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 and 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. NHS Lothian, the sole provider of abortion care in Edinburgh and the surrounding region, treats just over 2600 women each year 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, the service moved wholly to provision of abortion care by telemedicine and without routine ultrasound on 1 April 2020. 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 directed to the service’s online audiovisual resources on abortion care. 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, which are comparable to in-person models of care. Other studies in Britain and the USA have reported similar findings. 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. 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 previously) 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.
The day 4 questionnaire asked about intake of the abortion medications, including administration of misoprostol (route, number of doses and timing in relation to mifepristone), perceived timing of pregnancy expulsion, pain score during abortion (worst pain experienced on an 11-point Likert scale, where 0 is no pain and 10 is worst pain imaginable, as well as comparison of pain with expectations), analgesia use, antiemetic use, bleeding (using a 5-point Likert scale in comparison with a usual period, ranging from ‘much less than a normal period’ to ‘much more than a normal period’) and side effects (nausea, diarrhoea, vomiting and headache).

The day 14 questionnaire asked about prophylactic antibiotic use, preparedness for treatment (assessed on a 5-point Likert scale from ‘very unprepared’ to ‘very prepared’) and reflections on duration of the telephone consultation. See online supplemental file 1 for the full questionnaire and box 1 for the medication regimen used.

As medical abortion at home for women with pregnancies between 10 weeks and 12 weeks’ gestation was a novel practice, we have reported these data separately within the results.

The main outcomes were: 1) proportion of women administering mifepristone and misoprostol within the correct time frame (misoprostol administered within 24–72 hours of mifepristone), 2) total number of misoprostol doses used, 3) induction–expulsion interval (time from misoprostol administration until pregnancy tissue passed, when patient certain pregnancy expelled) in hours. Secondary outcomes were worst pain score, analgesia regimens used, rates of antiemetic use, rates of compliance with prophylactic antibiotic, bleeding duration and side effect profiles (nausea, diarrhoea, vomiting and headache).

Statistics
An independent statistical consultant performed all statistical analyses using SAS Enterprise Guide v 7.15 (SAS Institute Inc., Cary, North Carolina, USA) and Microsoft Excel 2016. Descriptive statistics with proportions are presented.

Approvals
The project received approval from the NHS Lothian Sexual and Reproductive Health Service quality improvement team and was not deemed to require ethical approval following review by the local NHS research ethics committee scientific officer.

Patient and public involvement
Patients and members of the public were not directly involved in the design of this study.

RESULTS
In the study period, 826 women had a teleconsultation. Sixty-eight women did not proceed to have an abortion following consultation. Of the remaining 758 women who proceeded to abortion, 663 (87%) had a medical abortion at home and were included in the study cohort. Almost all (n=652, 98.3%) the women provided responses to at least one follow-up questionnaire. Complete questionnaires at both day 4 and day 14 post-abortion were available for 605 (91.3%) women. Forty-five (6.8%) women responded to the day 4 contact only and 2 (0.3%) responded only to the day 14 contact. The full demographics and characteristics of the cohort are reported in full elsewhere.

Use of abortion medications
Mifepristone was administered by 649/663 women (98%). Two women (0.3%) did not use mifepristone and 12 women (1.8%) did not respond to the questionnaire. Misoprostol was used by 594/669 patients (92%) at the recommended interval following mifepristone administration; 542/663 (82%) used a single dose of misoprostol 800 μg and 89/663 (13%) used one further 400 μg dose. A total of 460/663 (69%) administered misoprostol sublingually. The mean (4.3 hours) and median (3 hours) induction–expulsion intervals were similar and calculated for women who were certain they had passed the pregnancy (those who were not, did not provide timings). Table 1 presents this in more detail and the subset of patients with pregnancies between 10 weeks and 11 weeks 6 days’ gestation. The proportion of women using medications correctly, mode of administration and induction–expulsion interval were similar in the higher and lower gestation groups.

Use of antibiotic and antiemetic medications
Antibiotic prophylaxis (doxycycline) was provided to 599/663 (90%) of patients. Of these, 383/599 (64%) took the full course as directed and 53/599 (9%) used some of the antibiotics. Antiemetic use was reported by 611/663 (92%) patients and of those who gave the total number of doses used, the mean was 2.1 doses. Further detail is provided in table 2.

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, diarrhoea 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.
Reynolds-Wright JJ, et al. BMJ Sex Reprod Health 2021;0:1–8. doi:10.1136/bmjsrh-2021-201263

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. 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. Prepariness 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. 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.

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.

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...

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### Table 2 Antibiotic and antiemetic provision and reported use

