**Safety, Effectiveness and Acceptability of Telemedicine for Medical Abortion up to 10 weeks’ Gestation**

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**Abstract**

Background

When the COVID pandemic emerged approval was granted in Britain for the home use of mifepristone and misoprostol for medical abortion up to 10 weeks’ gestation. This led to widespread implementation of telemedical abortion. We aimed to compare outcomes and acceptability of medical abortion before and after telemedicine became available.

Methods

We analysed data from the three main abortion providers in England and Wales. We defined two cohorts: ‘pre-Covid’ consisting of clients who accessed medical abortion in person from January-March 2020, and ‘post-Covid’ from April-June 2020, where patients largely accessed telemedicine medical abortion services. We classified patients as receiving in-person or telemedicine services; telemedicine was provision of medications for home use following phone/video consultation without pre-procedure ultrasound. We compared demographic and clinical characteristics, abortion success rates (complete abortion without surgical intervention or continuing pregnancy), significant adverse event rates (haemorrhage requiring transfusion, infection requiring intravenous antibiotics, major surgery, death) and significant outcomes (ectopic pregnancy, treatment ≥10 weeks’ gestation). Comparisons were conducted for the pre versus post-Covid cohorts, and the in-person versus telemedicine cohorts in the post-Covid period. We adjusted outcome comparisons for covariates. We obtained acceptability and preference data from each provider.

Findings

In the periods of interest 61,310 medical abortions were reported in England and Wales. We analysed outcomes for 52,142 abortions (85.0%); 22,158 pre-telemedicine and 29,984 post-telemedicine. Mean waiting times were 4.2 days shorter after telemedicine implementation and more treatments were provided at ≤6 weeks’ gestation (14% difference, p<0.001). Medical abortion success was the same pre- and post-telemedicine (98.2% vs. 98.8%, respectively, p=1.0). Serious adverse events and ectopic pregnancy, were rare and not different between groups (p=1.0). A small proportion (0.06%) were assessed as ≥10 weeks’ gestation after termination at home. When directly comparing abortions by telemedicine (n=18,435) to in-person (n=11,549), effectiveness was higher with telemedicine (99.2% vs. 98.1%, respectively, p<0.001) but safety outcomes were not different. Acceptability was high (x%) and 83% reported future preferences for telemedicine.

Interpretation

Telemedical abortion is non-inferior to in-person pathways and improves access to care.

Funding

None

**Research in context**

**Evidence before this study**

There is long-standing evidence that medical abortion at home is safe, effective and highly acceptable. Based on its systematic review into abortion service organisation, the UK’s National Institute for Health and Care Excellence (NICE) recommended that telemedicine should be considered to improve access to abortion care. Several models for using telemedicine to facilitate medical abortion have been described. Most existing trials are small, and many required attendances for investigations such as an ultrasound or blood tests.

**Added value of this study**

This is the first cohort study to evaluate outcomes of medical abortion since approvals in England and Wales that permitted widespread implementation of telemedicine for abortion care. The large sample size of 52,142 medical abortions represents 85% of the total performed in the 2 months prior and 2 months after telemedicine was implemented , so it is descriptive at the national population level. The sample size also permits reporting on low-event rates (e.g. ectopic pregnancy) that has not previously been possible. This is the largest study evaluating outcomes with a fully remote telemedical model of abortion care without the need for ultrasound or other pre-procedure testing.

**Implications of all the available evidence**

A telemedical abortion care pathway, with services accessed without the need for in-person assessment or ultrasound scan, is as safe and effective as in-person pathways for medical abortion care care . In the model assessed, 62% of medical abortions were able to be delivered through telemedicine suggesting the potential transformative impact of a permissive framework for medical abortion delivery. Telemedical abortion care improves access, reduces waiting times and gestation at time of abortion and is highly acceptable to people using the service. The use of communication technologies to facilitate assessment and removal of clinically unnecessary interventions such as a routine ultrasound or attendance at a clinic to have medications administered protects access to abortion care in the midst of a global pandemic and will remain a significant quality improvement to abortion care after the pandemic subsides.

