Impact of self-administration of misoprostol for early medical abortion: a prospective observational cohort study

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ABSTRACT

Introduction In October 2017, Scotland legalised the home use of misoprostol for the purpose of early medical abortion (EMA). Women up to 9+6 weeks' gestation can now self-administer the drug at home, 24–48 hours after receiving mifepristone in the clinic.

Objective To evaluate the impact of this change on the uptake and success rate of EMA, and on the provision of effective contraception on discharge.

Methods A prospective observational study was conducted to compare the outcomes of two cohorts of women in the 6 months before and 6 months after the introduction of home administration of misoprostol. The main outcome measures were uptake of EMA, success of EMA and provision of long-acting reversible contraception (LARC) to women undergoing EMA.

Results There was a statistically significant increase in the uptake of EMA from 698/1075 (64.9%) women in the first study period to 823/1146 (71.8%) in the second study period. There was no statistically significant difference in the success rate of EMA: 99.3% and 98.9% in clinic and home misoprostol cohorts, respectively. There was also no statistically significant difference in the proportion of women provided with LARC: 37.7% and 33.7% in clinic and home misoprostol cohorts, respectively.

Conclusions Self-administration of misoprostol at home increased uptake of EMA, with no effect on the high success rate that was previously seen with clinic administration of misoprostol. In addition, the reduced number of visits associated with home use of misoprostol has not affected the provision of effective contraception to women.

INTRODUCTION

The proportion of all abortions being performed medically with mifepristone and misoprostol in Great Britain is increasing, consistent with trends around the world.[1–4] In 2017, the majority of abortions in Scotland (72.1%) were performed at ≤9 weeks' gestation, and 90% of these used medication—'early medical abortions' (EMAs).[1] Until October 2017, women in Scotland who wished to have an EMA were required to make an additional visit to the clinic to obtain misoprostol, the second of the drugs given for medical abortion. This was commonly self-administered by women in the clinic,[5–7] after which they went home to abort the pregnancy. Women found these extra visits inconvenient and reported distressing bleeding or pain on their journey home due to the onset of action of misoprostol.[8 9] In October 2017, the Scottish government introduced legislation rendering the home use of misoprostol for EMA legal.[10] This was accompanied by updated clinical guidance from the Scottish Abortion Care Providers, advising that the upper gestational limit for EMA at home could be extended from 9+0 to 9+6 weeks,[10] with an additional dose of misoprostol to be taken by women at home in cases where expulsion of the pregnancy had not occurred within 4 hours.[11]

Despite evidence from a number of countries showing that EMA with self-administration of misoprostol at home is safe and preferred by women,[12–15] its recent introduction in Scotland was challenged on the pretext that it was not safe.[16] Although that legal challenge failed, it is important to evaluate the impact of home use of misoprostol on EMA up to 9+6 weeks.

The main purpose of this study was to determine if the success rate of EMA (defined as the successful expulsion of pregnancy without need for surgical intervention) differed between clinic and home administration of misoprostol.[17] In addition, we wished to determine the impact of home misoprostol use on uptake of EMA and on provision of long-acting reversible contraception (LARC). Finally, we wished to examine its effect on unscheduled contact rates with the service.

METHODS

A prospective observational study was conducted to follow the outcomes of two independent cohorts of women who received their abortion care from an integrated sexual and reproductive health centre in NHS Lothian (Edinburgh and surrounding region), before and after the introduction of home use of misoprostol ('home misoprostol').

Women who had an EMA in the 6 months before the introduction of home misoprostol (1 June to 17 December 2017[1] inclusive) were assigned to the 'clinic misoprostol' cohort, while women who had an EMA in the 6 months after the introduction of home misoprostol (18 December 2017 to 30 June 2018 inclusive) were assigned to the 'home misoprostol' cohort even if, for various reasons, they did not take their misoprostol at home. Women in each of the two cohorts were followed up to compare the outcome of EMA.

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A review of the computerised databases of the abortion service was conducted. These databases record the women's demographics (age, body mass index (BMI), reproductive history), gestation at presentation and method of contraception provided at discharge from the service.

The outcome of pregnancy was confirmed in all cases by checking the regional hospital computerised database and computerised national sexual health records to determine if there had been any subsequent visit to a hospital or clinic with an ongoing pregnancy, or with other complications such as haemorrhage requiring blood transfusion, presumed infection treated with antibiotics or further medical management of clinically or ultrasonically visible retained tissue. The databases are compiled prospectively by research nurses and meet data protection standards for National Health Service (NHS) databases.

