Adherence to treatment and prevalence of side effects when medical abortion is delivered via telemedicine: a prospective observational cohort study during COVID-19

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ABSTRACT

Background The Scottish government introduced legislation during the COVID-19 outbreak to permit medical abortion at home with telemedicine. All women received an initial telephone consultation. For those choosing medical abortion, we provided self-administered medications to eligible women with pregnancies under 12 weeks’ gestation.

Aims To assess adherence to the recommended abortion drug regimen, with particular focus on the number of misoprostol doses used and the interval between mifepristone and misoprostol administration and the induction–expulsion interval. Additionally, to evaluate use of analgesia, antiemetics, antibiotics, and the side effects, pain and bleeding profile of medical abortion at home.

Methods We conducted a prospective cohort study of 663 women choosing medical abortion at home via telemedicine at an NHS abortion service in Edinburgh, Scotland between 1 April and 9 July 2020. Interviewer-administered questionnaires were completed at telephone follow-up 4 and 14 days following treatment. Outcome measures were self-reported and included use of mifepristone and misoprostol, induction–expulsion interval (time from misoprostol administration until expulsion of pregnancy), antiemetics, antibiotics, analgesia use, pain scores, rates of side effects, bleeding and preparedness for treatment.

Results Among the respondents, 652/663 women (98%) answered at least one questionnaire, and 594/663 (89.6%) used both abortion medications as directed (24–72 hours between medications). The mean (SD) induction–expulsion interval was 4.3 (4.3) hours. Antiemetics were used by 611/663 (92%), 383/599 (64%) completed the course of prophylactic antibiotics, and 616/663 (93%) used analgesia, with mean (SD) worst-pain scores of 6.7 (2.2) out of 10. Regarding side effects, 510/663 (77%) experienced either nausea, vomiting, diarrhoea or headache, 101/663 (15%) experienced headache and 510/663 (77%) experienced bleeding that was heavier than a period, 554/663, (84%) felt prepared for their treatment by teleconsultation.

Conclusion Patients are able to correctly self-administer abortion medications following a telemedicine consultation. Further research is required to optimise pain management and gastrointestinal side effects during medical abortion.

INTRODUCTION

Until March 2020, medical abortion care in Britain routinely involved an in-person consultation and ultrasound scan to assess gestation. Administration of mifepristone needed to occur in a registered clinic or hospital, but women with pregnancies...
under 10 weeks’ gestation could self-administer misoprostol at home.

In response to the COVID-19 pandemic, legislation across the UK changed to allow home use of mifepristone. In England and Wales, gestation was limited to 10 weeks, but in Scotland clinical guidance supported medical abortion at home up to 12 weeks’ gestation.7 NHS Lothian, the sole provider of abortion care in Edinburgh and the surrounding region, treats just over 2600 women each year8 and is based at Chalmers Centre for Sexual and Reproductive Health. All care and medications are at no cost to the patient, as is the norm in the National Health Service (NHS). As a result of the new legislation and clinical guidance,9,10 the service moved wholly to provision of abortion care by telemedicine and without routine ultrasound on 1 April 2020.11 Surgical abortion and in-patient medical abortion were locally available for women with pregnancies up to 12 weeks’ and 20 weeks’ gestation, respectively; however, access was restricted due to COVID-19.

All women received a remote consultation and those who indicated they would prefer medical abortion were provided with verbal information on how to use the medications and directed to the service’s online audiovisual resources on abortion care.7 Consultations were by telephone and lasted between 30 and 60 min. Women could choose to collect a medication pack from a designated collection point at the clinic (accessible without entering the building) or to receive this via courier at their home. The contents of the medication pack are shown in Box 1. The pack contained a detailed information sheet written in simple English and with pictures. Antibiotics were provided to all women as pre-abortion STI testing was not available. Antibiotics were not provided if there was a clinical contraindication or the woman declined.

Women were provided with a direct telephone line to speak to a specialist nurse in the clinic during daytime hours or to the gynaecology ward at the regional hospital overnight. They could call if they had questions or concerns about an aspect of the procedure.

We have previously reported on the high levels of safety, effectiveness and acceptability of medical abortion at home delivered by our telemedicine model,6 which are comparable to in-person models of care. Other studies in Britain and the USA have reported similar findings.8–10 Yet, there are no studies reporting on adherence to medical abortion drug regimens or the interval between misoprostol administration and expulsion of pregnancy (induction–expulsion interval) when self-administered at home or in the context of a telemedicine-delivered service. Likewise, there are no studies reporting on the rates of side effects, pain score and analgesia use in telemedicine/at-home settings.