**Introduction**

Telemedicine is the use of information and communication technologies to improve patient outcomes by increasing access to care and medical information [REF]. Developed to overcome geographical boundaries, telemedicine has now been adopted even where care may be available close to home because it can increase convenience, decrease costs, reduce unnecessary interventions and, in some cases, improve safety.1

The global abortion rate is estimated at 39 abortions per 1000 women aged 15–49 years with 61% of unintended pregnancies ending in abortion.5 Legal restriction to abortion does not reduce the incidence of abortion but increases the frequency with which is it provided unsafely, leading to substantial morbidity and mortality [REF]. Even in places where abortion is legal, geographically inequitable provision, stigma and personal circumstances present significant barriers to accessing abortion [REF].

The development of a highly effective, well-tolerated and simple to use medical regimen for abortion has transformed abortion care worldwide. In many countries, use of the anti-progestogen mifepristone with prostaglandin-analogue misoprostol is now more commonly used for abortion than surgical evacuation up to 10-12 weeks of pregnancy. Self-management of medical abortion at home has been consistently shown to be safe, effective, and preferable to in-clinic care [REF]. 13

Medical abortion provided in part or fully by telemedicine has been studied in recent years as a means of alleviating logistical, personal, and legal barriers to abortion, reducing stigma, and improving clinical outcomes [REF]. Models described include ‘direct-to-clinic’ where a person seeks care locally and communicates with a provider who is off site via teleconference, ‘direct-to-consumer’ where the interaction between a patient and provider occurs via phone or video link followed by medications delivered by mail, to an entirely online self-sourced option [REF]. The routine or selective use of pre-procedure testing, including ultrasound, features variably with these approaches14 15 . Using telemedicine to improve access to abortion care was addressed in recent guidance from the National Institute for Health and Care Excellence (NICE) which produces evidence-based guidance in England.2 They recommended providing pre-abortion assessments by phone or video call3 noting that telemedicine was likely to improve access overall but especially for vulnerable groups, such as those in deprived areas, poor public transport provision and in rural areas.4 Improved access to abortion could also result in reduced waiting times, relieving distress for those with an unwanted pregnancy, and reduce complication rates by reducing gestation at which abortion occurs.8

The COVID-19 pandemic has required urgent action to ensure essential health services, including abortion, could be delivered. In March of 2020, the Royal College of Obstetricians and Gynaecologists (RCOG) published joint guidelines with other professional bodies to safeguard the delivery of abortion care in the UK. 9 It endorsed telephone consultation, the use of ultrasound only when indicated (e.g., inability to determine gestational age reliably by last menstrual period), and minimal contact in-person visits to take mifepristone followed by misoprostol use at home. The governments within Great Britain then issued emergency legal orders permitting home use of both mifepristone and misoprostol effective from 30th March 2020, permitting abortion providers to implement full telemedicine pathways shortly afterwards.10-12

In England and Wales, 74% of abortions are carried out by independent sector providers operating under contract to the National Health Service.16 This study represents a collaboration between the three main providers to examine the safety, effectiveness and acceptability of medical abortion provided before and after the legal authorisations that permitted implementation of a fully telemedical model at a national population level. We compared outcomes with the in-person model that was standard of care before COVID-19 emerged to those after telemedicine was permitted. We then compared outcomes between medical abortion delivered via a fully telemedical model to in-person care in the post-period.

**Methods**

**Cohorts and Definitions**

We used data on consultations and medical abortions provided up to 10 weeks’ gestation by British Pregnancy Advisory Service (BPAS), MSI Reproductive Choices (MSUK), and the National Unplanned Pregnancy Advisory Service (NUPAS).

For the analysis of clinical and demographic characteristics and outcomes, the cohorts and timeframes were: ‘pre-telemedicine’ consisting of medical abortions accessed in person from January-March 2020 and ‘post-telemedicine’ consisting of medical abortions accessed in person or via telemedicine from April-June 2020. For the analysis of ectopic pregnancies, we applied the same timeframes to all consultations for abortion because some clients referred to an Early Pregnancy Assessment Unit (EPAU) after a consultation will not proceed to an abortion.

We defined telemedicine as provision of medications for home use following phone/video consultation without in-person examination or pre-procedure ultrasound. Medications were either mailed to a person’s home or prepared for collection from a clinical site. Collection occurred with minimal contact and following identify verification. We defined in-person medical abortion when a face-to-face assessment was required, for example for an ultrasound scan to assess gestation. In the pre-telemedicine period this included administration of mifepristone in the clinic and either misoprostol taken within the clinic or provided to take and use at home.

