270 (27.5)
Moderate, *n* (%)	165 (39.2)	102 (34.0)	103 (39.8)	372 (37.8)
Strong, *n* (%)	110 (26.1)	105 (35.0)	85 (32.8)	300 (30.5)
Bleeding	*n* = 422	*n* = 300	*n* = 255	*n* = 977
None, *n* (%)	11 (2.6)	10 (3.3)	7 (2.7)	28 (2.9)
Light, *n* (%)	71 (16.8)	27 (9.0)	36 (14.1)	134 (13.7)
Moderate, *n* (%)	170 (40.3)	116 (38.7)	80 (31.4)	366 (37.5)
Heavy, *n* (%)	149 (35.3)	114 (38.0)	103 (40.4)	366 (37.5)
Very heavy, *n* (%)	21 (5.0)	33 (11.0)	29 (11.4)	83 (8.5)
Surgical evacuation, *n* (%)	18/435 (4.1)	10/310 (3.2)	22/270 (8.1)[b]	50/1018 (4.9)

Logistic regression analyses were made comparing the gestational age groups for all variables. No difference was found when corrected for parity and age except in the case of surgical evacuation.

[a]Two women were registered as <9 weeks but without further specifications.

[b]In comparison with gestational age <7 weeks (OR 2.06; 95% CI 1.08–3.93).

gestational age group of <49 days. There was no difference between gestational age groups 49–55 days and <49 days (OR 0.78; 95% CI 0.35–1.70). Prolonged bleeding was the most common reason for surgery (32/50, 64%, CI 50.7–77.3%) (Table 2). In this group the median number of days from intake of mifepristone to surgical vacuum aspiration was 42 (range 8–107) (Table S1). Six of the aspirations were performed <30 days after mifepristone intake. One woman (0.1%, CI 0.09–0.3%) needed blood transfusion. Her hemoglobin was 6.4 g/dL. She lived 12 min from hospital and contact the hospital due to profuse bleeding 3 weeks post-abortion. Four (8.0%, CI 0.5–15.5%) women had a surgical vacuum aspiration due to abundant bleeding. One of these aspirations was undertaken on the day of misoprostol use (Table S1). Twelve had surgery for suspected infections (1.2%, CI 0.5–1.8%) (Table S1). We found no correlation between endometrial thickness and the need for surgical intervention (Table S1).

In all, 980 (93.3%, CI 95.1–97.4%) women reported on their level of vaginal bleeding (Table 3). There was a marginally significant increase in the rate of heavy bleeding in the higher gestational age groups, 49–55 days vs. <49 days (OR 1.43; 95% CI 1.06–1.93) and the gestational age group 56–63 days compared with <49 days (OR 1.59; 95% CI 1.16–2.17). Among the 983 women (96.6%, CI 95.4–97.7%) who reported their level of pain (Table 3) we found that parous women experienced less pain than did nulliparous women (OR 0.27; 95% CI 0.19–0.38) (Figure 1). No difference was found in the level of pain between the three gestational age groups when this was adjusted for parity; 49–55 days compared with <49 days (OR 1.47; 95% CI 0.94–2.29) and 56–63 days compared with <49 days (OR 1.44; 95% CI 0.89–2.33).

The acceptability of the procedure is illustrated in Table 4. A total of 95.8% (CI 94.5–97.1%) were more content staying at home than in the hospital. There was no difference in the likelihood that women living more than 60 min travel away would prefer hospital (OR 0.33; 95% CI 0.05–2.4) compared with women living within 60 min of the hospital. Women living more than 60 min

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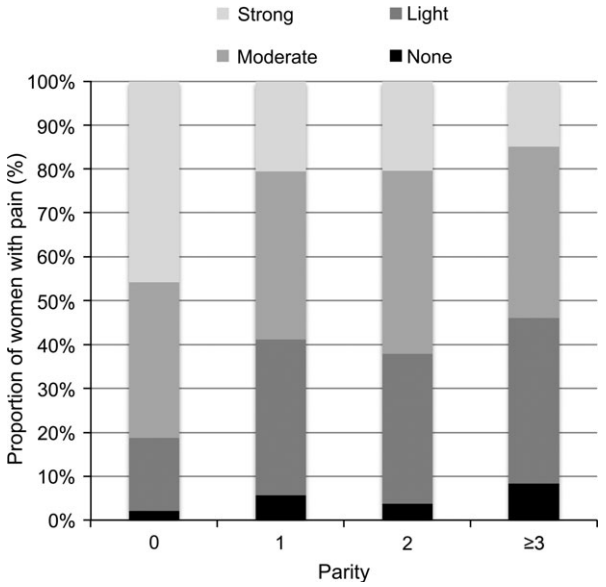

Figure 1. Self-reported pain vs. parity. Parous women have less likelihood of experiencing strong pain than nulliparous women (*n* = 983; OR 0.27; 95% CI 0.19–0.34).

from hospital did not differ from women living closer than 61 min away in their level of pain (OR 0.6; 95% CI 0.3–1.7), bleeding (OR 1.2; 95% CI 0.7–2.0) or need of surgery (OR 0.8; 95% CI 0.2–2.7).

Discussion

This study of 1018 women undergoing abortion with home administration of misoprostol up to 63 days' gestation represents the first report where the importance of proximity to the responsible institution has been examined. The protocol used was found to be effective and highly acceptable regardless of women's travel time to the clinic. Only two women experienced complications that needed medical intervention within the first 24 h after misoprostol application. In the course of the study period, the method became the preferred procedure for women at this gestational age in our region.