The aim of this analysis was therefore to assess adherence to the recommended abortion drug regimen, with particular focus on the number of misoprostol doses used and the interval between mifepristone and misoprostol administration and induction-expulsion interval. We also aimed to evaluate use of analgesia, antiemetics and antibiotics, and the side effects, pain and bleeding profile of medical abortion at home.

**METHODS**

We conducted a prospective observational study of women having medical abortion at home (<12 weeks’ gestation) via telemedicine.6 All women receiving telemedicine medical abortion from 1 April 2020 until 9 July 2020 were contacted by a researcher and asked to complete a questionnaire by telephone on days 4 and 14 after misoprostol administration. We contacted women at day 4 as this was when the abortion was likely to be completed and the experience fresh in the woman’s mind, without disturbing them during their treatment. We contacted women at day 14 to obtain the result of their post-abortion low-sensitivity pregnancy test. We asked for the result of this to evaluate effectiveness of treatment (reported previously6) and used this opportunity to ask further questions. The questionnaires relied on recall only and women were not asked to note timings prospectively or keep a diary.

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**Box 1 Medication pack contents:**

- A single dose of mifepristone 200 mg* to be taken orally and followed 24–72 hours later by
- An initial dose of misoprostol 800 μg (and up to three supplemental doses of 400 μg) to be administered sublingually, vaginally or buccally as preferred by the patient at 3–4 hourly intervals until expulsion of pregnancy.
- Five doses of cyclizine 50 mg – women were directed to use one tablet an hour before mifepristone and another an hour before misoprostol.
- A 7-day course of prophylactic doxycycline 100 mg twice daily, as routine testing for sexually transmitted infections was not available during the early COVID-19 pandemic.†
- Five doses of dihydrocodeine 30 mg – all women were encouraged to purchase a supply of paracetamol and ibuprofen.
- Short-acting hormonal contraception or condoms were included if requested.
- A low-sensitivity urine pregnancy test (positive at 1000 IU/mL human chorionic gondadotrophin) with instructions on how to use this at 2 weeks after misoprostol administration.
- Detailed written information on the use of the medications.
- *The abortion medications were labelled in the order that they should be administered (ie, mifepristone = 1, misoprostol = 2) and with plain language labels.
- †Antibiotics were provided to all women unless contraindicated or declined.
Experience of pain and use of analgesia

At day 4, 624/663 (94%) patients reported that they had experienced pain and 616/663 (93%) used at least one form of analgesic medication. The mean (SD) score for worst pain experienced (by day 4) was 6.7 (2.2). Compared with expectations, 375/663 (57%) rated their pain as better or the same as they were expecting. For analgesia, 610/663 (92%) patients used paracetamol (median total dose during abortion process was 2000 mg, 403/663 (61%) used ibuprofen (median total dose 800 mg), and 427/663 (64%) used dihydrocodeine (median total dose 60 mg); 34/663 patients (5%) used at least one additional form of analgesia that they had obtained outside of the clinic or already had in their possession, including cannabis or derivatives (n = 15), co-codamol preparations (n = 12), tramadol (n = 5), other non-steroidal drugs (n = 2) and buprenorphine (n = 1) (NB. Some patients used more
than one of these treatments). The mean (6.8) and median (7) pain scores in this group were similar to the cohort overall. Further detail is provided in table 3.

**Side effects and bleeding profile**

Regarding side effects, 510/663 (77%) women experienced either nausea, vomiting, diarrhea or headache; 21/663 (3%) reported all four side effects during treatment. Regarding bleeding profile, 510/663 (77%) reported bleeding that was more than their usual menstrual period. Of those patients reporting the same or less bleeding than a period, only four required further abortion medication to complete the abortion. Further detail is provided in table 4.

**Reflecting on timing and preparedness for treatment**

Patients were asked on day 14 about the duration of the consultation and how prepared they felt for treatment; 562/663 (85%) felt the consultation duration was ‘just right’, 15/663 (2%) thought it was too long and 2/663 (0.3%) thought it was too short. Likewise, 554/663 (84%) felt adequately prepared for abortion.
DISCUSSION

Main findings

This study contributes novel data on the patient use of medications when receiving medical abortion at home following a telemedicine consultation.