The principles of the STROBE statement were followed.20

**Treatment Regimens**

Providers worked to organisation-specific evidence-based policies informed by the RCOG’ COVID-specific abortion guideline9 and associated decision aid21 and earlier RCOG and NICE guidelines for general abortion care including in-person medical abortion 3 22.

Pre-telemedicine, some aspects of the pre-abortion consultation may have been carried out by phone (e.g., obtaining a medical history) but an in-person assessment for an ultrasound and administration of mifepristone was always required. Post-telemedicine, consultations were by phone/video link as standard with in-person care provided as needed. In-person care may have been required for an ultrasound for example if gestational age within the 10 weeks’ gestation limit defined in the government approval orders, of in the presence of symptoms or risk factors for an ectopic pregnancy. Other indications for in-person care included the need to carry out face-to-face safeguarding assessments or a service-user’s strong preference for or inability to complete a pre-abortion assessment remotely.

**Outcome Measures**

***Ectopic Pregnancy***

All ectopic pregnancies were recorded by the provider in line with their risk management policies. For the purposes of this analysis, all women referred for further diagnostics (e.g. serial βhCG monitoring) but who had no further treatment are included in the ectopic pregnancy group although a proportion of these will be pregnancy of unknown locations (PULs) that includes failed early intrauterine pregnancies. Ectopic pregnancies detected prior to receiving EMA, but where there had been an intention to proceed with an abortion, are also reported to enable an estimation of the population prevalence and effectiveness of the decision aid used. All cases where significant haemorrhage or tubal rupture were reported, and all those where investigation concluded a “near miss”, are included.

TO note for BPAS: We provided data on any ectopic pregnancy confirmed pre-treatment or post-treatment in both periods. Post-treatment period 1 we had 2 scar pregnancies that Abigail has removed. We have not included all EPAU referral regardless of outcome and we have not included cases where we did not know the outcome of referral.

***Acceptability***

Given the constraints of delivering healthcare during COVID-19 it was not possible to follow up all women to capture patient-reported outcomes. Two of the providers (BPAS and MSUK) conducted a sample throughout the study period where women were invited to complete a structured feedback interview, either by telephone or using an on-line form, up to one week after their misoprostol. All contact was by a non-clinician who had not been involved in the woman’s care.

For BPAS: We carried out a dedicated evaluation with clients accessing medical abortion from 11 May-10 July 2020. We sent a text message with a link to a web-survey 14-21 days after treatment. We evaluated satisfaction, experiences and future preferences for consultation and abortion care. NB: is this worth it??

**Analysis**

[For Abigail’s magic]

The primary analysis was to assess whether post-Covid abortion care, where services were largely provided via telemedicine, was non-inferior to pre-Covid abortion care, where all women were assessed in person with ultrasound scans. Non-inferiority is established by comparing effectiveness and safety, measured by significant adverse outcome rates. We compared key demographic and clinical characteristics, establishing the need to covariate-adjust our outcome measures.

We first evaluate efficacy by testing the hypothesis that the post-Covid period efficacy is lower than pre-period with a covariate-adjusted test of difference in proportions (did not find evidence of lower post-Covid success rate, p=1.000). We also performed a chi-squared test to evaluate whether the distribution of types of unsuccessful abortion outcomes (opted to continue pregnancy, surgical management of continuing pregnancy, surgical management of retained products) differed in the pre and post-Covid periods (no evidence that distributions were different, p=0.268).

We then evaluate safety by assessing whether significant adverse events (haemorrhage requiring transfusion, infection requiring intravenous antibiotics, major surgery, death) occurred at higher rates in the post-Covid period. We again use a covariate-adjusted hypothesis test for difference of proportions (no evidence that post-Covid adverse event outcome is higher, p=0.722). We also compared covariate-adjusted significant outcomes rates (ectopic pregnancy, treatment ≥10 weeks’ gestation) in the pre versus post-Covid periods (for ectopics, no evidence of difference in rates, p=0.769; for large for gestation, p<0.001, but unclear this is logical because there are no pre-period events). For ectopic pregnancies, we compare the distribution of ectopic types (identified before the medical abortion, managed after the medical abortion) across the pre and post-Covid periods (p=0.008, there is evidence these differ).