The project was approved by the NHS Lothian Quality Improvement Teams for abortion and also for sexual and reproductive health. The local NHS ethical officer confirmed that ethical committee approval was not required.

Women in both cohorts underwent the same clinical assessment, including a routine ultrasound scan for gestational age.[18] All women received mifepristone 200 mg orally at the clinic. Women in the clinic misoprostol cohort attended again 24–48 hours later to receive misoprostol and then went home to abort the pregnancy. Women in the home misoprostol cohort were provided with a 'take-home pack' containing misoprostol (6×200 µg) for self-administration at home. They were advised how to self-administer the drug (800 µg vaginally or sublingually) and agreed a time within the following 24–48 hours to do so. The extra dose of 400 µg misoprostol was provided with instructions that it should be taken if there was no or minimal bleeding within 4 hours of the initial dose, as this strategy has been associated with a reduced rate of ongoing pregnancy.[11] This extra dose was not an option for women in the clinic misoprostol group as, before October 2017, misoprostol had, by law, to be administered in approved premises.[19]

All women received the same take-home analgesia and a low-sensitivity pregnancy test with a detection limit of 1000 IU human chorionic gonadotrophin, for the purpose of 'self-assessment' of the success of the procedure 2 weeks later.[18 20] Women were instructed that if they had minimal bleeding, continuing pregnancy symptoms or a positive or invalid low-sensitivity pregnancy test, they should contact the service to arrange a clinic review to check for ongoing pregnancy.[18 20] Women were also provided with their chosen method of contraception. All methods, apart from intrauterine contraception, were provided at the second visit for women in the clinic misoprostol cohort, but at the initial (mifepristone) visit for women in the home misoprostol cohort. Women choosing intrauterine contraception were given an appointment for insertion at the service approximately 2 weeks later.[21]

Patient and public involvement

Patients were not involved in the design of this study.

Statistics

All statistical analysis was performed on coded data using SPSS software version 24 (Armonk, New York, USA: IBM Corp). The independent samples t-test, or the Mann-Whitney U test for skewed data, was used to compare the two groups where the dependent variable was continuous. The X^2 test or Fisher's exact test were used to compare the two groups where the dependent variables were categorical. Statistical significance was defined as a p value of <0.05.

Clinic records indicated that approximately 700 women undergo EMA in a 6-month period. With a sample of this size we would have approximately an 80% power to detect differences of 2% between the clinic misoprostol and home misoprostol cohorts for successful abortion and 7% for LARC uptake.