The majority of patients in our cohort were able to self-administer their medications correctly, required two doses of misoprostol or fewer, and had an induction–expulsion interval comparable to that reported in the literature—that is, the majority reporting expulsion between 3 and 6 hours after misoprostol administration.11 12 Of those with pregnancies less than 10 weeks’ gestation, 8/10 patients required only a single 800 μg dose of misoprostol.

Provision of antibiotics was high and of those receiving antibiotics, approximately two-thirds completed the full course. Antiemetic use was similarly high. Clinical advice at the time was to use a dose prophylactically before mifepristone and again before misoprostol. This may be why the mean number of doses used was 2. Despite this, nearly one-third of women experienced vomiting and many experienced nausea and diarrhoea. Gastrointestinal side effects and their optimal management require further investigation.

Although use of analgesia was widespread, including weak opioids, pain scores were still relatively high, suggesting an unmet need for optimal pain management. Headache was experienced by one in six patients and could be related to analgesia or abortion medications.

By day 4 the majority reported experiencing more bleeding than a period, which is consistent with literature, although we were not able to quantify this exactly in this study.13

Preparedness for the procedure was high when assessed at 14 days and the proportion rating themselves as prepared is similar to the proportion when asked at 4 days post-treatment.6 The duration of the teleconsultations was acceptable to the majority of patients. These findings are reflected in qualitative data from this cohort, indicating that women found the process straightforward and were well prepared by the telephone consultation.14

This cohort included a small number of patients receiving abortion care at home between 10 weeks and 11 weeks 6 days’ gestation; however, their experiences were comparable to the cohort overall for use of abortion medications and other outcomes of interest.

What this study contributes

The Scottish government recently conducted a public consultation on the continued use of telemedicine. Some respondents were concerned that evidence was lacking on women's adherence to medical abortion treatment in the context of telemedicine and self-administration of medications. This study robustly examines those concerns and demonstrates high rates of adherence to medical abortion regimens.13

The overall package of information—audiovisual and written information online, verbal information delivered by telephone consultation and written information leaflets included in treatment packs—was sufficient to adequately prepare women for medical abortion at home and empower them to correctly self-administer abortion medications.

We have identified that pain and other side effects are imperfectly managed with the current analgesia and antiemetic regimens used. Pain scores during medical abortion in other studies are inconsistently reported, but those that do report them are at similar levels to

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Antibiotic and antiemetic provision and reported use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prophylactic antibiotics given*</td>
<td>Entire cohort (n=663)</td>
</tr>
<tr>
<td>Yes</td>
<td>599 (90.3%)</td>
</tr>
<tr>
<td>No</td>
<td>44 (6.6%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>20 (3.0%)</td>
</tr>
<tr>
<td>Prophylactic antibiotics used†</td>
<td>Given antibiotics (n=599)</td>
</tr>
<tr>
<td>Took all</td>
<td>383 (63.9%)</td>
</tr>
<tr>
<td>Took some</td>
<td>53 (8.8%)</td>
</tr>
<tr>
<td>Took none</td>
<td>97 (16.2%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>66 (11.0%)</td>
</tr>
<tr>
<td>Antiemetic use†</td>
<td>Entire cohort (n=663)</td>
</tr>
<tr>
<td>Yes</td>
<td>611 (92.2%)</td>
</tr>
<tr>
<td>No</td>
<td>32 (4.8%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>20 (3.0%)</td>
</tr>
<tr>
<td>Number of doses of antiemetic used, of those answering ‘Yes’ to antiemetic use†</td>
<td>Cohort reporting number of doses (n=608, 3 did not report number of doses used)</td>
</tr>
<tr>
<td>Median</td>
<td>2</td>
</tr>
<tr>
<td>Mean</td>
<td>2.1</td>
</tr>
<tr>
<td>SD</td>
<td>0.9</td>
</tr>
</tbody>
</table>

*Antibiotics given were a 7-day course of oral doxycycline 100 mg twice daily. ‘Took all’ means completed the whole course, ‘Took some’ means they used at least one dose but did not complete the full course, ‘Took none’ means they did not use any doses.
†All patients were provided with five doses of cyclizine 50 mg and directed to use one tablet before mifepristone, one before misoprostol, and the remainder as required.

treatment, 12/663 (2%) felt neither prepared nor unprepared and 11/663 (2%) felt unprepared.
those in our study, between 5 to 7 out of 10 on visual analogue or numerical Likert scales.16

Although there have been various trials of analgesic medications17–23 during medical abortion, the optimal dosing and frequency remain unclear. Further research is required to identify an effective and acceptable regimen that is easy for patients to self-administer at home and with minimal side effects. We were only able to offer a single antiemetic in the form of oral cyclizine during this study. There may be other antiemetics that are better suited to managing nausea during medical abortion, such as metoclopramide,24 but further study is required.