The secondary analysis compares efficacy and safety of in-person versus telemedicine patients in the post-Covid period. We again evaluate demographic and clinical characteristic differences in groups, establishing the need for covariate-adjusted outcomes; however, these cohorts are fundamentally different despite covariate adjustment, as patients in the post-Covid period were directed to in-person treatment based on characteristics that would affect the outcome of their abortion. We perform covariate-adjusted tests for equal effectiveness (result is evidence of unequal props, p<0.001), and for equality of significant adverse outcome rates (result is no evidence rates differ, p=0.499), of in-person versus telemedicine cohorts in the post-Covid period.

All data were provided from the providers’ clinical records systems, with all adverse incidents included up to six weeks after treatment. All analysis was performed using R, version 3.6.2.

**Ethics Approval**

2425The Office of Research Support & Compliance (RSC) at the University of Texas assessed the trial protocol and determined the research did not meet the criteria for human subjects research as defined in the Common Rule (45 CFR 46) or FDA Regulations (21 CFR 56) and that Institutional Review Board (IRB) review and oversight was not required. Each provider ensured their own governance systems were followed.

**Results**

In total 52,142 medical abortions were accessed in the periods of interest; 22,158 in the pre-telemedicine group and 29,984 in the post-telemedicine group. Of those accessed after the approvals, 18,435 (61.5%) were via telemedicine and and 11,549 (38.5%) with in-person care. . Together this sample represents 85% of the total number of medical abortions performed in England and Wales over this period.26

**Clinical and Demographic Characteristics**

Clinical and demographic characteristics are described in Table 1. The mean age in the telemedicine pathway was 28.5 compared to 27.8 in the traditional pathway. There was a corresponding higher level of past pregnancies in the telemedicine cohort (44% had a previous abortion compared to 41%; 61% had a previous birth compared to 54%). All differences are controlled for in the analyses of effectiveness. Mean waiting time to treatment was declined from 10.7 (SD 19.9) days pre-telemedicine to 6.5 days (SD 13.5) days post-telemedicine (p<0.001). Mean gestational age at treatment also declined post-telemedicine resulting in a higher proportion of abortions performed at 6 weeks’ gestation or less (25.2% pre-telemedicine vs. 39.8% post-telemedicine, p<0.001).

Waiting times to treatment in the post-telemedicine period

**Effectiveness**

Results for the primary-outcome analysis (successful medical abortion), adjusted for clinical and demographic characteristics, are detailed in Table 2. The overall success rate was high and not lower in the post-Covid group (98.2% vs. 98.8% p=1.0). The distribution of types of failure (continuing pregnancy with or without surgical evacuation or surgical intervention for retained products of conception) also did not differ before and after implementation of telemedicine (p=0.26).

Treatment success between telemedical and in-person medical abortions provided in the post-telemedicine period

**Serious Adverse Events**

Serious adverse events (SAEs) were rare and not higher in the post-Covid group (Table 3). Haemorrhage requiring transfusion was reported in 0.04% of cases pre-Covid and 0.08% post-Covid (p=0.56) but no other SAEs including the need for IV antibiotics, major surgery or death.

**Significant Outcomes**The overall incidence of ectopic pregnancy was equivalent in both cohorts (0.2% in the traditional pathway and 0.2% in the telemedicine pathway); there was no evidence that more may have been missed as a result of TEMA. Review of each case that was detected after treatment showed that 3 cases had significant haemorrhage, tubal rupture or an adverse outcome / near miss where a delay in diagnosis could be a contributory factor. These were from the traditional pathway (1 case) and telemedicine pathway TEMA (1 case) / scanned (1 case). The learning points that arose on review were to ensure staff were aware that non-bleed EMA may be owing to an ectopic pregnancy, and not to place a blind faith in the findings of earlier ultrasound scans as they can be falsely reassuring.

There were 19 cases (0.06%) in the telemedicine pathway where the gestation was reported as being greater than the expected 10 weeks. In all cases the woman passed the pregnancy at home without additional complications.