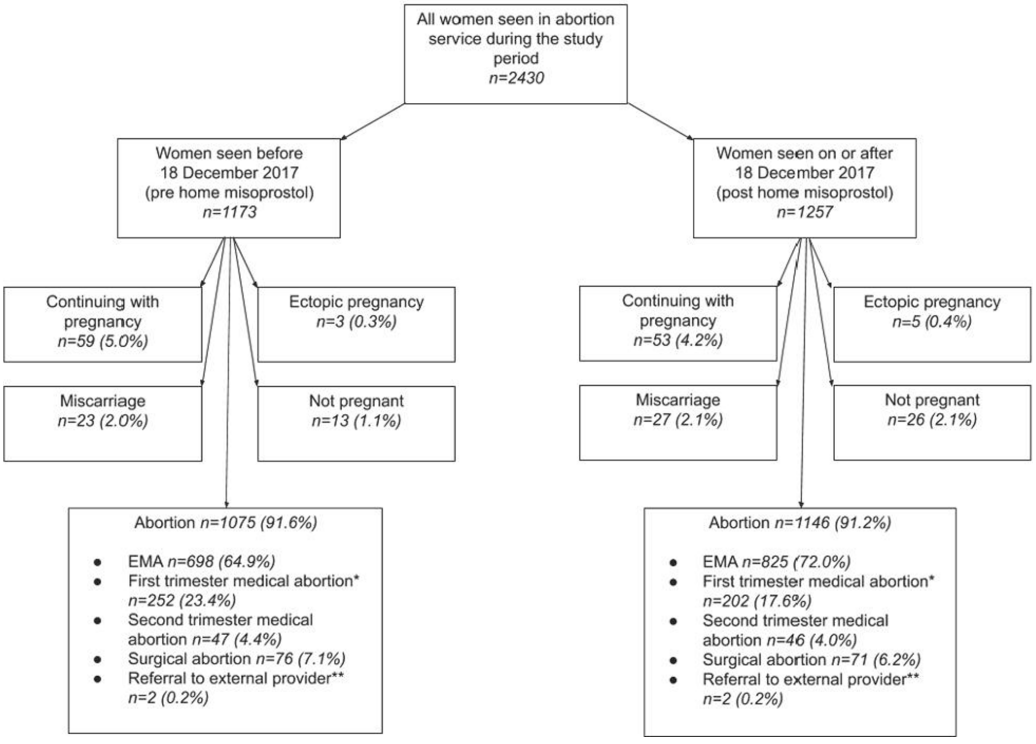

Figure 1 Early medical abortion (EMA) at home. *Medical abortion before 13+6 weeks that is carried out in a hospital setting as day-case procedure. **In both groups, a small number of women over 20 weeks' gestation were referred to a specialist abortion service in England, as this was service not available locally.[25]

RESULTS

Outcome of pregnancy among women requesting abortion

A total of 2430 women presented to the abortion service over the course of the study. Figure 1 shows the outcomes of pregnancy for these women. There was no statistically significant difference between the two groups (p=0.307), with the majority of women proceeding with abortion (>90%).

In the first study period, 698/1075 (64.9%) women who had an abortion chose to have an EMA (clinic misoprostol cohort). In the second study period, 825/1146 (72.0%) chose to have an EMA with home administration of misoprostol (home misoprostol cohort), but two of these women had indications requiring them to return to the clinic and thus received misoprostol on the clinic premises. These two women were excluded from the home misoprostol cohort. There was an increase of 7.1% (95% CI 3.2% to 10.9%) in the proportion of all women choosing EMA between the two study periods (p<0.001).

Of those women undergoing abortion who were eligible for EMA (9+0 weeks in first study period; n=917 or 9+6 weeks in second study period; n=1002), there was an increase in uptake by 6.0%, from 76.1% to 82.1% (p=0.001).

Characteristics of women having EMA

There was no statistically significant difference in the age or BMI of women in the two groups (table 1). Women in the clinic misoprostol cohort were statistically more likely to have had a previous abortion than those in the home misoprostol cohort (39.5% and 33.8%, respectively, p=0.020).

Women between 9+1 and 9+6 weeks were excluded when comparing gestations between the two cohorts, as these women were not given the option of EMA

Table 1 Demographics of women having early medical abortion in clinic misoprostol and home misoprostol cohorts.

Demographic	Clinic misoprostol (n=698)	Home misoprostol (n=823)	P value
Age (years)(mean (SD))	27.2 (6.5)	27.2 (6.7)	
BMI (kg/m^2)(mean (SD))	25.5 (5.3)	25.8 (5.2)	0.266
Reproductive history (n(%))			
Previous birth	341 (48.9)	380 (46.2)	0.297
Previous abortion	276 (39.5)	278 (33.8)	0.020
Previous miscarriage	88 (12.6)	114 (13.9)	0.476
Gestation (weeks+days)(n(%))			
All gestations			0.012*
≤7+0	478 (68.5)	489 (59.5)	
7+1–8+0	144 (20.6)	177 (21.5)	
8+1–9+0	74 (10.6)	118 (14.3)	
9+1–9+6	2 (0.3)†	39 (4.7)	

*Women between gestational ages 9+1 and 9+6 were excluded when comparing gestations between the two cohorts.
†Two women in the clinic misoprostol cohort were over 9+0 weeks' gestation but proceeded with early medical abortion out of choice.
BMI, Body Mass Index;

Table 2 Proportion of women with specified outcome measures in clinic misoprostol and home misoprostol cohorts.