Strengths and limitations

More than 98% of women in the study cohort completed at least one of the questionnaires. This group represents almost all of the women receiving medical abortion at home during the study period. This may have been influenced by the COVID-19 restrictions in place at the time of the study, meaning that patients were easily contactable by telephone.

Pain score, bleeding and side effect data were collected within a short time frame to minimise errors of recall, but they relied on women’s recall rather than on diaries or prospective recording.

This is a single-centre study in a high-resource setting with a well-developed community medical abortion service. The findings of this study may be reproducible more broadly—any centre than can offer clearly written patient information combined with verbal and online advice and telephone support before, during and after an abortion could adopt this approach.

This was an observational study which has inherent limitations in comparison with randomised controlled trials and comparison is only available in relation to previously published data prior to COVID-19 and requirements for some or all medications being administered in a clinical facility. Nevertheless, this study

<table>
<thead>
<tr>
<th>Table 3</th>
<th>Pain experience and analgesia use reported at day 4 following treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experienced pain</td>
<td>Entire cohort (n=663)</td>
</tr>
<tr>
<td>Yes</td>
<td>624 (94.1%)</td>
</tr>
<tr>
<td>No</td>
<td>22 (3.3%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>17 (2.6%)</td>
</tr>
<tr>
<td>Pain score of those answering ‘Yes’ to pain experienced*</td>
<td>Cohort reporting pain score (n=610, 14 did not report pain score)</td>
</tr>
<tr>
<td>Median</td>
<td>7</td>
</tr>
<tr>
<td>Mean</td>
<td>6.7</td>
</tr>
<tr>
<td>SD</td>
<td>2.2</td>
</tr>
<tr>
<td>Pain experienced compared with expectation, of those providing a pain score</td>
<td>Cohort responding (n=587, 23 did not respond)</td>
</tr>
<tr>
<td>Better than expected</td>
<td>227 (38.7%)</td>
</tr>
<tr>
<td>Same as expected</td>
<td>148 (25.2%)</td>
</tr>
<tr>
<td>Worse than expected</td>
<td>212 (36.1%)</td>
</tr>
<tr>
<td>Used analgesia</td>
<td>Entire cohort (n=663)</td>
</tr>
<tr>
<td>Yes†</td>
<td>616 (92.9%)</td>
</tr>
<tr>
<td>No</td>
<td>30 (4.5%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>17 (2.6%)</td>
</tr>
<tr>
<td>Paracetamol</td>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
<td>36 (5.4%)</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
<td>243 (36.7%)</td>
</tr>
<tr>
<td>Dihydrocodeine‡</td>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
<td>219 (33.0%)</td>
</tr>
</tbody>
</table>

*Pain score on an 11-point Likert scale from 0 to 10, and comparison of pain experienced with expectations of pain.
†Yes includes use of paracetamol, ibuprofen, dihydrocodeine, or any other pain relief treatment.
‡Patients were given five doses of dihydrocodeine 30 mg in their treatment packs and directed to purchase their own paracetamol and ibuprofen.
provides the first detailed descriptive information on women’s use of medication for medical abortion at home when delivered via telemedicine.

CONCLUSION


REFERENCES

Original research


Supplementary File 1: Questionnaire

DAY FOUR QUESTIONS

Question 1:
Did you take the first tablet (mifepristone, 1 tablet that you swallow)?
Circle: Yes / No
If yes, do you remember when:
Date: ___________________________ Time: ___________________________
Or circle: Don’t remember

Question 2:
Do you remember the date and time you took the first dose of your misoprostol tablets (4 tablets under the tongue or inside the vagina)?
Circle: Yes / No
If yes:
Date: ___________________________ Time: ___________________________
Did you take the tablets (circle): under the tongue / inside the vagina / between your cheek and gum?

Question 3:
Did you use any additional doses of misoprostol? (2 more tablets under the tongue or inside the vagina)
Circle: Yes / No
If yes:
How many further doses (i.e. pairs of tablets) did you take? ________________

Question 4:
Do you remember the date and time that you passed the pregnancy?
Circle: Yes / No / Unsure
If yes:
Date: ___________________________ Time: ___________________________
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Date: ______________________ Time: ______________________

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If yes:
Date: ______________________ Time: ______________________