**Acceptability**

The telemedicine pathway showed a significant reduction in mean waiting time compared to the traditional pathway (6.5 days vs 10.7 days, p<0.001), presumably accounting for a correspondingly lower mean gestation at time of abortion (6.0 weeks vs 6.4 weeks, p<0.001). Overall 40% of those on the telemedicine pathway had their EMA at 6 weeks and under, compared to 25% in the traditional pathway (p<0.001).

1,243 women provided patient-reported outcomes. 1220 (98.2%) rated their experience as good or very good. No woman reported that they were unable to consult privately. 1035 (83.3%) reported that they preferred telemedicine over face-to-face consultation, and 824 (66%) that they would prefer telemedicine in the future if COVID-19 were not an issue.

**Secondary Outcome Measures**

The outcomes of the TEMA and IPEMA groups within the telemedicine pathway are included in tables S1-S3. These showed similar, if more pronounced, trends in age and past pregnancies as demonstrated in the primary analysis of traditional vs telemedicine pathways. Waiting times and gestational age favoured TEMA (p<0.001). The TEMA group had significantly higher success rates (99.2% vs 98.1%, p<0.001) owing to a significantly reduced ongoing pregnancy rate. There was no difference in haemorrhage requiring transfusion.

**Discussion**

This large study confirms the previous literature to confirm that EMA is a safe and effective method of abortion with low rates of significant complications.27 There is no evidence of inferiority in the pathway in which telemedicine is included, in which 62% have care which is entirely remote-access with no-scan. There are advantages demonstrated – both waiting times and gestation at abortion are reduced in the telemedicine pathway, and there is a statistically if not clinically significant improvement in the successful abortion rate. All these advantages happened during the COVID-19 pandemic when access to healthcare was compromised. The benefits are more marked in the sub-analysis comparing TEMA directly with IPEMA, suggesting that it is the improved access for the group having TEMA that may account for the advantages.

**Adverse Outcomes**

The main concerns over introducing TEMA are over failing to detect ectopic pregnancies and inadvertent late gestations.

***Ectopic Pregnancy***

Although the rate of ectopic pregnancy in the general population in the UK and USA is reported as 1-2%28 29, the rate reported in women having an abortion is 10 times less30 which is also what is reported here. However given the volumes needing abortion care, some will inevitably have an ectopic pregnancy and some of these will be asymptomatic. The essential issue for safety is that these are detected prior to causing harm; having an EMA in itself will have no effect on an underlying ectopic pregnancy. Indeed, if telemedicine reduces waiting times it may facilitate earlier detection than traditional pathways where women present later, or are sent away to give additional time to visualise an intrauterine pregnancy on scan. Proceeding with early medical abortion with no scan (or if scanned with no evidence of intrauterine pregnancy) may permit earlier diagnosis of a developing ectopic pregnancy owing to increased surveillance and index of suspicion, especially where there is minimal bleeding after misoprostol3 9.

Where women are not presenting for abortion care there is no screening programme to exclude an ectopic pregnancy unless the woman develops symptoms. It is therefore illogical to assume that it is necessary in a population where the incidence is 10 times lower. A symptom and risk-based approach, with ultrasound only if indicated, seems a better solution. This is especially the case if women are presenting at lower gestations as ultrasound would be expected to have lower detection rates and more false positives. Our findings also show that ectopics are just as likely to be missed in the traditional pathway, so there is no evidence that telemedicine should be withheld owing to concerns over ectopic pregnancy.

1827

***Late Gestation***.

The complication that is specific to TEMA is that of inadvertently treating a later gestation than anticipated. The <10 weeks gestation limit in the English government’s approval order is a political and not a medical decision; the Scottish government did not stipulate a limit and leaves this to the discretion of the clinician in consultation with their patient. Women can determine the gestational age of their pregnancy with reasonable accuracy by LMP alone31. Nevertheless inadvertent treatment of gestations over 10 weeks is inevitable in some women, although the consequences for most are unlikely to be significant32. The reported success of self-managed abortions by women at >12–24 weeks’ gestation is 93%, with efficacy and safety similar to that expected in earlier gestations33. In this study the rate of unexpected late gestation is 0.06%. This is lower than many commonly accepted risks (e.g. annual risk of death from violent crime or from road traffic accidents in the UK34). Whilst those in this group would have been offered alternative treatment choices had their true gestation been known, every woman who requested one received a safe and effective abortion at home which was the objective of treatment.