<table>
<thead>
<tr>
<th>Prophylactic antibiotics given*</th>
<th>Entire cohort (n=663)</th>
<th>Gestation under 10 weeks (n=642)</th>
<th>Gestation 10 weeks – 11 weeks and 6 days (n=21)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>599 (90.3%)</td>
<td>581 (90.5%)</td>
<td>18 (85.7%)</td>
</tr>
<tr>
<td>No</td>
<td>44 (6.6%)</td>
<td>42 (6.5%)</td>
<td>2 (9.5%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>20 (3.0%)</td>
<td>19 (3.0%)</td>
<td>1 (4.8%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prophylactic antibiotics used*</th>
<th>Given antibiotics (n=599)</th>
<th>Gestation under 10 weeks given antibiotics (n=581)</th>
<th>Gestation 10 weeks – 11 weeks and 6 days given antibiotics (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Took all</td>
<td>383 (63.9%)</td>
<td>369 (63.5%)</td>
<td>14 (77.8%)</td>
</tr>
<tr>
<td>Took some</td>
<td>53 (8.8%)</td>
<td>52 (9.0%)</td>
<td>1 (5.6%)</td>
</tr>
<tr>
<td>Took none</td>
<td>97 (16.2%)</td>
<td>95 (16.4%)</td>
<td>2 (11.1%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>66 (11.0%)</td>
<td>65 (11.2%)</td>
<td>1 (5.6%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Antiemetic use†</th>
<th>Entire cohort (n=663)</th>
<th>Gestation under 10 weeks (n=642)</th>
<th>Gestation 10 weeks – 11 weeks and 6 days (n=21)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>611 (92.2%)</td>
<td>591 (92.1%)</td>
<td>20 (95.2%)</td>
</tr>
<tr>
<td>No</td>
<td>32 (4.8%)</td>
<td>31 (4.8%)</td>
<td>1 (4.8%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>20 (3.0%)</td>
<td>20 (3.1%)</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of doses of antiemetic used, of those answering ‘Yes’ to antiemetic use†</th>
<th>Cohort reporting number of doses (n=608)</th>
<th>Gestation under 10 weeks reporting number of doses (n=588)</th>
<th>Gestation 10 weeks – 11 weeks and 6 days reporting number of doses (n=20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Mean</td>
<td>2.1</td>
<td>2.1</td>
<td>2.7</td>
</tr>
<tr>
<td>SD</td>
<td>0.9</td>
<td>0.9</td>
<td>1.1</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.

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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.\textsuperscript{16}

Although there have been various trials of analgesic medications\textsuperscript{17–23} 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,\textsuperscript{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 3 Pain experience and analgesia use reported at day 4 following treatment

<table>
<thead>
<tr>
<th>Experienced pain</th>
<th>Entire cohort (n=663)</th>
<th>Gestation under 10 weeks (n=642)</th>
<th>Gestation 10 weeks – 11 weeks and 6 days (n=21)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Yes</strong></td>
<td>624 (94.1%)</td>
<td>603 (93.9%)</td>
<td>21 (100%)</td>
</tr>
<tr>
<td><strong>No</strong></td>
<td>22 (3.3%)</td>
<td>22 (3.4%)</td>
<td>0</td>
</tr>
<tr>
<td><strong>Unknown</strong></td>
<td>17 (2.6%)</td>
<td>17 (2.6%)</td>
<td>0</td>
</tr>
</tbody>
</table>

**Pain score of those answering ‘Yes’ to pain experienced**

<table>
<thead>
<tr>
<th>Cohort reporting pain score (n=610, 14 did not report pain score)</th>
<th>Gestation under 10 weeks (n=589)</th>
<th>Gestation 10 weeks – 11 weeks and 6 days (n=21)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Median</strong></td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td><strong>Mean</strong></td>
<td>6.7</td>
<td>6.7</td>
</tr>
<tr>
<td><strong>SD</strong></td>
<td>2.2</td>
<td>2.2</td>
</tr>
</tbody>
</table>

**Pain experienced compared with expectation, of those providing a pain score**

<table>
<thead>
<tr>
<th>Cohort responding (n=587, 23 did not respond)</th>
<th>Gestation under 10 weeks (n=568, 21 did not respond)</th>
<th>Gestation 10 weeks – 11 weeks and 6 days (n=19, 2 did not respond)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Better than expected</strong></td>
<td>227 (38.7%)</td>
<td>217 (38.2%)</td>
</tr>
<tr>
<td><strong>Same as expected</strong></td>
<td>148 (25.2%)</td>
<td>144 (25.4%)</td>
</tr>
<tr>
<td><strong>Worse than expected</strong></td>
<td>212 (36.1%)</td>
<td>207 (36.4%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Used analgesia</th>
<th>Entire cohort (n=663)</th>
<th>Gestation under 10 weeks (n=642)</th>
<th>Gestation 10 weeks – 11 weeks and 6 days (n=21)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Yes†</strong></td>
<td>616 (92.9%)</td>
<td>596 (92.8%)</td>
<td>20 (95.2%)</td>
</tr>
<tr>
<td><strong>No</strong></td>
<td>30 (4.5%)</td>
<td>29 (4.5%)</td>
<td>1 (4.8%)</td>
</tr>
<tr>
<td><strong>Unknown</strong></td>
<td>17 (2.6%)</td>
<td>17 (2.6%)</td>
<td>0</td>
</tr>
</tbody>
</table>

**Paracetamol**

| Yes | 610 (92.0%) | 593 (92.4%) | 17 (81.0%) |
| No  | 36 (5.4%)   | 32 (5.0%)   | 4 (19.0%)  |

**Ibuprofen**

| Yes | 403 (60.9%) | 390 (60.7%) | 13 (61.9%) |
| No  | 243 (36.7%) | 235 (36.6%) | 8 (38.1%)  |

**Dihydrocodeine†**

| Yes | 427 (64.4%) | 413 (64.3%) | 14 (66.7%) |
| No  | 219 (33.0%) | 212 (33.0%) | 7 (33.3%)  |

*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
Telemedicine can effectively deliver information to patients to prepare them to safely and correctly use abortion medications as part of medical abortion at home with remote support. Further research is required to optimise the management of pain and other side effects during medical abortion.

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Contributors JJR-W and SC designed the study, analysed the data and drafted the manuscript. AJ and KM contributed to questionnaire design and collected the data. EE undertook statistical analysis. All authors reviewed the final manuscript prior to submission. JJR-W is the guarantor of this paper.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement No data are available. The original data are not available in a public repository. Please contact the corresponding author for any data requests to be considered.

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