The rate of surgical intervention (4.9%) in our study is in line with that in other studies (2,7,13) and the World Health Organization goal/standard (14). Similar to findings in the World Health Organization study (15), we identified a statistically significant higher percentage of women in the group 56–63 days who needed a surgical aspiration (8.1%) compared with the two other gestational age groups (4.1% and 3.2%) (Table 3). This might indicate a need for a modified treatment protocol with additional misoprostol at this gestational age more similar to what is used for late 1st trimester abortions, where additional doses of 400 μg misoprostol is given (16). Even though the evacuation rate is higher between 56 and 63 days' gestation, the success rate is still acceptable at this gestational age. The decision to intervene surgically was related to the experience of the doctors on call, as no objective criteria were predetermined. As previously reported in other studies, we found no correlation between endometrial thickness and the need for surgical intervention (17). The medical indication for some of the aspirations is not clear in the medical records, or they are missing because the procedure was undertaken at a different institution. Retrospectively, some of the aspirations could have been avoided, which in turn would have improved the success rate. The considerable difference in the number of aspirations found in studies on medical abortion (13,18,19) shows that further studies into post-abortion treatment and indications for surgery would be useful.

Since many studies impose limitations on the travel time from provider for those who wish to administer misoprostol at home (7–9,18) it is interesting to note that almost all interventions took place more than 24 h after misoprostol application. Only one woman in the examined cohort needed a vacuum aspiration on the actual

Table 4. Acceptability of treatment at different gestational ages and more than 60 min travel to provider.

	<49 days	49–55 days	56–63 days	All	>60 min travel to provider	<61 min travel to provider
Would you rather have been at the hospital?	*n* = 414	*n* = 293	*n* = 255	*n* = 962	*n* = 65	*n* = 875
Yes, *n* (%)	13 (3.1)	12 (4.1)	17 (6.7)	42 (4.4)	1 (1.5)	39 (4.5)
No, *n* (%)	401 (96.9)	281 (95.9)	238 (93.3)	920 (95.6)	64 (98.5)	836 (95.5)
Are you more content with being at home?	*n* = 409	*n* = 290	*n* = 252	*n* = 953	*n* = 65	*n* = 864
Yes, *n* (%)	398 (97.3)	275 (94.8)	238 (94.4)	913 (95.8)	65 (100)	826 (95.6)
No, *n* (%)	11 (2.7)	15 (5.2)	14 (5.6)	40 (4.2)	0 (0)	38 (4.4)

day of the abortion; the majority made contact more than 1 week after the initial intake of mifepristone. No studies limit women's access to medical abortion due to their travel distance from provider if the abortion is terminated while present in a clinic. Complications are just as likely to happen at the same time in the course of the treatment after discharge from the clinic as when the misoprostol protocol is administered at home.

Our present study confirms that nulliparous women experience more pain than women who have given birth (20,21). Other studies have suggested that the level of pain also increases with gestational age (1,20). When adjusted for parity we could not confirm this.

In spite of numerous phone calls to try to contact the non-compliant women, 4.7% were lost to follow up. Haukeland University Hospital is the main provider of abortion in the region (approximately 95%) and it is rare for women to seek help at a different institution. Studies have shown previously that women are accurate at predicting the expulsion of the pregnancy during a medical termination (22,23). A reason for these women not to follow the control regimen could be that they were sure that they had expelled the fetus and did not feel the need for a control. On the other hand, we cannot be sure that these women did not seek treatment elsewhere.

The acceptance rate in our study is similar to what has been described by others and us earlier (5,7). The fraction of women choosing home administration of misoprostol for early first trimester abortions has more than doubled during the study period. We believe the increased use may be due to word of mouth and women sharing their experiences with this treatment alternative as an acceptable and favorable alternative.

All women were asked if they would rather have been in hospital or if they preferred being at home. At the time contact was made, some of the women may not yet have entered the more painful phase of the process. This could have resulted in a higher rate of acceptability. We chose to ask them at the time they were having the termination because it was the actual time they would have been in hospital if they had not chosen to be at home. The vast majority said that they preferred staying at home. The acceptance rate was, interestingly though not statistically significant, higher among those living more than 60 min away from the hospital.

Home administration reduces the number of visits to hospital, making this method particularly advantageous for women who live more than 1 h away. A study of medical abortion prescribed through telemedicine (24) has shown this to be acceptable and efficient. There were no differences in our study for any of the parameters regardless of travel distance to the clinic. Only a very limited number of women in our study lived further away than 1 h's travel, which limits the strength of the findings based on the travel distance parameters. On the other hand, we allow women to have a medical abortion in hospital regardless of their travel distance. In our study the complications occurred several days after intake of misoprostol. This suggests that travel distance restrictions are of minor importance in preventing adverse events. In comparison, the women in our study would also have had to travel the same distance for advanced pregnancies and deliveries. Knowing that medical abortion is a safer procedure than childbirth (25) there should be no medical reasons preventing the women living a greater distance from hospital from having the same possibilities and choices as women living closer to hospital.

In conclusion, according to our experience home administration of misoprostol is an effective and acceptable method for abortion up to 63 days' gestation. Over the course of the study period, home use of misoprostol has become the most commonly used method for abortion up to 63 days' gestation in our region. With only two women needing medical assistance on the day of misoprostol use and in light of previous knowledge (1) there should be no reason to impose other restrictions on women taking misoprostol at home than at the clinic. Women should be offered this treatment option regardless of where they live. We recommend similar studies in other settings to explore the generalizability of our findings.

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Supporting information

Additional Supporting Information may be found in the online version of this article:

Table S1. List of patients who received additional treatment.