It is unknown what the impact of the COVID-19 pandemic was on women seeking abortion, but it is possible that the dual fear both of an ongoing pregnancy, and of attending a healthcare facility, could have influenced how they presented. There is evidence that the rate of seeking illicit abortion medication reduced significantly in the UK, and the most likely explanation is that this was owing to easier access from the regulated sector via telemedicine as the opposite was seen in several other European countries who made no such provision [# - holding ref. https://doi.org/10.1101/2020.09.15.20195222]. Whilst it is impossible to know whether there is an overlap in those with late gestation and those who would previously have sought abortion from unregulated sources, they do represent a highly vulnerable population where later presentation is commoner, and who are most likely to benefit from the safeguarding and protection that can be offered through regulated, local abortion providers.

The implementation of the telemedicine pathway had to be rapid owing to the developing pandemic. There was therefore no time to test the accuracy of each element of the decision aid that determines who is eligible for TEMA21. This would be to investigate in future research.

**Limitations**

Although a cohort study has limitations and is more prone to bias than randomised controlled trials, the strength of this study is its size and that it includes the majority of women attending for an EMA across a whole national population, making it descriptive rather than sampling. Although the outcome data were prospectively defined in the trial protocol for the telemedicine cohort, the control group relied on retrospective data collection. The impact of COVID-19 on the population means that the two cohorts, whilst similar in terms of demographics and clinical presentation, are likely to have variance in their behaviour and acceptance of risk. It was impossible to actively follow-up women and therefore only serious adverse events can be reported with confidence. Although it is possible that some women presented to other providers and a serious adverse incident was not reported to the provider, in practice the risk management and reporting systems within the NHS are well established with serious incidents being routinely shared with regulators who would expect an investigation and action plan. Furthermore, if there is under-reporting there is no reason to suspect that it would be biased to favour the telemedicine cohort. Indeed, the governing body of the NHS in England alerted all commissioners of the need to report incidents relating to TEMA in May, and there were review meetings throughout this time attended by the providers, regulators, government, Royal Colleges and speciality groups to ensure experience was shared. We consulted with regulators and national agencies to ensure that we accounted for reports made directly to them. The Care Quality Commission (CQC) confirmed that all cases reported directly through the central NHS database of patient safety incident reports (the National Reporting and Learning System (NRLS) and the Strategic Executive Information System (StEIS)) were known to the providers.

**Conclusion**

This large trial of 52,145 women, which includes 84% of all medical abortions undertaken in England and Wales, demonstrates that incorporating remote-access telemedicine into the early medical abortion pathway is not inferior to the traditional pathway where all women are seen in person and have an ultrasound scan. There are advantages – waiting times and gestation at abortion are reduced and it is highly rated by women. There was no evidence of worse outcomes in haemorrhage, failure rate, need for surgery or poor outcome from ectopic pregnancy. A very small number (0.06%) had gestations later than anticipated, but this group still aborted successfully at home. Given the advantages to women in improving access to care, especially in vulnerable groups and in resource-poor healthcare systems or where women have to fund their own care, the evidence is compelling that telemedicine should become routine in the management of abortion care.

**Tables and Figures**

**Table 1: Client Clinical and Demographic Characteristics in the Pre-Policy Change and Post-Policy Change Periods (N=52,142)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Client Characteristic** | **Pre Period (N=22,158)** | **Post Period**  **(N=29,984)** | **P-value** |
| **Mean gestational age in weeks (s.d.)** | 6.4 (1.3) | 6.0 (1.4) | <0.001 |
| **Gestational age** |  |  |  |
| 6 weeks and under | 5,582 (25.2) | 11,947 (39.8) | <0.001 |
| Over 6 weeks | 16,576 (74.8) | 18,037 (60.2) |  |
| **Mean age in years (s.d.)** | 27.8 (6.6) | 28.5 (6.7) | <0.001 |
| **Ethnicity** |  |  |  |
| Asian | 2,038 (9.2) | 2,652 (8.8) | <0.001 |
| Black | 1,656 (7.5) | 2,282 (7.6) |  |
| Multiracial | 1,004 (4.5) | 1,361 (4.5) |  |
| White | 15,840 (71.5) | 20,910 (69.7) |  |
| Other | 489 (2.2) | 638 (2.1) |  |
| Unknown | 1,131 (5.1) | 2,141 (7.1) |  |
| **Previous abortions** |  |  |  |
| 0 | 13,098 (59.1) | 16,741 (55.8) | <0.001 |
| 1+ | 9,060 (40.9) | 13,243 (44.2) |  |
| **Parity** |  |  |  |
| 0 | 10,133 (45.7) | 11,741 (39.2) | <0.001 |
| 1+ | 12,025 (54.3) | 18,243 (60.8) |  |
| **Mean waiting time in days (s.d.)** | 10.7 (19.9) | 6.5 (13.5) | <0.001 |