Outcome measure	Clinic misoprostol (n=698)	Home misoprostol (n=823)	P value	% difference (95% CI)
Failed abortion				
Ongoing pregnancy	2 (0.3)	5 (0.6)	0.463	0.3 (–0.3 to 1.0)
Incomplete abortion	3 (0.4)	4 (0.5)	>0.99	0.1 (–0.6 to 0.7)
Total	5 (0.7)	9 (1.1)	0.443	0.4 (–0.6 to 1.3)
Unscheduled contact				
In-person attendance	7 (1.0)	22 (2.7)	0.018	1.7 (0.3 to 3.0)
Telephone contact	66 (9.5)	109 (13.2)	0.021	3.8 (0.6 to 6.8)
Total	73 (10.5)	131 (15.9)	0.002	5.4 (2.1 to 8.8)
Ultrasound review*	42 (6.0)	51 (6.2)	0.884	0.2 (–2.2 to 2.6)
Further medical management†	3 (0.4)	8 (1.0)	0.214	0.6 (–0.3 to 1.3)
Oral antibiotics	11 (1.6)	11 (1.3)	0.697	0.3 (–1.5 to 1.0)

All figures are number (%).
*Ultrasound review indicates those women for whom a clinic appointment for ultrasound was subsequently scheduled.
†Further medical management indicates those women who were treated with further mifepristone and/or misoprostol for clinically or ultrasound-visible retained products of conception.

before introduction of home misoprostol. There was a statistically significant difference in the gestations of women (p=0.012) due to a greater proportion of women in the clinic misoprostol cohort being less than 7+0 weeks and a greater proportion of women in the home misoprostol cohort being between 8+1 and 9+0 weeks (table 1).

Successful abortion and complications

There was no significant difference between the two cohorts in the success rate of EMA (99.3% and 98.9% in clinic and home misoprostol cohorts, respectively; p=0.443). A small proportion of women in each cohort had failed abortions, defined as ongoing pregnancies or incomplete abortions requiring surgical evacuation[17]— five (0.7%) and nine (1.1%) women in the clinic and home misoprostol cohorts, respectively (table 2).

Details of the cases of ongoing pregnancy in the two cohorts (n=2, 0.3% and n=5, 0.6% in clinic and home misoprostol cohorts, respectively; p=0.463) are shown in online supplementary table 1.

Three women (0.4%) in the clinic misoprostol cohort and four (0.5%) in the home misoprostol cohort had a surgical evacuation for incomplete abortion (p>0.99) (table 2). Three of these seven women (n=1 clinic misoprostol, n=2 home misoprostol) also received a blood transfusion (online supplementary table 2). There were no cases of severe infection requiring intravenous antibiotics but 11/698 (1.6%) and 11/823 (1.3%) women in the clinic and home misoprostol cohorts, respectively, received oral antibiotics for suspected infection (table 2). Data for women requiring further medical management with mifepristone and/or misoprostol for clinical or ultrasonically visible retained tissue are shown in table 2.

Table 3 Reasons for phoning the service cited by women following early medical abortion in clinic misoprostol and home misoprostol cohorts

Reason for telephone contact	Clinic misoprostol (n=66)	Home misoprostol (n=109)	P value
Pain and/or bleeding	27 (40.9)	41 (37.6)	0.502
Minimal bleeding	14 (21.2)	14 (12.8)	0.140
Pregnancy symptoms	1 (1.5)	8 (7.3)	0.221
Seeking advice/reassurance	3 (4.5)	14 (12.8)	0.172
Positive/invalid LSPT	21 (31.8)	32 (29.4)	0.609

All figures are number (%).
LSPT, low sensitivity pregnancy test.

Unscheduled contact rates

Table 2 shows data for women making unscheduled contact with the service—73 (10.5%) women in the clinic misoprostol cohort and 131 (15.9%) in the home misoprostol cohort, a difference of 5.4% (95% CI 2.1% to 8.8%; p=0.002) (table 2). Four of the 131 women who made unscheduled contact in the home misoprostol cohort were over 9+0 weeks' gestation (4/39; 10.3% of all women >9+0 weeks' gestation).

In both cohorts, the majority of cases of unscheduled contact were made via telephone (table 2). The reasons cited for telephone contact are shown in table 3. Those who did not make contact via telephone presented in-person to the hospital or walk-in service at the sexual and reproductive health centre. The proportion of women who made an in-person attendance increased by 1.7% (95% CI 0.3% to 3.0%; p=0.018) while the proportion of women making telephone contact increased by 3.8% (95% CI 0.6 to 6.8%; p=0.021).