**Table 2: Comparison of Effectiveness of Medical Abortions Conducted in the Pre-Policy change vs. the Post-Policy Change period (N=52,142)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Outcome** | **Pre-Period**  **N=22,158** | **Post-period**  **N=29,984** | **P-value** |
| **Successful medical abortion** | **21,769 (98.2)** | **29,618 (98.8)** | **1.0** |
| **Unsuccessful medical abortion** | **389 (1.8)** | **366 (1.2)** |  |
| Continuing pregnancy treated with surgical management | 161 (0.7) | 150 (0.5) | 0.268 |
| Continuing pregnancy opted to continue or unknown outcome | 3 (0.02) | 8 (0.03) |  |
| Retained products treated with surgical management (ERPC) | 225 (1.0) | 208 (0.7) |  |

Note: the p-value for Successful medication abortion is the co-variate adjusted p-value (i.e. all differences in client clinical and demographic characteristics, including gestational age, are controlled for) and was calculated using a hypothesis test where the null hypothesis is that the pre-period the same effectiveness rate as the post-period and the alternative hypothesis is that the pre-period has a higher effectiveness rate than the post period. The p-value for Unsuccessful medication abortion is for the chi-squared test of whether the distribution of types of failure differ between pre and post periods. (This will all be explained in the Methods section of the paper).

**Table 3: Comparison of Significant Adverse Events Following Medical Abortions Conducted in the Pre-Policy change vs. the Post-Policy Change period (N=52,142)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Outcome** | **Pre-Period**  **(N=22,158)** | **Post-period**  **(N=29,984)** | **P-value** |
| Haemorrhage requiring transfusion | 8 (0.04) | 7 (0.02) | 0.557 |
| Infection requiring IV antibiotics | 0 (0.0) | 0 (0.0) |  |
| Major surgery | 0 (0.0) | 0 (0.0) |  |
| Death | 0 (0.0) | 0 (0.0) |  |

Note: the p-value was calculated using a hypothesis test where the null hypothesis is that the pre-period the same rate of adverse events than the post-period and the alternative hypothesis is that the pre-period has a lower rate of adverse events than the post period. (This will all be explained in the Methods section of the paper).

Note: Jonathan brough up one potential presumed IV abx case for the post period. Perhaps you all can discuss whether or not to include it?

Note: Major surgery not related to uterine emptying is not included in the Cleland et al. paper, so there is no “official language”.

**Table 4: Significant Outcomes Among Clients Accessing Medical Abortion in the Pre-Policy change vs. the Post-Policy Change period (N=52,218)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Outcome** | **Pre-Period**  **(N=22,197)** | **Post-period**  **(N=30,021)** | **P-value** |
| Ectopic Managed Pre-Treatment | 39 (0.18) | 41 (0.14) |  |
| Ectopic Managed Post-Treatment | 2 (0.01) | 10 (0.03) |  |
| Gestational age later than expected\* | 0 (0.0) | 19 (0.06) |  |

Note: The column Ns include those who did not received an EMA because their ectopic pregnancy was identified pre-treatment.

\*Note: The column Ns for the gestational age later than expected category is all EMAs performed in the pre and post period (i.e. N = 52,142)

Note: How do we want to construct the p-value for these comparisons? I don’t think it makes sense to have one for gestational age later than expected, since this wasn’t really a possible outcome in the pre-period. But, there are a number of things we could do for the ectopic comparison…

**Supplementary Tables to Accompany Text in the Results Section**

**Table S1: Client Clinical and Demographic Characteristics in the In-Person vs. Telemedicine Groups for the Post-Policy Change Period (N=29,984)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Client Characteristic** | **In-Person (N=11,549)** | **Telemedicine**  **(N=18,435)** | **P-value** |
| **Mean gestational age in weeks (s.d.)** | 6.2 (1.4) | 5.8 (1.3) | <0.001 |
| **Gestational age** |  |  |  |
| 6 weeks and under | 3,673 (31.8) | 8,274 (44.9) | <0.001 |
| Over 6 weeks | 7,876 (68.2) | 10,161 (55.1) |  |
| **Mean age in years (s.d.)** | 27.9 (6.6) | 28.9 (6.7) | <0.001 |
| **Ethnicity** |  |  |  |
| Asian | 1,060 (9.2) | 1,592 (8.6) | <0.001 |
| Black | 946 (8.2) | 1,336 (7.2) |  |
| Multiracial | 557 (4.8) | 804 (4.4) |  |
| White | 7,868 (68.1) | 13,042 (70.7) |  |
| Other | 336 (2.9) | 302 (1.6) |  |
| Unknown | 782 (6.8) | 1,359 (7.4) |  |
| **Previous abortions** |  |  |  |
| 0 | 6,388 (55.3) | 10,353 (56.2) | <0.001 |
| 1+ | 5,161 (44.7) | 8,082 (43.8) |  |
| **Parity** |  |  |  |
| 0 | 4,931 (42.7) | 6,810 (36.9) | <0.001 |
| 1+ | 6,618 (57.3) | 11,625 (63.1) |  |
| **Mean waiting time in days (s.d.)** | 9.5 (20.3) | 4.7 (5.6) | <0.001 |

**Table S2: Comparison of Effectiveness of Medical Abortions Conducted In-Person vs. using Telemedicine for the Post-Policy Change Period (N=29,984)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Outcome** | **In-Person**  **N=11,549** | **Telemedicine**  **N=18,435** | **P-value** |
| **Successful medical abortion** | **11,329 (98.1)** | **18,289 (99.2)** | **<0.001** |
| **Unsuccessful medical abortion** | **220 (1.9)** | **146 (0.8)** |  |
| Continuing pregnancy treated with surgical management | 133 (1.2) | 17 (0.09) | <0.001 |
| Continuing pregnancy opted to continue or unknown outcome | 1 (0.01) | 7 (0.04) |  |
| Retained products treated with surgical management (ERPC) | 86 (0.7) | 122 (0.7) |  |

Note: the p-value for Successful medication abortion is the co-variate adjusted p-value (i.e. all differences in client clinical and demographic characteristics, including gestational age, are controlled for) and was calculated using a hypothesis test where the null hypothesis is that the in-person has the same effectiveness rate as the telemed group and the alternative hypothesis is that the in-person group has a lower effectiveness rate than the telemedicine group. The p-value for Unsuccessful medication abortion is for the chi-squared test of whether the distribution of types of failure differ between in-person and telemed groups. (This will all be explained in the Methods section of the paper).

**Table S3: Comparison of Significant Adverse Events Following MedicalAbortions Conducted In-Person vs. using Telemedicine for the Post-Policy Change Period (N=29,984)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Outcome** | **In-Person**  **N=11,549** | **Telemedicine**  **N=18,435** | **P-value** |
| Haemorrhage requiring transfusion | 4 (0.03) | 3 (0.02) | 0.532 |
| Infection requiring IV antibiotics | 0 (0.0) | 0 (0.0) |  |
| Major surgery | 0 (0.0) | 0 (0.0) |  |
| Death | 0 (0.0) | 0 (0.0) |  |

Note: the p-value was calculated using a hypothesis test where the null hypothesis is that the in-person group has the same rate of adverse events than the telemedicine group and the alternative hypothesis is that the in-person group has a lower rate of adverse events than the telemedicine group (This will all be explained in the Methods section of the paper).

Note: Major surgery not related to uterine emptying is not included in the Cleland et al. paper, so there is no “official language”.

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Declaration of interest

**Data Sharing Statement**

The collated datasets, which include participant data with identifiers, are held by AA at the University of Texas. Consideration will be given to sharing this with bonefide researchers on application. The original data resides with the co-authors’ own institutions. Although the data is de-identified, some relate to very rare events and could therefore result in identification. Therefore data on complications, and data arising from clinical incident reports, will be subject to the same access restrictions as those of the organisation supplying it.

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