Contraceptive uptake

Table 4 shows the methods of contraception provided. There was no statistically significant difference in the proportion of women in either group who were provided with a LARC method (intrauterine, injection or implant); 37.7% and 33.7% in the clinic and home misoprostol groups, respectively (p=0.107). Of the women who opted for an intrauterine method and were given an appointment to have this inserted, a similar proportion subsequently attended (50.5% and 52.6% in clinic and home misoprostol cohorts, respectively; p=0.693) (table 4).

Table 4 Methods of contraception provided at discharge to women undergoing early medical abortion

Contraceptive method	Clinic misoprostol (n=698)	Home misoprostol (n=823)	P value
IUC: referred*	198 (28.4)	213 (25.9)	0.297
IUC: inserted	100 (14.3)	112 (13.6)	0.711
Implant	99 (14.2)	110 (13.4)	0.655
Injectable	64 (9.2)	55 (6.7)	0.084
CHC	170 (24.4)	201 (24.4)	1.000
POP	105 (15.0)	173 (21.0)	0.003
Condoms	76 (10.9)	81 (9.8)	0.554
None	84 (12.0)	93 (11.3)	0.689

Figures shown are number (%).
*Women who indicated a wish for an intrauterine method of contraception and were given an appointment for insertion at a later date at the service.
CHC, combined hormonal contraception (pill, patch, vaginal ring);IUC, intrauterine method of contraception; POP, progestogen-only pill.

DISCUSSION

This study shows that self-administration of misoprostol at home as part of the protocol for EMA is a popular choice, with over 7 out of 10 women in this Scottish setting now choosing this option. We observed an increase in the uptake of EMA at home by 7.1%, largely accounted for by women between 9+0 and 9+6 weeks' gestation who can now have EMA at home.

Most importantly, there has been no change in the high success rate of EMA. In cases where there has been an ongoing pregnancy, most women can detect this early and make contact with the service for further management. The study also shows that EMA with home use of misoprostol is as safe as receiving misoprostol in a clinic. Complications such as haemorrhage requiring blood transfusion were uncommon and consistent with rates reported by national guidelines.[5] Our findings support those of studies from a range of settings showing that, with access to support, women can manage all steps of EMA at home themselves.[14 22 23]

There is some evidence that an additional dose of 400 µg misoprostol, taken if the pregnancy has not been expelled within 4 hours of the initial dose, is associated with a reduction in the rate of ongoing pregnancy.[11] We have not yet observed a difference in ongoing pregnancy rates with our current protocol. This may be because EMA is extremely effective, and larger numbers of women are needed to observe an effect. Furthermore, we know that not all women in our study with an ongoing pregnancy took the extra dose as advised.

Although this study showed a slight increase in unscheduled contact rates with home misoprostol, the rates are no different from those we have reported previously (1.9% in-person attendances and 10.9% telephone call), when we first introduced self-assessment for determining success of EMA.[20] It is therefore possible that this may simply reflect the 'newness' of the service and may settle over time as home use becomes the 'norm'. However, it should also be noted that women in the second study period were at a later stage of gestation and more likely to have had a previous abortion than those in the first study period, which may, in part, account for the higher rates of unscheduled contact.

The study showed no negative impact on the proportion of women provided with LARC methods. One might expect that with the time pressures of a single visit, provision of contraception might suffer, and it is reassuring that this was not the case.

This study is the first in the UK to report on the outcomes of EMA for women up to 9+6 weeks' self-administering misoprostol at home. A robust follow-up process was used, allowing us to accurately determine whether a woman had a successful abortion and exclude ongoing pregnancy, even if they presented elsewhere within the region. Clearly, however, we were unable to account for abortion-related presentations in women who had relocated to another region after the procedure. This study is limited by its assessment of a single site, and its sequential study design, which may result in residual confounding.

For healthcare systems such as the NHS, the provision of misoprostol for home use should result in improved cost-efficacy by removing the need for women to make an extra visit to the service, thus liberating clinician time for other activities. In addition, it gives women more control of their own care—an opportunity that 7 out of 10 are choosing to take.

CONCLUSION

Self-administration of misoprostol at home has resulted in increased uptake of EMA, with no effect on the high success rate that was previously seen with clinic administration of misoprostol. In addition, the reduced number of visits has not affected the provision of effective contraception to women. These findings would strongly support the changes in Scottish law, and more recently the laws in Wales and England, that permit women choosing EMA up to 9+6 weeks to self-administer misoprostol at home.[24]

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